Table of Contents

Introduction / CDCR Organization	1
Receivership / Initiatives	2
Triage / Access to Care / Schedules	3
Primary Care / Chronic Care	4
Documentation	5
Specialty Care	6
Medical Areas / Housing / In-Patient	7
Support Services: Pharmacy, Lab, X-Ray	8
Performance Expectations / Evaluation	9
Quality Management / Oversight	10
Patient Litigation / Malpractice	11
Correctional Medicine Special Topics	12
Resources	13
Miscellaneous Notes	14
	15

Department of Correctional Healthcare Services

- Vision
- Mission
- Values

Letter from the Chief Physician Executive

Acknowledgments

Organizational Chart

The Mission of Healthcare in CDCR –DCHCS

'THE PATIENT IS OUR PRIORITY'

- We support a culture of healthcare which embodies principles espoused by the Institute of Medicine and adopted by many organizations – a culture which supports a high degree of patient safety and system reliability.

- Healthcare we provide will be safe, and our systems will be designed to continually improve patient safety.

- Healthcare will be effective, based upon scientific knowledge.

- Access to care will be timely, reducing or eliminating potentially harmful delays.

- Healthcare will be efficient, and our systems will be intended to reduce over and underutilization.

- Teamwork, teambuilding and a high level of communication will be emphasized.

- Our providers will be of high quality, will be held to high standards of professionalism, and their professional development will be continually nurtured.

- Above all, our healthcare will be patient centered, intended to reduce unnecessary morbidity and mortality, to continually improve our patients' health status and functioning, and to serve our patients' best interests throughout the continuum of care.

The Primary Care Model

At CDCR, we believe that a Primary Care Model of patient care is the one that best serves the interests of our patients.

We recognize that the environment of prison healthcare is extremely challenging. Our patients can be poorly educated and may have a high degree of health illiteracy. They may have a high burden of disease which is the result of unhealthy lifestyles, (drug abuse, smoking, alcoholism) and mental illness. Language and cultural differences may cause significant barriers to good healthcare.

Our systems are not yet well developed or reliable. Test results, specialty reports, hospitalizations and emergency room visit documentation can be easily lost. Medical records and pharmacy databases are not always easily accessible.

Public safety and security is a major concern, and results in a very high rate of transfer and turnover and a need for a high level of cooperation and teamwork with custody.

As a result, the nature of prison healthcare can be highly fragmented and episodic, and our patients can easily fall through the cracks in the system.

We believe that in this environment, the best healthcare will occur when physicians, mid-level providers, and nurses know their patients and the patients in turn know their providers.

The primary care provider provides healthcare screening, manages the patients of acute and chronic medical conditions according to established guidelines for care, advocates for the patient, communicates with other providers, tracks test results and acts on them, follows the patient across all the points of care (acute, chronic, emergency room, hospital, specialty visit), and is ultimately accountable for the health outcomes of the patient.

Kent Imai, MD

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

VISION

We will end the causes and tragic effect of crime, violence, and victimization in our communities through a collaborative effort.

MISSION

To improve public safety through evidence-based crime prevention and recidivism reduction strategies

VALUES

We commit ourselves to principled leadership-a set of core values that guide our behavior.

Integrity-We conduct ourselves professionally, achieving the highest ethical standards.

Accountability-We take responsibility for our actions and the consequences.

Justice-Everyone receives equitable process and fair outcomes.

Collaboration-Everyone supports mutual understanding of ideas, open exploration of our differences, and works constructively and cooperatively with out stakeholders.

Employee Well Being-We foster an environment that supports professional development and personal health.

Welcome to the California Department of Corrections and Rehabilitation (CDCR).

You will be working in one of the largest correctional health care systems in the world, providing clinical services that are vitally important to achieving the mission of the CDCR. You are a critical member of the institutions' multi-disciplinary team that provides for safety, security, health care, education, and administrative services within the institutions.

You are arriving at a time of monumental change. Under the *Plata* Court Receivership, the Division of Correctional Health Care Services (DCHCS) is striving to provide high quality, evidence-based, cost-effective health care and build a cohesive, patient services team that is in alignment with the Receiver's Mission. The Receiver's mission is to create a system where custody and health care staff together guarantee that access to care and quality of medical services in California prisons meet constitutional standards.

We believe this Orientation Manual will facilitate your transition into the exciting world of correctional medicine. If you have questions, please contact your supervisor for further information.

Thank you for joining our team. We believe this new experience will be rewarding.

DWIGHT W. WINSLOW, M.D.
Chief Physician Executive
Division of Correction Health Care Services
California Department of Corrections and Rehabilitation

ACKNOWLEDGEMENTS

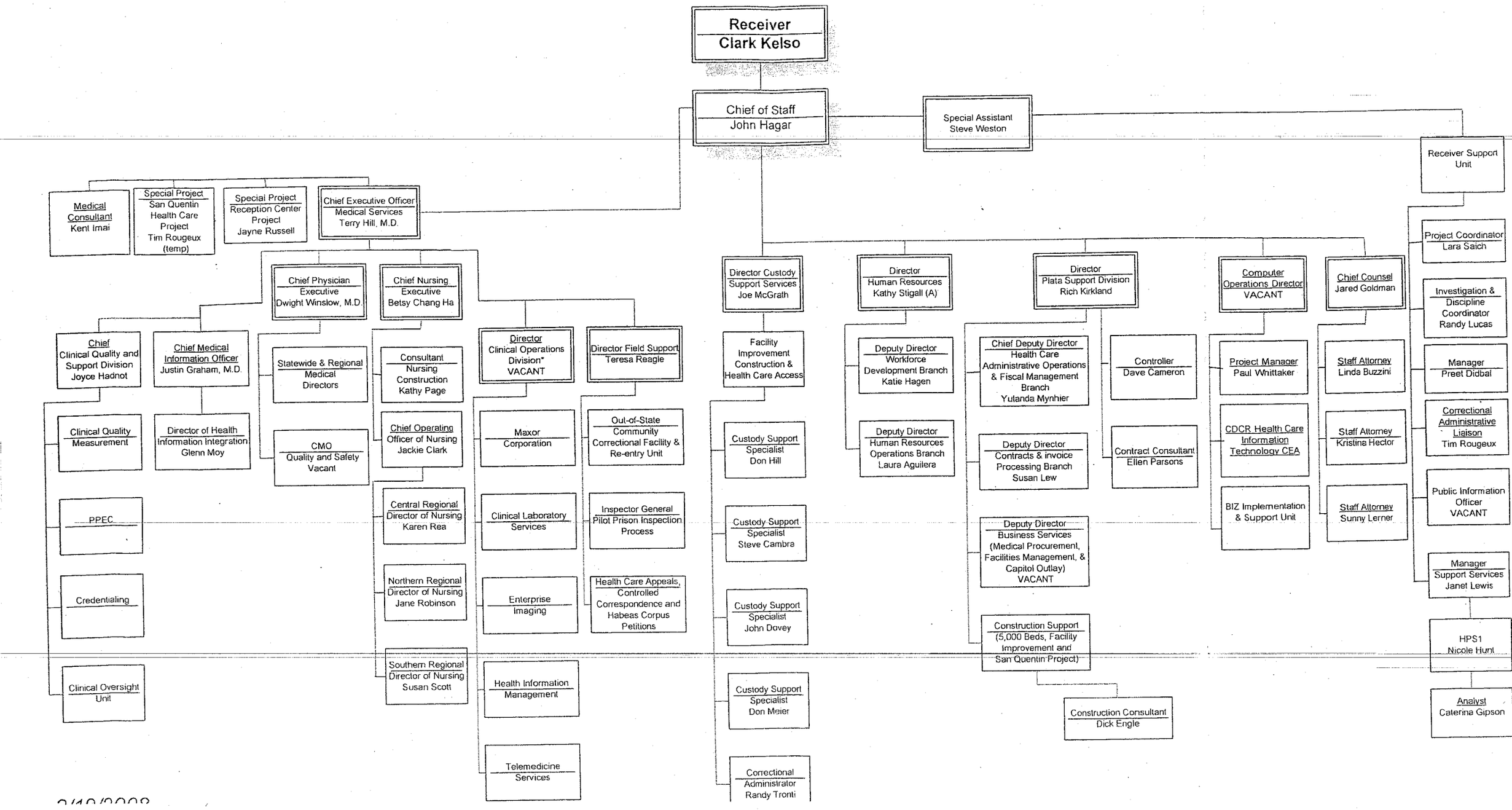
PROJECT TEAM

Dwight W. Winslow, M.D., Project Manager
Alan Frueh, M.D. Staff Development
Bonnie Gieschen MD
Tamara S. Robinson, M.D.
Rochelle Shadwick

CONTRIBUTORS

Dwight Winslow, MD
Angel Bailon
Glenn Thiel, D.O., Ph.D.
Tim Rougeux
Viginia Steele-Pirie, RN, MSN
Steve Ritter, DO
Carl Wolf, M.D.
Vicki Greene

CALIFORNIA PRISON HEALTH CARE RECEIVERSHIP CORPORATION ORGANIZATION CHART



2/10/2008

California Prison Receivership

Strategic Plan Framework

New Receiver

California Prison Receivership
Strategic Plan Framework
(January 23, 2008)

Our Vision

As soon as practicable, to establish a constitutionally adequate and sustainable prison medical delivery system for prisoner/patients confined by the California Department of Corrections and Rehabilitation (CDCR) that can successfully be returned to State management.

Our Mission

Reduce unnecessary morbidity and mortality, improve inmates' health status and functioning by providing adequate access to medical services, develop a continuum of medical delivery consistent with sound clinical services and fiscal standards, and coordinate the delivery of medical care with CDCR mental health, dental, and Americans with Disability Act programs.

Our Core Values

- Professionalism
- Integrity and Honesty
- Fiscal Responsibility
- Teamwork
- Collaboration
- Transparency
- Accountability

Our Strategic Goals

(1) Address Worst Case Problems Immediately (e.g., asthma initiative, top-five reasons for unnecessary deaths, emergency care, clinical leadership at the regional and institutional level)
(2) Implement Continuum of Health Care Services
(3) Ensure Appropriate Prisoner/Patient Access to Health Care Through Timely Implemented Access Programs That Adhere to *Plata* Access Standards
(4) Recruit, Train and Retain a Professional Quality Medical Care Workforce
(5) Establish the necessary CDCR medical delivery infrastructure to effectuate these Strategic Goals (including Human Resources, Clinical Support Services, Contracts, Fiscal Services and Controls, Procurement, Health Care Appeals, and Facility Planning and Operation)
(6) Construct Needed Health Care Facilities (including 5000 additional medical beds and necessary additional clinical and office space at existing institutions)

CALIFORNIA
PRISON HEALTH CARE
RECEIVERSHIP CORP.

J. Clark Kelso, Receiver

JUDGE APPOINTS NEW PRISON HEALTH CARE RECEIVER

FOR IMMEDIATE RELEASE: 23 January 2008

Contact: Rachael Kagan, Director of Communications (408) 436-6867, (510) 387-1292 cell, rachael.kagan@cprinc.org

SAN FRANCISCO, Calif. – Effective immediately, J. Clark Kelso is appointed Receiver in *Plata, et al. v. Schwarzenegger, et al.* Mr. Kelso is a Professor of Law and Director of the Capital Center for Government Law and Policy at the University of the Pacific McGeorge School of Law located in Sacramento, California. Mr. Kelso comes to the California Prison Health Care Receivership with more than fifteen years of experience in a wide variety of positions in all three branches of state government, including the California Judicial Council and Administrative Office of the Courts, where he worked in support of court unification; the Department of Insurance, where he replaced Insurance Commissioner Chuck Quackenbush, who abruptly resigned amid allegations of corruption; and as California's Chief Information Officer, where he turned around the State's troubled information technology program. Because of his achievements, Mr. Kelso has developed a well-regarded reputation for independence and integrity and maintaining a commitment to collaborative leadership and organizational change in government.

Mr. Kelso has been the recipient of numerous awards, including the prestigious 1998 Bernard E. Witkin Amicus Curiae Award from the California Judicial Council and the "Top 25 Award for 2004 Doers, Dreamers and Drivers" from Government Technology. He was also named by Computerworld to their list of "Premier 100 IT Leaders for 2007." He resides in Sacramento with his wife, Kari Kelso, Ph.D., and two daughters.

Mr. Kelso replaces Robert Sillen as Receiver. Since April 2006, Mr. Sillen has provided the bold, creative leadership necessary for the Receivership to effectively investigate, confront, and break down many of the barriers which stand in the way of providing constitutionally adequate medical care in California's prisons. In addition, under Mr. Sillen's direction, significant remedial progress has been achieved, including reducing clinical vacancy rates, resolving the California Department of Corrections and Rehabilitation contracting crisis, implementing successful pilot programs, and successfully recruiting a team of correctional and clinical experts to assist the Receivership with its remedial obligations. Mr. Kelso will build on such progress, as well as on the infrastructure created during Mr. Sillen's tenure, as he focuses the Receivership on implementing additional reforms necessary to creating a constitutionally adequate inmate health care system that will ultimately be transitioned back to the State of California's control.

501 J Street, Suite 100, Sacramento, CA 95814
(916) 323-1221 • Fax (916) 323-1257 • www.cprinc.org

United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MARCIANO PLATA, et al.,
Plaintiffs,
v.
ARNOLD SCHWARZENEGGER, et al.,
Defendants.

NO. C01-1351 TEH

ORDER APPOINTING NEW RECEIVER

On October 3, 2005, this Court issued detailed findings of fact and conclusions of law explaining the Court's June 30, 2005 oral ruling to establish a Receivership to take control of the delivery of medical services to all California state prisoners confined by the California Department of Corrections and Rehabilitation ("CDCR"). The Court concluded that "the California prison medical care system is broken beyond repair," and that an "unconscionable degree of suffering and death is sure to continue if the system is not dramatically overhauled." Oct. 3, 2005 Findings of Fact & Conclusions of Law at 1-2. The Court "impose[d] the drastic but necessary remedy of a Receivership in anticipation that a Receiver [could] reverse the entrenched paralysis and dysfunction and bring the delivery of health care in California prisons up to constitutional standards." *Id.* at 2. The Court further explained that, "[o]nce the system is stabilized and a constitutionally adequate medical system is established, the Court will remove the Receiver and return control to the State." *Id.*

On February 14, 2006, the Court appointed Robert Sillen "to serve as the Receiver in this case, at the pleasure of the Court, effective Monday, April 17, 2006." Feb. 14, 2006

Order Appointing Receiver at 2. In that appointment order, the Court also set forth the Receiver's duties and powers and provided for the establishment of an advisory board to assist and advise the Court and Receiver. *Id.* at 2-9.

Much progress has been made since the Receivership was established, and the Receiver has successfully recruited and hired a team of correctional and clinical experts to assist him with his remedial obligations. As detailed in the Receiver's bimonthly and, subsequently, quarterly reports to the Court, the Receiver and his staff, including the many CDCR employees who report to the Receiver, have undertaken significant efforts to improve the delivery of medical care to California inmates. For example, vacancy rates among clinical staff in prisons have been dramatically reduced as a result of increased salaries and improved hiring processes. Similarly, many clinically appropriate changes have been made, including the replacement of medical technical assistants with licensed vocational nurses, and several necessary clinical construction projects have been initiated. In its first two years, the Receivership has also resolved the CDCR specialty care contracting crisis, which was preventing inmates from receiving needed care from clinical specialists, and established a successful prison improvement pilot project at San Quentin State Prison. Nonetheless, it is beyond dispute that the system for delivering health care to California's inmate population remains below constitutional standards and continues to be in need of repair – not through any fault of the Receiver or his staff, but, rather, primarily as a result of the extreme dysfunction the Receiver inherited from the State, as well as the numerous problems and obstacles encountered by the Receiver that were not anticipated at the time the Receivership was established.

In addition to being charged with undertaking immediate and short-term measures "designed to improve medical care and begin the process of restructuring and development of a constitutionally adequate medical health care delivery system," the Receiver was also ordered to develop a detailed Plan of Action to complete the development and implementation of such a system. *Id.* at 2-3. The Court originally ordered the Receiver to file his Plan of Action within 180 to 210 days of his appointment, *id.* at 2, but later granted

the Receiver's request for an extension of time. On December 19, 2006, the Court granted the Receiver until May 15, 2007, to file his initial Plan of Action with metrics "that are realistic, fully informed, detailed, and effective," with a revised Plan of Action due by November 15, 2007. Dec. 19, 2006 Order at 2, 5. In the same order, the Court granted the Receiver's request to delay appointment of an advisory board until after the filing of the initial Plan of Action. *Id.* at 3-4.

The Receiver timely filed his initial Plan of Action on May 10, 2007. Following the Court's independent review of that plan and consideration of Plaintiffs' responses to the plan, including arguments raised during an August 27, 2007 hearing, the Court found that the initial Plan of Action failed to contain adequate metrics and time lines. The Court ordered that the Receiver include such benchmarks in his revised Plan of Action to be filed in November 2007. Sept. 6, 2007 Order Re (1) Receiver's May 2007 Preliminary Plan of Action, & Mot. for Order Modifying Stip. Inj. & Orders Entered Herein, & (2) Pls.' Mot. for Order Directing Receiver to Comply with April 4, 2003 Order etc. at 3-5. The Court also observed at the August 27, 2007 hearing that it had not furnished the type of hands-on leadership that, in retrospect, it wished it had, and the Court resolved to provide such leadership as this case moved forward.

To that end, the Court appointed Starr Babcock as a Pro Bono Special Assistant to the Court to assist with special projects, including the creation of "an advisory working group to assist the Court with evaluating the Receiver's [revised] Plan of Action . . . and determining how best to assemble the advisory board." Oct. 29, 2007 Order Appointing Pro Bono Special Assistant to the Court at 1. Following the Receiver's timely filing of his revised Plan of Action on November 15, 2007, the Court provided the advisory working group with a copy of the revised plan and convened the group for a one-day meeting on December 8, 2007. The Pro Bono Special Assistant to the Court had numerous individual conversations with advisory working group members both before and after the December 8 meeting.

The Receiver, as well as counsel for Plaintiffs and Defendants, made presentations to and answered questions from the advisory working group at that meeting. The group

United States District Court
For the Northern District of California

subsequently reached two main consensus opinions during closed-session discussions. First, the advisory group recommended that a professional planner be hired to assist the Receiver in revising the Plan of Action so that it both complied with the Court's orders and directions and could serve as a useful leadership document that would provide a common vision for all stakeholders. In addition, the working group was unanimous in its recommendation that an advisory board be formed to assist in the planning process and, more broadly, to advise the Court on issues relating to the Receivership's operation and progress towards implementing a prison medical care system that meets constitutional standards. The Court agrees with and adopts both of these recommendations, as ordered below.

The Receivership has reached a critical juncture at which it must now move from a primarily investigative and evaluative phase, during which the Receivership analyzed the current system to determine what reforms were necessary and worked to create the infrastructure required to effectuate such reforms, into an implementation phase, during which the Receivership must translate the conceptualized reforms into reality. Throughout its existence, the Receivership has developed and put into practice critical short-term measures, and such measures must continue to be adopted to address issues requiring urgent attention. However, the Receivership's focus can and must now shift towards long-term reform that will achieve the implementation of a sustainable, constitutionally adequate system of delivering medical care to Plaintiffs – and, not inconsequentially, a system that must ultimately be transitioned back to the State of California's control. Put another way, the Receivership's overarching goal should be working itself out of existence once delivery of medical care to California's inmates has been brought up to constitutional standards.

After careful reflection and deliberation, the Court has concluded that such work would best be accomplished by appointing a new Receiver who brings a different set of strengths appropriate to guiding the Receivership through its second phase. While the current Receiver has successfully used his unique skills and bold, creative leadership style to investigate, confront, and break down many of the barriers that existed at the inception of the Receivership, the second phase of the Receivership demands a substantially different set of

United States District Court
For the Northern District of California

administrative skills and style of collaborative leadership. The Receivership must continue to maintain its independence as an arm of the federal courts established to take over state operations, but it also must work more closely at this stage with all stakeholders, including State officials, to ensure that the system developed and implemented by the Receivership can be transferred back to the State in a reasonable time frame. Such collaboration appears to be more important now than ever, given the current budget crisis faced by the State of California.

Accordingly, with good cause appearing, IT IS HEREBY ORDERED that:

1. The Court's appointment of Robert Sillen as the Receiver in this case is hereby terminated, and all prior authority vested by the Court in Mr. Sillen is hereby revoked, effective immediately.

2. J. Clark Kelso is appointed to serve as the Receiver in this case, at the pleasure of the Court, effective immediately. All powers, privileges, and responsibilities of the Receiver, as set forth in the Court's February 14, 2006 Order Appointing Receiver, shall continue in full effect, except as modified by subsequent orders of this Court. A short biography of Mr. Kelso is attached to this order.

3. The Pro Bono Special Assistant to the Court shall assist the Receiver in reworking the November 15, 2007 Plan of Action so that it is a more useful leadership document. The Receiver and Pro Bono Special Assistant shall consider how best to choose and use the services of a professional planner to assist in this process, the costs of which shall be borne by Defendants as part of the Receivership's budget.

4. The Court will shortly be appointing an advisory board to assist and advise the Court and the Receiver as this case moves forward. All costs associated with the appointment and service of the advisory board shall be borne by Defendants as part of the Receivership's budget. Although the Court is cognizant of not making the advisory board so large as to be unhelpful and inefficient, the Court may expand the advisory board beyond the five individuals provided for by the February 14, 2006 Order Appointing Receiver to ensure that medical, correctional, and any other areas of necessary expertise are adequately

United States District Court
For the Northern District of California

represented. The Pro Bono Special Assistant to the Court shall continue to assist the Court in assembling and staffing the advisory board, in consultation with the Receiver. Details of the advisory board will be announced by subsequent order of the Court.

IT IS SO ORDERED.

Dated: 01/23/08

THELTON E. HENDERSON, JUDGE
UNITED STATES DISTRICT COURT

United States District Court
For the Northern District of California

J. Clark Kelso

Biographical Information

J. Clark Kelso is a Professor of Law and, for the last twelve years, has been the Director of the Capital Center for Government Law and Policy at the University of the Pacific McGeorge School of Law in Sacramento, California. He comes to the California Prison Health Care Receivership with over fifteen years of experience in a wide variety of positions in all three branches of state government. Throughout this service, he has successfully improved state programs and operations while developing a well-known reputation for independence, integrity, and collaborative leadership.

In the 1990s, Kelso worked with the California Judicial Council and Administrative Office of the Courts on a number of task forces and commissions. This work, particularly his efforts in support of unification of the state's trial courts, led to his receipt of the 1998 Bernard E. Witkin Amicus Curiae Award, the highest honor given to an individual other than a member of the judiciary for outstanding contributions to California's courts.

In July 2000, Kelso was selected by then Attorney General Bill Lockyer and Governor Gray Davis as the interim replacement for outgoing Insurance Commissioner Chuck Quackenbush, who abruptly resigned amid allegations of corruption. Kelso's leadership quickly restored public trust to the Department of Insurance.

In June 2002, Governor Davis appointed Kelso to serve as the State's Chief Information Officer and charged him with restoring the state's crumbling information technology program. After Governor Davis's recall, Governor Arnold Schwarzenegger retained Kelso in the State CIO position. Focusing on the disciplines of strategic planning, collaborative execution, and workforce development, Kelso turned the state's information technology ("IT") program around, in two years moving the state from 47th to 12th in Brown University's annual e-government report. In his State CIO role, Kelso also supported the development of state policies encouraging health information technologies and data sharing to improve quality, transparency, and accountability in public and private health care delivery systems. In recognition of his accomplishments, he received a "Top 25 Award for 2004 Doers, Dreamers and Drivers" from Government Technology and was named by Computerworld to their list of "Premier 100 IT Leaders for 2007."

A 1983 graduate of the Columbia University School of Law, Professor Kelso clerked for Judge Anthony M. Kennedy on the United States Court of Appeals for the Ninth Circuit. Kelso joined the faculty at Pacific McGeorge in 1986 after practicing law briefly in the New York offices of Kaye, Scholer, Fierman, Hays & Handler. A registered Republican, Kelso is married to Kari Kelso, Ph.D., and they have two daughters.

Clinical Initiatives

INTRODUCTION

The November 2007 iteration of the Receiver's Plan of Action focuses on 22 Initiatives, each of wide-ranging importance and impact. Each Initiative is described by a narrative that includes background information, current status, objectives for the next six months, 12 months, 24 months and 36 months, relevant metrics, and potential barriers. The Initiatives are summarized below:

INITIATIVES

1. Clinical Initiatives
   a. *Medical Staff Professional Development* (POA Objective A.7)

Implement a program to attract and retain excellent physicians, nurse practitioners, and physician assistants through the following strategies: assisting providers in maintaining and improving their clinical acumen with educational programs and support; offering targeted remedial opportunities for providers with remedial deficiencies; developing medical staff and interdisciplinary committees consistent with professional standards; developing a frontline cadre of managerial staff with quality improvement and leadership competencies; and establishing expectations and processes in the prisons in support of professionalism and ethical behavior.

   b. *Nursing Executive Leadership Initiative* (POA Objective A.7)

Establish a cadre of nurse executives through the Receiver's Career Executive Assignment program. Implement a three-prong support program: (1) effective recruitment and the establishment of relevant minimum job requirements; (2) defining roles and responsibilities and providing necessary assistance to meet those objectives; and (3) developing effective reporting mechanisms.

   c. *Healthcare Orientation, Nursing Preceptor Program, and Provider Proctoring Program* (POA Objective A.8.1 and A.8.5)

Implement a clinically-based nurse (licensed vocational nurse and registered nurse); physician, and mid-level provider orientation program at five prison pilot sites consisting of formal orientation programs, nurse preceptor program, and provider proctoring program.

   d. *Nursing Medication Delivery Process Redesign* (POA Objective B.8)

Redesign the prison medical delivery process to ensure patient-centered, common formulary, standardized, quality medication delivery in conjunction with the roll-out of the Maxor GuardianRx pharmacy system.

e. *Asthma Initiative* (POA Objective B.3.1)

Institute a pilot program to eliminate this common cause of preventable deaths within the CDCR, engaging six strategies of organizational change : (1) redesign of care practices based on best practices ; (2) use of information technology to support care givers ; (3) increasing clinical skills ; (4) developing team-based medical delivery systems ; (5) coordination of care ; and (6) incorporation of performance and outcome measures for tracking improvement and accountability.

f. *Emergency Response Initiative* (POA Objective B.1.1)

Improve emergency medical care within prisons, improve patient clinical outcome, and thereby decrease unexpected death due to lack of EMS care by establishing pilot projects to implement the Receiver,s approved statewide Emergency Medical Response System policy. This process will include training of staff, developing mechanisms to improve local preparedness, conducting assessments of emergency equipment, space, vehicles, staffing matrixes, developing accurate data concerning emergency responses, and the creation of prison-specific Emergency Response Review Committees.

2. Clinical Operations Initiatives

a. *Clinical Quality Measurement and Evaluation Initiative* (POA Objective C.2, C.6 and C.8)

Establish a new administrative unit of CDCR employees (who report to the Receiver) to develop and implement necessary clinical measurement and evaluation standards (clinical metrics). In addition, the unit will manage the Receiver's quality-based programs including CDCR healthcare credentialing and privileging unit, headquarters-based peer review (Professional Practice Executive Committee), death reviews, and the new Medical Oversight Unit (a collaborative pilot project to improve clinical investigations involving the Office of the Receiver, CDCR Internal Affairs, CDCR Legal Affairs, and the Office of the Inspector General).

b. *Clinical Support Services Initiative* (POA Objective B.12)

Establish a new administrative unit of CDCR employees (who report to the Receiver) to manage the Receiver's enhanced programs for radiology, medical records, laboratory services, pharmacy, and telemedicine.

3. Construction Initiatives

a. *San Quentin Construction Initiative* (POA Objective F.2)

Continue a number of essential construction projects currently underway at San Quentin State Prison, including establishing new, improved sick call units in facility rotundas, building a

temporary medical building to provide needed clinical offices and space, constructing a medical supply warehouse, and constructing the San Quentin Central Health Services Facility, a state of the art correctional health care center which serves the needs of four Federal Court class actions: *Armstrong*, *Coleman*, *Plata*, and *Perez*.

b. *5,000 Prison Medical Bed Construction Initiative* (POA Objective F.3)

Coordinate and lead a program to construct up to 5000 medical beds and up to 5000 mental health beds, utilizing carefully prepared patient demographic reports to establish the number and acuity levels of the beds needed. Working with a previously selected construction management firm, implement seven pre-construction strategies over the course of the next six months with the objective of commencing construction between April – June 2008: (1) site assessment and selection; (2) CEQA review and evaluation; (3) infrastructure review and development of remediation plans; (4) facility planning (a process which includes representatives from the other class actions); (5) program delivery; (6) obtaining funding; (7) development of an overall Project Management Plan.

c. *Facility Improvement Construction Initiative* (POA Objective F.1)

Provide desperately needed clinical space and clinical support space in existing California prisons, utilizing a carefully developed, coordinated (with other Federal Court class actions and AB 900 planning) formal space evaluation process. Facility improvement planning has been completed at Avenal State Prison and the Correctional Treatment Facility, and has begun at the California Rehabilitation Center. The evaluation/formal planning process will be completed at 15 prisons within 12 months, with an additional 13 prisons completed by December 2009. Construction will proceed according to an aggressive, formalized schedule subject to availability of funding.

4. Custody Access Initiative (POA Goal E)

Perform carefully designed formal health delivery oriented custody operational reviews at every California prison in order to establish the necessary correctional officer posts to provide adequate, timely prisoner/patient access to health care services. An initial review will be followed-up by a second evaluation relating in part to the Facility Improvement Construction Initiative, and eventually, pursuant to a time-phased schedule, the establishment of formal (and cost effective) health care Custody Access Teams at each prison.

5. Administrative Initiatives

a. *Out-of-State, Community Correctional Facilities, and Re-entry Facility Oversight Initiative*

Commence operation of a new administrative unit which will: (1) establish clinical standards and health care staffing standards for Out-of-State, Community Correctional Facilities, and Re-entry Facilities, manage necessary Out-of-State, Community Correctional Facilities, and Re-entry Facilities contract modifications to ensure compliance with the remedial orders of the

Federal Court health care class actions, establish and implement an Out-of-State, Community Correctional Facilities, and Re-entry Facilities inspection protocol and schedule; and (2) serve as an interface between the Office of the Receiver and the Inspector Generals' pilot *Plata* compliance prison inspection process, participating in the inspections as necessary.

b. *Contract and Invoice Processing Initiative* (POA Objective A.4 and A.6)

Roll out to 33 prisons the new Health Care Document Management System (HCDMS), providing phase one of an Information Technology solution to CDCR contract unit's chronic problems with timely procurement and invoice processing. Centralize, as part of the roll out process, invoice review and payment functions. Process, under HCDMS, 90% of bid contracts within 60 days. Process, under HCDMS, 98% of contract invoices within 30 days. Working with a retained consultant, enter into timely, cost effective agreements with hospitals who serve prisoner/patients, and provide training for contract personnel concerning hospital negotiations and contract processes. Secure a consultant review concerning the entire CDCR health care contracting process with the objective of developing a plan for a Statewide network of hospitals and specialty providers to serve all CDCR prisoner/patients.

c. *Fiscal Services Initiative* (POA Objective A.2.4 and A.2.5)

Develop and implement a Fiscal Management Section within the Plata Support Division to establish the necessary fiscal support infrastructure for the Receiver's medical care operation, both in the Central Office and in the prisons. Prepare budget related documents for the Department of Finance as necessary. Provide timely and accurate budget information to the Receiver and his staff to effectuate a more efficient and cost effective health care operation at all levels. Monitor and participate in the CDCR's implementation of the Business Information System (BIS).

d. *Personnel Services Initiative* (POA Objectives A.7, A.8, and A.8.5.3)

Create the necessary infrastructure, at Central Office and in the field, recruitment programs and expedited hiring practices to reduce the full-time, permanent, State employed clinical vacancies (Physicians, Mid-Level Provider, Registered Nurse, and Licensed Vocational Nurses) to less than 10% by December 2008. Also establish, within 6 months, the following programs: a program for recruiting and hiring of Receiver Career Executive Assignment personnel for key CDCR clinical leadership positions (and executive health care management positions at three pilot institutions); an appropriate credentialing tracking system; and a functioning employee discipline unit to provide manager education and "hands on" assistance concerning employee discipline matters.

e. *Health Care Appeals, Correspondence Control, and Habeas Corpus Petitions Initiative* (POA Objective C.3)

Centralize the controls and management over all CDCR health care prisoner/patient Appeals, Correspondence Control, and Habeas Corpus Petition responses, and include in this process a pilot project to utilize clinical personnel to evaluate/screen certain cases. Implement

timely changes to the existing appeal system as it pertains to the initial receipt of appeals and "third level" appeal responses. Develop and provide recommendations to the Receiver a long term, sustainable and improved system for a new appeal process within 6 months.

6. Information Technology Initiative (POA Goal D)

Establish a wide area network connection at all 33 CDCR prisons within six months. Install a local area wireless network within a selected number of pilot prisons within six months. Establish a data center, and thereafter a data repository, and the necessary clinical portal (a web based browser that will allow access by staff into the repository), all within 12 months. Utilize the recently established Health Care Information Technology Executive Committee (HITECH) to formulate recommendations concerning software and those applications which should assume priority for implementation.

7. Maxor Pharmacy Services Initiative (POA Goal B.8)

Continue the Maxor roadmap for change in the CDCR's pharmacy program, including the time-phased roll-out of the GuardianRx pharmacy system, developing and establishing revised policies, procedures and practices within the prison pharmacies, planning for and establishing a central fill pharmacy building, and continuing the implementation of existing Receivership/Maxor programs to manage CDCR pharmacy purchasing contracts.

8. Pilot Project Initiatives

a. *San Quentin Project Initiative* (POA Objective B.2)

Continue the San Quentin Pilot, including the development of improved nursing and administrative initiatives, the implementation of the enhanced , coordinated Reception Center process, and the construction of new clinical facilities at San Quentin as described above.

b. *Specialty Services Pilot at California State Prison – Los Angeles County and California Correctional Institution* (POA B.2 and B.3)

Continue the development of pilot programs at two prisons to provide enhanced prisoner/patient specialty services, focusing on improved contract procurement with specialty providers, more timely specialty provider invoice processing, improved specialty services scheduling and tracking, establishing additional controls and better responses to patient "refusals," and providing additional clinicians, correctional officers, and transport/escort vehicles to effectuate more timely out-of-prison specialty care delivery.

9. Class Action Coordination Initiative

Continue monthly meetings with the Court representatives (and quarterly meetings with the District Court Judges) overseeing the four Federal Court class action cases currently pending: *Armstrong* (Americans with Disabilities Act); *Coleman* (mental health); *Plata* (medical), and *Perez* (dental) to ensure coordinated and cost effective systemic remedial action, and to establish

various "coordination agreements" whereby the District Court Judges agree that the Receiver in *Plata* will take a leadership role when developing and implementing selected remedial programs which impact on all four class actions.

Chart of Initiatives

Receiver's Timeline for Accomplishing Plan of Action Objectives

Description	6 months	12 months	24 months	36 months
MEDICAL STAFF PROFESSIONAL DEVELOPMENT				
Develop a continuing medical education (CME) committee	◆			
Place a set of medical textbooks in clinic areas of each prison.	◆			
Make the CDCR Drug Formulary available for download to PDAs in partnership with ePocrates.	◆			
Develop CME programs held at local/regional sites and/or via distance learning		◆		
Develop need-based CME options to address specific provider deficiencies noted on assessments and quality reviews.		◆		
Improve access to health information and educational resources at all points of care delivery.		◆		
Develop medical library resources and staff		◆		
Develop a medical leadership curriculum and multimodal deployment strategies in partnership with University of California.		◆		
Collaborate with UC to establish specialized training programs using CDCR staff as clinical preceptors to residents and students (medical, NP, PA).			◆	
Collaborate with UC to establish academic appointments for CDCR clinicians.			◆	
Win accreditation for CDCR as a CME provider recognized by the Institute of Medical Quality and the Accreditation Council for Continuing Medical Education.				◆
NURSING EXECUTIVE LEADERSHIP				
Obtain approval for new salaries from DPA or obtain waiver from Court.	◆			
Begin hiring Nurse Executives.	◆			
Assign a mentor to each new pilot position.	◆			
Hire external evaluator with organizational development and human resources.	◆			
Repeat SPB and DPA process for Physician Executives and begin hiring.	◆			
Repeat SPB and DPA process for Administrators and begin hiring.	◆			
Complete evaluation.		◆		
Create a pool of limited-term positions in order to populate local, regional, and statewide leadership positions with qualified, responsive leaders.			◆	

Access to Care

Triage 7362
Medical Appointments
Availability of UHR/Chart
Female Health Care Visits
Lockdown

Access to Care Diagram

Sample Forms:

- 7362 – Healthcare Services Request Form
- Refusal of Exam / Treatment

Example of Ducat / Ducat List
CoPay Policy

Access to Care: (From The IMSP Volume 4 Chapter 4)

Purpose:
To ensure inmate-patients receive primary health care services based on medical necessity.

Triage: CDCR Form 7362

1. The CDCR Form 7362, Health Care Service Request, is a confidential medical document that is completed by the inmate patient.
2. If an inmate-patient is unable to complete a 7362 form, health care staff shall complete the form on behalf of the inmate-patient. Health care staff shall document the complaint, and reason the inmate-patient did not personally complete the form, and shall sign and date the 7362 form.
3. Translation services (including sign language) shall be available for inmate-patients, as necessary, via bilingual health care staff or by utilizing a certified interpretation service (i.e., AT&T Translation Services) when bilingual health care staff are unavailable. Each institution shall maintain a contract for certified interpretation services.
4. The 7362 forms are collected each day and initialed by the RN upon receipt. The 7362 forms are reviewed by the RN and if the treatment request involves another discipline (for example dental or mental health) the forms are immediately forwarded to that department.
5. If a form contains more than one request it is copied and distributed to the requested departments.
6. To ensure medication continuity, 7362 forms requesting medication refills or renewals shall be reviewed by the licensed staff member assigned to medication distribution for follow-up. Requests for medication refills or renewals do not require a face-to-face nurse triage.
7. Each 7362 requesting medical services for symptoms shall be reviewed each day by the RN. The RN shall establish medical priorities on an emergent or non-emergent basis. If there is no RN in the clinic, the Director of Nursing, or designee, shall be notified to provide direction.
8. Inmate-patients with emergent health care needs shall be seen by an RN, mental health clinician, and/or dentist immediately to establish disposition.
9. Inmate-patients with non-emergent medical needs shall be seen by an RN on the following business day for a face-to-face RN triage.
10. Requirements vary slightly on holidays and weekends, please see IMSP Chapter 4 Vol 4
11. During the face-face triage the if the RN determines that a physician referral is necessary, the RN shall document the referral on the CDCR Form 7362 and shall indicate the time frame in which inmate-patient shall be seen by the physician:

    Immediately (emergency)
    Within 24 hours (urgent)
    Within fourteen (14) calendar days (routine)

Medical Appointments

The physician/Midlevel line/clinic shall consist of but is not limited to the following inmate-patients:

- Triaged and referred by the RN
- Seen during off hours in the TTA by a physician or RN
- Returning for follow-up appointments, as ordered by the physician
- Returning from "out to medical" (back from hospitalization/procedure)
- Referred by the Receiving and Release RN
- Returning for diagnostic test results
- Returning from Specialty Service appointment or every 30 days until Specialty Service appointment is completed
- Chronic Care appointments
- High-Risk appointments (by qualified high-risk providers only)

Each inmate-patient ducated (appointed) for primary health care services shall be seen for his/her scheduled appointment in the clinic by the appropriate discipline. Primary health care services shall be available at least eight (8) hours per day, Monday through Friday, excluding holidays.

Priority health care ducat lists (appointment list) for routine appointments shall be prepared by the health care staff no later than one (1) day prior to the scheduled visit. Inmate-patients scheduled for routine appointments shall be ducated at designated intervals. Inmate-patients shall receive the priority health care ducat prior to their scheduled appointment and shall arrive at the clinic at the specified time as indicated on the priority health care ducat.

If an inmate-patient is a "no show" for a physician/midlevel visit, the Clinic staff (LVN, MA ,CNA assisting the provider) shall contact the housing unit supervisor to ascertain the reason for the "no show" and record in the UHR the reason given. The physician/midlevel who was to see the inmate-patient that day will determine, as clinically indicated, when the inmate-patient shall be rescheduled. If the provider determines that the inmate-patient does not need to be rescheduled for a physician/midlevel visit the reason should be documented in the UHR.

If the inmate-patient refuses the physician visit the clinic staff should complete a progress note (documenting the refusal) and a CDCR **Form 7225**, Refusal of Treatment.

Availability of UHR/Chart

The UHR/chart shall be available when the inmate-patient is seen except in exceptional circumstances. If the visit is routine and can be safely rescheduled the provider may occasionally request the patient be seen when the chart is available. If the problem is urgent the provider should see the inmate-patient without the chart, but document the absence of a chart on the progress note.

Female Health Care Visits

Each female medical visit, which requires an examination by a male health care provider, shall be attended by a female licensed health care staff person. The female licensed health care staff shall be present for the duration of the medical visit and is required to be present regardless of whether an unclothed examination is necessary. If clinical assistance with the examination is required by the licensed female health care staff member, she shall be appropriately licensed as indicated. The licensed female health care staff member shall be identified by name by the health care provider in the medical record (i.e., "examination performed in the presence of_____").

Lockdown

During a facility or prison lockdown, the clinic RN/MTA staff shall coordinate with custody staff to facilitate continuity of care. Custody personnel shall escort inmate-patients to scheduled clinic appointments; lockdown shall not prevent the completion of scheduled medical appointments.

Attachments:

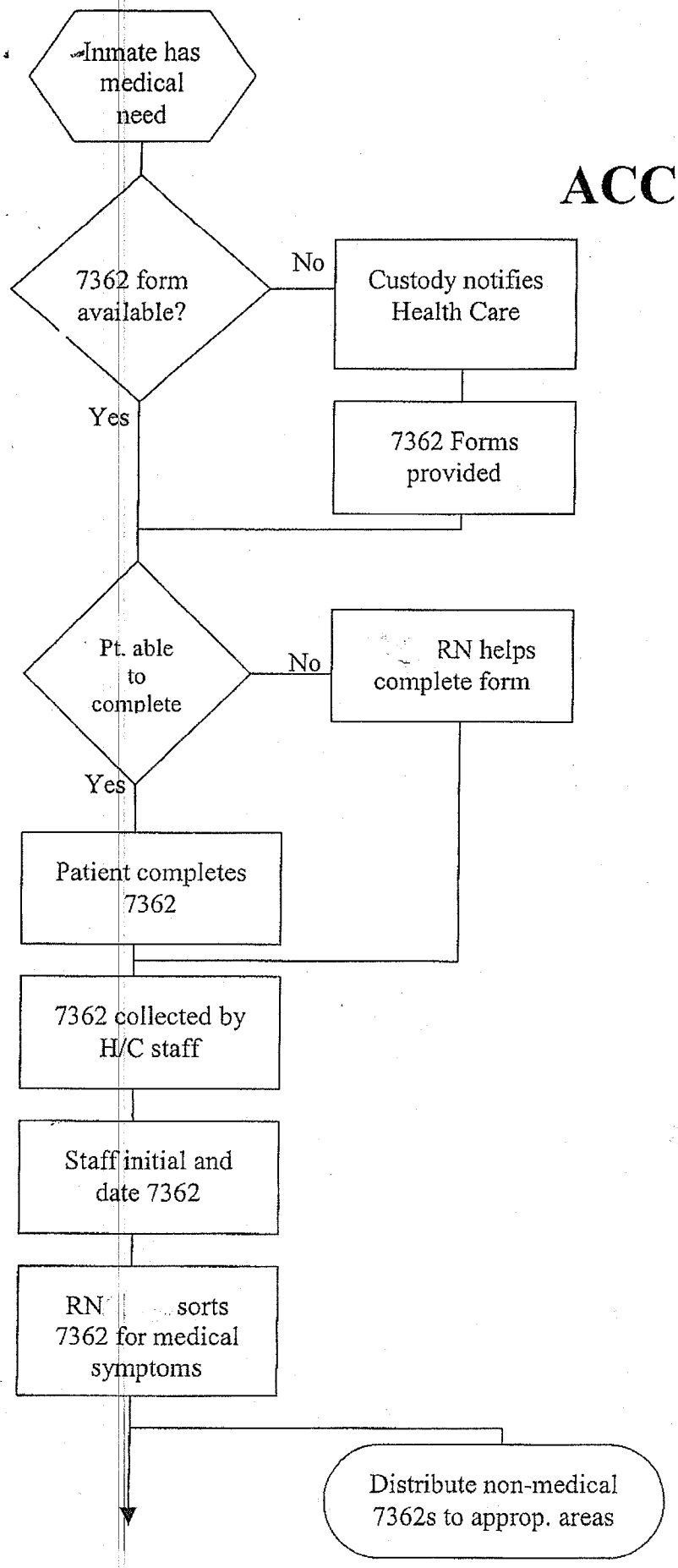
7362 Healthcare Services Request

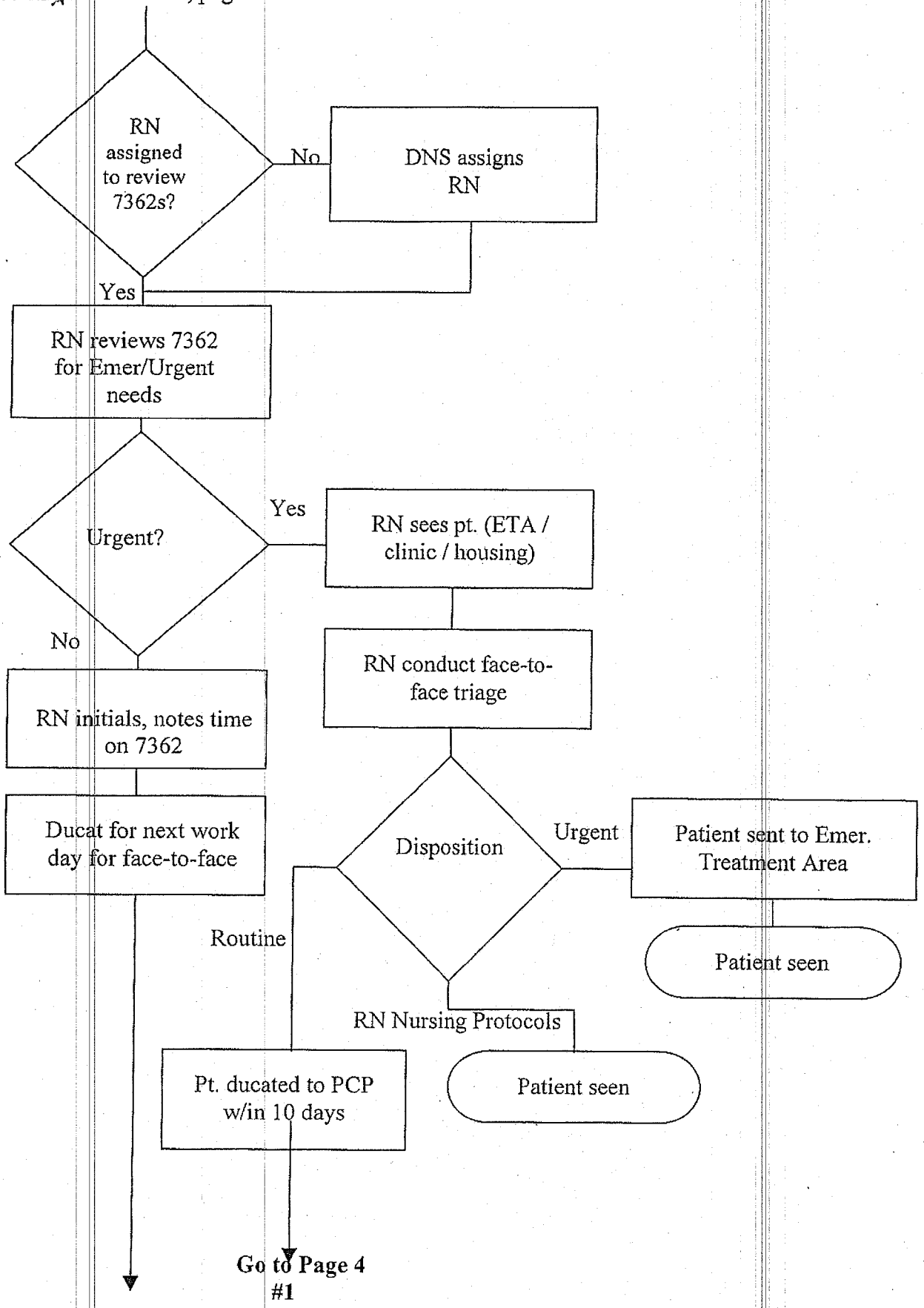
7225 Refusal of Treatment Form

Example of ducats and "Ducat List"

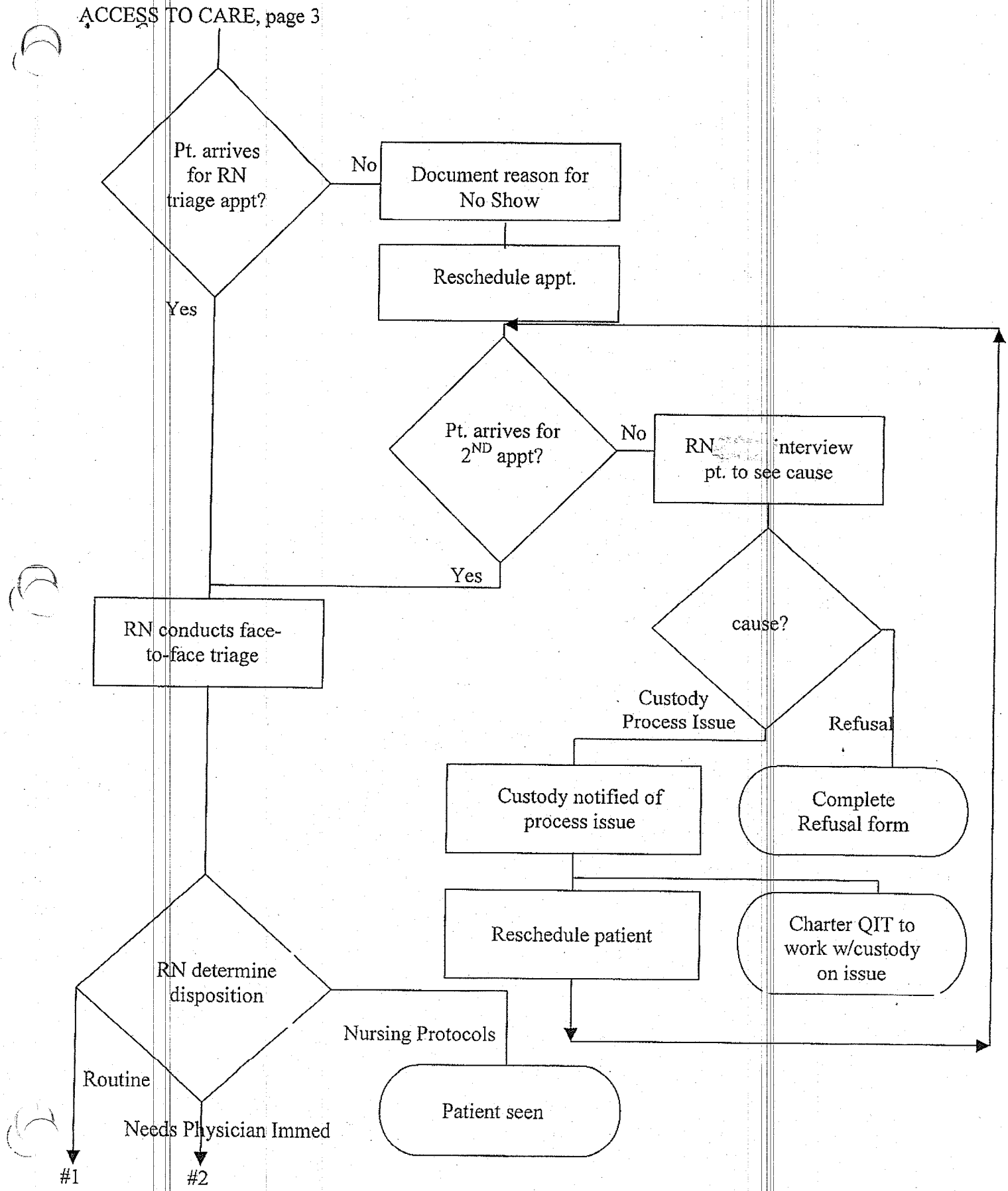
Clarification of inmate-patient co-pay policy

ACCESS TO CARE

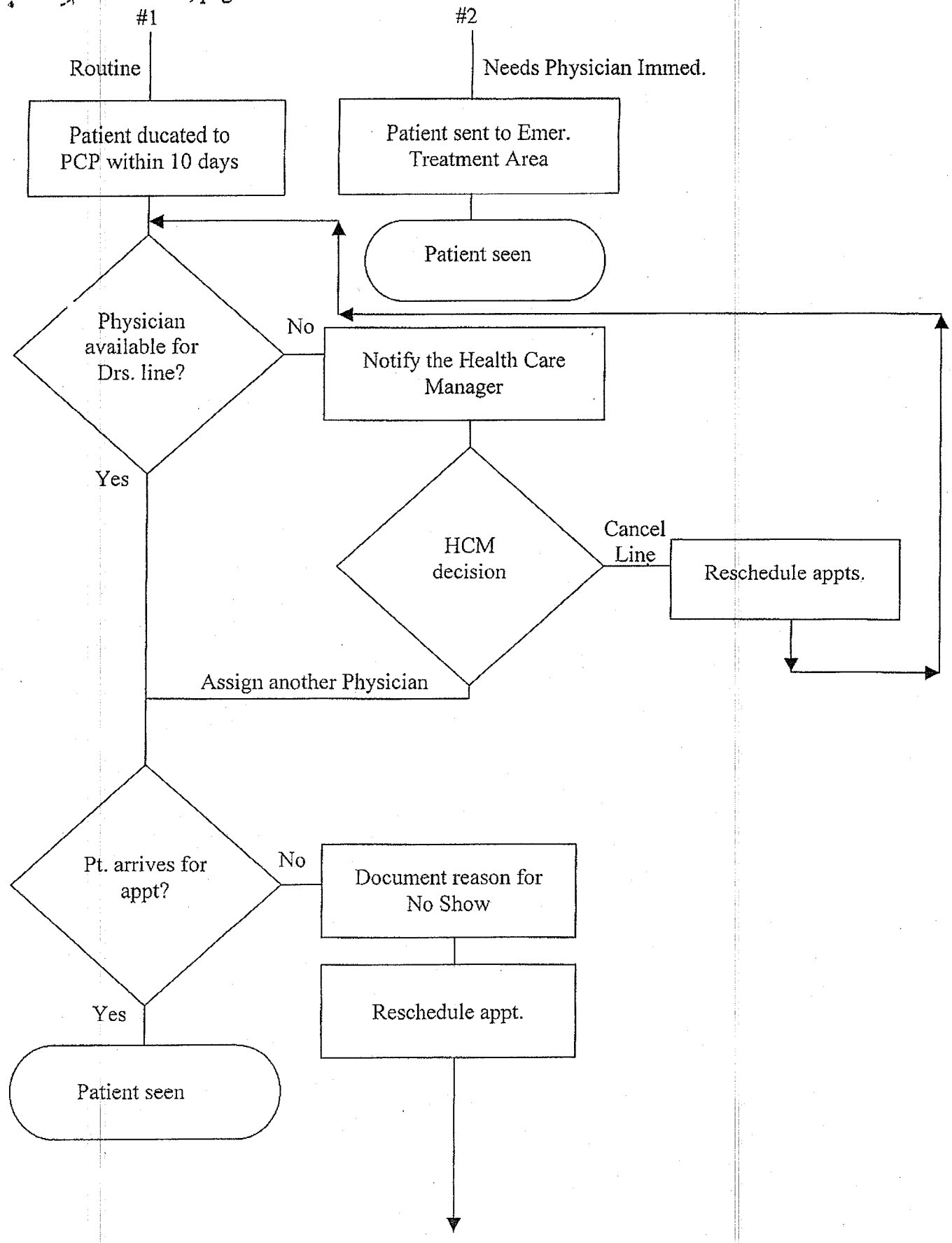


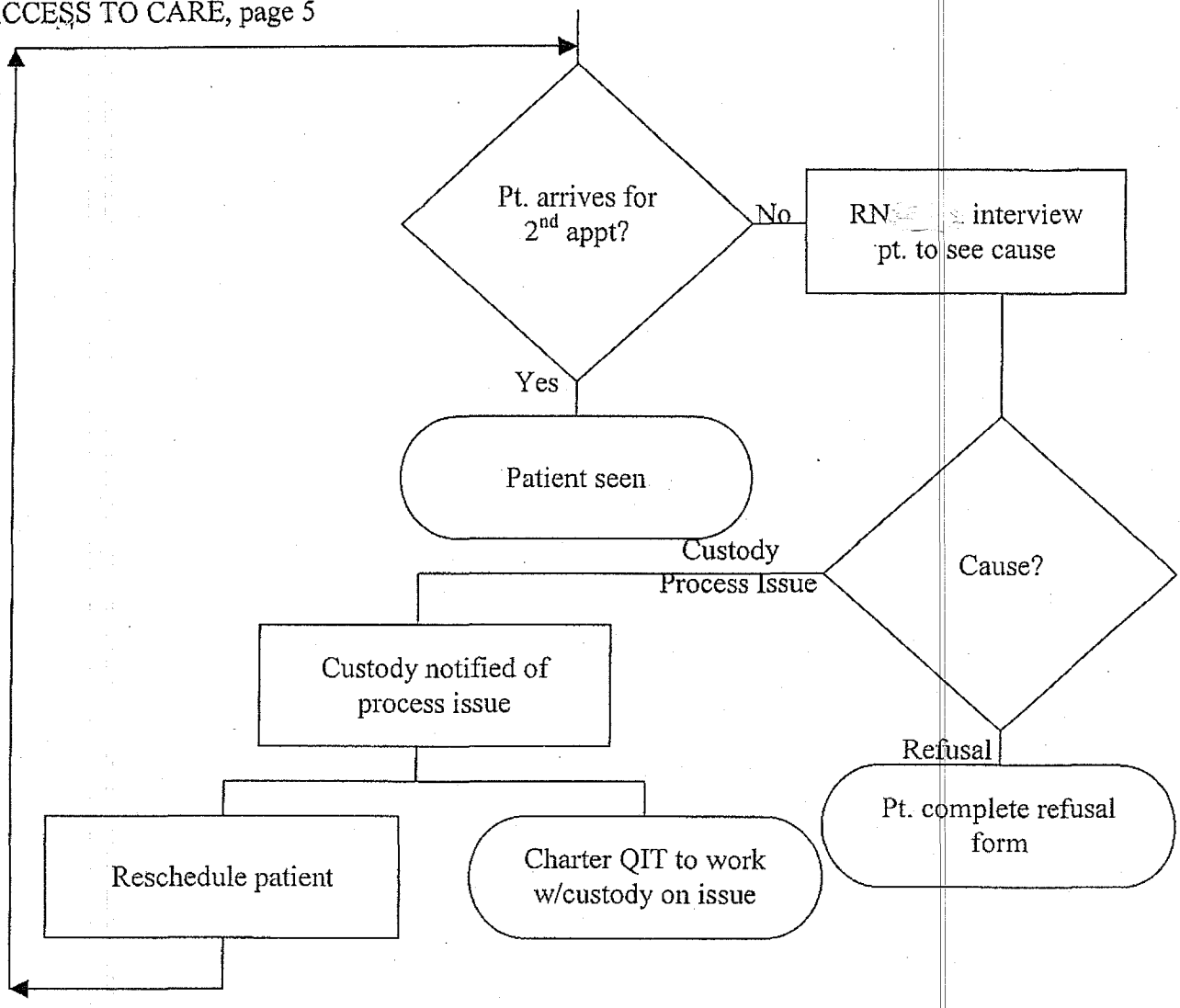

RN assigned to review 7362s?
No
DNS assigns RN
Yes
RN reviews 7362 for Emer/Urgent needs
Urgent?
Yes
RN sees pt. (ETA / clinic / housing)
No
RN conduct face-to-face triage
RN initials, notes time on 7362
Ducat for next work day for face-to-face
Disposition
Urgent
Patient sent to Emer. Treatment Area
Patient seen
Routine
RN Nursing Protocols
Pt. ducated to PCP w/in 10 days
Patient seen

Go to Page 4


Pt. arrives for RN triage appt?
No
Document reason for No Show
Reschedule appt.
Yes
Pt. arrives for 2ND appt?
No
RN interview pt. to see cause
Yes
RN conducts face-to-face triage
cause?
Custody Process Issue
Refusal
Custody notified of process issue
Complete Refusal form
Reschedule patient
Charter QIT to work w/custody on issue
RN determine disposition
Nursing Protocols
Routine
Needs Physician Immed
Patient seen
#1
#2

ACCESS TO CARE, page 4




Pt. arrives for 2nd appt?
No
RN interview pt. to see cause
Yes
Patient seen
Custody Process Issue
Cause?
Custody notified of process issue
Refusal
Pt. complete refusal form
Reschedule patient
Charter QIT to work w/custody on issue

734593

STATE OF CALIFORNIA
CDC 7362 (Rev. 03/04)

HEALTH CARE SERVICES REQUEST FORM

DEPARTMENT OF CORRECTIONS

PART I: TO BE COMPLETED BY THE PATIENT

A fee of $5.00 may be charged to your trust account for each health care visit.

If you believe this is an urgent/emergent health care need, contact the correctional officer on duty.

REQUEST FOR: MEDICAL ☐ MENTAL HEALTH ☐ DENTAL ☐ MEDICATION REFILL ☐

NAME	CDC NUMBER	HOUSING
PATIENT SIGNATURE		DATE

REASON YOU ARE REQUESTING HEALTH CARE SERVICES. (Describe Your Health Problem And How Long You Have Had The Problem) _____

NOTE: IF THE PATIENT IS UNABLE TO COMPLETE THE FORM, A HEALTH CARE STAFF MEMBER SHALL COMPLETE THE FORM ON BEHALF OF THE PATIENT AND DATE AND SIGN THE FORM

PART III: TO BE COMPLETED AFTER PATIENT'S APPOINTMENT

☐ Visit is not exempt from $5.00 copayment. (Send pink copy to Inmate Trust Office.)

PART II: TO BE COMPLETED BY THE TRIAGE REGISTERED NURSE

Date / Time Received:	**Received by:**
Date / Time Reviewed by RN:	**Reviewed by:**

S: Pain Scale: 1 2 3 4 5 6 7 8 9 10

O: T: P: R: BP: WEIGHT:

A:

P:

☐ **See Nursing Encounter Form**

E:

APPOINTMENT SCHEDULED AS: EMERGENCY (IMMEDIATELY) ☐ URGENT (WITHIN 24 HOURS) ☐ ROUTINE (WITHIN 14 CALENDAR DAYS) ☐

REFERRED TO PCP:	DATE OF APPOINTMENT:
COMPLETED BY	NAME OF INSTITUTION

PRINT / STAMP NAME	SIGNATURE / TITLE	DATE/TIME COMPLETED

REFUSAL OF EXAMINATION AND / OR TREATMENT

PATIENT NAME (*TYPE OR PRINT CLEARLY*)	CDC NUMBER	INSTITUTION

Having been fully informed of the risks and possible consequences involved in refusal of the examination and/or treatment in the manner and time prescribed for me, I nevertheless refuse to accept such examination and/or treatment. I agree to hold the Department of Corrections, the staff of the medical department and the institution free of any responsibility for injury or complications that may result from my refusal of this examination and/or treatment, specifically:

Describe the examination and/or treatment refused as well as the risks and benefit of the intervention:_____

_____

_____

_____

_____

_____

PATIENT SIGNATURE	DATE	☐ PATIENT REFUSES TO SIGN	DATE
WITNESS			
NAME OF WITNESS (*PRINT/TYPE*)		NAME OF WITNESS (*PRINT/TYPE*)	
WITNESS SIGNATURE	DATE	WITNESS SIGNATURE	DATE

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

REFUSAL OF EXAMINATION AND / OR TREATMENT

STATE OF CALIFORNIA
INMATE PRIORITY PASS

DEPARTMENT OF CORRECTIONS
CDC 129(7/88)

INMATE'S NAME	CDC #: F88386	HOUSING: B3SBT202L
ASSIGNMENT #:	DATE: 02-07-08	APPROVED BY: C/Lt
PASS TO: Hospital Door	DATE: 2/8/08	TIME: 1200
REASON: Psych,		
ARRIVAL TIME:	RECORDED BY:	
DEPART TO:	TIME: 1025	RECORDED BY:

STATE OF CALIFORNIA
INMATE PASS

DEPARTMENT OF CORRECTIONS
CDC 129 (7/88)

INMATE'S NAME	CDC #:	HOUSING #:
ISSUED BY:	DATE:	PASS FROM:
PASS TO:	DATE:	TIME:
REASON:		
ARRIVAL TIME:	RECORDED BY:	
DEPART TO: TIME:	RECORDED BY:	

TREATMENT PASS

Name:_____**CDC#**_____

PASS THE ABOVE NAMED INMATE TO THE MEDICAL CLINIC AT THE TIME AND DATE NOTED FOR THE TREATMENT INDICATED

Date:_____**thru**_____**Time:**_____

Treatment required:_____

Ordered by:
RN/MTA/MD_____

CDC#: _____ NAME: _____

EFFECTIVE FROM: _____ THRU: _____

"HOT" Medication Pass to pill line at the times noted below:

____ a.m. (0600 – 0800)

____ noon (1100 – 1300)

____ p.m. (1700 – 1900)

____ H.S. (2000 – 2100)

NOTE TO STAFF: When issuing, please initial appropriate time(s) and cross out others.

MEDICATION MAY IMPAIR ABILITY TO OPERATE MACHINERY

Issued by: _____ Date: _____

NO PASS – NO DRUGS!

CL – BS

Appointments for Bldg 3 Clinic on 2/8/2008

(by service)

Dr. Line

cc	Patient		Time	lengt	Provider	Housing	Race	Custody
		T96379	7:15	15	MD Line	B3SAT1 - 18L	BLA	CLOB
X		V23469	7:15	15	MD Line	B3SAT3 - 37L	BLA	MEDA
		C56988	7:15	15	MD Line	B3SBT1 - 33L	BLA	MEDA
X		B48404	7:15	15	MD Line	B3SAT1 - 31L	BLA	MEDA
		F21154	7:15	15	MD Line	B3SBT1 - 26L	WHI	MEDA
X		E08018 *	7:30	15	MD Line	-		
		P57958	8:15	15	MD Line	B3SAT4 - 2U	BLA	MEDA
X		D25114	8:15	15	MD Line	B3SAT1 - 15L	BLA	MEDA
		J14950	8:15	15	MD Line	B3SBT5 - 5U	WHI	MEDA
		T34031	8:15	15	MD Line	B3SAT2 - 38U	MEX	MEDA
X		F22962	8:15	15	MD Line	B3SAT4 - 10U	MEX	MEDA
X		V13508	9:15	15	MD Line	B3SBT2 - 27L	MEX	MEDA
X		H32632	9:15	15	MD Line	B3SBT5 - 24L	BLA	MEDA
		T55158	9:15	15	MD Line	B3SAT5 - 8L	MEX	MEDA

**** Not in DDPS; Inmate may no longer be in this institution***

This report includes confidential data and is governed by privacy laws and requirements. Unauthorized use is illegal. Shred to dispose.

State of California

Department of Corrections and Rehabilitation

Memorandum

Date : September 6, 2005

To : Health Care Managers

DCHCS Memo Number : 05-0008

Reason For Transmittal

[ ] State Law Change
[ ] Policy Change
[ ] Court Order or Settlement Agreement
[X] Clarification Request
[ ] Other _____

Supersedes: HCSD 01-0020

Subject: **INMATE COPAYMENT POLICY CLARIFICATIONS**

An analysis of data provided through our Inmate Medical Appeals Tracking Program reveals that there are inconsistencies in charging copayments. Approximately 7400 copayment appeals have been received during the period of January 2004 through June 2005, primarily involving follow-up visits, renewals of chronos and prescription refills or renewals. It is important that all institutions charge copayments consistently in an effort to reduce staff time spent researching and resolving copayment appeals.

To assist in proper interpretation of the policy, listed below is a more detailed explanation of the problematic areas of the copayment program.

Copayments shall not be charged for the following:

- Emergency services that are necessary to prevent death, severe or permanent disability, or to alleviate severe pain, as well as necessary crisis intervention of inmates/patients suffering from situation crises or acute episodes of mental illness.
- Diagnosis and treatment of communicable diseases.
- Follow-up health care services requested by a member of the health care staff for subsequent services.
- Health care services provided to comply with state law and/or regulations (such as annual TB testing).
- Reception center health screening and evaluation.
- Inpatient services, extended care, or skilled nursing services (including chronic care, outpatient care, chronic care program intake/follow-up).
- "No-shows"

Inmate-Initiated Health Care Visits

The copayment for any inmate-initiated health care visit covers the evaluation, assessment, and medically necessary treatment, including follow-up services that relate to the initial condition and which are determined by health care staff to be necessary.

Follow-up Visits

If licensed clinical staff indicates that a follow-up appointment is necessary at the time of the initial evaluation a copayment fee is not charged for the follow-up visit. Although follow-up care is defined in the California Code of Regulations (CCR) Title 15 as "...any request or recommendation by a member of the health care staff to provide subsequent health care services," circumstances do arise wherein an inmate/patient may request treatment related to the initial condition prior to the scheduled follow-up appointment. If an inmate-initiated request for health care services is submitted by an inmate/patient prior to the recommended follow-up date and the subsequent evaluation only relates to the initial condition, a copayment will not be charged (see page 8 of the attached administrative bulletin on the copayment program). This is the most misinterpreted copayment issue as nearly all health care staff charge a copayment for any request that is inmate-initiated.

If an inmate requests treatment for a new health problem during a follow-up appointment or chronic care appointment, the copayment is applicable. Requesting treatment for a new health problem at a follow-up appointment results in the visit becoming both a follow-up and inmate-initiated health care visit.

Prescription Renewals/Refills

The copayment fee charged for an inmate-initiated health care visit covers the evaluation, prescribed medications and any subsequent refills or renewals of medications that were prescribed at the time of the evaluation. As a result, if an inmate/patient submits a request to see a physician to obtain a renewal or refill of a prescribed medication related to the initial condition, an additional copayment is not charged.

Chrono Renewals

A copayment is not charged for an inmate-initiated request for a chrono renewal. Chronos are written to reflect an inmate/patient's medical restrictions based on custodial requirements and/or departmental/institutional policy. The expiration date of a chrono is based on departmental/institutional policy and/or the recommendation of the treating physician. Therefore, an inmate-initiated health care visit for a renewal of a chrono is considered a health care service provided to comply with state law and/or regulations, as the chrono is required based on departmental/institutional policy, or as a follow-up, as the chrono must be renewed or rescinded based on the physician's recommendation.

Dental

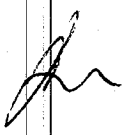
A copayment is not charged for initial dental screenings performed at reception centers. When a dental evaluation is initiated to develop a treatment plan for an inmate/patient, a copayment is not charged for the evaluation because it is mandated in CCR Title 15. Therefore, the dental

evaluation is considered to be health care provided to comply with state law and/or regulations. CCR Title 15, Section 3351.1(b) states "Each newly committed inmate shall within 14 days following transfer from a reception center to a program facility receive a complete examination by a dentist who shall develop an individual treatment plan for the inmate."

Copayments are not charged for follow-up dental visits which include, but are not limited to: suture removals, post-operative dental procedures initiated by the dentist, adjustments of new or repaired dentures, postponement of any dental procedure, or any health care staff-initiated visit.

For further clarification, refer to the attached Administrative Bulletin 94/11, dated October 14, 1994, which is still in effect. Please ensure this information is shared with your staff by September 29, 2005.

If you have any questions regarding the copayment program, they should be directed to Vicki O'Shaughnessy, Staff Services Manager I, Clinical Programs Risk Management Unit, Division of Correctional Health Care Services (DCHCS), at (916) 327-1205.



RENEE KANAN, M.D.
Director (A)
Division of Correctional Health Care Services

cc: Yulanda Mynhier, Deputy Director (A), Health Care Administrative Operations Branch, DCHCS
William Kuykendall, D.D.S., Chief Dentist, DCHCS
Chris Chrones, Regional Administrator-Central (A), DCHCS
Herb Spiwak, Regional Administrator-South (A), DCHCS
Calvin Smith, Regional Administrator-North (A), DCHCS
Lucinda McGill, Nurse Consultant III, QMAT, DCHCS
Tim Rougeux, Project Director, Medical Program Implementation, Medical Project Manager, DCHCS
Vicki O'Shaughnessy, Staff Services Manager I, Clinical Programs Risk Management Unit, DCHCS
Medical Appeals Analysts

Primary Care

Types of Visits

Chronic Care Program

- Definition
- Guidelines
- Referrals
- Intake
- Follow-Up

Preventive Service

Example of *Close Out Sheet*

Example Forms

- Progress Notes
- Chronic Care Intake
- Chronic Care Follow-Up

PRIMARY CARE

Background

Historically CDCR providers were responsible for addressing acute problems only in an episodic model of care. All of this has changed. We are now responsible for providing **chronic longitudinal care** in a **Primary Care model**, as well as **episodic care when needed**.

Why the change in mission?

A main influence of this change was the legal cases whose outcome deemed that the healthcare delivered in the California State Prison system was not constitutional. Inmate/patients were dying or suffering needless morbidity because of inadequate medical care. As you know, this led to the federal Receivership and the current court oversight of the California Prison Healthcare system.

Another significant influence in the change in mission to a Primary Care/ Chronic longitudinal care model is the fact that many of our patients suffer from serious chronic illness such as Hepatitis C, HIV, and Diabetes and deferring their care only leads to more complications. Our patients often have limited access to healthcare while out of prison, many have mental health challenges, or lifestyle issues that complicate their care and many have prolonged sentences (three strikes law) so are in our system for years. It is no longer acceptable to address only acute problems. The Division of Correctional Health Care Services **is** the Health care provider for these patients, and we as physicians and midlevel's, **are** their Primary Care Providers.

How does this affect me as a PCP?

Essentially as Primary Care Providers we each need to **take ownership** of our patients. You may not assume that "someone else will take care of this problem or follow-up this lab result, or be sure that this referral gets done". The buck stops at you, just at it would in a community setting.

You would not order a Chest CT scan on a patient you saw in a Sutter Clinic and then just assume that "someone" will be sure it gets done and will follow-up on the results. In a well run community clinic there are ways that systems can fail and patients can "fall through the cracks". In our broken (but healing) prison healthcare system there are even more challenges in making sure that our patients get the testing, referrals and follow-up that they need. It takes extra care, attention to detail and vigilance to be sure that your patients receive the care that you have ordered. You must make that extra effort to be sure that your patients get that care.

Each institution organizes their Clinic's in a slightly different way, some rotate providers every 3 months to various "yard clinics", some rotate once a year. Regardless of the details of how each institution functions the message is clear: the group of patients you are covering for whatever time you cover them constitute your **"panel"** and you are their **Primary Care Provider.** If for reasons of institutional need or other issues the providers at your institution continue to rotate clinics then you will need to build in a **small group practice model** in addition to the PCP panel model. In a small group practice model providers communicate frequently about challenging patients, make agreements on documentation and follow-up responsibilities and are accountable to the other members of the group. The collegiality and cross-education available in such a model often leads to increased provider satisfaction and can lead to even better care for our patients.

Clinic Organization

In a typical 'yard' clinic the provider will see 17-25 patients in a day. The chief complaints can vary as in a typical primary care practice. Some patients may be referred from the RN after triage of the patients 7362 form or may be a follow-up that the provider requested to discuss lab work or verify response to treatment. Other patients may be in the "Chronic Care" program (see below) and are being followed up as required for their chronic diseases. Patients who have pending referrals will be scheduled on a regular basis until that referral has been completed.

Types of visits:

1. **Episodic visits/follow up visits**: the provider will use CDCR **form 7230** (Interdisciplinary Progress Notes) and will use the S.O.A.P.E format for charting. (See Documentation section below)

2. **Chronic Care visits**: CDCR has developed the Chronic Care Program (CCP) described below. These visits are documented on specific forms.
3. Chronic Care intake visit : **4 page form (no number)**

4. Chronic Care Follow-up Visit **form 7254**

5. **Awaiting Specialty Referral**: Thirty Day Specialty Consult Progress Note: **form 7409**

6. **Disability Evaluation**: Disability Placement Program Verification: **form 1845**

7. **Medical Appeal:** Inmate/Parolee Appeal Form: **form 602**

Chronic Care Program:

This program was developed as an "organized method of providing medically necessary health care services to improve the health of inmate-patients diagnosed with chronic health conditions."

Definition: The CCP conditions include, but are not limited to, the following:

- Cardiovascular disease
- Diabetes mellitus
- General medicine
  a. Chronic conditions not covered by other clinics (e.g., inflammatory arthritis, hepatitis, SLE, colitis)
  b. **High-risk inmate-patients** (defined as a subset of patients with chronic diseases, whose severity of illness or multicity of diseases with poor, ongoing disease control.)
- Gynecological disease
- Human Immunodeficiency Virus (HIV)
- Pulmonary disease
- Seizure disorder
- Tuberculosis (TB)
- Hepatitis C
- Gastrointestinal/Gastroesophageal Reflux Disorder (GERD

Chronic Care Guidelines

In order to better track (and improve) the health/disease outcome of our patients with chronic diseases the CCP requires specific documentation be recorded at each visit.

- First an indication of **degree of control** of chronic condition

- Second the documentation of the **trend** of clinical control.

Degree of control:	G = Good Control;	F = Fair Control;	P = Poor Control
Clinical trend:	I = Improved	S = Stable	W = Worse

In general, the clinical trend will reflect a change in the degree of control. However, the clinical trend allows the identification of subtler changes than degree of control, and clinical judgment must be used. For example, if the systolic blood pressure changes from 159/99 to 140/90, the degree of control remains fair, the clinician may determine that the clinical trend is improved.

The following chart contains disease-specific history elements that should be recorded during each chronic care visit, as well as disease specific periodic laboratory studies, specialty referrals and vaccination requirements.

CHRONIC CARE CONTROL CRITERIA

HEALTH CARE INDICATORS	GOOD CONTROL	FAIR CONTROL	POOR CONTROL
HYPERTENSION: (use diastolic or systolic BP, whichever leads to the lower degree of control)			
Blood Pressure:	Systolic < 140 Diastolic < 90	Systolic 140 - 159 Diastolic 90-99	Systolic ≥ 160 Diastolic ≥ 100
If either DM or chronic renal disease is present:	Systolic < 130 Diastolic < 80	Systolic 130 – 159 Diastolic 80 – 99	
DIABETES MELLITUS:			
Hgb A1c:	< 7% AND	7% - 7.9% AND	> 7.9% OR
Hypoglycemic episodes since the last CCP visit:	0 0	1 1	>1 >1
HIV: (On ART ≤ 90 days)			
Symptoms:	No	No	Yes (wasting, thrush, FUO)
Viral Load:	<50,000	<100,000	≥ 100,000
CD4:	>350	200-349	<200
Weight as % ideal weight:	≥ 90%	≥ 85%	< 85%
Active OI's* or Malignancies:	None	None	New
HIV: (On ART > 90 days)			
Viral Load:	Undetectable	<5,000	> 5000
CD4:	Rising	Unchanged	< 50 or declining
Weight as % ideal weight:	≥ 90%	≥ 85%	< 85%
Active OI's*[1] or Malignancies:	None	None	New

[1] Opportunistic Infections

SEIZURE DISORDER:			
Seizures since the last CCP visit:	none	1 or 2	>2
ASTHMA			
Good Control: Use of no more than one short acting beta-agonist inhaler canister per month AND no awakening because of asthma symptoms AND no visits to an onsite TTA/ER for asthma since last CCP visit			
Fair Control: Use of no more than one short acting beta-agonist inhaler canister per month AND awakening with asthma symptoms no more than once per week AND no more than one on-site TTA/ER visit for asthma since last CCP visit			
Poor Control: Use of more than one short acting beta-agonist inhaler canister per month OR awakening more than once per week with asthma symptoms OR more than one on-site TTA/ER visit since last CCP visit			

Immunizations should include:

Immunization	**Criteria**
Annual influenza vaccination	▪ ≥ 65 years old ▪ chronic cardiopulmonary disorders (including asthma) ▪ diabetes ▪ hemoglobinopathy ▪ renal dysfunction ▪ immunosuppression
Pneumococcal vaccine	▪ 65 years old ▪ chronic cardiopulmonary disorders ▪ diabetes mellitus ▪ anatomic asplenia (excluding sickle cell disease)
Hepatitis B vaccine	All inmate-patients with Hepatitis C
Hepatitis A vaccine	All inmate-patients with Hepatitis C

Chronic Care Program referral:

- The patient can be referred to the Chronic Care program at the time of their Initial Health Screening in Receiving and Release (R&R), or at any other sick call or health care encounter.

- Inmate-patients identified as chronic care or high-risk during the History & Physical will require a **physician order** referring the inmate-patient for a CCP or high-risk evaluation and enrollment, and intake.

- At the time of referral for evaluation and enrollment, intake **lab tests** for the referral disease(s) will be ordered by the referring PCP.

- The CCP or high-risk Intake Evaluation shall be completed within **thirty (30) days** of the date of the provider's order or sooner if specified.

Chronic Care Program intake evaluation:

- All **initial health care evaluations** of inmate-patients in the CCP or high-risk program will include a targeted history and physical examination focusing on important historical information, physical findings, and diagnostic studies. (4 page)

- The provider orders appropriate medications, vaccinations, monitoring, diagnostic studies, laboratory tests, referrals to a specialist or other chronic care program, and orders the **follow-up visit** in accordance with the time lines specified in the CCP guidelines. (See below)

- The PCP provides **health care education** to the inmate-patient on their disease process, focusing and empowering the inmate-patient on nutrition, exercise, smoking cessation and medication adherence. The CCP nurse will enter the appropriate data on the flow sheet.

- If the inmate-patient has had medical evaluations prior to incarceration, which would be relevant to current CCP or high-risk problems, the inmate-patient will be asked to sign a release of information form in order to **obtain health records** from the treating facility or provider.

Interval between Chronic Care Program Visits

- The PCP needs to use clinical judgment to determine degree of control when standardized definitions are not provided.

Well controlled	If the degree of control is not likely to worsen with less frequent visits, inmate-patients whose disease process is well controlled over a six-month period and are not high-risk, as documented on two consecutive visits, may be seen every six (6) months, as determined by the provider.
Good control	Minimum of every ninety (90) days
Fair control	Every two months or more frequently as determined by provider
Poor control	Monthly or more frequently as determined by provider. (Some patients designated high risk are seen weekly.)
HIV Management of all HIV inmate-patients under treatment shall be under the supervision of an HIV specialist.	At least monthly, except that if the inmate-patient in the HIV CCP is followed by an Infectious Disease specialist and is in good control, the inmate-patient may be seen every three (3) months.

Chronic Care/High Risk Follow-up Visits:

In Chronic care follow-up visits the structured progress note is required, or the provider may use this as a guide and attach a more detailed note in the S.O.A.P. E format. The problem list and primary care flow sheets will be updated at each visit.

During the follow-up visit provider obtains an interval history from the date of the last visit to the date of the current visit, reviews the current medications, complaints or problems, and assesses compliance with the chronic care program. The provider reviews the results of laboratory tests, diagnostic studies, monitoring, reports from specialty referrals, and performs a focused physical examination.

The provider assesses the degree of control of each chronic disease based on standard definitions and the clinical status/trend in comparison to the prior visit, and then records the plan on the chronic care visit structured progress note. If the degree of control is fair or poor, or if the status has worsened, the plan must reflect strategies for improvement or document why there is not a change to the treatment plan

MD Line: Appointments for Bldg 3 Clinic on 2/8/2008

7:15 15 F21154 Dr. Line B3SBT1 - 26L WHI MEDA *Inmate Seen Y / N* *Refusal Signed Y / N*

Follows Dr. Line 2/1/2008 for RFS update *UHR Present Y / N* *Explanation (if not seen)* _____

MO Line Documentation: Chronic Care Program Y / N High Risk Y / N *Chronic Care/ High Risk Diagnosis:* *Chronic Care Control* *Chronic Care Trend Status*

Orders: Lab _____ *XRay* _____ Good Fair Poor Improved Stable Worse

Specialties Ordered: _____ Good Fair Poor Improved Stable Worse

Patient Diagnosis _____ *Follow Up: 30 60 90 Other:* ___ Good Fair Poor Improved Stable Worse

---

X 8:15 15 D25114 Dr. Line B3SAT1 - 15L BLA MEDA *Inmate Seen Y / N* *Refusal Signed Y / N*

Follows Dr. Line 11/6/2007 *UHR Present Y / N* *Explanation (if not seen)* _____

MO Line Documentation: Chronic Care Program Y / N High Risk Y / N *Chronic Care/ High Risk Diagnosis:* *Chronic Care Control* *Chronic Care Trend Status*

Orders: Lab _____ *XRay* _____ Good Fair Poor Improved Stable Worse

Specialties Ordered: _____ Good Fair Poor Improved Stable Worse

Patient Diagnosis _____ *Follow Up: 30 60 90 Other:* ___ Good Fair Poor Improved Stable Worse

---

10:15 15 F72920 Dr. Line B3SBT1 - 12U HIS MEDA *Inmate Seen Y / N* *Refusal Signed Y / N*

Follows Lab specimen collection 1/31/2008 for Chem 7, thyroid *UHR Present Y / N* *Explanation (if not seen)* _____

MO Line Documentation: Chronic Care Program Y / N High Risk Y / N *Chronic Care/ High Risk Diagnosis:* *Chronic Care Control* *Chronic Care Trend Status*

Orders: Lab _____ *XRay* _____ Good Fair Poor Improved Stable Worse

Specialties Ordered: _____ Good Fair Poor Improved Stable Worse

Patient Diagnosis _____ *Follow Up: 30 60 90 Other:* ___ Good Fair Poor Improved Stable Worse

---

8:15 15 J14950 Dr. Line B3SBT5 - 5U WHI MEDA *Inmate Seen Y / N* *Refusal Signed Y / N*

Follows Dr. Line 10/16/2007 *UHR Present Y / N* *Explanation (if not seen)* _____

MO Line Documentation: Chronic Care Program Y / N High Risk Y / N *Chronic Care/ High Risk Diagnosis:* *Chronic Care Control* *Chronic Care Trend Status*

Orders: Lab _____ *XRay* _____ Good Fair Poor Improved Stable Worse

Specialties Ordered: _____ Good Fair Poor Improved Stable Worse

Patient Diagnosis _____ *Follow Up: 30 60 90 Other:* ___ Good Fair Poor Improved Stable Worse

---

8:15 15 P57958 Dr. Line B3SAT4 - 2U BLA MEDA *Inmate Seen Y / N* *Refusal Signed Y / N*

Follows Dr. Line 1/25/2008 for HTN; seizure disorder: *UHR Present Y / N* *Explanation (if not seen)* _____

MO Line Documentation: Chronic Care Program Y / N High Risk Y / N *Chronic Care/ High Risk Diagnosis:* *Chronic Care Control* *Chronic Care Trend Status*

Orders: Lab _____ *XRay* _____ Good Fair Poor Improved Stable Worse

Specialties Ordered: _____ Good Fair Poor Improved Stable Worse

Patient Diagnosis _____ *Follow Up: 30 60 90 Other:* ___ Good Fair Poor Improved Stable Worse

---

**** Not in DDPS; Inmate may no longer be in this institution*** ***Name of clinical staff completing dispositions:*** _____

This report i[illegible]es confidential data and is governed by privacy laws and requirements. Unauthorized use [illegible] illegal. Shred to dispose.

Preventive Services

Preventive Services:

CDCR provides diagnostic and preventive health care services to all inmate-patients. Screening guidelines are generally consistent with evidence-based established guidelines, including those of the USPSTF and the NCCHC.

Laboratory testing, if applicable, shall include:

Test	Criteria
Fecal Occult Blood Testing- with Cards	≥ 50 years old.
Pap Smear	Annually for females who have been sexually active and who have a cervix or for females who have a history of cervical cancer or precancerous lesions. After three (3) consecutive normal tests are obtained, Pap smears shall be performed biannually. Pap smears may be discontinued for women older than 65 who after age 55 have had at least three (3) normal tests and no abnormal tests.
Mammography	Every 2 years for females ≥ 40 years old.

DATE	TIME	

NSTITUTION | HOUSING UNIT | CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

NTERDISCIPLINARY PROGRESS NOTES

Baseline Health History

Chronic Care Clinics (check all that apply)

- ☐ Pulmonary/Asthma/COPD
- ☐ General Medical
- ☐ Liver Disease
- ☐ Seizures
- ☐ HTN/CV
- ☐ Diabetes
- ☐ TB
- ☐ HIV

Medical History

** Any abnormal findings must be described in the text space provided*

General Description and Chief Complaint:

_____

_____

Cardiovascular/Hypertension/ Diabetes:_____ Date of onset of symptoms: _____

Y	N		Y	N		Y	N		Y	N	
☐	☐	Chest Pain	☐	☐	Claudication	☐	☐	Syncope/Dizziness	☐	☐	Blurred Vision
☐	☐	Shortness of Breath	☐	☐	Leg Swelling	☐	☐	Kidney Disease	☐	☐	Foot Problems
☐	☐	Palpitation	☐	☐	Prior Heart Attack/Stroke	☐	☐	Hypoglycemic Episodes	☐	☐	Nocturia
☐	☐	Epistaxis	☐	☐	Hyperlidemia	☐	☐	Weight Gain/Loss	☐	☐	Polyuria
☐	☐	Orthopnea	☐	☐	Headache						

Risk Factors:

Y	N		Y	N		Y	N	
☐	☐	Family History	☐	☐	Cholesterol	☐	☐	Sedentary Lifestyle
☐	☐	Smoking	☐	☐	High Blood Pressure	☐	☐	Diabetes

Details of checked boxes:

_____

_____

Asthma/Pulmonary/COPD/Tuberculosis:_____ Date of onset of symptoms: _____

Y	N		Y	N		Y	N	
☐	☐	Wheezing	☐	☐	Activity Intolerance	☐	☐	Fever
☐	☐	Nighttime Awaking Symptoms ____ per week	☐	☐	GERD	☐	☐	Liver Disease
☐	☐	Hospitalized for Asthma within the last year	☐	☐	Allergies	☐	☐	Night Sweats
☐	☐	Number of ER Visits in past 3 Months _____	☐	☐	# Asthma Attacks per week _____	☐	☐	Weight Loss
☐	☐	History of Intubations	☐	☐	Exposure to Environmental Risk	☐	☐	Persistent Cough
☐	☐	Short Acting Inhalers use ____ times per week	☐	☐	Hemoptysis	☐	☐	Prior TB History

Risk Factors:

Y	N		Y	N	
☐	☐	Family History	☐	☐	Smoking

Details of checked boxes:

_____

_____

Provider Signature:	Date:	CDCR Number, Name (Last, First, MI) and Date of Birth:
...tion:		

Baseline Health History (continued)

IV/HCV Infection _____ Date of Diagnosis: _____

Y	N		Y	N		Y	N		Y	N	
☐	☐	Anorexia	☐	☐	Diarrhea	☐	☐	Abdominal Swelling	☐	☐	Pregnancy
☐	☐	Exposure to Environmental Risk	☐	☐	Malaise	☐	☐	Joint Pain	☐	☐	Pruritis
☐	☐	High Risk Sexual Activity	☐	☐	Weight Loss	☐	☐	Stool Changes	☐	☐	Nausea/Vomiting
☐	☐	Skin Changes	☐	☐	Thrush	☐	☐	RUQ Pain	☐	☐	Jaundice

Risk Factors

Y	N		Y	N	
☐	☐	High Risk Sexual Activity	☐	☐	Drug Use
☐	☐	Tattooing	☐	☐	Alcohol

Seizures _____ Date of onset of symptoms: _____

Y	N		Y	N		Y	N	
☐	☐	Aura	☐	☐	Gum Disease:_____	☐	☐	Type of Seizures:_____
☐	☐	Postictal State	☐	☐	Headache	☐	☐	Date of Last Seizure:_____
☐	☐	Number of Seizure in past 3 mos. ___	☐	☐	History of Head Injury	☐	☐	Other Neurological Symptoms

Risk Factors

Y	N		Y	N	
☐	☐	Med. Adherence	☐	☐	Alcohol/Substance Abuse

ils of checked boxes:

_____

_____

Other Disease History: (current meds, prior hospitalizations, other problems including mental health, allergies, and substance use)

☐ For Additional Health History Use:

_____

_____

_____

_____

_____

Vital Signs:

Temp:	Pulse:	Resp:	Height:	Weight: lbs
(L) Blood Pressure Sitting	(L) Blood Pressure Standing	(R) Blood Pressure Sitting	(R) Blood Pressure Standing	

Provider Signature:	Date:	CDCR Number, Name (Last, First, MI) and Date of Birth:
ı:		

Baseline Health History (continued)

ıysical Exam: HEENT/Neck: _____ Heart: _____

Lungs: _____ Abdomen: _____

Extremities: _____ Rectal: _____

Neurological: _____ Other: _____

ASSESSMENT DIAGNOSES:

	DEGREE OF CONTROL			
	G	F	P	N/A
1.				
2.				
3.				
4.				
5.				

EDUCATION PROVIDED:

☐ Nutrition ☐ Exercise ☐ Smoking ☐ Test Results
☐ Medication Management ☐ Alcohol/Substance Abuse ☐ Other

PLAN:
Medication Changes:

LABS:

OTHER TEST(s):

MONITORING:
BP: _____ times per day/week/month Glucose: _____ times per day/week/month Peak Flow: _____ Other: _____

REFERRAL:
Specialist (indicate specialty and priority level):

OTHER CHRONIC CARE PROGRAM (specify): High Risk: Y ☐ N ☐

Number of days to next visit: ☐ 30 ☐ 60 ☐ 90 ☐ Other

Provider Signature:	Date:	CDCR Number, Name (Last, First, MI) and Date of Birth:
n:		

Baseline Health History (continued)

dditional Medical History

C ONIC CARE FOLLOW-UP VISIT

☐ continuation progress note attached

List chronic diseases: (1) _____; (2) _____; (3) _____

HISTORY:

Pharmacy profile attached (or list current medications here) _____

_____ RN/MTA Signature

Complaints/Problems:

CV / Hypertension: Chest Pain: Yes No SOB: Yes No

Diabetes Mellitus: # of hypoglycemic reactions since last visit: _____

Seizure Disorder: # seizures since last visit: _____

All CCP Conditions: other new symptoms: Yes No (if YES explain) _____

Asthma: # attacks since last visit: _____

short acting beta agonist canisters in last month: _____

visits to ETA for asthma since last visit: _____

times awakening with asthma symptoms per week: _____

Additional History: _____

CCP compliance with medications: yes no *diet: yes no* *exercise: yes no*

If no, describe:

EXAM: *HEENT:*

Neck:

Lungs:

Heart:

Abdomen:

Extremities/Pulses/Skin Changes:

Neuro:

Rectal/Other (specify):

Comments on BP, Glucose Monitoring, Lab Values

SSESSMENT:	Degree of Control				Clinical Trend			
	G	F	P	NA	I	S	W	NA
1.	☐	☐	☐	☐	☐	☐	☐	☐
2.	☐	☐	☐	☐	☐	☐	☐	☐
3.	☐	☐	☐	☐	☐	☐	☐	☐

PLAN: Primary Care Flow Sheet Reviewed: ☐

Medications:

Lab/Diagnostics:

Other:

Monitoring: o BP: _____ X week/month o Glucose: _____ X day/week / month o Other: _____

Education Provided: o Nutrition o Exercise o Smoking o Test Results o Medication Management o Other: _____

Referral: o Specialist (specify): _____ o High Priority | o Other Chronic Care Program (specify): _____

 # days to next visit: o 30 o 60 o 90 o 180 o Other: _____ | o Discharge from CCP (specify disease): _____

Provider Signature _____ **Date** _____

CDCR NUMBER, NAME (LAST, FIRST, MI), INSTITUTION AND DATE OF BIRTH

OUTPATIENT INTERDISCIPLINARY PROGRESS NOTES

CR 7254 REV 10/05

STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

CHRONIC CARE FOLLOW-UP VISIT

Documentation

- Why is good documentation needed?
- Documentation Expectations
- Problem List
- Documentation Errors

- Improving Documentation
- Summary of Documentation Expectations
- Abbreviations

- Orders
- Special Forms:
  - Chronos
  - 602 Appeals
  - 1845 Disability Evaluation

CDCR Clinical Documentation

Why is good documentation necessary?

The Unit Health Record (UHR)/chart is a shared document used by all caregivers involved in a patient's care both inside CDCR institutions and in the community when patients are admitted to outside hospitals or receive specialty care.. Data contained in the UHR records pertinent facts and observations regarding the inmate-patients health history.

Role of Medical Record

- A well documented record provides a precise picture of the patients status at the time of the encounter
- Allows healthcare professionals to evaluate and plan the inmate-patient's immediate treatment as well as to monitor the individuals care over time.
- The UHR is the key tool to communication and continuity of care among all providers and staff involved in the inmate patients' treatment.
- The data contained in the UHR allows for review of health care service utilization and quality of care monitoring. This facilitates training, peer review processes, and gives valuable information for program improvement.
- Well documented encounters **ultimately reduce work** and save time on subsequent encounters.

Key Fact: incomplete, illegible, and poorly documented medical records contribute to treatment errors resulting in patient injury and suffering. Poor documentation also increases professional liability and malpractice risk.

Key Fact: at the present time it is CDCR Standard of Care to document in the SOAPE format. This requirement was initiated because of a history of poor document in the system. If you have another complete format for your documentation you may use it, but it must in conjunction with the S.O.A.P.E indicators. This is because your charts will be audited by numerous departments including the Prison Law Office, and some of the auditors will not be medically trained so they may not realize that Chief Complaint and History of Present Illness represent "Subjective".

Documentation Expectations:

- Legibility and completeness are key
- The **date, time** and **legible** identification of the **provider** must be included on all notes
- Facts to include for each encounter include:
    - **Reason for the encounter** (chief complaint) (S)
    - **History** relevant to the encounter (which will include HPI , and pertinent PMHX,ROS-including pertinent negatives findings, FH,SH) (S)
    - **Focused Physical examination** findings, including vital signs (O)
    - List of **current medications**, or reference how you reviewed them (O)
    - Results of prior pertinent **diagnostic tests** (O)
    - **Assessment** or diagnostic impression addressing all symptoms and abnormal

findings. You should document your **medical decision making** such as what data supports your diagnosis or rules out red flag diagnoses. (A)
        - include information on the inmate/patient's progress, response to treatment, any changes in the treatment, and any revision of diagnosis
    - **Plan** of care relevant to the diagnostic impression, including follow-up plan or disposition. (P)
        - The rationale for ordering (or not ordering) diagnostic testing and specialty consultations should be documented
    - **Education** of the patient should be documented (E)

- Past and present diagnosis should be accessible in the chart. Use of the **Problem List is required** and facilitates finding that information
- In addition a provider should **document** the fact that **informed consent or refusal** was obtained when it is required.
- Use of the **Primary Care Flow Sheet** (7392) is expected and will help identify worrisome trends such as weight loss, or rising creatinine.
- Use of specific forms for specialized visit types (**Chronic Care Follow-up** {7254}, Thirty Day Specialty Consult Progress Note {7409}) is expected, but you made add additional pages if needed for thorough documentation.
- **If you do not have the UHR when seeing the patient, you must clearly document that fact on your note.**

Problem List

It is expected that ALL providers document on the Problem List. This is not just something for the Primary Care Provider to maintain. In the CDCR system we all share the care of complex patients and we need to help each other. It is crucial to good patient care to have an updated list of the patient's chronic or significant diagnoses, procedures and test results. This will help avoid medical errors and needless repeat testing.

The Problem Lists are found in the front of the UHR. If a new problem is identified at a visit and that problem is likely to have relevance in the future, put it on the Problem List. (i.e. if you are seeing a patient for a cough you determine to be caused by ACEI medication it should be on the Problem List. If the cough is from a self limited URI it would generally not be put on the Problem List.)

Documentation errors

If for some reason you need to change an entry, for example you make an entry on the wrong chart, you should:

- put one simple line through the incorrect entry and the
- initial the error
- date the error

Improving Documentation

<u>"Chart mistakes that can burn you"</u>

(From Medical Economics October 5, 2007)

Ill-chosen words can come back to haunt you

Choosing the right words is always important, but it's especially crucial in documenting patient care. Imprecise or incorrect language can make it seem that the doctor is shading the truth to protect himself, or can smack of poor clinical judgment. Plaintiffs' attorneys comb through patient records to find such linguistic missteps, says Tennenhouse, citing examples of what to avoid:

Understatement. Describing a semi-comatose patient as "drowsy" or noting that a patient who's doubled over in agony "complains of a little pain" is an inaccurate characterization, just as "a little blood" is an inadequate description of four units of blood. Never underestimate the danger of understatement, Tennenhouse says.

Exaggeration. Overstatement also gives a plaintiff's attorney an opportunity to undermine your credibility. "Let's say you jotted down, 'Every possible precaution was taken,'" says Tennenhouse. "If an attorney can prove there was one precaution you missed, your statement turns into a lie and the jury starts believing the plaintiff's story."

Noncommittal or vague words. "It's better to write, 'Patient says he ingested a bottle of aspirin' than 'Patient allegedly ingested a bottle of aspirin,'" says Tennenhouse. "You may think you're playing it safe, but 'allegedly' sounds like a defensive measure. It means, 'This is what I heard, but I don't know if I believe it.'"

In general, vague words are subject to hostile interpretation. Suppose, after evaluating a patient with congestive heart failure who presents with a headache, you tell her the headache isn't alarming but that she should notify you if it worsens. In the chart you note, "Patient was reassured about headache."

The headache indeed intensifies, but the patient never reports it. Then she suffers a stroke, which leads to a lawsuit. At the trial, her lawyer projects the word "reassured" on that giant screen. "The defendant," he says, "told Mrs. Jones she could *ignore* her headache—it wasn't serious."

"That's a common interpretation of the word 'reassure,'" Tennenhouse warns. "The trouble is, it misrepresents what you said."

Some things are best kept out of the record

Because sketchy charting can weaken a doctor's defense, risk managers and malpractice carriers have exhorted them to write everything down. Blindly following that advice, though, can get you in trouble.

"You give more ammunition to a plaintiff's attorney by writing long notes without paying attention to their quality," Tennenhouse says. Examples of what to omit include:

Negative characterization of a patient. Using words like "vindictive," "malicious," or "hostile" to describe a patient who threatens to sue "could strike a jury as defensive or judgmental and cost you support," says Tennenhouse. You shouldn't remain mum about dangerous behavior or threats, but document them from an objective, patient care perspective: "Mr. Williams' dissatisfaction and threats of a lawsuit may create problems with compliance."

Conjecture. Premature conclusions can create problems, too. If you discover a hospitalized patient crumpled on the floor, for instance, don't write, "Patient fell out of bed" unless you saw what happened; she could have fallen as she walked from the bathroom to the bed or tried to get back into bed. Simply note, "Patient found on floor," Tennenhouse says.

Are you omitting critical information?

Charting omissions, like careless words, can cost you dearly. Here are some examples of details that should never go unwritten:

Conversations with patient and family. To save time, doctors often do not document that they warned a patient—about, say, the dangers of drinking alcohol while taking certain medications. When a patient pays for his recklessness, the lack of a notation makes it easier for an attorney to argue that the doctor was negligent, says Tennenhouse.

Likewise, doctors often forget to write down relatives' comments. If a patient's wife says, "My husband is getting more confused," put a note in the chart. If that patient ever sues, his attorney could construe the absence of such an entry as evidence that you were asleep at the stethoscope. "Juries tend to put more stock in a family member's vivid recollection of a key conversation than a doctor's," Tennenhouse says.

Factors that interfere with an accurate assessment. A jury might excuse an incorrect or delayed diagnosis if there were mitigating factors—and you documented them. If you find it hard to trust a history taken from a habitually confused patient, for example, make a note of it.

Medical reasoning. A patient may present with atypical symptoms—a key reason to record what you're thinking when you rule out a particular disease.

"A patient with appendicitis might come in complaining of back pain," says Tennenhouse. If there's no evidence of the nausea and vomiting, right lower quadrant pain, or rebound tenderness usually associated with this condition, a doctor may have reason to rule out appendicitis. "But he needs to explain his thought process," Tennenhouse adds. "Otherwise, if the appendix ruptures and the patient sues, his attorney could argue, 'Nowhere in the chart does it say that Dr. Smith even thought about appendicitis.'"

"If you documented that you considered appendicitis and could rule it out, however, a jury would probably let you off the hook," he says. "A plaintiff's attorney might not even take the case because it looks unwinnable."

Remember that happy legal outcome the next time you write in a patient chart.

An abbreviated look at abbreviations

Excerpted from "Can You Read This?"

(Medical Economics April 6, 2007)

Even in the most careful hand, abbreviations on prescriptions and patient charts can be easily misinterpreted, such as *U* (for units) read as *0* or even *cc*; an elongated period after *q* in *q.d.* (every day) read as *q.i.d.* (four times/day), or *SC* (subcutaneous) mistaken as *SL* (sublingual). Patient-safety experts recommend that you spell out all words to prevent medication errors. The Institute for Safe Medication Practices (ISMP) has published a list of abbreviations that have caused drug mix-ups and confusion; you'll find it at http://www.ismp.org/tools/errorproneabbreviations.pdf. The Joint Commission has also asked hospitals to educate physicians to abstain from using problematic abbreviations.

Putting the indication for the drug on the prescription can also prevent errors from look-alike drugs written in less-than-perfect handwriting, such as Topamax for Toprol-XL, Lamisil for Lamictal, or Zyprexa for Zyrtec. "Physicians who don't want to write the indication for the drug can use prescription blanks with icons that can be circled indicating the diagnosis," says Allen Vaida, executive vice president of ISMP. Another option is to use preprinted prescriptions for the 40 or so drugs you frequently prescribe. "All you have to do is put in the dose, date, and patient's name," says Vaida.

(See Error prone abbreviation list attached.)

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the USP-ISMP Medication Error Reporting Program as being frequently misinterpreted and involved in harmful medication errors. They should NEVER be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

The Joint Commission (TJC) has established a National Patient Safety Goal that specifies that certain abbreviations must appear on an accredited organization's do-not-use list; we have highlighted these items with a double asterisk (**). However, we hope that you will consider others beyond the minimum TJC requirements. By using and promoting safe practices and by educating one another about hazards, we can better protect our patients.

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS **hs**	Half-strength At bedtime, hours of sleep	Mistaken as bedtime Mistaken as half-strength	Use "half-strength" or "bedtime"
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken as "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"
q.d. or QD**	Every day	Mistaken as q.i.d., especially if the period after the "q" or the tail of the "q" is misunderstood as an "i"	Use "daily"
qhs	Nightly at bedtime	Mistaken as "qhr" or every hour	Use "nightly"
qn	Nightly or at bedtime	Mistaken as "qh" (every hour)	Use "nightly" or "at bedtime"
q.o.d. or QOD**	Every other day	Mistaken as "q.d." (daily) or "q.i.d. (four times daily) if the "o" is poorly written	Use "every other day"
q1d	Daily	Mistaken as q.i.d. (four times daily)	Use "daily"
q6PM, etc.	Every evening at 6 PM	Mistaken as every 6 hours	Use "6 PM nightly" or "6 PM daily"
SC, SQ, sub q	Subcutaneous	SC mistaken as SL (sublingual); SQ mistaken as "5 every;" the "q" in "sub q" has been mistaken as "every" (e.g., a heparin dose ordered "sub q 2 hours before surgery" misunderstood as every 2 hours before surgery)	Use "subcut" or "subcutaneously"
ss	Sliding scale (insulin) or ½ (apothecary)	Mistaken as "55"	Spell out "sliding scale;" use "one-half" or "½"
SSRI **SSI**	Sliding scale regular insulin Sliding scale insulin	Mistaken as selective-serotonin reuptake inhibitor Mistaken as Strong Solution of Iodine (Lugol's)	Spell out "sliding scale (insulin)"
i/d	One daily	Mistaken as "tid"	Use "1 daily"
TIW or tiw	3 times a week	Mistaken as "3 times a day" or "twice in a week"	Use "3 times weekly"
U or u**	Unit	Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., 4U seen as "40" or 4u seen as "44"); mistaken as "cc" so dose given in volume instead of units (e.g., 4u seen as 4cc)	Use "unit"
Dose Designations and Other Information	**Intended Meaning**	**Misinterpretation**	**Correction**
Trailing zero after decimal point (e.g., 1.0 mg)**	1 mg	Mistaken as 10 mg if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers"
"Naked" decimal point (e.g., .5 mg)**	0.5 mg	Mistaken as 5 mg if the decimal point is not seen	Use zero before a decimal point when the dose is less than a whole unit

© ISMP 2007

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations* (continued)

Dose Designations and Other Information	Intended Meaning	Misinterpretation	Correction
Drug name and dose run together (especially problematic for drug names that end in "l" such as Inderal40 mg; Tegretol300 mg)	Inderal 40 mg Tegretol 300 mg	Mistaken as Inderal 140 mg Mistaken as Tegretol 1300 mg	Place adequate space between the drug name, dose, and unit of measure
Numerical dose and unit of measure run together (e.g., 10mg, 100mL)	10 mg 100 mL	The "m" is sometimes mistaken as a zero or two zeros, risking a 10- to 100-fold overdose	Place adequate space between the dose and unit of measure
Abbreviations such as mg. or mL. with a period following the abbreviation	mg mL	The period is unnecessary and could be mistaken as the number 1 if written poorly	Use mg, mL, etc. without a terminal period
Large doses without properly placed commas (e.g., 100000 units; 1000000 units)	100,000 units 1,000,000 units	100000 has been mistaken as 10,000 or 1,000,000; 1000000 has been mistaken as 100,000	Use commas for dosing units at or above 1,000, or use words such as 100 "thousand" or 1 "million" to improve readability
Drug Name Abbreviations	**Intended Meaning**	**Misinterpretation**	**Correction**
ARA A	vidarabine	Mistaken as cytarabine (ARA C)	Use complete drug name
AZT	zidovudine (Retrovir)	Mistaken as azathioprine or aztreonam	Use complete drug name
CPZ	Compazine (prochlorperazine)	Mistaken as chlorpromazine	Use complete drug name
DPT	Demerol-Phenergan-Thorazine	Mistaken as diphtheria-pertussis-tetanus (vaccine)	Use complete drug name
DTO	Diluted tincture of opium, or deodorized tincture of opium (Paregoric)	Mistaken as tincture of opium	Use complete drug name
HCl	hydrochloric acid or hydrochloride	Mistaken as potassium chloride (The "H" is misinterpreted as "K")	Use complete drug name unless expressed as a salt of a drug
HCT	hydrocortisone	Mistaken as hydrochlorothiazide	Use complete drug name
HCTZ	hydrochlorothiazide	Mistaken as hydrocortisone (seen as HCT250 mg)	Use complete drug name
MgSO4**	magnesium sulfate	Mistaken as morphine sulfate	Use complete drug name
MS, MSO4**	morphine sulfate	Mistaken as magnesium sulfate	Use complete drug name
MTX	methotrexate	Mistaken as mitoxantrone	Use complete drug name
PCA	procainamide	Mistaken as patient controlled analgesia	Use complete drug name
PTU	propylthiouracil	Mistaken as mercaptopurine	Use complete drug name
T3	Tylenol with codeine No. 3	Mistaken as liothyronine	Use complete drug name
TAC	triamcinolone	Mistaken as tetracaine, Adrenalin, cocaine	Use complete drug name
TNK	TNKase	Mistaken as "TPA"	Use complete drug name
ZnSO4	zinc sulfate	Mistaken as morphine sulfate	Use complete drug name
Stemmed Drug Names	**Intended Meaning**	**Misinterpretation**	**Correction**
"Nitro" drip	nitroglycerin infusion	Mistaken as sodium nitroprusside infusion	Use complete drug name
"Norflox"	norfloxacin	Mistaken as Norflex	Use complete drug name
"IV Vanc"	intravenous vancomycin	Mistaken as Invanz	Use complete drug name
Symbols	**Intended Meaning**	**Misinterpretation**	**Correction**
ʒ ♏	Dram Minim	Symbol for dram mistaken as "3" Symbol for minim mistaken as "mL"	Use the metric system
x3d	For three days	Mistaken as "3 doses"	Use "for three days"
> and <	Greater than and less than	Mistaken as opposite of intended; mistakenly use incorrect symbol; "< 10" mistaken as "40"	Use "greater than" or "less than"
/ (slash mark)	Separates two doses or indicates "per"	Mistaken as the number 1 (e.g., "25 units/10 units" misread as "25 units and 110" units)	Use "per" rather than a slash mark to separate doses
@	At	Mistaken as "2"	Use "at"
&	And	Mistaken as "2"	Use "and"
+	Plus or and	Mistaken as "4"	Use "and"
°	Hour	Mistaken as a zero (e.g., q2° seen as q 20)	Use "hr," "h," or "hour"

**These abbreviations are included on TJC's "minimum list" of dangerous abbreviations, acronyms and symbols that must be included on an organization's "Do Not Use" list, effective January 1, 2004. Visit www.jointcommission.org for more information about this TJC requirement.

© ISMP 2007

Permission is granted to reproduce material for internal newsletters or communications with proper attribution. Other reproduction is prohibited without written permission. Unless noted, reports were received through the USP-ISMP Medication Errors Reporting Program (MERP). Report actual and potential medication errors to the MERP via the web at www.ismp.org or by calling 1-800-FAIL-SAF(E). ISMP guarantees confidentiality of information received and respects reporters' wishes as to the level of detail included in publications.

Eliminating Error-prone Abbreviations, Symbols, and Dose Designations

The Problem

Ambiguous medical notations are one of the most common and preventable causes of medication errors.

Drug names, dosage units, and directions for use should be written clearly to minimize confusion.

Consequences of Using Error-Prone Abbreviations

- **Misinterpretation may lead to mistakes that result in patient harm**
- **Delay start of therapy due to time spent for clarification**

Implement "Do Not Use" List

The Institute for Safe Medication Practices (ISMP) and the Food and Drug Administration recommend that ISMP's list of error-prone abbreviations be considered whenever medical information is communicated.

Complete list is located at:

www.ismp.org/Tools/errorproneabbreviations.pdf

Consider All Communication Forms

- Written orders
- Internal communications
- Telephone/verbal prescriptions
- Computer-generated labels
- Labels for drug storage bins
- Medication administration records
- Preprinted protocols
- Pharmacy and prescriber computer order entry screens

Short List of Error-Prone Notations*

The following notations should NEVER be used.

Notation	Reason	Instead Use
U	Mistaken for 0, 4, cc	"unit"
IU	Mistaken for IV or 10	"unit"
QD	Mistaken for QID	"daily"

*Comprises "do not use" list required for JCAHO accreditation

Short List of Error-Prone Notations Continued

Notation	Reason	Instead Use
QOD	Mistaken for QID, QD	"every other day"
Trailing zero (X.0 mg)	Decimal point missed	"X mg"
Naked decimal point (.X mg)	Decimal point missed	"0.X mg"

Short List of Error-Prone Notations Continued

Notation	Reason	Instead Use
MS	Can mean morphine sulfate or magnesium sulfate	"morphine sulfate"
MSO_4 and $MgSO_4$	Can be confused with each other	"morphine sulfate" or "magnesium sulfate"
cc	Mistaken for U	"mL"

Short List of Error-Prone Notations Continued

Notation	Reason	Instead Use
Drug name abbreviations (especially those ending in "l")	Mistaken for other drugs or notations	Complete drug name
> or <	Mistaken as opposite of intended	"greater than" or "less than"
μ	Mistaken for mg	"mcg"

Short List of Error-Prone Notations Continued

Notation	Reason	Instead Use
@	Mistaken for 2	"at"
&	Mistaken for 2	"and"
/	Mistaken for 1	"per" rather than a slash mark
+	Mistaken for 4	"and"

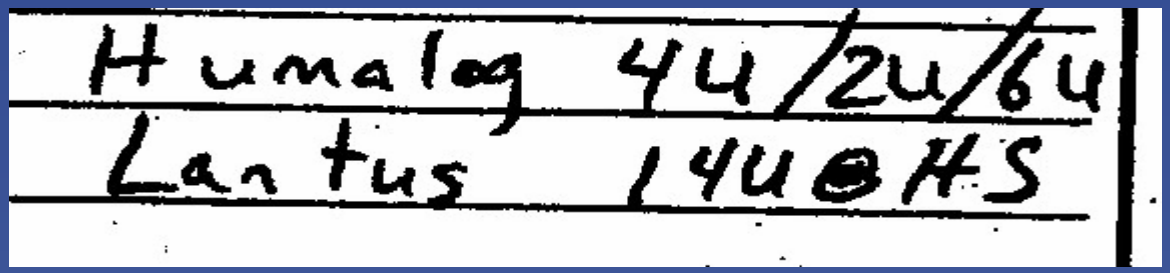
Short List of Error-Prone Notations Continued

Notation	Reason	Instead Use
AD, AS, AU	Mistaken for OD, OS, OU	"right ear," "left ear," or "each ear"
OD, OS, OU	Mistaken for AD, AS, AU	"right eye," "left eye," or "each eye"
D/C, dc, d/c	Misinterpreted as "discontinued" when followed by list of medications	"discharge" or "discontinued"

Other Good Practices

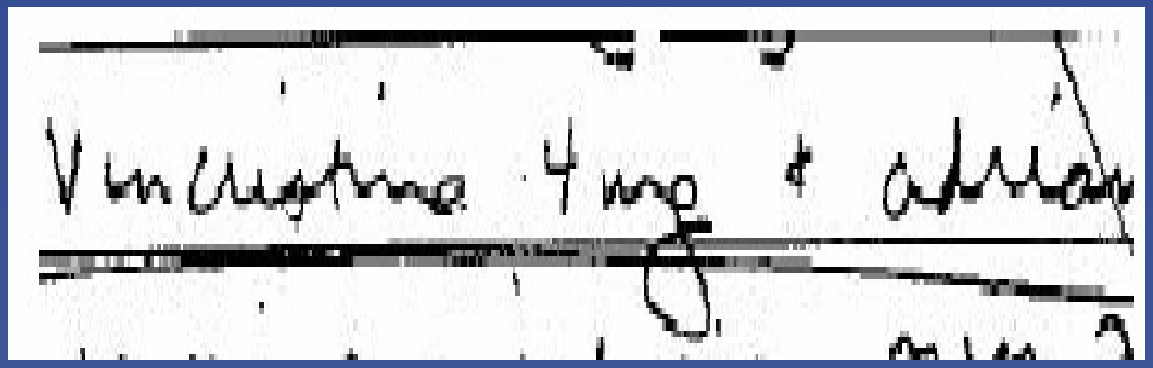
- **Drug name abbreviations can easily be confused. Always write out complete drug name.**
- **Apothecary units are unfamiliar to many practitioners. Always use metric units.**

Examples



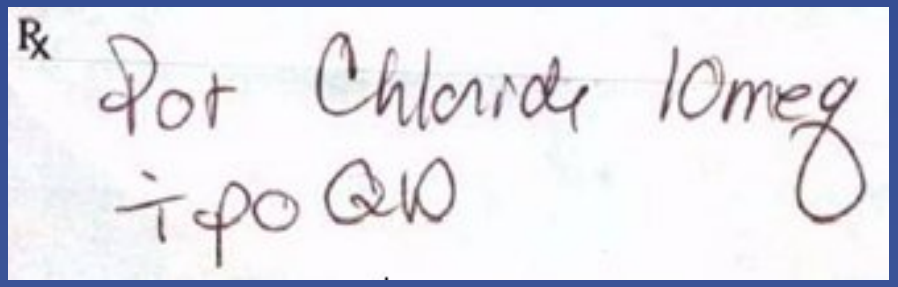
Intended dose of 4 units in patient history interpreted as 44 units. “U” should be written out as “unit.”

Examples



Intended dose of ".4 mg" interpreted as 4 mg from medication order. Should be written as "0.4 mg."

Examples



“Potassium chloride QD” in medication order interpreted as QID. Should be written as “daily.”

Examples

Intended recommendation of “less than 10” was interpreted as 4. “<” should be written out as “less than.”

Examples

“QD” in advertisement should be written out as “daily.”

Examples

warfarin therapy who received three to six months of unfractionated heparin (10,000 U subcutaneously twice daily), as compared with 1 of 40 patients who received dalteparin (5000 U subcutaneously twice daily) for the same length of time.[28]

"U" in prominent professional journal article should be written out as "unit."

Do Not Use Error-Prone Abbreviations Even in Print

- **May still be confused**
- **Perpetuates the impression that they are acceptable**
- **May be copied into written orders**

Recommendations for Healthcare Professionals

- **Avoid ambiguous abbreviations in written orders, computer-generated labels, medication administration records, storage bins/shelf labels, and preprinted protocols.**
- **Work with computer software vendors to make changes in electronic order entry programs.**
- **Provide examples when educating staff on how using error-prone abbreviations have led to serious patient harm.**
- **Provide staff with ISMP's list of error-prone abbreviations.**
- **Introduce healthcare students to the list of error-prone abbreviations.**

Recommendations for Pharmaceutical Industry

- **Review existing drug labeling and packaging as well as new drug applications for use of error-prone abbreviations.**
- **Eradicate use of ambiguous abbreviations in product advertising (both in graphics and text).**
- **Check for error-prone abbreviations in all communications vehicles, including slides, promotional kits, and sales staff training materials.**
- **Include ISMP's list in corporate editorial style guidelines.**
- **Incorporate list into software and medical device design.**

Recommendations for Medical Communications/Publishing Professionals

- **Make "do not use list" of notations as part of publishing style manuals and internal style guides for clinical writing.**
- **Add the list of error-prone abbreviations to instructions for journal authors.**
- **Review all internal and external communications products for ambiguous abbreviations.**
- **Eliminate error-prone abbreviations in company-wide educational and training sessions.**

Other Resources

For more information and tools to help promote safe practices, visit:

www.ismp.org/tools/abbreviations

or

www.fda.gov/cder/drug/MedErrors

PROBLEM LIST

No.	Date Listed	Medical Problem	When Noted	Treatment	Date Resolved

Name of Patient (Last, First):		CDC Number:
Year of Birth	Age:	Housing:

HEALTH MAINTENANCE

TEST	DATE OF LAST TEST							
Stool Guaiac:								
Chest X-ray:								
EKG:								
PPD:								
VDRL:								
Others:								

HOSPITALIZATION/SURGERY	Date	HOSPITALIZATION/SURGERY	Date

Allergies:	
Immunizations:	
Habits:	
Family History:	

Name of Patient: (Last, First): _____

CDC Number:

PRIMARY CARE FLOW SHEET

Date of Visit							
Enter values.							
Temp., Pulse, Resp.							
Blood Pressure							
Weight							
Peak Flow							
Enter "Normal" or "Abnormal."							
*EKG	☐	☐	☐	☐	☐	☐	☐
*CXR	☐	☐	☐	☐	☐	☐	☐
Enter values.							
*Hgb/Hct	☐	☐	☐	☐	☐	☐	☐
*Hgb A1c	☐	☐	☐	☐	☐	☐	☐
*Fasting LDL/HDL	☐	☐	☐	☐	☐	☐	☐
*Cholesterol/Triglycerides	☐	☐	☐	☐	☐	☐	☐
*Urinalysis	☐	☐	☐	☐	☐	☐	☐
*AST/ALT	☐	☐	☐	☐	☐	☐	☐
*HCV Viral Load	☐	☐	☐	☐	☐	☐	☐
*HIV Viral Load	☐	☐	☐	☐	☐	☐	☐
*CD-4	☐	☐	☐	☐	☐	☐	☐
*Fasting Blood Sugar	☐	☐	☐	☐	☐	☐	☐
*Urine Microalbumin	☐	☐	☐	☐	☐	☐	☐
*Drug Level	☐	☐	☐	☐	☐	☐	☐
Enter date of procedure. If patient refused, enter "Refused."							
*PAP Smear	☐	☐	☐	☐	☐	☐	☐
*FOBT/Guaiac	☐	☐	☐	☐	☐	☐	☐
*Eye Exam	☐	☐	☐	☐	☐	☐	☐
*Mammogram	☐	☐	☐	☐	☐	☐	☐
*Influenza Vaccine	☐	☐	☐	☐	☐	☐	☐
*Pneumococcal Vaccine	☐	☐	☐	☐	☐	☐	☐
*Tetanus Toxoid	☐	☐	☐	☐	☐	☐	☐
*Hepatitis A Vaccine	☐	☐	☐	☐	☐	☐	☐
*Hepatitis B Vaccine	☐	☐	☐	☐	☐	☐	☐
Clinic RN/MTA							
Clinic Provider							
ALLERGIES:							

* If the provider orders a procedure to be completed after the current visit, check the box under the date of the visit that the procedure was ordered. On the next visit, review the chart and document any pending results under the date of the visit that the procedure was ordered.

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

Consults:

Chronos:

CDCR Documentation Expectations: (2008)

- Legibility and completeness are key
- The **date, time** and **legible** identification of the **provider** must be included on all notes
- Facts to include for each encounter include:
    - **Reason for the encounter** (chief complaint) (S)
    - **History** relevant to the encounter (which will include HPI, and pertinent PMHX,ROS-including pertinent negatives findings, FH,SH) (S)
    - **Focused Physical examination** findings, including vital signs (O)
    - List of **current medications**, or reference how you reviewed them (O)
    - Results of prior pertinent **diagnostic tests** (O)
    - **Assessment** or diagnostic impression addressing all symptoms and abnormal findings. You should document your **medical decision making** such as what data supports your diagnosis or rules out red flag diagnoses. (A)
        - include information on the inmate/patient's progress, response to treatment, any changes in the treatment, and any revision of diagnosis
    - **Plan** of care relevant to the diagnostic impression, including follow-up plan or disposition. (P)
        - The rationale for ordering (or not ordering) diagnostic testing and specialty consultations should be documented
    - **Education** of the patient should be documented (E)

- Past and present diagnosis should be accessible in the chart. Use of the **Problem List is required** and facilitates finding that information
- In addition a provider should **document** the fact that **informed consent or refusal** was obtained when it is required.
- Use of the **Primary Care Flow Sheet** (7392) is expected and will help identify worrisome trends such as weight loss, or rising creatinine.
- Use of specific forms for specialized visit types (**Chronic Care Follow-up** {7254}, Thirty Day Specialty Consult Progress Note {7409}) is expected, but you made add additional pages if needed for thorough documentation.
- **If you do not have the UHR when seeing the patient, you must clearly document that fact on your note.**

To help protect our patients and ourselves expected documentation consists of:

1. Perform and document a focused history and physical.
2. Review the chart, nurses, notes, labs, etc.
    1. Address/act on/follow/explain abnormal vital signs
    2. Address/act on/explain chart entries which contradict your findings. i.e. nurses notes, 7362 entries.
    3. Address/act on/follow/explain consultation reports or abnormal diagnostic test results.
3. Make an assessment based on the above. Address all complaints/problems.
    1. Address all H&P abnormal findings.
    2. Document your medical decision making/thought process, what supports your diagnosis and what rules out or lessens red flag diagnosis?
4. Plan: Address each problem identified by the assessment. Order and treat appropriately (including pain). Do not forget timely follow up. Document
5. Reconsider your decision if you cannot easily justify it
6. Place patient well being and safety ahead of all else

UHR

Organized by tabs:

- Physician Orders/Medication Consents
- Death Summary/Problem List/Progress Notes/ER Records/MAR
- Physicals/Obstetrical
- Public Health
- Laboratory /Pathology
- Radiology /Imagery /Diagnostics
- Medical Chrono’s
- Consultations/Procedures/Treatments
- Misc/Outside Facility
- Dental
- Mental Health Chrono’s/Misc.
- Mental Health Interdisciplinary notes/Treatment Plan
- Face sheet /Medico legal
- Inpatient

S/P

DATE	TIME	PROB #	
11/27/2006			S: (history includes details pertinent to the patient's medical complaint) Colostomy 1986, Total hysterectomy 1986, Vaginal reconstruction 1986,
Meds:			
Protonix 40mg			No chest pain or SOB
Furosemide 40mg			
Hydralazine 40mg			
Norvasc 10mg			
Prometham 25mg PO TID			O: (physical assessment) T: 98.0 P: 70 R: 16 B/P: 106/75 Wt 165
			Colostomies - in place + working - one for urine one for bowel
			to also tendum (+) bowel sounds
			A: (medical/nsg diagnosis. MTAs may not independently analyze or interpret data.)
			S/P colostomies (2) HTN - good control
			(3) ~~Anemia~~ ~~Resonace TID~~
			P: (MTA = referral to a higher licensure for prioritization and evaluation.) (RN -action to be taken by the RN so that the patient receives appropriate medical care.)
			Cont meds including TID Resonace
			RTC ~~40 days~~ per CCC
			E: (education provided)

INSTITUTION Valley State Prison for Women | ROOM / WING B 2 000000000804L

OUTPATIENT INTERDISCIPLINARY PROGRESS NOTES

CDC NUMBER, NAME, (LAST, FIRST, MI)

4/3/1953

CDC 7254 (8/89)

STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS

[redacted]C CARE FOLLOW-UP VISIT [redacted]

GDA: HFS

☐ continuation progress note attached

53407

List chronic diseases: (1) HEPT C ; (2) HTN ; (3) ANEMIA

HISTORY:

- Pharmacy profile attached (or list current medications here)

DX ~ 2-3 MOS AGO
Ø IMMUNIZATION HEPA A&B
Ø ANTIVIRAL TX
SAW GASTROENTERIST → Ø NEW TX

ON NORVASC 5 qD
TOOK TODAY...
NEVER TAKES ASA (L)
TAKES NO NSAIDS

ON FeO 40 MG qD
+/- FATIGUE SX x MOS
Ø HEMATEMESIS
HISTORY OF MELENA

ALLERGIES: NKDA

RN/MTA Signature

Complaints/Problems: ENTIRE LEFT SIDE OF FACE WEAK, Ø NAUSEA

CV / Hypertension: Chest Pain: Yes No SOB: Yes No

Diabetes Mellitus: # of hypoglycemic reactions since last visit: ____

Seizure Disorder: # seizures since last visit: ____

All CCP Conditions: other new symptoms: Yes No (if YES explain)

Asthma: # attacks since last visit: ____
short acting beta agonist canisters in last month: ____
visits to ER for asthma since last visit: ____
times awakening with asthma symptoms per week: ____

Additional History: HX CERVICAL CA 4/06 IVP REPORT REVIEWED
DX ~ 1986 3/06 CT ABD - REPORT REVIEWED
HYSTERECTOMY + RECONSTRUCTION Ø ACUTE DIS
COLOSTOMY AAM CT CHEST - REPORT REVIEWED
VENA PATCH
LAST SPECIALIST APPT ~ 1 MO AGO

CRF
STABLE
LAST RENAL APPT ?
(+) WRIST BAND

7/20/06 GLU 71.0
BUN/CR 26.0/1.9
ALT 13.0
CRA 21.20 ?
NP 4.40
ANIONS 20.0
7/10/06 H/H 9.2/29.0
MCV 80.7

CCP compliance with medications: yes no *diet:* yes no *exercise:* yes no
If no, describe:

EXAM: *HEENT:* NOSE: LARGE / LIMITED DISCH
THROAT: CLEAR / MOIST
Neck: SUPPLE, Ø ADENOPATHY
Lungs: CTA (B), Ø WHEEZE
Heart: RR, Ø MURMUR
Abdomen: SOFT, NT, +BS

Extremities/Pulses/Skin Changes: Ø EDEMA, RADIAL PULSE 2+ (R)
Neuro:
Rectal/Other (specify):

Comments on BP, Glucose Monitoring, Lab Values
BP 160/102
P 73
WT 189

ASSESSMENT:	Degree of Control				Clinical Trend			
	G	F	P	NA	I	S	W	NA
1. HEPT C — s/p HX CERVICAL CA, s/p RADIAL RECONSTRUCTION	☐	✓	☐	☐	☐	✓	☐	☐
2. HTN, UNCONTROLLED	☐	☐	✓	☐	☐	☐	✓	☐
3. ANEMIA, STABLE	☐	✓	☐	☐	☐	✓	☐	☐

PLAN: 1) D/C NORVASC
2) COREG (5/10) + PO qD
3) VCT7 25 qD
4) CONT FeO 40 MG qD
5) CONT PROTONIX 40 qD
6) CONT CYANOCOBALAMIN 1 mg IM q MO
7) MVI + PO qD

Primary Care Flow Sheet Reviewed: ☐

Medications:

Lab/Diagnostics: 1) ✓ BASIC MET, ALT

Other:

Monitoring: O BP: X week/month O Glucose: X day/week / month O Other:

Education Provided: ● Nutrition ● Exercise O Smoking ● Test Results ● Medication Management O Other:

Referral: O Specialist (specify): BP ✓ O High Priority O Other Chronic Care Program (specify):

days to next visit: ● 30 O 60 O 90 O 180 ● Other: ~~45 DAYS~~ O Discharge from CCP (specify disease):

Provider Signature [signature] Date 8/11/06

S. Ali/Cantaluna

OUTPATIENT INTERDISCIPLINARY PROGRESS NOTES

CDCR 7254 REV 10/05

STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

CHRONIC CARE FOLLOW-UP VISIT

CDCR NUMBER, NAME (LAST, FIRST, MI), INSTITUTION AND DATE OF BIRTH

4-3-53

Orders

Orders:

Orders are written on Physician Orders form 7221. This is a standard appearing order sheet. Virtually any request you have regarding the patient must be written on the order sheet. In the prison setting orders will be 'taken off' by various medical staff members, including registry staff who may not be as familiar with the workings of your institution. To be sure that nothing falls through the cracks it is extremely important to be as clear and specific as possible.

When writing for a follow-up visit: write when and who you want the patient to see, and for what reason. (If you know there is another appointment pending that can be canceled because of your visit that day you may write that as well, which will help you with your appointment access.)

> Follow-up appointment with building 3 MD in 4 weeks for Hypertension follow-up. (Cancel appointment next week, patient seen today)

When writing for medication you will need to be specific about the usual things such as name of medication, route, dose, dose interval, and duration of therapy. In addition you will need to add if the patient will need supervision with medication administration. Medications are given as:

> KOP - Keep on person or carry meds (These can include short-term cold medications and many chronic medications such as antihypertensives, diuretics, diabetes medications, etc.)
>
> NAT- Nurse administered therapy
>
> DOT -Direct observed therapy. (Medications such as narcotics, TB medications, some HIV medications and mental health medications order under Keyhea provisions.)

The duration of therapy "allowed" by one order can vary. Some institutions require that you rewrite narcotic orders every 30 days, and there may also be a requirement for reordering Nonformulary medication at specified intervals.

> Tyelenol Codeine #3 2 po bid DOT x 30 days

In the orders you will also need to document any other type of service you have performed. You should write (in addition to filling out referral form)

> Referral for GI- urgent
> Routine referral for orthopedics

If you have completed a disability evaluation or a chrono on the patient document:

> 1845 evaluation complete for limited mobility
> Chrono for lower bunk done

NOTE: SEND COPY OF PHYSICIAN'S ORDER FOR MEDICATION TO PHARMACY AFTER EACH ORDER IS SIGNED.

Order Date	Time	Problem #	Physician's Order and Medication (Orders must be dated, timed, and signed.)

ALLERGIES:	INSTITUTION	ROOM/WING

CDC NUMBER, NAME (LAST, FIRST, MI)

Confidential
client information
See W & I Code, Sections 4514 and 5328

PHYSICIAN'S ORDERS

Special Forms:

- Chronos
- 602 Appeal
- 1845 Disability Evaluation

Chronos:

The word "chrono" applies to a variety of custody and medical forms that usually identify an inmate-patient's special status. Copies of chronos are sometimes carried by inmate-patients on their person. Medical chronos are signed by the health care provider, and may confer special privileges based on a medical condition or be informational, as in the case of lab, TB or Medication Noncompliance Chrono 128-C..

The comprehensive accommodation chrono (CDC Form 7410) is a form with checkboxes listing the most commonly issued medical chrono. Examples of the type of accommodations commonly provided, and a partial listing of qualifying criteria include:

Type of Accommodation	**Qualifying Criteria (Partial List)**
Low Bunk/Low Tier	▪ Seizure disorder ▪ Full-time wheelchair user ▪ Amputation or sever weakness of upper or lower extremity, or severe orthopedic conditions of hips, knees, ankles, feet or upper extremity ▪ Body Mass Index (BMI) greater than 40 ▪ Pregnancy
Canes, Walkers, Wheelchairs, Ice Packs, Ace Wraps	▪ Disability that significantly restricts ambulating ▪ Acute injury.
Soft Shoe Chrono	▪ Ulcers secondary to peripheral vascular disease ▪ Severe diabetic neuropathy ▪ Significant deformity of ankle or foot
Cotton Bedding (including cotton blankets)	▪ Wool allergy, documented by a wool patch test
Egg Crate Mattresses	▪ Skin breakdown ▪ Patients at high risk of skin breakdown (e.g. paraplegic)
Outpatient Therapeutic Diets	▪ Receiving dialysis treatment ▪ Celiac disease
Nourishment Bags/Supplements	▪ Pregnancy ▪ Diabetes Mellitus on insulin ▪ Malnourished ▪ Oropharyngeal conditions causing difficulty eating regular diets

COMPREHENSIVE ACCOMMODATION CHRONO

INSTRUCTIONS: A physician shall complete this form if an inmate requires an accommodation due to a medical condition. Circle P if the accommodation is to be permanent, or T if the accommodation is to be temporary. If the accommodation is temporary, write the date the accommodation expires on the line. A new form shall be generated when a change to an accommodation is required or upon renewal of a temporary accommodation. Any new form generated shall include previous accommodations, if they still apply. Chronos indicating permanent accommodations shall be reviewed annually. This form shall be honored as a permanent chrono at all institutions.

A. HOUSING

None

Barrier Free/Wheelchair Access P / T _____

Ground Floor Cell P / T _____

Continuous Powered Generator P / T _____

Bottom Bunk P / T _____

Single Cell (See 128-C date: _____) P / T _____

Permanent OHU / CTC (circle one) P / T _____

Other _____ P / T _____

B. MEDICAL EQUIPMENT/SUPPLIES

None

Limb Prosthesis P / T _____

Brace P / T _____

Crutches P / T _____

Cane: (type) _____ P / T _____

Walker P / T _____

Dressing/Catheter/Colostomy Supplies P / T _____

Shoe: (specify) _____ P / T _____

Dialysis Peritoneal P / T _____

Wheelchair: (type) _____ P / T _____

Contact Lens(es) & Supplies P / T _____

Hearing Aid P / T _____

Special Garment:

(specify) _____ P / T _____

Rx. Glasses: _____ P / T _____

Cotton Bedding P / T _____

Extra Mattress P / T _____

Other _____ P / T _____

C. OTHER

None

Attendant to assist with meal access and other movement inside the institution. P / T _____

Attendant will not feed or lift the inmate/patient or perform elements of personal hygiene.

Wheelchair Accessible Table P / T _____

Therapeutic Diet: (specify) P / T _____

_____

Communication Assistance P / T _____

Transport Vehicle with Lift P / T _____

Short Beard P / T _____

Other _____ P / T _____

D. PHYSICAL LIMITATIONS TO JOB ASSIGNMENTS

Based on the above, are there any physical limitations to job assignments? ☐ Yes ☐ No

If yes, specify: _____

INSTITUTION	COMPLETED BY (PRINT NAME)	TITLE
SIGNATURE	DATE	CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH
HCM/CMO SIGNATURE	DATE	
(CIRCLE ONE) APPROVED / DENIED		

COMPREHENSIVE ACCOMMODATION CHRONO

CDC 7410 (03/04)

Distribution:
Original - Unit Health Record Canary - Central File Pink - Correctional Counselor Gold - Inmate

California Department of Corrections
CDC 128-C Medication Noncompliance Chrono

Instructions:

- The purpose of this form is to notify healthcare providers of an inmate refusals, no-shows, suspected cheeking and/or failure to swallow medications. The CDC Form 128-C is to be completed prior to the end of the shift by the health care staff member administering medications.
- Enter inmate name, CDC #, and date issue was identified. Check the appropriate section i.e. Hoarding, No Shows, Refusals; and actions under each section. Complete Physician Notification section and fax/send to scheduler.
- **Reference:** IMSP: Volume IV Chapter 11 Medication Management

Inmate Name: _____ **CDC #:**_____ **Date** _____

____**1. Hoarding of Medications:** Medical / Psychiatric / Dental (Circle one)
Inmate failed to swallow Nurse Administered or Direct Observation Therapy (DOT). Inmate suspected of hoarding/selling medications. The following action was taken.
____Pill line Correctional Officer informed verbally.
____Physician notified for medication review.

____**2. No Shows:** Medical / Psychiatric / Dental (Circle one)
____Inmate failed to show for three (3) consecutive days of Nurse Administered or DOT medication. The inmate will be scheduled for an appointment with the prescriber within (7) days of this notice.
____Inmate failed to show for 50% of the Nurse Administered or DOT medication.
____Is a Keyhea inmate and has been a no show.
Psych notified: Person Contacted: _____ Date_____Time:____By Phone? Y N
____Schedule the inmate for an urgent appointment as a no-show for two consecutive doses of insulin, TB or HIV medications.

____**3. Refusals:** Medical / Psychiatric / Dental (Circle one)
____Inmate refused three (3) consecutive days of Nurse Administered or DOT medication. The inmate will be scheduled for an appointment with the prescriber within (7) days of this notice for medication follow-up counseling.
____Inmate is a Keyhea patient and has refused medications.
Psych notified: Name of Person Contacted: _____ Date_____Time:____By Phone? Y N
____Has refused two consecutive doses of insulin, TB or HIV medications. Refer to physician for urgent appointment.

____**4. Failure to Pick Up Self-Administered Medications:** Medical / Psychiatric / Dental (Circle one)
____Inmate failed to pick up the following physician ordered self administered medications.
After 5 days the medication was returned to the pharmacy. List medications:
_____

5. Physician Notification:
CDC Form 128-Medication Noncompliance Forwarded to (enter name):
PCP: _____ Psychiatrist: _____PHN_____
Date / Time notified: _____

_____
Sign and Print Name / Title of Person Completing this Form

ibution: Original: UHR Yellow: PCP Pink: C File Goldenrod: Custody

Appeal Process:

Two main types of appeals:

602 Appeal Process
ADA Appeal

602 Appeal

The 602 Appeal can involve any concern that a patient has that he is not getting what he needs. There are 4 levels to 602 appeals. If the appeal is Healthcare related then it goes through the institutions Healthcare Appeals Coordinator. He or she will determine what level the appeal will start at and who the appropriate person to respond to the appeal is.

Level	Time to respond
Informal level	10 working days
1st level	30 working days
2nd level	20 working days (5 if emergency)
3rd level (Directors)	60 days (5 if emergency)

The goal would be to resolve everything at informal level.

If patient is upset that he did not get a medication that was ordered by the provider, the appeals coordinator would send that to nursing or pharmacy to sort out.

If the patient is upset that a medication a provider prescribed is not taking care of his pain adequately the coordinator may decide that the patient should see that <u>same provider</u> again to discuss it.

On the other hand if the 602 is worded "Dr. X is refusing to treat my pain". Then the coordinator will try to schedule with a <u>different provider</u> to get a second opinion.

ADA Appeal

Related to issues significantly affecting the patient's ability to do his ADL's.
There is NO informal level.
1st level- responds in 15 working days
2nd level- responds in 20 working days

Appeals: 602

Patients incarceration in CDCR have the right to appeal any decision, action, condition or policy perceived as adversely affecting their welfare by completing and submitting a Form 602. This process is intended to provide an administrative avenue to address perceived wrongs. Inmate/patient appeals require response within specified time limits according to the level of appeal review from informal to first through third level. Each institution has a Medical Appeals Coordinator who monitors the responses to each medical 602 and ensures they are completed within the required time frame.

A patient may appeal such things as your denial of a certain treatment, special diet, access to a specialist, etc. It helpful to try to resolve the appeal at the first level called the "informal appeal". Sometimes improved communication with the patient can help them to understand your decision, or perhaps there are circumstances you were not aware of when you made the original decision. You have 10 working days to respond to an informal appeal.

All appeals are first routed to the Medical Appeals Coordinator for appropriate verification and tracking. If the appeal involves health care issues, PCPs assist in the appeals process by:

- interviewing the inmate-patient
- assessing the validity of the complaint
- determining an appropriate response and course of action
- completing the required section on the 602 form

If there is no resolution at the informal level the appeal proceeds to the following levels with the timelines for response noted.

First level- 30 working days
Second level- 30 working days
Third level- 60 working days

(See hints and example attached.)

Disability Evaluation: 1845

In an inmate/patient has a disability you are required to complete a Disability Placement Program Verification form 1845. Each institution may not be suitable for a patient with a specific disability. Safety of the patient is priority and if a disability is identified their housing assignment or even institution may need to be changed. For example one of the oldest intuitions, Folsom State Prison (FSP) , was built in the late 1800's and has stairs that patients must go up and down to access many of the medical and dental care areas. Therefore it is not appropriate for a mobility impaired patient to be housed at FSP.

The form (1845) contains the following sections:

- Section A. Reason for Initiation of Form: inmate-patient, observation of staff, third party or medical documentation.

- Section B. Disability Being Evaluated: vision/hearing/speech/mobility.

- Section C. Permanent disabilities impacting placement.

- Section D. Permanent disabilities not impacting placement.

- Section E. Additional Medical Information: health care appliances, assistance needed with activities of daily living, housing restrictions.

- Section F. Exclusions. This is an important section. If the PCP's evaluation does not support the claimed disability, or if the inmate-patient needs to be removed entirely from the program, this section needs to be completed and appropriate boxes checked.

- Section G. Effective Communication Factors. This section ensures that the inmate-patient understands the 1845 process, whether through sign language, lip reading, Braille, written notes or other means. This frequently omitted section documents whether communication barriers were present.

After all sections have been completed, the PCP signs and dates the 1845 form and submits it to the Chief Physician & Surgeon or the CMO.

RESPONDING TO MEDICAL APPEALS

DO NOT answer an appeal that has not been reviewed and logged by the Medical Appeals Office or assigned to you by a supervisor. If an inmate gives you an appeal, tell him you must send it to the Medical Appeal Office for screening first.

DO NOT take an appeal personally and always remain professional. If you are asked to answer an appeal, remember that your response will be reviewed by other staff or may be scrutinized should the inmate elect to file a complaint in civil court.

If you are handwriting a response, please write legibly and do not use terms or abbreviations the inmate or non-medical personnel can understand.

DO NOT state you are granting an appeal unless you have the authority to grant all requested actions. Also DO NOT say an appeal is granted if the action has not occurred. For instance, if an inmate is requesting surgery and the surgery has not actually taken place, then the appeal would only be partially granted.

Ensure you address each issue that the inmate has raised. When an inmate is requesting several action (Section B of the 602 Form), then be specific as to what you are granting. If you are unable to grant a specific action, then tell the inmate the reason(s) why.

DO NOT answer an appeal more than one time. For instance, if you already answered a specific appeal at the informal level, then it would be inappropriate for you to answer the same appeal at the first level. CCR, Title 15 Section 3084.5 states formal appeals (1st or 2nd level) SHALL NOT be reviewed by a staff person who participated in the event or decision being appealed, or who is of a lower administrative rank than any participating staff, or who participated in review of a lower level appeal refilled at a higher level. .

If an inmate elects to withdraw an appeal, ask the inmate to write "I withdraw this appeal because (must state reason, such as issue was resolved, etc.)..." The inmate must then sign and date under his statement. The statement should be written in the informal or first level response area (Section C or Section E). The staff person who witnesses the inmate withdrawing the appeal must also sign, along with the 2nd level supervisor or Division Head (i.e. SRN III, CP&S, Pharmacy Supervisor, etc.).

Remember that your response should be written as a "stand alone document" and therefore, please include names, titles, and dates of which an incident may have occurred. For example: "Your medical record indicates that you were evaluated by Dr. T. Jones on February 1, 2008, and you were referred to an orthopedic specialist at that time, etc." "You are currently on a waiting list and can expect to see the specialist at UC Davis within the next 30 to 60 days."

If you are unable to answer an appeal by the due date, please contact the Health Care Appeals Coordinator at extension 3467 or 3426.

Example of Informal Response

AGPA (Supplied)

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

INMATE/PAROLEE APPEAL FORM

CDC 602 (12/87)

Location: Institution/Parole Region 1. _____ 2. _____

Log No. 1. _____ 2. _____

Category _____

You may appeal any policy, action or decision which has a significant adverse affect upon you. With the exception of Serious CDC 115s, classification committee actions, and classification and staff representative decisions, you must first informally seek relief through discussion with the appropriate staff member, who will sign your form and state what action was taken. If you are not then satisfied, you may send your appeal with all the supporting documents and not more than one additional page of comments to the Appeals Coordinator within 15 days of the action taken. No reprisals will be taken for using the appeals procedure responsibly.

NAME	NUMBER	ASSIGNMENT	UNIT/ROOM NUMBER
[redacted]	[redacted]	CCCMS/MHSDS ad seg	10 - 149

A. Describe Problem: Medical. Refusal to Report custody staff violations and Deliberate indifference to severe medical problems. A Medical Request (CDC 7362 form) [redacted] is filed. #1 I have severe spinal problems and have medical necessity for mattress/egg crate. Custody staff at Solano in ad seg have twice taken extra mattress and said "You don't have a Med order/chrono" #2 Because of my infectious disease and secondary infections I need clean cloths & towel. I only have 1 towel and 2 boxers shorts. I also need daily shower. Further, I cannot have a cell mate.

If you need more space, attach one additional sheet

B. Action Requested: Please log & File as a Medical Complaint. Please issue proper medical order for egg/crate mattress or extra mattress. Please issue proper order(s) regarding hygiene ie cloths & daily showers. Please Notify Ct of violations of Armstrong/Coleman Ct Orders.

Inmate/Parolee Signature: Robert B. Smith Date Submitted: 7/24/07

C. INFORMAL LEVEL (Date Received: 8-9) due 8-23

Staff Response: You were recently evaluated by Dr. Noriega on 7-27-07 and he did not recommend a double mattress chrono. Egg crate or double mattress chronos are only approved for patients with Grade 1 or higher level pressure sores or complications from pressure sore, etc. If custody is not supplying you with enough showers, you must file a separate appeal through custody.

Staff Signature: M. Holiday, AGPA Date Returned to Inmate: 8-10-07

D. FORMAL LEVEL

If you are dissatisfied, explain below, attach supporting documents (Completed CDC 115, Investigator's Report, Classification chrono, CDC 128, etc.) and submit to the Institution/Parole Region Appeals Coordinator for processing within 15 days of receipt of response.

Signature: _____ Date Submitted: _____

Note: Property/Funds appeals must be accompanied by a completed Board of Control form BC-1E, Inmate Claim

CDC Appeal Number:

INMATE/PAROLEE APPEAL FORM

CDC 602 (12/87)

Location: Institution/Parole Region	Log No.	Category
1. _____	1. _____	_____
2. _____	2. _____	

You may appeal any policy, action or decision which has a significant adverse affect upon you. With the exception of Serious CDC 115s, classification committee actions, and classification and staff representative decisions, you must first informally seek relief through discussion with the appropriate staff member, who will sign your form and state what action was taken. If you are not then satisfied, you may send your appeal with all the supporting documents and not more than one additional page of comments to the Appeals Coordinator within 15 days of the action taken. No reprisals will be taken for using the appeals procedure responsibly.

NAME	NUMBER	ASSIGNMENT	UNIT/ROOM NUMBER

A. Describe Problem: _____

If you need more space, attach one additional sheet.

B. Action Requested: _____

Inmate/Parolee Signature: _____ Date Submitted: _____

C. INFORMAL LEVEL (Date Received: _____)

Staff Response: _____

Staff Signature: _____ Date Returned to Inmate: _____

D. FORMAL LEVEL

If you are dissatisfied, explain below, attach supporting documents (Completed CDC 115, Investigator's Report, Classification chrono, CDC 128, etc.) and submit to the Institution/Parole Region Appeals Coordinator for processing within 15 days of receipt of response.

Signature: _____ Date Submitted: _____

Note: Property/Funds appeals must be accompanied by a completed Board of Control form BC-1E, Inmate Claim

CDC Appeal Number:

First Level ☐ Granted ☐ P. Granted ☐ Denied ☐ Other _____

E. REVIEWER'S ACTION (Complete within 15 working days): Date assigned: _____ Due Date: _____

Interviewed by: _____

Staff Signature: _____ Title: _____ Date Completed: _____

Division Head Approved: Returned

Signature: _____ Title: _____ Date to Inmate: _____

F. If dissatisfied, explain reasons for requesting a Second-Level Review, and submit to Institution or Parole Region Appeals Coordinator within 15 days of receipt of response.

Signature: _____ Date Submitted: _____

Second Level ☐ Granted ☐ P. Granted ☐ Denied ☐ Other _____

REVIEWER'S ACTION (Complete within 10 working days): Date assigned: _____ Due Date: _____

See Attached Letter

Signature: _____ Date Completed: _____

Warden/Superintendent Signature: _____ Date Returned to Inmate: _____

H. If dissatisfied, add data or reasons for requesting a Director's Level Review, and submit by mail to the third level within 15 days of receipt of response.

Signature: _____ Date Submitted: _____

For the Director's Review, submit all documents to: Director of Corrections
P.O. Box 942883
Sacramento, CA 94283-0001
Attn: Chief, Inmate Appeals

DIRECTOR'S ACTION: ☐ Granted ☐ P. Granted ☐ Denied ☐ Other _____

See Attached Letter

Date: _____

DISABILITY PLACEMENT PROGRAM VERIFICATION (DPPV)
CDC 1845 (Rev. 01/04)

CHECK ALL APPLICABLE BOXES

THIS FORM ONLY VERIFIES OR DISCONFIRMS CLAIMED PHYSICAL DISABILITIES LISTED IN SECTION B

INMATE NAME:	CDC NUMBER:	INSTITUTION:	HOUSING ASSIGNMENT:	DATE FORM INITIATED:

Sections A - B to be completed by licensed medical staff.

SECTION A: REASON FOR INITIATION OF FORM

- ☐ Inmate self-identifies to staff
- ☐ Third party evaluation request
- ☐ Observation by staff
- ☐ Medical documentation or Central File information

SECTION B: DISABILITY BEING EVALUATED

- ☐ Blind/Vision Impaired
- ☐ Speech Impaired
- ☐ Deaf/Hearing Impaired
- ☐ Mobility Impaired

Sections C - G to be completed by a physician only.

SECTION C: PERMANENT DISABILITIES IMPACTING PLACEMENT

1. ☐ FULL TIME WHEELCHAIR USER - **DPW**
Requires wheelchair accessible housing and path of travel.

2. ☐ INTERMITTENT WHEELCHAIR USER - **DPO**
Requires lower bunk, wheelchair accessible path of travel and ***does not require*** wheelchair accessible cell.

3. ☐ MOBILITY IMPAIRMENT - With or Without Assistive Device (Wheelchairs shall not be prescribed) - **DPM**
Orthopedic, neurological or medical condition that substantially limits ambulation (cannot walk 100 yards on a level surface without pause). Requires lower bunk, no triple bunk, and no stairs in path of travel.

4. ☐ DEAF/HEARING IMPAIRMENT - **DPH**
Must rely on written communication, lip reading or signing as residual hearing, with assistive devices, will not enable them to hear, understand or localize emergency warnings or public address announcements.

5. ☐ BLIND/VISION IMPAIRMENT - **DPV**
Not correctable to central vision acuity of better than 20/200 with corrective lenses in at least one eye (See HOUSING RESTRICTIONS IN SECTION E).

6. ☐ SPEECH IMPAIRMENT - **DPS**
Does not communicate effectively speaking or in writing.

SECTION D: PERMANENT DISABILITIES *NOT* IMPACTING PLACEMENT

1. NO CORRESPONDING CATEGORY

2. NO CORRESPONDING CATEGORY

3. ☐ MOBILITY IMPAIRMENT (Lower Extremities) - **DNM**
Walks 100 yards without pause with or without assistive devices.
☐ No Housing Restrictions ☐ See HOUSING RESTRICTIONS in Section E
☐ Requires relatively level terrain and no obstructions in path of travel.
Do not place at: CCI, CMC-E, CRC, CTF-C, FSP, SAC, SCC I or II, SOL, or SQ. (CDC 128-C:_____)

4. ☐ HEARING IMPAIRMENT - **DNH**
With residual hearing at a functional level with hearing aid(s).

5. NO CORRESPONDING CATEGORY

6. ☐ SPEECH IMPAIRMENT - **DNS**
Does not communicate effectively speaking, but does when writing.

SECTION E: ADDITIONAL MEDICAL INFORMATION

CSR ALERT:
☐ Requires relatively level terrain and no obstructions in path of travel
☐ Complex medical needs affecting placement ☐ CDC 128-C _____

HEALTH CARE APPLIANCE / IDENTIFICATION VEST:
☐ Cane ☐ Crutch ☐ Walker ☐ Leg/Arm prosthesis ☐ Vest
☐ Other: _____ ☐ CDC 128-C(s) dated: _____

ASSISTANCE NEEDED WITH ACTIVITIES OF DAILY LIVING:
☐ Feeding or Eating ☐ Bathing ☐ Grooming ☐ W/C transferring
☐ Toileting ☐ Other: _____ ☐ CDC 128-C(s) dated:_____

OTHER DPP DESIGNATIONS:
☐ **NONE** _____ _____; _____ _____
CODE DATED CODE DATED

HOUSING RESTRICTIONS: ☐ Lower bunk ☐ No stairs ☐ No triple bunk. CDC 128-C(s) dated: _____

SECTION F: EXCLUSIONS

☐ VERFICATION OF CLAIMED DISABILITY NOT CONFIRMED: My physical examination or other objective data DOES NOT SUPPORT ***claimed*** disability. (Explain in Comments Section and CDC 128-C dated _____).

☐ REMOVAL FROM A DPP CODE: Removal from previous DPP code: _____. (Explain in Comments Section and CDC 128-C dated: _____.)

☐ REMOVAL FROM ENTIRE PROGRAM: Removal from DPP code(s): _____. (Explain in Comments Section and CDC 128-C dated: _____.)

SECTION G: EFFECTIVE COMMUNICATION FACTORS

☐ Uses Sign Language Interpreter (SLI) ☐ Reads Braille ☐ Communicates with written notes ☐ Requires large print or magnifier
☐ Reads lips ☐ NO "EFFECTIVE COMMUNICATION" ISSUES OBSERVED OR DOCUMENTED IN THE UNIT HEALTH RECORD

PHYSICIAN'S COMMENTS: *(Focus on affected systems and functional limitations. No specific diagnosis or other confidential medical information.)*

PHYSICIAN'S NAME (Print)	PHYSICIAN'S SIGNATURE	DATE SIGNED
HEALTH CARE MANAGER'S / DESIGNEE'S NAME (Print)	HEALTH CARE MANAGER'S / DESIGNEE'S SIGNATURE	DATE SIGNED

NOTE: After review by the Health Care Manager or Chief Physician & Surgeon, health care staff shall retain green copy for the UHR, send the inmate copy via institutional mail, and route the original and remaining copies to the C&PR/RC CC-III for tracking and further distribution according to the instructions below.

DISTRIBUTION: **Original** - Top General Chrono Section of C-File; **Green** - Chrono Section, Unit Health Record **Canary** - C&PR/CC-III; **Pink**-CC-I; **Gold**-Inmate

Specialty Care

- Overview
- How to Access Special Care
- Referral Processing / Time to Appointment
- Pending Specialty Appointments
- After Off-Site Specialty Appointment

SPECIALTY CARE PROGRAM

Overview

The Specialty Care Program includes a utilization management component to promote appropriate, cost-effective use of licensed beds and resources. The purpose of Specialty Services is to provide inmate-patients with medically necessary specialty health care services in order to establish a diagnosis, to make recommendations for a diagnostic work-up, to provide pharmacological therapy, and to establish a treatment plan. Each institution has a designated staff person assigned to monitor the provision of Specialty Services.

Contract community providers, including the UCSF Correctional Medicine Consultation Network and CDCR specialists provide specialty services, which may include a consultation with the specialist or a medical procedure. These services are provided:

- on-site in the institution by visiting specialists (specialties varies by institution though most institutions will have Optometrists)
- in community clinics or hospitals
- in the institution via CDCR Telemedicine Services Program. (specialties vary by institution but include ID, HIV, dermatology, orthopedics, neurology, ENT, gastroenterology, pain management, surgery and Psychiatry

Approximately 25 specialty services are used in treating the inmate-patient population. The most common and necessary specialties include: orthopedics, cardiology, gastroenterology, neurology, urology, hematology/oncology, and obstetrics and gynecology.

How to access Specialty Services

Once a provider has determined the need for Specialty Services/Consultation a **Physician Request for Services** (RFS) **form 7243** is completed. This must be filled out completely and include:

1. Patient demographics including estimated parole date

2. Principle diagnosis- be detailed with your clinical details/background information, remember the specialist will most likely not have the chart for review.

3. Requested services- be specific don't say "GI consult" say " GI to consider colonoscopy for new iron deficiency anemia"

4. Indicate if this is for Outpatient or Inpatient care, is an initial or follow-up evaluation.

5. Indicate if the service is :
    i. Emergent- take immediately to CMO to sign and process
    ii. Urgent- goes through Utilization Management Nurse/Committee
    iii. Routine- goes through Utilization Management Nurse/Committee

Documenting Specialty Referrals

Specialty services requests, including specialist consultations, diagnostic services such as MRI, CT, ultrasound, etc., must be documented in 3 places:

1. The Request for Services (RFS) CDCR Form 7243
2. PCP Orders, CDCR Form 7221
3. Interdisciplinary Progress Notes, CDCR Form 7230

Referral Processing/Time to appointment

- As noted above, if the referral is **emergent** it is taken directly to the CMO for approval and is processed **immediately.**

- If the referral is deemed **urgent** it goes through the Utilization Management (UM) approval process which at some facilities involves a Medical Authorization Review (MAR) committee. Urgent specialty referrals are to be completed within **14 calendar days** of approval

- Referrals deemed **routine** go through the UM process and are to be completed within **90 days** of approval

Pending Specialty Appointments

While the inmate-patient is waiting for the appointment to occur, the PCP must:

- If routine status, see the inmate-patient every 30 days until the appointment occurs. These visits should be documented on the CDCR form specific for this purpose. (Form 7409)

- If urgent referral, see the inmate-patient weekly until the appointment occurs.

- If the MAR committee denies the referral request inform the inmate-patient and provide education on alternative strategies.

- If the service is approved, inform the inmate-patient of the ***general*** time frame when the service will be provided. The inmate-patient is not to be told of the exact date and time of the service as this is a security/ escape risk.

- Inform the inmate-patient if the specialty service has to be rescheduled.

After the Offsite Specialty Services Appointment

1. All inmate-patients who receive specialty services outside the institution shall be processed by an RN in the TTA or emergency room upon return to the institution.

2. The specialty provider should submit a written report of their inmate-patient evaluation and recommendations to the institution. The RN reviews the specialist's recommendations, consults with a PCP if needed for any immediate needs, and arranges a follow-up appointment with the PCP.

3. The specialty provider may not order additional diagnostic tests or specialty services or make direct referrals. The PCP must review the consult report recommendations from the specialty provider within three business days and write the physician's orders for services and recommendations. The services and recommendations must adhere to the UM review process.

4. The PCP is responsible for discussing the report findings with the inmate-patient.

5. Follow-up visit requirements include that:
    i. If routine specialty services, a PCP must see the inmate-patient within 14 days.
    ii. If urgent referral was done, a PCP must see the inmate-patient within 3 business days.

6. • The PCP documentation of the follow-up visit must reflect an understanding of the specialist's recommendations and counseling of the inmate-patient.

7. • If the specialist's report/recommendations are not available, the PCP must attempt to contact the specialist to obtain them and document his/her attempts in the progress notes.

8. • If the PCP believes a plan (different than the specialist recommendation) is in the inmate-patient's best interest, this must be documented in the UHR.

After the Onsite Specialty Services Appointment

1. For inmate-patients who receive specialty services within the institution, the specialist shall document their recommendations and findings on the RFS Form.

2. The designated RN shall review the specialist's recommendations and findings and notify the PCP or provider on call of any immediate medication or follow-up requirements, note all orders, and ensure the inmate-patient's housing assignment is consistent with clinical needs.

3. The PCP must review the consult report within three business days. The RN shall arrange a follow-up appointment.

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

HEALTH CARE SERVICES
PHYSICIAN REQUEST FOR SERVICES

(To be completed by requesting Physician and forwarded to Utilization Management Unit)

PATIENT NAME	CDC NUMBER	INSTITUTION
DATE OF BIRTH	EPRD DATE	GENDER
PRINCIPLE DIAGNOSIS	ICD - 9 CODE	CPT CODE(S)
REQUESTED SERVICE(S)		# OF DAYS RECOMMENDED

Please circle all that apply: **Diagnostic Procedure/Consultation** **Outpatient/Inpatient** **Initial/Follow-up**

Requested Treatment/Service is: **EMERGENT** **URGENT** **ROUTINE**

For the purpose of retrospective review, if emergent or urgent, please justify: _____

Proposed Provider: _____ Anticipated Length of Stay: _____

Expected disposition (i.e.: outpatient follow-up, return to institution, transfer): _____

Medical Necessity (*briefly describe the clinical situation; the history of the illness, treatments used, pertinent lab and imaging studies, or questions for the consultant*): _____

Estimated time for service delivery, recovery, rehabilitation and follow-up: _____

Summary of preliminary or diagnostic work up, conservative treatment provided (if applicable, please provide TB code, CD4, viral load, albumin, total protein and dates within last 3 months): _____

Comments (diagrams, risk factors, prognosis, alternative management, etc.): _____

REQUESTING PHYSICIAN PRINTED NAME	APPROVED / AUTHORIZED / DENIED / DEFERRED BY	DATE
REQUESTING PHYSICIAN SIGNATURE	DATE	Utilization management tracking #:

DATE OF CONSULTATION	PRINTED NAME OF CONSULTANT

FINDINGS: _____

RECOMMENDATIONS: _____

FOLLOW-UP OR FURTHER EVALUATIONS REQUESTED: _____

CONSULTANT SIGNATURE	DATE
ETA RN SIGNATURE	DATE
PCP SIGNATURE	DATE

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

Attach Progress Note page for additional information.

THIS FORM MUST BE RETURNED WITH THE PATIENT!!!

DISTRIBUTION:

ORIGINAL - FILE IN UHR
GREEN - TO UHR PENDING ORIGINAL
CANARY - CONSULTANT
PINK - UM
GOLD - SPECIALTY SCHEDULER

THIRTY (30)-DAY SPECIALTY CONSULT PROGRESS NOTE

30 day or 14 day FU

TYPE OF SPECIALTY SERVICE REQUESTED	DATE OF REQUEST

PROBLEM SPECIALIST IS TO ADDRESS (Reason for consult):

DESCRIPTION OF PATIENT'S CURRENT CLINICAL STATUS:

☐ DOCUMENT CHANGE IN CLINICAL STATUS SINCE INITIAL VISIT (Improved, Stable, Worse):

☐ DOCUMENT CHANGE IN CLINICAL STATUS SINCE PREVIOUS VISIT (Improved, Stable, Worse):

CHOOSE ONE OF THE FOLLOWING:

☐ Scheduled appointment is clinically appropriate.

☐ Change referral Priority to Urgent (High Priority)

☐ Should be seen by the specialist within _____ days.

☐ Condition resolved / Consultation request withdrawn.

INTERIM PLAN FOR PROBLEM LEADING TO REFERRAL:

IF THE SCHEDULED SPECIAL APPOINTMENT IS GREATER THAN 30 DAYS AWAY, AN ORDER FOR A FOLLOW-UP WITH THE PRIMARY CARE ~~PHYSICIAN~~ provider (PCP) NEEDS TO BE WRITTEN.

PCP SIGNATURE	DATE

NAME OF INSTITUTION	CDCR NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

Medical Areas / Housing / In-Patient

- Reception Center
- Receiving and Release "R&R"
- Triage and Treatment Area "TTA"
- GACH – General Acute Care Hospital
- CTC – Correctional Treatment Center
- Hospice
- Dialysis
- OHU – Outpatient Housing Unit

Medical Areas/Inpatient Units

During an inmates stay in the CDCR system he or she will be evaluated at many points, by multiple providers. Done carefully and correctly each of these encounters is an opportunity for us to gain more information about the health history and needs of our patients. Each encounter is also an opportunity for disaster if we are not paying attention and a critical diagnosis or medication is not identified or continued. Below are described the various medical settings/units where our patients are housed and/or evaluated.

For most, if not all, new inmate-patients their first evaluation with us is done at one of our Reception Centers.

Reception Center Health Screening & Evaluation

Initial Health Screening

All inmates committed to a CDCR institution receive an initial health screening by licensed healthcare staff, [RN], upon arrival at a Reception Center (RC). The RC screening process includes evaluation of each inmate for medical, public health, mental health, and dental conditions, as well as developmental and physical disabilities. The health screening interview must be conducted in a manner that ensure the privacy of their health care information, while considering safety and security concerns. Any inmate patient with abnormal findings is referred to the RN immediately for further evaluation. Any inmate patient with a condition requiring prompt intervention, or immediate refill of a medication by a PCP or mental health clinician, is immediately taken to the institution's TTA or ER for treatment. All medical, Public health, mental health and dental conditions must be noted on the appropriate forms. All inmate patients are screened for Tuberculosis (TB), and have diagnostic and laboratory tests completed based on their age and gender, consistent with Volume 4, Chapter 2, IMSPP&P, as follows:

<u>Males:</u>

• Fecal occult blood test if age 50 or older,
• Cholesterol screening if age 35 or older,
• VDRL or RPR with confirmatory testing if positive,
• Gonorrhea and Chlamydia urine screen if less than 30 years of age, and
• HIV testing will be offered, and, if the inmate-patient agrees to be tested, referral for follow-up counseling and testing.

<u>Females:</u>

• Cancer screening that includes a pap smear, unless not required per US Preventive Services Task Force (USPSTF) guidelines,
• Fecal occult blood test if age 50 or older,
• Screening mammogram if age 40 or older and no mammogram within the previous two years,
• Serum pregnancy test,
• Cholesterol screening if 45 years of age or older,
• VDRL or RPR with confirmatory testing if positive,

• Gonorrhea and Chlamydia urine screen if less than 30 years of age, and
• HIV testing will be offered, and, if the inmate-patient agrees to be tested, referral for follow-up counseling and testing.

Comprehensive Examination at Reception Center

Within fourteen days of arrival at the RC, all inmate-patients receive a more comprehensive medical, mental health, and dental examination. Each inmate-patient receives a complete history and physical examination (H&P) performed by a PCP. Laboratory tests are ordered per policies and procedures, including testing for sexually transmitted diseases, and other diagnostic tests, as appropriate.

The PCP performing the RC H&P:

- completes the problem list,
- initiates management and orders follow-up visits of acute medical problems,
- arranges for referral to the Chronic Care Program (CCP) and for evaluation for high-risk designation, if indicated.

Program Referrals

Inmate-patients identified as having a chronic disease during the RC initial health evaluation or the physical examinations are enrolled in the CCP. Inmate-patients diagnosed with a serious mental disorder are enrolled in the Mental Health Services Delivery System (MHSDS). <u>These designations are important to identify as they may require that the inmate-patient receive a special housing assignment or assignment to a particular institution</u>.

Receiving and Release

Once an inmate-patient has completed their evaluation at the Reception Center they are assigned to a 'permanent' institution. They are placed on a bus and taken to that new facility with their CDCR Chart and transfer paperwork including a 7371 from the sending institution. Inmate-patients may spend several hours on the bus getting to their new institution and for the medically fragile this can be difficult.

When they reach their new institution they are evaluated in an area called Receiving and Release (R&R). This screening is generally done by an RN (some institutions may use a midlevel) who reviews the patients transfer records and makes sure that required medicine is continued. If the patient was on the medication from the sending institution the RN can send copies of the orders to the Pharmacy to fill. The RN also is able to make appropriate referrals to the Chronic Care program, mental health, or dental. If the patient has identified health issues the RN will arrange for the patient to be seen, either urgently in the TTA or routinely in a yard clinic. If an inmate has no identified medical issues an appointment with a provider is not made.

Yard and Camp Clinics

Generally each "yard" or building in the institution, or associated camp, will have an out-patent clinic where the patients housed in that area receive their care. There is generally one provider assigned to each 'yard' or 'camp' clinic and institutions vary on how often (or if) providers are rotated from clinic to clinic. CDCR is moving toward a PCP Panel management model. Although there are challenges with this model in the prison setting it is felt that having an identified responsible provider for each patient will improve the quality of care provided.

Triage & Treatment Area (TTA)

- Each institution has a TTA (sometimes improperly called an ER) that functions as a minor emergency clinic 24 hours per day and as the primary inmate-patient treatment area after normal operating hours.

- While this area and its staff provide excellent service to our patients it should not be considered similar to a community hospital ER. It is expected that a patient can get evaluated in the TTA with vital signs, O2 saturation, an ECG, possibly some labs, but ongoing monitoring of an unstable patient is not safe and therefore unstable (or possibly unstable) patients should be sent out.

- Occasionally a provider may find that outside ER's are hesitant to accept our patients because the outside provider may misunderstand the level of care available in our "ER", (TTA). Helping by educating them to our limitations will improve relationships.

- This area also functions as the screening area for inmate-patients returning from offsite health care appointments or hospitalizations.

- In order to provide inmate-patients with prompt access to high priority/emergent health care, health care staff responds to all inmate-patient medical or "man down" emergencies.

- In any medical emergency, policy requires direct inmate-patient contact with an RN or PCP. In selected cases, telephone contact will satisfy this requirement.

- Any inmate-patient, health care staff or other CDCR employees can initiate a request for high priority/ emergent health care. The request is based on the inmate-patient or staffs belief that a medical condition, symptom, or sign requires immediate attention. An inmate-patient may request medical attention for high priority/emergent health care needs from any CDCR employee on their own behalf or on the behalf of another inmate-patient.

- Once health care staff respond to high priority/emergent situation and stabilize the inmate-patient, they are transported to the TTA for further evaluation and treatment.

- Inmate-patients with medical emergencies requiring transfer to an offsite community hospital are usually brought to the TTA for stabilization pending arrival of ambulance transportation.

- Each institution has a process to ensure an adequate response to health care emergencies. All high priority/emergent encounters are to be documented and the inmate-patient scheduled to see their PCP within five business days or sooner, if clinically indicated.

- If the problem is a result of a chronic care condition, the inmate-patient must be seen by their PCP within five calendar days.

- A High Priority/Emergent Tracking System Log is maintained at each clinic and documents each high priority/ emergent encounter. There are specific procedures to follow relating to first responder responsibilities and performing cardiopulmonary resuscitation, which can be found in the IMSPP&P.

Inmate-Patient Transfers

- The CDCR has standardized the inmate-patient transfer process to ensure continuity of care when inmates are transferred between CDCR institutions. Inmates are transferred between institutions for a variety of reasons including custodial requirements, medical treatment and court appearances.

- Inmate-patients can be transferred permanently for medical treatment or custody requirements, or maybe transferred temporarily for court appearances or to obtain medical services, such as specialty care, that is available at the receiving institution.

- If a clinician determines that an inmate-patient requires medically necessary health care services, which are only accessible at or via a specific CDCR institution other than where the inmate-patient is housed, the inmate-patient is placed in a "Medical and Return" category. This allows the inmate-patient to be transferred to the institution and returned once the medical care has been rendered. This period can last from a several days to a number of months.

- The UHR and transfer envelope, containing pertinent health care information, are to accompany each inmate-patient to ensure continuity of care. Procedures for initiating inmate-patient transfers can be obtained from your supervisor. Upon arrival at the receiving institution the health care staff (in R&R) reviews the health information sent along with the inmate-patient. If any health care documentation appears to be missing, the R&R health care staff at the receiving institution will immediately contact the Health Records staff at the sending institution. The sending institution will fax the necessary information.

- The R&R nurse at the receiving institution will document the receipt of this information on the appropriate form. When receiving an inmate-patient, a licensed health care staff member must complete the health screening process. The screening

process is not necessary for same-day returns to an institution unless the inmate-patient has been out-to-court.

- Physician's orders from the sending institution will be honored at the receiving institution for medication continuity until a PCP and/or Psychiatrist evaluates the inmate-patient at the receiving institution. Licensed health care staff verifies prescription medications that were ordered from the sending institution and ensures adequate follow-up to prevent interruption of medication administration. Each inmate-patient with a condition requiring a clinical appointment is referred to an appropriate provider with the required time frame noted on the appropriate form.

INPATIENT SERVICES

The DCHCS provides licensed medical and mental health inpatient clinical services, including the following:

• General Acute Care Hospitals (2)
• Correctional Treatment Centers (17)
• Intermediate Care Facilities (2)
• Hospice (1)
• Dialysis Unit (2)

General Acute Care Hospitals (GACH)

There are two GACH's licensed by the Department of Health Services, within the CDCR system that provide 24-hour inpatient medical/surgical and mental health care. While the CDCR hospitals include operating suites, there are no intensive care services available. As a result, inmate-patients requiring extensive surgical intervention, emergency surgery, or in critical condition, are transferred to a community hospital. The DCHCS has contracts with preferred provider community hospitals for medical/surgical inmate-patients. The preferred provider hospitals have special guarding units for CDCR inmates that include security staffing by Departmental custody officers. DCHCS provides additional beds for acute mental health treatment through an interagency agreement with the Department of Mental Health (DMH). Acute mental health inpatient services include intensive, short-term treatment for inmate-patients who suffer impairment of functioning due to either an acute serious mental disorder or medical condition.

Institutions with a GACH
California Men's Colony
Corcoran State Prison
California Medical Facility

<u>Requirements for GACH Documentation</u>: (as in other in-patient settings)
Admission Orders
History and Physical
Daily progress notes
Discharge orders
Discharge note

Correctional Treatment Centers (CTC)

CTCs are licensed health facilities designed to provide health care to that portion of the inmate-patient population who are in need of professionally supervised 24-hour healthcare beyond that normally provided on an outpatient basis. CTCs provide physician, psychiatric, psychology, nursing, pharmacy, radiology, laboratory, emergency dental and dietary services. There is a CTC RN 24 hours per day and a PCP is available on-call. Inmate-patients admitted to the CTC are those who require sub-acute medical care and acute and sub-acute mental health care. It is intended for inmate-patients who require close medical observation, control, and PCP monitoring, continuous intravenous infusions or oxygen. The CTC mental health beds are also called "Mental Health Crisis Beds" (MHCB) and are described more fully in the Mental Health Program section, page 27. In practice, the CTC may also provide long-term skilled nursing care.

Institutions with a CTC

California Institution for Women
California State Prison, Los Angeles County
California State Prison, Sacramento
California State Prison, San Quentin
California State Prison, Solano
California Substance Abuse Treatment Facility
Centinela State Prison
Central California Women's Facility (SNF)
High Desert State Prison
Kern Valley State Prison
Mule Creek State Prison
North Kern State Prison
Pelican Bay State Prison
Pleasant Valley State Prison
R.J. Donovan Correctional Facility
Salinas Valley State Prison
Wasco State Prison

<u>Requirements for CTC Documentation</u>
Admission Orders
History and Physical
Progress notes minimum every 3 days , or as clinically indicated
Discharge orders
Discharge note

Intermediate Care Facility (ICF)

The ICF provides long-term inpatient mental health care (30 days or more) to patients with a major mental health disorder and active symptoms requiring stabilization that cannot be provided in an outpatient setting. The Department of Mental Health operates the two ICFs, which are located at the Salinas Valley State Prison (SVSP) and California Medical Facility (CMF).

Hospice

CDCR operates one licensed hospice at the CMF. If you determine that an inmate-patient may benefit from hospice care, you need to contact your supervisor to initiate a transfer. Unfortunately, there are often more patients needing end-of-life care than there are beds available in the hospice. Other options may include transfer to another CTC facility or caring for the patient with minimum needs in an OHU. Review the patient's skilled nursing and end-of-life care needs and discuss each case with your supervisor.

Hemodialysis

CDCR has fewer than 200 inmate-patients receiving dialysis treatment, over 90 percent are male. The DCHCS currently has licensed hemodialysis centers located at the CMF in Vacaville, CSP Corcoran and WSP in Wasco. This center has a maximum capacity of 42 inmate-patients. The DCHCS has contracts with various community health care facilities in different geographic locations to provide timely access to hemodialysis services for other inmate-patients.

If you encounter an inmate-patient who requires hemodialysis services, contact your supervisor to access these services. You and your supervisor will work with the Health Care Placement Unit to find the appropriate location for the inmate-patient to receive hemodialysis.

Outpatient Housing Unit (OHU)

The OHUs provide housing and nursing services to inmate-patients who cannot live in the general population due to a condition or illness that requires outpatient health services and/or assistance with the activities of daily living (ADLs) that cannot be provided in the general population. OHUs are staffed with a minimum of LVN/ CNA level licensure on site at all times, and an RN must make rounds on each shift. The OHU is NOT a licensed/skilled nursing care bed.

Some of the conditions and procedures appropriate for OHU placement include:

- Convalescence from childbirth, surgery, or illness;
- Intermittent intravenous therapy;
- Intermittent oxygen therapy;
- Observation for behaviors indicative of a mental health illness;
- Temporary dietary restrictions, such as needed for bowel preps;
- Supervision, or assistance with ADLs, e.g., because of contractures, neuromuscular disorders, dementia, or organic brain syndrome.

<u>Requirements for Documentation in OHU</u>
Although not licensed, most OHU's function similar to a Skilled Nursing Facility and a History & Physical and admitting orders are required.
Progress notes are required at minimum every 14 days or as clinically indicated.

General Considerations that apply to all units:

- If the patients needs exceed the level of care available, that patient may need to transfer to a community hospital or to another CDCR institution that can meet his or her needs.

- The patients condition is the key determinate of the frequency of rounding, not the stated minimum.

- Verbal orders must be signed within 48 hours

- H&P's must be written within 24 hours of admission.

RECEPTION CENTER HISTORY AND PHYSICAL CLINICAL EVALUATION FORM

Have you recently had symptoms of:

Chest Pain:	☐ Yes	☐ No
SOB:	☐ Yes	☐ No
Other:	☐ Yes	☐ No

Describe, if yes: _____

Do you have any current:

Injuries:	☐ Yes	☐ No
Disabilities:	☐ Yes	☐ No
Other:	☐ Yes	☐ No

Describe, if yes: _____

History of the following:

Mental Illness:	☐ Yes	☐ No
Hospitalizations:	☐ Yes	☐ No
Surgeries:	☐ Yes	☐ No
CAD:	☐ Yes	☐ No
CHF:	☐ Yes	☐ No
Hypertension:	☐ Yes	☐ No
Asthma/COPD:	☐ Yes	☐ No
Diabetes:	☐ Yes	☐ No
Hyperlipidemia:	☐ Yes	☐ No
Seizures:	☐ Yes	☐ No
TB disease:	☐ Yes	☐ No
Positive TB test:	☐ Yes	☐ No
HIV:	☐ Yes	☐ No
Hepatitis C:	☐ Yes	☐ No
Significant Family History:	☐ Yes	☐ No
Other:	☐ Yes	☐ No

Describe, if yes: _____

Current medications: _____

Drug allergies: _____

Lifestyle factors (alcohol, tobacco, drug use): _____

Women only:

Are you or could you be pregnant? ☐ Yes ☐ No

Document additional comments on a 7230 progress note.

PCP Signature: _____ Date: _____

PHYSICAL EXAMINATION:

HT ____ WT ____ Temp ____ Pulse ____ Resp ____

BP ____ Vision: Ⓡ____ Ⓛ____

	Normal	Abnormal	Describe
Appearance:	☐	☐	
Behavior:	☐	☐	
HEENT:	☐	☐	
Neck:	☐	☐	
Chest/Lungs:	☐	☐	
Heart:	☐	☐	
Breasts:	☐	☐	
Abdomen:	☐	☐	
Extremities:	☐	☐	
Neurological:	☐	☐	
Lymph Nodes:	☐	☐	
Skin:	☐	☐	
Genital/Pelvic:	☐	☐	
Rectal: (over age 50)	☐	☐	
Other:	☐	☐	

Describe, if yes: _____

ASSESSMENT: Problem List/Diagnoses

1. _____
2. _____
3. _____
4. _____
5. _____

PLAN: (Update problem list)

Refer to Chronic Care Program: ☐

Refer for High Risk Evaluation: ☐

Next visit: ☐ 30 days ☐ 60 days ☐ 90 days ☐ other: _____

CDCR NUMBER, NAME (LAST, FIRST, MI), INSTITUTION AND DATE OF BIRTH

STATE OF CALIFORNIA
CONFIDENTIAL MEDICAL/MENTAL HEALTH
INFORMATION TRANSFER-SENDING INSTITUTION
CDC 7371 (Rev. 03/04)

DEPARTMENT OF CORRECTIONS

☐ NEEDS IMMEDIATE ATTENTION

☐ Medical and Return ☐ Psychiatric and Return ☐ Return from Medical and Return

SENDING INSTITUTION	INMATE NAME	CDC NUMBER

Allergies: No known allergies ☐

SIGNIFICANT MEDICAL/ DENTAL / MENTAL HEALTH PROBLEMS / COMMENTS

e.g. suicide attempts, dental needs, special diet, pending or incomplete consults, laboratory tests, x-rays)	Chronic Care Program (List type)	Date of Last Visit

Date of Last Physical: Keyhea ☐

Mental Health Level of Care ☐ None ☐ CCCMS ☐ EOP ☐ MHCB Suicide History ☐ Yes ☐ No

Prosthetic device? ☐ Yes ☐ No Type:

Medical Hold Initiated? ☐ Yes ☐ No Reason:

Medical Chronos reviewed? ☐ Yes ☐ No | Type of Medical Chrono: | TB alert code:

MEDICATIONS PRESCRIBED

Medication Administration Recorded Attached ☐ Yes ☐ No | Pharmacy Profile Attached ☐ Yes ☐ No

Name of Medication (including TB)	Dose	Route	Frequency	Start Date	Stop Date	Heat Risk Med

DIAGNOSTIC TESTS PERFORMED

Pregnant? ☐ Yes ☐ No ☐ EDC _____

Tuberculosis
PPD Test _____ mm Date Read _____

Chest X-ray
☐ Normal ☐ Abnormal Date Read _____

Disability (See CDC 1845)

DPW ☐ DPS ☐
DPV ☐ DPM ☐
DPH ☐ DPO ☐

Developmental Disability

DDI ☐ DD2 ☐
DDIA ☐ DD3 ☐

LAB TESTS (*Check each box that applies to inmate*)

HIV/VDRL: ☐ Reactive ☐ Non-reactive Treated? ☐ Yes ☐ No Date treated: _____

Hepatitis: ☐ Positive ☐ Negative Type: _____ Treated? ☐ Yes ☐ No Date treated: _____

Other screening test results & date	Other Laboratory Data

Pending Medical/Mental Health Appointments	Date	Attachments ☐ Yes ☐ No
Chronic Care		Special Transport Instructions
Specialty		
Telemedicine		
Other		

COMPLETED BY SENDING INSTITUTION RN (Print/Stamp Name)	SIGNATURE / TITLE / DATE / TIME	CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH
RECEIVING INSTITUTION (Print/Stamp Name)	SIGNATURE / TITLE /DATE / TIME	
L - RECEIVING INSTITUTION - SENDING INSTITUTION	RECEIVING INSTITUTION	

STATE OF CALIFORNIA

INITIAL HEALTH SCREENING (ALL INSTITUTIONS)

DEPARTMENT OF CORRECTIONS

INMATE NAME	CDC NUMBER	DATE OF BIRTH

RECEIVING INSTITUTION	SENDING INSTITUTION	ARRIVAL DATE	ARRIVAL TIME

Vital Signs: B/P:_____ Pulse:_____ Weight:_____

The following shall be completed by CDC health care staff only. Inmates shall answer all questions. Complete a CDC Form 7277-A also for all female inmates.

	(Circle one)	
1. Are you currently under a doctor's care for medical, dental or mental health reasons? If "yes," describe conditions:	YES	NO
2. Are you taking any medications? If "yes," list medications:	YES	NO
Does the inmate appear to have a language problem?	YES	NO
3. Have you been seen, or are you scheduled to be seen by a specialist/physician either inside or outside of the prison? If "yes," describe condition:	YES	NO
4. Do you have any special health care needs or current medical complaints, including drug withdrawal symptoms? If "yes," please describe:	YES	NO
5. Do you have any physical deformity or disability? If "yes," describe. (Refer to Physican for completion of CDC 1845, if applicable):	YES	NO
6. Do you use any health care appliance? If "yes," list:	YES	NO
7. Do you have any of the following?: ☐ Cough ☐ Fever ☐ Night Sweats ☐ Unexplained weight loss	YES	NO
8. Do you have any allergies? If "yes," please list:	YES	NO
9. Have you ever been treated for a mental illness?	YES	NO
10. Do you have a mental health problem?	YES	NO
11. Have you been hearing voices or seeing things that are not there?	YES	NO
12. Have you had any thoughts of hurting yourself or others in the past year?	YES	NO
13. Are you thinking of committing suicide now or have you ever attempted suicide?	YES	NO
14. Does the inmate appear disoriented to time, place or person?	YES	NO
15. Does the inmate appear to have difficulty understanding the questions or in making appropriate responses to them? Explain:	YES	NO

Additional Comments:

RN/MTA DISPOSITION

If any question above is answered "yes," contact an MD or RN for an assessment and disposition

Release to custody? RN/MTA Signature: Date:	YES	NO

RN DISPOSITION

Referral required? If yes, when? ☐ Immediately ☐ Within 24 hours ☐ Within 72 hours Refer to: RN Signature: Date:	YES	NO

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS

INITIAL HEALTH SCREENING (SUPPLEMENTAL) - FEMALE INMATES

INMATE NAME	CDC NUMBER	DATE OF BIRTH

RECEIVING INSTITUTION	SENDING INSTITUTION	ARRIVAL DATE	ARRIVAL TIME

The following shall be completed by CDC health care staff only. Female inmates shall answer all questions.

- Supplement to CDC Form 7277

☐ Yes	☐ No	1. Are you pregnant (or do you think you are pregnant)? If "yes" _____ Weeks _____ Months
☐ Yes	☐ No	2. How many days has it been since your last menstrual period? _____ Days
☐ Yes	☐ No	3. Have you stopped having menstrual periods? If "yes", what is the date of your last period? _____ (Date)
☐ Yes	☐ No	4. Have you had an abortion? If "yes", when:
☐ Yes	☐ No	5. Are you taking birth control pills? If "yes", list medication:
☐ Yes	☐ No	6. Are you taking hormones? If "yes", explain:
☐ Yes	☐ No	7. Are you on methadone now?
☐ Yes	☐ No	8. Do you have pain deep inside your vagina when you have sex?
☐ Yes	☐ No	9. Do you have discharge from your vagina that smells bad?
☐ Yes	☐ No	10. Do you have sores or lumps around your vagina?
☐ Yes	☐ No	11. Do you have lower abdominal pain?
☐ Yes	☐ No	12. Do you have bleeding from your vagina when it is not your period?
☐ Yes	☐ No	13. Do you have blood in your urine when you are not having your period?
☐ Yes	☐ No	14. Do you have pain when you urinate or move your bowels?
☐ Yes	☐ No	15. Have you had a diagnosis of Pelvic Inflammatory Disease (PID)? If "yes", did you take all the medication? ☐ Yes ☐ No

Additional Comments:

RN/MTA OBSERVATIONS

RN/MTA DISPOSITION

If any question above is answered "yes", contact an MD or RN for an assessment and disposition

☐ Yes	☐ No	Release to custody? RN/MTA Signature: Date:

RN DISPOSITION

☐ Yes	☐ No	Referral required? If yes, when? ☐ Immediately ☐ Within 24 hours ☐ Within 72 hours Refer to: RN Signature: Date:

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

SAMPLE

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

EMERGENCY CARE FLOW SHEET

DATE:	
TIME IN	TIME OUT

PATIENT NAME (LAST, FIRST)	CDC NUMBER	HOUSING	DOB

TIME OF INCIDENT	LOCATION OF INCIDENT	MODE OF ARRIVAL

STAFF NAME (LAST, FIRST)	OCCUPATION	SEX	AGE	DOB

CHIEF COMPLAINT:	TB CODE	DATE OF LAST TETANUS

MECHANISM OF INJURY	SKIN COLOR	SKIN TEMP	SKIN MOISTURE	CAPILLARY REFILL
☐ STABBING	☐ NORMAL	☐ HOT	☐ NORMAL	☐ <2 SECONDS
☐ PHYSICAL ALTERCATION	☐ PALE	☐ WARM	☐ DRY	☐ >2 SECONDS
☐ GUNSHOT WOUND	☐ ASHEN	☐ COOL	☐ MOIST	☐ NONE
☐ BURN	☐ CYANOTIC	☐ COLD	☐ PROFUSE	
☐ SPORTS INJURY	☐ FLUSHED			
☐ ON THE JOB INJURY				
☐ OTHER_____				

GLASCOW COMA SCALE

EYE OPENING RESPONSE	SPONTANEOUS	4 4 4 4 4
	TO VOICE	3 3 3 3 3
	TO PAIN	2 2 2 2 2
	NONE	1 1 1 1 1
BEST VERBAL RESPONSE	ORIENTED	5 5 5 5 5
	CONFUSED	4 4 4 4 4
	INAPPROPRIATE WORDS	3 3 3 3 3
	INCOMPRESHENSIBLE SOUNDS	2 2 2 2 2
	NONE	1 1 1 1 1
BEST MOTOR RESPONSE	OBEYS COMMAND	6 6 6 6 6
	LOCALIZES PN.	5 5 5 5 5
	WITHDRAWS PN.	4 4 4 4 4
	FEXION PN.	3 3 3 3 3
	EXTENSION PN.	2 2 2 2 2
	NONE	1 1 1 1 1

LUNG SOUNDS		RESP. CHARACTER	EVIDENCE OF TRAUMA	
RT	LT	☐ LABORED	☐ CHEST	☐ HEAD
☐ CLEAR	☐	☐ UNLABORED	☐ ABDOMEN	☐ NECK
☐ WHEEZES	☐	☐ PAINFUL	☐ G/U	☐ EXTREMITIES
☐ RALES	☐	☐ SHALLOW	☐ PELVIS	☐ OTHER_____
☐ RHONCHI	☐	☐ DEEP	☐ BACK SPINE	_____
☐ DIMINISHED	☐	☐ RETRACTION		
☐ ABSENT	☐	☐ NASAL FLARING		

VITALS	TIME	TEMP	PULSE	RESP	BP	SaO_2	CURRENT MEDICATION

TIME	
PUPIL RESPONSE	
PUPIL SIZE	

KEY C=CLOSED B=BRISK SL=SLUGGISH F=FIXED

3 4 5 6 7 8

IV	TIME	SOL	SITE	GAUGE	RATE	MEDICATION ALLERGIES
						MEDICATION GIVEN IN ER

O2 ADMIN	TIME	ROUTE	RATE	SaO_2	

SOAP NOTATIONS

SUBJECTIVE: (PATIENTS STATEMENTS, HISTORY)

OBJECTIVE: (PHYSICAL EVALUATION)

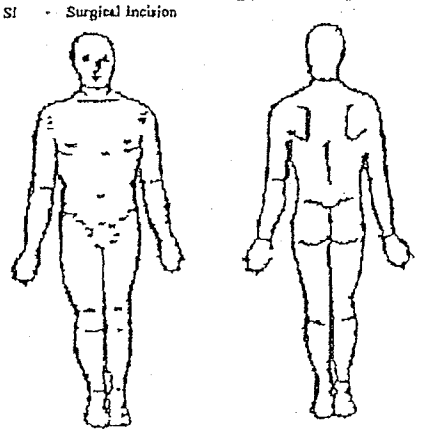
ASSESSMENT: (NURSING DIAGNOSIS)

PLAN: (PT EDUCATION, FOLLOWUP, MD ORDERS, ETC.)

PRINT NAME	SIGNATURE	PATIENT DISPOSITION
	RN/MTA/MD	☐ RETURN TO CUSTODY
	RN/MTA/MD	☐ ADMIT TO INFIRMARY / HOSPITAL
	RN/MTA/MD	☐ TRANSPORT TO COMM. HOSPITAL VIA:
		☐ AMBULANCE
	SUPERVISOR REVIEW	☐ STATE VEHICLE
		☐ RELEASED TO CORONER

ABBREVIATION CODE

Ab	Abrasion	E	Edema
Amp	Amputation	F	Closed Susp. Fracture
Av	Avulsion	H	Hematoma
B	Burn	L	Laceration
___%	Percent	P	Petechiae
CP	Compound Frac.	R	Rash
EC	Ecchymosis	S	Scar
ENT	Entrance Wound	Ex	Exit Wound
SI	Surgical Incision		



PATIENT CONDITION ON DISCHARGE

☐ STABLE ☐ UNSTABLE

☐ DECEASED TIME_____

REASON FOR REQUEST (STATEMENT OF CHIEF MEDICAL OFFICER)

PTION OF CONDITION SUGGESTING REMOVAL

DESCRIPTION OF EXAMINATION OR THERAPY RECOMMENDED

NATURE AND IMMEDIACY OF SERVICE: ☐ MANDATORY ☐ EMERGENCY ☐ ELECTIVE

NAME OF HOSPITAL, CLINIC, OFFICE OR OTHER PLACE RECOMMENDED

WHY CAN'T THE PROCEDURE BE DONE INTRAMURALLY?

AUTION INSTRUCTIONS (DEFINED ON REVERSE): ☒ UNIVERSAL ☐ RESPIRATORY ☐ ENTERIC

TIME AWAY FROM FACILITY (NOT MORE THAN 3 DAYS)

SIGNATURE OF CHIEF MEDICAL OFFICER	DATE

CUSTODIAL STATUS (STATEMENT OF ASSOCIATE WARDEN)

OFFENSE	TERM	RELEASE DATE	CUSTODIAL CLASSIFICATION ☐ MAXIMUM ☐ MEDIUM ☐ MINIMUM

COMMITTED FROM	DATE RECEIVED	CONDUCT DURING INCARCERATION	ESCAPE RISK

REMARKS

SIGNATURE OF ASSOCIATE WARDEN	DATE

UNDER THE PROVISIONS OF SECTION 2690 OF THE PENAL CODE, AUTHORIZATION IS GIVEN FOR THE TEMPORARY REMOVAL OF INMATE IDENTIFIED BELOW FROM THE FACILITY IN WHICH HE/SHE IS NOW CONFINED IN ORDER THAT HE/SHE MAY RECEIVE MEDICAL TREATMENT IN ACCORDANCE WITH THE ABOVE RECOMMENDATIONS

REQUEST: ☐ APPROVED ☐ DENIED

SPECIAL CONDITIONS:

WARDEN'S SIGNATURE	DATE	FACILITY

CDC NUMBER, NAME (LAST, FIRST, MI) AND DATE OF BIRTH

JEST FOR AUTHORIZATION OF TEMPORARY REMOVAL FOR MEDICAL TREATMENT

DC 7252 (3/93)

Pharmacy

- Overview
- Medical Reconciliation
- Therapeutic Equivalent

- Maxor Formulary
- Heat Plan / Heat Meds

SUPPORT SERVICES

Pharmacy

Overview

CDCR has recently begun standardizing every institution pharmacy with the help of a contracted group called Maxor. A standardized Drug Formulary has been established and is updated as needed. Clinicians can order medications from the Drug Formulary without additional authorization. Clinicians wishing to order a medication that is not listed in the DCHCS Drug Formulary can request approval by completing a Non-Formulary Request Form.

Ordering Medications

Each institution has a Pharmacy Services Committee (PSC), which may also be called the Pharmacy and Therapeutics Committee (P&T), to provide professional multidisciplinary oversight of the clinical aspects of pharmacy services.

Medications are prescribed by completing a Physician's Order Form. (And a Nonformulary Medication Request if indicated). As per community standards a medication order must include:

Name of medication
Dose of medication
Route of delivery
Dose frequency/interval
Duration of therapy
Indications if applicable (such as p.r.n*, or “for hypertension”)

In the correctional setting specific administration directions are usually needed to specify if a medication is to be KOP, NAT, or DOT.

KOP - Keep on person or carry meds (These can include short-term cold medications and many chronic medications such as antihypertensives, diuretics, diabetes medications, etc.)

NAT- Nurse administered therapy

DOT -Direct observed therapy. (Medications such as narcotics, TB medications, some HIV medications and mental health medications order under Keyhea provisions.) Mouth is inspected after watching patient take medication.

Medication Distribution

Pharmacy staff is responsible for dispensing prescribed medications and nursing staff is responsible for administering prescribed medications. Once a medication is ordered the time to administration can vary. The goal is to have the medication administered by the end of the next business day. Time frames for administering non-formulary medications vary, depending on the accessibility of obtaining the medication. There are many steps to medication processing which include:

- Order getting from clinic setting to pharmacy
- Medication being filed in pharmacy
- Medication distributed to building nursing staff
- Building nursing staff distributing medication twice daily in “pill-lines” (a location where inmate-patients come to receive their medication)
- Some institutions distribute packages of KOP at specific times

You will need to check with your specific institution to determine the exact process that is used in each of the housing levels. (I.e. medication distribution in general population will be different that medication distribution in Administrative Segregation).

STAT Medications

Institutions have different processes for obtaining STAT medications that are not immediately available. The STAT medication should be dispensed to the inmate patient within one hour of the order being processed. If the institution has a "Documed" dispensing machine, authorized nursing staff may obtain STAT medications from the machine when the pharmacy is not open. Ask your supervisor for further detail about your institution's process for obtaining medications outside of normal Pharmacy operating hours. Most importantly, if you have a medication that needs to be administered “STAT” you will need to personally see to it that you have followed your institutions procedures for obtaining the medication and making sure it was administered to the patient.

Medication Administration:

The nursing staff monitors the patients' medication compliance in the following manner:

Based on a weekly review of the Medication Administration Record (MAR) any patient who has missed 50% of his/her medications either by refusal or no-show is to be referred to the prescriber for medication follow-up counseling.

Any patient who refuses or no-shows for **one dose of a Keyhea** medication is **referred immediately** to the prescriber for follow-up counseling.

Any patient who refuses or no-shows for **two consecutive doses** of insulin, TB, or designated HIV medication shall be referred on urgent basis to the prescriber, Public Health Nurse or Physician on call for medication follow-up counseling.

Any patient who refuses or no-shows for **three consecutive days** of Nurse Administered , DOT, or self carry medication shall be referred in writing (Medication Noncompliance Chrono Form 128-C) to the scheduler for an urgent appointment with the appropriate PCP or psychiatrist.

MEDICATION RECONCILIATION (11/08/2007 - 02/08/2008)

RONALD BURKS
CDCR#: F86694 Unit#: 3A-T3-28L
Status: ACTIVE

FOLSOM STATE PRISON PHARMACY

	Drug Name (NDC)	*Last Dispense*	Expiration Date	Refills Left	Rx #	Doctor	Qty	Days
☐ REFILLS: PRN ☐ KOP ☐ STOP	**ASPIRIN 81 MG TABLET EC (00182106105)** SIG: TAKE 1 TABLET BY MOUTH EVERY DAY	12/28/2007	**3/27/2008**	2	**116043548-1**	S REDDY	30	30
☐ REFILLS: PRN ☐ KOP ☐ STOP	***NF* BD GLUCOSE TABLET CHEW (08290328230)** SIG: USE AS DIRECTED	12/21/2007	***1/20/2008**	2.8	**116042550-1**	M JEU	6	30
☐ REFILLS: PRN ☐ KOP ☐ STOP	**HUMULIN 70/30 VIAL (00169183711)** SIG: INJECT 34 UNITS SUBCUTANEOUSLY EVERY MORNING & 20 UNITS EVERY EVENING **DIRECTLY OBSERVED THERAPY**	1/22/2008	**4/21/2008**	2	**116049134-1**	I. CARDENO	10	5
☐ REFILLS: PRN ☐ KOP ☐ STOP	**NOVOLIN R 100 UNITS/ML VIAL (00169183311)** SIG: ACCUCHECK BID: IF BS...150-199= 2 UNITS; 200-250= 4 UNITS; 251-300= 6 UNITS; 301-350= 8 UNITS; 351-400= 10 UNITS; 401-450= 12 UNITS; > 450= 14 UNITS AND CALL MD **NURSE ADMINISTERED**	1/22/2008	**2/21/2008**	0	**116049135-1**	I. CARDENO	10	5

RONALD BURKS
CDCR#: F86694 Unit#: 3A-T3-28L
Status: INACTIVE

FOLSOM STATE PRISON PHARMACY

	Drug Name (NDC)	*Last Dispense*	Expiration Date	Refills Left	Rx #	Doctor	Qty	Days
☐ REFILLS: PRN ☐ KOP ☐ STOP	**HUMULIN 70/30 VIAL (00169183711)** SIG: INJECT 36 UNITS SUBCUTANEOUSLY EVERY MORNING & 22 UNITS EVERY EVENING **DIRECTLY OBSERVED THERAPY**	D/A 1/15/2008	***1/22/2008**	0	**116047473-1**	S REDDY	10	5
☐ REFILLS: PRN ☐ KOP ☐ STOP	**NOVOLIN 70/30 100 UNITS/ML VIA (00169183711)** SIG: INJECT 34 UNITS SUBCUTANEOUSLY EVERY MORNING & 20 UNITS EVERY EVENING **DIRECTLY OBSERVED THERAPY**	D/A 12/28/2007	***1/15/2008**	0	**116043552-1**	S REDDY	10	5
☐ REFILLS: PRN ☐ KOP ☐ STOP	**NOVOLIN R 100 UNITS/ML VIAL (00169183311)** SIG: ACCUCHECK BID: IF BS...150-199= 2 UNITS; 200-250= 4 UNITS; 251-300= 6 UNITS; 301-350= 8 UNITS; 351-400= 10 UNITS; 401-450= 12 UNITS; > 450= 14 UNITS AND CALL MD **NURSE ADMINISTERED**	D/A 12/21/2007	***1/22/2008**	0	**116042552-1**	M JEU	10	5

↑ ONLY CHANGE OR PROCESS CHECKED PRESCRIPTIONS

NEW PRESCRIPTION:

SUBSTITUTION PERMITTED SIGNATURE	DATE	PROV#	DISPENSE AS WRITTEN SIGNATURE	DEA# REQUIRED FOR CONTROLLED SUBSTANCES

**** SEND TO PHARMACY COMPLETE ****

STATE OF CALIFORNIA

DEPARTMENT OF CORRECTIONS

PATIENT MEDICATION ADMINISTRATION RECORD

7231-A (Rev. 11/02)

FOR THE MONTH OF:

YEAR:

NAME OF RN / MTA	Initial	NAME OF RN / MTA	Initial	NAME OF RN / MTA	Initial	NAME OF RN / MTA	Initial

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM																															
NOON																															
PM																															
HS																															

NAME: ALLERGIES: CDC # HOUSING:

NASAL STEROID
THERAPEUTICALLY EQUIVALENT
DRUG INTERCHANGE AUTHORIZATION

CDCR P&T Approved July 2007

Nonformulary Agent	Formulary Equivalent Agent	Common Dose
Nasal Steroids Nasacort Beconase AQ Flonase Nasonex Nasarel Rhinocort	Generic flunisolide (Nasalide)	2 sprays BID

I, the undersigned, do hereby authorize pharmacy personnel at pharmacies operated by CDCR to dispense interchangeably any of the above listed therapeutically equivalent products, whenever I order or prescribe by name any one of such listed products. I further authorize nursing personnel to administer any of the above listed therapeutically equivalent products as dispensed by such pharmacy personnel pursuant to this authorization.

I understand that the above listed therapeutic equivalent products will be dispensed and administered according to the corresponding dosing parameters for each product (if any) as shown above and are effective for my intended purpose.

If I intend that no substitution be made, I will so indicate with words "Do Not Substitute", or words of similar meaning, either orally for verbal orders or in handwriting on written orders for prescriptions. A request and authorization for nonformulary approval will be required.

This authorization shall remain in effect until I revoke it in writing or until it is superseded.

_____ _____
Prescriber (Signature) Date

_____
Prescriber (Printed or Typed)

_____ _____
Location Department

Note: To participate in this program, please sign and date this form.
RETURN SIGNED FORM to: **The Pharmacist In Charge**

CDCR CORRECTIONAL FORMULARY

Approved by the CDCR P&T Committee May 2007

December 2007 Update

CDCR Formulary Updates by Month

July-07

Deletions

Avandia (rosiglitazone)
Humalog (insulin lispro)
Novolog (insulin aspart)

Aug-07

Additions

Almacone (aluminum hydrox / magnesium hydrox / simethicone - 200/200/20mg)
Crestor (rosuvastatin) - 5mg, 10mg, 20mg, 40mg
Geodon (ziprasidone) 20mg/ml injection
Humulin Insulin R, NPH, 70/30
Norvasc (amlodipine) - 2.5mg, 5mg, 10mg
Retrovir (zidovudine) - 100mg restricted to dialysis use only
Tums (calcium carbonate 500mg chewable tabs)
Zerit (stavudine) - 20mg restricted to dialysis use only

Deletions

Lipitor (atorvastatin) - all strengths
Alamag (aluminum hydrox / magnesium hydrox)
Novolin Insulin R, NPH, 70/30
Wellbutrin (bupropion) - all strengths
Sulamyd (sodium sulfacetamide) ophth ointment
Rescriptor (delavirdine) - all strengths
Hivid (zalcitabine) - all strengths
Reyataz (atazanavir) - 100mg, 150mg caps
Crixivan (indinavir) - 100mg cap
Viracept (nelfinavir) 250mg tab
Videx (didanosine) 125mg, 200mg caps

Sep-07

Additions

Niacin (immediate release)
Asmanex (mometasone) Twisthaler 220mcg/actuation - 120 dose size

Deletions

Niacin (extended release)
Flovent HFA Inhaler (fluticasone) - all strengthe
Qvar Inhaler (beclomethasone) - all strengths
Azmacort Inhaler (triamcinolone)

Oct-07

Additions

Fiber Tablets (calcium polycarbophil - Fibercon, Konsyl) 625mg tab

Deletions

Metamucil (psyllium) packets

Changes to Restrictions

Actifed (triprolidine/pseudoeph) - restricted to a 7 day supply per prescription.
Claritin (loratidine) - quantity restricted to #30 tablets per month with a maximum of 2 refills per prescription.
Imitrex (sumatriptan) - restricted to 9 tabs per month.
Nasalide (flunisolide) - quantity restricted to 1 bottle with a maximim of 2 refills per prescription.
Robaxin (methocarbamol) - restricted to 7 day supply per prescription unless indicated for spinal cord injury.

Nov-07

Additions

Azithromycin (Zithromax) 250mg tablets - Restricted to the treatment of community acquired pneumonia
Benzocaine/Menthol/Cetylpy (Cepacol) Lozenges
Candesartan (Atacand) 4mg, 8mg, 16mg, 32mg tablets - restricted to patients who are intolerant to or have failed ACE Inhibitor therapy.
Fluoxetine (Prozac) 20mg/5ml oral solution - restricted to Keyhea patients only
Lorazepam (Ativan) 1mg tablets - restricted to a 7 day supply for the treatment of acute agitation in psychiatric diagnoses or delirium tremens. Diagnosis must be included on prescription.
Medroxyprogesterone Acetate (Depo-Provera) - 150mg/ml SDV
Methadone 10mg tablets will remain formulary until pain management guidelines are established
Morphine Sulfate SR (MS Contin) 15mg tablets
Nitrofurantoin (Macrobid) 100mg capsules
Oxcarbazepine (Trileptal) 300mg/5ml Suspension - restricted to Kehyea patients only
Penicillin Benzathine (Bicillin LA) 2.4 million units / 4 ml - restricted to the treatment of syphilis

Deletions

Azithromycin (Zithromax) 500mg tablets
Dextromethorphan (Hold DM) Lozenges
Losartan (Cozaar) - all strengths
Medroxyprogesterone Acetate (Depo-Provera) 400mg/ml MDV
Nitrofurantoin (Macrodantin) 100mg capsules
Penicillin Benzathine (Bicillin LA) 1.2 million units / 2 ml
Primidone (Mysoline) - all strengths
Telmisartan (Micardis) - all strengths
Valsartan HCT (Diovan HCT) - all strengths

Changes to Restrictions

Levetiracetam (Keppra) - restricted to psychiatric diagnoses. Diagnosis must be included on prescription.
Ketorolac (Torodal) Injection - restricted to infirmary, CTC, TTA and OHU settings.
Lamotrigine (Lamictal) - restricted to psychiatric diagnoses. Diagnosis must be included on prescription.
Oxcarbazepine (Trileptal) - restricted to psychiatric diagnoses. Diagnosis must be included on prescription.

Dec-07

Additions

Metoprolol (Lopressor) 25mg tablets
Azithromycin (Zithromax) 500mg tabs - restricted to the treatment of STD's. Diagnosis must be included on prescription.

Ceftriaxone (Rocephin) 250mg vial - restricted to the treatment of STD's. Should not be used as initial dose empiric treatment prior to oral therapy for nonSTD indications. Diagnosis must be included on prescription.
Benzocaine 20% Spray (Lanacane, Solarcaine, Americaine) - restricted to fire camps

Deletions

Fosphenytoin (Cerebyx)

CDCR Correctional Formulary

Updated 12/12/07

Approved by the CDCR P&T Committee May 2007

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
A&D Ointment	see Petrolatum/Lanolin		
Abacavir	Ziagen	Tablet: 300mg	
Abacavir/Lamivudine	Epzicom	Tablet: 600-300mg	
Abilify	see Aripiprazole		
Acetaminophen	Tylenol	Tablet: 325mg Suppositories: 650mg Suspension: 160mg/5ml	
Acetaminophen/Codeine	Tylenol #3	Tablet: 30/300mg Elixer: 12-120mg/5ml	
Acetazolamide	Diamox	Tablet: 250mg	
Acetic Acid + Alum. Acetate Otic Soln	Domeboro Otic	2% Otic Solution - 60ml	
Acetic Acid 2% + Hydrocortisone 1%	Vosol-HC	Otic Solution - 10ml	
Acetylcysteine	Mucomyst	10% Inhalation Solution - 10ml	
Actifed	see Triprolidine/Pseudo		
Actos	see Pioglitazone		
Acyclovir	Zovirax	Tablet: 400mg, 800mg	
Adalat-CC	see Nifedipine ER		
Adenocard	see Adenosine		
Adenosine	Adenocard	Injectable: 6mg/2ml vial	
Adrenalin	see Epinephrine		
AK-Spore	see Neomycin/ Polymyxin B/ Gramicidin		
Albuterol	Ventolin, Proventil	Nebulizer solution: 0.083% - 3ml Inhaler: 90mcg/puff - 200 doses	Nebulizer solution restricted to acute asthma/COPD management
Alcaine	see Proparacaine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Aldactone	see Spironolactone		
Alendronate	Fosamax	Tablet: 70mg weekly	
Allopurinol	Zyloprim	Tablet: 100mg, 300mg	
Almacone	see Aluminum/Magnesium /Simethicone		
Alphagan	see Brimonidine		
Aluminum/Magnesium Hydroxide with Simethicone	Almacone	Chew Tablet: 200-200-20mg	
Amantadine	Symmetrel	Capsule: 100mg	
Amiodarone	Cordarone	Tablet: 200mg Injectable: 50mg/ml	
Amitriptyline	Elavil	Tablet: 10mg, 25mg, 50mg, 75mg, 100mg, 150mg	NONKOP. Nonformulary approval required for psychiatric diagnoses. Diagnosis must be indicated on all prescription.
Amlodipine	Norvasc	Tablet: 2.5mg, 5mg, 10mg	
Amoxicillin	Amoxil	Capsule: 250mg, 500mg	
Amoxicillin/ Clavulanate	Augmentin	Tablet: 875mg/125mg	Restricted to bite wounds and hand lacerations from teeth. Diagnosis must be indicated on prescription. Dose is 875mg BID for 5-7 days
Amoxil	see Amoxicillin		
Amphotericin B	Fungizone	Injectable: 50mg	
Ampicillin	Omnipen	Injectable: 500mg Capsule: 250mg, 500mg	
Anaprox	see Naproxen		
Ancef	see Cefazolin		
Antilirium	see Physostigmine		
Antipyrine /Benzocaine Otic	Auralgan	Otic Soln: 10ml	
Antivert	see Meclizine		
Anusol	see Hydrocortisone		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Aplisol	see Tuberculin PPD		
Apresoline	see Hydralazine		
Aptivus	see Tipranavir		
Aricept	see Donepezil		
Aripiprazole	Abilify	Tablet: 2mg, 5mg, 10mg, 15mg, 20mg, 30mg Solution: 1mg/ml Discmelt: 10mg, 15mg Injectable: 9.7mg/1.3ml	
Atacand	see Candesartan		
Artane	see Trihexyphenidyl		
Artificial Tears	see Polyvinyl Alcohol		
Asacol	see Mesalamine		
Asmanex	see Mometasone		
Aspirin	Various	Tablets: 325mg, 325mg EC, 325mg buffered, 81mg EC	
Atarax	see Hydroxyzine		
Atazanavir	Reyataz	Tablet: 200mg, 300mg	
Atenolol	Tenormin	Tablets: 25mg, 50mg, 100mg	
Ativan	see Lorazepam		
Atomoxetine	Strattera	Capsules: 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg	
Atripla	see Efavirenz/Tenofovir/ Emtricitabine		
Atropine	Various	Injectable: 0.1mg/ml	
Atrovent HFA	see Ipratropium		
Augmentin	see Amoxicillin/Clavulanate		
Auralgan	see Antipyrine/Benzocaine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Azithromycin	Zithromax	Tablet: 250mg, 500mg, 600mg	Restricted to the treatment of community acquired pneumonia, STD's and opportunistic infections in HIV. Diagnosis must be included on prescription.
Azulfidine	see Sulfasalazine		
Bacitracin/ Polymyxin Oint	Double Antibiotic, Polysporin	Topical Ointment -15gm, UD foil pack	
Baclofen	Lioresal	Tablet: 10mg, 20mg	Restricted to spinal cord injury patients. Must be indicated on prescription.
Bactrim	see Sulfamethox/Trimeth		
Bactroban	see Mupirocin		
Benadry	see Diphenhydramine		
Benemid	see Probenecid		
Bentyl	see Dicyclomine		
Benzac	see Benzoyl Peroxide		
Benzocaine / Menthol / Cetylp	Cepacol	Lozenge	
Benzocaine Topical	Americaine, Lanacane, Solarcaine	20% Topical Spray	Restricted to Fire Camps
Benzoin Tincture	Various	2oz. Tincture	Clinic use only.
Benzoyl Peroxide	Benzac	10% Topical Gel - 1.5oz.	
Benztropine	Cogentin	Tablets: 0.5mg, 1mg, 2mg Injectable: 1mg/ml ampul	
Betadine	see Povidone Iodine		
Betamethasone Topical	Diprosone	Ointment: 0.05% - 45gm Cream: 0.05% - 15gm	
Biaxin	see Clarithromycin		
Bicillin LA	see Penicillin Benzathine		
Bicitra	see Citric Acid		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Bisacodyl	Dulcolax	Tablet: 5mg Suppository: 10mg	
Bismuth	Pepto Bismol	Chew Tablet: 262mg	
Brethine	see Terbutaline		
Brimonidine	Alphagan	0.2% Ophthalmic Solution - 5ml	
Bromocriptine	Parlodel	Tablet: 2.5mg, 5mg	
Bumetanide	Bumex	Tablet: 0.5mg, 1mg, 2mg	
Bumex	see Bumetanide		
Bupivacaine	Marcaine	Injectable: 2.5mg/ml (0.25%); 5mg/ml (0.5%)	
Burn Spray	see Benzocaine topical		
Buspar	see Buspirone		
Buspirone	BuSpar	Tablet: 5mg, 10mg, 15mg, 30mg	
Calamine Lotion	Various	120ml Lotion	
Calan SR	see Verapamil		
Calcium Acetate	Phoslo	Capsule: 667mg	
Calcium Carbonate	Os-cal, Tums	Tablet: 500mg Chew Tablet: 500mg	
Calcium Carbonate/Vit. D	Os-cal D	Tablet: 500mg/125 IU	
Calcium Polycarbophil	Fibercon, Konsyl	Tablet: 625mg	
Candesartan	Atacand	Tablet: 4mg, 8mg, 16mg, 32mg	Restricted to patients who are intolerant to or have failed ACE Inhibitor therapy. ARBs should not be used to treat simple hypertension without a compelling indication (CHF, nephropathy, post myocardial infarction, or stroke).
Carafate	see Sucralfate		
Carbamazepine	Tegretol	Tablet: 200mg	
Carbamide Peroxide	Debrox Otic, Gly-Oxide	6.5% Otic Solution - 15ml 10% Oral Rinse - 2oz.	
Cardizem	see Diltiazem		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Cardura	see Doxazosin		
Carvedilol	Coreg	Tablet: 3.125mg, 6.25mg, 12.5mg, 25mg	
Catapress	see Clonidine		
Cefazolin	Ancef	Injectable: 1gm vial	
Ceftazidime	Fortaz	Injectable: 500mg, 1gm vial	
Ceftriaxone	Rocephin	Injectable: 250mg, 1gm vial	Restricted to the treatment of STD's. Should not be used as initial dose empiric treatment prior to oral therapy for nonSTD indications. Diagnosis must be indicated on prescription.
Celexa	see Citalopram		
Cepacol	see Benzocaine / Menthol / Cetylp		
Cephalexin	Keflex	Capsule: 250mg, 500mg	
Chlorhexidine oral rinse	Peridex	0.12% Oral Rinse - 16oz.	
Chlorhexidine skin cleanser	Hibiclens	4% antimicrobial skin cleanser - 4oz.	
Chlorpheniramine	Chlortrimeton	Tablet: 4mg	
Chlorpromazine	Thorazine	Tablet: 10mg, 25mg, 50mg 100mg, 200mg Syrup: 10mg/5ml Injectable: 25mg/ml	
Chlor-Trimeton	see Chlorpheniramine		
Cholestyramine	Questran	4gm packets	
Chronulac	see Lactulose		
Cibalith-S	see Lithium		
Cipro	see Ciprofloxacin		
Ciprofloxacin	Cipro	Tablet: 250mg, 500mg 0.3% Ophthalmic Soln - 5ml	
Citalopram	Celexa	Tablet: 10mg, 20mg, 40mg	
Citric Acid	Oracit, Bicitra, Cyutra-2, Sholhl's Solution	16 oz.	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Clarithromycin	Biaxin	Tablet: 250mg, 500mg	Restricted to opportunistic infections in HIV patients or as prescribed by an Infectious Disease Specialist. Must be indicated on prescription.
Claritin	see Loratadine		
Cleocin	see Clindamycin		
Clindamycin	Cleocin	Capsule (HCL): 150mg Injectable (Phosphate): 150mg/ml - 6ml	
Clonidine	Catapress	Tablet: 0.1mg, 0.2mg, 0.3mg	
Clopidrogel	Plavix	Tablet: 75mg	
Clotrimazole	Lotrimin, Mycelex Troche	Cream: 1% - 15gm Topical Solution: 1% - 10ml Troches: 10mg	
Clozapine	Clozaril	Tablets: 25mg, 50mg, 100mg	
Clozaril	see Clozapine		
Coal Tar	Various	1% Shampoo	
Cogentin	see Benztropine		
Colace	see Docusate sodium		
Colchicine	Various	Tablet: 0.6mg	
Combivir	see Zidovudine/Lamivudine		
Compazine	see Prochlorperazine		
Condylox	see Podofilox		
Copegus	see Ribavirin		
Cordarone	see Amiodarone		
Coreg	see Carvedilol		
Cortaid	see Hydrocortisone		
Cortisporin Otic	see Neomy/Bacit/Poly/Hydrocortisone		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Cough Lozenge	see Benzocaine / Menthol / Cetylp		
Coumadin	see Warfarin		
Crestor	see rosuvastatin		
Crixivan	see Indinavir		
Cyclogyl	see Cyclopentolate		
Cyclopentolate	Cyclogyl	1% Ophthalmic Solution - 15ml	
Cyproheptadine	Periactin	Tablet: 4mg	
Dacriose	see Eye wash		
Dapsone	Various	Tablet: 100mg	
Daraprim	see Pyrimethamine		
Darunavir	Prezista	Tablet: 300mg	
Debrox	see Carbamide Peroxide		
Decadron	see Dexamethasone		
Decavac	see Tetanus & Diphtheria		
Delestrogen	see Estradiol valerate		
Deltasone	see Prednisone		
Depakene	see Valproic acid		
Depakote	see Divalproex Sodium		
Depo-Provera	see Medroxyprogesterone		
Desyrel	see Trazodone		
Dexamethasone	Decadron	Tablet: 0.5mg, 0.75mg, 4mg, 6mg Injectable: 4mg/ml vial	
Dextrose	Glutose, Glucose	40% oral gel - 15gm Injectable: 50% - 50ml syringe	
Diabeta	see Glyburide		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Diamox	see Acetazolamide		
Dicyclomine	Bentyl	Tablet: 20mg Capsule: 10mg	
Didanosine	Videx EC	Capsule: 250mg, 400mg	
Diflucan	see Fluconazole		
Digoxin	Lanoxin	Tablet: 0.125mg, 0.25mg Injectable: 0.25mg/ml - 2ml	
Dilacor	see Diltiazem		
Dilantin	see Phenytoin		
Diltiazem	Cardizem, Cardizem CD,	Tablet immediate release: 60mg, 90mg Capsule sustained release: 120mg, 180mg, 240mg, 300mg	
Diphenhydramine	Benadryl	Capsule: 25mg, 50mg Solution: 12.5mg/5ml Injectable: 50mg/ml	
Diprosone	see Betamethasone Topical		
Dipyridamole	Persantine	Tablet: 25mg, 50mg	
Disalcid	see Salsalate		
Ditropan	see Oxybutynin		
Divalproex Sodium, Extended Release	Depakote (Extended Release)	Tablet: 250mg, 500mg	
Docusate Sodium	Colace	Capsule: 100mg	
Domeboro Otic	See Acetic Acid + Alum. Acetate Otic Soln		
Donepezil	Aricept	Tablet: 5mg, 10mg	
Dopamine	Intropin	400mg in 5% dextrose - 250ml bag	
Dorzolamide	Trusopt	2% Ophthalmic Solution - 5ml	
Double Antibiotic	see Bacitracin/Polymyxin		
Doxazosin	Cardura	Tablet: 1mg, 2mg, 4mg, 8mg	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Doxepin	Sinequan	Capsule: 10mg, 25mg, 50mg, 75mg, 100mg, 150mg	NONKOP. Nonformulary approval required for psychiatric diagnoses. Diagnosis must be indicated on prescription.
Doxycycline	Vibramycin, Vibra-Tab	Tablet: 100mg Injectable: 100mg - 10ml	
D-T Toxoids	see Tetanus & Diphtheria		
Dulcolax	see Bisacodyl		
Duofilm	see Salicylic Acid		
Edrophonium	Tensilon	10mg/ml - 10ml	
Efavirenz	Sustiva	Tablet: 600mg	
Efavirenz/Tenofovir/ Emtricitabine	Atripla	Capsule: 600-300-200mg	
Effexor	see Vanlafaxine		
Elavil	see Amitriptyline		
Elimite	see Permethrin		
Emtricitabine	Emtriva	Capsule: 200mg	
Emtriva	see Emtricitabine		
Enalapril	Vasotec	Tablet: 2.5mg, 5mg, 10mg, 20mg	
Engerix B	see Hepatitis B Vaccine		
Enulose	see Lactulose		
Epinephrine	Adrenalin, Epipen	1:1000 - 1ml (1mg) ampule 1:10,000 - 10ml syringe (0.1mg) Epipen 1:1000 syringe- 2ml (0.3mg)	
Epipen	see Epinephrine		
Epivir	see Lamivudine		
Epoetin alfa (erythropoietin)	Epogen / Procrit	10,000 units/ml 20,000 units/ml 4,000 units/ml	
Epogen	see Epoetin alfa		
Epzicom	see Abacavir/Lamivudine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Ergotamine w/Caffeine	Wigraine	Tablet: 1-100mg	
Erythrocin	see Erythromycin		
Erythromycin	Erythrocin	Tablet (stearate): 250mg, 500mg Injectable (lactobionate): 1gm	
Erythromycin Ophth	Ilotycin	0.5% Ophthalmic ointment - 3.5gm	
Esidrix	see Hydrochlorothiazide		
Eskalith	see Lithium		
Estradiol Valerate	Delestrogen	20mg/ml vial - 5ml	
Estrogens, Conjugated	Premarin	Tablet: 0.3mg, 0.625mg, 0.9mg Injectable: 25mg vial Vaginal cream: 0.625mg/gram - 42.5gm	
Ethambutol	Myambutol	Tablet: 400mg	
Ethyl Alcohol 70%	Various	16oz.	Clinic use only
Eye Wash	Dacriose	Irrigation Solution - 4oz.	
Felodipine	Plendil	Tablet: 2.5mg, 5mg, 10mg	
Feosol	see Ferrous sulfate		
Ferrous Sulfate	Feosol	Tablet: 325mg	
Fibercon Tablets	see Calcium Polycarbophil		
Flagyl	see Metronidazole		
Flecainide	Tambocor	Tablet: 50mg, 100mg, 150mg	
Fleet Enema	see Sodium Phosphates		
Fleet Phosphosoda	see Sodium Phosphates		
Flour-I-Strips	see Fluorescein		
Fluconazole	Diflucan	Tablet: 100mg, 150mg, 200mg	Restricted to treatment of Valley Fever, opportunistic infections in HIV, and ID Specialists. 150mg restricted to single dose treatment of vaginal candidiasis. Indications must be included on the prescription.

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Flumazenil	Romazicon	0.1mg/ml - 5ml	
Flunisolide	Nasalide	0.025% nasal spray - 200 doses	Restricted to severe seasonal allergic rhinitis & asthma. Quantity restricted to 1 bottle with a maximim of 2 refills per prescription.
Fluocinolone	Synalar Soln.	0.01% topical solution - 60ml	
Fluocinonide	Lidex oint/cream	Ointment: 0.05% - 15gm Cream: 0.05% - 15gm	
Fluorescein	Fluor-I-strip, Fluorets	1mg ophthalmic strips - 100 count	
Fluorescein / Benoxinate	Fluress	0.25%/0.4% ophthalmic solution - 5ml	
Fluorets	see Fluorescein		
Fluoxetine	Prozac	Capsule: 10mg, 20mg Solution: 20mg/5ml	Solution restricted to Keyhea patients only
Fluphenazine	Prolixin	Tablet: 1mg, 2.5mg, 5mg, 10mg Elixer: 2.5mg/5ml Injectable: 2.5mg/ml vial Decanoate: 25mg/ml	
Fluress	see Fluorescein/Benoxinate		
Fluvoxamine	Luvox	Tablet: 25mg, 50mg, 100mg	
Fluzone	see Influenza Vaccine		
Folic Acid	Various	Tablet: 1mg	
Fortaz	see Ceftazidime		
Fosamax	see Alendronate		
Fosamprenavir	Lexiva	Tablet: 700mg	
Fungizone	see Amphotericin B		
Furosemide	Lasix	Tablet: 20mg, 40mg Injectable: 10mg/ml	
Gabapentin	Neurontin	Cap/Tablet: 100mg, 300mg, 400mg, 600mg, 800mg	Restricted to treatment of individuals requiring adjunctive anticonvulsant treatment to adequately control a seizure disorder or treatment of neuropathic pain (e.g. herpetic neuralgia, HIV-related neuropathy, or diabetic neuropathy)
Garamycin	see Gentamicin		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Gemfibrozil	Lopid	Tablet: 600mg	
Genoptic	see Gentamicin		
Gentak	see Gentamicin		
Gentamicin	Garamycin, Gentak, Genoptic	Injectable: 40mg/1ml, 80mg/100ml, 100mg/100ml Ophthalmic oint: 0.3% - 3.5gm Ophthalmic soln: 0.3% - 5mg	
Geodon	see Ziprasidone		
Glipizide	Glucotrol	Tablet: 5mg, 10mg	
Glucagon	Glucogen	1mg kit	
Glucogen	see Glucagon		
Glucophage	see Metformin		
Glucotrol	see Glipizide		
Glucose	see Dextrose		
Glutose	see Dextrose		
Glyburide	Diabeta	Tablet: 1.25mg, 2.5mg, 5mg	
Gly-Oxide	see Carbamide Peroxide		
Golytely	see Polyethylene Glycol & ES		
Guaifenesin/Dextrometh	Robitussin DM	Elixer: 10-100mg/5ml	
Guanfacine	Tenex	Tablet: 1mg, 2mg	
Haldol	see Haloperidol		
Haloperidol	Haldol	Tablet: 0.5mg, 1mg, 2mg, 5mg, 10mg, 20mg Decanoate: 50mg/ml, 100mg/ml Injectable: 5mg/ml Oral Soln: 2mg/ml	
Havrix	see Hepatitis A Vaccine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Heparin	Various	Injectable: 100 units/ml, 1,000 units/ml, 5,000 units/ml, 20,000 units/ml	
Hepatitis A Vaccine	Havrix	1440 EL.U/ml - syringe	
Hepatitis B Vaccine	Engerix B	20mcg/ml - 1ml vial	
Hibiclens	see Chlorhexidine skin cleanser		
Homatropine	Isopto-Homatropine	5% Ophthalmic Soln - 5ml	
Humulin	see Insulin, Human		
Hydralazine	Apresoline	Tablet: 25mg, 50mg	
Hydrochlorothiazide	Esidrix	Tablet: 25mg, 50mg	
Hydrocortisone	Hytone, Cortaid, Anusol HC Supp	1% Topical Cream - 30gm 1% Hemorrhoidal Cream - 30gm 25mg Rectal Supp - 12/box	
Hydrocortisone Sodium Succinate	Solu-Cortef	Injectable: 100mg, 250mg, 500, 1000mg vial	
Hydrogen Peroxide	Various	16 oz.	Clinic use only
Hydroxychloroquine	Plaquenil	Tablet: 200mg	
Hydroxyzine	Atarax	HCL Tablet: 25mg, 50mg Injectabale: 50mg/ml	
Hytone	see Hydrocortisone		
Hytrin	see Terazosin		
Ibuprofen	Motrin	Tablet: 200mg, 400mg, 600mg, 800mg Oral Susp: 100mg/5ml	
Ilotycin	see Erythromycin Ophth		
Imdur	see Isosorbide Mononitrate		
Imipramine	Tofranil	Tablet: 10mg, 25mg, 50mg	NONKOP. Nonformulary approval required for psychiatric diagnoses. Diagnosis must be indicated on prescription.
Imitrex	see Sumatriptan		
Imodium	see Loperamide		
Inderal	see Propranolol		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Indinavir	Crixivan	Capsule: 200mg, 400mg	
Indocin	see Indomethacin		
Indomethacin	Indocin	Capsule: 25mg, 50mg, 75mg-SR	
Influenza Vaccine	Fluzone	5ml MDV - 10 doses per vial	
INH	see Isoniazid		
Insulin, Glargine	Lantus	100 units/ml - 10ml vial	
Insulin, Human	Humulin	Regular 100 units/ml - 10ml vial NPH 100 units/ml - 10ml vial 70/30 100 units/ml - 10ml vial	
Intropin	see Dopamine		
Invirase	see Saquinavir		
IPOL	see Poliovirus Vaccine		
Ipratropium	Atrovent HFA	Inhaler: 17mcg/actuation - 200 doses Nebulizer Soln: 0.02% - 2.5ml	
Isoniazid	INH	Tablet: 300mg	
Isopropyl Alcohol	Various	16oz.	Clinic use only
Isoptin	see Verapamil		
Isopto Carpine	see Pilocarpine		
Isopto-Homatropine	see Homatropine		
Isosorbide Dinitrate	Sorbitrate	Tablet: 10mg, 20mg, 30mg, 40mg	
Isosorbide Mononitrate	Imdur	Tablet: 30mg ER, 60mg ER, 120mg ER	
Itraconazole	Sporonox	Capsule: 100mg	Restricted to valley fever and ID Specialists only. Diagnosis must be included in the sig field
Kaletra	see Lopinavir/Ritonavir		
Kayexalate	see Polystyrene Sulfonate		
Keflex	see Cephalexin		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Kenalog	see Triamcinolone		
Keppra	see Levetiracetam		
Ketoconazole 2% Topical	Nizoral	2% Topical Cream - 15gm	
Ketorolac	Toradol	Injectable: 30mg/ml	Restricted to infirmary, CTC, TTA, and OHU settings.
Konsyl Tablets	see Calcium Polycarbophil		
Labetalol	Normodyne, Trandate	Tablet: 100mg, 200mg, 300mg	
Lacrilube	see Lubricating Eye Ointment		
Lactulose	Chronulac, Enulose	Oral solution: 10gm/15ml - 473ml	
Lamivudine	Epivir	Tablet: 150mg, 300mg	
Lamotrigine	Lamictal	Tablet: 25mg, 100mg, 150mg, 200mg	Restricted to psychiatric diagnoses. Diagnosis must be included on prescription.
Lanoxin	see Digoxin		
Lantus	see Insulin, Glargine		
Lasix	see Furosemide		
Latanoprost	Xalatan	Ophthalmic Soln: 0.005% - 2.5ml	
Leucovorin	Wellcovorin	Tablet: 5mg	
Levaquin	see Levofloxacin		
Levetiracetam	Keppra	Tablet: 250mg, 500mg, 750mg, 1000mg	Restricted to psychiatric diagnoses. Diagnosis must be included on prescription.
Levodopa/ Carbidopa	Sinemet	Tablet (immediate release): 10/100mg, 25/100mg, 25/250mg Tablet (controlled release): 50/200mg, 25/100mg	
Levofloxacin	Levaquin	Tablet: 250mg, 500mg	Restricted to treatment of Community Acquired Pneumonia. Diagnosis must be indicated on the prescription.
Levothyroxine	Synthroid, Levoxyl	Tablet: 25mcg, 50mcg, 75mcg, 88mcg, 100mcg, 112mcg, 125mcg, 137mcg, 150mcg, 175mcg, 200mcg, 300mcg	
Levoxyl	see Levothyroxine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Lexiva	see Fosamprenavir		
Lidex	see Fluocinonide		
Lidocaine	Xylocaine	2% Viscous Oral Soln - 100ml 2% Jelly - 30ml 0.4% D5W IV INJ - 500ml 2% IV INJ (20mg/ml) - 5ml 1% Local INJ (10mg/ml) -50ml 2% Local INJ (20mg/ml) - 50ml 1% with EPI 1:100,000	
Lioresal	see Baclofen		
Lisinopril	Prinivil/Zestril	Tablet: 2.5mg, 5mg, 10mg, 20mg, 40mg	
Lithium Carbonate	Eskalith, Lithobid, Cibalith-S	Capsule: 300mg Extended Release Tablet: 300mg, 450mg Oral Citrate Soln: 8meq/5ml	
Lithobid	see Lithium		
Loniten	see Minoxidil		
Loperamide	Imodium	Caplet: 2mg	
Lopid	see Gemfibrozil		
Lopinavir/Ritonavir	Kaletra	Tablet: 200-50mg	
Lopressor	see Metoprolol		
Loratadine	Claritin	Tablet: 10mg	Quantity restricted to #30 tablets per month with a maximum of 2 refills per prescription
Lorazepam	Ativan	Tablets: 1mg Injectable: 2mg/ml - 1ml	Tablets restricted to a 7 day supply for the treatment of acute agitation in psychiatric diagnoses or delirium tremens. Diagnosis must be included on prescription.
Lotrimin	see Clotrimazole		
Loxapine Succinate	Loxitane	Capsule: 5mg, 10mg, 25mg, 50mg Injectable: 50mg/ml Oral soln: 25mg/ml	
Loxitane	see Loxapine		
Lubricating Eye Ointment	Lacrilube	Ophthalmic Oint (petrolatum/mineral oil/lanolin): 3.5gm	
Luvox	see Fluvoxamine		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Macrobid	see Nitrofurantoin		
Macrodantin	see Nitrofurantoin		
Magnesium Citrate	Various	Oral Soln: 300ml	
Magnesium Hydroxide	Milk of Magnesia,	Oral Soln: 400mg/5ml	
Magnesium Sulfate	Magnesium Sulfate	50% INJ - 2ml	
Marcaine	see Bupivacaine		
Maxide	see Triamterene/HCTZ		
Maxitrol	see Neomycin/Poly/Dexameth		
Measles/Mumps/Rubella Vaccine	see M-M-R vaccine	0.5ml SDV	
Mebendazole	Vermox	Chew Tablet: 100mg	
Meclizine	Antivert	Tablet: 25mg	
Medrol	see Methylprednisolone		
Medroxyprogesterone	Provera / Depo-Provera	Tablet: 2.5mg, 5mg, 10mg Injectable: 150mg/ml SDV	
Megace	see Megestrol		
Megestrol	Megace	Tablet: 20mg, 40mg Oral Susp: 40mg/ml	
Memantine	Namenda	Tablet: 5mg, 10mg	
Meningococcal Vaccine	Menomune	50mcg/0.5ml SDV	
Menomune	see Meningococcal Vaccine		
Mesalamine	Asacol	Tablet: 400mg EC	
Metformin	Glucophage	Tablet: 500mg, 850mg, 1000mg	
Methadone	Dolophine	Tablet: 10mg	
Methimazole	Tapazole	Tablet: 5mg, 10mg	
Methocarbamol	Robaxin	Tablet: 500mg, 750mg Injectable: 100mg/ml - 10ml	Restricted to 7 day supply per prescription unless indicated for spinal cord injury

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Methylprednisolone	Medrol Dose Pak, Solu-Medrol	Tablet: 4mg, Dose Pak Injectable (Sodium Succinate): 125mg/2ml vial	
Metoclopramide	Reglan	Tablet: 5mg, 10mg Injectable: 10mg/2ml vial	
Metolazone	Zaroxolyn	Tablet: 2.5mg, 5mg, 10mg	
Metoprolol	Lopressor	Tablet: 25mg, 50mg, 100mg Injectable: 5mg/5ml	
Metronidazole	Flagyl	Tablet: 250mg, 500mg Injectable: 500mg/100ml	
Mexiletine	Mexitil	Capsule: 150mg, 200mg, 250mg	
Mexitil	see Mexiletine		
Micatin	see Miconazole		
Miconazole	Micatin Crm, Monistat 7 Vag Supp/Crm.	2% Cream - 30gm 100mg vaginal supp - 7 supp/box	
Milk of Magnesia	see Magnesium Hydroxide		
Minoxidil	Loniten	Tablet: 2.5mg, 10mg	
Mirtazapine	Remeron	Tablet: 7.5mg, 15mg, 30mg, 45mg Soltab: 15mg, 30mg, 45mg	
M-M-R	see Measles/Mumps/Rubella		
Mometasone	Asmanex	Inhaler: 220mcg/actuation - 120 dose size	Provider Note: For patients on $\leq$ 2 puffs/day, 1 inhaler will last 60 days. Patient Note: Expires 60 days from first use
Monistat	see Miconazole		
Morphine Sulfate	MS Contin, Roxanol	Tablet (IR): 15mg, 30mg Tablet (SA): 15mg 30mg Oral Soln: 10mg/5ml Injectable: 10mg/ml vial	
Motrin	see Ibuprofen		
MS Contin	see Morphine Sulfate		
Mucomyst	see Acetylcysteine		
Multivitamin	various	Tablet	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Mupirocin	Bactroban	2% Ointment	Restricted to use in the decolonization of Staph aureaus for nasal passages. Bactroban availability is not intended for general topical antibiotic utilization due to development of resistance. All orders should include the statement “for use in S. aureaus decolonization".
Muro-128	see Sodium Chloride Ophth		
Myambutol	see Ethambutol		
Mycelex	see Clotrimazole		
Mycobutin	see Rifabutin		
Mycolog II	see Nystatin/Triamcinolone		
Mycostatin	see Nystatin		
Nafcillin	Unipen	Injectable: 1 gm vial	
Naloxone	Narcan	Injectable: 0.4mg/ml - 1ml	
Namenda	see Memantine		
Naphazoline	Naphcon	0.012% Ophthalmic Soln - 15ml	
Naphazoline / Pheniramine	Naphcon-A	0.025%-0.3% Ophthalmic Soln - 15ml	
Naphcon	see Nephazoline		
Naphcon-A	see Naphazoline/Pheniramine		
Naprosyn	see Naproxen		
Naproxen	Naprosyn/Anaprox	Tablet: 250mg, 500mg	
Narcan	see Naloxone		
Nasalide	see Flunisolide		
Navane	see Thiothixene		
NebuPent	see Pentamidine		
Nelfinavir	Viracept	Tablet: 625mg	
Neomycin	Various	Tablet: 500mg	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Neomycin/ Polymixin B/ Gramicidin	Neosporin Ophthalmic, AK- Spore	Ophthalmic Soln - 10ml	
Neomycin/ Polymyxin B/ Dexamethasone Ophth	Maxitrol	Ophthalmic Soln - 5ml Ophthalmic Oint - 3.5gm	
Neomycin/Bacitracin/ Polymyxin Ophth Oint	Neosporin Ophth Oint	Ophthalmic Oint: 3.5gm	
Neomycin/Polymyxin /Hydrocortisone	Cortisporin Otic	Otic Suspension - 10ml	
Neosporin Ophth Oint	see Neomycin/Bacitracin/ Polym Ophth Oint		
Neosporin Ophth Soln	see Neomycin/ Polymixin B/ Gramicidin		
Neo-Synephrine Ophth Soln	see Phenylephrine Ophth		
Neurontin	see Gabapentin		
Nevirapine	Viramune	Tablet: 200mg	
Niacin	Various	Tablet (immediate release): 250mg, 500mg	
Nifedipine ER	Adalat-CC	Tablet (extended release): 30mg, 60mg, 90mg	
Nitrobid	see Nitroglycerin		
Nitrofurantoin	Macrobid, Macrodantin	Capsule: 50mg, 100mg*	*100mg should be Macrobid or twice daily formulation
Nitroglycerin	Nitrostat/ Nitrobid IV	Tablet (SL): 0.4mg Trandsderm Patch: 0.2mg/h, 0.4mg/hr, 0.6mg/hr Injectable: 5mg/ml -10ml vial 2% Topical Oint	
Nitrostat	see Nitroglycerin		
Nix	see Permethrin		
Nizoral	see Ketoconazole 2% Topical		
Norethindrone/Ethinyl Estradiol	Ortho-Novum 1/35	28 day pack	
Norgestimate/Ethinyl Estradiol	Ortho-TriCyclen	28 day pack	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Normal Saline for Nebulizer	see Sodium Chloride		
Normodyne	see Labetalol		
Nortriptyline	Pamelor	Capsule: 10mg, 25mg, 50mg, 75mg	NONKOP. Nonformulary approval required for psychiatric diagnoses. Diagnosis must be indicated on prescription.
Norvasc	see Amlodipine		
Norvir	see Ritonavir		
Nystatin	Mycostatin	Topical cream: 100,000 units/gm - 30gm Oral Susp: 100,000 units/ml	
Nystatin/ Triamcinolone	Mycolog II	Topical cream & oint - 30gm	
Ocean Nasal	see Sodium Chloride Nasal		
Olanzapine	Zyprexa	Tablet: 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg Zydis: 5mg, 10mg, 15mg, 20mg	
Omeprazole	Prilosec	Capsule: 20mg	
Omnipen	see Ampicillin		
Oral Contraceptive	see Ortho-Novum 1/35 or Ortho-Tricyclen		
Ortho-Novum 1/35	see Norethindrone/Ethinyl estradiol		
Ortho-TriCyclem	see Norgestimate/Ethinyl Estradiol		
Os-cal	see Calcium Carbonate		
Os-cal D	see Calcium Carbonate/ Vit. D		
Oxcarbazepine	Trileptal	Tablet: 150mg, 300mg, 600mg Suspension: 300mg/5ml	Restricted to psychiatric diagnoses. Diagnosis must be included on prescription. Suspension restricted to Keyhea patients only.
Oxybutynin	Ditropan	Tablet: 5mg	
Pamelor	see Nortriptyline		
Pancrease	see Pancrelipase		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Pancrelipase	Pancrease	Tablet: lipase 8000 / amylase 30,000 / protease 30,000 units	
Parlodel	see Bromocriptine		
Paroxetine	Paxil	Tablet: 10mg, 20mg, 30mg, 40mg	
Paxil	see Paroxetine		
Pegasys	see Pegylated Interferon-alpha 2A		
Pegylated Interferon alfa 2A	Pegasys	Injectable: 180mcg/0.5ml PFS	
Penicillin Benzathine	Bicillin LA	Injectable: 2.4 million units/4ml	Restricted to the treatment of syphilis
Penicillin G Potassium	Pfizerpen	Injectable: 5 million units/injection	
Penicillin G Procaine	Wycillin	Injectable: 1.2 million units/2ml syringe	
Penicillin VK	Veetids	Tablets: 250mg, 500mg Oral Susp: 250mg/5ml	
Pentam	see Pentamidine		
Pentamidine	NebuPent, Pentam	Injectable: 300mg Inhalation Soln: 300mg	
Pepto Bismol	see Bismuth		
Periactin	see Cyproheptadine		
Peridex	see Chlorhexidine oral rinse		
Permethrin	Nix, Elimite	Topical Cream 5% - 60gm 1% Lotion - 2oz.	
Perphenazine	Trilafon	Tablet: 2mg, 4mg, 8mg, 16mg Injectable: 5mg/ml Oral Soln: 16mg/5ml	
Persantine	see Dipyridamole		
Petrolatum/Lanolin Skin Protectant Ointment	A&D Ointment	4 oz. tube	
Pfizerpen	see Penicillin G Potassium		
Phazyme	see Simethicone		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Phenazopyridine	Pyridium	Tablet: 200mg	
Phenergan	see Promethazine		
Phenylepherine Ophth	Neo-Synephrine	2.5% Ophth Soln - 5ml	
Phenytoin	Dilantin	Capsule: 100mg Oral Susp: 125mg/5ml Injectable: 50mg/ml vial	
Phoslo	see Calcium Acetate		
Physostigmine	Antilirium	Injectable: 1mg/ml - 2ml ampule	
Pilocarpine	Isopto Carpine	2% Ophth Soln - 15ml 4% Ophth Soln - 15ml	
Pioglitazone	Actos	Tablet: 15mg, 30mg, 45mg	
Plaquenil	see Hydroxychloroquine		
Plavix	see Clopidogrel		
Plendil	see Felodipine		
Pneumococcal Vaccine	Pneumovax-23	50mcg/0.5ml SDV	
Pneumovax-23	see Pneumococcal		
Podofilox	Condylox	0.5% Topical Soln - 3.5ml	
Poliovirus Vaccine	IPOL	0.5ml SC INJ	
Polyethylene glycol-ES	Golytely, Nulytely	Oral Soln 4 liters	
Polysporin	see Bacitracin/Polymyxin		
Polystyrene sulfonate	Kayexalate	15gm/60ml Suspension	
Polyvinyl Alcohol	Artificial Tears	1% ophthalmic solution - 15ml	
Potassium Chloride	Various	Tablet: 10meq, 20meq Injectable: 20meq in D5W-1000ml & 1/2NS-D5W 1000ml	
Povidone Iodine	Betadine	10% Oint 10% Soln	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Pravachol	see Pravastatin		
Pravastatin	Pravachol	Tablet: 10mg, 20mg, 40mg	Resticted to patients on coumadin, protease inhibitors, cyclosporine, or other medications impacted by the cytochrome P450 enzyme system
Pred Forte	see Prednisolone Ophth		
Pred MILD	see Prednisolone Ophth		
Prednisolone Ophth	Pred Forte, Pred MILD	1% Ophth Soln - 5ml 0.12% Ophth Soln - 5ml	
Prednisone	Deltasone	Tablet: 5mg, 10mg, 20mg	
Prenatal Vitamin	Various	Tablet	
Prezista	see Darunavir		
Prilosec	see Omeprazole		
Prinivil	see Lisinopril		
Probenecid	Benemid	Tablet: 500mg	
Procainamide	Procan	Tablet (SR): 500mg, 750mg, 1000mg Injectable: 100mg/ml - 10ml vial	
Procan	see Procainamide		
Prochlorperazine	Compazine	Tablet: 5mg, 10mg Injectable: 5mg/ml - 2ml vial	
Procrit	see Epoetin alfa		
Prolixen	see Fluphenazine		
Promethazine	Phenergan	Tablet: 25mg Injectable: 50mg/ml - 1ml vial Suppository: 25mg - 12/Box	
Proparacaine	Alcaine	0.5% Ophth Soln - 15ml	
Propranolol	Inderal	Tablet: 10mg, 20mg, 40mg, 60mg Injectable: 1mg/ml - 1ml	
Propylthiouracil	PTU	Tablet: 50mg	
Proventil	see Albuterol		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Provera	see Medroxyprogesterone		
Prozac	see Fluoxetine		
PTU	see Propylthiouracil		
Pyrazinamide	PZA	Tablet: 500mg	
Pyridium	see Phenazopyridine		
Pyridoxine	Vitamin B6	Tablet: 50mg	
Pyrimethamine	Daraprim	Tablet: 25mg	
PZA	see Pyrazinamide		
Questran	see Cholestyramine		
Quetiapine	Seroquel	Tablet: 25mg, 50mg, 100mg, 200mg, 300mg, 400mg	
Quinagluet	see Quinidine		
Quinidine	Quinaglute	Tablet (SR): 324mg	
Ranitidine	Zantac	Tablet: 150mg Injectable: 50mg/2ml vial	
Rebetol	see Ribavirin		
Reglan	see Metoclopramide		
Remeron	see Mirtazapine		
Renagel	see Sevelamer		
Retrovir	see Zidovudine		
Reyataz	see Atazanavir		
Ribasphere	see Ribavirin		
Ribavirin	Ribasphere	Tablet/Capsule: 200mg	
Rifabutin	Mycobutin	Capsule: 150mg	
Rifadin	see Rifampin		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Rifampin	Rifadin	Capsule: 300mg	
Risperdal	see Risperidone		
Risperidone	Risperdal	Tablet: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg M-Tab: 0.5mg, 1mg, 2mg, 3mg, 4mg Consta: 25mg/2ml, 37.5mg/2ml, 50mg/2ml Oral Soln: 1mg/ml	
Ritonavir	Norvir	Capsule: 100mg	
Robaxin	see Methocarbamol		
Robitussin DM	see Guaifenesin/Dextrometh		
Rocephin	see Ceftriaxone		
Romazicon	see Flumazenil		
Rosuvastatin	Crestor	Tablet: 5mg, 10mg, 20mg, 40mg	One of the following criteria must be noted on the prescription: 1.) Failure to reach goal LDL on maximum doses of simvastatin for 12 weeks of therapy or 2.) Greater than 45% LDL reduction required to meet goal
Roxanol	see Morphine Sulfate		
Rubbing Alcohol	see Isopropyl Alcohol		
Salicylic Acid	Duofilm	17% Topical Soln - 0.31 oz.	
Salmeterol	Serevent	Inhaler: 50mcg/actuation - 60 doses	
Salsalate	Disalcid	Tablet: 500mg	
Saquinavir	Invirase	Tablet: 500mg	
Selenium sulfide	Selsun	2.5% Susp - 4oz	
Selsum	see Selenium sulfide		
Septra	see Sulfamethox/Trimeth		
Serevent	see Salmeterol		
Seroquel	see Quetiapine		
Sertraline	Zoloft	Tablet: 25mg, 50mg, 100mg	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Sevelamer	Renagel	Tablet: 400mg, 800mg	
Silvadene	see Silver Sulfadiazine		
Silver Sulfadiazine	Silvadene	1% Topical cream - 50gm, 400gm	400gm size restriced to clinic use only
Simethicone	Phazyme	Chew Tab: 80mg	
Simvastatin	Zocor	Tablet: 5mg, 10mg, 20mg, 40mg, 80mg	
Sinemet	see Levodopa/Carbidopa		
Sinequan	see Doxepin		
Sodium Chloride Inhalation Soln	Various	0.9% Inhalation Solution - 5ml	
Sodium Chloride Nasal	Ocean Nasal	Nasal Spray - 45ml	
Sodium Chloride Ophthalmic	Muro-128	5% Ophth Oint - 3.5ml 2% Ophth Drops - 15ml 5% Ophth Drops - 15ml	
Sodium Phosphates	Fleet Phosphosoda, Fleet Enema	Fleets Enema - 133ml Oral Soln - 1.5 oz.	
Solu-Cortef	see Hydrocortisone Sodium Succinate		
Solu-Medrol	see Methylprednisolone		
Sorbitrate	see Isosorbide Dinitrate		
Spironolactone	Aldactone	Tablet: 25mg, 50mg, 100mg	
Sporonox	see Itraconazole		
Stavudine	Zerit	Capsule: 20mg, 30mg, 40mg	20mg capsule restricted to dialysis use only.
Stelazine	see Trifluoperazine		
Strattera	see Atomoxetine		
Sucralfate	Carafate	Tablet: 1gm	
Sulamyd	see Sulfacetamide		
Sulfacetamide	Sulamyd	10% Ophth Soln - 5ml	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Sulfameth / Trimethoprim	Bactrim, Septra	Tablet (single strength): 400-80mg Tablet (double strength): 800-160mg Oral Susp: 200-40mg/5ml	
Sulfasalazine	Azulfidine	Tablet: 500mg	
Sumatriptan	Imitrex	Tablet: 25mg, 50mg, 100mg	Restricted to 9 tablets per month
Sumycin	see Tetracycline		
Sunscreen	Various		
Sustiva	see Efavirenz		
Symmetrel	see Amantadine		
Synalar	see Fluocinolone		
Synthroid	see Levothyroxine		
Tambocor	see Flecainide		
Tapazole	see Methimazole		
Tegretol	see Carbamazepine		
Tenex	see Guanfacine		
Tenofovir	Viread	Tablet: 300mg	
Tenofovir/Emtricitabine	Truvada	Tablet: 300-200mg	
Tenormin	see Atenolol		
Tensilon	see Edrophonium		
Terazosin	Hytrin	Capsule: 1mg, 2mg, 5mg, 10mg	
Terbutaline	Brethine	Tablet: 2.5mg, 5mg Injectable: 1mg/ml vial	
Tetanus & Diphtheria	D-T Toxoids, Decavac	SDV	
Tetracycline	Sumycin	Capsule: 250mg, 500mg	
Theodur	see Theophylline		
Theophylline	Theodur	Tablet (SR): 200mg, 300mg	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Thiamine	Vitamin B1	Tablet: 100mg Injectable: 100mg/ml - 2ml	
Thiothixene	Navane	Capsule: 1mg, 2mg, 5mg, 10mg, 20mg Oral Soln: 5mg/ml	
Thorazine	see Chlorpromazine		
Timolol Ophth	Timoptic	Ophthalmic Soln: 0.25%, 0.5% - 5ml	
Timoptic	see Timolol		
Tinactin	see Tolnaftate		
Tipranavir	Aptivus	Capsule: 250mg	
Tofranil	see Imipramine		
Tolnaftate	Tinactin	1% Topical Cream - 15gm 1% Topical Soln - 10ml	
Toradol	see Ketorolac		
Trandate	see Labetalol		
Trazodone	Desyrel	Tablet: 50mg, 100mg, 150mg	
Triamcinolone	Kenalog	Injectable: 10mg/ml, 40mg/ml Topical Cream: 0.025% - 15gm , 0.1% - 15gm, 454gm Topical Oint: 0.025%, 0.1% - 15gm 1% in Orabase	
Triamterene/HCTZ	Maxzide	Tablet: 37.5/25mg, 75/50mg	
Trifluoperazine	Stelazine	Tablet: 1mg, 2mg, 5mg Oral Soln: 10mg/ml	
Trifluridine	Viroptic	1% Ophth Soln - 7.5ml	
Trihexyphenidyl	Artane	Tablet: 2mg, 5mg Oral Soln: 2mg/5ml	
Trilafon	see Perphenazine		
Trileptal	see Oxcarbazepine		
Triprolidine/Pseudoeph	Actifed	Tablet: 2.5-60mg	Restricted to 7 day supply per prescription

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Trizivir	see Zidovudine/ Lamivudine/Abacavir		
Tropicacyl	see Tropicamide		
Tropicamide	Tropicacyl	1% Ophth Soln - 15ml	
Trusopt	see Dorzolamide		
Truvada	see Tenofovir/Emtricitabine		
Tuberculin Purified Protein Derivative	Aplisol, Tubersol	50 tests / 5ml	
Tubersol	see Tuberculin PPD		
Tums	see Calcium Carbonate		
Tylenol	see Acetaminophen		
Tylenol #3	see Acetam/Codeine		
Unipen	see Nafcillin		
Valproic Acid	Depakene, Depakon	Capsule: 250mg Injectable: 500mg/5ml vial Oral Soln: 250mg/5ml	
Vancocin	see Vancomycin		
Vancomycin	Vancocin	Injectable: 1gm vial	Restrict to dialysis and CTC
Varicella Vaccine	Varivax	1350 PFU/0.5ml	
Varivax	see Varicella Vaccine		
Vasotec	see Enalapril		
Veetids	see Penicillin VK		
Venlafaxine	Effexor	Capsule (XR): 37.5mg, 75mg, 150mg Tablet: 25mg, 37.5mg, 50mg. 75mg, 100mg	
Ventolin	see Albuterol		
Verapamil	Isoptin/ Calan-SR	Tablet (IR): 40mg, 80mg, 120mg Tablet (SR): 120mg, 180mg, 240mg	
Vermox	see Mebendazole		

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Vibramycin	see Doxycycline		
Videx EC	see Didanosine		
Viracept	see Nelfinavir		
Viramune	see Nevirapine		
Viread	see Tenofovir		
Viroptic	see Trifluridine		
Vitamin B1	see Thiamine		
Vitamin B6	see Pyridoxine		
Warfarin	Coumadin	Tablet: 1mg, 2.5mg, 3mg, 5mg, 7.5mg, 10mg	
Wellcovorin	see Leucovorin		
Wigraine	see Ergotamine/Caffeine		
Wycillin	see Penicillin G Procaine		
Xalatan	see Latanoprost		
Xylocaine	see Lidocaine		
Zantac	see Ranitidine		
Zaroxolyn	see Metolazone		
Zerit	see Stavudine		
Zestril	see Lisinopril		
Ziagen	see Abacavir		
Zidovudine	Retrovir	Tablet: 100mg, 300mg	100mg tablet restricted to dialysis use only.
Zidovudine/Lamivudine	Combivir	Tablet: 150-300mg	
Zidovudine/Lamivudine/ Abacavir	Trizivir	Tablet: 300-150-300mg	
Ziprasidone	Geodon	Capsule: 20mg, 40gm, 60mg, 80mg Injection: 20mg/ml	

DRUG NAME	CROSS REFERENCE	DOSAGE FORMS	RESTRICTIONS
Zithromax	see Azithromycin		
Zocor	see Simvastatin		
Zoloft	see Sertraline		
Zovirax	see Acyclovir		
Zyloprim	see Allopurinol		
Zyprexa	see Olanzapine		

THERAPEUTIC CATEGORY INDEX

AHFS	Therapeutic Category	PAGE
4.00	ANTI-HISTAMINES	35
8.00	ANTI-INFECTIVES	35
10.00	ANTINEOPLASTICS	36
12.00	AUTONOMIC DRUGS	36
20.00	BLOOD FORMATION & COAGULATION	37
24.00	CARDIOVASCULAR AGENTS	37
28.00	CENTRAL NERVOUS SYSTEM AGENTS	38
36.00	DIAGNOSTIC AGENTS	40
40.00	ELECTROLYTE, CALORIC & WATER BALANCE	40
48.00	EXPECTORANTS, ANTITUSSIVES & MUCOLYTICS AGENTS	40
52.00	EYE, EAR, NOSE & THROAT (EENT) PREPARATIONS	41
56.00	GASTROINTESTINAL AGENTS	41
68.00	HORMONES & SYNTHETIC SUBSTITUTES	42
72.00	LOCAL ANESTHETICS	43
80.00	SERUMS, TOXOIDS & VACCINES	43
84.00	SKIN & MUCOUS MEMBRANE AGENTS	43
86.00	SMOOTH MUSCLE RELAXANTS	44
88.00	VITAMINS	44
92.00	UNCLASSIFIED THERAPEUTIC AGENTS	45
96.00	PHARMACEUTICAL AIDS	45

AHFS Therapeutic Category Index

* - Denotes Restrictions Apply

4:00 ANTI-HISTAMINES
chlorpheniramine
cyproheptadine
diphenhydramine
hydroxyzine
loratadine*
meclizine
promethazine
triprolidine / pseudoephedrine*

8:00 ANTI-INFECTIVES

8:08 Anthelmintics
mebendazole

8:12 Antibiotics

8:12.02 Aminoglycosides
gentamicin
neomycin

8:12.06 Cephalosporins
1st Generation
cefazolin
cephalexin
3rd Generation
ceftazidime
ceftriaxone*

8:12.12 Macrolides
azithromycin*
clarithromycin*
erythromycin

8:12.16 Penicillins
penicillin G benzathine*
penicillin G potassium
penicillin G procaine
penicillin VK

Penicillinase-Resistant Penicillins
nafcillin

Aminopenicillins
amoxicillin
amoxicillin-clavulanate*
ampicillin

8:12.20 Sulfonamides
sulfasalazine
sulfamethoxizole / trimethoprim

8:12.18 Quinolones
ciprofloxacin
levofloxacin*

8:12.24 Tetracyclines
doxycycline
tetracycline

8:12.28 Miscellaneous Antibiotics
clindamycin
dapsone
vancomycin*

8:14 Antifungals
amphotericin B
fluconazole*
itraconazole*
nystatin

8:16 Antimycobacterials
ethambutol
isoniazid
pyrazinamide
rifabutin
rifampin

8:18 Antivirals
acyclovir
amantadine
pegylated interferon alpha 2-A
ribavirin

8:18.08 Antiretrovirals
NRTI - Nucleoside Reverse Transcriptase Inhibitors
abacavir
didanosine
emtricitabine
lamivudine
stavudine*
zidovudine*

Nucleotide Reverse Transcriptase Inhibitors
tenofovir

NNRTI - Non-Nucleoside Reverse Transcriptase Inhibitors
efavirenz
nevirapine

Protease Inhibitors
atazanavir
darunavir
fosamprenavir
indinavir
lopinavir/ritonavir
nelfinavir
ritonavir
saquinavir
tipranovir

Combination Products
abacavir / lamivudine
efavirenz / tenofovir / emtricitabine
tenofovir / emtricitabine
zidovudine / lamivudine
zidovudine / lamivudine / abacavir

8:30 Antiprotozoals
hydroxychloroquine
metronidazole
pentamidine
pyrimethamine

8:36 Urinary Anti-Infectives
nitrofurantoin

10:00 ANTINEOPLASTICS
megestrol

12:00 AUTONOMIC DRUGS

12:04 Parasympathomimetic Agents
edrophonium
physostigmine

12:08 Anticholinergic Agents

12:08.04 Antiparkinson Agents
benztropine
trihexyphenidyl

12:08.08 **Antimuscarinic/Antispasmodic Agents**
atropine
dicyclomine
ipratropium

12:12 **Sympathomimetic Agents**
albuterol*
dopamine
epinephrine
salmeterol
terbutaline

12:16 **Sympatholytic Agents**
ergotamine / caffeine

12:20 **Skeletal Muscle Relaxants**
baclofen*
methocarbamol*

20:00 **BLOOD FORMATION & COAGULATION**

20:04 **Antianemia Drugs**

20:04.04 **Iron Preparations**
ferrous sulfate

20:12 **Coagulants & Anticoagulants**

20:12.04 **Anticoagulants**
heparin
warfarin

20:16 **Hematopoietic Agents**
epoetin alfa

24:00 **CARDIOVASCULAR AGENTS**

24:04 **Cardiac Drugs**
amiodarone
digoxin
flecainide
mexiletine
lidocaine
procainamide
quinidine

24:06 **Antilipemic Agents**

24:06.04 **Bile Acid Sequestrants**
cholestyramine

24:06.06 **Fibric Acid Derivatives**
gemfibrozil

24:06.08 **HMG-CoA Reductase Inhibitors**
pravastatin*
rosuvastatin*
simvastatin

24:06.92 **Miscellaneous Antilipemic Agents**
Niacin (immediate release)

24:08 **Hypotensive Agents**
Central Alpha-Adrenergic Agonists
clonidine
guanfacine

Peripheral Vasodilators
hydralazine
minoxidil

24:12 Vasodilating Agents
dipyridamole
isosorbide dinitrate
isosorbide mononitrate
nitroglycerin

24:20 Alpha-Adrenergic Blocking Agents
doxazosin
terazosin

24:24 Beta-Adrenergic Blocking Agents
atenolol
carvedilol
labetolol
metoprolol
propranolol

24:32 Renin-Aldosterone System Inhibitors
Angiotensin Converting Enzyme Inhibitors
enalapril
lisinopril

Angiotensin Receptor Blockers
candesartan*

Mineralocorticoids
spironolactone

24:28 Calcium Channel Blockers
diltiazem
verapamil

Dihydropyridines
amlodipine
felodipine
nifedipine

28:00 CENTRAL NERVOUS SYSTEM AGENTS

28:08 Analgesics and Antipyretics

28:08.04 Non-Steroidal Anti-Inflammatory Agents
aspirin
ibuprofen
indomethacin
ketorolac*
naproxen
salsalate

28:08.08 Opiate Agonists
acetaminophen / codeine
methadone
morphine

28:08.92 Miscellaneous Analgesics & Antipyretics
acetaminophen

28:10 Opiate Antagonists
naloxone

28:12 Anticonvulsants

28:12.08 Benzodiazepines
lorazepam*

28:12.12 Hydantoins
phenytoin

28:12.92 Miscellaneous Anticonvulsants
carbamazepine
divalproex sodium
gabapentin*
lamotrigine*
levetiracetam*

magnesium sulfate
oxcarbazepine*
valproic acid

28:16 Psychotherapeutic Agents

28:16.04 Antidepressants

Selective Serotonin Reuptake Inhibitors
citalopram
fluoxetine*
fluvoxamine
paroxetine
sertraline

Tricyclic Antidepressants
amitriptyline*
doxepin*
imipramine*
nortriptyline*

Miscellaneous Antidepressants
mirtazapine
trazodone
venlafaxine

28:16.08 Antipsychotics

Atypical
aripiprazole
clozapine
olanzapine
quetiapine
risperidone
ziprasidone

Typical
chlorpromazine
fluphenazine
haloperidol
loxapine
perphenazine
thiothixene
trifluoperazine

28:24 Anxiolytics, Sedatives, Hypnotics

28:24.08 Benzodiazepines
lorazepam

28:24.92 Miscellaneous
buspirone
donepazil
hydroxyzine
meclizine
memantine
promethazine

28:28 Antimanic Agents
lithium

28:32 Antimigraine Agents
sumatriptan*

28:92 **Miscellaneous Central Nervous System Agents**
atomoxetine
flumazenil
levodopa / carbidopa
memantine

36:00 **DIAGNOSTIC AGENTS**

36:56 **Myasthenia Gravis**
edrophonium

36:84 **Tuberculosis**
tuberculin PPD

40:00 **ELECTROLYTE, CALORIC & WATER BALANCE**

40:08 **Alkalinizing Agents**
citric acid

40:10 **Ammonia Detoxicants**
lactulose

40:12 **Replacement Perparations**
calcium acetate
calcium carbonate
dextrose
potassium chloride
sodium chloride

40:18.18 **Potassium Removing Agents**
polystyrene sulfonate

40:18.19 **Phosphate Removing Agents**
sevelamer

40:20 **Caloric Agents**
dextrose

40:28 **Diuretics**
bumetanide
furosemide
hydrochlorothiazide
metolazone

40:28.10 **Potassium Sparring Diuretics**
spironolactone
triamterene / HCTZ

40:36 **Irrigating Solutions**
ophthalmic irrigating solution (eye wash)
sodium chloride

40:40 **Uricosuric Agents**
probenecid

48:00 **EXPECTORANTS, ANTITUSSIVE & MUCOLYTIC AGENTS**

48:08 **Antitussives**
guaifenesin / dextromethorphan

48:16 **Expectorants**
guaifenesin / dextromethorphan

48:24 **Mucolytic Agents**
acetylcysteine

52:00 EYE, EAR, NOSE & THROAT (EENT) PREPARATIONS

52:04 Anti-Infectives

52:04.04 Antibiotics
ciprofloxacin ophth
doxycycline
erythromycin ophth
gentamicin ophth
neomycin / polymyxin / hydrocortisone otic
neomycin / polymyxin / gramicidin ophth
neomycin / polymyxin / dexamethasone ophth
neomycin / bacitracin / polymyxin ophth

52:04.06 Antivirals
trifluridine ophth

52:04.08 Sulfonamides
sulfacetamide ophth soln

52:04.12 Miscellaneous Anti-Infectives
acetic acid / aluminum acetate otic
acetic acid / hydrocortisone otic
carbamide peroxide
chlorhexidine

52:08 Anti-Inflammatory Agents
flunisolide*
neomycin / polymyxin / dexamethasone ophth
neomycin / polymyxin / hydrocortisone otic
prednisolone ophth

52:10 Carbonic Anhydrase Inhibitors
acetazolamide
dorzolamide

52:16 Local Anesthetics
antipyrine / benzocaine
Benzocaine/Menthol
lidocaine
proparicaine ophth

52:20 Miotics
pilocarpine

52:24 Mydriatics
cyclopentolate ophth
homatropine ophth
phenylephrine ophth
tropicamide ophth

52:28 Mouth Washes & Gargles
hydrogen peroxide*

52:32 Vasoconstrictors
naphazoline / pheniramine ophth
naphazoline ophth

52:36 Miscellaneous EENT Drugs
brimonidine ophth
carbamide peroxide
fluorescein strips
latanoprost ophth
petrolatum / mineral oil / lanolin ophth (lubricating oint)
polyvinyl alcohol / artificial tears
sodium chloride ophth
sodium chloride nasal
timolol ophth

56:00 GASTROINTESTINAL AGENTS

56:04 Antacids & Adsorbents
calcium carbonate
aluminum / magnesium hydroxide / simethicone
magnesium hydroxide

56:08 **Antidiarrheal Agents**
loperamide

56:10 **Antiflatulents**
simethicone

56:12 **Cathartics & Laxatives**
Bowel Evacuants
PEG-3350

Bulk Forming Laxatives
calcium polycarbophil

Saline Laxatives
magnesium citrate
magnesium hydroxide
sodium phosphates

Stimulant Laxatives
bisacodyl

Stool Softeners
docusate sodium

56:16 **Digestants**
pancrelipase

56:22 **Antiemetics**
meclizine
prochlorperazine
promethazine

56:28 **Gastric Acid Reducers**
H2 Antagonists
Ranitidine

Proton Pump Inhibitors
omeprazole

Protectants
sucralfate

56:32 **Prokinetics**
metoclopramide

56:36 **Anti-Inflammatory Agents**
mesalamine

56:40 **Miscellaneous GI Drugs**
bismuth subsalicylate

68:00 **HORMONES & SYNTHETIC SUBSTITUTES**

68:04 **Adrenals**
dexamethasone
methlyprednisolone
mometasone
prednisone

68:12 **Contraceptives**
Norethindrone / Ethinyl Estradiol
Norgestimate / Ethinyl Estradiol

68:16 **Estrogens**
estrogens, conjugated
estradiol valerate

68:20 Antidiabetic Agents

68:20.04 Biguanides
metformin

68:20.08 Insulins
insulin, glargine
insulin, human - NPH
insulin, human - regular
insulin, human - 70/30

68:20.20 Sulfonylureas
glyburide
glipizide

68:20.92 Miscellaneous Antidiabetic Agents
pioglitazone

68:22 Anti-Hypoglycemic Agents
glucagon

68:32 Progestins
medroxyprogesterone

68:36 Thyroid & Antithyroid Agents

68:36.04 Thyroid Agents
levothyroxine

68:36.08 Antithyroid Agents
methimazole
propylthiouracil

72:00 LOCAL ANESTHETICS
bupivacaine
lidocaine
lidocaine / epinephrine

80:00 SERUMS, TOXOIDS & VACCINES

80:08 Toxoids
tetanus & diphtheria

80:12 Vaccines
influenza virus vaccine
hepatitis A vaccine
hepatitis B vaccine
measles-mumps-rubella vaccine
meningococcal polysaccharide vaccine
pneumococcal vaccine, polyvalent
poliovirus vaccine, inactivated
varicella vaccine

84:00 SKIN & MUCOUS MEMBRANE AGENTS

84:04 Anti-Infectives

84:04.04 Antibiotics
bacitracin / polymyxin
mupirocin*

84:04.08 Antifungals
clotrimazole
miconazole
nystatin
nystatin / triamcinolone
tolnaftate

84:04.12 Scabicides & Pediculocides
permethrin

84:04.16 Miscellaneous Local Anti-Infectives
alcohol, ethyl*
alcohol, isopropyl*
calamine lotion
hydrogen peroxide
povidone iodine
selenium sulfide
silver sulfadiazine*

84:06 Anti-Inflammatory Agents
betamethasone dipropionate
fluocinolone
fluocinonide
hydrocortisone
nystatin / triamcinolone
triamcinolone
triamcinolone / orabase

84:08 Antipruritics & Local Anesthetics
benzocaine*
calamine
hydrocortisone
phenazopyridine

84:28 Keratolytic Agents
benzoyl peroxide
podofilox
salicyclic acid

84:32 Keratoplastic Agents
coal tar

84:36 Miscellaneous Agents
alcohol, ethyl
benzoin tincture*
petrolatum / lanolin (skin protectant)

84:80 Sunscreen Agents
sunscreen

86:00 SMOOTH MUSCLE RELAXANTS

86:08 Genitourinary Smooth Muscle Relaxants
oxybutynin

86:16 Respiratory Smooth Muscle Relaxants
theophylline

88:00 VITAMINS

88:08 Vitamin B Complex
folic acid
multivitamin
prenatal-vitamin
pyridoxine
thiamine

88:16 Vitamin D
calcium carbonate / vitamin D

88:28 Multivitamin Preparations
multivitamin
prenatal-vitamin

92:00 UNCLASSIFIED THERAPEUTIC AGENTS

adenosine
alendronate
allopurinol
bromocriptine
carbidopa / levodopa
chlorhexidine
clopidogrel
colchicine
leucovorin

96:00 PHARMACEUTICAL AIDS

sodium chloride inhalant

Heat Medications

Heat Medications

General population housing in most institutions is not air conditioned and the ambient temperature can get quite hot. This can cause problems with some patients who are on certain medications which CDCR refers to as "Heat medications". These medications include:

Anti-pyscotic's: Haloperidol, Olanzapine, Chlorpromazine, etc.
Anti-Parkinson: Trihexyphenidyl, Benztropine
Mood Stabilizers: Lithium (Not included Gabapentin, Divalproex, Carbamazepine)
Anti-depressants: Amitriptyline, Doxepin (Not included SSRI's)

From May 1-October 31 each year at each institution the "Heat Plan" is implemented. This consists of 3 Stages based on the ambient temperature.

Stage 1: **outside** temperature 90 degrees

Stage 2: **inside** temperature 90 degrees

Stage 3: **inside** temperature 95 degrees

Specific measures are taken at each step to ensure the safety of the inmate-patients. Patients on the medications listed are considered especially at risk for heat related complications and they may be required to stay indoors or be moved to alternate housing during a heat alert. The patients will also be given access to cool liquids, frequent showers and spray bottles for misting.

Conditions that predispose to heat complications include:

Advanced age	Fever
Cardiac problems	Dehydration
Strenuous exercise	High humidity
Obesity	Diuretics, thyroid hormone

Attached is a list of Heat Medication.

California Department of Corrections and Rehabilitation
Division of Correctional Health Care Services

HEAT PLAN
Critical Element

PRINTED NAME/TITLE: _____
INSTITUTION: _____

	HEAT PLAN	MET	NOT MET
1	Heat plan implemented every year at each institution from May 1- October 31.		
2	Identifies medications subject to execution of heat plan Anti-psychotics: Haloperidol, Olanzapine, Chlorpromazine, etc. Anti-Parkinson: Trihexyphenidyl, Benztropine ·Mood Stabilizers: Lithium Not included: Gabapentin, Divalproex, Carbamazepine ·Anti-depressants: Amitriptyline, Doxepin, Not Included: SSRIs: Paxil, Zoloft, Prozak		
3	Verbalizes sign and symptoms: Flushed / dry feeling Red, flushed, mottled skin Skin turning bluish Cramping of muscles Sleepiness Mental Confusion Loss of coordination· Convulsive behavior· Dizziness / fainting· Severe headaches / Giddiness· Nausea / vomiting;		
4	Works with custody: All heat risk patients must return to their housing unit unless they are in an area where the temperature is below 90 F. Patients working in a climate controlled environment less than 90 F are not required to return to their housing units.		
5	Affected patients will remain inside until the heat risk alert has been cancelled. Heat risk patients may be outside a maximum of 30 minutes per day for returning to housing units, receiving meds, meals, etc. This is travel time and is not to be used for other activities.		

	HEAT PLAN	MET	NOT MET
6	Describes ACTIVATION plan Plant Ops checks cooling / ventilation in each housing unit to ensure functioning • Stage 1: Outside temp @90°F. When the outside temperature reaches 90 F, heat risk patients are encouraged to: Drink cooled liquids Shower Use water in cell for cooling-body • Stage II: Inside temp @ 90° F. When the temperature inside the housing units reaches 90° F, heat risk patients must be given access to: Cooled liquids Frequent shower Spray bottles for misting • Stage III: Inside temp @ 95° F When the temperature inside the housing units reaches 95° F, heat risk patients must be given access to: Cooled liquids Frequent showers Spray bottles for misting During stage III: Medical staff visits all housing units and observes heat-risk patients every two hours.		
7	Describes DEACTIVATION Plan Stage I: Outside temp @90° F. After one hour of outside temperatures below 90° F, the watch commander deactivates a Stage I alert. Stage II: After one hour of housing unit temperatures below 90° F, the watch commander deactivates a Stage II alert. Stage III: Inside temp @ 95° F. After one hour of housing unit temperatures below 95° F, the watch commander deactivates a Stage III alert.		
	Documentation		
8	Any heat related illness on Interdisciplinary Progress Note		
9	Refers patient to RN or PCP for evaluation.		

Comments:

_____

_____

_____

Validated by: _____ Date: _____

Appendix A

HEAT ALERT MEDICATION LIST

Antipsychotics
Aripiprazole (Abilify)
Clozapine (Clozaril)
Olanzapine (Zyprexa)
Quetiapine (Seroquel)
Risperidone (Risperdal)
Ziprasidone (Geodon)
Haloperidol (Haldol)
Loxapine (Loxitane)
Chlorpromazine (Thorazine)
Fluphenazine (Prolixin)
Mesoridazine (Serentil)
Molindone (Moban)
Paliperidone (Invega)
Pimozide (Orap)
Perphenazine (Trilafon)
Prochlorperazine (Compazine)
Trifluoperazine (Stelazine)
Thioridazine (Mellaril)
Thiothixene (Navane)

Antiparkinson
Benztropine (Cogentin)
Biperiden (Akineton)
Trihexyphenidyl (Artane)

Antidepressants
Amitriptyline (Elavil)
Amoxapine (Asendin)
Clomipramine (Anafranil)
Desipramine (Norpramin)
Doxepin (Sinequan)
Imipramine (Tofranil)
Nortriptyline (Pamelor)
Phenelzine (Nardil)
Protriptyline (Vivactil)
Tranylcypromine (Parnate)
Trimipramine (Surmontil)

Stomach, Intestinal, Bladder
Belladonna Alkaloids (Donnatal)
Glycopyrrolate (Robinul)
Scopolamine (Transderm Scop)
Diphenoxylate/Atropine (Lomotil)

Mood Stabilizers & Anticonvulsants
Lithium (Lithane, Eskalith, Lithobid)
Topiramate (Topamax)
Zonisamide (Zonegran)

Miscellaneous Agents
Lanoxin (Digoxin)
Tagamet (Cimetidine)

Lab

Laboratory:

In general, each institution will have a small lab with a few personnel who are responsible for drawing blood, processing samples and, for the most part, shipping them out. A few simple tests such as a CBC or UA may be available at an average institution during standard working hours but each institution is different. For the most part you can assume that labs you order will be sent out and take at least 24 hours to return. (It will take longer for 'reference tests' like ANA, etc.)

How do I order labs?

In most institutions the provider completes a Physician's Order form requesting a specific diagnostic test. Nursing staff then take off the order and completes the necessary requisition forms and routes them per local policy. At some facilities the provider may actually fill out the requisition, you will need to check with your staff.
When ordering remember:

- There are no CDCR "Standard Panels" so for the most part order each test you want by name (i.e Na/K/Cr/BUN, not "Chem Panel", unless it is used routinely at your institution.)

- Write clearly and completely. Don't use abbreviations unless they are standard.

- Be very specific (i.e if you want fasting say that, not just "morning labs", these guys are up EARLY and eating.)

- Routine diagnostic services requests are performed within 14 days so if you need it sooner see below.

What if I need STAT labs?

While providers have the ability to write STAT lab orders and these tests can be drawn STAT, they will for the most part be 'sent out', often to a local hospital for processing.
So the question to ask if you feel you need STAT labs is:

Is my patient safe in the institution if I am requesting STAT labs?

For the most part, if you feel you need something like STAT cardiac enzymes, the patient is generally safer being sent out for the work-up.

Urgent orders are processed immediately and carried out within the next business day. After normal business hours, weekends, and on holidays, staff may be called in to perform necessary diagnostic tests.

How do I find out the results? What are my responsibilities?

Each institution will have a procedure for distributing lab results. Some will place them in a mailbox for you, others distribute at a morning meeting. You are responsible for reviewing them immediately and initialing/signing and dating each page to document that you are aware of the results.

If the labs are abnormal you must address the abnormal result by whatever is appropriate such as ordering the chart to review, writing an order for additional testing, medications, and/or follow-up appointment.

Many of our institutions use Quest Lab as their contractor and Quest has access to 'on-line' results. In general there will be a computer in the institutions lab where the Quest results can be obtained in 'real-time'. Many institutions are working on getting 'in clinic' computers for each provider so that the online lab results will be available at each visit, you will need to check with your institution.

How are patients informed of the results?

It is mandatory that the patient receive information on their results. This is done by a Notification of Diagnostic Test Results (form 7393) Here is the official language:

- Upon receipt of the diagnostic test results, the PCP or designee shall complete a Notification of Diagnostic Test Results form within two business days of the date of receipt of the lab result, and include the plan for follow-up care.

- The PCP must review, initial and date all diagnostic test reports.

- A copy of the Notification of Diagnostic Test Results Form shall be sent to the inmate-patient and a copy filed in the UHR.

- The PCP must document clinically significant diagnostic tests results, treatments and orders on an Interdisciplinary Progress Note form, and CDC Form 7221. All lab test results must be reviewed within 14 calendar days.

As in most busy medical practices, you will need to devise a way to keep track of important pending labs and any necessary follow-up testing. It will take a while for you to become familiar with your new patients, many of whom have multiple chronic diseases. Many people use the Primary Care Flow sheet and Problem List as a way to track pending results or needed follow-up.

Although CDCR is making major improvements in many area's of patient care it is still possible for things to 'fall through the cracks" unless each provider 'double checks' each patient each visit.

STATE OF CALIFORNIA
CDC 7393 (11/02)

DEPARTMENT OF CORRECTIONS

NOTIFICATION OF DIAGNOSTIC TEST RESULTS

NAME	CDC NUMBER
INSTITUTION	HOUSING
TYPE OF TEST	DATE OF TEST

YOUR TEST RESULTS HAVE BEEN EVALUATED BY A PHYSICIAN AND THE FOLLOWING HAS BEEN DETERMINED:

- ☐ Your test results are essentially within normal limits or are unchanged and no physician follow up is required.
- ☐ You are being scheduled for a follow up medical appointment. You will be receiving a ducat indicating your appointment time.
- ☐ A repeat test will be ordered. You will be ducated for this test.
- ☐ A chronic care appointment has been scheduled for you. You will be receiving a ducat indicating your appointment time.

NAME / TITLE

PHYSICIAN SIGNATURE

DATE

ORIGINAL - File in UHR CANARY - Scheduler PINK - Patient

X-Ray / Imaging

Radiological Studies

Routine, plain x-rays may be done at most institutions during working hours. Things like a chest x-ray or bone/joint films may be ordered.

- Routine

  Routine x-rays (plain film) must be completed within 14 calendar days. The radiological technician schedules the appointment and ducats the inmate-patient to the department. If they cannot be scheduled within the 14 day time period, the HCM/CMO is notified.

- STAT

  STAT x-rays can be taken immediately during the hours that the radiology technician is present. The radiological technician generally sends the inmate-patient and the films back to the ordering provider for him or her to 'wet read'. In some institutions it is the provider who is assigned to the TTA who reviews the x-ray and makes disposition of the patient. THE PROCESS VARIES GREATLY. You will need to check with your institution.

Whoever provides the 'wet-read' must document their findings in the chart. That provider then returns the films to the radiology department for prompt send out for an official reading by a radiologist.

How do I get x-ray results?

The same as with lab results, you will get these distributed to you per your institutions procedure. You must document that you saw the result by initialing and dating each result before it goes to the chart.

How is the patient notified of results?

The same as with lab results, by the use of the Notification of Diagnostic Test Results (form 7393)

How do I order other imaging studies such as CT Scans, MRI, and Ultrasound?

In general these studies require Utilization Management (UM) approval, and are requested using the same form and process as a specialty services request RFS (CDC Form 7243). A few institutions such as CMF will have requisitions that you will need to fill out, providing detailed clinical information.

Other diagnostic testing

Tests such as EEG, EMG, NCV, ETT, Holter, ECHO, are all ordered as above using the RFS system.

NAME	CDC NUMBER	STATE OF CALIFORNIA–DEPARTMENT OF CORRECTIONS REQUEST FOR DIAGNOSTIC IMAGING SERVICES				
		HOUSING	SEX	HEIGHT	WEIGHT	BIRTHDATE
		REQUESTED EXAM(S) ARE: √			RADIOLOGY USE ONLY	
		EMERGENT (STAT)	URGENT DAYS/HOURS:	ROUTINE 30 DAYS	R T INT # FILMS # EXPOSURES	
ADDRESSOGRAPH						

DETAILED PATIENT HISTORY PERTINENT TO EXAMINATION(S) ORDERED

RADIOGRAPHIC EXAMINATION(S) REQUESTED: Mark all appropriate boxes to the left of the exam

CHEST CAVITY	CEPHALIC	EXTREMITIES			SPINES	KUB/SPECIALS
PA CHEST	FACIAL BONES	DIGIT(s)	RT SHOULDER	RT TIB/FIB	C-SPINE	KUB
PA/LAT CHEST	MANDIBLE	RT HAND	LT SHOULDER	LT TIB.FIB	LAT C-S	ACUTE ABDOMEN
PORT CHEST	MASTOIDS	LT HAND	RT SCAPULA	RT KNEE	SOFT NECK	UPPER GI
RT ANT RIB	NASAL BONE	RT WRIST	LT SCAPULA	LT KNEE	T-SPINE	ESOPHAGRAM
LT ANT RIB	ORBITS	LT WRIST	TOE(S)	R PATELLA	L-SPINE	SMALL BOWEL
RT POST RIB	SELLA TURCIA	R FOREARM	RT FOOT	L PATELLA	FLX/EXT	BARIUM ENEMA
LT POS RIB	SINUS SERIES	L FOREARM	LT FOOT	RT FEMUR	PELVIS	BE AIR CONT
STERNUM	TMJ	RT ELBOW	RT HEEL	LT FEMUR	RT HIP	CHOLECYSTOGRAM
AC JOINTS	SKULL	LT ELBOW	LT HEEL		LT HIP	INTRAVENOUS PYLOGRAM
RT CLAVICLE	MRI SCREENING	R HUMERUS	RT ANKLE		SI JOINTS	
LT CLAVICLE		L HUMERUS	LT ANKLE		SACRUM	RETROCYSTOGRAM
					COCCYX	CONTRABAND MOUTH TO ANNUS

OTHER:

NAME OF ORDERING PHYSICIAN	EXTENSION/PAGER	DATE ORDERED
		DATE COMPLETED

SCHEDULING OFFICE: **Patient to return to Dr.** _____ **for test results in** _____ **days** _____ **weeks**

Distribution: **White** (original): Radiology **Pink**: Scheduling Office **Golden Rod**: Unit Health Record

Peer Review / Performance Evaluation

- Conduct Expectations
- Clinical Performance Appraisal
- California State Probationary Employee
- Job Description / Duty Statement
  - Physician and Surgeon
  - Nurse Practitioner
  - Physician Assistant

PEER REVIEW/PERFORMANCE EVALUATION

I. Peer Review/Performance Evaluation

A. Your credentials are reviewed upon hiring
B. After 10 days of clinical orientation at your facility a Clinical Preceptor will review your work, called surprisingly enough, a "10 day review". If this is satisfactory you will be allowed to practice independently.
C. After 60 days a review of 20 of your randomly selected charts will be done. This "60 Day Review" will be done by Clinical Support Unit (CSU) Consultant.
D. As a Physician and Surgeon you have a 6 month probation before becoming Civil Service. Your CMO should provide you with a 2, 4 and 6 month Report of Performance for Probationary Employees.

Primary Care Provider Conduct Expectations (Orientation Manual March 2006)

This document describes the expectations that practitioners have of each other as members of the Division of Correctional Health Care Services (DCHCS) Medical Staff. The expectations described below reflect current Medical Staff Bylaws, Policies and Procedures and organizational policies. This document is designed to bring together the most important issues found in those documents and key concepts reflecting our Medical Staff's culture and vision.

Medical Staff leaders will work to improve individual and aggregate Medical Staff performance through non-punitive approaches. Through positive and constructive feedback, each practitioner will be given the opportunity to grow and develop in his or her capability to provide quality inmate-patient health care and valuable contributions to improving healthcare services.

All Medical Staff are expected to work collaboratively toward a common goal of providing accessible, quality health care, and each provider will be required to meet the standards set forth by the Department. When standards and expectations are not met, the Department will, where indicated, address specific provider deficiencies utilizing the processes established by Departmental regulations.

Technical Quality of Care

- Achieve inmate-patient outcomes that consistently meet or exceed generally accepted Medical Staff standards as defined by comparative data, medical literature and results of peer review activities.

- Provide appropriate inmate-patient health care, including the use of evidence-based

guidelines/clinical policies developed by DCHCS.

- Promptly and effectively manage an inmate-patient's acute and chronic pain according to accepted standards in the medical literature and DCHCS Policies and Procedures.

Quality of Service

- Thoroughly evaluate each inmate-patient brought to the medical area before leaving at the conclusion of the scheduled session/work day.
- Order inmate-patient follow-up appointments according to policy or medically appropriate schedules.
- In order to achieve desired outcomes, function as an advocate for your inmate-patients so that they receive ordered and necessary health care services.
- Respond to pages, consultations, and facility staff requests in a timely manner.
- Communicate effectively with other practitioners, health care staff, custody staff, and inmate-patients and, when appropriate, their families.

Clinical Safety/Inmate-Patient Rights

- Participate in the DCHCS efforts and policies to reduce clinical errors through safe inmate-patient health care practices, including following DCHCS Policies and Procedures and guidelines for prevention of nosocomial infections.
- Document inmate-patients' physical limitations or disabilities, necessary accommodative devices, duty/activity restrictions, and housing needs and follow-up as appropriate to ensure institution compliance.
- Document every inmate-patient encounter in the Unit Health Record in a timely and legible manner with all relevant information required by DCHCS Policies and Procedures.
- Ensure that consents for treatment and/or refusals of treatment are appropriately documented as well as the tests or treatments being provided or refused and the risks/benefits of the consent or refusal.
- Respect inmate-patient privacy by not discussing inmate-patient health care information and issues in public settings.

- Discuss end-of-life issues with an inmate-patient when it is appropriate to their condition, including advance directives and inmate-patient, family, and DCHCS support, and honor the inmate-patient's desires unless they are in conflict with Law.

Resource Utilization

- Strive to provide quality inmate-patient health care that is cost effective by cooperating with efforts to appropriately use valuable health care resources.
- Cooperate with guidelines for appropriate admission, level of care transfer, inmate-patient
  instructions, and timely discharge to outpatient management and institutional transfers when medically appropriate.

Productivity

- Report to work on time and complete assigned tasks.
- Participate in assigned on call coverage as required by the DCHCS.

Peer and Co-Worker Relationships

- Act in a professional, respectful manner at all times to enhance a spirit of cooperation, mutual respect and trust among members of the inmate-patient health care team, including custody staff.
- Refrain from inappropriate behavior including, but not limited to, impulsive, disruptive, sexually harassing or disrespectful behavior, or any documentation in the medical record that does not directly relate to the inmate-patient's clinical status or plan of care, or that is derogatory or inflammatory.
- Address disagreements in a constructive, respectful manner away from inmate-patients or other non-involved staff.

Citizenship

- Review your individual performance and utilize this information for self-improvement to continuously improve inmate-patient health care.
- Respond in the spirit of continuous improvement when contacted regarding concerns about your inmate-patient care.
- Make positive contributions to the Medical Staff by actively participating in Medical Staff functions and serving on Committees when requested.

In the spirit of early assistance, help to identify issues affecting the physical and mental health of fellow Medical Staff members and cooperate with programs designed to provide assistance.

Job Description/Duty Statements

There are specific job descriptions for each provider classification on the State Personnel web site. These are fairly nonspecific and somewhat outdated. Each institution should have a duty statement for the Physician and Surgeon classification. (Examples attached)

Nurse Practitioners and Physician Assistants work under detailed Policies and Procedures which are attached.

Clinical Performance Appraisal

Division of Correctional Health Care Services

Clinical Performance Appraisal

(Confidential Peer Review Document)

Last Name	**First Name**	**Date of Review**
Classification (Choose One)	**Status** (Choose One)	**Institution**
Reviewer:		**Region** (Choose One)

Reason for Review	(Choose One)
Prior Reviews	None
Current Privileges	Unrestricted
Summary	***Total Cases Reviewed*** 0 ***Cases with No Departure*** 0 0% ***Cases with Simple Departure(s)*** 0 0% ***Cases with Extreme Departure(s)*** 0 0% ***Legibility*** (Choose One) ***Signature Readable*** (Choose One) ***Departures – History*** 0 0% ***Departures – Physical*** 0 0% ***Departures – Assessment*** 0 0% ***Departures - Plan*** 0 0% ***Departures - Total*** 0 0% **Summary of Findings:** lorem ipsum. **Documentation was legible.** Lorem ipsum
Recommendation	**(Choose One)** ☐ **Repeat Review in:**

INTERVIEWS: *(Including supervisor and interviews with the provider*

Lorem ipsum

METHODOLOGY: *(Including how cases were selected for review)*

Number of charts received: 00 (00 death cases, 0 TTA cases, 0 Sick Call cases, 0 Chronic Care cases, 0 CTC/OHU/SNF/GACH cases)

Criteria for selection:

OTHER INFORMATION:

CASE DETAILS, EXTREME DEPARTURES FROM THE STANDARD OF CARE: *(Include enough clinical context to show the complexity of the case and the significance of departures from the standard of care. State what a reasonable provider should do. State the possible adverse outcome and indicate the likelihood of its occurrence.)*

3	**A12321**, **SMITH**	**70**	**M**	**3 VISITS 9/24/07-10/15/07**	**TTA**	**EXTREME DEPARTURE**

Clinical Information Pertinent to this Encounter: Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Sed euismod nisi sit amet nulla. Fusce fringilla, dui ac aliquet rutrum, erat ante mollis nulla, at ornare magna nibh a enim. Nunc sit amet ante. Ut ac velit porttitor lorem tempor vehicula. Fusce ullamcorper gravida est. Sed eu urna. Pellentesque sed velit ac odio ornare gravida. Vivamus ut dui sed ipsum mattis eleifend. Phasellus interdum bibendum turpis.

Departures from Standard: Not including a cras molestie arcu non erat rutrum faucibus. Curabitur pretium arcu eget mi. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos hymenaeos. Aliquam tempus, tellus et elementum viverra, turpis tortor facilisis elit, at sagittis dui risus a magna, was an **extreme departure** from community standard of care.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

CHART SUMMARY:

CDC #, Date	*Clinical Context*	**Departure in**							
		No Departure	***History***	***Exam***	***Assessment***	***Plan/Orders***	***Simple Departure***	***Extreme Departure***	***Departures***
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
16.									

17.

Total Number Departures								
Percent Departures								

California State

Report of Performance for Probationary Employee

STATE OF CALIFORNIA – PERSONNEL ADMINISTRATION

REPORT OF PERFORMANCE PROBATIONARY EMPLOYEE

436 (REV 8/2002)

RATER — Before marking this report, read instructions on the back.

☐ FIRST
☐ SECOND
☐ THIRD

(Last First Initial)	SOCIAL SECURITY NUMBER	REPORT DATE
CIVIL SERVICE TITLE	POSITION NUMBER	DATE PROBATION ENDS
DEPARTMENT NAME	DIVISION / UNIT	EMPLOYEE'S HEADQUARTERS

YOUR WORK PERFORMANCE WILL DETERMINE WHETHER YOU OBTAIN PERMANENT CIVIL SERVICE STATUS

QUALIFICATION FACTORS	RATINGS ARE INDICATED BY "X" MARKS			
	UNACCEPTABLE	IMPROVEMENT NEEDED	STANDARD	OUTSTANDING
1. **SKILL**–Expertise in doing specific tasks; accuracy; precision, completeness, neatness, quantity.				
2. **KNOWLEDGE**–Extent of knowledge of methods, materials, tools, equipment, technical expressions and other fundamental subject matter.				
3. **WORK HABITS**–Organization of work; care of equipment; punctuality and dependability; industry; follows good practices of vehicle and personal safety.				
4. **RELATIONSHIPS WITH PEOPLE**–Ability to get along with others; effectiveness in dealing with the public, other employees, patients or inmates.				
5. **LEARNING ABILITY**–Speed and thoroughness in learning procedures, laws, rules and other details; alertness; perseverance.				
6. **ATTITUDE**–Enthusiasm for the work; willingness to conform to job requirements and to accept suggestions for work improvement; adaptability.				
7. **COMMUNICATION**–Exhibits aptitude toward good writing and verbal skills, can give concise information in working situations.				
8. **ABILITY AS SUPERVISOR**–Proficiency in training employees and planning, organizing, assigning and expediting work; leadership; understanding of and effectiveness in implementing departmental and SPB personnel management policies including equal employment opportunity and affirmative action.				
ADMINISTRATIVE ABILITY–Promptness of action; soundness of decision, application of good management practices; understanding and effective implementation of departmental and SPB personnel management policies related to equal employment opportunity and affirmative action.				
10. **FACTORS NOT LISTED ABOVE** *(Use additional sheets if more space is needed.)*				
OVERALL RATING–The overall rating must be consistent with the factor ratings and comments, but there is no prescribed formula for computing the overall rating.				

COMMENTS TO EMPLOYEE–*(Supervisor should include factual examples of exceptional or poor work and give suggestions as to how performance can be improved. Factor and overall ratings of unacceptable and overall ratings of outstanding must be substantiated. Use additional sheets if more space is needed).*

Rater discussed report with employee ☐ YES ☐ NO

I RECOMMEND YOU BE GRANTED PERMANENT CIVIL SERVICE STATUS (To be checked only on Final Report. If the probationer is rejected, notification must be given as prescribed by Government Code Section 19173.) ☐ YES ☐ NO

RATER'S SIGNATURE	TITLE	DATE SIGNED

In signing this report I do not necessarily agree with the conclusions of the rater.

E'S SIGNATURE	DATE SIGNED	☐ I would like to discuss this report with the reviewing officer.

cur in the ratings given by the rater. I have made no change in this report.

ING OFFICER'S SIGNATURE	DATE SIGNED	AS REQUESTED, REVIEWING OFFICER DISCUSSED REPORT WITH EMPLOYEE ON DATE

DISTRIBUTION Copies: 1 — Departmental Files 2 — Employee 3 — Supervisor 4 — Miscellaneous

RATING THE QUALIFICATIONS OF A PROBATIONARY EMPLOYEE

(INFORMATION FOR RATERS, REVIEWERS, AND APPOINTING AUTHORITIES)

PURPOSE OF THE RATING

This is a progress report to the employee. In addition to letting the employee know how well he/she is doing his/her job, and helping the employee orient his/her efforts, it should be helpful to supervisors in:

(a) Making careful analysis of the employee's work.

(b) Making work assignments that will be to the best advantage of the employee and the organization.

(c) Determining the additional training needs of the employee.

(d) Determining whether the employee should be granted permanent status.

DOING THE RATING

Soon after he/she comes to work, the probationer should be given a sample copy of this report and told of the standards of performance upon which his/her qualifications will be rated.

A Report of Performance may be prepared at any time during the probationary period. A report must be prepared for each probationary employee within ten days after the end of each one-third portion of his/her probationary period. If the employee is rejected during probation a final report may be prepared at that time.

Each department designates the Raters. Usually the immediate supervisor does the rating. Two or more supervisors may prepare the report together. All Raters sign ort. The Rater gives the employee his/her copy, and discusses it with the ee.

y the qualification factors necessary for success in doing the duties of the n are rated. At least five factors must be rated. The examples listed after each factor are for illustration and explanation. They do not include every element that may properly be considered in rating the factor.

A person appointed with civil service status is presumed to have an initial overall performance rating of Standard. Thereafter, changes in his/her level of performance are shown by the Report of Performance. Probationary employees are rated on those factors that are of greatest significance in predicting success in the work, and on progress toward fully competent performance.

The ratings are defined as follows:

OUTSTANDING–Performance on the job indicates qualifications are definitely superior–performance by the end of the probationary period can be expected to be well above the standard required of a competent permanent employee in that job. (If the overall rating is Outstanding, the Rater must give a written statement of factual substantiation for the rating. General statements such as "Outstanding in skill and knowledge" are not acceptable.)

STANDARD–Performance on the job indicates qualifications are thoroughly satisfactory–performance by the end of the probationary period can be expected to be up to, or somewhat above, the standard required of a competent permanent employee in that job.

IMPROVEMENT NEEDED–Performance on the job indicates qualifications are somewhat inadequate–to reach the standard required of a competent permanent employee by the end of the probationary period, greater effort or training is needed.

UNACCEPTABLE–Performance on the job indicates qualifications are very inadequate–special training, reassignment, or rejection may be advisable. (Any factor or overall rating of Unacceptable must be substantiated by the Rater's written statement of specific reasons for each such rating.)

COMMENTS–Minimum requirements as to the use of comments to support Outstanding or Unacceptable ratings are explained above. Agencies may establish additional requirements. Comments should be made on any aspect of the employee's performance which has a significant influence on his/her effectiveness. Suggestions which may help the employee improve his/her performance should be made. They should be specific, and not merely refer to previous discussion or comments on previous reports.

EMPLOYEE DISCUSSION–Constructive discussion with an employee regarding his/her work performance and progress is an essential element of good supervision. The Report of Performance interview provides an excellent opportunity to review with the employee problems relating to his/her work, answer his/her questions, explain departmental or unit objectives or plans, and to develop better supervisor-employer understanding.

THE REVIEWING OFFICER

The responsibilities of the Reviewing Officer include:

1. Keeping uniformity in the application of standards by the Raters under his/her direction.
2. Securing corrective action when bias or a misinterpretation of rating standards is evidenced in ratings.
3. Making sure reports are thoroughly and promptly prepared.
4. Discussing the report with the Rater or employee when requested, or otherwise appropriate.
5. Checking the statements made in support of Unacceptable or Outstanding to see that the reasons are specific, substantial and accurate.

The Reviewing Officer may discuss a report with the Rater and employee, but cannot change the report. If the Reviewing Officer recommends changes with which the Rater agrees, the Rater either makes the changes or prepares a new report. The changes are not valid unless the employee is notified and the changes are re-recorded on the employee's copy of the report.

If the Rater and the Reviewing Officer do not reach agreement, the matter is forwarded to the head of the department for decision. The department head may designate a different Rater and/or Reviewing Officer. The official report as finally effective must be signed by at least two persons who have been designated officially as the "Rater" and "Reviewing Officer," and who agree on all statements and ratings made in the report.

The Reviewing Officer signs the reports in which he/she concurs. All signed reports are transmitted as directed by the department. General reviews are made by administrative officials to see whether results in different units of the agency are logical and consistent.

FILING OF REPORTS

Each agency files reports within the agency in the manner prescribed by the appointing authority of that agency. A report should be retained for three years if there is indication of punitive action.

INFORMATION ON PROBATIONARY REPORTS OF PERFORMANCE

The Report of Performance system is based on the principle that an employee should be kept informed of his/her supervisor's evaluation of his/her work. When a person is appointed as a probationary employee he/she is considered to be capable of Standard performance, and is presumed to have an initial overall performance rating of Standard. Thereafter, changes in his/her level of performance are shown by the Report of Performance. A probationary period of not less than six months or more than one year is required before permanent civil service status is attained; and reports must be prepared at the end of each one-third portion of the period. Additional reports may be prepared at any time during the probationary period.

The purpose of the Report of Performance is to help the supervisor and employee measure how well the employee is adapting to his/her job, and to provide a tool for guidance in training assignments, and granting of permanent civil service status.

The qualifications of each probationary employee, as demonstrated by his/her work performance, are rated on not less than five of the factors listed. Factors that do not apply are not rated. For example, Administrative Ability is not rated if the position does not have regular administrative responsibility. Any important qualification factors not listed in items 1 through 9 are described by the Rater and rated under item 10.

To indicate the rating on any factor, an "X" mark is placed in the appropriate rating column. (The location of the "X" in the rating column may be varied to give the employee a more precise indication as to his/her qualifications. When this is done, the farther the "X" is placed to the right the stronger the rating.)

ome significant aspect of the work is above or below the level indicated by factor ratings, this may be pointed out by a statement in Comments to ployee. Where feasible, comments will also include suggestions as to how rmance can be improved and suggestions regarding desirable training.

6. When the necessary skills or knowledge to do thoroughly satisfactory work have to be acquired on the job, a rating of Improvement Needed on factors 1 or 2 on the First and Second report does not definitely indicate progress is not satisfactory unless a statement as to unsatisfactory progress is made in Comments to Employee. On the Final Report, any rating of Improvement Needed indicates progress has not been satisfactory.

7. Any rating of Unacceptable or an overall rating of Improvement Needed indicates progress has been unsatisfactory.

8. The Rater will discuss the report with the employee and give the employee a copy. In signing the report, the employee merely acknowledges that he/she has seen it. His/her signature does not indicate agreement. If he/she wishes to add a written statement concerning any part of the report, he/she uses the Comments space. His/her comments are not considered a formal appeal from the report.

9. After the report is prepared, it is considered by the Reviewing Officer. If the Rater and Reviewing Officer do not reach agreement on the report, it is referred to the appointing authority or his/her representative. If any changes are made, the report is not valid unless they are reported to the employee and recorded on his/her copy.

10. It is the duty of the appointing authority to reject any probationary employee who fails to demonstrate fitness for the position. In this event the appointing authority must give the employee written notice as prescribed in Government Code Section 19173. A Final Report of Performance may be prepared at that time.

DEFINITIONS OF RATINGS

UTSTANDING– Performance on the job indicates qualifications are definitely superior—performance by the end of the probationary period can be expected to be well above the standard required of a competent permanent employee in that job. (If the overall rating is Outstanding, the Rater must give a written statement of factual substantiation for the rating. General statements such as "Outstanding in skill and knowledge" are not acceptable.)

TANDARD– Performance on the job indicates qualifications are thoroughly satisfactory—performance by the end of the probationary period can be expected to be up to, or somewhat above, the standard required of a competent permanent employee in that job.

IMPROVEMENT NEEDED– Performance on the job indicates qualifications are somewhat inadequate—to reach the standard required of a competent permanent employee by the end of the probationary period, greater effort or training is needed.

UNACCEPTABLE– Performance on the job indicates qualifications are very inadequate—special training, reassignment, or rejection may be advisable. (Any factor or overall rating of Unacceptable must be substantiated by the Rater's written statement of specific reasons for each such rating.)

THESE DEFINITIONS MUST BE USED IN MARKING THE PERFORMANCE FACTORS AND IN ARRIVING AT THE OVERALL RATING.

APPEAL PROCEDURE

loyee believes his/her rating is improper, he/she should discuss it with the still not satisfied, he/she should sign the report and place an "X" in the space y his/her signature to indicate he/she wishes to discuss the report with the Officer. An employee who wishes consideration in addition to the review the Reviewing Officer and Rater should follow the grievance procedure of his/her ency.

An appeal to the Personnel Board for a formal hearing on a Report of Performance can be made only on the basis that it has been used to abuse, harass, or discriminate against the employee and only after the departmental grievance procedure has been exhausted. Such appeal must be filed with the Personnel Board in writing within thirty days after the employee receives the departmental decision.

STATE OF CALIFORNIA — DEPARTMENT OF PERSONNEL ADMINISTRATION

PERFORMANCE APPRAISAL SUMMARY

OF PAST JOB PERFORMANCE OF PERMANENT EMPLOYEES

7 (REV. 7-94c) (REVERSE)

PERFORMANCE FACTORS	I	M	E*	COMMENTS*
1. **QUALITY OF WORK:** Consider the extent to which completed work is accurate, neat, well-organized, thorough, and effective.				
2. **QUANTITY OF WORK:** Consider the extent to which the amount of work produced compares to quality standards for the job.				
3. **WORK HABITS:** Consider the employee's effectiveness in organizing and using work tools and time, in caring for equipment and materials, in following good practices of vehicle and personal safety, etc.				
4. **RELATIONSHIPS WITH PEOPLE:** Consider the extent to which the employee recognizes the needs and desires of other people, treats others with respect and courtesy, and inspires their respect and confidence, etc.				
5. **TAKING ACTION INDEPENDENTLY:** Consider the extent to which the employee shows initiative in making work improvements, identifying and correcting errors, initiating work activities, etc.				
IEETING WORK COMMITMENTS: Consider the extent to which the employee completes work assignments, meets deadlines, follows established policies and procedures, etc.				
7. **ANALYZING SITUATIONS AND MATERIALS:** Consider the extent to which the employee applies consistently good judgment in analyzing work situations and materials, and in drawing sound conclusions.				
8. **SUPERVISING THE WORK OF OTHERS:** Consider the employee's effectiveness in planning and controlling work activities, motivating and developing subordinates, improving work methods and results, encouraging and supporting employee suggestions for work improvement, applying policies, selecting and developing subordinates in accordance with State Personnel Board and departmental affirmative action policies.				
9. **PERSONNEL MANAGEMENT PRACTICES:** Consider the extent to which the employee understands and applies good personnel management practices including affirmative action and upward mobility. Does the employee contribute effectively to the implementation of State Personnel Board and departmental equal employment opportunity policies and to the attainment of affirmative action goals?				

GENERAL COMMENTS OR COMMENTS ON OTHER FACTORS

*The supervisor may make "comments" only, or may use rating categories only, or may use either or both methods of appraisal on any performance factor, as he or she prefers. The rating categories are:

I - Improvement needed for performance to meet expected standards
M - Performance fully meets expected standards
E - Performance consistently exceeds expected standards

STATE OF CALIFORNIA — DEPARTMENT OF PERSONNEL ADMINISTRATION

INDIVIDUAL DEVELOPMENT PLAN

FOR FUTURE JOB PERFORMANCE OF PERMANENT EMPLOYEES

7 (REV. 7-94c)

EE NAME *(Last, First, Middle Initial)*	DATE OF THIS PERFORMANCE DISCUSSION	
CIVIL SERVICE TITLE	POSITION NUMBER	LAST PERFORMANCE DISCUSSION DATE
STATE DEPARTMENT NAME	DEPARTMENT SUBDIVISION	EMPLOYEE'S HEADQUARTERS

PERFORMANCE OBJECTIVES — Goals for further improvements in job performance during the next year in order to meet or exceed standards for the employee's present job or to develop employee skills.

PLANS FOR ACHIEVING OBJECTIVES — Specific methods by which the employee can work toward accomplishing his or her performance objectives (in-service training courses, college courses, rotation, special work assignments for training purposes, etc.).

I HAVE PARTICIPATED IN A DISCUSSION OF OVER-ALL JOB PERFORMANCE

EMPLOYEE'S SIGNATURE	DATE SIGNED	SUPERVISOR'S SIGNATURE	DATE SIGNED

(Over)

Physician and Surgeon

SPEC: PHYSICIAN AND SURGEON (INTERMITTENT)
CALIFORNIA STATE PERSONNEL BOARD

SPECIFICATION

Schematic Code: SB50

Class Code: 7565

Established: 9/27/46

Revised: 10/7/98

Title Changed: --

PHYSICIAN AND SURGEON (INTERMITTENT)

DEFINITION

Under general direction, in an intermittent capacity, to perform responsible medical and surgical work; and to do other related work.

TYPICAL TASKS

In an intermittent capacity, examines and diagnoses patients and prescribes and administers medical treatments; advises on problems relating to physical disabilities and makes recommendations concerning possible corrective measures; reviews medical reports and indicates the need for further special examinations; reviews plans for physical rehabilitation and indicates if they are feasible and adequate; examines and treats patients brought into the office and answers emergency calls; performs or assists in performing surgical operations; supervises the pre- and postoperative care of surgical cases; orders laboratory examinations and analyses, x-rays, and special diets; writes prescriptions; makes rounds and reviews reports, records, and general progress of patients; supervises the work of medical and ancillary personnel; makes health and sanitary inspections and makes recommendations and reports; keeps or supervises the keeping of records and case histories; and prepares reports and related correspondence.

MINIMUM QUALIFICATIONS

Possession of the legal requirements for the practice of medicine in California as determined by the California Board of Medical Quality Assurance or the California Board of Osteopathic Examiners. (Applicants who are in the process of securing approval of their qualifications by the Board of Medical Quality Assurance or the Board of Osteopathic Examiners will be admitted to the examination, but the Board to which application is made must determine that all legal requirements have been met before candidates will be eligible for appointment.)

and

One year of experience in the practice of medicine exclusive of internship.

****New Requirement is Board Certification in Family Practice or Internal Medicine.**

KNOWLEDGE AND ABILITIES

Knowledge of and skill in: Applying the methods and principles of medicine and surgery; hospital standards; organization and procedure.

Familiarity with: Principles of mental hygiene; social work; physical therapy; rehabilitation therapies; principles of supervision.

Ability to: Direct the work of medical and ancillary personnel; interpret laboratory analyses and x-rays; prepare and supervise the preparation of case histories and hospital records; analyze situations accurately and adopt an effective course of action.

SPECIAL PERSONAL CHARACTERISTICS

Tact, patience and emotional stability.

California Institution for Women
DUTY STATEMENT

EMPLOYEE NAME:

POSITION NUMBER:

DEPARTMENT: HEALTH CARE SERVICES

CIVIL SERVICE TITLE/CLASSIFICATION: Physician and Surgeon, Correctional Facility

SUPERVISED BY: Health Care Manager / Chief Medical Officer

POSITION TITLE: Physician and Surgeon, Correctional Facility

FORMULATION DATE:

SUMMARY STATEMENT: (General Description of Duties)
In addition to the typical tasks as described in the California State Personnel Board specifications for this classification, a Physician and Surgeon under the supervision of the Health Care Manager/Chief Medical Officer examines patients, diagnoses, prescribes and administers medical treatments; advises on problems relating to physical disabilities and makes recommendations concerning possible corrective measures; reviews medical reports and indicates the need for further special examinations; reviews plans for physical rehabilitation and indicates if they are feasible and adequate; examines and treats patients brought into the office and answers emergency calls; performs or assists in performing minor surgical operations; orders laboratory examinations and analysis, x-rays, diagnostic studies, special diets, writes prescriptions; prepares reports and related correspondence.

50% Emergent/Urgent/Outpatient evaluation, diagnosis and treatment of patients throughout the watch and when assigned to Physician on Call.

30% Physical examinations of patients for institution assignments, modified/restricted duties and camp eligibility.

15% Inpatient Medical Care, inpatient evaluation, diagnosis and treatment of patients placed in the OpHU/Infirmary/CTC and consults with community health care providers.

5% Continuing medical education in the various specialties and general medicine to compliment the current practices and procedures to assure quality health care.

EMPLOYEE SIGNATURE: _____ **DATE:** ___/___/___

SUPERVISORS SIGNATURE: _____ **DATE:** ___/___/___

Position Number: 028-213-9263-xxx
Employee: Vacant

STATE OF CALIFORNIA
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
DUTY STATEMENT

CLASSIFICATION: PHYSICIAN AND SURGEON, CORRECTIONAL FACILITY
DEPARTMENT: MEDICAL

Under the direct supervision of the Chief Physician and Surgeon, the Physician and Surgeon, C.F. performs assigned medical duties and provides care for inmate/patients. Performs all phases of the medical services, and makes professional decisions regarding surgery and general medical care.

DUTIES:

40% Examines, diagnosis, prescribes, and administers treatment to inmates; performs minor surgical operations; refers and supervises pre-operative and post-operative cases. Diagnoses cases and prescribes medical and surgical treatment. Attends daily sick call and provides medical care to inmates in the medical clinic setting. Orders diagnostic examinations; and analyzes and interprets results.

15% Plans, organizes, coordinates and prepares medical operational instructions and pertinent operational procedures. Assists in the recruitment and hiring of medical staff. Assists in the negotiation of contracts with consultants, reviews bills and laboratory procedures in order to monitor the medical budget. Maintains ongoing infection control and hazardous materials programs. Responds to inquiries from inmates, families of inmates, or attorneys. Determines the equipment needs of the physicians and surgeons in the Medical Department.

15% Supervises medical staff. Develops policies and operational procedures for the Medical Department. Monitors professional and career training for staff members. Helps develop goals and philosophy for the Medical Department.

15% Coordinates activities of physicians and surgeons in the Department. Schedules on-call medical coverage. Performs performance evaluations for physicians and surgeons.

10% Monitors quality assurance program. Ensures compliance with regulatory agencies, mandated programs, and other California Department of Corrections requirements.

5% Performs emergency medical treatment for staff, routine annual and Class B driver license examinations for staff that are required to drive a State vehicle in the performance of their duties. Attends appropriate in-service training and medical staff meetings; maintains continuing education for Physician and Surgeon license; performs other related duties as assigned by supervisor.

CENTINELA STATE PRISON
JOB DESCRIPTION/ESSENTIAL FUNCTIONS

Job Title: Physician and Surgeon
Division: Health Care Services
Department: Medical
Reports To: Chief Medical Officer

SUMMARY:
Under the supervision of the Chief Medical Officer, the Physician and Surgeon is responsible for the medical care of assigned patients and the supervision of Nurses, Medical Technical Assistant and other staff engaged in the care and treatment of patients.

ESSENTIAL DUTIES AND RESPONSIBILITIES INCLUDE, BUT ARE NOT LIMITED, THE FOLLOWING (other duties may be assigned):

80% Examines patients and diagnoses their illness, prescribes and administers medical treatment; performs or assists in performing minor surgical operations; supervises pre- and post-operative care of surgical patients, assists in anti-luetic treatments; orders laboratory examinations and anlyses, x-rays and special diets; writes prescriptions, makes round of infirmary patients and reviews reports, records and general progress of each case.

10% Instructs and supervises nurses, technicians, and personnel assigned for special training. Keeps and/or supervises the keeping of records and case histories; prepares reports and related correspondence.

10% Attends and participates in staff conferences for the discussion of the surgical, medical and mental condition of various patients and their final diagnosis and treatment; as assigned make routine psychiatric examinations; services periodically as medical officer of the day. Participates in In-Service Training classes to keep abreast of Institutional Policy and Departmental Procedures.

NON-ESSENTIAL DUTIES AND RESPONSIBILITIES INCLUDE, BUT ARE NOT LIMITED, THE FOLLOWING: None noted.

SUPERVISORY RESPONSIBILITIES: The Physician and Surgeon provides clinical direction to nursing and ancillary staff, but does not directly supervise.

QUALIFICATIONS: To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE: Possession of adequate education and experience to meet licensing requirements.

LANGUAGE SKILLS: Ability to read, analyze and interpret medical journals, texts, medical records, consultation notes, policies and procedures; interview and provide information to people of varying backgrounds; accurately and clearly complete medical records, abstracts, and other reports; prepare and supervise the preparation of case histories; unambiguously communicate orders for treatment; and clearly communicate the medical necessity for consultations and restricted treatments.

MATHEMATICAL SKILLS: Ability to work with concepts such as probability and statistical inference; apply such concepts as fractions, percentages, ratios, and proportions to practical situations; and calculate dosages.

REASONING ABILITY: Ability to formulate diagnoses and treatment plans; organize and prioritize work; interpret conflicting or ambiguous information; and analyze situations accurately and adopt an effective course of action.

CERTIFICATES, LICENSES, REGISTRATIONS: Possession of the legal requirements for the practice of medicine in California as determined by the Medical Board of California or the California Board of Osteopathic Examiners. (Applicants who are in the process of securing approval for their qualifications by the Medical Board of California or the Board of Osteopathic Examiners will be admitted to the examination, but the Board to which application is made must determine that all legal requirements have been met before candidates will be eligible for appointment.)

OTHER SKILLS AND ABILITIES: Ability to examine, diagnose, and treat physical and mental disorders; interpret laboratory analyses and x-rays; direct the work of ancillary personnel; instruct in the principles and practices of general medicine and surgery; manage medical emergencies according to community standards of care; and lead an Advanced Cardiac Life Support Team, and maintain regular attendance and be punctual. Proficient in performing medical procedures including but not limited to: endotracheal intubation, emergency vascular access, defibrillation, laceration repair; removal of foreign bodies from skin, eyes, ears, nose; application and removal of dressings, splints, and casts; incision and drainage of abscesses; and superficial biopsies.

OTHER QUALIFICATIONS: Knowledge of principles and methods of general medicine and skill in their application; methods and principles of surgery and skill in their application; recent developments in general medicine and surgery; hospital organization and procedure; psychiatric social work, physical therapy, and the various rehabilitation therapies; methods of diagnosing and treating mental disorders.

SPECIAL PERSONAL CHARACTERISTICS: Empathetic understanding of patients of a State correctional facility; willingness to work in a State correctional facility; alertness; keenness of observation; tact; patience; and emotional stability.

SPECIAL PHYSICAL CHARACTERISTICS: Have and maintain sufficient strength, agility and endurance to perform during stressful (physical, mental and emotional) situations encountered on the job without compromising their health and well-being or that of their fellow employees or that of inmates.

OTHER QUALIFICATIONS/REQUIREMENTS: Assignments may include sole responsibility for the supervision of inmates and/or the protection of personal and real property.

PHYSICAL DEMANDS: The physical demands described here are representative of those that must be met of an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The following is a definition of the on-the-job time spent in physical activities:

Constantly:	Involves 2/3 or more of workday.
Frequently:	Involves 1/3 to 2/3 of workday.
Occasionally:	Involves 1/3 or less of workday.
N/A:	Activity or condition is not applicable.

Standing: Occasionally - to perform physical examinations of inmates and minor surgical procedures, usually for brief periods, but may be up to 45 minutes at a time for some suturing procedures.
Walking: Occasionally - to walk from the sally port to the work area (approximately 125 yards) at the beginning and end of each day, within the medical offices and a clinic area for meetings and patient care intermittently throughout the day, and back and forth to other facilities to attend meetings or access other records.
Sitting: Frequently - to attend meetings or prepare records and reports for periods of up to four hours at a time, with the ability to stand and walk as desired.
Lifting: Frequently - to handle paperwork and medical instruments weighing under one pound, and some files weighing several pounds. Occasionally lifting and wearing of a 15-pound protective vest when working in the AD SEG unit. On rare occasion, to assist with the transferring of patients between beds or gurneys, generally with three other staff.
Carrying: Occasionally - to transport paperwork, retrieve small items within the clinic, and to wear a 15-pound vest in the AD SEG unit.
Bending/Stooping: Occasionally - to work over patients on beds and gurneys including performing examinations and to perform procedures such as applying casts for 15 to 20 minutes or suturing for up to 45 minutes. Rarely, to perform CPR and attend to inmate or staff patients on the ground during emergencies.
Reaching in Front of Body: Frequently - to reach for tools and dressings, to acquire supplies from shelves, to examine patients, to work at a desk or table taking notes, reviewing files, or answering a telephone.
Reaching Overhead: Occasionally - to obtain supplies from upper shelves in the clinic.
Climbing: Occasionally - to ascend and descend one flight of stairs in and out of medical administrative office area to attend meetings. Rarely, to take stairs to the second tier of housing units in an emergency.
Balancing: Occasionally - to reach to the opposite side of a gurney to examine or treat patients.
Pushing/Pulling: Occasionally - to open and close doors, gates and drawers; to perform some medical procedures and exams requiring some light pushing and pulling. Rarely, CPR is administered requiring heavier pressure.
Kneeling/Crouching: Occasionally - on very rare occasion may choose one of these positions to examine, assess and perform procedures on patients on the ground in emergencies.
Crawling: N/A
Fine Finger Dexterity: Occasionally to Frequently - to take notes and fill out forms, operate medical instruments and perform minor surgical procedures.
Hand/Wrist Movement: Constantly - to perform office tasks including handling paperwork, using a telephone, and writing; to perform examinations and procedures on patients, and handle supplies and instruments.
Driving Cars/Trucks/Forklifts or Other Moving Equipment: Occasionally - electric carts may be driven in an emergency, but are not usually available for transport.
Hearing/Speech: Constantly - to evaluate and diagnose patients, and to maintain awareness and safety.
Sight: Constantly - to review records, identify medications, evaluate and diagnose patients, and to maintain awareness and safety.

WORK ENVIRONMENT: The work environment characteristics described here are representative of those an employee encounters when performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The Physician and Surgeon works in an office, as well as in a medical clinic located in an inmate housing facility. All of these areas are linoleum covered concrete floors, have florescent lighting and are thermostatically controlled. The Physician and Surgeon will also go outside to move between facilities, traveling on asphalt and going through sally port areas, which are subject to delays. On very rare occasions, the physician may go into cell areas or a prison yard to respond to emergencies.

The following is a definition of the on-the-job time spent in exposure to the environmental conditions listed:

Constantly: Involves 2/3 or more of workday
Frequently: Involves 1/3 to 2/3 of workday
Occasionally: Involves 1/3 or less of workday
N/A: Activity or condition is not applicable

Fumes or Dust: Occasionally - N/A
Temperature Extremes: Occasionally - exposed to some outdoor weather conditions when traveling between the facilities.
Architectural Barriers: N/A
Working Surfaces: concrete, linoleum, turf, asphalt, dirt.
Risks of Electrical Shock: Occasionally - performs defibrillation.
Toxic or Caustic Chemicals: Occasionally - uses disposal procedures for hazardous medical waste.
Noise or Vibration: N/A
Work in High, Precarious Places: N/A
Bloodborne Pathogens: Occasionally - uses proper equipment and patient care procedures to limit exposure to blood and other body fluids in an inmate population with some incidents of hepatitis, and HIV.

MACHINES, TOOLS, EQUIPMENT, AND WORK AIDS: Usual office equipment, computer, telephone, stethoscope, opthalmoscope, otoscope, laryngoscope, sigmoidoscope, anoscope, electrocardiogram, cardiac monitor, defibrillator, syringes, scalpels, other surgical instruments, basic medical supplies, gloves, gurney, beeper, telephone, fax machine, cellular phone, whistle, personal alarm, and protective vest.

COMMENTS: Work hours are from 7:30 a.m. to 3:30 p.m., but may be varied according to the needs of the institution. On-call evening and weekend work is rotated week to week among the physicians of Centinela State Prison and may require the physician to return to the institution outside regular hours for emergencies. Information for this document was obtained by reviewing the State Personnel Board Specification for this classification, interview with the Health Care Manager, and interview with the incumbent.

EMPLOYEE'S COMMENTS:

Print Employee's Name	**Employee's Signature**	**Date**

Supervisor's Statement: I have discussed the duties of the position with the employee.

Print Supervisor's Name	**Supervisor's Signature**	**Date**

GENERAL POST ORDER/DUTY STATEMENT ADDENDUM

Reasonable Modification/Accommodation: Reasonable modification or accommodation is the process of modifying policy, procedure, physical plant, etc. to facilitate access to programs, services, and activities for inmates with disabilities. Under the Americans with Disabilities Act (ADA), inmates with disabilities have a right to request reasonable modification or accommodation to access programs, services, and activities of the Department. The ARP provides that such requests may be denied only if one or more of the following four defenses apply:

1. Legitimate Penological Interest,
2. Undue Burden and Fundamental Alteration,
3. Direct Threat,
4. Equally Effective Means;

These defenses are derived from the ADA and from the 1987 United States Supreme Court decision in *Turner v. Safley*. Staff should consult ARP II.H, Justification for Denial of Requests for Reasonable Accommodation for detail on the applicability of these defenses. If CDCR staff denies requests for reasonable modification or accommodation where these defenses do not apply, the denial may not be legally defensible and the CDCR will continue to be deficient with respect to compliance with federal law and federal court order.

Equally Effective Communication: The ARP and the American with Disabilities Act (ADA) require public agencies to ensure equally effective communication with inmates, in particular where important interests such as due process, health care delivery, legal, etc. are at stake. In these instances, the ADA requires public agencies to give primary consideration to the preferred method of communication of the individual with a disability. Staff is required to dedicate additional time and/or resources as needed to ensure equally effective communication with inmates who have communication barriers such as hearing, vision, speech, learning, or developmental disabilities. Inmates with severe hearing impairments who rely on sign language for effective communication have been most underserved in this area. It is my expectation that DAI staff will take necessary steps to obtain the services of a qualified sign language interpreter for communications that involve due process, appeals, notice of conditions of parole, classification committee hearings etc; attempting to use written communication for these contacts violates the ARP and the ADA. The ARP and CDCR policy require staff to document their determination that the inmate understood the communication, the basis for the determination, and how the determination was made. A good technique is asking the inmate to explain what was communicated in his or her own words.

Tracking: The ARP requires Classification and Parole Representatives (C&PR) and Reception Center Correctional Counselors-III (RC CC-III) to develop local procedures for tracking inmates with disabilities based upon the CDCR Form 1845. Deputy Director Memorandum 159/03, dated November 25, 2003, implemented the *Armstrong Clark* Tracking System (ACTS) and requires all institutions to use this system for tracking all inmates with DPP and DDP codes. The ACTS was designed to work in conjunction with the CDCR 1845, rev. 01/04, and includes fields dedicated for entering and reporting housing restrictions such as lower bed/lower tier housing, accommodations for effective communication, and prescribed health care appliances. C&PRs and RC CC-IIIs are required to distribute updated ACTS housing rosters to division heads bi-weekly and division heads are required to distribute the rosters to housing units, custody supervisors, correctional counselors, etc. It is my expectation that custody supervisors will ensure ACTS rosters are used to identify inmates with housing restrictions and ensure they are housed appropriately. Staff shall also use ACTS rosters to identify effective communication needs, in particular the need for as sign language interpreter.

Inmates with Housing Restrictions: The ARP requires doctors to generate chronos with physical limitations for inmates verified with certain CDCR 1845 disabilities. These limitations often involve housing restrictions. It is custody staff's responsibility to ensure inmates are housed consistent with housing restrictions; therefore, institutions shall establish local procedures to ensure chronos with housing restrictions are forwarded to the C&PR/RC CC-III and to the custody supervisor responsible for inmate housing. If the inmate has a DPP code, the C&PR/RC CC-III or designee shall update the housing restriction information in the ACTS. The custody supervisor shall conduct bed moves if necessary to accommodate the inmate expeditiously according to the documented housing restrictions. Also, custody supervisors shall train housing officers to report all cases where inmates are not housed consistent with documented housing restrictions.

Prescribed Health Care Appliances: ARP IV.F.3 provides that inmates shall not be deprived of appliances that were properly obtained while in CDCR custody unless for documented safety or security reasons or a physician determines it is no longer necessary or appropriate. Unless an inmate misuses a prescribed appliance in a manner that threatens safety or security, there is no legally defensible reason for custody staff to take it away after the custody captain or designee has reviewed it for safety and security concerns and approved it.

Nurse Practitioner

SPEC: NURSE PRACTITIONER, CORRECTIONAL FACILITY
CALIFORNIA STATE PERSONNEL BOARD

SPECIFICATION

Schematic Code: TJ93

Class Code: 9278

Established: 6/15/93

Revised: --

Title Changed: --

NURSE PRACTITIONER, CORRECTIONAL FACILITY

DEFINITION

Under the supervision of a physician, in a State correctional facility in the Department of Corrections or the Department of the Youth Authority, to provide direct and indirect patient care services under written and approved standardized procedures; to maintain order and supervise the conduct of inmates or youthful offenders; to protect and maintain the safety of persons and property; and to do other related work.

TYPICAL TASKS

In accordance with established standardized procedures and in collaboration with a physician, provides clinical assessment and case management services to individuals including constructing and interpreting a medical history, performing a physical assessment, evaluating patient behavior, performing and interpreting selected laboratory tests, identifying problems, and developing and implementing treatment plans for patients; refers patients to physician in accordance with standardized procedures or as determined by the Nurse Practitioner; maintains order and supervises the conduct of persons committed to the California Department of Corrections or the Department of the Youth Authority; prevents escapes and injury by these persons to themselves, others or to property; maintains security of working areas and work materials; inspects premises and searches inmates or youthful offenders for contraband, such as weapons or illegal drugs.

MINIMUM QUALIFICATIONS

Possession of a current license as a registered nurse in California. (Applicants who do not meet this requirement will be admitted to the examination, but they must secure the required license before they will be considered eligible for appointment.)

and

Possession of a current certification as a Nurse Practitioner by the Board of Registered Nurses. (Applicants who do not meet this requirement will be admitted to the examination, but they must secure

the required certificate before they will be considered eligible for appointment.)

KNOWLEDGE AND ABILITIES

Knowledge of: Current trends and concepts of professional nursing practices; laws and regulations relating to the nurse practitioner scope of practice; principles and practices of clinical assessment of common health problems; principles of mental health; causes, treatment and prevention of communicable diseases, chronic diseases, mental illness and other disabling conditions; continuity of patient care, and the community health care resources.

Ability to: Work effectively with individuals to assist them in solving physical, mental and social health problems; communicate effectively; prepare clear and concise reports; recognize social problems which affect health; instruct in the prevention of disease, good health practices, and the health care of an ill or injured person; participate in the development of standardized procedures; construct and interpret a medical history, perform a physical assessment, evaluate patient behavior, perform and interpret laboratory tests, and identify problems and develop and implement treatment plans for patients; maintain effective working relationships with health care professionals and others.

SPECIAL PERSONAL CHARACTERISTICS

Empathetic understanding of patients of a State correctional facility; willingness to work in a State correctional facility; emotional stability; patience; tact; alertness; and keenness of observation.

SPECIAL PHYSICAL CHARACTERISTICS

Persons appointed to this position must be reasonably expected to have and maintain sufficient strength, agility and endurance to perform during stressful (physical, mental and emotional) situations encountered on the job without compromising their health and well-being or that of their fellow employees or that of inmates or youthful offenders.

Assignments may include sole responsibility for the supervision of inmates or youthful offenders and/or the protection of personal and real property.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION DIVISION OF CORRECTIONAL HEALTH CARE SERVICES INMATE MEDICAL SERVICES		
☒ Policy	☐ Procedure	☐ Attachment
Title: Nurse Practitioner	Policy #:	
	Effective Date: January 1, 2008	
	Last Review Date: December 2007	
	Revision Date: December 2007	
	Approval Date: December 2007	
This policy applies to the following client population (s): **(X) Adult** (18-65 yrs) **(X) Geriatric** (65 yrs+)		

I. POLICY

It is the policy of the California Department of Corrections and Rehabilitation (CDCR), Division of Correctional Health Care Services (DCHCS) to integrate Nurse Practitioners into the health care delivery system as Primary Care Providers. Nurse Practitioners shall work within their scope of practice as defined in Business and Professions Code, Nursing Practice Act, Section 2725 (b)(4) and further clarified in California Code of Regulations (CCR), Section 1480.

Business and Professions Code, Section 2725 (b)(4) authorizes Nurse Practitioners to perform functions that would otherwise be considered the practice of medicine, in accordance with Standardized Procedures. In providing primary care services to inmates, Nurse Practitioners shall provide only those health care services that are specified in department approved Standardized Procedures, for which they are deemed competent.

Under the direction of the Receiver, CDCR has embarked upon an ambitious program to recruit, properly orient and train, and retain competent, primary care providers (PCPs), including complementing the current staffing by incorporating a strong contingent of mid-level practitioners (i.e., Physician Assistants/PAs and Nurse Practitioners/NPs). Thus, the Department sees physicians and mid-level practitioners as both integral and inseparable components of a successful, health care delivery system.

Accordingly, what follows are the latest revisions in the Department's Policies and Procedures for mid-level practitioners which describe not only what they do within CDCR, but also how they relate to their physician colleagues. This policy will go a long way towards defining each practitioner's (NP's and PA's) roles, responsibilities, and scope of practice and ensure that the mid-level providers are integrated into the health care team.

II. PURPOSE

To provide CDCR staff with standardized guidelines for hiring and supervising Nurse Practitioners, to establish the functions that Nurse Practitioners in the CDCR, DCHCS may perform, and to assist health care providers in understanding the role and scope of practice of Nurse Practitioners.

III. GENERAL REQUIREMENTS

A. Standardized Procedure Development, Review and Revision

Standardized Procedures shall be developed through collaboration with Physicians, Nurse Practitioners, and Administrators in the DCHCS, and adhere to the regulations jointly promulgated by the California Board of Registered Nursing and the Medical Board of California.

The DCHCS shall establish a Professional Practice Committee to oversee the development of all Standardized Procedures. The Professional Practice Committee shall be comprised of Physicians, Mid-level Practitioners, and other clinical disciplines as deemed appropriate. Standardized Procedures shall be reviewed annually and revised as necessary.

B. Approval of Standardized Procedures

All Standardized Procedures shall be approved by the Professional Practice Committee and accompanied by a dated and signed approval sheet (see Attachment A, *Statement of Approval and Agreement*). Signature on the "Statement of Approval and Agreement," implies the following:

- Approval of all attached Standardized Procedures;
- The intent of all parties to abide by the Standardized Procedures in theory and in practice; and
- The willingness of all parties to maintain a collaborative working relationship.

Standardized Procedures approved by the Professional Practice Committee shall be maintained in a separate manual at each institution.

C. Hiring of Nurse Practitioners

Nurse Practitioners may be hired into the DCHCS as civil servants or as contract employees. The hiring process for Nurse Practitioners shall follow established State laws and departmental standards. The physician manager at each institution (i.e., Chief Medical Officer [CMO] or Chief Physician and Surgeon [CP&S]) shall obtain approval from the Headquarters Credentialing Unit prior to making a permanent job offer to Nurse Practitioner applicants.

D. Education, Experience, and Certification

All Nurse Practitioners hired by the DCHCS (civil service and contract employees) shall possess the following:

- Active California Registered Nurse license
- Nurse Practitioner certificate issued by the California Board of Registered Nursing
- Current Basic Life Support certification
- At least two (2) years of relevant primary care experience: For specialized facilities (e.g., women's prisons), the 2 years of experience in primary care can be substituted with other relevant experience (e.g., 2 years as a Nurse-Midwife).

- National certification (by the American Academy of Nurse Practitioners or the American Nurses Credentialing Center) as a Family or Adult Nurse Practitioner, or have graduated from a Nurse Practitioner program within the past twelve months, with the intention of seeking national certification
- Within one year of hire, possession of a furnishing number and DEA certificate.

E. Orientation

All Nurse Practitioners (civil service and contract employees) shall attend new employee orientation at their assigned institution. Orientation shall include pertinent information regarding the work environment as well as job expectations. A copy of the duty statement shall be provided to all newly hired Nurse Practitioners during clinical orientation (see Attachment B, *Nurse Practitioner Duty Statement*).

F. Scope

Nurse Practitioners working in the DCHCS may perform the following functions within their specialty area, and consistent with their experience and credentialing: assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status, including but not limited to ordering laboratory procedures, x-rays and physical therapies, recommending diets, and referring patients to specialty clinics when indicated.

G. Setting

Nurse Practitioners working in the DCHCS may perform Standardized Procedures in Reception Centers, Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Outpatient Housing Units, Correctional Treatment Centers (CTC), General Acute Care Hospitals (GACH), Hospice Units, and other clinical settings as determined by the Chief Medical Officer or designee.

The physician manager shall ensure that each Nurse Practitioner is properly credentialed and receives appropriate privileges. Only those Nurse Practitioners with appropriate credentials and privileges may provide care in licensed inpatient settings. Credentialing and privileging for practice in licensed inpatient settings shall be in accordance with the Title 22 regulations. When providing care in an inpatient setting, the Nurse Practitioner shall closely collaborate with the clinical supervisor who shall be the physician of record.

In extreme, unforeseen circumstances and when deemed medically necessary for the preservation of life and limb, Nurse Practitioners may provide emergency health care services in accordance with their training and experience, in others areas of the institution or off grounds as necessary.

H. Consultation

Physician consultation shall be obtained as specified in individual protocols and under the following circumstances.

- Whenever situations arise which go beyond the intent of the Standardized Procedures or the competence, scope of practice, or experience of the Nurse Practitioner;

- Whenever patient conditions fail to respond to the treatment plan in an appropriate timeframe;
- Any rare or unstable patient condition;
- Any patient condition that does not fit the commonly accepted diagnostic pattern for a disease or disorder;
- Any unexplained physical examination or historical finding;
- At the Nurse Practitioner's or physician's request;
- All emergency situations after initial stabilization.

Whenever a physician is consulted a notation to that effect, including the date, time, and physician's name shall be recorded in the Unit Health Record (UHR).

All patient consultations or treatment related to new or recurrent diagnosis of depression, anxiety, or any other mental health condition or diagnosis, shall immediately be referred to the Mental Health Department at the institution. Whenever a Nurse Practitioner makes a mental health referral, a notation to that effect shall be made in the patient's UHR.

I. Patient Records

The Nurse Practitioner shall be responsible for the preparation of a complete medical record for each patient encounter. All information relevant to patient care shall be recorded in the UHR (e.g., assessments, diagnoses, treatment plans, procedure notes, discharge notes, etc.).

J. Supervision

The physician manager at each institution shall be responsible for ensuring that Nurse Practitioners receive adequate supervision. Appropriately qualified physicians may provide clinical supervision to Nurse Practitioners. Physician consultation shall be available at all times, either onsite, by telephone, or via electronic device, and no physician shall supervise more than four (4) Nurse Practitioners at one time.

It is the physician manager's responsibility to:

- Ensure that all physicians assigned to provide clinical supervision to Nurse Practitioners receive adequate orientation to their role and responsibilities.
- Delegate, if appropriate, the clinical supervision of Nurse Practitioners to appropriately qualified physicians based on approved ratios.
- Ensure that all Nurse Practitioners (civil service and contract employees) receive new employee orientation in accordance with institutional guidelines.
- Ensure that all Nurse Practitioners (civil service and contract employees) receive adequate orientation to their job responsibilities.
- Ensure that each Nurse Practitioner complies with all department policies, procedures, and standards.
- Ensure that UHR reviews for each Nurse Practitioner are completed within established timeframes as specified in this policy.
- Complete probationary reports and annual performance evaluations for each Nurse Practitioner as identified in this policy.

K. Evaluation of Clinical Competence

Initial Evaluation

Initial evaluation of clinical competence for civil service and contract Nurse Practitioners shall be provided as follows:

- For the first month following employment, the physician supervisor or designee shall meet with the Nurse Practitioner at least weekly to review the practitioner's clinical care. Evaluation shall include a review of at least five percent (5%) of the medical records for patients treated by the Nurse Practitioner.
- A 10-day and 60-day Clinical Evaluation Program shall be implemented to monitor performance and assist in the completion of performance appraisals.
- After the first month of employment the physician supervisor or designee shall ensure that at least five percent (5%) of the medical records for patients treated by the Nurse Practitioner are reviewed monthly for a period of six (6) months.
- The physician manager shall ensure that three (3) probationary reports are completed thoroughly and in a timely manner for all civil service Nurse Practitioners.
- Informal consultations shall occur as deemed necessary, and as mutually agreed upon by the physician manager and Nurse Practitioner.
- Contract Nurse Practitioners shall be evaluated at least as often as civil service Nurse Practitioners, utilizing the methods identified above.

Ongoing Evaluation

- At least weekly, the designated physician manager at each institution shall meet with physicians and Nurse Practitioners to discuss clinical practice issues.
- A peer review process shall be utilized to monitor compliance with current practice standards.
- The physician manager shall ensure that an Individual Development Plan (IDP) is completed annually for all civil service Nurse Practitioners that have satisfactorily completed probation.
- Areas requiring increased proficiency as determined by initial or routine evaluation shall be reassessed by the physician supervisor at appropriate intervals until acceptable skill level is achieved.

L. On-Call

Nurse Practitioners may be scheduled to provide "on-call" services in all areas of the institutions, except the GACH. Nurse Practitioners and rank and file physicians shall be scheduled on an equal basis, with no individual or group receiving preferential treatment.

- Nurse Practitioners scheduled "on-call" shall be available by phone or other electronic means, and be available to return to the institution if necessary.
- Nurse Practitioners scheduled "on-call" shall provide primary care services and determine the appropriate disposition for patients. When a Nurse Practitioner is "on-call," a physician manager (i.e., CP&S, CMO, or Regional Medical Director) shall be available onsite, by telephone, or via electronic device to provide supervision and clinical support.
- Nurse Practitioners "on-call" shall be compensated in accordance with the Bargaining Unit 17 Memorandum of Understanding.

REFERENCES:

Business and Professions Code, Section 2725(b)(4)
Business and Professions Code, Section 2836.1, 2836.2
California Code of Regulations, Title 16, Section 1379
California Code of Regulations, Title 16, Section 1474
California Board of Registered Nursing Publication NPR-B-20. An Explanation of Standardized Procedure Requirements for Nurse Practitioner Practice (12/1998).
California Board of Registered Nursing Publication NPR-I-16. Criteria for Furnishing Number Utilization by Nurse Practitioners. (12/2004).

STATEMENT OF APPROVAL AND AGREEMENT

The attached Standardized Procedures have been approved by the CDCR, DCHCS, Professional Practice Committee. The Standardized Procedures were developed in accordance regulations jointly promulgated by the California Board of Registered Nursing and the Medical Board of California.

Signature on the "Statement of Approval and Agreement" implies the following:

- Approval of the Standardized Procedures, and all the policies and protocols contained in this document;
- The intent to abide by the Standardized Procedures contained in this document both in theory and in practice; and
- The willingness of all parties to maintain a collaborative and collegial working relationship.

WINSLOW 10/4/07

Chair, Professional Practice Committee — Date

WINSLOW 10/4/07

Statewide Medical Director — Date

Susan Odegard Turner 10/01/07

Statewide Nursing Director — Date

STATE OF CALIFORNIA
DEPARTMENT OF CORRECTIONS AND REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
DUTY STATEMENT

JOB TITLE: NURSE PRACTITIONER-CF
DIVISION: HEALTH CARE SERVICES
DEPARTMENT: MEDICAL

DEFINITION:

Utilizing standardized procedures under the clinical supervision of a physician manager, the Nurse Practitioner-CF provides routine primary care services to the adult male and female inmate population, including assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status. Care may be provided in Reception Centers, Outpatient Housing Units, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Correctional Treatment Centers, General Acute Care Hospitals, Hospice Units, and other clinical settings as determined by the Health Care Manager or designee.

DUTIES:

80% Responsible for the evaluation and treatment of inmates in (a) outpatient settings; and/or (b) inpatient settings[1] by carrying out the following functions:

1. Obtain relevant medical histories. Perform physical examinations based on age and history.
2. Conduct preventive screening procedures based on age and history.
3. Formulate the appropriate differential diagnosis based upon the history, physical examination and clinical findings.
4. Develop and implement appropriate treatment plans that include:
   - Ordering appropriate diagnostic tests (laboratory, x-rays, electrocardiograms, etc);
   - Identifying and ordering appropriate pharmacologic agents, adhering to the CDCR statewide formulary whenever possible;
   - Identifying non-pharmacologic interventions;
   - Making appropriate referrals to other health professionals (mental health, specialty services, dentistry, etc) and community agencies upon release from CDCR;
   - Consulting with a supervisory or collaborating physician on-site or via electronic means, as clinically indicated;
   - Developing a patient education plan that promotes inmate-patient participation in the plan of care;
   - Counseling and educating patients on health behaviors, self-care skills, and treatment options.
5. Document all assessments and care provided for each patient contact, maintaining detailed, legible, and confidential medical records in accordance with Department policies and procedures.

---

[1] Functions described in this document may be performed in licensed inpatient settings if the Nurse Practitioner possesses the appropriate credentials and/or experience.

6. Monitor patients to determine the effectiveness of the plan of care. Reassess and modify the plan of care as necessary to achieve medical and health goals.
7. Conduct patient rounds in the inpatient setting.
8. Perform pre-parole evaluations.
9. Perform administrative segregation clearances.
10. Perform evaluations of patients to determine their suitability or fitness for vocational/education programs.
11. Complete CDC Form 128-C in accordance with department policy.
12. Perform other duties related to patient care as assigned by the Health Care Manager or designee.

10% Respond to medical emergencies in the clinics, Outpatient Housing Units, Correctional Treatment Center, General Acute Care Hospital, or off grounds as necessary. Conduct emergency examinations on injured staff and provide First Aid care.

10% Participate in multidisciplinary care conferences and professional practice group meetings (e.g., Peer Review, Continuous Quality Improvement, Pharmacy and Therapeutics, etc.). Assist in updating Standardized Procedures as necessary. Attend continuing education seminars necessary to maintain licensure and certification requirements.

_____	_____
Nurse Practitioner	Date Reviewed
_____	_____
Supervisor's Signature	Date Reviewed

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES

REFERENCE BOOKS
FOR NURSE PRACTITIONERS

REQUIRED BOOKS

Two (2) copies of each of the following textbooks shall be maintained in the Nurse Practitioner Resource Library

California Department of Corrections and Rehabilitation Formulary

Cecil Textbook of Medicine (Two Volume with CD-ROM), Goldman, L., (2001).
21st Edition, W.B. Saunders Company

Clinical Guidelines in Family Practice, Uphold, C., Graham, M., (2003).
Barmarrae Books

Clinical Practice in Correctional Medicine, Puisis, M., (2006).
2nd Edition, Mosby-Yearbook Inc.

Ferri's Clinical Advisor 2006: Instant Diagnosis and Treatment
(Text with CD-ROM for Windows), Ferri, F. , Mosby-Yearbook, Inc.

Guide to Clinical Preventive Services: Report to the U.S. Preventive Services Task Force, 3rd Edition, January 2002

Guidelines to Clinical Preventive Services: Report of the U.S. Preventive Services Task Force, U.S. Public Health, 2005

Outpatient Medicine, Fihn, S.D., DeWitt, D.E., (1997).
2nd Edition, W.B. Saunders Company

Physician's Desk Reference, 2006 Library Edition.
60th Edition, Medical Economics, Inc.

Textbook of Primary Care Medicine, Noble, J., (2000).
3rd Edition, Mosby-Yearbook Inc.

Washington Manual of Medical Therapeutics, Washington University (2007).
32nd Edition, Lippincott Williams & Wilkens

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PRIMARY CARE

A. DEFINITION:
This protocol covers the procedure for age-appropriate health care management in clinics, Reception Centers, and inpatient units. Scope of care includes assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Reception Centers, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:

1. Subjective Data:
   a. Screening: age appropriate history that includes but is not limited to: past medical history, surgical history, hospitalizations/injuries, habits, family history, psychosocial history, allergies, current medications, treatment, and review of systems.
   b. Ongoing/Continuity: review of symptoms and history of relevant to the disease process or presenting complaint.
   c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

D. DIAGNOSIS:
Assessment of data from the subjective and objective findings identifying risk factors and disease processes. May include a statement of current status of disease (e.g., stable, unstable, uncontrolled).

E. PLAN:

1. Treatment:
   a. Age appropriate screening tests and/or diagnostic studies for purposes of disease identification.
   b. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   c. Immunization update.
   d. Referral to specialty clinics and supportive services as needed.

2. Patient Conditions Requiring Physician Consultation:
   a. Whenever situations arise which go beyond the competence, scope of practice, or experience of the Nurse Practitioner/Physician Assistant.
   b. Whenever patient condition fails to respond to the treatment plan in an appropriate timeframe.
   c. Acute decompensation of patient condition.
   d. Any patient condition that does not fit the commonly accepted diagnostic pattern for a disease or disorder.
   e. Unexplained historical, physical or laboratory findings.
   f. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.
   g. Initiation or change of medication other than those in the formulary.
   h. Problem requiring hospital admission or potential hospital admission.
   i. When ordering complex imaging studies or procedures.

3. Education:
   a. Patient education appropriate to diagnosis including treatment modalities and lifestyle counseling (e.g., diet, exercise).
   b. Anticipatory guidance and safety education that is age and risk factor appropriate.

4. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, laboratory tests/diagnostic studies, treatment plan, procedure notes, patient education, and discharge notes. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

URGENT/ACUTE CARE

A. DEFINITION:
This protocol covers the procedure for patient visits for urgent problems, which include but are not limited to common acute problems, uncommon, unfamiliar, unstable, or complex conditions.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Triage Treatment Area (TTA), Outpatient Housing Units (OHU), Correctional Treatment Centers (CTC).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:

1. Subjective Data:
   a. History and review of symptoms relevant to the presenting complaint and/or disease process.
   b. Pertinent past medical history, surgical history, family history, psychosocial and occupational history, hospitalizations/injuries, current medications, allergies, and treatments.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

D. DIAGNOSIS:
Assessment of data from the subjective and objective findings to identify disease processes. May include a statement of current status of disease (e.g., stable, unstable, uncontrolled).

E. PLAN:

1. Treatment:
   a. Common acute problems: perform diagnostic studies for the purposes of disease identification.
   b. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   c. Referral to physician, specialty clinics, and supportive services as needed. Supervising physician is notified if his/her name is used on a referral to a specialty physician or department.
   d. For uncommon, unfamiliar, unstable, or complex conditions consult a physician regarding evaluation, diagnosis, and/or treatment plan. Management of the patient is either in conjunction with a supervising physician or by complete referral to a community provider and/or facility.

2. Education:
   a. Patient education including treatment modalities.
   b. Discharge information and instructions.

3. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, laboratory tests/diagnostic studies, treatment plan, procedure notes, patient education, and discharge notes. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

TERTIARY CARE

A. DEFINITION:
This protocol covers the procedure for patients who present with acute, life threatening conditions including but not limited to respiratory or cardiac arrest.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:
1. Setting: Yard Clinics, Sick Call Clinics, Triage Treatment Area (TTA), Correctional Treatment Centers (CTC), Outpatient Housing Units (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:
1. Subjective Data:
   a. Brief history, including precipitating event or mechanism of injury if applicable, and review of symptoms relevant to the presenting complaint.
   b. Pertinent past medical history, hospitalizations/injuries, allergies, current medications, and tetanus immunization status if applicable.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory tests as indicated.

D. DIAGNOSIS:
Assessment of data from subjective and objective findings. May include a statement of current status (e.g., stable or unstable).

E. PLAN:
1. Treatment:
   a. Initial evaluation and stabilization of the patient with concomitant notification of and immediate management by a physician. Initial treatment may include all modalities of Advanced Cardiac Life Support.
   b. Transfer to higher level of care as indicated.

2. Education:
   Patient education consistent with the assessment of the condition.

3. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, treatment, procedures, and final disposition. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

FURNISHING DRUGS AND DEVICES

A. DEFINITION:
This protocol covers the procedure for Nurse Practitioners/Physician Assistants furnishing drugs or devices. "Furnishing is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure." The ordering of drugs and devices includes the initiation, discontinuation and/or renewal of prescription medications and/or over-the-counter equivalents.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Reception Centers, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Physician supervision required. The physician must be available at least by telephone.
3. Patient Conditions:
   Nurse Practitioners who possess a current furnishing number may furnish or order drugs and devices incidental to the provision of:
   - Family planning services
   - Routine health care rendered to essentially healthy persons
4. Other:
   Nurse Practitioners/Physician Assistants may furnish Schedule II through Schedule V controlled substances when in possession of a Drug Enforcement Administration (DEA) registration number.

   Physician Assistants must obtain advance approval (specific to the patient being treated) from a supervising physician prior to issuing drug orders for non-formulary drugs.

   In addition, Physician Assistants must obtain advance approval from a supervising physician before writing a drug order for Schedule II through Schedule V controlled substances, unless the Physician Assistant has completed an education course that covers controlled substances and, the course meets standards approved by the Physician Assistant Committee.

C. DATABASE:
1. Subjective Data:
   a. Age appropriate history and review of symptoms relevant to the presenting complaint or disease process to include current medication, allergies, current treatments and substance abuse history.

b. No personal and/or family history, which is an absolute contraindication to use of the drug or device.
c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation to indicate or contraindicate use of the drug or device if necessary.

D. DIAGNOSIS:
Assessment data consistent with use of the drug or device. No absolute contraindications to use of the drug or device.

E. PLAN:
1. Treatment:
   a. Initiate, adjust, discontinue, and/or renew medication and devices included on, but not limited to the attached formulary. Use lowest effective dosage per pharmaceutical references. The name and furnishing number of the Nurse Practitioner shall be included on all Nurse Practitioner prescription transmittal order forms.
   b. Orders for Schedule IV and V controlled substances shall not exceed 90 days in duration.
   c. For chronic conditions such as acute, intermittent but recurrent pain, **or** continuous chronic pain the treatment plan shall be established in collaboration with a physician.
   d. Monitor the effectiveness of the prescribed drug or device.

2. Patient Conditions Requiring Physician Consultation:
   a. Non-responsiveness to appropriate therapy.
   b. Unusual or unexpected side effects.
   c. Initiation or change of medication other than those in the formulary.
   d. Unexplained historical, physical or laboratory findings.
   e. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.

3. Education:
   a. Provide education on why medication is being prescribed, expected outcomes, side effects, and precautions.
   b. Provide instruction to the patient on how to take the medication or use the device correctly. Communicate effectively and appropriately based upon the patient's primary language spoken.

4. Follow-up:
As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, name of the drug (or device), condition for which the drug or device is prescribed, dose, route, frequency, quantity, number of refills authorized, patient education, and

timeframe for follow-up. For controlled substances the name, title, signature, and DEA number of the Nurse Practitioner/Physician Assistant shall be included on the prescription transmittal order form. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PATIENT-SPECIFIC PROTOCOL
SCHEDULE II AND SCHEDULE III CONTROLLED SUBSTANCES

A. DEFINITION:
This protocol covers the procedure for Nurse Practitioners/Physician Assistants furnishing or ordering drugs classified as Schedule II and Schedule III controlled substances. Schedule II and Schedule III controlled substances must be furnished in accordance with a patient-specific protocol. "A patient-specific protocol is a protocol contained within a standardized procedure that specifies which categories of patients may be furnished this class of drugs."

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Physician supervision required. The physician must be available at least by telephone.
3. Patient Conditions:
   Schedule II and Schedule III controlled substances may be ordered for patients in the following categories:

Category	Examples
Respiratory	Marked cough; injury
Dermatology	Shingles; dermal injuries
Musculoskeletal	Marked strain, sprain or fracture; marked arthritis Inflammatory disorders
Neurological	Headache, marked myofascial pain or neuropathies
EENT	Severe pain from EENT infection or injury
GU	Urinary calculi
Post-operative pain	

4. Other:
   Nurse Practitioners/Physician Assistants must possess a current Drug Enforcement Administration (DEA) registration number in order to furnish controlled substances.

   Physician Assistants must obtain advance approval (specific to the patient being treated) from a supervising physician prior to issuing drug orders for Schedule II through Schedule V controlled substances, unless the Physician Assistant has completed an education course that covers controlled substances and, the course meets standards approved by the Physician Assistant Committee.

C. DATABASE:

1. Subjective Data:
   a. Age appropriate history and review of symptoms relevant to the presenting complaint or disease process to include current medication, allergies, current treatments and substance abuse history.
   b. No personal and/or family history, which is an absolute contraindication to use of the drug.
   c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation to indicate or contraindicate use of the drug if necessary.

D. DIAGNOSIS:

Assessment data consistent with use of the drug or device. No absolute contraindications to use of the drug or device.

E. PLAN:

1. Treatment:
   a. Initiate, adjust, discontinue, and/or renew medication. Limit quantity of tablets as appropriate to the condition being treated. Orders for controlled substances shall not exceed 90 days in duration.
   b. Monitor the effectiveness of the medication.

2. Patient Conditions Requiring Physician Consultation:
   a. Non-responsiveness to appropriate therapy.
   b. Unusual or unexpected side effects.
   c. Unexplained historical, physical or laboratory findings.
   d. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.

3. Education:
   a. Provide education on why medication is being prescribed, expected outcomes, side effects, and precautions.
   b. Provide instruction to the patient on how to take the medication correctly. Communicate effectively and appropriately based upon the patient's primary language spoken.

4. Follow-up:

   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:

All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, name of the medication, condition for which medication is prescribed, dose, route, frequency, quantity, number of refills authorized, patient education, and timeframe for follow-up. The name, title, signature, and DEA number of the Nurse Practitioner/Physician Assistant shall be included on the prescription transmittal order form. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PROCEDURES AND MINOR SURGERY

A. DEFINITION:
This protocol covers the process to be utilized by Nurse Practitioners/Physician Assistants when performing minor surgical procedures.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Triage Treatment Area (TTA).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.
3. Patient Conditions:
   Minor surgical procedures performed by Nurse Practitioners/Physician Assistants shall be limited to the following:*
   - Casting, simple
   - Chemical or electrocautery of external, non-facial, non-malignant lesions less than 1 cm in size (e.g., warts)
   - Epidermal cyst removal (non-facial) less than 3 cm in size
   - Incision and drainage of non-facial abscess less than 5 cm in size
   - Suture non-facial lacerations less than 5 cm in size
   - Mole removal (non-facial)
   - Punch or shave biopsy
   - Toenail removal
4. Other:
   The Nurse Practitioner/Physician Assistant must complete appropriate training and satisfactorily demonstrate competence prior to performing the above procedure(s) independently. Competency shall be assessed by the supervising physician through direct observation of the Nurse Practitioner/Physician Assistant performing the above procedure(s).

   A physician consult shall be obtained prior to applying any casting.

C. DATABASE:

1. Subjective Data:
   a. History and review of symptoms relevant to the presenting complaint or procedure to be performed.
   b. Pertinent past medical history, surgical history, family history, psychosocial and occupational history, hospitalizations/injuries, current medications, allergies.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

*With additional training and demonstrated competence, exceptions can be made on a case-by-case basis.

D. DIAGNOSIS:
Assessment of subjective and objective data to identify disease processes.

E. PLAN:
1. Treatment:
   a. Physician consultation shall be obtained before applying any casting.
   b. Patient consent shall be obtained before procedure is performed.
   c. The Nurse Practitioner/Physician Assistant shall follow standard medical technique for the procedures as described in department approved reference books.
   d. All moles and biopsy specimens shall be sent to the Pathologist for analysis.
   e. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   f. Referral to physician, specialty clinics, and supportive services as needed.

2. Patient Conditions Requiring Physician Consultation:
   a. Acute decompensation of patient situation
   b. Unexplained historical, physical or laboratory findings
   c. Uncommon, unfamiliar, unstable, and/or complex patient conditions
   d. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician
   e. Initiation or adjustment of medication other the those in the formulary
   f. Problem requiring hospital admission or potential hospital admission
   g. When ordering complex imaging studies or procedures

3. Education:
   Discharge information and instructions.

4. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
Patient visit, consent forms, and other procedure specific information shall be documented in the patient's chart. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

Nurse Practitioner — Date
Registered Nurse License# — Furnishing #
Nurse Practitioner Certification # — DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PRENATAL CARE

A. DEFINITION:
This protocol covers the procedure for the routine prenatal care for pregnant inmate-patients.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Yard Clinics, Sick Call Clinics, Outpatient Housing Units (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE (Initial Visit):

1. Subjective Data:
   a. Screening: complete age appropriate history including but not limited to: menstrual history, obstetrical history, medical history including past illnesses, surgeries, current use of medications, habits, family history, psychosocial history, allergies, and current concerns.
   b. Symptoms relevant to the prenatal health process.

2. Objective Data:
   a. Complete physical examination, including internal gynecologic exam and bimanual exam.
   b. Initial prenatal laboratory work to include complete blood count, urinalysis, Pap test, blood type and Rh factor, antibody screening for Rh antibody, Rubella titer, Hepatitis viral screening, testing for sexually transmitted diseases.
   c. Diagnostic studies based on information provided on the Hollister Maternal/Newborn Record System form.

D. DIAGNOSIS:
Assessment and diagnosis of pregnancy status, risk factors, or disease process consistent with subjective and objective findings.

E. PLAN:

1. Treatment Plan:
   a. Routine prenatal examinations shall be done at the following intervals:
      1. Every four (4) weeks during the first trimester and up to 24-26 weeks gestation
      2. Every three (3) weeks up to 30 weeks gestation
      3. Every two (2) weeks up to 36 weeks gestation
      4. Weekly after 36 weeks gestation up until delivery

b. Routine prenatal examination shall include:
   1. Questioning the patient about any present problems
   2. Weighing the patient
   3. Blood pressure
   4. Urinalysis for protein, glucose, and albumin
   5. Measurement of the uterine fundus
   6. Auscultation of the fetal heart with fetoscope or doptone, or both
   7. Determination of the position of the fetus if possible
   8. Physical examination for edema
c. Glucose screen for gestational diabetes at 24 to 28 weeks or initial visit if history is positive for diabetes. Plasma glucose value > 160 mg/dL requires glucose tolerance test.
d. Hematocrit should be repeated at 28 to 36 weeks and at the following visit if the patient's previous reading was below 36%.
e. Immunization update. Repeat Rh antibody titer at 26 to 28 weeks gestation. If patient is Rh-negative administer Rhogam.
f. Additional diagnostic studies shall be ordered based on information provided on the Hollister Maternal/Newborn Record System forms.
g. Refer to Specialty Clinics and supportive services as needed (e.g., Medical Social Worker for Case Management, Dentist, HIV counseling and testing, etc).
h. Initiate prenatal vitamins, iron, and folic acid per Furnishing Drugs and Devices protocol.
i. Positively identified pregnant inmate-patient's shall be provided with the following:
   1. Two (2) extra cartons of milk, two (2) extra servings of fresh fruit, and two (2) extra servings of fresh vegetables daily. Additional nutrients may be ordered as necessary.
   2. Comprehensive Accommodation Chrono (CDCR Form 7410) for any indicated medical clearances or restrictions.
j. The Supervising Obstetrician shall examine all prenatal patients at 36 weeks gestation.

2. Patient Conditions Requiring Physician Consultation:
   a. Whenever situations arise which go beyond the competence, scope of practice, or experience of the Nurse Practitioner/Physician Assistant.
   b. No fetal heart tones heard by 22 weeks gestation.
   c. The patient feels no movement by 22 weeks, or none for one (1) week at any time after this.
   d. Blood pressure above 140/90 mm Hg on two checks after bed rest.
   e. Patient has albuminuria or persistent edema.
   f. Patient has glycosuria, proteinuria, or symptoms of pylelonephritis.
   g. Hematocrit is below 33%.
   h. Lack of regular fetal growth.

i. If the Nurse Practitioner/Physician Assistant questions the position of the fetus (e.g., breech or transverse lie) or any time the Nurse Practitioner/Physician Assistant is in doubt about the patient's status.
j. Uterus size is 2 weeks greater or smaller than expected from estimated weeks of gestation.
k. Upon the request of the Nurse Practitioner/Physician Assistant, or Supervising Obstetrician.
l. Significant condylotomy or herpes develop.

3. Education:
   a. Normal process and progression of pregnancy
   b. Psychosocial issues related to pregnancy
   c. Pregnancy information pamphlets and other pertinent material
   d. Signs and symptoms of complications
   e. Fetal kicks, stages of labor
   f. Pain management during labor and delivery

4. Follow-up:
   As indicated in above treatment plan.

F. RECORD KEEPING:
All information related to prenatal care shall be documented in the Unit Health Record. Physician consultation and referral for support services shall be noted in the patient's chart.

RECORD OF NURSE PRACTITIONERS AUTHORIZED TO PERFORM THIS PROCEDURE

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Nurse Practitioner Date
Registered Nurse License# Furnishing #
Nurse Practitioner Certification # DEA #

Physician Assistant

SPEC: PHYSICIAN ASSISTANT, CORRECTIONAL FACILITY
CALIFORNIA STATE PERSONNEL BOARD

SPECIFICATION

Schematic Code: TH01

Class Code: 8016

Established: 12/6/05

Revised: --

Title Changed: --

PHYSICIAN ASSISTANT, CORRECTIONAL FACILITY

DEFINITION

Under the clinical supervision of a physician, in a State Correctional facility in the Department of Corrections and Rehabilitation, the Physician Assistant assesses and manages the health care needs of patients in primary care, acute care, and specialized clinic settings; performs and interprets physical examinations and routine laboratory, screening, and therapeutic procedures; educates and counsels patients regarding matters pertaining to their physical and mental health; maintains order and supervises the conduct of inmates or youthful offenders; protects and maintains the safety of persons and property; and does other related work.

TYPICAL TASKS

In accordance with established standardized procedures and in collaboration with a physician, provides diagnostic, preventative, and health maintenance services such as taking health histories; performs physical and mental status examinations utilizing diagnostic techniques; evaluates physical signs and symptoms; orders X-rays and laboratory tests; performs routine diagnostic tests such as drawing venous blood, taking cultures, performing and reading skin tests, EKG tracings, and pap smears; interprets results of tests; establishes diagnoses; treats and manages patient health problems; performs routine therapeutic procedures such as injections, immunizations, removal of sutures, strapping, and casting and splinting sprains; instructs and counsels patients; provides continuing care to patients; provides preventative health care services; administers treatments and medications prescribed by physicians; performs minor surgery; acts as first or second assistant during surgery; responds to life-threatening emergencies; maintains order and supervises the conduct of persons committed to the California Department of Corrections and Rehabilitation; prevents escapes and injury by these persons to themselves, others, or to property; maintains security of working areas and work materials; and inspects premises and searches

inmates and youthful offenders for contraband, such as weapons or illegal drugs.

MINIMUM QUALIFICATIONS

Possession of a current Physician Assistant license for the State of California. (Applicants who do not meet this requirement will be admitted to the examination, but they must secure the required license before they will be considered eligible for appointment.)

KNOWLEDGE AND ABILITIES

Knowledge of: The laws and regulations governing Physician Assistants, disease conditions and procedures involved in treatment and diagnosis of these conditions, basic pharmacology, concepts in clinical medicine and surgery, mental health and preventive medicine, and routine laboratory and screening techniques.

Ability to: Interview patients and compile complete and accurate medical histories; perform routine physical examinations; observe and evaluate patients' mental health status; diagnose medical conditions and identify problems that require immediate consultation with a physician; assess and manage the care of patients; provide health education and counseling to patients; maintain good working relationships with other members of the health care team; and prepare and maintain clear and concise patient case records and reports.

SPECIAL PERSONAL CHARACTERISTICS

Empathetic understanding of patients in a State correctional facility; willingness to work in a State correctional facility; alertness; keenness of observation; tact; patience; and emotional stability.

SPECIAL PHYSICAL CHARACTERISTICS

Persons appointed to this position must be reasonably expected to have and maintain sufficient strength, agility, and endurance to perform during stressful (physical, mental, and emotional) situations encountered on the job without compromising their health and well-being or that of their fellow employees or that of inmates or youthful offenders.

Assignments may include sole responsibility for the supervision of inmates or youthful offenders and/or protection of personal and real property.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION DIVISION OF CORRECTIONAL HEALTH CARE SERVICES INMATE MEDICAL SERVICES		
☒ Policy	☐ Procedure	☐ Attachment
Title: Physician Assistant	Policy #:	
	Effective Date: January 1, 2008	
	Last Review Date: December 2007	
	Revision Date: December 2007	
	Approval Date: December 2007	
This policy applies to the following client population (s): **(X) Adult** (18-65 yrs) **(X) Geriatric** (65 yrs+)		

I. POLICY

It is the policy of the California Department of Corrections and Rehabilitation (CDCR), Division of Correctional Health Care Services (DCHCS) to integrate Physician Assistants into the health care delivery system as Primary Care Providers. Physician Assistants shall work within their scope of practice as defined in Business and Professions Code, Chapter 7.7, Article 1, Section 3500-3503.5, and further clarified in Title 16, California Code of Regulations (CCR), Section 1399.540-1399.546.

Physician Assistants are dependent practitioners who act as agents on behalf of a supervising physician. Business and Professions Code, Section 3502 authorizes Physician Assistants to perform medical services set forth in Section 1399.541 of the Physician Assistant Regulations when those services are rendered under direct supervision of a licensed physician and surgeon. In providing primary care services to inmates, Physician Assistants shall provide only those health care services, which are delegated in writing by a supervising physician, for which they are deemed competent.

Under the direction of the Receiver, CDCR has embarked upon an ambitious program to recruit, properly orient and train, and retain competent, primary care providers (PCPs), including complementing the current staffing by incorporating a strong contingent of mid-level practitioners (i.e., Physician Assistants/PAs and Nurse Practitioners/NPs). Thus, the Department sees physicians and mid-level practitioners as both integral and inseparable components of a successful, health care delivery system.

Accordingly, what follows are the latest revisions in the Department's Policies and Procedures for mid-level practitioners which describe not only what they do within CDCR, but also how they relate to their physician colleagues. This policy will go a long way towards defining each practitioner's (NP's and PA's) roles, responsibilities, and scope of practice and ensure that the mid-level providers are integrated into the health care team.

II. PURPOSE

To provide CDCR staff with standardized guidelines for hiring and supervising Physician Assistants, to establish the functions that Physician Assistants in the CDCR, DCHCS may perform, and to assist health care providers in understanding the role and scope of practice of Physician Assistants.

III. GENERAL REQUIREMENTS

A. Hiring of Physician Assistants

Physician Assistants may be hired into the DCHCS as civil servants or as contract employees. The hiring process for Physician Assistants shall follow established State laws and departmental standards. The physician manager at each institution (i.e., Chief Medical Officer [CMO] or Chief Physician and Surgeon [CP&S]) shall obtain approval from the Headquarters Credentialing Unit prior to making a permanent job offer to Physician Assistant applicants.

B. Education, Experience, and Certification

All Physician Assistants hired by the DCHCS (civil service and contract employees) shall possess the following:

- Current California Physician Assistant license
- Current Basic Life Support certification
- At least two (2) years of relevant primary care experience; for specialized facilities (e.g., women's prison), the 2 years of primary care experience can be substituted with other, relevant experience (e.g., women's health).
- National certification as a Physician Assistant (PA-C) from the National Commission on Certification of Physician Assistants (NCCPA)
- Within one year of hire, possession of a DEA registration number.

C. Delegation of Services Agreement

Physician Assistants employed by the DCHCS may provide medical services consistent with the Physician Assistant's education, training, and experience, for which they are deemed competent and, which are delegated in writing by a supervising physician. Hence, a supervising physician must delegate in writing (see Attachment A, *Delegation of Services Agreement Between Supervising(s) Physician and Physician Assistant*) those medical services to be performed by the Physician Assistant. The Delegation of Services Agreement shall be retained on file for the duration of employment.

D. Orientation

All Physician Assistants (civil service and contract employees) shall attend new employee orientation at their assigned institution. Orientation shall include pertinent information regarding the work environment as well as job expectations. A copy of the duty statement shall be provided to all newly hired Physician Assistants during clinical orientation (see Attachment B, *Physician Assistant Duty Statement*).

E. Scope

Pursuant to a signed Delegation of Services Agreement, Physician Assistants working in the DCHCS may perform the following functions within their specialty area, consistent with their experience and credentialing: assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status, including but not limited to ordering laboratory procedures, x-rays and physical therapies, recommending diets, and referring patients to specialty clinics when indicated.

F. Setting

Physician Assistants working in the DCHCS may provide health care services to inmates in Reception Centers, Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Outpatient Housing Units, Correctional Treatment Centers (CTC), General Acute Care Hospitals (GACH), Hospice Units, and other clinical settings as determined by the Chief Medical Officer or designee. The Physician Assistant also may act as first or second assistant in surgery under the supervision of a qualified physician and surgeon.

The physician manager shall ensure that each Physician Assistant is properly credentialed and receives appropriate privileges. Only those Physician Assistants with appropriate credentials and privileges may provide care in licensed inpatient settings. Credentialing and privileging for practice in licensed inpatient settings shall be in accordance with the Title 22 regulations. When providing care in an inpatient setting, the Physician Assistant shall closely collaborate with the clinical supervisor who shall be the physician of record.

In extreme, unforeseen circumstances and when deemed medically necessary for the preservation of life and limb, Physician Assistants may provide emergency health care services consistent with their training and experience, in others areas of the institution or off grounds as necessary.

G. Consultation

Physician consultation shall be obtained as specified by the supervising physician and under the following circumstances.

- Whenever situations arise which go beyond the competence, scope of practice, or experience of the Physician Assistant;
- Whenever patient conditions fail to respond to the treatment plan in an appropriate timeframe;
- Any rare or unstable patient condition;
- Any patient condition that does not fit the commonly accepted diagnostic pattern for a disease or disorder;
- Any unexplained physical examination or historical finding;
- At the Physician Assistant's or supervising physician's request;
- All emergency situations after initial stabilization.

Whenever a physician is consulted a notation to that effect, including the date, time, and physician's name shall be recorded in the Unit Health Record (UHR).

All patient consultations or treatment related to new or recurrent diagnosis of depression, anxiety, or any other mental health condition or diagnosis, shall immediately be referred to the Mental Health Department at the institution. Whenever a Physician Assistant makes a mental health referral, a notation to that effect shall be made in the patient's UHR.

H. Patient Records

The Physician Assistant shall be responsible for the preparation of a complete medical record for each patient encounter. All information relevant to patient care shall be recorded in the UHR (e.g., assessments, diagnoses, treatment plans, procedure notes, discharge notes, etc.). Each time the Physician Assistant provides care for a patient and enters his or her name, signature, initials, or computer code on a patient's record, chart or written order, the Physician Assistant shall also enter the name of the supervising physician who is responsible for the patient. When the Physician Assistant transmits a verbal order, he or she shall also state the name of the supervising physician responsible for the patient.

I. Supervision

The physician manager at each institution shall be responsible for ensuring that Physician Assistants receive adequate supervision. Appropriately qualified physicians may provide clinical supervision to Physician Assistants. Physician consultation shall be available at all times, either onsite, by telephone, or via electronic device, and no physician shall supervise more than four (4) Physician Assistants at one time.

It is the physician manager's responsibility to:

- Delegate, if appropriate, the clinical supervision of Physician Assistants to appropriately qualified physicians based on approved ratios.
- Ensure that all physicians assigned to provide clinical supervision to Physician Assistants receive adequate orientation to their role and responsibilities.
- Ensure that a copy of the *Delegation of Services Agreement Between Supervising Physician(s) and Physician Assistant* is signed by each Physician Assistant and supervising physician, and is retained on file for the duration of the parties employment.
- Ensure that all Physician Assistants (civil service and contract employees) receive new employee orientation in accordance with institutional guidelines.
- Ensure that all Physician Assistants (civil service and contract employees) receive adequate orientation to their job responsibilities.
- Ensure that each Physician Assistant complies with all department policies, procedures, and standards.
- Ensure that UHR reviews are completed for each Physician Assistant within established timeframes as specified in this policy.
- Complete probationary reports and annual performance evaluations for each Physician Assistant as identified in this policy.

J. Evaluation of Clinical Competence

Initial Evaluation

Initial evaluation of clinical competence for civil service and contract Physician Assistants shall be provided as follows:

- For the first month following employment, the supervising physician or designee shall meet with the Physician Assistant at least weekly to review the practitioner's clinical care. Evaluation shall include a review of at least five percent (5%) of the medical records for patients treated by the Physician Assistant. The supervising physician shall select for review those cases, which by diagnosis, patient complaint, treatment or procedure, represent, in his or her judgment, the most significant risk to the patient.
- After the first month of employment the supervising physician or designee shall select, review, sign and date at least five percent (5%) of the medical records for patients treated by the Physician Assistant. This review must be completed within 30 days of treatment.
- The physician manager shall ensure that three (3) probationary reports are completed thoroughly and in a timely manner for all civil service Physician Assistants.
- Informal consultations shall occur as deemed necessary, and as mutually agreed upon by the supervising physician and Physician Assistant.
- Contract Physician Assistants shall be evaluated at least as often as civil service Physician Assistants, utilizing the methods identified above.

Ongoing Evaluation

- At least weekly, the designated physician manager at each institution shall meet with Physician Assistants to discuss clinical practice issues.
- A peer review process shall be utilized to monitor compliance with current practice standards.
- The physician manager shall ensure that an Individual Development Plan (IDP) is completed annually for all civil service Physician Assistants that have satisfactorily completed probation.
- Areas requiring increased proficiency as determined by initial or routine evaluation shall be reassessed by the physician supervisor at appropriate intervals until acceptable skill level is achieved.

K. On-Call

Physician Assistants may be scheduled to provide "on-call" services in all areas of the institutions, except the GACH. Physician Assistants, Nurse Practitioners, and rank and file physicians shall be scheduled on an equal basis, with no individual or group receiving preferential treatment.

- Physician Assistants scheduled "on-call" shall be available by phone or other electronic means, and be available to return to the institution if necessary.
- Physician Assistants scheduled "on-call" shall provide primary care services and determine appropriate disposition for patients. When a Physician Assistant is "on-call," a physician manager (i.e., CP&S, CMO, or Regional Medical Director)

shall be available onsite, by telephone, or via electronic device to provide supervision and clinical support.

- Physician Assistants "on-call" shall be compensated in accordance with the Bargaining Unit 19 Memorandum of Understanding.

REFERENCES:

Business and Professions Code, Chapter 7.7, Article 1, Section 3500-3503.5
Title 16, Division 13.8, California Code of Regulation, Article 4, Section 1399.540-1399.546

Delegation of Services Agreement
Between Supervising Physician(s) and Physician Assistant
(Title 16, *California Code of Regulations*, Section 1399.540)

This Delegation of Services Agreement ("Agreement") is entered into between the physicians whose signatures appear below (each of which shall be referred to herein as "Supervising Physician"), and _____, PA/PA-C ("PA"). The purpose of this Agreement is to comply with the requirements of Title 16, Article 4, of the California Code of Regulations, hereinafter referred to as the "*Physician Assistant Regulations*."

Section 1399.540 of the *Physician Assistant Regulations* state, in part, "A physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience and, which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant." In accordance with Section 1399.540 of the Physician Assistant Regulations, the Supervising Physician hereby delegates the performance of certain medical services to the above-named PA. The Supervising Physician(s) shall provide clinical supervision to the PA in accordance with Section 1399.545 of the Physician Assistant Regulations.

1. QUALIFICATIONS

a) _____ Physician Assistant, graduated from the _____
(Name of PA) (Name of PA Training Program)

physician assistant training program on _____.
(Date)

b) _____ is licensed by the California Physician Assistant Committee and
(Name of PA)

current licensure expires on _____.
(Date)

c) _____ holds current certification as a physician assistant (hence, PA-C)
(Name of PA)

through the National Commission of Physician Assistants (NCCPA).

2. AUTHORIZED SERVICES

a) The PA is authorized by the physician(s) whose name(s) and signature(s) appear below to perform all the tasks set forth in subsections (a), (b), (c), (d), (e), (f), and (g) of Section 1399.541 of the Physician Assistant Regulations, subject to the limitations and conditions described in this Agreement or established by Supervising Physician(s) in any applicable protocols or otherwise.

b) As required by Section 1399.540 of the *Physician Assistant Regulations*, PA may only provide those medical services which he or she is competent to perform and which are consistent with PA's education, training and experience. PA shall consult with Supervising Physician(s) or another qualified health care practitioner regarding any task, procedure or diagnostic problem which PA determines exceeds his or her level of competence, or shall refer such cases to Supervising Physician or another appropriate practitioner.

c) PA shall perform delegated medical services under the supervision of the Supervising Physician(s) as specified in the *Physician Assistant Regulations*, this Agreement, any applicable protocols, and the specific instructions of Supervising Physician(s).

d) As required by Section 1399.546, each time a PA provides care for a patient and enters his or her name, signature, initials, or computer code on the patient's record or written order, PA shall also enter the name of the Supervising Physician responsible for the patient.

3. DRUG ORDERS

a) PA may administer or provide medication to a patient, or issue a drug order, orally or in writing in a patient's chart or drug order form, subject to the conditions and limitations as set forth in Section 3502.1 of the Business and Professions Code, this Agreement, any applicable protocols as described in subsection (b) below, or the specific instructions of the Supervising Physician. Such medications may include Controlled Substances in schedules II through V. PA may sign for the request and receipt of samples of drugs specified in the protocols in subsection (b) below.

b) Drug orders shall either be based on protocols established or adopted by Supervising Physician(s), or shall be approved by Supervising Physician for the specific patient prior to being issued or carried out. Notwithstanding the foregoing, all drug orders for Controlled Substances shall be approved by the Supervising Physician for the specific patient prior to being issued or carried out.

c) Supervising Physician shall review, countersign, and date the medical record of any patient for whom PA issues or carries out a drug order for a Schedule II Controlled Substance within seven days.

4. EMERGENCY TRANSPORT AND BACKUP

a) In a medical emergency requiring the services of a hospital emergency room, the PA shall activate the institution's internal emergency medical response system to have the patient transported to an outside facility.

b) In the event Supervising Physician is not available when needed, PA may call and/or refer patients to other authorized physicians as designated by the Supervising Physician, or as otherwise deemed appropriate by PA.

5. SUPERVISION REQUIRED

The physician assistant named above (hereinafter referred to as PA) will be supervised in accordance with the written supervisor guidelines required by Section 1399.545 of the *Physician Assistant Regulations*.

6. SUPERVISING PHYSICIAN'S RESPONSIBILITIES

a) Supervising Physician(s) shall remain electronically available at all times while PA is performing medical services, unless another approved supervising physician who has signed a Delegation of Services Agreement for PA is so available.

b) To the extent required by Section 4(c) above, Supervising Physician shall review, countersign, and date within seven (7) days the medical record of any patient for whom PA issues or carries out a drug order for a Schedule II Controlled Substance. For other patients, Supervising Physician shall utilize one or more of the following mechanisms to supervise PA, as required by Section 1399.545 of the *Physician Assistant Regulations*.

☐ Examination of the patient by Supervising Physician the same day as care is given by PA

☐ Supervising Physician shall review, audit, and countersign every medical record written by PA within 30 days of the encounter.

☐ Supervising Physician shall audit the medical records of at least five percent (5%) of the patients managed by PA under protocols that shall be adopted by Supervising Physician and PA, pursuant to Section 1399.545(e)(3) of the *Physician Assistant Regulations*. Supervising Physician shall select for review those cases, which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient.

c) If PA is operating under interim approval, Supervising Physician shall review, sign, and date the medical records of all patients cared for by the PA within seven (7) days if Supervising Physician was on the premises when the patient was diagnosed or treated. If Supervising Physician was not on the premises at the time, he or she shall review, countersign, and date such medical records within 48 hours of the time the medical services were provided.

7. PROTOCOLS

This Agreement does not constitute the protocols required by Section 3502.1 of the Business and Professions Code or, if applicable, Section 1399.545(e)(3) of the *Physician Assistant Regulations*. Such protocols are on file at the practice site and may incorporate by reference appropriate medical texts.

8. NO THIRD PARTY BENEFICIARIES

This Agreement shall not be construed as creating rights in or obligations to any third party. It is the intent of the parties solely to fulfill the requirements of the *Physician Assistant Regulations* for a Delegation of Services Agreement and for the mechanisms to be used by the Supervising Physician in supervising the PA.

Physician Assistant	Date
Supervising Physician	Dated
Supervising Physician	Dated
Supervising Physician	Dated
Supervising Physician	Dated

STATE OF CALIFORNIA
DEPARTMENT OF CORRECTIONS AND REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
DUTY STATEMENT

JOB TITLE: PHYSICIAN ASSISTANT-CF
DIVISION: HEALTH CARE SERVICES
DEPARTMENT: MEDICAL

DEFINITION:

Under the direction of a supervising physician, the Physician Assistant-CF provides routine primary care services to the adult male and female inmate population, including assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status. Primary Care Services to be provided by a Physician Assistant-CF must be delegated in writing by the supervising physician. Primary care services may be provided in Reception Centers, Outpatient Housing Units, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Correctional Treatment Centers, General Acute Care Hospitals, Hospice Units, and other clinical settings as determined by the Health Care Manager or designee. The Physician Assistant-CF also may act as first or second assistant in surgery under the supervision of an approved supervising physician.

DUTIES:

80% Responsible for the evaluation and treatment of inmates as assigned by carrying out the following functions:

1. Obtain relevant medical histories. Perform physical examinations based on age and history.
2. Conduct preventive screening procedures based on age and history.
3. Formulate the appropriate differential diagnosis based upon the history, physical examination and clinical findings.
4. Develop and implement appropriate treatment plans that include:
   - Ordering appropriate diagnostic tests (laboratory, x-rays, electrocardiograms, etc);
   - Identifying and ordering appropriate pharmacologic agents, adhering to the CDCR statewide formulary whenever possible;
   - Identifying non-pharmacologic interventions;
   - Making appropriate referrals to other health professionals (mental health, specialty services, dentistry, etc) and community agencies upon release from CDCR;
   - Consulting with a supervisory or collaborating physician on-site or via electronic means, as clinically indicated;
   - Developing a patient education plan that promotes inmate-patient participation in the plan of care;
   - Counseling and educating patients on health behaviors, self-care skills, and treatment options.
5. Document all assessments and care provided for each patient contact, maintaining detailed, legible, and confidential medical records in accordance with Department policies and procedures.

6. Monitor patients to determine the effectiveness of the plan of care. Reassess and modify the plan of care as necessary to achieve medical and health goals.
7. Conduct patient rounds in the inpatient setting.
8. Perform pre-parole evaluations.
9. Perform administrative segregation clearances.
10. Perform evaluations of patients to determine their suitability or fitness for vocational/education programs.
11. Complete CDC Form 128-C in accordance with department policy.
12. Perform other duties related to patient care as assigned by the Health Care Manager or designee.

10% Respond to medical emergencies in the clinics, Outpatient Housing Units, Correctional Treatment Center, General Acute Care Hospital, or off grounds as necessary. Conduct emergency examinations on injured staff and provide First Aid care.

10% Participate in multidisciplinary care conferences and professional practice group meetings (e.g., Peer Review, Continuous Quality Improvement, Pharmacy and Therapeutics, etc.). Assist in updating Standardized Procedures as necessary. Attend continuing education seminars necessary to maintain licensure and certification requirements.

Nurse Practitioner	Date Reviewed
Supervisor's Signature	Date Reviewed

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES

REFERENCE BOOKS
FOR PHYSICIAN ASSISTANTS

REQUIRED BOOKS

Two (2) copies of each of the following textbooks shall be maintained in the Physician Assistant Resource Library

California Department of Corrections and Rehabilitation Formulary

Cecil Textbook of Medicine (Two Volume with CD-ROM), Goldman, L., (2001).
21st Edition, W.B. Saunders Company

Clinical Guidelines in Family Practice, Uphold, C., Graham, M., (2003).
Barmarrae Books

Clinical Practice in Correctional Medicine, Puisis, M., (2006).
2nd Edition, Mosby-Yearbook Inc.

Current Emergency Diagnosis & Treatment, Stone, C.K., Humphries, R.L. (2004).
McGraw-Hill Companies, Inc.

Current Medical Diagnosis, McPhee, S.J., Papadakis, M.A., Tierney Jr., L.M. (2007).
Forty-Sixth Edition, McGraw-Hill Companies, Inc.

Current Obstetric & Gynecological Diagnosis and Treatment (2002).
9thEdition, McGra w-Hill Companies, Inc.

Current Surgical Diagnosis &Treatment, Way, L.W., Dpherty, G.M. (2002).
McGraw-Hill/Appleton & Lange

Ferri's Clinical Advisor 2006: Instant Diagnosis and Treatment
(Text with CD-ROM for Windows), Ferri, F. , Mosby-Yearbook, Inc.

Guide to Clinical Preventive Services: Report to the U.S. Preventive Services Task Force,
3rd Edition, January 2002

Guidelines to Clinical Preventive Services: Report of the U.S. Preventive Services Task Force,
U.S. Public Health, 2005

Outpatient Medicine, Fihn, S.D., DeWitt, D.E., (1997).
2nd Edition, W.B. Saunders Company

Physician's Desk Reference, 2006 Library Edition.
60th Edition, Medical Economics, Inc.

Textbook of Primary Care Medicine, Noble, J., (2000).
3rd Edition, Mosby-Yearbook Inc.

Tintinalli's Emergency Medicine: A Comprehensive Guide, (2004).
6thEdition, McGra w-Hill Companies, Inc.

Washington Manual of Medical Therapeutics, Washington University (2007).
32nd Edition, Lippincott Williams & Wilkens

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PRIMARY CARE

A. DEFINITION:
This protocol covers the procedure for age-appropriate health care management in clinics, Reception Centers, and inpatient units. Scope of care includes assessment, diagnosis, management and treatment of episodic illness and chronic illness, as well as health promotion and general evaluation of health status.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Reception Centers, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:

1. Subjective Data:
   a. Screening: age appropriate history that includes but is not limited to: past medical history, surgical history, hospitalizations/injuries, habits, family history, psychosocial history, allergies, current medications, treatment, and review of systems.
   b. Ongoing/Continuity: review of symptoms and history of relevant to the disease process or presenting complaint.
   c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

D. DIAGNOSIS:
Assessment of data from the subjective and objective findings identifying risk factors and disease processes. May include a statement of current status of disease (e.g., stable, unstable, uncontrolled).

E. PLAN:

1. Treatment:
   a. Age appropriate screening tests and/or diagnostic studies for purposes of disease identification.
   b. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   c. Immunization update.
   d. Referral to specialty clinics and supportive services as needed.

2. Patient Conditions Requiring Physician Consultation:
   a. Whenever situations arise which go beyond the competence, scope of practice, or experience of the Nurse Practitioner/Physician Assistant.
   b. Whenever patient condition fails to respond to the treatment plan in an appropriate timeframe.
   c. Acute decompensation of patient condition.
   d. Any patient condition that does not fit the commonly accepted diagnostic pattern for a disease or disorder.
   e. Unexplained historical, physical or laboratory findings.
   f. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.
   g. Initiation or change of medication other than those in the formulary.
   h. Problem requiring hospital admission or potential hospital admission.
   i. When ordering complex imaging studies or procedures.

3. Education:
   a. Patient education appropriate to diagnosis including treatment modalities and lifestyle counseling (e.g., diet, exercise).
   b. Anticipatory guidance and safety education that is age and risk factor appropriate.

4. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, laboratory tests/diagnostic studies, treatment plan, procedure notes, patient education, and discharge notes. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

URGENT/ACUTE CARE

A. DEFINITION:
This protocol covers the procedure for patient visits for urgent problems, which include but are not limited to common acute problems, uncommon, unfamiliar, unstable, or complex conditions.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Triage Treatment Area (TTA), Outpatient Housing Units (OHU), Correctional Treatment Centers (CTC).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:

1. Subjective Data:
   a. History and review of symptoms relevant to the presenting complaint and/or disease process.
   b. Pertinent past medical history, surgical history, family history, psychosocial and occupational history, hospitalizations/injuries, current medications, allergies, and treatments.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

D. DIAGNOSIS:
Assessment of data from the subjective and objective findings to identify disease processes. May include a statement of current status of disease (e.g., stable, unstable, uncontrolled).

E. PLAN:

1. Treatment:
   a. Common acute problems: perform diagnostic studies for the purposes of disease identification.
   b. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   c. Referral to physician, specialty clinics, and supportive services as needed. Supervising physician is notified if his/her name is used on a referral to a specialty physician or department.
   d. For uncommon, unfamiliar, unstable, or complex conditions consult a physician regarding evaluation, diagnosis, and/or treatment plan. Management of the patient is either in conjunction with a supervising physician or by complete referral to a community provider and/or facility.

2. Education:
   a. Patient education including treatment modalities.
   b. Discharge information and instructions.

3. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, laboratory tests/diagnostic studies, treatment plan, procedure notes, patient education, and discharge notes. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistan0t Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

TERTIARY CARE

A. DEFINITION:
This protocol covers the procedure for patients who present with acute, life threatening conditions including but not limited to respiratory or cardiac arrest.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:
1. Setting: Yard Clinics, Sick Call Clinics, Triage Treatment Area (TTA), Correctional Treatment Centers (CTC), Outpatient Housing Units (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE:
1. Subjective Data:
   a. Brief history, including precipitating event or mechanism of injury if applicable, and review of symptoms relevant to the presenting complaint.
   b. Pertinent past medical history, hospitalizations/injuries, allergies, current medications, and tetanus immunization status if applicable.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory tests as indicated.

D. DIAGNOSIS:
Assessment of data from subjective and objective findings. May include a statement of current status (e.g., stable or unstable).

E. PLAN:
1. Treatment:
   a. Initial evaluation and stabilization of the patient with concomitant notification of and immediate management by a physician. Initial treatment may include all modalities of Advanced Cardiac Life Support.
   b. Transfer to higher level of care as indicated.

2. Education:
   Patient education consistent with the assessment of the condition.

3. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, treatment, procedures, and final disposition. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

FURNISHING DRUGS AND DEVICES

A. DEFINITION:
This protocol covers the procedure for Nurse Practitioners/Physician Assistants furnishing drugs or devices. "Furnishing is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure." The ordering of drugs and devices includes the initiation, discontinuation and/or renewal of prescription medications and/or over-the-counter equivalents.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Reception Centers, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Physician supervision required. The physician must be available at least by telephone.
3. Patient Conditions:
   Nurse Practitioners who possess a current furnishing number may furnish or order drugs and devices incidental to the provision of:
   - Family planning services
   - Routine health care rendered to essentially healthy persons
4. Other:
   Nurse Practitioners/Physician Assistants may furnish Schedule II through Schedule V controlled substances when in possession of a Drug Enforcement Administration (DEA) registration number.

   Physician Assistants must obtain advance approval (specific to the patient being treated) from a supervising physician prior to issuing drug orders for non-formulary drugs.

   In addition, Physician Assistants must obtain advance approval from a supervising physician before writing a drug order for Schedule II through Schedule V controlled substances, unless the Physician Assistant has completed an education course that covers controlled substances and, the course meets standards approved by the Physician Assistant Committee.

C. DATABASE:
1. Subjective Data:
   a. Age appropriate history and review of symptoms relevant to the presenting complaint or disease process to include current medication, allergies, current treatments and substance abuse history.

b. No personal and/or family history, which is an absolute contraindication to use of the drug or device.
c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation to indicate or contraindicate use of the drug or device if necessary.

D. DIAGNOSIS:
Assessment data consistent with use of the drug or device. No absolute contraindications to use of the drug or device.

E. PLAN:
1. Treatment:
   a. Initiate, adjust, discontinue, and/or renew medication and devices included on, but not limited to the attached formulary. Use lowest effective dosage per pharmaceutical references. The name and furnishing number of the Nurse Practitioner shall be included on all Nurse Practitioner prescription transmittal order forms.
   b. Orders for Schedule IV and V controlled substances shall not exceed 90 days in duration.
   c. For chronic conditions such as acute, intermittent but recurrent pain, **or** continuous chronic pain the treatment plan shall be established in collaboration with a physician.
   d. Monitor the effectiveness of the prescribed drug or device.

2. Patient Conditions Requiring Physician Consultation:
   a. Non-responsiveness to appropriate therapy.
   b. Unusual or unexpected side effects.
   c. Initiation or change of medication other than those in the formulary.
   d. Unexplained historical, physical or laboratory findings.
   e. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.

3. Education:
   a. Provide education on why medication is being prescribed, expected outcomes, side effects, and precautions.
   b. Provide instruction to the patient on how to take the medication or use the device correctly. Communicate effectively and appropriately based upon the patient's primary language spoken.

4. Follow-up:
As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, name of the drug (or device), condition for which the drug or device is prescribed, dose, route, frequency, quantity, number of refills authorized, patient education, and

timeframe for follow-up. For controlled substances the name, title, signature, and DEA number of the Nurse Practitioner/Physician Assistant shall be included on the prescription transmittal order form. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PATIENT-SPECIFIC PROTOCOL
SCHEDULE II AND SCHEDULE III CONTROLLED SUBSTANCES

A. DEFINITION:
This protocol covers the procedure for Nurse Practitioners/Physician Assistants furnishing or ordering drugs classified as Schedule II and Schedule III controlled substances. Schedule II and Schedule III controlled substances must be furnished in accordance with a patient-specific protocol. "A patient-specific protocol is a protocol contained within a standardized procedure that specifies which categories of patients may be furnished this class of drugs."

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Yard Clinics, Sick Call Clinics, Chronic Care Clinics, Hospice Unit, Correctional Treatment Centers (CTC), Outpatient Housing Unit (OHU).
2. Supervision: Physician supervision required. The physician must be available at least by telephone.
3. Patient Conditions:
   Schedule II and Schedule III controlled substances may be ordered for patients in the following categories:

Category	Examples
Respiratory	Marked cough; injury
Dermatology	Shingles; dermal injuries
Musculoskeletal	Marked strain, sprain or fracture; marked arthritis Inflammatory disorders
Neurological	Headache, marked myofascial pain or neuropathies
EENT	Severe pain from EENT infection or injury
GU	Urinary calculi
Post-operative pain	

4. Other:
   Nurse Practitioners/Physician Assistants must possess a current Drug Enforcement Administration (DEA) registration number in order to furnish controlled substances.

   Physician Assistants must obtain advance approval (specific to the patient being treated) from a supervising physician prior to issuing drug orders for Schedule II through Schedule V controlled substances, unless the Physician Assistant has completed an education course that covers controlled substances and, the course meets standards approved by the Physician Assistant Committee.

C. DATABASE:

1. Subjective Data:
   a. Age appropriate history and review of symptoms relevant to the presenting complaint or disease process to include current medication, allergies, current treatments and substance abuse history.
   b. No personal and/or family history, which is an absolute contraindication to use of the drug.
   c. Pain history to include onset, location, and intensity.

2. Objective Data:
   a. Physical exam consistent with history and clinical assessment of the patient.
   b. Laboratory and imaging evaluation to indicate or contraindicate use of the drug if necessary.

D. DIAGNOSIS:

Assessment data consistent with use of the drug or device. No absolute contraindications to use of the drug or device.

E. PLAN:

1. Treatment:
   a. Initiate, adjust, discontinue, and/or renew medication. Limit quantity of tablets as appropriate to the condition being treated. Orders for controlled substances shall not exceed 90 days in duration.
   b. Monitor the effectiveness of the medication.

2. Patient Conditions Requiring Physician Consultation:
   a. Non-responsiveness to appropriate therapy.
   b. Unusual or unexpected side effects.
   c. Unexplained historical, physical or laboratory findings.
   d. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician.

3. Education:
   a. Provide education on why medication is being prescribed, expected outcomes, side effects, and precautions.
   b. Provide instruction to the patient on how to take the medication correctly. Communicate effectively and appropriately based upon the patient's primary language spoken.

4. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:

All information related to patient care shall be documented in the Unit Health Record. Documentation shall be patient-specific and include but not be limited to assessment, diagnosis, name of the medication, condition for which medication is prescribed, dose, route, frequency, quantity, number of refills authorized, patient education, and timeframe for follow-up. The name, title, signature, and DEA number of the Nurse Practitioner/Physician Assistant shall be included on the prescription transmittal order form. Physician consultation and/or referral shall be noted in the patient's chart, and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

Physician Assistant Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PROCEDURES AND MINOR SURGERY

A. DEFINITION:
This protocol covers the process to be utilized by Nurse Practitioners/Physician Assistants when performing minor surgical procedures.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Specialty Clinics, Triage Treatment Area (TTA).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.
3. Patient Conditions:
   Minor surgical procedures performed by Nurse Practitioners/Physician Assistants shall be limited to the following*:
   - Casting, simple
   - Chemical or electrocautery of external, non-facial, non-malignant lesions less than 1 cm in size (e.g., warts)
   - Epidermal cyst removal (non-facial) less than 3 cm in size
   - Incision and drainage of non-facial abscess less than 5 cm in size
   - Suture non-facial lacerations less than 5 cm in size
   - Mole removal (non-facial)
   - Punch or shave biopsy
   - Toenail removal
4. Other:
   The Nurse Practitioner/Physician Assistant must complete appropriate training and satisfactorily demonstrate competence prior to performing the above procedure(s) independently. Competency shall be assessed by the supervising physician through direct observation of the Nurse Practitioner/Physician Assistant performing the above procedure(s).

   A physician consult shall be obtained prior to applying any casting.

C. DATABASE:

1. Subjective Data:
   a. History and review of symptoms relevant to the presenting complaint or procedure to be performed.
   b. Pertinent past medical history, surgical history, family history, psychosocial and occupational history, hospitalizations/injuries, current medications, allergies.

2. Objective Data:
   a. Physical exam appropriate to presenting symptoms.
   b. Laboratory and imaging evaluation, as indicated, relevant to history and exam.

*With additional training and demonstrated competence, exceptions can be made on a case-by-case basis.

D. DIAGNOSIS:
Assessment of subjective and objective data to identify disease processes.

E. PLAN:
1. Treatment:
   a. Physician consultation shall be obtained before applying any casting.
   b. Patient consent shall be obtained before procedure is performed.
   c. The Nurse Practitioner/Physician Assistant shall follow standard medical technique for the procedures as described in department approved reference books.
   d. All moles and biopsy specimens shall be sent to the Pathologist for analysis.
   e. Initiation or adjustment of medication per Furnishing Drugs and Devices protocol.
   f. Referral to physician, specialty clinics, and supportive services as needed.

2. Patient Conditions Requiring Physician Consultation:
   a. Acute decompensation of patient situation
   b. Unexplained historical, physical or laboratory findings
   c. Uncommon, unfamiliar, unstable, and/or complex patient conditions
   d. Upon the request of the Nurse Practitioner/Physician Assistant, or Physician
   e. Initiation or adjustment of medication other the those in the formulary
   f. Problem requiring hospital admission or potential hospital admission
   g. When ordering complex imaging studies or procedures

3. Education:
   Discharge information and instructions.

4. Follow-up:
   As indicated and appropriate to patient health status and diagnosis.

F. RECORD KEEPING:
Patient visit, consent forms, and other procedure specific information shall be documented in the patient's chart. Physician consultation and/or referral shall be noted in the patient's chart and include the name of the physician.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
INMATE MEDICAL SERVICES
STANDARDIZED PROCEDURE
NURSE PRACTITIONER/PHYSICIAN ASSISTANT

PRENATAL CARE

A. DEFINITION:
This protocol covers the procedure for the routine prenatal care for pregnant inmate-patients.

B. CIRCUMSTANCES UNDER WHICH THE NURSE PRACTITIONER/PHYSICIAN ASSISTANT MAY PERFORM THESE FUNCTIONS:

1. Setting: Ambulatory Care Clinics, Yard Clinics, Sick Call Clinics, Outpatient Housing Units (OHU).
2. Supervision: Per department policy for Nurse Practitioners and Physician Assistants.

C. DATABASE (Initial Visit):

1. Subjective Data:
   a. Screening: complete age appropriate history including but not limited to: menstrual history, obstetrical history, medical history including past illnesses, surgeries, current use of medications, habits, family history, psychosocial history, allergies, and current concerns.
   b. Symptoms relevant to the prenatal health process.

2. Objective Data:
   a. Complete physical examination, including internal gynecologic exam and bimanual exam.
   b. Initial prenatal laboratory work to include complete blood count, urinalysis, Pap test, blood type and Rh factor, antibody screening for Rh antibody, Rubella titer, Hepatitis viral screening, testing for sexually transmitted diseases.
   c. Diagnostic studies based on information provided on the Hollister Maternal/Newborn Record System form.

D. DIAGNOSIS:
Assessment and diagnosis of pregnancy status, risk factors, or disease process consistent with subjective and objective findings.

E. PLAN:

1. Treatment Plan:
   a. Routine prenatal examinations shall be done at the following intervals:
      1. Every four (4) weeks during the first trimester and up to 24-26 weeks gestation
      2. Every three (3) weeks up to 30 weeks gestation
      3. Every two (2) weeks up to 36 weeks gestation
      4. Weekly after 36 weeks gestation up until delivery

b. Routine prenatal examination shall include:
   1. Questioning the patient about any present problems
   2. Weighing the patient
   3. Blood pressure
   4. Urinalysis for protein, glucose, and albumin
   5. Measurement of the uterine fundus
   6. Auscultation of the fetal heart with fetoscope or doptone, or both
   7. Determination of the position of the fetus if possible
   8. Physical examination for edema
c. Glucose screen for gestational diabetes at 24 to 28 weeks or initial visit if history is positive for diabetes. Plasma glucose value > 160 mg/dL requires glucose tolerance test.
d. Hematocrit should be repeated at 28 to 36 weeks and at the following visit if the patient's previous reading was below 36%.
e. Immunization update. Repeat Rh antibody titer at 26 to 28 weeks gestation. If patient is Rh-negative administer Rhogam.
f. Additional diagnostic studies shall be ordered based on information provided on the Hollister Maternal/Newborn Record System forms.
g. Refer to Specialty Clinics and supportive services as needed (e.g., Medical Social Worker for Case Management, Dentist, HIV counseling and testing, etc).
h. Initiate prenatal vitamins, iron, and folic acid per Furnishing Drugs and Devices protocol.
i. Positively identified pregnant inmate-patient's shall be provided with the following:
   1. Two (2) extra cartons of milk, two (2) extra servings of fresh fruit, and two (2) extra servings of fresh vegetables daily. Additional nutrients may be ordered as necessary.
   2. Comprehensive Accommodation Chrono (CDCR Form 7410) for any indicated medical clearances or restrictions.
j. The Supervising Obstetrician shall examine all prenatal patients at 36 weeks gestation.

2. Patient Conditions Requiring Physician Consultation:
   a. Whenever situations arise which go beyond the competence, scope of practice, or experience of the Nurse Practitioner/Physician Assistant.
   b. No fetal heart tones heard by 22 weeks gestation.
   c. The patient feels no movement by 22 weeks, or none for one (1) week at any time after this.
   d. Blood pressure above 140/90 mm Hg on two checks after bed rest.
   e. Patient has albuminuria or persistent edema.
   f. Patient has glycosuria, proteinuria, or symptoms of pylelonephritis.
   g. Hematocrit is below 33%.
   h. Lack of regular fetal growth.

i. If the Nurse Practitioner/Physician Assistant questions the position of the fetus (e.g., breech or transverse lie) or any time the Nurse Practitioner/Physician Assistant is in doubt about the patient's status.
j. Uterus size is 2 weeks greater or smaller than expected from estimated weeks of gestation.
k. Upon the request of the Nurse Practitioner/Physician Assistant, or Supervising Obstetrician.
l. Significant condylotomy or herpes develop.

3. Education:
   a. Normal process and progression of pregnancy
   b. Psychosocial issues related to pregnancy
   c. Pregnancy information pamphlets and other pertinent material
   d. Signs and symptoms of complications
   e. Fetal kicks, stages of labor
   f. Pain management during labor and delivery

4. Follow-up:
   As indicated in above treatment plan.

F. RECORD KEEPING:
All information related to prenatal care shall be documented in the Unit Health Record. Physician consultation and referral for support services shall be noted in the patient's chart.

RECORD OF PHYSICIAN ASSISTANTS AUTHORIZED TO PERFORM THIS PROCEDURE

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Physician Assistant — Date
Physician Assistant License#
DEA #

Quality Management / Oversight

- Overview
- Clinical Support Unit
- Professional Practice Executive Committee
- Death Reviews
- Utilization Management

- Pattern of Practice Reviews

- Death Review

QUALITY MANAGEMENT

Overview

The CDCR provides a variety of programs and systems to assure that the quality of medical care for inmate-patients is maintained, providers maintain clinical standards, and the utilization of resources are appropriate. Many of these programs and requirements are a result of the Class action lawsuit and Receivership. These programs consist of the following areas:

CLINICAL SUPPORT UNIT

An important component of the quality management program is the Clinical Support Unit (CSU) which was formerly known as Quality Management Assessment Team (QMAT). There are three CSU teams, one each for the Southern, Central and Northern Region. Eache CSU team consists of experienced physicians and mid-level providers who perform independent audits/assessments of the quality of medical care delivered at each institution. These include involvement in:

- 10 day Clinical Performance Appraisal of new providers
- 60 day Clinical Performance Appraisal of new providers
- Periodic Clinical Performance Appraisal of all providers (planned)
- Detailed review of each inmate-patient death
- Pattern of Practice review of individual provider (as needed)
- Sentinel event reviews
- Case monitoring
- Clinical Preceptoring
- Provider improvement education and monitoring

The results of these evaluations are shared with the provider and management and are meant to ensure that our inmate-patients are receiving appropriate constitutional healthcare. The reviews help to identify system problems as well as deficiencies with individual providers. The CSU is an essential part of the DCHCS strategy to improve the access, quality and continuity of health care services.

PROFESSIONAL PRACTICE EXECUTIVE COMMITTEE (PPEC)

The Professional Practices Program places all Medical Staff into one statewide Medical Staff Organization. Both State employee and contractor Physicians, Dentists, Podiatrists, Psychologists, Nurse Practitioners, Physician Assistants, Certified Registered Nurse Anesthetists, and Psychiatric Social Workers are members of the organized Medical Staff.

The **Professional Practices Executive Committee (PPEC)** is the official peer review body for the Division of Correctional Health Care Services. It is comparable to a hospital's Medical Executive and Quality/Patient Safety Committees. PPEC is composed of the Regional Medical Directors and other clinical chiefs. Dr. Kent Imai, the representative from the receiver's office also attends PPEC meetings. PPEC meets at least twice monthly and sserves two major functions:

1. Reviews all allegations of clinical misconduct involving CDCR HCS licensed independent practitioners
    - Manages for cause peer review process
    - Takes action to assure patient safety
2. Makes recommendations regarding statewide professional practice policies

How are cases brought to the committee?

- **Death Reviews** and other **sentinel events** account for approximately 70% of PPEC referrals
- Concerns can come from many sources but must be deemed credible by managers or PPEC members
- These cases are meticulously evaluated by CSU Consultants for standard of care and system issues
- Findings of questionable professional practice are referred to PPEC
- PPEC makes every effort to thoroughly investigate and objectively and reasonably decide questions of quality of care which arise from referrals. The investigation often includes performance of a review of the provider's cases to obtain a "**Pattern of Practice**".
- PPEC's foremost responsibility is to decide if a provider's practice constitutes a danger to inmate/patients. That is the critical issue which underlies all decisions at each step of the process
- If a provider's practice if felt to constitute a danger to inmate-patients restriction or suspension of clinical privileges may occur at any time during the PPEC process

If the case has not been dismissed and full privileges cannot be restored after investigation and an informal hearing by PPEC, a proposal for final action will be recommended to the **Governing Body**. (The Governing Body is made up by medical and legal leadership within CDCR.) PPEC may make a recommendation for:

- Monitoring
- Retraining
- Restriction of privileges
- Any combination of the above
- The recommendation could also be for revocation of privileges

The PPEC advises the Governing Body. The Governing Body **may or may not follow the recommendations** of the PPEC.
Providers have due process during the PPEC proceedings and the right to a formal evidentiary hearing if they dispute the Governing Body's proposed final action.

Death Review (IMSPP&P Volume 1, Chapter 7)

All inmate-patient deaths are reported to the DCHCS and reviewed according to IMSPP&P. Reporting and review is completed on each inmate-patient death for the following reasons:

- To determine the appropriateness of the health care provided.
- To determine the cause of death.
- To ensure that corrective measures are implemented, where indicated.
- To allow for statistical analysis and research for the purpose of improving the delivery of health care.

Utilization Management

The purpose of the Utilization Management (UM) Program is to enhance the value and quality of care through the appropriate use of Specialty Services, optimal clinical practice, and the use of resources. The UM Program operates under the Specialty Care Program Subcommittee.

Each institution has a UM Nurse. This RN is responsible for the review of clinical referrals for inpatient beds and specialty care services to ensure that referrals are appropriate. The UM Program combines prospective, concurrent, and retrospective reviews to ensure that requested specialty services are medically necessary and are provided at the appropriate level and site of care.

The UM review process can involve various steps:

- UM Nurse designated is the designated first level reviewer. The UM Nurse reviews the Physician Requests for Services (RFS) is able to process those that meet program guidelines/

- The HCM, or designee, is the second level reviewer, reviewing any requests the UM Nurse is unable to approve per program guidelines.

- The Medical Authorization Review (MAR) Subcommittee is the third level reviewer. The MAR Subcommittee reviews requests for service that the second level reviewer approves which do not meet criteria, and also reviews appeals and complex cases.

- The fourth and final level of review and appeal is the Health Care Review Committee (HCRC). Refer to the UM Guidelines for a detailed description of the review and appeal processes.

Pattern of Practice

Review

Division of Correctional Health Care Services

Pattern of Practice Review

(Confidential Peer Review Document)

Last Name	**First Name**	**Date of Review**
Classification (Choose One)	**Status (Choose One)**	**Institution**
Reviewer:		**Region (Choose One)**

Reason for Review	
Summary	***Total Cases Reviewed*** ***Cases with No Departure*** % ***Cases with Simple Departure*** % ***Cases with Extreme Departure*** % ***Legibility*** (Choose One) ***Signature Readable*** (Choose One) ***Overall quality of care*** (choose one) ***Would you send your mother to be cared for by this provider?*** (choose one)
Recommendation	

BACKGROUND INFORMATION: *(Including Credentials, QICM Results, Current Work Assignment)*

Medical Education

Medical School

Post-Graduate

Internship

Residency

Licensing

Board Certification

INTERVIEWS: *(Including supervisor and interviews with the provider)*

METHODOLOGY: *(Including how cases were selected for review)*

Number of charts received: 00 (00 death cases, 0 TTA cases, 0 Sick Call cases, 0 Chronic Care cases, 0 CTC/OHU/SNF/GACH cases)

Number of charts requested: 00(including death charts)

Review of death charts for the last 6 months: 00

Criteria for selection:

OTHER INFORMATION: *(Including death reviews and results of prior reviews)*

CASE SUMMARY: *(Indexed to case details below)*

Case #	***Clinical Context***	***No Departure***	***Simple Departure***	***Extreme Departure***
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.				

CASE DETAILS: *(Include enough clinical context to show the complexity of the case and the significance of departures from the standard of care. When there is a departure from the standard of care, state what a reasonable provider should do. If the patient was at risk of adverse outcome, state the possible adverse outcome and indicate the likelihood of its occurrence.)*

1. A12321, SMITH 70 M 3 VISITS 9/24/07-10/15/07 TTA SIMPLE DEPARTURE

Clinical Information Pertinent to this Encounter: Ut hendrerit purus. Donec condimentum. Pellentesque pulvinar dignissim lorem. Cras gravida mauris et ligula. Sed aliquam neque. Cras gravida placerat urna. Cras nisl. Duis congue. Nullam vitae dolor id nunc ultricies dapibus. Nam vitae velit. Duis laoreet mollis lacus. Nam laoreet tellus a nisi.

Departures from Standard: Suspendisse mollis. Curabitur nec purus. Phasellus sit amet dui vitae justo tristique mollis. Proin non odio. Nam pharetra, nulla eget tincidunt vulputate, risus ante placerat erat, eu aliquam lorem velit ac quam. Maecenas nunc. Suspendisse a sem eget odio posuere euismod. Maecenas in ipsum. Nullam tellus dui, mollis ac, condimentum in, feugiat id, purus. Sed ullamcorper iaculis massa. Integer lobortis justo venenatis nisl.

2.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

3.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

4.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

5.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

6.

Note – copy one of these tables and paste it in again when you want to add more cases to this review.

Death

Review

Division of Correctional Health Care Services

Death Review Summary

(Confidential Peer Review Document)

CDCR#		**Institution**		**Date of Birth**	
Last Name		**First Name**		**Date of Death**	
Death Type	**(Choose One)**	**Resuscitation Effort:**	**Y** ☐ **N** ☐ **DNR** ☐ **Unknown** ☐		
Autopsy Performed?	**Y** ☐ **N** ☐	**Results Available?**	**Y** ☐ **N** ☐	**Time of Death**	
				Location *(ie: cell, ER, yard, etc.)*	
Date of Review:		**Reviewing Physician:**			

Primary Cause of Death			
Secondary Cause Death			
Tertiary Cause of Death			
Coexisting Conditions			
Diagnostic Categories of Death	**(Choose One)**	**Was the Death Preventable?**	**(Choose One)**

Was the cause of death the result of a pre-existing medical condition or did the inmate develop the condition after admission? *(Not applicable –cause of death was accidental injury, intoxication, suicide, or homicide.)*	**(Choose One)**
Had the inmate been receiving treatment for the medical condition after admission to the correctional facilities? (if "yes" answer questions below, otherwise leave blank *(Not applicable –cause of death was accidental injury, intoxication, suicide, or homicide.)*	**Y** ☐ **N** ☐ **Undetermined** ☐ **N/A** ☐
Evaluated by physician/medical staff	**Y** ☐ **N** ☐ **Undetermined** ☐
Had diagnostic tests (e.g. x-rays, MRI)	**Y** ☐ **N** ☐ **Undetermined** ☐
Received medications	**Y** ☐ **N** ☐ **Undetermined** ☐
Received treatment/care other than medications	**Y** ☐ **N** ☐ **Undetermined** ☐
Had surgery	**Y** ☐ **N** ☐ **Undetermined** ☐
Confined in special medical unit	**Y** ☐ **N** ☐ **Undetermined** ☐

Date(s)

Materials Reviewed: ie:

- ☐ Comprehensive Death Review _____
- ☐ Inmate Death Report _____
- ☐ Laboratory results _____
- ☐ Physician orders _____
- ☐ Progress notes _____
- ☐ Primary Care Flow Sheet _____
- ☐ Medication administration record _____
- ☐ Laboratory evaluations _____
- ☐ Other (please specify) _____

_____

_____

Summary: *(Please describe the patient's age, past medical history, and cause of death. List each relevant patient encounter, specifying the date of the encounter. Summarize each relevant encounter, emphasize provider care, also include relevant nursing and systemic issues.)*

Standard of Care: *(This is with regard to providers only. Describe what a reasonable and prudent practitioner would do in the same or similar circumstances. If applicable, describe how the care departed from the standard. Indicate whether the care met standards, was a simple departure, or an extreme departure from the standard of care. Discuss the competence (knowledge, skills, and attitudes) of involved providers.)*

Conclusion: *(Briefly summarize your overall findings. Discuss important nursing and systemic issues.)*

Recommendations: *(ie: close case, peer review investigation for a particular provider, referral for nursing practice review, specific system reforms, etc. If imminent danger to patient safety is determined, please indicate here as well as contact, via telephone, Drs. Chapnick or Winslow)*

1. Provide the Health Care Manager with a copy of this review and of the provider key. The Health Care Manager should review the systemic issues and take appropriate action. Each provider should be informed of their identifier and review the review findings.

2. Professional Practices Executive Committee referrals for providers with one or more extreme departures from the standard of care:

3. Nursing Executive referrals:

4. Regional Medical Director referrals:

5. Custody referrals:

Patient Litigation / Malpractice

PATIENT LITIGATION / MALPRACTICE

Liability Coverage / Malpractice Coverage for State Employees

Health care staff is provided with legal defense by the Attorney General's Office. Judgments against staff for actions arising out of the course or their employment are paid by the State of California under the provisions of the Government Code. Section 995 of the Government Code states:

> *Except as otherwise provided in Sections* 995.2 *and* 995.4, *upon request of an employee or former employee, a public entity shall provide for the defense of any civil action or proceeding brought against him, in his official or individual capacity or both, on account of an act or omission in the scope of his employment as an employee of the public entity.. .For the purposes of this part a cross-action, counter claim, or cross-complaint against an employee or former employee shall be deemed a civil action or proceeding brought against him.*

This section applies specifically to the State agreeing to defend you against civil actions brought against you in the course of your work as a State employee. The State will not pay for damages awarded as a result of a deliberate, malicious, or felonious act.

Notice that the Government will defend you against civil actions, not against criminal actions. If you commit a crime at work, the State will not defend you against the criminal charges. The next section lists reasons why the state may refuse to defend you against civil charges:

995.2. (a) A public entity may refuse to provide for the defense of a civil action or proceeding brought against an employee or former employee if the public entity determines any of the following:

(1) The act or omission was not within the scope of his or her employment.

(2) He or she acted or failed to act because of actual fraud, corruption, or actual malice.

(3) The defense of the action or proceeding by the public entity would create a specific conflict of interest between the public entity and the employee or former employee. For the purposes of this section, "specific conflict of interest" means a conflict of interest or an adverse or pecuniary interest, as specified by statute or by a rule or regulation of the public entity.

(b) If an employee or former employee requests in writing that the public entity, through its designated legal counsel, provide for a defense, the public entity shall, within 20 days, inform the employee or former employee whether it will or will not provide a defense, and the reason for the refusal to provide a defense.

(c) If an actual and specific conflict of interest becomes apparent subsequent to the 20-day period following the employee's written request for defense, nothing herein shall prevent the public entity from refusing to provide further defense to the employee. The public entity shall inform the employee of the reason for the refusal to provide further defense.

. (a) If a state employee provides his or her own defense against an action brought for an alleged violation of Section 8547.3, and if it is established that no violation of Section 8547.3 occurred, the public entity shall reimburse the employee for any costs incurred in the defense.

(b) A public entity which does provide for the defense of a state employee charged with a violation of Section 8547.3 shall reserve all rights to be reimbursed for any costs incurred in that defense. If a state employee is found to have violated Section 8547.3, he or she is liable for all defense costs and shall reimburse the public entity for those costs.

995.4. A public entity may, but is not required to, provide for the defense of:

(a) An action or proceeding brought by the public entity to remove, suspend or otherwise penalize its own employee or former employee, or an appeal to a court from an administrative proceeding by the public entity to remove, suspend or otherwise penalize its own employee or former employee.

(b) An action or proceeding brought by the public entity against its own employee or former employee as an individual and not in his official capacity, or an appeal there from.

Correctional Medicine
Special Topics

- Hepatitis C
- Transgender
- HIV
- Pain Management
- Diabetes
- Cocci
- Gastroenteritis
- TB
- M.R.S.A.
- Hospice / Pallative Care / DNR

Hepatitis C

Department of Corrections And Rehabilitation

Inmate Medical Services Policies and Procedures

Volume 7, Chapter 12 Chronic Care Program

Hepatitis C

Revised April 2008

TABLE OF CONTENTS

Section **Page(s)**

1. Policy…….....3

2. Background…….……3-5

3. Screening Procedure……5-6

4. Description of the HCV Chronic Care Program……..6-9

5. Counseling of the Newly Diagnosed …….……..10

6. HCV Primary Care and Cirrhosis Management…..……10-12

7. Pretreatment Evaluation for HCV Treatment……..12-13

8. Exclusion Criteria for HCV Treatment…….....13-14

9. Special Situations……14-15

10. Candidate for HCV Treatment and the Role of Liver Biopsy……...……15-16

11. HCV Treatment Procedure……16-19

12. Monitoring During HCV Treatment…….……..19

13. Duration of HCV Treatment……..19-20

14. Follow-Up After Completion of Treatment……20

15. Retreatment of HCV…….....20

16. Infection Control…….20-22

17. References…….……..23-25

18. Resources…….26

19. Attachments……27-40

1) POLICY

a) The Division of Correctional Health Care Services (DCHCS) shall operate a Hepatitis C Chronic Care Program that encompasses education, prevention, diagnosis, treatment, management, and infection control.

b) This program shall be periodically reviewed and revised to ensure that it reflects current scientific information and outcome data.

c) The DCHCS shall:
   i) Ensure that clinicians are familiar with the Hepatitis C Chronic Care Program.
   ii) Ensure that the Hepatitis C Chronic Care Program Policies and Procedures are available to the CDCR patient population.

2) BACKGROUND

a) Information about the virus
   i) Hepatitis C virus (HCV) is a single-stranded, enveloped, RNA virus with at least 6 major genotypes and more than 50 subtypes.
   ii) In the United States, the majority of isolates are genotype 1a (60%) or 1b (20%).[1]
   iii) Response to therapy is dependent upon genotype, with the best responses seen in genotypes 2 and 3.

b) Epidemiology[1-3]
   i) Prevalence
      (a) Approximately 4.5 million individuals in the United States (U.S.) have been infected with HCV, or 1.8% of the general population.
      (b) In the U.S., an estimated 3.3 million have persistent (chronic) infection.
      (c) In the U.S., the prevalence of HCV infection is strongly associated with socioeconomic status and high risk drug use.
      (d) In the U.S., the prevalence of HCV is greatest in African Americans, followed by Caucasians and then Hispanics.
      (e) Two recent serostudies of incoming prisoners to the CDCR demonstrated an HCV seroprevalence of approximately 34%.
   ii) Incidence[1]
      (a) The annual incidence of HCV in the U.S. has declined over the past 10-15 years.
      (b) The majority of newly acquired HCV infections in this country are related to illicit drug use.
      (c) Household and sexual exposure to HCV is less commonly identified as the probable mechanism of transmission.
      (d) Transfusions, occupational exposures, maternal to infant exposures, and other factors are infrequently implicated.

c) Transmission[1-6]. HCV is not spread by kissing, sneezing, hugging, coughing, sharing eating utensils, drinking glasses, or toilet seats, consuming food or beverages prepared by someone who is infected with HCV, or other types of casual contact.
   i) Percutaneous Transmission
      (a) Intravenous drug use
      (b) Use of contaminated needles and other paraphernalia associated with illicit drug use accounts for the majority of HCV infections in the United States.
      (c) Within one year of sharing needles, approximately 70% of individuals will acquire HCV.
      (d) Transfusions of blood and blood products.

(i) Infection occurs in more than 90% of seronegative recipients of blood from HCV antibody positive donors.
(ii) Since the routine screenings of blood for HCV was initiated in 1992, the risk for transfusion-associated HCV has decreased significantly.
(iii) Transmission can still uncommonly occur from donors who have recently become HCV infected but have not yet developed antibodies or elevated transaminases.
(iv) Clotting factors and immune globulin are treated by various viral inactivation procedures that markedly decrease the risk of HCV transmission.

ii) Occupational Transmission
(a) The risk for transmission following an accidental needlestick exposure to HCV infected individuals is approximately 1.8%.
(b) The risk for transmission of HCV following an accidental needlestick exposure is approximately six times greater than the risk for HIV (0.3%) and one-fifteenth the risk for acquiring HBV (30%).
(c) HCV infection has also been reported from blood splashed on the conjunctiva.
(d) Despite these risks, the prevalence of HCV infection among health care workers is commonly less than or similar to the general population.
(e) There has not been a single documented case of HCV transmission through urine, saliva, or feces unless these materials are visibly contaminated with blood.
(f) The prevalence of HCV among correctional officers is similar to that in the general population.

iii) Tattooing has been associated with HCV infection in some studies.

iv) Human bites that involve blood may be associated with HCV infection.

v) Sharing of razor blades, tooth brushes
(a) The risk associated with sharing of razor blades and tooth brushes has not been quantified.
(b) Individuals should be discouraged from sharing personal items that may be contaminated with blood.

vi) Sexual Transmission
(a) Data suggest that HCV is not efficiently transmitted through sexual contact.
(b) Persons with a history of sexually transmitted diseases and/or multiple sexual partners may have an increased risk of acquiring HCV infection.
(c) Individuals who are HCV infected should be informed of the low risk for sexual transmission and encouraged to discuss this risk and the use of barrier precautions with their sexual partners.

vii) Maternal to Infant Transmission
(a) HCV is uncommonly transmitted from mother to infant.
(b) The estimates for perinatal transmission frequency range from 0-8%.
(c) The timing of HCV transmission from mother to infant is not clear.
(d) Although HCV RNA has been detected in breast milk, most studies have shown no increased risk for HCV transmission among breast-fed infants.
(e) Neither the Centers for Disease Control and Prevention nor the American Academy of Pediatrics recommends that HCV infected mothers bottle feed to prevent HCV transmission.

d) Natural History of Infection[1,5]

i) Acute Infection
(a) Acute infection with HCV is usually asymptomatic.

(b) Acute infection can lead to nausea, malaise, right upper quadrant pain, jaundice, and dark urine. These signs and symptoms are indistinguishable from other types of acute viral hepatitis.
(c) Approximately 80-85% of persons infected with HCV develop persistent viremia, while 15- 20% of newly infected persons are able to clear the virus spontaneously.

ii) Chronic Infection
(a) The majority of persons with chronic HCV infection are asymptomatic.
(b) Chronic HCV infection has an unpredictable course that may be characterized by fluctuations in ALT levels.
(c) Some HCV infected persons develop fibrosis which can progress to cirrhosis.
(d) There is a poor correlation between serum ALT levels, serum HCV RNA levels, and the extent of inflammation or fibrosis on the liver biopsy.
(e) An estimated 15-25% of persons with chronic HCV infection develop progressive fibrosis of the liver leading to cirrhosis.
(f) High levels of alcohol consumption, older age at the time of infection, HIV infection, chronic HBV infection, steatosis, iron overload, and male gender increase the risk of disease progression.
(g) The degree of viremia ("viral load") and the HCV genotype do not affect the progression of liver disease.
(h) The degree of ALT elevation does not strongly correlate with the risk of disease progression, but persons who develop cirrhosis are more likely to have marked elevations in serum ALT levels.
(i) Once cirrhosis develops in persons with chronic HCV infection, 10-20% of individuals will decompensate within 5 years as evidenced by esophageal varices, ascites, coagulopathy, encephalopathy, or hepatocellular carcinoma (HCC).
(j) The risk for HCC in those with cirrhosis due to Hepatitis C is 1-4% per year.
(k) End Stage Liver Disease has emerged as the leading cause of death in HIV-infected persons in the U.S. largely due to HCV.

iii) Extrahepatic Manifestations of Hepatitis C Infection
(a) Essential Mixed Cryoglobulinemia. Up to half of HCV infected persons have circulating cryoglobulins.
(b) Membranoproliferative Glomerulonephritis. Membranoproliferative glomerulonephritis may occur in association with HCV-related cryoglobulinemia.
(c) Porphyria Cutanea Tarda. Chronic HCV infection has been found in 60-80% of those with non-familial porphyria cutanea tarda.

3) **SCREENING PROCEDURE**

a) All newly incarcerated patients shall be provided educational information regarding the prevention of HCV transmission
i) See attachment A, "Hepatitis C Patient Information"
ii) Several online resources for HCV and HIV/HCV co-infection educational materials and videos exist at http://www.hcvadvocate.org/hepatitis/factsheets.asp#Guides.
iii) A useful booklet and companion video for providers and patients, The "Get The Facts" Hepatitis C Patient Workbook, can be found at http://www.oasisclinic.org/8_BOOKS_VIDEOS.html.

b) Testing for HAV, HBV and HCV infections shall be offered to all newly incarcerated patients at intake and to all inmates with ongoing risk factors by their primary care provider.

c) **For those with a nonreactive (negative) HCV antibody test**. Patients who have a negative HCV antibody test can generally be considered not to be HCV infected. A false negative HCV antibody test can occur in the following situations:
   i) Acute HCV infection
   ii) Immunosuppressed states, such as HIV infection and chronic renal failure.
   iii) If the patient has unexplained liver disease and a negative HCV antibody test, consider HCV viral load testing.

d) **For those with a reactive HCV antibody test.** Patients who have a positive HCV antibody test shall be offered quantitative HCV viral load testing. Viral load testing is required to distinguish between those who have chronic persistent infection and those who have cleared their infection.
   i) If the quantitative HCV viral load test is negative, the more sensitive qualitative HCV nucleic acid test (lower limit of detection of 50 IU/mL) shall be obtained.
   ii) If the qualitative HCV viral load test is also negative, the patient is unlikely to be chronically infected with HCV and shall not be enrolled in the HCV Chronic Care Program. If the patient is co-infected with HIV, viral load testing shall be repeated once in 6-12 months.
   iii) If either viral load test is positive, the patient can be considered to be chronically infected with HCV and shall be enrolled in the HCV Chronic Care Program.
   iv) **Reporting:** All new cases of acute and chronic HCV shall be reported to the county health department by completing a Confidential Morbidity Report (CMR) form, in accordance with CDCR policy and California State law. The CMR forms may be obtained by fax from any local health center registrar or through the public health nurse at each CDCR institution.

4) DESCRIPTION OF THE HEPATITIS C CHRONIC CARE PROGRAM

a) The Hepatitis C Chronic Care Program shall:
   i) Educate patients and clinicians about hepatitis C
   ii) Provide HCV primary care, including health care maintenance and surveillance for cirrhosis and hepatocellular carcinoma
   iii) Treat appropriately selected hepatitis C infected patients based upon current scientific information and outcome data.

b) Roles and Expectations of Multidisciplinary Team (see tables 1 and 2 below)
   i) Primary Care Provider
      (a) provides individual counseling and education to the newly diagnosed patient (see attachment A, "Hepatitis C Patient Information" and B, "General Instructions for Hepatitis C Patients")
      (b) completes protocol for baseline assessment, including testing and health care maintenance, and refers appropriate patients for treatment to the HCV-treating Clinician (*see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")*
      (c) completes protocol for monitoring of chronically infected patients and for hepatocellular surveillance in patients with cirrhosis *(see attachment D, "Monitoring Chronic Hepatitis C Flowsheet")*
      (d) **prior to and during HCV therapy:**
         (i) follows the treatment algorithm as per protocol (see attachment E, "Algorithm for Hepatitis C Treatment")
         (ii) completes the pretreatment evaluation prior to referral to the HCV Chronic Care Program (*see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")*
         (iii) performs a baseline assessment for mental illness prior to HCV therapy and coordinates the assessment and treatment by psychiatrist, when indicated *(see*

attachment F, "Hepatitis C Antiviral Treatment Candidate Psychiatric and Psychological Review")

(iv) reviews all laboratory results, prescriptions, and side effects of HCV therapy such as anemia, leucopenia, and depression with HCV-treating Clinician, Pharmacist, Psychiatrist, and/or HCV Clinic Coordinator

(v) will be readily accessible to patients on therapy

ii) HCV Clinic Coordinator (RN, PA or NP)

(a) ensures the completion of the pretreatment evaluation (see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")

(b) ensures the completion of the baseline assessment for mental illness prior to HCV therapy and coordinates the ongoing assessment and treatment by psychiatrist, when indicated *(see attachment F, "Hepatitis C Antiviral Treatment Candidate Psychiatric/Psychological Review"*)

(c) follows the treatment algorithm as per protocol (see attachment E, "Algorithm for Hepatitis C Treatment")

(d) reviews the exclusion criteria for HCV treatment (see attachment G, "Exclusion Criteria for Combination Therapy")

(e) provides pretreatment education and review potential side effects of HCV therapy with all treatment candidates *(see attachment H, "Potential Side Effects of Interferon and Ribavirin Therapy")*

(f) obtains written consent for liver biopsy (when applicable) and HCV treatment for all individuals starting therapy *(see attachment I, "Hepatitis C Biopsy and Treatment Contract"*)

(g) monitors all patients on treatment as per protocol *(see attachments J1 and J2, "Hepatitis C Treatment Flow Sheet")*, and reviews all laboratory results and prescriptions with Pharmacist, Primary Care Provider, HIV Specialist, and HCV-treating Clinician in patients on HCV therapy

(h) manages side effects of HCV therapy as per protocol *(see attachment K, "Management of Side Effects")* in consultation with HCV-treating Clinician, Psychiatrist, HIV Specialist, and Pharmacist as needed

(i) will be readily accessible to patients on therapy

(j) works with medical personnel to ensure HCV screening is being be offered to all newly incarcerated patients at intake and to all inmates with ongoing risk factors

(k) coordinates and runs the peer health education/support groups

iii) HCV-treating Clinician

(a) is responsible for the overall care and treatment of HCV for individuals in the HCV Chronic Care Program

(b) determines appropriateness and readiness of each patient for treatment

(c) follows the treatment algorithm as per protocol (see attachment E, "Algorithm for Hepatitis C Treatment")

(d) refers patients for liver biopsy and for transplant, when indicated

(e) acts as a consultant for providers

(f) facilitates provider training and awareness of HCV

(g) **When HCV Clinic Coordinator is not available:**

(i) ensure the completion of the pretreatment evaluation (see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")

(ii) ensures the completion of the baseline assessment for mental illness prior to HCV therapy and coordinates the ongoing assessment and treatment by psychiatrist, when

indicated *(see attachment F, "Hepatitis C Antiviral Treatment Candidate Psychiatric/Psychological Review"*)

(iii) provides pretreatment education and review potential side effects of HCV therapy with all treatment candidates *(see attachment H , "Potential Side Effects of Interferon and Ribavirin Therapy")*

(iv) monitors all patients on treatment as per protocol (see attachments J1 and J2, "Hepatitis C Treatment Flow Sheet")

(v) manages side effects of HCV therapy as per protocol *(see attachment K, "Management of Side Effects")* and offer dose adjustment, use of GCSF, erythropoietin, and/or anti-depressant in consultation with Primary Care Provider, HIV Specialist, Psychiatrist, and Pharmacist as needed

(vi) will be readily accessible to patients on therapy

(vii) works with medical personnel to ensure HCV screening is being offered to all newly incarcerated patients at intake and to all inmates with ongoing risk factors

(viii) coordinates and runs the peer health education/support groups

iv) HCV Pharmacist

(a) performs education regarding medications and adherence counseling

(b) monitors drug-drug interactions both pre-treatment and at monthly intervals during treatment

(c) assists with monitoring, management, and counseling of side effects (e.g. anemia, leucopenia, depression, etc) in consultation with the HCV-treating Clinician

(d) dose adjusts and initiates GCSF and erythropoietin as per protocol *(see attachment K, "Management of Side Effects")*

(e) works with Primary Care Provider and HIV Specialist regarding medication management

v) Peer Health Educators

(a) provides support and attends education and support groups

vi) Hepatologist or Interventional Radiologist

(a) obtains liver biopsies for the assessment of fibrosis as indicated

vii) Psychiatrist or other Mental Health Professional

(a) assesses and treats those with underlying or emerging psychiatric illness prior to and during HCV therapy.

Table 1: Hepatitis C Chronic Care Program Team Model without HCV Clinic Coordinator

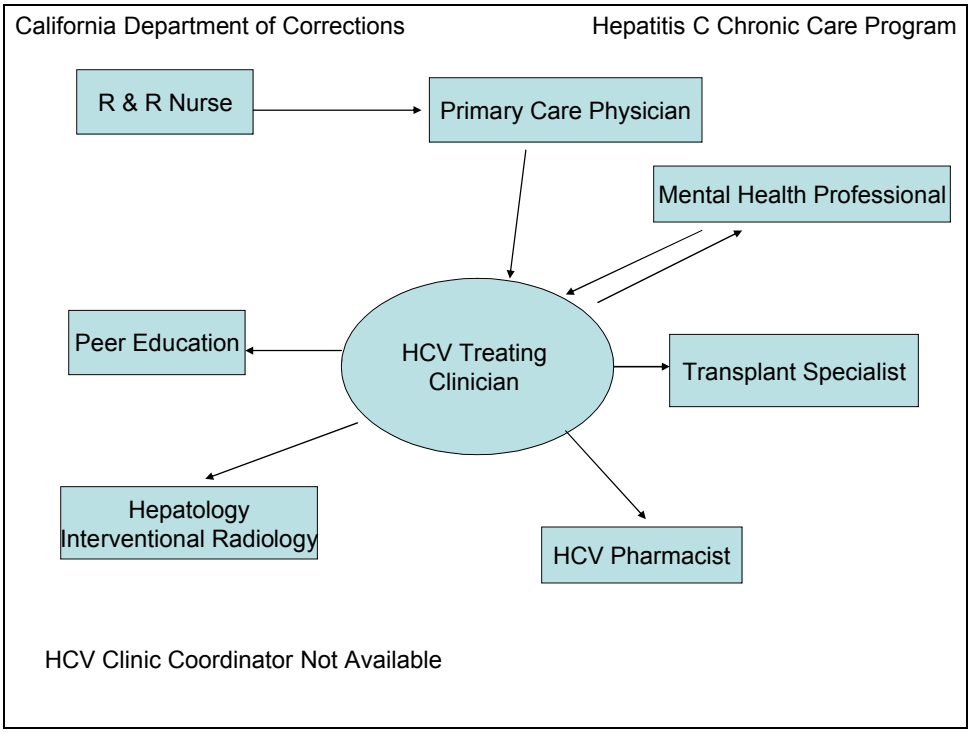
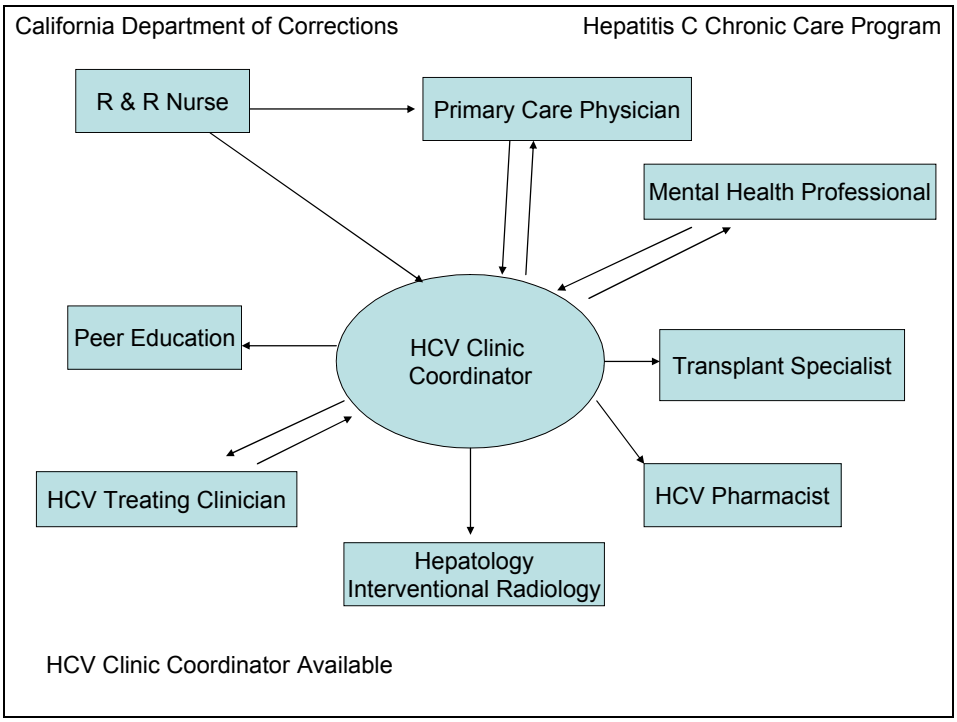


Table 2: Hepatitis C Chronic Care Program Team Model with HCV Clinic Coordinator



5) **COUNSELING OF THE NEWLY DIAGNOSED HCV INFECTED PATIENT.** All patients who are chronically infected with HCV shall be provided written information (*see attachment B, "General Instructions for Hepatitis C Patients")* and shall receive counseling by the Primary Care Provider. Counseling shall include:
   a) The natural history of the infection. Even without treatment, most patients with chronic infection do not die of liver disease, and most live a normal lifespan.
   b) The diagnostic work up for chronic HCV
   c) Current treatment options
   d) Specific measures for preventing transmission of HCV infection to others during incarceration and upon release, including:
      i) Do not inject drugs
      ii) If you choose to continue to inject drugs, do not reuse or share syringes, needles, water, and cotton or other paraphernalia.
      iii) Patients should limit their alcohol intake to fewer than 4 drinks per week. The threshold amount of alcohol in HCV-infected patients that increases the fibrosis progression rate remains unclear, but it is almost certainly greater than one daily drink. Therefore, it seems reasonable to set a limit to about half that amount.
      iv) Patients should consult with a clinician prior to taking any new medications, including over-the-counter medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) and herbal remedies.
      v) Patients with hepatitis C should be warned about the increased risk of disease progression associated with obesity.
      vi) Infected patients should inform their sexual partners and practice safer sex.
      vii) Consider testing the patient's partner for HCV infection.
      viii) Do not get a tattoo or body piercing while incarcerated.
      ix) Do not share personal items that might have your blood on them, such as toothbrushes, dental appliances, nail-grooming equipment or razors.
      x) Cover cuts and skin sores to keep blood from contacting other persons with nonintact skin.
      xi) Upon release, do not donate blood, body organs, other tissue or semen.
      xii) Upon release, discuss your HCV status with all sex partners and any needle-sharing partners.

6) **HCV PRIMARY CARE AND CIRRHOSIS MANAGEMENT**
   a) **Avoidance of hepatotoxic medications**
      i) All HCV infected persons shall be counseled to consult with a clinician prior to taking any new medications, including over-the-counter medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) and herbal remedies. For analgesia, small doses of aspirin and/or acetaminophen (< 2 g/d) are vastly preferable to NSAIDs in patients with liver disease.
   b) **Baseline testing in all HCV-infected patients** (see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")
      i) Liver function tests
      ii) Complete Blood Count with Differential
      iii) Hepatitis A (HAV) IGG (or total) antibody
      iv) Hepatitis B (HBV) surface antibody, hepatitis B surface antigen, hepatitis B core antibody total
      v) HIV test
   c) **Health Care Maintenance** (see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")
      i) Influenza vaccine (annually)
      ii) Pneumococcal pneumonia vaccine once and repeat in five years

iii) Hepatitis A (HAV) vaccine
   (a) Patients who are positive for IgG (or total) shall be considered to be immune.
   (b) Patients who are negative for IgG (or total) should be considered to be non-immune and shall be offered the HAV vaccination series
iv) Hepatitis B (HBV) vaccine
   (a) Patients who are positive for HBsAb shall be considered to be immune.
   (b) Patients who are HBsAg positive shall be considered to have chronic active HBV, and should be evaluated as per HBV guidelines.
   (c) Patients who are positive for HBcAb only could be acutely infected, chronically infected, especially if immunocompromised, or cleared of infection. These patients should be evaluated further with HBV DNA qualitative test and repeat HBcAb test. If patient is not viremic, then they should be given one HBV vaccine and retested for HBsAb in 1-2 months after vaccination.
   (d) Patients who are negative for HBsAg, HBsAb and HBcAb shall be considered to be non-immune and shall be offered the HBV vaccination series.

d) **Monitoring for signs of cirrhosis** (see attachment D, "Monitoring Chronic Hepatitis C Flowsheet")
   i) Liver function tests shall be initially obtained every three to six months.
   ii) The following laboratory findings are consistent with advanced cirrhosis: serum albumin <3 g/dl, INR>1, platelets <100 $x10^3/mm^3$, elevated liver function tests, and macrocytic anemia. Thrombocytopenia usually precedes other manifestations.
   iii) Signs of liver disease include spider nevi, palmar erythema, jaundice, hepatosplenomegaly, ascites, encephalopathy and gastroesophageal varices are signs of more advanced disease.

e) **Cirrhosis Management**[7]
   i) Educate
      (a) Eat from the CDCR low-salt, low fat, "heart healthy" diet.
      (b) Avoid high salt, high fat food from the canteen and or packages.
      (c) Completely abstain from alcohol use during incarceration and after release.
      (d) Avoid iron supplements.
   ii) **Screening for hepatocellular carcinoma in HCV-infected patients with cirrhosis** *(see attachment D, "Monitoring Chronic Hepatitis C Flowsheet")*. It is unnecessary to screen for HCV-associated hepatocellular carcinoma in the absence of cirrhosis because it is rare that they do not occur together. Combining ultrasound with tests for alpha fetoprotein levels may have better sensitivity than either modality alone. Results from a cohort study suggest that such combination screening may detect hepatocellular carcinoma at an earlier, resectable stage.[8]
      (a) Obtain serum alpha-fetoprotein every 6-12 months. Screening with alpha fetoprotein levels has been shown to range from insensitive (< 20%) to moderately sensitive (> 80%) as the cut-off point decreases from 400 µg/L to 10 µg/L, at the cost of dramatically decreasing specificity.
      (b) Obtain ultrasonography of liver annually. Screening with ultrasound has varying sensitivities but generally high specificity (> 90%).
   iii) Provide Low Protein Diet
      (a) Only to those who have experienced symptoms of encephalopathy.
   iv) Detect/Treat Varices
      (a) Perform baseline endoscopy to screen for esophageal varices. (Follow-up annual screening can be considered on a case-by-case basis, but the benefit of repeated screening is unclear. Once esophageal varices have been identified the risk of future variceal hemorrhage is 25-35 %.).

(b) Prescribe nonselective beta-blocker therapy, such as propranolol or nadolol, for patients with large esophageal varices on endoscopy. The dose of beta-blocker should be titrated weekly to reduce the resting heart rate by 25%, but not below 55 beats/minute or reducing the systolic blood pressure to lower than 90 mm Hg.).

(c) Long-acting nitrates can be added to nonselective beta-blockers in patients who do not respond to beta-blockers alone, but long-acting nitrates should not be used alone.

v) Provide prophylaxis for spontaneous bacterial peritonitis (SBP) with an antibiotic, such as ciprofloxacin or trimethoprim-sulfamethoxazole for patients who are at high risk.

(a) Those with ascites

(b) Those with prior episode of SBP

f) **Transplantation Issues**

i) Liver transplantation is the treatment of choice for patients with hepatic failure from chronic HCV infections.

ii) Due to the lack of available donor organs this option is limited.

iii) Even with transplantation there is a high rate of re-infection and progressive liver disease in the transplanted organ.

iv) Patients with hepatic failure from viral hepatitis shall be assessed on a case-by-case basis.

(a) The Model for End-stage Liver Disease (MELD) score[9]

(i) predicts liver disease severity and the risk of three month mortality based on serum creatinine, serum total bilirubin, and prothrombin time (INR).

(ii) Patients with decompensated cirrhosis should have a MELD score determined to assess mortality risk.

(iii) The MELD score can be calculated by utilizing a calculator provided by United Network for Organ Sharing (UNOS) available at: http://www.unos.org/resources/MeldPeldCalculator.asp?index=98

(iv) Data required includes: date of birth, bilirubin, creatinine, INR and dialysis status.

(v) Patients who have a MELD score of 30 or greater shall be considered for evaluation for transplantation.[10]

(b) Contraindications for transplantation

(i) Mental health instability

(ii) Ongoing substance abuse

(iii) Other life threatening condition

(iv) Inability to adhere to therapy

7) PRETREATMENT EVALUATION FOR HCV TREATMENT (see attachment C, "Hepatitis C New Patient Intake and Pretreatment Evaluation")

a) HCV genotype

i) The HCV genotype must be determined prior to pursuing treatment, since the genotype will affect the decision to treat, the duration of treatment, and the recommended drug regimen.

ii) Once the HCV genotype has been determined in a specific patient, repeated genotype testing is not indicated.

iii) Persons monoinfected with HCV genotypes 2 or 3 have a 70% response rate to 24 weeks of pegylated interferon/ribavirin therapy (74% response in those without cirrhosis, 58% in those with compensated cirrhosis). Those coinfected with HIV and HCV genotype 2 or 3 have a 62% response rate to 24 weeks of pegylated interferon/ribavirin therapy.[11-16]

iv) Persons with genotype 1 have a 46% response rate to 48 weeks of pegylated interferon/ribavirin therapy if HCV viral load is >2,000,000 and a 61% response rate if HCV viral load is

<2,000,000. Those coinfected with HIV and HCV genotype 1 have a 29% response rate to 48 weeks of pegylated interferon/ribavirin therapy.[11-17]

b) Complete Blood Count with Differential
c) Liver function tests, including ALT, AST, albumin, alkaline phosphatase, total bilirubin levels, and coagulation studies (PT, PTT, INR).
   i) The greater the ALT level, the more likely it is that a person has significant liver disease; therefore, those with markedly elevated ALT levels shall be prioritized for further evaluation and treatment. However, it must be remembered that even persons with normal ALT levels may have liver disease.
   ii) Serial determinations of ALT levels over time may provide a better means of assessing liver injury, but the accuracy of this approach has not been well documented. Patients who initially have a normal ALT level shall undergo serial measurements over several months to confirm the persistence of normal ALT levels.
d) Serum Creatinine
e) TSH
f) Pregnancy test. HCV treatment is contraindicated in pregnancy.
g) Length of stay
h) Presence of depressive symptoms (see attachment F, "Hepatitis C Antiviral Treatment Candidate Psychiatric/Psychological Review")
i) Presence of cardiopulmonary disease, diabetes, hypertension and thyroid disease
j) Fundoscopic examination for patients at risk for retinal disease, e.g. those with diabetes and/or hypertension
k) Ongoing alcohol ingestion within past 12 months
l) Ongoing injection drug use within past 12 months
m) HIV test
n) CD4 and HIV viral load. In patients co-infected with HIV, CD4 and HIV viral loads tests shall be obtained to determine the stage of HIV disease with CD4 and HIV viral load, and HAART shall be initiated if necessary.

8) EXCLUSION CRITERIA FOR HCV TREATMENT (see attachment E, "Algorithm for Hepatitis C Treatment" and G, "Exclusion Criteria for Combination Therapy")

a) Absolute Contraindications
   i) Decompensated cirrhosis. Patients who have decompensated cirrhosis are not candidates for HCV treatment (e.g. INR > 1.5, albumin ≤ 3.4 g/dL, platelet count < 75,000 k/mm3, hepatic encephalopathy, ascites)
   ii) Duration until discharge date.
      (a) Less than 16 months for HCV-monoinfected persons with genotypes 1, 4 and 6 HIV-infected persons of all HCV genotypes.
      (b) Less than 8 months in HCV-monoinfected persons with genotypes 2 and 3 who will not need a liver biospy.
   iii) Poorly controlled depression. Patients who have poorly controlled depression and/or active suicidal behavior shall not be treated with interferon. Ribavirin monotherapy is not recommended (*see attachment H, "Hepatitis C Antiviral Treatment Candidate Psychiatric/Psychological Review*).
   iv) Medical conditions. Patients with poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, blood dyscrasias (WBC <1,500/mm^3, platelets <75,000/mm^3, hemoglobin <11gm/dL or hematocrit <33%), seizures, diabetes mellitus (hemoglobin$_{A1C}$ >8.5%), and those with hemolytic anemia, hemaglobinopathies (thalassemia or sickle cell anemia), cancer, or autoimmune disease
   v) Renal, heart, or lung transplantation recipient

vi) Allergy to interferon or ribavirin
vii) Patients who are unwilling or unable to abstain from alcohol intake
viii) Patients who are actively involved in ongoing substance abuse
ix) Inability to cooperate with treatment
x) Inability to give informed consent
xi) Pregnancy
(a) Due to the risk of fetal malformations and fetal death with ribavirin use; a negative pregnancy test is required before treatment consideration.
(b) Women of childbearing potential must use two forms of effective contraception during treatment and during the six-month post-treatment.
(c) Men whose female partners are pregnant or may become pregnant must use barrier contraception during treatment and during the six-month post-treatment.

b) Relative Contraindications
i) Creatinine clearance < 50 ml/min or serum creatinine > 2.0 is a contraindication to treatment with ribavirin. Patients with renal dysfunction should be considered for treatment with pegylated interferon alfa 2a monotherapy at doses modified for renal disease (see under 11. TREATMENT OF HCV section).
ii) Nonresponders: Patients who have not adequately responded to previous antiviral therapy by achieving an early virologic response (EVR). In genotypes 1, 4, 5 and 6, an EVR is defined as a 2 log drop in viral load at 12 weeks. In genotypes 2 and 3, an EVR is defined as an undetectable viral load at 12 weeks.
(a) Patients who were nonresponders to treatment regimens other than pegylated interferon alfa 2a and ribavirin can be considered on a case-by-case basis for treatment with pegylated interferon alfa 2a and ribavirin.

c) HIV-related Absolute Contraindications
i) CD4 <200
ii) Currently under treatment for a major opportunistic infection or malignancy

9) SPECIAL SITUATIONS

a) **HIV and HCV Co-infection.** HIV increases the rate of progression of HCV related hepatic fibrosis and end-stage liver disease. Given the acceleration of fibrosis seen in patients co-infected with HIV and HCV, it may not always be necessary to perform a liver biopsy to make a decision to treat.
i) Treatment response rates are lower in HIV infected patients and the risk of serious adverse effects are greater.
ii) Treatment for HIV and HCV infections should not be initiated simultaneously.
iii) Patients who are candidates for both HIV treatment and HCV treatment should first receive antiretroviral therapy. Once HIV disease is well controlled (CD4>200) HCV treatment can be considered.
iv) Patients with HIV infection are at greater risk of hepatotoxicity with interferon/ribavirin therapy, particularly if they are on a HAART regimen. Full-dose **ritonavir** and **nevirapine** have been specifically implicated in some studies, although other studies suggest an increased risk with any HAART regimen.[11]
v) **Didanosine (ddI)** and **stavudine (D4T)** should not be co-administered with either interferon or ribavirin due to the increased risk of pancreatitis and lactic acidosis.[11]

vi) Bone marrow suppression from HIV infection or antiretrovirals, such as **zidovudine (AZT)** may complicate treatment for hepatitis C. In order to avoid severe anemia from ribavirin-induced hemolysis, erythropoietin therapy or an alternative HAART regimen may be warranted.

b) **Hemodialysis Patients**
   i) Interferon is contraindicated after renal transplantation. HCV treatment should be considered prior to transplant for patients who are suitable kidney transplant candidates.
   ii) For dialyzed patients, the recommended dose of pegylated interferon alfa 2a is 135 µg q week subcutaneously as monotherapy.

c) **HCV Postexposure Management**[4,10]
   (i) No vaccine or passive immunization is available to prevent acquisition of HCV infection following an exposure.
   (ii) The source of the exposure shall be tested for anti-HCV, unless the source's infection status is already known.
   (iii) Exposed persons shall be tested for anti-HCV (confirmed by HCV RNA, if positive) immediately after exposure and at weeks 12 and 24. Consider testing for HCV RNA PCR at week 6 when source patient is known to have documented HCV.
   (iv) Those with evidence of newly acquired HCV infection shall be appropriately counseled and referred for further medical evaluation including possible treatment for acute hepatitis C.

d) **Acute HCV**
   i) HCV RNA levels should be monitored for a period of 8-12 weeks from time of initial exposure in order to monitor for spontaneous resolution of infection.
   ii) For those who fail to resolve infection spontaneously, treatment should be initiated with pegylated interferon alfa 2a alone for 24 weeks, regardless of genotype, starting less than 6 months after HCV seroconversion, if there are no absolute contraindications to its use. [18]

10) CANDIDATES FOR HCV TREATMENT AND ROLE OF LIVER BIOPSY (see attachment E, "Algorithm for Hepatitis C Treatment")

a) Testing for ALT levels is the most inexpensive and noninvasive, but relatively insensitive, means of assessing disease activity. In most studies, a weak association exists between degree of ALT elevation and severity of the histopathological findings on liver biopsy. Up to 20% of patients with normal serum ALT levels have bridging fibrosis or cirrhosis.

b) Liver biopsy is currently the most accurate way to stage liver disease and to predict disease progression. The decision to obtain a liver biopsy before proceeding to treatment is based on a combination of factors, including the liver function tests, HCV genotype, HIV status, and patient preference.

c) **For persons infected with genotypes 1, 4, 5 and 6**, who otherwise qualify for treatment, liver biopsy shall be obtained. Those with elevated ALT levels shall be prioritized for evaluation with liver biopsy. However, it must be remembered that even persons with normal ALT levels may have liver disease. Given the acceleration of fibrosis from HCV seen in patients co-infected with HIV, it may not always be necessary to perform a liver biopsy to make a decision to treat.

d) **For persons infected with genotypes 2 and 3** who otherwise qualify for treatment consideration, liver biopsy should be deferred and antiviral therapy empirically offered due to the high response rates to treatment for these patients. These patients can be offered a liver biopsy to help determine the urgency of therapy in light of the side effects of HCV treatment.

e) Individuals with persistently normal or slightly elevated ALT levels and minimal or no fibrosis on liver biopsy may decide to defer HCV treatment in light of the side effects. Evaluation for repeat

liver biopsy should be performed in 3 years for those with HIV/HCV coinfection and in 5 years for those with HCV monoinfection.[11]

f) Patients with a liver biopsy showing at least portal or bridging fibrosis, and at least moderate inflammation and necrosis (Metavir stage 2 or greater, Ishak stage 2-3 or greater, Grade 2 or greater) shall be offered treatment.

11) TREATMENT OF HCV

a) **Pegylated interferon plus ribavirin** is the preferred drug regimen for treating chronic hepatitis C in the absence of contraindications to either drug. Pegylated interferon alone is less efficacious than combination therapy with ribavirin, but sometimes may be appropriate when contraindications to ribavirin exist. Ribavirin is completely ineffective as monotherapy and should never be prescribed without interferon.
   i) Pegylated interferon is available as Pegasys® (alfa 2a) within the CDCR
      (a) Pegasys® is dosed at 180 mcg subcutaneously q week regardless of patient weight.
   ii) Ribavirin. Generic preparations are the preferred form of ribavirin for use in the CDCR.
      (a) Generic preparations that are considered bioequivalent
      (b) Ribavirin is dosed as follows:
         (i) Genotype 1, 4, 6
            1. Patient <75 kg**:** 2 X 200mg capsules PO QAM & 3 X 200mg capsules PO QPM (1000mg/day)
            2. Patient ≥ 75 kg **:** 3 X 200mg PO QAM & 3 X 200mg capsules PO QPM (1200mg/day)
         (ii) Genotypes 2, 3, all weights: 2 X 200mg capsules PO BID

b) **Efficacy of treatment** with pegylated interferon alfa 2a plus ribavirin
   i) Virologic response is the most common way to evaluate the effectiveness of HCV treatment, which is usually associated with histologic improvement. Virologic responses are defined as followed:
      (a) Rapid virologic response (RVR): HCV RNA <50 IU/mL at 4 wk into treatment.
      (b) Early virologic response (EVR): ≥ 2 $\log_{10}$ reduction from baseline HCV RNA at 12 wk into treatment.
      (c) End-of-treatment response (ETR): undetectable HCV RNA at the completion of treatment.
      (d) Sustained virologic response (SVR): undetectable HCV RNA at 24 wk after completion of treatment.
      (e) Relaspe: undetectable HCV RNA during and/or at ETR but virus is detectable after treatment is stopped.
      (f) Nonresponse: detectable HCV RNA throughout treatment.
   ii) Genotype 1
      (a) the strongest negative predictor of response to pegylated interferon alfa 2a plus ribavirin.
      (b) In two randomized, controlled trials, SVR with pegylated interferon alfa 2a plus ribavirin was observed in 42-46% of patients with genotype 1.[12-13]
   iii) Genotypes 2 and 3
      (a) In two randomized, controlled trials, SVR with pegylated interferon alfa 2a plus ribavirin was observed in 76-82% of patients with genotypes 2 or 3.[12-14]
   iv) Genotypes 4, 5, and 6
      (a) In one randomized, controlled trial, SVR with pegylated interferon alfa 2a plus ribavirin was observed in 50% of patients with genotypes 4, 5 or 6.[12]

c) **HIV/HCV coinfection**

i) Lower efficacy of combination therapy with pegylated interferon alfa 2a plus ribavirin has been observed in co-infected individuals. Two recent studies show that in HIV/HCV coinfected patients, SVR with pegylated interferon alfa 2a plus ribavirin (at varying doses) was observed in 14-29% of patients with genotype 1 and in 62-73% of patients with non-Genotype 1.[15-16]

ii) For HIV/HCV-coinfected patients, prior to initiating HCV therapy, antiretroviral therapy should be optimized by:
   (a) ensuring that the patient is on a stable regimen with maximal CD4 benefit
   (b) avoiding didanosine and stavudine
   (c) considering a discontinuation of zidovudine because the risk of synergistic myelosuppression[11]

d) **Side effects and adverse reactions to interferon and ribavirin**. Patients treated for chronic hepatitis C should be counseled by a clinician before and during treatment regarding potential side effects/adverse reactions of interferon and ribavirin. (Patients should be provided attachment H, *"Potential Side Effects of Interferon and/or Ribavirin Therapy").*

i) **Pegylated interferon alfa 2a**[19]
   (a) An influenza-like reaction often occurs within 6-8 hours of initial treatment with interferon.
   (b) Fatigue, headache, fever, and myalgias often abate with subsequent treatments and can be partially aborted by premedication with antipyretics.
   (c) Acetaminophen can be given safely up to 2 gm/day in divided doses.
   (d) Chronic side effects of interferon can include severe fatigue, weight loss, reversible alopecia, irritability, rage, confusion, and neuropsychiatric disorders.
   (e) Severe and incapacitating depression can occur, even in persons without previous histories of depression.
   (f) Antidepressants, such as selective serotonin re-uptake inhibitors, may be useful in the management of depression associated with antiviral therapy, and can be started prophylactically prior to interferon therapy to prevent depression.
   (g) Bone marrow suppression resulting in neutropenia and thrombocytopenia are potentially serious effects of interferon that should be anticipated and monitored closely particularly in patients with cirrhosis or HIV infection.
   (h) When platelets fall below 80,000, dose reduction of pegylated interferon is recommended. Recommendations for dose modifications can be found in attachment K, *"Management of Side Effects"*.
   (i) The absolute neutrophil count should be maintained at greater than 500/mm^3 with the use of granulocyte colony-stimulating factor (G-CSF) 300mcg SQ TIW. Recommendations for dose modifications can be found in attachment K, *"Management of Side Effects"*.
   (j) Thyroid dysfunction occurs in approximately 4% of persons treated with interferon and may result in irreversible thyroid dysfunction, even with cessation of drug therapy. Resultant hypothyroidism can be treated on a case-by-case basis with hormone replacement therapy, while continuing interferon. Hyperthyroidism usually necessitates discontinuation of interferon.
   (k) Serious sequelae may occur in less than 1% of persons receiving interferon treatment and can include: renal failure, pneumonitis, severe bone marrow suppression, visual and hearing loss, retinal hemorrhage, acute psychosis, and suicide.
   (l) Pegylated interferon alfa 2a monotherapy should be used cautiously in patients with renal dysfunction. Signs and symptoms of interferon toxicity should be closely monitored. Doses should be adjusted, generally using a step-wise approach from 180mcg to 135mcg to 90mcg SC weekly. The recommended starting dose of pegylated interferon alfa 2a in patients on hemodialysis is 135mcg SC once weekly.

ii) **Ribavirin**

(a) Anemia. Ribavirin causes a dose-related red cell hemolysis to variable degrees in nearly all persons who are treated. Anemia ordinarily develops between initiation and 4 weeks of initiating therapy. A decrease in the hemoglobin of 2-3 gm/dL and a decrease in hematocrit of 5-10% should be anticipated.

(i) Persons with a preexisting hemolysis or severe anemia (hemoglobin < 11 g or hematocrit < 33%) or underlying cardiovascular or cerebrovascular disease should not receive ribavirin.

(ii) New onset of episodic chest pain during therapy should be presumed to be angina pectoris until proven otherwise.

(iii) Symptoms of sudden hemolysis such as dyspnea, fatigue, headache, and palpitations may develop.

(b) **Dose adjustment** due to anemia and the use of erythropoietin. Studies increasingly demonstrated that a reduction in the ribavirin dose has been associated with a significant reduction in SVRs and higher relapse rates.[17,20]

(i) Erythropoietin should be utilized to avoid the reduction of ribavirin due to anemia.[21-23] Recommendations for dose modifications can be found in attachment K, *"Management of Side Effects"*.

(ii) The FDA issued a **black box warning for erythropoietin** in March of 2007, based on the analyses of studies in patients with cancer and chronic kidney disease which found a higher chance of serious and life-threatening side effects (risk of death, blood clots, strokes, heart attacks, faster tumor growth) and/or death with the use of erythropoiesis-stimulating agents. The new boxed warning advises physicians to monitor red blood cell levels (hemoglobin) and to adjust the erythropoietin dose to maintain the lowest hemoglobin level needed to avoid the need for blood transfusions. Physicians and patients should carefully weigh the risks of erythropoietin against transfusion risks.

(c) Patients with **chronic renal insufficiency**. Clearance of ribavirin is significantly impaired in renal insufficiency; thus, the risk of adverse effects, particularly hemolytic anemia, increases significantly with a decline in renal function.

(i) Ribavirin should be used cautiously in those with mild renal impairment (creatinine > 1.5 mg/dL). There are published recommendations on dose modifications for these individuals.[24] If used, serum drug levels must be monitored closely.

(ii) Ribavirin is contraindicated if the creatinine is > 2.0 mg/dL, or the creatinine clearance is < 50 ml/min.

(iii) Ribavirin is absolutely contraindicated in dialysis patients as it is not dialyzable.

(d) Ribavirin also causes histamine-like side effects such as nasal stuffiness, itching, and skin irritations. More severe effects can include an asthma-like syndrome or bronchitis.[25]

(e) Ribavirin may cause fetal abnormalities

(i) All female inmates of childbearing potential must have a negative pregnancy test prior to initiating therapy.

(ii) Both women AND men must be counseled to use adequate birth control during treatment and for 6 months after treatment is completed.

(iii) Counseling of both women AND men regarding the risk of birth defects is particularly important for patients awaiting release.

12) MONITORING DURING HCV TREATMENT (see attachments J1 and J2, "Hepatitis C Treatment Flow Sheet")

a) Clinical Evaluations:
   i) Patients should be seen weekly for one month, then at least monthly thereafter, to assess drug side effects and potential complications.
   ii) Assessment for depression should occur at every visit, and mental health consultations should be provided as clinically indicated while inmates are taking interferon.
   iii) Pregnancy test should be obtained and pregnancy risk should be assessed at every visit for women of child-bearing age.
b) Laboratory Monitoring:
   i) Patients receiving interferon and ribavirin therapy shall have lab work routinely obtained.
      (a) Liver function tests at baseline and weeks 2 and 4, and at 4 week intervals thereafter.
      (b) CBC with differential at baseline and weeks 2 and 4, and at 4 week intervals thereafter.
      (c) Thyroid function studies at baseline and every 12 weeks during interferon therapy and 12 weeks after conclusion of therapy.
      (d) Serum Creatinine at baseline and at 4 week intervals.
      (e) Blood glucose at baseline and at 12 week intervals.
      (f) HCV RNA at baseline and week 4 and at 12 week intervals thereafter.
      (g) For **HIV-infected persons**, CD4 count and HIV viral load should be obtained at baseline and at 12 week intervals.

13) DURATION OF HCV TREATMENT

a) **Definitions of treatment endpoints** for HCV are the same for HCV-monoinfected patients and HIV/HCV-coinfected patients.
   i) **EVR:** Early virologic response (EVR) is defined as an undetectable HCV RNA level among those with genotype 2 or 3, or a 2-log reduction in HCV RNA levels among those with genotypes 1,4,5 or 6 at 12 weeks into HCV treatment. Because failure to achieve an EVR has been shown to predict strongly an inability to achieve an SVR in both HCV-monoinfected and HIV/HCV-coinfected patients, discontinuation of therapy should be strongly considered at 12 weeks in the absence of an EVR ("nonresponders"). Conversely, if EVR is achieved, the patient should undergo the full recommend course of treatment.
   ii) **ETR:** End-of-treatment response (ETR), defined as an undetectable HCV RNA at the end of therapy, is encouraging and predicts a sustained virologic response.
   iii) **SVR:** Sustained virologic response (SVR), an undetectable HCV RNA 6 months after completion of therapy, is the goal of therapy.
   iv) **RVR**: Rapid virologic response (RVR) is defined as an undetectable HCV RNA at 4 weeks of therapy.
b) For **HIV-negative patients with genotypes 1, 4, 5, and 6 and all HIV-positive patients regardless of HCV genotype:**
   i) Antiviral therapy for HCV is administered for 12 weeks followed by the measurement of quantitative HCV RNA.
   ii) A 2 log drop in viral load at 12 weeks, referred to as an EVR, predicts an SVR.
   iii) Failure to achieve an EVR predicts treatment failure. Antiviral therapy should be discontinued in these patients after 12 weeks of treatment.
   iv) Patients with an EVR should be treated for another 36 weeks (total 48 weeks course of treatment).
   v) At the completion of 48 weeks of therapy, the ETR should be measured by obtaining an HCV RNA level.
   vi) 24 weeks after completing therapy, the SVR should be assessed by obtaining another HCV RNA level.

vii) It should be noted that studies evaluating even shorter treatment courses (24 week courses) for HIV/HCV-coinfected individuals with genotypes 1, 4, 5, and 6 and rapid virologic responses (RVR), an undetectable HCV RNA at 4 weeks of therapy, have shown excellent results.[25-26]

c) For **HIV-negative patients with genotypes 2 and 3:**
   i) Antiviral therapy for HCV is administered for 12 weeks followed by the measurement of quantitative HCV RNA.
   ii) An undetectable viral load at 12 weeks, referred to an EVR, predicts an SVR.
   iii) Failure to achieve an EVR predicts treatment failure. Antiviral therapy should be discontinued in these patients after 12 weeks of treatment.
   iv) Patients with an EVR should be treated for another 12 weeks (total 24 week course of treatment).
   v) At the completion of 24 weeks of therapy, the ETR should be measured by obtaining an HCV RNA level.
   vi) 24 weeks after completing therapy, the SVR should be assessed by obtaining another HCV RNA level.
   vii) It should be noted that studies evaluating even shorter treatment courses (16 week courses) for HCV-monoinfected individuals with genotypes 2 and 3 and rapid virologic responses (RVR), an undetectable HCV RNA at 4 weeks of therapy, have shown excellent results.[26-27]

14) FOLLOW-UP AFTER COMPLETION OF TREATMENT

a) After treatment, it is recommended to obtain a HCV RNA at the end of treatment to determine the ETR, and at 6 months after the end of treatment to determine the SVR.
b) Birth control should be continued for at least 6 months after the completion of treatment.

15) RETREATMENT AND MAINTENANCE HCV THERAPY

a) Retreatment in Nonresponders and Relaspers
   i) Nonresponders: These patients do not adequately respond to antiviral therapy by achieving an EVR at 12 weeks. Nonresponders to pegylated interferon alfa 2a and ribavirin are not candidates for retreatment.
      (a) Patients who were nonresponders to treatment regimens other than pegylated interferon alfa 2a and ribavirin can be considered on a case by case basis for treatment with pegylated interferon alfa 2a and ribavirin.
   ii) Relapsers: These patients have undetectable levels of HCV RNA at the end of treatment (ETR), but do not attain a SVR (HCV RNA is detectable 24 weeks after completion of initially effective antiviral therapy). Relapsers to pegylated interferon alfa 2a and ribavirin are not candidates for retreatment.
      (a) Patients who were relapsers to treatment regimens other than pegylated interferon alfa 2a and ribavirin can be considered on a case by case basis for treatment with pegylated interferon alfa 2a and ribavirin.
b) **Maintenance Therapy** is investigational and shall not be prescribed**.**

16) INFECTION CONTROL

a) Patient Education
   i) All inmates should be counseled during orientation to the institution and, when appropriate, during clinical evaluations of the importance of preventing exposures to the blood of others during activities of daily living such as sharing toothbrushes and razors and through unsafe behaviors such as injection drug use, tattooing, and sexual contact with other inmates.
b) Reporting

i) Reporting procedure for new cases of HCV infection varies by county. All new cases of acute and chronic HCV shall be reported to the county health department by completing a Confidential Morbidity Report (CMR) form, in accordance with CDCR policy and California State law. The CMR forms may be obtained by fax from any local health center registrar or through the public health nurse at each CDCR institution.

c) Containment
   i) Patients with acute or chronic HCV do not require isolation, but shall be counseled on the specific measures necessary for preventing further transmission of HCV to others during incarceration and upon release and shall be managed while incarcerated about using standard infection control precautions.
   ii) Non-disposable patient-care items must be appropriately cleaned, disinfected, or sterilized based on the use; and measures must taken to prevent cross-contamination during patient care, e.g., dialysis, vascular access, cauterizing, dental procedures, etc., in accordance with Centers for Disease Control and Prevention guidelines.[5,10]

d) Hemodialysis
   i) Patients receiving hemodialysis who are HCV negative shall have serum ALT levels measured monthly and anti-HCV measured by an immunoassay semi-annually to screen for newly acquired HCV infection.
   ii) Patients receiving hemodialysis who have a positive anti-HCV screening immunoassay shall have a supplemental qualitative HCV RNA performed.
   iii) Measures to reduce HCV transmission during hemodialysis shall be implemented in accordance with Centers for Disease Control and Prevention guidelines.[5,10]
   iv) Patients with HCV infection receiving dialysis need not be isolated from other patients or dialyzed separately on dedicated machines
   v) Dialyzers used for inmates with HCV infection can be reused.

e) Post-exposure Management[10]
   i) Emergent care
      (a) Wounds and skin sites that have been in contact with blood or bloody body fluids shall be washed with soap and flushed with large amounts of water.
      (b) Exposed mucous membranes shall be flushed with water.
      (c) Squeezing the wound and treating with topical antiseptics are not recommended.
   ii) Counseling
      (a) Inmates with percutaneous or mucosal exposures to blood shall be assessed and counseled regarding their risk of acquiring HCV infection, the natural history of HCV infection, and the recommendations for post-exposure management.
   iii) Post-exposure Follow-up[4,10]
      (a) No vaccine or passive immunization is available to prevent acquisition of HCV infection following an exposure.
      (b) The source of the exposure shall be tested for anti-HCV, unless the source's infection status is already known.
      (c) Exposed persons shall be tested for anti-HCV (confirmed by HCV RNA, if positive) immediately after exposure and at weeks 12 and 24. Consider testing for HCV RNA PCR at week 6 when source patient is known to have documented HCV.
      (d) Those with evidence of newly acquired HCV infection shall be appropriately counseled and referred for further medical evaluation including possible treatment for acute hepatitis C.

f) HCV-infected patients who are about to be released must be provided follow up information and counseling regarding hepatitis C. They should be provided information which identifies community

resources and counseling to seek follow-up care. A list of resources for patients with HCV can be found at the California Department of Health Services' Hepatitis C Unit's website http://www.dhs.ca.gov/ps/dcdc/disb/pdf/hcv_resources.pdf.

References

1. Management of Hepatitis C: 2002. National Institute of Health Consensus Conference Statement. http://consensus.nih.gov/2002/2002HepatitisC2002116html.htm

2. Ruiz JD, Molitor F, Plagenhoef, JA. Trends in hepatitis C and HIV infection among inmates entering prisons in California, 1994 versus 1999. AIDS. 2002, 16:2236-38.

3. Fox RK, Currie SL, Evans J, et al. Hepatitis C virus infection among prisoners in the California state correctional system. *Clin Infect Dis.* 2005; 41:177-186.

4. Centers for Disease Control and Prevention. U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR.* 2001; 50(No. RR-11):1-42. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm

5. Centers for Disease Control and Prevention. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. *MMWR*. 1998; 47(No. RR-19);1-39. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm

6. Menon KVN, Kamath PS. Managing the complications of cirrhosis. *Mayo Clin Proc*. 2000; 75:501-509.

7. Strader DB, Wright T, Thomas DL, et al. Diagnosis, management, and treatment of hepatitis C. American Association for the Study of Liver Diseases (AASLD) practice guideline. *Hepatology.* 2004; 39:1147-1171. Available from: https://www.aasld.org/eweb/docs/hepatitisc.pdf

8. Kamath PS, Wiesner RH, Malinchoc M, et al. A model to predict survival in patients with end-stage liver disease. *Hepatology*. 2001; 33:464-470.

9. Wiesner R, Edwards E, Freeman R, et al. Model for end-stage liver disease (MELD) and allocation of donor livers. *Gastroenterology* 2003; 124:91-96

10. Centers for Disease Control and Prevention. Prevention and control of infections with hepatitis viruses in correctional settings. *MMWR*. 2003; 52(No. RR-1):1-36. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm

11.Tien PC. Management and treatment of hepatitis C virus infection in HIV-infected adults: Recommendations from the Veterans Affairs Hepatitis C Resource Center Program and National Hepatitis C Program Office. *Am J Gastroenterol.* 2005; 100:2338-54.

12. Manns MP, McHuthison JG, Gordon SC, et al. Peginterferon alfa-2a plus ribavirin for initial treatment of chronic hepatitis C: A randomized trial. Lancet 2001:358:958-65.

13. Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C. N Engl J Med 2002;347:975-82.

14. Shiffman ML, Suter F, Bacon BR, Nelson D, Harley H, Solá R, Shafran SD, Barange K, Lin A, Soman A, Zeuzem S; ACCELERATE Investigators. Peginterferon alfa-2a and ribavirin for 16 or 24 weeks in HCV genotype 2 or 3. N Engl J Med. 2007 Jul 12;357(2):124-34.

15. Torriani FJ, Rodriguez-Torres M, Rockstroh JK, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV-infected patients. N Eng J Med 2004; 351 (5): 438-50.

16. Chung RT, Andersen J, Volberding P, et al. Peginterferon alfa-2a plus ribavirin versus interferon alfa-2a plus ribavirin for chronic hepatitis C in HIV-coinfected persons. N Eng J Med 2004;351(5):451-9.

17. Hadziyannis SJ, Sette H Jr., Morgan TR, et al. Peginterferon-alpha-2a and ribavirin combination therapy in chronic hepatits C: A randomized study of treatment duration and ribavirin dose. Ann Intern Med 2004;140(5):346-55.

18. Gerlach JT, Diepolder HM, Zachoval R, et al. Acute hepatitis C: high rate of both spontaneous and treatment-induced viral clearance. *Gastroenterology* 2003; 125: 80-88.

19. Pegasys®. Nutley, NJ: Hoffman-La Roche Inc, 2005.

20. McHuthison JG, Manns M, Patel K, et al. Adherence to combination therapy enhances sustained response in genotype-1-infected patients with chronic hepatitis C. Gastroenterology 2002;123:1061-9.

21. Afdhal NH, Dieterich DT, Pockros PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: A prospective, double-blind, randomized controlled study. Gastroenterology 2004;126(5):1302-11.

22. Pockros PJ, Shiffman ML, Schiff ER, et al. Epoetin alfa improves quality of life in anemia HCV-infected patients receiving combination therapy. Hepatology 2004;40:1450-8.

23. Sulkowski MS, Dieterich DT, BiniEJ, et al. Epoetin alfa once weekly improves anemia in HIV/hepatitis C virus-coinfected patients treated with interferon/ribavirin: a randomized controlled trial. J Acquir Immune Defic Syndr. 2005 Aug 1;39(4):504-6.

24. Bruchfeld A, Lindahl K, Stahle L, Soderberg M, et al. Interferon and ribavirin treatment in patients with hepatitis C-associated renal disease and renal insufficiency. Nephrol Dial Transplant (2003) 18:1573-80.

25. Rebetol®. Kenilworth, NJ: Schering Corporation, 2002.

26. Ferenci P, Bergholz U, Laferl H, et al. 24 weeks treatment regimen with peg interferon alpha 2ª plus ribavirin in HCV genotype 1 or 4 'super-responders'. J Hepatol 2006; 44 (suppl 2): 6.

27. Soriano V, Puota M, Sulkowski M, et al. Care of patients coinfected with HIV and hepatitis C virus: 2007 updated recommendations from the HCV-HIV Internacional Panel. AIDS 2007; 27:1073-89.

28. Mangia A, Santoro R, Minerrva N, et al. Peginterferon alfa-2b and ribavirin for 12 vs. 24 weeks in HCV genotype 2 or 3. *N Engl J Med.* 2005; 352:2609-2617.

Resources

Prevention and Treatment of Viral Hepatitis
American Association for the Study of Liver Diseases
https://www.aasld.org/eweb/StartPage.aspx

Centers for Disease Control and Prevention
National Center for Infectious Diseases - Hepatitis Branch
http://www.cdc.gov/ncidod/diseases/hepatitis/

MELD Score Calculator
The MELD score can be calculated by utilizing a calculator provided by United Network for Organ Sharing available at:
http://www.unos.org/resources/MeldPeldCalculator.asp?index=98

National Institutes of Health
National Institute of Diabetes and Digestive Disease
http://www.niddk.nih.gov

National Clinicians' Post-Exposure Prophylaxis Hotline
(888) 448-4911

Veterans Affairs National Hepatitis C Web Site
http://hepatitis.va.gov/

Pocket guide to HCV management
Educate; test all patients for HAV, HBV, HCV
    HAV and HBV vaccinations if non-immune

If HCV infected, HCV viral load
Assess for contraindications
    (Length of stay, mental illness, ongoing IDU/alcohol use,
    poorly controlled comorbid conditions)
Assess for indications
    ALT, Liver Biopsy, HIV infection
If treat, determine duration
    Monitor for side effects during treatment
    Monitor for EVR, ETR, SVR
Post-exposure Management
Management of Cirrhosis
    immunize, educate, diet, alcohol/iron/hepatotoxic
    medications, varices, SBP
Screen for hepatocellular carcinoma
Transplantation
    Meld score, Contraindications for transplantation

H E P A T I T I S C PATIENT INFORMATION

WHAT IS HEPATITIS C or HEP C?

Hepatitis is irritation and damage of the liver. The most common causes of liver irritation are viruses, drugs, and alcohol. Hep C is one of the viruses that can irritate the liver.

HOW DO YOU GET IT?

You get Hep C from dirty needles (tattoos, piercing with sharp things), snorting drugs, sharing works (drug equipment), unprotected sex, or from a blood transfusion before 1990. You can get Hep C from human blood. There is no vaccine or medicine to protect you from Hep C.

HOW DO YOU KNOW IF YOU HAVE HEP C?

Most people with Hep C look and feel fine. You can have Hep C for a long time and not know you have it. Lots of people find out they have it when they try to give blood to the blood bank. There is a blood test that will tell you if you have the infection. The blood test is not perfect and you will need a second test to make sure you really have Hep C. There are lots of different Hep C viruses and there is a blood test to see which kind of Hep C you have.

WHAT DOES THE HEP C VIRUS DO TO YOU?

You can't live without your liver. Your liver cleans your blood and also makes things your body needs. Hep C lives in your liver cells and damages the liver cells so they don't work like they need to. The damage takes a long time but if you have HIV or if you drink alcohol, hep C can damage your liver faster. Hep C does not always damage your liver. There are other tests you can have to see if hep C has damaged your liver.

HOW DO YOU FEEL WHEN YOU HAVE HEP C?

Most people with Hep C feel fine until Hep C has done a lot of damage to your liver. Hep C can make you feel tired, make your joints hurt, upset your stomach, give you night sweats, and make you feel sad. There are more serious problems if your liver is very damaged and you have what is called cirrhosis. Hep C can make it easier to get liver cancer.

HEP C CAN BE TREATED, GET TESTED!

INSTRUCTIONS FOR PEOPLE WITH HEPATITIS C

- DON'T DRINK ALCOHOL
- DON'T SHOOT OR SNORT DRUG
- DON'T GET TATTOOS IN PRISON
- DON'T SHARE YOUR TOOTHBRUSH, RAZOR, OR OTHER PERSONAL ITEMS
- TRY TO LOSE WEIGHT IF YOU ARE OVERWEIGHT
- EAT A HEALTHY DIET
- DRINK PLENTY OF WATER
- GET PLENTY OF REST AND REGULAR EXERCISE
- QUIT SMOKING CIGARETTES
- ASK YOUR DOCTOR BEFORE YOU TAKE ANY PAIN MEDICINE
- YOU CAN TAKE *ACETAMINOPHEN (TYLENOL)* FOR PAIN OR OTHER *ACETAMINOPHEN* CONTAINING MEDICATIONS, BUT DON'T TAKE MORE THAN 2 GRAMS OR 4 EXTRA STRENGTH PILLS A DAY
- D0 NOT DONATE BLOOD, TISSUE, OR ORGANS
- **SEE YOUR DOCTOR FOR REGULAR CHECK UPS**

Hepatitis C New Patient Intake and Pretreatment Evaluation

Name:
CDCR #:
DOB:
Release Date:

Past Medical History

CAD	DM
COPD	Thyroid Dz
HTN	Seizure D/O
CVA	Autoimmune dz
Hematologic dz	Other

Hx of depression/other psychiatric/suicide/psych hospitalizations, CCCMS, EOP:

Current:	Past:

Drug dependence (ETOH, IDU, other):

Current:	Past:

Immunization History:

Hepatitis A series:	Pneumococcal vaccine:
Hepatitis B series:	Last Influenza:

Baseline Physical Exam

BP	Neck	Abd
Eyes	Cardiac	Skin
OP	Pulm	Ext

Baseline Tests

Lab	Result	Date	Lab	Result	Date
HCV RNA			Hepatitis A total Ab		
HCV genotype			HepB sAb		
WBC			HepB sAg		
ANC			HepB cAb		
Hg/Hct			AST		
Plat			ALT		
Cr			Alk Phos		
TSH			Tbili		
HIV test			Alb		
CD4			PT/PTT/INR		

Prior to Referral to HCV Treating Clinician:

- ☐ Obtain a thorough medical screening including history and physical exam
- ☐ Document any history of retinopathy, autoimmune disorders, diabetes, thyroid, cardiac, hematological, renal, and pulmonary diseases
- ☐ Obtain a psychiatric history and complete the Psychiatric/Psychologic Review Form (attachment H)
- ☐ Estimated release date more than 16 months
- ☐ Patient Education
- ☐ *(for HIV-infected)* initiate HAART if necessary

Send the following laboratory studies for the HCV treating clinician to review:

- ☐ Quantitative HCV RNA PCR
- ☐ HCV genotype
- ☐ CBC with differential
- ☐ Liver function panel including ALT, AST, total bilirubin, albumin, alkaline phosphatase
- ☐ PT/PTT/INR
- ☐ TSH
- ☐ Creatinine
- ☐ *(for HIV-infected)* CD4 and HIV viral load
- ☐ *(for women)* pregnancy test

Clinician Name: _____

Clinician Signature:_____

Date: _____

CDCR Stamp

Patient name:
CDCR number:
DOB:

Monitoring Chronic Hepatitis C Flowsheet for Primary Care Providers

Monitor	Baseline	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
ALT (q 3-6 mos)												
Platelets (q 6-12 mos)												
Total and direct bilirubin (q 3-6 mos)												
INR (q 3-6 mos)												
Albumin (q 3-6 mos)												
PATIENTS WITH CIRRHOSIS												
AFP (q 6-12 mos)												
U/S or CT (q 1 yr)												
Endoscopy (baseline and as needed)												

Clinician Name: _____

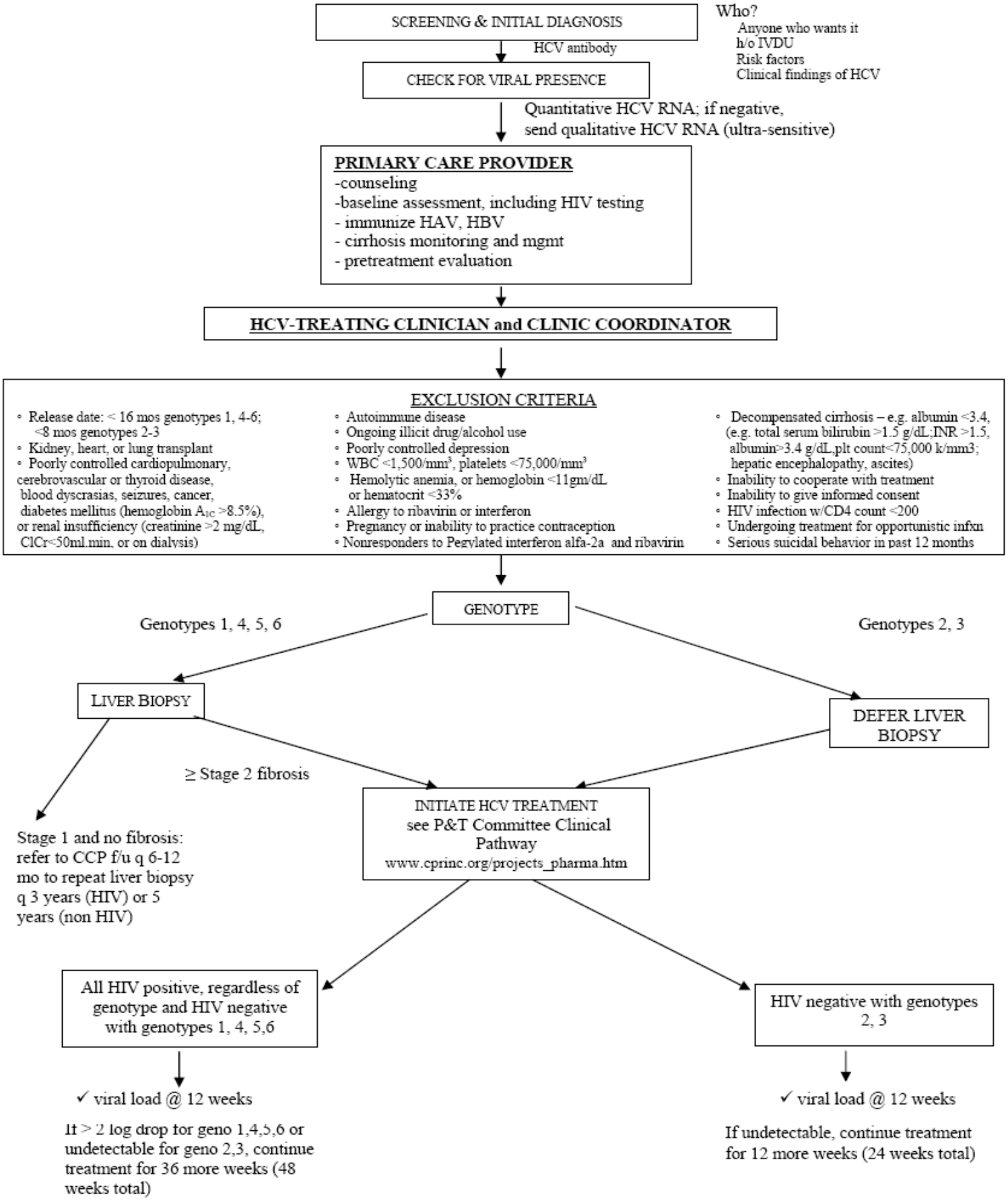
Clinician Signature:_____

Date:_____

CDCR Stamp

Patient name:
CDCR number:
DOB:

ALGORITHM FOR HEPATITIS C TREATMENT



HEPATITIS C ANTIVIRAL TREATMENT CANDIDATE

PSYCHIATRIC/PSYCHOLOGIC REVIEW

for referral to HCV Treating Clinician by primary care provider

Ask the patient to rate the following symptoms on a scale 0-3:

Never	0
Sometimes	1
Always	2
Feels painful	3
Can't stand it	3

1. Sadness	___	12. Social withdrawal	___
2. Pessimism	___	13. Indecisiveness	___
3. Sense of failure	___	14 Change in body image	___
4. Dissatisfaction	___	15. Retardation	___
5. Guilt	___	16. Insomnia	___
6. Expectation of punishment	___	17. Fatigability	___
7. Dislike of self	___	18. Loss of appetite	___
8. Self Accusation	___	19. Loss of Weight	___
9. Suicidal ideation	___	20. Somatic preoccupation	___
10. Episodes of crying	___	21. Low level of energy	___
11. Irritability	___	Total score	___

Disposition/Plan: (check appropriate box)

IF TOTAL SCORE >10 OR OTHERWISE MEETS DIAGNOSTIC CRITERIA FOR A PSYCHIATRIC CONDITION, the patient should be referred to a mental health specialist for management prior to initiating antiviral treatment

☐ Refer to mental health professional for evaluation prior to HCV treatment

IF TOTAL SCORE <10 AND DOES NOT OTHERWISE MEET DIAGNOSTIC CRITERIA FOR A PSYCHIATRIC CONDITION:

☐ Evaluation by mental health professional not required prior to HCV treatment

Clinician Name: _____

Clinician Signature:_____

Date:_____

CDCR Stamp

Patient name:
CDCR number:
DOB:

Exclusion Criteria for Combination Therapy*

- Decompensated cirrhosis. Patients who have decompensated cirrhosis are not candidates for HCV treatment (e.g. INR > 1.5, albumin ≤3.4 g/dL, platelet count < 75,000 k/mm3, hepatic encephalopathy, ascites)
- Duration until discharge date less than 16 months in persons with genotypes 1, 4 and 6 and duration until parole date less than 8 months in persons with genotypes 2 and 3.
- Poorly controlled depression. Patients who have poorly controlled depression and/or active suicidal behavior shall not be treated with interferon. Ribavirin monotherapy is not recommended (*see attachment H, "Hepatitis C Antiviral Treatment Candidate Psychiatric/Psychological Review*).
- Medical conditions. Patients with poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, blood dyscrasias (WBC <1,500/mm^3, platelets <75,000/mm^3, hemoglobin <11gm/dL or hematocrit <33%), seizures, diabetes mellitus (hemoglobin$_{A1C}$ >8.5%), and those with hemolytic anemia, hemaglobinopathies (thalassemia or sickle cell anemia), cancer, or autoimmune disease.
- Renal, heart, or lung transplantation recipient
- Allergy to interferon or ribavirin
- Patients who are unwilling or unable to abstain from alcohol intake
- Patients who are actively involved in ongoing substance abuse
- Inability to cooperate with treatment
- Inability to give informed consent
- Pregnancy
    - Due to the risk of fetal malformations and fetal death with ribavirin use; a negative pregnancy test is required before treatment consideration.
    - Women of childbearing potential must use two forms of effective contraception during treatment and during the six-month post-treatment.
    - Men whose female partners are pregnant or may become pregnant must use barrier contraception during treatment and during the six-month post-treatment.
- Relative Contraindications
    - Creatinine clearance < 50 ml/min or serum creatinine > 2.0 is a contraindication to treatment with ribavirin. Patients with renal dysfunction should be considered for treatment with pegylated interferon alfa 2a monotherapy at doses modified for renal disease (see under section 11. TREATMENT OF HCV).
    - Nonresponders: Patients who have not adequately responded to previous antiviral therapy by achieving an early virologic response (EVR). In genotypes 1, 4, 5 and 6, an EVR is defined as a 2 log drop in viral load at 12 weeks. In genotypes 2 and 3, an EVR is defined as an undetectable viral load at 12 weeks.
        - Patients who were nonresponders to treatment regimens other than pegylated interferon alfa 2a and ribavirin can be considered on a case-by-case basis for treatment with pegylated interferon alfa 2a and ribavirin.
- HIV-related Absolute Contraindicatons
    - CD4 <200
    - Currently under treatment for a major opportunistic infection or malignancy

***Refer to drug manufacturer's warnings in addition to highlighted contraindications**

POTENTIAL SIDE EFFECTS
INTERFERON AND RIBAVIRIN THERAPY

While you are taking interferon and/or ribavirin you may experience some of the side effects listed below. The problem most commonly reported is flu-like symptoms. These symptoms are reduced by taking acetaminophen (Tylenol®) before each interferon injection. Drinking plenty of water and getting adequate rest and exercise also help to minimize ill effects.

- Injection site inflammation
- Nonspecific flu-like symptoms, *such as:*
  - headache
  - chills
  - fatigue
  - fever
- Gastrointestinal symptoms, *such as:*
  - loss of appetite
  - nausea
  - vomiting
  - diarrhea
  - heartburn or indigestion
- Psychiatric symptoms, *such as:*
  - depression
  - insomnia
  - anxiety
  - irritability
- Respiratory symptoms, *such as:*
  - cough
  - shortness of breath
- Skin disorders, *such as:*
  - hair loss
  - rash
  - itching
  - dry skin
- Blood element problems, *such as:*
  - reduced number of white blood cells
  - reduction in platelets
  - anemia
- Possible birth defects during and for 6 months after completion of therapy
- Worsening of problems with vision due to retinopathy

HEPATITIS C BIOPSY AND TREATMENT CONTRACT

Treatment of hepatitis C is reserved for those eligible patients who understand the commitment to therapy, will tolerate and comply with the course of treatment, and agree to avoid all activities that may worsen their liver disease, or infect themselves or others with the hepatitis C virus or other bloodborne pathogens. Every patient who is considered for treatment must complete this contract before a liver biopsy is performed and/or before initiation of therapy.

Patient's Initials

- ☐ I understand that the therapy may be of no benefit to me and that it may not eradicate my hepatitis C infection.
- ☐ I have been informed that side effects of treatment of hepatitis C may include fatigue, body aches, and other serious side effects that may persist throughout the course of therapy.
- ☐ I understand that I may be tested for HIV before beginning treatment as the presence of the HIV virus could seriously affect rny hepatitis C infection and its treatment.
- ☐ I understand that the course of therapy may continue for up to 12 months and that periodic blood testing will be a necessary part of the hepatitis C treatment program.
- ☐ I understand that treatment for hepatitis C may cause psychiatric side effects, especially depression.
- ☐ I understand that I must not become pregnant or attempt to impregnate my spouse during my hepatitis C antiviral treatment or for 6 months after cessation of treatment. I understand that I must use two forms of birth control during heterosexual activity during treatment and for 6 months after treatment ends.
- ☐ I understand that my failure to comply with the therapy or its monitoring may result in discontinuation of therapy.
- ☐ I understand that alcohol injures the liver and that drinking alcohol is forbidden.

I understand that I must abstain from any activity that permits exchange of body fluids that may transmit the hepatitis C virus or other bloodborne pathogens. This includes tattooing, sexual activity in prison, IV drug use, and intranasal drug use.

- ☐ I understand that I may be required to undergo random blood or urine testing for substance abuse and that any positive test will result in discontinuation of, or loss of eligibility for, treatment.
- ☐ *For those receiving a liver biopsy*: I understand that a medical hold will be placed on me until the liver biopsy is performed and the biopsy results are discussed with me.
- ☐ I understand that completion of this contract does not guarantee that I will be approved for hepatitis C treatment.
- ☐ My initials above and my signature below signify my understanding of, and agreement to comply with, the requirements enumerated above. I understand that failure to comply may result in loss of eligibility for therapy or discontinuation of therapy in progress.

Clinician Name: _____

Clinician Signature:_____

Patient Signature:_____ Date:_____

CDCR Stamp

Patient name:
CDCR number:
DOB:

v. 4/7/08

Monitoring during HCV Treatment Flowsheet-Genotype 1, 4, 5 or 6 and all HIV co-infected

Date	baseline	2weeks	4 weeks	8 weeks	12 weeks	16 weeks	20 weeks	24 weeks	28 weeks	32 weeks	36 weeks	40 weeks	44 weeks	48 weeks
WBC														
ANC														
Hb														
Platelets														
Cr														
LFTs														
HCV RNA QUANT														
TSH														
Assess depression														
Assess pregnancy risk														
Assess side effects														

Clinician Name: _____

Clinician Signature:_____

Date:

CDCR Stamp

Patient name:
CDCR number:
DOB:

Monitoring during HCV Treatment Flowsheet-Genotype 2 or 3

Date	baseline	2weeks	4 weeks	8 weeks	12 weeks	16 weeks	20 weeks	24 weeks	28 weeks	32 weeks	36 weeks
WBC											
ANC											
Hb											
Platelets											
Cr											
LFTs											
HCV RNA QUANT											
TSH											
Assess depression											
Assess pregnancy risk											
Assess side effects											

Clinician Name: _____

Clinician Signature:_____

Date:

CDCR Stamp

Patient name:
CDCR number:
DOB:

Management of Side Effects

It is important to ***drink lots of fluids*** and stay hydrated.

Flu-Like Symptoms	Acetaminophen or NSAID
Fatigue/Insomnia	Moderate exercise and frequent rest periods. Avoid caffeine, late in the day
Anorexia/Weight Loss	Small frequent meals, focus on foods that appeal
Depression/Emotional lability	Treat aggressively with anti-depressants; refer to mental health professional and support groups
Alopecia	Reversible, hair grows back after treatment

Anemia

HEMOGLOBIN g/dL	RIBAVIRIN DOSE AT THE TIME OF TOXICITY	ACTION
A decrease to < 12.0 and ≥ 10.0 (or symptomatic anemia at any level thought to be significant by the clinician)	1000 to 1200 mg/day	Continue same RBV dose. Initiate Epo 20,000u sq q week + FeSO4 325mg po TID. Recheck Hgb weekly. If Hgb returns to > 12, decrease Epo dose to maintain (10-20k weekly).
A decrease to < 10.0 and ≥ 8.5	1000 to 1200 mg/day	Decrease RBV to 600 mg/day if < 75kg; 800 mg/day if ≥75kg. (See below for re-escalation) Initiate Epo 20,000u sq q week + FeSO4 325mg po TID. Recheck Hgb weekly.
A decrease to < 8.5	All doses	Temporarily stop drug (See below for reintroduction) Initiate Epo 20,000u sq q week + FeSO4 325mg po TID. Recheck Hgb weekly.
A decrease of ≥ 2.0 during any 4-week period	All doses	Initiate Epo 20,000u sq q week + FeSO4 325mg po TID. Recheck Hgb weekly. If Hgb returns to baseline, decrease Epo dose to maintain (10-20k weekly).
A decrease of ≥ 4.0 (or ≥ 2.5 for subjects with stable cardiovascular disease) during any 4-week period	All doses	Temporarily stop drug (See below for reintroduction) Initiate Epo 20,000u sq q week + FeSO4 325mg po TID. Recheck Hgb weekly.

If RBV is temporarily stopped due to anemia, then

- recheck hemoglobin within 2 weeks and at 2-week intervals until stable.
- if hemoglobin > 10.0, restart RBV at a dose of 600 mg/day if < 75kg; 800 mg/day if ≥ 75kg.
- raise by 200 mg/day at 2-week intervals back to the initial dose reached as long as hemoglobin remains > 10.0.

If RBV dose reduced for anemia

- increase the dose by 200 mg/day at 2-week intervals back to the initial dose is reached as long as the hemoglobin remains >10.0.

Thrombocytopenia

Platelets < 50,000: Reduce dose to 90mcg/wk and reevaluate
< 25,000: Discontinue dose until resolution

Leukopenia/Neutropenia

WBC <1.0: Discontinue dose until resolution

ANC <750/mm3: Reduce dose to 135mcg/wk and reevaluate
<500/mm3: Discontinue dose until resolution

GCSF may be appropriate for patients who are cirrhotic, post liver transplant, or HIV/HCV coinfected with an ANC <500/mm3, particularly if neutropenia persists despite dose reduction. Typical dosing of GCSF is 300mcg sq once to twice weekly; doses can be titrated to desired ANC >500/mm

Current management of the complications of portal hypertension: variceal bleeding and ascites

Nina Dib, Frédéric Oberti, Paul Calès

ABSTRACT

Portal hypertension is one of the main consequences of cirrhosis. It results from a combination of increased intrahepatic vascular resistance and increased blood flow through the portal venous system. The condition leads to the formation of portosystemic collateral veins. Esophagogastric varices have the greatest clinical impact, with a risk of bleeding as high as 30% within 2 years of medium or large varices developing. Ascites, another important complication of advanced cirrhosis and severe portal hypertension, is sometimes refractory to treatment and is complicated by spontaneous bacterial peritonitis and hepatorenal syndrome. We describe the pathophysiology of portal hypertension and the current management of its complications, with emphasis on the prophylaxis and treatment of variceal bleeding and ascites.

CMAJ 2006;174(10):1433-43

Portal hypertension is one of the main consequences of cirrhosis. It can result in severe complications, including bleeding of esophagogastric varices as well as spontaneous bacterial peritonitis or hepatorenal syndrome as complications of ascites. We describe in brief the pathophysiology of portal hypertension and review the current management of its complications, with emphasis on variceal bleeding and ascites.

Pathophysiologic background

Portal hypertension

Portal hypertension is defined as an increase in blood pressure in the portal venous system. The portal pressure is estimated indirectly by the hepatic venous pressure gradient — the gradient between the wedged (or occluded) hepatic venous pressure and the free hepatic venous pressure. A normal hepatic venous pressure gradient is less than 5 mm Hg.

In cirrhosis, portal hypertension results from the combination of increased intrahepatic vascular resistance and increased blood flow through the portal venous system (Fig. 1). According to Ohm's law, portal venous pressure (P) is the product of vascular resistance (R) and blood flow (Q) in the portal bed ($P = Q \times R$). Intrahepatic resistance increases in 2 ways: mechanical and dynamic. The mechanical component stems from intrahepatic fibrosis development; various pathologic processes are thought to contribute to increased intrahepatic resistance at the level of the hepatic microcirculation (sinusoidal portal hypertension): architectural distortion of the liver due to fibrous tissue,[1] regenerative nodules,[1] and collagen deposition in the space of Disse.[2] The dynamic component results from a vasoconstriction in portal venules secondary to active contraction of portal and septal myofibroblasts, to activated hepatic stellates cells and to vascular smooth-muscle cells.[3–5] Intrahepatic vascular tone is modulated by endogenous vasoconstrictors (e.g., norepinephrine, endothelin-1, angiotensin II, leukotrienes and thromboxane A_2) and enhanced by vasodilators (e.g., nitric oxide). In cirrhosis, increased intrahepatic vascular resistance results also from an imbalance between vasodilators and vasoconstrictors.[6]

Portal hypertension is characterized by increased cardiac output and decreased systemic vascular resistance,[7] which results in a hyperdynamic circulatory state with splanchnic and systemic arterial vasodilation. Splanchnic arterial vasodilation leads to increased portal blood flow, which in turn leads to more severe portal hypertension. Splanchnic arterial vasodilation results from an excessive release of endogenous vasodilators such as nitric oxide, glucagon and vasointestinal active peptide.

An increase in the portocaval pressure gradient leads to the formation of portosystemic venous collaterals in an attempt to decompress the portal venous system. Esophageal varices, drained predominantly by the azygos vein, are clinically the most important collaterals because of their propensity to bleed. Esophageal varices can develop when the hepatic venous pressure gradient rises above 10 mm Hg.[8–10] All factors that increase portal hypertension can increase the risk of variceal bleeding, including deterioration of liver disease,[11] food intake,[12,13] ethanol intake,[14] circadian rhythms,[15] physical exercice[16] and increased intra-abdominal pressure.[17] Factors that alter the variceal wall, such as ASA and other NSAIDs, could also increase the risk of bleeding.[18,19] Bacterial infection can promote initial and recurrent bleeding.[20]

Ascites and hepatorenal syndrome

In advanced cirrhosis, splanchnic arterial vasodilation promoted by portal hypertension is pronounced and leads to the

DOI:10.1503/cmaj.051700

© 2006 CMA Media Inc. or its licensors

impairment of systemic and splanchnic circulation.[21] Systemic vasodilation leads to relative hypovolemia, with a decrease in effective blood volume and a fall in mean arterial pressure. States of homeostasis and antinatriuresis are activated to maintain arterial pressure, which results in sodium and fluid retention.[21] In addition, a combination of portal hypertension and splanchnic arterial vasodilation alters splanchnic microcirculation and intestinal permeability, facilitating the leakage of fluid into the abdominal cavity.[21] As cirrhosis progresses, the kidneys' ability to excrete sodium and free water is impaired; sodium retention and ascites develop when the amount of sodium excreted is less than the amount consumed.[21] Decreased free water excretion leads to dilutional hyponatremia and eventually to impaired renal perfusion and hepatorenal syndrome.[21]

Variceal bleeding

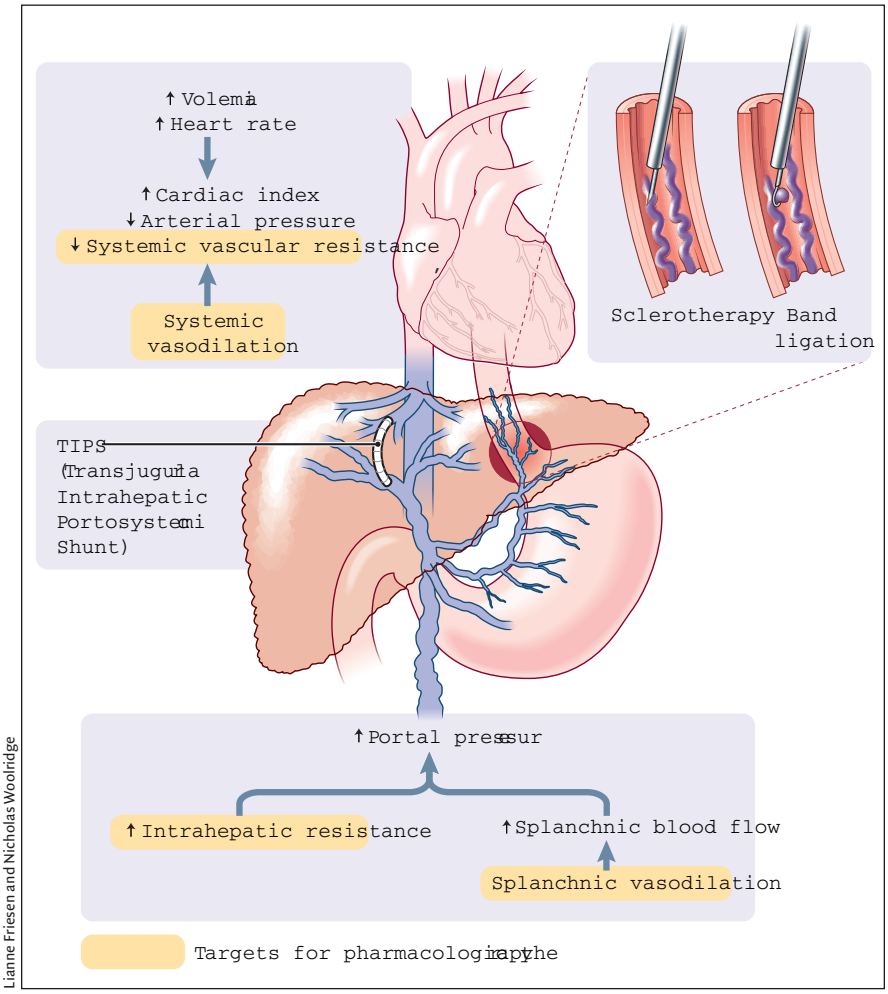
Variceal bleeding is a medical emergency associated with high rates of recurrence and death.[22–25] Its management is based on specific treatments, including pharmacologic therapy, endoscopic treatment and antibiotic therapy.

Pharmacologic therapy

Vasopressin and its analogue terlipressin: Vasopressin is a potent splanchnic vasoconstrictor; however, its use was abandoned 25 years ago in most countries because of its severe vascular side effects. Terlipressin, a vasopressin analogue not currently licensed for use in Canada, has similar effects,[26] reducing the hepatic venous pressure gradient, variceal pressure and azygos blood flow.[27,28] Terlipressin has been found to be superior to placebo in the control of variceal bleeding.[29] It has also been found to decrease renal vasoconstrictor system activity and improve renal function in patients with hepatorenal syndrome.[30–33] However, terlipressin can induce ischemic complications, particularly in cases of severe hypovolemic shock,[34] and it is contraindicated in patients with cardiovascular disease (arterial disease with severe obstruction, cardiac insufficiency, arrhythmias, hypertension).

Somatostatin and its analogues octreotide and vapreotide: Somatostatin significantly reduces the hepatic venous pressure gradient,[35–37] variceal pressure[38] and azygos blood flow;[36] however, because its hemodynamic effect is transient, continuous infusion is required.[36] Four placebo-controlled studies showed contrasting results. Somatostatin was more effective than placebo in controlling variceal bleeding,[39,40] but its effectiveness in reducing the need for transfusion[41,42] and balloon tamponade[41] remains unproven. Terlipressin appears to be as effective as somatostatin in the control of bleeding.[29]

Octreotide and vapreotide have a longer half-life than somatostatin and are useful in the management of portal hypertension. Octreotide decreases the hepatic venous pressure gradient and azygos blood flow[43–46] but not variceal pressure.[27,47] However, the effect of octreotide is transient[43–46] and controversial.[48] It prevents the increase in hepatic blood flow after a



Lianne Friesen and Nicholas Woolridge

Fig. 1: Pathophysiology of portal hypertension in cirrhosis. Portal hypertension results from increased intrahepatic vascular resistance and portal–splanchnic blood flow. In addition, cirrhosis is characterized by splanchnic and systemic arterial vasodilation. Splanchnic arterial vasodilation leads to increased portal blood flow and thus elevated portal hypertension. An increased hepatic venous pressure gradient leads to the formation of portosystemic venous collaterals. Esophagogastric varices represent the most clinically important collaterals given their associated high risk of bleeding. Treatment consists of pharmacologic therapy to decrease portal pressure, endoscopic treatment of varices (band ligation or sclerotherapy) to treat variceal bleeding, and creation of a transjugular intrahepatic portosystemic shunt (TIPS) to reduce portal pressure if drug therapy and endoscopic treatment fail.

meal,[49] and it seems to be as efficient as terlipressin in treating variceal bleeding and in improving the efficacy of endoscopic therapy.[50–52] Only one double-blind randomized controlled trial of octreotide has been published (in brief) to date, and it showed that octreotide was not more effective than placebo in controlling and preventing early recurrent variceal bleeding.[53] In a randomized controlled trial, vapreotide, a long-acting analogue of somatostatin not currently licensed for use in Canada, was administered before endoscopic treatment and was found to result in fewer blood transfusions and better control of bleeding than endoscopic treatment alone.[54]

No major toxic effects and practically no complications are associated with the use of somatostatin or its analogues.

Endoscopic diagnosis and treatment

Endoscopy is useful in the diagnosis and treatment of bleeding esophagogastric varices. Three endoscopic techniques are currently used: endoscopic band ligation, endoscopic sclerotherapy and variceal obturation with glue.

Endoscopic band ligation: Currently, endoscopic band ligation is the first choice of endoscopic treatment for esophagogastric varices. The procedure involves placing an elastic band on a varix, which allows aspiration of the varix in a cylinder attached to an endoscope. A maximum of 5–8 elastic bands should be used per session. Sessions should be performed every 2–3 weeks until the varices have been obliterated or have become so small that ligation is impossible.[55] Complications of endoscopic band ligation are fewer than those with endoscopic sclerotherapy. Generally, bleeding from a post-ligation ulcer is moderate.[56]

Endoscopic sclerotherapy: There are several sclerosant agents (polidocanol, ethanolamine, ethanol, tetradecyl sulfate and sodium morrhuate), and they provide similar results. The treatment involves intravariceal or paravariceal injections of the sclerosant agent (total volume 10–30 mL per session) every 1–3 weeks until the varices have been obliterated.[56] Given that varices recur in 50%–70% of cases,[57] surveillance endoscopy every 3–6 months is required.[57,58] Frequent complications of endoscopic sclerotherapy are retrosternal pain, dysphagia and postsclerotherapy bleeding ulcers. More severe complications, such as esophageal perforation or stricture, have been reported.[56]

Variceal occlusion with glue: This treatment is especially useful in patients who have had gastric or gastroesophageal variceal bleeding. It consists of embolization of varices by injecting them with the tissue adhesive *N*-butyl-2-cyanoacrylate; the adhesive polymerizes in contact with blood. One millilitre of adhesive is injected at a time, with a maximum of 3 injections per session. The most serious risk associated with this procedure is embolization of the lung, spleen or brain.[59]

Transjugular intrahepatic portosystemic shunt

Percutaneous creation of a transjugular intrahepatic portosystemic shunt (TIPS) through a jugular route connects the hepatic and portal veins in the liver. The goal is to reduce portal pressure and thus prevent variceal bleeding.[60] TIPS diverts portal blood flow from the liver, but it increases the risk of encephalopathy.[61–63] In most cases encephalopathy responds to standard therapy, but in some cases the calibre of the shunt has to be reduced;[60] rarely, when encephalopathy does not respond to treatment (in 5% of cases) the shunt should be occluded.[60] Thrombosis and stenosis are other complications that can cause TIPS dysfunction.[60] Recently, it has been reported that the use of a polytetrafluoroethylene-covered stent decreases the rate of shunt dysfunction.[64] The putative increased risk of hepatocellular carcinoma remains to be clarified.

Other treatment options

Balloon tamponade: In cases of massive or uncontrolled bleeding, balloon tamponade provides a "bridge" to definitive treatment with TIPS or portosystemic surgical shunt.[55,65] The most frequently used balloon is the 4-lumen modified Sengstaken–Blakemore tube, which employs a gastric and esophageal balloon.[56] In cases of bleeding gastric varices, use of the Linton–Nachlas tube with a large gastric balloon is recommended.[56]

Portosystemic surgical shunt: Its usefulness has dramatically decreased since the advent of TIPS. Moreover, the procedure requires an experienced surgeon. In cases of refractory bleeding and when TIPS is technically impossible, creation of a nonselective portosystemic shunt may be suitable in patients with cirrhosis provided that the liver dysfunction is not too severe (Child–Pugh class A or B, Appendix 1).

Practical management

Variceal bleeding should be managed in an intensive care unit.[55] Treatment should include nonspecific therapy, such as blood volume replacement and antibiotic prophylaxis, as well as specific treatments, such as pharmacologic therapy and endoscopic treatment (Box 1, Fig. 2).

Nonspecific treatment

Nonspecific treatment aims to correct hypovolemia and to prevent complications. Blood volume replacement should be done cautiously using concentrated erythrocytes to obtain a hemoglobin level of about 70–80 g/L.[55,65] Overtransfusion should be avoided given the risk of increased portal pressure[37,66,67] and continued or recurrent bleeding.[68] Plasma expanders are used to maintain hemodynamic stability and renal perfusion pressure.[55,65] Either a crystalloid (isotonic saline solution) or colloid solution can be used, but a crystalloid solution is preferred because it is harmless.[55]

Infection occurs in 25%–50% of patients with cirrhosis and gastrointestinal bleeding.[69] Failure to control bleeding and rates of death are increased in infected patients.[69,70] The early administration of antibiotic prophylaxis will benefit all patients with variceal bleeding and improve survival.[55,65,71,72] One recommended protocol is oral administration of norfloxacin (400 mg twice daily for 7 days).[55,73]

The routine use of a nasogastric tube is not recommended.

Box 1: Recommendations for the treatment of acute variceal bleeding*

- Variceal bleeding is a medical emergency and should be managed in the intensive care unit
- Blood volume replacement should be performed cautiously using:
  - concentrated erythrocytes, to obtain a hemoglobin level of about 70-80 g/L
  - plasma expanders (crystalloid or colloid), to maintain hemodynamic stability and renal perfusion pressure
- Antibiotic prophylaxis should be given to all patients
- Endoscopy should be performed as soon as possible (within 12 h after hospital admission)
- Specific treatment should consist of combination therapy with a vasoactive drug and endoscopic treatment:
  - Intravenous vasoactive therapy with one of the following drugs should be started as soon as possible after hospital admission, before diagnostic endoscopy, and maintained for 2-5 d:
    - Terlipressin:† 1-2 mg every 4 h[74]
    - Somatostatin: bolus of 250 μg followed by infusion of 250 μg/h[74]
    - Octreotide: infusion of 25-50 μg/h, possibly preceded by bolus of 50-100 μg[74]
    - Vapreotide:† bolus of 50 μg followed by infusion of 50 μg/h[54]
  - Either endoscopic band ligation or endoscopic sclerotherapy can be performed, but band ligation is the recommended first-line treatment. In cases of acute gastric variceal bleeding, variceal obturation with a tissue adhesive (*N*-2-butyl-cyanoacrylate) is recommended[65]
- If combined therapy with vasoactive drug and endoscopic treatment fails, endoscopic treatment should be repeated or TIPS performed (second-line treatment). If repeat endoscopic treatment fails, TIPS is justified

Note: TIPS = transjugular intrahepatic portosystemic shunt.
*These recommendations are based on information from recent consensus statements on the management of portal hypertension.[55,65]
†Not currently licensed for use in Canada.

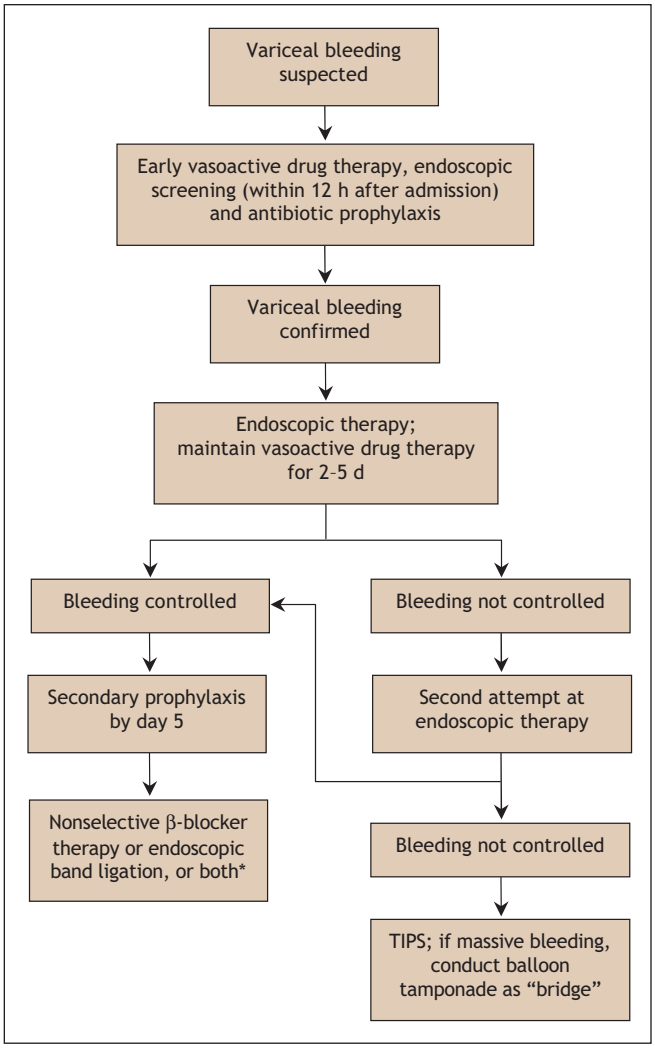


Fig. 2: Algorithm for the treatment of variceal bleeding. TIPS = transjugular intrahepatic portosystemic shunt. *The therapeutic option depends on what was done in primary prophylaxis.

Patients with encephalopathy should be given lactulose;[65] however, insufficient information exists to recommend its use in the prevention of hepatic encephalopathy.[55,65]

Specific treatment

Intravenous therapy with a vasoactive drug should be started as soon as possible following hospital admission, before diagnostic endoscopy, and maintained for 2–5 days (Box 1).[54,55,65,74] Vasopressin is not recommended because of its deleterious side effects.

Endoscopy should be performed within 12 hours after hospital admission on an empty stomach, which can be achieved by either intravenous injection of erythromycin (250 mg begun 30–60 minutes before endoscopy) or lavage through a nasogastric tube.[55,65] Endoscopy is useful in confirming the source of bleeding and allowing hemostatic treatment. Either endoscopic band ligation or endoscopic sclerotherapy may be used.[55,65] However, endoscopic band ligation is the recommended first-line treatment.[65] In patients who have bled from gastric or gastroesophageal varices, endoscopic obliteration with the tissue adhesive *N*-butyl-2-cyanoacrylate should be performed.[65] However, endoscopic band ligation is also possible to treat gastroesophageal varices.

If combined vasoactive and endoscopic therapy fails, a second attempt at endoscopic therapy is justified if the bleeding is mild and the prognosis not compromised.[55,65,75] TIPS is a second-line treatment option.[65] Balloon tamponade can be used as a "bridge" in cases of massive bleeding.[55,65] If bleeding persists or compromises prognosis, TIPS or surgical shunt creation should be offered as a rescue therapy.[55,65]

Esophagogastric varices

At present, there is no satisfactory nonendoscopic indicator to detect the presence of esophagogastric varices.[65,76] Endoscopic screening is the best technique.[76,77] The goal of management is to prevent variceal bleeding. This is achieved in 3

ways: by preventing the development of varices (preprimary prophylaxis), by preventing a first variceal bleeding episode once varices have developed (primary prophylaxis) and by preventing recurrent bleeding (secondary prophylaxis) (Fig. 3).

Pharmacologic therapy

Pharmacologic therapy is used to control and prevent variceal bleeding. The 2 classes of drugs used are β-blockers and nitrates.

β-Blockers: β-Blockers lower portal pressure by reducing portal blood flow. The blood flow is reduced as a consequence of decreased cardiac output (β_1 receptor blockade) and arteriolar splanchnic vasoconstriction by an unopposed α-vasoconstrictive effect (β_2 receptor blockade).[78] Nonselective β-blockers such as propranolol, nadolol and timolol are more effective than selective β_1-blockers in reducing the hepatic venous pressure gradient.[79,80] The median reduction of the gradient by nonselective β-blockers is about 15%.[79,81–84] Nonselective β-blockers reduce variceal pressure[85] and azygos blood flow[86–88] even in patients who do not exhibit a marked decrease in the hepatic venous pressure gradient (propranolol "nonresponders").[87,89] Propranolol has been found to prevent increases in portal pressure related to physical exercise in patients with cirrhosis[90] and to decrease the rate of bacterial translocation.[91] It has also been found to reduce postprandial peak in portal pressure;[92] however, this effect with long-term use was not confirmed in 2 recent trials.[93,94]

It has been suggested that the hepatic venous pressure gradient could be measured to evaluate the efficiency of β-blocker treatment.[95] Several studies have shown that variceal bleeding does not occur if the gradient is reduced to below 12 mm Hg[81,96] or that bleeding occurs at a low rate if the gradient is reduced by at least 20% of the basal value.[96–99] However, the prognostic value of the hepatic venous pressure gradient on survival is still controversial.[100,101] Besides, the measurement of the gradient is invasive and not cost-effective; its use is not recommended in clinical practice and is limited to selected hospitals.[76]

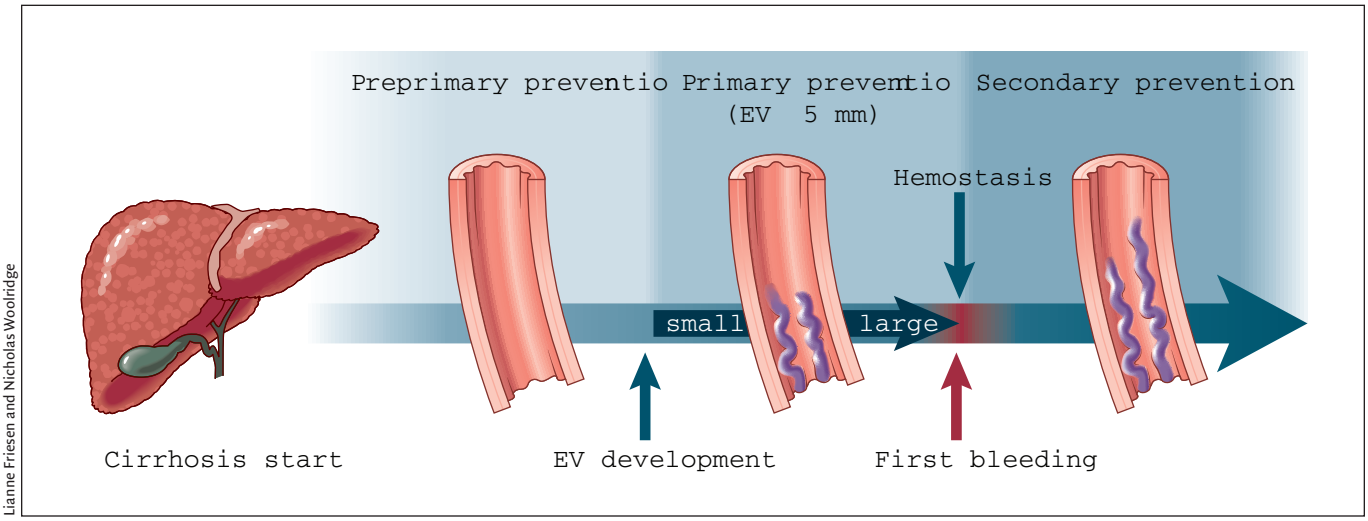
Nitrates: The mechanism of the vasodilatory effects of nitrates — vascular tone reduction and decreased intrahepatic resistance — is not completely understood. It likely involves nitric oxide release. Isosorbide mononitrate is the only nitrate that has been tested in randomized trials. It has been found to reduce the hepatic venous pressure gradient[102] and to enhance the splanchnic hemodynamic effect of propranolol.[103] However, its systemic effects can lead to deleterious arterial hypotension. Nitrates are used in association with vasopressin or its analogue terlipressin.

Preprimary prophylaxis

Three clinical trials have studied this issue, but the results are not concordant.[104–106] According to a statement from the Baveno international consensus conference, the use of β-blocker therapy is not recommended for preprimary prophylaxis.[65]

Primary prophylaxis

Endoscopic screening for the presence of esophagogastric varices should be done in all patients after the diagnosis of cirrhosis (Box 2).[55,65] Screening should be repeated every 3 years in patients without varices and every 2 years in those with small varices (Fig. 4).[55] Endoscopic follow-up should then relate to the initial size of detected varices. In case of large varices, endoscopic follow-up is not necessary, and primary prophylaxis with a nonselective β-blocker (propranolol or nadolol) should be started.[55] Endoscopic band ligation is useful in preventing variceal bleeding in patients with medium or large varices; however, its long-term benefit requires



Lianne Friesen and Nicholas Woolridge

Fig. 3: Prophylaxis of variceal bleeding in cirrhosis. Preprimary prophylaxis is aimed at preventing esophagogastric varices (EV) from developing. The goal of primary prophylaxis is to prevent a first variceal bleeding episode once medium or large varices have formed. Secondary prophylaxis is used to prevent recurrent variceal bleeding.

Box 2: Recommendations for the primary prevention of variceal bleeding*

- All patients with newly diagnosed cirrhosis should undergo screening endoscopy for the detection of esophagogastric varices; follow-up should be adapted according to the initial size of the varices and the degree of liver failure
- Patients with medium or large varices should be given treatment with a nonselective β-blocker initially; treatment should be continued indefinitely
- Patients with medium or large varices who have contraindications to or do not tolerate β-blocker therapy should undergo endoscopic band ligation of the varices
- In patients with small varices who have red signs on varices or who have Child-Pugh class C cirrhosis may benefit from nonselective β-blocker therapy
- The usual dose of nonselective β-blocker therapy is 80-160 mg/d for propranolol and 80 mg/d for nadolol
- The dose should be adjusted to obtain a 20%-25% reduction in heart rate or a heart rate of less than 55 beats/min

*These recommendations are based on information from recent consensus statements on the management of portal hypertension.[55,65]

further research,[65] and it is not currently proposed for use in primary prophylaxis unless the patient has contraindications to or side effects from nonselective β-blocker therapy.

Therapy with a nonselective β-blocker is effective in reducing the risk of a first variceal bleeding episode in patients with medium or large varices.[65,107–111] Conventional treatment consists of administering the drug orally twice daily and titrating the dose according to the patient's tolerance and to the treatment objectives based on heart rate response.[112,113] However, results of a pharmacodynamic study suggested that a single daily dose of long-acting propanolol is sufficient[114] (80 or 160 mg, depending on the available dose in each country[115]). In all cases, doses should be adjusted to obtain a 20%–25% reduction in heart rate or a heart rate of less than 55 beats/min.[55] Propranolol is effective for a few days in cirrhotic patients after the last dose is administered.[114] β-Blocker therapy should be maintained indefinitely,[55] since late withdrawal can be deleterious on survival despite the lack of an increased risk of bleeding.[116] In patients who do not tolerate or have contraindications to β-blocker therapy, endoscopic band ligation is recommended[55,65] (Fig. 4). Nitrates (isosorbide mononitrate) are ineffective in preventing variceal bleeding if used alone,[117,118] and their use in primary prophylaxis is not recommended.[55,65]

Secondary prophylaxis

All patients who survive a variceal bleeding episode should receive treatment to prevent recurrent episodes. As a first-line treatment, both pharmacologic and endoscopic treatments can be used to prevent a recurrence. Pharmacologic therapy includes use of a nonselective β-blocker.[111,119–122] Although it has been proposed,[123] combined treatment with isosorbide mononitrate and propranolol is not recommended.[55,65]

Eradication of varices by endoscopic procedures is also effective in preventing recurrent variceal bleeding. Only endoscopic sclerotherapy has been compared with placebo, and it was associated with a significant reduction in recurrent bleeding and mortality.[56,124] Endoscopic band ligation is currently preferable to endoscopic sclerotherapy,[55] since it has been found to be more effective in reducing the risk of recurrent variceal bleeding and the incidence of variceal stricture.[125–127] Combined therapy with the 2 endoscopic procedures does not appear to be more effective than endoscopic band ligation alone.[128] However, endoscopic sclerotherapy may be effective in preventing the recurrence of varices when endoscopic band ligation is no longer feasible. One trial of endoscopic band ligation with and without therapy with nadolol and sucralfate for secondary prophylaxis showed reduced rates of recurrent variceal bleeding in the group given the combined therapy.[129] Such a beneficial effect was not confirmed for combined therapy with endoscopic sclerotherapy and nonselective β-blockers.[130,131]

If secondary prophylaxis with a nonselective β-blocker or endoscopic band ligation, or both, fails to prevent variceal

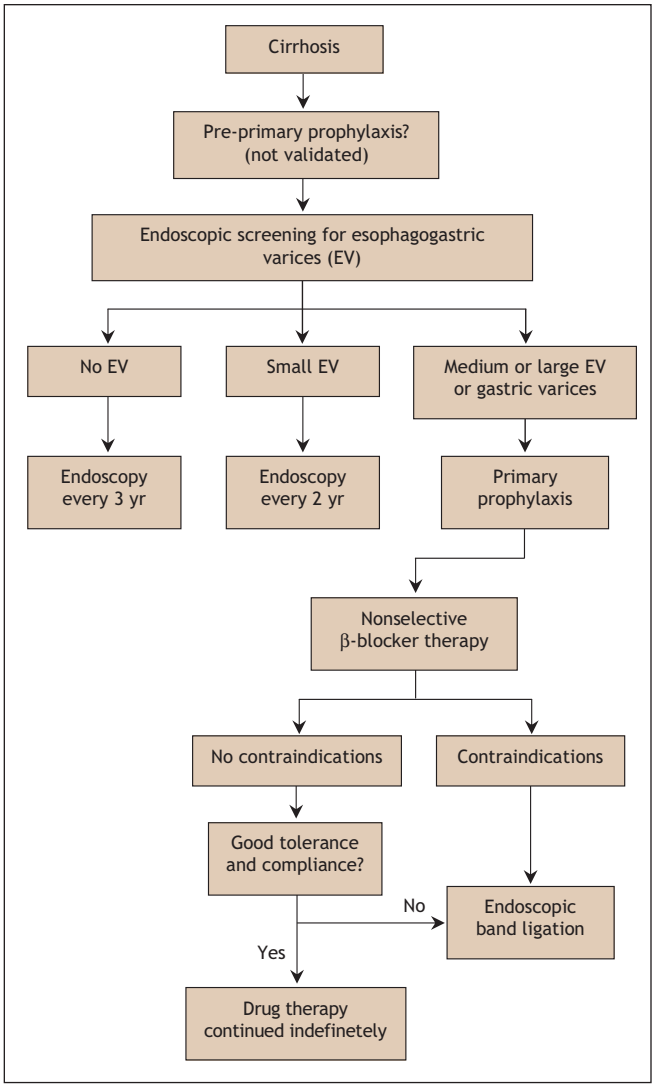


Fig. 4: Algorithm for the primary prophylaxis of variceal bleeding in cirrhosis.

Box 3: Recommendations for the secondary prevention of variceal bleeding*

- For patients who did not receive primary prophylaxis (see Box 2), prescribe therapy with a nonselective β-blocker or perform endoscopic band ligation (EBL) of varices, or both
- For patients who did receive primary prophylaxis with a β-blocker, evaluate whether the dose is appropriate:
  - If the dose is appropriate, the β-blocker therapy should not be continued alone; perform EBL
  - If the dose is not appropriate, either adjust the dose to an optimal amount or perform EBL
- Patients who have contraindications to or do not tolerate β-blocker therapy should undergo EBL
- If EBL fails as a primary prophylactic treatment, TIPS should be performed. In all cases, liver transplantation should be considered, particularly in patients with Child-Pugh class B or C cirrhosis

Note: TIPS = transjugular intrahepatic portosystemic shunt.
*These recommendations are based on information from recent consensus statements on the management of portal hypertension.[55,65]

bleeding, rescue therapies should be considered. Both TIPS and surgical shunt creation are effective in preventing recurrent variceal bleeding.[125] TIPS is more effective than endoscopic treatment,[132] and surgical shunt creation is more effective than endoscopic sclerotherapy;[133] however, neither TIPS nor surgical shunt creation has been found to improve survival, and both are associated with a high risk of encephalopathy.[132,133]

The 2 consensus statements on portal hypertension[55,65] have established recommendations on prophylaxis status before variceal bleeding (Box 3). In patients who have not received previous primary prophylaxis, therapy with a nonselective β-blocker or endoscopic band ligation, or both, can be used. If primary prophylaxis with a β-blocker at an appropriate dose fails, the β-blocker therapy should not be continued alone and endoscopic band ligation should be performed. If the β-blocker dose is not found to be appropriate, either changing it to an optimal dose or performing endoscopic band ligation is possible. If endoscopic band ligation fails as primary prophylaxis, TIPS is the next option. Liver transplantation should be considered in all cases, particularly in patients with severe cirrhosis (Child–Pugh class B or C).

Ascites and its complications

Ascites occurs in cases of advanced cirrhosis and severe portal hypertension. The ultimate complications of ascites are refractory ascites, hepatorenal syndrome and spontaneous bacterial peritonitis.

Uncomplicated ascites

All patients with ascites should undergo an evaluation of ascitic fluid content to rule out spontaneous bacterial peritonitis.[134,135] The evaluation should include cell count, bacterial culture in blood culture medium, measurement of protein concentration and cytologic examination in cases of suspected malignant ascites.[134,135] The use of leukocyte reagent strips has been recently proposed for the early detection of leukocytes in ascites and spontaneous bacterial peritonitis.[136–139]

For subclinical ascites detectable only by ultrasonography, no specific treatment is necessary.[135] However, a reduction in daily sodium intake (to 90 mmol/d) is recommended.

In cases of moderate ascites, renal function is usually preserved and treatment can be administered on an outpatient basis.[134] Moderate dietary sodium restriction (90 mmol of sodium per day) should be imposed.[135] Spironolactone, an anti-mineralocorticoid, is the drug of choice at the onset of treatment because it promotes better natriuresis more often than loop diuretics.[140] It blocks the aldosterone-dependent exchange of sodium in the distal and collecting renal tubules, thus increasing the excretion of sodium and water.[141] The initial dose is about 100–200 mg/d.[134,135] About 75% of patients respond to treatment after only a few days.[135] Side effects of spironolactone are gynecomastia, metabolic acidosis, hyperkalemia and renal impairment.[135] In the presence of edema, treatment with furosemide (20–40 mg/d) may be added for a few days to increase natriuresis.[134,135] Loop diuretics act by increasing sodium excretion in the proximal tubules. In cirrhosis, the effect of loop diuretic monotherapy is limited and therefore is more commonly used as an adjunct to spironolactone therapy.[135] The side effects of furosemide include hypokaliemia, metabolic hypochloremic alkalosis, hyponatremia, hypovolemia and related renal dysfunction.[135] Amiloride (5–10 mg/d) may be used when spironolactone is contraindicated or if side effects such as gynecomastia occur.[134,135] It also acts in the distal tubule.[135] Diuretic therapy should be monitored by measuring the patient's weight and levels of serum electrolytes, urea and creatinine daily.[135] Maximum weight loss should not exceed 500 g/d in patients without peripheral edema and 1000 g/d in those with it.[135] If the therapeutic effect is insufficient, urinary sodium excretion should be determined to identify nonresponsive patients (characterized by a urinary sodium excretion below 30 mmol/d).[135]

Patients with severe ascites will have marked abdominal discomfort. In such cases, higher diuretic doses are needed (i.e., up to 400 mg of spironolactone and 160 mg of furosemide daily).[134,135] However, in some patients, free-water excretion is impaired and severe hyponatremia may develop.[134] Frequently, large-volume paracentesis should be done.[135] Paracentesis should be routinely combined with plasma volume expansion. If the volume of ascites removed is less than 5 L, a synthetic plasma substitute may be used.[135,142] If more than 5 L of ascitic fluid is removed, albumin should be given at a dose of 8 g per litre of fluid removed.[135]

Refractory ascites develops in about 10% of cases.[143] In such cases, liver transplantation should be considered.[55,135] In the meantime, therapeutic strategies can involve repeated large-volume paracentesis and plasma volume expansion with albumin or TIPS.[55,134,135] TIPS improves renal function and sodium excretion[60,144,145] and is more effective than paracentesis in removing ascites.[61,63] TIPS has a mortality not significantly differerent from that associated with paracentesis.[63]

Nevertheless, a recent meta-analysis has reported a tendency toward improved survival with TIPS.[61]

Hepatorenal syndrome

Hepatorenal syndrome is the most serious circulatory renal dysfunction in cirrhosis[21] and is the most severe complication of portal hypertension. It occurs in up to 10% of patients with ascites.[146] The syndrome is defined by a serum creatinine concentration greater than 1.5 mg/dL (> 133 µmol/L).[134] Type 1 hepatorenal syndrome involves the rapid impairment of renal function, characterized by a doubling of the initial serum creatinine concentration to more than 2.5 mg/dL (> 221 µmol/L) within 2 weeks.[146] In type 2 hepatorenal syndrome, renal impairment is stable or progresses at a slower rate than that in type 1.[146]

The ideal treatment of hepatorenal syndrome is liver transplantation.[55] Besides transplantation, vasoactive drug therapy in combination with albumin (20–40 g/d for 5–15 days) can be used.[55,134] The efficiency of terlipressin (0.5–1 mg intravenously every 4–12 hours) has been reported in several uncontrolled trials.[31–33] Therapy with norepinephrine (0.5–3.0 mg/h intravenously)[147] or midodrine (7.5–12.5 mg orally 3 times daily) in association with octreotide (100–200 µg subcutaneously 3 times daily)[148] has been suggested to improve hepatorenal syndrome, but its effectiveness remains to be confirmed. TIPS has been found to be effective in the management of hepatorenal syndrome by improving renal function, particularly in patients with a Child–Pugh score of 12 or less and a serum bilirubin level below 85 µmol/L.[149]

Spontaneous bacterial peritonitis

Spontaneous bacterial peritonitis, an infection of the ascitic fluid, occurs in 10%–30% of patients with ascites.[73] All cases in which the neutrophil count is at least 250×10^6/L in ascitic fluid should be treated empirically, since ascites culture yields negative results in about 40% of patients with symptoms suggestive of spontaneous bacterial peritonitis.[55,73] Empirical treatment should also be started if leukocytes are detected in ascitic fluid at a significant level on reagent strips.[136–139]

Because most cases of peritonitis are due to gram-negative bacteria (e.g., *Escherichia coli*),[134] therapy with a third-generation cephalosporin is the treatment of choice (cefotaxime 2–4 g/d, intravenously, for 5 days).[55,73] Alternative treatments include combination therapy with amoxicillin and clavulinic acid (1 g and 0.125 g respectively, given intravenously or orally 3 times daily) or norfloxacin (400 mg/d, orally) for 7 days.[55,73] Antibiotic therapy should be used in conjunction with albumin infusion (1.5 g/kg on day 1 and 1 g/kg on day 3)[55] to prevent renal failure and death.[150] Treatment efficacy should be assessed by means of evaluating clinical symptoms and determining the neutrophil count in ascitic fluid after 48 hours.[55,73] If treatment fails, antibiotic therapy should be shifted toward a broader-spectrum drug or to one adapted to the organism's antibiogram.[55,73]

Primary prophylaxis of spontaneous bacterial peritonitis with continuous oral norfloxacin therapy (400 mg/d) in hospital patients with cirrhosis who have a low ascitic protein concentration (< 10 g/L) is still debated.[55,73] The same treatment is recommended for secondary prophylaxis of spontaneous bacterial peritonitis until the ascites resolves, a treatment option that is more easily accepted by clinicians.[55,73]

Summary

Portal hypertension can lead to severe outcomes in patients with cirrhosis, including bleeding of esophagogastric varices and complications of ascites.

Variceal bleeding is a clinical emergency and requires blood volume replacement, early vasoactive drug therapy, prophylactic antibiotic treatment and endoscopic treatment. Prophylaxis of variceal bleeding involves the use of β-blocker therapy (first-line treatment in primary and secondary prophylaxis) and endoscopic treatment, especially band ligation (second-line step in primary and first-line step in secondary prophylaxis).

Treatment of ascites includes diuretic therapy and dietary sodium reduction. Main complications of ascites are refractory ascites, hepatorenal syndrome and spontaneous bacterial peritonitis. In refractory ascites, repeated large-volume paracentesis (with volume expansion using albumin) and TIPS can be proposed. In hepatorenal syndrome, the most serious complication of ascites, liver transplantation should be considered; vasoactive drug therapy in combination with albumin infusion can be given in the meantime. All patients with ascites should be screened for spontaneous bacterial peritonitis; if detected, treatment consists of antibiotics and albumin infusion to prevent hepatorenal syndrome.

This article has been peer reviewed.

From the Department of Hepato-Gastroenterology, University Hospital, and HIFIH Laboratory, Université d'Angers, Angers, France (all authors).

Competing interests: None declared for Nina Dib, Frédéric Oberti. Paul Calès has received honoraria for clinical research from Debiovision, Montréal.

Contributors: All of the authors made substantial contributions to the conception and design of the study, the acquisition, analysis and interpretation of the data, the drafting of the article and the critical revision of it for important intellectual content. All gave final approval of the version to be published.

Acknowledgment: We thank Myriam Brian for her help with English-language revisions.

REFERENCES

1. Shibayama Y, Nakata K. Localization of increased hepatic vascular resistance in liver cirrhosis. *Hepatology* 1985;5:643-8.
2. Orrego H, Medline A, Blendis LM, et al. Collagenisation of the Disse space in alcoholic liver disease. *Gut* 1979;20:673-9.
3. Pinzani M, Gentilini P. Biology of hepatic stellate cells and their possible relevance in the pathogenesis of portal hypertension in cirrhosis. *Semin Liver Dis* 1999;19:397-410.
4. Rockey DC, Weisiger RA. Endothelin induced contractility of stellate cells from normal and cirrhotic rat liver: implications for regulation of portal pressure and resistance. *Hepatology* 1996;24:233-40.
5. Wiest R, Groszmann RJ. The paradox of nitric oxide in cirrhosis and portal hypertension: too much, not enough. *Hepatology* 2002;35:478-91.
6. Abraldes JG, Angermayr B, Bosch J. The management of portal hypertension [review]. *Clin Liver Dis* 2005;9:685-713, vii.
7. Menon KV, Kamath PS. Regional and systemic hemodynamic disturbances in cirrhosis. [viii.]. *Clin Liver Dis* 2001;5:617-27.
8. Bosch J, Mastai R, Kravetz D, et al. Hemodynamic evaluation of the patient with portal hypertension. *Semin Liver Dis* 1986;6:309-17.

9. Garcia-Tsao G, Groszmann RJ, Fisher RL, et al. Portal pressure, presence of gastroesophageal varices and variceal bleeding. *Hepatology* 1985;5:419-24.
10. Lebrec D, De Fleury P, Rueff B, et al. Portal hypertension, size of esophageal varices, and risk of gastrointestinal bleeding in alcoholic cirrhosis. *Gastroenterology* 1980;79:1139-44.
11. Dell'era A, Bosch J. Review article: the relevance of portal pressure and other risk factors in acute gastro-oesophageal variceal bleeding [review]. *Aliment Pharmacol Ther* 2004;20(Suppl 3):8-15; discussion 16-7.
12. Lee SS, Hadengue A, Moreau R, et al. Postprandial hemodynamic responses in patients with cirrhosis. *Hepatology* 1988;8:647-51.
13. McCormick PA, Dick R, Graffeo M, et al. The effect of non-protein liquid meals on the hepatic venous pressure gradient in patients with cirrhosis. *J Hepatol* 1990;11:221-5.
14. Luca A, Garcia-Pagan JC, Bosch J, et al. Effects of ethanol consumption on hepatic hemodynamics in patients with alcoholic cirrhosis. *Gastroenterology* 1997;112:1284-9.
15. Garcia-Pagan JC, Feu F, Castells A, et al. Circadian variations of portal pressure and variceal hemorrhage in patients with cirrhosis. *Hepatology* 1994;19:595-601.
16. Garcia-Pagan JC, Santos C, Barbera JA, et al. Physical exercise increases portal pressure in patients with cirrhosis and portal hypertension. *Gastroenterology* 1996;111:1300-6.
17. Luca A, Cirera I, Garcia-Pagan JC, et al. Hemodynamic effects of acute changes in intra-abdominal pressure in patients with cirrhosis. *Gastroenterology* 1993;104:222-7.
18. De Ledinghen V, Heresbach D, Fourdan O, et al. Anti-inflammatory drugs and variceal bleeding: a case-control study. *Gut* 1999;44:270-3.
19. De Ledinghen V, Mannant PR, Foucher J, et al. Non-steroidal anti-inflammatory drugs and variceal bleeding: a case-control study. *J Hepatol* 1996;24:570-3.
20. Thalheimer U, Triantos CK, Samonakis DN, et al. Infection, coagulation, and variceal bleeding in cirrhosis. *Gut* 2005;54:556-63.
21. Arroyo V, Colmenero J. Ascites and hepatorenal syndrome in cirrhosis: pathophysiological basis of therapy and current management. *J Hepatol* 2003;38(Suppl 1):S69-89.
22. D'Amico G, De Franchis R. Upper digestive bleeding in cirrhosis. Post-therapeutic outcome and prognostic indicators. *Hepatology* 2003;38:599-612.
23. D'Amico G, Luca A. Natural history. Clinical-haemodynamic correlations. Prediction of the risk of bleeding. *Baillieres Clin Gastroenterol* 1997;11:243-56.
24. De Franchis R, Primignani M. Natural history of portal hypertension in patients with cirrhosis. *Clin Liver Dis* 2001;5:645-63.
25. McCormick PA, O'Keefe C. Improving prognosis following a first variceal haemorrhage over four decades. *Gut* 2001;49:682-5.
26. Chiu KW, Sheen IS, Liaw YF. A controlled study of glypressin versus vasopressin in the control of bleeding from oesophageal varices. *J Gastroenterol Hepatol* 1990;5:549-53.
27. Nevens F, Van Steenbergen W, Yap SH, et al. Assessment of variceal pressure by continuous non-invasive endoscopic registration: a placebo controlled evaluation of the effect of terlipressin and octreotide. *Gut* 1996;38:129-34.
28. Moreau R, Soubrane O, Hadengue A, et al. [Hemodynamic effects of the administration of terlipressin alone or combined with nitroglycerin in patients with cirrhosis]. *Gastroenterol Clin Biol* 1992;16:680-6.
29. Ioannou GN, Doust J, Rockey DC. Systematic review: terlipressin in acute oesophageal variceal haemorrhage. *Aliment Pharmacol Ther* 2003;17:53-64.
30. Bosch J, Dell'era A. [Vasoactive drugs for the treatment of bleeding esophageal varices]. *Gastroenterol Clin Biol* 2004;28 Spec No 2:B186-9.
31. Moreau R, Durand F, Poynard T, et al. Terlipressin in patients with cirrhosis and type 1 hepatorenal syndrome: a retrospective multicenter study. *Gastroenterology* 2002;122:923-30.
32. Ortega R, Gines P, Uriz J, et al. Terlipressin therapy with and without albumin for patients with hepatorenal syndrome: results of a prospective, nonrandomized study. *Hepatology* 2002;36:941-8.
33. Uriz J, Gines P, Cardenas A, et al. Terlipressin plus albumin infusion: an effective and safe therapy of hepatorenal syndrome. *J Hepatol* 2000;33:43-8.
34. Feu F, Ruiz del Arbol L, Banares R, et al. Double-blind randomized controlled trial comparing terlipressin and somatostatin for acute variceal hemorrhage. Variceal Bleeding Study Group. *Gastroenterology* 1996;111:1291-9.
35. Bosch J, Kravetz D, Rodes J. Effects of somatostatin on hepatic and systemic hemodynamics in patients with cirrhosis of the liver: comparison with vasopressin. *Gastroenterology* 1981;80:518-25.
36. Cirera I, Feu F, Luca A, et al. Effects of bolus injections and continuous infusions of somatostatin and placebo in patients with cirrhosis: a double-blind hemodynamic investigation. *Hepatology* 1995;22:106-11.
37. Villanueva C, Ortiz J, Minana J, et al. Somatostatin treatment and risk stratification by continuous portal pressure monitoring during acute variceal bleeding. *Gastroenterology* 2001;121:110-7.
38. Nevens F, Sprengers D, Fevery J. The effect of different doses of a bolus injection of somatostatin combined with a slow infusion on transmural oesophageal variceal pressure in patients with cirrhosis. *J Hepatol* 1994;20:27-31.
39. Avgerinos A, Nevens F, Raptis S, et al. Early administration of somatostatin and efficacy of sclerotherapy in acute oesophageal variceal bleeds: the European Acute Bleeding Oesophageal Variceal Episodes (ABOVE) randomised trial. *Lancet* 1997;350:1495-9.
40. Burroughs AK, McCormick PA, Hughes MD, et al. Randomized, double-blind, placebo-controlled trial of somatostatin for variceal bleeding. Emergency control and prevention of early variceal rebleeding. *Gastroenterology* 1990;99:1388-95.
41. Gotzsche PC, Gjorup I, Bonnen H, et al. Somatostatin v placebo in bleeding oesophageal varices: randomised trial and meta-analysis. *BMJ* 1995;310:1495-8.
42. Valenzuela JE, Schubert T, Fogel MR, et al. A multicenter, randomized, double-blind trial of somatostatin in the management of acute hemorrhage from esophageal varices. *Hepatology* 1989;10:958-61.
43. Escorsell A, Bandi JC, Andreu V, et al. Desensitization to the effects of intravenous octreotide in cirrhotic patients with portal hypertension. *Gastroenterology* 2001;120:161-9.
44. Zironi G, Rossi C, Siringo S, et al. Short- and long-term hemodynamic response to octreotide in portal hypertensive patients: a double-blind, controlled study. *Liver* 1996;16:225-34.
45. Ottesen LH, Flyvbjerg A, Jakobsen P, et al. The pharmacokinetics of octreotide in cirrhosis and in healthy man. *J Hepatol* 1997;26:1018-25.
46. Jenkins SA, Nott DM, Baxter JN. Pharmacokinetics of octreotide in patients with cirrhosis and portal hypertension; relationship between the plasma levels of the analogue and the magnitude and duration of the reduction in corrected wedged hepatic venous pressure. *HPB Surg* 1998;11:13-21.
47. Avgerinos A, Armonis A, Rekoumis G, et al. The effect of somatostatin and octreotide on intravascular oesophageal variceal pressure in patients with cirrhosis. *J Hepatol* 1995;22:379-80.
48. Moller S, Brinch K, Henriksen JH, et al. Effect of octreotide on systemic, central, and splanchnic haemodynamics in cirrhosis. *J Hepatol* 1997;26:1026-33.
49. Albillos A, Rossi I, Iborra J, et al. Octreotide prevents postprandial splanchnic hyperemia in patients with portal hypertension. *J Hepatol* 1994;21:88-94.
50. Besson I, Ingrand P, Person B, et al. Sclerotherapy with or without octreotide for acute variceal bleeding. *N Engl J Med* 1995;333:555-60.
51. Sung JJ, Chung SC, Yung MY, et al. Prospective randomised study of effect of octreotide on rebleeding from oesophageal varices after endoscopic ligation. *Lancet* 1995;346:1666-9.
52. Zuberi BF, Baloch Q. Comparison of endoscopic variceal sclerotherapy alone and in combination with octreotide in controlling acute variceal hemorrhage and early rebleeding in patients with low-risk cirrhosis. *Am J Gastroenterol* 2000;95:768-71.
53. Group IOVS, Burroughs AK. Double blind RCT of 5-day octreotide versus placebo, associated with sclerotherapy for trial/failures [abstract]. *Hepatology* 1996;24:352A.
54. Calès P, Masliah C, Bernard B, et al. Early administration of vapreotide for variceal bleeding in patients with cirrhosis. French Club for the Study of Portal Hypertension. *N Engl J Med* 2001;344:23-8.
55. Lebrec D, Vinel JP, Dupas JL. Complications of portal hypertension in adults: a French consensus. *Eur J Gastroenterol Hepatol* 2005;17:403-10.
56. Luketic VA. Management of portal hypertension after variceal hemorrhage [review]. *Clin Liver Dis* 2001;5:677-707, ix.
57. Waked I, Korula J. Analysis of long-term endoscopic surveillance during follow-up after variceal sclerotherapy from a 13-year experience. *Am J Med* 1997;102:192-9.
58. Westaby D, Macdougall BR, Williams R. Improved survival following injection sclerotherapy for esophageal varices: final analysis of a controlled trial. *Hepatology* 1985;5:827-30.
59. Seewald S, Sriram PV, Naga M, et al. Cyanoacrylate glue in gastric variceal bleeding. *Endoscopy* 2002;34:926-32.
60. Boyer TD, Haskal ZJ. The role of transjugular intrahepatic portosystemic shunt in the management of portal hypertension. *Hepatology* 2005;41:386-400.
61. D'Amico G, Luca A, Morabito A, et al. Uncovered transjugular intrahepatic portosystemic shunt for refractory ascites: a meta-analysis. *Gastroenterology* 2005;129:1282-93.
62. Henderson JM. Salvage therapies for refractory variceal hemorrhage. *Clin Liver Dis* 2001;5:709-25.
63. Saab S, Nieto JM, Ly D, et al. TIPS versus paracentesis for cirrhotic patients with refractory ascites [review]. *Cochrane Database Syst Rev* 2004;(3):CD004889.
64. Bureau C, Garcia-Pagan JC, Otal P, et al. Improved clinical outcome using polytetrafluoroethylene-coated stents for TIPS: results of a randomized study. *Gastroenterology* 2004;126:469-75.
65. De Franchis R. Evolving consensus in portal hypertension. Report of the Baveno IV consensus workshop on methodology of diagnosis and therapy in portal hypertension [published erratum in *J Hepatol* 2005;43(3):547]. *J Hepatol* 2005;43:167-76.
66. Duggan JM. Review article: transfusion in gastrointestinal haemorrhage — If, when and how much? *Aliment Pharmacol Ther* 2001;15:1109-13.
67. McCormick PA, Jenkins SA, McIntyre N, et al. Why portal hypertensive varices bleed and bleed: a hypothesis. *Gut* 1995;36:100-3.
68. Castaneda B, Debernardi-Venon W, Bandi JC, et al. The role of portal pressure in the severity of bleeding in portal hypertensive rats. *Hepatology* 2000;31:581-6.
69. Bleichner G, Boulanger R, Squara P, et al. Frequency of infections in cirrhotic patients presenting with acute gastrointestinal haemorrhage. *Br J Surg* 1986;73:724-6.
70. Goulis J, Armonis A, Patch D, et al. Bacterial infection is independently associated with failure to control bleeding in cirrhotic patients with gastrointestinal hemorrhage. *Hepatology* 1998;27:1207-12.
71. Bernard B, Grange JD, Khac EN, et al. Antibiotic prophylaxis for the prevention of bacterial infections in cirrhotic patients with gastrointestinal bleeding: a meta-analysis. *Hepatology* 1999;29:1655-61.
72. Soares-Weiser K, Brezis M, Tur-Kaspa R, et al. Antibiotic prophylaxis of bacterial infections in cirrhotic inpatients: a meta-analysis of randomized controlled trials. *Scand J Gastroenterol* 2003;38:193-200.
73. Rimola A, Garcia-Tsao G, Navasa M, et al. Diagnosis, treatment and prophylaxis of spontaneous bacterial peritonitis: a consensus document. International Ascites Club. *J Hepatol* 2000;32:142-53.
74. Nevens F. Review article: a critical comparison of drug therapies in currently used

therapeutic strategies for variceal haemorrhage [review]. *Aliment Pharmacol Ther* 2004;20(Suppl 3):18-22; discussion 23.
75. Bosch J, Abraldes JG, Groszmann R. Current management of portal hypertension. *J Hepatol* 2003;38(Suppl 1):S54-68.
76. Dib N, Konate A, Oberti F, et al. Non-invasive diagnosis of portal hypertension in cirrhosis. Application to the primary prevention of varices. *Gastroenterol Clin Biol* 2005;29:957-87.
77. Calès P, Oberti F, Bernard-Chabert B, et al. Evaluation of Baveno recommendations for grading esophageal varices. *J Hepatol* 2003;39:657-9.
78. Garcia-Tsao G. Current management of the complications of cirrhosis and portal hypertension: variceal hemorrhage, ascites, and spontaneous bacterial peritonitis. *Gastroenterology* 2001;120:726-48.
79. Hillon P, Lebrec D, Munoz C, et al. Comparison of the effects of a cardioselective and a nonselective beta-blocker on portal hypertension in patients with cirrhosis. *Hepatology* 1982;2:528-31.
80. Mills PR, Rae AP, Farah DA, et al. Comparison of three adrenoreceptor blocking agents in patients with cirrhosis and portal hypertension. *Gut* 1984;25:73-8.
81. Groszmann RJ, Bosch J, Grace ND, et al. Hemodynamic events in a prospective randomized trial of propranolol versus placebo in the prevention of a first variceal hemorrhage. *Gastroenterology* 1990;99:1401-7.
82. Lebrec D, Hillon P, Munoz C, et al. The effect of propranolol on portal hypertension in patients with cirrhosis: a hemodynamic study. *Hepatology* 1982;2:523-7.
83. Garcia-Tsao G, Grace ND, Groszmann RJ, et al. Short-term effects of propranolol on portal venous pressure. *Hepatology* 1986;6:101-6.
84. Vorobioff J, Picabea E, Gamen M, et al. Propranolol compared with propranolol plus isosorbide dinitrate in portal-hypertensive patients: long-term hemodynamic and renal effects. *Hepatology* 1993;18:477-84.
85. Feu F, Bordas JM, Garcia-Pagan JC, et al. Double-blind investigation of the effects of propranolol and placebo on the pressure of esophageal varices in patients with portal hypertension. *Hepatology* 1991;13:917-22.
86. Bosch J, Groszmann RJ. Measurement of azygos venous blood flow by a continuous thermal dilution technique: an index of blood flow through gastroesophageal collaterals in cirrhosis. *Hepatology* 1984;4:424-9.
87. Calès P, Braillon A, Jiron MI, et al. Superior portosystemic collateral circulation estimated by azygos blood flow in patients with cirrhosis. Lack of correlation with oesophageal varices and gastrointestinal bleeding. Effect of propranolol. *J Hepatol* 1985;1:37-46.
88. Bosch J, Masti R, Kravetz D, et al. Effects of propranolol on azygos venous blood flow and hepatic and systemic hemodynamics in cirrhosis. *Hepatology* 1984;4:1200-5.
89. Feu F, Bordas JM, Luca A, et al. Reduction of variceal pressure by propranolol: comparison of the effects on portal pressure and azygos blood flow in patients with cirrhosis. *Hepatology* 1993;18:1082-9.
90. Bandi JC, Garcia-Pagan JC, Escorsell A, et al. Effects of propranolol on the hepatic hemodynamic response to physical exercise in patients with cirrhosis. *Hepatology* 1998;28:677-82.
91. Perez-Paramo M, Munoz J, Albillos A, et al. Effect of propranolol on the factors promoting bacterial translocation in cirrhotic rats with ascites. *Hepatology* 2000;31:43-8.
92. Bendtsen F, Simonsen L, Henriksen JH. Effect on hemodynamics of a liquid meal alone and in combination with propranolol in cirrhosis. *Gastroenterology* 1992;102:1017-23.
93. Bellis L, Berzigotti A, Abraldes JG, et al. Low doses of isosorbide mononitrate attenuate the postprandial increase in portal pressure in patients with cirrhosis. *Hepatology* 2003;37:378-84.
94. Vorobioff JD, Gamen M, Kravetz D, et al. Effects of long-term propranolol and octreotide on postprandial hemodynamics in cirrhosis: a randomized, controlled trial. *Gastroenterology* 2002;122:916-22.
95. Grace ND, Groszmann RJ, Garcia-Tsao G, et al. Portal hypertension and variceal bleeding: an AASLD single topic symposium. *Hepatology* 1998;28:868-80.
96. Feu F, Garcia-Pagan JC, Bosch J, et al. Relation between portal pressure response to pharmacotherapy and risk of recurrent variceal haemorrhage in patients with cirrhosis. *Lancet* 1995;346:1056-9.
97. Gluud C, Henriksen JH, Nielsen G. Prognostic indicators in alcoholic cirrhotic men. *Hepatology* 1988;8:222-7.
98. Moitinho E, Escorsell A, Bandi JC, et al. Prognostic value of early measurements of portal pressure in acute variceal bleeding. *Gastroenterology* 1999;117:626-31.
99. Vinel JP, Cassigneul J, Levade M, et al. Assessment of short-term prognosis after variceal bleeding in patients with alcoholic cirrhosis by early measurement of portohepatic gradient. *Hepatology* 1986;6:116-7.
100. Abraldes JG, Tarantino I, Turnes J, et al. Hemodynamic response to pharmacological treatment of portal hypertension and long-term prognosis of cirrhosis. *Hepatology* 2003;37:902-8.
101. Huet PM, Pomier-Layrargues G. The hepatic venous pressure gradient: "remixed and revisited" [review]. *Hepatology* 2004;39:295-8.
102. Navasa M, Chesta J, Bosch J, et al. Reduction of portal pressure by isosorbide-5-mononitrate in patients with cirrhosis. Effects on splanchnic and systemic hemodynamics and liver function. *Gastroenterology* 1989;96:1110-8.
103. Garcia-Pagan JC, Navasa M, Bosch J, et al. Enhancement of portal pressure reduction by the association of isosorbide-5-mononitrate to propranolol administration in patients with cirrhosis. *Hepatology* 1990;11:230-8.
104. Calès P, Oberti F, Payen JL, et al. Lack of effect of propranolol in the prevention of large oesophageal varices in patients with cirrhosis: a randomized trial. French-Speaking Club for the Study of Portal Hypertension. *Eur J Gastroenterol Hepatol* 1999;11:741-5.
105. Groszmann RJ, Garcia-Tsao G, Makuch RW, et al. Multicenter randomized placebo-controlled trial of non-selective beta-blockers in the prevention of the complications of portal hypertension: final results and identification of a predictive factor. *Hepatology* 2003;38:206A.
106. Merkel C, Marin R, Angeli P, et al. A placebo-controlled clinical trial of nadolol in the prophylaxis of growth of small esophageal varices in cirrhosis. *Gastroenterology* 2004;127:476-84.
107. Propranolol prevents first gastrointestinal bleeding in non-ascitic cirrhotic patients. Final report of a multicenter randomized trial. The Italian Multicenter Project for Propranolol in Prevention of Bleeding. *J Hepatol* 1989;9:75-83.
108. Conn HO. Propranolol-induced reduction in recurrent variceal hemorrhage in schistosomiasis. *Hepatology* 1990;11:1090-2.
109. Lebrec D, Poynard T, Capron JP, et al. Nadolol for prophylaxis of gastrointestinal bleeding in patients with cirrhosis. A randomized trial. *J Hepatol* 1988;7:118-25.
110. Pascal JP, Calès P. Propranolol in the prevention of first upper gastrointestinal tract hemorrhage in patients with cirrhosis of the liver and esophageal varices. *N Engl J Med* 1987;317:856-61.
111. Talwalkar JA, Kamath PS. An evidence-based medicine approach to beta-blocker therapy in patients with cirrhosis. *Am J Med* 2004;116:759-66.
112. Bosch J, Garcia-Pagan JC. Complications of cirrhosis. I. Portal hypertension. *J Hepatol* 2000;32:141-56.
113. Bosch J, Garcia-Pagan JC. Prevention of variceal rebleeding. *Lancet* 2003;361:952-4.
114. Calès P, Grasset D, Ravaud A, et al. Pharmacodynamic and pharmacokinetic study of propranolol in patients with cirrhosis and portal hypertension. *Br J Clin Pharmacol* 1989;27:763-70.
115. Calès P. Optimal use of propranolol in portal hypertension. *Gastroenterol Clin Biol* 2005;29:207-8.
116. Abraczinskas DR, Ookubo R, Grace ND, et al. Propranolol for the prevention of first esophageal variceal hemorrhage: A lifetime commitment? *Hepatology* 2001;34:1096-102.
117. Angelico M, Carli L, Piat C, et al. Effects of isosorbide-5-mononitrate compared with propranolol on first bleeding and long-term survival in cirrhosis. *Gastroenterology* 1997;113:1632-9.
118. Garcia-Pagan JC, Villanueva C, Vila MC, et al. Isosorbide mononitrate in the prevention of first variceal bleed in patients who cannot receive beta-blockers. *Gastroenterology* 2001;121:908-14.
119. Burroughs AK, Jenkins WJ, Sherlock S, et al. Controlled trial of propranolol for the prevention of recurrent variceal hemorrhage in patients with cirrhosis. *N Engl J Med* 1983;309:1539-42.
120. Colombo M, de Franchis R, Tommasini M, et al. Beta-blockade prevents recurrent gastrointestinal bleeding in well-compensated patients with alcoholic cirrhosis: a multicenter randomized controlled trial. *Hepatology* 1989;9:433-8.
121. Lebrec D, Poynard T, Bernuau J, et al. A randomized controlled study of propranolol for prevention of recurrent gastrointestinal bleeding in patients with cirrhosis: a final report. *Hepatology* 1984;4:355-8.
122. Rossi V, Calès P, Burtin P, et al. Prevention of recurrent variceal bleeding in alcoholic cirrhotic patients: prospective controlled trial of propranolol and sclerotherapy. *J Hepatol* 1991;12:283-9.
123. Gournay J, Masliah C, Martin T, et al. Isosorbide mononitrate and propranolol compared with propranolol alone for the prevention of variceal rebleeding. *Hepatology* 2000;31:1239-45.
124. Thabut D. [Gastrointestinal hemorrhage. How to prevent rebleeding: role of pharmacological and endoscopic treatments]. *Gastroenterol Clin Biol* 2004;28(Spec No 2):B73-82.
125. D'Amico G, Pagliaro L, Bosch J. The treatment of portal hypertension: a meta-analytic review. *Hepatology* 1995;22:332-54.
126. Heresbach D, Jacquelinet C, Nouel O, et al. [Sclerotherapy versus ligation in hemorrhage caused by rupture of esophageal varices. Direct meta-analysis of randomized trials]. *Gastroenterol Clin Biol* 1995;19:914-20.
127. Laine L, Cook D. Endoscopic ligation compared with sclerotherapy for treatment of esophageal variceal bleeding. A meta-analysis. *Ann Intern Med* 1995;123:280-7.
128. Karsan HA, Morton SC, Shekelle PG, et al. Combination endoscopic band ligation and sclerotherapy compared with endoscopic band ligation alone for the secondary prophylaxis of esophageal variceal hemorrhage: a meta-analysis. *Dig Dis Sci* 2005;50:399-406.
129. Lo GH, Lai KH, Cheng JS, et al. Endoscopic variceal ligation plus nadolol and sucralfate compared with ligation alone for the prevention of variceal rebleeding: a prospective, randomized trial. *Hepatology* 2000;32:461-5.
130. Ink O, Martin T, Poynard T, et al. Does elective sclerotherapy improve the efficacy of long-term propranolol for prevention of recurrent bleeding in patients with severe cirrhosis? A prospective multicenter, randomized trial. *Hepatology* 1992;16:912-9.
131. O'Connor KW, Lehman G, Yune H, et al. Comparison of three nonsurgical treatments for bleeding esophageal varices. *Gastroenterology* 1989;96:899-906.
132. Luca A, D'Amico G, La Galla R, et al. TIPS for prevention of recurrent bleeding in patients with cirrhosis: meta-analysis of randomized clinical trials. *Radiology* 1999;212:411-21.
133. Spina GP, Henderson JM, Rikkers LF, et al. Distal spleno-renal shunt versus endoscopic sclerotherapy in the prevention of variceal rebleeding. A meta-analysis of 4 randomized clinical trials. *J Hepatol* 1992;16:338-45.
134. Gines P, Cardenas A, Arroyo V, et al. Management of cirrhosis and ascites. *N Engl J Med* 2004;350:1646-54.
135. Moore KP, Wong F, Gines P, et al. The management of ascites in cirrhosis: report

on the consensus conference of the International Ascites Club. *Hepatology* 2003; 38:258-66.
136. Castellote J, Lopez C, Gornals J, et al. Rapid diagnosis of spontaneous bacterial peritonitis by use of reagent strips. *Hepatology* 2003;37:893-6.
137. Sapey T, Mena E, Fort E, et al. Rapid diagnosis of spontaneous bacterial peritonitis with leukocyte esterase reagent strips in a European and in an American center. *J Gastroenterol Hepatol* 2005;20:187-92.
138. Thevenot T, Cadranel JF, Nguyen-Khac E, et al. Diagnosis of spontaneous bacterial peritonitis in cirrhotic patients by use of two reagent strips. *Eur J Gastroenterol Hepatol* 2004;16:579-83.
139. Vanbiervliet G, Rakotoarisoa C, Filippi J, et al. Diagnostic accuracy of a rapid urine-screening test (Multistix8SG) in cirrhotic patients with spontaneous bacterial peritonitis. *Eur J Gastroenterol Hepatol* 2002;14:1257-60.
140. Perez-Ayuso RM, Arroyo V, Planas R, et al. Randomized comparative study of efficacy of furosemide versus spironolactone in nonazotemic cirrhosis with ascites. Relationship between the diuretic response and the activity of the renin-aldosterone system. *Gastroenterology* 1983;84:961-8.
141. Wilkinson SP, Jowett TP, Slater JD, et al. Renal sodium retention in cirrhosis: relation to aldosterone and nephron site. *Clin Sci (Lond)* 1979;56:169-77.
142. Peltekian KM, Wong F, Liu PP, et al. Cardiovascular, renal, and neurohumoral responses to single large-volume paracentesis in patients with cirrhosis and diuretic-resistant ascites. *Am J Gastroenterol* 1997;92:394-9.
143. Suzuki H, Stanley AJ. Current management and novel therapeutic strategies for refractory ascites and hepatorenal syndrome. *QJM* 2001;94:293-300.
144. Wong F, Sniderman K, Liu P, et al. Transjugular intrahepatic portosystemic stent shunt: effects on hemodynamics and sodium homeostasis in cirrhosis and refractory ascites. *Ann Intern Med* 1995;122:816-22.
145. Wong F, Sniderman K, Liu P, et al. The mechanism of the initial natriuresis after transjugular intrahepatic portosystemic shunt. *Gastroenterology* 1997;112:899-907.
146. Arroyo V, Gines P, Gerbes AL, et al. Definition and diagnostic criteria of refractory ascites and hepatorenal syndrome in cirrhosis. International Ascites Club. *Hepatology* 1996;23:164-76.
147. Duvoux C, Zanditenas D, Hezode C, et al. Effects of noradrenalin and albumin in patients with type I hepatorenal syndrome: a pilot study. *Hepatology* 2002;36:374-80.
148. Angeli P, Volpin R, Gerunda G, et al. Reversal of type 1 hepatorenal syndrome with the administration of midodrine and octreotide. *Hepatology* 1999;29:1690-7.
149. Brensing KA, Textor J, Perz J, et al. Long term outcome after transjugular intrahepatic portosystemic stent-shunt in non-transplant cirrhotics with hepatorenal syndrome: a phase II study. *Gut* 2000;47:288-95.
150. Sort P, Navasa M, Arroyo V, et al. Effect of intravenous albumin on renal impairment and mortality in patients with cirrhosis and spontaneous bacterial peritonitis. *N Engl J Med* 1999;341:403-9.
151. Pugh RN, Murray-Lyon IM, Dawson JL, et al. Transection of the oesophagus for bleeding oesophageal varices. *Br J Surg* 1973;60:646-9.
152. D'Amico G, Garcia-Tsao G, Pagliaro L. Natural history and prognostic indicators of survival in cirrhosis: a systematic review of 118 studies. *J Hepatol* 2006;44:217-31.

Correspondence to: *Dr. Paul Calès, Centre hospitalier universitaire, 49933 Angers Cedex 09, France; fax (33) 2 41 35 41 19 ; paul.cales@univ-angers.fr*

Appendix 1: Child-Pugh classification of cirrhosis severity[151] and survival rate by class[152]

	No. of points assigned		
Variable	1	2	3
Hepatic encephalopathy	Absent	Mild to moderate	Severe to coma
Ascites	Absent	Slight	Moderate
Bilirubinemia, µmol/L	< 30	30-50	> 50
Albuminemia, g/L	> 35	28-35	< 28
Prothrombin time, seconds above normal	1-4	4-6	> 6

		Survival rate, %	
Child-Pugh class	Total score	At 1 yr	At 2 yr
A	5-6	95	90
B	7-9	80	70
C	10-15	48	38

MELD and PELD: Application of Survival Models to Liver Allocation

Russell H. Wiesner, Sue V. McDiarmid, Patrick S. Kamath, Eric B. Edwards, Michael Malinchoc, Walter K. Kremers, Ruud A.F. Krom, and W. Ray Kim

In 1998, the Department of Health and Human Services (DHHS) issued the final rule,[1] in which the principles of organ allocation were defined, to govern the operation of the Organ Procurement and Transplant Network (OPTN). This rule included the following guidelines for organ allocation: (1) organs should be allocated to transplant candidates in the order of medical urgency; (2) the role of waiting times should be minimized, and (3) attempts should be made to avoid futile transplants and to promote efficient use of our scarce donor organs. The consensus opinion to minimize waiting time was based on 2 recent reports that analyzed the impact of waiting time on survival of liver patients on the United Network for Organ Sharing (UNOS) waiting list: one from the Institute of Medicine[2] and a second report from Freeman et al.[3] Both studies concluded that waiting time did not correlate with death on the waiting list and therefore should be de-emphasized in developing a new allocation algorithm. The challenge put forth by this conclusion was to create an allocation policy that made the most effective use of organs especially by making them available, whenever feasible, to the most medically urgent patients who are appropriate candidates for transplantation.

This challenge was accepted by the UNOS Liver and Intestinal Committee, whose task it was to (1) make an assessment of the current allocation policy including the Child-Turcotte-Pugh (CTP) score, (2) evaluate a number of previously published survival models that were developed to estimate survival of patients with end-stage liver disease, and (3) develop a new disease severity index to be utilized to allocate liver donor organs in the future.

After careful deliberation and extensive input from transplant hepatologists and surgeons, a number of guidelines were established for creating an index of disease severity to estimate survival in patients with chronic liver disease. By consensus, it was determined that such a disease severity index should rely on a few, readily available, objective variables that would be generally applicable to a heterogeneous group of patients with end-stage liver disease, to determine the risk of dying. Finally, the severity index should be clinically and statistically validated and be able to predict the probability of death in groups of patients with chronic liver disease who are demographically diverse and of varying etiology and disease severity. There was agreement among the committee that such a new index should not be introduced without careful prospective evaluation of the potential impact that such a model may have on the gravely ill patients awaiting liver transplant.

The Child-Turcotte-Pugh Classification

The CTP classification, which has been used since minimal listing criteria were first defined in 1998,[4] is a widely used index of disease severity for patients with end-stage liver disease and is currently applied to assess severity of liver disease in the UNOS allocation algorithm. Historically, the purpose of CTP classification was to assess the operative risk of patients with end-stage liver disease with variceal bleeding undergoing portosystemic shunt surgery.[5,6] It was based on 5 variables including ascites, encephalopathy, nutritional status, and serum levels of bilirubin and albumin. In 1973, Pugh et al[7] used a modified version of this severity index in describing the outcome of patients undergoing surgical ligation of esophageal varices. Pugh assigned a score ranging from 1 to 3 to each of the variables in the classification. Classes A, B, and C were designated by criteria applied to the sum of the individual scores (Table 1). Nutritional status in the Child-Turcotte classification was replaced with prothrombin time.

While the development of the CTP classification was based on empiric assessment and never prospec-

From the Liver Transplant Center, Mayo Clinic, Rochester, MN.

Address reprint requests to Russell H. Wiesner, MD, Professor of Medicine, Liver Transplant Center, Mayo Clinic, 200 First St SW, Rochester, MN 55905. Telephone: 507-266-1586; FAX: 507-266-2810; E-mail: rwiesner@mayo.edu

Copyright © 2001 by the American Association for the Study of Liver Diseases

1527-6465/01/0707-0014$35.00/0

doi:10.1053/jlts.2001.25879

Table 1. CTP Classification

A. Original Child-Turcotte classification Variable	Class A	Class B	Class C
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	3.0-3.5	<3.0
Encephalopathy grade	None	Minimal	Advanced "coma"
Ascites	None	Easily controlled	Poorly controlled
Nutritional status	Excellent	Good	Poor "wasting"
B. Pugh's modification of the Child-Turcotte classification Variable	**1**	**2**	**3**
Encephalopathy grade	None	1-2	3-4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin time (sec prolonged)	<4	4-6	>6
Bilirubin (mg/dL)	<2	2-3	>3
For cholestatic disease	<4	4-10	>10

NOTE. Child-Pugh score class A = 5-6, B = 7-9, and C = 10-15.

tively validated, many subsequent studies have shown the CTP index to be useful in the assessment of prognosis in patients with end-stage liver disease.[8-11] One such example is the work by Christensen et al,[8] in which the Child-Pugh score was applied in a group of patients with liver cirrhosis of diverse etiology. These studies demonstrated that each of the 5 individual clinical variables as well as the overall Child-Pugh classification had prognostic significance. However, routine tests of renal function have been found to significantly improve the prognostic accuracy of the Child-Pugh score and to be an independent predictor of survival in patients with end-stage liver disease (Fig. 1).[12-15] Thus, an assessment of renal function is now considered a critical component in the development of a future liver disease severity index for patients with end-stage liver disease.

Image Unavailable.
Please See Print Journal.

Figure 1. Survival of patients with cirrhosis and ascites as a function of serum creatinine level. (Reprinted with permission from Gines P, Fernandez Esparrach SG. Prognosis of cirrhosis with ascites. In: Arroyo V, Gines P, Rodes J, Schrier RW (eds). Ascites and Renal Dysfunction in Liver Disease. Blackwell Science.[15])

Limitations of the UNOS Liver Allocation Policy

While the current allocation system utilizes the CTP classification for determining medical urgency, a number of limitations of both the UNOS allocation algorithm and the CTP score have become obvious. The most important shortcoming is that the UNOS allocation policy defines only 3 categories of disease severity for patients with end-stage liver disease: Status 3 (CTP score ≥7), status 2B (CTP score ≥10), and status 2A (CTP score ≥10, in the intensive care unit [ICU] and less than 7 days to live).[16] With only 3 categories of disease severity, it is obvious that waiting time has become an important factor as a tiebreaker within each category. This is particularly problematic for patients classified as status 2B, who form the largest group of patients undergoing liver transplantation (56%) and who exhibit a broad range of liver disease severity.[17] In status 2B, patients range from those who are at home and working full time to those who require continuous hospitalization for complications related to their liver disease, but who do not meet the strict criteria for 2A status.

Waiting time was introduced into the current allocation scheme based on the principle that in case of the

same degree of disease severity, donor organs should be allocated to those patients who have waited the longest. However, with only 3 categories of disease severity for patients with chronic liver disease, by default, waiting time has become the major determinant for prioritization of donor organs. This problem has been further magnified by the fact that currently waiting time accrued while on the waiting list in status 3 is applied when the patient advances to 2B status. Therefore, waiting time has become a dominant factor in prioritization of donor organs with almost complete disregard to the severity of liver disease.[16]

Finally, the criteria for 2A status are also problematic, as uniform guidelines for admission to the intensive care unit are lacking. In addition, a consensus is lacking regarding what constitutes criteria for a patient having less than 7 days to live. It is not surprising that the current liver allocation scheme has led to substantial debates, resulting in widespread mistrust among regional liver transplant centers. This has ultimately led to a call for change of the present allocation algorithm to one which would direct organs to patients based on severity of their liver disease rather than to patients with the longest waiting time.

Shortcomings of the CTP Score

While the UNOS allocation scheme has clearly failed to prioritize liver allocation on the basis of medical urgency, the CTP score itself was also found to have limited usefulness as an index of disease severity. These limitations mainly are related to the limited discriminatory ability and variability of the CTP score. The CTP index, as used in organ allocation, not only has a limited number of disease categories, but is also limited by its inability to discriminate disease severity among the sickest patients. For example, patients with serum bilirubin levels of 3 mg/dL and 30 mg/dL are given the same CTP score (Table 1), which suggests the same severity of liver disease, despite the fact that serum bilirubin level has been shown to be an important prognostic parameter in patients with chronic liver disease. Similarly, based on the CTP score, 2 patients with a serum albumin of 2.8 g/dL and 2.1 g/dL, respectively, are placed in the same category of severity, despite the marked differences in hepatic synthetic function.

The CTP score is further limited by its marked variability. The assessment of 2 parameters used in the CTP score, namely ascites and encephalopathy, depend on how they are evaluated. Should ascites be assessed by subjective findings on physical examination, as it was when the original CTP score was developed, or should the more sensitive ultrasonography method for detecting ascites be used? Do vague symptoms such as forgetfulness, fatigue, and insomnia constitute the diagnosis of portosystemic encephalopathy, or should more objective criteria be required? Not only is there a lack of uniform standards for diagnosing and grading the severity of ascites and encephalopathy, but these symptoms can improve or even resolve with simple dietary or medical treatment. Therefore, the time of assessment of these symptoms plays a role in defining the CTP score for organ allocation.

Even the more objective laboratory elements in the CTP system may vary from one institution to another. In particular, the measurement of prothrombin time depends on the sensitivity of the thromboplastin reagent used for the assay,[18] which creates variability between centers in the reporting of prothrombin time. Similarly, while electrophoresis is usually considered to be the gold standard for measurement of albumin levels, clinical laboratories frequently use the less expensive, but also less sensitive, colorimetric method. Based on these shortcomings, the UNOS Liver and Intestinal Committee unanimously agreed that change of the UNOS allocation algorithm was necessary to meet the final rule guidelines for liver allocation issued by the DHHS.

Survival Model Development

Given the limitation of both the current allocation scheme and the CTP score, implementation of the final rule required the development of an index, which accurately assessed severity of liver disease on a continuous and broad scale and was based on sound clinical and statistical validity. Therefore, previously published prognostic models developed for patients with primary biliary cirrhosis, primary sclerosing cholangitis, alcoholic liver disease, and Wilson's disease were evaluated.[19-26] However, after careful assessment it was felt that these models were often applicable only to patients with a specific end-stage liver disease, but not to patients having a wide spectrum of liver disease etiologies. Moreover, a number of these models required a liver biopsy for risk stratification, which was felt to be inappropriate for a generally applicable model to predict survival because of sampling variability and inconsistent histologic interpretation.[21-23,27,28] Many of these models excluded patients with decompensated cirrhosis[22,23,29] and many used quantitative measures of hepatic function such as aminopyrine breath test, galactose elimina-

tion capacity, and monoethylglycinexylidide test, studies which are currently not uniformly performed nor provide incremental prognostic information.[9,30-35] Other models utilize variables such as plasma levels of norepinephrine, pseudocholinesterase, and renin, laboratory tests which are usually not readily available at most institutions and frequently are determined using local assays, which may not be comparable.[36,37] Still other models used subjective variables such as cognitive dysfunction, degree of encephalopathy, nutritional status, degree of ascites, and hepatorenal syndrome, all of which are poorly defined and open to wide range of interpretations.[12,22,28,38] Finally, a number of models use politically charged variables such as age, gender, and race, or third-party payer status, which would discriminate against some groups of patients and therefore could not be incorporated in a model to be used nationally to select patients for organ allocation.[19-21]

Model for End-Stage Liver Disease (MELD)

The MELD model (model for end-stage liver disease), which was derived from a heterogenous group of patients from 4 medical centers throughout the United States and was validated on an independent data set from The Netherlands, was originally developed to assess the short-term prognosis of patients with liver cirrhosis undergoing transjugular intrahepatic portosystemic shunt (TIPS) procedure (Fig. 2).[39] This recently described model uses serum creatinine, total serum bilirubin, international normalized ratio (INR) of prothrombin time, as well as etiology of cirrhosis as its parameters (Fig. 3).[39] Since it has previously been shown that survival following portosystemic shunt surgery is predominantly determined by severity of underlying liver disease, it was hypothesized that the MELD model could be used as a prognostic indicator for patients with advanced chronic liver disease and potentially could be applied to prioritize patients waiting for liver transplantation on the UNOS waiting list. In addition, the model had many characteristics for an ideal model: it relies on a few objective parameters using standardized tests, which should be readily available and reproducible. Finally, none of the parameters are subjective or have political overtones that might make utilization of such a model controversial.

$$\text{Meld Risk Score} = 10 \times [0.957 \times \log_e(\text{creatinine mg/dL}) + 0.378 \times \log_e(\text{bilirubin mg/dL}) + 1.120 \times \log_e(\text{INR}) + 0.643 \times \text{Cause of cirrhosis (0 alcohol, cholestatic, 1 other etiologies)}]$$

Figure 2. MELD survival model. The original MELD score included etiology of liver disease; the future MELD model will be used without using liver etiology.

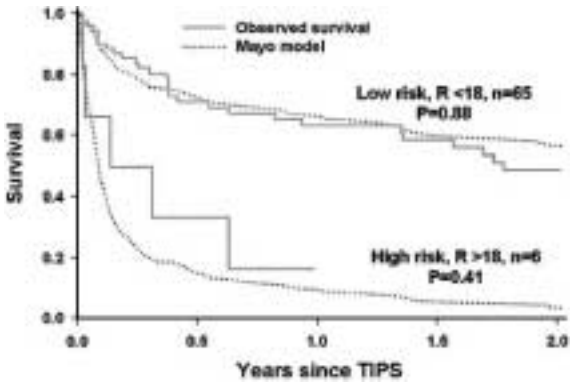


Figure 3. Survival of 71 independent TIPS patients from The Netherlands who were stratified according to their risk score into 2 risk groups, namely a high-risk group with a median survival less than 3 months ($R > 18$) and a low-risk group with a median predicted survival more than 3 months ($R < 18$). Actual and expected survivals using the Mayo model were compared using the one-sample log-rank test. For the low- and high-risk patients, observed and expected survivals were similar ($P = .88$ and $P = .41$, respectively.) (Modified and reprinted with permission.[39])

Validation of the MELD Model

Since the MELD model was developed to determine the short-term prognosis for patients undergoing a TIPS procedure, its prognostic usefulness needed to be assessed in patients with end-stage liver disease not undergoing TIPS. To validate the MELD model, a group of 282 adult patients hospitalized at the Mayo Clinic between January 1994 and January 1999 for complications of liver disease were studied.[40] Individual hospital records were reviewed to verify the diagnosis of cirrhosis and extract other relevant disease related information and laboratory data. Patients with concurrent hepatocellular cancer, alcohol use within 30 days of hospitalization, and advanced cardiopulmonary comorbidity, sepsis, or intrinsic renal disease, and those who were hospitalized for liver transplantation were excluded from the study. Patient survival was assessed as the interval from the day of hospitalization until death or last follow-up. Since the aim was to validate the MELD score as a severity index of liver disease to predict short-term mortality, 3-month mortality was cho-

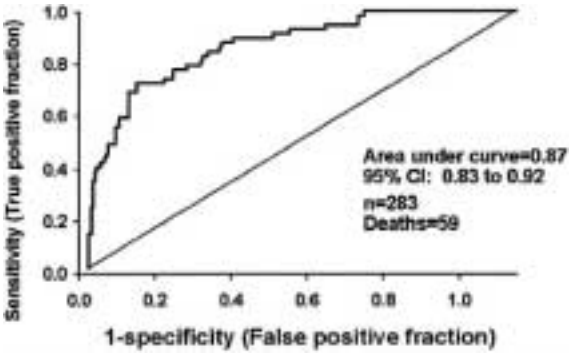


Figure 4. ROC curve for the MELD score in hospitalized cirrhotic patients predicting 3-month mortality.

sen as the primary outcome measure. The validity of the model was determined using the c-statistic (concordance—equivalent to the area under the receiving/operating/characteristic curve).[41] In this context, the c-statistic is the probability of assigning greater risk to a randomly selected patient with 3-month mortality when compared with a randomly selected patient without 3-month mortality. The receiver operating characteristic graph depicts the true-positive proportion plotted against the false-positive proportion for the different cutoff values of the decision criterion. The c-statistic may range from 0 to 1, with 1 corresponding to perfect discrimination while 0.5 would be the result expected from chance alone. A c-statistic of 0 would result if the prediction was wrong 100% of the time. The c-statistic is used commonly in evaluating prognostic models.[42,43] A c-statistic between 0.8 and 0.9 indicates excellent accuracy, while a c-statistic >0.7 is generally considered a useful test result. In this study, the c-statistic for prediction of 3-month mortality by the MELD model was 0.87 (95% confidence interval 0.82 to 0.92) (see Table 2 and Fig. 4). Moreover, when this group of patients was stratified according to the CTP score, the 3-month mortality in patients with CTP class A was 4%, CTP class B was 14%, and CTP class C was 51%. The c-statistic for the CTP score for predicting 3-month mortality was 0.84% (95% confidence level 0.78 to 0.90). The relationship between the MELD score, the CTP score, and the 3-month mortality is shown in Table 3.

In summary, the MELD score appeared to be at least as good as the CTP score in predicting mortality and had the distinct advantage of using variables that were readily available, standardized, reproducible, and objective.

Further Validation of the MELD Score

In addition to the initial group of 282 Mayo Clinic patients (group A), the MELD model was further validated in 3 other groups of patients: patients with compensated cirrhosis from a Palermo (Italy) database (group B), outpatient PBC patients from the Mayo Clinic (group C), and a retrospectively generated cohort of "historical" patients, diagnosed with cirrhosis between 1984 and 1988 at the Mayo Clinic (group D). The ability of the MELD model to predict 3-month mortality in these 4 groups of patients, expressed as the c-statistic, ranged from 0.78 to 0.87 (Table 2). The 3-month death rates in relation to the MELD scores for the patients in these 4 groups are shown in Table 4. These validation studies confirm that the MELD model is a reliable predictor of both short-term and medium-term mortality risk in patients with cirrhotic-stage liver disease of diverse etiologies and is applicable over a wide spectrum of disease severity. The results support the hypothesis that the MELD model can be used as an index of liver disease severity and therefore may be of value to prioritize patients waiting for liver transplantation.

Table 2. Summary of Validation Studies: Concordance in Predicting 3-Month and 1-Year Mortality

	No. of Patients	No. of Deaths Within 3 Mo	3-Month Mortality (concordance)	1-Year Mortality (concordance)
Hospitalized cirrhotics (group A)	282	59	0.87 (0.82-0.92)	0.85 (0.80-0.90)
Outpatient cirrhotics (group B)	491	34	0.80 (0.69-0.90)	0.78 (0.70-0.85)
PBC outpatients (group C)	326	5	0.87 (0.71-1.00)	0.87 (0.80-0.93)
Historical cirrhotics (group D)	1,179	220	0.78 (0.74-0.81)	0.73 (0.69-0.76)

NOTE. Concordance expressed as c statistic.

Table 3. Relationship Between MELD, CTP Score, and 3-Month Mortality in Hospitalized Cirrhotics (Group A)

	3-Month Death Rates				
MELD	≤9	10-19	20-29	30-39	≥40
Mortality	4 (6/148)	27 (28/103)	76 (16/21)	83 (5/6)	100 (4/4)
CTP		A	B		C
Mortality		4 (3/77)	14 (13/93)		51 (35/69)

NOTE. Values expressed as percent (number/total).

Do Complications of Portal Hypertension Add to the MELD Score's Ability to Predict Mortality Risk?

It has been suggested that complications of portal hypertension such as ascites, encephalopathy, variceal bleeding, and spontaneous bacterial peritonitis are predictors of mortality for patients with liver cirrhosis.[44-47] However, in studies comparing surgical or endoscopic treatment for variceal bleeding , survival appears to be solely dependent on the severity of the underlying liver disease.[48-50] It is now recognized that the degree of hepatic dysfunction is of overriding prognostic significance for patient survival.

Therefore, the following question needed to be addressed: Do complications of portal hypertension provide further prognostic information in predicting mortality above and beyond the MELD score? Hereto the initial group of 282 patients (group A) with a history of variceal bleeding, ascites, and encephalopathy was studied. The impact of spontaneous bacterial peritonitis (SBP) was analyzed in our historical patient group (group D) by reconstructing the diagnosis of SBP using the results of the peritoneal fluid analysis. In addition, a data set of 64 patients was evaluated who were diagnosed with ascites and SBP, using conventional criteria (absolute neutrophil count $> 250/\mu L$), which was provided by Dr Miguel Navasa from Barcelona, Spain.

The impact of variceal bleeding was analyzed in the historical patients group (group D) and in an additional group of 404 patients who underwent endoscopic therapy for variceal hemorrhage in the Mayo Clinic between 1988 and 1999. The test results, collected immediately prior to the initial endoscopic intervention, were used to compute the MELD model, and all patients were followed for at least 3 months.

Finally, the impact of ascites and encephalopathy on the MELD score's ability to predict mortality was evaluated in the group of outpatient PBC patients (group C). Overall, minimal change was noted in the MELD score's ability to predict 3-month mortality by adding individual complications of portal hypertension (Table 5). These results strengthen the hypothesis that severity of liver disease, as measured by the MELD score, gives us important prognostic information that is nearly independent of the development of complications of portal hypertension.

The Importance of Liver Disease Etiology in the MELD Model

The MELD model, by using liver disease etiology, gives a lower risk score to patients with alcoholic and cholestatic liver disease compared to other diagnoses. In this context two concerns were raised at the initial public hearing, where the MELD model was proposed for use in organ allocation. The first concern was that using etiology in the MELD score for patients with alcoholic liver disease would discriminate against such patients for the purpose of organ allocation. It is well known that

Table 4. 3-Month Death Rates

MELD Score	≤9	10-19	20-29	30-39	≥40
Hospitalized (group A)	4 (6/148)	27 (28/103)	76 (16/21)	83 (5/6)	100 (4/4)
Outpatient cirrhotics (group B)	2 (5/213)	6 (14/248)	50 (15/30)	—	—
Ambulatory PBC (group C)	1 (3/308)	13 (2/16)	0 (0/2)	—	—
Historical (group D)	8 (55/711)	26 (90/344)	56 (47/84)	66 (23/35)	100 (5/5)

NOTE. Values expressed as percentage of mortality (number/total).

Table 5. Impact of Complications of Portal Hypertension on MELD Score Outcome of 3-Month Mortality

Ascites	Hospitalized (Group A)		Cholestatic (Group C)
No. of patients	116		94
MELD	0.87		0.80
MELD + ascites	0.88		0.83
Variceal bleeding	**Hospitalized (Group A)**	**Historical Cirrhotics (Group D)**	**Bleeding Team (Mayo)**
No. of patients	30	107	404
MELD	0.87	0.78	0.83
MELD + bleed	0.88	0.78	0.83
SBP	**Historical Cirrhotics (Group D)**		**Barcelona Group**
No. of patients	18		64
MELD	0.78		0.85
MELD + SBP	0.78		0.86
Encephalopathy	**Hospitalized (Group A)**		**Cholestatic (Group C)**
No. of patients	52		21
MELD	0.87		0.80
MELD + encephalopathy	0.88		0.81

NOTE. All values expressed as c statistic (concordance) for 3-month mortality.

long-term absence from alcohol use improves overall liver function. The fact that the MELD model was developed in patients who were recently using alcohol therefore seems to inappropriately discriminate against alcoholic patients on the waiting list, most of whom have been abstinent for 6 months or longer and who are less likely to experience further improvements in liver function and prognosis with additional abstinence.[51] The consensus opinion was that the mortality risk of such alcoholic patients listed for liver transplant is unlikely to be different from patients with other chronic liver diseases of similar disease severity. Thus, the recommendation was that etiology should not be used in the MELD score to avoid potential discrimination against patients with alcoholic liver disease.

A second concern was that the MELD model, like the CTP score, discriminates against patients with cholestatic liver disease who in general have the best long-term outcome following liver transplantation.[52,53] Primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC) patients often suffer from extreme fatigue, pruritus, osteoporosis, fat malabsorption, and malnutrition, which significantly diminish quality of life. In addition, patients with PSC often have associated inflammatory bowel disease and have an increased risk of developing colon cancer as well as an increased risk of developing cholangiocarcinoma; conditions which can impact negatively on prognosis.[54] A further concern is that PSC patients are frequently on ursodeoxycholic acid treatment which may lower serum bilirubin levels.[55] While this biochemical improvement has not been shown to be associated with a survival benefit, it would result in an inappropriately low MELD score and consequently such patients would be given an inappropriately low priority to receive a donor organ. For all these reasons, it was felt that a severity index to be used to allocate liver organs should not discriminate against the patients with cholestatic liver disease.

Based on these concerns, we further analyzed the impact of etiology of liver disease on the MELD model's predictive ability. We found that excluding liver disease etiology in the MELD model had minimal influence on its overall ability to predict mortality as expressed by c-statistic (Table 6). Based on these findings and concerns, a consensus was reached that in the future the MELD model should be used without including cause of liver disease so as not to discriminate against patients solely on the basis of etiology.

Applying the MELD Model to the UNOS Waiting List

To compare the 3-month mortality predicted by the MELD model with the actual pretransplant mortality on the waiting list, the MELD model was applied to a group of 311 pretransplant patients with chronic liver

Table 6. Impact of Excluding Cause of Liver Disease on MELD Score's Predictive Ability

	Hospitalized (n = 282)	Ambulatory Noncholestatic (n = 491)	Ambulatory PBC (n = 326*)	Historical (n = 1,179)
With cause in the model	0.87 (0.82-0.92)	0.80 (0.69-0.90)	0.87 (0.71-1.00)	0.78 (0.74-0.81)
Without cause in the model	0.86 (0.81-0.92)	0.82 (0.73-0.91)	0.87 (0.71-1.00)	0.78 (0.74-0.81)

NOTE. Values expressed as concordance (95% confidence interval).
* Because all patients included in these data had PBC, there is no effect from excluding the cause.

disease who were added to the UNOS waiting list between November 1999 and June 2000.[56] During this period of time, a total of 2,732 patients were listed as status 2A or 2B for liver transplantation on the UNOS list. Of this group, 514 had complete data at listing with many patients reporting a prothrombin time instead of an INR. Transforming a prothrombin time to an INR would be, at best, a guess; therefore, we attempted to keep the data as pure as possible for MELD model scoring. Of this group, 166 patients were transplanted within 3 months, 13 were removed from the list for being "too sick," 17 patients at the end of the study had < 3 months of follow-up, 2 refused transplant, and 5 patients were transferred to another center or downgraded to status 3, leaving a study group of 311 patients. The mean age was 49 years, 65% were male, and 71% were white. The patients had the following diagnoses: chronic hepatitis C (41.5%), alcohol-related liver disease (21.5%), cryptogenic cirrhosis (10.6%), and cholestatic liver disease (5.1%). For the 26 patients listed on UNOS status 2A the median MELD score was 27, while for the 285 patients listed on status 2B it was 14. At 3 months after listing, the group of patients with a MELD score greater than 18 experienced a 29% death rate compared to 6% in those patients, who had a MELD score of less than 18 ($P < .01$). Using the MELD model without etiology of liver disease, the c-statistic (concordance) for 3-month mortality in the 311-patient cohort was 0.82, which indicated an excellent ability of the MELD model to predict pretransplant mortality on the UNOS waiting list. By comparison, the c-statistic for the Child-Turcotte-Pugh score for 3-month mortality was only 0.73.

As this analysis was based on only a small sample of patients on the UNOS waiting list, a consensus developed in the Liver and Intestinal Committee that further studies using larger numbers of patients would be important prior to general application of the MELD model in organ allocation. However, the data did suggest that use of the MELD model could eliminate waiting time as a major factor in determining organ allocation. In addition, the MELD model might have a significant impact by reducing the number of deaths on the waiting list, as donor organs will be allocated to the patients with the highest MELD score but prior to the development of the life-threatening disease (i.e., UNOS status 2A).

Impact of a Continuous Severity Score for Liver Allocation

One of the UNOS regions recently developed a variance to the UNOS liver allocation policy, which redefined status 2A by more rigid criteria and prioritized allocation for 2B patients by using a continuous medical urgency score based on the CTP score in combination with certain complications of liver disease.[57] In this variance, waiting time was only used as a tiebreaker for 2B candidates with equal medical urgency scores. The outcome of 67 patients listed for transplantation during the 6 months prior to the implementation of the continuous system were compared with 75 patients who were followed prospectively for a 6-month period after implementation of the continuous score. The results revealed a significant reduction in the number of liver transplantations, performed in patients listed as status 2A (46.3% *v* 14.7%, $P = .002$), and an increase in the number of patients listed as 2B status who received a liver transplant (70.7% *v* 44.8%) (Fig. 5A and 5B). More dramatically, a 37.1% reduction in overall deaths on the waiting list was found during the period in which the continuous medical severity score was used ($P < .005$), while patient and graft survival following liver transplantation were similar in both periods. From this pilot study, it was suggested that by using a system with a continuous medical urgency score, donor livers were more fairly allocated to those with the most medical need. The variance appeared to reduce waiting list mortality without sacrificing efficacy. This study also suggested that de-emphasizing waiting time for liver allo-

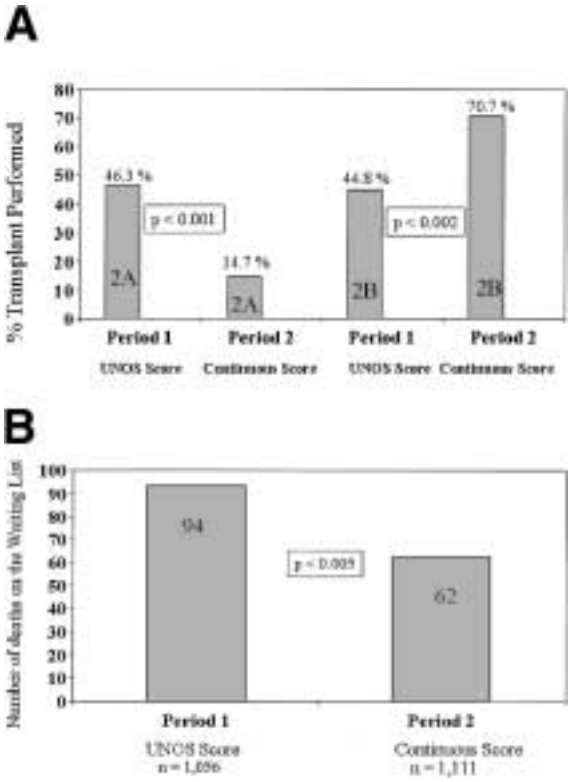


Figure 5. (A) Percentage of patients who underwent transplantation at status 2A and 2B during period 1 (old score used) and period 2 (continuous severity score applied to liver organ allocation). (Data from Freeman et al.[57]) (B) Total number of deaths or removal from UNOS waiting list because patient was too ill to transplant during period 1 (old scheme) and period 2 (continuous severity score applied for liver organ allocation). (Data from Freeman et al.[57])

cation prioritization directed organs to more severely ill patients in the 2B category. As a consequence, patients at status 2B were less frequently advanced to status 2A, which is often associated with decreased survival as well as increased resource utilization following liver transplantation.

Pediatric Liver Disease Severity Score (PELD)

Because the development of the MELD model was based on data from adult patients, its applicability to pediatric patients is unknown. Since there were no known data sets with large numbers of pediatric patients to evaluate the MELD model, we used the Studies of Pediatric Liver Transplantation (SPLIT) database.[58,59] On June 15, 2000, 884 pediatric patients with chronic liver disease without a prior liver transplant were registered into the SPLIT database. Of these 884 patients, 779 were not in the intensive care unit at the time of listing for liver transplantation. For the purpose of development of a severity index, primary outcome was defined as death, transplant, or admission to the intensive care unit prior to receiving a liver transplant. Admission into an intensive care unit was considered an endpoint, since the current UNOS allocation scheme allows these pediatric patients to be listed at UNOS status 1. Seventy-four of the 779 patients had a primary outcome. Death occurred in 41 children without a transplant and 33 pediatric patients were transferred to an intensive care unit because of deterioration in their condition.

When the outcome of pediatric patients on the UNOS waiting list was analyzed, it showed that 14% of children under age 1 year died or were transferred to an intensive care unit pretransplant, compared to 6.3% of children above 1 year of age. Furthermore, children with a height and weight of 2 standard deviations below normal experienced a higher incidence of one of the primary outcomes, 14.2% versus 7.2%. Using multivariate analysis with factors that were found to be significant in univariate analysis, 3 models to predict primary outcome were developed: (1) Pediatric Severity Scale Model (PSS), which included serum albumin level, total serum bilirubin level, INR, and growth failure; (2) Pediatric Severity Scale Model Plus Age (PSSAGE), which included the same factors as in the PSS model plus age; and (3) the Pediatric Death Severity Scale Model (PDSS), which was developed to predict death using age, total serum bilirubin level, and INR as predictors of outcome. The best model for predicting the primary outcome (pretransplant death, or transfer to the ICU) was the PSS model, which did not include age. However, age was found to be highly predictive of pretransplant death in both univariate analysis and in the PDSS model. Because of the perception that age <1 year is a strong predictor of death, an arbitrary decision was made by the Pediatric Liver Group to add age <1 year to the final pediatric model because of its perceived clinical significance.

In contrast to adult patients, serum creatinine did not reach significance as a univariate variable, and thus was not a predictor of the primary outcome in the pediatric patients. Therefore, the MELD model was found to be not applicable to pediatric chronic liver disease patients. A comparison between the three pediatric severity models and the MELD model was assessed by computing the area under the curve for receiver operating characteristics (ROC) predicting the primary outcomes at 3 months. Using the SPLIT database, the 3 pediatric severity scores consistently performed better

Table 7. Comparison of Pediatric Liver Severity Score Using the Area Under the ROC Curve to Determine the c Statistic for 3-Month Mortality/ICU Admission

	Pretransplantation Death or ICU Admission	Pretransplantation Death
PSS	0.82	0.91
PSS AGE	0.82	0.92
PDSS	0.76	0.88
MELD	0.71	0.82

than the MELD score (Table 7), and the area under the curve of the ROC for the PSSAGE model was at least 10% higher than the MELD score. The PSSAGE model (which will be further referred to as the Pediatric End-Stage Liver Disease [PELD] model) was the best overall model and, therefore, has been proposed as the model to be assessed further for prioritization of pediatric patients for liver transplantation (Fig. 6A). However, since the PELD model was developed on a single data set, additional validation is needed to assess its overall predictive ability. Preliminary data from the University of Pittsburgh's pediatric database suggests concordance of >0.80 in predicting 3-month mortality, thus validating the PELD model. Like the MELD model, the PELD model will prioritize patients by estimating probability of 3-month mortality. Further, this estimated probability of mortality at 3 months using the PELD score can be equated to a MELD score, which predicts the same probability of 3-month mortality. Note, for two survival probability estimates based upon Cox-Regression, the numerical score for the one can be converted to the numerical score of the other by adding a constant. This demonstrates that the conversion of a PELD to MELD or MELD to PELD should be a practical matter (Fig. 6B). A conversion factor for possible use in organ allocation should first be described following validation of the PELD in ranking patients and calibration of both the MELD and PELD in terms of actual survival probabilities using patients listed for transplantation.

Limitations of The PELD and MELD Models

The MELD model has been validated using a number of retrospective databases and has performed well with regard to its ability to predict short- and medium-term mortality in patients with chronic liver disease. However, in order to apply the MELD model for the purpose of prioritizing patients for liver allocation, several concerns need to be addressed. First, the effect of age, gender, and body mass on serum creatinine level may introduce a bias independent from severity of liver disease. In many patients with chronic liver disease, who have moderate to marked muscle wasting, serum creatinine levels may be falsely low and not reflective of true renal dysfunction. For example, using the MELD model, in which serum creatinine is an important factor, a nutritionally wasted 40-kg woman will be disadvantaged by having a low serum creatinine level, which is reflective of decreased muscle mass. A recent study, however, has shown that the contribution of lean body mass to serum creatinine is only 2.9%.[60] Indeed, our initial assessment of body mass index did not seem to significantly improve the MELD model's predictive ability, but further assessment is needed.[40] Therefore, the UNOS validation study, which will start in 2001, will incorporate the Crockoff-Gault equation in which estimates of creatinine clearance will be used to determine the potential impact that body mass on the prognostic capabilities of the MELD model.[61]

A second issue is related to how patients with hepatocellular cancer, who often have less severe liver disease, will be incorporated in the new algorithm. Presently, patients with cirrhosis and hepatocellular cancer are given UNOS status 2B, if their cancers meet the

A

PELD Risk Score = 0.436 age (<1 yr)
- 0.687 $\log_e$ albumin g/dL
+ 0.480 $\log_e$ total bilirubin mg/dL
+ 1.857 $\log_e$ INR
+ 0.667 growth failure (<-2SD)

B

$$R_m = R_p - R_{po} + R_{mo} - 10 \log_e \left[\frac{\mathrm{Log}_e S_{mo}(t)}{\mathrm{Log}_e S_{po}(t)}\right]$$

R_m = MELD risk score equivalent to the PELD risk score
R_p = PELD risk score
R_{mo} = Average MELD risk score
R_{po} = Average PELD risk score
$S_{mo}(t)$ = Baseline survival at t months based upon MELD score
$S_{po}(t)$ = Baseline survival at t months form the PELD model

Figure 6. (A) PELD survival model. (B) Formula for conversion of PELD score to MELD score.

following conditions: (1) one lesion less than 5 cm, or (2) three lesions less than 3 cm without evidence of metastatic disease. As survival in this group of patients with hepatocellular cancer is similar to that of patients undergoing liver transplantation for other chronic liver diseases,[62,63] discrimination against these patients with regard to organ allocation is not justified. Currently, a proposal is being considered to enter chronic liver disease patients with qualifying concomitant hepatocellular cancers on the waiting list at a MELD score reflecting a 40% probability of dying in 3 months. The rationale for choosing a 40% probability of dying in 3 months is based on the tumor doubling time, particularly in those patients who have a rapid doubling time. Every 3 months additional points would be added to the MELD score until the patient is transplanted, dies, or becomes medically unsuitable for liver transplantation.Similarly, patients with conditions in which the severity of disease is not reflected by the MELD score, like the hepatopulmonary syndrome and familial amyloidosis, will also need to be prioritized in a manner in which they are able to compete for donor allocation.

A third concern is how waiting time will enter into the allocation scheme. The current proposal from the UNOS Liver and Intestinal Committee is that waiting time would only be a tiebreaker for patients with whole-integer MELD scores. In this system, waiting time will move backward but not forward. If a patient improved from a MELD score of 24 to a score of 22, waiting time will be applied as a tiebreaker with other patients at the lower MELD score. On the contrary, waiting time for a patient with a MELD score of 22 would not be applied if the patient advanced to a MELD score of 24. In general, severity of liver disease would remain the major prioritization factor.

The major limitation of the PELD score is that it has not been prospectively validated on an independent UNOS data set at this time. However, the PELD score like the MELD score is based on only a few variables, which can be objectively assessed and are reproducible. Special conditions such as metabolic liver diseases or hepatoblastoma will need to be dealt with on an individual basis by regional review boards.

Finally, many experts questioned if the PELD and MELD models would be able to predict outcome following liver transplantation. An additional component of an ideal allocation model was thought to be the ability to identify which patients can benefit most from liver transplantation resulting in optimal use of our scarce donor resource.[1]

MELD Model for Predicting Outcomes of Liver Transplantation

The impact of the pretransplant MELD score on post-transplant mortality and resource utilization was analyzed using a multicenter database comprising a select group of adult recipients who underwent liver transplant since January of 1990 at the Mayo Clinic Rochester and Baylor University Dallas.[64] Patients with fulminant liver disease or malignancy were excluded from the analysis. A total of 1,185 patients in 4 diagnostic categories (viral hepatitis 30%, alcoholic liver disease 15%, cholestatic disease 31%, and other liver diseases 24%) met the inclusion criteria. The median MELD score, computed immediately before liver transplantation, was 13. Outcome parameters included graft and patient survival at 3 months, intraoperative blood transfusion requirement, and length of intensive care unit and hospital stay. The outcome parameters were found to become progressively worse as the pretransplant MELD score increased (Table 8). However, because of a number of random deaths, the model's prediction of mortality within 3 months following liver transplant, expressed as the c-statistic, was only 0.62 (confidence interval 0.55 to 0.69). Although these results suggest a

Table 8. Effect of MELD Score on Patient and Graft Survival, Intraoperative Blood Transfusions, Intraoperative Red Blood Cell Transfusions, and ICU and Hospital Days After Liver Transplantation

MELD Score	<10 (n = 392)	10-19 (n = 527)	20-29 (n = 164)	30-39 (n = 63)	>40 (n = 39)
Death (3 mo) (%)	5	6	10	10	26
Graft failure (3 mo) (%)	7	8	14	14	33
RBCs (L)	1.5	2.3	3.5	3.5	3.7
ICU (d)	2	3	4	5	6
Hospital (d)	14	15	17	21	19

Abbreviation: RBCs, red blood cells.

relationship between the MELD score and postoperative patient and graft survival and resource utilization, it also suggests that the MELD model is not able to predict random postoperative deaths which are unrelated to pretransplant liver disease severity. Nevertheless, we believe this study represents an initial step in the process of attempting to optimize the benefit of liver transplantation based on estimating pre- and posttransplant mortality.

Summary

Compared to the CTP score (Table 9), the MELD and PELD models provide the means to more accurately measure liver disease severity and to better predict which patients are at risk of dying on the waiting list. The relation between the MELD score and the risk of 3-month mortality is shown in Fig. 7. Most importantly, by de-emphasizing waiting time these two models will allow organ allocation based on medical urgency, as mandated in the DHHS final rule.

However, while the MELD score is an extremely powerful predictor of the probability of death in patients with chronic liver disease, it does not address one of the guidelines in the final rule, that an organ allocation system should promote the most efficient use of scarce donor resources and should avoid futile transplants. Thus, a future challenge will be to modify the MELD model in order to predict the probability of death with and without a liver transplant and thus to allow further optimization of the timing of this life-saving procedure. Finally, ongoing studies are needed to further define when the severity of liver disease of a patient has deteriorated to the point that the transplant procedure itself becomes futile. Hopefully, ongoing data collection, as mandated by the Final Rule of HHS, can help us address some of these extremely complex and challenging issues.

Table 9. Comparison of MELD and CTP Models

	MELD	CTP
Reason developed	Shunt outcome	Shunt outcome
Derived	Prospective data	Empiric
Parameters	Objective	Subjective components
Parameter variability	Minimal	Center-to-center variability
Spectrum	Continuous	Ceiling effect, few categories
Validation studies	Yes	No
Allocation emphasis	Disease severity	Waiting time

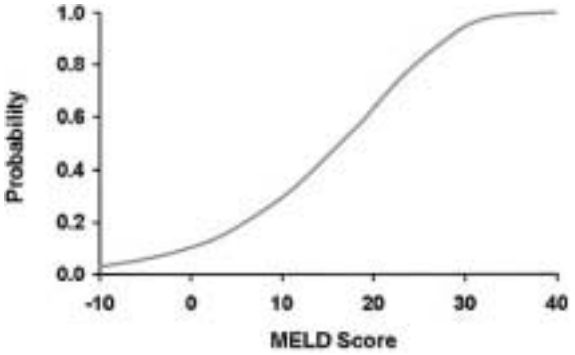


Figure 7. Relationship between the MELD score and estimated 3-month mortality in chronic liver disease patients.

References

1. Anonymous. Organ procurement and transplantation network—HRSA. Final rule with comment period. Federal Register 1998;63:16296-16338.
2. Institute of Medicine. Analysis of waiting times. In: Committee on Organ Transplantation. Assessing current policies and the potential impact of the DHHS final rule. Washington, DC: National Academy Press, 1999;57-78.
3. Freeman R, Edwards E. Liver transplant waiting time does not correlate with waiting list mortality: Implications for liver allocation policy. Liver Transpl 2000;6:543-552.
4. Lucey MR, Brown KA, Everson GT, Fung JJ, Gish R, Keeffe EB, et al. Minimal criteria for placement of adults on the liver transplant waiting list: A report of a national conference organized by the American Society of Transplant Physicians and the American Association for the Study of Liver Diseases. Liver Transpl Surg 1997;3:628-637.
5. Child CG II, Turcotte JG. Surgery and portal hypertension. In: Child CG III (ed) The liver and portal hypertension. Philadelphia: Saunders, 1964;50-58.
6. Conn HO. A peek at the Child-Turcotte classification. Hepatology 1981;1:673-676.
7. Pugh RN, Murray-Lyon IM, Dawson JL, Pietroni MC, Williams R. Transection of the oesophagus for bleeding oesophageal varices. Br J Surg 1973;60:646-649.
8. Christensen E, Schlichting P, Fauerholdt L, Gluud C, Anderson PK, Juhl E, et al. Prognostic value of Child-Turcotte criteria in medically treated cirrhosis. Hepatology 1983;3:889-895.
9. Infante-Rivard C, Esnaola S, Villeneuve JP. Clinical and statistical validity of conventional prognostic factors in predicting short-term survival among cirrhotics. Hepatology 1987;7:660-664.
10. Shetty K, Rybicki L, Carey WD. The Child-Pugh classification as a prognostic indicator for survival in primary sclerosing cholangitis. Hepatology 1997;25:1049-1053.
11. Kim WR, Poterucha JJ, Wiesner RH, LaRusso NF, Lindor KD, Petz J, et al. The relative role of the Child-Pugh classification and the Mayo natural history model in the assessment of survival in

patients with primary sclerosing cholangitis. Hepatology 1999; 29:1643-1648.
12. Abad-Lacruz A, Cabre E, Gonzalez-Huix F, Fernandez-Banares F, Esteve M, Planas R, et al. Routine tests of renal function, alcoholism, and nutrition improve the prognostic accuracy of the Child-Pugh score in nonbleeding advanced cirrhotics. Am J Gastroenterol 1993;88:382-389.
13. Fernandez-Esparrach G, Sanchez-Fueyo A, Gines P, Uriz J, Quinto L, Ventura PJ, et al. A prognostic model for predicting survival in cirrhosis with ascites. J Hepatol 2001;34:46-52.
14. Moroto A, Gines A, Salo J, Claria J, Gines P, Anibarro L, et al. Diagnosis of functional renal failure of cirrhosis by Doppler sonography. Prognostic value of resistive index. Hepatology 1994;20:839-844.
15. Gines P, Fernandez Esparrach SG. Prognosis of cirrhosis with ascites. In: Arroyo V, Gines P, Rodes J, Schrier RW (eds). Ascites and renal dysfunction in liver disease. Oxford, UK: Blackwell Science, 1999:431-441.
16. United Network for Organ Sharing. Policy 3.6. Allocation of livers. Available at: www.unos.org. Accessed: October 13, 2000.
17. Annual Report of the US Scientific Registry for Organ Transplantation and the Organ Procurement and Transplantation Network—Transplant Data 1990-1999. UNOS, Richmond, VA, and the Division of Transplantation, Bureau of Health Resources and Services Administration, US Department of Health and Human Services, Rockville, MD, 2000.
18. Robert A, Chazoulleres O. Prothrombin time in liver failure: Time, ratio, activity percentage, or international normalized ratio? Hepatology 1996;24:1392-1394.
19. Dickson ER, Grambsch PM, Fleming TR, Fisher LD, Langworthy A. Prognosis in primary biliary cirrhosis: Model for decision making. Hepatology 1989;10:1-7.
20. Farrant JM, Hayllar KM, Wilkinson ML, Karani J, Portmann BC, Westaby D, et al. Natural history and prognostic variables in primary sclerosing cholangitis. Gastroenterology 1991;100: 1710-1717.
21. Wiesner RH, Grambsch PM, Dickson ER, Ludwig J, MacCarty RL, Hunter EB, et al. Primary sclerosing cholangitis: Natural history, prognostic factors, and survival analysis. Hepatology 1989;10:430-436.
22. Orrego H, Israel Y, Blake JE, Medline A. Assessment of prognostic factors in alcoholic liver disease: Toward a global quantitative expression of severity. Hepatology 1983;3:896-905.
23. Chedid A, Mendenhall CL, Gartside P, French SW, Chen T, Ranin L. Prognostic factors in alcoholic liver disease. Am J Gastroenterol 1991;86:210-216.
24. Nazer H, Ede RJ, Mowat AP, Williams R. Wilson's disease: Clinical presentation and use of prognostic index. Gut 1986;27: 1377-1381.
25. Schenker S. Alcoholic liver disease: Evaluation of natural history and prognostic factors. Hepatology 1984;4:S36-S43.
26. Maddrey WC, Boitnott JK, Bedine MS, Weber FL Jr, Mezey E, White RI Jr. Corticosteroid therapy of alcoholic hepatitis. Gastroenterology 1978;75:193-199.
27. Christensen E, Schlichting P, Andersen PK, Fauerholdt L, Schou G, Pedersen BV, et al. Updating prognosis and therapeutic effect evaluation in cirrhosis with Cox's multiple regression model for time-dependent variables. Scand J Gastroenterol 1986;21:163-174.
28. D'Amico G, Marabito A, Pagliaro L, Marubini E, and the Liver Study Group. Survival and prognostic indicators in compensated and decompensated cirrhosis. Dig Dis Sci 1986;31:468-475.
29. Gines P, Quintero E, Arroyo V, Teres J, Burguera M, Rimola A, et al. Compensated cirrhosis: Natural history and prognostic factors. Hepatology 1987;7:122-128.
30. Albers I, Hartmann H, Bircher J, Creutzfeldt W. Superiority of the Child-Pugh classification to quantitative liver function tests for assessing prognosis of liver cirrhosis. Scand J Gastroenterol 1989;24:269-276.
31. Merkel C, Bolognesi M, Bellon S, Bianco S, Honisch B, Lampe H, et al. Aminopyrine breath test in prognostic evaluation of patients with cirrhosis. Gut 1992;33:836-842.
32. Beuers U, Jager F, Wahllander A, Ansari H, Kirsch CM. Prognostic value of the intravenous ^{14}C-aminopyrine breath test compared to the Child-Pugh score and serum bile acids in 84 cirrhotic patients. Digestion 1991;50:212-218.
33. Arrigoni A, Gindro T, Aimo G, Capello N, Meloni A, Benedetti P, et al. Monoethylglycinexylidide test: A prognostic indicator of survival in cirrhosis. Hepatology 1994;20:383-387.
34. Oellerich M, Burdelski M, Lautz H-U, Binder L, Pichlmayr R. Predictors of one year pretransplant survival in patients with cirrhosis. Hepatology 1991;14:1029-1034.
35. Salerno F, Borroni G, Moser P, Sangiovanni A, Almasio P, Budillon G, et al. Prognostic value of the galactose test in predicting survival of patients with cirrhosis evaluated for liver transplantation. J Hepatol 1996;25:474-480.
36. Tage-Jensen U, Henriksen JH, Christensen E, Widding A, Ring-Larsen H, Christensen NJ. Plasma catecholamine level and portal venous pressure as guides to prognosis in patients with cirrhosis. J Hepatol 1988;6:350-358.
37. Arroyo V, Bosch J, Gaya-Beltran J, Kravetz D, Estrada L, Rivera F, et al. Plasma renin activity and urinary sodium excretion as prognostic indicators in nonazotemic cirrhosis with ascites. Ann Intern Med 1981;94:198-201.
38. Cooper GS, Bellamy P, Dawson NV, Desbiens N, Fulkerson WJ, Goldman L, et al. A prognostic model for patients with end-stage liver disease. Gastroenterology 1997;113:1278-1288.
39. Malinchoc M, Kamath PS, Gordon FD, Peine CJ, Rank J, ter-Borg PL. A model to predict poor survival in patients undergoing transjugular intrahepatic portosystemic shunts. Hepatology 2000;31:864-871.
40. Kamath PS, Wiesner RH, Malinchoc M, Kremers W, Therneau TM, Kosberg CL, et al. A model to predict survival in patients with end-stage liver disease. Hepatology 2001;33:464-470.
41. Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. Radiology 1982; 143:29-36.
42. Talwalkar JA, Seaberg E, Kim WR, Wiesner RH. Predicting clinical and economic outcomes after liver transplantation using the Mayo primary sclerosing cholangitis model and Child-Pugh score. Liver Transpl 2000;6:753-758.
43. Schepis F, Camma C, Niceforo D, Magnano A, Pallio S, Cinquegrani M, et al. Which patients with cirrhosis should undergo endoscopic screening for esophageal variceal detection? Hepatology 2001;33:333-338.
44. Arroyo V, Gines P, Gerbes A, Dudley F, Gentilini P, Laffi G, et al. Definition and diagnostic criteria of refractory ascites and hepatorenal syndrome in cirrhosis. Hepatology 1996;23:164-176.
45. Bustamante J, Rimola A, Ventura PJ, Navasa M, Cirera I, Reggiardo V, et al. Prognostic significance of hepatic encephalopathy in patients with cirrhosis. J Hepatol 1999;30:890-895.

46. Graham D, Smith J. The course of patients after variceal hemorrhage. Gastroenterology 1981;80:800-806.
47. Altman C, Grange JD, Amiot X, Pelletier G, Lacaine F, Bodin F, et al. Survival after a first episode of spontaneous bacterial peritonitis. Prognosis of potential candidates for orthotopic liver transplantation. J Gastroenterol Hepatol 1995;10:47-50.
48. Garrett KO, Reilly JJ, Schade RR, Van Thiel DW. Sclerotherapy of esophageal varices: Long-term results and determinants of survival. Surgery 1988;104:813-818.
49. DiMagno EP, Zinsmeister AR, Larson DE, Viggiano TR, Clain JE, Laughlin BL, et al. Influence of hepatic reserve and cause of esophageal varices on survival and rebleeding before and after the introduction of sclerotherapy: A retrospective analysis. Mayo Clin Proc 1985;60:149-157.
50. Milliken WJ, Warren DW, Henderson JM, Smith RB, Salam AA, Galambos JT, et al. The Emory prospective randomized trial: Selective versus nonselective shunt to control variceal bleeding: Ten year follow-up. Ann Surg 1985;201:712-722.
51. Everhart JE, Bereford TP. Liver transplantation for alcoholic liver disease: A survey of transplantation in the United States. Liver Transpl Surg 1997;3:220-226.
52. Kim WR, Wiesner RH, Therneau T, Poterucha JJ, Porayko ME, Evans RW, et al. Optimal timing of liver transplantation for primary biliary cirrhosis. Hepatology 1998;28:35-38.
53. Graziadei IW, Wiesner RH, Batts KP, Marotta PJ, LaRusso NF, Porayko MK, et al. Long-term results of patients undergoing liver transplantation for primary sclerosing cholangitis. Hepatology 1999;30:1121-1127.
54. Chalasani N, Baluyut A, Ismail A, Zaman A, Sood G, Ghalib R, et al. Cholangiocarcinoma in patients with primary sclerosing cholangitis: A multicenter case-control study. Hepatology 2000; 31:7-11.
55. Mayo PSC Study Group. Ursodiol for primary sclerosing cholangitis. N Engl J Med 1997;336:690-695.
56. Wiesner RH, Edwards EB, Kamath PS, Kim WR, Kremers WK, Freeman RB, et al. Mayo end-stage liver disease model (MELD) score predicts liver transplant waiting list mortality: Implications for liver allocation policy [abstract]. Transplantation 2001; 71(suppl 1):461.
57. Freeman RB, Rohrer RS, Katz E, Lewis WD, Jenkin R, Cosimi AB, et al. Preliminary results of a liver allocation plan using a continuous medical severity score that de-emphasizes waiting time. Liver Transpl 2001;7:173-178.
58. McDiarmid S. 2000 Report of the Studies of Pediatric Liver Transplantation (SPLIT). Potomac, MD, EMMES Corp, 2000.
59. McDiarmid SV, Anand R, and SPLIT Research Group. Development of a pediatric end-stage liver disease score [abstract]. Transplantation 2001;71(suppl 1):461.
60. Swaminathan R, Major P, Snieder H, Spector T. Serum creatinine and fat-free mass (lean body mass). Clin Chem 2000;46: 1695-1696.
61. Cockroft RW, Gault MN. Prediction of creatinine clearance from creatinine. Nephron 1976;16:31-41.
62. Harnois DM, Steers J, Andrews JC, Rubin JC, Pitot HC, Burgart L, et al. Preoperative hepatic artery chemoembolization followed by orthotopic liver transplantation for hepatocellular carcinoma. Liver Transpl Surg 1999;5:192-199.
63. Mazzafero V, Regalia V, Doci E, Andreola S, Purvirent A. Liver transplantation for treatment of small hepatocellular carcinomas in patients with cirrhosis. N Engl J Med 1996;334:693-699.
64. Kim WR, Wiesner RH, Kamath PS, Malinchoc M, Kremers WK, Rosen CB, et al. Prediction of liver transplant outcome using the MELD scale [abstract]. Transplantation 2001; 71(suppl 1):284.

Table 3. Relationship Between MELD, CTP Score, and 3-Month Mortality in Hospitalized Cirrhotics (Group A)

	3-Month Death Rates				
MELD	≤9	10-19	20-29	30-39	≥40
Mortality	4 (6/148)	27 (28/103)	76 (16/21)	83 (5/6)	100 (4/4)
CTP		A	B		C
Mortality		4 (3/77)	14 (13/93)		51 (35/69)

NOTE. Values expressed as percent (number/total).

Creatinine	1.2
Bilirubin	1.5
INR	1.6
Cause	Other
Score	14.97152
est 3 month mortality, hospitalized patients	27%

Meld Risk Score = 10 x [0.957 x $\log_e$ (creatinine mg/dL) + 0.378 x $\log_e$ (bilirubin mg/dL) + 1.120 x $\log_e$ (INR) + 0.643 x Cause of cirrhosis (0 alcohol, cholestatic, 1 other etiologies)]

Below is for automation of the cause of cirrhosis - do not alter

Alcohol	3
Cholestatic	1
Other	

Transgender

Correctional Medicine Consultation Network
UCSF Box # 1308
1940 Bryant Street, San Francisco, CA 94110
PHYSICIAN's HOTLINE:
1-888-883-9432

OFFICE

Office Phone	476-2041
Main Office Fax	476-2207
Alternate Office Fax	476-2043
Financial Fax	476-6051
Travel Coordinator Fax	(951) 486-5620
Telemedicine Fax	476-4263 or 4261
San Quentin Fax	455-5011

Name	Title	Work Phone	Cell Phone	Pager	E-mail
San Quentin	Office	454-1460 ext. 5500		443-0584	4154430584@archwireless.net
Telemedicine	Office 1	476-2147			
Telemedicine	Office 2	476-4262			
Telemedicine	Office 3	476-4267			

FACULTY

Name	Title	Work Phone	Cell Phone	Pager	E-mail
Lori Kohler	Director	476-2040	516-5215	443-7329	lkohler@fcm.ucsf.edu
Shira Shavit[4]	Associate Director, Faculty SQ	476-2148	672-5053	443-4585	sshavit@fcm.ucsf.edu
Michele DiTomas	Faculty CMF	476-2041	510-734-2712	707-420-	Michele.Ditomas@cdcr.ca.gov
Larry Boly	Faculty	476-4264/764-4127	672-7418	443-0580	lboly@fcm.ucsf.edu
Megan Mahoney	Faculty	476-2041	244-3106	443-1531	mmahoney@nccc.ucsf.edu
Tri Do	Faculty	597-9261	517-0767	517-0767	tri.do@ucsf.edu
George Beatty	Faculty	476-4082x419	265-6239	443-8802	Gbeatty@php.ucsf.edu
Sonali Kulkarni	Faculty SOL		317-5228	443-1729	Sonali.Kulkarni@ucsf.edu
Conall McCabe	Faculty Fresno	559-459-5741	559-493-8816	559-488-8604	mccabec@fcm.ucsf.edu
Silver Sisneros	Faculty HIV	476-2041			
Cecily Crosby	NP Faculty Transgender	476-2145			cosbycd@fcm.ucsf.edu
Joanne Imperial	Faculty Hep-C	476-2041			
Ingrid Nelson	NP Faculty HIV	476-4266	265-6238	443-1520	NelsonI@fcm.ucsf.edu
Susan Shea[1]	NP Faculty HIV	476-4686	672-6237	443-1775	sshea@fcm.ucsf.edu
Tina Clark	NP Faculty HIV	476-5069	290-0895		clarkti@fcm.ucsf.edu
Sharon O'Leary	RN Faculty/Telemed	476-5066	680-5727	443-7515	OlearyS@fcm.ucsf.edu
Diane Norcio	NP PhD	476-2041	314-5815		NorcioD@fcm.ucsf.edu
Naomi Zubin	NP Faculty HIV	476-2042			ZubinN@fcm.ucsf.edu
Katie Shuton	RN Faculty/Telemed	476-5659			ShutonK@fcm.ucsf.edu
Betty Dong	PharmD	476-1972		443-9699	DongB@pharmacy.ucsf.edu
Helena Tang	PharmD	206-4207	650-200-7092	443-7269	HTang@nccc.ucsf.edu
Margery Lazarus	Program Evaluation	476-2041			LazarusM@fcm.ucsf.edu
Stephen Rao	Director of Pain Management	476-5274	310-0241	831-4999	Stephen.Rao@ucsf.edu
Robert Brody	Faculty Telemedicine	206-8267		650-997-9576	robert.brody@ucsf.edu
Ed Lor	PharmD			650-997-4419	Ed.Lor@sfdph.org

1=Octavio 2= 3=Ruth 4=Oona 5=Ivy 6= (numbers correspond to the faculty to whom the program assistants are assigned)
* Please use 415 for numbers that do not have an area code.

CHAPTER 26
Hormone Therapy for Transgender Inmate-Patients

I. POLICY
The California Department of Corrections and Rehabilitation (CDCR) recognizes that Gender Identity Disorders require appropriate medical and mental health management. The Division of Correctional Health Care Services (DCHCS) shall provide evaluation and hormone therapy for patients with Gender Identity Disorders, including patients identifying themselves as transgender, based upon each individual's specific needs and the criteria below.

II. PURPOSE
The purpose of the policy for Hormone Therapy of Transgender Patients is threefold:

- To ensure medically necessary evaluation and hormone therapy for transgender patients;
- To provide continuity of hormone therapy for transgender patients who are transferred or; paroled; and
- To provide information to the appropriate Classification Committee(s) for consideration associated with the housing of patients with gender identity conditions.

III DEFINITIONS
A. Gender Identity Disorder

An individual with Gender Identity Disorder has a strong and persistent cross-gender identification. The individual experiences persistent discomfort with his or her sex, or a sense of inappropriateness in the gender role as manifested by symptoms such as the desire to be treated as the other sex, frequent passing as the other sex, and the conviction that he or she has the typical feelings and reactions of the other sex. The disturbance is not concurrent with a physical intersexual condition. The disturbance causes clinically significant distress or impairment in social, occupational, and/or other important areas of functioning.

B. Transgender

A transgender person is a person born with the physical characteristics of one gender who identifies himself or herself as having the internalized identity of another gender.

C. Hormone Therapy

Hormone Therapy refers to hormones that are provided to transgender patients to enable physical changes consistent with the patients' internalized gender identities.

III. PROCEDURES
A. **The CDCR shall provide clinical consultants** experienced in the therapy of transgender patients. The consultant(s) shall be available at each institution in person, by telephone, or by telemedicine consultation.

B. **Transgender patients entering the CDCR shall** be treated with hormone therapy according to the Guidelines approved by the DCHCS. These Guidelines shall be based upon current community standards. Current DCHCS Hormone Therapy Guidelines are documented in Attachment 1.

C. Transgender Patients Entering the CDCR on Hormone Therapy

Transgender patients entering the CDCR who either document or attest to current or recent hormone treatment will continue their hormone therapy in accordance with Hormone Therapy Guidelines approved by the DCHCS.

D. Transgender Patients Entering the CDCR Not on Hormone Therapy

Transgender patients entering the CDCR who request hormone therapy, but have not recently received such therapy, shall be evaluated within ninety (90) days of that request by a consultant experienced in the therapy of transgender patients. Evaluation may be in person, by telemedicine consultation, or in telephone consultation with the patient's primary care provider (PCP). The patient may be started on hormone therapy at the discretion of that consultant in accordance with DCHCS approved Hormone Therapy Guidelines.

E. Changes in Hormone Therapy

Hormone therapy shall be continued without change within an institution, and upon transfer of the patient between institutions, with the following exceptions:

- Hormone therapy may be changed or discontinued in consultation with and with the consent of a clinical provider experienced in the therapy of transgender patients.
- Hormone therapy may be stopped on an urgent or emergent basis in the presence of a suspected or a documented significant adverse reaction. This discontinuance should be followed by prompt notification of and consultation with a clinical provider experienced in the therapy of transgender patients.

F. Parole

Transgender patients on hormone therapy shall be provided with 30 days of maintenance hormone therapy upon parole. The hormone therapy shall be by the same dose and route, if arrangements can be made to support it. In the case of injectable hormone therapy, 30 days of equivalent oral therapy shall be provided if arrangements cannot be made for injectable administration.

G. Housing

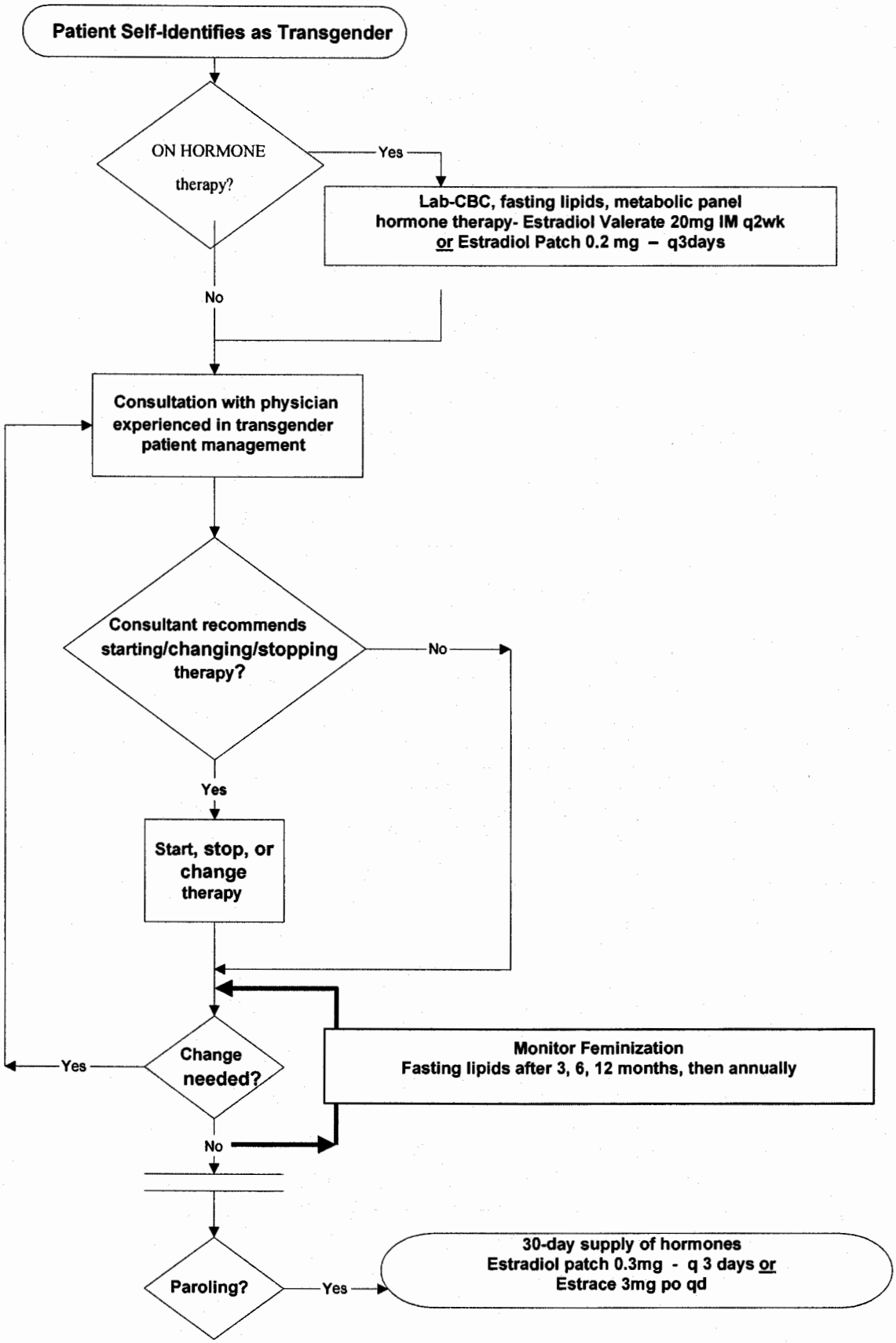
No patient receiving hormone therapy in the CDCR shall be placed in restrictive work or school assignments, or housing units, such as Administrative Segregation (Ad Seg), solely because of being on hormone therapy. All transgender inmates in CDCR shall be referred to the appropriate classification committee for consideration for placement in a Special Needs Yard (SNY) based upon security concerns.

H. Clothing

Gender-specific articles of clothing (athletic supporters, brassieres, etc.) are not medical devices and shall be addressed by existing custody clothing regulations.

I. Training

Training shall be provided to all staff impacted by this policy.


Patient Self-Identifies as Transgender
ON HORMONE therapy?
Yes
Lab-CBC, fasting lipids, metabolic panel
hormone therapy- Estradiol Valerate 20mg IM q2wk
or Estradiol Patch 0.2 mg – q3days
No
Consultation with physician experienced in transgender patient management
Consultant recommends starting/changing/stopping therapy?
No
Yes
Start, stop, or change therapy
Change needed?
Yes
Monitor Feminization
Fasting lipids after 3, 6, 12 months, then annually
No
Paroling?
Yes
30-day supply of hormones
Estradiol patch 0.3mg - q 3 days or
Estrace 3mg po qd

THE VICTIMIZATION OF TRANSGENDER INMATES: AN EMPIRICAL EXAMINATION OF A VULNERABLE POPULATION IN PRISON

Topic or Issue to be Studied

With the passage of the Prison Rape Elimination Act of 2003 (42 USC § 15601), also known as the PREA, newfound attention has been directed toward a particular type of institutional violence—prison rape—as a problem with immense consequences for inmates and correction officials alike. It is difficult to accurately assess the incidence and prevalence of prison rape and other forms of sexual assault in correctional facilities because research on victimization in correctional facilities has often produced contradictory findings. As Gaes and Goldberg's (2004) inventory of estimates of sexual assault in correctional facilities reveals, prevalence estimates run from zero to 40%.[1] Research on sexual assault in correctional facilities is limited and most research that does exist often suffers from small sample sizes, definitional problems, and low response rates (Gaes & Goldberg, 2004).

The extent and nature of the problem in California, however, is documented in a recent report by Jenness, Maxson, Matsuda, & Sumner (2007).[2] This report relies on self-report data from 322 randomly sampled inmates and 39 purposively sampled transgender inmates in California state prisons to detail the prevalence of sexual assault in California correctional facilities, the characteristics of victims, and the contextual and relational characteristics of incidents. While over 4% of the randomly selected inmates reported being sexually assaulted while in a California correctional facility, sexual assault is 13 times more prevalent among transgender inmates, with 59% of transgender inmates reporting being sexually assaulted while in a California correctional facility (Jenness et al., 2007).

Building on this prior work, the current study continues to address the main objective of the Prison Rape Elimination Act of 2003—to reduce prison rape in the U.S. and to respond to it more effectively when it does occur. This study responds to the California Department of Corrections and Rehabilitation's (CDCR) recent call for more research on the victimization of transgender inmates. By focusing on transgender inmates, the group with the highest reported rate of sexual assault in California correctional facilities, this research both replicates and elaborates upon the previous study. With regard to the latter, it is designed to focus on three additional domains of interest: inmates' past and current living environments (i.e., housing while incarcerated), social networks (i.e., interpersonal relationships while incarcerated), and experiences in the community (especially as they pertain to victimization and interpersonal relationships).

The focus on housing is particularly important because anecdotal evidence and the precedent-setting case brought by a transgender inmate (*Farmer v. Brennan* [114 S.Ct. 1970 (1994)]) suggests that transgender inmates are more vulnerable in non-segregated environments. However, this suggestion has not been subjected to a systematic empirical test. We know that transgender inmates are at high risk, but we know very little about how that risk is statistically

---

[1] Gaes, G.G., & Goldberg, A.L. (2004). *Prison Rape: A Critical Review of the Literature.* Working Paper, National Institute of Justice, Washington, D.C.

[2] Jenness, V., Maxson, C.L., Matsuda, K.N., & Sumner, J.M. (2007). *Violence in California Correctional Facilities: An Empirical Examination of Sexual Assault.* Report Submitted to the California Department of Corrections and Rehabilitation.

associated with specific housing assignments as opposed to other factors that might also be amenable to intervention, such as surveillance, programming, and physical features of the carceral environment in which they reside (Jenness et al., 2007). (See also *Alexis Giraldo v. the California Department of Corrections and Rehabilitation*. Superior Court of California, City and County of San Francisco. Case No. CGC-07-461473.)

Major Project Goals and Research Questions
The purpose of the study is to develop an understanding of the variation in the likelihood and nature of victimization among transgender inmates in CDCR facilities. In addition to the adapted interview constructed for the first study on sexual assault by Jenness et al. (2007), interview questions will be added to further explore the features of the environment in which victimization occurs, as well as the broader transgender inmate culture, including the structure of social networks operating to negotiate the challenges of conditions of confinement (one of which is increased vulnerability to sexual victimization). In addition, this work seeks to provide an understanding of the differential vulnerability to sexual victimization by transgender persons while they are incarcerated compared to their experiences of victimization in the community.

The findings of this study can be used by the CDCR to fashion and implement policies and interventions designed to reduce victimization in California prisons. As such, there are potential long-term benefits to this investigation, most notably the provision of safety for inmates throughout the system via the development of scientifically informed policy. This is especially promising research along these lines insofar as the CDCR is embracing a mission that includes a commitment to "evidence-based" practices, loosely defined as using the findings from social science studies (such as this one) to inform policy and practice.

Data or Information Sources
Data for this study will be collected in two primary ways: through in-depth, confidential, in-person interviews with transgender inmates and official C-file and incident data retrieved from the CDCR.

Narrative Description of Plan to Address the Issue
This project will provide empirical findings that can guide the development of viable policy and programmatic interventions designed to respond to and reduce sexual assault among transgender inmates in adult California correctional facilities. A research team from the University of California, Irvine (UCI), led by Professor Valerie Jenness, will take responsibility for the design and execution of the project in addition to the dissemination of study findings.

Procedure
An application to the University's Institutional Review Board (IRB) is under review and an application to the state's Committee for the Protection of Human Subjects (CPHS) is being prepared for submittal.

The interview instrument employed in the original study of sexual assault by Professors Jenness and Maxson will be adapted and expanded to be amenable to data collection on transgender victimization while incarcerated in consultation with Professors Maxson and O'Brien. Once finalized, a team of interviewers will be trained extensively in preparation for data collection at each facility.

This study will primarily include male-to-female transgender inmates given their disproportionately large numbers; however, for further insight we will also include female-to-

male transgender inmates residing in the state's prisons. Wardens will be asked to identify transgender inmates residing in their prisons and provide this roster to the research team. This roster will serve as the recruitment list. We will then send the list of selected inmates at each prison to our liaison at the site to ensure that the inmates are scheduled and notified to meet with an interviewer on the research team. Once at the facility, snowball sampling may be employed to ensure that all transgender inmates at the facility are included in the study even if they were not included on the official roster. Inmates will then report to the specified location where the researchers will be conducting the interviews.

The interviewer will conduct the interviews in confidential settings in which the interview cannot be overheard. Once the inmate and the interviewer are in a private location amenable to conducting a confidential interview, the interviewer will identify him/herself as a researcher and then proceed to invite the inmate to participate in the study by briefly describing the nature and purpose of the study, thoroughly explaining that participation is voluntary and that there are no consequences for declining to participate, and ensuring confidentiality if the inmate agrees to participate in the interview. Upon obtaining informed consent, the interviewer will conduct the interview.

In addition to interviewing each inmate, the research team will also collect official data from the inmate's Central File via CDCR maintained databases. Data will be obtained on all inmates residing in each prison during the data collection period in order to maximize the confidentiality of transgender inmates, whether they have participated or not, as well as in order to assess the degree to which transgender participants represent the full transgender inmate population and allow for analyses between groups (transgender inmates versus non-transgender inmates).

This portion of the research investigation consists of the analysis of secondary data provided to the research team by the CDCR. These official data are collected by the CDCR and are stored primarily in its Offender Based Information System (OBIS). The subjects of the data are current or previously incarcerated adults in California. The key variables of interest consist of (but are not limited to) CDCR number, name, race/ethnicity, date of birth, height, weight, term start date, minimum adjusted release date/EPRD, length of current sentence, current location, current commitment offense, sexual offender registration, mental health status, most recent classification score, custody level, gang, age at first arrest in California, three strike status, and lifer status. These variables constitute independent variables to be used to predict sexual assault and violence more generally. Unlike the previous study, more detailed data on movement history throughout the state prisons across prison terms will be gathered in order to confirm locations/environments and dates in which victimization incidents occurred.

Finally, we will secure incident reports of all assaults (sexual and otherwise) on file in all CDCR facilities. These records, which come in many forms, will enable us to code and analyze the officially detected incidents of sexual assault in California correctional facilities operated by the CDCR.

Once all data are collected, coded, and matched, we will use standard multivariate statistical techniques to examine the effects of both officially collected variables and data collected during in-person interviews on prison violence in general and sexual assault in particular. Recognizing that reports of sexual assault in correctional facilities constitute rare events, we will treat

violence of all sorts as more frequently occurring events to be predicted by these types of variables. Doing so allows us to assess the degree to which the factors that predict assaults of all sorts and also predict sexual assaults in particular. The main objective is to statistically discern features of the physical and policy environment as well as the human environment in which prison violence occurs and gets reacted to in some ways (and not others).

Research Personnel with Access to Protected Personal Information
While additional research personnel will conduct interviews for this study, the following list represents only those research personnel who also may have access to protected personal information in the form of official data retrieved from the CDCR.

Lead Researcher: Valerie Jenness, Ph.D.
Valerie Jenness is a Professor of Criminology, Law and Society and Sociology and an Affiliate of the Center for Evidence-Based Corrections at the University of California, Irvine. As the Lead Researcher Dr. Jenness will be responsible for the scientific direction and the general administration of all aspects of the project including data collection, data analyses and preparation of reports and publications resulting from the proposed project.

Project Manager: Jennifer Sumner, M.A.
Jennifer Sumner is an advanced graduate student in the Department of Criminology, Law and Society at the University of California, Irvine. As project manager Ms. Sumner will be responsible for the scientific direction and the general administration of all aspects of the project including data collection and coding, data analyses and preparation of reports and publications resulting from the proposed project.

Research Assistants: Lori Sexton, M.A., Kristy Matsuda, M.A., Philip Goodman, M.A., Lynn Pazzani, M.A.

Lori Sexton is a second year graduate student in the Department of Criminology, Law and Society at the University of California, Irvine. Ms. Sexton will assist with all aspects of the research including conducting literature reviews of the relevant topics, interview construction, training interviewers, facilitating interview data collection at state prisons, cleaning and coding interview and official data, and data analyses.

Kristy Matsuda is an advanced graduate student in the Department of Criminology, Law and Society at the University of California, Irvine. Ms. Matsuda will conduct interviews and assist with data coding and analyses.

Philip Goodman is an advanced graduate student in the Department of Criminology, Law and at the University of California, Irvine. Mr. Goodman will conduct interviews and assist with data coding and analyses.

Lynn Pazzani is an advanced graduate student in the Department of Criminology, Law and Society at the University of California, Irvine. Ms. Pazzani will conduct interviews and assist with data coding and analyses.

Description of Measures to be Taken to Protect Confidentiality

How Personal Information Will be Protected from Improper Use

One database will store the official data collected from the CDCR pertaining to all inmates housed in state prisons during the study period. While this will contain personal identifiers (i.e., CDC numbers and names), they will be removed before analyses are conducted. A separate database will contain data for transgender inmates (both interview participants and non-participants). In this database, official data will be matched to interview data through a random study identification number. Once matched, these data will be stripped of identifying variables such as name and CDC number so that the database used for analyses will identify inmates only through study identification numbers. An electronic key code will exist separate from this database matching inmate CDC numbers and names to the study identification number. This key code will only be used to match inmate answers to their official data. That is, interview answers will only be indirectly linked to an inmate's identity. Only those researchers approved by CPHS will have access to the official data which contain personal identifiers (i.e., CDC number and name). Data containing personal identifiers will be housed on password protected computers and data located on discs will be stored securely under lock and key in the lead researcher's research office or a designated research office accessible only to the research team. No data containing personal identifiers will be stored on laptop computers that can be transported. Any study data that identify the subjects will not be voluntarily released or disclosed without the subjects' separate consent, except as specifically required by law. Publications and/or presentations that result from this study will not include subject identifiable information.

Plan to Destroy or Return all Personal Information

Data containing any personal identifiers will be destroyed five years after the last publication resulting from the data is released. After that time, only an electronic data file without any personal subject identifiers will be stored indefinitely.

Assurance that the Personal Information will not be Reused or Disclosed

All data containing personal identifiers will be kept in a locked file cabinet located in the lead researcher's research office or a locked file cabinet in a UCI research office only accessible to those on the research team listed on this application. Electronic data containing personal identifiers will be stored on project-dedicated computers in the same location. We anticipate using technical safeguards such as: use of password-protected access, screensavers that have a timeout that locks after a period of non-use and audit trails that record who has created or changed data in the system. Wherever feasible, person-identifiable elements of the computerized research records will be stored separately. Though official data will include personal identifiers of incarcerated persons these will only be used to link data across databases. All identifiers will be removed for analyses, reports, and publications. In addition, all data will only be accessible to those on the research team.

Project Budget

See attachment.

Time Constraints

The expected project completion date is December 30, 2008. In order to meet this deadline, official data need to be provided to the UCI research team by CDCR staff by March 31, 2008 and interview data collection completed by July 1, 2008.

Project Milestones	**Expected Date of Completion**[3]
Complete Literature Review on Victimization of Transgender Persons	January 28, 2008
Complete Draft of Interview Instrument (to pilot test)	January 28, 2008
Pilot Test Instrument	January 28, 2008
Complete Report/Chapter on State and Local Policies on Transgender Inmates	January 28, 2008
Complete Training Manual for Interviewers	February 1, 2008
Conduct Day-Long Training Session for Interviewers	February 15, 2008
Complete Final Interview Instrument	February 29, 2008
Obtain Official Roster from Facilities	March 14, 2008
Obtain C-File Data from CDCR	March 31, 2008
Complete Interview Data Collection	July 1, 2008
Complete First (i.e., "Working") Draft of the Interview Data Codebook	July 1, 2008
Complete Data Coding, Entry, and Cleaning	August 31, 2008
Complete the Interview Data Codebook	August 31, 2008
Complete Data Analysis for the Final Report	October 31, 2008
Submit Final Report to the CDCR	December 30, 2008

Distribution
Secretary, CDCR
Institutions Division
Regulations and Policy Management Branch
Wardens
The Legislature
Activist Organizations (e.g., Stop Prisoner Rape, Transgender Activist Organizations)
Academic Organizations (e.g., American Society of Criminology)

Contract Staff: Valerie Jenness, Ph.D.

Consultants: Cheryl Maxson, Ph.D. (University of California, Irvine), Richard McCleary (University California, Irvine), Jodi O'Brien, Ph.D. (Seattle University)

CDCR Support Staff: Assistance from staff in the Office of Research to secure demographic data on transgender inmates (downloaded from OBIS) and download data on official reports of sexual assault in California correctional facilities operated by the CDCR.

[3]The deadlines reported below are estimates.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

The Victimization of Transgender Inmates: An Empirical Examination of a Vulnerable Population in Prison

presented at the

The Wardens Retreat

California Department of Corrections and Rehabilitation

by

Valerie Jenness, Ph.D.

Center for Evidence-Based Corrections
Department of Criminology, Law and Society
University of California, Irvine

Santa Barbara, California
February 5, 2008

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Objectives

1. Describe the context for research
2. Summarize past related research
3. Introduce current plans for research
4. Solicit feedback, input, and cooperation

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

1. The Context for Research

Why Research?

Why Research on Transgender Inmates?

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Evidence-Based Corrections: From Principle to Practice

The CDCR Mission:

The overarching mission is to improve public safety through evidence-based crime prevention and recidivism reduction strategies.

What is "Evidence-Based Corrections?"

The conscientious, explicit, and judicious use by correctional administrators of current best research evidence in selecting programs designed to manage offenders, reduce recidivism, and increase public safety (Grattet 2005).

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Why Research on Sexual Assault / Transgender Inmates?

- Legislative Mandates
  - Prison Rape Elimination Act
  - Sexual Abuse in Detention Elimination Act
- Legal Concerns
  - *Farmer v. Brennan*
  - *Giraldo v. the CDCR*
- Insufficient research

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Highlights of the PREA

- Supports the elimination, reduction, and prevention of sexual assault within corrections system
- Mandates several national data collection activities
- Creates a national commission to develop standards and accountability measures
- Provides funding for program development and additional research

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Sexual Abuse in Detention Elimination Act

"…the purposes of which would be to protect all inmates and wards from sexual abuse while held in institutions operated by the Department of Corrections and the Department of the Youth Authority…"

"This law lays the foundation for California, the largest prison system in the country, to be a national leader in the fight to end prisoner rape."

--Stop Prisoner Rape

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Farmer v. Brennan (1994)

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Giraldo v. the CDCR (2007)

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Why Research on Transgender Inmates?

- **In March 2004 NIJ published a comprehensive literature review of the existing research titled "Prison Rape: A Critical Review of the Literature," which:**
  - Describes research conducted since 1968
  - Describes both convergence and divergence across findings, noting the difficulties encountered when comparing across facilities of different sizes, security levels, missions, types of inmates, etc.
  - Describes how conducting such research presents a unique set of challenges
  - Offers suggestions to help guide future research
  - But, only one prison in California studied!
- *Violence in California Correctional Facilities: An Empirical Examination of Sexual Assault* (2007), by Valerie Jenness, Cheryl L. Maxson, Kristy N. Matsuda, and Jennifer M. Sumner. A report submitted to the CDCR.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

2. Past Related Research

Violence in California Correctional Facilities: An Empirical Examination of Sexual Assault (2007), by Valerie Jenness, Cheryl L. Maxson, Kristy N. Matsuda, and Jennifer M. Sumner.*

*For details, see the Bulletin in the folder distributed at the retreat.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Violence in California Correctional Facilities:

An Empirical Examination of Sexual Assault

by

Valerie Jenness
Cheryl L. Maxson
Kristy N. Matsuda
Jennifer Macy Sumner

Criminology, Law and Society
University of California
Irvine, California 92697-7080

Center for Evidence-Based Corrections

April 27, 2007

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Purpose of the Study

Key Questions:

1.What proportion of inmates in California prisons housing adult males has been sexually assaulted in a California correctional facility?

2. What are the demographic characteristics of victims?

3. What are the contextual and relational characteristics of the sexual assault/misconduct incidents reported by inmates in California prisons housing adult males?

Main Objective:

By addressing these questions, this study sheds insight into the contours of sexual assault in order to contribute to ongoing efforts to create viable interventions designed to prevent and respond to sexual assault in ways that are humane, effective, and constitutional.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Select Differences between the Random Sample and the Transgender Sample

	Random Sample	Transgender Sample
Prevalence of Sexual Assault	4.4%	59%
Prevalence of undesirable sexual acts	1.3%	48.3%
Weapon actually used if involved	20%	75%
Officer Aware of the Incident	60.6%	29.3%
Provision of Medical Attention (if needed)	70%	35.7%
Racial composition (% of incidents interracial)	17.2%	63.9%
Relational Distance	Evenly distributed	Skewed toward familiarity

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Recommendations: Research

- Research on other incarcerated populations, such as women and juveniles.
  - Additional research on transgender inmates, non-heterosexual inmates, inmates of color, inmates with mental health problems, and inmates that are small in stature.
- Collect empirical data on a broader range of types of sexual assault, especially
  - staff-on-inmate assault.
- Focus empirical research on perpetration as well as victimization to ascertain if there are similar patterns and correlates.
- Support studies that assess current efforts to respond to sexual assault in California correctional facilities.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Post Report "Hearing" and "Discussion," Pt. I

Violence in California Correctional Facilities: An Empirical Examination of Sexual Assault (2007), by Valerie Jenness, Cheryl L. Maxson, Kristy N. Matsuda, and Jennifer M. Sumner.

- Orally presented to the wardens in attendance at the Wardens retreat at Green Valley Training Center on May 16, 2007 and thereafter to the Secretary and Executive Staff of the CDCR on May 20, 2007.
- Orally presented to a plethora of audiences with a stake in prison violence, including a state level Commission devoted to reducing sexual assault in prisons, Executive Officers and staff for Stop Prisoner Rape (SPR), the Executive Director of the National Prison Rape Elimination Act Commission, and the Chief of Staff for the California Majority Whip, Assemblywoman Fiano Ma.
- Entered into evidence and orally presented in a recent high profile Superior Court trial in San Francisco, *Alexis Giraldo v. the California Department of Corrections and Rehabilitation*, which involved a transgender inmate unsuccessfully suing the CDCR for failing to protect her from serial sexual assault in Folsom State Prison.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Post Report "Hearing" and "Discussion," Pt. II

• Posted on multiple organizations' web pages, including the Center for Evidence-Based Corrections at the University of California, Irvine, the National Institute of Corrections, Stop Prisoner Rape, Corrections Community, AELE Law Enforcement/Legal Center, and the California Coalition Against Sexual Assault.

Note: In less than seven months (from June 2007-December 2007), over 13,500 "hits" are associated with this report on the web site for the Center for Evidence-Based Corrections at the University of California, Irvine—far more than any other report posted on the Center's website.

• Referenced in an Associated Press article that appeared in over 30 newspapers, including *The Los Angeles Times*, the *San Francisco Chronicle*, *The Guardian* (in London), *Forbes*, *The San Diego Union-Tribune*, *The Houston Chronicle*, *The San Francisco Examiner*, and *The Washington Post.*

• Referenced in testimony given by Wendy Still, Associate Director, CDCR, before the National Prison Rape Elimination Commission in New Orleans, Louisiana on December 5, 2007.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Acknowledgments

CDCR

- Bubpha Chen
- John Dovey
- Sharon English
- Nola Grannis
- Nancy Hardy
- Kimberly Kaufman
- Sandi Menefee
- Wendy Still
- Jeanne Woodford
- Wardens and other prison administrators and correctional officers at seven prisons from which data were collected

Research Consultants

- Allen Beck
- Mark Fleisher
- Alexander L. Lee
- Merry Morash
- Andie Moss

Stop Prisoner Rape

- Lovisa Stannow
- Lara Stemple

UC Research Team/Consultants

- Victoria Basolo
- Lyndsay Boggess
- Philip Goodman
- Ryken Grattet
- John Hipp
- Lynn Pazzani
- Joan Petersilia
- Amelia Regan
- Michael Smyth
- Rebecca Trammell
- Susan Turner
- Sylvia Valenzuela
- Guadalupe Vidales

Inmates

- Hundreds whose names will remain confidential

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Now what?

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

3. Current Plans for Research

The Victimization of Transgender Inmates: An Empirical Examination of a Vulnerable Population, Valerie Jenness*

*For more details, see Exhibit A, Agreement #C07.227 in the folder distributed at the retreat.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Rethinking, revising, and elaborating!

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Previous Research Design

ADULT MALE INSTITUTIONS

Six Facilities*

Roster
(Non-Reception Center, non-EOP)

Random Selection of Inmates

Secure Informed Consent

INTERVIEW INSTRUMENT

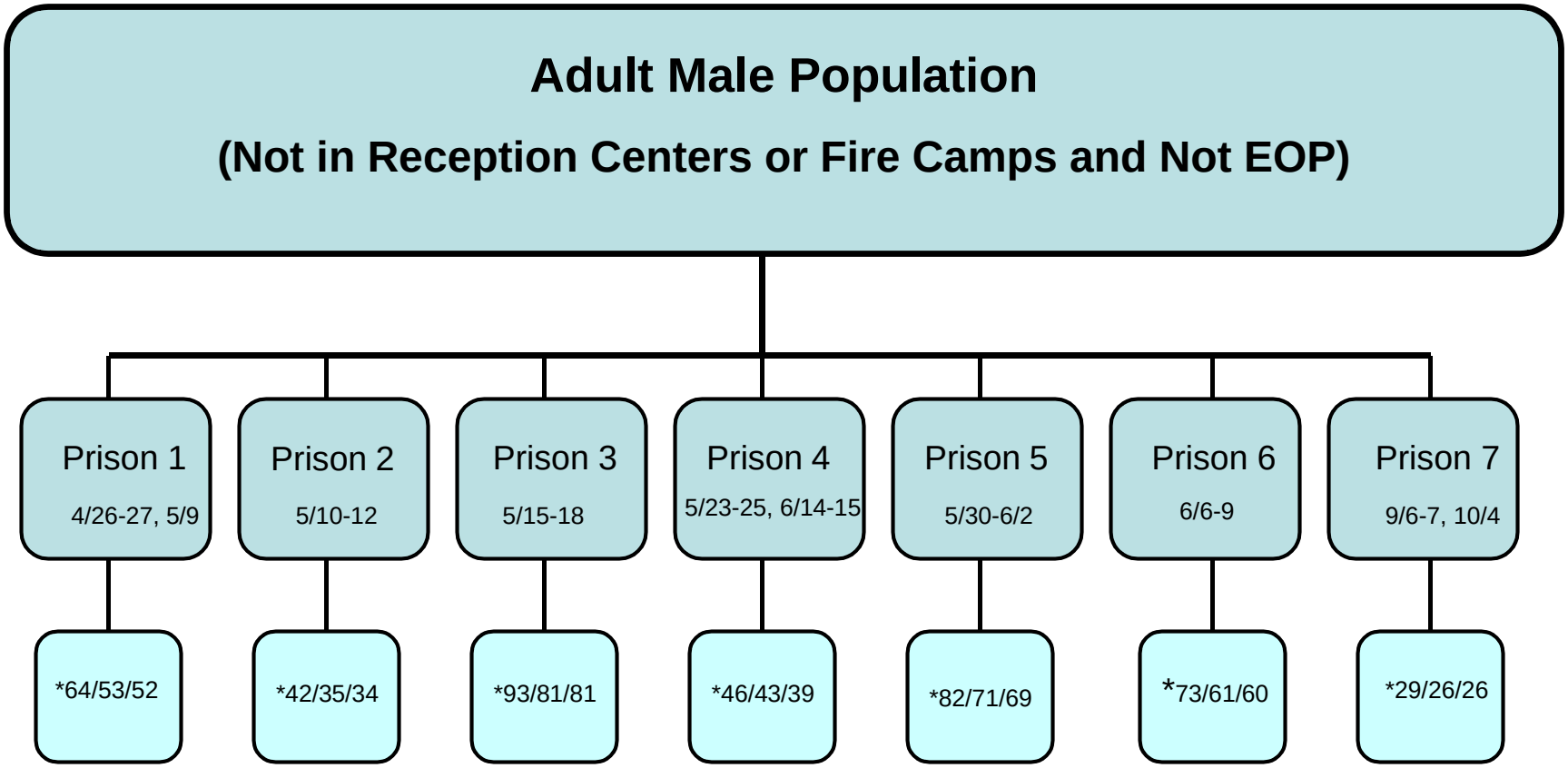
Life in Prison/Routine Activities; Social Support in Prison; Inmate General Well-Being/Emotional Health; Fear of Victimization in Prison; Actual Victimization in Prison; Opinions on Safety and Reporting; Demographics, including Gang Affiliation, Criminal History, and Past and Current Incarcerations

* Data were also collected from a seventh prison in order to over sample transgender inmates.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Previous Data Collection

(April 26, 2006 – October 4, 2006)



***First number = Total number of inmates seen; Second number = Total number of inmates who consented to be interviewed; Third number = Total number of usable interviews.**

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Previous Samples: Size and Participation Rate

- Random Sample
  - Total = 322
  - Participation Rate = 83.5%

- Transgender Sample
  - Total = 39
  - Participation Rate = 93.5%

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Assessment of Previous Samples

- Random Sample
  - Statistically similar to the population of inmates in the six prisons from which data were collected
  - Statistically comparable to the CDCR population in terms of sex offender registration and “lifer status”
  - Statistically different from the CDCR population in terms of age, race/ethnicity, offense category, custody level, gang status, and mental health problems
  - The magnitude of the statistical differences between the sample and the CDCR population is small, but the study sample has fewer Hispanic inmates and more inmates with officially recognized mental health issues
- Transgender Sample
  - Not designed to generalize to larger populations

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Current Research Design

ALL ADULT INSTITUTIONS

33 Facilities

List of TG inmates
(Non-Reception Center, non-EOP)

Identification and Selection of all Transgender Inmates

Secure Informed Consent

Face-to-Face Interview, with a focus on:

PART I: Housing History
PART II: General Perceptions and Actual Experiences
PARTIII: Individual/Demographic Characteristics

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

The UCI Interview Schedule*

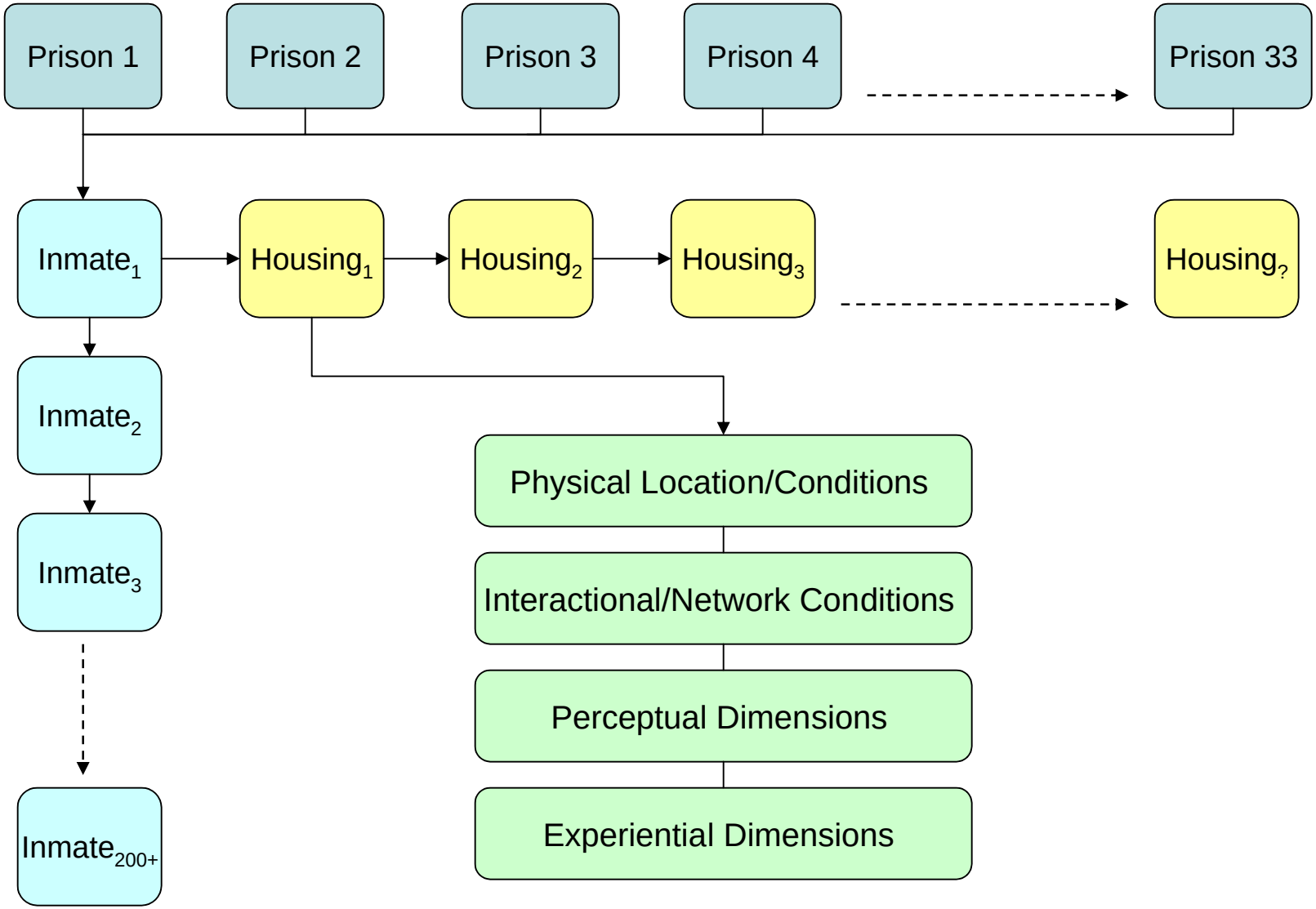
Preamble/Informed Consent

1. **Housing History, with a focus on four dimensions of the housing environment:**
   - Physical location/conditions
   - Interactional/network conditions
   - Perceptual dimensions
   - Experiential dimensions
2. **General Perceptions and Experiences of Incarceration:**
   - Opinions of safety and housing
   - Understandings/interpretations of violence
   - History of actual victimization while incarcerated and in the community
3. **Individual Characteristics:**
   - Education
   - Family
   - Gang and substance abuse history
   - Identity
   - Incarceration

* This list reflects the current draft of the instrument, but not necessarily the final draft of the instrument.

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Current Interview Format



UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Key Tasks and Estimated Timeline

Complete Literature Review	January 28, 2008
Complete Draft of Interview Instrument	January 28, 2008
Pilot Test Interview Instrument	January 28, 2008
Complete Report on State/Local Policies on Transgender Inmates	January 28, 2008
Complete Training Manual for Interviews	February 1, 2008
Conduct Training for Interviewers	February 15, 2008
Complete Final Interview Instrument	February 29, 2008
Obtain Official Roster of TG Inmates from Facilities	March 14, 2008
Obtain C-File/OBIS Data from CDCR	March 31, 2008
Complete Interview Data Collection	July 1, 2008
Complete Working Draft of Codebook for Interview Data	July 1, 2008
Complete Data Coding, Entry, & Cleaning	August 31, 2008
Complete Final Draft of Codebook for Interview Data	August 31, 2008
Complete Data Analysis for Final Report	October 31, 2008
Submit Final Report to the CDCR	December 30, 2008

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

4. Soliciting Feedback, Input, and Cooperation

Help!!!!!

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Acknowledgments

CDCR

- Bubpha Chen
- John Dovey
- Sharon English
- Nola Grannis
- Nancy Hardy
- Kimberly Kaufman
- Sandi Menefee
- Wendy Still
- Jeanne Woodford
- Wardens and other prison administrators and correctional officers at seven prisons from which data were collected

Research Consultants

- Allen Beck
- Mark Fleisher
- Alexander L. Lee
- Merry Morash
- Andie Moss

Stop Prisoner Rape

- Lovisa Stannow
- Lara Stemple

UC Research Team/Consultants

- Victoria Basolo
- Lyndsay Boggess
- Philip Goodman
- Ryken Grattet
- John Hipp
- Lynn Pazzani
- Joan Petersilia
- Amelia Regan
- Michael Smyth
- Rebecca Trammell
- Susan Turner
- Sylvia Valenzuela
- Guadalupe Vidales

Inmates

- Hundreds whose names will remain confidential

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Key Concerns

1. Identifying transgender inmates in all prisons
   - Wardens
   - Inmate Support Groups
   - Health Records/Dr. Lori Kohler
2. Accessing all transgender inmates/providing all transgender inmates an opportunity to be interviewed
3. Determining the scope of move history captured:
   - Time frame
   - What “counts” as a housing assignment
4. Capturing multiple dimensions of “housing environments”
5. Scheduling data collection at all 33 facilities within a tight time frame

UCIrvine
CENTER FOR EVIDENCE-BASED CORRECTIONS

Contact information

Valerie Jenness, Ph.D.

Department of Criminology, Law & Society
University of California
Irvine, California 92697-7080

Tel: (949) 824-3017
FAX: (949) 824-3001
E-mail: jenness@uci.edu

HIV

The Basics of HIV Infection and AIDS

for Correctional Health Care Providers

PACIFIC AIDS Education and Training Center

INTRODUCTION

The world first became aware of the disease now known as Acquired Immune Deficiency Syndrome (AIDS) in 1981. Since then it has become a major worldwide epidemic, with approximately 40 million people worldwide infected with the human immunodeficiency virus (HIV), the virus that causes AIDS.

The Centers for Disease Control and Prevention (CDC) estimates that about 1 million people in the United States are living with HIV or AIDS, about one-quarter of whom are unaware of their infection. Approximately 40,000 new HIV infections occur every year in the U.S. The epidemic is growing most rapidly among minority populations; people of color, gay men, women, young people and transgender persons are disproportionately represented among new infections.

The rate of confirmed AIDS cases in state and federal prisons (0.50%) is more than 3 times higher than in the total U.S. population (0.15%). About one-quarter of people with HIV infection in the U.S. have spent time in a correctional facility. In California there are over 1,600 prisoners or parolees identified as HIV+; approximately half are diagnosed with AIDS. Current state law does not require mandatory testing to identify all HIV+ inmates, and the actual number of HIV+ prisoners is thought to be much higher. In addition to HIV/AIDS, incarcerated populations are also disproportionately affected by higher rates of other communicable and chronic diseases such as tuberculosis and hepatitis. **Up to 40% of prison inmates are infected with hepatitis C virus.**

WHAT IS HIV?

HIV, the human immunodeficiency virus, is the virus that causes AIDS. HIV is a retrovirus that attacks the body's natural immune system. By finding and killing or damaging certain types of cells that the immune system must have to fight disease, HIV progressively destroys the body's ability to fight certain infections, cancers and diseases. The CD4 T lymphocyte (CD4 cell or T-cell) is the major component of the immune system that is infected by HIV. As HIV disease progresses, it slowly wears down the immune system.

HOW HIV IS and IS NOT TRANSMITED

HIV is primarily found in the blood, semen, or vaginal fluid of an infected person and is transmitted in 3 main ways:

1) Sexual contact (anal, vaginal, or oral) with someone infected with HIV.
2) Sharing needles/syringes with someone infected with HIV.
3) Being exposed (fetus or infant) to HIV before or during birth or through breast feeding.

The most common route of HIV transmission is through having unprotected sex with an infected partner. The virus can enter the body through the lining of the vagina, vulva, penis, rectum, or mouth during sex.

NO confirmed cases of HIV infection among prison staff in the U.S. have been attributed to contact with inmates.

Infected blood

HIV also can be transmitted through contact with blood infected with HIV. However, since 1985, all donated blood in the United States has been tested for HIV. Therefore, the risk for HIV infection through the transfusion of blood or blood products is extremely low.

Tattooing, a widespread activity in prisons, increases the risk of HIV transmission since it involves multiple skin punctures and is usually performed without sterile instruments.

Contaminated needles

HIV is frequently spread among injection drug users (IDUs) by the sharing of needles or syringes contaminated with very small quantities of blood from someone infected with the virus. Imprisoned IDUs may share injection equipment more frequently and without sterilization.

It is rare, however, for a patient to give HIV to a health care worker or vice-versa by accidental sticks with contaminated needles or other medical instruments. As of December 2001, occupational exposure to HIV has resulted in 57 documented cases of HIV seroconversion among healthcare personnel in the United States.

Mother-to-child transmission

Women can transmit HIV to their babies during pregnancy or birth. HIV also can be spread to babies through the breast milk of mothers infected with the virus. Approximately one-quarter to one-third of all untreated pregnant women infected with HIV will pass the infection to their babies. Certain drugs given during pregnancy or delivery can significantly reduce the chances that a baby will get infected with HIV. Perinatal transmission of HIV has been almost eradicated in the U.S. due to appropriate treatment.

Casual contact

HIV is a fragile virus that cannot live for very long outside the body. As a result, **the virus is not transmitted through day-to-day activities** like shaking hands, hugging or a casual kiss. HIV is not spread through casual contact such as toilet seats, drinking fountains, doorknobs, dishes, drinking glasses, food, or pets.

HIV is not transmitted by biting insects such as mosquitoes or bedbugs.

Saliva, tears and sweat

Although very low quantities of HIV have been found in saliva and tears of infected people, there is no evidence that contact with saliva, tears, or sweat has ever resulted in transmission of HIV. Laboratory studies have shown that saliva has natural properties that limit the power of HIV to infect, and the amount of virus in saliva appears to be very low. The lining of the mouth, however, can be infected by HIV, and instances of HIV transmission through oral intercourse have been reported.

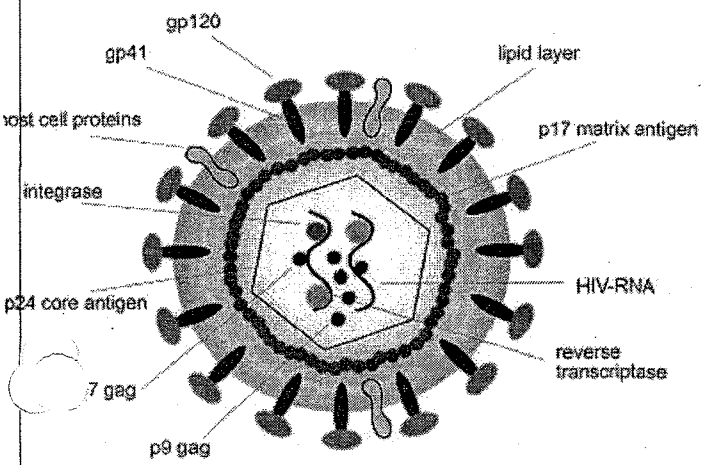
Sexually transmitted infections

Co-infection with sexually transmitted infections (STIs) such as syphilis, genital herpes, Chlamydia, or gonorrhea directly increases the risk of transmitting HIV.

DIAGNOSIS

Early HIV infection often causes no symptoms. Diagnosis is made by serologic testing for detection of antibodies to HIV. The standard is a screening EIA (ELISA) followed by a confirmatory Western Blot. Diagnosis may also be established by obtaining a quantitative HIV RNA PCR (viral load) test.

HIV antibodies generally develop within two weeks to three months from exposure. If a high-risk patient has a negative ELISA, repeat testing should be considered at a later date, when antibodies to HIV are more likely to have developed. Virtually all patients seroconvert within six months. Screening for the presence of HIV genetic material can determine whether a patient has been recently infected (acute infection). Direct screening of HIV is extremely critical in order to prevent transmission of HIV from recently infected individuals. **Early testing is also an opportunity to alert patients to avoid high-risk behaviors that could spread the virus to others.**



EARLY HIV INFECTION

Acute infection

Many people will not have any symptoms when first infected with HIV. Within a month or two after exposure to the virus, a flu-like illness may develop with symptoms including:

- ☑ Fever
- ☑ Headache
- ☑ Adenopathy
- ☑ Diarrhea
- ☑ Pharyngitis
- ☑ Nausea & vomiting
- ☑ Rash
- ☑ Tiredness

These symptoms usually disappear within two to four weeks and are often mistaken for those of another viral infection. During this period, people are very infectious, and HIV is present in large quantities in genital fluids.

Asymptomatic/Clinical latency period

More persistent or severe symptoms may not appear for 10 years or more after HIV first enters the body in adults. This period of "asymptomatic" infection or "clinical latency" varies greatly in each individual. Some people may begin to have symptoms within a few months, while others may be symptom-free for more than 10 years.

Even during the asymptomatic period, the virus is actively multiplying, infecting, and killing cells of the immune system. The virus can also hide within infected cells and lay dormant. The most obvious effect of HIV infection is a decline in the number of CD4+ T-cells found in the blood. The virus slowly disables or destroys these cells without causing symptoms.

As the immune system worsens, a variety of complications start to take over. For many people, the first signs of infection are large lymph nodes or "swollen glands" that may be enlarged for more than three months. Other symptoms often experienced months to years before the onset of AIDS include:

- ☑ Lack of energy
- ☑ Weight loss
- ☑ Frequent fevers and sweats
- ☑ Persistent or frequent yeast infections (oral or vaginal)
- ☑ Persistent skin rashes or flaky skin
- ☑ Pelvic inflammatory disease in women that does not respond to treatment
- ☑ Short-term memory loss

Some people develop frequent and severe herpes infections that cause mouth, genital, or anal sores, or a painful nerve disease called shingles.

WHAT IS AIDS?

Acquired Immune Deficiency Syndrome, or AIDS, is the final, most advanced stage of HIV infection. It can take years for a person infected with HIV, even without treatment, to reach this stage. AIDS is diagnosed when the immune system is severely weakened to the point at which the body has a difficult time fighting infections.

The CDC defines an HIV-positive person with a CD4 cell count of fewer than 200 CD4+ T cells per cubic millimeter of blood as having AIDS. (Healthy adults usually have CD4+ T-cell counts of 1,000 or more.) In addition, the definition includes over 20 clinical conditions that affect people with advanced HIV disease. Most of these conditions are opportunistic infections that generally do not affect healthy people. In people with AIDS, these infections are often severe and sometimes fatal because the immune system is so ravaged by HIV that the body cannot fight off certain bacteria, viruses, fungi, parasites, and other microbes.

What are the AIDS-defining conditions?

- Candidiasis of brochi, trachea or lungs
- Candidiasis, esophageal
- Cervical cancer (invasive)
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (> one month duration)
- Cytomegalovirus disease (other than liver, spleen or nodes)
- Encephalopathy (HIV-related)
- Herpes simplex (severe infection)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (> one month duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt's
- Lymphoma, immunoblastic
- Lymphoma, primary, of brain
- Mycobacterium avium complex
- Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)
- Pneumocystis carinii/jiroveci pneumonia
- Pneumonia (recurrent)
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia (recurrent)
- Toxoplasmosis of the brain

Symptoms of opportunistic infections common in people with AIDS may include:

- ☑ Coughing and shortness of breath
- ☑ Seizures and lack of coordination
- ☑ Difficult or painful swallowing
- ☑ Mental symptoms such as confusion and forgetfulness
- ☑ Severe and persistent diarrhea
- ☑ Fever
- ☑ Vision loss
- ☑ Nausea, abdominal cramps, and vomiting
- ☑ Weight loss and extreme fatigue
- ☑ Severe headaches
- ☑ Coma

People with AIDS are also particularly prone to developing various cancers, especially those caused by viruses such as Kaposi's sarcoma and cervical cancer, or cancers of the immune system known as lymphomas. These cancers are usually more aggressive and difficult to treat in people with AIDS. Signs of Kaposi's sarcoma in light-skinned people are round brown, reddish, or purple spots that develop in the skin or in the mouth. In dark-skinned people, the spots are more pigmented.

During the course of HIV infection, most people experience a gradual decline in the number of CD4+ T cells, although some may have abrupt and dramatic drops in their CD4+ T-cell counts. A person with CD4+ T cells above 200 may experience some of the early symptoms of HIV disease. Others may have no symptoms even though their CD4+ T-cell count is below 200.

TREATMENT

There is no cure for AIDS or vaccine against HIV. HIV treatment includes antiretroviral medications to prolong life and improve the quality of life, and medications administered for primary and secondary prophylaxis of HIV-related opportunistic infections.

There are now over 20 FDA-approved antiretroviral medications for HIV treatment. Antiretroviral mediations are used to control viral reproduction and slow the progression of HIV disease. The U.S. Department of Health and Human Services (DHHS) HIV treatment guidelines recommend a combination treatment to effectively suppress the virus. Use of multiple drugs (three or more) used in combination is referred to as **H**ighly **A**ctive **A**ntiretroviral **T**herapy, or HAART. HAART is used by people who are newly infected with HIV as well as people with AIDS, and is the standard of care for HIV/AIDS both in prison and in the community. **HAART does not cure AIDS and antiretroviral medications do not kill HIV.**

Although the DHHS HIV treatment guidelines recommend "preferred" HAART regimens, each should be tailored to the needs of the individual patient. The decision to begin HAART should be based on:

1) Symptoms of advanced HIV disease
2) CD4+ T-cell count
3) HIV viral load.

HAART should be considered for HIV-positive patients who have:

1. Severe symptoms of HIV infections or a diagnosis of AIDS
2. CD4+ T-cell count of 350 cells/mm^3 or less (treatment should always be offered to patients with a CD4+ T-cell count of 200 cells/mm^3 or less)
3. HIV viral load of 100,000 copies/mL or more.

HIV can become resistant to any of the HAART medications, and adherence to anti-HIV therapies in the range of 90-95% is required for treatment success. Missing medication doses is the most common reason for treatment failure and developing drug resistance. A thorough assessment of

patient willingness, readiness and ability to begin treatment is vital. Other factors to consider when determining an anti-HIV medication regimen include:

- ☑ Drug resistance testing results
- ☑ Number of pills and how often they must be taken
- ☑ Food requirements
- ☑ Ability to access medications
- ☑ Drug interactions with other medications
- ☑ Other diseases and conditions.

Side effects

Despite the beneficial effects of HAART, there are side effects associated with the use of antiviral drugs that can be severe or even life threatening. Some possible side effects of antiretroviral therapy include:

- ☑ nausea, vomiting, diarrhea, and other gastrointestinal symptoms
- ☑ fatigue
- ☑ headache
- ☑ skin rash
- ☑ liver problems (hepatotoxicity)
- ☑ diabetes (hyperglycemia)
- ☑ abnormal fat distribution (lipodystrophy syndrome)
- ☑ high cholesterol (hyperlipidemia)
- ☑ decreased bone density
- ☑ pancreatitis
- ☑ nerve problems

Patients on HAART should be monitored for drug toxicity and encouraged to report any adverse effect symptoms immediately, since side effects that may seem minor such as fever, nausea, and fatigue can be indicators of a more serious problem.

Provisions should be made to minimize disruption in antiretroviral therapy due to inmate transfer or release from custody. Connecting soon-to-be-released inmates with community resources for health care support is critical to assuring continuity of care and follow-up of HIV/AIDS patients, especially those on antiretroviral therapy. Health care providers caring for HIV/AIDS patients in California state prisons should be familiar with their local or regional Transitional Case Management Program (TCMP) and encourage paroling HIV-positive patients to enroll with a TCMP case manager.

HIV PREVENTION

No vaccine for HIV is available and the only way to prevent infection by the virus is to avoid behaviors associated with risk of infection, such as sharing needles or having unprotected sex.

Traditional community approaches to HIV prevention are often controversial in prisons. While it is well known that sexual activity and drug use do occur, these activities are prohibited among prison inmates. Current law does not allow access to condoms or clean needles. **Ongoing HIV prevention education is essential, and the crucial messages are:**

1. **no risk activity is safe; and,**
2. **exposure to bloody body fluids and semen should be avoided.**

Inmate peer education and counseling, and support groups run by and for prisoners can be successful educational models.

Although health care concerns may not be a primary focus upon release, HIV prevention education and risk reduction counseling should be included in transition and discharge planning.

REFERENCES AND RESOURCES

This handout includes material adapted from:

AIDS*info*
http://aidsinfo.nih.gov
Comprehensive resource for up-to-date HIV/AIDS information, clinical trials, and the most current, federally approved guidelines for treatment and prevention

AIDS InfoNet
http://www.aidsinfonet.org/
HIV/AIDS treatment information provided in the form of single-topic fact sheets.

Case Finding and Secondary Prevention with the Incarcerated and Recently Released: Clinical Risk Assessment and Screening Guide Pennsylvania/Mid Atlantic AETC, September 2006.
http://www.aids-etc.org/pdf/p02-et/et-03-00/pama-incarc_screening.pdf

CDC Fact Sheet: HIV and Its Transmission
http://www.cdc.gov/hiv/resources/factsheets/transmission.htm

Correctional Settings Chapter: *Clinical Manual for Management of the HIV-Infected Adult*, AIDS Education and Training Centers National Resource Center, 2006.
http://www.aids-etc.org/aetc/aetc?page=cm-00-00

HIV/AIDS Basic Information from the Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/hiv/topics/basic/index.htm

HIV and Its Treatment: What You Should Know
Fact sheet series from NIH AIDS*info* including information on testing, medications, treatment adherence, pregnancy, and prevention.
http://aidsinfo.nih.gov/contentfiles/HIVandItsTreatment_cbrochure_en.pdf

HIV Transmission and Prevention in Prisons
HIV InSite *Knowledge Base* Chapter, April 2006.
http://hivinsite.ucsf.edu/InSite?page=KB

Maruschak, L. Bureau of Justice Statistics Bulletin: HIV in Prisons, 2004. U. S. Department of Justice, Office of Justice Programs, Washington, DC, November 2006.
http://www.ojp.usdoj.gov/bjs/pub/pdf/hivp04.pdf

Nieto, M. Health Profile of California Inmates and Prison. The Urban Institute, Justice Policy Center, Los Angeles, CA, December 2002.

NIH Fact Sheet: HIV Infection and AIDS
http://www.niaid.nih.gov/factsheets/hivinf.htm
Overview of HIV infection, including transmission, symptoms, diagnosis, treatment, and prevention of HIV/AIDS.

Spaulding, A., et. al. Human Immunodeficiency Virus in Correctional Settings: A Review. *Clinical Infectious Diseases* 2002, 35: 305-12.

National HIV Telephone Consultation Service (Warmline):
1-800-933-3413

National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline):
1-888-448-4911

Perinatal HIV Hotline:

Clinical Manual
for Management of the HIV-Infected Adult

2006 Edition

Updated July 2007

Providing Healthcare Professionals with
Quality Education to Improve HIV Care

AETC
AIDS EDUCATION &
TRAINING CENTERS
www.aidsetc.org

About the AETC National Resource Center

The AETC National Resource Center (NRC) provides education and training resources for the regional AIDS Education and Training Centers (AETCs) to support their mission to offer timely, high-quality, state-of-the-art information to healthcare professionals working with existing and emerging populations affected by HIV. In partnership with the Center for HIV Information (CHI), the AETC NRC works to identify and develop information on HIV care, prevention, and policy through electronic media, including Internet and CD-ROM. The AETC NRC is administered by the François-Xavier Bagnoud (FXB) Center at the University of Medicine and Dentistry of New Jersey. The FXB Center provides clinical care, education and technical assistance in the United States and globally to support capacity development for addressing the HIV/AIDS epidemic.

This publication is supported by grant number H4AHA00063 from the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB).

How to Obtain Copies of the Manual

This manual is available both online and in print from the AETC National Resource Center. To access the online version of the manual, visit the following website: www.aidsetc.org. Limited supplies of print copies of the manual are available. To request a print copy of the manual, please contact:

- **AETC National Resource Center**
  François-Xavier Bagnoud Center
  University of Medicine and Dentistry of New Jersey
  30 Bergen Street, ADMC 4
  Newark, NJ 07107
  (973) 972-6587
  info@aidsetc.org
  www.aidsetc.org

Table of Contents

Preface i-vi

Section 1: Testing and Assessment . . . . . 1-1 — 1-38

Initial History 1-1
Initial Physical Examination. 1-11
Initial and Interim Laboratory and Other Tests 1-15
Interim History and Physical Examination 1-21
HIV Classification: CDC and WHO Staging Systems 1-23
Determining Risk of HIV Progression 1-27
CD4 Monitoring and Viral Load Testing 1-29
Primary HIV Infection 1-33
Rapid HIV Testing 1-35

Section 2: Health Maintenance and Disease Prevention . . . . . 2-1 — 2-46

Immunizations for HIV-Infected Adults and Adolescents 2-1
Nutrition 2-5
Nonoccupational Postexposure Prophylaxis. 2-13
Occupational Postexposure Prophylaxis 2-17
Preventing HIV Transmission/Prevention with Positives 2-23
Preventing Exposure to Opportunistic and Other Infections. 2-29
Opportunistic Infection Prophylaxis 2-35
Latent Tuberculosis 2-39
Treatment of Latent Tuberculosis in Resource-Limited Settings 2-45

Section 3: Antiretroviral Therapy . . . . . 3-1— 3-52

Antiretroviral Therapy 3-1
Adherence 3-11
Resistance Testing 3-17
Reducing Maternal-Infant HIV Transmission 3-21
Care of HIV-Infected Pregnant Women 3-39
Antiretroviral Medications and Oral Contraceptive Agents 3-51

Section 4: Complications of Antiretroviral Therapy . . . . . 4-1 — 4-37

Abnormalities of Body-Fat Distribution. 4-1
Dyslipidemia 4-5
Insulin Resistance and Hyperglycemia on Antiretroviral Therapy 4-13
Drug-Drug Interactions with HIV-Related Medications 4-17
Adverse Reactions to HIV Medications 4-21
Recreational Drugs and Antiretroviral Therapy 4-27
Immune Reconstitution Syndrome 4-33

Section 5: Complaint-Specific Workups . . . . . 5-1 — 5-48

Anemia 5-1
Diarrhea 5-5
Ear, Nose, Sinus, Mouth. 5-9
Esophageal Problems 5-13
Eye Problems 5-17
Fatigue 5-21
Fever 5-25
Headache 5-27
Lymphadenopathy. 5-29
Nausea and Vomiting 5-33
Neurologic Symptoms 5-37
Pulmonary Symptoms 5-41
Vaginitis/Vaginosis. 5-45

Section 6: Disease-Specific Treatment. . . . . 6-1 — 6-123

Anal Dysplasia. 6-1
Candidiasis, Oral and Esophageal 6-5
Candidiasis, Vulvovaginal 6-9
Cervical Dysplasia 6-13
Cryptococcal Disease 6-17
Cryptosporidiosis 6-21
Cytomegalovirus Disease 6-25
Dermatologic Staphylococcal Infections 6-29
Gonorrhea and Chlamydia 6-33
Hepatitis B Infection 6-37
Hepatitis C Infection 6-41

Herpes Simplex, Mucocutaneous . . . 6-45
Herpes Zoster/Shingles . . . 6-49
Histoplasmosis . . . 6-51
Kaposi Sarcoma . . . 6-55
Molluscum Contagiosum . . . 6-59
Mycobacterium avium Complex . . . 6-61
Mycobacterium tuberculosis: Treatment in the United States and Other High-Income Nations . . . 6-65
Tuberculosis Treatment in Resource-Limited Settings . . . 6-75
Non-Hodgkin Lymphoma . . . 6-81
Pelvic Inflammatory Disease . . . 6-85
Pneumocystis Pneumonia . . . 6-89
Progressive Multifocal Leukoencephalopathy . . . 6-93
Seborrheic Dermatitis . . . 6-95
Sinusitis . . . 6-97
Syphilis . . . 6-99
Toxoplasmosis . . . 6-105
Linear Gingival Erythema . . . 6-109
Necrotizing Ulcerative Periodontitis and Gingivitis . . . 6-111
Oral Health . . . 6-113
- Aphthous Ulceration . . . 6-113
- Atrophic Glossitis; Burning Mouth Syndrome . . . 6-113
- Bruxism . . . 6-114
- Dental Caries due to "Meth Mouth" . . . 6-114
- Recurrent Herpes Simplex . . . 6-115
- Maxillary Tori; Mandibular Tori . . . 6-115
- Oral Cancer . . . 6-116
- Oral Piercing . . . 6-116
- Periodontal Disease . . . 6-117
- Xerostomia (Dry Mouth) . . . 6-118

Oral Hairy Leukoplakia . . . 6-119
Oral Ulceration . . . 6-121
Oral Warts . . . 6-123

Section 7: Pain and Palliative Care . . . . . 7-1 — 7-12

Pain Syndrome and Peripheral Neuropathy 7-1

Palliative Care and HIV 7-7

Section 8: Neuropsychiatric Disorders . . . . . 8-1 — 8-20

Anxiety Disorders 8-1

Depression 8-5

Panic Disorder 8-9

Insomnia 8-13

Suicidal Ideation 8-15

HIV-Associated Dementia and Minor Cognitive Motor Disorder 8-17

Section 9: Populations . . . . . 9-1 — 9-4

Correctional Settings 9-1

Section 10: Resources for Clinicians and Patients . . . . . 10-1 — 10-8

Karnofsky Performance Scale 10-1

Sulfa Desensitization 10-3

Patient Education 10-5

Web-Based Resources 10-7

Clinical Manual for Management of the HIV-Infected Adult

About This Manual

This guide is the collaborative effort of clinical faculty associated with the AIDS Education and Training Centers. *(See the list of contributors below.)* The 2006 edition comes 13 years after the first edition, which was produced by the Midwest AETC (MATEC) and the Southeast AETC (SEATEC). The original manual was conceived to address the needs of the "midlevel" clinician—advanced practice nurses, physician assistants, etc—who comprise a significant proportion of the HIV primary care providers in the United States (and elsewhere). Experience has shown us that the whole range of providers—physicians, pharmacists, nurse practitioners and advanced practice nurses, physician assistants, dentists, and others, appreciate the nuts-and-bolts format of the guide. This edition maintains the practical approach of prior editions, but its content has been broadened somewhat, in recognition of its wide audience.

Editors and Contributors: 2006 Edition

Editorial Team

- **Susa Coffey, MD; Editor**
- Kirsten Balano, PharmD; Associate Editor
- Suzan Stringari-Murray, RN, MS, ANP; Associate Editor
- Mary Lawrence Hicks, FNP; Associate Editor
- Charlotte Graeber, Project Coordinator
- Nicolé Mandel, Project Manager
- David Alexander, Copy Editor
- Jamie Steiger, Project Coordinator
- Karen Forgash, Designer

Contributors

- Laura Armas, MD; Texas/Oklahoma AETC
- Oliver Bacon, MD; AETC National Resource Center
- Kirsten Balano, PharmD; AETC National Resource Center, National HIV/AIDS Clinicians' Consultation Center
- Julie Barroso, PhD, ANP, APRN, BC; Southeast AETC, Duke University School of Nursing
- Carolyn K. Burr, EdD, RN; National Pediatric HIV Resource Center, FXB Center, University of Medicine and Dentistry of New Jersey
- Suzanne Carlberg-Racich, MSPH, PhD (Cand.); Midwest AETC (MATEC), Illinois Local Performance Site
- Margrit Carlson, MD; Pacific AETC, UCLA Local Performance Site
- Diane Casdorph, R.Ph.; Pennsylvania/MidAtlantic AETC, West Virginia Local Performance Site
- Susa Coffey, MD; AETC National Resource Center, University of California San Francisco
- Jonathan Cohn, MD, MS; Midwest AETC (MATEC), Michigan Local Performance Site
- Lorinda A. Coombs, RN, MSN, NP; Pacific AETC, San Francisco Local Performance Site
- Ross Cranston, MD; Pacific AETC, UCLA Local Performance Site
- Louis DePaola, DDS, MS; Pennsylvania/MidAtlantic AETC, University of Maryland, Baltimore, Dental School Local Performance Site
- Neil M. Flynn, MD, MPH; Pacific AETC, University of California, Davis
- Abigail Gallucci; New York/New Jersey AETC
- Marshall Glesby, MD; New York/New Jersey AETC, Cornell Clinical Trials Unit Local Performance Site
- Charlotte Graeber; AETC National Resource Center
- Veronica Greene, BA, DDS, MPH; Pacific AETC, University of Southern California School of Dentistry
- Elaine Gross, RN, MS, CNS-C; AETC National Resource Center
- Lois Hall, ARNP, MSN; Florida/Caribbean AETC
- Harold Henderson, MD; Delta AETC, Mississippi Local Performance Site

2006 Edition, Continued

- Mary Lawrence Hicks, FNP; Pacific AETC, San Francisco Local Performance Site
- Suzanne Jed, FNP-C; Mountain Plains AETC
- Bethsheba Johnson, MSN, CNS, GNP-BC; Midwest AETC (MATEC), Illinois Local Performance Site
- Hazel Jones-Parker, MSN, CRNP, AACRN; Pennsylvania/MidAtlantic AETC
- Valli Meeks, DDS, MS, RDH, BS; Pennsylvania/MidAtlantic AETC, University of Maryland, Baltimore, Dental School Local Performance Site
- Mary Monastesse, NP; Texas/Oklahoma AETC
- Tonia Poteat, PA; Southeast AETC (SEATEC)
- Paula Reid, RCN, MSN, WHCNP; Texas/Oklahoma AETC
- Monica G. Reiss, DrPH; FXB Center, University of Medicine and Dentistry of New Jersey
- David Reznik, DDS; Southeast AETC (SEATEC)
- John R. Roberts, MSN, APRN, BC, AAHIVS; New England AIDS Education & Training Center
- Barbara Scott, MPH, RD; Pacific AETC, Nevada Local Performance Site
- Andrew Talal, MD; New York/New Jersey AETC, Cornell Clinical Trials Unit Local Performance Site
- Antonio Urbina, MD; New York/New Jersey AETC
- Milton Wainberg, MD; New York/New Jersey AETC
- Sarah Walker, MS; New York/New Jersey AETC
- Dianne Weyer, RN, MS, CFNP; Southeast AETC (SEATEC)

2003 Edition

This edition of the manual was a collaborative effort of the Southeast AIDS Training and Education Center, Department of Family and Preventive Medicine, Emory University School of Medicine; Grady Health Systems Infectious Disease Program; the Midwest AIDS Training and Education Center at the University of Illinois at Chicago; and the US Department of Health and Human Services. Development of this manual was funded in part by HRSA Grant #1H4A HA 00067-01.

Editors

- Patricia Yeargin, RN, MN, MPH, CANP, Southeast AIDS Training and Education Center, Emory University School of Medicine
- Rosemary Donnelly, RN, MN, CANP, Georgia Department of Human Resources
- Dianne Weyer, RN, MN, CFNP, Southeast AIDS Training and Education Center

Contributors

- Section Editors: Grady IDP
- Jeffrey L. Lennox, MD, Director, Adult HIV Program
- David Reznik, DDS, Director, Oral Health
- J. Stephen McDaniel, MD, Director, Mental Health Services
- Susan Chuck, PharmD, BCPS

Grady IDP contributors:

- MaryLynn Adamski, PA-C
- Minh Nguyen, MD
- Molly Eaton, MD
- Marcia Peters, C-FNP
- Linda Gates, RN
- Susan Richardson, NP
- Cliff Gunthel, MD
- Sanjay Sharma, MD
- Mark Hebert, C-FNP
- Angelle Vuchetich, C-ANP
- Michael Leonard, MD
- William Walker, PA-C
- Sophie Lukashok, MD
- Sandra Ward, PA-C
- Susan Miller, RN, CPN, BS Ed
- Pamela Weizell, C-FNP
- Clara Zelasky, PA-C

Georgia DHR Contributors:

- Helen Sawyer, RN - DHR Consultant
- Harold Katner, MD

MATEC Contributors:

- Caroline Teter, PA-C
- Eric Jorgenson

Previous Editions

Atlanta Contributors

- Sumner Thompson III, MD, MPH, Grady IDP (deceased)
- Michelle Moorwessel, RD, Grady IDP
- Tony DeBalsi, FNP, Grady IDP
- Daynese Santos, PA-C, Grady IDP
- Amy Swartz, MD, Grady IDP
- Sharne Hampton, MD, Grady IDP
- David Rimland, MD, Atlanta VA
- Michelle Gensemer, FNP, Grady IDP
- Michelle White, PharmD, Georgia DHR
- Peggy Keen, PhD, MN, Grady IDP
- Cathy McCarroll, RD, Georgia DHR
- Sabrina Bowman, PA-C, Grady IDP
- Joseph A. Wilber, MD, Georgia DHR
- Thomas Geckler, PA-C, Grady IDP
- Candy Ferguson, CANP, SEATEC
- Sheila Rossell-Lincoln, NP, Grady IDP
- Diana Kirkpatrick, MPH, Georgia DHR
- Felicia Guest, MPH, SEATEC
- Camilla Taylor, MSW, MAG
- John Blevins, M.Div., SEATEC
- Chris Rodriquez, RN, CFNP, DHHS Region IV Office
- Dennis M. Melton, MD, MAG
- Melanie A. Thompson, MD, AIDS Research Consortium of Atlanta

Chicago Contributors

- Bradford Farrington, RN, C-ANP, Midwest AIDS Training and Education Center
- Richard Novak, MD, Director, Family Center for Immune Deficiency and Infectious Diseases, University of Illinois at Chicago Hospital and Clinics (UICHC)
- Kenneth Pursell, MD, Family Center for Immune Deficiency and Infectious Diseases, UICHC
- John Krzemien, PhD, RN, DHHS Region V Office
- Joanne Despotes, RN,C, BSN, Midwest AIDS Training and Education Center
- Eric Noel, Midwest AIDS Training and Education Center
- Elyse Nowak, RN, BSN, MA, Midwest AIDS Training and Education Center
- Barbara Schechtman, MPH, Midwest AIDS Training and Education Center
- Michael Dempsey, MD, Rush-Presbyterian-St. Luke's Medical Center

Terms of Use

This manual is intended for use in collaborative practice models, for example, those involving medical, nursing, physician assistant, and pharmacy staff. Geographic variations in health care practice conventions and frequent changes in HIV care require that clinicians maintain familiarity with current HIV practice standards. The treatment guidelines should be carefully reviewed by the clinical care team in your facility to make sure they conform to acceptable local and contemporary approaches. Medical treatment updates are posted frequently to several Web sites, including the http://www.aidsinfo.nih.gov site, and it is recommended that every provider be familiar with all relevant guidelines.

This manual may be reproduced in whole or in part for noncommercial use, with appropriate attribution. However, reproduction for commercial purposes is prohibited. Please note that these treatment recommendations are not intended to replace clinical research literature or current U.S. Department of Health and Human Services (DHHS) guidelines, and may not include the full range of treatment options for all HIV-infected patients. Independent verification of all information is necessary before undertaking care of HIV-infected clients, particularly in the face of rapidly changing HIV treatment standards. Some recommendations are not in accord with U.S. Food and Drug Administration (FDA)-approved usage for certain drugs, but are based on findings from clinical trials and recommendations from expert providers. For more information or to offer comments, please contact us at editor@aidsetc.org.

Initial and Interim Laboratory and Other Tests

Background

This chapter provides guidelines for monitoring patients with HIV infection.

Note that documentation of a confirmed HIV serologic test should be included in the chart.

O: Objective

Monitor patients with laboratory testing for HIV, hepatitis, sexually transmitted diseases, and other opportunistic infections (Table 1).

Table 1. Initial Laboratory Evaluations for HIV-Infected Patients

Test	Rationale	Result	Frequency and Comments
HIV Staging and Antiretroviral Therapy (ART) Monitoring			
CD4 Count	• For HIV staging and prognosis • Guides initiation of ART • Indicates risk of opportunistic illnesses and guides initiation of prophylaxis against opportunistic infections • Used to monitor immune reconstitution during ART	• Reported in cells/µL	• Repeat every 3-4 months for patients not taking ART. • Repeat every 2-4 months for patients taking ART. • Repeat if results are inconsistent with the clinical picture or with previous trends. • See chapter *CD4 Monitoring and Viral Load Testing.*
CD4 Count Percentage	• Used in addition to the absolute CD4 count for monitoring trends; may be discrepant from absolute CD4 • PCP prophylaxis is indicated for CD4% <14 regardless of absolute count (see below).	**CD4 count** / **Expected CD4%** >500 / >29% 200-500 / 14-28% <200 / <14%	• Usually obtained with absolute CD4 count
Quantitative Plasma HIV RNA (HIV Viral Load)	• Estimates level of HIV replication • Monitors effect of ART • Diagnoses acute HIV infection (Not FDA approved for diagnosis of HIV, but has high sensitivity in setting of acute infection. Must be confirmed by positive HIV antibody test.)	• Reported in copies/mL. • In untreated patients, detectable (with rare exceptions) and measured to the upper limit of detection (usually >500,000 copies/mL). • In patients taking ART, ideally suppressed to undetectable levels (usually <50 or ≤75 copies/mL).	• Baseline. values (2 tests) • For patients on new or modified ART regimen: perform 2-8 weeks after initiation or change in ART. • For patients on stable ART: perform every 3-4 months. • For patients not taking ART: perform every 3-4 months; more frequently if CD4 count is low. *Factors that may temporarily alter viral load:* • Immunizations • Active infections
Drug Resistance Testing (Genotype, Phenotype)	• To assess antiretroviral medications to which the patient's HIV virus is likely to be resistant	• Genotype: detects specific mutations to ARV medications • Phenotype: measures HIV viral replication in the presence of ARVs	• Genotype (one time) is recommended in all ARV-naive patients. For greatest accuracy, should be done as early as possible in the course of HIV infection. • Acute or primary infection: recommended • Chronic infection and treatment naive: recommended before initiation of ART. • Pregnancy: recommended before initiation of ART or in those with detectable HIV RNA during ART. • Virologic failure: recommended (See chapter *Resistance Testing* for additional information.)

Complete Blood Count (CBC) **with Differential and Platelets**	• Detects anemia, thrombocytopenia, leukopenia	• Normal	• Repeat every 3-6 months.
		• Abnormal	• Requires follow-up evaluation as indicated; may influence choice of ARVs. • Repeat more frequently if the patient's results are abnormal or he/she is taking bone marrow suppressive drugs.
Chemistry Profile (Electrolytes, Creatinine, Blood Urea Nitrogen, Liver Transaminases)	• Detects electrolyte abnormalities, renal insufficiency, hepatic enzyme elevations	• Normal/abnormal	• Repeat every 3-6 months, and as needed to monitor ART. • May influence ARV selection. • May be useful to monitor drug toxicities. • Abnormalities should prompt evaluation of cause.
Lipid Profile (Total Cholesterol, LDL, HDL, Triglycerides) **Glucose** (preferably fasting)	• Baseline before starting ART • Monitoring during ART	• Normal	• Repeat annually or more frequently (every 3-6 months) based on initial results, ARV use, or risk of cardiovascular disease.
		• Abnormal	• For interventions, see chapter *Dyslipidemia*.
Hepatitis Screening			
Hepatitis A Serology (HAV IgG)	• Screen for immunity to hepatitis A; vaccinate those not immune	• Negative	• Offer hepatitis A vaccine if indicated. (See chapter *Immunizations for HIV-Infected Adults and Adolescents.*)
		• Positive	• Immune; no vaccine necessary
Hepatitis B Serology	• Assess hepatitis B status		
Hepatitis B Surface Antigen (HBsAg)	• Indicates active hepatitis B	• sAg negative	• Consider vaccination if HBsAb negative (not immune).
		• sAg positive	• Indicates chronic or acute hepatitis B infection; requires further evaluation (check HBV DNA)
Hepatitis B Core Antibody (Anti-HBc, IgG)	• Indicates past exposure or ongoing infection	• Anti-HBc negative	• The patient most likely has not been infected with hepatitis B; consider vaccination if HBsAb negative and HBsAg negative.
		• Anti-HBc positive	• The patient most likely has been infected with hepatitis B; this test alone does not distinguish past exposure from active infection. • In rare cases, may be falsely negative in some with chronic infection. • If sAb negative and sAg negative, check HBV DNA to rule out active infection. • If sAb is positive, patient is immune.
Hepatitis B Surface Antibody (Anti-HBs)	• Indicates immunity status	• Anti-HBs negative	• The patient is not immune to hepatitis B; consider vaccination, unless patient has active hepatitis (sAg positive or HCV DNA positive).
		• Anti-HBs positive	• The patient is immune to hepatitis B either by previous infection or by immunization; may be negative in acute hepatitis B infection.

Hepatitis C Serology			
Anti-HCV Antibody (HCV Ab)	• Hepatitis C status	• HCV negative	• Patient is not infected with hepatitis C. • Consider annual screening in high-risk patients.
		• HCV positive	• Patient has chronic hepatitis C infection or past infection with immunity; confirm positive results with HCV RNA.
Other Opportunistic Infection Screening Tests			
***Toxoplasma gondii* IgG**	• Detects exposure; if positive, increased risk of developing CNS toxoplasmosis if CD4 count <100 cells/µL	• Normal/negative	• Repeat if patient becomes symptomatic or when CD4 count drops to ≤100 cells/µL.
		• Abnormal/positive	• Note as baseline information. • Start toxoplasmosis prophylaxis when CD4 count drops to ≤100 cells/µL.
PPD (tuberculin skin test) (if no history of TB or positive PPD)	• Detects latent TB infection	• Normal	• Repeat every 6-12 months. • Repeat if CD4 count was <200 cells/µL on initial test but increases to >200 cells/µL.
		• Abnormal (induration ≥5 mm)	• Evaluate for active TB. (See chapter *Latent Tuberculosis.*)
Chest X-Ray (if pulmonary symptoms are present or positive PPD)	• Detects latent or active diseases	• Normal	• Repeat as indicated for pulmonary symptoms or positive PPD.
		• Abnormal	• Evaluate for TB, PCP, or other pathology.
Papanicolaou Smear (cervical for women; anal for women and men)	• Detects abnormal cell changes, dysplasia	• Normal	• Repeat in 6 months; then annually if negative on 2 smears and no ongoing risk factors.
		• Abnormal	• Perform workup, treat (see chapters *Cervical Dysplasia* and *Anal Dysplasia*) and follow up more frequently as indicated by condition.
STD Testing: Identify sexually transmitted infections in any patient at risk.			
Venereal Disease Research Laboratory (VDRL); **or Rapid Plasma Reagin** (RPR)	• Syphilis screening	• Negative titer	• Repeat every 3-12 months, depending on risk factors.
		• Positive titer: confirm with treponemal test	• Treat patient; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex. • Perform serial testing if monitoring active disease. (See chapter *Syphilis*.)

Women			
Gonorrhea, Chlamydia, and Trichomoniasis Testing	• STD screening in sexually active women at risk	• Negative	• Counsel about safer sex and avoiding STDs. • Repeat every 6-12 months; more frequently if at high risk.
		• Positive	• Treat patient; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex.
Gonorrhea and Chlamydia Testing, Rectal	• STD screening in sexually active women at risk • STD screening in sexually active women who have receptive anal sex	• Negative	• Counsel about safer sex and avoiding STDs. • Repeat every 6-12 months; more frequently if at high risk.
		• Positive	• Treat patient; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex.
Men			
Gonorrhea and Chlamydia Testing, Urethral	• STD screening in sexually active men who are at risk, especially men who have sex with men (MSM)	• Negative	• Retest every 3-6 months in patients with risk factors.
		• Positive	• Treat; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex.
Gonorrhea and Chlamydia Testing, Pharyngeal	• STD screening in sexually active men who are at risk, especially MSM who have oral-genital contact	• Negative	• Retest every 3-6 months in patients with risk factors.
		• Positive	• Treat; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex.
Gonorrhea and Chlamydia Testing, Rectal	• STD screening in sexually active men who are at risk, especially MSM who have receptive anal sex	• Negative	• Retest every 3-6 months in patients with risk factors.
		• Positive	• Treat; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex.
Consider/Optional			
G6PD Level	• Prevent hemolytic reactions by screening susceptible men of African, Mediterranean, Asian, Sephardic Jewish descent • Some would recommend screening all patients	• Normal range	• No intervention is necessary beyond documentation.
		• Abnormal range	• Avoid oxidant drugs such as dapsone, primaquine, and sulfonamides, if possible.
Cytomegalovirus (CMV) **Antibody** (anti-CMV IgG) for those at low risk of CMV, especially those who are not MSM or injection drug users	• Detects exposure; may reveal future disease risk	• Negative	• Avoid exposure by practicing safer sex. • If blood transfusion is required, use CMV-negative or leukocyte-reduced blood.
		• Positive	• Be aware of disease risk in advanced HIV infection, when CD4 count <50 cells/µL.
Prostate Specific Antigen (PSA)	• Prostate cancer screen (African American men over 45; other men over 50 with >10-year life expectancy)	• Normal	• Repeat annually.
		• Abnormal	• Refer to urology specialist for evaluation.
Urinanalysis (UA)	• Detects proteinuria or pyuria	• Normal	• Repeat annually.
		• Abnormal	• Rule out HIV-associated nephropathy and other causes of nephropathy.
Dilated Retinal Examination	• Detects CMV, ophthalmic toxoplasmosis, or HIV retinopathy	• Normal	• CD4 count >100 cells/µL: repeat annually. • CD4 count <50 cells/µL or symptoms of retinal changes: repeat every 6 months.
		• Abnormal	• Follow up immediately with ophthalmologist.

Patient Education

- Discuss safer sex (review specifics appropriate to the patient's sexual practices and infections) to prevent the patient's exposure to herpes, hepatitis B, hepatitis C, and other sexually transmitted diseases, and to prevent the patient from exposing others to HIV or other pathogens. (See chapters *Preventing Transmission/Prevention with Positives* and *Preventing Exposure to Opportunistic and Other Infections.*)
- If toxoplasma IgG test result is negative, see chapter *Preventing Exposure to Opportunistic and Other Infections*.
- If cytomegalovirus (CMV) test result is negative, counsel the patient that CMV is shed in semen, vaginal and cervical secretions, saliva, and urine of infected people. Latex condoms will help reduce risk. For women considering childbearing, CMV should be avoided assiduously to prevent severe disease and even death of the neonate. (See chapter *Preventing Exposure to Opportunistic and Other Infections.*)
- For people who are hepatitis C negative and still use injection drugs, offer referral to a drug treatment program. (See chapters *Preventing Transmission/Prevention with Positives* and *Preventing Exposure to Opportunistic and Other Infections.*)

References

- Aberg, Gallant, et al. *Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America.* Clin Infect Dis 2004 Sep 1;39(5):609-29. Available online at www.journals.uchicago.edu/CID/.
- Bartlett JG, Cheever L. *A Guide to Primary Care of People with HIV/AIDS, 2004 Edition.* Rockville, MD: Department of Health and Human Services, HIV/AIDS Bureau. 2004. Available online at hab.hrsa.gov/tools/primarycareguide/.
- Bartlett JG, Gallant JE. *2005-2006 Medical Management of HIV Infection.* Baltimore: Johns Hopkins University Division of Infectious Diseases; 2005. Available online at hopkins-aids.edu/mmhiv/order.html.
- Centers for Disease Control and Prevention. *Sexually transmitted diseases treatment guidelines 2006*. MMWR 2006;55(No. RR-11):1-100.
- Feinberg J, Maenza J. *Primary Medical Care*. In: Anderson JR, ed. *A Guide to the Clinical Care of Women with HIV*. Rockville, MD: Health Services and Resources Administration; 2001:354-359. Available online at hab.hrsa.gov/publications/womencare05/.
- Hecht F, Soloway B. *Laboratory Tests for Monitoring HIV Infection*. In: *HIV Infection: A Primary Care Approach, Revised Edition*. Waltham, MA: Massachusetts Medical Society; 1993;17.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 3, 2007.
- U.S. Public Health Service, Infectious Diseases Society of America. *Guidelines for preventing opportunistic infections among HIV-infected persons—2002.* MMWR Recomm Rep. 2002 Jun 14;51(RR08);1-46. Available online at aidsinfo.nih.gov/Guidelines/. Accessed May 19, 2006.

Interim History and Physical Examination

Background

This chapter suggests information to gather and document for a standard written record of clinically important data over many visits. With this information, the clinician can track disease progression and formulate and maintain an appropriate care plan.

It is important to document new or ongoing symptoms and functional limitations at each visit. This information is particularly useful when outside agencies must determine the patient's disability status. (See chapter *Karnofsky Performance Scale*.)

Table 1 lists the suggested frequency and follow-up intervals of the history and physical examination for monitoring HIV-infected patients. Note that specific medications and abnormalities may call for additional directed examinations.

Table 1. History and Physical Examination: Frequency and Follow-Up Intervals

History				Physical Examination	
Every visit (at least every 3 months)					

• New symptoms
• Medications
  • HIV-related medications
  • Medications for other conditions
  • Over-the-counter medications
  • Herbs or vitamins
	• Adherence to medications and clinical care visits
	• Risk reduction; prevention with positives
		• Mood
		• Alcohol and recreational drug use
		• Tobacco use
		• Allergies
		• Pain
			• Social supports
			• Housing
			• Insurance
			• Domestic violence
				• Vital signs (temperature, blood pressure, heart rate, respiratory rate)
				• Weight
				• General appearance, body habitus (including evaluation for lipodystrophy)
				• Skin
					• Oropharynx
					• Lymph nodes
					• Heart and lungs
					• Abdomen
					• Psychiatric–mood, affect
					• Neurologic

Every 6 months					
As above	**As above plus:** • Visual and funduscopic exam	• Ears/nose	• Screening for chlamydia, gonorrhea, and syphilis in all patients at risk for these infections		
Every 6 months (twice) , and, if both are normal, annually thereafter (See chapters *Cervical Dysplasia* and *Anal Dysplasia*.)					
As above	• Women: cervical and anal Papanicolaou smear, pelvic exam			• Men: anal Papanicolaou smear	
Annually					
Update initial history: HIV-related symptoms, hospitalizations, major illnesses, family history				Complete physical to include: • Genitorectal exam • Prostate exam	• Breast exam • Testicular exam

References

- Bartlett JG, Gallant JE. *2005-2006 Medical Management of HIV Infection.* Baltimore: Johns Hopkins University Division of Infectious Diseases; 2005. Available online at hopkins-aids.edu/mmhiv/order.html.
- U.S. Public Health Service, Infectious Diseases Society of America. *Guidelines for preventing opportunistic infections among HIV-infected persons — 2002.* MMWR Recomm Rep. 2002 Jun 14;51(RR08);1-46. Available online at aidsinfo.nih.gov/Guidelines/. Accessed May 19, 2006.
- Hecht F, Soloway B. *The physical exam in HIV infection.* AIDS Clinical Care. 3(1):4-5.
- Hollander H. I*nitiating Routine Care for the HIV-Infected Adult.* In: Sande MA, Volberding PA, eds. *The Medical Management of AIDS, 5th ed*. Philadelphia: WB Saunders; 1997:107-112.

HIV Classification: CDC and WHO Staging Systems

Background

HIV disease staging and classification systems are critical tools for tracking and monitoring the HIV epidemic and for providing clinicians and patients with important information about HIV disease stage and clinical management. Two major classification systems currently are in use: the U.S. Centers for Disease Control and Prevention (CDC) classification system and the World Health Organization (WHO) Clinical Staging and Disease Classification System.

The CDC disease staging system (last revised in 1993) assesses the severity of HIV disease by CD4 cell counts and by the presence of specific HIV-related conditions. The definition of AIDS includes all HIV-infected individuals with CD4 counts of <200 cells/μL (or CD4 percentage <14%) as well as those with certain HIV-related conditions and symptoms. Although the fine points of the classification system rarely are used in the routine clinical management of HIV-infected patients, a working knowledge of the staging criteria (in particular the definition of AIDS) is useful in patient care. In addition, the CDC system is used in clinical and epidemiologic research.

In contrast to the CDC system, the WHO Clinical Staging and Disease Classification System (revised in 2005) can be used readily in resource-constrained settings without access to CD4 cell count measurements or other diagnostic and laboratory testing methods. The WHO system classifies HIV disease on the basis of clinical manifestations that can be recognized and treated by clinicians in diverse settings, including resource-constrained settings, and by clinicians with varying levels of HIV expertise and training.

S: Subjective

When a patient presents with a diagnosis of HIV infection, review the patient's history to elicit and document any HIV-related illnesses or symptoms (see chapter *Initial History*).

O: Objective

Perform a complete physical examination and appropriate laboratory studies (see chapters *Initial Physical Examination* and *Initial and Interim Laboratory and Other Tests*).

A: Assessment

Confirm HIV infection and perform staging.

P: Plan

Evaluate symptoms, history, physical examination results, and laboratory results, and make a staging classification according to the CDC or WHO criteria (see below).

CDC Classification System for HIV Infection

The CDC categorization of HIV/AIDS is based on the lowest documented CD4 cell count (Table 1) and on previously diagnosed HIV-related conditions (Tables 2 and 3). For example, if a patient had a condition that once met the criteria for Category B but now is asymptomatic, the patient would remain in Category B. Additionally, categorization is based on specific conditions, as indicated below. Patients in categories A3, B3, and C1-C3 are considered to have AIDS.

Table 1. CDC Classification System for HIV-Infected Adults and Adolescents

CD4 Cell Categories	Clinical Categories		
	A Asymptomatic, Acute HIV, or PGL	B Symptomatic Conditions,#* not A or C	C AIDS-Indicator Conditions*
(1) ≥500 cells/µL	A1	B1	C1
(2) 200-499 cells/µL	A2	B2	C2
(3) <200 cells/µL	A3	B3	C3

Key to abbreviations: CDC = U.S. Centers for Disease Control and Prevention; PGL = persistent generalized lymphadenopathy.

For symptomatic conditions, see Table 2.

* For AIDS-indicator conditions, see Table 3.

Table 2. CDC Classification System: Category B Symptomatic Conditions

Category B symptomatic conditions are defined as symptomatic conditions occurring in an HIV-infected adolescent or adult that meet at least 1 of the following criteria:

a) They are attributed to HIV infection or indicate a defect in cell-mediated immunity.

b) They are considered to have a clinical course or management that is complicated by HIV infection.

Examples include, but are not limited to, the following:

- Bacillary angiomatosis
- Oropharyngeal candidiasis (thrush)
- Vulvovaginal candidiasis, persistent or resistant
- Pelvic inflammatory disease (PID)
- Cervical dysplasia (moderate or severe)/cervical carcinoma in situ
- Hairy leukoplakia, oral
- Idiopathic thrombocytopenic purpura
- Constitutional symptoms, such as fever (>38.5° C) or diarrhea lasting >1 month
- Peripheral neuropathy
- Herpes zoster (shingles), involving ≥2 episodes or ≥1 dermatome

Table 3. CDC Classification System: Category C AIDS-Indicator Conditions

- Bacterial pneumonia, recurrent (≥2 episodes in 12 months)
- Candidiasis of the bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical carcinoma, invasive, confirmed by biopsy
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1-month duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcers (>1-month duration), or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1-month duration)
- Kaposi sarcoma
- Lymphoma, Burkitt, immunoblastic, or primary central nervous system
- *Mycobacterium avium* complex (MAC) or *M kansasii*, disseminated or extrapulmonary
- *Mycobacterium tuberculosis*, pulmonary or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jiroveci* (formerly *carinii*) pneumonia (PCP)
- Progressive multifocal leukoencephalopathy (PML)
- Salmonella septicemia, recurrent (nontyphoid)
- Toxoplasmosis of brain
- Wasting syndrome due to HIV (involuntary weight loss >10% of baseline body weight) associated with either chronic diarrhea (≥2 loose stools per day ≥1 month) or chronic weakness and documented fever ≥1 month

WHO Clinical Staging of HIV/AIDS and Case Definition

The clinical staging and case definition of HIV for resource-constrained settings were developed by the WHO in 1990 and revised in 2005. Staging is based on clinical findings that guide the diagnosis, evaluation, and management of HIV/AIDS, and does not require a CD4 cell count. This staging system is used in many countries to determine eligibility for antiretroviral therapy. Clinical stages are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS (Table 4). These stages are defined by specific clinical conditions or symptoms. For the purpose of the WHO staging system, adolescents and adults are defined as individuals aged ≥15 years.

Table 4. WHO Clinical Staging of HIV/AIDS for Adults and Adolescents (Interim Definitions)

Primary HIV Infection		
• Asymptomatic	• Acute retroviral syndrome	
Clinical Stage 1		
• Asymptomatic	• Persistent generalized lymphadenopathy	
Clinical Stage 2		
• Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (respiratory tract infections, upper respiratory infections, sinusitis, bronchitis, otitis media, pharyngitis) • Herpes zoster		• Minor mucocutaneous manifestations (angular cheilitis, recurrent oral ulcerations, seborrheic dermatitis, prurigo, papular pruritic eruptions, fungal fingernail infections)
Clinical Stage 3		
Conditions for which a presumptive diagnosis can be made on the basis of clinical signs or simple investigations		
• Severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhea for >1 month • Unexplained persistent fever for >1 month (intermittent or constant) • Oral candidiasis (thrush) • Oral hairy leukoplakia • Pulmonary tuberculosis within the last 2 years		• Severe presumed bacterial infections (eg, pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Conditions for which confirmatory diagnostic testing is necessary		
• Unexplained anemia (hemoglobin <8 g/dL) • Neutropenia (neutrophils <500 cells/µL)		• Thrombocytopenia (platelets <50,000 cells/µL)
Clinical Stage 4		
Conditions for which a presumptive diagnosis can be made on the basis of clinical signs or simple investigations		
• HIV wasting syndrome, as defined by the CDC (see Table 3, above) • *Pneumocystis jiroveci* (formerly *carinii*) pneumonia • Recurrent severe or radiologic bacterial pneumonia • Chronic herpes simplex infection (oral or genital, or anorectal site) for >1 month		• Esophageal candidiasis • Extrapulmonary tuberculosis • Kaposi sarcoma • Central nervous system toxoplasmosis • HIV encephalopathy
Conditions for which a confirmatory diagnostic testing is necessary		
• Cryptococcosis, extrapulmonary • Disseminated nontuberculosis Mycobacteria infection • Progressive multifocal leukoencephalopathy • Candida of the trachea, bronchi, or lungs	• Cryptosporidiosis • Isosporiasis • Visceral herpes simplex infection, cytomegalovirus infection (retinitis or organ other than liver, spleen, or lymph node)	• Any disseminated mycosis (eg, histoplasmosis, coccidioidomycosis, penicilliosis) • Recurrent nontyphoidal salmonella septicemia • Lymphoma (cerebral or B-cell non-Hodgkin) • Invasive cervical carcinoma • Visceral leishmaniasis

References

- Centers for Disease Control and Prevention. *1993 revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults.* MMWR Recomm Rep. 1992 Dec 18;41(RR-17):1-19. Available online at www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm.
- Centers for Disease Control and Prevention. *Guidelines for national human immunodeficiency virus case surveillance, including monitoring for human immunodeficiency virus infection and acquired immunodeficiency syndrome.* MMWR Recomm Rep. 1999 Dec 10;48(RR-13):1-27, 29-31. Available online at www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm.
- Hare CB. *WHO Staging System for HIV Infection and Disease in Adolescents and Adults, Table 3; Clinical Overview of HIV Disease.* In: Peiperl L, Coffey S, Volberding PA, eds. *HIV InSite Knowledge Base* [textbook online]. San Francisco: UCSF Center for HIV Information; 2006. Accessed March 23, 2006. Available online at hivinsite.ucsf.edu/InSite?page=kb-03-01-01.
- World Health Organization. *Interim WHO Clinical Staging of HIV/AIDS and HIV/AIDS Case Definitions for Surveillance.* 2005. Accessed March 23, 2006. Available online at www.who.int/hiv/pub/guidelines/casedefinitions/en/index.html.

CD4 Monitoring and Viral Load Testing

Background

CD4 Monitoring

CD4 cells (also called T cells or T-helper cells) are the primary targets of the HIV virus. The CD4 count is the number of CD4 cells per microliter (μL) of blood. It is the standard test for assessing HIV stage and prognosis, and for monitoring progression to AIDS and risk of opportunistic illnesses. It also guides the provider in formulating differential diagnoses in symptomatic patients (see Table 1, below), deciding about initiating antiretroviral treatment (ART), and beginning prophylaxis for opportunistic infections.

Most laboratories report the CD4 count as part of a list of several types of lymphocytes, as both an absolute count and a relative percentage. The important numbers are the absolute number of CD4 cells per microliter and the CD4 cell percentage, which is the proportion of CD4 cells as a subset of all lymphocytes.

The CD4 count typically declines over time as HIV infection progresses. Many other factors may affect CD4 counts more transiently, including illness, vaccination, diurnal variation, laboratory error, and inter-laboratory differences (see "Patient Education" below). Because fluctuations in the absolute CD4 count are likely, definitive conclusions should rarely be drawn from a single CD4 value. When results are inconsistent with previous trends, tests should be repeated, and treatment decisions usually should be based on 2 or more similar values. The CD4 percentage sometimes is used in coordination with the absolute value to assess the significance of changes in the absolute CD4 count. The absolute CD4 count can fluctuate as overall lymphocyte counts vary, but the CD4 percentage often remains stable during insignificant CD4 fluctuations. CD8 cell (or cytotoxic T cell) counts do not appear to predict clinical outcomes.

As untreated HIV infection progresses, the CD4 count declines by approximately 4% per year. In response to successful ART, the CD4 count typically increases by >50 cells/μL within weeks after viral suppression, and then increases by 50-100 cells/μL per year thereafter until a threshold is reached. In some patients, CD4 counts may not increase this quickly or steadily, even with durable viral load suppression.

The CD4 count is one of many factors (including clinical status, viral load status, and medication adherence) that should be assessed before starting or changing ART. The U.S. Department of Health and Human Services has provided recommendations for starting therapy based on symptoms, CD4 count, and viral load (Table 2). (See chapters *Antiretroviral Therapy* and *Adherence*.) Prophylaxis against opportunistic infections also is based on CD4 count, and sometimes on CD4 percentage. For example, a CD4 count of <200 cells/μL or a CD4 percentage of <14% is an indication for prophylaxis against *Pneumocystis jiroveci* pneumonia; a CD4 count of <50 cells/μL is an indication for prophylaxis against *Mycobacterium avium* complex. (See chapter *Opportunistic Infection Prophylaxis*.)

For monitoring purposes, the CD4 count should be repeated approximately every 3-4 months both in stable untreated patients and in patients on stable ART. The CD4 count should be checked more frequently according to the clinical situation (Table 3).

Viral Load Testing

In untreated HIV infection, replication usually produces billions of new viral copies daily. Plasma HIV RNA (viral load) testing quantifies the HIV viral burden in the plasma. In areas of the world with access to viral load monitoring, the viral load is a standard tool used to monitor treatment response in patients taking ART and, in conjunction with the CD4 cell count, to assess HIV progression. In certain settings in which HIV antibody tests may be negative or misleading, such as in acute HIV infection or neonatal infection, the HIV viral load may be used to help diagnose HIV infection. In some situations, the viral load may factor into decisions to initiate or change ART.

Viral load assays include HIV RNA polymerase chain reaction (Amplicor HIV-1 Monitor; Roche Laboratories), the branched chain DNA (Versant HIV-1 RNA assay; Bayer), and nucleic acid sequence-based amplification (NucliSens HIV-1 QT test; bioMerieux). The lowest level of detection differs for each test. Ultrasensitive assays (which are preferred in most circumstances) measure viral loads to 50-80

copies/mL, depending on the specific test, whereas the older assays usually have a cut-off at <400 copies/mL. A viral load below the level of detection ("undetectable") indicates inability of the assay to detect HIV in the plasma, but does NOT indicate absence or clearance of the virus from the body. Suppressing HIV RNA to an undetectable level (<50-75 copies/mL as measured by the ultrasensitive assay) is an important goal of ART. These assays also have different values for the highest levels of detection, ranging between 500,000 copies/mL and 750,000 copies/mL. Viral loads higher than these levels are reported, for example, as >500,000 copies/mL.

Whereas the absolute CD4 cell count is more predictive of clinical disease progression than is the baseline viral load, studies have shown that patients who have high plasma viral loads have an increased risk of progression to symptomatic disease and AIDS compared with patients who have low or undetectable levels. Patients with acute HIV infection who are undergoing seroconversion, and those with advanced disease, may have viral loads >500,000 copies/mL, whereas asymptomatic persons with chronic infection usually have considerably lower viral loads. Viral loads, like CD4 counts, are affected by laboratory variation, assay fluctuations, and patient variables such as acute illness and recent vaccinations. Variations less than approximately 0.5 $\log_{10}$ copies/mL (3-fold) usually are not clinically significant. Viral load results that are inconsistent with previous trends should be repeated, and treatment decisions usually should be based on 2 or more similar values. If patients have had recent illnesses or vaccinations, viral load measurement should be deferred for 4 weeks, if possible.

Viral load should be checked at least twice at baseline, before starting an ART regimen. Follow-up viral load measurement should be performed at regular intervals, depending on the patient's clinical situation (Table 3). In the stable patient, viral load should be monitored every 3-4 months. With new therapy or changes in therapy, significant change in viral load or CD4 count, or declining clinical status, the viral load should be measured at closer intervals.

S: Subjective

A patient presents with HIV infection.

O: Objective

Complete the initial or interim physical examination according to the protocol. (See chapters *Initial Physical Examination* and *Interim History and Physical Examination*.)

A: Assessment

See chapters *Initial History, Initial Physical Examination*, and *Initial and Interim Laboratory and Other Tests*.

P: Plan

Laboratory

- Obtain a CD4 count and perform viral load testing. See chapter *Initial and Interim Laboratory and Other Tests* for other recommended laboratory work.
- Monitor the results and manage patients using the schematic in Table 2 as a guide. See chapter *Antiretroviral Therapy* for more specific information.

Table 1. Correlation between CD4 Cell Counts and Complications of HIV Infection

CD4 Count* (cells/µL)	Infectious Complications	Noninfectious Complications#	
>500	• Acute retroviral syndrome • Candidal vaginitis	• Persistent generalized lymphadenopathy (PGL) • Guillain-Barré syndrome	• Myopathy • Aseptic meningitis
200-500	• Pneumococcal and other bacterial pneumonias • Pulmonary tuberculosis • Herpes zoster • Oropharyngeal candidiasis (thrush) • Cryptosporidiosis (self-limited) • Kaposi sarcoma (cutaneous) • Oral hairy leukoplakia • Herpes simplex (oral/genital)	• Cervical intraepithelial neoplasia • Cervical cancer • B-cell lymphoma • Anemia • Mononeuronal multiplex	• Idiopathic thrombocytopenic purpura • Hodgkin lymphoma • Lymphocytic interstitial pneumonitis • Fatigue
<200	• *Pneumocystis jiroveci* pneumonia (PCP) • Disseminated histoplasmosis and coccidioidomycosis • Miliary/extrapulmonary tuberculosis • Progressive multifocal leukoencephalopathy (PML)	• Wasting • Peripheral neuropathy • HIV-associated dementia • Cardiomyopathy	• Vacuolar myelopathy • Progressive polyradiculopathy • Non-Hodgkin lymphoma
<100	• Disseminated herpes simplex virus • Toxoplasmosis • Cryptococcosis • Cryptosporidiosis, chronic • Microsporidiosis • Candidal esophagitis • Kaposi sarcoma (visceral/pulmonary)		
<50	• Disseminated cytomegalovirus (CMV) • Disseminated *Mycobacterium avium* complex (MAC)	• Central nervous system (CNS) lymphoma	

* Most complications occur with increasing frequency at lower CD4 cell counts.

\# Some conditions listed as "noninfectious" are probably associated with transmissible microbes. Examples include lymphoma (Epstein-Barr virus) and cervical cancer (human papillomavirus).
Adapted from Bartlett JG, Gallant JE. Medical Management of HIV Infection. Baltimore: Johns Hopkins University School of Medicine; 2005-2006. Used with permission.

Table 2. DHHS Guidelines for Initiating Antiretroviral Therapy in Chronically Infected Adults

Clinical Category	CD4 Count (cells/µL)	Plasma HIV Viral Load (copies/mL)	Antiretroviral Therapy Recommendations	Repeat CD4 and HIV Viral Load Test
Asymptomatic	>350	<100,000	Defer therapy	Every 3-4 months if not on ART (see below if on ART)
Asymptomatic	>350	≥100,000	Most clinicians recommend deferring therapy, some may treat	Every 3-4 months until ART is started, then check for viral load response at 2-8 weeks; monitor CD4 and viral load every 3-4 months if satisfactory response
Asymptomatic	≥200 but ≤350	Any value	Treatment should be offered	As above
Asymptomatic, AIDS	<200	Any value	Treat	As above
AIDS-defining illness or severe symptoms	Any value	Any value	Treat	As above

Adapted from U.S. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. October 10, 2006.

Table 3. Indications for CD4 Count and Plasma HIV RNA (Viral Load) Testing

Clinical Indication	Test and Information Provided	Use
Syndrome consistent with acute or primary HIV infection	HIV viral load: establishes diagnosis when HIV antibody test is negative or indeterminate	Diagnosis (should be confirmed by standard HIV antibody test 2-4 months after initial test)
Initial evaluation of newly diagnosed HIV infection	Baseline CD4 and viral load values; disease staging	Decision to start or defer ART*
Every 3-4 months in patients not on therapy	CD4 cell count and viral load; disease monitoring	Decision to start or defer ART*
2-8 weeks after initiation of or change in ART	CD4 count and viral load: Initial assessment of drug regimen efficacy	Decision to start or defer ART*
3-4 months after starting ART	CD4 count and viral load: Assess treatment efficacy; viral load should be undetectable by 16-24 weeks; CD4 cell count likely to continue to increase	Decision to start or defer ART*
Every 3-4 months in patients on ART	CD4 count and viral load: Assess durability of immunologic response (CD4 increase) and virologic suppression (undetectable viral load)	Decision to start or defer ART*
Clinical event, or significant decline in CD4 cells or increase in viral load	CD4 count and viral load: Check for association of clinical events with changing or stable CD4 cell count and/or plasma HIV viral load; confirm changes in CD4 and viral load	Decision to initiate, continue, or change therapy*

* Decisions to initiate or change antiretroviral therapy (ART) should be based on 2 or more similar CD4 and viral load values.
Adapted from U.S. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. October 10, 2006.

Patient Education

- CD4 counts are the best indicator of how healthy the immune system is and whether a person is at risk of getting certain infections.
- CD4 counts are variable. Caution patients not to pin emotions and hopes to a single lab result.
- The HIV viral load is the best indicator of how active HIV is in the patient's body.
- Several ARVs may be used in combination to reduce the amount of virus in the body of someone with HIV. For each of these regimens, it is important to take each dose on time, every time. (See chapters on *Antiretroviral Therapy* and *Adherence* if the patient is getting ready to start ART.)
- ART directly affects the activity of HIV in the body and will lower the viral load. With less HIV present, the body is able to produce more CD4 cells and improve the immune system.
- An undetectable viral load does not mean HIV is cured or that the patient is not infectious to others. It means that virus cannot be detected in the blood, although it exists in other parts of the body.
- If the patient's CD4 count increases with successful ART, he or she may be protected from infections and other illnesses related to HIV.

References

- Bartlett JG, Gallant JE. *2005-2006 Medical Management of HIV Infection.* Baltimore: Johns Hopkins University Division of Infectious Diseases; 2005. Available online at hopkins-aids.edu/mmhiv/order.html.
- U.S. Public Health Service, Infectious Diseases Society of America. *Guidelines for preventing opportunistic infections among HIV-infected persons — 2002.* MMWR Recomm Rep. 2002 Jun 14;51(RR08);1-46. Available online at aidsinfo.nih.gov/Guidelines/. Accessed May 19, 2006.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.* October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 7, 2007.
- Hogg RS, Yip B, Chan KJ, et al. *Rates of disease progression by baseline CD4 cell count and viral load after initiating triple-drug therapy.* JAMA. 2001 Nov 28;286(20):2568-77.
- Palella FJ, Deloria-Knoll M, Chmiel JS, et al. *Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4+ cell strata.* Ann Intern Med. 2003 Apr 15;138(8):620-6.

Occupational Postexposure Prophylaxis

Background

Health care workers (HCWs) and other employees in medical, public safety, sanitation, and laboratory settings are at risk of occupational exposure to HIV. Although avoiding exposure to HIV is the only reliable way of preventing HIV infection, postexposure prophylaxis (PEP), defined as antiretroviral (ARV) therapy initiated soon after exposure to HIV, has been highly effective in preventing HIV infection in exposed HCWs.

This chapter examines the general issues involved with PEP in occupational settings. The information is based on the U.S. Public Health Service (USPHS) guidelines for PEP (see "References" below). For information on PEP for nonoccupational HIV exposures (such as sexual exposure), see chapter *Nonoccupational Postexposure Prophylaxis*. Note that other bloodborne pathogens, particularly hepatitis B virus (HBV) and hepatitis C virus (HCV), also may be transmitted through occupational exposure; it is important to consider these potential infections when assessing occupational exposures. For information on the management of occupational exposures to HBV and HCV, refer to the 2001 USPHS PEP guidelines on (see "References" below). In addition, the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) is available 24 hours a day for telephone consultation at 888-HIV-4911 (888-448-4911).

The risk of HIV infection after exposure depends on several factors that are related to the exposure itself and to the source patient (see below). Before deciding whether to recommend PEP and what PEP regimen to recommend, the clinician must assess the risk of HIV infection from the particular exposure, as well as other factors such as the exposed worker's willingness and ability to take ARV medications. After this assessment, the clinician and the exposed worker must weigh the possible benefit of PEP (in relation to the risk of HIV transmission from the injury) against the potential toxicity of the regimen. HCWs who are pregnant at the time of their exposure also must weigh the risk of fetal exposure to HIV against the potential teratogenic and other risks of the ARV drugs. The efficacy of PEP is related to the specific PEP regimen, the timing of PEP, and the exposed worker's adherence to the PEP regimen. PEP should be initiated within 72 hours of the exposure, but is more likely to be effective when it is initiated within hours of the exposure. The optimal duration of PEP is not known; studies support treatment for 28 days.

In the work setting, HIV infection may occur through percutaneous injuries (eg, needlesticks) or mucocutaneous exposures (eg, mucous membrane or nonintact skin exposure to blood or other infectious body fluids). The risk of HIV seroconversion after occupational exposure is best described for needlestick injuries: 0.3%, on average after a needlestick with an HIV-contaminated hollow-bore needle. The risk varies depending on the specific incident. In general, exposures that involve prolonged contact with larger volumes of infectious body fluids, or higher HIV RNA levels in the blood or fluid, convey a higher risk of HIV transmission. In a retrospective case-control study of HCWs with percutaneous exposure to HIV, the following exposure and source patient factors were associated with an increased risk of HIV transmission:

- Large-gauge (<18-gauge) hollow-bore needle
- Deep injury
- Visible blood on the device
- Procedure with needle in a blood vessel
- Terminal AIDS in the source patient

Compared with percutaneous injury, mucocutaneous exposure of infectious body fluids to mucous membranes (eg, eye or mouth) or to skin with an obvious impairment of integrity (eg, abrasion or wound) typically involves a lower risk of HIV transmission. However, mucocutaneous exposures that involve large volumes of blood or other infectious fluid from an HIV-infected patient with a high HIV RNA level may be significant.

S: Subjective

The HCW reports possible exposure to HIV through a needlestick injury or mucocutaneous exposure.

Ideally, the HCW immediately decontaminated the injured or exposed skin with soap and water, or flushed

the exposed mucous membranes with copious amounts of water or saline. The HCW should report the exposure immediately to the appropriate authorities in his or her health care institution (eg, the institution's needlestick hotline).

Take a thorough history of the specific exposure, including the type of exposure, the type and amount of body fluid involved, the point of entry or exposure, the time it occurred, the HIV status of the source patient (if known), and HIV risk factors of the source patient (if HIV status is not known).

A: Assessment

Assess potential exposure to HIV (as well as HBV and HCV). The HIV status of the source and the characteristics of the exposure should be assessed to estimate the risk of HIV infection. The decision about whether to offer PEP should be based on the estimated risk of HIV exposure. See Table 1 (percutaneous exposures) and Table 2 (mucocutaneous exposures) for recommendations about PEP.

Table 1. Recommended HIV Postexposure Prophylaxis after Percutaneous Injuries

	Infection Status of Source*				
Exposure Type	**HIV Negative**	**HIV Positive (Class 1)**	**HIV Positive (Class 2)**	**Unknown HIV Status**	**Unknown Source**
Less Severe (eg, solid needle, superficial injury)	No PEP warranted	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors*# §	Generally, no PEP warranted; however, consider basic 2-drug PEP if exposure to HIV-infected persons is likely
More Severe (eg, large-bore hollow needle, deep puncture, visible blood on device, needle used in patient's artery or vein)	No PEP warranted	Recommend expanded ≥3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP if exposure to HIV-infected persons is likely

* HIV positive (class 1): asymptomatic HIV infection or known low HIV RNA viral load (eg, <1,500 copies/mL); HIV positive (class 2): symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load; unknown HIV status: for example, a deceased source person with no samples available for HIV testing; unknown source: for example, a needle from a sharps disposal container.

The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the clinician regarding the risks versus benefits of PEP.

§ If PEP is offered and administered, and the source is later determined to be HIV negative, PEP should be discontinued.

Adapted from: Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. MMWR Recomm Rep. 2005 Sep 30; 54(RR09); 1-24. Available online at http://aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10.

Table 2. Recommended HIV Postexposure Prophylaxis after Mucous Membrane Exposures and Nonintact Skin Exposures*

	Infection Status of Source#				
Exposure Type	**HIV Negative**	**HIV Positive (Class 1)**	**HIV Positive (Class 2)**	**Unknown HIV Status**	**Unknown Source**
Small Volume (eg, a few drops)	No PEP warranted	Consider basic 2-drug PEP §	Recommend basic 2-drug PEP	Generally, no PEP warranted	Generally, no PEP warranted
Large Volume (eg, a major blood splash)	No PEP warranted	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors**	Generally, no PEP warranted; however, consider basic 2-drug PEP if exposure to HIV-infected persons is likely

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (eg, dermatitis, abrasion, or open wound).

HIV positive (class 1): asymptomatic HIV infection or known low HIV RNA viral load (eg, <1,500 copies/mL); HIV positive (class 2): symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load; unknown HIV status: for example, a deceased source person with no samples available for HIV testing; unknown source: for example, a needle from a sharps disposal container. .

§ The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the clinician regarding the risks versus benefits of PEP.

** If PEP is offered and administered, and the source is later determined to be HIV negative, PEP should be discontinued.

Adapted from: Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis.* MMWR Recomm Rep. 2005 Sep 30; 54(RR09); 1-24. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10.

P: Plan

Laboratory Testing

Provide pretest counseling and perform a baseline HIV antibody test. Test for other infections transmitted through occupational exposure, particularly hepatitis B (HBV surface antigen, surface antibody, core antibody), and hepatitis C (HCV antibody). Obtain complete blood count (CBC), chemistry panel, and liver function tests (LFTs) at baseline, before treatment with ARV medications. For women who may be pregnant, perform a pregnancy test.

Treatment

Consult Table 1 or Table 2 to determine whether the worker should be offered PEP medications. For occupational exposures to infectious body fluids from an HIV-infected source patient, the USPHS guidelines state that PEP should be recommended or considered, depending on the assessed risk. The assessed risk also helps to determine whether a "basic" 2-drug regimen or "expanded" ≥3-drug regimen should be selected. Other considerations in choosing the medications for a PEP regimen include:

- The likelihood that the source patient's virus is resistant to ARV medication(s)
- Possible drug toxicities for the exposed HCW
- Drug-drug interactions with other medications the HCW may be taking

If the HCW is a candidate for PEP, counsel him or her about the potential risks and benefits of PEP. If the worker elects to start therapy, consider potential regimens (Table 3). Select a regimen that is likely to be effective but tolerable; consider the potential adverse effects of ARVs. Note that certain ARV agents, including nevirapine, should not be used for PEP. Efavirenz should be avoided in pregnant women.

Table 3. Antiretroviral Options for Occupational Postexposure Prophylaxis of HIV Infection

Basic 2-NRTI Regimens	
Preferred	
• Zidovudine 300 mg + lamivudine 150 mg twice daily (available as Combivir, 1 tablet twice daily) • Zidovudine 300 mg twice daily + emtricitabine 200 mg once daily	• Tenofovir 300 mg once daily + lamivudine 300 mg once daily • Tenofovir 300 mg once daily + emtricitabine 200 mg once daily (available as Truvada, 1 tablet once daily)
Expanded Regimens (one of the following may be added to a basic regimen)	
Protease Inhibitors	
Preferred	
• Lopinavir/ritonavir combination 400/100 mg twice daily	
Alternative	
• Atazanavir 300 mg once daily + ritonavir 100 mg once daily • Atazanavir 400 mg once daily*	• Fosamprenavir 1,400 mg twice daily • Fosamprenavir 700 mg twice daily + ritonavir 100 mg twice daily
NNRTI Regimen	
• Efavirenz 600 mg once daily (not recommended in pregnant women)	

Key to abbreviations: NRTI = nucleoside analogue reverse transcriptase inhibitor; NNRTI = nonnucleoside reverse transcriptase inhibitor.

* Atazanavir cannot be used as a sole protease inhibitor if it is coadministered with tenofovir (use atazanavir + ritonavir).

Adapted from: Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. MMWR Recomm Rep. 2005 Sep 30; 54(RR09); 1-24. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10.

If the HIV status of the source patient is unknown, a rapid HIV test may help in determining the need for PEP (see chapter *Rapid Testing*). Although a positive rapid test requires confirmation before the individual is diagnosed as HIV infected, for the purposes of PEP, it should be considered a true positive until proven otherwise, and the exposed worker should be counseled accordingly. If, upon further testing, the source patient is determined to be HIV uninfected, PEP can be discontinued. A negative rapid test is considered reliable unless the source reports recent high-risk HIV exposure or symptoms of primary HIV (see chapter *Primary HIV Infection*). If a rapid test is not available, PEP is considered "generally not warranted" for exposures involving source patients whose HIV status is unknown. However, PEP can be considered if the source patient has risk factors for HIV infection. PEP should not be delayed (beyond 1-2 hours) while awaiting information about the source patient. PEP is not recommended for exposures to HIV-seronegative source patients.

If the source patient is known or suspected to have infection with HIV that is resistant to ARV medications, seek expert consultation in selecting an appropriate PEP regimen. However, PEP should not be delayed while consultation is obtained.

Additional alternative ARVs are included in the USPHS guidelines, but certain ARVs are not recommended for PEP, including abacavir, delavirdine, nevirapine, and the combination of didanosine + stavudine. Refer to the appendix in the updated USPHS guidelines for a more complete discussion of the dosing, advantages, and disadvantages of the various ARV agents available for PEP.

Begin ARV prophylaxis as soon as possible after the exposure, but always within 72 hours. Treatment should be continued for 28 days.

Provide counseling about the efficacy of PEP, including the importance of protection against future HIV exposures, timely initiation of PEP medications, and adherence to these medications for 28 days. Counsel exposed workers to use latex barriers with their sexual partners until HIV infection has been ruled out.

Follow-Up

Exposed workers should be evaluated at 1 week for review of all test results. For patients taking PEP, adherence assessment and evaluation of any side effects also should be included. At 2 weeks, blood testing (eg, CBC, LFTs) should be done for patients on a 28-day PEP regimen to monitor for PEP toxicity, as indicated by the particular ARV regimen. PEP is discontinued at 4 weeks, and generally no laboratory studies should be repeated unless there is a need to recheck an abnormal result. Follow-up HIV antibody testing should be done at 6 weeks, 3 months, and 6 months after the exposure. In addition to health-education counseling, some patients may need emotional support during their follow-up visits.

Symptoms of primary HIV infection such as fever, rash, and lymphadenopathy (see chapter *Primary HIV Infection*) may occur in HCWs who have been infected with HIV through occupational exposure. Every exposed HCW should be counseled about the symptoms of primary HIV infection and instructed to return for reevaluation as soon as possible if symptoms develop. If symptoms consistent with primary HIV appear within 4-6 weeks after an occupational exposure, the HCW should be evaluated immediately. If the worker is found to be infected with HIV, he or she should be referred immediately to an HIV specialist for further evaluation and care.

Expert Consultation

For consultation on the treatment of occupational exposures to HIV and other bloodborne pathogens, the clinician managing the exposed patient can call the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-HIV-4911 (888-448-4911). This service is available 24 hours a day, at no charge (additional information on the Internet is available at http://www.ucsf.edu/hivcntr). PEPline support may be especially useful in challenging situations, such as when drug-resistant HIV strains are suspected or the HCW is pregnant.

Prophylaxis against HBV and HCV

Prophylaxis against hepatitis B is recommended for patients with potential exposure to HBV who have not been vaccinated against HBV. Give hepatitis B immune globulin (HBIG) as a 0.06-mL/kg intramuscular injection and initiate the vaccination series. For patients who received the vaccine series but did not develop protective antibody (HBV surface antibody positive), give HBIG at the time of the postexposure workup and repeat in 1 month. For patients with immunity to hepatitis B, no treatment is indicated.

For hepatitis C, no recommended prophylactic treatments are available. After potential exposure, conduct a baseline HCV antibody test. If the source is known to have HCV infection, consider alanine aminotransferase (ALT) and HCV viral load testing at 4-6 weeks. HCV antibody testing should be repeated at 4-6 months. If HCV seroconversion occurs (indicated by ALT elevation, detectable HCV viral load, or confirmed positive HCV antibody test), refer the patient to a hepatologist because early treatment of HCV may be indicated.

Addendum: Workplace Obligations

The health care institution has certain obligations to an exposed employee.* The institution should do the following:

- Evaluate the circumstances of the exposure, the type of fluid, and possible entry points.
- Evaluate the source patient.
- Perform baseline HIV antibody testing of the exposed worker, after appropriate pretest counseling.
- Counsel the exposed employee about the possible risks and benefits of PEP.
- Offer or recommend PEP as soon as possible after the exposure, preferably within the first several hours.
- Counsel the worker about avoiding secondary transmission to others (safer sex and other risk-reduction practices, as indicated).
- Support and maintain the confidentiality of the worker.
- For workers taking PEP, monitor for medication toxicity and adherence.
- Repeat HIV testing at 6 weeks, 3 months, and 6 months.
- Report the exposure as required by federal and state regulations (including Occupational Safety and Health Administration requirements).

* *Legal issues vary from state to state. In many states, institutions and clinics have no obligation toward students or non-employees who have HIV exposures in their settings. In such situations, clinical supervisors or school or university officials often are the first contact for notification. However, anyone working in a health care setting should be familiar with the procedures and financial responsibility for HIV exposure management to avoid delays in HIV PEP treatment.*

Patient Education

- Persons who have possible exposures to HIV in the work setting should contact the PEP service of their employer or a qualified medical provider as soon as possible after the exposure, or they should go to an emergency room. Although PEP may be effective if it is started within 72 hours of exposure, the sooner medications are initiated, the better the chance for preventing HIV transmission.
- PEP medications should be taken as directed for the full 28 days. Adherence to PEP medications is essential for successful teratment.
- PEP recipients should be advised to contact their providers if they experience uncomfortable side effects. Providers may prescribe medications to alleviate the side effects, or may prescribe different PEP medications.
- Until HIV infection has been ruled out, exposed workers should be advised to use latex barriers to prevent transmission of HIV to their sex partners.
- Exposed workers should be counseled about the symptoms of primary HIV infection and instructed to contact their care providers immediately if symptoms develop.

References

- Bassett IV, Freedberg KA, Walensky RP. *Two drugs or three? Balancing efficacy, toxicity, and resistance in postexposure prophylaxis for occupational exposure to HIV.* Clin Infect Dis. 2004 Aug 1;39(3):395-401.
- Cardo DM, Culver DH, Ciesielski CA, et al. *A case-control study of HIV seroconversion in health care workers after percutaneous exposure.* Centers for Disease Control and Prevention Needlestick Surveillance Group. N Engl J Med. 1997 Nov 20;337(21):1485-90.
- Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis*. MMWR Recomm Rep 2001 Jun 29;50(RR11);1-42. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10. Accessed May 19, 2006.
- Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. MMWR Recomm Rep. 2005 Sep 30; 54(RR09); 1-24. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10. Accessed May 19, 2006.
- Do AN, Ciesielski CA, Metler RP, et al. *Occupationally acquired human immunodeficiency virus (HIV) infection: national case surveillance data during 20 years of the HIV epidemic in the United States.* Infect Control Hosp Epidemiol. 2003 Feb;24(2):86-96.
- Gerberding JL. Clinical practice. *Occupational exposure to HIV in health care settings*. N Engl J Med. 2003 Feb 27;348(9):826-33.
- Puro V, Francisci D, Sighinolfi L, et al. *Benefits of a rapid HIV test for evaluation of the source patient after occupational exposure of healthcare workers*. J Hosp Infect. 2004 Jun;57(2):179-82.
- Wang SA, Panlilio AL, Doi PA, et al. *Experience of healthcare workers taking postexposure prophylaxis after occupational HIV exposures: findings of the HIV Postexposure Prophylaxis Registry.* Infect Control Hosp Epidemiol. 2000 Dec;21(12):780-5.

Antiretroviral Therapy

Background

Potent combination antiretroviral therapy (ART), consisting of 3 or more antiretroviral drugs (ARVs), has greatly improved the health and survival rates of HIV-infected patients in areas of the world with access to ARVs.

More than 20 individual ARVs are available in the resource-sufficient world, in addition to several fixed-dose combination preparations. These can be combined to construct a number of effective regimens for initial and subsequent therapy. ART is not without limitations, however. ART does not cure HIV infection and it requires that multiple medications be taken for very long periods of time (usually for the duration of life). It is expensive, may cause a variety of adverse effects (some severe), requires close adherence to be effective and to prevent the emergence of resistance, and often fails (because of the patient's imperfect adherence or other factors). The failure of an ARV regimen when accompanied by drug resistance usually means that subsequent regimens are less likely to succeed.

Greatly overshadowing the limitations of ART, however, is the overwhelming evidence that ART saves lives and improves or restores immune system function. Mortality and morbidity benefits are particularly obvious in patients with relatively advanced immune suppression or with symptoms related to HIV infection. For asymptomatic patients with relatively high CD4 cell counts (>350 cells/μL), it is less clear whether or when to start ART. In deciding when to start ART for any patient, practitioners must weigh the expected benefits of ART for that individual (in terms of morbidity and mortality) against the possible risks (eg, toxicity, drug resistance, adverse drug interactions).

Although implementing ART is complex, a number of guidelines from expert panels are available to help practitioners select effective regimens for particular patients. The U.S. Department of Health and Human Services (DHHS) keeps a repository of "living documents" of frequently updated recommendations on the use of ARV medications in children, adults and adolescents, and pregnant women. All clinicians treating HIV-infected patients should be familiar with the most current versions of these treatment guidelines. They are available on the Internet at the AIDSinfo Web site "Clinical Guidelines" section (http://aidsinfo.nih.gov/Guidelines). This chapter frequently references the *Adult and Adolescent ARV Guidelines*. (U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7.)

S: Subjective

Obtain the patient's history, including the following:

- CD4 cell count history, including nadir
- HIV viral load history, including before therapy if the patient is currently taking ARVs
- History of HIV-related conditions
- Previous and current ARV regimens, including regimen efficacy, toxicity, resistance, start and stop dates
- Current medications, including herbal preparations, supplements, and over-the-counter medications
- Medication allergies, intolerances, or prominent adverse effects
- Comorbid conditions (eg, hepatitis C, hepatitis B, depression)
- Occupation and daily schedule
- Current and previous substance use, including alcohol and recreational drugs
- Self-assessment of adherence to previous regimens
- Desire to start or continue an ARV regimen
- Commitment to adherence (see chapter *Adherence*)
- Indicators of ability to adhere to various types of regimens (eg, once daily, twice daily, every 8 hours, with or without food) given current life situation
- For women of childbearing potential: last menstrual period, current method of birth control (if any), current pregnancy status, thoughts on whether or when to have children
- History and review of systems (see chapter *Initial History*)

O: Objective

Perform the following objective tests:

- Complete physical examination (see chapter *Initial Physical Examination*)
- Current CD4 count and HIV viral load: preferably 2 or more separate results approximately 1 month apart
- Drug resistance test. To try to detect the presence of transmitted ARV resistance mutations, a genotype should be performed in all patients before initiating ART. This should be done as early in the course of infection as possible, because mutations may revert to wild type. Review the results of previous resistance testing or obtain a baseline resistance test, if this was not done earlier. (See chapter *Resistance Testing*.)
- Complete blood count (CBC) and platelet count, liver function tests (LFTs), renal function tests, fasting lipid panel (see chapter *Initial and Interim Laboratory and Other Tests*) fasting glucose, rapid plasma reagin (RPR), tuberculin skin test, hepatitis serologies

A: Assessment

Make the following basic decisions:

- The patient is or is not likely to benefit from ART at this time (ie, do potential benefits outweigh the risks)? See the *Adult and Adolescent ARV Guidelines* noted above, which thoroughly address the issue. A brief summary is included in the tables in the chapter *Determining Risk of HIV Progression* and in the chapter *CD4 Monitoring and Viral Load Testing*.
- The patient is or is not willing to start ARVs at this time (the choice to accept or decline therapy ultimately lies with the patient).
- The patient is or is not likely to adhere to an ARV regimen (an adherence counselor, with or without a mental health clinician, may be able to assist with this assessment and should be called upon if available). No patient should be automatically excluded from consideration of ART; the likelihood of adherence must be discussed and determined individually.

P: Plan

After educating the patient about the purpose and logistics of the proposed regimen and assessing the patient's potential for adherence, the ART regimen can be initiated, changed, or postponed accordingly.

The goals of therapy are to achieve maximal and durable viral suppression, restore or preserve immune function, improve quality of life, and reduce HIV-related morbidity and mortality.

Considerations before Initiating ART

No "average patient" exists. Some patients will do better during treatment and some will do worse than clinical studies would predict. Health care providers must work with each patient to develop a treatment strategy that is both clinically sound and appropriate for that individual's needs, priorities, and circumstances of daily life. Not all patients will be able to tolerate all drugs, and the patients understanding, readiness to commit to the regimen, and history of adherence to previous regimens must be considered when choosing ARV combinations. Major considerations are as follows:

- Willingness of the individual to begin therapy, coupled with understanding of the purpose and the mechanics of the planned regimen, and how it will fit into his or her life
- Degree of immunodeficiency and risk of disease progression as reflected by the CD4 count and HIV RNA level (see tables in the chapter *Determining Risk of HIV Progression* and the chapter *CD4 Monitoring and Viral Load Testing*)
- Potential benefits and risks of ARV drugs
- Likelihood of adherence to the prescribed regimen
- Resistance, if any, to ARV medications (obtain resistance testing prior to ARV initiation in ARV-naive patients)

The patient has the right to decline or postpone ART. This decision should not affect any other aspect of care, and ART should be offered again at each visit to patients who meet the criteria for treatment. If mental health issues, addiction, or the patient's social situation are barriers to adherence, initiate appropriate referrals and reassess adherence barriers at regular intervals.

Initiating Therapy: DHHS ARV Guidelines

The following recommendations have been adapted from the DHHS *Adult and Adolescent ARV Guidelines*.

- ART is *recommended* for all patients with a history of AIDS-defining illness or severe symptoms of HIV infection regardless of the CD4 cell count.
- ART is also *recommended* for asymptomatic patients with a CD4 count of <200 cells/μL.
- Therapy *should be offered* to asymptomatic patients with CD4 counts of 201-350 cells/μL. The urgency of treatment recommendations may be based on various factors, including the following:
  - Rate of CD4 cell decline
  - Plasma HIV RNA >100,000 copies/mL
  - Patient's interest
  - Risk of toxicity
- Therapy should probably be *deferred* for asymptomatic patients with CD4 counts of >350 cells/μL and plasma HIV RNA <100,000 copies/mL.

The question of when to initiate ART in asymptomatic patients remains an area of research and debate. It is clear that ART should be initiated before the CD4 count declines to <200 cells/μL, if at all possible. However, it is not yet known at what CD4 threshold ≥200 cells/μL therapy should be started. Clinicians must weigh the anticipated benefits of immune reconstitution against the possible risks of ARV toxicity and the likelihood of emergent ARV resistance, in the individual patient. With the increasing availability of ARV regimens that are more tolerable, consist of fewer pills, and offer easier dosing schedules, many clinicians are choosing to initiate therapy earlier in the course of HIV infection.

Special Situations

- Pregnancy (see chapter *Care of HIV-Infected Pregnant Women*)
- Acute or primary HIV infection (see chapter *Primary HIV Infection*)
- Postexposure prophylaxis (see chapters *Occupational Postexposure Prophylaxis* and *Nonoccupational Postexposure Prophylaxis*)

Preparing the Patient for ART

Before starting ART, it is necessary to have a detailed discussion with the patient about his or her readiness to commit to a difficult, potentially toxic medication regimen, and to return for the required follow-up visits. The patient also must understand that the first treatment regimen offers the best opportunity for effective viral suppression, and immune reconstitution, which are the primary goals of ART.

Supporting Adherence

Numerous strategies are being tested for their effectiveness in supporting patients' adherence to the ART regimen. These may include extensive patient education, telephone contact with office staff members who can answer questions about adverse effects or other difficulties, family meetings, and peer support. Trust and accessibility appear to be important predictors of adherence, and some practitioners see the patient for 2 or 3 appointments before starting ART. Patients also may be given "test regimens" for a few weeks using inactive pills or mints, to help them understand how the medication schedule may fit into their lives before starting the actual ARVs. The choice to accept or decline ART ultimately lies with the patient (see chapter *Adherence*).

Anticipating Difficulties

Choosing an initial regimen that fits the patients lifestyle and that is likely to be tolerable will improve the likelihood of long-term success with that regimen. If patients develop toxicities to 1 or more components of an initial regimen, substitutions typically can be made without limiting the success of the regimen. Close monitoring and "check-in" appointments allow these adjustments to be made under clinical supervision. Close monitoring also can help to identify medication toxicities that may limit treatment and to detect early signs of inadequate medication adherence; early intervention to treat adverse effects and to support adherence may increase the likelihood of treatment success.

Considerations in Regimen Selection

Regimens should be selected with consideration of both patient factors and medication factors. The patient's schedule, adherence history, and self-defined goals of ARV therapy should be considered in selecting

a regimen to which the patient will best adhere. The patient's comorbid conditions and potentially interacting medications should be evaluated for potential contraindications or synergism. The ARV history and any available resistance profiles should be reviewed carefully to choose a regimen that will be likely to achieve durable viral suppression. The CD4 cell count should be considered, especially if nevirapine will be used. In women who are pregnant or likely to become pregnant, ARV pregnancy categories and ARV teratogenicity should be taken into account. Table 9 of the *Adult and Adolescent ARV Guidelines* reviews the advantages and disadvantages of various drug classes and individual drugs in initial therapy.

Use of Multiple Classes of Drugs

For initial therapy, the *Adult and Adolescent ARV Guidelines* recommend the use of 2 nucleoside reverse transcriptase inhibitors (NRTIs) in combination with either a nonnucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). Drug combinations that include only NRTIs generally do not reduce virus levels as effectively as 2-class combinations. The question of whether to use an NNRTI or a PI in initial therapy is a matter of debate. Some clinicians advocate using 2 NRTIs with an NNRTI to preserve the PI class for later and avoid PI-related toxicities. Others are more concerned about the potential toxicities of NNRTIs and their low genetic barrier to resistance and instead recommend starting with a PI-containing regimen. In the end, the regimen should be selected with the individual patient in mind because the only effective combination is the one that the patient is willing and able to take on a consistent basis. See the information on drug resistance and toxicities below as well as the full text of the *Adult and Adolescent ARV Guidelines* for more complete discussions.

Boosted Protease Inhibitors

Ritonavir may be used at low doses in combination with several other PIs to enhance or "boost" the serum level and prolong the half-life. This strategy generally decreases the dosing frequency and the number of pills required, and improves the activity of some PIs.

Preferred Starting Regimens

More than 20 ARVs in 4 drug classes have been approved by the FDA (see Tables 11, 12, and 13 in the *Adult and Adolescent ARV Guidelines*). In recent years, an increasing number of fixed-dose combinations (FDCs) have become available to simplify dosing and reduce pill burden. These include 4 NRTI combinations:

- abacavir + lamivudine (Epzicom)
- abacavir + lamivudine + zidovudine (Trizivir)
- emtricitabine + tenofovir (Truvada)
- lamivudine + zidovudine (Combivir)

and 1 PI coformulation:

- lopinavir + ritonavir (Kaletra)

Also available is a 1-pill-per-day formulation of 2 NRTIs and 1 NNRTI:

- emtricitabine + tenofovir + efavirenz (Atripla).

The DHHS guidelines suggest "preferred" and "alternative" components for initial therapy (Table 1). Clinicians should note that these recommendations change over time as new data regarding efficacy or toxicity become available. In constructing a regimen with adequate potency (taking into account possible ARV resistance), drug selection should be guided by factors such as anticipated tolerability, pill burden, drug interactions, and the patient's comorbid conditions. Other agents or combinations may be appropriate in individual patients (see Table 6b of the *Adult and Adolescent ARV Guidelines*).

Avoiding Drug Resistance

ARV medications never should be given as single agents, in 2-drug regimens, in suboptimal regimens, or in lower doses than recommended because of the potential for development of resistance. High-level resistance to NNRTIs, as well as to emtricitabine and lamivudine, may develop quickly (ie, within days to weeks) in these situations. It may take longer for high-level resistance to develop with other NRTIs and PIs. Patients must be instructed to take the full dosage of all medications on schedule, and to avoid skipping doses or taking "days off" from their regimens. Careful medication dosing is important because resistance to 1 drug within a particular class may transfer to other drugs in the same class (cross-resistance). Cross-resistance can limit the options for future therapy significantly or require very complicated regimens in the future. Resistant viral strains, once developed, may be transmitted to other people.

Table 1. Initial Antiretroviral Regimens

Recommended Components of Initial ART						
To construct a regimen, choose 1 NNRTI or PI component from column A and 1 dual-NRTI combination from column B						
	Column A: NNRTI or PI Options				**Column B: Dual-NRTI Options**	
Preferred Components	NNRTI • efavirenz[a]	*or*	PI • atazanavir + ritonavir • fosamprenavir + ritonavir (BID) • lopinavir/ ritonavir (BID)	+	**Preferred Components**	• tenofovir/ emtricitabine[b] • zidovudine/ lamivudine
Alternative Components	NNRTI • nevirapine[c]	*or*	PI • atazanavir[d] • fosamprenavir • fosamprenavir + ritonavir (QD) • lopinavir/ ritonavir (QD)	+	**Alternative Components**	• abacavir/ lamivudine • didanosine + (emtricitabine or lamivudine)

Key to abbreviations: ART = antiretroviral therapy; BID = twice daily; NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside/nucleotide analogue; PI = protease inhibitor; QD=once daily.

a. Efavirenz is not recommended for use in the 1st trimester of pregnancy or in sexually active women with childbearing potential who are not using effective contraception.

b. Emtricitabine may be used in place of lamivudine and vice versa.

c. Nevirapine should not be initiated in women with CD4 cell count >250 cells/µL or in men with CD4 cell count >400 cells/µL because of increased risk of hepatotoxicity.

d. Atazanavir must be boosted with ritonavir if used in combination with tenofovir.

Adapted from U.S. Department of Health and Human Services. Table 6a. *Antiretroviral Components Recommended for Treatment of HIV-1 Infection in Treatment Naive Patients*. In: *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. October 10, 2006.

Acquired or "primary" resistance, in which a patient is infected with ARV-resistant virus, is common in parts of the United States. Because both multi- and single-class resistance has been found among drug-naive persons in many U.S. cities, it is recommended that individuals with newly diagnosed HIV infection and those new to care should receive a baseline resistance test as early as possible, and before initiation of ART (see chapter *Resistance Testing*).

Drug Interactions

Many of the ARVs interact with one another as well as with other common medications. When starting or changing an ARV regimen, review all the patient's current medications carefully for possible drug interactions. See chapter *Drug-Drug Interactions with HIV-Related Medications* for a summary of this issue and for references and resources to review medication lists and combinations. For further information on drug interactions involving ARVs, see Tables 20, and 22a-c, and 21a-b in the *Adult and Adolescent ARV Guidelines*.

Once-Daily Regimens

Convenient and simplified dosing is an obvious strategy to improve adherence, particularly with the availability of coformulations that reduce pill burden (see "Preferred Starting Regimens," above). The *Adult and Adolescent ARV Guidelines* currently include 2 once-daily combinations among "preferred" regimens, and list several other possibilities as "alternative" regimens.

The combinations indicated below (2 NRTIs + 1 NNRTI or PI) are likely to be effective in initial therapy (Table 2). Some of these combinations, however, have not been studied in clinical trials.

Table 2. Once-Daily Regimens for Initial Therapy

NRTI Combinations	NNRTI or PI
• Lamivudine or emtricitabine + abacavir • Lamivudine or emtricitabine + didanosine • Lamivudine or emtricitabine + tenofovir[#] • Didanosine + tenofovir[*#]	• Efavirenz* • Nevirapine*^ • Atazanavir[#] • Atazanavir/ritonavir • Fosamprenavir/ ritonavir • Lopinavir/ritonavir

Key to abbreviations: NRTI = nucleoside reverse transcriptase inhibitor; NNRTI = nonnucleoside reverse transcriptase inhibitor; PI = protease inhibitor.

* Didanosine + tenofovir should not be used with efavirenz or nevirapine.

^ Nevirapine is not FDA approved for once-daily dosing.

Tenofovir cannot be used with unboosted atazanavir. Adapted from Coffey S. *Options for Once-Daily Dosing of Antiretrovirals*. AETC National Resource Center Web site. Available at http://aidsetc.org/aidsetc?page=et-03-00-01.

Drugs and Drug Combinations That Should Not Be Used

Drugs with similar mechanisms of action and resistance mutations (eg, lamivudine and emtricitabine, or efavirenz and nevirapine) offer no significant advantage when combined and may increase toxicities. Drugs with additive or overlapping toxicities, such as stavudine and didanosine, should not be combined. Zidovudine and stavudine, which compete intracellularly and therefore cause antagonism, should not be used together. Most clinicians in the United States avoid using the NRTI stavudine if other options are available because of the high rate of metabolic abnormalities associated with that drug. Certain 3-drug combinations have suboptimal efficacy and are not recommended (eg, tenofovir + didanosine + NNRTI). Some ARVs require specific dosing intervals in particular patients. For example, once-daily dosing of lopinavir/ritonavir is not recommended patients receiving concomitant efavirenz or nevirapine, and some once-daily PIs or combinations should not be used in treatment-experienced patients. For further information, see Table 7 and Table 8 of the *Adult and Adolescent ARV Guidelines*.

Follow-Up of Patients Starting ART

Patients who start a new ARV regimen should be seen at least twice within the first month to assess effectiveness, adherence, tolerability, and adverse effects of the regimen.

At 2 weeks on a new regimen, practitioners should check the following:

- CBC with platelets, especially for patients starting a zidovudine-containing regimen, to monitor for anemia
- LFTs, especially for patients starting a nevirapine-containing regimen, to monitor for hepatotoxicity

At 4-8 weeks on a new regimen, and every 3 months on a stable regimen, check the following:

- HIV viral load, to monitor initial virologic response to therapy
- CD4 cell count, to monitor initial CD4 response to therapy (note that CD4 response may lag behind virologic response)
- CBC with platelets (as above)
- LFTs (as above) and renal function tests

Patients should have glucose and lipid profiles (preferably when fasting) checked at baseline and, if normal, repeated every 4-6 months after starting ART. If the results are abnormal or if the patient has cardiac risk factors, recheck every 3-4 months while on the regimen.

Regimen Failure

A treatment regimen may fail for several reasons.

Inadequate virologic response

- Viral load does not decline below the level of detection (<50-75 copies/mL, especially in patients taking initial therapy) within 6 months of initiating therapy. (In patients with previous treatment experience and in those with ARV resistance, it may not be possible to decrease plasma HIV viral load to undetectable levels, and stabilization of viral load below the previous baseline may be an appropriate goal of therapy.)

Virologic rebound

- Virus is repeatedly detected in plasma after initial suppression to undetectable levels. The degree of increase should be considered, however. Repeat testing is required to rule out "blips" of virus (isolated elevations in viral load of less than about 1,000 copies/mL) that are not clinically significant and to ensure that the increase is not due to infection, vaccination, or problems with test methodology.
- A reproducible, significant increase occurs in viral load, reaching 3-fold or greater from the lowest plasma HIV RNA level, that is not due to intercurrent infection, vaccination, or problems with test methodology.

Immunologic failure

- The CD4 cell count, measured on at least 2 separate occasions, shows a persistent decline.
- The CD4 cell count fails to increase by at least 25-50 cells/μL above baseline in the first year of ART.

Clinical deterioration or progression

- Recurrent, persistent, or new HIV-related illness occurs after at least 3 months on ART. Note that new or recurrent symptoms of opportunistic illness occurring in the first weeks to months after starting ART, especially in patients with severe immunosuppression, may not reflect a failure of ART. Rather, these symptoms could be due to persistence of severe opportunistic infections that may require longer treatment, or they could be due to an immune reconstitution syndrome (see chapter *Immune Reconstitution Syndrome*).

Responding to Apparent Treatment Failure

Refer to the *Adult and Adolescent ARV Guidelines* and consult with HIV-expert clinicians about the use of resistance testing and alternative regimens before discontinuing therapy.

Carefully assess patient adherence, because inadequate adherence to ARVs is a common reason for regimen failure. In some cases, adherence support, treatment of adverse drug effects, substitution for poorly tolerated ARVs, or other measures to enhance adherence may result in virologic suppression. In other cases, ARV resistance may have developed. Poor adherence may affect the decision to change therapy, and adherence issues should be addressed before a new regimen is initiated.

The availability of effective alternative ARVs is critical consideration in deciding whether or when to change therapies. If treatment possibilities are limited or nonexistent, it may be necessary to weigh the value of partial virologic suppression with the current regimen against the likelihood of further resistance. Consultation with an experienced HIV provider and use of HIV resistance testing are appropriate when considering changes in therapy. When no treatment options remain among currently approved drugs, refer the patient to an appropriate clinical trial if possible.

Susceptibility or Resistance Testing

It is fairly common for a first regimen to fail because of resistance to only 1 or 2 drugs in a multidrug combination (see chapter *Resistance Testing*). Resistance testing, although expensive and time consuming, can identify drugs that are less likely to be effective against the patient's virus. During resistance testing, the patient should still be taking the failing regimen so that resistant viral populations will be present in detectable numbers. Resistance testing is recommended before changing regimens because of virologic rebound during ARV therapy or suboptimal suppression of viral load on ARV therapy.

Cross-resistance exists among ARVs, such that resistance to 1 drug in a class of agents often extends to other agents in that class. For example, cross-resistance between efavirenz and nevirapine is almost complete, and resistance mutations to NRTIs and to PIs often decrease viral susceptibility to other drugs in those classes. As a result, selecting a new ARV regimen can be complicated because it requires knowledge of expected resistance patterns. The likelihood of sustained viral suppression is lower when resistant virus is present even if a subsequent regimen contains new ARVs.

Guidelines for Changing an ARV Regimen for Suspected Drug Failure

The following recommendations are adapted from the *Adult and Adolescent ARV Guidelines*.

- Distinguish between the need to change a regimen because of drug intolerance or inability to adhere to the regimen and the failure to achieve the goal of sustained viral suppression. In the event of intolerance, single agents usually can be changed without resistance testing.
- In general, do not change a single drug or add a single drug to a failing regimen; it is important to use at least 2 or, preferably, 3 active drugs. If resistance testing (performed while the patient is taking the failing regimen) shows resistance to only 1 agent in a regimen, it may be possible to replace only that drug; however, this approach requires clinical validation.
- In general, the goal of ART is to suppress HIV RNA to undetectable levels, in order to improve or maintain immune function. This is increasingly possible even for patients with resistance to multiple drugs as new ARV agents and new classes of ARVs become available.
- However, many patients have limited options for new regimens that will achieve durable virologic suppression. In some of these cases it is rational to continue the same regimen if partial virologic suppression and clinical and immunologic stability were achieved.
- In some cases, it is reasonable to continue regimens identified as suboptimal for initial therapy in patients with limitations imposed by toxicity, intolerance, or nonadherence, especially in late-stage disease. Even when these patients fail to achieve durable viral suppression on these regimens, they may remain clinically stable, with stable CD4 cell counts. The risk of maintaining patients on a partially suppressive regimen, however, is the emergence of additional resistance mutations.
- Data are limited on the value of restarting a drug that the patient has previously received. Resistant virus can be archived and will reemerge for patients

who are rechallenged with regimens on which they had previously developed resistance. As a result, resistance tests from previous regimens should be used with current resistance tests to determine what drugs might be active in a new regimen.

- If virologic failure occurs on an NNRTI-containing regimen, avoid changing among NNRTIs because high-level cross-resistance is likely.
- The decision to change therapy and the choice of a new regimen require that the clinician have considerable expertise in the care of people with HIV infection. Those less experienced in the care of persons with HIV are strongly encouraged to obtain assistance by consulting with or referring to an expert clinician.

For a general strategy for selecting a new regimen after virologic failure of an initial regimen, see Table 25 in the *Adult and Adolescent ARV Guidelines*. Note that other possibilities exist, and resistance testing and expert consultation should be sought to help guide treatment choices.

Follow-Up of Patients Not Started on ART

Patients who may benefit from ART, but are not on therapy

These patients should continue their regular visits for monitoring, prophylaxis, and other medical treatment. Changes in laboratory results and the patients' condition should be taken as opportunities to reassess their decisions about ARVs, to educate them about new medications and research findings, and to discuss the risks of delayed treatment, including the risk of progression to AIDS or death. ARVs should be discussed again and offered at regular intervals to anyone who initially refuses treatment. If lack of readiness or probable adherence difficulties are issues, an adherence counselor (if available) or a mental health provider should be engaged to bolster the patients support and coping mechanisms (see the *Adult and Adolescent ARV Guidelines* or check tables in the chapter *CD4 Monitoring and Viral Load Testing*).

Patients who do not meet the DHHS criteria for starting ARVs

These patients should be monitored regularly with laboratory tests and physical examination (see Section 1, *Testing and Assessment* for chapters on physical examinations and laboratory tests), offered prophylaxis as appropriate, and reassessed for ARV therapy when they do meet the criteria for starting treatment.

Special Situations for ART

ART during acute or primary HIV infection

Patients with acute or primary HIV infection may experience symptoms such as rash, fever, lymphadenopathy, fatigue, weight loss, nausea, and headache within the first few weeks after becoming infected, and still have a negative or indeterminate result on the HIV antibody test. If a careful HIV risk history reveals the patient to be at significant risk for recent HIV infection, an HIV RNA test can be performed to ascertain whether viremia is present. (Note that a low viral load may suggest a false-positive result.) It is not yet known whether ART has a long-term benefit when started during primary HIV infection. However, for the appropriate patient, it is reasonable to consider starting therapy, with the goal of maximal virologic suppression. Before starting an ARV regimen, patients must be counseled carefully about potential limitations, such as toxicity, pill burden, cost, and the possible development of drug resistance. Patients should be monitored with HIV viral load, CD4 counts, and other parameters, as in patients with established infection who are taking ARV therapy. Because no definitive data exist on the clinical benefit of early treatment and because ART involves certain risks, including drug toxicity and resistance, persons with acute HIV infection ideally should be treated in controlled clinical trials. (See chapter *Primary HIV Infection*.)

Pregnant women

Since 1994, zidovudine has been recommended to reduce the risk of mother-to-child transmission of HIV, but zidovudine monotherapy is less effective than combination therapy in reducing perinatal transmission and is inadequate for treatment of the pregnant woman. Combination ARV regimens are now used during pregnancy, if possible, to reduce the risk of transmission to the infant and to treat HIV infection in the mother. Certain ARVs are recommended during pregnancy, whereas others should be avoided. Because of potential teratogenic effects, efavirenz should not be used. (See chapters *Reducing Maternal-Infant HIV Transmission* and *Care of HIV-Infected Pregnant Women*; also refer to the *Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*. October 12, 2006. Available online at http://aidsinfo.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=9.)

ARV treatment in resource-limited settings

The discussion of ARV management is futile for the majority of people in the world today who are living with HIV/AIDS. According to the Joint United Nations Programme on HIV/AIDS, as of June 2005, only 11% of those needing ARV therapy in low- and middle-income countries were receiving treatment.

ARV medications are becoming available in many parts of the developing world, but the increase in availability is slow and in no way is occurring at the pace and with the efficiency warranted in this dire situation. Medication choices are limited by the availability and cost of drugs. Most resource-limited countries that are able to provide ARVs use an NNRTI-based combination for initial therapy. This regimen typically includes nevirapine or efavirenz plus 2 NRTIs such as zidovudine or stavudine plus lamivudine. Second-line therapies or substitutions needed because of toxicities or intolerance often are not readily available.

Widespread use of nevirapine to prevent mother-to-child transmission of HIV has lowered the rate of HIV transmission to infants, but the drug resistance that may emerge after even single-dose administration to the mother during labor has raised many concerns regarding effective treatment options for the mother. Without the availability of resistance testing, many women are subsequently started on an ARV regimen that includes an NNRTI. For women who have developed NNRTI resistance during previous nevirapine exposure, these regimens probably will be ineffective. In addition, NRTI resistance is likely to develop, further limiting treatment options.

Concern about adherence in resource-limited settings, although often cited as a treatment-limiting factor, has proven to be less of an issue than it is in the United States and western Europe. Many treatment programs require a lengthy educational process before ARVs are initiated. In addition, the limited availability of treatments paired with the widespread devastation of entire communities and countries has enhanced the motivation for strict adherence to therapies among patients able to acquire ARV therapy.

CD4 count and viral load testing to identify patients who should begin ART, and to monitor ARV effectiveness and potential drug toxicities, are severely limited by the lack of sufficient laboratories, equipment, and funds to perform costly blood tests. In some settings, patients are started on therapy based on clinical presentation alone, and monitoring is based solely on clinical criteria. Success of treatment may be assessed by clinical response, such as resolution of opportunistic infections, weight gain, and improvements in quality of life. ARV toxicity may be assessed by clinical signs and symptoms of adverse effects such as anemia or hepatitis.

Comorbid conditions such as tuberculosis and malaria, and potential drug interactions associated with their treatments, often complicate therapy choices. Competing priorities of poverty, lack of clean water or sanitation, and overburdened health care settings and health care providers combine to complicate the distribution of effective ARV treatment. Regardless of the numerous challenges to treatment in resource-limited settings, human compassion and responsibility dictate that we find a way to provide care for those who require treatment.

Expert Consultation

The National HIV/AIDS Clinicians' Consultation Center (NCCC) is a valuable resource for any clinician seeking expert advice about ART, HIV clinical manifestations, laboratory evaluations, and other issues. Its National HIV Telephone Consultation Service (Warmline) is staffed by HIV-experienced physicians and pharmacists. The Warmline operates Monday through Friday, 8 AM to 8 PM EST and is available free of charge in the United States at 800-933-3413.

Patient Education

- Starting ARVs is rarely an emergency. Before starting ARVs, health care providers must work with patients to determine how important therapy would be for them, what goals of therapy are likely to be achieved, and which personal issues are pertinent for selecting the best regimen to fit their lifestyles.
- Providers should review the proposed drug regimen with their patients. Be sure patients understand the instructions about dosage, scheduling, food requirements or restrictions, drug storage, adverse effects, toxicities, and type of reactions that must be reported immediately, as well as remedies for common adverse effects.
- Providers should explain to patients that ART requires a commitment to taking the medications precisely as prescribed. There is a limited number of ARVs, and if they are taken incorrectly, the virus can quickly become resistant to the medications. This will mean even fewer choices and less effective treatment in the future. It might also mean that they

could transmit resistant virus to a partner or, if they are pregnant, to an infant.

- Patients should know that HIV medications do not prevent transmission of infection to others. Safer-sex recommendations must be followed and other high-risk activities (eg, needle sharing) must be carefully avoided to keep from spreading the virus to others (see chapter *Preventing HIV Transmission/Prevention with Positives* for more information).
- Experts recommend using latex barriers during sex (safer sex) and not sharing needles or other drug-using equipment, even with other HIV-infected persons. Patients should know that if their virus develops resistance to some ARVs and they pass that virus on to another person, HIV medications may not be effective in that person. If a patient's partner happens to have a drug-resistant strain of HIV, it is possible for the patient to become infected with a resistant virus in addition to the one he or she has already, and this may limit treatment options.
- Hepatitis C, hepatitis B, and other sexually transmitted infections such as syphilis and gonorrhea can be transmitted between partners who both have HIV.
- If ARVs must be discontinued, it is usually best to stop all ARVs at once. The exception to this recommendation may be NNRTI-containing regimens; in this case, the NRTIs should be continued for about 1 week after discontinuation of the NNRTI, if possible. Even carefully managed interruptions can cause drug resistance mutations. Again, this will limit future treatment options, and should be avoided if possible.
- Discuss contingencies in the event that the client is unable to take ARVs for a day or more (eg, illness, severe adverse effects, hospitalization, or other unexpected circumstances).

References

- Centers for Disease Control and Prevention. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*. MMWR Recomm Rep. 2005 Sep 30; 54(RR09); 1-24. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=10. Accessed May 19, 2006.
- Centers for Disease Control and Prevention. *Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*. October 12, 2006. Available online at http://aidsinfo.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=9. Accessed July 8, 2007.
- Coffey S. *Options for Once-Daily Dosing of Antiretrovirals*. Accessed May 19, 2006.
- Kojic E, Carpenter C. *Initiating Antiretroviral Therapy*. In: Peiperl L, Coffey S, Volberding PA, eds. HIV InSite Knowledge Base [textbook online]; San Francisco: UCSF Center for HIV Information; 2006. Accessed February 7, 2006.
- Hirsch M. *Highly Active Antiretroviral Therapy in 2005: Recent Data for Clinical Practice*. Accessed February 7, 2006.
- New York AIDS Institute. *Criteria for the Clinical Care of Adults with HIV Infection: Antiretroviral Therapy*; revised June 2005. Accessed February 7, 2006.
- U.S. Department of Health and Human Services. *Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States*. MMWR Recomm Rep. 2005 Jan 21;54(RR02);1-20. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=11. Accessed May 19, 2006.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 7, 2007.
- World Health Organization. *Progress on Global Access to Antiretroviral Therapy: An Update on "3 X 5"*; June 2005. Accessed February 7, 2006.

Dyslipidemia

Background

In HIV-infected people treated with antiretroviral therapy (ART), improved life expectancy and the aging process are likely to increase morbidity and mortality from coronary heart disease (CHD). Thus, identification and reduction of modifiable risk factors for CHD are important aspects of primary care for HIV-infected patients. Several risk factors for CHD are common among HIV-infected populations in the United States and Europe. Dyslipidemia is a well-described independent risk factor for CHD that occurs in a high proportion of patients treated with antiretroviral (ARV) medications. Other metabolic abnormalities such as insulin resistance and diabetes may be caused or compounded by ARVs. In addition, some traditional CHD risk factors, including smoking, hypertension, and inactivity, are prevalent in many HIV-infected populations.

Before the widespread use of ARV medications, increases in triglyceride (TG) levels and decreases in total cholesterol (TC), high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol were reported in individuals with HIV disease. The introduction of combination ART, particularly the use of protease inhibitors (PIs), increased the prevalence of dyslipidemia in HIV-infected patients. In fact, dyslipidemia is associated with certain agents in each of the 3 major classes of ARVs. In the PI class, ritonavir and ritonavir-boosted PIs (with the exception of atazanavir) are particularly likely to cause marked elevations of TG and LDL levels. Nonnucleoside reverse transcriptase inhibitors (NNRTIs) also may contribute to increases in TC, LDL, and TG levels although the effects, particularly with efavirenz, are more variable. Nucleoside analogue reverse transcriptase inhibitors (NRTIs), specifically stavudine, may increase TC and TG levels.

The pathogenesis of ARV-induced dyslipidemia is not well understood. Current research suggests that the dyslipidemia observed in patients taking ART is caused by a combination of factors related to HIV disease, ARV regimens, and individual patient characteristics. Lipid abnormalities may appear or worsen within a few weeks to months after starting ART. Not all ARV-treated patients experience lipid abnormalities to the same degree. Patients with a personal or family history of dyslipidemia, glucose intolerance, diabetes, obesity, or a combination of these health problems may be genetically predisposed to lipid abnormalities that become evident once ART is initiated.

Published research regarding the relationship between ARVs and the risk of cardiovascular disease has not been conclusive. The largest prospective study of CHD events related to ARVs (the DAD study), showed a small but significant increase in the risk of myocardial infarction among HIV-infected patients treated with ART; moreover, the effect increased with cumulative years of ARV exposure. While awaiting definitive results from this and other studies, it is important to screen and treat patients for lipid abnormalities and for other known CHD risk factors. For patients with CHD or CHD risk equivalents (see below), ARV regimens should, if possible, be selected to minimize the risk of hyperlipidemia.

Guidelines for the evaluation and management of dyslipidemia have been developed by the National Cholesterol Education Program (NCEP). These recommendations and follow-up reports are based on studies of HIV-uninfected patients and may not be entirely applicable to HIV-infected patients. Despite this limitation, expert panels generally recommend similar treatment goals when evaluating and managing dyslipidemia in patients with HIV infection. (For recommendations on screening, see chapter *Initial and Interim Laboratory and Other Tests*.)

S: Subjective

The history should focus on factors indicating coronary artery disease or cardiovascular risk. CHD risk factors are conditions associated with a greater risk of serious cardiac events. A CHD risk equivalent, such as diabetes, is considered to be equal in risk to known CHD. Both CHD risks and CHD equivalents should be the focus of lifestyle modification strategies and lipid-normalizing treatment.

- Assess for CHD or CHD equivalents.
  - CHD includes a history of myocardial infarction, unstable angina, stable angina, CHD procedures, or evidence of clinically significant myocardial ischemia.
  - CHD equivalents include diabetes, peripheral vascular disease, carotid artery disease, abdominal aortic aneurysm, transient ischemic attacks, or 2 or more CHD risk factors with a 10-year risk of CHD >20% (see "Calculations to Estimate the 10-Year Risk of Cardiac Events for Men and Women", below, or the online risk calculator at http://hin.nhlbi.nih.gov/atpiii/calculator.asp?usertype=prof).
- Assess CHD risks. Major risk factors include hypertension, diabetes, smoking, low HDL, age, and family history of CHD.
- Assess for causes of secondary dyslipidemias, including diabetes, hypothyroidism, obstructive liver diseases, chronic renal failure, and medications such as corticosteroids or progestins.
- Screen for other factors that contribute to hyperlipidemia, including obesity, chronic liver diseases, alcohol abuse, high-fat or high-carbohydrate diet, and prothrombotic or proinflammatory states.
- Screen for health behaviors that increase CHD risk, including smoking, high-fat diet, sedentary lifestyle, and use of recreational drugs such as cocaine or methamphetamine.
- Review the patient's family history for premature CHD, obesity, diabetes, and lipid abnormalities.
- Review the patient's medications, with special attention to ARVs known to increase LDL or TG levels (particularly ritonavir and ritonavir-boosted PIs) or decrease HDL.

O: Objective

Check vital signs, weight, and height. Calculate body mass index (BMI). (See chapter *Initial Physical Examination* for information on BMI.)

Perform a focused physical examination with particular attention to signs of hyperlipidemia, such as xanthelasma, and to the cardiovascular system.

Table 1. Low-Density Lipoprotein Cholesterol Goals and Thresholds for Treatment*

Risk Category	Initiate Therapeutic Lifestyle Changes	Consider Drug Therapy	LDL Goal*
Lower risk: No CHD or CHD equivalents and <0-1 risk factor	LDL ≥160 mg/dL (≥4.1 mmol/L)	≥190 mg/dL (≥4.9 mmol/L) (at 160-189 mg/dL, LDL drug therapy is optional)	<160 mg/dL (<4.1 mmol/L)
Moderate risk: No CHD or CHD equivalents and ≥2 risk factors, with 10-year estimated risk <10%	LDL ≥130 mg/dL (≥3.4 mmol/L)	≥160 mg/dL (≥4.1 mmol/L)	<130 mg/dL (<3.4 mmol/L)
Moderately high risk: No CHD or CHD equivalents and ≥2 risk factors and 10-year estimated risk 10-20%	LDL ≥130 mg/dL (≥3.4 mmol/L)	≥130 mg/dL (≥3.4 mmol/L)	<130 mg/dL (<3.4 mmol/L) (optional goal of <100 mg/dL)
High risk: CHD or CHD equivalent	LDL ≥100 mg/dL (≥2.6 mmol/L)	≥100 mg/dL (≥2.6 mmol/L)	<100 mg/dL (<2.6 mmol/L) (optional goal of <70 mg/dL)

*Non-HDL cholesterol target levels are 30 mg/dL higher than corresponding LDL cholesterol levels.

Adapted from: Adult Treatment Panel III, National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. May 2001; NIH publication 01-3670. http://www.nhlbi.nih.gov/guidelines/cholesterol/

Table 2. Classification of Triglyceride Levels

Risk Category	Triglyceride Measurement
Normal triglycerides	<150 mg/dL
Borderline-high triglycerides	150-199 mg/dL
High triglycerides	200-499 mg/dL
Very high triglycerides	≥500 mg/dL

Hypertriglyceridemia is an independent risk factor for CHD. In addition, severe hypertriglyceridemia (eg, TG >1,000 mg/dL) increases the risk for pancreatitis. Patients with marked TG elevations should be treated to reduce this risk.

A: Assessment

Determine whether intervention is appropriate based on the patient's lipid values and identified CHD risks, as indicated in Tables 1 and 2. Aside from LDL, the following major CHD risk factors are listed by the NCEP as requiring intensive lipid management.

- Cigarette smoking
- Hypertension (systolic blood pressure ≥140 mm Hg or taking antihypertensive medication)
- HDL <40 mg/dL (if HDL is ≥60 mg/dL, subtract 1 risk factor)
- Patient age ≥45 for men, or ≥55 for women

Family history of premature CHD in first-degree relatives aged <55 (men) or <65 (women)

For patients who do not have diabetes or preexisting CHD and who have 2 or more CHD risk factors, calculate the "10-year risk of cardiovascular events" by using the risk-estimate page at the end of this chapter or the online tool at the National Institutes of Health Web site: http://hin.nhlbi.nih.gov/atpiii/calculator.asp.

P: Plan

Laboratory

Before starting ART, obtain baseline fasting lipid panel, fasting glucose, and comprehensive metabolic panel.

- Measure serum lipids after the patient has fasted at least 8 hours (ideally 12 hours). Include TC, HDL, TGs, non-HDL cholesterol with calculated LDL, and TC/HDL cholesterol ratio.

Repeat the fasting lipid panel within 3-6 months after starting an ARV regimen, and sooner (1-2 months) for patients who have abnormalities at baseline. Patients with normal lipid values should receive annual screening. Those with abnormal values may need more intensive monitoring (eg, every 4-6 weeks) until the LDL goal is met, after which monitoring every 4-6 months is adequate. If a new ARV regimen is begun, repeat the fasting lipid panel at 3-6 months.

Treatment of dyslipidemia usually involves a multimodal approach, including diet and exercise in all cases, and potentially including lipid-modifying medication, changes in ARV medication, or both as indicated. The primary goal of lipid-lowering therapy is to reduce LDL to target levels. Very high TG levels, may have to be reduced before LDL is treated directly (see below). Table 1 shows the LDL levels at which either therapeutic lifestyle change (TLC) or drug therapy should be initiated, as well as the target goals for LDL cholesterol. The response to therapy should be monitored and therapeutic interventions should be intensified or augmented until lipid targets are met.

Therapeutic Lifestyle Change

TLC, consisting of diet modification and exercise, is fundamental to the management of dyslipidemia in HIV-infected patients. Target goals for lipid abnormalities will be difficult to achieve without prioritizing these efforts. Although TLC is hard to maintain, it can yield significant results in reducing CHD risk and improving quality of life. Effective TLC is best achieved with a multidisciplinary team approach. HIV/AIDS primary care providers can be instrumental in identifying TLC as a treatment priority and providing referrals to nutritionists for dietary counseling, to mental health professionals for assessment of treatable mood disorders, and to social workers, peer counselors, or clinical nurse specialists for assistance with health-behavior changes, self-care strategies, and identification of resources in the community for smoking cessation support and exercise programs.

Treatment for Hypercholesterolemia

All patients with elevated lipid levels should initiate TLC. If pharmacologic intervention is indicated, hydroxymethylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins) are the first-line treatment for most patients. These agents can be effective in reducing TC, LDL, and non-HDL cholesterol levels in HIV-infected patients (Table 3).

In patients with serum TGs >400 mg/dL, the LDL cholesterol calculation is unreliable. In this situation,

non-HDL cholesterol (TC minus HDL) can be used as a surrogate target of therapy; the non-HDL goal is 30 mg/dL higher than the LDL goal. For these individuals, dietary intervention is warranted, and drug therapy to decrease LDL (or non-HDL) can be considered if TC is >240 mg/dL or HDL cholesterol is <35 mg/dL. For those with TG levels of 200-500 mg/dL, achieving the LDL cholesterol target is the primary goal and lowering non-HDL cholesterol levels is a secondary goal (see Table 1 for LDL intervention levels). (For treatment of high TGs, see "Treatment of Hypertriglyceridemia" below.)

Clinicians should note that PIs interact with most statins and can significantly increase serum statin levels, thus increasing the risk of rhabdomyolysis. Of the statin drugs, pravastatin is the least affected by PIs and is the recommended statin for patients with hypercholesterolemia without hypertriglyceridemia. Atorvastatin, if used, must be initiated cautiously and at a low dosage (note that atorvastatin may lower TGs as well as TC and LDL levels). Lovastatin and simvastatin should not be used in patients taking PIs (Table 4). Cerivastatin has been removed from the market in the United States because of reports of fatal rhabdomyolysis. Other available HMG-CoA reductase inhibitors include rosuvastatin and fluvastatin. These agents have not been as well studied as the others, but given their metabolic pathway, no significant interactions with PIs would be expected. Be aware that various formulations and combination products contain these statins. Check the generic name of components in new or unfamiliar cardiac prescriptions to determine whether they contain lipid-lowering agents.

Recommended starting dosages of statins in patients taking PIs are as follows:

- Pravastatin: 20 mg orally daily
- Atorvastatin: 10 mg orally daily

Niacin may be effective as adjunctive therapy, but may worsen insulin resistance. Ezetimibe (Zetia) has not been studied thoroughly in HIV-infected individuals, but in HIV-uninfected patients, it has been effective in combination with statins for patients whose cholesterol is not controlled adequately with a statin alone. Bile acid sequestrants generally should be avoided because they may interfere with the absorption of other drugs, and may increase TG levels. When given concomitantly, statins and fibrates increase the risk of rhabdomyolysis; these must be used cautiously and with careful monitoring.

Treatment of Hypertriglyceridemia

Patients with TG levels between 200 and 500 mg/dL should begin non-drug interventions such as diet modification, reduction in alcohol consumption, aerobic exercise, and smoking cessation. When TG level is >500 mg/dL, a low-fat diet (≤15% of caloric intake) is recommended to help prevent pancreatitis, and pharmacologic therapy will probably be required. Patients with CHD or CHD equivalents, those at high risk of CHD, and those with TG levels >200 mg/dL may need pharmacologic therapy.

Fibrates are the first-line drug option for isolated hypertriglyceridemia and are an alternative treatment for combined hypertriglyceridemia and hypercholesterolemia. Fenofibrate or gemfibrozil reduce TG levels effectively in patients on ARVs. Because they are not metabolized by the cytochrome P450 hepatic enzyme system, they do not have significant drug interactions with ARVs. Fibrates are contraindicated in patients with renal failure. Recommended dosages of these agents are as follows:

- Fenofibrate: 50-200 mg orally daily
- Gemfibrozil: 600 mg orally twice daily, 30 minutes before meals

If a fibrate alone is inadequate in reducing TGs, several options are possible. A statin (notably atorvastatin, which acts on TGs as well as cholesterol) could be added cautiously, although there is an increased risk of skeletal muscle toxicity with concomitant use of a fibrate and a statin. N-3 (omega-3) fatty acid supplements, administered at 2 g 3 times a day, have decreased TG levels in patients taking ART. Niacin also decreases both TG and TC levels, although its clinical utility is restricted because of associated insulin resistance and flushing.

Switching Antiretroviral Therapy

In patients with CHD or CHD equivalents, ARV medications should, if possible, be selected to minimize the risk of hyperlipidemia. In patients with dyslipidemia caused by ARV agents, data suggest that it may be beneficial to discontinue the offending ARVs if reasonable alternatives exist. Substituting atazanavir or nevirapine in place of a lipogenic PI, or replacing stavudine with abacavir or tenofovir, may improve the lipid profile. Before making ARV substitutions, however, consider carefully the possible effect of the substitution on HIV virologic control and the potential adverse effects of new ARVs. In some cases, antihyperlipidemic agents may still be necessary after ARV substitution.

Table 3. Drug Treatments for Lipid Abnormalities

Lipid Abnormality	First Choice	Second Choice	Comments
Isolated high LDL, non-HDL cholesterol	Statin	Fibrate	Start with pravastatin or atorvastatin. Use low statin dosages and titrate upward; patients taking PIs may have increased risk of myopathy.
Isolated high triglycerides	Fibrate	Statin, N-3 (omega-3) fatty acids	Start with gemfibrozil or fenofibrate. Combined statin and fibrate may increase myopathy risk.
High cholesterol and triglycerides (TG level 200-500 mg/dL)	Statin	Fibrate	Start with pravastatin or atorvastatin. Use fluvastatin, rosuvastatin, gemfibrozil, or fenofibrate as alternative. Combined statin and fibrate may increase myopathy risk.
High cholesterol and triglycerides (TG level >500 mg/dL)	Fibrate	N-3 (omega-3) fatty acids, niacin, statin	Start with gemfibrozil or fenofibrate. Niacin is associated with insulin resistance. May need to add statin if cholesterol is not controlled adequately.

Table 4. Interactions between Statin Agents and Antiretroviral Medications*

Statin	Considerations
Atorvastatin	• Some CYP3A4 metabolism. • Large increase in atorvastatin levels when given with protease inhibitors (PIs). Use lowest possible dosage. Monitor antilipid activity and titrate the statin dosage cautiously. • Monitor closely.
Fluvastatin	• Metabolized by CYP2C9, so no significant interactions with PIs or nonnucleoside reverse transcriptase inhibitors (NNRTIs) are expected. Decreased levels of nelfinavir are likely.
Lovastatin; Simvastatin	• Extensively metabolized by CYP3A4. Statin levels are increased substantially if coadministered with PIs. **These should not be used in patients taking PIs.**
Pravastatin	• Renal excretion and some hepatic metabolism. Levels of pravastatin are increased 30% when it is given with lopinavir/ritonavir. Levels of pravastatin are decreased 35% when it is given with ritonavir/saquinavir and decreased 40% when it is given with efavirenz. The clinical significance of these changes in pravastatin levels is unknown. • PI and NNRTI concentrations are not affected. Titrate pravastatin dosage based on antilipid activity.
Rosuvastatin	• Metabolized by CYP2CP and CYP2C19. Mostly excreted in bile. No significant interactions with PIs or NNRTIs expected. Studies are ongoing.

* Note that various formulations and combination products contain statins and other lipid-lowering agents. Check the generic name of components in new or unfamiliar cardiac prescriptions to determine whether they contain lipid-lowering agents.

Calculations to Estimate the 10-Year Risk of Cardiac Events for Men and Women

To calculate the 10-year risk of cardiac events, add up points from the following 5 tables pertaining to age, HDL, systolic blood pressure, TC, and smoking status (Tables 5.1-5.5). Note that in Tables 5.3-5.5, women's points are in parentheses. After adding points from all of the tables, consult Table 5.6. (Alternatively, an online calculator is available at http://hin.nhlbi.nih.gov/atpiii/calculator.asp.)

Table 5.1. Estimate of 10-Year Risk of Cardiac Events: Age

Age (year)	Points–Men	Points–Women
20-34	-9	-7
35-39	-4	-3
40-44	0	0
45-49	3	3
50-54	6	6
55-59	8	8
60-64	10	10
65-69	11	12
70-74	12	14
75-79	13	16

Table 5.2. Estimate of 10-Year Risk of Cardiac Events: High-Density Lipoprotein Cholesterol

HDL (mg/dL)	Points–Men	Points–Women
≥60	-1	-1
50-59	0	0
40-49	1	1
<40	2	2

Table 5.3. Estimate of 10-Year Risk of Cardiac Events: Systolic Blood Pressure

Systolic Blood Pressure	Points if Untreated–Men (Women)	Points if Treated–Men (Women)
<120	0 (0)	0 (0)
120-129	0 (1)	1 (3)
130-139	1 (2)	2 (4)
140-159	1 (3)	2 (5)
≥160	2 (4)	3 (6)

Table 5.4. Estimate of 10-Year Risk of Cardiac Events: Total Cholesterol

Total Cholesterol (mg/dL)	Points for Men (Women)				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
160-199	4 (4)	3 (3)	2 (2)	1 (1)	0 (1)
200-239	7 (8)	5 (6)	3 (4)	1 (2)	0 (1)
240-279	9 (11)	6 (8)	4 (5)	2 (3)	1 (2)
≥280	11 (13)	8 (10)	5 (7)	3 (4)	1 (2)

Table 5.5. Estimate of 10-Year Risk of Cardiac Events: Smoking Status

Smoking Status	Points for Men (Women)				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoker	8 (9)	5 (7)	3 (4)	1 (2)	1 (1)

Table 5.6. Estimate of 10-Year Risk of Cardiac Events: Calculating Risk

Men		Women	
Point Total	10-Year Risk (%)	Point Total	10-Year Risk (%)
<0	<1	<9	<1
0	1	9	1
1	1	10	1
2	1	11	1
3	1	12	1
4	1	13	2
5	2	14	2
6	2	15	3
7	3	16	4
8	4	17	5
9	5	18	6
10	6	19	8
11	8	20	11
12	10	21	14
13	12	22	17
14	16	23	22
15	20	24	27
16	25	≥25	≥30
≥17	≥30		

Tables are adapted from: Adult Treatment Panel III, National Cholesterol Education Program. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults.* May 2001. NIH publication 01-3670.

Patient Education

- Review the importance of reducing cardiovascular risk factors.
- Educate patients about the benefits of diet and exercise in improving lipid levels and reducing cardiovascular risk.
- If lipid-lowering medications are prescribed, advise patients on possible adverse effects, and advise them to call the clinic if these develop.

References

- *Adult AIDS Clinical Trials Metabolic Guides: Lipid Disturbances.* August 2002. Accessed February 7, 2006. Available online at http://aactg.s-3.com/metabolic/default.htm.
- Calza L, Roberto M, Chiodo F. *Comparison between switching therapy from protease inhibitors to a NNRTI and lipid-lowering therapy with pravastatin or bezafibrate for the management of HAART-related dyslipidemia.* In: Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections; February 22-25, 2005; Boston. Abstract 859.
- De Truchis P, Kirstetter M, Perier A, et al. Maxepa-VIH Study Group. *Treatment of hypertriglyceridemia in HIV-infected patients under HAART by (n-3) polyunsaturated fatty acids: A double-blind randomized prospective trial in 122 patients.* In: Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections; February 22-25, 2005; Boston. Abstract 39.
- Dube MP, Stein JH, Aberg JA, et al. *Guidelines for the evaluation and management of dyslipidemia in human immunodeficiency virus (HIV)-infected adults receiving antiretroviral therapy: recommendations of the HIV Medical Association of the Infectious Disease Society of America and the Adult AIDS Clinical Trials Group.* Clin Infect Dis. 2003 Sep 1;37(5):613-27.
- Expert Panel on Detection Evaluation and Treatment of High Blood Cholesterol in Adults. *Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III).* JAMA. 2001 May 16;285(19):2486-97.
- Friis-Møller N, Sabin CA, Weber R, et al. *Combination antiretroviral therapy and the risk of myocardial infarction.* N Engl J Med. 2003 Nov 20;349(21):1993-2003.
- Gallant JE, Staszewski S, Pozniak AL, et al. *Efficacy and safety of tenofovir DF vs stavudine in combination therapy in antiretroviral-naive patients: a 3-year randomized trial.* JAMA. 2004 Jul 14;292(2):191-201.

- Grundy SM, Cleeman JI, Merz CN, et al. *Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines.* Circulation. 2004 Jul 13;110(2):227-39.
- Martinez E, Arnaiz JA, Podzamczer D, et al. *Substitution of nevirapine, efavirenz, or abacavir for protease inhibitors in patients with human immunodeficiency virus infection.* N Engl J Med. 2003 Sep 11;349(11):1036-46.
- Milinkovic A, Lopez S, Vidal S. *A randomized open study comparing the effect of reducing stavudine dose vs switching to tenofovir on mitochondrial function, metabolic parameters, and subcutaneous fat in HIV-infected patients receiving antiretroviral therapy containing stavudine.* In: Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections; February 22-25, 2005; Boston. Abstract 857.
- Moyle G, Sabin C, Cartledge J, et al. *A 48-week, randomized, open-label comparative study of tenofovir DF vs abacavir as substitutes for a thymidine analog in persons with lipoatrophy and sustained virological suppression on HAART.* In: Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections; February 22-25, 2005; Boston. Abstract 44LB.
- National Cholesterol Education Program (NCEP), National Heart, Lung, and Blood Institute, National Institutes of Health. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel III). NIH Publication No. 02-5215. September 2002. Available online at http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm.
- Schambelan M, Benson CA, Carr A, et al. *Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: recommendations of an International AIDS Society-USA panel.* J Acquir Immune Defic Syndr. 2002 Nov 1;31(3):257-75.
- Shor-Posner G, Basit A, Lu Y. *Hypocholesterolemia is associated with immune dysfunction in early human immunodeficiency virus-1 infection.* Am J Med. 1993 May;94(5):515-9.
- Sension M, Grinsztejn B, Molina J. A1424067: *Improvement in lipid profiles alter 12 weeks of switching to atazanavir from boosted or unboosted protease inhibitors in patients with no previous PI virologic failure and hyperlipidemia at baseline.* In: Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections; February 22-25, 2005; Boston. Abstract 858.
- Stein JH. *Managing cardiovascular risk in patients with HIV infection.* J Acquir Immune Defic Syndr. 2005 Feb 1;38(2):115-23.

Insulin Resistance and Hyperglycemia on Antiretroviral Therapy

Background

Patients taking antiretroviral therapy (ART), particularly certain regimens containing a protease inhibitor (PI), appear to have an increased risk of hyperglycemia and diabetes mellitus. Hyperglycemia with or without diabetes has been reported in 3-17% of patients and has occurred at a median of about 60 days, with a range of 2 days to more than a year, after starting therapy. Disorders of glucose metabolism may present as the following:

- Insulin resistance, in which higher concentrations of insulin are required to exert normal effects; blood glucose levels may be normal but fasting insulin levels will be high because of compensatory insulin secretion by the pancreas
- Impaired glucose tolerance (ie, a glucose level of 140-199 mg/dL 2 hours after a 75-g oral glucose load)
- Impaired fasting glucose (ie, 110-125 mg/dL)
- Diabetes mellitus, which is diagnosed when the fasting blood sugar is ≥126 mg/dL, or the confirmed 2-hour glucose level is ≥200 mg/dL during glucose tolerance testing

The incidence of new-onset hyperglycemia in HIV-infected patients taking ART has been reported as about 5%, on average. Even if fasting glucose levels remain normal in patients taking ART, up to 40% of those on a PI-containing regimen will show impaired glucose tolerance. The etiology of insulin resistance and hyperglycemia in HIV-infected patients is probably multifactorial, with varying contributions from traditional risk factors (eg, obesity, family history), comorbid conditions (eg, hepatitis C virus infection), and antiretroviral-related factors (eg, direct effects of PIs, hepatic steatosis, and fat redistribution).

Patients who have preexisting diabetes must be monitored closely when starting ART; some experts would consider a PI-sparing regimen for these patients. Alternatively, PIs with favorable metabolic profiles (eg, atazanavir) may be preferred for such patients. Those with no history of diabetes should be advised about the warning signs of hyperglycemia (polydipsia, polyuria, and polyphagia) and the need to use diet and exercise to maintain an ideal body weight.

S: Subjective

The patient is about to begin ART, has been on an antiretroviral (ARV) regimen that includes a PI, or is overweight, has central fat accumulation, or has lipoatrophy. Although most patients with hyperglycemia are asymptomatic, some may report polydipsia, polyuria, and polyphagia.

History

Include the following in the patient's history:

- Fat redistribution on ART (see chapter *Abnormalities of Body Fat Distribution*)
- Family history of diabetes
- Obesity, or habitual physical inactivity
- Racial or ethnic heritages at higher risk: African, Hispanic, Native American, Asian-Pacific Islander
- Hypertension
- History of low level of high-density lipoprotein
- History of elevated triglycerides
- Gestational diabetes or delivery of infant weighing >9 lbs
- Current pregnancy
- Hepatitis C virus coinfection
- Polycystic ovary syndrome

O: Objective

Review previous or baseline blood glucose levels. Document weight and any weight changes or fat redistribution.

A: Assessment

Determine whether the patient has normal blood glucose, impaired fasting glucose, or diabetes (see laboratory recommendations and definitions below).

P: Plan

Laboratory

Most experts (eg, the International AIDS Society-USA) recommend monitoring routine fasting blood glucose levels at baseline and 3-6 months after starting therapy if baseline results are normal. Some recommend 2-hour postprandial measurements or a 75-g oral glucose tolerance test within the first 3-4 months of starting therapy and every 3-4 months thereafter. Monitoring should be more frequent if abnormalities are detected, or any additional risk factors exist, as noted earlier. Patients with these risk factors must be counseled about prevention of hyperglycemia before starting ART.

Treatment

Patients with insulin resistance

For patients with insulin resistance (impaired glucose tolerance) and normal blood glucose levels, current evidence is inadequate to recommend drug treatment. However, lifestyle modifications can be recommended, including exercise, weight loss, and diet changes. Weight loss is strongly recommended if the patient is overweight. Refer the patient to a dietitian. Some studies of insulin resistance in HIV-infected individuals are under way, and patients with access to clinical trials may be interested in these studies.

Patients with hyperglycemia and insulin resistance require treatment. A trial of lifestyle modifications may be attempted, including weight loss (if indicated), diet changes, and exercise. When drug treatment is required, because patients meet the diagnosis of diabetes and lifestyle changes are not adequate, the insulin sensitizers metformin or thiazolidinediones (pioglitazone or rosiglitazone) should be considered. Oral antidiabetic agents may increase the risk of hepatic and renal abnormalities, so patients should be monitored for hepatic toxicity (thiazolidinediones) and lactic acidosis (metformin). Thiazolidinediones should be avoided in patients with significant liver disease. Patients with elevated serum creatinine (>1.5 mg/dL in men or >1.4 mg/dL in women), hepatic impairment, or metabolic acidosis should not take metformin. In some cases, insulin may be the safest drug therapy for symptomatic hyperglycemia, although episodes of hypoglycemia are much more common with insulin than with most oral agents. For hyperglycemia that is associated with the use of PIs, switching to an alternative agent (eg, a nonnucleoside reverse transcriptase inhibitor or a different PI) may be effective if the HIV treatment history and resistance profile permit.

Patients with diabetes

Treatment should be instituted to control blood sugar and to modify other cardiovascular risk factors, with the aim of preventing heart disease and other end-organ disease.

- Control glucose: maintain the glycosylated hemoglobin (HbA1c) level at <7%.
- Treat dyslipidemia: maintain low-density lipoprotein (LDL) at <100 mg/dL and maintain triglycerides at <200 mg/dL.
- Treat hypertension: maintain systolic blood pressure at <130 mm Hg and diastolic blood pressure at <85 mm Hg.
- Reduce cardiovascular risk with lifestyle modifications: smoking and alcohol cessation, exercise, weight loss, nutritional counseling.
- Decrease the risk of end-organ complications:
  - Measure urine microalbumin and creatinine; if the urine albumin/creatinine ratio is >30 mg/g, treat with an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker to slow the progression of nephropathy.
  - Schedule annual retinal examination by an ophthalmologist.
  - Perform an annual foot exam.
- Start aspirin therapy if the patient has evidence of macrovascular disease, a family history of coronary artery disease, a history of smoking, or previous vascular events.

For further information, see the American Diabetes Association, *Clinical Practice Recommendations, Diabetes Care*, at: http://care.diabetesjournals.org.

Patient Education

- Antiretroviral therapy can increase the risk of diabetes in some individuals. Patients should report any difficulty with excessive hunger and thirst and increased urination. Health care providers will monitor blood glucose when doing laboratory work, but it is important for the patient to call if any symptoms are present.
- Review exercise possibilities to determine what activities might be realistic and acceptable for the patient.
- Review the patient's eating habits and explain the need to work with a dietitian to keep blood glucose (and triglycerides) within normal limits. A proper diet can reduce the risk of permanent damage to the blood vessels of the eye, the kidney, the brain, and can reduce the risk of a heart attack.
- Emphasize other lifestyle modifications, such as weight loss (if appropriate).
- Provide medication-specific education, especially if the patient will be taking metformin or insulin.
- Consider referral to a diabetic clinic for specialty needs.

References

- Dube MP, Stein JH, Aberg JA, et al. *Guidelines for the evaluation and management of dyslipidemia in human immunodeficiency virus (HIV)-infected adults receiving antiretroviral therapy: recommendations of the HIV Medical Association of the Infectious Disease Society of America and the Adult AIDS Clinical Trials Group.* Clin Infect Dis. 2003 Sep 1;37(5):613-27.
- Hardy H, Esch LD, Morse GD. *Glucose disorders associated with HIV and its drug therapy.* Ann Pharmacother. 2001 Mar;35(3):343-51.
- Schambelan M, Benson CA, Carr A, et al. *Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: recommendations of an International AIDS Society-USA panel.* J Acquir Immune Defic Syndr. 2002 Nov 1;31(3):257-75.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.* October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 7, 2007.
- Wlodarczyk D. *Managing Medical Conditions Associated with Cardiac Risk in Patients with HIV.* In: Peiperl L, Volberding PA, eds. HIV InSite Knowledge Base [textbook online]; San Francisco: UCSF Center for HIV Information; August 2004. Accessed February 7, 2006.

Drug-Drug Interactions with HIV-Related Medications

Background

Drug-drug interactions are common concerns of both patients with HIV and their health care providers. The issues involved in evaluating and drug interactions are complex. Although many questions can be articulated simply (eg, "What antidepressant is least likely to have drug interactions with HIV medications?"), the responses to these questions involve more complex concerns (eg, "In choosing an antidepressant for my patient with HIV, I must consider efficacy, adverse effects, and tolerability as well as drug interactions.").

This complexity is increased because antiretroviral agents, particularly protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs), can cause and be affected by alterations in the activity of the cytochrome P450 enzymes in the liver. These enzymes are responsible for metabolizing many medications. Understanding the relevance of the influence of P450 enzymes is challenging because of several factors, including the following:

- Different drugs affect different P450 enzymes.
- Some medications have dosage-related responses that influence their effects on P450 enzymes.
- Formal pharmacokinetic studies on drug combinations are limited.
- Even when pharmacokinetic data exist for specific drug combinations, the clinical significance of any changes in pharmacokinetic parameters may not be clear.
- Patients taking HIV medications often have complex drug regimens. The interaction of only 2 drugs is rarely the concern; more often, patients are taking 3 or more medications that could influence interactions. Pharmacokinetic studies that evaluate the clinical significance of drug interactions involving more than 2 medications are less likely to be available.
- The P450 system is not the only influence on medication activity. Other influences include absorption, food-drug interactions, protein binding, altered activation of medications intracellularly, and altered efflux-pump activity.

Information on various drug-drug interactions is available in guidelines and via the Internet (see "Resources" below). Such resources can provide data regarding 2-drug combinations, but rarely consider all the complexities outlined above. What follows, therefore, is a suggested approach to considering drug-drug interactions in the management of HIV-infected patients and making patient-specific decisions.

S: Subjective

A new patient arrives for his clinic intake appointment. The patient receives his medical care from a local infectious-disease physician who has only a handful of HIV-infected patients in her practice. The patient was recently released from the hospital with a discharge diagnosis of pneumonia and *Mycobacterium avium* complex (MAC). He is not yet taking HIV medications, but is likely to start them in the next several weeks after the establishment of care and adherence support programs. Other problems include hyperlipidemia, erectile dysfunction, diabetes, depression, and herpes. The clinician wants to review the patient's medication list to check for any potential drug-drug interactions.

O: Objective

Review the patient's pharmacy records for current medications. As requested, the patient has brought in all his medications from home for review. His current medication list includes the following:

- Clarithromycin 500 mg twice daily
- Ethambutol 1,000 mg daily
- Rifabutin 300 mg daily
- TMP-SMX (Septra, Bactrim) DS 1 tablet daily
- Lovastatin 20 mg daily
- Metformin 500 mg twice daily
- Bupropion 150 mg daily
- Acyclovir 400 mg twice daily
- Milk thistle *(silymarin)*
  (patient takes as needed for energy and liver health)

A: Assessment

Step 1: Identify interactions and classify them as follows:

- Definite interactions
- Probable interactions
- Possible interactions

Definite Drug Interactions

A drug interaction is definite if a high level of evidence is available regarding the drug combination, the clinical significance of the interaction is well understood, and consensus exists regarding the management strategy (eg, dosage adjustments). Common definite interactions for HIV patients include:

- Certain combinations of HIV agents (eg, boosted PIs, NNRTI + PI combinations)
- Rifamycins and PIs or NNRTIs
- Statins and PIs + NNRTIs
- Erectile dysfunction agents and PIs
- Methadone and PIs

Probable Drug Interactions

A drug interaction is probable if the limited available evidence suggests that an interaction may occur, even if the clinical outcome or significance may not be clearly established. Effective management of a probable interaction is based on assessment and clinical judgment about the risks and benefits of a particular combination for that patient. Examples of probable interactions with HIV-related medications include:

- Antidepressants and PIs or NNRTIs
- Oral contraceptives and PIs
- Warfarin and PIs or NNRTIs
- Proton pump inhibitors or H-2 blockers and atazanavir

Possible Drug Interactions

Possible drug interactions may be difficult to distinguish from probable drug interactions, but in these cases, only theoretical evidence is available. The proper management of such an interaction requires weighing the risks and benefits of the combination and making sound clinical judgments. Examples of possible drug interactions with HIV medications include:

- Herbal products and PIs or NNRTIs (except in the case of St. John's wort, for which definite information on interactions is available)
- Antidiabetic medications and PIs or NNRTIs
- Antifungal agents and PIs or NNRTIs (except in the case of voriconazole, for which definite information on interactions is available)
- Antiseizure medications and PIs or NNRTIs
- Antipsychotic agents and PIs or NNRTIs

Memorizing all the potential drug interactions is impossible. It is possible, however, to remember a few commonly used drug combinations with the potential for clinically significant interactions. The above examples of definite, probable, and possible interactions are reasonable "red flag" drug combinations that can be recalled easily. In addition, certain Internet resources allow you to submit all of a patient's current medications and planned additions (eg, lopinavir/ritonavir as part of a new antiretroviral regimen) and receive feedback on potential interactions (see "Resources" below). Finally, consultation with clinical pharmacists can aid in identifying and classifying potential interactions.

P: Plan

Step 2: The patient described above will start an antiretroviral regimen of lopinavir/ritonavir + zidovudine + lamivudine. The PI may cause problematic drug-drug interactions with some of his other medications. Develop a plan for management when lopinavir/ritonavir is added to this regimen.

For this patient, the following definite interactions should be of concern:

- Rifabutin and lopinavir/ritonavir
- Lovastatin and lopinavir/ritonavir

Refer to available references for management suggestions. Such references include:

- DHHS Adult and Adolescent Antiretroviral Treatment Guidelines *http://www.aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?MenuItem=Guidelines&GuidelineID=7*
- HIV InSite Database of Antiretroviral Drug Interactions: *http://hivinsite.ucsf.edu/arvdb?page=ar-00-02*

- Toronto General Hospital Drug Interaction Tables *http://tthhivclinic.com/interact_tables.html*
- Discover Drug Interaction Checker *http://health.discovery.com/encyclopedias/checker/checker.jsp*
- Check my Meds on AIDSMeds.com *http://aidsmeds.com/cmm/DrugsNewContent.asp*

Most of these sites include specific dosage adjustments or alternative agents to consider when managing these drug combinations. The following are suggestions for the above interactions:

- The rifabutin dosage should be 150 mg every other day with standard lopinavir/ritonavir dosing. Alternatively, discuss with the patient's primary care provider whether rifabutin is important to the current MAC regimen or whether the patient could be treated adequately with just clarithromycin + ethambutol to avoid the above interactions.
- Lovastatin should be discontinued in this patient when lopinavir/ritonavir is begun. To manage hyperlipidemia, the patient should be switched to safer statins such as pravastatin or low-dose atorvastatin.

Although this patient's current medication list does not contain an erectile dysfunction agent, the patient should be educated about the definite interactions and dosage adjustments recommended for patients using those agents with PIs. Some patients may obtain erectile dysfunction agents outside the care of their physician and, if unaware of the interactions and suggested dosage adjustments, may be at risk for life-threatening consequences.

Some additional probable or possible interactions should be considered if PIs are begun, including:

- Bupropion with lopinavir/ritonavir
- Milk thistle with lopinavir/ritonavir

The Web sites and references listed above include some information about these potential interactions, but no specific management or dosage adjustments are given. This patient should be monitored for increased effects of bupropion and educated about potential interactions with milk thistle. Clinical judgment and decision making with the primary care provider and other subspecialists (eg, psychiatrists) may be required. Consultation with clinical pharmacy services also may assist in evaluating the potential significance of an interaction and developing management strategies.

Patient Education

- Instruct patients that HIV medications, in particular PIs and NNRTIs, have a high potential for significant drug interactions.
- Tell patients to take all their medicines, including any herbal supplements and over-the-counter remedies, with them to all medical appointments. If they cannot take the actual bottles with them, they should make a list of current prescribed medications, supplements, and over-the-counter medications.
- Patients should have their primary care provider or pharmacist review any newly prescribed medications along with their current list of medicines. This is especially important if another physician prescribes a new medication.
- Patients should not "borrow" medications from friends or family. Assure patients that if they have a problem that needs medical treatment, their primary care provider will discuss it and choose the safest treatments for them.
- Tell patients that if they are considering buying a new nutritional or herbal supplement or an over-the-counter product, they should consult their pharmacist or primary care provider about interactions with drugs on their current medication list.
- Not all drug interactions are cause for alarm. Some drug combinations are safe for certain people, but less safe for others. Warn patients not to stop taking any medicines without the advice of their primary care provider.

References

- Liedtke MD, Lockhart SM, Rathbun RC. *Anticonvulsant and antiretroviral interactions.* Ann Pharmacother. 2004 Mar;38(3):482-9.
- Rainey PM. *HIV drug interactions: the good, the bad, and the other.* Ther Drug Monit. 2002 Feb;24(1):26-31.
- Piscitelli SC, Gallicano KD. *Interactions among drugs for HIV and opportunistic infections.* N Engl J Med. 2001 Mar 29;344(13):984-96.
- Sheehan NL, Kelly DV, Tseng AL, et al. *Evaluation of HIV drug interaction web sites.* Ann Pharmacother. 2003 Nov;37(11):1577-86.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.* October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 7, 2007.

Resources

- *HIV InSite Database of Antiretroviral Drug Interactions:* http://hivinsite.ucsf.edu/arvdb?page=ar-00-02
- *Toronto General Hospital Drug Interaction Tables:* http://tthhivclinic.com/interact_tables.html
- *Discover Drug Interaction Checker:* http://health.discovery.com/encyclopedias/checker/checker.jsp
- *Check my Meds on* AIDSMeds.com*:* http://aidsmeds.com/cmm/DrugsNewContent.asp

Pain Syndrome and Peripheral Neuropathy

Background

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." Pain is subjective, it is whatever patient says it is, and it exists whenever the patient says it does. Pain is a common symptom in people with HIV infection, especially in those with advanced HIV disease. It occurs in 30-60% of HIV/AIDS patients and can diminish their quality of life significantly. Like cancer patients, HIV patients experience, on average, 2.5 to 3 types of pain at once. Pain in HIV-infected patients may have many causes (as discussed below).

Peripheral Neuropathy

Pain from HIV-associated peripheral neuropathy is particularly common, and may be debilitating. Peripheral neuropathy is clinically present in approximately 30% of HIV-infected individuals and typically presents as distal sensory polyneuropathy (DSP). It may be related to HIV itself (especially at CD4 counts <200 cells/μL), to medication toxicity (eg, from certain nucleoside analogues such as didanosine or stavudine), or to the effects of chronic illnesses (eg, diabetes mellitus). Patients with peripheral neuropathy may complain of numbness or burning, a pins-and-needles sensation, shooting or lancinating pain, and a sensation that their shoes are too tight or their feet are swollen. These symptoms typically begin in the feet and progress upward; the hands may be affected. Patients may develop difficulty walking because of discomfort. Factors associated with increased risk of peripheral neuropathy include the following:

- Previous peripheral neuropathy
- Low CD4 count (≤100 cells/μL)
- Prior AIDS-defining opportunistic infection or neoplasm
- Vitamin B12 deficiency
- Concomitant use of other drugs associated with peripheral neuropathy (eg, isoniazid)
- Use of neurotoxic agents (eg, alcohol)

Patients should be assessed carefully before the introduction of a potentially neurotoxic nucleoside analogue (eg, didanosine, stavudine) to avoid the use of these medications in patients at greatest risk of developing peripheral neuropathy.

Pain is significantly undertreated, especially in HIV-infected women, because of factors ranging from providers' lack of knowledge about the diagnosis and treatment of pain to patients' fear of addiction to analgesic medications. Pain, as the so-called fifth vital sign, should be assessed at every patient visit.

S: Subjective

The patient complains of pain. The site and character of the pain will vary with the underlying cause. Ascertain the following from the patient:

History

- Duration, onset, progression
- Distribution, symmetry
- Character or quality (eg, burning, sharp, dull)
- Intensity
- Severity (see below)
- Neurologic symptoms (eg, weakness, cranial nerve abnormalities, bowel or bladder abnormalities)
- Exacerbating or relieving factors
- Response to current or past treatments
- Past medical history (eg, AIDS, diabetes mellitus)
- Alcohol intake (amount, duration)
- Medications, current and recent (particularly zalcitabine, didanosine, stavudine, and isoniazid)
- Nutrition (vitamin deficiencies)
- Meaning of the pain to the patient

O: Objective

Measure vital signs (an increase in blood pressure,

respiratory rate, and heart rate can correlate with pain). Perform a symptom-directed physical examination, including a thorough neurologic examination. Look for masses, lesions, and localizing signs. Pay special attention to sensory deficits (check for focality, symmetry, and distribution [such as "stocking-glove"]), muscular weakness, reflexes, and gait. Patients with significant motor weakness or paralysis, especially if progressive over days to weeks, should be evaluated emergently.

A: Assessment

Pain assessment includes determining the type of pain: nociceptive or neuropathic. Nociceptive pain occurs as a result of tissue injury (somatic) or activation of nociceptors resulting from stretching, distention, or inflammation of the internal organs of the body. Nociceptive pain usually is well localized; may be described as sharp, dull, aching, throbbing, or gnawing in nature; and typically involves bones, joints, and soft tissue. Neuropathic pain occurs from injury to peripheral nerves or central nervous system structures. Neuropathic pain may be described as burning, shooting, tingling, stabbing or like a vise or electric shock; it involves the brain, central nervous system, nerve plexuses, nerve roots, or peripheral nerves.

Assess the severity of the pain. Have the patient rate the pain severity on a numeric scale of 0-10 (0 = no pain and 10 = worst imaginable pain), a verbal scale (none, small, mild, moderate, or severe), or a pediatric faces pain scale (when verbal or language abilities are absent). Note that pain ratings >3 usually indicate pain that interferes with daily activities. Use the same scale for evaluation of treatment response.

Although pain in HIV-infected patients is often due to opportunistic infections, neoplasms, or medication-related neuropathy, it is important to include non-HIV-related causes of pain in a differential diagnosis. Some of these other causes may be more frequent in HIV-infected individuals. A partial list for the differential diagnosis includes:

- Anorectal carcinoma
- Aphthous ulcers
- Appendicitis
- Arthritis, myalgias
- Candidiasis, oral or esophageal
- Cholecystitis
- Cryptococcal disease
- Cytomegalovirus colitis
- Dental abscesses
- Gastroesophageal reflux disease (GERD)
- Ectopic pregnancy
- Herpes simplex
- Herpes zoster
- Kaposi sarcoma
- Lymphoma
- Medication-induced pain syndromes (eg, due to growth hormone, granulocyte colony-stimulating factor)
- Medication-induced peripheral neuropathy (eg, due to didanosine, stavudine, isoniazid, vincristine)
- *Mycobacterium avium* complex
- Myopathy
- Other neuropathy
- Pancreatitis
- Pelvic inflammatory disease
- Toxoplasmosis

P: Plan

Perform a diagnostic evaluation based on the suspected causes of pain.

Treatment

Treatment should be aimed at eliminating the source of pain, if possible. If symptomatic treatment of pain is needed, begin treatment based on the patient's pain rating scale, using the least invasive route. The goal is to achieve optimal patient comfort and functioning with minimal medication adverse effects. Use the 3-step pain analgesic ladder originally devised by the World Health Organization (WHO).

Nonpharmacologic Interventions

Interventions such as relaxation techniques, guided imagery, massage, reflexology, acupuncture, thermal modalities, prayer, deep breathing, and meditation can be used as adjunctive therapy at any step in the treatment plan.

Pharmacologic interventions

The following 3 steps are adapted from the WHO analgesic ladder.

Step 1: Nonopiates for mild pain (scale 1-3)

- The most common agents in this step include acetaminophen and nonsteroidal antiinflammatory drugs (NSAIDs), and cyclooxygenase-2 (COX-2) inhibitors.
- Acetaminophen has no effect on platelets and no antiinflammatory properties; avoid use in patients with hepatic insufficiency.
- Note that COX-2 inhibitors have been associated with an increased risk of cardiovascular events and should be used with caution.
- Tramadol (Ultram) is a centrally acting nonopiate that can be combined with NSAIDs. Avoid coadministration with selective serotonin reuptake inhibitors (SSRIs) and monoamine oxidase inhibitors (MAOIs) because of serotonin syndrome; also avoid in patients with a seizure history.

Step 2: Mild opiates with or without non-opiates for moderate pain (scale 4-6)

- Most agents used to treat moderate pain are combinations of opioids and Step 1 agents.
- The most common agents are acetaminophen combined with codeine, oxycodone, or hydrocodone.
- Meperidine (Demerol) should be avoided because its active metabolite, normeperidine, has activating properties that may cause delirium and seizures.
- Chronic pain is more likely to be controlled when analgesics are dosed on a continuous schedule rather than "as needed." Sustained-release formulations of opioids should be used whenever possible.
- For breakthrough pain, use "as needed" medications in addition to scheduled-dosage analgesics.

Step 3: Opioid agonist drugs for severe pain (scale 7-10)

- Morphine is the drug of choice in this step. Others used are oxycodone, hydromorphone, fentanyl, levorphanol, methadone, codeine, hydrocodone, oxymorphone, and buprenorphine.
- Avoid meperidine because of the increased risk of delirium and seizures.
- Around-the-clock, oral, sustained-release dosing will achieve optimum pain relief. Patients unable to take oral therapy may use transdermal fentanyl patches or rectal administration of sustained-release tablets.
- Anticipate and treat complications and adverse effects of opioid therapy, such as nausea, vomiting, and constipation.

Adjunctive Treatments

The addition of antidepressant medications can improve pain management, especially for chronic pain syndromes. These agents, and anticonvulsants, are usually used to treat neuropathic pain (discussed in more detail below), but should be considered for other chronic pain syndromes as well.

Treatment of Neuropathic Pain

Assess the underlying etiology, as discussed above, and treat the cause as appropriate. Review the patient's medication list for medications that can cause neuropathic pain. Discontinue the offending agents, if possible. Consider dosage reductions of stavudine to reduce peripheral neuropathy (consult with an HIV expert). For isoniazid regimens, ensure that patients are taking vitamin B6 (pyridoxine) regularly to avoid isoniazid-related neuropathy.

Nonpharmacologic interventions for neuropathic pain

The nonpharmacologic interventions described above also can be useful in treating neuropathic pain.

Pharmacologic interventions for neuropathic pain

Follow the WHO ladder of pain management described above. If Step 1 medications are ineffective, consider adding antidepressants, anticonvulsants, or both before moving on to opioid treatments.

Antidepressants

Antidepressant medications often exert analgesic effects at dosages that are lower than those required for antidepressant effects. However, as with antidepressant effects, optimum analgesic effects may not be achieved until several weeks of therapy.

- Tricyclic antidepressants (TCAs): Doses may be titrated upward every 3-5 days, as tolerated.
- Amitriptyline (Elavil): Starting dose is 10-25 mg at bedtime. Usual maintenance dosage is 25-150 mg at bedtime.
- Desipramine (Norpramin): Starting dose is 25 mg at bedtime. Usual maintenance dosage is 25-250 mg at bedtime.

- Nortriptyline (Pamelor): Starting dose is 10 mg at bedtime. Usual maintenance dosage is 20-150 mg at bedtime.
  - Adverse effects include sedation, anticholinergic effects (eg, dry mouth, urinary retention), and orthostatic hypotension. There is a risk of overdose if taken in excess.
- SSRIs: See chapter *Depression* for dosing, side effects, and drug interactions associated with this class of agents. SSRIs are less effective than TCAs in treating chronic pain.
- Venlafaxine (Effexor): Starting dosage is 37.5 mg daily. Usual maintenance dosage is 75-300 mg daily in divided doses or by extended-release formulation (Effexor XR).

Anticonvulsants

The following may be effective for neuropathic pain.

- Gabapentin (Neurontin): Starting dosage is 100-300 mg 2 or 3 times daily. Usual maintenance dosage is 1,200-3,600 mg/day in divided doses. Monitor response and increase the dosage every 1-2 weeks by 300-600 mg/day.
  Adverse effects include somnolence, dizziness, fatigue, and nausea.
- Lamotrigine (Lamictal): Starting dosage is 25 mg twice daily. Usual maintenance dosage is 50-300 mg/day in divided doses.
  Adverse effects include sedation, dizziness, ataxia, confusion, nausea, blurred vision, and rash.
- Valproic acid (Depakote): Starting dosage is 500 mg twice daily. Usual maintenance dosage is 500-1,500 mg 2 or 3 times daily. Monitor valproic acid serum levels.
  Adverse effects include weight gain, sedation, ataxia, nausea, and diarrhea.
- Although phenytoin and carbamazepine have some effectiveness in treating neuropathy, they have significant drug interactions with protease inhibitors and nonnucleoside reverse transcriptase inhibitors, and their use in HIV-infected patients is limited.

Substance Abuse, HIV, and Pain

Some health care providers hesitate to treat pain in patients with current or past substance abuse because of concern about worsening these patients' dependence on opioids or suspicion that such patients are seeking pain medications for illicit purposes. However, the following points should be considered:

- Many patients with current or past substance abuse do experience pain, and this pain should be evaluated by care providers and treated appropriately.
- Failure to distinguish among addiction, tolerance, and dependence can lead to undertreatment of chronic pain by health care providers.
  - Addiction (substance abuse) is a complex behavioral syndrome characterized by compulsive drug use for the secondary gain of euphoria.
  - Pharmacologic tolerance refers to the reduction of effectiveness, over time, of a given dosage of medication.
  - Physical dependence is the consequence of neurophysiologic changes that take place in the presence of exogenous opioids.
- Aberrant use of pain medications, if it develops, is best managed by an interdisciplinary team of providers from HIV clinical care, psychiatry, psychology, pharmacy, social services, and drug addition management.
- Drug-drug interactions between certain antiretroviral medications and methadone can decrease methadone serum concentrations (see chapter *Drug-Drug Interactions with HIV-Related Medications*). If this occurs, methadone dosages may need to be increased to prevent opiate withdrawal.
- As part of chronic pain management in patients with substance abuse, consider establishing a written pain-management contract to be signed by the clinician and the patient. The contract should:
  - Clearly state limits and expectations for both the patient and provider
  - Identify a single clinician responsible for managing the pain regimen
  - Tell the patient what to do if the pain regimen is not working
  - Describe the procedure for providing prescriptions (eg, 1 prescription given to the patient, in person, for a limited period of time, such as 1 month).
  - List the rules for dealing with lost medications or prescriptions

Patient Education

- Pain management is part of HIV treatment and patients should give feedback to allow the best treatment decisions. If pain persists for more than 24 hours at a level that interferes with daily life, patients should call so that their health care provider can change the plan and try additional measures if needed.
- Patients should not expect full pain relief in most cases, but enough relief that they can perform their daily activities.
- "Mild" pain medications (eg, NSAIDs, aspirin, acetaminophen) usually are continued even after "stronger" medications are started because their mechanism of action is different from that of opiates. This combination of pain medication has additive effects, so that pain may be controllable with a lower narcotic dosage.
- Patients taking "around the clock" medications, should take them on schedule. Those taking "as needed" medications should take them between doses if they have breakthrough pain.
- Opiates are noted for causing severe constipation. Patients must remain hydrated and may need stool softeners, laxatives, or other measures. They should call their health care provider quickly if constipation occurs.
- Patients should avoid recreational drugs or alcohol when taking opiates because opiates can interact with them or cause additive adverse effects, possibly resulting in central nervous system depression, coma, or death.
- Patients taking opiates should avoid driving and operating machinery.

References

- Alexander C. *Palliative and End-of-Life Care. In:* Anderson JR, ed. *A Guide to the Clinical Care of Women with HIV*. Rockville, MD: Health Services and Resources Administration; 2005. Available online at hab.hrsa.gov/publications/womencare05/. Accessed May 20, 2006.
- American Academy of HIV Medicine. *Pain Management. The HIV Medicine Self-Directed Study Guide (2003 ed.)*. Los Angeles: AAHIVM; 2003.
- Association of Nurses in AIDS Care. *Pain*. In: Kirton C, ed. *Core Curriculum for HIV/AIDS Nursing, 2nd ed.* Thousand Oaks, CA: Sage Publications; 2003:143-155.
- Breitbart W. *Suicide Risk and Pain in Cancer and AIDS*. In: Chapman CR, Foley KM, eds. *Current and Emerging Issues in Cancer Pain: Research and Practice.* New York: Raven Press; 1993:49-66.
- Hahn K, Arendt G, Braun JS, et al. *A placebo-controlled trial of gabapentin for painful HIV-associated sensory neuropathies.* J Neurol. 2004 Oct;251(10):1260-6.
- O'Neill WM, Sherrard JS: *Pain in human immunodeficiency virus disease: a review.* Pain. 1993 Jul;54(1):3-14.
- Singer EJ, Zorilla C, Fahy-Chandon B, et al. *Painful symptoms reported by ambulatory HIV-infected men in a longitudinal study*. Pain. 1993 Jul;54(1):15-9.
- Slaughter A, Pasero C, Manworren R. *Unacceptable pain levels*. Am J Nurs. 2002 May;102(5):75, 77.
- Swica Y, Breitbart W. *Treating pain in patients with AIDS and a history of substance use*. West J Med. 2002 Jan;176(1):33-9.
- U.S. Department of Health and Human Services. *Management of Cancer Pain*. Rockville, MD: Department of Health and Human Services; 1994.
- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. October 10, 2006. Available online at aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 7, 2007.
- Weinreb NJ, Kinzbrunner BM, Clark M. *Pain Management*. In: Kinzbrunner BM, Weinreb NJ, Policzer JS, eds. *20 Common Problems: End-of-life Care.* New York: McGraw Hill Medical Publishing Division; 2002:91-145.
- World Health Organization. *Cancer Pain Relief and Palliative Care, Report of a WHO Expert Committee.* Geneva: World Health Organization; 1990.

Palliative Care and HIV

Background

Palliative care is not curative care, but is supportive, symptom-oriented care. It is usually needed throughout the course of disease progression to relieve patients' suffering and promote quality of life. Palliative care is important for patients with any medical condition. It may be used in conjunction with disease-specific care or as the sole approach to care. Palliative care includes the following:

- Management of symptoms (eg, fatigue, pain)
- Treatment of adverse effects (eg, nausea, vomiting)
- Psychosocial support (eg, depression, advance care planning)
- End-of-life care

Following is the widely used definition of palliative care according to the World Health Organization:

> Palliative medicine is the study and management of patients with active, progressive, far advanced disease for whom the prognosis is limited and the focus of care is the quality of life. [It is] the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social, and spiritual problems, is paramount. The goal of palliative care is achievement of the best quality of life for patients and their families.

Palliative care in AIDS patients comprises a continuum of treatment consisting of therapy directed at AIDS-related illnesses (eg, infection or malignancy) and treatments focused on providing comfort and symptom control throughout the life span. This care may involve multidimensional and multidisciplinary services, including HIV medicine, nursing, pharmacy, social work, complementary/alternative medicine, and physical therapy.

Palliative Care in the Era of Antiretroviral Therapy

With advances in HIV-specific therapy and care, HIV infection is no longer a rapidly fatal illness. Instead, those patients who are able to tolerate antiretroviral therapy (ART) often experience a manageable, chronic illness.

The death rate from AIDS, however, continues to be significant: approximately 15,000-16,000 per year in the United States. In many parts of the world, patients are not able to obtain specific treatments for HIV or for opportunistic illnesses, and supportive or palliative care may be the primary mode of care available to patients with advanced AIDS. Regardless of access to disease-specific treatment, people living with HIV continue to experience symptoms from HIV disease and its comorbid conditions, and those taking ART may experience adverse effects. Integrating palliative care with disease-specific care is important in the treatment of patients with HIV to promote quality of life and to relieve suffering.

S: Subjective

The patient with advanced HIV disease complains of 1 or more of the following:

- Agitation
- Anorexia
- Chronic pain
- Constipation
- Cough
- Decubitus ulcers or pressure sores
- Delirium
- Dementia
- Depression
- Diarrhea
- Dry skin
- Dyspnea
- Fatigue
- Fever
- Increased secretions *("death rattle")*
- Nausea
- Pruritus
- Sweats
- Vomiting
- Weakness
- Weight loss

O: Objective

Conduct a complete symptom-directed physical examination.

A: Assessment and P: Plan

Treatment

Table 1 lists common symptoms of AIDS and their possible causes. Also included are disease-specific treatments and palliative interventions. Depending on the situation, either or both of these treatments may be appropriate. Consider the patient's disease stage and symptom burden, the risks and benefits of therapies, and the patient's wishes. Practitioners should note that some of the palliative treatments may have substantial long-term adverse effects and should be used to alleviate symptoms only in late-stage or dying patients.

Table 1. Common Symptoms in Patients with AIDS and Possible Disease-Specific and Palliative Interventions

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment*
CONSTITUTIONAL			
Fatigue, weakness	• AIDS • Opportunistic infections (OIs) • Anemia	• ART • Treat specific infections • Erythropoietin, transfusion	• Psychostimulants (methylphenidate, pemoline, dextroamphetamine, modafinil) • Testosterone/androgens • Corticosteroids (prednisone, dexamethasone)
Weight loss/ anorexia	• HIV • Malignancy	• ART • Chemotherapy • Nutritional support/enteral feedings	• Testosterone/androgens • Oxandrolone • Megestrol acetate • Dronabinol • Recombinant growth hormone • Corticosteroids
Fevers, sweats	• Disseminated MAC and other infections • HIV lymphoma, and other malignancies	• Specific treatment of OIs or malignancy • ART	• Nonsteroidal anti-inflammatory drugs (NSAIDs, ibuprofen, naproxen, indomethacin) • Anticholinergics (hyoscine, thioridazine) • H2-antagonists (cimetidine)
PAIN			
Nociceptive, somatic, visceral	• Opportunistic infections • HIV-related malignancies, nonspecific	• Specific treatment of disease entities	• NSAIDS • Opioids • Corticosteroids

Neuropathic	• HIV-related peripheral neuropathy
	• Cytomegalovirus (CMV)
	• Varicella zoster virus (VZV)
	• Medications (eg, dideoxynucleosides: didanosine, zalcitabine, stavudine), isoniazid, vincristine
		• ART
		• Discontinue offending medication;
		• Change antiretroviral or other regimen
			• NSAIDS
			• Neuropathic pain medications:
			  ◦ tricyclics (amitriptyline, imipramine)
			  ◦ benzodiazepines (clonazepam)
			  ◦ anticonvulsants (gabapentin, lamotrigine)
			• Opioids (eg, methadone) and adjuvants
			• Corticosteroids
			• Acupuncture

GASTROINTESTINAL			
Nausea, vomiting	• Antiretroviral medications • Esophageal candidiasis • CMV	• Specific treatment of disease entities • Change antiretroviral regimen	• Dopamine antagonists (prochlorperazine, haloperidol) • Prokinetic agents (metoclopramide) • Antihistamines (diphenhydramine, promethazine) • Anticholinergics (hyoscine, scopolamine) • Serotonin antagonists (granisetron, ondansetron, dolasetron) • H2 blockers (cimetidine) • Proton pump inhibitors (omeprazole) • Somatostatin analogues (octreotide) • Benzodiazepines (lorazepam) • Marijuana, dronabinol
Diarrhea	• MAC • Cryptosporidiosis • CMV microsporidiosis • Other intestinal infections • Malabsorption • Medications (eg, protease inhibitors)	• Specific treatment of disease entities • Discontinue offending medication	• Bismuth, methylcellulose • Psyllium • Kaolin • Diphenoxylate + atropine • Loperamide • Calcium carbonate • Ferrous sulfate • Octreotide • Tincture of opium

Constipation	• Dehydration
	• Malignancy
	• Anticholinergic medications
	• Opioids
		• Hydration
		• Radiation and chemotherapy
		• Medication adjustment
			• Activity/diet
			• Prophylaxis for patients taking opioids
			• Peristalsis-stimulating agents:
			  ◦ anthracenes (senna)
			  ◦ polyphenolics (bisacodyl)
			  ◦ Softening agents:
			  –surfactant laxatives (docusate)
			  –bulk-forming agents (bran, methylcellulose)
			  –osmotic laxatives (lactulose, sorbitol)
			  –saline laxatives (magnesium hydroxide)

RESPIRATORY			
Dyspnea	• PCP • Bacterial pneumonia • Anemia • Pleural effusion, mass, or obstruction • Decreased respiratory muscle function	• Specific treatment of disease entities • Erythropoietin, transfusion • Drainage, radiation, or surgery	• Use of fan, open windows, oxygen • Opioids • Bronchodilators • Methylxanthines • Benzodiazepines (eg, lorazepam)
Cough	• PCP, bacterial pneumonia • TB • Acid reflux • Postnasal drip	• Specific treatment of disease entities	• Cough suppressants (dextromethorphan, codeine, other opioids) • Decongestants, expectorants (various)
Increased secretions ("death rattle")	• Fluid shifts • Ineffective cough • Sepsis • Pneumonia	• Antibiotics as indicated	• Atropine, hyoscine, transdermal scopolamine, glycopyrrolate • Fluid restriction, discontinue intravenous fluids

DERMATOLOGIC			
Dry skin	• Dehydration • End-stage renal disease • End-stage liver disease • Malnutrition medications (eg, indinavir)	• Hydration • Dialysis • Nutritional support • Discontinue offending medication	• Emollients with or without salicylates • Lubricating ointments or creams (eg, petrolatum, Eucerin)
Pruritus	• Fungal infection • End-stage renal disease • End-stage liver disease • Dehydration • Eosinophilic folliculitis	• Antifungal agents (itraconazole for eosinophilic folliculitis) • Dialysis • Hydration • Topical corticosteroids	• Topical agents (menthol, phenol, calamine, doxepin, capsaicin) • Antihistamines (doxepin - oral, diphenhydramine) • Corticosteroids (topical or systemic) • Serotonin antagonists (ondansetron) • Opioid antagonists (naloxone, naltrexone) • Antidepressants • Anxiolytics • Neuroleptics • Thalidomide
Decubitus ulcers, Pressure sores	• Poor nutrition • Decreased mobility, prolonged bed rest	• Increase mobility • Enhance nutrition	• Prevention (nutrition, mobility, skin integrity) • Wound protection (semipermeable film, hydrocolloid dressing) • Debridement (normal saline, enzymatic agents, alginates)
NEUROPSYCHIATRIC			
Delirium/agitation	• Electrolyte imbalances, glucose abnormalities • Dehydration • Toxoplasmosis • Cryptococcal meningitis • Sepsis • Medication adverse effects (eg, benzodiazepines, opioids, efavirenz) • Intoxication	• Correct imbalances • Hydration • Specific treatment of disease entities • Discontinue offending medications	• Neuroleptics (haloperidol, risperidone, chlorpromazine) • Benzodiazepines (eg, lorazepam, midazolam) (Note: in some patients, these may have adverse effects.)
Dementia	• AIDS-related dementia • Other dementia	• ART	• Psychostimulants (methylphenidate) • Low-dose neuroleptics (haloperidol)
Depression	• Chronic illness • Reactive depression, major depression	• Antidepressants (SSRIs, tricyclics, other)	• Psychostimulants (methylphenidate, pemoline, dextroamphetamine, modafinil) • Corticosteroids (prednisone, dexamethasone)

Key to abbreviations: ART = antiretroviral therapy; MAC = *Mycobacterium avium* complex; NSAIDs = nonsteroidal antiinflammatory drugs; CMV = cytomegalovirus; PCP = *Pneumocystis jiroveci* pneumonia; TB = tuberculosis; SSRI = selective serotonin reuptake inhibitor.

* Some of the palliative treatments may have substantial long-term adverse effects and should be used to alleviate symptoms only in late-stage or dying patients.

Adapted with permission from Selwyn PA, Rivard M. Palliative care for AIDS: Challenges and opportunities in the era of highly active anti-retroviral therapy. Innovations in End-of-Life Care. 2002;4(3), Available at http://www.edc.org/lastacts.

Advance Care Planning

Advance care planning involves planning for future medical care. Two main documents are produced:

- Advance directive (living will)
- Health care proxy (a person to speak for the patient or make decisions if the patient is too sick to do so)

The clinician should initiate these conversations and make referrals to helpful resources.

Patient Education

- Discuss advance care planning with patients, and the option of hospice care, if appropriate.
- Provide the patient and his or her family with detailed information so that they understand the illness and associated treatments.
- Instruct patients to discuss their pain or other bothersome symptoms with their health care providers.
- Encourage patients to talk with their health care providers if they are feeling anxious, depressed, or fearful.
- Discuss with patients what their death might be like. Some patients may feel relieved to be able to talk openly about their last days. Assure them that their pain will be controlled and that their health care providers will be there to help them.

References

- American Academy of HIV Medicine. *Palliative Care. The HIV Medicine Self-Directed Study Guide* (2003 ed.). Los Angeles: AAHIVM; 2003.
- National Hospice Organization. *Guidelines for Determining Prognosis for Selected Non-Cancer Diagnoses.* Alexandria, VA: National Hospice Organization; 1996.
- O'Neill JF, McKinney M. *Caring for the Caregiver.* In: O'Neill JF, Selwyn PA, Schietinger H, eds. *The Clinical Guide to Supportive and Palliative Care for HIV/AIDS.* Rockville, MD: Health Resources and Services Administration; 2003. Available online at hab.hrsa.gov/tools/palliative/. Accessed May 20, 2006.
- Selwyn PA, Rivard M. *Palliative care for AIDS: Challenges and opportunities in the era of highly active anti-retroviral therapy.* Innovations in End-of-Life Care. 2002;4(3). Available online at www.edc.org/lastacts.
- Selwyn PA, Rivard M. *Palliative care for AIDS: challenges and opportunities in the era of highly active anti-retroviral therapy.* J Palliat Med. 2003 Jun;6(3):475-87.
- University of Washington Center for Palliative Care Education. *Module 1: Overview of HIV/AIDS Palliative Care.* Accessed February 7, 2006.
- U.S. Health Resources and Services Administration. *A Guide to Primary Care of People with HIV/AIDS, 2004 ed.* Rockville, MD: Health Resources and Services Administration; 2004:123-131. Available online at hab.hrsa.gov/tools/primarycareguide/. Accessed May 20, 2006.
- Weinreb NJ, Kinzbrunner BM, Clark M. *Pain Management.* In: Kinzbrunner BM, Weinreb NJ, Policzer JS, eds. 20 *Common Problems: End-of-life Care*. New York: McGraw Hill Medical Publishing Division; 2002:91-145.
- World Health Organization. *Cancer Pain Relief and Palliative Care, Report of a WHO Expert Committee.* Geneva: World Health Organization; 1990.

Correctional Settings

Background

Caring for the HIV-infected incarcerated patient is complex and challenging. For many of these patients, the prison health service provides their first opportunity for access to health care. HIV seroprevalence rates among inmates in the United States are 5 times higher than in the nonincarcerated population (CDC, 2001). Within the prison system in the United States, mortality due to AIDS has dropped dramatically since the advent of effective combination antiretroviral therapy (ART), with the number of AIDS-related deaths decreasing by 72% in state prisons between 1995 and 2002 (Maruschak, 2001).

Often, behaviors that lead to incarceration also put inmates at high risk for becoming infected with HIV, hepatitis C virus (HCV), and other infectious diseases. These risk factors may include unsafe substance use behaviors, such as sharing syringes and other injection equipment, and high-risk sexual practices, such as having multiple sex partners or unprotected sex. Many inmates also may have conditions that increase the risk of HIV transmission or acquisition, such as untreated sexually transmitted diseases (STDs).

Of the approximately 1.8 million inmates in the United States, 30-40% are infected with HCV. The incidence is 10 times higher among inmates than among noninmates and is 33% higher in women than in men (Nerenberg et al, 2002). Chronic hepatitis B virus (HBV) infection and tuberculosis are substantially more common in the incarcerated population than in the general public. The presence of any of these conditions should prompt HIV testing (Nicodemus and Paris, 2002).

Incarcerated Women

Women represent 5-10% of the prison population in the United States. The HIV epidemic in the United States increasingly affects women of color, and this trend is reflected in HIV rates among the incarcerated. Incarcerated women have higher HIV seroprevalence rates than incarcerated men (3% vs 1.9%). Several risk factors for HIV are present in abundance among female inmates, including the following:

- History of childhood sexual abuse and neglect
- History of sex work, with increased frequency of forced, unprotected sex
- High rates of STDs
- High rates of mental illness
- History of injection drug use (IDU) and/or sex partners with IDU history
- Poverty

Among all women entering a correctional facility, 10% are pregnant (De Groot and Cu Uvin, 2005). These women should be offered HIV testing, and HIV-infected pregnant women should be offered ART immediately to prevent perinatal HIV transmission. Many incarcerated women will receive their first gynecologic care in prison. Because the incidence of cervical cancer is higher in women with HIV, referrals for colposcopy should be made for any HIV-infected woman with an abnormal Papanicolaou test.

Testing and Prevention

The correctional facility is an ideal location for identifying those already infected with HIV, HCV, and/or HBV, and for preventing infection among those at highest risk for these diseases. The corrections setting is often the first site at which an HIV-infected person interacts with the health care system, making it an important avenue for HIV testing. HIV testing policies in correctional facilities vary from state to state and among local, state, and federal penal institutions. Depending on the setting, policies may require testing of inmates upon entry, upon release, or both. Testing may be based on clinical indication or risk exposure during incarceration, and may be voluntary or mandatory (Bartlett et al, 2000). The U.S. Centers for Disease Control and Prevention (CDC) recommends routine counseling and testing in settings with an HIV prevalence of 1% or higher. In high-risk settings such as correctional facilities, routine, voluntary HIV testing has been shown to be cost-effective and clinically advantageous (Paltiel, 2005).

Testing and treatment of HIV-infected inmates prior to release is critical. Given the high HIV seroprevalence rates among inmates, the reentry of inmates into the community presents the danger of spreading HIV and other infectious diseases, and thus is a public health

concern. Inmates need adequate HIV prevention counseling before release both to protect themselves and to decrease transmission of HIV to others in their communities (Gaiter, 1996).

Health care providers in correctional settings are in a key position to evaluate inmates for HIV risk factors, to offer HIV testing, and to educate and counsel this high-risk group about HIV. Inmates often are hesitant to be tested for HIV because of fear of a positive diagnosis and because of the potential stigma involved. Often, they lack accurate information about HIV, including awareness of behaviors that may have put them at risk and knowledge of means for protecting themselves from becoming infected.

The World Health Organization (WHO) has stated: "All inmates and correctional staff and officers should be provided with education concerning transmission, prevention, treatment, and management of HIV infection. For inmates, this information should be provided at intake and updated regularly thereafter" (see: http://www.who.int/en/). Risk reduction counseling addresses specific ways the inmate can reduce the risk of becoming infected with HIV. If already HIV infected, the goal of counseling is to reduce the risk of infecting others or becoming infected with a drug-resistant strain of HIV. Education should focus on the use of latex barriers with all sexual activity. Although condoms and dental dams are not available in most prisons and jails, the inmate should receive education regarding their proper use.

Inmates with a history of IDU should be educated that needle sharing conveys a high risk of transmitting HIV, HCV, and HBV. Substance abuse treatment should be provided when appropriate.

Recovery from addiction often is a chronic process and relapses are common. In addition to treatment, risk reduction strategies should include planning for support after release. For example, prior to release, inmates should be provided with information about needle exchange or clean needle access programs in their communities. These programs have proved to be quite effective in decreasing the rate of parenteral HIV transmission (CDC, 1999).

Antiretroviral Therapy in Correctional Facilities

In correctional facilities, as in any setting, a consideration of HIV treatment must begin with educating the patient about the risks and benefits of treatment and the need to fully adhere to the entire regimen, as well as with an assessment of the patient's motivation to take ART.

Correctional facilities have two medical policies for dispensing medications. Each has advantages and disadvantages that can impact treatment adherence.

Directly Observed Therapy

Directly Observed Therapy (DOT) is the system in which the inmate goes directly to the medical unit or pharmacy for all medication doses. This system offers the advantage of more frequent interaction between the patient and the health care team, allowing for earlier identification of side effects and other issues. In general, patients have better medication adherence in this system, resulting in better control of HIV. For some inmates, however, the need for frequent visits to the medical unit or pharmacy may be a barrier to treatment, particularly if they are housed at a distance from the unit. Another disadvantage of DOT is the potential loss of confidentiality, as many inmates feel that the frequency of treatment and the large number of pills they must take will reveal clues that they are HIV infected. In addition, this system puts the inmate in a passive role in terms of medication treatment and does not foster self-sufficiency.

Keep on Person

Keep on Person (KOP) is the system that allows the inmates to keep their medications in their cells and take them independently. Monthly supplies are obtained at the medical unit or pharmacy. This system offers greater privacy and confidentiality regarding HIV status. It also allows the inmate to develop self-sufficiency in managing medications, which may facilitate improved adherence upon release. However, as the KOP system involves less interaction with medical staff, problems with adherence can be more difficult to identify (Ruby, 2000).

In a study comparing DOT in HIV-infected inmates with KOP in nonincarcerated HIV-infected patients receiving ART as part of a clinical trial, a higher percentage of DOT patients achieved undetectable viral loads compared with the KOP patients (85% vs 50%) over a 48-week period (Fischl, 2001).

Adherence

Adherence is one of the most important factors in determining success of ART. For the HIV-infected inmate starting ART, a number of issues can affect medication adherence. These include patient-related factors, factors related to systems of care (including the medication dispensing systems described above), and medication-related factors. The following are suggestions for supporting adherence to ART.

Patient-Related Factors

- Provide alcohol and substance abuse treatment prior to initiating ART. Without appropriate treatment during incarceration, linkages to supports, and follow-up treatment upon discharge, the inmate is at risk for returning to high-risk behaviors that may interfere with adherence to ART.
- Utilize mental health consultation to identify inmates with psychiatric needs. Treatment for underlying mental health disorders should precede or occur simultaneously with the initiation of ART to ensure successful adherence. Depression and other psychiatric illnesses are more prevalent among inmates than among the general population (Maruschak, 2001).
- Correct misconceptions about HIV and ART that are common among inmates and could affect adherence adversely. The inmate should be educated about the disease process and the role of the medications, along with the potential risks and benefits of taking ART.
- Encourage participation in peer support groups. These can be effective ways to foster self-esteem, empower inmates to come to terms with a positive diagnosis, allay fears and correct misconceptions about HIV disease, and aid adherence. Upon release, telephone hotlines may be available to provide follow-up support and linkages to community services. To the extent possible, family and friends should be included in the education process.
- Use teaching tools that are appropriate in terms of language and reading level. Illiteracy and low-level reading ability are common among inmates. Diagrams and videos may be more effective than reading-intensive material in some cases. Basic HIV education prior to initiation of ART should include:
  - How the medications work
  - Consequences of nonadherence
  - Names and dosages of all medications
  - Potential side effects with strategies to manage them

Factors Related to Systems of Care

- Educate security staff about the importance of timely medication dosing, and communicate with other facilities in advance of a transfer; this can eliminate or limit missed doses.
- Schedule frequent follow-up medical visits in the early weeks after ART is initiated; these can make the difference in whether or not patients "stay the course."
- Consult with an HIV specialist, if possible. If a facility's medical provider lacks experience in treating patients with HIV, the results may be undertreatment of side effects, or ART prescribing errors. Because caring for HIV patients is complicated, HIV specialists can provide assurance that patients are receiving proper care. Of particular concern are patients whose current ART regimens are failing, those who are declining clinically, and those who are coinfected with other infectious diseases such as tuberculosis, HCV, and HBV.

Medication-Related Factors

Any consideration of HIV treatment must begin with educating the patient about the risks and benefits of treatment and the need to fully adhere to the entire regimen, as well as with assessing the patient's motivation to take ART.

- *Aggressively monitor and treat side effects.* The most common barrier to adherence to ART is side effects from the medications. The inmate should be educated in advance about potential adverse events to observe and report. In the first weeks after starting a new ART regimen, patients should be assessed frequently for side effects. For treating gastrointestinal toxicities, antiemetics and antidiarrheals should be available on an as-needed basis. As with all patients on ART, inmates should have appropriate laboratory monitoring.
- *Be aware of food requirements.* Various food requirements must be considered carefully when administering ART. This can be especially challenging in the correctional environment,

particularly if the facility does not allow inmates to self-administer medications. Make arrangements with prison authorities to provide food when inmates are taking medications that require administration with food.

- *Avoid complex regimens and regimens with large pill burdens, if possible.* Simple regimens with few pills appear to help improve adherence.
- *Avoid drug-drug interactions.* Some antiretroviral medications have clinically significant interactions with other drugs (eg, methadone, oral contraceptives, cardiac medications, antacids). These interactions may cause failure of either the antiretroviral drug or the other medication, or may cause additional toxicity. Consult an HIV specialist or pharmacologist for information on drug interactions.
- The patient should be questioned about medication adherence at each appointment.
- ART regimens need to fit into each patient's schedule and lifestyle. This becomes a bigger issue when the inmate is close to release. Education about HIV management, including ART adherence, should begin well before the inmate is discharged back to the community.At the time of discharge from the correctional facility, all HIV-infected inmates should have a discharge plan that addresses:
  - Housing
  - Health insurance
  - 30-day supply of HIV medications
  - Follow-up appointments for medical care and, if necessary, psychiatric and substance abuse care

A number of HIV education resources for inmates and correctional health care providers are cited on Albany Medical College's Web site at http://www.amc.edu/Patient/Services/HIV/HIVMedicine/index.html (go to the section on correctional education).

Chapter contributors

Minda Hubbard, ANP-C, Research Nurse Practitioner; Douglas G. Fish, MD, Medical Director; Sarah Walker, MS, Correctional Education Coordinator; and Abigail V. Gallucci, Director of HIV Education—Albany Medical College's Division of HIV Medicine (Upstate Local Performance Site and Regional Resource for Corrections, New York/New Jersey AIDS Education & Training Center).

References

- Bartlett J, Rappaport E, Ruby W, et al. *HIV in Corrections, Correctional Medical Institute.* Available online at www.cm-institute.org/hivin.htm. Accessed February 7, 2006.
- Centers for Disease Control and Prevention. *Drug Use, HIV, and the Criminal Justice System.* Available online at www.cdc.gov/idu/facts/druguse.htm. Accessed February 7, 2006.
- DeGroot A, Cu Uvin S. *HIV Infection among Women in Prison: Considerations for Care.* Infectious Diseases in Corrections Report. Vol. 8, Issues 5 & 6; 2005. Available online at www.idcronline.org/archives/mayjune05/article.html. Accessed May 22, 2006.
- Fischl M, Castro J, Monroid R, et al. *Impact of directly observed therapy on long-term outcomes in HIV clinical trials.* In: Program and abstracts of the 8th Conference on Retroviruses and Opportunistic Infections; February 4-8, 2001; Chicago, IL. Abstract 528.
- Maruschak L. *HIV in Prisons, 2000.* Bureau of Justice Statistics Bulletin, NCJ 196023; 2001. Available online at www.ojp.usdoj.gov/bjs/abstract/hivp00.htm. Accessed May 22, 2006.
- Nerenberg R, Wong M, DeGroot A. *HCV in corrections: Front line or backwater?* HEPP News. Vol 5 (4); 2002. Available online at www.idcronline.org/archives/april02/. Accessed May 22, 2006.
- Nicodemus M, Paris P. *Bridging the Communicable Disease Gap: Identifying, Treating and Counseling High Risk Inmates.* HIV Education Prison Project; August/September 2001. Accessed February 7, 2006.
- Paltiel AD, Weinstein MC, Kimmel AD, et al. *Expanded screening for HIV in the United States--an analysis of cost-effectiveness.* N Engl J Med. 2005 Feb 10;352(6):586-95.
- Ruby W, Tripoli L, Bartlett J, et al. *HIV in Corrections in Medical Management of HIV Infection.* Philadelphia: Lippincott, Williams & Wilkins; 2000.

Karnofsky Performance Scale

Background

The Karnofsky Performance Scale is an assessment tool used to assist clinicians and caretakers in measuring a patient's ability to carry out activities of daily living. It is important to assess a patient's performance on a regular basis, especially as the effects of HIV progress.

Documentation of Karnofsky scores may be very helpful if a patient applies for disability benefits, and may be useful for some research applications.

Table 1. The Karnofsky Performance Scale

Description	Percent (%)
Normal; no complaints; no evidence of disease	100
Able to carry on normal activity; minor signs and symptoms of disease	90
Normal activity with effort; some signs and symptoms of disease	80
Cares for self; unable to carry on normal activity or do work	70
Requires occasional assistance, but is able to care for most personal needs	60
Requires considerable assistance and frequent medical care	50
Disabled; requires special care and assistance	40
Severely disabled; hospitalization indicated although death not imminent	30
Very sick; hospitalization necessary; requires active support treatment	20
Moribund; fatal processes progressing rapidly	10
Dead	0

Sulfa Desensitization

Background

Trimethoprim-sulfamethoxazole (TMP-SMX), also known as Septra, Bactrim, and cotrimoxazole, is a key antibiotic for prophylaxis and treatment of several HIV-related illnesses. It is the most effective prophylaxis and the first-line treatment for *Pneumocystis jiroveci pneumonia* (PCP). In addition, it is effective in preventing toxoplasmosis encephalitis in severely immunocompromised patients who have evidence of previous infection, and it is effective against certain bacterial infections. TMP-SMX also is quite inexpensive, which is a rarity in the world of HIV treatment. Because of its effectiveness and availability, it is used widely throughout the world. However, adverse reactions to TMP-SMX and other sulfa drugs occur in a high proportion of HIV-infected patients (roughly 25%), and such reactions may limit treatment.

Desensitization to TMP-SMX should be considered when there are no reasonable or available alternatives and the patient has not experienced severe reactions (eg, Stevens-Johnson syndrome) to sulfa drugs. Several methods of desensitizing patients with previous reactions to TMP-SMX have been tried. These methods vary in starting dosage and length of dosage escalation, but success rates are around 80% in most cases and may be higher in those patients with <200 CD4 cells/μL.

S: Subjective

The patient reports a previous adverse reaction to sulfa drugs, such as erythema, pruritus, or rash. The patient has no history of anaphylaxis, Stevens-Johnson syndrome, or toxic epidermal necrolysis, and no reaction involving vesiculation, desquamation, ulceration, exfoliative dermatitis, etc.

O: Objective

CD4 count <200 cells/μL, or other important indication for TMP-SMX.

A: Assessment

Reaction to sulfa, possibly reversible with desensitization protocol.

P: Plan

Begin 9- to 13-day desensitization protocol, starting with pediatric oral suspension, which contains 40 mg of TMP and 200 mg of SMX per 5 mL (1 teaspoon). Gradually increase the dosage according to the protocol.

If there is any question about the severity of a previous reaction, have the patient take the initial morning dose in the clinic so that the patient may be monitored for 3-4 hours before going home. (This assumes that emergency treatment, including IV access materials and IV fluids, antihistamines, and steroids, are readily available.)

Treat with an antihistamine medication 1 day before starting the desensitization regimen and continue daily until the dose escalation is completed.

More rapid desensitization protocols are available (see References below) for patients urgently needing treatment with TMP-SMX.

Desensitization Regimen

Use commercially available pediatric suspension (containing TMP 8 mg and SMX 40 mg per mL), followed by double-strength tablets, as follows:

Table 1. Sulfa Desensitization Regimen

Days	Dosage (TMP/SMX)	Volume or Tablet
1-3	8 mg/40 mg	1 mL
3-6	16 mg/80 mg	2 mL
5-9	40 mg/200 mg	5 mL
7-12	80 mg/400 mg	1/2 double-strength tablet (or 1 single-strength tablet)
9-10 and thereafter	160 mg/800 mg	1 double-strength tablet

In the event of mild reaction: If the patient experiences a mild reaction or itching, the same dosage should be given for an additional day. If the reaction diminishes, the patient may advance to the next dosage; if the reaction worsens, the TMP-SMX should be discontinued. Antihistamines or antipyretics may be used to treat symptoms of mild reactions.

In case of severe reaction: the desensitization regimen should be discontinued.

Patient Education

For home desensitization regimen

Explain the benefits of using TMP-SMX. Be sure the patient understands and is able to follow instructions.

- Measure your dose carefully and take it each morning, followed by a glass (6-8 oz) of water. (The patient should do a demonstration, if possible, using the syringe that will be used for the actual measuring at home.)
- TMP-SMX can make you very ill unless you pay attention to any problems you have. It is extremely important that you check your temperature each afternoon. If your temperature is more than 100.5° F by mouth, stop taking the drug and contact your clinician. Note: If you have shaking chills, check your temperature as soon as the shaking stops, and contact the clinic. If you continue the medication despite a red rash and/or fever, serious illness or a life-threatening reaction may occur. Report any adverse event immediately.
- Stop the regimen and return to the clinic or emergency room immediately if you develop a red rash, blisters on your skin or in your mouth, or vomiting. Check your skin each evening, and any time you notice itching.

If you have mild itching or a faint rash, you can take diphenhydramine (Benadryl) 25-50 mg. every 4 hours as needed. If this persists, stay with the same dosage for an additional day; and call or go to the clinic if you have questions or concerns.

- Call or go to the clinic for alternate dosage instructions in the event of persistent itching without rash.

For all desensitized patients

- After desensitization is complete, continue to take the daily dosage. If the drug is stopped, the entire regimen may have to be repeated.

References

- Bartlett JG, Cheever L. *A Guide to Primary Care of People with HIV/AIDS*, 2004 Edition. Rockville, MD: Department of Health and Human Services, HIV/AIDS Bureau. 2004. Available online at hab.hrsa.gov/tools/primarycareguide/.
- Carr A, Penny R, Cooper DA. *Efficacy and safety of rechallenge with low-dose trimethoprim-sulphamethoxazole in previously hypersensitive HIV-infected patients.* AIDS. 1993 Jan;7(1):65-71.
- Conant M, Dybul M. *Trimethoprim-sulfphamethoxazole hypersensitivity and desensitization in HIV disease.* In: Program and abstracts of the VIII International Conference on AIDS/III STD World Congress; July 19-24, 1992; Amsterdam. Abstract PO-B-3291.
- Leoung GS, Stanford JF, Giordano MF, et al. *Trimethoprim-sulfamethoxazole (TMP-SMZ) dose escalation versus direct rechallenge for Pneumocystis Carinii pneumonia prophylaxis in human immunodeficiency virus-infected patients with previous adverse reaction to TMP-SMZ.* J Infect Dis. 2001 Oct 15;184(8):992-7.
- Nguyen MT, Weiss PJ, Wallace MR. *Two-day oral desensitization to trimethoprim-sulfamethoxazole in HIV-infected patients.* AIDS. 1995 Jun;9(6):573-5.
- Piketty C, Gilquin J, Kazatchkine MD. *Efficacy and safety of desensitization to trimethoprim-sulfamethoxazole in human immunodeficiency virus-infected patients.* J Infect Dis. 1995 Aug;172(2):611.
- Torgovnick J, Arsura E. *Desensitization to sulfonamides in patients with HIV infection.* Am J Med. 1990 May;88(5):548-9.
- White MV, Haddad ZH, Brunner E, et al. *Desensitization to trimethoprim sulfamethoxazole in patients with acquired immune deficiency syndrome and Pneumocystis carinii pneumonia. Ann Allergy.* 1989 Mar;62(3):177-9.

Patient Education

Background

It has long been acknowledged that informed and empowered patients are better able to achieve healthy outcomes due to improved communication and development of trust with their care providers. HIV patient education provides patients with knowledge about HIV infection and tools to enable them to participate more actively in decisions regarding their medical care. Given the complexity and the rapid evolution of HIV information, patients should be given ample and multiple opportunities to receive this information and to learn of updates in our understanding of HIV care. Similarly, the clinical management of HIV patients should include educating the patient on the various aspects of living with HIV infection. This chapter will review the areas that should be addressed in patient education and discuss some strategies for integrating patient education into HIV care.

S: Subjective

A newly diagnosed patient presents to clinic after being referred from a testing center in the community. He received his positive HIV results more than a year ago, but it took him this long to seek care. He wasn't ready to hear that he was "going to die." Now, he is ready to consider facing his "terminal" illness. He received some information about HIV infection at the testing center, but that was several months ago.

O: Objective

See *Initial History, Initial Physical Examination*, and *Initial and Interim Laboratory* and *Other Tests* chapters.

A: Assessment/Plan

This patient will need extensive information and education about HIV infection in general, his individual health status and prognosis, and the support and care systems available to him. Below are some suggestions about specific areas to review with a new patient.

What Should Be Included in Patient Education?

Patient education should cover the following topics:

- What is HIV?
- How HIV is transmitted
- Prognosis/progression of HIV
- Interpretation of lab results
- Treatment information
  - Indications for treatment, goals of treatment
  - General information regarding the benefits of treatment
  - General information regarding potential side effects of treatment
  - Access to medication
  - Insurance information
- Treatment options
- Prevention for positives
- Support services and support groups available to the patient

Who Should Provide Patient Education?

In most clinics, various personnel may take on the responsibilities of providing health education to patients. They may include primary care providers, nurses, social workers, case managers, and pharmacists. Some clinics have designated health educators whose role is to provide this type of support for patients. Even when a formal health educator is available, a collaborative, multidisciplinary approach to patient education serves both patients and providers optimally. However, it is important to ensure that patient education messages are coordinated and that patients are receiving consistent information.

Patient education must be provided in a language and at a literacy level appropriate for the patient. Patient education should be conducted in the patient's primary language, if possible; otherwise, skilled medical interpreters should be involved.

How Should Patient Education Be Provided?

Rarely are patients able to absorb all of the necessary information in a single session. Attention and comprehension levels are optimal during the first 15-20 minutes of a visit, after which an individual's ability to absorb and retain information declines. Therefore, clinics should consider strategies to integrate these patient education messages throughout the course of patient care and to engage patients in this process. Support groups, case managers, and peer educators can be invaluable in this process of engagement.

It is also important to keep the medical information specific to the patient. Although there are some areas of education that should be considered for all patients (see above), patients should not be required to have a high level of understanding in each area. Patients should be given the opportunity to learn as much about an area as they would like and to retain the volume of information necessary to keep them healthy and safe. For example, in the area of "What is HIV?" there may be some patients who want to know details about the basic science and immunologic impact of HIV. With this information, these patients might then want to take the lead in making treatment and care decisions for themselves, in consultation with their care providers. Other patients, however, would feel overwhelmed by this volume of information and involvement and may be best engaged in participating in their care by knowing how HIV is transmitted, how to keep themselves healthy, and how to access more information if they want it. Some patients would prefer for their care providers to "just tell them what to do" rather than take the lead in their own treatment decisions.

There are a number of Web sites that provide HIV information for patients (see *Web-Based Resources* chapter). Many patients may prefer this form of self-education. Encourage patients to bring any information they discover to clinic for further discussion. Reminding patients that they can be teachers as well as students can be a useful strategy for engaging patients in this process. In addition, patients may learn of novel tools and information sources that could be useful to others.

The following are some useful suggestions that providers can convey to their patients:

- Define your goals for each visit; please let your provider know your concerns and what you hope to learn in the course of the visit.
- Write down questions and concerns as they arise, and take that list with you to your appointments.
- Meet all the members of your care team and learn their areas of expertise and what they might be able to offer you.
- Ask about support groups and other peer groups that might be able to provide support/education.
- Review brochures and/or Web sites that provide additional information.
- Ask supportive friends or family members to accompany you to clinic visits. They may be able to obtain information that is helpful for their role in supporting your health or reminding you of information discussed at visits.

Web-Based Resources

Background

The care and management of HIV-infected patients is a rapidly evolving field. Keeping up to date with clinical information about HIV care has in the past required attendance at national and international conferences. With the increasing availability of the Internet, clinicians and patients are able to access the most current advances through Web coverage, without requiring travel or time away from work.

The challenge of using Internet resources is in determining which Web sites are accurate and current. Check for dates of authorship, the credentials of the site sponsors and authors, and how well supported any recommendations or analysis may be. Be aware of any possible commercial bias. Finally, it is important to remember that information on these sites does not replace clinical judgment or consultation with HIV experts.

Listed below are a selection of useful and accurate Internet sites. Many of these Web sites also link out to additional information resources, and many allow users to subscribe to receive updates via email. Many providers find it helpful to review sites geared toward patients, in order to maintain familiarity with patients' concerns and patient-based information resources.

Web-Based Resources for Providers

- **AIDS Education and Training Centers National Resource Center**
  http://www.aidsetc.org
  Clinical training resources, including curricula, self-study, and slide sets, including slides for all national guidelines. Online home for the Clinical Manual for Management of the HIV-Infected Adult.
- **AIDSInfo**
  http://aidsinfo.nih.gov
  Official repository for HIV/AIDS information from the U.S. Public Health Service. Content includes HIV/AIDS treatment guidelines, national clinical trial information, drug and vaccine overviews, and fact sheets for patients.
- **Aidsmap**
  http://www.aidsmap.org
  London-based HIV/AIDS news and treatment information site. Patient information written at both lower and higher literacy levels. International focus.
- **Clinical Care Options for HIV**
  http://clinicaloptions.com
  CME materials related to HIV/AIDS including conference reviews.
- **HIV InSite**
  http://hivinsite.ucsf.edu
  Major HIV/AIDS portal from the University of California San Francisco. Includes HIV InSite Knowledge Base, updated ARV information, including an interactions database, global country profiles, and links out to other useful sites.
- **HIV Resistance Web**
  http://hivresistanceweb.com
  Information on resistance mutations to antiretroviral medications.
- **HIV Web Study**
  http://hivwebstudy.org
  Northwest AETC, University of Washington. Dozens of online clinical cases featuring downloadable tables, charts, and images.

- **HIVandHepatits.com**
  http://www.hivandhepatitis.com/
  Clinical information on HIV and hepatitis B and hepatitis C viruses, including conferences reviews.
- **International Training and Education Center on HIV**
  http://go2itech.org
  The international AETC. Web site features extensive database of international HIV/AIDS training materials.
- **International AIDS Society-USA**
  http://iasusa.org
  ARV resistance mutations charts and "Cases on the Web" online CME courses.
- **Johns Hopkins AIDS Service**
  http://www.hopkins-aids.edu/
  Major clinical information site that includes expert Q&A, the popular Pocket Guide to Adult HIV/AIDS Treatment, and the online and PDA-based POC-IT HIV Guide.
- **Medscape HIV/AIDS Topic Area**
  http://www.medscape.com/hiv-home?src=pdown
  Continuing Medical Education (CME) materials related to HIV/AIDS, including conference coverage, news, and special features.
- **National HIV/AIDS Clinicians' Consultation Center**
  http://www.ucsf.edu/hivcntr
  An AIDS Education and Training Centers clinical resource for health care professionals, with contact information for the Warmline, PEPline, and Perinatal HIV Hotline.
- **VA National HIV/AIDS Program**
  http://www.hiv.va.gov/
  Comprehensive information portal for patients and providers.
- **Women, Children, and HIV**
  http://www.womenchildrenhiv.org/
  Expert-selected, evidence-based information on prevention of mother-to-child transmission of HIV, care of women and children with HIV, and related topics.

Web-Based Resources for Patients and the Community

- **AIDS.org**
  http://www.aids.org/
  Online home of AIDS Treatment News.
- **AIDS InfoNet**
  http://www.aidsinfonet.org/
  Comprehensive collection of fact sheets on clinical topics, available in English and Spanish, in print-friendly and downloadable formats. Regularly updated.
- **AIDSmeds**
  http://aidsmeds.com
  Information regarding HIV-related medications for patients, including drug interactions calculator.
- **AIDS Project Los Angeles**
  http://www.apla.org/
  Fact sheets, newsletters, and program information. Some information in Spanish.
- **The Body**
  http://thebody.com
  Major HIV information resource geared toward patients and the community.
- **Gay Men's Health Crisis**
  http://www.gmhc.org/
  Patient and program information from one of the oldest community organizations. Some information in Spanish.
- **Project Inform**
  http://projectinform.org
  Comprehensive information and advocacy information geared toward individuals infected and affected by HIV.
- **San Francisco AIDS Foundation**
  http://www.sfaf.org/
  AIDS 101, BETA treatment newsletter, and prevention and program information. Some information in Spanish.
- **Test Positive Aware Network (TPAN)**
  http://www.tpan.com/index.shtml
  Chicago-based community organization with newsletter, drug guide, and service information.
- **VA National HIV/AIDS Program**
  http://www.hiv.va.gov/
  Comprehensive information portal for patients and providers.

Pain Management

Addiction

Pain Management

- The under-treatment of pain has been identified as a serious problem in this country. The DCHCS believes that pain management is an essential aspect of quality medical practice for all inmate-patients with acute or chronic pain.

- Pain should be assessed and treated promptly, effectively, and for as long as the pain persists.

- It is important to recognize that pain is a subjective complaint, and that the degree of pain an inmate-patient is experiencing may not be reflected by objective findings.

- Pain treatment may involve the use of medications and/or non-pharmacological treatment modalities.

- For some patients, opioid analgesics, when used as directed, are the most effective, and at times the only, treatment option that provides significant relief.

Pain management in the prison setting is a complex issue.

- Many inmate-patients suffer from acute trauma, terminal illnesses, HIV disease and non-cancer chronic pain and/or have histories of serious trauma such as head injuries, gun shot wounds, and motor vehicle/motorcycle accidents.

- Many of these inmate-patients also have a history of substance use/abuse. Inmate-patients with a history of drug addiction are less likely to receive adequate pain management.

- Many clinicians and nurses fear that they are being manipulated by inmate-patients with substance abuse histories or intrinsically believe that these inmate-patients are undeserving of adequate pain relief.

- Many others under-treat pain due to a concern that they may exacerbate inmate-patients' problems with addiction. Such attitudes lead to inappropriate health care decisions. Health care professionals must ensure that the most effective pain medications are available to those inmate-patients who need them, whether or not they have a history of substance abuse.

PAIN MANAGEMENT GUIDELINES

The following guidelines, adapted from the Medical Board of California's statement on pain management, are intended to assist the clinician in providing effective pain management by avoiding under treatment, over treatment or other inappropriate treatment of an inmate-patent's pain.

History/Physical Examination

A medical history and physical examination must be performed. This includes an assessment of the pain (including its effect on physical and psychological function), a substance abuse history, a history of prior pain treatment and an assessment of underlying or coexisting diseases or conditions.

Treatment Plan

The treatment plan should state objectives by which the plan can be evaluated, such as pain relief and/or improved physical and psychosocial function and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each inmate-patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Informed Consent

The clinician should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the inmate-patient.

Periodic Review

The clinician should periodically review the treatment plan and its effectiveness with the inmate-patient. Continuation or modification of the treatment plan depends on the clinician's evaluation of progress toward the treatment objectives and the inmate-patient's compliance with the plan.

Consultation

The clinician should refer inmate-patients with complex pain problems to a pain medicine specialist for additional evaluation and treatment in order to achieve treatment objectives. In addition, clinicians should give special attention to those inmate-patients who are at risk for misusing or diverting their medications. Telemedicine services are available at headquarters.

Record Keeping

The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the inmate-patient and periodic reviews of the treatment plan.

REVIEW ARTICLE

MECHANISMS OF DISEASE

Drug Addiction

Jordi Camí, M.D., Ph.D., and Magí Farré, M.D., Ph.D.

DRUG ADDICTION IS A CHRONIC, RELAPSING DISORDER IN WHICH compulsive drug-seeking and drug-taking behavior persists despite serious negative consequences. Addictive substances induce pleasant states (euphoria in the initiation phase) or relieve distress. Continued use induces adaptive changes in the central nervous system that lead to tolerance, physical dependence, sensitization, craving, and relapse (Table 1). The addictive drugs discussed here are opioids, cannabinoids, ethanol, cocaine, amphetamines, and nicotine.

The World Health Organization[1] and the American Psychiatric Association[2] use the term "substance dependence" rather than "drug addiction." "Drug addiction," however, emphasizes the behavioral connotation of the term and is less likely to be confused with physical dependence.[3] We use both terms interchangeably in this review. The American Psychiatric Association's definition of substance dependence[2] requires a patient to meet at least three of the seven criteria listed in Table 1. Tolerance and physical dependence reflect physiological adaptation to the effects of a drug, whereas the remaining criteria define uncontrollable drug consumption. However, tolerance and physical dependence are neither necessary nor sufficient for a diagnosis of substance dependence. Substance abuse[2] or harmful use,[1] a less severe disorder, may result in dependence.

Theories of addiction have mainly been developed from neurobiologic evidence and data from studies of learning behavior and memory mechanisms. They overlap in some aspects and are not mutually exclusive. None of them alone can explain all aspects of addiction. It is not our purpose to present a detailed assessment of these theories, especially because of the complexity of the problem. Generally, addictive drugs can act as positive reinforcers (producing euphoria) or as negative reinforcers (alleviating symptoms of withdrawal or dysphoria). Environmental stimuli (cues) associated with drug use itself can also induce a conditioned response (withdrawal or craving) in the absence of the drug.[4,5]

Koob and Le Moal[6,7] have proposed that the organism tries to counteract the effects of a given drug through a vicious circle in which the hedonic set point (the point at which pleasure is achieved) continually changes in response to the administration of the substance. They argue that drug addiction results from dysregulation of the reward mechanism and subsequent allostasis, the ability to achieve stability through change. Robinson and Berridge[8,9] emphasize the dissociation between the incentive value of the drug ("wanting") and its pleasurable or hedonic effects ("liking"), so that the brain system involved in the reward mechanism becomes hypersensitized to both the direct effects of the drug and associated stimuli that are not directly attributable to the drug. This hypersensitization causes pathologic wanting, or craving, independently of the presence of withdrawal symptoms and leads to compulsive drug-seeking and drug-taking behavior. Although liking progressively decreases, drugs become pathologically wanted (craving). Complementary to this incentive–sensitization theory,[8,9] compulsive drug-seeking and drug-taking behavior is facilitated by difficulties in decision making and the ability to judge the consequences of one's own actions. These cognitive difficulties have been linked to deficits in the activation of areas in the prefrontal cortex.[10,11] An overlap in

From the Institut Municipal d'Investigació Mèdica (J.C., M.F.), Universitat Pompeu Fabra (J.C.), and Universitat Autònoma de Barcelona (M.F.) — all in Barcelona, Spain. Address reprint requests to Dr. Camí at Institut Municipal d'Investigació Mèdica, Doctor Aiguader 80, E-08003 Barcelona, Spain, or at jcami@imim.es.

N Engl J Med 2003;349:975-86.
Copyright © 2003 Massachusetts Medical Society.

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

Table 1. **Definitions of Terms Used in Drug Addiction.**

Craving (formerly called **psychological dependence**) is an intense desire to re-experience the effects of a psychoactive substance. Craving is the cause of relapse after long periods of abstinence.

Physical or physiological dependence is an outdated term that refers to physical tolerance and the withdrawal syndrome.

Priming refers to a new exposure to a formerly abused substance. This exposure can precipitate rapid resumption of abuse at previous levels or at higher levels.

Relapse is a resumption of drug-seeking or drug-taking behavior after a period of abstinence. Priming, environmental cues (people, places, or things associated with past drug use), and stress can trigger intense craving and cause a relapse.

Reward is a stimulus that the brain interprets as intrinsically positive or as something to be attained.

Sensitization is the increase in the expected effect of a drug after repeated administration (e.g., increased locomotor activation after the administration of psychostimulants). Sensitization also refers to persistent hypersensitivity to the effect of a drug in a person with a history of exposure to that drug (or to stress). Sensitization is one of the neurobiologic mechanisms involved in craving and relapse.

Substance abuse is characterized by recurrent and clinically significant adverse consequences related to the repeated use of substances, such as failing to fulfill major role obligations, use of drugs in situations in which it is physically hazardous, occurrence of substance-related legal problems, and continued drug use despite the presence of persistent or recurrent social or interpersonal problems.

Substance dependence is a cluster of cognitive, behavioral, and physiological symptoms indicating that a person is continuing to use a substance despite having clinically significant substance-related problems. For substance dependence to be diagnosed, at least three of the following must be present: symptoms of tolerance; symptoms of withdrawal; the use of a substance in larger amounts or for longer periods than intended; persistent desire or unsuccessful attempts to reduce or control use; the spending of considerable time in efforts to obtain the substance; a reduction in important social, occupational, or recreational activities because of drug use; and continued use of a substance despite attendant health, social, or economic problems.

Withdrawal syndrome is a constellation of signs and symptoms that follows the abrupt discontinuation or reduction in the use of a substance or after blockage of the actions of a substance with antagonists (e.g., naloxone in heroin addiction). The syndrome can also be produced by cues associated with substance use (**conditioned withdrawal**). Symptoms tend to be the opposite of those produced after short-term exposure to a drug. Withdrawal is one of the causes of compulsive drug-taking behavior and short-term relapse.

memory mechanisms and the mechanisms of drug addiction has also been proposed.[12]

FACTORS INFLUENCING DRUG ABUSE AND DEPENDENCE

PHARMACOLOGIC AND PHYSICOCHEMICAL PROPERTIES OF DRUGS

Pharmacologic and physicochemical properties of drugs are important factors in how drugs are consumed. Liposolubility increases the passage of a drug through the blood–brain barrier, water solubility facilitates the injection of a drug, volatility favors the inhalation of drugs in vapor form, and heat resistance favors smoking of the drug.[13] Characteristics such as rapid onset and intensity of effect increase the potential for abuse[14,15]; therefore, substances that rapidly reach high levels in the brain are usually preferred (e.g., flunitrazepam is preferred over triazolam, and smoking "crack" cocaine is preferred to intranasal administration).[16,17] A short half-life (e.g., that of heroin) produces more abrupt and intense syndromes of withdrawal than does a long half-life (e.g., that of methadone).[13]

PERSONALITY AND PSYCHIATRIC DISORDERS

Personality traits and mental disorders are major conditioning factors in drug addiction. Risk-taking or novelty-seeking traits favor the use of addictive drugs.[18] Polydrug use is frequent among those with drug addiction, and many fulfill the criteria for dependence on or abuse of (or both) more than one substance.[19] Psychiatric disorders, particularly schizophrenia, bipolar disorder, depression, and attention-deficit–hyperactivity disorder, are associated with an increased risk of abuse. A dual diagnosis (substance abuse and mental disorder) has unfavorable implications for management and outcome.[20]

GENETIC FACTORS

Genetic factors that influence the metabolism and the effects of drugs contribute to the risk of addiction.[21] Men whose parents were alcoholics have an increased likelihood of alcoholism even when they were adopted at birth and raised by parents who were not alcoholic, and they also have a reduced sensitivity to alcohol that predicts the development of alcoholism.[22] Carriers of an allele of aldehyde dehydrogenase that encodes an isoenzyme with reduced activity are less likely to abuse alcohol owing to the presence of increased levels of acetaldehyde, which is responsible for aversive effects.[23] A Leu7Pro polymorphism of the neuropeptide Y gene has been correlated with increased alcohol consumption,[24] and single-nucleotide polymorphisms of the gene encoding the μ opioid receptor correlates with an increased likelihood of heroin abuse.[25] A deficiency in the cytochrome P-450 2D6 gene blocks the enzymatic conversion of codeine to morphine, thereby preventing codeine abuse.[26]

With regard to nicotine dependence, subjects with defective cytochrome P-450 2A6 *2 and *4 alleles, which impair the metabolism of nicotine,

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

smoke fewer cigarettes and are less likely to be dependent than subjects who are homozygous for these alleles.[27] A single-nucleotide polymorphism in the gene encoding fatty acid amide hydrolase, a major endocannabinoid-inactivating enzyme, has recently been associated with both an increased likelihood of recreational use of illegal drugs and problem use of drugs or alcohol.[28] The minor (A1) allele of the *Taq*IA D2 dopamine receptor gene has been linked to severe alcoholism; polysubstance, psychostimulant abuse or dependence; and opioid and nicotine dependence.[29] Advances in genomic scanning (for quantitative trait loci) will allow the identification of allelic variants that contribute to the vulnerability to addiction.[30]

DRUG EFFECTS AND MECHANISMS OF ACTION

OPIOIDS

Short-term administration of heroin or morphine produces euphoria, sedation, and a feeling of tranquility. Repeated administration rapidly produces tolerance and intense physical dependence. Overdose can cause lethal respiratory depression. Numerous reports have documented impairments in health related to long-term heroin use.[31,32]

Opioids activate specific receptors (μ, δ, and κ) that couple the G protein (Fig. 1 and 2). Knockout mice lacking the μ receptor neither exhibit the behavioral effects induced by opioids nor become physically dependent when given opioids (Table 2). The μ receptor has also been implicated in mediating or modulating the rewarding effect of other drugs of abuse (e.g., cannabinoids). Mice in which different receptors (CB_1 cannabinoid and D2 dopamine receptors) and transporters (dopamine) have been knocked out have been used to demonstrate the effect of systems other than the opioid on opioid-induced pharmacologic responses.[33]

CANNABINOIDS

The use of marijuana or hashish produces feelings of relaxation and well-being and impairs cognitive function and performance of psychomotor tasks. Overdose can induce panic attack and psychosis.[34] A high incidence of cannabis consumption has been reported among patients with schizophrenia.[35] Symptoms of withdrawal — restlessness, irritability, and insomnia — are subtle and appear in heavy consumers.[36] The long-term effects of high doses of cannabinoids is a complex and controversial subject. Although there is evidence that long-term use of cannabis impairs memory,[37,38] the cause of the marijuana amotivational syndrome — loss of energy and drive to work — remains unclear.[34]

G-protein–coupled cannabinoid CB_1 receptors (Fig. 1 and 2), which are richly distributed in basal ganglia and cerebral-cortex regions, are implicated in cannabinoid abuse and addiction. In contrast to other neurotransmitters, endocannabinoids act as retrograde messengers at many central synapses. They are released from postsynaptic neurons and activate CB_1 receptors on presynaptic neurons, inhibiting the release of neurotransmitters.[39] Natural ligands of CB_1 receptors (anandamide, 2-arachidonylglycerol, and noladin ether) have a shorter period of action than synthetic or plant-derived cannabinoids.[39] Selective synthetic agonists and antagonists of CB_1 receptors are currently being developed for medical purposes.[40,41]

ETHANOL

When ethanol is given at low doses or initially during acute ethanol intoxication, it is perceived as a stimulant owing to the suppression of central inhibitory systems, but as the plasma levels of ethanol increase, sedation, motor incoordination, ataxia, and impaired psychomotor performance appear.[42] The withdrawal syndrome (seizures and delirium tremens) may be severe and clinically challenging. The long-term effects of ethanol consumption have been extensively reviewed elsewhere.[43,44]

Ethanol modifies the activity of serotonin (5-hydroxytryptamine$_3$ [5-HT_3]) receptors, nicotinic receptors, γ-aminobutyric acid type A ($GABA_A$) receptors, and the N-methyl-D-aspartate (NMDA) subtype of glutamate receptors. Ethanol acutely inhibits binding to the δ-opioid receptor, and long-term exposure to ethanol increases the density of μ and δ receptors.[45] Its actions on nearly all receptors are the result of a direct interaction with the receptor protein.[46]

COCAINE AND AMPHETAMINES

Short-term administration of psychostimulants such as amphetamine produces euphoria, a feeling of well-being, and alertness as well as increased arousal, concentration, and motor activity. These substances increase blood pressure and the pulse rate and induce the release of corticotropin-releasing factor, corticotropin, and cortisol.[47-49] Long-term use may cause irritability, aggressive and stereotyped behavior, and paranoid-like psychosis.

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

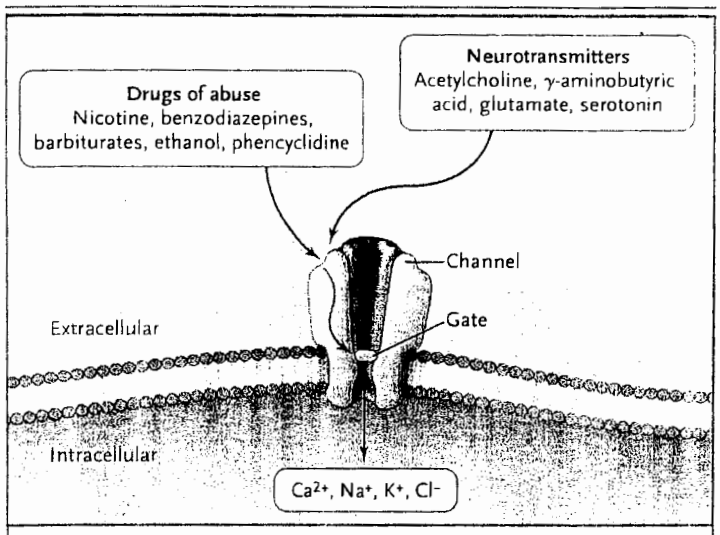


Figure 1. **Ionotropic Mechanisms of Action of Drugs of Abuse.**
Drugs of abuse are usually receptor agonists, such as endogenous neurotransmitters, that act on two different types of membrane receptors: ionotropic (shown in this figure) and metabotropic (shown in Fig. 2). Ionotropic receptors (ligand-gated ion channels) mediate fast synaptic transmission. The neurotransmitter or the drug binds to the receptor, which undergoes a conformational change, opening the gate and allowing ions to enter the cytoplasm and causing depolarization or polarization of the membrane and activation of various proteins. Nicotine binds to nicotinic cholinergic receptors, which contain a sodium channel. Benzodiazepines, barbiturates, and ethanol bind to γ-aminobutyric acid (GABA) type A receptors, facilitating the entry of chloride. Ethanol and phencyclidine inhibit *N*-methyl-D-aspartate–sensitive glutamate receptors, which contain calcium and sodium channels. Phencyclidine also acts as an antagonist.

Whereas signs of withdrawal can be mild (depression, lack of energy, and insomnia), craving is very intense.[50] So-called designer derivatives of amphetamine (3,4-methylenedioxymethamphetamine [MDMA], or "ecstasy") produce euphoria[51,52] and increased empathy (an "entactogenic" effect), but some derivatives have hallucinogenic effects. Acute intoxication with a psychostimulant can cause cerebral hemorrhage, hyperthermia and heat stroke, the serotonin syndrome, panic, and psychosis. The serotonin syndrome is characterized by altered mental status, autonomic instability, and neuromuscular abnormalities resulting in hyperthermia. So-called designer derivatives of amphetamine may have toxic effects on dopamine and serotonin neurons.[53,54]

Cocaine is a potent blocker of the dopamine-, norepinephrine-, and serotonin-uptake transporters. Amphetamines have a more complex mechanism of action. Amphetamines cause neuronal storage vesicles in the cytoplasm to release neurotransmitters to the synapse; inhibit the uptake of dopamine, norepinephrine, and serotonin by membrane transporters; and act as mild inhibitors of monoamine oxidase (Fig. 2). Amphetamine and methamphetamine seem to be more selective for dopamine and norepinephrine than for serotonin transporters, but MDMA and designer amphetamines are more selective for the serotonin transporter.[55]

OTHER ADDICTIVE SUBSTANCES

Nicotine binds to neuronal nicotinic acetylcholine receptors,[56] and barbiturates and benzodiazepines bind and modulate the ion-channel–gated $GABA_A$ receptors (Fig. 1 and 2).[57] The psychotomimetic actions of dissociative anesthesics (phencyclidine and ketamine) are mediated by their noncompetitive antagonism at the NMDA-sensitive glutamate receptor (ligand-gated ion channel).[58] Lysergide or mescaline (classic hallucinogens) are partial agonists at $5\text{-}HT_{2A}$ receptors,[58] whereas salvinorin A induces their effects through the activation of κ-opioid receptors.[59]

NEUROBIOLOGY

ANIMAL MODELS

Various animal behavioral paradigms have been used to study the neuronal substrates involved in addiction, especially euphoria and rewarding effects, including self-stimulation, self-administration, and conditioned place-preference models (Fig. 3).[60] In the place-preference model, the rewarding properties of a compound are associated with the particular characteristics of a given environment (place); after conditioning, the animal prefers to spend more time in the environment associated with the drug. Molecular studies have identified regulatory processes that occur after drug administration at the level of receptors, membrane transporters, and their associated signaling proteins. Useful strains of mice have been developed by genetically disrupting drug targets (receptors and transporters) or proteins in the pathways of these targets. Genetic alterations are generally present throughout development in these mice. Therefore, when the phenotypes of interest are absent, the effect of a drug could actually reflect compensatory changes in other neurobiologic systems.[33,61] To avoid this limitation, conditioned and tissue-specific knockout animals have been developed.[62]

For some drugs, the risk of abuse in humans can

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

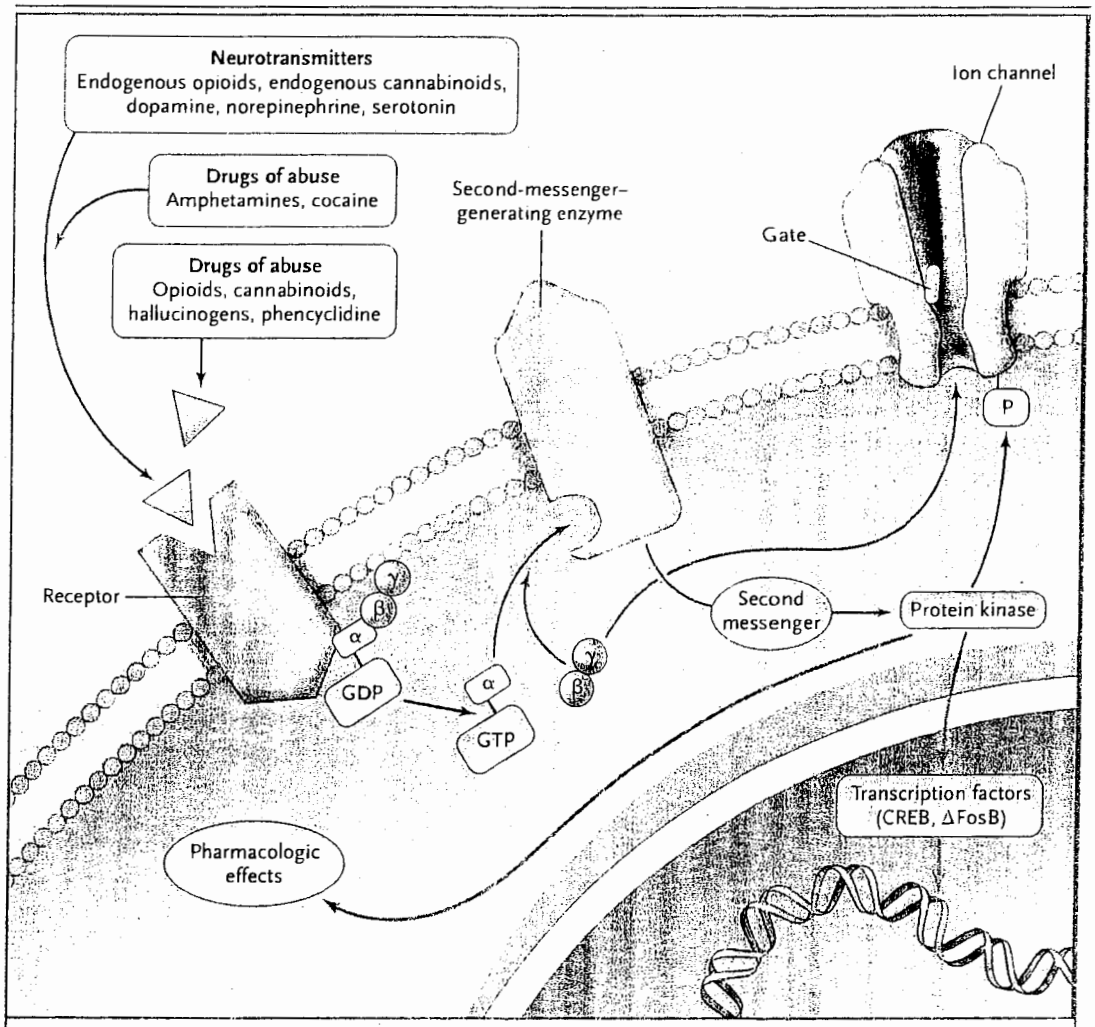


Figure 2. **Metabotropic Mechanisms of Action of Drugs of Abuse.**

Metabotropic (G-protein–coupled) receptors mediate slow synaptic transmission. G proteins are trimeric structures composed of two functional units: an α subunit that catalyzes GTPase activity (converting guanosine triphosphate [GTP] to guanosine diphosphate [GDP]), and a β–γ dimer that interacts with the α subunit when bound to GDP (inactive state). The binding of the agonist activates a nearby G protein. The α subunit bound to GTP subsequently dissociates from its β and γ subunits. Both can activate or inhibit enzymes (adenylyl cyclase or phospholipase C) that synthesize second messengers such as cyclic adenosine monophosphate (cAMP), cyclic guanosine monophosphate, inositol triphosphate, and diacylglycerol. In addition, the β and γ subunits directly regulate calcium-, sodium-, and potassium-ion channels. Second messengers also regulate ion channels by activating protein kinases, which phosphorylate (P) such channels. Protein kinases induce pharmacologic effects and produce changes in transcription factors such as cAMP-responsive element–binding protein (CREB) and ΔFosB. Opioids bind to opioid receptors (which reduce cAMP levels), and cannabinoids bind to cannabinoid receptors. Classic hallucinogens are partial agonists of serotonin receptors. Amphetamines and cocaine have an indirect action on receptors, increasing the synaptic levels of dopamine, norepinephrine, and serotonin (facilitating release and inhibiting reuptake, respectively). These neurotransmitters activate different subtypes of dopaminergic, adrenergic, and serotonergic receptors.

be predicted with the use of tests based on behavioral paradigms in animals. These methods, however, are not systematically used during the development of centrally acting drugs,[63] probably because the methods are not required by regulatory agencies.

NEUROANATOMICAL SUBSTRATES

The neuronal pathways of drug addiction are components of the mesocorticolimbic dopamine systems that originate in neurons in the ventral tegmental area (Fig. 4).[64] All drugs of abuse act on this

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

Table 2. Inactivation of Opioid Receptors in Knockout Mice.

Opioid Receptor That Is Knocked Out	Withdrawal Syndrome	Self-Administration Model*	Place-Preference Model*	Analgesia
μ Receptor	No	No	No	No
δ Receptor	Yes	Unknown	Unknown	Yes
κ Receptor	Yes (reduction in symptoms)	Unknown	Yes	Yes

* The model is defined in Figure 3.

system at different levels. The mesolimbic circuit includes projections from cell bodies of the ventral tegmental area to limbic structures, such as the nucleus accumbens, amygdala, and hippocampus. This circuit has been implicated in acute reinforcing effects, memory, and conditioned responses linked to craving and the emotional and motivational changes of the withdrawal syndrome. The mesocortical dopamine circuit includes projections from the ventral tegmental area to the prefrontal cortex, orbitofrontal cortex, and anterior cingulate. It is involved in the conscious experience of the effects of drugs, drug craving, and the compulsion to take drugs. The mesolimbic and the mesocortical dopamine circuits operate in parallel and interact with each other and with other areas — forming the so-called extended amygdala — by means of projections from the GABA neurons of the nucleus accumbens to the ventral tegmental area and prefrontal cortex and glutamatergic projections from the prefrontal cortex to the nucleus accumbens and ventral tegmental area.[11,12,64]

THE LEADING ROLE OF THE DOPAMINE PATHWAY

Both natural rewards (food, drink, and sex) and addictive drugs stimulate the release of dopamine from neurons of the presynaptic ventral tegmental area into the nucleus accumbens, causing euphoria and reinforcement of the behavior. In the case of natural rewards, there is a very rapid adaptive change, or habituation, after a few experiences, and the novelty or unexpectedness of the reward seems to play a major part in the initial response. The response to addictive drugs is not influenced by habituation, and each dose of the drug stimulates the release of dopamine.[65] Moreover, dopamine mediates the hedonic consequences of a reinforcing stimulus, promoting associative learning about the stimulus or anticipating its rewarding effects.[65] During the withdrawal syndrome associated with opioids, cannabinoids, ethanol, psychostimulants, and nicotine, there is a substantial decrease in dopamine levels in the nucleus accumbens.[66]

Dopamine binds to a G-protein–coupled receptor with two main subtypes, D1-like receptors (D1 and D5) and D2-like receptors (D2, D3, and D4). D1-like receptors activate adenylyl cyclase, whereas D2-like receptors inhibit the enzyme (Fig. 1 and 2). A membrane dopamine transporter moves the released neurotransmitter from the extracellular space back into the presynaptic neuron (uptake). Animals can be taught to self-administer D1-like and D2-like receptor agonists.[55,67]

Dopamine and Opioids

Opioids release dopamine mainly by an indirect mechanism that decreases the activity of GABA-inhibitory interneurons in the ventral tegmental area. Rodents can be taught to self-administer μ-receptor agonists into both the ventral tegmental area and the nucleus accumbens. Stimulation of κ receptors decreases dopamine levels in the nucleus accumbens and produces aversive responses. Rodents will continue to self-administer opioid into the nucleus accumbens even in the presence of dopaminergic lesions or after a dopamine antagonist has been given. Reward and physical dependence on opioids are mediated by the activation of μ receptors (Table 2), since reinforcement is blocked by selective receptor antagonists. Mice in which the μ receptor has been knocked out do not exhibit place preference or withdrawal signs after the administration of morphine.[68]

Dopamine and Cannabinoids

Δ^9-Tetrahydrocannabinol and other cannabinoids increase the efflux of dopamine in the nucleus accumbens and cell firing in the ventral tegmental area by their actions on CB_1 receptors in glutamatergic and GABA-ergic neurons associated with the nucleus accumbens and ventral tegmental area.[69] Laboratory animals cannot be taught to self-administer Δ^9-tetrahydrocannabinol, and spontaneous symptoms of withdrawal do not appear after such drugs are stopped. Highly potent, short-acting synthetic cannabinoid agonists (e.g., Win 55,212-2) induce self-administration behavior in rodents.[70] Selective cannabinoid antagonists (e.g., SR 141716A) precipitate a withdrawal syndrome in cannabinoid-dependent animals, but at doses that are difficult

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

to extrapolate to the consumption of plant-derived cannabis in humans.[71]

Dopamine and Ethanol

Ethanol raises dopamine levels in the nucleus accumbens by an indirect mechanism: it increases the firing of dopamine neurons in the ventral tegmental area by activating $GABA_A$ receptors or by inhibiting NMDA receptors. Alcohol administration induces specific, long-lasting adaptive changes in the composition of NMDA receptor subunits, which enhances the function of NMDA receptors. These findings are the basis of the experimental and clinical use of NMDA antagonists for treating the ethanol-withdrawal syndrome and reducing alcohol intake and relapse rate.[43,72] Opioid and serotonin receptors seem to have a role in the reinforcing effects of ethanol. In rats, naltrexone decreases the rate of self-administration of ethanol, and selected $5\text{-}HT_3$ antagonists block the release of dopamine induced by ethanol and reduce alcohol consumption.[45,72]

Dopamine and Cocaine and Amphetamines

Cocaine and amphetamines increase synaptic dopamine levels by inhibiting the activity of dopamine transporters. Imaging of the brain has shown that cocaine and amphetamines increase extracellular dopamine levels in the striatum and that euphoria is related to the occupancy of dopamine transporters by cocaine and amphetamines.[73] Lesions in dopamine pathways, inhibition of dopamine synthesis, and dopamine antagonists markedly attenuate the rate of self-administration of cocaine in rats. Dopamine-transporter–knockout mice are insensitive to the locomotor stimulatory effects and are less sensitive than normal mice to the behavioral effects of psychostimulants, but they will still self-administer cocaine and amphetamine. This effect may indicate a contribution of the serotonin and norepinephrine systems to the maintenance of the rewarding properties of cocaine.[55,61]

Dopamine and Nicotine

Nicotine exerts its positive reinforcing effects by acting on $\alpha4\beta2$ nicotinic acetylcholine receptors located on the somatodendritic membranes of the dopamine cells of the ventral tegmental area and possibly by sensitizing $\alpha7$ nicotinic acetylcholine receptors located on glutamate terminals. Experiments with mutant mice lacking $\beta2$ nicotinic acetylcholine receptors confirm the primary role of this receptor in promoting the self-administration of nicotine.[74,75]

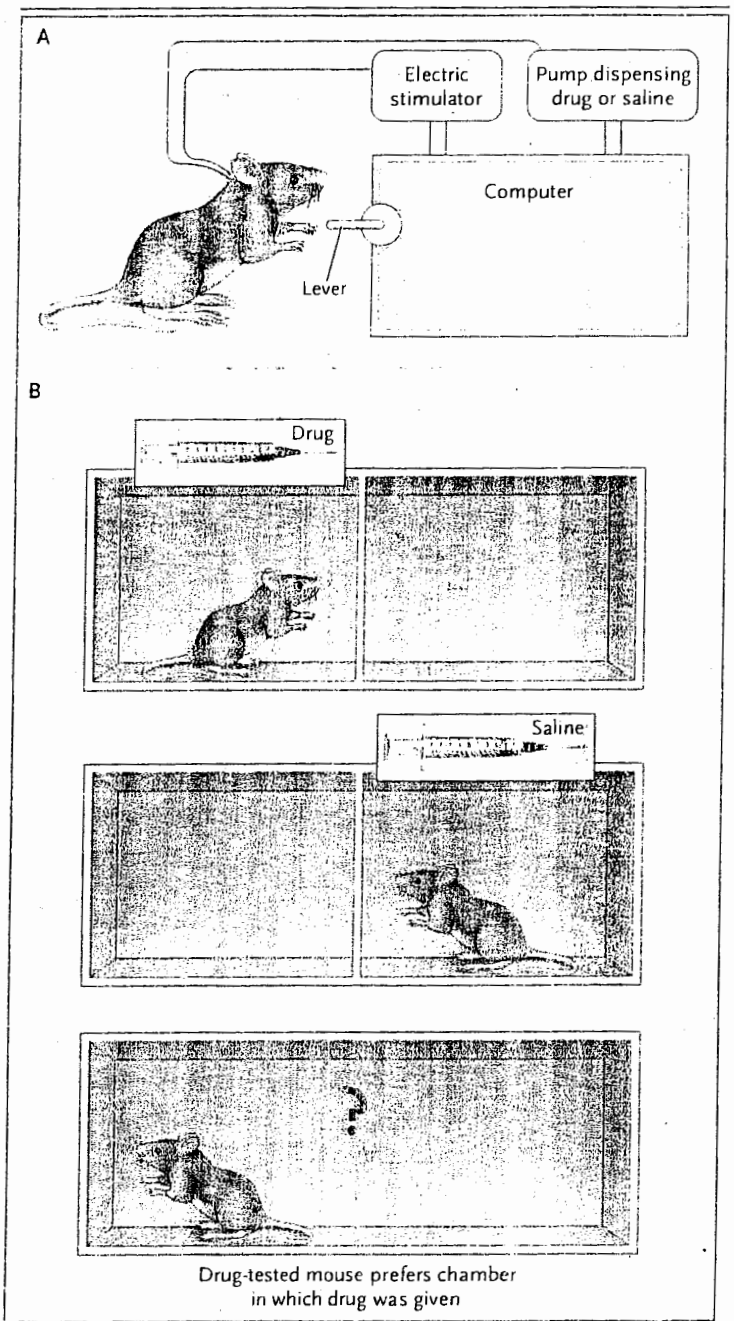


Figure 3. **Animal Behavioral Paradigms Used to Study Positive Reinforcing (Rewarding) Actions of Drugs.**

In Panel A, animals are trained to press a lever to obtain a drug or saline (self-administration) or to receive intracranial current in brain-rewarding loci (self-stimulation). In Panel B, mice are placed in a box with two discrete chambers, or environments, and are then repeatedly injected with a drug in one environment and with saline in the other environment. In a drug-free state, the animal is allowed access to both environments, and the amount of time spent in each environment is recorded. A positively reinforcing effect of the drug is apparent if the mouse spends more time in the environment in which the drug was administered (place preference) than in the one in which saline was administered.

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

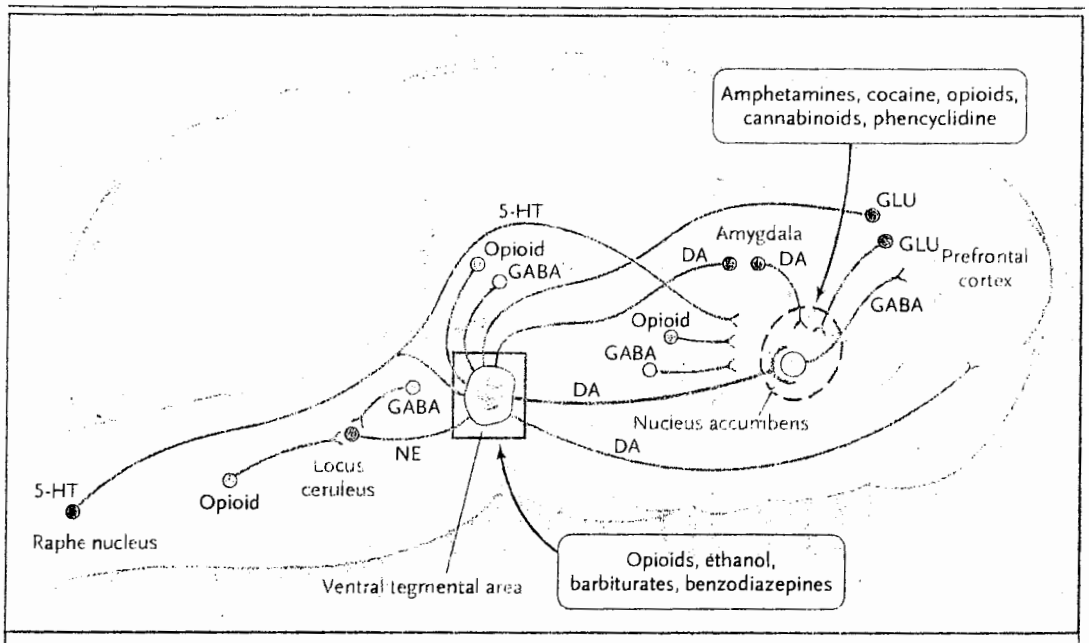


Figure 4. **Neural Reward Circuits Important in the Reinforcing Effects of Drugs of Abuse.**
As shown in the rat brain, mesocorticolimbic dopamine (DA) systems originating in the ventral tegmental area include projections from cell bodies of the ventral tegmental area to the nucleus accumbens, amygdala, and prefrontal cortex; glutamatergic (GLU) projections from the prefrontal cortex to the nucleus accumbens and the ventral tegmental area; and projections from the γ-aminobutyric acid (GABA) neurons of the nucleus accumbens to the prefrontal cortex. Opioid interneurons modulate the GABA-inhibitory action on the ventral tegmental area and influence the firing of norepinephrine (NE) neurons in the locus ceruleus. Serotonergic (5-HT) projections from the raphe nucleus extend to the ventral tegmental area and the nucleus accumbens. The figure shows the proposed sites of action of the various drugs of abuse in these circuits.

THE OPIOID PATHWAY

The opioid system is another pathway in the brain involved in the rewarding effects of addictive drugs.[71] The importance of this system in addiction to cannabinoids was brought out by studies in which opioid-receptor antagonists were found to attenuate the self-administration of cannabinoids and precipitate behavioral signs of withdrawal in rats treated with cannabinoid agonists for long periods.[76] Opioid antagonists reduce the consumption and self-administration of ethanol in animals, but naltrexone does not reduce the rate of relapse or alcohol consumption in patients with alcoholism.[77] By contrast, μ-receptor–knockout mice cannot be induced to self-administer alcohol.[72] The opioid system also inhibits the self-administration of nicotine in animals. Indeed, naloxone precipitates withdrawal in rats that receive nicotine for long periods and reduces cigarette consumption in smokers.[74] In addition, nicotine-induced conditioned place preference is abolished in μ-receptor–knockout mice.[78]

LONG-TERM DRUG USE AND NEUROADAPTATION

TOLERANCE AND WITHDRAWAL

Tolerance leads to modifications of drug use to obtain desired effects, by increasing the dose, reducing the intervals between doses, or both. Withdrawal compels addicts to resume drug use to prevent or reduce physical symptoms and dysphoria. Both tolerance and withdrawal increase compulsive drug-seeking and drug-taking behavior and are essential in maintaining the addiction. Sensitization, however, is also important. Molecular adaptations related to tolerance and dependence have been studied extensively in animal models of opioid and cocaine addiction, and the results can be extrapolated to other substances.[12,79,80]

Opioid Tolerance

Short-term administration of opioid activates the μ-opioid $G\alpha_{i/o}$-coupled receptor, which inhibits

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

adenylyl cyclase, lowers cyclic adenosine monophosphate (cAMP) levels, decreases cAMP-dependent protein kinase A activity, and reduces phosphorylation of cytoplasmic and nuclear targets, including cAMP–responsive element–binding protein (CREB), a transcription factor. Activation of μ receptors can also cause the phosphorylation of some mitogen-activated protein kinases, which in turn phosphorylate CREB and other transcription factors.[12,79,81,82] Decreases in the number of opioid receptors have been related in some reports to the development of opioid tolerance. Continuous stimulation desensitizes opioid receptors, which become phosphorylated by G-protein–coupled receptor kinases; β-arrestins then bind to the receptors, causing them to be internalized by the neuron.[83] Other studies, however, have found that opioids that cause internalization of the opioid receptors are inefficient in initiating tolerance.[84]

Opioid Withdrawal

Chronic activation of opioid receptors produces effects opposite to those of acute activation. It up-regulates cAMP signaling pathways by increasing the activity of adenylyl cyclases (subtypes I and VII), cAMP-dependent protein kinase A, and tyrosine hydroxylase. In addition, chronic activation of opioid receptors increases the phosphorylation of CREB and ΔFosB, factors regulating gene transcription.[66,79,85] These changes correlate with the manifestations of the withdrawal syndrome.

Up-regulation of cAMP is a homeostatic response to the inhibition of the locus ceruleus by opioids and a key mechanism in withdrawal. The locus ceruleus is a noradrenergic nucleus that regulates arousal, responses to stress, and the activity of the autonomic nervous system. Tolerance to the inhibitory effects of opioids occurs in the locus ceruleus during long-term administration. When opioid levels fall, the firing rates of neurons in the locus are unopposed and lead to adrenergic overactivation. A direct relation between overactivity of the locus ceruleus neurons and the somatic expression of opioid withdrawal has been demonstrated.[86] Mechanisms other than noradrenergic neurons may also participate in opioid withdrawal because destruction of the locus ceruleus does not alter naloxone-precipitated or spontaneous opioid withdrawal.[87]

In the nucleus accumbens, a similar up-regulation of the cAMP pathway, including activation of CREB, occurs after long-term administration of opioids, ethanol, or cocaine. CREB increases the production of dynorphin, which activates κ receptors in the neurons of the ventral tegmental area and decreases the release of dopamine in the nucleus accumbens. These changes contribute to the negative emotions (dysphoria and anhedonia) present during the early phases of abstinence.[66,79]

Stress Systems

Drug administration and withdrawal activate central and peripheral stress systems.[88] Short-term administration elevates peripheral glucocorticoid levels and central corticotropin-releasing factor levels. These hormonal elevations have been related to the rewarding properties of drug use. During withdrawal, an increase in corticotropin-releasing factor in the amygdala has been related to stress and negative effects of abstinence.[47,80]

MOLECULAR MECHANISMS OF SENSITIZATION AND RELAPSE

Long-term administration of addictive drugs produces alterations in the brain that increase vulnerability to relapse and facilitate craving even months or years after successful detoxification. Factors involved in relapse and craving include acute reexposure to the drug or drug-priming, exposure to environmental stimuli previously paired with drug use or conditioned drug cues, and exposure to environmental stressors (Table 1). The extent of sensitization varies with different drugs and is responsible for responses, craving, and relapse.

Functional Changes

Repeated administration of opioids, psychostimulants, or nicotine sensitizes laboratory animals to the stimulant or rewarding effects, or both, of these addictive substances. Behavioral sensitization is associated with marked and long-lasting alterations in the functional activity of the mesocorticolimbic dopamine system, particularly in glutamate and dopamine transmission in the nucleus accumbens.[12,67] Elevated levels of the R1 subunit of α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) subtype of glutamate receptors seems to be involved in sensitization and relapse.[89] Stress or a single dose of addictive substances with different molecular mechanisms of action (cocaine, amphetamine, morphine, ethanol, or nicotine) produces similar degrees of enhancement in the strength of glutamate excitatory synapses (AMPA-sensitive glutamate receptors) on dopamine neurons in the ventral tegmental area. The administra-

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

tion of a glucocorticoid antagonist blocked the actions of stress but not those of addictive substances. These changes can have a role in behavioral sensitization.[90]

Sensitization is associated with long-lasting adaptive changes in the patterns of expression of genes of the terminal mesolimbic dopamine systems,[79] in particular the activation of proteins belonging to the family of transcription factor activator protein 1, such as Fos proteins. In self-administration models, long-term treatment with morphine, cocaine, or nicotine increases the expression of the family of Fos-related transcription factors, particularly the extremely stable isoforms of ΔFosB. The persistent increase in the expression of Fos genes in mesolimbic structures is in part a consequence of the activation of the cAMP cascade through D1 dopamine receptors in the ventral tegmental area.[85,91,92]

Structural Changes

Exposure to addictive drugs can cause long-lasting structural changes in neurons. Opioids decrease the size and the caliber of dendrites and soma of dopamine neurons of the ventral tegmental area.[93] Repeated use of cocaine or amphetamine increases the number of dendritic branch points and spines on both medium spiny neurons in the nucleus accumbens and pyramidal neurons in the medial prefrontal cortex.[94] Neurotrophic factors seem to be responsible for these changes. Modifications in the density of dendritic spines and neurotrophic factors have also been implicated in long-term potentiation and long-term depression by AMPA-sensitive glutamate receptors.

The glutamate system of the brain is responsible for the long-term plasticity associated with learning and memory. It is therefore not surprising that the same glutamatergic mechanisms also underlie addiction-related behavior.[12,66,79,95,96] Behavioral sensitization can persist for weeks or months and is augmented by environmental cues (e.g., people, places, or paraphernalia associated with past drug use).[12] These cues and sensitization contribute to relapse. Interestingly, the processes involved in sensitization overlap the neuronal substrates and pathways involved in the rewarding properties of drug abuse.[7,9]

COMMENTS

Advances in the neurobiology of drug addiction have led to the identification of neuronal substrates responsible for the rewarding effects of prototypical drugs of abuse, which are crucial to the addictive process. There is increasing evidence that prolonged exposure to drugs of abuse produces long-lasting effects in cognitive and drug-rewarding circuits. For this reason, addiction should be considered a chronic medical illness.[97,98] Symptoms of withdrawal can be treated, and maintenance therapy is available for most drugs of abuse,[43,98-101] but the development of long-term strategies based on medication, psychosocial support, and continued monitoring[97,98] is a challenging clinical goal.

Supported in part by grants from Generalitat de Catalunya (2001SGR00407), Fondo de Investigación Sanitaria (98/0181 and 01/1336), and Biomed 2 (BMH4-CT98-2267).

We are indebted to Rafael Maldonado, M.D., Ph.D., for valuable scientific review and helpful comments, and to Marta Pulido, M.D., for editorial assistance.

REFERENCES

1. World Health Organization. The ICD-10 classification of mental and behavioral disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization, 1992.
2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders, 4th ed., text revision: DSM-IV-TR. Washington, D.C.: American Psychiatric Association, 2000.
3. Maddux JF, Desmond DP. Addiction or dependence? Addiction 2000;95:661-5.
4. Stolerman I. Drugs of abuse: behavioural principles, methods and terms. Trends Pharmacol Sci 1992;13:170-6.
5. Spanagel R, Weiss F. The dopamine hypothesis of reward: past and current status. Trends Neurosci 1999;22:521-7.
6. Koob GF, Le Moal M. Drug abuse: hedonic homeostatic dysregulation. Science 1997;278:52-8.
7. *Idem.* Drug addiction, dysregulation of reward, and allostasis. Neuropsychopharmacology 2001;24:97-129.
8. Robinson TE, Berridge KC. Incentive-sensitization and addiction. Addiction 2001; 96:103-14.
9. *Idem.* Addiction. Annu Rev Psychol 2003; 54:25-53.
10. Franklin TR, Acton PD, Maldjian JA, et al. Decreased gray matter concentration in the insular, orbitofrontal, cingulate, and temporal cortices of cocaine patients. Biol Psychiatry 2002;51:134-42.
11. Goldstein RZ, Volkow ND. Drug addiction and its underlying neurobiological basis: neuroimaging evidence for the involvement of the frontal cortex. Am J Psychiatry 2002; 159:1642-52.
12. Hyman SE, Malenka RC. Addiction and the brain: the neurobiology of compulsion and its persistence. Nat Rev Neurosci 2001; 2:695-703.
13. Farre M, Cami J. Pharmacokinetic considerations in abuse liability evaluation. Br J Addict 1991;86:1601-6.
14. Mumford GK, Evans SM, Fleishaker JC, Griffiths RR. Alprazolam absorption kinet-

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

ics affects abuse liability. Clin Pharmacol Ther 1995;57:356-65.
15. Roset P, Farre M, de la Torre R, et al. Modulation of rate of onset and intensity of drug effects reduces abuse potential in healthy males. Drug Alcohol Depend 2001; 64:285-98.
16. Farre M, Teran MT, Roset PN, Mas M, Torrens M, Cami J. Abuse liability of flunitrazepam among methadone-maintained patients. Psychopharmacology (Berl) 1998; 140:486-95.
17. Hatsukami DK, Fischman MW. Crack cocaine and cocaine hydrochloride: are the differences myth or reality? JAMA 1996;276: 1580-8.
18. Helmus TC, Downey KK, Arfken CL, Henderson MJ, Schuster CR. Novelty seeking as a predictor of treatment retention for heroin dependent cocaine users. Drug Alcohol Depend 2001;61:287-95.
19. Leri F, Bruneau J, Stewart J. Understanding polydrug use: review of heroin and cocaine co-use. Addiction 2003;98:7-22.
20. Kavanagh DJ, McGrath J, Saunders JB, Dore G, Clark D. Substance misuse in patients with schizophrenia: epidemiology and management. Drugs 2002;62:743-55.
21. Crabbe JC. Genetic contributions to addiction. Annu Rev Psychol 2002;53:435-62.
22. Schuckit MA, Edenberg HJ, Kalmijn J, et al. A genome-wide search for genes that relate to a low level of response to alcohol. Alcohol Clin Exp Res 2001;25:323-9.
23. Nestler EJ. Genes and addiction. Nat Genet 2000;26:277-81.
24. Lappalainen J, Kranzler HR, Malison R, et al. A functional neuropeptide Y Leu7Pro polymorphism associated with alcohol dependence in a large population sample from the United States. Arch Gen Psychiatry 2002;59:825-31.
25. Kreek MJ. Drug addictions: molecular and cellular endpoints. Ann N Y Acad Sci 2001;937:27-49.
26. Kathiramalainathan K, Kaplan HL, Romach MK, et al. Inhibition of cytochrome P450 2D6 modifies codeine abuse liability. J Clin Psychopharmacol 2000;20:435-44.
27. Rao Y, Hoffmann E, Zia M, et al. Duplications and defects in the CYP2A6 gene: identification, genotyping, and in vivo effects on smoking. Mol Pharmacol 2000;58: 747-55.
28. Sipe JC, Chiang K, Gerber AL, Beutler E, Cravatt BF. A missense mutation in human fatty acid amide hydrolase associated with problem drug use. Proc Natl Acad Sci U S A 2002;99:8394-9.
29. Noble EP. D2 dopamine receptor gene in psychiatric and neurologic disorders and its phenotypes. Am J Med Genet 2003;116B: 103-25.
30. Uhl GR, Liu QR, Naiman D. Substance abuse vulnerability loci: converging genome scanning data. Trends Genet 2002;18:420-5.
31. Gonzalez G, Oliveto A, Kosten TR. Treatment of heroin (diamorphine) addiction: current approaches and future prospects. Drugs 2002;62:1331-43.
32. Fiellin DA, O'Connor PG. Office-based treatment of opioid-dependent patients. N Engl J Med 2002;347:817-23.
33. Kieffer BL, Gavériaux-Ruff C. Exploring the opioid system by gene knockout. Prog Neurobiol 2002;66:285-306.
34. Hall W, Solowij N. Adverse effects of cannabis. Lancet 1998;352:1611-6.
35. Zammit S, Allebeck P, Andreasson S, Lundberg I, Lewis G. Self reported cannabis use as a risk factor for schizophrenia in Swedish conscripts of 1969: historical cohort study. BMJ 2002;325:1199.
36. Budney AJ, Hughes JR, Moore BA, Novy PL. Marijuana abstinence effects in marijuana smokers maintained in their home environment. Arch Gen Psychiatry 2001;58:917-24.
37. Solowij N, Stephens RS, Roffman RA, et al. Cognitive functioning of long-term heavy cannabis users seeking treatment. JAMA 2002;287:1123-31. [Erratum, JAMA 2002; 287:1651.]
38. Bolla KI, Brown K, Eldreth D, Tate K, Cadet JL. Dose-related neurocognitive effects of marijuana use. Neurology 2002;59: 1337-43.
39. Wilson RI, Nicoll RA. Endocannabinoid signaling in the brain. Science 2002;296: 678-82.
40. Maldonado R. Study of cannabinoid dependence in animals. Pharmacol Ther 2002; 95:153-64.
41. Martin BR. Identification of the endogenous cannabinoid system through integrative pharmacological approaches. J Pharmacol Exp Ther 2002;301:790-6.
42. Holdstock L, de Wit H. Individual differences in the biphasic effects of ethanol. Alcohol Clin Exp Res 1998;22:1903-11.
43. Swift RM. Drug therapy for alcohol dependence. N Engl J Med 1999;340:1482-90.
44. O'Connor PG, Schottenfeld RS. Patients with alcohol problems. N Engl J Med 1998; 338:592-602.
45. Weiss F, Porrino LJ. Behavioral neurobiology of alcohol addiction: recent advances and challenges. J Neurosci 2002;22:3332-7.
46. Zhang L, Hosoi M, Fuzuzawa M, Sun H, Rawlings RR, Weight FF. Distinct molecular basis for differential sensitivity of the serotonin type 3A receptor to ethanol in the absence and presence of agonist. J Biol Chem 2002;277:46256-64.
47. Sarnyai Z, Shaham Y, Heinrichs SC. The role of corticotropin-releasing factor in drug addiction. Pharmacol Rev 2001;53:209-43.
48. Farre M, de la Torre R, Gonzalez ML, et al. Cocaine and alcohol interactions in humans: neuroendocrine effects and cocaethylene metabolism. J Pharmacol Exp Ther 1997;283:164-76.
49. Mello NK, Mendelson JH. Cocaine's effects on neuroendocrine systems: clinical and preclinical studies. Pharmacol Biochem Behav 1997;57:571-99.
50. Mendelson JH, Mello NK. Management of cocaine abuse and dependence. N Engl J Med 1996;334:965-72.
51. Cami J, Farre M, Mas M, et al. Human pharmacology of 3,4-methylenedioxymethamphetamine ("ecstasy"): psychomotor performance and subjective effects. J Clin Psychopharmacol 2000;20:455-66.
52. Harris DS, Baggott M, Mendelson JH, Mendelson JE, Jones RT. Subjective and hormonal effects of 3,4-methylenedioxymethamphetamine (MDMA) in humans. Psychopharmacology (Berl) 2002;162:396-405.
53. Ernst T, Chang L, Leonido-Yee M, Speck O. Evidence for long-term neurotoxicity associated with methamphetamine abuse: a 1H MRS study. Neurology 2000;54:1344-9.
54. Ricaurte GA, Yuan J, Hatzidimitriou G, Cord BJ, McCann UD. Severe dopaminergic neurotoxicity in primates after a common recreational dose regimen of MDMA ("ecstasy"). Science 2002;297:2260-3.
55. Everitt BJ, Wolf ME. Psychomotor stimulant addiction: a neural systems perspective. J Neurosci 2002;22:3312-20. [Erratum, J Neurosci 2002;22:1a.]
56. Mansvelder HD, McGehee DS. Cellular and synaptic mechanisms of nicotine addiction. J Neurobiol 2002;53:606-17.
57. Smith DE, Wesson DR. Benzodiazepines and other sedative-hypnotics. In: Galanter M, Kleber HD, eds. The American Psychiatric Press textbook of substance abuse treatment. 2nd ed. Washington, D.C.: American Psychiatric Press, 1999:239-50.
58. Abraham HD, McCann UD, Ricaurte GA. Psychedelic drugs. In: Davis KL, Charney D, Coyle JT, Nemeroff C, eds. Neuropsychopharmacology: the fifth generation of progress. Philadelphia: Lippincott Williams & Wilkins, 2002:1545-56.
59. Roth BL, Baner K, Westkaemper R, et al. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A 2002;99: 11934-9.
60. Balster RL. Drug abuse potential evaluation in animals. Br J Addict 1991;86:1549-58.
61. Laakso A, Mohn AR, Gainetdinov RR, Caron MG. Experimental genetic approaches to addiction. Neuron 2002;36:213-28.
62. Mantamadiotis T, Lemberger T, Bleckmann SC, et al. Disruption of CREB function in brain leads to neurodegeneration. Nat Genet 2002;31:47-54.
63. Cami J. Human drug abuse liability: testing times ahead. Br J Addict 1991;86: 1525-6.
64. Kalivas PW. Neurocircuitry of addiction. In: Davis KL, Charney D, Coyle JT, Nemeroff C, eds. Neuropsychopharmacology: the fifth generation of progress. Philadelphia: Lippincott Williams & Wilkins, 2002:1357-66.
65. Di Chiara G. Drug addiction as dopamine-dependent associative learning disorder. Eur J Pharmacol 1999;375:13-30.
66. Nestler EJ. Molecular basis of long-term plasticity underlying addiction. Nat Rev

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

Neurosci 2001;2:119-28. [Erratum, Nat Rev Neurosci 2001;2:215.]
67. Konipsky KL, Hyman SE. Molecular and cellular biology of addiction. In: Davis KL, Charney D, Coyle JT, Nemeroff C, eds. Neuropsychopharmacology: the fifth generation of progress. Philadelphia: Lippincott Williams & Wilkins, 2002:1367-79.
68. De Vries TJ, Shippenberg TS. Neural systems underlying opiate addiction. J Neurosci 2002;22:3321-5.
69. Robbe D, Alonso G, Duchamp F, Bockaert J, Manzoni OJ. Localization and mechanisms of action of cannabinoid receptors at the glutamatergic synapses of the mouse nucleus accumbens. J Neurosci 2001;21:109-16.
70. Fattore L, Cossu G, Martellotta CM, Fratta W. Intravenous self-administration of the cannabinoid CB1 receptor agonist WIN 55,212-2 in rats. Psychopharmacology (Berl) 2001;156:410-6.
71. Maldonado R, Rodriguez de Fonseca F. Cannabinoid addiction: behavioral models and neural correlates. J Neurosci 2002;22:3326-31.
72. Spanagel R. Behavioral and molecular aspects of alcohol craving and relapse. In: Maldonado R, ed. Molecular biology of drug addiction. Totowa, N.J.: Humana Press, 2002:295-313.
73. Volkow ND, Fowler JS. Application of imaging technologies in the investigation of drug addiction. In: Davis KL, Charney D, Coyle JT, Nemeroff C, eds. Neuropsychopharmacology: the fifth generation of progress. Philadelphia: Lippincott Williams & Wilkins, 2002:1475-90.
74. Merlo E, Heidbreder C, Mugnaini M, Teneggi V. Molecular and behavioral aspects of nicotine dependence and reward. In: Maldonado R, ed. Molecular biology of drug addiction. Totowa, N.J.: Humana Press, 2002:315-38.
75. Picciotto MR, Corrigall WA. Neuronal systems underlying behaviors related to nicotine addiction: neural circuits and molecular genetics. J Neurosci 2002;22:3338-41.
76. Navarro M, Chowen J, Rocio A, et al. CB1 cannabinoid receptor antagonist-induced opiate withdrawal in morphine-dependent rats. Neuroreport 1998;9:3397-402.
77. Krystal JH, Cramer JA, Krol WF, Kirk GF, Rosenheck RA. Naltrexone in the treatment of alcohol dependence. N Engl J Med 2001;345:1734-9.
78. Berrendero F, Kieffer BL, Maldonado R. Attenuation of nicotine-induced antinociception, rewarding effects, and dependence in mu-opioid receptor knock-out mice. J Neurosci 2002;22:10935-40.
79. Nestler EJ. Molecular neurobiology of addiction. Am J Addict 2001;10:201-17.
80. Shalev U, Grimm JW, Shaham Y. Neurobiology of relapse to heroin and cocaine seeking: a review. Pharmacol Rev 2002;54:1-42.
81. Taylor DA, Fleming WW. Unifying perspectives of the mechanisms underlying the development of tolerance and physical dependence to opioids. J Pharmacol Exp Ther 2001;297:11-8.
82. Watts VJ. Molecular mechanisms for heterologous sensitization of adenylate cyclase. J Pharmacol Exp Ther 2002;302:1-7.
83. Nestler EJ, Landsman D. Learning about addiction from the genome. Nature 2001;409:834-5.
84. He L, Fong J, von Zastrow M, Whistler JL. Regulation of opioid receptor trafficking and morphine tolerance by receptor oligomerization. Cell 2002;108:271-82.
85. Nestler EJ, Aghajanian GK. Molecular and cellular basis of addiction. Science 1997;278:58-63.
86. Rasmussen K, Beitner-Johnson DB, Krystal JH, Aghajanian GK, Nestler EJ. Opiate withdrawal and the rat locus coeruleus: behavioral, electrophysiological, and biochemical correlates. J Neurosci 1990;10:2308-17.
87. Caille S, Espejo EF, Reneric JP, Cador M, Koob GF, Stinus L. Total neurochemical lesion of noradrenergic neurons of the locus ceruleus does not alter either naloxone-precipitated or spontaneous opiate withdrawal nor does it influence ability of clonidine to reverse opiate withdrawal. J Pharmacol Exp Ther 1999;290:881-92.
88. Cami J, Gilabert M, San L, de la Torre R. Hypercortisolism after opioid discontinuation in rapid detoxification of heroin addicts. Br J Addict 1992;87:1145-51.
89. Carlezon WA Jr, Nestler EJ. Elevated levels of GluR1 in the midbrain: a trigger for sensitization to drugs of abuse? Trends Neurosci 2002;25:610-5.
90. Saal D, Dong Y, Bonci A, Malenka RC. Drugs of abuse and stress trigger a common synaptic adaptation in dopamine neurons. Neuron 2003;37:577-82. [Erratum, Neuron 2003;38:359.]
91. Kelz MB, Nestler EJ. DeltaFosB: a molecular switch underlying long-term neural plasticity. Curr Opin Neurol 2000;13:715-20.
92. Nestler EJ, Barrot M, Self DW. DeltaFosB: a sustained molecular switch for addiction. Proc Natl Acad Sci U S A 2001;98:11042-6.
93. Sklair-Tavron L, Shi WX, Lane SB, Harris HW, Bunney BS, Nestler EJ. Chronic morphine induces visible changes in the morphology of mesolimbic dopamine neurons. Proc Natl Acad Sci U S A 1996;93:11202-7.
94. Robinson TE, Gorny G, Mitton E, Kolb B. Cocaine self-administration alters the morphology of dendrites and dendritic spines in the nucleus accumbens and neocortex. Synapse 2001;39:257-66.
95. Berke JD, Hyman SE. Addiction, dopamine, and the molecular mechanisms of memory. Neuron 2000;25:515-32.
96. Duman RS, Malberg J, Nakagawa S. Regulation of adult neurogenesis by psychotropic drugs and stress. J Pharmacol Exp Ther 2001;299:401-7.
97. McLellan AT, Lewis DC, O'Brien CP, Kleber HD. Drug dependence, a chronic medical illness: implications for treatment, insurance, and outcomes evaluation. JAMA 2000;284:1689-95.
98. Kreek MJ, LaForge KS, Butelman E. Pharmacotherapy of addictions. Nat Rev Drug Discov 2002;1:710-26. [Erratum, Nat Rev Drug Discov 2002;1:920.]
99. Johnson RE, Chutuape MA, Strain EC, Walsh SL, Stitzer ML, Bigelow GE. A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. N Engl J Med 2000;343:1290-7.
100. Farre M, Mas A, Torrens M, Moreno V, Cami J. Retention rate and illicit opioid use during methadone maintenance interventions: a meta-analysis. Drug Alcohol Depend 2002;65:283-90.
101. Fudala PJ, Bridge TP, Herbert S, et al. Office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. N Engl J Med 2003;349:949-58.

Copyright © 2003 Massachusetts Medical Society.

Downloaded from www.nejm.org by TAMARA ROBINSON MD on August 3, 2007 .
Copyright © 2003 Massachusetts Medical Society. All rights reserved.

Diabetes

Diabetes Management in Correctional Institutions

AMERICAN DIABETES ASSOCIATION

At any given time, over 2 million people are incarcerated in prisons and jails in the U.S (1). It is estimated that nearly 80,000 of these inmates have diabetes, a prevalence of 4.8% (2). In addition, many more people pass through the corrections system in a given year. In 1998 alone, over 11 million people were released from prison to the community (1). The current estimated prevalence of diabetes in correctional institutions is somewhat lower than the overall U.S. prevalence of diabetes, perhaps because the incarcerated population is younger than the general population. The prevalence of diabetes and its related comorbidities and complications, however, will continue to increase in the prison population as current sentencing guidelines continue to increase the number of aging prisoners and the incidence of diabetes in young people continues to increase.

People with diabetes in correctional facilities should receive care that meets national standards. Correctional institutions have unique circumstances that need to be considered so that all standards of care may be achieved (3). Correctional institutions should have written policies and procedures for the management of diabetes and for training of medical and correctional staff in diabetes care practices. These policies must take into consideration issues such as security needs, transfer from one facility to another, and access to medical personnel and equipment, so that all appropriate levels of care are provided. Ideally, these policies should encourage or at least allow patients to self-manage their diabetes. Ultimately, diabetes management is dependent upon having access to needed medical personnel and equipment. Ongoing diabetes therapy is important in order to reduce the risk of later complications, including cardiovascular events, visual loss, renal failure, and amputation. Early identification and intervention for people with diabetes is also likely to reduce short-term risks for acute complications requiring transfer out of the facility, thus improving security.

This document provides a general set of guidelines for diabetes care in correctional institutions. It is not designed to be a diabetes management manual. More detailed information on the management of diabetes and related disorders can be found in the American Diabetes Association (ADA) Clinical Practice Recommendations, published each year in January as the first supplement to *Diabetes Care*, as well as the "Standards of Medical Care in Diabetes" (4) contained therein. This discussion will focus on those areas where the care of people with diabetes in correctional facilities may differ, and specific recommendations are made at the end of each section.

INTAKE MEDICAL ASSESSMENT

Reception screening

Reception screening should emphasize patient safety. In particular, rapid identification of all insulin-treated persons with diabetes is essential in order to identify those at highest risk for hypo- and hyperglycemia and diabetic ketoacidosis (DKA). All insulin-treated patients should have a capillary blood glucose (CBG) determination within 1–2 h of arrival. Signs and symptoms of hypo- or hyperglycemia can often be confused with intoxication or withdrawal from drugs or alcohol. Individuals with diabetes exhibiting signs and symptoms consistent with hypoglycemia, particularly altered mental status, agitation, combativeness, and diaphoresis, should have finger-stick blood glucose levels measured immediately.

Intake screening

Patients with a diagnosis of diabetes should have a complete medical history and physical examination by a licensed health care provider with prescriptive authority in a timely manner. If one is not available on site, one should be consulted by those performing reception screening. The purposes of this history and physical examination are to determine the type of diabetes, current therapy, alcohol use, and behavioral health issues, as well as to screen for the presence of diabetes-related complications. The evaluation should review the previous treatment and the past history of both glycemic control and diabetes complications. It is essential that medication and medical nutrition therapy (MNT) be continued without interruption upon entry into the correctional system, as a hiatus in either medication or appropriate nutrition may lead to either severe hypo- or hyperglycemia that can rapidly progress to irreversible complications, even death.

Intake physical examination and laboratory

All potential elements of the initial medical evaluation are included in Table 5 of the ADA's "Standards of Medical Care in Diabetes," referred to hereafter as the "Standards of Care" (4). The essential components of the initial history and physical examination are detailed in Fig. 1. Referrals should be made immediately if the patient with diabetes is pregnant.

Recommendations

- Patients with a diagnosis of diabetes should have a complete medical history and undergo an intake physical examination by a licensed health professional in a timely manner. (E)
- Insulin-treated patients should have a CBG determination within 1–2 h of arrival. (E)
- Medications and MNT should be continued without interruption upon entry into the correctional environment. (E)

SCREENING FOR DIABETES — Consistent with the ADA Standards of Care, patients should be evaluated for diabetes risk factors at the intake physical and at appropriate times thereafter. Those

Originally approved 1989. Most recent review, 2006.

Abbreviations: CBG, capillary blood glucose; DKA, diabetic ketoacidosis; GDM, gestational diabetes mellitus; MNT, medical nutrition therapy.

DOI: 10.2337/dc07-S077

© 2007 by the American Diabetes Association.

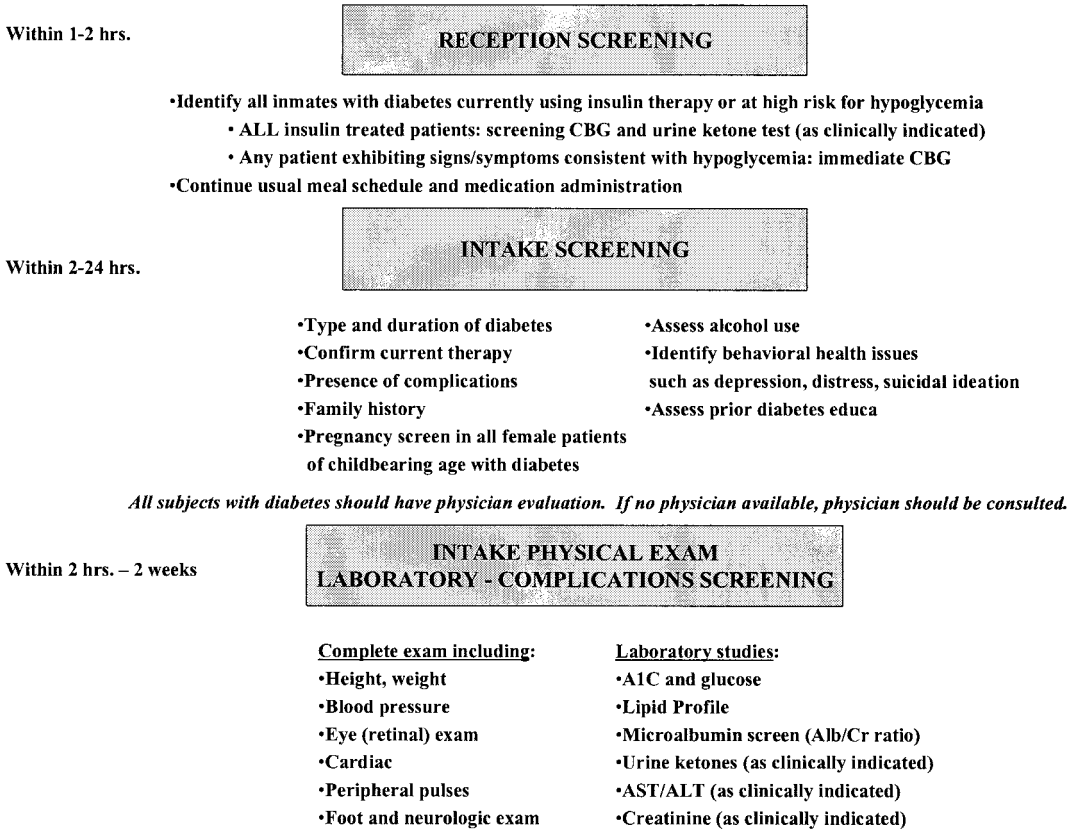


Figure 1—*Essential components of the initial history and physical examination. Alb/Cr ratio, albumin-to-creatinine ratio; ALT, alanine aminotransferase; AST, aspartate aminotransferase.*

who are at high risk should be considered for blood glucose screening. If pregnant, a risk assessment for gestational diabetes mellitus (GDM) should be undertaken at the first prenatal visit. Patients with clinical characteristics consistent with a high risk for GDM should undergo glucose testing as soon as possible. High-risk women not found to have GDM at the initial screening and average-risk women should be tested between 24 and 28 weeks of gestation. For more detailed information on screening for both type 2 and gestational diabetes, see the ADA Position Statement "Screening for Type 2 Diabetes" (5) and the Standards of Care (4).

MANAGEMENT PLAN — Glycemic control is fundamental to the management of diabetes. A management plan to achieve normal or near-normal glycemia with an A1C goal of <7% should be developed for diabetes management at the time of initial medical evaluation. Goals should be individualized (4), and less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, elderly adults, and individuals with comorbid conditions (4). This plan should be documented in the patient's record and communicated to all persons involved in his/her care, including security staff. Table 1, taken from the ADA Standards of Care, provides a summary of recommendations for setting glycemic control goals for adults with diabetes.

People with diabetes should ideally receive medical care from a physician-coordinated team. Such teams include, but are not limited to, physicians, nurses, dietitians, and mental health professionals with expertise and a special interest in diabetes. It is essential in this collaborative and integrated team approach that individuals with diabetes assume as active a role in their care as possible. Diabetes self-management education is an integral component of care. Patient self-management should be emphasized, and the plan should encourage the involvement of the patient in problem solving as much as possible.

It is helpful to house insulin-treated patients in a common unit, if this is possible, safe, and consistent with providing access to other programs at the correctional institution. Common housing not only can facilitate mealtimes and medication administration, but also potentially provides an opportunity for diabetes self-management education to be reinforced by fellow patients.

NUTRITION AND FOOD SERVICES — Nutrition counseling and menu planning are an integral part of the multidisciplinary approach to diabetes management in correctional facilities. A combination of education, interdisciplinary communication, and monitoring food intake aids patients in understanding their medical nutritional needs and can facilitate diabetes control during and after incarceration.

Nutrition counseling for patients with diabetes is considered an essential component of diabetes self-management. People with diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of MNT for persons with diabetes.

Table 1—*Summary of recommendations for adults with diabetes*

Glycemic control	
A1C	<7.0%*
Preprandial capillary plasma glucose	90–130 mg/dl (5.0–7.2 mmol/l)
Peak postprandial capillary plasma glucose†	<180 mg/dl (<10.0 mmol/l)
Blood pressure	<130/80 mmHg
Lipids‡	
LDL	<100 mg/dl (<2.6 mmol/l)
Triglycerides	<150 mg/dl (<1.7 mmol/l)
HDL	>40 mg/dl (>1.0 mmol/l)§

Key concepts in setting glycemic goals:
- A1C is the primary target for glycemic control
- Goals should be individualized
- Certain populations (children, pregnant women, and elderly) require special considerations
- More stringent glycemic goals (i.e., a normal A1C, <6%) may further reduce complications at the cost of increased risk of hypoglycemia
- Less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia
- Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †Postprandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes. ‡Current NCEP/ATP III guidelines suggest that in patients with triglycerides ≥200 mg/dl, the "non-HDL cholesterol" (total cholesterol minus HDL) be utilized. The goal is ≤130 mg/dl (121). §For women, it has been suggested that the HDL goal be increased by 10 mg/dl.

Educating the patient, individually or in a group setting, about how carbohydrates and food choices directly affect diabetes control is the first step in facilitating self-management. This education enables the patient to identify better food selections from those available in the dining hall and commissary. Such an approach is more realistic in a facility where the patient has the opportunity to make food choices.

The easiest and most cost-effective means to facilitate good outcomes in patients with diabetes is instituting a heart-healthy diet as the master menu (6). There should be consistent carbohydrate content at each meal, as well as a means to identify the carbohydrate content of each food selection. Providing carbohydrate content of food selections and/or providing education in assessing carbohydrate content enables patients to meet the requirements of their individual MNT goals. Commissaries should also help in dietary management by offering healthy choices and listing the carbohydrate content of foods.

The use of insulin or oral medications may necessitate snacks in order to avoid hypoglycemia. These snacks are a part of such patients' medical treatment plans and should be prescribed by medical staff.

Timing of meals and snacks must be coordinated with medication administration as needed to minimize the risk of hypoglycemia, as discussed more fully in the MEDICATION section of this document. For further information, see the ADA Position Statement "Nutrition Principles and Recommendations in Diabetes" (7).

URGENT AND EMERGENCY ISSUES — All patients must have access to prompt treatment of hypo- and hyperglycemia. Correctional staff should be trained in the recognition and treatment of hypo- and hyperglycemia, and appropriate staff should be trained to administer glucagon. After such emergency care, patients should be referred for appropriate medical care to minimize risk of future decompensation.

Institutions should implement a policy requiring staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician (e.g., <50 or >350 mg/dl).

Hyperglycemia

Severe hyperglycemia in a person with diabetes may be the result of intercurrent illness, missed or inadequate medication, or corticosteroid therapy. Correctional institutions should have systems in place to identify and refer to medical staff all patients with consistently elevated blood glucose as well as intercurrent illness.

The stress of illness in those with type 1 diabetes frequently aggravates glycemic control and necessitates more frequent monitoring of blood glucose (e.g., every 4–6 h). Marked hyperglycemia requires temporary adjustment of the treatment program and, if accompanied by ketosis, interaction with the diabetes care team. Adequate fluid and caloric intake must be ensured. Nausea or vomiting accompanied with hyperglycemia may indicate DKA, a life-threatening condition that requires immediate medical care to prevent complications and death. Correctional institutions should identify patients with type 1 diabetes who are at risk for DKA, particularly those with a prior history of frequent episodes of DKA. For further information see "Hyperglycemic Crisis in Diabetes" (8).

Hypoglycemia

Hypoglycemia is defined as a blood glucose level <60 mg/dl. Severe hypoglycemia is a medical emergency defined as hypoglycemia requiring assistance of a third party and is often associated with mental status changes that may include confusion, incoherence, combativeness, somnolence, lethargy, seizures, or coma. Signs and symptoms of severe hypoglycemia can be confused with intoxication or withdrawal. Individuals with diabetes exhibiting signs and symptoms consistent with hypoglycemia, particularly altered mental status, agitation, and diaphoresis, should have their CBG levels checked immediately.

Security staff who supervise patients at risk for hypoglycemia (i.e., those on insulin or oral hypoglycemic agents) should be educated in the emergency response protocol for recognition and treatment of hypoglycemia. Every attempt should be made to document CBG before treatment. Patients must have immediate access to glucose tablets or other glucose-containing foods. Hypoglycemia can generally be treated by the patient with oral carbohydrates. If the patient cannot be relied on to keep hypoglycemia treatment on his/her person, staff members should have ready access to glucose tablets or equivalent. In general, 15–20 g oral glucose will be adequate to treat hypoglycemic events. CBG and treatment should be re-

peated at 15-min intervals until blood glucose levels return to normal (>70 mg/dl).

Staff should have glucagon for intramuscular injection or glucose for intravenous infusion available to treat severe hypoglycemia without requiring transport of the hypoglycemic patient to an outside facility. Any episode of severe hypoglycemia or recurrent episodes of mild to moderate hypoglycemia require reevaluation of the diabetes management plan by the medical staff. In certain cases of unexplained or recurrent severe hypoglycemia, it may be appropriate to admit the patient to the medical unit for observation and stabilization of diabetes management.

Correctional institutions should have systems in place to identify the patients at greater risk for hypoglycemia (i.e., those on insulin or sulfonylurea therapy) and to ensure the early detection and treatment of hypoglycemia. If possible, patients at greater risk of severe hypoglycemia (e.g., those with a prior episode of severe hypoglycemia) may be housed in units closer to the medical unit in order to minimize delay in treatment.

Recommendations

- Train correctional staff in the recognition, treatment, and appropriate referral for hypo- and hyperglycemia. (E)
- Train appropriate staff to administer glucagon. (E)
- Train staff to recognize symptoms and signs of serious metabolic decompensation, and immediately refer the patient for appropriate medical care. (E)
- Institutions should implement a policy requiring staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician (e.g., <50 or >350 mg/dl). (E)
- Identify patients with type 1 diabetes who are at high risk for DKA. (E)

MEDICATION — Formularies should provide access to usual and customary oral medications and insulins necessary to treat diabetes and related conditions. While not every brand name of insulin and oral medication needs to be available, individual patient care requires access to short-, medium-, and long-acting insulins and the various classes of oral medications (e.g., insulin secretagogues, biguanides, α-glucosidase inhibitors, and thiazolidinediones) necessary for current diabetes management.

Patients at all levels of custody should have access to medication at dosing frequencies that are consistent with their treatment plan and medical direction. If feasible and consistent with security concerns, patients on multiple doses of short-acting oral medications should be placed in a "keep on person" program. In other situations, patients should be permitted to self-inject insulin when consistent with security needs. Medical department nurses should determine whether patients have the necessary skill and responsible behavior to be allowed self-administration and the degree of supervision necessary. When needed, this skill should be a part of patient education. Reasonable syringe control systems should be established.

In the past, the recommendation that regular insulin be injected 30–45 min before meals presented a significant problem when "lock downs" or other disruptions to the normal schedule of meals and medications occurred. The use of multiple-dose insulin regimens using rapid-acting analogs can decrease the disruption caused by such changes in schedule. Correctional institutions should have systems in place to ensure that rapid-acting insulin analogs and oral agents are given immediately before meals if this is part of the patient's medical plan. It should be noted however that even modest delays in meal consumption with these agents can be associated with hypoglycemia. If consistent access to food within 10 min cannot be ensured, rapid-acting insulin analogs and oral agents are approved for administration during or immediately after meals. Should circumstances arise that delay patient access to regular meals following medication administration, policies and procedures must be implemented to ensure the patient receives appropriate nutrition to prevent hypoglycemia.

Both continuous subcutaneous insulin infusion and multiple daily insulin injection therapy (consisting of three or more injections a day) can be effective means of implementing intensive diabetes management with the goal of achieving near-normal levels of blood glucose (9). While the use of these modalities may be difficult in correctional institutions, every effort should be made to continue multiple daily insulin injection or continuous subcutaneous insulin infusion in people who were using this therapy before incarceration or to institute these therapies as indicated in order to achieve blood glucose targets.

It is essential that transport of patients from jails or prisons to off-site appointments, such as medical visits or court appearances, does not cause significant disruption in medication or meal timing. Correctional institutions and police lock-ups should implement policies and procedures to diminish the risk of hypo- and hyperglycemia by, for example, providing carry-along meals and medication for patients traveling to off-site appointments or changing the insulin regimen for that day. The availability of prefilled insulin "pens" provides an alternative for off-site insulin delivery.

Recommendations

- Formularies should provide access to usual and customary oral medications and insulins to treat diabetes and related conditions. (E)
- Patients should have access to medication at dosing frequencies that are consistent with their treatment plan and medical direction. (E)
- Correctional institutions and police lock-ups should implement policies and procedures to diminish the risk of hypo- and hyperglycemia during off-site travel (e.g., court appearances). (E)

ROUTINE SCREENING FOR AND MANAGEMENT OF DIABETES COMPLICATIONS — All patients with a diagnosis of diabetes should receive routine screening for diabetes-related complications, as detailed in the ADA Standards of Care (4). Interval chronic disease clinics for persons with diabetes provide an efficient mechanism to monitor patients for complications of diabetes. In this way, appropriate referrals to consultant specialists, such as optometrists/ophthalmologists, nephrologists, and cardiologists, can be made on an as-needed basis and interval laboratory testing can be done.

The following complications should be considered.

- Foot care: Recommendations for foot care for patients with diabetes and no history of an open foot lesion are described in the ADA Standards of Care. A comprehensive foot examination is recommended annually for all patients with diabetes to identify risk factors predictive of ulcers and amputations. Persons with an insensate foot, an open foot lesion, or a history of such a lesion should be referred for evaluation by an appropriate licensed health profes-

sional (e.g., podiatrist or vascular surgeon). Special shoes should be provided as recommended by licensed health professionals to aid healing of foot lesions and to prevent development of new lesions.

- Retinopathy: Annual retinal examinations by a licensed eye care professional should be performed for all patients with diabetes, as recommended in the ADA Standards of Care. Visual changes that cannot be accounted for by acute changes in glycemic control require prompt evaluation by an eye care professional.
- Nephropathy: An annual spot urine test for determination of microalbumin-to-creatinine ratio should be performed. The use of ACE inhibitors or angiotensin receptor blockers is recommended for all patients with albuminuria. Blood pressure should be controlled to <130/80 mmHg.
- Cardiac: People with type 2 diabetes are at a particularly high risk of coronary artery disease. Cardiovascular disease risk factor management is of demonstrated benefit in reducing this complication in patients with diabetes. Blood pressure should be measured at every routine diabetes visit. In adult patients, test for lipid disorders at least annually and as needed to achieve goals with treatment. Use aspirin therapy (75–162 mg/day) in all adult patients with diabetes and cardiovascular risk factors or known macrovascular disease. Current national standards for adults with diabetes call for treatment of lipids to goals of LDL ≤100, HDL >40, triglycerides <150 mg/dl and blood pressure to a level of <130/80 mmHg.

MONITORING/TESTS OF GLYCEMIA — Monitoring of CBG is a strategy that allows caregivers and people with diabetes to evaluate diabetes management regimens. The frequency of monitoring will vary by patients' glycemic control and diabetes regimens. Patients with type 1 diabetes are at risk for hypoglycemia and should have their CBG monitored three or more times daily. Patients with type 2 diabetes on insulin need to monitor at least once daily and more frequently based on their medical plan. Patients treated with oral agents should have CBG monitored with sufficient frequency to facilitate the goals of glycemic control, assuming that there is a program for medical review of these data on an ongoing basis to drive changes in medications. Patients whose diabetes is poorly controlled or whose therapy is changing should have more frequent monitoring. Unexplained hyperglycemia in a patient with type 1 diabetes may suggest impending DKA, and monitoring of ketones should therefore be performed.

Glycated hemoglobin (A1C) is a measure of long-term (2- to 3-month) glycemic control. Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

Discrepancies between CBG monitoring results and A1C may indicate a hemoglobinopathy, hemolysis, or need for evaluation of CBG monitoring technique and equipment or initiation of more frequent CBG monitoring to identify when glycemic excursions are occurring and which facet of the diabetes regimen is changing.

In the correctional setting, policies and procedures need to be developed and implemented regarding CBG monitoring that address the following.

- Infection control
- Education of staff and patients
- Proper choice of meter
- Disposal of testing lancets
- Quality control programs
- Access to health services
- Size of the blood sample
- Patient performance skills
- Documentation and interpretation of test results
- Availability of test results for the health care provider (10)

Recommendations

- In the correctional setting, policies and procedures need to be developed and implemented to enable CBG monitoring to occur at the frequency necessitated by the individual patient's glycemic control and diabetes regimen. (E)
- A1C should be checked every 3–6 months. (E)

SELF-MANAGEMENT EDUCATION — Self-management education is the cornerstone of treatment for all people with diabetes. The health staff must advocate for patients to participate in self-management as much as possible. Individuals with diabetes who learn self-management skills and make lifestyle changes can more effectively manage their diabetes and avoid or delay complications associated with diabetes. In the development of a diabetes self-management education program in the correctional environment, the unique circumstances of the patient should be considered while still providing, to the greatest extent possible, the elements of the "National Standards for Diabetes Self-Management Education" (11). A staged approach may be used depending on the needs assessment and the length of incarceration. Table 2 sets out the major components of diabetes self-management education. Survival skills should be addressed as soon as possible; other aspects of education may be provided as part of an ongoing education program.

Ideally, self-management education is coordinated by a certified diabetes educator who works with the facility to develop polices, procedures, and protocols to ensure that nationally recognized education guidelines are implemented. The educator is also able to identify patients who need diabetes self-management education, including an assessment of the patients' medical, social, and diabetes histories; diabetes knowledge, skills, and behaviors; and readiness to change.

STAFF EDUCATION — Policies and procedures should be implemented to ensure that the health care staff has adequate knowledge and skills to direct the management and education of persons with diabetes. The health care staff needs to be involved in the development of the correctional officers' training program. The staff education program should be at a lay level. Training should be offered at least biannually, and the curriculum should cover the following.

- What is diabetes
- Signs and symptoms of diabetes
- Risk factors
- Signs and symptoms of, and emergency response to, hypo- and hyperglycemia
- Glucose monitoring
- Medications
- Exercise
- Nutrition issues including timing of meals and access to snacks

Recommendations

- Include diabetes in correctional staff education programs. (E)

Table 2—*Major components of diabetes self-management education*

Survival skills	Daily management issues
• Hypo-/hyperglycemia	• Disease process
• Sick day management	• Nutritional management
• Medication	• Physical activity
• Monitoring	• Medications
• Foot care	• Monitoring
	• Acute complications
	• Risk reduction
	• Goal setting/problem solving
	• Psychosocial adjustment
	• Preconception care/pregnancy/gestational diabetes management

ALCOHOL AND DRUGS— Patients with diabetes who are withdrawing from drugs and alcohol need special consideration. This issue particularly affects initial police custody and jails. At an intake facility, proper initial identification and assessment of these patients are critical. The presence of diabetes may complicate detoxification. Patients in need of complicated detoxification should be referred to a facility equipped to deal with high-risk detoxification. Patients with diabetes should be educated in the risks involved with smoking. All inmates should be advised not to smoke. Assistance in smoking cessation should be provided as practical.

TRANSFER AND DISCHARGE— Patients in jails may be housed for a short period of time before being transferred or released, and it is not unusual for patients in prison to be transferred within the system several times during their incarceration. One of the many challenges that health care providers face working in the correctional system is how to best collect and communicate important health care information in a timely manner when a patient is in initial police custody, is jailed short term, or is transferred from facility to facility. The importance of this communication becomes critical when the patient has a chronic illness such as diabetes.

Transferring a patient with diabetes from one correctional facility to another requires a coordinated effort. To facilitate a thorough review of medical information and completion of a transfer summary, it is critical for custody personnel to provide medical staff with sufficient notice before movement of the patient.

Before the transfer, the health care staff should review the patient's medical record and complete a medical transfer summary that includes the patient's current health care issues. At a minimum, the summary should include the following.

- The patient's current medication schedule and dosages
- The date and time of the last medication administration
- Any recent monitoring results (e.g., CBG and A1C)
- Other factors that indicate a need for immediate treatment or management at the receiving facility (e.g., recent episodes of hypoglycemia, history of severe hypoglycemia or frequent DKA, concurrent illnesses, presence of diabetes complications)
- Information on scheduled treatment/appointments if the receiving facility is responsible for transporting the patient to that appointment
- Name and telephone/fax number of a contact person at the transferring facility who can provide additional information, if needed

The medical transfer summary, which acts as a quick medical reference for the receiving facility, should be transferred along with the patient. To supplement the flow of information and to increase the probability that medications are correctly identified at the receiving institution, sending institutions are encouraged to provide each patient with a medication card to be carried by the patient that contains information concerning diagnoses, medication names, dosages, and frequency. Diabetes supplies, including diabetes medication, should accompany the patient.

The sending facility must be mindful of the transfer time in order to provide the patient with medication and food if needed. The transfer summary or medical record should be reviewed by a health care provider upon arrival at the receiving institution.

Planning for patients' discharge from prisons should include instruction in the long-term complications of diabetes, the necessary lifestyle changes and examinations required to prevent these complications, and, if possible, where patients may obtain regular follow-up medical care. A quarterly meeting to educate patients with upcoming discharges about community resources can be valuable. Inviting community agencies to speak at these meetings and/or provide written materials can help strengthen the community link for patients discharging from correctional facilities.

Discharge planning for the patients with diabetes should begin 1 month before discharge. During this time, application for appropriate entitlements should be initiated. Any gaps in the patient's knowledge of diabetes care need to be identified and addressed. It is helpful if the patient is given a directory or list of community resources and if an appointment for follow-up care with a community provider is made. A supply of medication adequate to last until the first postrelease medical appointment should be provided to the patient upon release. The patient should be provided with a written summary of his/her current heath care issues, including medications and doses, recent A1C values, etc.

Recommendations

- For all interinstitutional transfers, complete a medical transfer summary to be transferred with the patient. (E)
- Diabetes supplies and medication should accompany the patient during transfer. (E)
- Begin discharge planning with adequate lead time to insure continuity of care and facilitate entry into community diabetes care. (E)

SHARING OF MEDICAL INFORMATION AND RECORDS— Practical considerations may prohibit obtaining medical records from providers who treated the patient before arrest. Intake facilities should implement policies that *1*) define the circumstances under which prior medical records are obtained (e.g., for patients who have an extensive history of treatment for complications); *2*) identify person(s) responsible for contacting the prior

provider; and 3) establish procedures for tracking requests.

Facilities that use outside medical providers should implement policies and procedures for ensuring that key information (e.g., test results, diagnoses, physicians' orders, appointment dates) is received from the provider and incorporated into the patient's medical chart after each outside appointment. The procedure should include, at a minimum, a means to highlight when key information has not been received and designation of a person responsible for contacting the outside provider for this information.

All medical charts should contain CBG test results in a specified, readily accessible section and should be reviewed on a regular basis.

CHILDREN AND ADOLESCENTS WITH DIABETES

— Children and adolescents with diabetes present special problems in disease management, even outside the setting of a correctional institution. Children and adolescents with diabetes should have initial and follow-up care with physicians who are experienced in their care. Confinement increases the difficulty in managing diabetes in children and adolescents, as it does in adults with diabetes. Correctional authorities also have different legal obligations for children and adolescents.

Nutrition and activity

Growing children and adolescents have greater caloric/nutritional needs than adults. The provision of an adequate amount of calories and nutrients for adolescents is critical to maintaining good nutritional status. Physical activity should be provided at the same time each day. If increased physical activity occurs, additional CBG monitoring is necessary and additional carbohydrate snacks may be required.

Medical management and follow-up

Children and adolescents who are incarcerated for extended periods should have follow-up visits at least every 3 months with individuals who are experienced in the care of children and adolescents with diabetes. Thyroid function tests and fasting lipid and microalbumin measurements should be performed according to recognized standards for children and adolescents (12) in order to monitor for autoimmune thyroid disease and complications and comorbidities of diabetes.

Children and adolescents with diabetes exhibiting unusual behavior should have their CBG checked at that time. Because children and adolescents are reported to have higher rates of nocturnal hypoglycemia (13), consideration should be given regarding the use of episodic overnight blood glucose monitoring in these patients. In particular, this should be considered in children and adolescents who have recently had their overnight insulin dose changed.

PREGNANCY

— Pregnancy in a woman with diabetes is by definition a high-risk pregnancy. Every effort should be made to ensure that treatment of the pregnant woman with diabetes meets accepted standards (14,15). It should be noted that glycemic standards are more stringent, the details of dietary management are more complex and exacting, insulin is the only antidiabetic agent approved for use in pregnancy, and a number of medications used in the management of diabetic comorbidities are known to be teratogenic and must be discontinued in the setting of pregnancy.

SUMMARY AND KEY POINTS

— People with diabetes should receive care that meets national standards. Being incarcerated does not change these standards. Patients must have access to medication and nutrition needed to manage their disease. In patients who do not meet treatment targets, medical and behavioral plans should be adjusted by health care professionals in collaboration with the prison staff. It is critical for correctional institutions to identify particularly high-risk patients in need of more intensive evaluation and therapy, including pregnant women, patients with advanced complications, a history of repeated severe hypoglycemia, or recurrent DKA.

A comprehensive, multidisciplinary approach to the care of people with diabetes can be an effective mechanism to improve overall health and delay or prevent the acute and chronic complications of this disease.

Acknowledgments— The following members of the American Diabetes Association/National Commission on Correctional Health Care Joint Working Group on Diabetes Guidelines for Correctional Institutions contributed to the revision of this document: Daniel L. Lorber, MD, FACP, CDE (chair); R. Scott Chavez, MPA, PA-C; Joanne Dorman, RN, CDE, CCHP-A; Lynda K. Fisher, MD; Stephanie Guerken, RD, CDE; Linda B. Haas, CDE, RN; Joan V. Hill, CDE, RD; David Kendall, MD; Michael Puisis, DO; Kathy Salomone, CDE, MSW, APRN; Ronald M. Shansky, MD, MPH; and Barbara Wakeen, RD, LD.

References

1. National Commission on Correctional Health Care: *The Health Status of Soon-to-Be Released Inmates: A Report to Congress.* Vol. 1. Chicago, NCCHC, 2002
2. Hornung CA, Greifinger RB, Gadre S: *A Projection Model of the Prevalence of Selected Chronic Diseases in the Inmate Population.* Vol. 2. Chicago, NCCHC, 2002, p. 39–56
3. Puisis M: Challenges of improving quality in the correctional setting. In *Clinical Practice in Correctional Medicine.* St. Louis, MO, Mosby-Yearbook, 1998, p. 16–18
4. American Diabetes Association: Standards of medical care in diabetes—2007 (Position Statement). *Diabetes Care* 30 (Suppl. 1):S4–S41, 2007
5. American Diabetes Association: Screening for type 2 diabetes (Position Statement). *Diabetes Care* 27 (Suppl. 1):S11–S14, 2004
6. Krauss RM, Eckel RH, Howard B, Appel LJ, Daniels SR, Deckelbaum RJ, Erdman JW Jr, Kris-Etherton P, Goldberg IJ, Kotchen TA, Lichtenstein AH, Mitch WE, Mullis R, Robinson K, Wylie-Rosett J, St Jeor S, Suttie J, Tribble DL, Bazzarre TL: American Heart Association Dietary Guidelines: revision 2000: a statement for healthcare professionals from the Nutrition Committee of the American Heart Association. *Stroke* 31:2751–2766, 2000
7. American Diabetes Association: Nutrition recommendations and interventions for diabetes (Position Statement). *Diabetes Care* 30 (Suppl. 1):S48–S65, 2007
8. American Diabetes Association: Hyperglycemic crisis in diabetes (Position Statement). *Diabetes Care* 27 (Suppl. 1):S94–S102, 2004
9. American Diabetes Association: Continuous subcutaneous insulin infusion (Position Statement). *Diabetes Care* 27 (Suppl. 1):S110, 2004
10. American Diabetes Association: Tests of glycemia in diabetes (Position Statement). *Diabetes Care* 27 (Suppl. 1):S91–S93, 2004
11. American Diabetes Association: National standards for diabetes self-management education (Standards and Review Criteria). *Diabetes Care* 30 (Suppl. 1):S96–S103, 2007
12. International Society for Pediatric and Adolescent Diabetes: *Consensus Guidelines 2000: ISPAD Consensus Guidelines for the*

Management of Type 1 Diabetes Mellitus in Children and Adolescents. Zeist, Netherlands, Medical Forum International, 2000, p. 116, 118
13. Kaufman FR, Austin J, Neinstein A, Jeng L, Halyorson M, Devoe DJ, Pitukcheewanont P: Nocturnal hypoglycemia detected with the continuous glucose monitoring system in pediatric patients with type 1 diabetes. *J Pediatr* 141:625–630, 2002
14. American Diabetes Association: Gestational diabetes mellitus (Position Statement). *Diabetes Care* 27 (Suppl. 1):S88–S90, 2004
15. Jovanovic L (Ed.): *Medical Managementof Pregnancy Complicated by Diabetes.* 3rd ed. Alexandria, VA, American Diabetes Association, 2000

Cocci

COCCIDIOIDOMYCOSIS (VALLEY FEVER) FACTS

Biology

- Causative agent Coccidioides immitis or Coccidioides posadasii.
- Soil borne spore endemic in the SW US-Southern Arizona, Southern New Mexico, West Texas and Central and Southern California.
- Epidemics occur when soil disturbed (wind or earthquakes). Outbreaks are more frequent with a wet spring followed by a dry summer

Epidemiology

- Estimated 150,000 US cases per year
- 50% to 66% of cases are sub clinical
- 5%-10% result in residual pulmonary sequelae
- First episode almost always protective from reinfection
- 0.5% Risk of dissemination.
- Higher risk of dissemination in persons of African, Filipino, Asian and Native American
  ancestry (7x).
- Higher risk of dissemination in immunocompromised patients-HIV, Transplant, High Dose Steroids

Natural History

- Broad spectrum of illness. Mild Respiratory Illness/Uncomplicated Pneumonia which may resolve spontaneously to Progressive Pulmonary Destruction or Dissemination requiring intensive medical intervention and result in morbidity or death
- Symptom onset 1-3 weeks after infection
- Symptoms may be indistinguishable from bacterial
- May reactivate after treatment and requires clinical observation for up to two years or life long
- Pulmonary Disease-Uncomplicated Acute Coccidioidal Pneumonia, Diffuse Pneumonia, Pulmonary Nodule +/- Cavity, Progressive Pulmonary Firbrocavitary Pneumonia
- Disseminated Infection-Skin, Bone, Abscess Formation, Pericardial Infections, Joint,
  Spinal Infections, Meningeal Infection

Diagnosis

- High index of suspicion-resident of endemic area, travel to SW US, decreased immune state
- Culture of Fluids or Sputum-Special Media/Handling
- CXR-findings not specific-lobar, bilateral, hilar adenopathy, nodules, abscess, cavitary
- Cocci Titers 1:16-consider serial titers
- Rule out other Dx in cavitary lung lesions (CA)

Therapy

- Early treatment may prevent dissemination-controversial with no data to support
- Treatment of uncomplicated pulmonary disease is not settled due to lack of prospective controlled studies
- Treat immunocompromised patients, diabetics, chronic cardiac disease, and extra pulmonary disease
- Other indications for treatment of pulmonary cocci-weight loss> 10%, night sweats over three weeks, increasing infiltrates over ½ of lungs, persistent hilar adenopathy, comp fix titers over 1:16, inability to work, persistent symptoms over 2 months, age over 55
- Treatment Course-Weeks to Months (possibly life long)
- Azoles are initial therapy-Ketoconazole 400 mg per day po, Itraconazole 200 mg bid-tid po, Fluconazole 400-800 mg/day po or IV
- Amphotericin B-0.5-1.5 mg/kg per day or qod, indicated in respiratory failure, treatment failures, pregnancy
- Combo therapy not evaluated
- Surgical intervention-excision of pulmonary cavities, I&D, debridement
- Response to therapy-look for clinical improvement, decreased antibodies, end organ
  improvement
- HIV-prophylaxis not indicated, treat disease if CD4 count < 250
- Transplant patients-consider prophylaxis with Fluconazole

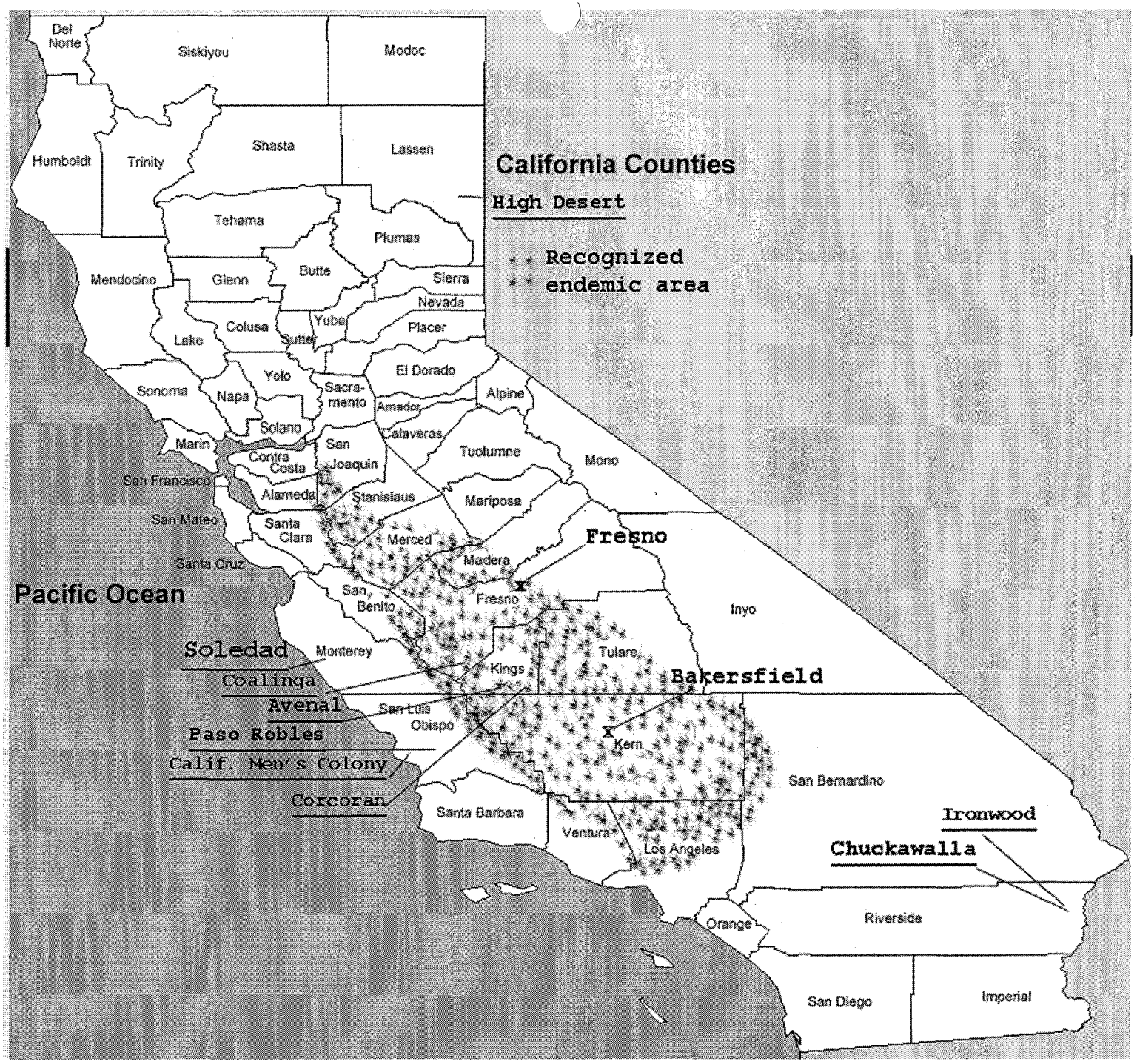

California Counties
High Desert
* * Recognized
* * endemic area
Del Norte
Siskiyou
Modoc
Humboldt
Trinity
Shasta
Lassen
Tehama
Plumas
Mendocino
Glenn
Butte
Sierra
Nevada
Colusa
Yuba
Placer
Lake
Sutter
Yolo
El Dorado
Sonoma
Napa
Sacra-
mento
Amador
Alpine
Solano
Calaveras
Marin
Contra
Costa
San
Joaquin
Tuolumne
Mono
San Francisco
Alameda
Stanislaus
Mariposa
San Mateo
Santa
Clara
Merced
Fresno
Madera
Santa Cruz
Pacific Ocean
San
Benito
Fresno
Inyo
Soledad
Monterey
Tulare
Kings
Coalinga
Bakersfield
Avenal
San Luis
Obispo
Paso Robles
Kern
Calif. Men's Colony
San Bernardino
Corcoran
Santa Barbara
Ventura
Ironwood
Los Angeles
Chuckawalla
Orange
Riverside
San Diego
Imperial

Table 1. Inmate Coccidioidomycosis* Cases in California Correctional Institutions 2000 to Jan-Aug 2007

Institutions: Bold = Prisons in Hyperendemic Area	Year Opened	2000--2001 **	Mar 2003--Feb 2004	2005	2006	Jan 2007 -- Aug 2007	TOTAL by Prison
Pleasant Valley (Coalinga)	**1994**	-	127+1 ***	150	514	216	1008
Avenal	**1987**	36***	22+1 ***	47	91	61	258
Corcoran State Prison	**1988**	14	21	23	12	9	79
Corcoran (SATF)	**1997**	-	-	2	22	10	34
North Kern (Delano)	**1993**	-	-	1	-	11	12
Wasco	**1991**	-	1	-	-	21	22
CCI (Tehachapi)		-	-	-	-	4	4
CMC (San Luis Obispo)		16	7	3	12	7	45
CMF (Vacaville)		8	1	-	2	1	12
CSP(Solano)		-	-	4	2	1	7
Mule Creek (Ione)		-	-	-	1	2	3
CCWF (Chowchilla)		-	1	-	-	-	1
VSPW (Chowchilla)		-	-	-	-	1	1
ISP (Blythe)		1	3	1	3	-	8
CVSP (Blythe)		1	1	-	1	2	5
CTF (Soledad)		-	-	5	4	3	12
HDSP (Susanville)		-	-	-	1	-	1
CEN (El Centro)		-	-	-	-	1	1
CSP (Sacramento/Folsom 2)		-	-	-	-	1	1
RJD (San Diego)		-	-	-	-	4	4
SCC (Jamestown)		-	-	-	-	1	1
LAC (Lancaster)		-	-	-	-	1	1
Miscellaneous State Prisons		10	18	8	-	-	36
Ventura Youth Authority (Pasa Robles)		23****	5	-	6	-	34
TOTAL		**109**	**209**	**244**	**671**	**357**	**1590**

* Using positive serum test for Coccidioidomycosis as bases for diagnosis
** In some instances, onset of disease may have been earlier than 2000
*** One case in prison employee
**** The CYA cases in 2000 were in inmates who had been assigned to fight grass fires in McKittrick in the highly endemic area of Kern County.
Note 1: **Kern Valley State Prison** (KVSP) is the only prison in the CA hyperendemic area that has not reported a case for this table.
Note 2: Table 1 was compiled from information provided by D. Pappagianis, M.D., PhD. UC Davis Coccidioidomycosis Serology Laboratory.

September 2007

COCCIDIOIDOMYCOSIS---RISK FACTORS FOR METAPULMONARY DISSEMINATION

INNATE

ETHNIC (Genetic)

Filipino, other Asian

African-American

Blood Group B

HLA Class II allele-
DRBI*1301

IL-10 (Experimental,
Fierer et al)

Mannose binding lectin?

ACQUIRED

lymphoma

AIDS

immunosuppression

diabetes mellitus

pregnancy

age (with comorbid
condition)

locus minoris resistentiae

Coccidioidomycosis at California State Prison - Coalinga (Pleasant Valley)

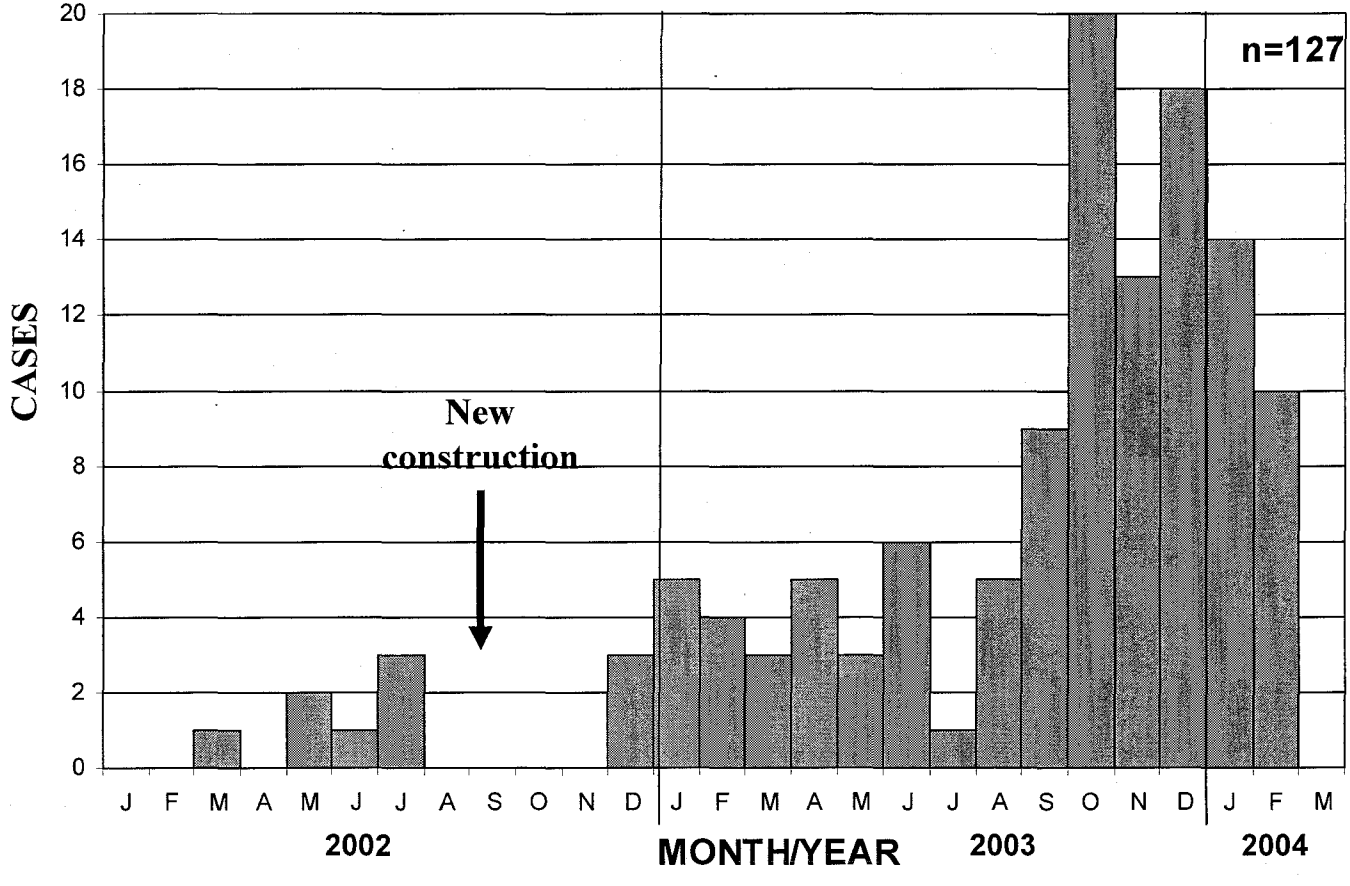


Table 4. Coccidioidomycosis in California Correctional Institutions, 2006

Facility	Number of Cases
Pleasant Valley State Prison – Coalinga	514*
Avenal	88
Camarillo	1
Corcoran (SATF)	12
Corcoran State Prison	22
CMC – San Luis Obispo	12
Vacaville (CMF)	2
California State Prison (Solano)	2
Mule Creek	1
Ventura Youth Authority	6
Ironwood (Blythe)	3
Chuckawalla (Blythe)	1
Soledad	2
Soledad CTF	2
Susanville	1
Total	669

*Incidence rate at PVSP approximately 10,000/100,000.

Memorandum

Date : NOV 2 0 2007

To : Wardens
Health Care Managers/Chief Medical Officers
Directors of Nursing
Classification and Parole Representatives
Correctional Counselor IIIs, Reception Centers
Classification Staff Representatives

Subject : **EXCLUSION OF INMATE-PATIENTS SUSCEPTIBLE TO COCCIDIOIDOMYCOSIS FROM HIGHEST RISK (HYPERENDEMIC) AREA INSTITUTIONS**

The following memorandum provides direction on the transfer process of inmate-patients that meet coccidioidomycosis (cocci) susceptibility exclusion criteria from highest risk (hyperendemic) area institutions. This memorandum supersedes the August 3, 2006 memorandum titled, *INMATE-PATIENTS AT HIGH RISK OF VALLEY FEVER EXCLUDED FROM SPECIFIC CENTRAL VALLEY INSTITUTIONS.*

In calendar year 2005, two San Joaquin Valley institutions, Pleasant Valley State Prison and Avenal State Prison, identified significant increases in the number of inmate-patients presenting with cocci, with deaths attributed to this disease. The California Department of Health Services (DHS) worked with California Department of Corrections and Rehabilitation (CDCR) staff in analyzing the problem and in assisting in designing an approach to mitigate the effects of the organism that causes cocci or "Valley Fever."

This approach includes identifying those inmate-patients most susceptible to developing severe or disseminated cocci and implementing strategies to prevent these susceptible inmate-patients from being housed in the hyperendemic area. Movement of these inmate-patients shall begin immediately. ***It is not necessary to transfer inmate-patients that have already been infected with cocci.***

The following institutions are located in the hyperendemic area:

Avenal State Prison
California Correctional Institution
California State Prison-Corcoran
California Substance Abuse Treatment Facility and State Prison at Corcoran
Kern Valley State Prison
North Kern State Prison
Pleasant Valley State Prison
Wasco State Prison

Inmate-patients requiring dialysis may continue to be housed at Kern Valley State Prison, California Substance Abuse Treatment Facility and State Prison at Corcoran, Wasco State Prison, and Security Housing Unit inmate-patients at Corcoron.

Human Immunodeficiency Virus (HIV)-infected inmate-patients that require Sensitive Needs Yard (SNY) placement shall be housed at the Richard J. Donovan Correctional

Facility. HIV-infected inmate-patients with Level IV placement scores who are not appropriate for Level III housing or are sentenced to Life Without the Possibility of Parole, and/or have an active Security Housing Unit Term, shall be housed at the California State Prison, Sacramento.

Based on DHS recommendations we are implementing the following plan, which includes:

1. Identifying susceptible inmate-patients in the institutions located in the hyperendemic area.
2. Transferring identified inmate-patients out of the hyperendemic area.
3. Developing a methodology as part of the Reception Center (RC) Intrasystem transfer process that includes identification and classification of inmate-patients at the highest risk of developing severe or disseminated cocci disease so that they are not transferred to an institution within the hyperendemic area.
4. Selecting environmental controls consistent with recommendations provided by DHS at institutions in the hyperendemic area.

It is imperative custody, classification, and health care staff closely collaborate to ensure effective and efficient implementation.

IMPLEMENTATION PROCEDURES – HEALTH CARE

The following clinical criteria, which define susceptible inmate-patients for morbidity related to cocci, will be used by health care staff to identify inmate-patients who cannot be housed at institutions within the hyperendemic area.

Criteria a. All identified HIV infected inmate-patients
Criteria b. History of lymphoma
Criteria c. Status post solid organ transplant
Criteria d. Chronic immunosuppressive therapy (e.g. severe rheumatoid arthritis)
Criteria e. Moderate to severe Chronic Obstructive Pulmonary Disease (COPD) requiring ongoing intermittent or continuous oxygen therapy
Criteria f. Inmate-patients with cancer on chemotherapy

The sources used to identify the above inmate-patients include:

1. Chronic disease lists
2. Pharmacy medication lists
3. Nursing input
4. Specialty clinic list
5. Return from a higher level of care, i.e., Hospital
6. Triage and treatment log

A CDCR physician will review the Unit Health Records (UHR) derived from the above sources and identify inmate-patients by name and CDCR number who will require transfer out of the current institution. The physician shall complete a CDCR Form 128-C, Medical Chrono, and forward a copy to the Classification and Parole Representative's (C&PR) office within three days of the UHR review. The CDCR Form 128-C shall indicate that the inmate-patient, due to environmental conditions (Valley Fever organism), (enter the criteria code, i.e. a-f), present at (enter prison name here), and the inmate's current health condition, must be transferred out of the hyperendemic area. The CDCR Form 128-C shall indicate whether inmate-patients are appropriate for general population housing.

When an inmate-patient's level of care dictates placement in a medical bed the Health Care Placement Unit (HCPU) shall be contacted to facilitate the endorsement transfer process, which shall include a Chief Medical Officer (CMO) to CMO agreement. In all other cases, CMO to CMO notification is required to ensure continuity of care. A copy of this CDCR Form 128-C shall be sent to the C&PR for classification action to be taken within seven days. The inmate-patient must be endorsed for transfer and the transfer must be coordinated with the receiving C&PR, and it must be expedited.

No later than December 15, 2007, at all institutions, the Receiving and Release (R&R) Registered Nurse (RN) shall review all scheduled transfers out of the institution via the CDCR Form 7343, Medical Advance Transfer Notice, and determine if any transferring inmate-patients meet the cocci susceptibility exclusion criteria listed above. If the answer is "Yes", the RN shall determine if the inmate-patient is endorsed for transfer to an institution within the hyperendemic (affected) area. The case records office shall notify the medical department of any changes to the CDCR Form 7343. The Health Care Manager (HCM) or designee shall place a medical hold on the inmate-patient's transfer after notification by the RN. The R&R RN shall complete a CDCR Form 128-C indicating that due to environmental conditions (Valley Fever organism), (enter the criteria code, i.e. a-f), present at (enter prison name here), and the inmate's current health status, he must be re-endorsed to an institution out of the hyperendemic area. The CDCR Form 128-C shall indicate whether inmate-patients are appropriate for general population housing.

When an inmate-patient's level of care dictates placement in a medical bed the HCPU shall be contacted to facilitate the endorsement and transfer process, which shall include a CMO to CMO agreement. A copy of this CDCR Form 128-C shall be sent to the C&PR for referral to a classification committee for endorsement by the Classification and Staff Representative (CSR) to an alternate institution outside the hyperendemic area. The transfer must be expedited.

For inmates arriving at institutions located within the hyperendemic area, the R&R, RN shall review new arrivals to determine if they meet the cocci susceptibility exclusion criteria. If the answer is "Yes", the R&R, RN shall complete a CDCR Form 128-C indicating that due to environmental conditions (Valley Fever organism), (enter the criteria code, i.e. a-f), present at (enter prison name here) and the inmate's current health status, he must be transferred out of the hyperendemic area. The CDCR Form 128-C shall indicate whether inmate-patients are appropriate for general population housing.

When an inmate-patient's level of care dictates placement in a medical bed the HCPU shall be contacted to facilitate the endorsement and transfer process, which shall include a CMO to CMO agreement. A copy of this CDCR Form 128-C shall be sent to the C&PR for referral to a classification committee for endorsement by the CSR to an alternate institution. The inmate-patient must be endorsed for transfer and the transfer must be expedited. Additionally, as inmate-patients' health care needs change, i.e. require chemotherapy, these inmate-patients are to be referred for transfer out of the hyperendemic area as described above. In all cases, common sense must be applied. Patients should not be transferred in a manner that will lead to interruptions in essential treatment.

IMPLEMENTATION PROCEDURES – CUSTODY/CLASSIFICATION

Institution C&PRs/RC Correctional Counselors (CC) III within the hyperendemic area are to receive the CDCR Form 128-C within three days of the inmate-patient being identified as meeting the exclusion criteria. The C&PR/ RC CC III is to ensure that the inmate-patient is referred to the CSR for endorsement to an alternate institution by a classification committee or appropriate RC process. Every attempt will be made to transfer the inmate-patient within 60 days of the date of the CDCR Form 128-C. If an RC inmate-patient is not processed and transferred within the 60-day timeframe, the RC CC III shall coordinate the transfer of the inmate-patient to the California State Prison, Los Angeles County to complete the processing. The HCPU is to be notified of any delayed transfers and will work collaboratively with Classification Services Unit (CSU) towards resolution.

C&PRs/RC CC IIIs shall continue to be familiar with the list of institutions within the cocci hyperendemic area. Upon receipt of the CDCR Form 128-C documenting preclusion of endorsement to institutions within the hyperendemic area and the medical hold, the C&PR/RC CC III's office shall ensure the case is reviewed immediately by a classification committee for appropriate action.

The CSR staff must be familiar with the list of institutions located within the hyperendemic area in order to avoid the inappropriate placement or transfer of susceptible inmate-patients. Prior to endorsing a case, the CSR shall ensure inmates meeting the above exclusion criteria are not endorsed to institutions located in the hyperendemic area. Additionally, the CSR shall document the following in the CDCR Form 128-G, Classification Chrono, "Inmate meets the cocci susceptibility exclusion criteria, see CDCR Form 128-C dated_____; therefore, this inmate should not be retained or transferred into the hyperendemic or affected areas unless there is a change in his medical condition."

For difficult to place inmate-patients (i.e., Bulldogs, SNY, wheelchair dependent), a case conference with HCPU, CSU, a headquarters health care clinician, and the sending institution C&PR staff will take place in order to identify an appropriate institution for transfer or potential retention at the current institution if no reasonable alternative can be identified. If retention at the current institution is the decision, the inmate-patient will be provided with environmental safeguards; i.e., protective mask when outside.

IMPLEMENTATION PROCEDURES -- ENVIRONMENTAL CONTROLS

Institutions within the hyperendemic area shall implement the DHS recommended environmental controls, including:

1. Continue to provide educational material to medical and custody staff and to inmate-patients regarding cocci disease.
2. Consider planting ground cover or grass on open dirt areas within the prison grounds.
3. When digging, use a protective mask and wet the ground prior to digging.

Thank you in advance for your compliance. Should you require additional information regarding classification issues, please contact Eric Arnold, Chief, CSU, at (916) 323-3660. For questions regarding medical concerns, please contact your respective Regional Medical Director.

SUZAN L. HUBBARD
Director
Division of Adult Institutions

DWIGHT WINSLOW, M.D.
Statewide Medical Director
Plata Support Division

cc: Scott Kernan, Chief Deputy Secretary, Adult Operations
Robin Dezember, Chief Deputy Secretary, Correctional Health Care
Nadim Khoury, M. D., Chief Deputy, Clinical Services, Plata Support Division (PSD)
Terry Hill, M. D., Chief Medical Officer, California Prison Health Care Receivership
Associate Directors-DAI
Regional Medical Directors, PSD
Regional Administrators-DCHCS
Tim Rougeux, *Plata* Implementation Project Manager, PSD
Janet Rodriguez, Chief, Case Records Services, DAI
Rick Johnson, CC III, HCPU, Division of Correctional Health Care Services (DCHCS)
Eric Arnold, Chief, CSU, Division of Adult Institutions (DAI)
Regional Director of Nursing, PSD
CSU Facility Captains
CSU CC IIIs
CSU CC IIs
HCPU CC IIIs

Chapter #: Current Effective Date: January 2007
Status: Last Review Date:

CHAPTER

Coccidioidomycosis Identification and Reporting

I. POLICY

All cases of Coccidioidomycosis shall be reported to the Division of Correctional Health Care Services (DCHCS) and the institution's respective County Health Department.

II. PURPOSE

The purpose of this policy is to describe the process for identifying, confirming and reporting Coccidioidomycosis cases within correctional institutions. Reporting will enable DCHCS to identify outbreaks of infection and disseminated Coccidioidomycosis in their early stages and prevent new infections.

Eight CDCR institutions are located in areas of California where Coccidioidomycosis is hyperendemic, [1] meaning the population has an elevated risk of exposure. Inmate-patients with certain health conditions are susceptible to morbidity-related Coccidioidomycosis and are to be transferred out of the hyperendemic areas within 30 days of these health conditions being identified by the primary care provider.

III. PROCEDURE

A. CASE DEFINITION

Coccidioidomycosis is caused by inhaling the spores of the fungus *Coccidioides immitis*, and is also known as Valley Fever. Infection may be asymptomatic, may produce an acute or chronic disease or may become disseminated. Acute pulmonary Coccidioidomycosis is almost always mild, with few or no symptoms, and resolves without treatment. The incubation period is 7 to 21 days. Chronic pulmonary Coccidioidomycosis can develop 20 or more years after initial infection and is less common than the acute form. Although the disease initially resembles an influenza-like febrile illness primarily involving the bronchopulmonary system, dissemination can occur to virtually any organ system. If disseminated, the disease can spread to the bones, lungs, liver, meninges, brain, skin, heart, and pericardium.

There is no person-to-person transmission of the disease. There is no need to isolate inmate-patients diagnosed with Coccidioidomycosis.

[1] Institutions in the hyperendemic area are Avenal State Prison, California Correctional Institution, California State Prison – Corcoran, California Substance Abuse Treatment Facility and State Prison at Corcoran, Kern Valley State Prison, North Kern Valley State Prison, Pleasant Valley State Prison, and Wasco State Prison.

B. CASE CONFIRMATION

A confirmed case of Coccidioidomycosis must meet both the clinical case definition and be laboratory confirmed. It is important to utilize laboratories that are experienced in diagnosis of Coccidioidomycosis.

1. Clinical Case Definition: An illness characterized by one or more of the following:

   a. Influenza-like signs and symptoms including fever, chest pain, cough, myalgia, arthralgia and headache
   b. Focal or diffuse pulmonary infiltrates, thin-walled cavitary lesion(s), pulmonary nodule(s), and/or hilar adenopathy, by Chest X-ray
   c. Rash, including erythema nodosum, erythema multiforme, or erythema marginatum
   d. Involvement of the bones, joints, or soft tissue/skin abscesses (maculopapular lesions, ulcerations, or subcutaneous abscesses) by dissemination
   e. Meningitis
   f. Involvement of viscera and lymph nodes

2. Laboratory Criteria for Diagnosis: Laboratory-confirmed Coccidioidomycosis requires at least one of the following criteria listed below.

   a. Evidence of growth in cultures, histopathologic identification of spherules in tissue, or molecular evidence of presence of *C. immitis* by polymerase chain reaction (PCR) methods; or
   b. Immunologic evidence of infection: Serologic (testing of serum, cerebral spinal fluid, or other body fluid):
      1. Detection of coccidioidal IgM by immunodiffusion, enzyme immunoassay (EIA), or complement fixation (acute titer).
      2. Detection of rising convalescent titer of coccidioidal IgG by immunodiffusion, enzyme immunoassay (EIA), or complement fixation.

   The absence of detectable anti-coccidioidal antibodies does not exclude the diagnosis of Coccidioidomycosis, especially in the early course of clinical illness.

   The results of these immunologic tests must be interpreted in the context of the varied clinical presentations and the duration and clinical type of Coccidioidomycosis. Inmate-patients that have positive laboratory tests without signs or symptoms of the disease do not have Coccidioidomycosis and should not be reported.

   Routine laboratory screening for Coccidioidomycosis should not be done.

3. Dissemination: Dissemination is defined as involvement of skin, bones, joints, meninges, viscera, or lymph nodes. Diagnosis of dissemination is made on the basis of history, physical examination, and appropriate diagnostic studies, including cultural, histopathologic or molecular evidence of *C. immitis*. Erythema nodosum, erythema multiforme, and erythema marginatum are not diagnostic of dissemination. Pulmonary involvement alone, even if severe, is not considered to be disseminated disease.

IgG titers should be measured by complement fixation periodically in inmate-patients with active Coccidioidomycosis. A titer of $\geq$ 1:16 is associated with extrapulmonary dissemination. High and rising IgG titers are an indication of ongoing infection and/or dissemination.

C. REPORTING

Under State law, health care providers are required to report certain diseases and conditions of public health importance. Health care staff shall report cases of Coccidioidomycosis (symptomatic or disseminated) as follows:

1. Reporting to DCHCS:

All cases of symptomatic or disseminated Coccidioidomycosis that meet the definition described in this policy shall be documented on the *Coccidioidomycosis Report Log, (Attachment 1).*

The *Report Log* includes diagnostic information for inmate-patients who have acute symptoms or who have progressed to disseminated Coccidioidomycosis. If the diagnosis is first made at the time that the disease has disseminated, information about the early general symptoms may not be available. The *Report Log* also includes the date the case was reported to the local County Health Department.

For those institutions that are in the hyperendemic area for Coccidioidomycosis, the *Report Log* shall be submitted to DCHCS on a monthly basis and is due on the 15th of the month following the "report month". If there are no new cases that month, indicate "no new cases" on the *Report Log*. Submit it to:

DCHCS
FAX (916) 327-3406

All other institutions will report new cases of Coccidioidomycosis by the 15th of the month following the month that the case was diagnosed.

2. Reporting to local County Health Department:

All new cases of Coccidioidomycosis shall be reported within seven (7) days of identification on the Confidential Morbidity Report (PM 110) (*Attachment 2*).

D. TRANSFER OF INMATE-PATIENTS OUT OF INSTITUTIONS WITHIN THE HYPER-ENDEMIC AREA

In the hyperendemic area, inmate-patients with certain, specific clinical conditions are to be transferred out of the institution within 30 days of the primary care provider documenting their clinical status. The CDCR Form 128-C shall indicate that the inmate-patient, due to environmental conditions present at the institution and the inmate's current

health condition must be transferred out of the hyperendemic area. The following are the clinical conditions that require the inmate-patient to be transferred out of the hyperendemic area:

a. HIV infected with a T-cell count of less than 250
b. History of lymphoma
c. Status post solid organ transplant
d. Chronic immuno therapy (e.g. severe rheumatoid arthritis)
e. Chronic lung disease requiring oxygen therapy
f. Cancer patient on chemotherapy

A copy of the CDCR Form 128-C shall be sent to the institution's Classification and Parole Representative for classification action to be taken within seven days. The inmate-patient must be endorsed for transfer and the transfer expedited to meet the 30 day transfer time frame.

IV. AUTHORITY

California Code of Regulations, Title 17 §2500
Health and Safety Code, §120295

V. FORMS

Coccidioidomycosis Report Log
Confidential Morbidity Report, PM 110 (2/02)

Coccidioidomycosis

John N. Galgiani,[1,2,3] Neil M. Ampel,[1,2,3] Janis E. Blair,[4] Antonino Catanzaro,[5] Royce H. Johnson,[6] David A. Stevens,[7,8] and Paul L. Williams[9]

[1]Valley Fever Center for Excellence, [2]Southern Arizona Veterans Affairs Health Care System, and [3]University of Arizona, Tucson, and [4]Mayo Clinic, Scottsdale, Arizona; and [5]University of California, San Diego, [6]Kern Medical Center, Bakersfield, [7]Santa Clara Valley Medical Center and [8]Stanford University, San Jose, and [9]Kaiser Permanente Medical Center, Fresno, California

EXECUTIVE SUMMARY

Management of coccidioidomycosis first involves recognizing that a coccidioidal infection exists, defining the extent of infection, and identifying host factors that predispose to disease severity. After these assessments, patients with localized acute pulmonary infections and no risk factors for complications often require only periodic reassessment to demonstrate resolution of their self-limited process. On the other hand, patients with extensive spread of infection or who are at high risk of complications because of immunosuppression or other preexisting factors require a variety of treatment strategies that may include antifungal drug therapy, surgical debridement, or a combination of both. Azole antifungals, primarily fluconazole and itraconazole, have replaced amphotericin B as initial therapy for most chronic pulmonary or disseminated infections. Amphotericin B is now usually reserved for patients with respiratory failure due to infection with *Coccidioides* species, those with rapidly progressive coccidioidal infections, or women during pregnancy. Therapy often ranges from many months to years in duration, and in some patients, lifelong suppressive therapy is needed to prevent relapses.

Received 12 July 2005; accepted 13 July 2005; electronically published 20 September 2005.

These guidelines were developed and issued on behalf of the Infectious Diseases Society of America.

Reprints or correspondence: Dr. John N. Galgiani, Valley Fever Center for Excellence, 3601 S. 6th Ave., VA Med Ctr. and Univ. of Arizona, Tucson, AZ 85723 (spherule@u.arizona.edu).

Clinical Infectious Diseases 2005;41:1217–23
© 2005 by the Infectious Diseases Society of America. All rights reserved.
1058-4838/2005/4109-0001$15.00

INTRODUCTION

Coccidioidomycosis (also known as valley fever) results from inhaling the spores (arthroconidia) of *Coccidioides* species (*Coccidioides immitis* or *Coccidioides posadasii*) [1]. Most infections in the United States are acquired within the major regions of endemicity of southern Arizona, central or other areas of California, southern New Mexico, and west Texas. Travelers who have recently visited the region of endemicity or previously infected patients with immunosuppression who experience reactivation of latent infections can develop clinical disease and require medical management outside of the region of coccidioidal endemicity [2].

The estimated numbers of infections per year has risen to ~150,000 as a result of population increases in southern Arizona and central California. Of these infections, one-half to two-thirds are subclinical, and virtually all patients with these infections are protected from second primary infections. The most common clinical presentation of coccidioidomycosis is a self-limited acute or subacute community-acquired pneumonia that becomes evident 1–3 weeks after infection. Such illnesses are usually indistinguishable from bacterial or other infections without specific laboratory tests, such as fungal cultures or coccidioidal serological testing. For such patients, symptoms—especially fatigue interfering with normal activities—may last for weeks to many months. Approximately 5%–10% of infections result in residual pulmonary sequelae, usually nodules or peripheral thin-walled cavities. An even smaller proportion of all infections result in illnesses related to chronic pulmonary or extrapulmonary infection. For extrapulmonary complications, estimates range as low as 0.5% of infections for persons of Caucasian ancestry, several-fold higher for persons of African or Filipino ancestry (possibly also for persons of Asian, Hispanic,

or Native American ancestry), and as high as 30%–50% of infections for heavily immunosuppressed patients, such as those with AIDS, lymphoma, receipt of a solid-organ transplant, or receipt of rheumatologic therapies, such as high-dose corticosteroids or anti-TNF medications. Disseminated infections also appear to be more frequent in adults than in children. Although virtually any site in the body may be involved, extrapulmonary dissemination most frequently involves the skin, the skeletal system, and the meninges [3–6].

Objective. The objective of this practice guideline is to provide recommendations for which patients with coccidioidomycosis are likely to benefit from treatment and which therapies are most appropriate for various forms of infection.

Treatment options. Coccidioidomycosis encompasses a broad spectrum of illness. At one end of that spectrum, it may produce a mild respiratory syndrome or an uncomplicated community-acquired pneumonia, either of which may resolve spontaneously. At the other end of that spectrum, infection may result in progressive pulmonary destruction or lesions in other parts of the body. Because severity varies widely, the optimal management strategies also vary widely among individual patients. Although the vast majority of patients who present with early infections will resolve their infection without specific antifungal therapy, management should routinely include repeated patient encounters every 3–6 months for up to 2 years, either to document radiographic resolution or to identify evidence of pulmonary or extrapulmonary complications as early as possible. Patients who present with severe pneumonia soon after infection warrant antifungal therapy. Patients who develop chronic pulmonary or disseminated disease also warrant antifungal therapy, which is typically prolonged—potentially lifelong—especially in patients with overt immunocompromising conditions. Exact management guidelines for these clinical forms will vary according to disease type and, to an extent, must be individualized. For example, the role of surgical debridement, which, in some patients, is a critical component of therapy, is not addressed in this guideline. However, all patients with progressive or disseminated disease will require some combination of periodic physical examinations, laboratory studies, and imaging studies to guide management decisions.

Specific antifungal drugs and their usual dosages for treatment of coccidioidomycosis include amphotericin B deoxycholate (0.5–1.5 mg/kg per day or alternate day administered intravenously), lipid formulations of amphotericin B (2.0–5.0 mg/kg or greater per day administered intravenously), ketoconazole (400 mg every day administered orally), fluconazole (400–800 mg/day administered orally or intravenously), and itraconazole (200 mg twice per day or 3 times per day administered orally). If itraconazole is used, measurement of itraconazole concentration in serum samples may determine if absorption is satisfactory. Cyclodextrin suspensions of itraconazole afford greater absorption, although published clinical trials of itraconazole for the treatment of coccidioidomycosis have not used this formulation. In general, the more rapidly progressing a coccidioidal infection, the more likely amphotericin B will be selected by most authorities for initial therapy. Conversely, subacute or chronic presentations are more likely to be treated initially with an azole antifungal.

Newly available antifungal agents of possible benefit for the treatment of refractory coccidioidal infections are voriconazole and caspofungin. Voriconazole has not been approved by the United States Food and Drug Administration (FDA) for the treatment of coccidioidomycosis. Although there are no reports of voriconazole therapy for experimental coccidioidal infections, case reports have suggested that voriconazole may be effective in selected patients [7–9]. Caspofungin has been effective in treating experimental murine coccidioidomycosis [10], but in vitro susceptibility of isolates varies widely [11], and there is only 1 report regarding its value [12]. Posaconazole, not yet approved by the FDA, was shown to be an effective treatment in a small clinical trial [13] and in patients with refractory infections [14]. Its efficacy relative to other triazole antifungals is unknown.

Combination therapy with members of different classes of antifungal agents has not been evaluated in patients, and there is a hypothetical risk of antagonism [15]. However, some clinicians feel that outcome in severe cases is improved when amphotericin B is combined with an azole antifungal. If the patient improves, the dosage of amphotericin B can be slowly decreased while the dosage of azole is maintained.

Despite there being several antifungal therapies available for treatment of coccidioidomycosis, occasional patients have exceptionally widespread, debilitating, and potentially life-threatening complications, either at the time of first diagnosis or despite therapy. This is especially true for patients with coccidioidal meningitis. Because of the regional nature of coccidioidomycosis, many of the clinicians most familiar with such problems practice in the southwestern regions of endemnicity. Occasionally seeking advice or obtaining a second opinion from a specialist who is particularly familiar with coccidioidomycosis may be of benefit in formulating a treatment plan that best fits a specific clinical situation.

Outcomes. Desired outcomes of treatment are resolution of signs and symptoms of infection, reduction of serum concentrations of anticoccidioidal antibodies, and return of function of involved organs. It would also be desirable to prevent relapse of illness on discontinuation of therapy, although current therapy is often unable to achieve this goal.

Evidence to support recommendations. Before the availability of antifungal therapy, initial uncomplicated pulmonary infections in the absence of comorbidity resolved in at least

95% of patients. Randomized, prospective clinical trials of antifungal drugs have not been completed to determine whether drug therapy hastens the resolution of immediate symptoms or prevents subsequent complications.

Published reports of intravenous amphotericin B treatment of chronic pulmonary or extrapulmonary nonmeningeal coccidioidomycosis are limited to small numbers of patients treated in open-label, nonrandomized studies [13]. Coccidioidal meningitis treatment with intrathecal amphotericin B has been reported as the accumulated experience of individual investigators [16].

The response of symptomatic chronic pulmonary and extrapulmonary disseminated infections to several oral azole antifungal agents has been studied in large, multicentered, open-label, nonrandomized trials by the Mycoses Study Group, as well as by other investigators [17–26]. The majority of patients in these studies were treated for periods ranging from months to years and exhibited decreased numbers of symptoms, improved appearance of chest radiographs or extrapulmonary lesions, decreased concentrations of complement fixing-type antibodies in their serum or CSF samples, and sputum cultures that converted from positive for *Coccidioides* species to negative. Follow-up cultures of samples obtained from extrapulmonary lesions often would have required invasive procedures and frequently were not carried out. Moreover, when therapy was stopped, these abnormalities often recurred, suggesting that sterilization of lesions was not accomplished. A randomized trial of oral itraconazole (200 mg administered twice per day) versus oral fluconazole (400 mg administered every day) has been published [27]. In the primary analysis, there was no difference between these 2 treatments when analyzed at the 8-month time point. Subanalyses indicated that itraconazole therapy may be more potent in the treatment of skeletal lesions and superior when analyzed at 12 months overall.

Values. Principal value is afforded to patients who receive treatment. Coccidioidomycosis is not contagious by the respiratory route and therefore control of individual infections will not have additional public health benefit.

Benefits, harms, and costs. A diagnosis of coccidioidomycosis in itself may benefit a patient by (1) reducing the use of unnecessary antibacterial therapies, (2) avoiding further diagnostic evaluations, (3) allaying patient anxiety about an otherwise uncertain respiratory condition, and (4) affording patients prognostic information. Early identification and treatment of complications will decrease the amount of tissue destruction and resulting morbidity. Effective therapy is potentially lifesaving.

Use of amphotericin B often engenders untoward effects. Surgical risks depend on the specific procedure.

The cost of antifungal medication can be as high as $20,000 per year of treatment. Recently, generic fluconazole has become available at considerably lower cost. For managing critically ill patients with coccidioidomycosis, there are considerable additional costs, including intensive care support for many days or weeks. In a recent Centers for Disease Control and Prevention (CDC) analysis, hospital costs in Arizona during 1998–2001 were a mean of $33,762 per patient with coccidioidomycosis [28].

Validation. Below are descriptions of management strategies for several manifestations of coccidioidomycosis. A revision of the original Practice Guidelines for Coccidioidomycosis [29] was circulated among the authors. Subsequently revised drafts were reviewed for comment by members of the Arizona Infectious Diseases Society (6–7 March 2004) and by health care professionals who attended the 48th Annual Coccidioidomycosis Study Group Meeting (held on 3 April 2004). The strength of and evidence for recommendations, expressed using the Infectious Diseases Society of America–US Public Health Service grading system for ranking recommendations in clinical guidelines (table 1), is shown following each specific recommendation.

MANAGEMENT OF CLINICAL ENTITIES

Primary Respiratory Infection

Primary infections due to *Coccidioides* species most frequently manifest as community-acquired pneumonia 1–3 weeks after exposure [30, 31]. Distinguishing coccidioidomycosis from other etiologies is usually difficult without specific laboratory confirmation, such as detection of anticoccidioidal antibodies in serum samples [32] or identification of *Coccidioides* species in sputum samples or another respiratory specimen. Therefore, residents of and recent travelers to regions where community-acquired pneumonia is endemic should be evaluated for *Coccidioides* species as a possible etiologic agent. *Coccidioides* species are listed by the CDC as Select Agents, and their growth in culture requires handling in a secure and contained fashion [33].

Uncomplicated acute coccidioidal pneumonia. How best to manage primary respiratory coccidioidal infections is an unsettled issue because of the lack of prospective controlled trails. For many (if not most) patients, management may rely on periodic reassessment of symptoms and radiographic findings to assure resolution without antifungal treatment. On the other hand, some authorities propose treatment of all symptomatic patients to decrease the intensity or duration of symptoms. Although physicians speculate that early treatment may decrease the frequency or severity of dissemination, there are no data to support this speculation (C-III). Several special circumstances are usually considered to warrant initiation of therapy. Chief among these is concurrent immunosuppression, such as that which accompanies AIDS, receipt of an organ transplant, therapy with high-dose corticosteroids, or receipt of inhibitors

Table 1. Infectious Diseases Society of America–US Public Health Service Grading System for ranking recommendations in clinical guidelines.

Category, grade	Definition
Strength of recommendation	
A	Good evidence to support a recommendation for use; should always be offered
B	Moderate evidence to support a recommendation for use; should generally be offered
C	Poor evidence to support a recommendation; optional
D	Moderate evidence to support a recommendation against use; should generally not be offered
E	Good evidence to support a recommendation against use; should never be offered
Quality of evidence	
I	Evidence from ≥1 properly randomized, controlled trial
II	Evidence from ≥1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from >1 center); from multiple time-series; or from dramatic results from uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

of TNF (such as etanercept or infleximab). Also, other patients who are likely to handle pulmonary coccidioidal infection less well include those with diabetes mellitus or preexisting cardiopulmonary disease (A-II). The diagnosis of primary infection during pregnancy, especially in the third trimester or immediately postpartum, frequently prompts the initiation of treatment (A-III). During pregnancy, amphotericin B is the treatment of choice because fluconazole (and likely other azole antifungals) are teratogenic (A-III). Persons of Filipino or African descent have a higher risk for dissemination, and this may also be taken into consideration (B-III). Finally, patients who are judged to have exceptionally severe primary infections may be more likely to benefit from treatment than those patients with a more mild illness. Although opinion varies as to the most-relevant factors for judging severity of illness, commonly used indicators include weight loss of >10%, intense night sweats persisting longer than 3 weeks, infiltrates involving more than one-half of one lung or portions of both lungs, prominent or persistent hilar adenopathy, anticoccidiodial complement-fixing antibody concentrations in excess of 1:16 (as determined by a reference method or equivalent titer) [32], inability to work, symptoms that persist for >2 months, or age >55 years. Commonly prescribed therapies include currently available oral azole antifungal agents at dosages of 200–400 mg per day. Courses of typically recommended treatment range from 3 to 6 months.

As the patient's illness improves, either with or without antifungal therapy, continued monitoring at 1–3-month intervals for 1 year or longer is advised to assess the resolution of pulmonary infiltrates and to identify, as early as possible, those patients who develop infection outside of the chest. Monitoring usually should include patient interviews, physical examinations (as appropriate), serologic tests, and radiographic examinations. Determining pulmonary lesions that evolve into residual nodules is useful because it obviates the need for establishing the nodule's etiology at a future time. Identifying dissemination is accomplished with histologic examination and culture of suspicious skin lesions, analysis of aspirates of joint effusions, and lumbar puncture of patients who develop progressively severe or persistent headaches, mental status changes, or other meningeal signs. Although extrapulmonary dissemination is infrequent, early detection of patients in whom dissemination does occur would afford benefit by earlier initiation of treatment and a resulting reduction in tissue destruction.

Diffuse pneumonia. Bilateral reticulonodular or miliary infiltrates produced by *Coccidioides* species suggest either an underlying immunodeficiency state with concurrent fungemia or an exposure to a high inoculum of fungal spores, as may occur as a result of laboratory accidents or at archeology sites. In such patients, therapy is usually begun either with amphotericin B or high-dose fluconazole. Amphotericin B is more frequently used as initial therapy if significant hypoxia is present or if deterioration is rapid (A-III). Several weeks of therapy are often required to produce clear evidence of improvement. After this time, during convalescence, amphotericin B therapy may be discontinued and replaced with treatment with an oral azole antifungal (B-III). In combination, the total length of therapy should be at least 1 year, and for patients with severe immunodeficiency, oral azole therapy should be continued as secondary prophylaxis (A-III). Because diffuse pneumonia due to *Coccidioides* species is usually a manifestation of fungemia, patients should be evaluated for the possibility of other extrapulmonary lesions that may also require attention.

Pulmonary Nodule, Asymptomatic

If a stable solitary nodule is determined to be due to *Coccidioides* species by noninvasive means or by fine-needle aspiration, specific antifungal therapy or resection is unnecessary (E-II). Similarly, in the absence of significant immunosuppression, anti-

fungal therapy is not recommended if the lesion is completely resected and the diagnosis is determined from the excised tissue. Stability can be determined by repeated radiographic examination of the chest for 2 years demonstrating no change in the size of the nodule. Should enlargement of the nodule occur, reevaluation with sputum cultures and measurement of coccidioidal serum antibodies may help to determine whether the patient's infection is active and warrants therapy. Consideration also should be given to the possibility of cancer coexistent with the coccidioidal infection, in which case resection of the nodule would usually be necessary.

Pulmonary Cavity

Asymptomatic. Many cavities caused by *Coccidioides* species are benign in their course and do not require intervention. Such cavities may harbor viable fungus, and cultures of samples of sputum or other respiratory secretions commonly yield colonies of *Coccidioides* species. Many authorities do not consider these characteristics of asymptomatic cavities sufficient reason to initiate treatment. Moreover, in the absence of controlled clinical trials, evidence is lacking that antifungal therapy has a salutary effect on the course of asymptomatic coccidioidal cavities (B-III). With the passage of time, some cavities disappear, obviating the need for intervention. Although an indefinite follow-up period without intervention is appropriate for many patients, eventual resection from 1 to several years after the cavity is identified may be recommended to avoid future complications, especially if the cavity is still detectable after 2 years, if it demonstrates progressive enlargement, or if it is immediately adjacent to the pleura (B-III).

Symptomatic. Complications of coccidioidal cavities include local discomfort, superinfection with other fungi or possibly bacteria, or hemoptysis. Should these complications occur, oral therapy with azole antifungals may result in improvement, although recurrence of symptoms (at least in some patients) may occur on cessation of therapy. If a bacterial superinfection is present, treatment for several weeks with an oral antibacterial may also reduce symptoms. However, such therapies usually do not result in the closure of the cavity. In cases in which the surgical risks are not unusually high, resection of localized cavities is likely to resolve the problem and may be recommended as an alternative approach to chronic or intermittent therapy.

Ruptured. Rupture of a coccidioidal cavity into the pleural space, resulting in a pyopneumothorax, is an infrequent but serious complication of a necrotizing coccidioidal pneumonia [34]. In young, otherwise-healthy patients, surgical closure by lobectomy with decortication is the preferred management (A-II). Antifungal therapy is recommended for treatment, particularly in cases with delay of diagnosis and coexistent diseases (C-III). For patients in whom the diagnosis was delayed a week or more or for patients in whom there are coexistent diseases, management approaches are less uniform and may include courses of therapy with amphotericin B or oral azole antifungal drugs prior to surgery or chest tube drainage without surgery (C-III).

Chronic Progressive Fibrocavitary Pneumonia

Initial treatment with oral azole antifungal agents is recommended (A-II). If the patient improves sufficiently, therapy should be continued for at least 1 year. If therapy is not satisfactory, switching to an alternative azole antifungal, raising the dosage of the azole, or therapy with amphotericin B are alternative strategies (B-III). Surgical resection may be a useful option for refractory lesions that are well localized or in cases in which significant hemoptysis has occurred.

Disseminated Infection (Extrapulmonary)

Nonmeningeal. Initial therapy is usually initiated with oral azole antifungal agents, most commonly fluconazole or itraconazole (A-II). Clinical trials have used 400 mg per day of ketoconazole, itraconazole, or fluconazole. Some experts recommend higher dosages (up to 2000 mg per day of fluconazole; up to 800 mg per day of itraconazole, administered in 200-mg doses) (B-III). Amphotericin B is recommended for alternative therapy, especially if lesions are appearing to worsen rapidly and are in particularly critical locations, such as the vertebral column (B-III). Amphotericin B dosage is similar to that for diffuse coccidioidal pneumonia, although the duration of therapy may be longer. In patients experiencing failure of conventional deoxycholate amphotericin B therapy or experiencing intolerable drug-related toxicities, lipid amphotericin B formulations have been demonstrated to be safe and to cause less nephrotoxicity and may be considered. Animal model studies have indicated that the higher amphotericin B dosages that can be given via lipid formulations produce results superior to those seen with the maximally tolerated deoxycholate amphotericin B [35–37]. However, there have been no clinical trials assessing the efficacy of lipid formulations of amphotericin B.

Combination therapy with amphotericin B and an azole has been administered to some patients, especially when infection is widespread or in cases in which there has been disease progression during treatment with a single agent. Although combination therapy may improve responses, there is no evidence that such an approach is superior to treatment with a single agent, and for other fungal infections, there are examples of antagonism with combination therapy [38], as has been demonstrated in vitro with *Coccidioides* species [11].

Surgical debridement or stabilization is an occasionally important, if not critical, adjunctive measure. Factors that favor a recommendation for surgical intervention are large size of abscesses, progressive enlargement of abscesses or destructive lesions, presence of bony sequestrations, instability of the spine,

or impingement on critical organs (such as a pericardial effusion on the heart) or tissues (such as an epidural abscess on the spinal cord).

Meningitis. Therapy with oral fluconazole is currently preferred by most clinicians. The dosage used in reported clinical trials was 400 mg per day (A-II). Some physicians begin therapy with 800 or 1000 mg per day of fluconazole (B-III). Itraconazole, administered in dosages of 400–600 mg per day, has also been reported to be comparably effective [39] (B-II). Some physicians also initiate therapy with intrathecal amphotericin B in addition to an azole on the basis of their belief that responses are more prompt with this approach. The dose and duration of intrathecal amphotericin B in this circumstance ranges between 0.1 mg and 1.5 mg per dose (C-III). Patients who respond to azole therapy should continue this treatment indefinitely [40] (A-III). Hydrocephalus nearly always requires a shunt for decompression (A-III). Hydrocephalus may develop regardless of the therapy being used and need not require switching to alternative therapy (B-III). Patients who do not respond to fluconazole or itraconazole would be candidates for intrathecal amphotericin B therapy with or without continuation of azole treatment. The intrathecal dosage of amphotericin B normally ranges between 0.1 mg and 1.5 mg per dose, administered at intervals ranging from daily to weekly, beginning at a low dosage and increasing the size of the dosage until the appearance of patient intolerance (indicated by severe vomiting, prostration, or transient dose-related mental status) [16].

The most common life-threatening complication of coccidioidal meningitis in the modern era is CNS vasculitis leading to cerebral ischemia, infarction, and hemorrhage [41]. Some physicians have personal experience demonstrating the efficacy of administering high-dose, intravenous, short-term corticosteroids for this condition, whereas other physicians have not noted similar benefit.

Prophylaxis for Coccidioidomycosis in Solid-Organ Transplant Recipients

The risk of coccidioidomycosis among solid-organ transplant recipients in an area of endemicity was 4%–9% [42], with the majority of infections occurring within 1 year after transplantation [43]. Because infection in such patients frequently disseminates and carries a high risk of mortality, there is interest in reducing the number of these complications in patients from or within the regions of endemicity by use of preemptive prophylactic antifungal therapy. One transplantation program in the area of endemicity has employed a strategy of targeted prophylaxis, whereby patients with certain risk factors for coccidioidomycosis (a positive serological test result prior to receipt of a transplant or a history of coccidioidomycosis) receive prophylactic fluconazole at the time of transplantation, and thus far, the results are encouraging [44].

Management of Patients Infected with HIV-1

Before the introduction of HAART, coccidioidomycosis was a major opportunistic infection in the area of endemicity among individuals infected with HIV-1 [45]. The incidence of clinically apparent coccidioidal infection has since decreased. Prevention of coccidioidomycosis among HIV-1–infected patients living in the area of coccidioidal endemicity by prophylactic use of an antifungal is not effective for most patients [46]. Treatment is recommended for all patients with HIV-1 infection and peripheral blood $CD4^+$ lymphocyte counts <250 cells/μL who have clinically active coccidioidomycosis. Therapy should be continued as long as the $CD4^+$ cell count is <250 cells/μL [45, 47]. However, it may be reasonable to stop therapy in those patients with higher $CD4^+$ cell counts if there is clinical evidence of control of the coccidioidal infection (except for patients with meningitis, for whom therapy should be life-long).

Acknowledgments

Financial support. Supported in part by the US Office of Veterans Affairs.

Potential conflicts of interest. A.C. has received grant support from Schering and has lectured for Pfizer. J.N.G. has received research support or has been a consultant for Pfizer, Janssen, Merck, Schering, Enzon, and Lilly. R.H.J. has received grant support from Pfizer; is a member of the speakers' bureaus for Sanofi-Aventis, Enzon, and Merck; and has been on the speakers' bureau of Bristol Myers-Squibb and Bayer. D.A.S. has received research support from and has been a consultant for Janssen, Ortho-McNeil, Pfizer, Gilead, Enzon, and Schering. All other authors: no conflicts.

References

1. Fisher MC, Koenig GL, White TJ, Taylor JT. Molecular and phenotypic description of *Coccidioides posadasii* sp nov., previously recognized as the non-California population of *Coccidioides immitis*. Mycologia 2002; 94:73–84.
2. Galgiani JN. Coccidioidomycosis: a regional disease of national importance—rethinking approaches for control. Ann Intern Med 1999; 130:293–300.
3. Chiller TM, Galgiani JN, Stevens DA. Coccidioidomycosis. Infect Dis Clin North Am 2003; 17:41–57, viii.
4. Stevens DA. Current concepts: coccidioidomycosis. N Engl J Med 1995; 332:1077–82.
5. Drutz DJ, Catanzaro A. Coccidioidomycosis: part II. Am Rev Respir Dis 1978; 117:727–71.
6. Drutz DJ, Catanzaro A. Coccidioidomycosis: part I. Am Rev Respir Dis 1978; 117:559–85.
7. Caraway NP, Fanning CV, Stewart JM, Tarrand JJ, Weber KL. *Coccidioidomycosis osteomyelitis* masquerading as a bone tumor: a report of 2 cases. Acta Cytol 2003; 47:777–82.
8. Prabhu RM, Bonnell M, Currier BL, Orenstein R. Successful treatment of disseminated nonmeningeal coccidioidomycosis with voriconazole. Clin Infect Dis 2004; 39:e74–7.
9. Proia LA, Tenorio AR. Successful use of voriconazole for treatment of *Coccidioides* meningitis. Antimicrob Agents Chemother 2004; 48:2341.
10. Gonzalez GM, Tijerina R, Najvar LK, et al. Correlation between antifungal susceptibilities of *Coccidioides immitis* in vitro and antifungal treatment with caspofungin in a mouse model. Antimicrob Agents Chemother 2001; 45:1854–9.
11. Stevens DA. Drug interaction of caspofungin with conventional agents against pathogens of endemic mycoses [abstract 863]. In: Program and abstracts of the 42nd Interscience Conference on Antimicrobial Agents

and Chemotherapy. Washington, DC: American Society for Microbiology, 2002.
12. Antony S. Use of the echinocandins (caspofungin) in the treatment of disseminated coccidioidomycosis in a renal transplant recipient. Clin Infect Dis **2004**; 39:879–80.
13. Blum D, Catanzaro A, Cloud G. Safety and tolerance of posaconazole (SCH 56592) in patients with nonmeningeal disseminated coccidioidomycosis [abstract 1417]. In: Program and abstracts of the 40th Interscience Conference on Antimicrobial Agents and Chemotherapy.Washington, CD: American Society for Microbiology, **2000**.
14. Stevens DA, Rendon A, Gaona V, et al. Posaconazole therapy for chronic refractory coccidioidomycosis [abstract 663]. In: Program and abstracts of the 44th Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, DC: American Society for Microbiology, **2004**.
15. Sugar AM. Use of amphotericin B with azole antifungal drugs: what are we doing. Antimicrob Agents Chemother **1995**; 39:1907–12.
16. Stevens DA, Shatsky SA. Intrathecal amphotericin in the management of coccidioidal meningitis. Semin Respir Infect **2001**; 16:263–9.
17. Galgiani JN, Stevens DA, Graybill JR, Dismukes WE, Cloud GA. Ketoconazole therapy of progressive coccidioidomycosis: comparison of 400- and 800-mg doses and observations at higher doses. Am J Med **1988**; 84:603–10.
18. Graybill JR, Stevens DA, Galgiani JN, Dismukes WE, Cloud GA. Itraconazole treatment of coccidioidomycosis. NAIAD Mycoses Study Group. Am J Med **1990**; 89:282–90.
19. Catanzaro A, Galgiani JN, Levine BE, et al. Fluconazole in the treatment of chronic pulmonary and nonmeningeal disseminated coccidioidomycosis. Am J Med **1995**; 98:249–56.
20. Galgiani JN, Catanzaro A, Cloud GA, et al. Fluconazole therapy for coccidioidal meningitis: the NIAID-Mycoses Study Group. Ann Intern Med **1993**; 119:28–35.
21. Diaz M, Negroni R, Montero-Gei F, et al. A pan-American 5-year study of fluconazole therapy for deep mycoses in the immunocompetent host. Clin Infect Dis **1992**;14(Suppl 1):S68–S76.
22. Tucker RM, Galgiani JN, Denning DW, et al. Treatment of coccidioidal meningitis with fluconazole. Rev Infect Dis **1990**; 12(Suppl 3):S380–S9.
23. Tucker RM, Denning DW, Arathoon EG, Rinaldi MG, Stevens DA. Itraconazole therapy for nonmeningeal coccidioidomycosis: clinical and laboratory observations. J Am Acad Dermatol **1990**; 23:593–601.
24. Stevens DA, Stiller RL, Williams PL, Sugar AM. Experience with ketoconazole in three major manifestations of progressive coccidioidomycosis. Am J Med **1983**; 74:58–63.
25. Brass C, Galgiani JN, Campbell SC, Stevens DA. Therapy of disseminated or pulmonary coccidioidomycosis with ketoconazole. Rev Infect Dis **1980**; 2:656–60.
26. Stevens DA. Azoles in the treatment of coccidioidomycosis. In: Einstein HE, Pappagianis D, Catanzaro A, eds. Coccidioidomycosis: proceedings of the 5th International Conference on Coccidioidomycosis. Washington: National Foundation for Infectious Diseases, **1996**:255–64.
27. Galgiani JN, Catanzaro A, Cloud GA, et al. Comparison of oral fluconazole and itraconazole for progressive, nonmeningeal coccidioidomycosis: a randomized, double-blind trial. Mycoses Study Group. Ann Intern Med **2000**; 133:676–86.
28. Park BJ, Sigel K, Vaz V, et al. An epidemic of coccidioidomycosis in Arizona associated with climate changes, 1998–2001. J Infect Dis **2005**; 191:1981–7.
29. Galgiani JN, Ampel NM, Catanzaro A, Johnson RH, Stevens DA, Williams PL. Practice guideline for the treatment of coccidioidomycosis. Infectious Diseases Society of America. Clin Infect Dis **2000**; 30:658–61.
30. Panackal AA, Hajjeh RA, Cetron MS, Warnock DW. Fungal infections among returning travelers. Clin Infect Dis **2002**; 35:1088–95.
31. Feldman BS, Snyder LS. Primary pulmonary coccidioidomycosis. Semin Respir Infect **2001**; 16:231–7.
32. Pappagianis D. Serologic studies in coccidioidomycosis. Semin Respir Infect **2001**; 16:242–50.
33. Centers for Disease Control and Prevention Select Agent Program Web page. Available at: http://www.cdc.gov/od/sap/. Accessed 30 August 2005.
34. Cunningham RT, Einstein H. Coccidioidal pulmonary cavities with rupture. J Thorac Cardiovasc Surg **1982**; 84:172–7.
35. Clemons KV, Stevens DA. Efficacies of amphotericin B lipid complex (ABLC) and conventional amphotericin B against murine coccidioidomycosis. J Antimicrob Chemother **1992**; 30:353–63.
36. Clemons KV, Hanson LH, Perlman AM, Stevens DA. Efficacy of SCH39304 and fluconazole in a murine model of disseminated coccidioidomycosis. Antimicrob Agents Chemother **1990**; 34:928–30.
37. Clemons KV, Sobel RA, Williams PL, Pappagianis D, Stevens DA. Efficacy of intravenous liposomal amphotericin B (AmBisome) against coccidioidal meningitis in rabbits. Antimicrob Agents Chemother **2002**; 46:2420–6.
38. Steinbach WJ, Stevens DA, Denning DW. Combination and sequential antifungal therapy for invasive aspergillosis: review of published in vitro and in vivo interactions and 6281 clinical cases from 1966–2001. Clin Infect Dis **2003**; 37(Suppl 3):S188–S224.
39. Tucker RM, Denning DW, Dupont B, Stevens DA. Itraconazole therapy for chronic coccidioidal meningitis. Ann Intern Med **1990**; 112:108–12.
40. Dewsnup DH, Galgiani JN, Graybill JR, et al. Is it ever safe to stop azole therapy for *Coccidioides immitis* meningitis? Ann Intern Med **1996**; 124:305–10.
41. Williams PL. Vasculitic complications associated with coccidioidal meningitis. Semin Respir Infect **2001**; 16:270–9.
42. Blair JE, Logan JL. Coccidioidomycosis in solid organ transplantation. Clin Infect Dis **2001**; 33:1536–44.
43. Cohen IM, Galgiani JN, Potter D, Ogden DA. Coccidioidomycosis in renal replacement therapy. Arch Intern Med **1982**; 142:489–94.
44. Awasthi S, Cox RA. Transfection of murine dendritic cell line (JAWS II) by a nonviral transfection reagent. Biotechniques **2003**; 35:600–2, 604.
45. Ampel NM, Dols CL, Galgiani JN. Coccidioidomycosis during human immunodeficiency virus infection: results of a prospective study in a coccidioidal endemic area. Am J Med **1993**; 94:235–40.
46. Woods CW, McRill C, Plikaytis BD, et al. Coccidioidomycosis in human immunodeficiency virus–infected persons in Arizona, 1994–1997: incidence, risk factors, and prevention. J Infect Dis **2000**; 181:1428–34.
47. Ampel NM. Delayed-type hypersensitivity, in vitro T-cell responsiveness and risk of active coccidioidomycosis among HIV-infected patients living in the coccidioidal endemic area. Med Mycol **1999**; 37:245–50.

Official reprint from
UpToDate®
www.uptodate.com

Primary coccidioidal infection

Author
John N Galgiani, MD

Section Editor
Carol A Kauffman, MD

Deputy Editor
Anna R Thorner, MD

Last literature review for version 16.1: Thu Jan 31 00:00:00 GMT 2008 | This topic last updated: Fri Jan 18 00:00:00 GMT 2008

INTRODUCTION — Coccidioidomycosis is the infection caused by the dimorphic fungi of the genus Coccidioides (C. immitis and C. posadasii) [1] . Most infections are caused by inhalation of spores. The clinical expression of disease ranges from self-limited acute pneumonia (Valley Fever) to disseminated disease, especially in immunosuppressed patients. The concentration of cases of coccidioidomycosis in the United States is in the southwestern part of the country, where the cumulative incidence of patients requiring hospitalization in 2002 was 28.65 per 1 million persons [2] .

The clinical manifestations of uncomplicated primary infection, specific diagnostic tests, and current management strategies of primary infection will be reviewed here. Complicated infections related to coccidioidomycosis are discussed elsewhere. (See "Management of pulmonary sequelae and complications of coccidioidomycosis" and see "Coccidioidal meningitis" and see "Manifestations and treatment of extrapulmonary coccidioidomycosis" and see "Coccidioidomycosis in special hosts").

EPIDEMIOLOGY AND MICROBIOLOGY — Coccidioides spp. are endemic to certain lower deserts of the western hemisphere including southern Arizona, central California, southwestern New Mexico, and west Texas in the United States. They are also found in parts of Mexico, and Central and South America.

All isolates within the genus Coccidioides were formerly designated C. immitis. However, based upon DNA sequence analysis, two species have been identified as distinct [3,4] . Isolates from one species are geographically distributed predominantly in California and have retained the name C. immitis. The other

species is distributed in Arizona, Utah, Texas, and other endemic regions throughout the western hemisphere and is now designated C. posadasii.

The spectrum of diseases caused by the two species are indistinguishable, and clinical laboratories are not routinely able to determine species. For this reason, it is simplest to refer to all isolates as Coccidioides species.

Coccidioides spp. grow as mold a few inches below the surface of the desert soil. With dry conditions, the mycelia become very fragile, are easily fractured by even slight air turbulence into single-cell spores (arthroconidia) approximately 3 to 5 microns in size, and can remain suspended for prolonged periods of time in the air.

PATHOGENESIS — Infection is virtually always acquired by inhalation of a single arthroconidium. Within the lung, an arthroconidium changes from a barrel-shaped cell to a spherical structure and then greatly enlarges, sometimes becoming 70 µm or more in diameter. Enlarging spherules produce internal septations and within each of the resulting subcompartments, individual cells (endospores) evolve. After several days, mature spherules rupture, releasing endospores into the infected tissue; each endospore is potentially capable of producing another spherule [1] . Specimens from patients which yield growth show a reversion to mycelia on most laboratory media [5,6] .

RISK OF INFECTION — Current estimates of the risk of endemic exposure to Coccidioides spp. are approximately three percent per year [7] . Thus, even persons who have lived in endemic regions for many years may still be susceptible to a new infection.

The risk of exposure within endemic regions is seasonal, typically being highest in dry periods following a rainy season. As an example, periods of high incidence in Arizona range from May into July and then between October and early December [8] . In contrast, the central California valley, which rarely receives significant summer rain, has a single peak from late spring to late fall. The estimated number of infections per year has risen to approximately 150,000 as a result of population increases in southern Arizona and central California [9] . Based upon population sizes within the most highly endemic regions, it is estimated that approximately 60 percent of all United States coccidioidal infections occur within Maricopa, Pinal, and Pima counties of Arizona and 30 percent within Kern, Tulare, and Fresno counties of California.

CLINICAL MANIFESTATIONS — After infection, a wide spectrum of manifestations is possible. It is estimated that fewer than one half of all infections come to medical attention because illness is often subclinical [10,11] . The proportion of infections that become clinically significant increases with more intensive dust exposure. It is presumed that this represents higher arthroconidial inoculum exposure, as occurs during archeological excavations or desert military maneuvers [12,13] .

When illness is clinically significant, a subacute process known as Valley Fever with respiratory and systemic complaints is typical, often lasting for weeks to months. In the great majority of such infections, resolution occurs without specific antifungal therapy.

Primary infections due to Coccidioides species most frequently manifest as community acquired pneumonia approximately 7 to 21 days after exposure. In a study from Pima County, Arizona, 29 percent of patients diagnosed with a CAP syndrome were serologically positive for coccidioidal infection [14] . The most common presenting symptoms are chest pain, cough, and fever (show table 1) [15-22] . Hemoptysis may occur and suggests the development of a pulmonary cavity.

Fatigue can persist for months and the frequent complaint of arthralgias has contributed to the alternate name of "desert rheumatism" for this illness. Cutaneous manifestations of primary coccidioidal infection include erythema nodosum and erythema multiforme. E. nodosum is much more common in women than in men and often is the symptom prompting evaluation for Valley fever. (See "Erythema nodosum").

Most routine laboratory findings are unremarkable [23] . A common but nonspecific abnormality is the erythrocyte sedimentation rate which often is one or two-fold above the upper limits of normal. The peripheral blood leukocyte count is usually normal or only slightly elevated. However, eosinophilia (>5 percent) was found in approximately one quarter of patients [1] . In occasional patients, eosinophilia can be striking.

Although initial infections usually have a respiratory component, standard PA and lateral chest radiographs may be unremarkable in up to one half of all patients. Common radiographic abnormalities include unilateral infiltrate and ipsilateral hilar adenopathy. Less frequent is evidence of a parapneumonic effusion. Peripheral thin-walled pulmonary cavities or nodules are detected in from four to eight percent of all patients [24] . Rare cases of empyema have been reported [25] .

FREQUENT ABSENCE OF EARLY DIAGNOSIS — Given the nonspecificity of the presenting symptoms, signs, and routine laboratory findings of primary coccidioidal infection, many, if not most, infections are not identified because clinicians do not consider the diagnosis. As an example, a cluster of 21 cases of a flu-like illness with rash in the majority of patients was noted in a church group returning to Washington State after building an orphanage in Mexico [26] . Sixteen patients were symptomatic and sought medical attention but the diagnosis of coccidioidomycosis was only confirmed in one case.

Although this cluster was located outside of the southwest in an area in which Valley Fever is not common, low rates of disease recognition have occurred in endemic areas. In Arizona, the number of cases of coccidioidomycosis reported to the Department of Public Health from 1999 to 2001 averaged 1900 per year [8] . This number is less than 10 percent of the expected number of illnesses, as estimated by several methods [27] .

Additional studies suggest that approximately one-third of community acquired pneumonia (CAP) in southern Arizona is caused by Coccidioides spp. [28] . A similarly high proportion may be evident in persons who develop CAP within the one to three week incubation period after visiting an endemic area.

Some practitioners consider the failure to diagnose early coccidioidal infections as an insignificant problem, since many infections resolve without specific therapy. However, identifying coccidioidal infections as early as possible has many benefits, including [29] :

- Allaying patient anxiety by arriving at a specific diagnosis, often simultaneously dispelling the fear of cancer
- Reducing the need for additional diagnostic testing, some of which involve invasive or costly procedures
- Eliminating empiric or protracted use of antibacterial treatments
- Reducing the morbidity of less frequent but progressively destructive extrapulmonary complications, most of which develop within the first several months following the initial infection.

For these reasons, the standard of care for management of this disease could be improved by a greater attention to early diagnosis. This approach is emphasized in

the 2005 Infectious Diseases Society of America revised practice guidelines for coccidioidomycosis [9] . Because coccidioidomycosis is such a frequent cause of pneumonia in Arizona, the Arizona Medical Association and the Arizona Osteopathic Medical Association have both supported the recommendation by the Arizona Department of Health Services to routinely test patients with newly diagnosed CAP for coccidioidomycosis. (www.azdhs.gov/diro/pio/preventionbulletin/septoct05.pdf)

METHODS OF DIAGNOSIS — Considering the diagnosis of coccidioidomycosis is an essential first step for detecting most coccidioidal infections. Because exposure usually occurs within an endemic region, it is critical to obtain an accurate travel history. Even brief exposures, such as changing planes in Phoenix, Arizona, has been sufficient to cause infection [26,30-33] . In most cases, the incubation period for onset of symptoms is 7 to 21 days. However, for patients who are immunocompromised due to AIDS, solid organ transplantation, or lymphoma, reactivation can occur after much longer time periods [34,35] .

Culture — Isolation of Coccidioides species in culture definitively establishes the diagnosis, even in patients with relatively mild pneumonia. Although fungal cultures are usually requested only in hospitalized patients or in those with more extensive disease, there is value to early diagnosis as noted above. Direct examination of the smear with KOH preparation or calcofluor white staining is also helpful.

There are two disadvantages to culture: growth may take several days to weeks with subsequent delays in diagnosis. Furthermore, the propagation of Coccidioides spp. in the clinical laboratory represents a significant health risk, since secondary cases have been reported in workers opening the plates for inspection [36,37] . Thus, laboratory personnel should be notified when a sample with suspected Coccidioides is being sent for processing. In contrast, specimens for culture can be safely collected by health care workers since coccidioidal infection is not transmitted person to person. Coccidioides is listed by the CDC as a select agent. Special rules govern its handling and storage. (http://www.cdc.gov/od/sap for further information concerning the handling of select agents).

Serologic tests — Serologic testing is helpful for making the diagnosis and for monitoring patients on therapy. (See "Patient monitoring" below).

In patients with primary infections managed as outpatients, diagnosis usually relies upon serologic testing. Commercial products are now available to perform screening coccidioidal serologies in any general clinical laboratory. Alternatively, reference

laboratories are also available to carry out more detailed testing. The details of the laboratory diagnosis of coccidioidomycosis are discussed separately. (See "Laboratory diagnosis of coccidioidomycosis").

However, regardless of the method chosen for detecting coccidioidal antibodies, three general principles guide interpretation.

- Any positive serologic result is very likely to be clinically relevant. Most patients lose serologic reactivity within months of an infection unless residual lesions are evident or infection is active.
- A negative serologic result lowers the likelihood, but does not exclude, the diagnosis of coccidioidomycosis. Although most tests for coccidioidal antibodies are very specific, they are relatively insensitive, especially during the first one to two weeks after infection [1] .
- Repeating tests, if a first serologic test is negative, will improve diagnostic sensitivity [38] .

Histopathology — The diagnosis of coccidioidomycosis is occasionally made by identification of spherules in tissue specimens. Staining with hematoxylin and eosin, periodic acid-Schiff, or Grocott-methenamine silver stain will all demonstrate the organism, although silver stain is considered the most sensitive [1] .

Polymerase chain reaction — A real-time polymerase chain reaction (PCR) assay was developed and tested in 266 respiratory specimens and demonstrated 100 percent sensitivity and 98 percent specificity for Coccidioides spp. compared with culture [39] . Sensitivity in paraffin-embedded tissue samples was found to be lower (73 percent). If these preliminary results are validated with larger sample numbers, real-time PCR may offer a rapid and safe means of detecting Coccidioides directly from patient specimens, including fixed tissue.

Skin testing — Reagents for skin testing are not currently available [1] and the utility of this modality is limited in patients with severe infection due to anergy. Skin testing is more useful for epidemiologic studies, since dermal reactivity remains present for life.

RISK FACTORS FOR COMPLICATIONS AND DISEASE SEVERITY — After diagnosis, the presence of complications should be assessed with a careful history and physical examination. Risk factors for complications include:

- HIV or AIDS
- Immunosuppressive medications used in transplants patients
- Glucocorticoids (20 mg or more per day of prednisone or its equivalent)
- Lymphoma
- Anti-tumor necrosis factor (TNF) therapy
- Chemotherapy for solid tumors
- Diabetes mellitus
- Pregnancy
- Preexisting cardiopulmonary conditions

The most significant of these risk factors is major suppression of cellular immunity, as in HIV infection [40,41] , organ transplantation [42-44] , or high dose glucocorticoid administration [45] . Coccidioidomycosis first developing during pregnancy (especially during the third trimester) is a significant risk factor for severe, disseminated disease [46,47] . Diabetes mellitus has been associated with more slowly resolving pulmonary infection and residual pulmonary cavitation. Individuals of African or Philippine descent also have an increased risk of extrapulmonary complications [22,48,49] (see "Coccidioidomycosis in special hosts" and see "Coccidioidal meningitis").

To detect extrapulmonary infection, careful review of symptoms and physical examination is usually adequate. Extrapulmonary infection can be found at any site, but skin, bones and joints, and central nervous system localization are the most common [50-52] . Active coccidioidal lesions typically produce regional symptoms. These may include local discomfort, swelling, or ulceration. Any focal abnormality of this sort that has developed since the onset of the primary infection should be a source of concern. These physical exam findings should prompt further imaging or sampling for histology and culture.

MANAGEMENT OF UNCOMPLICATED INFECTIONS — Otherwise healthy patients without evidence of extensive coccidioidal infection or risk factors for more serious infection usually do not need antifungal therapy. However, it is important that the patient be followed for a year or longer, to monitor for the development of complications. Therapy can be considered for certain patients on an individual basis. (See "Who to treat" below).

Patient monitoring — We often monitor patients every three to six months after the acute illness for up to two years to document radiographic resolution and to identify any evidence of pulmonary or extrapulmonary complications [9] .

Systemic signs of weight loss or fever typically resolve or markedly diminish within the first several weeks of illness. Respiratory symptoms often resolve more slowly and fatigue and lethargy can persist for several months. Their protracted nature may be compounded by deconditioning resulting from lack of physical activity early in the course of the illness. Developing a structured physical rehabilitation program is often helpful.

Serial serologic testing for complement fixing-type anti-coccidioidal antibodies should be repeated at intervals of several weeks to months, since a rise in antibody concentrations may be associated with progressive disease [53] . Although the original descriptions of this test noted that titers greater than 1:16 were often found in patients with disseminated infection, this correlation is now less reliable due to differences in commercial assays. Serologic studies may also be compromised in patients with altered immunity (transplant patients or HIV-infected patients) [1] .

Radiographic abnormalities should be rechecked to determine if they resolve or leave a residual nodule or cavity. Determining whether pulmonary lesions evolve into residual nodules is also useful because it obviates the need to investigate the etiology of this radiographic finding in the future. (See "Management of pulmonary sequelae and complications of coccidioidomycosis").

An evaluation for disseminated disease should begin if a patient develops any suspicious skin lesions, severe or persistent headaches, or new joint effusions. (See "Risk factors for complications and disease severity" above).

Who to treat — The value of antifungal therapy for patients with uncomplicated early coccidioidal infection is not known because prospective randomized trials have not performed. While it is clear from older studies that most patients resolve their infection without therapy, it is possible that some patients might benefit from treatment, either by shortening the course of illness or by preventing complications.

The possible role of treatment was evaluated in an observational study of 104 patients with primary pulmonary coccidioidomycosis who were seen at a clinic devoted to the treatment of coccidioidomycosis; 53 were treated while 51 were not treated [54] . Patients with an elevated symptom score were significantly more likely

to be treated. Among 40 patients seen in follow-up, there was no difference in symptom score or complement fixation titer at the final visit between treated and untreated patients. However, two patients, both from the group that received treatment, developed extrapulmonary lesions after treatment was stopped.

Given the absence of definitive data, it is a matter of judgment as to whether an individual patient might benefit from therapy with available oral antifungals, most frequently itraconazole or fluconazole. Opinion also varies about the most relevant factors to judge the severity of illness. Commonly used indicators include:

- Greater than 10 percent loss of body weight
- Night sweats persisting greater than three weeks
- Infiltrates involving more than half of one lung or portions of both lungs
- Prominent or persistent hilar adenopathy
- Anti-coccidioidal complement fixing antibody concentrations in excess of 1:16
- Inability to work
- Persisting symptoms for more than two months

Treatment regimens — If a decision to begin treatment is made, reasonable doses would be up to 400 mg/day for ketoconazole, 400 mg/day for fluconazole, or 200 mg twice daily for itraconazole [9] . Fluconazole has fewer drug interactions, while itraconazole has less of a drying effect on skin and mucus membranes. Both fluconazole and itraconazole have a lower incidence of gastrointestinal side effects compared with ketoconazole. Ketoconazole has also been associated with decreased testosterone synthesis and gynecomastia.

The duration of azole therapy for uncomplicated primary coccidioidal infection generally ranges from three to six months [9] . There is virtually no information available about the value of newer azoles such as voriconazole or posaconazole for treating primary coccidioidal pneumonia.

An amphotericin B preparation should be considered only in the most severe cases of coccidioidal pneumonia due to its toxicity and problems with administration.

Use of *UpToDate* is subject to the Subscription and License Agreement.

REFERENCES

1. Saubolle, MA, McKellar, PP, Sussland, D. Epidemiologic, clinical, and diagnostic aspects of coccidioidomycosis. J Clin Microbiol 2007; 45:26.
2. Chu, H, Feudtner, C. Heydon, K, et al. Hospitalizations for endemic mycoses: a population-based national study. Clin Infect Dis 2006; 42:822.
3. Fisher, MC, Koenig, GL, White, TJ, Taylor, JW. Molecular and phenotypic description of Coccidioides Posadasii sp nov., previously recognized as the non-California population of Coccidioides immitis. Mycologia 2002; 94:73.
4. Umeyama, T, Sano, A, Kamei, K, et al. Novel approach to designing primers for identification and distinction of the human pathogenic fungi Coccidioides immitis and Coccidioides posadasii by PCR amplification. J Clin Microbiol 2006; 44:1859.
5. Sun, SH, Cole, GT, Drutz, DJ, Harrison, JL. Electron-microscopic observations of the Coccidioides immitis parasitic cycle in vivo. J Med Vet Mycol 1986; 24:183.
6. Cole, GT, Sun, SH. Arthroconidium - spherule - endospore transformation in Coccidioides immitis. In: Fungal Dimorphism, Szaniszlo, PJ (Ed), Plenum Publishing Corporation, New York 1985. p.281.
7. Dodge, RR, Lebowitz, MD, Barbee, RA, Burrows, B. Estimates of C. immitis infection by skin test reactivity in an endemic community. Am J Public Health 1985; 75:863.
8. Park, B, Sigel, K, Vaz, V, et al. An epidemic of coccidioidomycosis in Arizona associated with climatic changes, 1998-2001. J Infect Dis 2005; 191:1981.
9. Galgiani, J, Ampel, N. Blair, J, et al. Coccidioidomycosis. Clin Infect Dis 2005; 41:1217.
10. Smith, CE, Beard, RR. Varieties of Coccidioidal Infection in Relation to the Epidemiology and Control of the Diseases. Am J Public Health Nations Health 1946; 36:1394.
11. Smith, CE. Epidemiology of Acute Coccidioidomycosis with Erythema Nodosum ("San Joaquin" or "Valley Fever"). Am J Public Health Nations Health 1940; 30:600.
12. Crum, N, Lamb, C, Utz, G, et al. Coccidioidomycosis outbreak among United States Navy SEALs training in a Coccidioides immitis-endemic area-Coalinga, California. J Infect Dis 2002; 186:865.
13. Perera, P, Stone, S. Coccidioidomycosis in workers at an archeologic site-Dinosaur National Monument, Utah, June-July 2001. Ann Emerg Med 2002; 39:566.
14. Valdivia, L, Nix, D, Wright, M, et al. Coccidioidomycosis as a common cause of community acquired pneumonia. Emerg Infect Dis 2006; 12:958.
15. Lundergan, LL, Kerrick, SS, Galgiani, JN. Coccidioidomycosis at a university outpatient clinic: A clinical description. In: Coccidioidomycosis, Einstein, HE, Catanzaro, A (Eds), Proceedings of the Fourth International Conference. Washington: National Foundation for Infectious Diseases; 1985:47.

16. Goldstein, DM, Louie, S. Primary pulmonary coccidioidomycosis; report of an epidemic of 75 cases. War Med 1943; 4:299.
17. Colburn, JR. Roentgenological types of pulmonary lesions in primary coccidioidomycosis. Am J Roentgenol 1944; 51:1.
18. Willett, FM, Weiss, A. Coccidioidomycosis in Southern California; report of a new endemic area with a review of 100 cases. Ann Intern Med 1945; 23:349.
19. Sweigert, CF, Turner, JW, Gillespie, JB. Clinical and roentgenologic aspects of coccidioidomycosis. Am J Med Sci 1946; 212:652.
20. Taylor, AB, Briney, AK. Observations on primary coccidioidomycosis. Ann Intern Med 1949; 30:1224.
21. Werner, SB, Pappagianis, D, Heindl, I, Mickel, A. An epidemic of coccidioidomycosis among archeology students in northern California. N Engl J Med 1972; 286:507.
22. Crum, NF, Lederman, ER, Stafford, CM, et al. Coccidioidomycosis: A Descriptive Survey of a Reemerging Disease. Clinical Characteristics and Current Controversies. Medicine (Baltimore) 2004; 83:149.
23. Yozwiak, ML, Lundergan, LL, Kerrick, SS, Galgiani, JN. Symptoms and routine laboratory abnormalities associated with coccidioidomycosis. West J Med 1988; 149:419.
24. Lonky, SA, Catanzaro, A, Moser, KM, Einstein, H. Acute coccidioidal pleural effusion. Am Rev Respir Dis 1976; 114:681.
25. Crum-Cianflone, NF, Truett, AA, Teneza-Mora, N, et al. Unusual presentations of coccidioidomycosis: a case series and review of the literature. Medicine (Baltimore) 2006; 85:263.
26. Cairns, L, Blythe, D, Kao, A, et al. Outbreak of coccidioidomycosis in Washington State residents returning from Mexico. Clin Infect Dis 2000; 30:61.
27. Campion, JM, Gardner, M, Galgiani JN. Coccidioidomycosis (valley Fever) in older adults: An increasing problem. Arizona Geriatr Soc J 2003; 8:3.
28. Valdivia, L Nix, D, Fagan, T, et al. Estimating the frequency of coccidioidomycosis as community acquired pneumonia within endemic primary care settings. Presented at the 49th Annual Coccidioidomycosis Study Group. April 2, 2005.
29. Galgiani, JN. Coccidiodomycosis: A regional disease of national importance. Ann Intern Med 1999; 130:293.
30. Coccidioidomycosis in workers at an archeologic site--Dinosaur National Monument, Utah, June-July 2001. MMWR Morb Mortal Wkly Rep 2001; 50:1005.
31. Desai, SA, Minai, OA, Gordon, SM, et al. Coccidioidomycosis in non-endemic areas: a case series. Respir Med 2001; 95:305.
32. From the Centers for Disease Control. Coccidiodomycosis in travelers returning for Mexico--Pennsylvania, 2000. JAMA 2000; 284:2990.
33. Chaturvedi, V, Ramani, R, Gromadzki, S, et al. Coccidioidomycosis in New York State. Emerg Infect Dis 2000; 6:25.

34. Hernandez, JL, Echevarria, S, Garcia-Valtuille, A, et al. Atypical coccidioidomycosis in an AIDS patient successfully treated with fluconazole. Eur J Clin Microbiol Infect Dis 1997; 16:592.
35. Vartivarian, SE, Coudron, PE, Markowitz, SM. Disseminated coccidioidomycosis. Unusual manifestations in a cardiac transplantation patient. Am J Med 1987; 83:949.
36. Johnson, JE, Perry, JE, Fekety, FR, et al. Laboratory-acquired coccidioidomycosis: A report of 210 cases. Ann Intern Med 1964; 60:941.
37. Pappagianis, D. Coccidioidomycosis (San Joaquin or Valley Fever). In: Occupational Mycoses, DiSalvo, A (Ed), Lea and Febiger, Philadelphia 1983. p.13.
38. Wieden, MA, Lundergan, LL, Blum, J, et al. Detection of coccidioidal antibodies by 33-kDa spherule antigen, Coccidioides EIA, and standard serologic tests in sera from patients evaluated for coccidioidomycosis. J Infect Dis 1996; 173:1273.
39. Binnicker, MJ, Buckwalter, SP, Eisberner, JJ, et al. Detection of coccidioides species in clinical specimens by real-time PCR. J Clin Microbiol 2007; 45:173.
40. Singh, VR, Smith, DK, Lawerence, J, et al. Coccidioidomycosis in patients infected with human immunodeficiency virus: Review of 91 cases at a single institution. Clin Infect Dis 1996; 23:563.
41. Fish, DG, Ampel, NM, Galgiani, JN, et al. Coccidioidomycosis during human immunodeficiency virus infection. A review of 77 patients. Medicine (Baltimore) 1990; 69:384.
42. Hall, KA, Sethi, GK, Rosado, LJ, et al. Coccidioidomycosis and heart transplantation. J Heart Lung Transplant 1993; 12:525.
43. Cohen, IM, Galgiani, JN, Potter, D, Ogden, DA. Coccidioidomycosis in renal replacement therapy. Arch Intern Med 1982; 142:489.
44. Holt, CD, Winston, DJ, Kubak, B, et al. Coccidioidomycosis in liver transplant patients. Clin Infect Dis 1997; 24:216.
45. Rutala, PJ, Smith, JW. Coccidioidomycosis in potentially compromised hosts: The effect of immunosuppressive therapy in dissemination. Am J Med Sci 1978; 275:283.
46. Peterson, CM, Schuppert, K, Kelly, PC, Pappagianis, D. Coccidioidomycosis and pregnancy. Obstet Gynecol Surv 1993; 48:149.
47. Wack, EE, Ampel, NM, Galgiani, JN, Bronnimann, DA. Coccidioidomycosis during pregnancy. An analysis of ten cases among 47,120 pregnancies. Chest 1988; 94:376.
48. Pappagianis, D, Lindsay, S, Beall, S, Williams, P. Ethnic background and the clinical course of coccidioidomycosis [letter]. Am Rev Respir Dis 1979; 120:959.
49. Crum, NF, Lederman, ER, Hale, BR, et al. A cluster of disseminated coccidioidomycosis cases at a US military hospital. Mil Med 2003; 168:460.
50. Galgiani, JN. Coccidioidomycosis. West J Med 1993; 159:153.
51. Stevens, DA. Current concepts: Coccidioidomycosis. N Engl J Med 1995; 332:1077.

52. Drutz, DJ, Catanzaro, A. Coccidioidomycosis, Part II. Am Rev Respir Dis 1978; 117:727.
53. Pappagianis, D, Zimmer, BL. Serology of coccidioidomycosis. Clin Microbiol Rev 1990; 3:247.
54. Ampel, NM, Giblin, A, Chavez, S. Factors and outcomes assocated with the decision to treat primary pulmonary coccidiodomycosis (abstract). Infectious Diseases Society of America 45th annual meeting, October 4-7, 2007. San Diego, CA.

GRAPHICS

Initial symptoms and signs of coccidioidal pneumonia

Complaint	Median percentage (range)
Constitutional	
Fever	61 (30-99)
Fatigue	59 (32-83)
Pulmonary	
Chest pain	73 (52-95)
Cough	64 (44-89)
Dyspnea	21 (12-63)
Hemoptysis	5 (3-21)
Other	
Headache	27 (17-74)
Sore throat	24 (14-41)
Arthralgia	23 (8-52)
Erythema nodosum	9 (3-23)

© 2008 UpToDate, Inc. All rights reserved. | Subscription and License Agreement |Support
Tag: [ecapp0604p.utd.com-153.48.52.241-9BD811703B-19006]
Licensed to: California Prison Healthcare

Official reprint from
UpToDate®
www.uptodate.com

Manifestations and treatment of extrapulmonary coccidioidomycosis

Author
John N Galgiani, MD

Section Editor
Carol A Kauffman, MD

Deputy Editor
Anna R Thorner, MD

Last literature review for version 16.1: January 31, 2008 | This topic last updated: January 8, 2008

INTRODUCTION — Coccidioidomycosis is the infection caused by the dimorphic fungi, Coccidioides immitis, or Coccidioides posadasii. These organisms are endemic to certain lower deserts of the western hemisphere. Infection is virtually always acquired by inhalation, and primary infection frequently goes unrecognized [1,2] . Dissemination of infection beyond the lungs can occur, but it is difficult to estimate the incidence of overt disseminated disease. (See "Primary coccidioidal infection", section on Microbiology and epidemiology).

The manifestations and treatment of extrapulmonary coccidioidomycosis other than involvement of the central nervous system will be reviewed here. Primary infection, laboratory diagnosis, pulmonary sequelae, coccidioidal meningitis, and infection in immunocompromised hosts are discussed separately. (See "Primary coccidioidal infection" and other appropriate topic reviews).

INCIDENCE OF DISSEMINATED INFECTIONS — Coccidioidomycosis occasionally spreads from the initial pulmonary lesion to other parts of the body. Estimates of this risk vary from approximately 4.7 percent of recognized infections [3] to 0.2 percent of all respiratory exposures to Coccidioides spp. [4] . This substantial range in estimates is probably due to the under recognition of mild infections (show figure 1) [5] .

For extrapulmonary complications, patient groups at risk include those of African or Filipino ancestry and immunosuppressed patients.

PATHOGENESIS — Disseminated infection represents a progression of primary infection, frequently becoming evident within weeks and usually within two years after the initial exposure. Thus, it is common for dissemination to be clinically evident at the time infection is first diagnosed in those who develop extrapulmonary coccidioidomycosis.

Extrapulmonary dissemination is usually the result of hematogenous spread of the organism. It is possible that some infections occur by Coccidioides spp. gaining access to the bloodstream directly from venous drainage of the lungs. However, hilar adenopathy is a frequent feature of coccidioidal pneumonia, and progression of infection to paratracheal and even supraclavicular lymph nodes prior to the development of extrapulmonary lesions is well documented. The common involvement of lymph nodes suggests that some, if not most, disseminated infections result from lymphatic drainage, eventually to the common lymphatic duct and from there to the rest of the body.

CLINICAL MANIFESTATIONS — The most common sites of disseminated lesions are [6,7] :

- Skin or subcutaneous soft tissue
- Meninges of the brain and spinal cord
- Skeleton

To a lesser degree, other sites of dissemination may include: endocrine glands [8,9] , the eye [10-12] , the liver [13] , kidneys [14] , genital organs [15-19] , the prostate [20,21] , and the peritoneal cavity [22] . Lesions have rarely been noted in the subserosal intestines, the heart, and the urinary bladder. Of all sites of dissemination, meningitis is the most uniformly serious and poses special problems in management that will be addressed separately. (See "Coccidioidal meningitis").

Lesions typically become evident in a subacute or chronic fashion. The timing and nature of the symptoms may depend upon the exact location and number of individual lesions. Symptoms usually reflect the site of infection and are often indistinguishable from infection of these organs due to other pathogens. Because of the indolent nature of the infection and lack of specificity of symptoms including pain, the diagnosis of extrapulmonary coccidioidomycosis is frequently delayed by weeks or even months. This is especially true if the initial pulmonary infection has not yet been recognized.

ANTIFUNGAL DRUG SELECTION — The Infectious Diseases Society of America (IDSA) published treatment guidelines for coccidioidomycosis in 2005 [23] . The following principles are covered in the consensus statement:

- Oral azole antifungal agents are the customary initial drugs of choice.
- Amphotericin B is usually reserved for patients with lesions that are worsening rapidly or are located in vital sites, such as the spine.
- Surgical debridement or stabilization, in some cases, are important and even critical as adjunctive treatment.

Azole therapy — The consensus statement is pointedly silent with respect to which oral azole should be used. Only ketoconazole of the commercially available azoles has been approved for the treatment of coccidioidomycosis by the United States Food and Drug Administration (FDA). However, the NIAID Mycoses Study Group has published descriptions of large prospective clinical trials using either fluconazole or itraconazole as treatment of coccidioidomycosis. These reports indicate that both drugs are also efficacious [24,25] . Although neither itraconazole nor fluconazole has been compared directly with ketoconazole, they are now commonly used in the treatment of coccidioidal infections. (See "Pharmacology of triazoles").

Itraconazole versus fluconazole — A prospective, randomized, blinded comparison of itraconazole versus fluconazole in the treatment of progressive nonmeningeal coccidioidal infections provides the most complete data to address the selection of antifungal agents [26] .

Patients with chronic pulmonary, soft tissue, or skeletal lesions were randomized to receive either fluconazole (400 mg once daily) or itraconazole (200 mg BID). The primary comparison of the two drugs was performed after eight months, although protocol treatment was continued for a full year. The following results were noted:

- More patients receiving itraconazole than fluconazole responded by eight months, although the difference was not statistically significant (61 of 97 [63 percent] versus 47 of 94 [50 percent], p = 0.08).
- In a secondary analysis, most of the apparent difference in response rates occurred in patients with skeletal lesions; 12 of 23 (52 percent) receiving itraconazole responded compared with only 7 of 27 (26 percent) with fluconazole.

- In another secondary analysis, the difference in response rates between itraconazole and fluconazole widened further after 12 months of therapy, with itraconazole appearing to be better.
- Relapse rates were similar irrespective of the azole given in patients who completed protocol therapy and had therapy stopped.

This study suggests that fluconazole and itraconazole are quite similar for treating chronic pulmonary and soft tissue coccidioidal lesions. However, itraconazole may be more potent at the doses studied than fluconazole for treating skeletal lesions.

Posaconazole — Posaconazole is a novel triazole agent that has potent in vitro activity against a wide range of fungal pathogens, including both yeasts and molds. Published data are limited but suggest efficacy as illustrated by the following findings.

In an open-label study of 15 patients with chronic refractory coccidioidomycosis, posaconazole (800 mg/day in divided doses) produced a complete response in four and a partial response in seven [27] . The sites of involvement included lungs, bones, joints, skin, soft tissue, lymph nodes, central nervous system, eye, and heart valves.

Similar findings were noted in a series of 20 patients with chronic pulmonary or nonmeningeal disseminated coccidioidomycosis who were treated with posaconazole (400 mg/day) [28] . Seventeen had a treatment response, defined as any reduction in Mycoses Study Group (MSG) score by week 16 and a ≥50 percent reduction in the MSG score by week 24.

Voriconazole — Voriconazole has had limited use in patients with coccidioidomycosis, especially those with refractory infections. There are case reports suggesting that voriconazole may be effective [29-31] .

MANAGEMENT APPROACHES FOR SPECIFIC ANATOMIC LOCATIONS OF DISSEMINATED INFECTION — The IDSA guidelines recommend that most patients with disseminated infections should be treated and that optimal management may require combined medical and surgical interventions. However, it is frequently difficult to determine the need for surgery in management because of the diversity of possible locations and severity of coccidioidal lesions; guidelines cannot address all of the various situations that might be seen. The following specific

examples have been commonly encountered by clinicians at the Valley Fever Center for Excellence (www.vfce.arizona.edu/) and are illustrative of approaches followed within that program.

Supraclavicular adenopathy — As indicated above, the presence of enlarged supraclavicular nodes probably represents lymphatic drainage from the lung rather than hematogenous spread. However, to reach the supraclavicular region reflects exceptional progression of infection along the lymphatic chain, indicating that host defenses are not effectively limiting the infection to the lungs. Thus, supraclavicular adenopathy is usually treated in a similar fashion to that used for disseminated lesions. One or more such nodes may be evident at the time of diagnosis. These lymph nodes occasionally drain spontaneously but with therapy often resolve without requiring surgical resection. Retropharyngeal abscesses also occur but more likely represent extension of cervical osteomyelitis rather then lymphangitic spread from the mediastinum.

Solitary cutaneous lesions in children — A single small skin lesion is occasionally biopsied or excised entirely and found histologically to be the result of coccidioidal infection. Most clinicians would recommend beginning treatment in adults based upon this finding alone. However, in an otherwise healthy child with no other evidence of disseminated infection, some pediatricians familiar with coccidioidomycosis have elected to observe the patient closely rather than initiating therapy.

Prostatic infection — Occasional patients have been discovered to have an asymptomatic coccidioidal infection of the prostate; such infections are usually discovered during the evaluation of an elevated serum prostate-specific antigen level or less commonly during a fine needle biopsy of a palpable prostatic nodule. We have followed several such patients without treatment, using periodic office visits and coccidioidal serologies yearly or twice yearly as monitors. To date, none of the prostatic lesions have become symptomatic, nor has any patient developed a new lesion elsewhere.

In contrast, if coccidioidal involvement of the prostate is discovered as the result of a transurethral or radical prostatectomy, the greater anatomic disruption of those procedures compared to a fine needle biopsy greatly increases the risk of subsequent complications from the infection. In these situations, antifungal therapy would be appropriate.

Monoarticular arthritis — Disseminated coccidioidomycosis frequently involves only a single joint. Monoarticular infection of the knee is the most common, with a presentation that mimics a degenerative or traumatically injured joint. This has led to an unexpected diagnosis at the time of arthroscopy and even after total knee replacement. The infection may be limited completely to the synovium, and, in such cases, antifungal treatment without surgical intervention is often quite effective in completely resolving the signs and symptoms of infection.

Vertebral osteomyelitis — Vertebrae are a common site for coccidioidal osteomyelitis. Lesions may be single or multiple, occasionally also involving the sacrum and ileum. There may be no other identified lesions of disseminated infection in some cases of multiple vertebral lesions, which suggests either a predilection for vertebral osteomyelitis in certain patients, a tropism for the spine among certain strains of C. immitis, or spread to the vertebrae through venous channels of Batson's plexus.

The management of these lesions is especially important because of their potential impact on the spinal cord and mobility. There is no doubt that some of these lesions require surgical debridement and stabilization to control the infection. However, determining which lesions will benefit from surgery is not always clear, and practices among different clinicians vary substantially in managing these lesions. Radionuclide bone scans are useful to identify possible areas of infection [32] . Magnetic resonance (MR) imaging with gadolinium enhancement has been especially useful in defining the extent of individual lesions [33] .

Once these studies and a careful neurologic evaluation are completed, patients are initially managed depending upon immediate or pending cord impingement and stability of the vertebral bodies. For those with evidence of cord impingement, immediate surgical decompression is usually recommended. For other patients without cord compression and with stable vertebrae, medical treatment is often initiated without immediate surgical intervention. Subsequent management depends upon the evolution of lesions as evidenced by neurologic examination and repeated MR imaging (often within one or two months). For progressive lesions, surgical options are reconsidered. For those that are stable or show improvement, medical management alone is continued with repeated MR imaging at progressively longer intervals.

DISCONTINUATION OF TREATMENT AND THE SUBSEQUENT RISK OF RELAPSE — For patients who respond to antifungal therapy, there is a significant

potential for relapse once drug treatment is discontinued. In the comparison of fluconazole and itraconazole treatment cited above, relapse rates following the completion of 12 months of therapy were 28 and 18 percent, respectively [26] . However, many responding patients continued therapy off protocol. Moreover, a subanalysis indicated that patients continuing therapy were more likely to have had prior relapses, higher serologic titers, and greater extent of disease. These results suggest that relapse rates might be even higher than those recorded in patients whose therapy was discontinued.

Although the risk of relapse is substantial, perhaps as many as two-thirds of patients who complete therapy do not relapse; thus it would seem reasonable to discontinue therapy at least once. This practice is reinforced by the observation that most relapses occur at the site of previously identified lesions rather than at new sites. On the other hand, if the site of any of the initial lesions is particularly critical, then recurrence, even if detected early, might be seriously deleterious to the patient. Thus, in cases of vertebral infection, for example, treatment durations are often extended well beyond 12 months; occasionally, a physician may be unwilling to ever attempt discontinuing treatment.

Use of *UpToDate* is subject to the Subscription and License Agreement.

REFERENCES

1. Smith, CE, Beard, RR. Varieties of Coccidioidal Infection in Relation to the Epidemiology and Control of the Diseases. Am J Public Health Nations Health 1946; 36:1394.
2. Smith, CE. Epidemiology of Acute Coccidioidomycosis with Erythema Nodosum ("San Joaquin" or "Valley Fever"). Am J Public Health Nations Health 1940; 30:600.
3. Johnson, RH, Caldwell, JW, Welch, G, Einstein, HE. The great coccidioidomycosis epidemic: Clinical features. In: Einstein HE, Catanzaro A, eds. Coccidioidomycosis. Proceedings of the 5th International Conference. Washington: National Foundation for Infectious Diseases; 1996:77.
4. Barnato, AE, Sanders, GD, Owens, DK. Cost-effectiveness of a potential vaccine for Coccidioides immitis. Emerg Infect Dis 2001; 7:797.
5. Campion, JM, Gardner, M, Galgiani, JN. Coccidioidomycosis (Valley Fever) in older adults: An increasing problem. Arizona Geriatrics Society Journal 2003; 8:3.

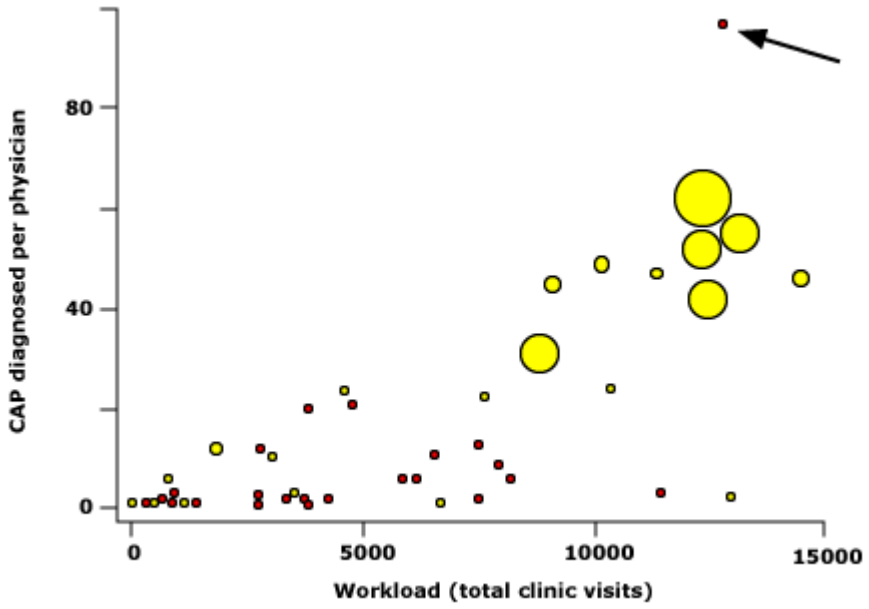
6. Galgiani, JN. Coccidioidomycosis. West J Med 1993; 159:153.
7. Crum, NF, Lederman, ER, Stafford, CM, et al. Coccidioidomycosis: A Descriptive Survey of a Reemerging Disease. Clinical Characteristics and Current Controversies. Medicine (Baltimore) 2004; 83:149.
8. Papadopoulos, KI, Castor, B, Klingspor, L, et al. Bilateral isolated adrenal coccidioidomycosis. J Intern Med 1996; 239:275.
9. Smilack, JD, Argueta, R. Coccidioidal infection of the thyroid. Arch Intern Med 1998; 158:89.
10. Rodenbiker, HT, Ganley, JP. Ocular coccidioidomycosis. Surv Ophthalmol 1980; 24:263.
11. Cunningham, ET Jr, Seiff, SR, Berger, TG, et al. Intraocular coccidioidomycosis diagnosed by skin biopsy. Arch Ophthalmol 1998; 116:674.
12. Stone, JL, Kalina, RE. Ocular coccidioidomycosis. Am J Ophthalmol 1993; 116:249.
13. Goldberg, B, Loeffler, AM. Respiratory distress and a liver mass. Pediatr Infect Dis J 1999; 18:1105.
14. Huntington, RW. Pathology of coccidioidomycosis. In: Coccidioidomycosis: A text, Stevens, DA, (Ed), Plenum Medical Book Co, New York 1980. p.113.
15. Kuntze, JR, Herman, MH, Evans, SG. Genitourinary coccidioidomycosis. J Urol 1988; 140:370.
16. Liao, JC, Reiter, RE. Coccidioidomycosis presenting as testicular mass. J Urol 2001; 166:1396.
17. Dykes, TM, Stone, AB, Canby-Hagino, ED. Coccidioidomycosis of the epididymis and testis. AJR Am J Roentgenol 2005; 184:552.
18. Halsey, ES, Rasnake, MS, Hospenthal, DR. Coccidioidomycosis of the male reproductive tract. Mycopathologia 2005; 159:199.
19. Sohail, MR, Andrews, PE, Blair, JE. Coccidioidomycosis of the male genital tract. J Urol 2005; 173:1978.
20. Lawrence, MA, Ginsberg, D, Stein, JP, et al. Coccidioidomycosis prostatitis associated with prostate cancer. BJU Int 1999; 84:372.
21. Niku, SD, Dalgleish, G, Devendra, G. Coccidioidomycosis of the prostate gland. Urology 1998; 52:127.
22. Phillips, P, Ford, B. Peritoneal coccidioidomycosis: case report and review. Clin Infect Dis 2000; 30:971.
23. Galgiani, JN, Ampel, NM, Blair, A, et al. Coccidioidomycosis. Clin Infect Dis 2005; 41:1217.
24. Catanzaro, A, Galgiani, JN, Levine, BE, et al. Fluconazole in the treatment of chronic pulmonary and nonmeningeal disseminated coccidioidomycosis. NIAID Mycoses Study Group. Am J Med 1995; 98:249.
25. Graybill, JR, Stevens, DA, Galgiani, JN, et al. NAIAD Mycoses Study Group. Itraconazole treatment of coccidioidomycosis. Am J Med 1990; 89:282.
26. Galgiani, JN, Catanzaro, A, Cloud, GA, et al. Comparison of oral fluconazole and itraconazole for progressive, nonmeningeal coccidioidomycosis. A

randomized, double-blind trial. Mycoses Study Group. Ann Intern Med 2000; 133:676.

27. Stevens, DA, Rendon, A, Gaona-Flores, V, et al. Posaconazole therapy for chronic refractory coccidioidomycosis. Chest 2007; 132:952.
28. Catanzaro, A, Cloud, GA, Stevens, DA, et al. Safety, tolerance, and efficacy of posaconazole therapy in patients with nonmeningeal disseminated or chronic pulmonary coccidioidomycosis. Clin Infect Dis 2007; 45:562.
29. Prabhu, RM, Bonnell, M, Currier, BL, Orenstein, R. Successful treatment of disseminated nonmeningeal coccidioidomycosis with voriconazole. Clin Infect Dis 2004; 39:e74.
30. Proia, LA, Tenorio, AR. Successful use of voriconazole for treatment of Coccidioides meningitis. Antimicrob Agents Chemother 2004; 48:2341.
31. Cortez, KJ, Walsh, TJ, Bennett, JE. Successful treatment of coccidioidal meningitis with voriconazole. Clin Infect Dis 2003; 36:1619.
32. Stadalnik, RC, Goldstein, E, Hoeprich, PD, et al. Diagnostic value of gallium and bone scans in evaluation of extrapulmonary coccidioidal lesions. Am Rev Respir Dis 1980; 121:673.
33. Erly, WK, Carmody, RF, Seeger, JF, Lund, PJ. Magnetic resonance imaging of coccidioidal spondylitis. Int J Neuroradiol 1997; 3:385.

GRAPHICS

Physician-specific diagnosis of Valley Fever in relation to workload and diagnosis of community-acquired pneumonia



Size of solid circles is proportional to diagnoses of Valley Fever (1 to 10 patients). Red circles indicate physicians who have not diagnosed Valley Fever. The black arrow points to a physician who had not diagnosed this infection despite making the diagnosis of CAP 98 times.
Reproduced with permission from: Campion, JM, Gardner, M, Galgiani, JN. Coccidiodomycosis

(Valley Fever) in older adults: An increasing problem. Arizona Geriatrics Society Journal 2003; 8:3.
Copyright © Arizona Geriatrics Society.
© 2008 UpToDate, Inc. All rights reserved. | Subscription and License Agreement |Support
Tag: [ecapp0604p.utd.com-153.48.52.241-C60335629B-19006]
Licensed to: California Prison Healthcare

Official reprint from
UpToDate®
www.uptodate.com

Laboratory diagnosis of coccidioidomycosis

Author
John N Galgiani, MD

Section Editor
Carol A Kauffman, MD

Deputy Editor
Anna R Thorner, MD

Last literature review for version 16.1: January 31, 2008 | This topic last updated: April 18, 2006

INTRODUCTION — Coccidioides spp. (C. immitis and C. posadasii), fungi endemic in desert regions of the southwestern United States, Central and South America, cause coccidioidomycosis. (See "Primary coccidioidal infection", section on Microbiology and epidemiology).

Coccidioidomycosis has protean manifestations and is frequently unrecognized, especially in travelers to endemic areas who return to locations where the disease is not typically encountered. Without specific laboratory tests, it is generally not possible to differentiate coccidioidal infections from numerous other illnesses. Several routine tests are commonly abnormal, especially with early coccidioidal pneumonia, but are nonspecific. These include slight increase in peripheral white blood cell count, peripheral eosinophilia, and an elevated erythrocyte sedimentation rate [1] . Similarly, chest radiographs or other imaging procedures may also disclose abnormalities. Although occasionally suggestive of the precise diagnosis [2] , confirmatory tests are nearly always needed. (See "Primary coccidioidal infection").

Conventional approaches to diagnosing coccidioidomycosis involve recovery of Coccidioides spp. from clinical specimens and detection of specific anti-coccidioidal antibodies in serum or other body fluids.

RECOVERY OF COCCIDIOIDES SPP. FROM CLINICAL SPECIMENS — Since Coccidioides spp. are never "normal flora", identifying this fungus in respiratory secretions, tissue, or other patient specimens is definitive evidence of a coccidioidal infection. This can be accomplished by either identifying the organism by direct examination or by growing it in subculture. Despite this specificity, cultures are not routinely obtained in the majority of coccidioidal infections. Whether this should be

recommended for standard practice is a point of conjecture. On the one hand, obtaining fungal cultures in many office settings may be logistically difficult, and specimens that yield Coccidioides spp. in culture pose a certain degree of risk to laboratory personnel [3] . In addition, since Coccidioides spp. are listed by the CDC as select agents of bioterrorism (www.cdc.gov/od/sap), laboratories (even clinical laboratories) which handle these fungi must follow extensive and documented security practices. On the other hand, positive cultures may be the earliest and in some instances the only means of diagnosis. As a general rule, seeking to isolate Coccidioides spp. becomes increasingly important for patients with more debilitating or widespread infections. (See "Manifestations and treatment of extrapulmonary coccidioidomycosis").

Staining characteristics — The most common morphologic form of Coccidioides spp. seen in clinical specimens during infection are spherules. These are often sufficiently large (20 to 70 µm) to be seen with magnification of 100- to 400- fold. However, Gram stain of respiratory tract specimens will miss these structures since spherules do not take up the stain. The simplest method to detect spherules is to make a "wet preparation" using saline or potassium hydroxide solution. Calcofluor staining may also improve direct detection of spherules [4] . Bronchoalveolar washings are often analyzed with Papanicolaou staining which also reacts with spherules [5] .

For tissue, hematoxylin and eosin staining will usually be sufficient to detect spherules although occasionally special stains such as PAS or Gomori methenamine silver will be needed. However, spherules generally number fewer than one per 10 high-power fields in most specimens; thus, an extensive examination of such preparations will improve detection. Occasionally, mycelial elements are present in coccidioidal lesions, but these cannot be distinguished from other fungal species on morphologic characteristics. In one report, hyphal forms were demonstrated in the cerebrospinal fluid (CSF) or brain tissue from five patients with plastic devices present in the central nervous system [6] . Techniques are now available to identify Coccidioides in fixed tissue by PCR [7,8] .

Culture — Coccidioides spp. are capable of growing on nearly any laboratory media, and, therefore, even routine cultures for bacterial isolation can be used. Growth usually is evident within the first week although prior receipt of antifungal agents can delay isolation. Most strains of Coccidioides spp. are non-pigmented. However, this is

not always the case, and laboratory personnel should handle any culture in which hyphal growth becomes evident with appropriate biocontainment procedures [9] .

In order to determine if an isolated fungus is within the Coccidioides genus, additional testing is necessary. In the past, the most common approach was to prepare a formalin extract of the fungus and determine if it contained a "Coccidioides-specific" antigen [10,11] . Although extremely reliable, this approach takes two or more weeks to complete. A more rapid procedure is now available as a commercial kit (Genprobe, San Diego CA) which detects C. immitis-specific DNA sequence. This has also been highly reliable and takes less than one day to complete [12] . At present there are no commercially available tests to distinguish between C. immitis and C. posadasii [13] .

DETECTION OF ANTI-COCCIDIOIDAL ANTIBODIES — Patients exposed to Coccidioides spp. develop symptoms of their acute illness seven to 21 days later. Concurrently, antibodies develop against specific coccidioidal antigens in many, if not most, patients. When detected, anti-coccidioidal antibodies are quite specific. However, the ability to detect these antibodies may lag behind the onset of illness by several weeks or even months [14] . For this reason, the absence of detectable anti-coccidioidal antibodies does not generally exclude the diagnosis of coccidioidomycosis, especially early in the course of the clinical illness. When antibodies are present, the concentrations decrease to undetectable levels during the course of illness for most patients who resolve their infection. Thus, patients who demonstrate measurable anti-coccidioidal antibodies are likely to have a recent illness or one that continues to be active. Within these general principles, the interpretation of the specific serologic tests varies as discussed below [15] .

Tube precipitin-type antibodies — One of the two original methods for detecting anti-coccidioidal antibodies was to demonstrate the formation of an antigen-antibody precipitin when an extract of C. immitis was mixed with serum from an infected patient [16] . These antibodies are directed against carbohydrate antigens of the fungal cell wall and develop relatively early during infection. Up to 90 percent of patients will have tube precipitin-type antibodies detected at some time within the first three weeks of symptoms. For patients with a self-limited illness, these antibodies decline to less than 5 percent within seven months.

The precipitin assay is considered to be an "IgM test" because IgM antibodies are large and most capable of generating a precipitin reaction and because these reactions were detected early after the onset of infection. This test has been largely

supplanted by a commercial immunodiffusion kit which measures the same antigen and accurately parallels the results of the original assay [10,17] .

Complement fixing antibodies — The other original method for detecting coccidioidal antibodies is a complement fixation (CF) assay. This test is based upon the depletion of complement that results after antibodies in a specimen from an infected patient form an immune complex when mixed with a coccidioidal antigen. The complement depletion is assessed by the failure of tanned red blood cells to lyse when added to the mixture; these cells are normally lysed in the presence of complement. This CF assay is often referred to as the "IgG test" since IgG is the immunoglobulin class usually involved in such immune complexes. Although the coccidioidal antigen used in this procedure is a complex extract of C. immitis, it is now known that the antigen involved in this reaction is a chitinase, a protein enzyme important for the structure of the fungal cell wall [18,19] .

In early coccidioidal infections, CF antibodies are detected somewhat later and for longer periods than tube precipitin-type antibodies. CF-type antibodies can be detected in body fluids other than serum, and their detection in the CSF is an especially important aid to the diagnosis of coccidioidal meningitis. Antibody concentration is determined by assaying two-fold serial dilutions of patient specimens for complement consumption. As a general rule, the greater the dilution that still results in complement consumption, the more likely the patient has extensive infection. Because the exact end-point result in relation to actual antibody concentration is difficult to standardize among laboratories, relative changes in results from the same laboratory may be more helpful in gauging whether a patient's infection is worsening (increasing titers) or improving (decreasing titers). Thus, serial determinations of CF-type antibodies have prognostic as well as diagnostic value.

Although the original assay for CF-type antibodies continues to be used routinely by reference laboratories, a commercial immunodiffusion kit can mimic the qualitative result of the reference procedure [10] . Since immunodiffusion kits for both IgM and IgG antibodies are in common use, the clinician may need to contact the reporting laboratory for further clarification if test results (as is frequent practice) are reported simply as an immunodiffusion result.

Enzyme-linked immunoassays — An enzyme-linked immunoassay (EIA) for coccidioidal antibodies has been made commercially. Since specific antibodies are detected by reagents for different immunoglobulin classes, results from these tests are specific for IgM or IgG antibodies. Positive EIA results are highly sensitive for

coccidioidal infection [14] . In one study of 160 serum and 66 CSF specimens tested by CF, tube precipitin, and EIA, the EIA had a sensitivity, specificity and positive and negative predictive values of 100, 98, 96 and 100 percent, respectively, compared to CF [20] . However, occasionally false positive results are noted, especially with the commercial enzyme-linked immunoassay for IgM anti-coccidioidal antibodies. Thus, these results are not interchangeable with procedures that measure tube precipitins-type or CF-type antibodies.

Latex tests — A latex test for coccidioidal antibodies is also available from commercial sources. Latex tests are attractive because of their ease of use and rapidity of obtaining a result. However, for detecting anti-coccidioidal antibodies, the latex tests have thus far appeared to have a significant number of false-positive reactions [21] . For this reason, a positive latex test is not as reliable as any of the other tests described in this section.

Detection of dermal delayed-type hypersensitivity — Most patients who become infected with Coccidioides spp. develop dermal hypersensitivity to coccidioidal antigens as manifested by induration to skin testing [22] . For this reason, it is recommended by some to use skin testing as a diagnostic screening test. One drawback to this approach is that dermal hypersensitivity remains present for life and a reactive skin may reflect infect in the distant past rather than the patient's current illness. Another problem is that occasional patients with the more extensive complications of coccidioidomycosis may be anergic; in these cases, a negative skin test could conceivably delay the correct diagnosis.

Skin testing can be used for epidemiologic purposes. As an example, a study was performed in a city in northern Mexico to assess the prevalence of exposure to Coccidioides and risk factors for infection [23] . Among 1,653 skin tests placed, 40 percent were positive. The skin testing reagents, coccidioidin or spherulin, are not commercially available currently in the United States, and thus, this test cannot be used for the diagnosis of individual patients or epidemiologic determinations. This test is of historic interest only since the reagents are no longer available. Thus, the test is not used clinically any longer.

SUMMARY

- Specific tests must be performed to make a diagnosis of coccidioidomycosis since the illness has protean manifestations and cannot be distinguished from a variety of other infections on clinical grounds alone.

- Coccidioidomycosis is typically diagnosed by serologic testing for antibodies. A commercial immunodiffusion kit that measures IgM and IgG antibodies directed against the organism is the most common test ordered currently. The two antibody classes can be measured separately, although laboratories frequently combine the two and simply report a positive test.
- Complement fixation (CF) was the original established method used to measure anti-coccidioidal antibodies but is generally reserved for specimens other than serum, especially cerebrospinal fluid.
- Enzyme-linked immunoassays (EIA) are highly sensitive but false positive results can be seen.
- Latex tests are easy to perform but have a higher rate of false positives than EIA.
- Skin testing antigens are not available in the United States.

Use of *UpToDate* is subject to the Subscription and License Agreement.

REFERENCES

1. Lundergan, LL, Kerrick, SS, Galgiani, JN. Coccidioidomycosis at a university outpatient clinic: A clinical description. In: Coccidioidomycosis: Proceedings of the Fourth International Conference, Einstein, HE, Catanzaro, A, (Eds), National Foundation for Infectious Diseases, Washington 1985. p.47.
2. Yozwiak, ML, Lundergan, LL, Kerrick, SS, Galgiani, JN. Symptoms and routine laboratory abnormalities associated with coccidioidomycosis. West J Med 1988; 149:419.
3. Pappagianis, D. Coccidioidomycosis (San Joaquin or Valley Fever). In: Occupational Mycoses. DiSalvo A, (Ed), Lea and Febiger, Philadelphia, 1983. p.13.
4. Monheit, JE, Cowan, DF, Moore, DG. Rapid detection of fungi in tissues using calcofluor white and fluorescence microscopy. Arch Pathol Lab Med 1984; 108:616.
5. Sobonya, RE, Barbee, RA, Wiens, J, Trego, D. Detection of fungi and other pathogens in immunocompromised patients by bronchoalveolar lavage in an area endemic for coccidioidomycosis. Chest 1990; 97:1349.
6. Hagman, HM, Madnick, EG, D'Agostino, AN, et al. Hyphal forms in the central nervous system of patients with coccidioidomycosis. Clin Infect Dis 2000; 30:349.

7. Bialek, R. Amplification of coccidioidal DNA in clinical specimens by PCR. J Clin Microbiol 2005; 43:1492;.
8. Bialek, R, Gonzalez, GM, Begerow, D, Zelck, UE. Coccidioidomycosis and blastomycosis: advances in molecular diagnosis. FEMS Immunol Med Microbiol 2005; 45:355.
9. Huppert, M, Sun, SH, Bailey, JW. Natural variability in Coccidioides immitis. In: Coccidioidomycosis. The Second Symposium on Coccidioidomycosis, Ajello, L, (Ed), University of Arizona Press, Tucson 1965. p.323.
10. Huppert, M, Bailey, JW, Chitjian, P. Immunodiffusion as a substitute for complement fixation and tube precipitin tests in coccidioidomycosis. In: Coccidioidomycosis. The Second Symposium on Coccidioidomycosis, Ajello, L, (Ed), University of Arizona Press, Tucson 1967. p.221.
11. Huppert, M, Sun, SH, Rice, EH. Specificity of Exoantigens for Identifying Cultures of Coccidioides immitis. J Clin Microbiol 1978; 8:346.
12. Sandhu, GS, Kline, BC, Stockman, L, Roberts, GD. Molecular probes for diagnosis of fungal infections [published erratum appears in J Clin Microbiol 1996 May;34(5):1350]. J Clin Microbiol 1995; 33:2913.
13. Fisher, MC, Koenig, GL, White, Taylor, JT. Molecular and phenotypic description of Coccidioides Posadasii sp nov., previously recognized as the non-California population of Coccidioides immitis. Mycologia 2002; 94:73.
14. Wieden, MA, Lundergan, LL, Blum, J, et al. Detection of coccidioidal antibodies by 33-kDa spherule antigen, Coccidioides EIA, and standard serologic tests in sera from patients evaluated for coccidioidomycosis. J Infect Dis 1996; 173:1273.
15. Pappagianis, D, Zimmer, BL. Serology of coccidioidomycosis. Clin Microbiol Rev 1990; 3:247.
16. SMITH, CE, SAITO, MT, SIMONS, SA. Pattern of 39,500 serologic tests in coccidioidomycosis. J Am Med Assoc 1956; 160:546.
17. Huppert, M, Bailey, JW. Immunodiffusion as a screening test for coccidioidomycosis serology. Sab 1963; 2:284.
18. Johnson, SM, Pappagianis, D. The coccidioidal complement fixation and immunodiffusion-complement fixation antigen is a chitinase. Infect Immun 1992; 60:2588.
19. Yang, MC, Magee, DM, Cox, RA. Mapping of a Coccidioides immitis-specific epitope that reacts with complement-fixing antibody. Infect Immun 1997; 65:4068.
20. Zartarian, M, Peterson, EM, de la, Maza LM. Detection of antibodies to Coccidioides immitis by enzyme immunoassay. Am J Clin Pathol 1997; 107:148.
21. Huppert, M, Peterson, ET, Sun, SH, et al. Evaluation of a latex particle agglutination test for coccidioidomycosis. Am J Clin Pathol 1968; 49:96.
22. Smith, CE, Whiting, EG, Baker, EE,et al. The use of coccidioidin. Am Rev Tuberc Pulm Dis 1948; 57:330.
23. Padua y Gabriel, A, Martinez-Ordaz, VA, Velasco-Rodreguez, VM, et al. Prevalence of skin reactivity to coccidioidin and associated risks factors in subjects living in a northern city of Mexico. Arch Med Res 1999; 30:388.

© 2008 UpToDate, Inc. All rights reserved. | Subscription and License Agreement |Support
Tag: [ecapp0604p.utd.com-153.48.52.241-C60335629B-19006]
Licensed to: California Prison Healthcare

Gastroenteritis

Control Measures for Gastroenteritis (GI) Outbreak – Norovirus[1,2]

Quarantine:

1. At the onset of an outbreak, there should be no new admissions to the Housing Unit or Yard involved.
2. Continue releasing inmates, as scheduled. Provide them with information about the GI outbreak and how to prevent its transmission (hand washing, cleaning their environment with bleach solution, etc.).
3. All group activities need to be canceled (programs, visits, yard time, religious services, etc.).
4. Do not discontinue quarantine efforts put in place to control the spread of the virus until there have been no new cases for 72 hours.
5. Limit inmate staff to essential workers (food prep, industry, grounds). These can be people who either have or have not already been ill.
6. Make frequent announcements asking inmates to stay in their cells if ill.
7. Any staff with any of the symptoms currently or within the past 24 to 48 hours should be sent home.

Outbreak case confirmation

8. Screen inmate staff for nausea, vomiting, and diarrhea prior to each shift.
9. Submit stool samples from correctional staff and inmates to CDHS labs.
   a. Ideally, stool samples should be obtained from at least 8 to 10 ill persons within 48 to 72 hours after the onset of symptoms.
   b. However, PCR can detect viral particles for at least a week after the symptoms have resolved.

Infection Control Measures:

10. Correctional staff and inmates need to receive handouts on Norovirus, hand hygiene, and keeping environment clean.
11. Staff are to use gloves when handling ill inmates.
12. Facility cleaning:
    a. Clean surfaces (dining facilities, showers, units [cells]) with bleach solution made fresh daily (e. g. 1 cup bleach to 3 gallons of water).
    b. Protocol for cleaning body fluids (stool, vomitus): wear masks, apply bleach solution to fluids for ten minutes, and use mops dedicated to contaminated areas to clean up fluids. Take care not to contaminate clothing while cleaning.
    c. Remove Handi-wipes from units. Inmates and staff can use soap and water or alcohol based hand sanitizer (under supervision by staff at officers station) to cleanse hands.
13. Inmates:
    a. Well-inmates shower as a group first. Ill-inmates shower as a group next. Showers need to be cleaned with bleach solution after ill-inmates use them.
    b. Well-inmates eat in groups by unit housed in facility. Dining areas need to be cleaned with bleach solution between groups.
    c. Strict hand washing for ALL inmates prior to meals, reinforced by regular announcements.
    d. Ill-inmates stay in cells until 24 to 48 hours after symptoms cease. Ill-inmates receive all meals in cells.
14. Food handlers must use gloves and wash hands frequently.

---

[1] Recommendations made to San Quentin State Prison staff by the Marin County Department of Health and Human Services and the California Department of Health Services; January 4, 2007.

[2] Please see Recommendations for the Prevention and control of Viral Gastroenteritis Outbreaks in California Long-Term Care Facilities (CDHS, October 2006) for additional information.
[http://www.dhs.ca.gov/ps/dcdc/dcdcindex.htm]

GASTROENTERITIS FACT SHEET

Gastroenteritis

- Infectious diseases that can cause nausea, vomiting and diarrhea
- Extremely common. Millions of cases per year in US
- Most adults will have at least one episode per year
- Many causes
- Most commonly due to viruses like the Norovirus
- Also hundreds of thousands of cases due to bacteria each year in the US
- (#1 bacteria is campylobacter, others: e coli; salmonella; shigella, staphylococcal food poisoning)
- Some transmitted from food, water, person-to-person
- Very common in long term care facilities and other closed settings (nursing homes, hospitals, military, cruise ships, prisons)
- Outbreaks usually last 2 weeks or so

Norovirus

- A group of similar viruses
- Includes Norwalk virus, Hawaii, snow mountain, others
- Infection with these viruses is very common
- +/- 50% of adults have been infected at some time, you can be infected multiple times
- Transmitted year round, most common in winter
- Very contagious, takes only a small number of viral particles to get infected
- Spread by exposure to stool and vomit from infected persons; this can also contaminate food, water, ice, surfaces, etc.
- Food handlers can spread the virus even before or after they are ill.
- After exposure, illness usually develops in 24 to 48 hours (up to 72 hours)
- Illness usually lasts 2 to 3 days
- People can shed virus in stool for up to 3 weeks but greatest concentration of virus in stool is within 48 to 72 hours of diarrhea onset.

APPENDIX B

GENERAL INSTRUCTIONS for COLLECTION of STOOL SPECIMENS*

Instructions for collecting specimens	TYPE OF AGENT TO BE TESTED FOR		
	VIRUS	**BACTERIUM**	**PARASITE**
When to collect	As soon as possible – within 48-72 hours of diarrhea onset	During period of active diarrhea (preferably as soon after onset of illness as possible).	Any time after onset of illness (preferably as soon after onset of illness as possible).
How much to collect	As much stool sample from each of 10 ill persons as soon as possible (at least 10 cc per person).	Fresh stool (or swabs with visible fresh fecal material if necessary) from each of 10 ill persons, size of walnut.	A fresh stool sample from each of 10 ill persons.
Method of collection	Place a fresh stool specimen (liquid preferable) unmixed with urine, in clean dry containers (e. g. urine specimen cups) Do not add any liquid or preservatives. Do not collect in Carey-Blair medium.	For bulk stool, prefer in container mixed will with transport media (obtained from laboratory). For swabs, place into Cary-Blair medium tube, break off top portions of swab sticks and discard sticks.	Collect a bulk sample, unmixed with urine, in a clean container. Place a portion of each stool sample into 10% formalin and polyvinyl alcohol preservatives at a ratio of 1 part stool to 3 parts preservative. Mix well.
Storage of specimen after collection	Immediately refrigerate at 4 degrees C. DO NOT FREEZE. If electron microscopy is anticipated.	Immediately refrigerate at 4 degrees C if testing is to be done (should be within 4 hours if NOT in transport media)	Store at room temperature or immediately refrigerate preserved specimen at 4 degrees C. DO NOT FREEZE.
Transportation	Keep refrigerated. Place bagged and sealed specimens on ice or with frozen refrigerant pack in insulated box. Send by overnight mail. DO NOT FREEZE.	Refrigerate (as directed for viral specimens) if fresh. If possible, get to laboratory in transport media within 24 hours. If in transport media, can be at room temperature.	For room-temperature samples: mail in transport media, in waterproof containers. DO NOT FREEZE.

* Label each specimen container with a waterproof marker with patient's last name, first name and date collected. Put samples in sealed, waterproof containers (e. g. plastic bags). Batch collection and send by overnight mail., scheduled to arrive at destination on a weekday during business hours.

For parasites: Mix fresh bulk-stool specimens thoroughly with each of two preservatives, 10% formalin and polyvinyl alcohol fixative, at a ratio of 1 part stool to 3 parts preservative. These are available in commercial kits. If there is a delay, refrigerate untreated stool specimens at 4 degree C. (do not freeze) for up to 48 hours. Once preserved, the specimens can be stored and transported at room temperature or refrigerated. DO NOT FREEZE.

Transportation (specimen handling)

1. ***Refrigerated Specimens***: Enclose each specimen in a secure container to which has been affixed a waterproof label. Place the container in a waterproof bag with tissue, towels, or other blotting material to absorb leakage. Batch specimen containers as long as this does NOT result in delay beyond 24 hours, pack with ice or frozen refrigerant packs in an insulated box, and send by overnight mail scheduled to be delivered during business hours on a weekday.
2. ***Frozen Specimens:*** (for bacterial testing only): So that they remain frozen, ship frozen specimens on dry ice. Use enough dry ice to keep the specimen frozen until it is received at the laboratory that will process it (i. e. enough dry ice to fill one-third to one-half of the shipping container). Do not allow glass tubes to be in direct contact with dry ice. To prevent excess exposure of specimens to carbon dioxide, tighten the screw caps on the Cary-Blair tubes and seal them with electrical tape or seal the specimens in a plastic bag within the dry ice container.

Serum

1. General Guidelines:
   a. ***Timing of collection of specimens***: Submit two serum specimens (an acute-phase specimen and a convalescent-phase specimen) for each patient thought to have an illness caused by viruses. Obtain the acute-phase serum specimen as close to the time of onset of illness as possible (at most, within 10days of after onset) and the convalescent-phase serum specimen 4-6 weeks after onset of illness.
   b. ***Source(s) of specimens:*** If possible, obtain paired serum specimens from the same 10 patients from whom stool samples were obtained. Ten paired serum specimens obtained from well persons can serve as control specimens.
2. Methods for collection and storage: Collect blo0d specimens for adults (15 ml) in tubes that do not contain anticoagulants (usually red top tubes). Centrifuge the blood and send only the serum for analysis. If no centrifuge is available, store the blood specimens in a refrigerator until a clot is formed. Then, remove the serum and pipette it into an empty sterile tube (using a Pasteur pipette). Refrigerate the tubes of spun serum until they are shipped. Refrigerate, but do not freeze, tubes containing unspun serum.

PRACTICAL GUIDANCE—
NOROVIRUS OUTBREAK at CDCR INSTITUTIONS

This guidance contains recommendations for medical, nursing, and custody staff in the institutions to use in building a framework for intervening in viral gastroenteritis outbreaks. Each institution has factors that will affect their planning including the institution's mission, size, inmate custody levels, and the staff available to intervene in an outbreak. Each outbreak episode needs to be approached with an open mind. Consider all possible causes for the symptom outbreak – food, viral, bacterial. Is the outbreak wide spread (consider food borne/water borne event)? Where did it start? Is there a contagion pattern – a sentinel case with concentric rings of dissemination (consider viral)?

For highly contagious viral gastroenteritis, like Norovirus:

1. Items to consider:
   a. What are the circumstances in the community? Is there an outbreak of a specific viral agent? Number of cases involved? What symptoms are presenting? What is the location of those affected?
   b. What are the circumstances in the prison – institutional community? Is there an identified viral agent in neighboring institutions? In local jails?
2. If there is vomiting with diarrhea – suspect Norwalk. Assume the viral gastroenteritis is Norovirus until proven otherwise.
3. Confine symptomatic inmates to quarters, then conduct contact investigation and disease identification activities. (The challenge is to balance inmate civil liberties with effective infection control and containment for suspected highly contagious viruses, like Norwalk.)
4. Staff need to be educated that they are to not report to work if they have any symptoms of the virus and that they need to be symptom free for 24 to 48 hours before returning to work.

Communication: Ask for help early and often:

Based on your clinical judgment, anytime there is an increase in the number of inmate cases with any communicable condition that leads you to believe that a change in medical condition will change programs, movement, visitation, and inmate transfers, implement the following:

1. Notify custody early and regularly:
   a. Include information on symptoms
   b. Include reminder about hand washing – have unit managers reinforce this training with their respective staff
   c. It is essential that transportation be alerted at the earliest opportunity.
2. Establish a central command structure for communication early in the outbreak. The earlier the better. Key staff to include are the CMO, Public Health Nurse, Director of Nurses, Infection Control Nurse, Warden, and key custody staff.
3. Notify central headquarters early and regularly (within 24 hours of the outbreak starting):
   a. To help mobilize additional staff if needed
   b. To provide additional authority for stopping movement within and without the institution, if indicated.
   c. Headquarters can determine when and if to notify the receiver.
4. To help in communicating with, and educating inmates, involve the Men's Advisory Committee, Peer Education group and Inmate cable TV, as available in your institution.
5. Alert the staff unions about the outbreak, including custody and medical/nursing staff.
6. Post signage to visitors indicating that there is an outbreak at the prison and specify methods to stop transmission, symptoms and sequelae – important to reduce anxiety in families – require/recommend hand washing before and after visiting

Additional Resources:

1. In addition to contacting the Local Health Department immediately by telephone to report the outbreak, they can be of assistance in contact investigation and for other resources –
   a. If Norwalk virus is suspected, use the local public health laboratory as they are experienced in viral analysis of stool and vomitus specimens.
   b. Collect stool and vomitus specimens as early as possible. Make arrangements for the analysis to be expedited.
   c. Need a minimum of four (4) specimens and a maximum of 10 fresh specimens. Ideally, stool specimens should be obtained during the acute phase of the illness (within 48 – 72 hours of diarrhea onset).
2. The CA Department of Health Services, Division of Communicable Disease Control can be helpful with epidemiology issues such as determining the trajectory of the outbreak and whether it is waxing or waning.

Infection Control Measures:

1. Institute infection control measures including increased hand washing -- essential to controlling spread of infection.
2. Wear PPE – protect clothing from contamination.
3. Establish cleaning crews who can be mobilized quickly – educate them on cross contamination prevention -- wear gloves and mask when cleaning stool or vomitus.
4. Increase cleaning especially in outbreak areas -- use bleach solution (1 cup bleach to 3 gallons water – prepare it daily).

Containment:

1. Stopping transmission will require stopping movement of exposed inmates. Effective collaboration between medical/nursing staff and custody staff is essential for this operation to be successful.
2. Start by closing the institution to incoming inmates.
3. Restrict movement within the institution, as much as possible.
4. Close as many units as needed to confine the outbreak.
5. At the same time, determine with custody the service activities that are essential to safety and the functioning of critical systems in the institution.
   a. Determine which inmates are involved in these functions and where they are located. Are they in an outbreak area?
   b. Are other inmates available to provide these essential services? Restrict the movement of inmates from housing units that have active cases.
   c. During the outbreak period, restrict work provided by inmates that occurs outside the institution.
   d. Limit opportunities for congregation of inmates – evaluate stopping religious meetings, mental health groups
   e. Do not stop medical ducats.
7. Any inmate with symptoms should be provided daily observation while symptomatic and hydration therapy to prevent dehydration.

Tracking:

1. Collect information about inmate condition systematically.
   a. Assign a single person (and designee for days off) to be the focal point of all reports tracking outbreak symptoms.
   b. Collect the same information across the institution (in all housing units) including the housing unit/wing; name, bed number, CDC #, date CTQ started, date CTQ ended and symptoms presenting, note if specimen was collected.

c. Document any new cases for that day, any continuing cases (still symptomatic) and date cases resolved.
d. Collate the information into a single report each day with total cases in each housing unit and within the institution.

2. Establish a consistent nursing team to do daily face-to-face evaluation of all inmates in any housing unit that has a case of viral gastroenteritis
   a. Inmates with symptoms should be evaluated by a Registered Nurse as soon as possible. The RN should determine if the inmate needs medical evaluation and can initiate hydration therapy.
   b. Have the same staff evaluate the inmates face-to-face for the same housing unit/yard, to the degree possible. This provides for continuity and will help determine if the cases are emerging or resolving.
   c. Consider having one or two team members work over the weekend (e. g. Friday through Monday) to improve communication among staff who have not participated in the face-to-face evaluations. These staff can train the weekend staff on how to use the data collection instruments and answer any questions they may have.
3. Establish collaborative relationship with custody in case finding. If they see an inmate with symptoms, have them notify nursing immediately for assessment and intervention, as appropriate.

Education:

1. Develop and have available inmate education materials that are in multiple languages, low-literacy, and American Sign Language for the hearing impaired.
2. Develop and have available staff education materials for custody and medical/nursing staff – about Norwalk Virus, hand washing and prevention.

Additional Resources:

1. CDC MMWR: Norwalk-Like Viruses" Public Consequences and Outbreak Management. June 1, 2001. Vol. 50, No RR-9. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5009a1.htm
2. Recommendations for the Prevention and Control of Viral Gastroenteritis Outbreaks in California Long-Term Care Facilities (CDHS, October 2006) http://www.dhs.ca.gov/ps/dcdc/disb/disbindex.htm
3. CDC: Viral Gastroenteritis (Fact sheet in English and Spanish) http://www.cdc.gov/ncidod/dvrd/revb/gastro/faq.htm]
4. CDC: Norovirus: Q&A http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-qa.htm
5. Norovirus: Foodhandlers. http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-foodhandlers.htm

RECOMMENDATIONS FOR THE PREVENTION AND CONTROL OF VIRAL GASTROENTERITIS OUTBREAKS IN CALIFORNIA LONG-TERM CARE FACILITIES

California Department of Health Services
Division of Communicable Disease Control
In Consultation with Licensing and Certification Program

850 Marina Bay Parkway
Richmond, California 94804

October 2006

ARNOLD SCHWARZENEGGER
Governor
State of California

Kimberly Belshé, Secretary
Health and Human Services Agency

Sandra Shewry, Director
Department of Health Services

Introduction

Outbreaks of gastroenteritis in long-term care facilities (LTCFs) are not uncommon, and can become epidemic during the winter and early spring. Viruses (norovirus specifically) cause most of these outbreaks, and they are almost always transmitted from **person-to-person** (including residents, staff, visitors and volunteers). Norovirus can persist in the environment and is resistant to most disinfectants, and as a result **contamination of the environment** plays a key role in transmission. Only occasionally is an outbreak in a LTCF caused by contaminated food.

While norovirus infection is usually mild in otherwise healthy adults, illness can be severe in the elderly, particularly in those with underlying medical problems. In one recent 2-year period (July 2002 - June 2004), California had 480 reported outbreaks of viral gastroenteritis. Over half the outbreaks occurred in LTCFs, and 80% of these were in skilled nursing facilities (nursing homes). In these nursing homes over 6500 persons became ill, 120 residents were hospitalized, and 29 died.

Norovirus outbreaks can be detected early by recognizing the typical symptoms of illness, and can be controlled by promptly taking specific steps to prevent the virus from being transmitted from person-to-person. When appropriate infection prevention and control measures are **not** implemented immediately, outbreaks can continue for weeks with many residents becoming ill resulting in some hospitalizations and occasionally death from dehydration and other complications of vomiting and diarrhea.

The California Department of Health Services (CDHS) Division of Communicable Disease Control developed these recommendations in consultation with the Licensing and Certification Program. This information is intended to be advisory only and was developed to assist facility infection control committees in the development of a rational approach to the control of viral gastroenteritis outbreaks in LTCFs. This is an update of the guideline initially released in 2002. A comprehensive guide to the prevention and control of gastroenteritis in LTCFs is available at http://www.dhs.ca.gov/ps/dcdc/disb/disbindex.htm. Information on norovirus is available from CDC at http://www.cdc.gov/ncidod/diseases/submenus/sub_norwalk.htm.

What causes viral gastroenteritis in LTCFs?

Gastroenteritis is an inflammation of the stomach and intestines. This usually results in vomiting and/or diarrhea. Outbreaks of gastroenteritis in LTCFs are almost always due to a group viruses called caliciviruses, which includes norovirus. Bacteria such as *Salmonella, Shigella,* or *Campylobacter* also occasionally cause gastroenteritis in LTCFs, but are more likely to be foodborne and the patterns of illness that occur are usually different from viral gastroenteritis.

What are the signs and symptoms of viral gastroenteritis?

The main symptoms of viral gastroenteritis are sudden onset of vomiting and diarrhea. Vomiting is usually prominent but may be infrequent or absent. Diarrhea tends to be watery, short-lived and less severe than that which results from gastroenteritis caused by bacteria. Vomiting is more common in the young, and diarrhea in adults. The affected person may also have headache, fever (usually low-grade), chills and abdominal cramps ("stomach ache"). These symptoms can occur in various combinations during an outbreak. When viral gastroenteritis occurs in winter it is often referred to as “intestinal influenza” or “stomach flu”, although it has no relationship to respiratory infections caused by the influenza virus.

Illness begins between one to two days following exposure to the virus. Unless complicated by underlying illness, age, or dehydration, the illness is generally mild and of short duration (one to two days), although some individuals may continue to feel weak for several days. Immunity occurs following infection but lasts only a short time, so that everyone is at risk of becoming infected again, from the same virus, five or six months later.

How is viral gastroenteritis spread?

Norovirus is extremely contagious and is primarily spread when microscopic viral particles are transferred from contaminated hands to the mouth and ingested (fecal-oral). Millions of particles are present in the stool and vomitus and it takes only a small number to cause illness. Excretion of virus in the stool begins a few hours before the onset of symptoms and reaches a maximum 24–72 hours after exposure. The virus can continue to be present in the stool of infected persons for a week or more after symptoms have subsided. Persons who have been exposed but do not develop symptoms may also transmit the virus. Vomiting will also disperse viral particles through the air, resulting in exposure of persons nearby and in contamination of environmental surfaces and objects. Norovirus can remain infectious on environmental surfaces for many days and is relatively resistant to common disinfecting products, heat, and cold.

In a healthcare facility the virus is spread primarily when ill persons (residents, healthcare workers, visitors) contaminate their hands with feces or vomitus containing the viral particles. It is impossible to be sure that hand hygiene eliminates the virus from the hands of symptomatic persons. Ill healthcare workers dispensing medication have been responsible for person-to-person transmission in some outbreaks.

Can viral gastroenteritis be spread by food and water?

Norovirus can also be transmitted by food and water. This is uncommon in LTCFs where transmission is usually from person-to-person. Food preparers or handlers who have viral gastroenteritis may contaminate food, especially if they do not wash their hands regularly after using the bathroom or do not wear gloves while handling food. Cold foods such as salad and sandwiches have been common sources for outbreaks. Shellfish may be contaminated by sewage, but are unlikely to be served in LTCFs. Drinking water can also be contaminated due to faulty plumbing.

How is viral gastroenteritis diagnosed?

Viral gastroenteritis cannot be diagnosed by traditional stool cultures (for bacteria) or examination of stool for ova and parasites. Norovirus can be identified by polymerase chain reaction (PCR), which is available at CDHS and some local health departments. This requires fresh (unfrozen) stool. Ideally, stool samples should be obtained from at least 6 ill persons within 48-72 hours after the onset of symptoms. However PCR testing can detect viral particles for at least a week after the symptoms have resolved. Vomitus can be tested if that is the only specimen available. Antibody testing is possible but requires acute (collected during illness) and convalescent sera (typically collected about four weeks after onset of illness). While PCR can be completed within one day of receiving a specimen, decisions to institute control measures should not be delayed while waiting for results.

How can an outbreak of viral gastroenteritis be identified?

Facilities should establish and maintain a program of surveillance for viral gastrointestinal disease. An outbreak of viral gastroenteritis should be suspected when two or more residents and/or staff develop a new onset of vomiting and diarrhea within one to two days. Vomiting may be present in at least half of the ill persons. Other symptoms may include nausea with or without vomiting and low grade fever.

During the winter, and occasionally into the spring, many norovirus outbreaks may occur in LTCFs. Local health departments are encouraged to notify LTCFs if this is occurring in their jurisdiction. LTCFs that are aware of outbreaks in the community should be extremely vigilant of the development of acute viral gastrointestinal illness occurring in their facilities.

How is an outbreak of viral gastroenteritis controlled?

Interrupting person-to-person transmission will limit the extent of the outbreak if transmission prevention precautions are implemented when the first two to three cases are suspected. There is probably little that can be done to prevent the initial introduction of the virus, since an infected healthcare worker or visitor may be shedding the virus even before they are ill, or may never be symptomatic. The following recommendations may assist facility personnel in controlling an outbreak of viral gastroenteritis

I. Limit transmission when initial cases of viral gastroenteritis are suspected

A. Notification

1. Each nursing unit should immediately report any resident(s) or staff member(s) with a sudden onset of symptoms suggestive of viral gastroenteritis to the infection control practitioner or the Director of Nurses.
2. New cases should be recorded daily using a case log (see Appendix 1).
3. Notify the medical director immediately.

4. Notify the local health department and the Licensing and Certification district office with jurisdiction over your facility (www.dhs.ca.gov/lnc/org/default.htm). Consult with the local health department about laboratory testing.

B. Management of Residents and Staff

1. Confine symptomatic residents to their rooms until 48 hours after symptoms cease. Exclude non-essential staff from entering room.
2. Request symptomatic staff, visitors and volunteers to stay home until symptom–free for at least 24 hours.
3. Discontinue "floating" staff from the affected unit to non-affected units, if possible.

II. Institute control measures when a viral gastroenteritis outbreak is suspected without waiting for diagnostic confirmation

A. Notification: see above. All outbreaks must be reported immediately to the local health department and the Licensing and Certification district office with jurisdiction over your facility.

B. Management of Residents

1. Minimize movement of residents. Asymptomatic, exposed residents should **not** be moved from an affected to an unaffected nursing unit. The value in moving asymptomatic residents who have been exposed (e.g., to a symptomatic roommate) is uncertain since they may already be infected.

2. Cancel or postpone group activities until at least 48 hours after the last identified case.

3. Clean and disinfect equipment such as blood pressure cuffs, stethoscopes and electronic thermometers before use for another resident.

4. Consider use of antiemetics for patients with vomiting.

5. Limit new admissions until the incidence of new cases has reached zero for at least 48 hours. If new admissions are necessary, admit resident to an unaffected unit or to a unit that has had no new cases for at least two days.

C. Management of Staff

1. Staff assignments
   a. Maintain the same staff to resident assignments, if possible.
   b. Limit staff from moving between affected and unaffected units.

2. Implement Transmission Prevention Precautions:
   a. Wear gloves, gown and a surgical or procedure mask when in contact with the symptomatic resident.

b. Remove gloves and then gown, perform hand hygiene and then remove mask after contact with the ill resident and before contact with an unaffected resident in the same room or exiting the resident's room.
c. Perform hand hygiene immediately after removal of gloves and gown.
   i. If gloves or hands are visibly soiled with feces or vomitus, wash hands with soap and water.
   ii. Alcohol hand gels may be used if gloves or hands have not been visibly soiled.
d. After glove and gown removal and hand hygiene, ensure that hands and clothes do not touch potentially contaminated environmental surfaces or items in the resident's room, such as bed rails and tables.

D. Management of Ill Staff

3. The loss of a large number of staff may place a significant burden on those remaining at work but exclusion of the ill staff is still an important transmission control strategy.

4. A staff illness policy outlining the requirements for exclusion and the circumstances for returning to work should be developed and all employees should be educated about the policy.

5. A log should be maintained to record ill staff symptoms, the date when they became ill, and when they returned to work (see Appendix 1).

6. During an outbreak, staff should exclude themselves from resident care at the onset of symptoms including nausea, vomiting, abdominal pain and/or diarrhea.

7. Educate staff about the need to maintain strict hand hygiene and a clean environment to minimize the risk of household transmission of norovirus infection.

8. Staff should be allowed to return to work after being symptom free for <u>at least</u> 24 hours. Virus may be excreted in stool for 2 or more weeks. Testing for norovirus is not required before staff return to work. Because of continued excretion of virus, the need for good hand hygiene should be stressed to staff returning from illness.

E. Management of Environment

1. Clean and disinfect vomit and fecal spillages promptly.

2. Increase the frequency of routine environmental cleaning including bathrooms and the area surrounding the resident's living space. Particular attention should be given to cleaning objects that are frequently touched such as faucets, door handles, and bed rails.

3. Environmental services personnel should wear a gown, gloves and a surgical or procedure mask when cleaning surfaces soiled with vomitus or fecal material.

4. Use an Environmental Protection Agency (EPA)-approved disinfectant or a freshly prepared sodium hypochlorite solution (e.g., household chlorine bleach in a 1:100 {500 ppm} to 1:10 {5,000 ppm} dilution) to disinfect surfaces contaminated with feces or vomitus (see Appendix 2). The reliability of disinfectants other than those containing chlorine to kill norovirus is uncertain, even with EPA approval, so that the use of chlorine containing (hypochlorite) solutions is recommended for use whenever possible.

5. Clean carpets and soft furnishings with hot water and detergent or steam clean. Dry vacuuming is not recommended.

F. Management of Visitors

1. Visits to symptomatic residents should be discouraged.

2. If visitation is necessary, health care workers should instruct visitors on the appropriate procedure for putting on and removing gowns and gloves (and masks if resident is vomiting), and hand hygiene.

References

Chadwick PR, Beards G, Brown D, et al. Report of the Public Health Laboratory Service Viral Gastroenteritis Working Group. Management of hospital outbreaks of gastro-enteritis due to small round structured viruses. J Hosp Infect (2000) 45: 1–10. http://www.phls.co.uk/topics_az/norwalk/hospital_srsv.pdf.

New Zealand Ministry of Health. Guidelines for the Management of Norovirus Outbreaks in Hospitals and Elderly Care Institutions. January, 2005. http://www.moh.govt.nz/publications/guidelines.

CDC. Norovirus in Healthcare Facilities. http://www.cdc.gov/ncidod/dhqp/id_norovirusFS.html.

CDC. Norwalk-like viruses - Public Health Consequences and Outbreak Management. http://www.cdc.gov/ncidod/dhqp/id_norovirusFS.html.

Appendix 1

Sample Case Log of Residents and Staff with Acute Gastrointestinal Illness

Resident/Staff identification			Resident/ Staff location			Illness description								Laboratory test date and results (optional)				Antiemetic	Antibiotic	Illness outcomes			
Name	Age	Sex (M/F)	Building	Unit	Room #, Bed designation	Date onset Illness	Highest temperature	Vomiting (Y/N) (Projectile (Y/N)	Nausea (Y/N)	Diarrhea (Watery (Y/N) Bloody (Y/N)	Abdominal cramps (Y/N)	Chills (Y/N)	Date Illness stopped	Stool PCR for NLV	Stool bacteria; culture	Stool O&P	Other	Date started/Date ended	Date started/Date ended	Tx for dehydration (Y/N)	Hospitalized (Y/N)	Days hospitalized	Died (Y/N, if yes, date)

Noroviruses

Noroviruses (genus *Norovirus*, family *Caliciviridae*) are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was recently approved as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses" (NLV). This group of viruses has also referred to as caliciviruses (because of their virus family name) and as small round structured viruses, or SRSVs (because of their morphologic features). Another genus of the calicivirus family that can cause gastroenteritis in humans is *Sapovirus*, formerly described as "Sapporo-like virus" (SLV) and sometimes referred to as classic or typical calicivirus.

Noroviruses are named after the original strain "Norwalk virus," which caused an outbreak of gastroenteritis in a school in Norwalk, Ohio, in 1968. Currently, there are at least four norovirus genogroups (GI, GII, GIII and GIV), which in turn are divided into at least 20 genetic clusters.

Clinical Presentation

The incubation period for norovirus-associated gastroenteritis in humans is usually between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure. Norovirus infection usually presents as acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and vomiting is more common in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually last 24 to 60 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae. Studies with volunteers given stool filtrates have shown that asymptomatic infection may occur in as many as 30% of infections, although the role of asymptomatic infection in norovirus transmission is not well understood.

Virus Transmission

Noroviruses are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Environmental and fomite contamination may also act as a source of infection. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed. No evidence suggests that infection occurs through the respiratory system.

Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. During outbreaks of norovirus gastroenteritis, several modes of transmission have been documented; for example, initial foodborne transmission in a restaurant, followed by secondary person-to-person transmission to household contacts. Although presymptomatic viral shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after

recovery. It is unclear to what extent viral shedding over 72 hours after recovery signifies continued infectivity.

Immunity to Norovirus

Mechanisms of immunity to norovirus are unclear. It appears that immunity may be strain-specific and lasts only a few months; therefore, given the genetic variability of noroviruses, individuals are likely to be repeatedly infected throughout their lifetimes. This may explain the high attack rates in all ages reported in outbreaks. Recent evidence also suggests that susceptibility to infection may be genetically determined, with people of O blood group being at greatest risk for severe infection.

Disease burden of Norovirus Gastroenteritis

CDC estimates that 23 million cases of acute gastroenteritis are due to norovirus infection, and it is now thought that at least 50% of all foodborne outbreaks of gastroenteritis can be attributed to noroviruses.
Among the 232 outbreaks of norovirus illness reported to CDC from July 1997 to June 2000, 57% were foodborne, 16% were due to person-to-person spread, and 3% were waterborne; in 23% of outbreaks, the cause of transmission was not determined. In this study, common settings for outbreaks include restaurants and catered meals (36%), nursing homes (23%), schools (13%), and vacation settings or cruise ships (10%).

Most foodborne outbreaks of norovirus illness are likely to arise though direct contamination of food by a food handler immediately before its consumption. Outbreaks have frequently been associated with consumption of cold foods, including various salads, sandwiches, and bakery products. Liquid items (e.g., salad dressing or cake icing) that allow virus to mix evenly are often implicated as a cause of outbreaks. Food can also be contaminated at its source, and oysters from contaminated waters have been associated with widespread outbreaks of gastroenteritis. Other foods, including raspberries and salads, have been contaminated before widespread distribution and subsequently caused extensive outbreaks.

Waterborne outbreaks of norovirus disease in community settings have often been caused by sewage contamination of wells and recreational water.

Diagnosis of Norovirus

Human. In the last 10 years, diagnosis of norovirus illness in outbreaks has improved with the increasing use of reverse transcriptase polymerase chain reaction (RT-PCR). Currently, 27 state public health laboratories have the capability to test for noroviruses by RT-PCR. RT-PCR can be used to test stool and emesis samples, as well as to detect the presence of noroviruses on environmental swabs in special studies. Identification of the virus can be best made from stool specimens taken within 48 to 72 hours after onset of symptoms, although good results can be obtained by using RT-PCR on samples taken as long as 5 days after symptom onset. Virus can sometimes be found in stool samples taken as late as 2 weeks after recovery.

Older methods for diagnosis include direct and immune electron microscopy of fecal specimens, and detection of a fourfold increase of specific antibodies in acute- and convalescent-phase blood samples. An enzyme-linked immunosorbent assay for detection of virus in stools is under development.

Sequencing of noroviruses found in clinical samples has helped in conducting epidemiologic investigations by linking cases to each other and to a common source and by differentiating outbreaks that were mistakenly connected. Sequences can be entered into CaliciNet, a database used to store the different sequences of norovirus that cause disease throughout the United States, thereby allowing rapid assessment of the relationships between strains.

In addition to microbiological techniques, several epidemiologic criteria have been proposed for use in determining whether an outbreak of gastroenteritis is of viral origin. Kaplan's criteria for this purpose are as follows: 1) a mean (or median) illness duration of 12 to 60 hours, 2) a mean (or median) incubation period of 24 to 48 hours, 3) more than 50% of people with and 4) no bacterial agent previously found." Although quite specific, these criteria are not very sensitive, and therefore the possibility of a viral etiology should not be discarded if the criteria are not met.

Environmental. Assays to detect virus in food need to be adapted for each food substance; these have been only rarely used, with the exception of assays to detect virus in shellfish. Water can be tested for noroviruses by using RT-PCR to detect virus when large volumes of water are processed through specially designed filters.

Management of Norovirus Infection

No specific therapy exists for viral gastroenteritis. Symptomatic therapy consists of replacing fluid losses and correcting electrolyte disturbances through oral and intravenous fluid administration.

Prevention

Prevention of foodborne norovirus disease is based on the provision of safe food and water. Noroviruses are relatively resistant to environmental challenge: they are able to survive freezing, temperatures as high as 60°C, and have even been associated with illness after being steamed in shellfish. Moreover, noroviruses can survive in up to 10 ppm chlorine, well in excess of levels routinely present in public water systems. Despite these features, it is likely that relatively simple measures, such as correct handling of cold foods, frequent handwashing, and paid sick leave, may substantially reduce foodborne transmission of noroviruses.

Surveillance of Norovirus Infection in the United States

CDC currently does not conduct active surveillance to monitor outbreaks of gastroenteritis caused by noroviruses. Outbreaks are reported to CDC's Viral Gastroenteritis Section, Respiratory and Enteric Viruses Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases (NCID) when states send

specimens for testing or sequencing, or outbreaks are reported directly by states to the database maintained by the Foodborne Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, NCID.

Recently, a system called CaliciNet has been developed on the basis of the PulseNet model. CaliciNet is a database of norovirus sequences identified from outbreaks of norovirus that can then help to determine links between outbreaks. For further details please email calicinet@cdc.gov

Food and drinks can very easily become contaminated with norovirus because the virus is so small and because it probably takes fewer than 100 norovirus particles to make a person sick. Food can be contaminated either by direct contact with contaminated hands or work surfaces that are contaminated with stool or vomit, or by tiny droplets from nearby vomit that can travel through air to land on food. Although the virus cannot multiply outside of human bodies, once on food or in water, it can cause illness.

Some foods can be contaminated with norovirus ***before*** being delivered to a restaurant or store. Several outbreaks have been caused by the consumption of oysters harvested from contaminated waters. Other produce such as salads and frozen fruit may also be contaminated at source.

Why is norovirus infection important for food handlers?

People working with food who are sick with norovirus gastroenteritis are a particular risk to others, because they handle the food and drink many other people will consume. Since the virus is so small, a sick food handler can easily – without meaning to – contaminate the food he or she is handling. Many of those eating the contaminated food may become ill, causing an outbreak.

Outbreaks of norovirus gastroenteritis have taken place in restaurants, cruise ships, nursing homes, hospitals, schools, banquet halls, summer camps, and family dinners – in other words, places where often people have consumed water and/or food prepared or handled by others. It is estimated that as many as half of all food-related outbreaks of illness may be caused by norovirus. In many of these cases, sick food handlers were thought to be implicated.

What can I do to prevent norovirus gastroenteritis?

Many local and state health departments require that food handlers and preparers with gastroenteritis ***not*** work until 2 or 3 days after they feel better. In addition, because the virus continues to be present in the stool for as long as 2 to 3 weeks after the person feels better, strict hand washing after using the bathroom and before handling food items is important in preventing the spread of this virus. Food handlers who were recently sick can be given different duties in the restaurant so that they do not have to handle food (for example, working the cash register or hostessing).

People who are sick with norovirus illness can often vomit violently, without warning, and the vomit is infectious; therefore, any surfaces near the vomit should be promptly cleaned and disinfected with bleach solution and then rinsed. Furthermore, food items that may have become contaminated with norovirus should be thrown out. Linens (including clothes, towels, tablecloths, napkins) soiled to any extent with vomit or stool should be promptly washed at high temperature. Oysters should be obtained from reputable sources and appropriate documentation kept. Washing raw vegetables thoroughly before eating and appropriate disposal of sewage and soiled diapers also help to reduce the spread of norovirus and prevent illness. In small home-based catering businesses or family owned or operated restaurants, sick children and infants in diapers should be excluded from food preparation areas.

How is norovirus gastroenteritis diagnosed?

In special cases, when there is an outbreak of gastroenteritis there is a need to identify norovirus as the cause of the illness. In these cases, norovirus can often be found in stool samples of infected persons by using special tests. Sometimes blood tests looking for antibodies against norovirus are also performed, when the stool tests are inconclusive or were not done. Food handlers will often be asked for a stool sample or even a blood sample to help investigate the cause of an outbreak.

Can a person have norovirus gastroenteritis more than once?

Yes, a person can be infected with norovirus more than once in their lifetime. This is because there are many different noroviruses, and being infected with one type does not prevent infection from another type later. For this reason, it is difficult to develop a vaccine against norovirus.

Appendix 1

Sample Case Log of Residents and Staff with Acute Gastrointestinal Illness

Resident/Staff identification			Resident/ Staff location			Illness description								Laboratory test date and results (optional)				Antiemetic	Antibiotic	Illness outcomes			
Name	Age	Sex (M/F)	Building	Unit	Room #, Bed designation	Date onset Illness	Highest temperature	Vomiting (Y/N) (Projectile (Y/N)	Nausea (Y/N)	Diarrhea (Watery (Y/N) Bloody (Y/N)	Abdominal cramps (Y/N)	Chills (Y/N)	Date Illness stopped	Stool PCR for NLV	Stool bacteria; culture	Stool O&P	Other	Date started/Date ended	Date started/Date ended	Tx for dehydration (Y/N)	Hospitalized (Y/N)	Days hospitalized	Died (Y/N, if yes, date)

Appendix 2

Preparation of Chlorine Solutions

		Desired Chlorine Concentration		
		500 ppm (0.05%)	1,000 ppm (0.1%)	5,000 ppm (0.5%)
Dilution of standard (5.25%) bleach prepared fresh for use within 24 hours	Bleach/water	1:100	1:50	1:10
	Preparation	2 ½ tablespoons (1/6 cup) bleach in a gallon of water	5 tablespoons (1/3 cup) bleach in a gallon of water	25 tablespoons (1 2/3 cup) bleach in a gallon of water
Dilution of standard (5.25%) bleach prepared fresh and used for 1-30 days	Bleach/water	1:50	1:25	1:5
	Preparation	5 tablespoons (1/3 cup) bleach in a gallon of water	10 tablespoons (2/3 cup) bleach in a gallon of water	50 tablespoons (3 1/3 cup) bleach in a gallon of water

“Ultra” concentrations of bleach contain 6-7.35% hypochlorite and are not recommended to avoid producing higher than intended concentrations of chlorine.

Noroviruses: Q&A

What are noroviruses?

Noroviruses are a group of viruses that cause the "stomach flu," or gastroenteritis (GAS-tro-en-ter-I-tis), in people. The term norovirus was recently approved as the official name for this group of viruses. Several other names have been used for noroviruses, including:

- Norwalk-like viruses (NLVs)
- caliciviruses (because they belong to the virus family *Caliciviridae*)
- small round structured viruses.

Viruses are very different from bacteria and parasites, some of which can cause illnesses similar to norvirus infection. Viruses are much smaller, are not affected by treatment with antibiotics, and cannot grow outside of a person's body.

What are the symptoms of illness caused by noroviruses?

The symptoms of norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people additionally have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. The illness is usually brief, with symptoms lasting only about 1 or 2 days. In general, children experience more vomiting than adults. Most people with norovirus illness have both of these symptoms.

What is the name of the illness caused by noroviruses?

Illness caused by norovirus infection has several names, including:

- stomach flu – this "stomach flu" is ***not*** related to the flu (or influenza), which is a respiratory illness caused by influenza virus.
- viral gastroenteritis – the most common name for illness caused by norovirus. Gastroenteritis refers to an inflammation of the stomach and intestines.
- acute gastroenteritis
- non-bacterial gastroenteritis
- food poisoning (although there are other causes of food poisoning)
- calicivirus infection

How serious is norovirus disease?

Norovirus disease is usually not serious, although people may feel very sick and vomit many times a day. Most people get better within 1 or 2 days, and they have no long-term health effects related to their illness. However, sometimes people are unable to drink enough liquids to replace the liquids they lost because of vomiting and diarrhea. These persons can become dehydrated and may need special medical attention. This problem with dehydration is usually only seen among the very young, the elderly, and persons with weakened immune systems. There is no evidence to suggest that an infected person can become a long-term carrier of norovirus.

How do people become infected with noroviruses?

Noroviruses are found in the stool or vomit of infected people. People can become infected with the virus in several ways, including:

- eating food (see food handler fact sheet) or drinking liquids that are contaminated with norovirus;
- touching surfaces or objects contaminated with norovirus, and then placing their hand in their mouth;
- having direct contact with another person who is infected and showing symptoms (for example, when caring for someone with illness, or sharing foods or eating utensils with someone who is ill).

Persons working in day-care centers or nursing homes should pay special attention to children or residents who have norovirus illness. This virus is very contagious and can spread rapidly throughout such environments.

When do symptoms appear?

Symptoms of norovirus illness usually begin about 24 to 48 hours after ingestion of the virus, but they can appear as early as 12 hours after exposure.

Are noroviruses contagious?

Noroviruses are very contagious and can spread easily from person to person. Both stool and vomit are infectious. Particular care should be taken with young children in diapers who may have diarrhea.

How long are people contagious?

People infected with norovirus are contagious from the moment they begin feeling ill to at least 3 days after recovery. Some people may be contagious for as long as 2 weeks after recovery. Therefore, it is particularly important for people to use good handwashing and other hygienic practices after they have recently recovered from norovirus illness.

Who gets norovirus infection?

Anyone can become infected with these viruses. There are many different strains of norovirus, which makes it difficult for a person's body to develop long-lasting immunity. Therefore, norovirus illness can recur throughout a person's lifetime. In addition, because of differences in genetic factors, some people are more likely to become infected and develop more severe illness than others.

What treatment is available for people with norovirus infection?

Currently, there is no antiviral medication that works against norovirus and there is no vaccine to prevent infection. Norovirus infection cannot be treated with antibiotics. This is because antibiotics work to fight bacteria and not viruses.

Norovirus illness is usually brief in healthy individuals. When people are ill with vomiting and diarrhea, they should drink plenty of fluids to prevent dehydration. Dehydration among young children, the elderly, the sick, can be common, and it is the most serious health effect that can result from norovirus infection. By drinking oral rehydration fluids (ORF), juice, or water, people can reduce their chance of becoming dehydrated. Sports drinks do not replace the nutrients and minerals lost during this illness.

Can norovirus infections be prevented?

Yes. You can decrease your chance of coming in contact with noroviruses by following these preventive steps:

- Frequently wash your hands, especially after toilet visits and changing diapers and before eating or preparing food.
- Carefully wash fruits and vegetables, and steam oysters before eating them.
- Thoroughly clean and disinfect contaminated surfaces immediately after an episode of illness by using a bleach-based household cleaner.
- Immediately remove and wash clothing or linens that may be contaminated with virus after an episode of illness (use hot water and soap).
- Flush or discard any vomitus and/or stool in the toilet and make sure that the surrounding area is kept clean.

Persons who are infected with norovirus should not prepare food while they have symptoms and for 3 days after they recover from their illness (see food handler information sheet). Food that may have been contaminated by an ill person should be disposed of properly.

Los CDC responden a sus preguntas sobre los norovirus: preguntas y respuestas

¿Qué son los norovirus?

Los norovirus son un grupo de virus que causan la “gripe estomacal”, o gastroenteritis en las personas. El término norovirus fue aprobado recientemente como el nombre oficial de este grupo de virus. Se han usado varios otros nombres para referirse a los norovirus, entre ellos:

- virus parecidos al Norwalk (NLV, por sus siglas en inglés)
- calvicivirus (porque pertenecen a la familia Caliciviridae)
- virus esféricos de tamaño pequeño.

Los virus son muy diferentes de las bacterias y los parásitos, algunos de los cuales pueden causar enfermedades similares a la infección por los norovirus. Los virus son mucho más pequeños, no los afecta el tratamiento con antibióticos y no pueden sobrevivir fuera del cuerpo de una persona.

¿Cuáles son los síntomas de la enfermedad causada por los norovirus?

Por lo general, entre los síntomas de la enfermedad causada por los norovirus se cuentan la náusea, el vómito, la diarrea y calambres estomacales. Además, algunas veces las personas tienen fiebre, escalofríos, dolor de cabeza, dolor muscular y una sensación general de cansancio. La enfermedad se presenta a menudo en forma repentina y la persona infectada puede sentirse muy mal. Usualmente, la enfermedad es breve, y los síntomas duran solo 1 ó 2 días aproximadamente. En general, los niños vomitan más que los adultos. La mayoría de las personas que están enfermas con el norovirus presentan algunos de estos síntomas.

¿Cómo se llama la enfermedad causada por los norovirus?

La enfermedad causada por el norovirus se conoce por varios nombres, entre ellos:

- gripe estomacal. Esta “gripe estomacal” no está relacionada con la gripe (influenza o flu), la cual es una enfermedad respiratoria causada por el virus de la gripe.
- gastroenteritis viral. Es el nombre más común de la enfermedad causada por el norovirus. La gastroenteritis se refiere a la inflamación del estómago y los intestinos.
- gastroenteritis aguda
- gastroenteritis no bacteriana
- intoxicación con alimentos (aunque hay otras causas de intoxicación con alimentos).
- infección por el calvicivirus

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
SAFER • HEALTHIER • PEOPLE™

¿Qué tan grave es la enfermedad causada por el norovirus?

Por lo general, la enfermedad causada por el norovirus no es grave, aunque las personas pueden sentirse muy mal y vomitar muchas veces al día. La mayoría de las personas se sienten mejor en 1 ó 2 días y no experimentan efectos en la salud a largo plazo relacionados con esta enfermedad. Sin embargo, algunas veces las personas no están en capacidad de tomar suficientes líquidos para reemplazar los líquidos que han perdido debido al vómito y a la diarrea. Estas personas pueden deshidratarse y necesitar atención médica especial. Por lo general, este problema de deshidratación solo se observa entre los jóvenes de corta edad, las personas de edad avanzada y las personas con el sistema inmunológico debilitado. No hay evidencia que parezca indicar que una persona infectada pueda convertirse en un portador a largo plazo del norovirus.

¿Cómo contraen las personas la infección por los norovirus?

Los norovirus se encuentran en las heces o el vómito de las personas infectadas. Las personas pueden quedar infectadas con el virus de diversas maneras, entre ellas por:

- consumir alimentos (consulte la hoja informativa sobre la preparación de alimentos) o tomar líquidos contaminados con el norovirus;
- tocar superficies u objetos contaminados con el norovirus, y luego llevarse las manos a la boca.
- tener contacto directo con otra persona que está infectada y presenta síntomas (por ejemplo, al cuidar a alguien que tiene la enfermedad, o al compartir alimentos o cubiertos con alguien que tiene esta enfermedad).

Las personas que trabajan en guarderías o asilos de ancianos deben prestar mucha atención a los niños o residentes que tienen la enfermedad causada por el norovirus. Este virus es muy contagioso y puede propagarse rápidamente en tales ambientes.

¿Cuándo aparecen los síntomas?

Por lo general, los síntomas de la enfermedad causada por el norovirus comienzan aproximadamente entre 24 y 48 horas después de la ingestión del virus, pero pueden aparecer tan solo 12 horas después de la exposición a este virus.

¿Son contagiosos los norovirus?

Los norovirus son muy contagiosos y se pueden propagar fácilmente de una persona a otra.
Tanto las heces como el vómito son contagiosos.
En particular, se debe prestar mucha atención a los niños de corta edad en pañales que puedan tener diarrea.

¿Durante cuánto tiempo permanecen contagiosas las personas?

Las personas infectadas por el norovirus son contagiosas desde el momento en que comienzan a sentirse mal hasta por lo menos 3 días después de recuperarse. Algunas personas pueden permanecer contagiosas hasta por 2 semanas después de recuperarse. Por consiguiente, es especialmente importante que las personas se laven bien las manos y usen otras prácticas de higiene después de recuperarse de la enfermedad causada por el norovirus.

¿Quién contrae la infección por el norovirus?

Cualquier persona puede quedar infectada por estos virus. Hay muchas cepas diferentes del norovirus, lo que hace difícil que el cuerpo de una persona desarrolle inmunidad por mucho tiempo. Por consiguiente, la enfermedad causada por el norovirus puede repetirse en el transcurso de la vida de una persona. Además, debido a las diferencias en los factores genéticos, algunas personas tienen más probabilidades de quedar infectadas y contraer enfermedades más graves que otras.

¿Qué tratamiento se encuentra a disposición de las personas infectadas con el norovirus?

En la actualidad, no hay medicina antiviral que sea eficaz contra el norovirus y no hay vacuna que prevenga la infección. La infección causada por el norovirus no puede ser tratada con antibióticos. Esto se debe a que los antibióticos son eficaces para combatir las bacterias, pero no los virus.

Por lo general, la enfermedad causada por el norovirus es de corta duración en personas que gozan de buena salud. Cuando las personas están enfermas y tienen vómito y diarrea, deben tomar abundantes líquidos para evitar la deshidratación. La deshidratación entre los niños de corta edad, las personas de edad avanzada y los enfermos puede ser común, y es el efecto más grave sobre la salud que puede resultar de la infección por el norovirus. Al tomar soluciones rehidratantes orales (ORF, por sus siglas en inglés), las personas pueden reducir las probabilidades de deshidratarse. Las bebidas deportivas no reemplazan los nutrientes y minerales perdidos durante esta enfermedad.

¿Pueden prevenirse las infecciones causadas por el norovirus?

Sí. Observe las siguientes medidas preventivas para evitar el riesgo de entrar en contacto con los norovirus:

- Lávese las manos con frecuencia, especialmente después de ir al baño y de cambiar los pañales a un bebé y antes de comer o preparar la comida.
- Lave cuidadosamente frutas y vegetales, y cocine al vapor las ostras antes de comerlas.
- Limpie y desinfecte bien las superficies contaminadas inmediatamente después de un episodio de la enfermedad con un limpiador doméstico a base de cloro.
- Retire la ropa o lencería que pueda estar contaminada con el virus después de un episodio de la enfermedad y lávela de inmediato (use jabón y agua caliente).
- Tire el vómito o heces por el inodoro y descárguelo. Asegúrese de que el área circundante se mantenga limpia.

Las personas que estén infectadas con el norovirus no deben preparar alimentos mientras tengan los síntomas y hasta 3 días después de recuperarse de la enfermedad (consúltese la hoja informativa sobre la preparación de alimentos). Los alimentos que hayan sido contaminados por una persona enferma deben ser desechados de la manera adecuada.

For more information, visit www.bt.cdc.gov,
or call CDC at 800-CDC-INFO (English and Spanish) or 888-232-6348 (TTY).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
SAFER • HEALTHIER • PEOPLE™

T.B.

Tuberculosis

Tuberculosis is of special concern within correctional institutions because of the potential for epidemic outbreaks in confined populations and the high risk such infection poses to HIV infected and otherwise immune compromised inmate-patients.

TB Codes

All inmate-patients within the CTC are assigned a 2 digit "TB code" based upon their history results of their TB skin testing, whether they are on TB medication, and whether they can infect others. This code is primarily used by custody to determine constraints on transporting an inmate-patient outside of the institution. Inmate-patient TB code assignments are updated annually as part of the annual TB surveillance and skin testing process[†].

The most critical code assignment is 31: Suspected or Confirmed Active Disease, Infectious. Inmate-patients assigned TB code 31 may be able to transmit TB to others.

Other commonly used codes you should be familiar with include:
Code 22: TST negative
Code 32: Prior infection, treated
Code 33: LTBI on Rx
Code 43: Active TB on Rx

Any time active TB is diagnosed or suspected, the inmate-patient is assigned code 31, placed in isolation and usually started on four drug therapy per protocol. If active disease is confirmed, the TB code assignment remains code 31 while the inmate-patient is on Rx, until he is not infectious, at which time he is assigned code 43 for the duration of therapy. When therapy is complete, TB code 32 is assigned.

The TB guidelines have the following components:

- Surveillance
  - Annual
  - On transfer
- Latent TB Infection (LTBI) management
- Active TB management
  - Individual isolation and treatment
  - Contact investigation and management

Each of these areas is addressed briefly below. Details can be found in the TB treatment guideline policy.

Surveillance

All inmates are evaluated for TB annually, as described above, and whenever transferred to or arriving at an institution, regardless of whether they arrive from a jail, court or another CDCR prison, unless the outside stay is less than 72 hours. Surveillance involves:

[†]This is not to be confused with the commonly used 5 class TB classification system adopted by the American Thoracic Society and American Lung Association in 1990: Diagnostic Standards and Classification of Tuberculosis Amer Rev Resp Dis 142. 1990 725-735

- A medical evaluation for TB signs and symptoms
- TST testing for inmates who are not known to be TST positive (inmates who can document a negative TST within the past 30 days do not need to be retested).
- For inmate-patients known to be positive, a baseline CXR must be in the record. The x-ray is repeated during annual TB testing, and if the patient is returning from another location after more than a six month absence. For inmate-patients returning after a shorter absence, the CXR is at the discretion of the PCP.
- A CXR for inmate-patients known to be HIV infected, regardless of TST results.
- Transfers in from outside of CDCR must have a repeat TB evaluation after 10-12 weeks, including repeat TST testing if not known to be positive. Repeat evaluation is not required for intra-system transfers from other CDCR institutions.

Latent TB Infection

Diagnosis: A diagnosis of LTBI is made when a person has a positive TST and no clinical, bacteriological or radiographic evidence of active TB. Isolated calcified granulomas and apical pleural thickening are suggestive of LTBI but are not considered radiographic evidence of active TB.

Eligibility for LTBI Rx:

- An inmate-patient should be treated for LTBI if he or she has not previously completed a course of treatment for LTBI or TB disease.
- Previously treated individuals may require another course of therapy if exposed to a highly
  infectious TB case where extensive transmission has been documented, where circumstances
  suggest a high likelihood of transmission, or where the exposed inmate-patient is immmuno-supressed (eg HIV/AIDS patients).
- Active TB disease must always be ruled out before starting treatment for LTBI

Treatment

The standard therapy used within the CDCR is INH 900 milligrams with 25 mg of vitamin B6, given twice weekly over nine months for a total of 76 doses. Inmate-patients with HIV infection are treated with the same regimen. TB medications are always DOT or NAT.

Monitoring

- A RN monitors inmate-patients on INH every month for clinical signs and symptoms of adverse drug reactions. If baseline labs are normal, no ongoing laboratory monitoring is required. Monthly LFT's should be obtained for inmate-patients with:
- Pior adverse reaction to INH.
- Excessive alcohol use
- Hepatic disease.
- Concurrent Dilantin or Valproic Acid therapy.
- Pregnant or in the three month postpartum period.
- Over 35 years of age.

HCV inmate-patients at risk should have liver enzymes checked every other month.

Active or Suspect TB Disease

Initial Management:

- Place the inmate-patient-patient into respiratory isolation.
- Begin therapy with four anti-tubercular medications plus Vitamin B6. Do not postpone medications while sputum is being collected.
- Collect three sputum specimens, on consecutive days, for acid-fast bacilli (AFB) smear and culture.
- Report the suspect case within one working day to the headquarters Public Health Office and to the Local County Health Officer.
- The inmate-patient should not be released from respiratory isolation until all of the following
  conditions are fulfilled:
    - A minimum of two weeks of therapy with, typically, four anti-TB medications (INH, RIF, EMB, and PZA) has been completed;
    - The inmate-patient is improving clinically;
    - Three consecutive sputum smears are negative for AFB.
- For suspect cases, if
    - Sputum is negative on smear and culture;
    - Clinical and radiographic follow-up do not support the diagnosis of "clinical TB"

It may be appropriate to remove the designation "TB suspect", discontinue TB medications and release the inmate-patient to General Population.

Treatment

Treatment takes place in two phases and can take from 6 to 24 months to complete.

- Phase I
    - Eight weeks of 4 drug treatment (INH, Rifampin, Pyrazinamide, Ethambutal), if the eight week sputum is negative
    - If the eight week sputum is positive, but the organism is sensitive to all first line drugs, phase I continues until the sputum converts to negative.
- Phase II
    - 18 weeks of INH and Rifampin (total duration of therapy, six months) if:
        - Organism is sensitive to all firstline medications.
        - Eight week sputum culture is negative
        - Initial CXR does not show cavitation
    - 31 weeks of INH and Rifampin (total duration of therapy at least nine months) if either one of the following conditions is present:
        - The eight week sputum is positive
        - Cavitation is initially present
    - Drug resistant TB should be co-managed with an Infectious Disease consultant.

TB medications are always DOT or NAT.

Monitoring

- An RN monitors the inmate-patient monthly for toxicity, with LFT's if indicated as with LTBI therapy.
- Visual acuity and red/green color vision testing should be checked at baseline and monthly while inmate-patient is on Ethambutal.
- Chest x-rays are not usually needed if the inmate-patient is responding clinically and bacteriologically. However, if the initial sputum culture is negative and inmate-patient's diagnosis is based on clinical and radiographic findings only, the CXR should be rechecked in two months.

Prophylaxis

During a contact investigation in connection with a case of active TB disease, all close contacts are clinically evaluated for TB symptoms; e.g. cough, fatigue, chills, night sweats or weight loss. If TB disease is suspected, the inmate-patient should be isolated and managed as "TB suspect".

A TST is administered to all close contacts except those who have a documented past positive TST.

Prophylactic therapy (twice weekly INH 900mg/B6 25mg) should be given for 12 weeks to:

- HIV-infected close contacts with normal CXRs and no TB signs or symptoms.
- Any close contact who is immunocompromised or whose circumstances suggest a high probability of infection regardless of TST results or previous preventive therapy.
- Therapy can be discontinued if the 12 week follow-up is negative.

TB ALERT CODES

CODE	TB STATUS	TRANSPORTATION
Code 00 **(Blank)**	**TST Status Unknown:** Arriving with no documentation even if stating TST positive. Can wait 24 hours to access previous TST. Also used for annual testing or contact investigation. Change within 72 hours.	Do Not Transport
Code 11	**TST Test Performed/ Status Unknown** **Not on TB Medication** Received TST; not interpreted yet. **If symptomatic for TB disease, inmates shall be labeled "Code 31" and placed into respiratory isolation as TB suspects.** Change within 72 hours.	Limit Transport May Need Respiratory Precautions
Code 21	**PPD Test Result Significant (Positive)** **Inmate Under Diagnosis** **Not on TB Medication** Until all diagnostic procedures are complete, not to exceed two months. **If symptomatic for TB disease, inmates shall be labeled "Code 31" and placed into respiratory isolation as TB suspects.** Can also use "**Code 21**" for contact investigations, until thorough evaluation, including CXRs, are done	Limit Transport May Need Respiratory Precautions
Code 22	**TST Test Result Insignificant (Negative)** Not on TB Medication	Use Regular Transportation
Code 23 ***New; identifies TB contacts***	**TST Result not Significant (Negative)** **Not Infectious; on TB Medications** May need repeat TST when meds are complete (usually two months)	Use Regular Transportation
Code 31	**Suspected or Confirmed Active TB Disease** **Possibly Infectious** May or May Not be on TB Medications	Use Special Transportation & Respiratory Precautions
Code 32	**TST Test Result Significant (Positive) Prior Infection** **Currently Not Infectious** **NOT on TB Medications**	Use Regular Transportation
Code 33	**TB Infection Or Exposure to TB Infection** **Not Infectious** **On TB Medications**	Use Regular Transportation
Code 34	**TB Infected, Not Infectious** **TB Medications Prescribed** Refused or contraindicated.	Use Regular Transportation
Code 43	**TB Disease, Not Infectious** **On Multiple TB Medications** Remains "**Code 43**" *throughout the treatment period* for TB disease. Upon completion of treatment, change to "**Code 32.**"	Use Regular Transportation
Code 51	**MDR-TB Infection, Active Disease, Infectious** **On TB Medications** When non-infectious becomes "**Code 53**" for the remainder of the treatment period.	Use Special Transportation & Respiratory Precautions
Code 52	**MDR-TB, Prior History, Treated, Not Infectious** **Not on TB Medications**	Use Regular Transportation
Code 53	**MDR-TB, Active Disease, Not Infectious** **On Medication**	Use Regular Transportation

State of California | Department of Corrections and Rehabilitation

Memorandum

Date : November 30, 2005

To : Health Care Regional Administrators
Regional Medical Directors
Health Care Managers

DCHCS Memo Number:

Reason For Transmittal

[ ] State Law Change
[ ] Policy Change
[ ] Court Order or Settlement Agreement
[ ] Clarification Request
[X] Other: *Policy, Procedures, and Protocols*

Supersedes:

Subject: **TUBERCULOSIS PREVENTION, TREATMENT, MANAGEMENT, AND CONTROL PROGRAM: POLICY, PROCEDURES, AND PROTOCOLS**

Attached please find two sets of the California Department of Corrections and Rehabilitation (CDCR), Division of Correctional Health Care Services (DCHCS), July 2005, final draft of the *Tuberculosis (TB) Prevention, Treatment, Management, and Control Program: Policy, Procedures, and Protocols* as well as the program's 28 attachments. Please ensure that one set is forwarded to the prison law library. A CD containing electronic pdf files of the program and the individual attachments is also provided. Additionally, a pdf file of the program, including all the attachments is available on the CDCR **intranet** at the following location:

http://intranet/HCD/Clinical-Support-Services/commdisease.asp.

On June 30, 2005, a videoconference training session introduced an earlier draft of the *TB Prevention, Treatment, Management, and Control Program: Policy, Procedures, and Protocols* statewide to clinical staff. A videotape of the training session will be sent under separate cover, when available.

Feedback from the June 2005 videoconference resulted in a few minor modifications to the *TB Prevention, Treatment, Management, and Control Program: Policy, Procedures, and Protocols.* Primarily these are:

- A change in the length of therapy, found in Part II, Section A, in the paragraphs titled *Duration of Primary Preventive Therapy.*
- Changes in the delivery of TB medications, which are now to be administered by Directly Observed Therapy (DOT) for active TB and suspect TB and by Nurse Administered Therapy (NAT) for Latent Tuberculosis Infection (LTBI) and contact treatment. However, inmate-patients being treated for Human Immunodeficiency Virus (HIV) will have TB medications *always* administered by DOT, and whenever a prescriber fails to specify or the pharmacy fails to identify DOT or NAT for TB medications, the medications will be administered by DOT. These changes are reflected throughout the policy and in Attachment 12, *TB Medication Administration.*

The Power Point slide presentation used in the videoconference is also included on the attached CD, with appropriate revisions.

Should you have any clinical questions concerning this program please contact David Hellerstein, M.D., at (916) 323-4614 or me at (916) 323-6811.

ORIGINAL SIGNED BY:

RENEE KANAN, M.D.
Director (A)
Division of Correctional Health Care Services

Attachments

cc: Yulanda Mynhier, Deputy Director (A), Health Care Administrative Operations Branch, DCHCS
David Hellerstein, M.D., Ph.D., Chief Medical Officer (A), Medical and Public Health Program, DCHCS
Robert Chapnick, M.D., Chief Medical Officer, Quality Management Assistance Team, DCHCS
Lucinda McGill, Nurse Consultant III, Quality Management Assistance Team, DCHCS
Tim Rougeux, Project Director, Medical Programs Implementation, DCHCS
Christine Martin, Chief, Program Planning, Policy and Support Section, DCHCS

TB PREVENTION, TREATMENT, MANAGEMENT, AND CONTROL

INTRODUCTION

The need for improved health care in correctional facilities has been advocated by position statements from the American College of Physicians, the National Commission on Correctional Health Care, and the American Correctional Health Services Association. In 1992, the California State legislature, recognizing that tuberculosis (TB) was a problem in correctional facilities; enacted *Penal Code* Section 7570 et seq., which mandates TB testing of inmates on an annual basis.

Tuberculosis continues to be a major public health concern in correctional institutions across the nation where the environment is often conducive to airborne transmission among inmates, staff, and visitors. Large numbers of inmates housed in congregate settings with inadequate ventilation and crowded conditions increase the inmates' risk for contracting and transmitting infectious diseases. Inmates who are foreign born, intravenous drug users, homeless, elderly, immunocompromised, or long-term care residents are at even higher risk for either acquiring TB infection or developing active disease. In addition, persons infected with the human immunodeficiency virus (HIV) have a ten times higher risk for TB infection progressing to disease than do individuals without HIV infection.

Correctional facilities vary in size, plant design, and mission but are governed by the same basic regulations, obligations, and responsibilities. Institutions have the responsibility to provide medical care consistent with community medical health care standards. The inmate population is linked to the community and reflects the incidence of TB and other communicable diseases occurring in society. Aggressive TB case management and prompt contact investigation reduce transmission within the institution, as well as to the communities from which inmates arrive and to which inmates are released.

The risk for acquiring TB infection and progressing to TB disease while incarcerated is magnified by factors such as infection with HIV, substance abuse, and being a member of a lower socioeconomic population with poor access to health care. Residents of correctional facilities are also at increased risk for TB infection because many of the facilities have poor ventilation and overcrowded conditions, which are conducive to the transmission of TB.

The burden of TB disease decreases as the institutional TB control program is refined and improved, and training and education of staff enhanced. Factors essential to this decrease include prompt identification of suspects and cases, prompt isolation, rapid diagnosis, and prompt initiation and completion of Nurse Administered Therapy.

I. POLICY

In response to the need for prevention and standardized control measures when managing communicable diseases, the California Department of Corrections and Rehabilitation (CDCR), Division of Correctional Health Care Services (DCHCS), has updated these guidelines for the assessment, screening, treatment, and containment of TB in the correctional setting. These guidelines are consistent with community standards and recommendations of the American Thoracic Society (ATS) and the Centers for Disease Control and Prevention (CDCP). Each institution shall update and maintain a local operating procedure in accordance with the CDCR TB Treatment, Management, and Control Program to ensure compliance with the Medical Programs Policies and Procedures.

II. PURPOSE

The CDCR TB Treatment, Management, and Control Program ensures a consistent, appropriate, effective, and efficient approach to the assessment, treatment, and containment of *Mycobacterium tuberculosis (Mt b)* resulting in a lower active TB case rate, decreased incidence of new infection, and decreased transmission among CDCR inmates.

III. PROCEDURES AND PROTOCOLS

The procedures and protocols of the TB Prevention, Management, and Control program are separated into the following sections. Each section begins as a separate part of this document for easier reference. A brief summary of each section follows.

Part I: Surveillance – procedures related to finding persons with active TB disease or Latent TB Infection (LTBI), detecting outbreaks or clusters of cases, evaluating effectiveness of control and preventive measures, and performing epidemiological studies. Surveillance also entails TB sign and/or symptom review, serial tuberculin skin testing, and reporting to determine the incidence and prevalence of TB infection and disease.

Part II: Tuberculosis Exposure; No Infection (Class 1), and Latent Tuberculosis Infection (LTBI)(Class 2) – procedures for determining eligibility for and treatment of exposure to TB disease and latent TB infection (based on the American Thoracic Society's TB classification system), therapeutic options, housing and paroling inmates on TB treatment(s).

Part III: Active Tuberculosis Disease (Class 3), and Tuberculosis Suspect (Class 5 – Diagnosis Pending) – procedures for defining, evaluating, providing housing, transporting, radiographic examinations, laboratory and drug susceptibility testing, and medical treatment and monitoring of inmates with these classifications of TB (based on the American Thoracic Society's TB classification system).

Part IV: *Managing the Non-Adherent Inmate* – procedures for managing inmates with TB disease or suspected TB disease who refuse to comply with testing and/or treatment.

Part V: *Contact Investigation* – procedures for conducting a contact investigation in order to control any suspected TB outbreak and minimize disease transmission.

Part VI: *Tuberculosis Control Mandates* – encompasses legal reporting requirements, planning, code requirements, and personal respiratory protection devices.

Part VII: *Information Systems Management* – provides a brief description of the various computerized information systems used to track the treatment of suspected and active TB disease patients.

Part VIII: *Inmate TB Alert System* – a description of the rapid method CDCR staff use to determine the most current TB *transportation* status of an inmate.

PART I: Surveillance

"***The tuberculin skin test*** (TST) remains the standard method for detection of *M. tb* infection. The dose of purified protein derivative (PPD) is 0.1 milliliter (ml), containing five tuberculin units as per the *Administration of the Mantoux Tuberculin Skin Test (Attachment 1)*. The ***standard*** of practice is to record TST results in ***millimeters (mm) of induration*** as per the *Reading/Interpretation of the Mantoux Tuberculin Skin Test (Attachment 2)* and not solely as "positive or negative." The TST is used to identify individuals infected with TB. It does *not* distinguish between recent or past exposure, infection with other mycobacterial specias, or prior receipt of BCG immunization; and it does *not* screen for active TB disease.

Definition of a Positive TST

- For *any* inmate in the CDCR, induration of **≥ 10 mm is considered a positive TST**
- For inmates in the following high risk groups, induration of **≥5 mm is considered a positive TST:**
  - HIV-positive inmates or inmates who refuse HIV testing
  - Inmates having recent contact with an individual with active TB
  - Inmates with changes on a chest x-ray (CXR) consistent with old TB
  - Inmate-patients with organ transplants
  - Inmate-patients otherwise immunosuppressed (receiving the equivalent of ≥15mg/day of prednisone for ≥ one month)

Note: For *anyone* (including CDCR staff, visitors, contractors) involved in a contact investigation, induration **≥5 mm is considered a positive TST**.

Tuberculin Skin Test Conversion

Tuberculin Skin Test (TST) conversion is defined as a change from a documented negative to a positive TST within a two-year period.

A. Inmate Testing and Evaluation

All inmates shall be tested and/or evaluated for TB[1] as follows:

1. Arrivals

Upon arrival to CDCR all inmates shall be tested and/or evaluated for TB. They shall be tested and/or evaluated again after 10 to 12 weeks, and again upon any inter-system transfer between CDCR facilities. The 10-to-12 week testing is *not* required for *intra*-system transfers.

Results will be recorded on CDCR Form 7331 *Tuberculin Testing Order/Report (Attachment 3)*. CDCR Form 128-C *Medical/Psychiatric/Dental Chrono (TB Chrono, Attachment 4)*, which records TB status and code, will be updated with

[1] "tested and/or evaluated for TB", for the purposes of this document, means: patients are immediately evaluated for signs and symptoms of TB. Patients whose prior documented TST's are negative, and patients who do not have documentation of prior TST results, shall have TST testing in accordance with the time requirements described in this section. Patients with documentation of prior positive TST results shall be managed without TST testing as described in this section.

each TST and evaluation performed, even if the inmate's TB status and code have not changed. The current TB Alert Code (TBAC) will be entered into the Distributed Data Processing System (DDPS) with the date of the test and/or evaluation. Inmates who have documentation of testing within the last 30 days should be evaluated for signs and/or symptoms of TB disease; they do not need to be tested on arrival. However, inmates who are not tested for this reason and whose arrival is not an intra-system transfer, should be re-evaluated and/or tested in 10-12 weeks. **The TB status and code, as recorded on CDCR Form 128-C *TB Chrono*, shall not be considered documentation of TST testing for purposes of surveillance and screening.**

All new arrivals receiving a TST and/or TB evaluation shall be offered counseling and testing for HIV.

Evaluation for signs and/or symptoms of TB must be done immediately. Placement and reading of TSTs must be completed within 72 hours (per DOM section 54055.7) of arrival for newly arriving inmates at Reception Centers or within ten days of arrival as inter-system transfers at Reception Centers and mainline facilities. Inmates with a documented history of a positive TST will be evaluated for signs and symptoms of TB and for completion of treatment for LTBI, and will receive a CXR unless their transfer papers include a documented CXR report dated within the past six months. Inmates with a history of a positive TST that cannot be documented are to be managed according to the policies and procedures for inmates who have never had a positive TST. Unless medically contraindicated, treatment for LTBI shall be considered if previous treatment was incomplete or inadequate. *(Attachment 5, Evaluation of Inmates with Positive TST.)*

2. **Inmates returning from "out to court" (OTC)**

   Inmates returning from OTC absences shall be tested and/or evaluated for TB immediately upon arrival back at the institution **if the OTC absence exceeded three days.** Evaluation for signs and/or symptoms of TB must be done immediately. Placement and reading of TSTs must be completed within 72 hours of arrival.

   If, as a result of the OTC absence, the inmate's **date of prison release is now within 30 days,** the TST is not repeated upon the inmate's arrival back at the institution.

   All inmates must have a repeat TB evaluation for TB signs and symptoms within 10 to 12 weeks after returning from an OTC absence. At that time, inmates with a prior negative TST need to be retested. All inmates who have signs or symptoms suspicious for TB disease, a newly positive TST, TST converters, or who are known to be HIV-infected or otherwise immunosuppressed shall receive CXRs, which are to be interpreted within 24 hours.

3. **Inmates with identified HIV infection**

   Inmates known to be HIV infected shall receive a CXR upon arrival at the institution unless their records received contain documentation of a CXR within the preceding 30 days, in which case a repeat CXR is not needed. A TST shall be placed, but there is a greater likelihood of a false negative reading because of the immunosuppression due to HIV infection. CXRs in those co-infected with HIV and TB disease can frequently be atypical. Therefore, any HIV infected patient with a CXR abnormality that cannot be documented as stable for 60 or more days by previous records in an asymptomatic individual, with the exception of an isolated calcified granuloma or apical pleural thickening, shall be isolated and evaluated by a physician as described in Part III, subparagraph A, *"Tuberculosis Disease Suspects: Class 5."* HIV infected patients with symptoms suggestive of TB shall be isolated and evaluated by a physician as described in the "TB Suspect" section, regardless of x-ray findings.

4. **Inmates with documented prior negative TSTs, and inmates without documentation of prior TSTs.**

   Inmates with documented prior negative TSTs and inmates without documentation of prior TSTs shall:

   - Have a TST administered unless there is documentation that one was administered within the last 30 days.
   - Have a medical evaluation for signs and symptoms of TB.
   - Have the appropriate TBAC entered into the DDPS.[2]
   - Have an updated chrono 128-C printed and filed in the UHR.
   - Have the TST repeated if the inmate's TST is now negative, but a previous chrono indicates he or she was TST positive. If the TST is still negative, the inmate shall have a CXR and be counseled to have HIV-testing.

5. **Inmates with documented prior positive TSTs**

   Inmates with documented prior positive TSTs shall:

   - Be evaluated for signs and symptoms of TB upon arrival and annually thereafter, either during annual inmate testing or during the inmate's birth month.
   - Have a baseline CXR in the medical record. The need for a repeat CXR shall be evaluated on an individual basis. A CXR shall be repeated if done more than six months prior to entry or re-entry into CDCR, and an updated chrono 128-C printed and filed in the UHR.

6. **Inmates Refusing Tuberculosis Examination**

   Penal Code (PC) 7570-7576 (Attachment 6) requires inmates to have a TST upon incarceration and at least annually thereafter. Inmates refusing to be tested shall

[2] The TB status and code, as recorded in DDPS or on the CDCR form 128-C *TB Chrono*, shall *not* be considered documentation of TST results for surveillance and screening purposes.

be educated by a licensed healthcare provider. Inmates who continue to refuse shall have their refusal documented on CDCR form 7225/7338, *Information for Consent/Refusal for TB Evaluation or Drug Treatment (Attachment 7)* and shall be tested involuntarily. Healthcare staff should coordinate and cooperate with custody staff to document procedures and processes necessary prior to involuntary testing. Adequate documentation is essential.

7. Enrouters (Short Stay Inmates)

Inmates arriving for an overnight stay while en route to another institution should have a TB symptom review and medical evaluation, but a new TST is not necessary. Until the status is verified and the inmate is determined to be non-infectious, proper medical precautions must be taken including respiratory isolation for inmates with signs or symptoms of TB. **If there is no TBAC** on the CDCR 135 *CDCR Transfer Record* (Bus List – *Attachment 8*), the inmate must be treated as TB status unknown. The receiving institution must review medical records and TB chronos and/or contact the transferring institution to document the inmate's current TB status. **The inmate must not be transferred out of the receiving institution, except for emergencies, until the inmate's TB status has been determined.**

8. Category "S" Inmates

Category "S" inmates are inmates transferred into state institutions for short stays from county/city jails for reasons such as riots, earthquake, etc. All category "S" inmates shall have a TB symptom review and medical evaluation upon arrival. The absence of TB signs and symptoms does not guarantee that the inmate is free of infectious TB. If signs and symptoms of TB disease are present, the inmate will be placed into respiratory isolation and evaluated for active TB disease. Prior to the inmate returning to his or her original place of confinement, medical information must be sent using the *Correctional Facility Tuberculosis Patient Plan (CFTP)(Attachment 9)*, to inform the previous facility of the need to isolate the inmate until active TB has been excluded. If the inmate is found to have active TB disease, a TB contact investigation shall ensue to determine if the disease was transmitted from or to close contacts of the inmate. A copy of the CFTP must also be sent to the DCHCS, Clinical Policy and Programs Branch (CPPB), Public Health Coordinator (PHC), Medical and Public Health Programs (M&PHP), at (916) 327-2465, or (916) 327-2476 (fax), and to the Local County Health Officer (LCHO). If the inmates are expected to stay for seven days or more, they will receive a TST (if none is documented within the prior 30 days), and a CXR if appropriate. Efforts shall be made to contact the transferring institution to procure the inmate's permanent, complete medical record.

9. Pregnant Inmates

- The TST has no adverse effects on pregnancy.
- No documented episodes of fetal harm have resulted from a TST.
- Pregnancy shall not exclude a female from receiving a TST.

- Pregnant women have a greater likelihood of a false-negative TST.
- All pregnant women shall be screened for signs and symptoms of TB disease, and the TST shall be repeated 6 to 12 weeks postpartum.
- A CXR shall be delayed if at all possible (if no TB signs or symptoms) until the second trimester, and proper precautions must be taken to shield the abdomen from the effects of radiation.
- The CXR should be repeated for consideration of treatment for LTBI after delivery. During pregnancy and the first six weeks post-partum the risk of progression to TB disease from TB infection is high.

B. Annual Inmate Tb Testing and Evaluation Program

The Annual Inmate TB Testing and Evaluation program must comply with *Penal Code (PC)* Sections 7570 to 7576, which *mandate* annual (and medically necessary) testing and evaluation of all inmates for TB. Annual inmate test results will be used to calculate TB prevalence rates for each institution, and overall for the CDCR. Annual testing usually occurs the last weekend in April.

Each institution is responsible for preparing the local procedures to test and evaluate inmates; determining staffing needs and schedules; ordering sufficient supplies, report forms and educational materials; and training new staff as required. Wherever possible, staff schedules should be adjusted to accommodate the needs of the institution while minimizing the use of overtime.

Inmate movement between and within institutions must stop at 0001 hours, on Saturday, until 0001 hours on Tuesday. The key test dates for the FY Annual Inmate TST and Evaluation Program are: on Saturday, administer the TSTs; and on Monday, read and interpret the TSTs.

On or about March 30th of each year the TB Alert Codes (TBACs) (*see page 41*) will automatically be changed in the DDPS as follows.

- Code 11 (TST Injected, Status Undetermined) will change to __ (blank);
- Code 22 (PPD Non-significant, Requires Annual Testing), will change to Code 02

Please note that:

- All inmates with a Code __ (blank) or 02 must receive a TST.
- Inmates with a Code 02 may be moved using regular transportation prior to, or after, the three-day annual testing period.
- Inmates tested after the DDPS code conversion, but before the annual testing weekend will **not** need to be retested during annual testing.

The code changes will continue in effect until each institution has completed the reporting process as certified by a signed *Annual Inmate TB Testing Program Record Conversion Verification form*. This form shall be transmitted to the PHC, CPPB, DCHCS by electronic facsimile (fax) at (916) 327-2476.

The DDPS identifies the most recent evaluation data entered for inmates within the CDCR. Whether the annual evaluation is done during the inmate's birth month or during the annual testing cycle, ***it must occur annually.*** The DDPS code must be updated by re-entering the TBACs "over" the current DDPS code, *even if the code is unchanged*, as this will automatically cause a date change within 24 hours, indicating a current evaluation. A new *TB Chrono* CDCR Form 128C *(Attachment 4)* showing the date of the most current evaluation must be issued.

It is important to obtain the Medical Advance Transfer Notice prior to testing. Prioritize those inmates currently up for endorsement. For those inmates scheduled to transfer in the five days following the inmate testing, it is critical to ensure that their updated TB Alert Code is entered into the DDPS so that there will be no delay in the endorsement process relating to the lack of the TB Alert chrono.

Inmate Orientation

Each institution must inform the inmates of the TST and Evaluation Program, including the purpose and the legal mandate. Each institution should have inmate education materials and information, including a video in English and Spanish, to reduce confusion and refusals. This should be shown over closed-circuit television at each institution.

Involuntary Inmate Testing

- *PC* Section 7572 authorizes the Chief Medical Officer (CMO) of a jurisdiction to inspect, examine, quarantine, or isolate all inmates for the suspicion of infectious TB.
- Inmates requiring involuntary TB testing and/or CXRs shall be educated regarding the risks and consequences of refusal using CDCR Form 7225/7338 *Information for Consent/Refusal of TB Evaluation or Drug Treatment*.
- The CMO and the Warden shall designate protocols to be used for timely involuntary testing and/or evaluation for those inmates who choose to be non-compliant with the Annual Inmate TB Testing and Evaluation program.

C. Evaluation of Persons with a Positive TST for Latent TB Infection and TB Disease - Symptom Review and Chest Radiography

All inmates-patients who have a positive TST should undergo symptom review and have a CXR for radiographic evidence of active TB disease. (Isolated calcified granulomas and apical pleural thickening are not considered radiographic evidence of active TB disease.)

- If the CXR has no radiographic evidence of active TB disease and the inmate is asympotomatic, treatment for LTBI may be indicated (see Part II, Paragraph B – *Eligibility for Treatment of Latent TB Infection (Class 2)*
- If the CXR is normal but the inmate has a clinical presentation consistent with tuberculosis, the inmate should be masked, isolated, and evaluated for active

disease. Treatment for LTBI should be delayed until active TB disease has been ruled out.

- If the CXR is abnormal (excluding isolated calcified granulomas and apical pleural thickening), in the setting of a TST conversion, bacteriologic studies should be obtained even when the radiographic abnormalities appear stable. Treatment for LTBI should not be initiated until final culture results are available.

D. Chronos

Section 54055.8 of the *Department Operations Manual* (DOM) states:

> Every time an inmate's TB Alert Code changes, Medical Care Services staff shall complete a CDCR Form 128-C or CDCR Form 128-C-1. This shall be done within 24 hours of reading the PDD skin test results and diagnosing the inmate's TB status.
>
> **If the TB Alert Code is 31**, the TB Alert Code shall be documented on the CDCR Form 128-C or CDCR Form 128-C-1 by the **end of the shift** in which the diagnosis was made.
>
> The TB Alert Code shall be identified on the CDCR Form 128-C or CDCR Form 128-C-1.
>
> Medical Care Services staff shall input the inmate's TB Alert Code into the DDPS file within **24 hours** of reading the PPD skin test results, diagnosis, or any change in the TB Alert Code.
>
> **If the TB Alert Code is 31**, the TB Alert Code shall be entered into the DDPS by the **end of the shift** in which the diagnosis was made.

The TB status and code, as recorded on the CDCR Form 128-C *TB Chrono*, are intended for custody and transportation use, and shall not be considered documentation of TST results for TB surveillance and screening purposes.

PART II: Tuberculosis Exposure; No Infection (Class 1), and Latent Tuberculosis Infection (LTBI) (Class 2)

The American Thoracic Society has developed a TB classification system based on the broad host-bacterial relationships as described by exposure history, infection, and disease. This is the standard classification system recognized by local community, state, and federal health departments, and health care providers throughout the world. *Classification of Tuberculosis (Attachment 10)* is a full description of the American Thoracic Society's TB classifications.

No Infection (Class 1) designates individuals with a history of exposure and a negative reaction to the TST. LTBI (Class 2) designates individuals with a positive reaction to the TST but no clinical, laboratory, and/or radiographic evidence of TB.

A. Eligibility for Treatment of Exposure to TB Disease (Class 1)

Exposure to TB disease occurs when an individual with active TB disease shares air space with a susceptible host. The level of the exposure is affected by other aspects of transmission such as infectiousness of the TB index case, susceptibility of the host, shared environment, ventilation in the shared environment, and duration of time spent in the shared environment. Any inmate identified as a "contact" to a suspected or confirmed case of TB disease shall be tested and/or evaluated within seven working days of such identification.

In close contacts to infectious cases, the initial tuberculin skin test may be negative despite underlying infection with *M. tb* if the TST is placed before the contact has mounted an immune response to the tuberculin antigen. It takes two - 12 weeks after infection with *M. tb* to develop a positive TST reaction.

If circumstances suggest a high probability of infection, for example if other contacts with a similar degree of exposure demonstrate a high infection or conversion rate, such high-risk close contacts should have a symptom review and CXR to exclude TB disease. Once TB disease is excluded, high-risk close contacts should be started on primary preventive therapy regardless of age or TST.

Primary preventative therapy should also be considered for those close contacts who are immunocompromised regardless of whether transmission has been documented. Examples of immunosuppression include:

- HIV infection
- Chronic corticosteroid or other immunosuppressive therapy
- Hematologic or reticulo-endothelial disease or malignancy
- End-stage renal disease
- Clinical conditions associated with weight loss or chronic malnutrition such as chronic malabsorption, , intestinal bypass surgery, etc.
- Injection drug use
- Substance abuse
- Silicosis
- Transplant

Primary Preventive Therapy

The standard therapy used within CDCR is 900 milligrams (mg) of Isoniazid (INH) plus 25 mg of vitamin B_6, given twice weekly. Alternative regimens include INH 300mg/B_6 25 mg administered daily, or at a minimum 5 days per week (Monday through Friday).

Duration of Primary Preventive Therapy

*Contacts with a positive **TST***

Primary Preventive Therapy generally should continue for nine months for close contacts whose initial TST is positive (≥ 5mm), as well as for contacts who are HIV infected, after active disease has been excluded with a CXR, medical evaluation, and symptom review, with the following exception.

In the event that the inmate-patient has had a previously documented positive TST, therapy can be stopped when and if all of the following conditions are met:

1. The contact has previously completed a course of treatment for LTBI
2. Prior TST testing has been documented in mm
3. The current TST is not 5mm or more larger than the most recent prior TST
4. The contact is retested after 10-12 weeks and the TST has not increased 5mm or more in size
5. The contact has been re-evaluated after 10-12 weeks, and has no signs or symptoms of active tb disease
6. The contact is HIV negative, and is not known to be otherwise immunosuppressed.

Contacts with a negative TST

For those close contacts with an initial TST < 5 mm who are started on therapy, a repeat tuberculin skin test should be performed 10 to 12 weeks after the last contact with the infectious case, to determine if the skin test has become positive. The decision to continue therapy should be made once the result of repeat skin testing is available. If the repeat TST is negative and exposure has ended, treatment should be stopped, unless the patient is infected with HIV. Consideration for continuing treatment should also be given to inmates at risk for *undiagnosed* HIV infection. If the TST result is positive, the inmate is considered a converter and should have a repeat CXR and a repeat medical evaluation and symptom review. If active disease is again excluded, continue INH for six more months for a total of nine months, consistent with treatment of LTBI (see section C, subparagraph *LTBI Therapy*). If the CXR or medical evaluation and symptom review is abnormal, INH should be stopped and the inmate evaluated as a TB suspect (see Part III: *Active Tuberculosis Disease (Class 3), and Tuberculosis Suspect (Class 5 – Diagnosis Pending)* Section A,).

Primary Preventive Treatment is given to contacts only after active TB disease has been excluded by clinical evaluation, symptom review, current CXR, and

bacteriologic studies when indicated. The treatment is intended to prevent infection in those exposed to the disease.

Note: In HIV infected contacts, treatment should be completed, regardless of the result of the repeat skin test.

Preventive medications do not confer life-long immunity to TB. An exposed person, even one who has previously taken a course of preventive TB medication, may develop new TB disease after exposure to an individual with active TB. A course of preventive therapy must be offered to *any* newly exposed close contact who is immunocompromised or in a setting where the risk of TB transmission is high, even if he or she has previously had a positive TST and completed treatment.

B. Eligibility for Treatment of Latent TB Infection (Class 2)

LTBI Diagnosis: A diagnosis of LTBI is made when a person has a positive TST and no clinical, bacteriological, or radiographic evidence of active TB. Isolated calcified granulomas and apical pleural thickening are suggestive of LTBI but are not considered radiographic evidence of active TB.

Eligibility for LTBI Treatment

An inmate shall be considered eligible for treatment of LTBI if he or she has a ***positive*** TST, he or she has not previously completed a course of treatment for LTBI or TB disease, and there is no radiographic evidence of active TB.

In some cases, previously treated individuals may require another course of therapy. Indications for re-treatment include persons with HIV/AIDS or other significant immunosuppression who have a new close contact to an infectious case. Providers may also choose to retreat persons previously treated for LTBI or active TB, if the exposure is to a highly infectious TB case where extensive transmission has been documented, or where circumstances suggest a high likelihood of transmission.

An inmate shall be considered eligible for treatment of LTBI if he or she has a previously documented positive TST, has not previously completed a course of treatment for LTBI, and has no radiographic evidence of active TB. Patients with HIV infection or who are otherwise immunosuppressed may fall into this category.

Before beginning treatment of LTBI, active TB disease must be excluded by obtaining the inmate's medical history and performing a physical examination, TB symptom review, CXR, and bacteriologic sputum studies when indicated. No person shall be started on any TB medications until these steps are completed.

For HIV infected inmates whose CD4 count is less than 100, who have a negative TST, who have no signs or symptoms of TB, and who have a normal or stable CXR for 60 days, optimum therapy is HAART to raise CD4 count to 100 or above. For those inmates who are unable to tolerate HAART, or whose CD4 count remains less than 100 despite HAART, after active TB disease has been excluded, serious consideration should be given to ongoing prophylactic INH therapy in environments where they are likely to be exposed to TB, or in which the TST

conversion rate is elevated. Periodic evaluation to exclude active TB should be undertaken in those HIV-positive inmates who are on prophylactic INH. In cases of exposure to INH-resistant isolates, this strategy will not be effective in preventing infection.

Pregnancy: LTBI therapy for pregnant inmates shall be delayed until six weeks after delivery unless the patient is:

- Infected with HIV and has AIDS with a CD4 count of < 100, or other immunocompromised condition.
- A recent TST converter.
- A close contact to a newly diagnosed case of pulmonary TB disease.

All pregnant inmates on TB therapy must have liver enzyme levels monitored at least monthly.

Age Considerations: Treatment of LTBI is no longer contraindicated for patients over the age of 35 years, but such cases should be carefully monitored.

Inmates must receive the appropriate fact sheet for anti-TB medications *(Attachments 11a, b, c, and d).*

C. Therapeutic Options

Multiple regimes are available for preventive TB treatment and for treatment of LTBI.

LTBI Therapy

The standard therapy used within the CDCR is 900 milligrams (mg) of Isoniazid (INH) plus 25 mg of vitamin B_6, given twice weekly over nine months for a total of 76 doses. Inmates with HIV infection are treated with the same regimen. Other regimens may be acceptable under special circumstances, such as medication intolerance or exposure to INH resistant organisms. Other regimens should be instituted in consultation with an infectious disease specialist.[3]

TB therapeutic options shall be Nurse Administered Therapy (NAT) for LTBI and contact treatment, *(Attachment 12,TB Medication Administration)* unless the inmate-patient is HIV co-infected, in which case TB medications shall be administered by Directly Observed Therapy (DOT). TB medications for active TB and TB suspect cases shall be administered DOT. The prescriber and the pharmacy shall make this distinction as follows:

If the prescriber writes DOT or NAT on the order for INH, PZA, EMB, or Rifampin:

- The pharmacy will write DOT or NAT on the sticky that goes on the MAR.
- The nurse will administer the medication accordingly.

If the prescriber does not specify DOT or NAT on the order for INH, PZA, EMB, or Rifampin:

[3] The combination of RIF and PZA is no longer recommended for treatment of LTBI in the prison setting for either HIV-negative or HIV-infected persons, because of reported severe and occasionally fatal hepatotoxicity.

- The pharmacy will write DOT on the sticky that goes on the MAR.
- The nurse will administer the medication accordingly.

If the pharmacy fails to write DOT or NAT on the sticky for INH, PZA, EMB, or Rifampin:

- The nurse will administer the medication DOT.

Interruption of Therapy

The goal for LTBI therapy within the CDCR is the completion of prescribed medication within a given period of time.

Completion of therapy is based on the *total number* of doses administered – not on the duration of therapy. If treatment is interrupted, resume treatment if a total of 76 biweekly doses can be completed within 12 months.

If treatment is interrupted and a total of 76 biweekly doses cannot be completed within 12 months of the original start of treatment date, extend treatment until a total of 76 biweekly doses have been administered within a 12 month period.

When therapy is restarted after an interruption of more than two months, perform a medical examination, symptom review, and, when indicated, a CXR and bacteriologic studies to exclude active disease. After an interruption of more than six months, a CXR is required.

Monitoring

Inmate-patients receiving INH shall have documentation of their clinical status, including adherence to prescribed regimen, and baseline laboratory values recorded in their UHR, with hepatic enzymes, bilirubin, serum creatinine, blood urea nitrogen, complete blood count, platelet count, and HCV serology (if not known). Relative contraindications to treatment for LTBI include liver transaminases that exceed three times the upper limit of normal if associated with symptoms, and five times the upper limit of normal if the inmate-patient is asymptomatic.

Monthly clinical monitoring shall include questions with regard to: energy level, nausea, vomiting, brown urine, anorexia, fever, and observation of skin for jaundice and eyes for scleral icterus, per *Tuberculosis Monthly Monitoring For Drug Toxicity (Attachment 13).* Patients with serologic evidence of HCV infection, or whose baseline liver function tests are abnormal, **shall have repeat liver function tests at the end of one, three, five, and seven months of INH therapy, including AST, ALT, and bilirubin.**

Special consideration and monthly laboratory testing of hepatic function is recommended for patients:

- With prior adverse reaction to INH.
- With known excessive alcohol use.
- With known hepatic disease.
- On concurrent Dilantin or Valproic Acid therapy.
- Who are pregnant or in the three month postpartum period.

- Who are over 35 years of age.

These patients require more frequent observation, laboratory monitoring, and modification of treatment to detect and manage hepatic toxicity.

1. Common Side Effects of INH Therapy

When utilizing INH therapy, the following common side effects should be considered:

- Peripheral neuropathy (numbness, tingling in the extremities). Giving 25 mg of pyridoxine (B_6) with each dose of INH may decrease or eliminate the risk for peripheral neuropathy.
- Inmate-patients with a history of seizures shall be followed for possible increased seizure activity, especially if maintained on Dilantin. Because of interaction with liver metabolism, previously stable Dilantin levels may decrease, so monitoring is required and adjustment may be necessary.

2. Hypersensitivity Reactions to INH Therapy

The following reactions may be observed in individuals hypersensitive to INH therapy:

- Itching.
- Rash or skin eruptions.
- Fever.
- Lymphadenopathy.
- Vasculitis.

If hypersensitivity reactions are mild and not life threatening, therapy with INH may be re-started in daily smaller doses in conjunction with diphenhydramine (Benadryl) or other appropriate symptomatic therapy, based upon medical judgment. If symptoms recur, INH therapy should be discontinued and expert consultation obtained in regard to alternative medications.

3. Hepatotoxic Side Effects of INH Therapy

If any of the following side effects are observed, the patient shall be promptly evaluated for INH hepatotoxicity and possible cessation of therapy:

- Anorexia.
- Nausea/Vomiting.
- Malaise/Fatigue.
- Fever of more than three days duration.
- Hematuria or brown urine.
- Jaundice.
- Abdominal tenderness (especially right upper quadrant).

Treatment for LTBI should ordinarily be discontinued if liver transaminases exceed three times the upper limit of normal if associated with symptoms and five times the upper limit of normal if the inmate is asymptomatic.

Inmate-patients should be counseled to avoid alcoholic beverages and any illicit substance while on anti-TB medications.

Inmate-patients with acute hepatocellular disease shall have treatment for LTBI withheld until their acute hepatic process has resolved. Inmate-patients with chronic liver disease and mildly (two to three times) elevated liver enzymes have been known to successfully complete therapy with INH. In both instances, close monitoring of liver function tests is indicated.

All inmate-patients off therapy but at risk for TB disease shall be followed closely with monthly symptom review and medical evaluation for the development of possible signs and symptoms of TB, especially if the therapy was initiated because of recent exposure to active TB or the TST converted to positive. If signs and/or symptoms of active TB are present, the inmate-patient should be isolated and further evaluated with a CXR and bacteriologic studies when indicated.

Close Contacts to INH-Resistant or Multidrug-Resistant TB

Multidrug-resistant (MDR) TB is defined as culture-confirmed TB with an isolate that shows in-vitro resistance to both isoniazid and another first-line TB medication. If laboratory studies confirm INH-resistant or MDR disease in the index case, primary care providers should seek expert consultation in managing inmate-patients in close contact with the index case.

As with TB that is not INH or MDR, if, after treatment for primary prophylaxis, the TST remains negative on retesting at 10 to 12 weeks and exposure has ended, medications may be discontinued if inmate-patient is immunocompetent.

If the TST result is positive, the inmate is considered a converter and should have a repeat CXR and a repeat medical evaluation and symptom review. If active disease is again excluded, expert consultation should be obtained to guide clinical management. If the CXR or medical evaluation and symptom review is abnormal, medications should be stopped and the inmate evaluated as a TB suspect (see Part III: *Active Tuberculosis Disease (Class 3), and Tuberculosis Suspect (Class 5 – Diagnosis Pending)* section A).

Housing Inmates on LTBI or TB Disease Treatment

Inmate-patients on preventive TB treatment or LTBI (Class 2) treatment are not infectious and may be housed in any facility supporting Nurse Administered Therapy, that is otherwise consistent with their program and security needs. These inmate-patients must be returned to a medical hub no less than monthly while on therapy to enable monitoring for medication side effects. Inmate-patients with TB disease (Class 3) who are receiving treatment and are not infectious shall be retained in facilities that are consistent with their medical needs and support DOT. They are *not* camp eligible until therapy is complete.

Paroling/Discharging Inmates on Preventive TB or LTBI Treatment

Arrangements shall be made to provide a four-week supply of INH/pyridoxine at the time of parole or discharge. The inmate shall be instructed to continue

INH/pyridoxine therapy and seek follow-up medical care in the community. The inmate should be educated about medication side effects and instructed to seek medical care immediately if any side effects are present. This education shall be documented. The local county health officer (LCHO) in the county where the inmate will reside shall be notified using the *Sample Memorandum, Continuation for Anti-Tuberculosis Therapy (Attachment 14)*

PART III: Active Tuberculosis Disease (Class 3), and Tuberculosis Suspect (Class 5 – Diagnosis Pending)

Class 3, *Active Tuberculosis Disease*, includes patients with culture confirmed *M. tb*, clinical TB disease based on medical judgment of signs and symptoms, and/or radiographic evidence of active disease. Class 5, *Tuberculosis Suspect*, includes patients suspected of having TB disease, whose diagnostic evaluation is incomplete. Persons shall not remain in this class for more than three months.

A. Tuberculosis Disease Suspects: Class 5

A suspect is defined as:

- A person who is considered a probable case or an epidemiologically linked case, or has supported lab findings under the most recent communicable disease surveillance case definitions established by the CDCP. "Epidemiologically linked case" is defined as a case in which the patient has shared air space with one or more persons who have the disease, and transmission of the agent by the usual modes of transmission (respiratory) is plausible.
- A person who has been diagnosed by a health care provider, after weighing signs and symptoms and/or laboratory findings, to *probably* have TB. "Laboratory findings" are defined as the results of a laboratory exam of any specimen derived from the human body that yields microscopic, microbiologic, or other evidence suggestive of TB. "Laboratory" also refers to the results of CXRs; e.g., patients, even without positive sputum smears or "typical symptoms," with CXRs suspicious of TB disease are also "suspect cases."
- Any patient who has sputum ordered for TB smear and culture, ***even if done with low suspicion as only a "rule out TB" is considered to be a TB suspect.***
- ***Any patient with a positive smear for a mycobacterial species.***
- Any HIV-infected inmate-patient whose housing, dayroom, work, or classroom area is in air contact with an area where an individual has been who is a diagnosed TB case is to be considered an "epidemiologically linked suspect." The index of suspicion for the HIV-infected must be at a higher level than for non-immunosuppressed persons, given their higher risk.

Any inmate defined above as "TB suspect" shall be immediately placed into respiratory isolation, considered a "TB suspect" and evaluated for TB Disease.

Medical Evaluation

Medical evaluation shall include prompt **identification** and **respiratory isolation** of the TB suspect. Suspects should be masked immediately, and remain masked until they are in the respiratory isolation room. Employees in the physical area around the suspect must wear an N95 respirator. Inmates with suspected TB shall receive: a TST, an evaluation for TB signs and symptoms (e.g., cough of two or more weeks duration, night sweats, fever, chills, weight loss, hemoptysis), an evaluation of past medical history, a physical examination, a CXR, and appropriate bacteriologic examinations

(at least three separate sputum collections, collected on three separate days, for AFB smear and culture). Suspects must be reported to the LCHO and the PHC, CPPB, DCHCS within one working day.

Availability of Respiratory Isolation Room

If a patient requires respiratory isolation and an approved respiratory isolation room is not available at the institution, healthcare staff will make immediate arrangements for transfer to another institution or contract community hospital where isolation is available. Arrangements for transfer to another CDCR available isolation bed can be made by the Health Care Placement Unit (HCPU), DCHCS at (916) 327-2207 (Northern Region), (916) 327-1072 (Central Region), or (916) 327-1164 (Southern Region). The HCM of the sending institution must notify the HCM at the receiving institution.

Transporting Suspects Requiring Respiratory Isolation

If a respiratory isolation room is not immediately available, arrangements ***must*** be made to ***transfer*** the inmate using ***proper respiratory protection***. Notify custody's transportation crew that the inmate may be infectious and respiratory precautions shall be taken. Place a surgical mask on the inmate and ensure that the mask is changed when it becomes moist. ***Staff shall wear an appropriately fit-tested N95 respirator when transporting a suspected or confirmed infectious inmate.*** Ensure this occurs when in close environmental conditions such as near open doors from, or inside of, respiratory isolation rooms, or when inside of enclosed vehicles transporting the suspected or confirmed TB case. The HCPU, DCHCS, (see contact numbers above) can further assist in this process by locating available neighboring isolation rooms, arranging for transportation, etc. Before transport, review *What Precautions Should Be Taken When Transporting a TB Patient (Attachment 15)*.

Radiographic Examination

The CXR shall be completed within 72 hours of either positive TST results or respiratory isolation for TB signs and symptoms, and shall include a Posterior/Anterior (PA) view. The CXR report(s) shall be forwarded to the institution's Public Health designee physician for review and recommendations, with a "wet reading" (immediate impression by the ordering physician) to enable immediate respiratory isolation if appropriate. Infectious TB shall be suspected when:

- An inmate-patient presents with any new infiltrates or cavitary lesion especially, but not necessarily limited to, the upper lobes.
- An inmate-patient presents with lymphadenopathy, a mass or a new nodule on CXR
- An inmate-patient presents with any abnormal process consistent with active TB disease (isolated calcified granulomas and apical pleural thickening are not considered radiographic evidence of active TB).
- An HIV-infected inmate or an inmate at high risk for HIV infection presents with any pulmonary infiltrate(s). Providers should keep a high index of

suspicion for TB disease in any HIV infected inmate, even those with a normal CXR.

- An inmate-patient identified as a close contact of a confirmed TB case presents with pulmonary infiltrate(s).
- An inmate-patient, regardless of CXR findings (clear or otherwise), is identified as having AFB organisms on sputum smear.
- An inmate-patient has symptoms of active TB, regardless of CXR, especially if HIV positive.

Any inmate-patient with infiltrates, cavitary lesions, or other findings consistent with active TB disease shall ***immediately*** be referred to medical staff for further evaluation, respiratory isolation, and treatment. Any inmate-patient suspected of having active TB disease shall wear a surgical mask when outside of the respiratory isolation room.

Laboratory Testing

Sputum collection on three consecutive days is necessary for AFB smear, culture, and sensitivity to detect the presence of *M. tb*. Collect the three sputum samples on consecutive days initially, and then monthly until two consecutive monthly sets of **three** sputum samples each are negative on culture for *M. tb*.

The DCHCS mandates that all sputum specimens for AFB (*M. tb*) smear, culture, and sensitivity be submitted to a local County Public Health Laboratory.

Drug Susceptibility Testing

Drug susceptibility testing identifies emerging drug resistance and monitors control efforts. Susceptibility testing for first-line *M. tb* drugs is required on at least the first isolate from *M. tb* positive sputum cultures. Additional isolate testing, to include second line *M. tb* drug susceptibility testing, shall be performed if cultures fail to convert to negative within three months of therapy or when the clinical and/or radiographic presentation does not improve or worsens with therapy.

Medical Treatment of Suspects

- Place the inmate-patient into respiratory isolation.
- Collect three sputum specimens, on consecutive days, for acid-fast bacilli (AFB) smear and culture, as per *Sputum Collection for Mycobacterium Tuberculosis Procedure (Attachment 16)*.
- Begin DOT with four anti-tubercular medications plus Vitamin B_6. **Do *not* postpone medications while sputum is being collected.**
- **Report the suspect case within *one* working day** to the PHC, CPPB, DCHCS and to the LCHO using the *Correctional Facility Tuberculosis Patient Plan (CFTP)* as the documented record.

- The suspect shall not be released from respiratory isolation until:
  - a minimum of two weeks of therapy with, typically, four anti-TB medications (INH, RIF, EMB, and PZA) has been completed; AND
  - symptom improvement is observed; AND
  - three consecutive sputum smears have proved negative for AFB

  NOTE: After meeting medical criteria, inmate-patients who remain on effective anti-TB therapy can be released without waiting for the culture reports.
- The majority of inmate-patients will be released from isolation in two weeks, with multi-drug DOT continued until TB disease is verified or ruled out.
- **If sputum cultures are positive for *M. tb*, or if it is determined on the basis of radiographic and clinical improvement under therapy that the inmate-patient is a "clinical case" of TB, the inmate-patient should be managed as specified in section B. *"Treatment of Tuberculosis Disease (Class 3)"* below.**
- If sputum samples are negative on smear and culture, and if it is also determined that the inmate-patient is not a "clinical case" of TB, it may be appropriate to discontinue medication. However, the decision to stop treatment must take into consideration that approximately one in four culture positive cases of pulmonary M tb is sputum smear negative.

B. Treatment of Tuberculosis Disease (Class 3)

The CMO shall require any inmate with suspected or confirmed TB disease to be placed immediately into a negative pressure respiratory isolation room and started on four drug anti-TB therapy until the inmate is no longer infectious. Authority for these actions is found in *PC Sections 7570-76,* and inmates cannot refuse this bed change.

For treatment of TB disease (Class 3) and suspect TB disease (Class 5), four drugs, generally INH, RIF, PZA, EMB plus Vitamin B_6, are used for eight weeks during the Initial Phase of therapy. If the TB isolate is sensitive to all first-line medications INH, RIF, and Vitamin B_6, are continued for the next 18 weeks during the Continuation Phase of therapy *(see paragraph #2 below).*

Treatment of TB can take from six to 24 months to complete. Completion of treatment is determined by the total number of doses taken by the inmate-patient rather than the duration of treatment.

For treatment to be effective the TB organisms must be sensitive to the anti-TB drugs used; the treatment must last long enough to be effective; and the inmate-patient must follow the prescribed regimen. DOT and case management increase the likelihood of treatment success.

Treatment for inmate-patients with confirmed active TB disease shall be managed in consultation with an infectious disease specialist..

1. **Initial Phase – Treatment Goals:**
   - Render the inmate-patient non-infectious.
   - Remove the public health hazard of transmitting *M. tb* to others.
   - Reverse the physical manifestations of TB such as weight loss, fever, and productive cough.
2. **Continuation Phase – Treatment Goals:**
   - Avoid treatment failure.
   - Prevent relapse.
   - Prevent the development of drug-resistant organisms.

Treatment Regimens

If initial sputum cultures are positive for *M. tb*, *initial phase treatment* consists of four drugs, INH/B_6, RIF, PZA, and EMB, given DOT for eight weeks. After eight weeks, if the isolate is found to be pan-sensitive, the eight week sputum smear and culture results and the presence or absence of cavitation on the initial CXR determine *continuation phase* therapy:

- **If the eight week sputum smear and culture are negative and the initial CXR does not show cavitation**, PZA and EMB are stopped; INH and RIF are continued for 18 additional weeks for a total of 26 weeks (six months) of treatment.
- **If the eight week sputum smear or culture is positive and cavitation is present on the initial CXR,** the minimum duration of therapy is nine months. The initial phase regimen continues until sputum converts to negative. PZA and EMB are then stopped; INH and RIF are continued for 31 additional weeks after sputum cultures become negative, for a total of at least 39 weeks (nine months) of treatment.
- **If either the eight week sputum smear is positive OR cavitation is present on the initial CXR (but not both),** in selected cases the continuation phase of INH and RIF may be shortened to 18 weeks for a total of 26 weeks (six months) of treatment. The decision to limit the continuation phase to 18 weeks should be made in consultation with an infectious disease specialist.

If sputum smear or culture remain positive after 12 weeks, send culture for repeat susceptibility testing and evaluate inmate-patient for treatment failure/acquired drug resistance.

- **If initial sputum cultures are negative for *M. tb***, depending on the clinical features, alternative diagnoses and other diagnostic testing, such as bronchoalveolar lavage and biopsy, should be considered before a presumptive diagnosis of culture negative TB is made. ***Initial phase treatment again consists of four drugs, INH/B_6, RIF, PZA, and EMB, given by DOT for eight weeks***. If, after eight weeks of four drug treatment, the CXR has improved and signs and symptoms have resolved, and if it is determined that the inmate-patient is a "clinical case" of TB, treatment should be

continued with three or two drugs, as specified below. Because of the high level of INH resistance in California, adults with smear- and culture negative TB should be treated for **18 additional weeks for a total of 26 weeks (six-months)** of treatment with a regimen of INH, RIF, PZA, and EMB. As an alternative, PZA may be stopped after initial phase treatment is complete so that the continuation phase consists of three drugs: INH, RIF, and EMB.

- **If the inmate-patient is HCV positive or has abnormal baseline liver enzymes, the patient should be managed in consultation with an infectious disease consultant, and monitored closely for evidence of hepatotoxicity**.

Drug Administration Alternatives

Any one of the following drug administration options is acceptable for treating TB disease. All treatment for TB disease must be DOT.

1. Phase I: Eight weeks of therapy consisting of the **daily** administration of four drugs, usually INH, RIF, EMB, PZA. All drugs shall be administered together in a single daily dose, not split over the day. All medications must be DOT.

   Phase II: 18 weeks of DOT consisting of the **daily** administration of two drugs*, INH and RIF, if the isolate is sensitive to these agents. (Total treatment period equals 26 weeks.)

2. Phase I: Eight weeks of therapy consisting of **daily administration for two weeks**, followed by **twice-weekly administration for six weeks**, of four drugs, usually INH, RIF, EMB, PZA. All medications DOT.

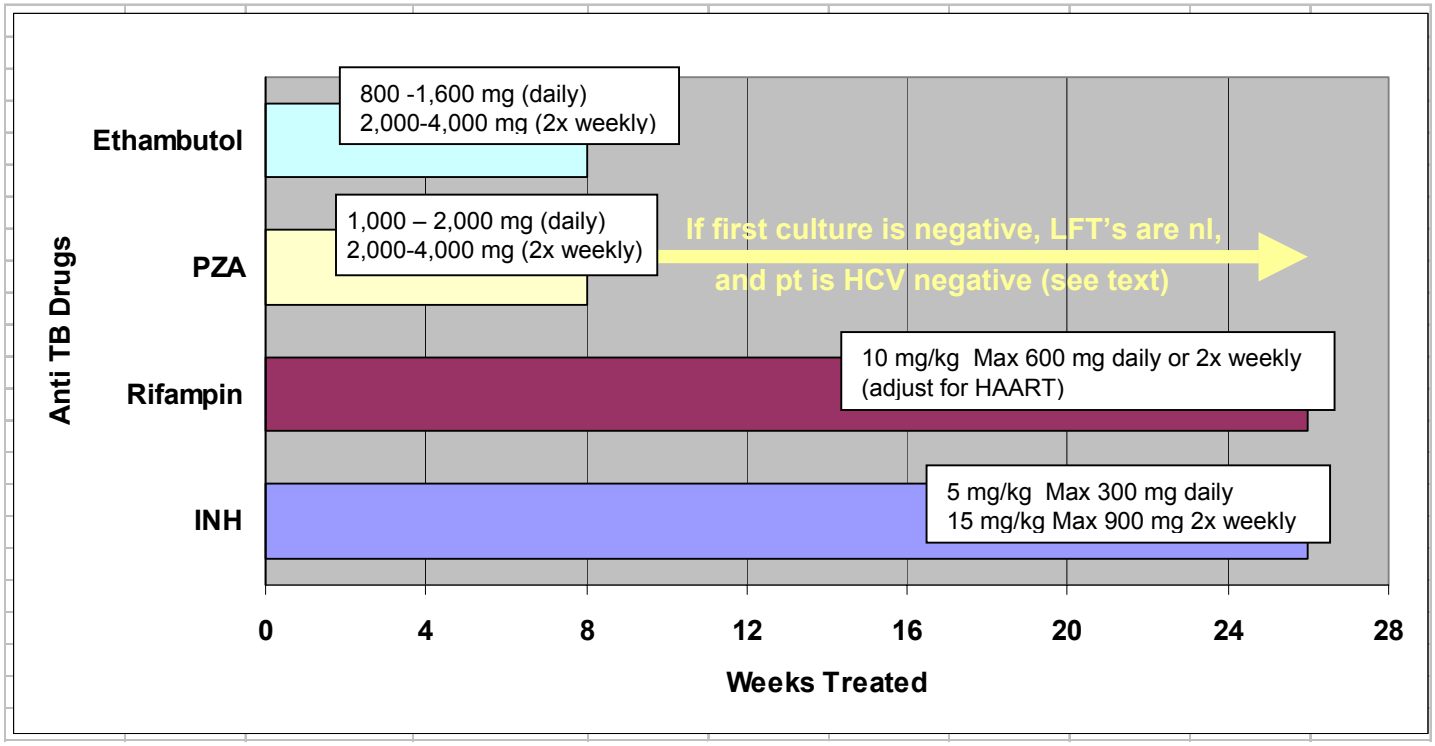
   Phase II: 18 weeks of DOT consisting of **twice weekly** administration with two drugs*, INH and RIF, if the isolate is sensitive to these agents. (Total treatment period equals 26 weeks.)

The CMO, CPPB, DCHCS recommends option number one. This is the preferred option unless medically contraindicated. Use of this option will promote consistency and standardized care, and alleviate unnecessary confusion regarding treatment regimens in the event an inmate-patient undergoing treatment transfers.

NOTE: Any regimen with EMB requires monthly visual acuity and red/green color vision testing. Other medication side effects, as described earlier, include: peripheral neuropathy (numbness, tingling in the extremities), hypersensitivity (itching, rash or skin eruptions, fever, lymphadenopathy). Toxic side effects to INH, RIF, and PZA therapy include anorexia, nausea/vomiting, malaise/fatigue, fever of more than three days duration, hematuria or brown urine, jaundice, abdominal tenderness, (especially right upper quadrant), AST (SGOT) or ALT (SGPT) greater than three times

* If patient is culture negative on initial evaluation, phase II therapy consists of three or four drugs, INH, RIF, and EMB. PZA should be included unless contraindicated.

baseline value, and AST (SGOT) or ALT (SGPT) greater than five times normal value.



Clinical Monitoring

- Clinical monitoring is to be done monthly.
- Liver enzymes are tested at baseline, and HCV antibody screening obtained on patients not known to be HCV positive. Patients with abnormal baseline LFT's, or who are HCV positive, will have liver enzyme testing at the end of the first month of treatment, bimonthly thereafter while on therapy, and at any time during the course of therapy if symptomatic. Repeat at least monthly if the inmate-patient is pregnant, in the immediate (three-month) postpartum period, at high risk for adverse reactions, or has symptoms of adverse reactions.
- An end-of-treatment CXR should be obtained to provide a new baseline for comparison with follow-up films. A CXR should be obtained during treatment if clinically indicated, and as required below if initial sputum is negative.
- Inmate-patients whose initial sputum smear and culture are negative must have a CXR at two months to assess response to treatment and guide the need for re-evaluation of the diagnosis.
- Sputum samples are sent monthly for smear and culture, until two consecutive sets of monthly cultures are negative for *M. tb*.

- Collect two sputum specimens for smear and culture at the completion of therapy for inmate-patients with a delay in response to therapy or at high risk of relapse (i.e., cavitary/extensive disease, lack of culture conversion for > two months, or advanced HIV disease.

  NOTE: *Sputum that remains smear or culture positive after three months of therapy suggests the possibility of acquired drug-resistance, failure of the inmate-patient to take medications, or inappropriate treatment regimen. The same medications shall not be continued until the susceptibility pattern is known, unless the inmate-patient is clinically improving.* ***Always*** *add at least three new drugs, never previously used for treatment, to a failing treatment regimen.* ***Never add a single drug to a failing regimen, as acquired resistance is likely to occur.*** *Expert consultation is recommended in this situation. (National TB Center 415-502-4700 or State of California MDR-TB laboratory service, 510-412-3700). For sputum that remains positive on smear and/or culture after three months, new laboratory susceptibility testing is needed, including susceptibility testing to second line drugs.*

ExtraPulmonary TB

Drug regimens used for the treatment of pulmonary TB disease are also effective for treating extrapulmonary TB disease although a longer course of treatment may be required. Consult with the LCHO and the PHC, CPPB, DCHCS, when treating an inmate-patient for extrapulmonary TB disease. Physicians may also consult the Francis J. Curry National TB Center Warmline at (415) 502-4700, or the State of California TB Control Branch at (510) 620-3000.

Multi-Drug Resistant TB Disease

Multi-Drug Resistant (MDR) TB disease is defined as culture-confirmed TB with an isolate that shows in-vitro resistance to isoniazid and one other first-line drug.

Acquired Drug Resistance is defined as resistance to one or more anti-TB drugs that develops while a patient is on therapy. This often results from non-compliance and/or only partially completing medications on the part of the patient, or inadequate therapy prescribed by the health care provider.

Preventable mistakes in the treatment of MDR include:

- Inadequate initial medication regimens.
- Improper modifications of initial medication regimens (e.g., adding a single drug to a failing regimen).
- Insufficient drug susceptibility testing.
- Inmate-patient non-compliance with therapy.

Treatment for MDRTB

Multi-Drug Resistant TB must be managed only in consultation with a physician who is an expert in the management of drug-resistant TB.

Medical management for MDR TB is complex. Health care providers treating contacts of MDR TB shall consult the PHC, CPPB; DCHCS, the LCHO; the Francis J. Curry Warmline (415-502-4700), or the State of California MDR-TB Laboratory Service (510-412-3700) for care and treatment recommendations. Contacts to MDR TB need to have preventive therapy adjusted based on the susceptibility results of the source case's isolate.

Current drug susceptibility results and a history of previous treatment with anti-TB drugs must be considered when tailoring drug treatment regimens for patients with MDR TB. Treatment for MDR TB shall include at least three to five drugs to which the organism shows in vitro sensitivity, must be administered for a prolonged period after culture conversion, and may require second-line anti-TB drugs that are often less effective and more toxic than the more commonly used first-line drugs.

NOTE: **The second line anti-Tb drugs listed in this table are to be used only in consultation with a physician who is an expert in the management of drug-resistant TB.**

Second-Line Anti-TB Drugs		
Drug Name	**Daily Dose**	**Adverse Reactions**
Ciprofloxacin Ofloxin	750 mg p.o. bid 400 mg p.o. bid	Abdominal cramps; gastrointestinal upset; tremors; insomnia; headache; photosensitivity
Clofazimine	100-300 mg p.o.	Orange/brown skin discoloration; gastrointestinal upset
Cycloserine	250-500 mg p.o.	Psychosis; seizures; headache; depression; rash
Ethionamide	750-1000 mg p.o.	Gastrointestinal upset; hepatotoxicity; hypothyroidism; metallic taste
Kanamycin	15 mg/kg IM	Auditory, vestibular, & renal toxicity; hypokalemia; hypomagnesemia; eosinophilia
Capreomycin	15 mg/kg IM	Auditory, vestibular, and renal toxicity; hypokalemia, hypomagnesemia; eosinophilia
Para-Amino Salicylic Acid	4 grams bid p.o.	Gastrointestinal upset; hepatotoxicity; sodium load
Streptomycin*	15 mg/kg IM Max. dose 1 Gm.	Hearing loss or vestibular dysfunction. Renal toxicity

*Streptomycin is often considered "first line" in eradicating disease. However, streptomycin is very toxic and shall be reserved for only difficult cases.

HIV/TB Co-Infection

Inmate-patients with active TB who are co-infected with HIV receive 39 weeks (nine months) treatment for TB disease. Experts in the treatment of TB in HIV-infected patients *must* be consulted when managing HIV/TB co-infected inmates.

Worldwide, TB is the leading opportunistic co-infection with HIV, causing death in 20% to 35% of all HIV-infected persons. Early diagnosis and effective treatment

of TB among HIV-infected inmates is critical for minimizing the negative effects of TB on the course of HIV infection, curing TB, and interrupting transmission of TB. Diagnosis of TB disease in HIV-infected inmates is difficult because CXRs may be normal and TSTs may be negative, due to the patient's inability to mount a sufficient immune response and because the patient's minimal symptoms are sometimes attributed to his or her HIV disease. For these reasons, **the most reliable method for confirming the presence of *M. tb* in the TB-exposed, HIV-infected person is sputum collection.**

NOTE: This does not mean sputum screening needs to be done on an asymptomatic, HIV-positive inmate-patient with a normal CXR. This protocol is only appropriate for HIV-infected inmates who are designated as close contacts in a TB investigation or who have signs and symptoms consistent with TB.

Early intervention in TB/HIV co-infected inmate-patients significantly decreases morbidity, mortality, and transmission of disease. Upon entry, every inmate shall be interviewed for HIV status and risk factors during the screening/evaluation process. ***All* inmates with unknown HIV status shall be counseled and advised to have HIV testing. Inmates found to have TB disease shall be counseled and advised to have HIV testing.**

C. Class 5 and Class 3 Pregnant Inmates

Pregnant inmate-patients with a positive TST reaction and one or more symptoms suggestive of TB need to be admitted to respiratory isolation and considered "TB suspects". The CXR must be taken with proper precautions to shield the abdomen from the effects of radiation. Anti-TB therapy for Class 3 or Class 5 TB disease should ***not*** be delayed during pregnancy, and expert consultation is required.

Pregnant inmate-patients with active TB disease shall be treated without delay. A pregnant woman with a positive TST, abnormal CXR findings consistent with TB, and a positive smear and/or culture shall be started on anti-TB therapy. The initial treatment regimen shall consist of INH, RIF, and EMB. All pregnant inmate-patients with TB disease are to be managed in consultation with an infectious disease specialist. The following precautions shall be noted:

- Expert consultation must be obtained.
- Streptomycin shall not be prescribed since it has been shown to cause congenital deafness.
- While PZA has not been approved for use in pregnancy in the United States due to inadequate data on teratogenicity, it has been used safely throughout the world and its use should be considered in consultation with an infectious disease specialist:
    - If PZA is *not* used, the minimum duration of therapy is nine months.
    - PZA is recommended for use by the CDCP in HIV-infected pregnant women.

    - PZA should be considered when there is suspected or known drug-resistant disease.
- The fluoroquinolones should be avoided, if possible, in pregnant women as they have been associated with arthropathies in young animals.
- Because of the unknown risk of second-line drugs to the fetus, pregnant women being treated for MDR-TB should be counseled accordingly, and expert consultation obtained.
- Breast-feeding is permissible since only small concentrations of anti-TB drugs are detectable in breast milk.

D. Discharging Class 3 and Class 5 Inmates from Isolation

The decision to discharge an inmate-patient with suspected or active TB from respiratory isolation may be difficult. The length of time required for an inmate-patient to become non-infectious after starting anti-TB therapy varies considerably. Failure to take a proper medication regimen for an adequate length of time is one of the most common reasons that an inmate-patient remains infectious. **Respiratory isolation should be continued until *all* of the following have occurred:**

- The inmate-patient has completed at least two weeks of effective four-drug anti-TB therapy.
- The inmate-patient is improving clinically.
- Sputum smears from three consecutive days are negative for AFB.

If an outside facility (hospital or jail) releases a patient who is a TB suspect (Class 5) back to CDCR after less than two weeks of respiratory isolation on four anti-TB medications, arrangements must be made prior to transfer to assure that CDCR's two-week protocol is followed. Coordination of the institutional CMO and outside facility staff, the HCPU, and the LCHO is necessary to maintain this standard. If assistance is needed, call the CMO, CPPB, DCHCS.

E. Class 5 and Class 3 Paroling or Discharging Inmates

When an inmate paroles, or is discharged, who is: (1) suspected to have TB disease; (2) known to have TB disease; or (3) known to have been a close contact to an inmate with suspected or confirmed TB disease, *Health and Safety Code* Sections 121350-460 *(Attachment 17)* mandate that written notification and a treatment plan be sent to the appropriate parties, as follows:

The inmate paroling or being discharged shall receive:

- *Notice of Requirement to Participate in Follow-Up Tuberculosis Treatment (Attachment 18)*. A copy shall also be filed in the UHR of the inmate who is paroling or being discharged.
- *Parole/Discharge Notification Letter (Attachment 19).*

The LCHO of the sending county shall receive:

- *CFTP.*

The LCHO of the receiving county shall receive:

- CFTP.
- Notice of Requirement to Participate in Follow-Up Tuberculosis Treatment.
- *Parole/Discharge Notification Letter.*

All of the above notifications shall be made as soon as possible ***before*** the inmate paroles or is discharged. If the transferred inmate or parolee will continue to require TB medications, an advance phone call is necessary for notification, or as soon as the sending provider is aware of the parole or discharge.

The following notifications should be made within one working day, and in all cases no less than two weeks ***after*** the inmate paroles or is discharged.

The Chief Psychiatrist of the appropriate Parole and Community Services Division (P&CSD) Regional Headquarters shall receive:

- *Notice of Requirement to Participate in Follow-Up Tuberculosis Treatment.*
- *Parole/Discharge Notification Letter.*
- *Sample Memorandum for Possible Exposure to Tuberculosis Disease (Attachment 20)* for close contacts to a TB disease case.

The inmate's Parole Agent shall receive:

- *Parole/Discharge Notification Letter.*

The PHC, CPPB, DCHCS shall receive copies of the:

- *CFTP.*
- *Notice of Requirement to Participate in Follow-Up Tuberculosis Treatment.*
- *Parole/Discharge Notification Letter.*
- *County Health Department Appointment Notification (Attachment 21).*

The LCHO of the receiving county shall receive:

- *Sample Memorandum for Possible Exposure to Tuberculosis Disease*

PART IV: Managing the Non-Adherent Inmate

California PC Section 7572 authorizes the CMO to inspect, examine, quarantine, or isolate all inmates suspected to have infectious TB. Ensuring inmate adherence to TB drug therapy reduces the risk and spread of TB disease. It is expected that the following standardized procedures will be used to document the inmate's refusal of the mandatory TST, the evaluation for signs and/or symptoms of TB, or the recommended treatment for LTBI or TB disease.

- Inmates refusing mandatory TB testing shall be educated regarding the risks and consequences of refusal using CDCR Form 7225/7338, *Information for Consent/Refusal for TB Evaluation or Drug Treatment*. After completion of this form, the inmate shall be involuntarily tested for TB, including TSTs and CXRs if necessary.
- The CMO shall order any necessary involuntary testing/evaluation of inmates and shall notify custody staff, who shall assist with the involuntary testing and evaluation.
- If the inmate refuses preventive therapy, he or she shall be educated regarding the risks and consequences of refusal and delay of treatment, and given a CDCR Form 7225/7338 *Information for Consent/Refusal for TB Evaluation or Drug Treatment* to sign. The inmate's stated reasons for refusal of the prescribed preventive therapy shall be entered on this form. If the inmate refuses to sign the form, the treating physician and a witness to the inmate's refusal shall sign to document the refusal. The witness may be a medical or custody staff member.

Inmates with the following characteristics who refuse preventive therapy or therapy for LTBI shall be regarded at high risk for developing TB disease, and consideration given for monthly evaluation by a health care professional, with appropriate documentation, for two years:

- Risk factors for suspecting HIV, proven HIV infection or other high-risk diseases.
- Recent TST conversion.
- Exposure to TB within the past two years.

If an inmate who has refused preventive therapy develops one or more TB symptoms shall be treated as TB suspect, placed into respiratory isolation, given a CXR, and three consecutive sputum samples for AFB smear and culture shall be obtained.

Note: Inmates shall not be disciplined for refusing anti-TB therapy.

All inmates refusing preventive anti-TB therapy or therapy for LTBI shall have a baseline CXR with follow up as determined by their attending physician.

- Monitoring of inmates who refuse preventive anti-TB therapy or therapy for LTBI shall be in effect for 24 continuous months, or until the inmate complies with the prescribed course of preventive therapy.
- If an inmate with known active TB (class 5) or TB suspect (class 3) is non-adherent with DOT, even if still within the facility,

the LCHO will be notified per *Health and Safety Code* Sections 121350-121460. The *CFTP* shall be sent within 30 days of release or as soon as possible.

Inmate-patients who refuse to take medications prescribed for TB disease or TB suspect will be placed into respiratory isolation and given daily counseling until TB disease has been ruled out, or until a physician determines that the inmate-patient is non-infectious.

- If a non-adherent inmate who has been a close contact to TB disease (active or suspected) is scheduled for parole or discharge within the 24 month monitoring period, the LCHO will be notified using the *Sample Memorandum for Possible Exposure to Tuberculosis for Inmates.*

PART V: Contact Investigation

The primary method to minimize TB disease transmission is to put the inmate-patient with suspected or active TB disease into respiratory isolation ***immediately*** and to conduct a prompt and thorough case contact investigation when an active TB case is identified.

The contact investigation is a means to identify contacts to an active TB case who may have been exposed to *M. tb.* A prompt initial interview with the TB suspect/case provides information to assist with establishing the period of infectiousness and to identify contacts. For further information, see the California Department of Health Services/California TB Controllers Association (CDHS/CTCA) Joint Guidelines, concerning interviewing contacts, available on the Internet at the following address. http://www.ctca.org/publications/guidelines/guidelines04/IID1contactinvestigation.pdf

Goals of a Contact Investigation

1. Identify the source or index case.
2. Diminish secondary transmission of disease.
3. Prevent TB infection from progressing to active disease in newly infected inmates.
4. Identify undiagnosed TB disease suspects and/or cases for respiratory isolation, evaluation, and treatment.

Because TB disease is most likely to be transmitted by individuals with unrecognized infectious pulmonary or laryngeal TB, it is important to have a TB control program in the workplace that includes surveillance, containment, assessment, treatment, and training.

A case contact investigation is a means of identifying a TB disease suspect or active source case and any other individual who may have been exposed. It also serves to help clarify if suspected TB is actually TB disease, as is probable if many close contact patients are found to have converted their TSTs from negative to positive.

For a contact investigation, a TST of ***5mm*** or greater is considered positive.

New TST conversions are especially indicative of recent TB transmission, possibly within the institution. Therefore, when an inmate's TST converts from negative to positive, a thorough history and an evaluation shall be immediately undertaken to determine if the reaction was simply a "boosted" reaction from previously acquired LTBI, or a recent, new exposure to an active TB case who now needs to be identified, evaluated, and treated.

Once exposed individuals are identified, they shall be evaluated and, depending on their signs, symptoms, CXR findings, and results of the TST and evaluation, either offered preventive medicine, treatment for LTBI, or immediately isolated and evaluated for suspected active TB disease.

Conducting a Contact Investigation

The HCM/CMO is legally responsible for ensuring that a complete contact investigation is done. Most of the following steps can be done concurrently with ***team*** effort. ***The team must work together. No one staff member can do this job alone. Health care staff and custody staff coordination within the institution is vital to this process. The local public health officer, and Division of Correctional Health Care Services staff may also participate.*** See Attachment 22, ***Division of Correctional Health Care Services*** *Contact Investigations*.

The team shall meet **within *one* working day** after the identification of the index case. The team shall consist of the CMO/HCM, Warden, Public Health and/or Infection Control Nurse, Health and Safety Officer (HSO) or Return to Work (RTW) Coordinator, Supervising Registered Nurse, Senior Medical Technical Assistant, California Correctional Peace Officers Association (CCPOA) representative, plant operations staff, and others as indicated. The CMO assigns responsibilities to the team, which include:

- Planning the investigation and assigning individual responsibilities.
- Discussing **lockdown of a building, a specific site, and/or the cessation of entire institutional movement until the investigation has been completed. The CMO, M&PHP, Clinical Policy and Programs Branch, in conjunction with HCPU and the Director, DCHCS, Division of Adult Operations can order cessation of institutional movement.**
- Initiating specific processes to assure that critical services are maintained, for example testing kitchen or other "essential" inmate-workers before the lock-down process.
- Assigning staff to ensure there are adequate medical supplies and forms on hand to give TSTs, to read and record TST results, to assess for TB signs and symptoms, to tabulate results, and to arrange that CXRs be given and read.

The investigation will begin immediately on detection of a confirmed active TB index case, and on identification of a TB suspect case with a high index of suspicion. Staff shall ***not wait for positive TB culture(s) to begin an investigation if there is a high index of suspicion. The use of gene probe and PCR technology is encouraged because it can provide a rapid confirmation of M. tb following the detection of a positive sputum smear.*** The team will continue to meet on a regular, preferably daily, basis to assess the status of the investigation until it has been completed.

NOTE: The California Correctional Peace Officers Association (CCPOA) shall also be notified within one working day, by formal memo, that a contact investigation has been initiated. The memo should be signed by the CMO/HCM, and routed through the chain of command with a copy to the Warden.

Establishing the Infectious Period

The period of infectivity is related to the time that tubercule bacilli have been expelled into the air. **ALWAYS** include the period when the inmate had a cough, even if it was attributed to another illness at the time of onset. Symptoms shall

include, but are not limited to: cough, hemoptysis, weight loss, fever, night sweats. Chart review and staff and index case interviews will be used to determine the date of symptom onset. To determine the infectious period, count ***eight to 12 weeks*** prior to the onset of symptoms or, if asymptomatic, prior to identification of the suspected or confirmed TB, e.g., by newly abnormal CXR, sputum smears for AFB, etc.

NOTE: The infectious period should be defined according to Appendix 4 of the CDHS/CTCA Contact Investigation Guidelines available on the internet at http://www.ctca.org/publications/guidelines/guidelines04/IID1contactinvestigation.pdf (The guidelines are in pdf format and all or part may be printed out if desired.)

Review the medical records for:

- The earliest date of clinical signs and symptoms for TB disease.
- History of TSTs to document date of conversion.
- CXR results and comparison with past CXRs.
- Disease site(s).
- Bacteriology, AFB smear and culture results.
- Previous treatment history.

Interview the index case to:

- Establish rapport and reassure him or her of confidentiality.
- Provide information and materials about TB, TB transmission, and preventative therapy.
- Confirm information that has been obtained from other sources and, if possible, rectify conflicting information.
- Obtain additional information about the index case's potential level of infectiousness or other needed clinical data (e.g., how long has the index case been symptomatic).
- Define a likely period of infectiousness.
- Determine settings in which the index case may have transmitted TB during the entire likely period of infectiousness.
- Identify potentially exposed contacts for the entire likely period of infectiousness.
- Obtain locating/demographic/risk factor information (home, work, school, social and recreational activities) for the identified contacts.

The end of the period of infectiousness is the date when the inmate is placed into respiratory isolation.

Establish Movement and Personal History

Determine the inmate's movement history during the infectious period:

- Use DDPS, Offender Based Information System (OBIS), and MedFile applications. The institution's Assistant Information Systems Analyst (AISA)

or the CDCR's Information Services Division (ISD) can assist with this tracking if necessary.

- If the inmate is a recent arrival from a county jail, other prison, or the community, it is important to identify and call the LCHO of the county and the jail health care staff. Alternatively, the LCHO of the host institution could be contacted and asked to notify the other LCHO. If the LCHO of the host institution does the follow up, CDCR staff is relieved of that responsibility.
- Determine the inmate's type of housing (i.e., single cell, double cell, open gym).
- Identify the inmate's visitors, close contacts at work or school assignments, recreational activities and the location of these activities (for example religious services, law library, attorney visits) and determine whether these contacts occurred in enclosed spaces or outdoors.
- Ascertain the frequency, duration, and nature of visits. Report names and addresses of visitors to the LCHO on CDCR Form 7328B*, Tuberculosis Contact Investigation Report - Visitor Contacts (Attachment 23A)* within two weeks of the exposure.

Identify staff members who worked in the inmate's housing, school, or work area during the infectious period. Report names of employees on CDCR form 7328A, *Tuberculosis Contact Investigation Report – Employee Contacts (Attachment 23B).* Notify exposed employees who shared the same air space with the index case. Include with the notification, the date and place for the employee to be evaluated. Notify the LCHO of employee contacts using *Sample Memorandum: Possible Exposure to Tuberculosis (Attachment 24).*

Management of Phase I

All inmates identified as close contacts shall be tested/evaluated within seven working days. The TST is to be given to all close contacts **except those who:**

- Have a documented past positive TST.
- Have documented past or current TB disease.
- Are currently on preventive treatment or treatment for LTBI.
- Are currently on treatment for active disease.
- Have had a TST within the preceding ten days.

Regardless of TST results, *all* close contacts shall be clinically evaluated for TB symptoms; e.g., cough, fatigue, chills, night sweats or weight loss.

Evaluation of Inmates in Phase I

- Conduct baseline TST/evaluation for signs and symptoms of TB. Inmates with positive TB symptoms shall be immediately masked and, as soon as possible, placed into respiratory isolation to be further evaluated for TB disease.
- Assess for HIV risk factors. Inmates infected with HIV have the highest risk for rapidly progressing to TB disease after minimal exposure and may become

overwhelmingly ill and die from this treatable illness. It is recommended that all inmates who are close contacts be offered testing for HIV.

- Order and complete CXRs within 24 hours for any contacts who have symptoms, known HIV infection, or immunocompromised conditions regardless of TST results; and for those inmates who are converters or those with newly positive TSTs.
- Order and complete CXRs within 72 working hours for all other close contacts to the suspected or active TB case, regardless of TST results or negative signs and symptoms.
- The ordering physician shall do a "wet read" (immediate reading) of CXRs within one working day after obtained.
- Order liver function tests on all inmates who are close contacts, unless the inmate has had a test within the last 30 days.
- Identify all HIV-infected contacts who have new CXR abnormalities as "TB suspects" (Class 5). Mask immediately, and place into respiratory isolation as soon as possible. Contacts shall remain in respiratory isolation for at least two weeks while undergoing further diagnosis testing, including sputum collection for AFB smear and culture on three consecutive days. HIV-infected contacts who have new CXR abnormalities shall be reported to the LCHO and to the PHC, Medical and Public Health Programs, Clinical Policy and Programs Branch, DCHCS, as "TB disease suspects" within 24 hours, and begin four-drug anti-TB treatment until culture results are returned.
- **Place all HIV-infected close contacts with normal CXRs and no TB signs or symptoms, on primary preventive therapy. This is extremely important in an outbreak situation.** If CXR is abnormal but stable over at least 60 days and TB signs/symptoms are absent, obtain infectious disease specialty consultation. If there is a new CXR abnormality or TB signs/symptoms are present, treat as a TB suspect.

Prophylactic Therapy in Contact Investigations

Any close contact who is immunocompromised or whose circumstances suggest a high probability of infection shall be started on preventive therapy regardless of negative signs and/or symptoms, TST results (including previous positive TSTs), or completion of previous preventive therapy.

The duration of preventive therapy will be based upon the twelve week follow-up TST and/or evaluation. Therapy can be discontinued if the twelve week follow-up is negative.

A minimum of 12 weeks of preventive therapy is recommended for patients with a previously positive TST who have completed preventive therapy in the past if they are immunocompromised or if circumstances suggest a high probability of infection. Specialty consultation should be sought to establish duration of treatment.

- Prior to beginning therapy, all contacts shall have a review for TB signs and symptoms and a CXR to exclude TB disease.
- New TST converters shall be evaluated for TB disease. If TB disease is ruled out, treatment for LTBI shall be initiated. HIV negative patients are treated for nine months.
- Close contacts who would otherwise receive preventive therapy, but refuse the medications, shall be evaluated for TB disease monthly for at least six months. The first two years after newly acquired TB infection is the highest risk period for progressing to active TB disease. Monthly clinical evaluation including TB symptom review with adequate documentation is appropriate for this period.
- **Patients on preventive therapy shall be monitored monthly for medication compliance, questioned for side effects and documented as per *Tuberculosis Monthly Monitoring for Drug Toxicity*. Liver enzymes will be tested at baseline, and HCV antibody screening obtained on patients not known to be HCV positive. Patients with abnormal baseline LFT's, or who are HCV positive, will have liver enzyme testing at the end of one, three, five, and seven months, and more often if clinically indicated. They shall also have reinforcing education at each encounter. Preventive treatment should be given by Nurse Administered Therapy and the nurse giving the medication should observe the patient's medical status at the time of each dose.**

Management of Phase II

Re-evaluate all close contacts 10 to 12 weeks after the initial exposure. If the TST is negative < 5mm for close contacts), and there are no contacts with signs or symptoms of TB disease, follow up by health care staff may be discontinued.

Anyone found to have a newly positive TST, or to have symptoms of TB disease shall be immediately referred for evaluation per the CDCR *TB Treatment, Management, and Control Guidelines*.

When there is a lack of evidence for further transmission of TB infection, after consultation with the CMO, CPPB, DCHCS, the team will terminate the contact investigation.

The *Contact Investigation Checklist (Attachment 25)* should be utilized by the public health staff to ensure all steps of the Contact Investigation have been properly completed.

Reports

The following information and forms must be completed, reviewed with the institutional CMO/HCM, and faxed to the indicated locations within the noted timeframes.

INFORMATION	***TIMEFRAME***	***SEND TO***
Correctional Facility Tuberculosis Patient Plan (CFTP)	Within one working day of identification of suspected active, or active TB disease.	LCHO, DCHCS, PHC, CPPB
Copies of all sputum or TB-inspected specimen laboratory reports, HIV reports (if any), and CXR reports from index case and/or TB suspect case	Within seven days of the exposure and within seven days for subsequent reports.	DCHCS, PHC, CPPB
Initial Summary Report of Case Contact Investigation (Attachment 26).	One month after initial exposure.	LCHO, DCHCS, PHC, CPPB Warden
All AFB or TB sputum or other specimen reports including results from microscopic smears and cultures	Monthly, until smear and culture negativity (conversion) is documented. The results of HIV-testing should be sent as soon as obtained.	DCHCS, PHC, CPPB
Final Summary Report of Case Contact Investigation. (Attachment 26)	No later than four months after the initial exposure.	LCHO DCHCS, PHC, CPPB Warden
CFTP	When there is a change in treatment, movement, completion of or change in medication.	LCHO DCHCS, PHC, CPPB

PART VI: Tuberculosis Control Mandates

Requirement

Reporting communicable diseases is a legal requirement and the responsibility of every health care provider. The *California Code of Regulations* Title 17, Section 2500 (*Appendix 27*), ***mandates* that every health care provider knowing of, or in attendance on, a CASE or SUSPECT of a disease/condition listed in *Section 2500,* is required to submit a report to the LCHO. For TB, the report is to be submitted within one working day to LCHO and CMO, CPPB, DCHCS.**

Correctional Facility Tuberculosis Patient Plan (CFTPP)

The *Correctional Facility Tuberculosis Patient Plan (CFTP)* is the form to be used for reporting all suspected (Class 5) and active (Class 3) cases of TB within the institution.

Health and Safety Code Sections 121350-121460

The *Health and Safety Code*, Sections 121350-121460 mandates that CDCR not discharge, transfer, parole, or release an inmate with suspected (Class 5) or confirmed (Class 3) TB disease **until the written treatment plan** (*CFTP)* has been received by the LCHO in the county where the inmate will be discharged, transferred, paroled, or released. When prior notification would jeopardize the person's health, the public safety, or the safety and security of the correctional facility, the notification and treatment plan shall be submitted within 24 hours of discharge, release, parole, or transfer.

All inmates arriving ***to*** the institution from the community, county jails, or other institutions, who have suspected active (Class 5) or confirmed active (Class 3) TB disease will have a CFTP sent to the receiving institution, to the LCHO/TB Controller and to the CMO, CPPB, DCHCS within ***one*** working day of identification.

Personal Respiratory Protection

Respirators provide a barrier, reducing health care worker exposure to *M. tb*. The protection afforded by the respirator depends on the efficiency of the filter material and proper fit to the face of the wearer. The California Occupational Safety and Health Act (Cal/OSHA) requires that all respirators used to control worker exposures be tested and certified by the National Institute for Occupational Safety and Health (NIOSH). Staff shall wear personal respiratory protective equipment (minimum N95 protection) under the following circumstances:

- When entering TB isolation rooms where patients with suspected or confirmed TB disease are housed, or wherever an occupied isolation room door is opened, and until contaminated air is exchanged with fresh air.
- During interaction with suspect TB patients who are not yet in isolation rooms. The inmate-patient shall wear a surgical mask. Staff shall wear a N95 respirator.
- While present during cough inducing or aerosol generating procedures performed on inmate-patients who have suspected TB disease, and until contaminated air is exchanged with fresh air.
- While transporting patients who have suspected or confirmed TB disease in enclosed vehicles, and until the vehicle air is exchanged with fresh air.

PART VII: Information Systems Management

The management of health information is an important component of the health care delivery system. Such information is used to furnish current clinical status on the patient's condition, diagnosis, and treatment. The exchange of health information allows health care providers to maintain continuity of care, determine incidence and prevalence of diseases, and conduct studies necessary for proactive planning. Efficient collaboration among public health agencies in the exchange of medical information aids in the prevention and control of communicable diseases.

Health information must be completed in the Unit Health Record (UHR) and in CDCR's computerized information system. The computerized system has several automated sub-systems, which are tools for information sharing, data collection, and report generating, including:

- Offender Based Information System (OBIS).
- Distributed Data Process System (DDPS).
- Medical Alert System (MAS).
- Chrono Data, MAS.
- Inmate TB Alert System.
- Pharmacy TB/HIV/HEP Treatment Data.
- Lab Data.
- MedFile (a Microsoft Access application that is a compilation of the above data to assist the health care staff in maintaining information on inmates with communicable diseases and mandatory reporting).

CDCR health information systems promote the exchange of information to enhance medical care for inmates and parolees in the correctional setting and the community. This exchange provides a means for tracking the treatment of suspected and active TB disease patients, as well as surveillance by data retrieval.

PART VIII: Inmate TB Alert System

Moving individuals who are at high risk for TB disease, as are inmates, without knowledge of their TB disease status creates the potential for TB disease transmission. The Inmate TB Alert System provides a rapid method for CDCR Medical, Classification, Case Records, and Transportation staff to determine the most current TB transportation status of an inmate. The TB Alert Code, a two-digit code, is entered into the DDPS to identify the inmate's needs for respiratory precautions during transportation. ***No*** inmate will be moved out of an institution by "regular CDCR transport" ***unless*** it is determined that the inmate's TB status allows movement without respiratory precautions. The TB Alert Code is ***for transportation purposes only.*** Any medical information must be obtained from the inmate's evaluation and/or UHR.

CODE	TB STATUS	TRANSPORTATION POLICY
CODE **(Blank)**	**TST Status Unknown**: Arriving with no documentation even if stating TST positive. Can wait 24 hours to access previous TST. Also used for annual testing or contact investigation. *Change within 72 hours*.	Do Not Transport
CODE 11	**TST Performed/ Status Unknown** **NOT ON TB MEDICATION** Received TST; not interpreted yet. If symptomatic for TB disease, inmates shall be labeled **"Code 31"** and placed into respiratory isolation as TB suspects. *Change within 72 hours*.	Limit Transport May Need Respiratory Precautions
CODE 21	**TST Result Significant (Positive)** **Inmate Under Diagnosis** **NOT ON TB MEDICATION** Until all diagnostic procedures are complete, not to exceed two months. If symptomatic for TB disease, inmate shall be labeled **"Code 31"** and placed into respiratory isolation as TB suspect. Can also use **"Code 21"** for contact investigations until thorough evaluation, including CXRs, is complete	Limit Transport May Need Respiratory Precautions
CODE 22	**TST Result Insignificant (Negative)** **NOT ON TB MEDICATION**	Use Regular Transportation
CODE 23	**TST Result Insignificant (Negative)** **Not Infectious; ON TB MEDICATIONS**	Use Regular Transportation
CODE 31	**Suspected or Confirmed Active TB Disease Possibly Infectious** **MAY OR MAY NOT BE ON TB MEDICATIONS**	Use Special Transportation & Respiratory Precautions
CODE 32	**TST Result Significant (Positive) Prior Infection** **Currently Not Infectious** **NOT ON TB MEDICATIONS**	Use Regular Transportation
CODE 33	**TB Infection Or Exposure to TB Infection** **Not Infectious** **ON TB MEDICATIONS**	Use Regular Transportation

CODE	TB STATUS	TRANSPORTATION POLICY
CODE 34	**TB Infected, Not Infectious** **TB MEDICATIONS PRESCRIBED** Refused or contraindicated.	Use Regular Transportation
CODE 35	**TST Result not Significant (Negative)** **Not Infectious** **ON TB MEDICATIONS**	Use Regular Transportation
CODE 43	**Diagnosis of TB, Not Infectious** **ON TB MEDICATIONS** Remains "**Code 43**" *throughout the treatment period* for TB disease. Upon completion of treatment, change to "**Code 32**."	Use Regular Transportation
CODE 51	**MDR-TB Infection, Active Disease, Infectious** **On TB Medications** When becomes non-infectious, change to "**Code 53**" for the remainder of the treatment period.	Use Special Transportation & Respiratory Precautions
CODE 52	**MDR-TB, Prior History, Treated, Not Infectious NOT ON TB MEDICATIONS**	Use Regular Transportation
CODE 53	**MDR-TB, Active Disease, Not Infectious ON TB MEDICATIONS**	Use Regular Transportation

Refer to the *Department Operations Manual* (DOM), Section 54055 for additional information concerning the TB Alert System.

Definitions

Acid-Fast Bacilli Bacteria that retain certain dyes even when washed with an acid solution. Mycobacterium tuberculosis, (*M. tb*) is the most common, belonging to a family of acid-fast bacilli called mycobacterium. When seen on a stained smear of sputum or other clinical specimen, a diagnosis of tuberculosis (TB) shall be considered but not confirmed until the diagnosis is supported by positive polymerase chain reaction (PCR) testing or confirmed by culture .

Anergy The inability to react to skin test antigens because of a suppressed immune system, caused by disease (e.g. HIV infection) or by medication.

Bactericidal Capable of killing bacteria. Isoniazid (INH) and rifampin (RIF) are the two most potent bactericidal anti-TB drugs. Pyrazinamide (PZA) is also commonly used as a bactericidal anti-TB drug.

Bacteriostatic Capable of preventing bacterial growth but not necessarily capable of killing bacteria. Drugs such as ethambutol and para-aminosalicylic acid are primarily bacteriostatic.

Bacillus Calmette-Guerin (BCG) A vaccine given to humans to prevent TB disease. It is used primarily in foreign countries with high TB prevalence. Although not routinely used in the United States because it has not been determined to be effective in adults, it is sometimes used with select persons who meet specific criteria. It may be effective in preventing TB meningitis in children.

Booster Reaction or Phenomenon (Two-Step Tuberculosis Skin Test, [TST]) One to three weeks after an initial negative tuberculin skin test, a second test is administered resulting in a positive reaction. This is a result of the immune system being "boosted" to remember the tubercle protein if there had been a remote previous TB infection.

Although the booster phenomenon may occur at any age, it is most frequently seen in persons over age 55 or in immunosuppressed persons.

California Office of Safety and Health Administration (Cal/OSHA) The California Division of Labor and Standards Enforcement that is the primary enforcer of State and Federal labor laws. Cal/OSHA has the ability to advise, inspect, audit and cite with financial and civil penalties for violations of the state and federal health and safety codes.

Cavity A hole in the lung resulting from destruction of pulmonary tissue. It may be caused by TB, but may also be caused by other pulmonary infections and conditions. TB patients with cavities in their lungs are said to have "cavitary disease" and are often more infectious than patients without lung cavities.

Clinical Case A case in the absence of laboratory confirmation in which the patient exhibits the signs and symptoms of TB disease, has a positive TST, an abnormal CXR compatible with current TB disease, is put on TB medication, and recovers without ever having a positive sputum.

Contact Person at risk for TB infection and subsequent disease because he or she has shared the same air space with a person with active pulmonary or laryngeal TB disease.

Contact Investigation The procedure for identifying persons potentially exposed to a newly diagnosed or suspect case of pulmonary or laryngeal TB, screening and evaluating those persons

for TB infection and disease, and referring them for proper treatment.

Culture Organisms grown on a media (substances containing nutrients) so that they can be identified: a positive culture for *M. tb* contains tubercle bacilli, whereas a negative culture contains no detectable tubercle bacilli.

Nurse Administered Therapy (NAT) A dose-by-dose administration process that does not require Directly Observed Therapy procedures. Appropriately licensed health care staff (RN, LVN, MTA, or LPT) administers and watches the patient swallow each dose of medication.

Directly Observed Therapy (DOT) An adherence enhancing strategy in which a health care worker or another designated person watches the patient swallow each dose of medication, and verifies that the medication has been swallowed by completing a visual mouth check and viewing the empty cup.

Distributed Data Processing System (DDPS) California Department of Corrections and Rehabilitation (CDCR) software used to track inmates and their locations *within* the California Correctional Institutions. Contrast with "OBIS"; used to track inmates *between* the institutions, in outside systems, and on parole.

Droplet Nuclei Microscopic particles (1 to 5 microns in diameter) produced when a person coughs, sneezes, speaks, shouts, or sings. In a person with infectious TB, the droplets can carry tubercle bacilli, circulate in the air through normal air currents, and remain suspended in the air for several hours, depending on the environment.

False Positive Tuberculin Skin Test Tuberculin skin test results that incorrectly identify TB infection when TB infection is actually not present. May be caused by prior BCG immunization, or infection with non-tubercular mycobacteria.

Index Case The first person who is identified as a confirmed or suspected case of pulmonary and/or laryngeal TB.

Infectious Period The period during which the person with suspected or known TB disease is most likely capable of transmitting the TB infection to others. This is considered to be eight to 12 weeks prior to the first symptom or identification of the person as a TB suspect or case, and ends when the person has negative sputum smear results and has been on anti-TB medication for two weeks. (See CDHS/CTCA Contact Investigation Guidelines, Appendix 4 at www.ctca.org for explanation of determining length of time.)

Latent Tuberculosis Infection (LTBI) A condition where the TB bacteria have infected a person without producing clinically active disease. Thus the bacteria are considered dormant or "latent." LTBI is not infectious and cannot be transmitted to others. The person with LTBI has no symptoms, but usually will have a positive tuberculin skin test.

MedFile A Microsoft Access based software program developed by the Public Health Section, Division of Correctional Health Care Services. It functions within a personal computer by accepting a disc containing an institution's DDPS data and a disc from the pharmacy's medications file. It enables the user to track and match inmate movement, TB alert codes, and medications; hepatitis and human immunodeficiency viral infections (HIV) codes; and other information as can be programmed in this system.

Multi-Drug Resistant TB Culture-confirmed TB disease with resistance to at lease isoniazid and one or more other first-line anti-TB drug(s). Treatment of MDR TB requires consultation with

(MDR) experts, prolonged therapy, close laboratory monitoring, and very strict directly observed therapy.

Mycobacterium Family of bacteria that primarily spread via respiratory secretions. Some members of this family cause severe lung or other body damage and can be fatal; some cause milder infections; and some cause no discernible damage. This family of bacteria retains certain dyes even when washed with acid (Acid Fast Bacteria or AFB), and can be seen under the microscope when sufficient numbers are present. However, other laboratory techniques are needed to determine which variety of mycobacterium (e.g., *M. tb, M bovis*, other varieties) is being stained.

Offender Based Information System (OBIS) CDCR software used to track the locations and basic demographics of inmates moving *between* the California Correctional Facilities, in outside systems, and in parole regions. Information dates back to before 1990. Contrast with "DDPS", which tracks inmates *within* CDCR institutions.

Prophylaxis Preventive treatment given to an individual after a recent exposure to TB disease. This is done even before TST conversion has occurred, and before the newly transmitted TB bacteria have established infection or disease in the body. Thus the immune system has not yet responded and the TST will still be negative. This treatment averts the TB infection.

Purified Protein Derivative (PPD) Purified tuberculin preparation used in the Mantoux skin test technique. It is made from proteins in the tuberculin bacteria, and contains no live bacteria. No one can develop TB or become systemically ill from the use of PPD, but local skin reactions can occur, and are occasionally severe.

Significant Exposure to Tuberculosis This is determined using professional judgment involving the infectiousness of the index case, length of exposure, proximity, environmental conditions, the susceptibility of the contact, and respiratory protective protection used, by both the index case and the contact. Each situation must be individually evaluated.

Suspect Case A person who is a known contact to an active TB case or who is identified by a health care provider as having signs and symptoms and/or radiological/bacteriologic findings consistent with active pulmonary or laryngeal TB.

Several, but not all, examples of a TB suspect would be:

- A person who has orders for any, (although the standard is to order a total of three [3]) sputum to be collected for AFB.
- A person with a respiratory specimen that is culture positive for *M. tb* complex and who has been started on anti-TB therapy.
- Radiologic findings consistent with active pulmonary or laryngeal TB even without a culture growing *M. tb*, unless other clinical evidence makes a TB diagnosis unlikely.
- A person with a respiratory specimen that is smear positive for AFB.
- A person started on anti-TB drugs, pending laboratory or radiological results.
- A person with symptoms of TB (including, but not limited to, cough, weight loss, night sweats, fever, fatigue).

Tuberculosis (TB) An infectious disease of man and animals caused by the species, *Mycobacterium tuberculosis* and characterized by the formation of tubercles and caseous necrosis in the tissues.

TB Alert Code (TBAC) A two-digit numbering system used only within CDCR (not in the community) to instruct transportation officers on the proper precautions to take while transporting inmates. The code is applied to all inmates, and provides some limited surveillance data. However it is not a substitute for proper inmate-patient evaluation and thorough chart review. It is also not intended for use on any medical information forms utilized when moving patients between facilities or between the CDCR and outside agencies such as hospitals, jails, or courts. The purpose of TB Alert Codes is to prevent movement of possibly infectious TB patients and to assure that there are no interruptions in TB treatment.

TB Disease (i.e., Active TB disease) A condition where *M. tb* are present in the body and the disease is clinically active, causing tissue or organ damage in the host. If the site of disease is the larynx or lungs, the disease can be transmitted to others in microscopic moist droplets shed by coughing, sneezing, singing, speaking, or even breathing. Persons with TB disease have symptoms and generally (not always) have a positive TB skin test. Because of slow growth, these bacteria require long periods of treatment with multiple antibiotics to eliminate them. If not consistently treated, these bacteria may mutate and can become resistant to medications.

TB Infection A condition where *M. tb* are present in the body without producing clinically active disease. The bacteria are dormant or contained in harmless "pockets" by the body's natural immune system. Persons with TB infection usually have a positive tuberculin skin test but no symptoms of TB disease or illness and are not infectious. However, TB infection can become active and result in TB disease.

Tuberculin Skin Test (TST) A method of evaluating the immune response to *M. tb* indicating the bacteria's presence in the body. This reflects TB infection from recent or distant exposure. The recommended skin test method is the Mantoux Tuberculin Skin Test (TST): 5 tuberculin units (TU) of purified protein derivative (PPD) an inactive protein from the TB bacteria, is injected into the dermis (second layer of skin). The test is "read" by measuring induration (swelling) not erythema (redness) at the injection site 48 to 72 hours (two to three days) after administration. (See Definition of a positive TST and Tuberculin Skin Test.) Although the TST is the recommended method for detecting TB infection, false positives and false negatives may occur.

REFERENCES

3. American Thoracic Society, Centers for Disease Control an Prevention, and Infectious Diseases Society of America. *Treatment of Tuberculosis,* MMWR 2003; 52 (RR-11).
4. American Thoracic Society, Centers for Disease Control and Prevention. *Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children*. Am. J. Resp Critical Med 1994; 149: 1359-1374.
5. American Thoracic Society/Centers for Disease Control and Prevention. *Diagnostic Standards and Classification of Tuberculosis*. Am Rev Resp Dis 1990; 142: 725-35.
6. Centers for Disease Control and Prevention. Notice to readers. Clinical update: Impact of HIV Protease Inhibitors on the Treatment of HIV-Infected tuberculosis patients with Rifampin. MMWR 1996; 45 (42); 921-25.
7. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. *Guidelines for Coordination of TB Prevention and Control by Local and State Health Departments and California Department of Corrections*. May. 1998.
8. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. *Tuberculosis Treatment and Control in California*. June, 2000.
9. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. *Guidelines for the Treatment of Active Tuberculosis Disease*. April. 2003.
10. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. *Contact Investigation Guidelines*. November 1998. (Available at www.ctca.org.)
11. Centers for Disease Control and Prevention. MMWR; Recommendations and Reports; October 28, 1994/Vol. 43/ No. RR-13
12. Centers for Disease Control and Prevention. TB Care Guide; Highlights from Core Curriculum on Tuberculosis.
13. U.S. Department of Health and Human Services, Public Health Service. Core Curriculum on Tuberculosis. *What the Clinician Should Know*. Fourth Edition, 2000.
14. Division of Occupational Safety and Health. Policy and Procedures Manual; Interim Tuberculosis Control; Enforcement Guidelines. Issue Date: 12/1/92; last revision: 3/1/97.
15. Centers for Disease Control and Prevention. MMWR Recommendations and Reports. *Essential Components of a Tuberculosis Prevention and Control Program; Screening for Tuberculosis Infection in High-Risk Populations*; September 8, 1995/ Vol. 44 / No. RR-11.
16. Centers for Disease Control and Prevention. MMWR Recommendations and Reports; *Prevention and Control of Tuberculosis in Correctional Facilities* June 7, 1996/ Vol. 45/ No. RR-8
17. Federal Register 10-17-97 Vol. 62 No 201 Department of Health and Human Services. Centers for Disease Control and Prevention. 42 CFR Part 84. National Institute for Occupational Safety and Health; Certification of Respiratory Devices Used to Protect Workers in Hazardous Environments.
18. Federal Register 10-17-97 Vol. 62 No. 201. Department of Labor. Occupational Safety and Health Administration. 29 CFR Part 1910. Docket No. H-371; RIN 1218-AB46. Occupational Exposure to Tuberculosis.
19. Centers for Disease Control and Prevention. MMWR. *The Role of BCG Vaccine in the Prevention and Control of TB in the United States*. April 26, 1996/Vol 45/No.RR-4.
20. American Thoracic Society, *Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection*, May 2000.
21. Francis J. Curry National Tuberculosis Center, Institutional Consultation Services, *Isolation Rooms: Design, Assessment, and Upgrade*, 1999.

INMATE NAME **CDCR NUMBER** **CDCR 128-C**

DISTRIBUTION:
CENTRAL FILE: ☐
MEDICAL FILE: ☐
INMATE: ☐

TB CHRONO
TB SKIN TESTING/EVALUATION
INMATE TB ALERT CODE

DATE

MEDICAL SIGNATURE

CDCR 128-C (Rev. 07/2005) STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

INMATE NAME **CDCR NUMBER** **CDCR 128-C**

DISTRIBUTION:
CENTRAL FILE: ☐
MEDICAL FILE: ☐
INMATE: ☐

TB CHRONO
TB SKIN TESTING/EVALUATION
INMATE TB ALERT CODE

DATE

MEDICAL SIGNATURE

CDCR 128-C (Rev. 07/2005) STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

INMATE NAME **CDCR NUMBER** **CDCR 128-C**

DISTRIBUTION:
CENTRAL FILE: ☐
MEDICAL FILE: ☐
INMATE: ☐

TB CHRONO
TB SKIN TESTING/EVALUATION
INMATE TB ALERT CODE

DATE

MEDICAL SIGNATURE

CDCR 128-C (Rev. 07/2005) STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

INDICATE REASON FOR TB SKIN TEST: ☐ **INITIAL** ☐ **ANNUAL** ☐ **TRANSFER-IN** ☐ **HIGH RISK*** ☐ **SIGNS & SYMPTOMS** ☐ **CONTACT INVESTIGATION**

SITE OF MANTOUX TEST (5 TU/0.1 milliliter):	DATE MANTOUX TEST ADMINISTERED:	PPD LOT #: _____
☐ LEFT FOREARM ☐ RIGHT FOREARM	_____	MANUFACTURER: _____
☐ OTHER _____		EXPIRATION DATE: _____

TEST ADMINISTERED BY:

_____ _____ _____

NAME (PRINT/TYPE) TITLE SIGNATURE

DATE MANTOUX TEST READ: _____ _____ TEST RESULT: _____MM INDURATION

TEST READ BY (PRINT OR TYPE):

NAME: _____ TITLE: _____

SIGNATURE: _____

Immediate physician evaluation needed: ☐ Yes ☐ No. Isolate until physician evaluation: ☐ Yes ☐ No

SYMPTOMS: (CHECK ALL THAT APPLY)

☐ COUGH (START DATE/DURATION): _____ PRODUCTIVE (DESCRIBE) _____ _____

☐ NO SYMPTOMS ☐ FEVER/CHILLS ☐ NIGHT SWEATS ☐ LOSS OF APPETITE

☐ FATIGUE ☐ WEIGHT LOSS (UNINTENTIONAL) AMOUNT: _____

PRIOR HISTORY OF POSITIVE TB SKIN TEST: ☐ YES ☐ NO IF YES, DATE: _____

PRIOR INH/RIFAMPIN PREVENTATIVE THERAPY: ☐ YES ☐ NO ☐ INCOMPLETE. YEAR: _____

CXR: ☐ YES ☐ NO RESULTS: ☐ INFILTRATE ☐ CAVITARY ☐ FIBROTIC ☐ OTHER: _____

EVALUATED BY (PRINT NAME): _____ SIGNATURE _____ DATE: _____

REVIEWED BY INFECTION CONTROL NURSE (PRINT NAME) _____ SIGNATURE _____ DATE _____

☐ HIV counseled/date _____ ☐ HIV tested/Date _____

*High risk category includes inmates who are: HIV positive, or have an immune compromised condition that puts them at high risk of developing Tuberculosis. These conditions include, but are not limited to: diabetes, renal failure, inmates on steroid or other immunosuppressive therapy, cancer, or severe chronic debilitating illness. All inmates with TB infection shall be counseled and encouraged to agree to be tested for HIV infection.

Comments: _____

_____

_____

FACILITY: _____

HOUSING: _____ RACE: _____

CDCR NUMBER, NAME (LAST, FIRST, MI), AND DATE OF BIRTH

TUBERCULIN TESTING/ EVALUATION REPORT

DISTRIBUTION:
Original: Unit Health Record
Canary: Infection Control Nurse

CDCR 7331 (Rev. 07/2005) State of California Department of Corrections and Rehabilitation

READING/INTERPRETATION OF THE MANTOUX TUBERCULIN SKIN TEST

May be performed by:	**Effective date: 1993**
All licensed Health Care personnel whose scope of practice permits the administration and interpretation of the Mantoux tuberculin skin test	**Revision date: July 2005**

PURPOSE:

Interpretation of the Mantoux method tuberculin skin test (TST) is to determine if exposure to *Mycobacterium tuberculosis* has occurred and infection is present.

SUPPLIES/EQUIPMENT NEEDED:

- California Department of Corrections and Rehabilitation (CDCR) form 7331 *TB Testing/Order Report (see Attachment 3).*
- Flexible millimeter (mm) ruler

PROCEDURE:

The skin test should be read between 48 and 72 hours after administration. Inmate-patients who do not return within 72 hours will need to be rescheduled for another skin test.

1. Visually inspect the TST site under good light for erythema (reddening of the skin) and induration (hard, dense, raised formation). Only induration is measured.

2. Mark induration margins. Use fingertip to palpate the margins of induration. Mark the widest edges of induration across forearm using a fine tip pen.

3. Measure induration (not erythema) in millimeters (mm), from inside the right edge mark to inside the left edge mark. Use the lower measurement if between two gradations on the ruler. Record measurement of induration in mm. If no induration, record as 0 mm. Do not record as "positive" or "negative".

INTERPRETATION:

A reaction of 10 mm or greater is positive for most inmates. Inmates shall be interviewed for history and signs/symptoms of tuberculosis (TB). Refer for medical evaluation, chest x-ray, and follow-up.

A reaction of 5 mm or greater is positive for inmates in the following high-risk categories:

- HIV-positive (or who have refused HIV testing).
- Recent contact with an individual known to have active TB.
- Changes on CXR consistent with old TB.
- Organ transplant recipients.
- Otherwise immunosuppressed (receiving the equivalent of $\geq$ 15 mg/day of prednisone for one month.

Any individual in a contact investigation with a change of 5 mm from a previously negative TST is considered to be positive.

> ***NOTE:*** The federal Centers for Disease Control and Prevention have set a higher threshold for positive TSTs than the CDCR. However, as California ranks as one of the top five states for incidence of TB disease and has a low incidence of atypical mycobacteria, the California Department of Health Services, TB Control Branch and the CDCR have established the criteria above for a positive TST.

RECORD KEEPING:

- CDCR form 7331 is used to document the TST and interpretation.
- Document the following on CDCR form 7331, to be filed in the inmate's Unit Health Record (UHR):
    1. Millimeters (mm) of induration. If there is no induration, record "0 mm."
    2. Date, time of reading the TST.
    3. Signature/title of individual who read the test.
    4. Blistering or other abnormal reactions.

FALSE POSITIVE AND FALSE NEGATIVE TST REACTIONS

Factors Associated with False-Positive TSTs:

- Cross reaction with other mycobacteria, such as infection with atypical forms
- Vaccination with Bacillus of Calmette-Guerin (BCG) within one year; note, the BCG reaction and TB infection cannot be distinguished reliably by TST

Factors Associated with False-Negative TSTs:

- Infections: HIV and other viral infections (e.g., measles, mumps, chickenpox); bacterial (e.g., typhoid fever, typhus, pertussis); or fungal infections.
- Live virus vaccinations within three months: measles, mumps, varicella, polio, yellow fever, typhoid
- Metabolic illness causing chemical derangement such as chronic renal failure
- Nutritional problems causing severe protein depletion
- Illness affecting lymphoid organs, such as lymphoma
- Chronic use of steroids or other immunosuppressive medications
- Age
- Stress

TST Solution or Administration Factors Associated with False-Negative TSTs:

- PPD exposure to heat and light
- PPD improperly stored or diluted
- PPD contaminated
- PPD expired
- Too little PPD injected
- Leakage of solution from the injection site

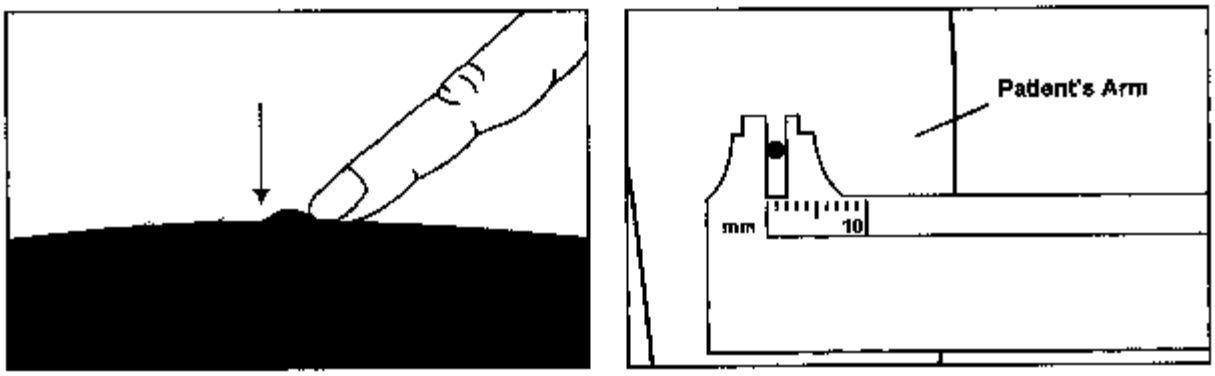
- Injection was not intradermal (too deep or too shallow)
- Pre-filled syringes used, reducing potency or using incorrect solutions

REMINDER:

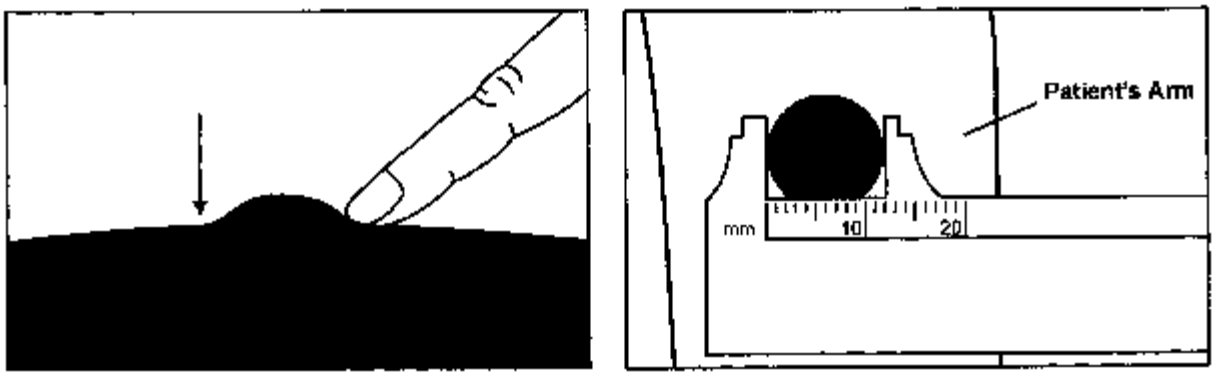
- Update the DDPS and the inmate chrono (CDCR form 128C, see *Attachment 5*) with copies to the UHR and to the Custody "C" file.

Reading the Tuberculin Skin Test (TST)

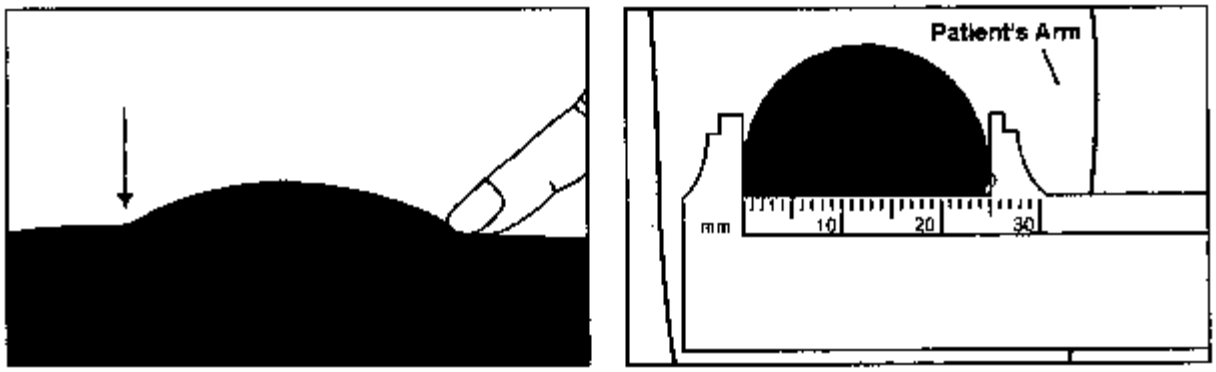
TST Reading: 2 mm induration



TST Reading: 12 mm induration



TST Reading: 25 mm induration



The illustrations above show palpation and measurement of TST induration. Erythema or redness should not be considered in palpation and measurement.

Source: Centers for Disease Control and Prevention. *The Mantoux Tuberculin Skin Testing* poster, 1990.

ADMINISTRATION OF THE MANTOUX TUBERCULIN SKIN TEST

May be performed by:	**Effective date: 1993**
All licensed Health Care personnel whose scope of practice permits the administration and interpretation of the Mantoux tuberculin skin test	**Revision date: July 2005**

PURPOSE:

The Mantoux method for tuberculin skin testing (TST) is administered to identify individuals with tuberculosis (TB) infection. Purified Protein Derivative (PPD) is given by intradermal injection on the inner aspect of the forearm. Only PPD solutions containing 5 tuberculin units (TU) 0.1 milliliter (ml) should be used for TSTs on routine inmate arrivals and their follow-up, for employees or inmates in contact investigations, and during annual TB evaluation/testing cycles.

The TST elicits a delayed (cellular) hypersensitivity reaction to detect *Mycobacterium tuberculosis* (*Mtb*) infection, which may begin as soon as five to six hours after administration. A significant reaction is indicative of previous infection with *M tb*.

NOTE: The Centers for Disease Control and Prevention (CDCP) has established three thresholds for a positive TST: 5mm, 10mm, and 15mm of induration, depending upon the patient's history and clinical status. However, since California is one of the top five states for TB disease prevalence, although with a lower prevalence of atypical mycobacteria than many other states, the California Department of Health Services (DHS) has discarded the highest cutoff altogether. A positive TST for a CDCR inmate without other risk factors is $\geq$ 10 mm of induration. For CDCR inmates in the following groups considered to be medically at "high risk" for TB infection and/or disease, the definition of a positive TST is induration $\geq$ 5 mm. High risk groups include HIV positive inmates or inmates who refuse HIV screening; inmates with changes on their CXR consistent with old TB; inmates with organ transplants; inmates otherwise immunosuppressed; and inmates and employees with recent contact with an individual with active TB.

See Attachment 2 "*Reading/Interpretation of the Mantoux Tuberculin Skin Test"* for further information on TST interpretation.

SUPPLIES/EQUIPMENT NEEDED:

- California Department of Corrections and Rehabilitation (CDCR) form 7331 R9/04 *TB Testing Order/Report (see Attachment 3)*.
- Shielded or "safety" 26 or 27 gauge needles that are ¼ to ½ inch long, tuberculosis (TB) syringes or syringes calibrated in tenths of ml.
- PPD 5 TU/0.1 ml
- Alcohol wipes
- Sharps container
- Gloves
- Cotton balls
- Epinephrine 1:1000

Note: In rare instances anaphylactic shock has been reported following testing, although this has not been recorded in the CDCR. If this occurs a report must be made to the institution Health and Safety Officer or Return to Work Coordinator, to the DCHCS PHC, CSSU and to the Food and Drug Administration using the form provided for this purpose in the back of the Physician's Desk Reference.

PROCEDURE:

1. Explain the procedure and care of the injection site (do not scratch, rub, etc.).
2. Locate test site on inner aspect of forearm, two to three inches below the elbow. The chosen site should be free of lesions and away from veins.
3. Cleanse injection site with alcohol and allow to dry.
4. Ascertain vial contains desired tuberculin at desired unit strength. Using aseptic technique, cleanse the rubber cap of the vial with a cotton ball moistened with alcohol and allow to dry. Draw up 0.1 ml of PPD 5TU solution into syringe.
5. Draw skin tight. Insert needle **intradermally** at a 10-15 degree angle with the needle **bevel upward** under the most superficial layers of the skin on the inner side of the forearm, away from veins or skin lesions, and inject the PPD solution. If the intradermal injection is performed properly, a definite wheal will rise at the needlepoint, about 6-10 millimeters (mm) in diameter. This will disappear within minutes.
6. The needle shall be quickly withdrawn. The site shall not be massaged. No dressing shall be applied. No leakage of solution should be observed. In the event of an incorrect TST application (no wheal formed, given too deep or too shallow) the test should be repeated immediately at a different site on the same arm, at least two inches from the initial test site.
7. Properly dispose of syringe/needle in Sharps container ***(needles should not be recapped, bent, broken, or removed from syringe).***
8. Instruct individual to return for skin test reading in 48-72 hours after administration, and notify the individual of the date, time, and location to return for skin test reading.
9. Document on CDCR form 7331, to be filed into the medical records:
    - Date, time of administration
    - Brand, lot number, and expiration date of the antigen
    - Injection site (left forearm is standard)
    - Name and classification of individual administering test

TST SOLUTION

1. To minimize reduction in potency by absorption and possible contamination, tuberculin should never be transferred from one container to another.
2. Skin tests should be given as soon as possible after the syringe has been filled. Syringes filled, but not used within **two hours** (as during annual mass inmate testing) should be discarded.
3. Overnight pre-loading of syringes is discouraged due to the antigen's vulnerability to light, loss of potency due to adsorption, and possible contamination.

4. The PPD solution is stabilized with Tween 80 to help prevent adsorption of PPD to the walls of vials and syringes, which can cause minor skin redness in certain sensitive individuals.
5. Vials **must** be refrigerated between 35 and 46 degrees Fahrenheit. Staff opening vial shall ensure the expiration date is current, write date opened, and their initials on vial. Once syringe contains PPD solution, it must be kept refrigerated between 35 and 46 degrees Fahrenheit until administered.
6. Vials **must be discarded 30 days** after opening, according to manufacturer's directions, because oxidation and degradation may have reduced the potency.
7. If antigen is accidentally frozen, **it should be discarded**. Tuberculin solution should be stored in the dark, and excessive exposure to light should be avoided. If antigen is exposed to light for a long or undetermined amount of time, **it should be discarded**.
8. Refer to the CDCP videotape, *Tuberculin Skin Testing*. If your facility cannot locate its copy, please write to CDCP at P.O. Box 6003, Rockville, MD, 20849-6003; call for information at (888) 232-3228; or visit their website at www.cdc.gov/nchstp/tb/pubs/videos.htm. If you still cannot obtain a copy, contact the DCHCS, PHC, CSSU, for a replacement.
9. To prevent needle stick injuries, needles should **always be safety shielded and never be recapped, bent, or broken by hand, carried in pockets, removed from syringe, or otherwise manipulated by hand.** After use, needles and syringes should be disposed of immediately in a puncture resistant, properly labeled and stored, Sharps container.
10. Pregnancy is not a contraindication to receiving a TST although it may result in a false negative reaction.

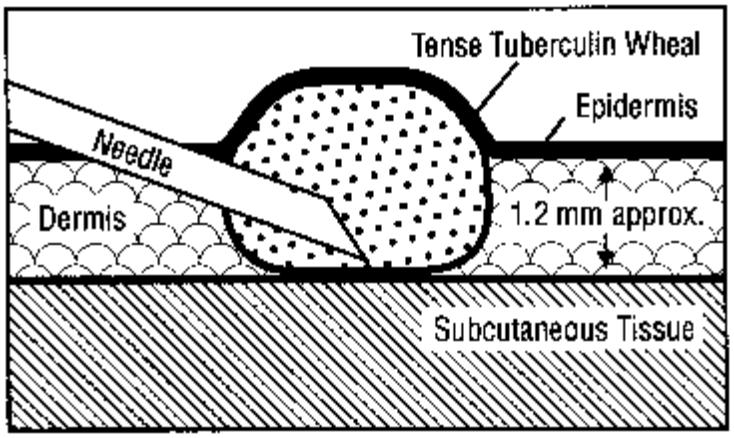
BCG Considerations:

Reported efficacy of BCG vaccine is variable. Use of the vaccine is not recommended in the United States (US), except for certain specific categories of infants and children. (Mortality and Morbidity Weekly Report, April 26, 1996/Vol. 45/No. RR-4). The vaccine BCG is used in areas with a high percentage of endemic TB disease. It usually does not prevent TB transmission or pulmonary disease, but may be effective in reducing extrapulmonary TB such as TB meningitis.

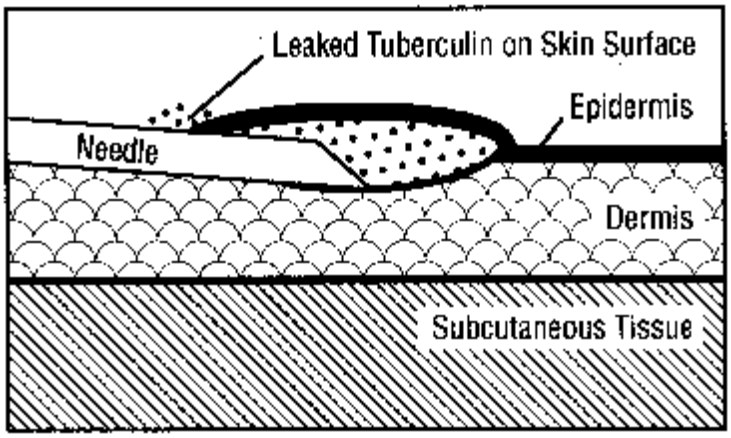
1. Individuals who have recently (within one year) received BCG vaccine may have positive TST results but this does not tell their status for latent or active TB infection/disease.
2. Because of the risk of TB disease and the high variability for BCG vaccination reactions, the CDCP and DHS recommend evaluation for TB infection and disease in anyone with a positive TST.
3. A variety of other atypical *Mycobacteria*, mainly in the eastern and southeastern U.S., as well as Bacille Calmette-Guerin (BCG) vaccination within the last 12 months, may also elicit a cell-mediated response but are not contraindications to administration of the TST.

Applying the Tuberculin Skin Test

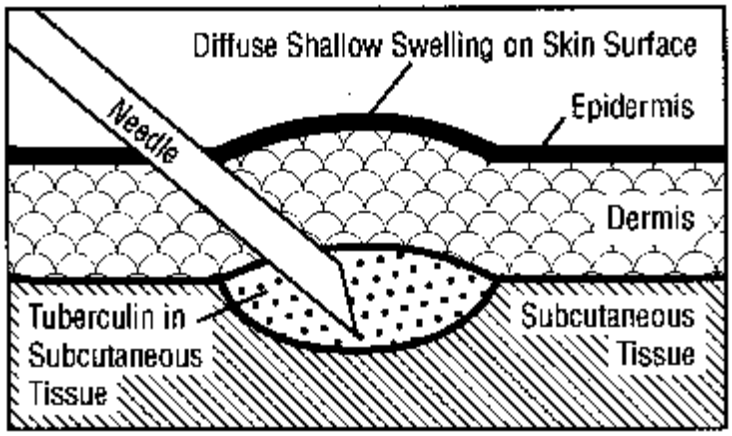
Needle Properly Inserted at Angle of 10° - 15°



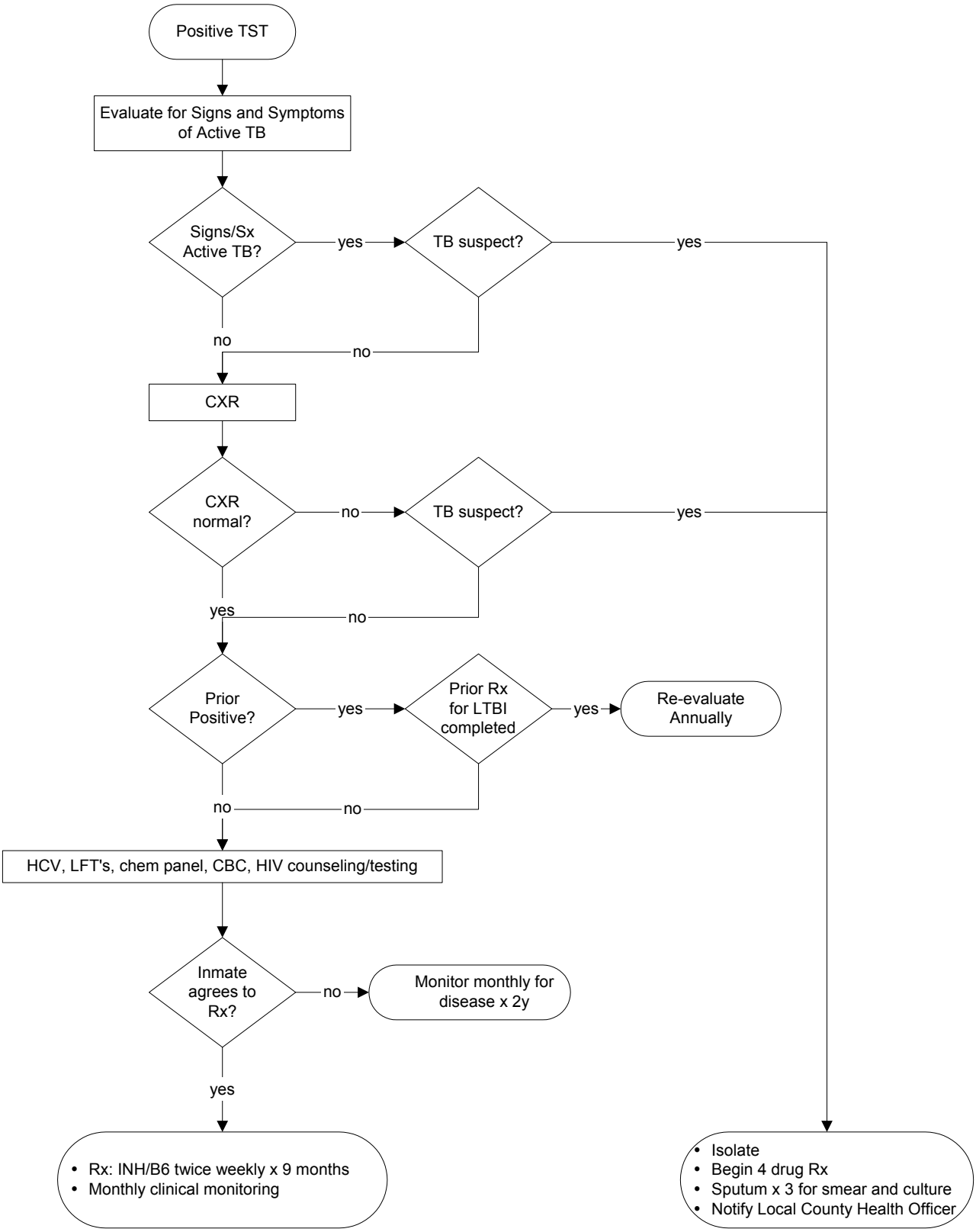
Needle Too Shallow



Needle Too Deep



EVALUATION OF INMATES WITH POSITIVE TST



CORRECTIONAL FACILITY TUBERCULOSIS PATIENT PLAN

☐ Initial Report Date _____
☐ Transfer Date _____
☐ Discharge Date _____

Inmate Name: _____ DOB: _____ AKA: _____ Sex: ☐M ☐F

MR# / ID# / CDCR#: _____

Facility Patient is Leaving: _____ Admission Date: _____ Discharge/Transfer Date: _____

Planned Discharge/Transfer to: ☐Home ☐Shelter ☐SNF ☐Jail/Prison ☐Residential Facility ☐Other

Household Members: Children < 5 yrs. ☐Yes ☐No Elderly ☐Yes ☐No Immunocomp. ☐Yes ☐No

Known contact to another case? ☐Yes ☐No If yes, name of source case _____ Co.: _____

Address/Facility patient is going to: _____ Phone: _____

Other Locating Information: _____

MD / Provider Assuming Care: _____ Phone: _____

Date / Time / Location of Follow-up Appointment: _____

DIAGNOSIS: ☐Active TB ☐Suspect Active TB ☐Pulmonary ☐Extra pulmonary (site) _____

Symptoms: ☐Cough (duration _____) ☐ Fatigue ☐Night Sweats ☐ Hemoptysis

☐Weight Loss (_____lbs.) ☐ Fever ☐ Other _____

History of Previous TB Treatment (Where/When/What): _____

Name of Laboratory _____ Phone: _____

BACTERIOLOGY RESULTS

		Initial			Most Recent		
		-1	-2	-3	-1	-2	-3
DATES							
SOURCE							
SMEAR AFB							
CULT	MTB						
	OTHER						

DRUG SUSCEPTIBILITY TESTING DONE : ☐YES ☐NO

DATE (Specimen Obtained From Patient): _____

DRUG RESISTANCE ☐YES ☐NO

TO WHAT DRUGS (Attach Report): _____

OTHER TESTS

	DATE PLACED	DATE READ	RESULTS
TUBERCULIN SKIN TEST (PPD)			MM
			MM
CHEST X-RAY (Attach Report)		☐CAVITY ☐INFILTRATE ☐UNK ☐NEGATIVE	
F/U CXR (Attach Report)		☐STABLE ☐IMPROVING ☐WORSE ☐UNK	

IMMCOMP ☐ YES ☐NO

IDU ☐ YES ☐NO ALCOHOL ABUSE ☐YES ☐NO

OTHER SUBSTANCE ABUSE ☐YES ☐NO

TREATMENT: Adherent ☐Yes ☐No Explain: _____

Will case management include Directly Observed Therapy (DOT) or Nurse Administered Therapy (NAT)? ☐Yes ☐No

If no, explain: _____

MEDICATIONS	DOSAGE	DATE STARTED	DATE STOPPED	REASON FOR D/C
1. INH/B6				
2. RIFAMPIN				
3. PYRAZINAMIDE				
4. ETHAMBUTOL				
5.				

COMMENTS: (e.g. language spoken, other medical/health issues)

_____

_____

_____

Race: ☐White ☐Black ☐American Indian/Alaskan Native ☐ Asian or Pacific Islander (Specify: _____) ☐Other _____

Ethnicity ☐Hispanic ☐Non Hispanic

US Born: ☐Yes ☐No

Completed by: _____ Phone: _____ Fax: _____ Date: _____

STATE OF CALIFORNIA **DEPARTMENT OF CORECTIONS AND REHABILITATION**

TRANSFER RECORD

CDCR 135 (07/05)

DATE:	DISTRIBUTION: ☐ ORIG – CASE RECORDS – RECEIVING FACILITY ☐ COPY – CONTROL ROOM – RECEIVING FACILITY ☐ COPY – TRANSPORTATION OFFICER ☐ COPY – CONTROL ROOM – SENDING FACILITY ☐ COPY – CASE RECORDS – SENDING FACILITY
TO: (NAME OF RECEIVING FACILITY)	
ATTENTION: **RECORDS OFFICER**	

The following identified persons will be transferred this date.

FROM:	TO:

NUMBER	NAME	LEVEL HOUSING	ETH	MEDICAL STATUS	REMARKS

SIGNATURE	TITLE	SENDING FACILITY

Receipt of the above-named persons and their records is acknowledged

SIGNATURE OF TRANSPORTING OFFICER	TITLE	FACILITY
SIGNATURE OF RECEIVING OFFICER	TITLE	FACILITY

INFORMATION ABOUT TUBERCULOSIS EVALUATION OR TREATMENT

I have been told that tuberculosis (TB) is a contagious illness, which is spread when the bacteria (germ) is coughed or breathed into the air. When a person has been exposed to TB, a TB skin test (done with a needle in the forearm skin) will usually be "positive" (become hard, swollen, and red). Most people who have a positive TB skin test are not ill or contagious (able to spread the disease to others). A chest x-ray (CXR) may help to determine if the disease is active or progressing. When the disease is active, symptoms such as cough, fever, and weight loss may be present, and the TB germ can be spread from person to person.

Anybody with a positive TB skin test can develop active, contagious TB at any time in his or her life. Taking medications when a positive test is first discovered can usually prevent this from happening. TB testing and evaluation, including CXRs if needed, are mandatory under *Penal Code* Sections 7571-7574. I understand that I will put my friends, family and others at risk if I have TB infection and am not treated. I understand that if I am infected and postpone treatment, I may develop active TB disease, which requires more antibiotics and may be more difficult to treat.

I understand that TB disease may kill me. I understand the risks I take if I refuse needed treatment.

FACTS ABOUT TB IN THE CALIFORNIA CORRECTIONAL SYSTEM

Inmates in the CDCR correctional facilities *are required by law* to be checked annually (or more often if medically necessary) and *must have a TB skin test, CXR, and/or examination*.

Active TB disease can cause fever, night sweats, cough, weight loss, or death. Inmates with any of these symptoms must tell Health Care staff in order to be evaluated and, if necessary, treated.

A Chest X-ray may help doctors find out if an inmate has active TB disease in his or her lungs.

Inmates do not have the right to refuse a TB skin test and Chest X-ray. Any *inmate who refuses will be tested or x-rayed against his or her will.*

You have the right to refuse drug treatment for TB. If you refuse, you have a right to withdraw that refusal and to consent to treatment at any time.

☐ I refuse drug treatment for TB infection or disease.

Refusal reasons: _____

_____

INMATE SIGNATURE FOR REFUSAL OF TREATMENT		DATE
WITNESS NAME/SIGNATURE		DATE
STAFF NAME AND TITLE (PLEASE PRINT)	STAFF SIGNATURE	DATE

If needed: Every word of this form needs to be ☐Interpreted into_____ ☐ Read to Inmate

Interpreter/Reader (print): _____(sign): _____Date: _____

Distribution: ☐Unit Health Record
☐Inmate Upon Request

INFORMATION FOR TB EVALUATION, TREATMENT, AND REFUSAL OF TREATMENT

CDCR 7225/7338 (Revised 07/2005)

NAME

CDCR NUMBER

DATE OF BIRTH

INFORMATION FOR CONSENT/REFUSAL OF TUBERCULOSIS EVALUATION OR TREATMENT

POLICY

An inmate who is exposed to or infected with TB must be given adequate information about his or her health status so that personal health and the health of other persons can be protected. When a clinician recommends that an inmate be evaluated or treated for tuberculosis (TB) exposure, infection, or disease, the inmate shall complete the ***Information For Tb Evaluation, Treatment, And Refusal Of Treatment*** (CDCR 7225-7338 Rev. 07/05). CDCR 7225-7338 (Rev. 07/05) provides information to the inmate about TB evaluation and treatment. CDCR 7225-7338 (Rev. 07/05) documents the benefits, risks, and detrimental impacts of postponing or refusing treatment, and, where applicable, documents the inmate's refusal of treatment.

DEFINITION

CDCR 7225-7338 (Rev. 07/05) is designed to provide the inmate with knowledge about TB and the detrimental effects of refusing treatment. The information shall be such that a reasonable person in the inmate's position can understand the ramifications of his or her decision to refuse treatment. CDCR 7225-7338 (Rev. 07/05) documents that while the patient has exercised the right to choose or reject treatment, that choice is an informed decision.

PURPOSE

The information provided about recommended TB evaluation and treatment includes the risks and benefits, the potential of transmitting active TB to other persons, the effects of TB on the body, and the possible adverse effects of the treatment drugs.

CDCR 7225-7338 (Rev. 07/05) establishes uniform documentation of the inmate's refusal when he or she is at risk for TB and has been offered and refuses preventive or curative TB drug therapy. CDCR 7225-7338 (Rev. 07/05) documents the inmate's refusal in writing and serves as a base of information for attending health care personnel. CDCR 7225-7338 (Rev. 07/05) documents the nature of the information that was given and indicates what conclusion the patient reached regarding the recommended treatment.

INSTRUCTIONS

The healthcare provider must ascertain that the inmate can understand the form, and read or have the form read to the inmate in whatever language the inmate can understand. After informing the inmate of the beneficial and detrimental effects of the prescribed treatment, if the inmate refuses treatment, the healthcare staff shall ask the inmate to indicate that refusal on the ***Information For Tb Evaluation, Treatment, And Refusal Of Treatment*** CDCR 7225-7338 (Rev. 07/05) form. If the inmate refuses treatment, he or she shall be asked to provide a written statement of the reason for refusal and to sign and date the form. The staff person shall sign and date the form as witness. In the event the inmate refuses to sign the CDCR 7225-7338 (Rev. 07/05), a second witness shall sign and date the form as indicated.

DISTRIBUTION

The original of the completed form CDCR 7225-7338 (Rev. 07/05) will be filed in the Unit Health Record-Public Health Section. A copy may be given to the inmate upon request.

CALIFORNIA PENAL CODE
SECTIONS 7570 – 7576

7570 *In enacting this chapter, the Legislature hereby finds and declares that tuberculosis is a serious contagious disease. It is vital to the health and safety of inmates, employees, and the public at large, to conduct appropriate examinations, testing, and treatment in order to control the spread of tuberculosis in California's institutions.*

7571 *For purposes of this title, the following definitions shall apply:*

(a) "Chief medical officer" means the chief medical officer or acting chief medical officer of a state prison or any facility under the jurisdiction of the Department of Corrections or the Department of the Youth Authority.

(b) "Inmate or ward" means any person incarcerated within the jurisdiction of the Department of Corrections or the Department of the Youth Authority, with the exception of a person on parole.

(c) "Institution" means any state prison, camp, center, office, or other facility under the jurisdiction of the Department of Corrections or the Department of the Youth Authority.

(d) "Examination, test, or treatment" means methods, processes, or other means, including medical evaluations, testing, follow-up examinations, or treatment, in accordance with the recommendations of the Centers for Disease Control and Prevention and as specified in the guidelines for tuberculosis control of the Department of Corrections and the Department of the Youth Authority.

(e) "Medical evaluation" means taking a history or gathering other information and may include, but is not limited to, listening to the chest or other examinations or tests as specified in the guidelines for tuberculosis control of the Department of Corrections and the Department of the Youth Authority.

(f) "Department" means the Department of Corrections and the Department of the Youth Authority.

(g) "Chief of medical services" means the medical officer, acting medical officer, or designee responsible for all medical services of the Department of Corrections or the Department of the Youth authority.

7572 *The chief of medical services, or his or her designee, shall use every available means to ascertain the existence of, and to immediately investigate all reported or suspected cases of, tuberculosis in the infectious stages and to ascertain the source or sources of the infections. In carrying out these investigations, the chief of medical services, or his or her designee, is herebyinvested with full powers of inspection, examination, and quarantine or isolation of all inmates or wards known to be, or reasonably suspected to be, infected with tuberculosis in an infectious stage.*

7573 *(a) The chief medical officer shall order an inmate or ward to receive an examination or test, or may order an inmate or ward to receive treatment if the medical officer has a reasonable suspicion that the inmate or ward has, has had, or has been exposed to tuberculosis in an infectious stage and the chief medical officer has reasonable grounds to believe that it is necessary for the preservation and protection of staff and inmates or wards.*

(b) The chief medical officer shall ensure that examinations or tests for tuberculosis on all inmates or wards are conducted upon incarceration and at least annually thereafter.

7574 *Notwithstanding Section 2600 or 2601, or any other provision of law, any inmate or ward who refuses to submit to an examination, test, or treatment for tuberculosis as described in Section 7572 or 7573, or who refuses treatment for tuberculosis, or who, after notice, violates, or refuses or neglects to conform to, any rule, order, guideline, or regulation prescribed by the department with regard to tuberculosis control shall be tested involuntarily and may be treated involuntarily. This inmate or ward shall be subject to disciplinary action as described in Title 15 of the California Code of Regulations.*

7575 *To provide effective control of the spread of tuberculosis in institutions and to identify those among the inmate and ward populations with tuberculosis, the Department of Corrections shall operate pursuant to guidelines developed in consultation with the State Department of Health Services, which shall be adopted on or before July 1, 1994. The guidelines shall include, but not be limited to, establishing a reporting system which emphasizes standardized, uniform data collection, reporting, and assessment, as specified in Section 7576.*

7576 *(a) The Department of Corrections, the Department of the Youth Authority, the Board of Prison Terms, and the Youthful Offender Parole Board shall compile information through each department's respective reporting systems for individual institutions and each respective department as a whole and shall provide the results to the State Department of Health Services annually. The information reported shall consist of the following:*

(1) Prevalence rates and conversion rates (tuberculin incidence) for tuberculosis infection for inmates or wards and staff in each institution.

(2) Case numbers and case rates for tuberculosis disease for inmates or wards in each institution.

(b) Subject to additional staffing resources provided through the state budget process, the departments described in subdivision (a) shall also compile the following information for individual institutions and each respective department as a whole and shall provide the results to the State Department of Health Services annually:

(1) Percentage of inmates and wards with tuberculosis disease who complete the prescribed course of directly observed curative therapy in accordance with the Centers for Disease Control and Prevention recommendations and as specified in the department's guidelines for tuberculosis control.

(2) Percentage of inmates and wards with culture positive sputum that convert to culture negative in accordance with the Centers for Disease Control and Prevention recommendations and as specified in the department's guidelines for tuberculosis control.

(3) Percentage of inmates and wards with tuberculosis who complete the prescribed INH (isoniazid) or other appropriate directly observed preventive therapy in accordance with the Centers for Disease Control and Prevention recommendations and as specified in the department's guidelines for tuberculosis control.

CLASSIFICATION OF TUBERCULOSIS

The American Thoracic Society has developed a tuberculosis classification system based on the broad host-bacterial relationships as described by exposure history, infection, and disease. This is the standard classification system recognized by local community, states' health departments, federal, and world health care providers. In contrast, the *TB Alert Codes* are a system **only used for transportation of inmates within the California Department of Corrections and Rehabilitation.**

CLASS 0	**NO TUBERCULOSIS EXPOSURE; NO INFECTION**
	Individual has no history of exposure, negative reaction to TST.
CLASS 1	**TUBERCULOSIS EXPOSURE; NO EVIDENCE OF INFECTION**
	Individual has history of exposure, negative reaction to TST.
CLASS 2	**TUBERCULOSIS INFECTION; NO DISEASE**
	Individual has a positive reaction to TST. No clinical, laboratory, and/or radiographic evidence of TB. Preventive chemotherapy should be considered if appropriate.
CLASS 3	**TUBERCULOSIS; ACTIVE DISEASE**
	Individual has a positive reaction to TST (but up to 25% of active TB cases have negative TST), *M tb* confirmed by positive culture, clinical TB disease using medical judgment of signs or symptoms as determined by a licensed provider able to give this diagnosis, negative smear with positive culture, and/or radiographic evidence of active disease.
CLASS 4	**TUBERCULOSIS; NO ACTIVE DISEASE**
	Individual has a history of previous TB disease; OR abnormal but stable radiographic findings in a person with a positive reaction to TST. "Stable" is defined as no radiographic change in three or more months. There are negative bacteriologic studies and no clinical evidence of active disease. Individuals in Class 4 may have never received chemotherapy, may be receiving treatment for latent TB infection, or may have completed a previously prescribed course of chemotherapy
CLASS 5	**TUBERCULOSIS SUSPECT (DIAGNOSIS PENDING)**
	This classification shall be used when a diagnosis of TB is being considered, whether or not treatment has been started, until diagnostic procedures have been completed. Persons shall not remain in this class for more than three months. When diagnostic procedures are completed, the person shall be placed in one of the preceding classes.

TUBERCULOSIS (TB) MONTHLY MONITORING

TB Medications Reason: ☐ CONTACT (☐Close ☐Casual) TB CLASS _____ ☐ CONVERTER

Symptoms: **0** = absent **1** = mild **2** = moderate **3** = severe

DATE:	(baseline):										
WEIGHT (LBS)											
WEIGHT CHANGE ↓ OR ↑	N/A										
↓ APPETITE											
FEVER/CHILLS											
COUGH											
MALAISE/FATIGUE/WEAK											
NAUSEA/VOMITING											
JAUNDICE/ICTERUS											
DARK URINE											
PARESTHESIAS											
RASH											
ABD PAIN											
JOINT PAIN											
OTHER (specify on back)											
TOXICITY INSTRUCTIONS											

Medications: **I** = INH; **R** = RIF; **E** = EMB; **P** = PZA; **S** = Streptomycin; **Q** = Quinolone; **OT** = other

DATE ORDERED/Rx												
DATE COMPLETED/Rx												
VISUAL ACUITY (IF ON EMB)	L	R										
RED/GREEN VISION (IF ON EMB)												
AUDIOGRAPH (on streptomycin)	L	R										
GAIT (on streptomycin)												
HCP initials												
RN initials												

End of Therapy (complete the first column and one of the following columns)

DATE FINISHED:	☐ **LTBI: TREATMENT COMPLETE**	☐ **TB Disease: TREATMENT COMPLETE**	☐ **TREATMENT INCOMPLETE**
Meds taken for _____ months	☐ 76 doses within 12 month period	☐ 4 drugs x 8 weeks; then 2 drugs x 18 weeks (6 mo. total)	☐ Died
	☐ Other (specify) _____ _____ _____	☐ 4 drugs x 8 weeks; then 3 drugs x18 weeks (6 mo. total)	☐ Paroled/Transferred
		☐ 4 drugs x 8 weeks; then 2 drugs x 31 weeks (9 mo. total)	☐ D/C Rx Adverse reaction
		☐ Other (specify) _____	☐ File lost, other error
			☐ Patient Self-stopped
			☐ D/C Rx on medical advice (other than adverse reaction)
PCP: (print name):		**Signature:**	**Date:**

FACILITY:	**CDCR NUMBER:** **NAME:** **DOB:**

CDCR Form # TBRX (Rev. 07/05) Distribution: Inmate Unit Health Record

Instructions: Tuberculosis (TB) Monthly Monitoring

Purpose: This form is designed to document signs and symptoms of TB disease and adverse reactions to anti-TB medications. Any adverse reaction requires immediate referral to a physician for evaluation.

This form can be completed by any healthcare provider (HCP) licensed to administer or interview inmate-patients. A registered nurse must review and sign the form if there is a weight loss of five pounds or more, if any signs or symptoms of TB disease or adverse drug reaction are present, and on discontinuation or completion of therapy.

Abbreviations and terms used in this form include:			R	=	Right
Rx	=	Medication(s)	L	=	Left
SX	=	Symptoms	↓	=	Decreased
ABD	=	ABDominal	↑	=	Increased
INH	=	IsoNicotinic Acid Hydrazide or Isoniazid	Quinolone	=	Levofloxacin, Ciprofloxacin, Ofloxacin, etc.
RIF	=	RIFampin	EMB	=	EthaMButol
PZA	=	PyraZinAmide	Other	=	Kanamycin, Ethianomide, etc.

Symptoms: During the monthly evaluation with the inmate-patient, the HCP shall record the date at the top of the next available column. The HCP shall weigh the inmate-patient, and review the listed symptoms with the inmate-patient.

The HCP shall review appropriate information with the inmate-patient, and provide instructions regarding possible toxicity of the medications the inmate-patient is taking. If the inmate-patient has not received prior information and instructions, the HCP shall give instructions (written and/or oral) to the inmate-patient. The reviewer-HCP must complete, initial, and date the appropriate column(s) on the form.

Medications: The HCP shall record the medications (by code) and the date the medications were ordered in the "Date Ordered" line (a one-time notation is sufficient). When medications are completed or stopped, the HCP shall record the medications (by code) and the date completed or stopped in the "Date Completed" line.

If the inmate-patient is taking ethambutal, the HCP shall test and record the inmate-patient's visual acuity and color vision.

If the inmate-patient is taking streptomycin, the HCP shall test and record the inmate-patient's hearing by audiography, and observe and record the inmate-patient's gait.

Names: All HCPs and RN's initialing this form shall print their names, sign, and date the form here:

Name (Print)	Signature	Date

End of Therapy: The End of Therapy section shall be completed at the time that TB medications are discontinued, for any reason. It must be signed by the Primary Care Provider (PCP) Physician or Nurse Practitioner and filed in the inmate-patient's Unit Health Record. If the inmate-patient has been transferred, this form must also be faxed to the receiving facility.

TB MEDICATION ADMINISTRATION

May be performed by:	**Effective Date: 1994**
Appropriately Licensed Health Care Staff	**Revision Date: July 2005**

PURPOSE:

To minimize public health risks and ensure inmate-patient compliance, medications are sometimes administered dose-by-dose by appropriately licensed healthcare staff (RN, LVN, MTA, or LPT). Directly Observed Therapy (DOT)[1] shall be given for active or suspected tuberculosis (TB) disease and, if the inmate-patient is HIV co-infected, for treatment of Latent TB Infection (LTBI) and TB exposure (prophylaxis). For all other inmate-patients, Nurse Administered Therapy (NAT)[2] shall be given for treatment of Latent TB Infection (LTBI) and for prevention of TB after exposure to TB disease (prophylaxis). Inmate-patients on DOT or NAT shall remain on DOT or NAT until completion of treatment.

PROCEDURE:

1. Provide an anti-TB medication line daily or, at a minimum, twice a week.

2. Provide the inmate-patient with a "special pass" (varies with institution) indicating what anti-TB medications are being dispensed, duration of therapy, and times and days of administration.

3. Explain to the inmate-patient the reason for the medications ordered, and describe possible reactions and adverse effects of the medications.
   - Instruct the inmate-patient to promptly notify health care staff of any reactions or adverse effects.
   - Provide the inmate-patient with the appropriate *Information Sheet(s) for Anti-TB Medication(s) (Attachment 11a, 11b, 11c, 11d).*

4. Health Care staff administering anti-TB medications must be familiar with the common drug reactions and adverse effects. Health care staff shall, prior to delivering each dose of medication, assess the inmate-patient to determine if he or she is experiencing any adverse effects. The most common complaints concerning isoniazid are: nausea, vomiting, anorexia, jaundice, dark urine, lethargy and peripheral paresthesia (numbness/tingling of extremities, especially the fingers and toes). A *Tuberculosis (TB) Monthly Monitoring for Drug Toxicity* form *(Attachment 14)*, **must be completed** *monthly* **while the inmate-patient remains on TB therapy, signed by the counseling nurse with time and date, and filed in the Unit Health Record (UHR).**

5. Health Care staff responsible for administering TB medications shall be responsible for counseling, within 24 hours, any inmate-patient who fails to appear (a "no show,") at the

[1] Inmate Medical Services Policies & Procedures, Vol 4, Chapter 11, section: *Methods of Delivery,* p. 3

[2] ibid p. 4

medication line to receive medication prescribed for LTBI or for TB prophylaxis. ***Note:*** Intra-facility housing *may* impact an inmate-patient's ability to get to the medication line. Some institutions (or buildings) deliver NAT to the housing units, while others expect inmate-patients to arrive at the medication lines at specified times. *It is imperative that health care staff be aware of any inmate-patients on their assigned list who are on TB medications in order to be able to notify the Public Health Nurse/Designee whenever the inmate-patient is a "no show." The inmate-patient shall then be ducated and escorted to the medication line, or to the nurse or physician, for evaluation and counseling.*

6. An inmate-patient who misses, refuses, or is a "no show" for two consecutive doses of TB medication shall be referred to the prescriber, public health nurse, or the POC on an urgent basis. An inmate-patient who misses, refuses, or is a "no show" for TB medication twice in 30 days shall be ducated to the Public Health staff, nurse, or physician for further counseling.

7. **Inmate-patients refusing any TB medications** must sign CDC form 7225/7338 *Information for Consent/Refusal for TB Evaluation or Treatment (Attachment 7)*. If the inmate-patient refuses to sign the form, this shall be noted on the form, witnessed by two staff members other than the treating physician, and the form shall be filed in the UHR.

8. **LTBI:** Inmates with the following characteristics who refuse therapy for LTBI shall be regarded at high risk for developing TB disease, and consideration should be given for monthly evaluation by a health care professional, with appropriate documentation, for two years:
   - Risk factors for suspecting HIV, proven HIV infection or other high-risk diseases.
   - Recent TST conversion
   - Exposure to TB within the past two years.

9. **Prophylaxis:** During a TB outbreak, any inmate-patient who refuses prophylaxis after exposure to TB disease, shall be counseled and monitored at least monthly for signs and symptoms of TB disease, with appropriate documentation in the UHR, for a period of two years following exposure.

10. **Symptoms after Refusal:** If an inmate who has refused preventive therapy or therapy for LTBI develops one or more TB symptoms, the inmate shall be treated as TB suspect, placed into respiratory isolation, given a CXR, and three consecutive sputum samples for AFB smear and culture shall be obtained.

11. **Active Disease:** Inmate-patients who refuse to take medications prescribed for TB disease or TB suspect will be placed into respiratory isolation and given daily counseling until TB disease has been ruled out, or until a physician determines that the inmate-patient is non-infectious.

12. **Discipline:** Inmates shall not be disciplined for refusing anti-TB therapy.

ISONIAZID FACT SHEET

You have been prescribed Isoniazid (INH), an antibiotic for treating or preventing active tuberculosis (TB). This medication should be taken **ONLY** as directed by the physician or nurse. The dosage will depend on how often you are taking the medication:

- If taken daily (every day), dosage is 300 milligrams (mg), with 25 mg of vitamin B6
- If taken twice a week, dosage is 900 mg, with 25 mg of vitamin B6
- If taken three times per week, dosage is still 900 mg, with 25 mg of vitamin B6

Before using this medicine, be sure to tell your physician or nurse about:

- Previous allergies to this or any other medication
- Early pregnancy (your doctor will make a decision about whether or not you should take this medication**)**
- Other prescription or non-prescription medication you are taking, especially Antabuse (drug treatment) Aluminum hydroxide (found in some antacids), seizure medications, especially phenytoin (Dilantin), valproic acid (Depakote, Depakene), and carbamazepine (tegretol).
- Other medical problems, especially alcoholism, hepatitic C, and other liver diseases

Let your nurse or physician know so that you receive correct treatment appropriate for your situation.

If INH upsets your stomach, you may take it with food. Antacids may help, but **DO NOT TAKE ANTACIDS CONTAINING ALUMINUM OR MAGNESIUM WITHIN 1 HOUR OF THE TIME YOU TAKE INH** since they may keep the medicine from working well. To eliminate the TB bacteria from your body, it is very important that you keep taking this medicine for the **FULL** period of treatment. **DO NOT** stop the medicine without contacting your physician or nurse. Try not to miss your daily or twice weekly dose but **DO NOT** try to make up for a missed dose by taking more than one dose a day.

This information cannot cover all the possible uses, actions, precautions, side effects, or interactions of this medicine. However, it is very important that you report development of any of the following to your physician or nurse **AS SOON AS POSSIBLE**:

- fever
- changes in vision; clumsiness or unsteadiness;
- numbness, tingling burning, or pain in hands or feet;
- yellowing of eyes or skin;
- unusual tiredness or weakness;
- changes in emotions or behaviors
- abdominal pain
- dark urine
- loss of appetite;
- nausea or vomiting;
- itchy skin rash;
- joint pains;

If you develop any of these symptoms while taking INH tell your nurse or physician **IMMEDIATELY!** If you cannot reach your physician or nurse immediately, stop taking the medication until you are able to obtain medical advice.

You must be monitored regularly while taking this medication. When you start on INH, your nurse or physician will tell you how often you will be monitored. Be sure to keep your appointments. It is important that the nurse or physician see you frequently. These appointments give nurses and physicians an opportunity to follow you for signs of TB disease and for evidence of medication side effects, so that they can act quickly if the infection is not controlled, or if side effects develop.

If you have any questions about taking INH, please talk to the nurse or physician at your designated clinic area.

RIFAMPIN FACT SHEET

You have been prescribed Rifampin, an antibiotic for treating or preventing active tuberculosis (TB). Rifampin is almost always given with one or more other medicines for TB. This medication needs to be taken **ONLY** as directed by the physician or nurse.

Before using this medicine, be sure to tell your physician or nurse about:

- Previous allergies to this or any other medication
- Early pregnancy (your doctor will make a decision about whether or not you may take this medication at this time**)**
- Other prescription or non-prescription medication you are taking, especially cortisone-like medicines (steroids), digitalis (heart medicine), methadone, oral anticoagulants (blood thinner), oral contraceptives (birth control pills), diabetes pills, quinidine (heart medicine), theophylline (asthma medication), barbiturates (seizure medicine) or Valium (tranquilizer or seizure medicine)
- Other medical problems, especially alcoholism or liver disease

Let your nurse or physician know so that he or she can decide if Rifampin is appropriate for you.

Take Rifampin with a full glass of water on an empty stomach either 1 hour before or 2 hours after a meal. However, if this medicine upsets your stomach your physician may suggest taking it with meals. To eliminate the TB bacteria from your body, it is very important that you keep taking this medicine for the **FULL** period of treatment. **DO NOT** stop the medicine without contacting your physician or nurse. Try not to miss your regular dose but **DO NOT** take more than one dose daily to make up for a missed dose.

Rifampin will cause the urine, stool, saliva, sputum, sweat, and tears to turn reddish orange to reddish brown. This is to be expected while you are taking this medicine. Soft contact lenses may be permanently discolored and should not be worn during the period of use of Rifampin. Hard contact lenses are not affected. Oral contraceptives (birth control pills) may not work as well while you are taking Rifampin, and unplanned pregnancies may occur. Women taking birth control pills may wish to consult with the physician for a different means of birth control while taking this medicine.

This information cannot cover all the possible uses, actions, precautions, side effects, or interactions of this medicine. Although most people do not experience any side effects from Rifampin, except for a change in urine color, side effects may occur. It is very important that you report any of the following to your physician or nurse **AS SOON AS POSSIBLE**: fever; difficult breathing; muscle, joint, or bone pain; itchy skin rash; abdominal pain; loss of appetite; nausea or vomiting; diarrhea; tiredness or weakness; changes in emotions or behavior; decreased urination or amount of urine.

If you develop any of these symptoms while taking Rifampin, tell your nurse or physician **IMMEDIATELY!** If you are unable to reach your physician or nurse, stop taking this medicine until you are able to obtain medical advice.

You must be medically monitored regularly while taking this medication. When you start on Rifampin, your nurse or physician will tell you how often you will be monitored. Be sure to keep your appointments. It is important that the nurse or physician see you frequently. These appointments give nurses and physicians an opportunity to follow you for signs of TB disease and for evidence of medication side effects, so that they can act quickly if the infection is not controlled, or if side effects develop.

If you have any questions about taking Rifampin, please talk to the nurse or physician at your designated clinic area

ETHAMBUTOL FACT SHEET

You have been prescribed Ethambutol, an antibiotic for treating or preventing active tuberculosis (TB). Ethambutol is almost always given with one or more other medicines for TB. This medication needs to be taken **ONLY** as directed by the physician or nurse.

Before using this medicine, be sure to tell your physician or nurse about:

- Previous allergies to this or any other medication
- Early pregnancy (your doctor will make a decision about whether or not you may take this medication at this time**)**
- Other prescription or non-prescription medications you are taking
- Other medical problems, especially eye nerve damage, or other eye disease, kidney disease, or gout

Let your nurse or physician know so that he or she can decide if Ethambutol is appropriate for you.

Ethambutol may be taken with food or on an empty stomach with a glass or water. To eliminate the TB bacteria from your body, it is very important that you keep taking this medicine for the **FULL** period of treatment. **DO NOT** stop the medicine without contacting your physician or nurse. Try not to miss your regular dose but **DO NOT** take more than one dose daily to make up for a missed dose.

This information cannot cover all the possible uses, actions, precautions, side effects, or interactions of this medicine. However, it is very important that you report development of any of the following to your physician or nurse **AS SOON AS POSSIBLE**. Changes such as:

- Blurring or loss of vision
- Eye pain
- Color blindness
- Numbness in hands or feet
- Tingling burning, or pain in hands or feet
- Itchy skin rash

If you develop any of these symptoms while taking Ethambutol tell your nurse or physician **IMMEDIATELY!**

You must be monitored regularly while taking this medication. When you start on Ethambutol, your nurse or physician will tell you how often you will be monitored. Be sure to keep your appointments. It is important that the nurse or physician see you frequently. These appointments give nurses and physicians an opportunity to follow you for signs of TB disease and for evidence of medication side effects, so that they can act quickly if the infection is not controlled, or if side effects develop.

If you have any questions about taking Ethambutol, please talk to the nurse or physician at your designated clinic area.

PYRAZINAMIDE FACT SHEET

You have been prescribed to take Pyrazinamide which is an antibiotic agent for treating or preventing active tuberculosis (TB) and is almost always given with one or more other medicines for TB. This medication needs to be taken **ONLY** as directed by the physician or nurse.

Before using this medicine, be sure to tell your physician or nurse about:

- Previous allergies to this or any other medication
- Early pregnancy (your doctor will make a decision about whether or not you may take this medication at this time**)**
- Other prescription or non-prescription medication you are taking
- Other medical problems you may have, especially eye nerve damage, or other eye disease, kidney disease, or gout

Let your nurse or physician know so that he or she can decide if Pyrazinamide is appropriate for you.

Pyrazinamide may be taken with food or on an empty stomach with a glass or water. To eliminate the TB bacteria from your body, it is very important that you keep taking this medicine for the **FULL** period of treatment. **DO NOT** stop the medicine without contacting your physician or nurse. Try not to miss your daily dose but **DO NOT** take more than one dose daily to make up for a missed dose.

This information cannot cover all the possible uses, actions, precautions, side effects, or interactions of this medicine. However, it is very important that you report development of any of the following to your physician or nurse **AS SOON AS POSSIBLE**:

- dark urine
- loss of appetite
- nausea and vomiting
- joint paint and/or swelling
- yellowing of eyes or skin
- unusual tiredness or weakness
- skin rash

If you develop any of these symptoms while taking Pyrazinamide tell your nurse or physician **IMMEDIATELY!**

You must be monitored regularly while taking this medication. When you start on Pyrizinamide, your nurse or physician will tell you how often you will be monitored. Be sure to keep your appointments. It is important that the nurse or physician see you frequently. These appointments give nurses and physicians an opportunity to follow you for signs of TB disease and for evidence of medication side effects, so that they can act quickly if the infection is not controlled, or if side effects develop.

If you have any questions about taking Pyrazinamide, please talk to the nurse or physician at your designated clinic area.

State of California **Department of Corrections and Rehabilitation**

Memorandum

Date :

SAMPLE MEMORANDUM

To :

Subject : **CONTINUATION OF ANTI-TUBERCULOSIS THERAPY**

Inmate Name: _____ CDCR#: _____ DOB: _____

The above inmate has a positive tuberculin skin test. The chest x-ray did not indicate active tuberculosis disease. On _____, 20___, the inmate was started on Isoniazid (INH) _____milligrams (mg) and vitamin B6 ____mg ☐ daily ☐ twice weekly *(check one)* for _____months.

_____The inmate was not started on medications prior to transfer/parole.

The inmate was also placed on the following medications:

_____

_____

_____

The inmate was transferred/paroled to your institution/Parole Region on _____ .
(Date)

If you need any further information, contact me at _____.
(Phone Number)

_____ _____
(Signature – Public Health Nurse or Designee) ***(Title)***

Institution Name: _____

Address: _____

_____

cc: ☐ Receiving Institution
☐ Unit Health Record

State of California **Department of Corrections and Rehabilitation**

Memorandum

Date :

To : Warden
Health Care Manager
Chief Medical Officer, Medical and Public Health Section, DCHCS

Subject : **SUMMARY REPORT OF CASE CONTACT INVESTIGATION**

The following is a summary report of: *(check one)* ☐Phase I, ☐Phase II, ☐ Final contact investigation on inmate: _____ _____
Name **CDCR #**

Index Case Housing Unit: *(check one)* ☐gym, ☐single cell, ☐dorm, ☐other _____

	Initial/Phase I	**10-12 Weeks**
# of Total Inmate Contacts Identified		
# of Inmate Close Contacts Identified		
# of Inmate Contacts Identified with HIV/immunosuppression		
# of Inmate Contacts Remaining at Institution		
# of Inmate Contacts Identified With Prior Positive TB Infection/Disease		
Total # of Inmates given Tuberculin Skin Test (TST)		
# of Inmates Received Hepatitis Screen and Liver Tests ***(should be all close contacts)***		
# of Inmates Having CXR ***(should be all close contacts)***		
# of Inmate New TB Suspects Identified/Isolated		
# of Inmate New Converters		
# of Inmate Close Contacts Started on Preventive Rx ***(should be all close contacts)***		
# of HIV-infected Inmate Contacts Started on Preventive Rx ***(should be all close and nearby contacts)***		
# of Inmates with Negative TST		
# of Inmates Refusing Preventive Rx		
# of Inmates Paroled (Attach names, CDC#s, parole region/unit and send to CMO, MPHP, DCHCS)		
# of Inmates Transferred to Other Institutions. (Attach list with names, CDC#s, and names of receiving institutions and send to PHS)		
# of Inmates with HIV/immunosuppression transferred or paroled (Attach names, CDCR#s, where transferred or paroled, send to PHC)		
# of Inmate Close Contacts Completing 2 months Preventive Rx		
# of Employee Contacts Identified		
# of Employees with Completed TST/Evaluation		
# of Employee New Converters		
# of Employees with TB Disease		

Phase II (or Final Report) due on:**(date)** _____

Health Care Manager, Warden notified of non-compliant employees on: **(date)** _____

Name, Title_____Institution_____Phone #_____

CONTACT INVESTIGATION CHECKLIST Date: _____

1.	☐	Immediately put a surgical mask on the inmate, and N95 masks on yourself and other nearby staff.
2.	☐	Interview the inmate case/suspect, as soon as possible -- prior to leaving for isolation if possible. Counsel the inmate to have HIV testing.
3.	☐	Inmate placed into respiratory isolation immediately.
4.	☐	Schedule a meeting as soon as possible with investigation team, to include at a minimum, the Public Health staff, Warden, HCM/CMO, SRN, PHN, SMTA, HSO or RTW coordinator, CCPOA representative. Take minutes at the meeting and fax them to the CMO, MPHP, DCHCS, at (916) 327-2465.
5.	☐	Schedule repeat meetings to update progress of investigation. Dates: _____ _____ _____ _____
6.	☐	Establish list of various responsibilities, names of responsible persons, dates to complete tasks, and report back to team.
7.	☐	Fax the **Correctional Facility TB Patient Plan** *(CFTP, Attachment 9)* to notify the Local County Health Officer (LCHO) of the jurisdiction housing the institution who identified the inmate with suspected or active TB, **within one working day of identification.**
8	☐	Fax the **CFTP to the CMO, MPHP, DCHCS within one working day of identification of the inmate TB suspect or confirmed case.** Include all TB-related laboratory results, HIV results (if any) and CXR reports.
9.	☐	Begin investigation within 72 hours of identification of the inmate suspect/case. **Do not wait for confirmation of *M tb* before initiating a contact investigation.**
10.	☐	Determine dates and to the extent of stopping inmate movement. The **CMO, MPHP, DCHCS, has legal authority and must be contacted if institutional movement needs to be stopped.** The request is called to the CMO, MPHP, DCHCS and to the Health Care Placement Unit, in conjunction with notification to the warden. **The CMO of the institution may request, in conjunction with the warden, that a single building or a yard be closed to movement, if that is all that is necessary.**
11.	☐	Review the Unit Health Record of index case within 24 hours to obtain pertinent information regarding TB.
12.	☐	Identify the period of infectivity, using eight weeks prior to onset of symptoms or clinical evidence of illness as the beginning date. Use the date when the contact is broken and/or the inmate is isolated as the end of infectivity. **ALWAYS include the period when the inmate had a cough, even if it was not initially recognized as suspected active TB disease.**
13.	☐	Obtain the movement history and identify all areas where the inmate suspect/case was housed during period of infectivity, within one week of starting the investigation; contact Information Systems Division (916) 358-3382 for printout of movements.
14.	☐	Verify inmate suspect/case cellmates, work assignments, school attendance, visitors, recreational activities to determine contacts, within one week of starting the investigation.
15.	☐	Identify and report names and addresses of visitors to LCHO, within ten days of starting the investigation.
16.	☐	Identify close and casual contacts. Prioritize contacts into high risk vs. low risk contacts, and do the TST and/or TB evaluation of high-risk contacts first.
17.	☐	**Evaluate all close contacts for TB symptoms regardless of TST results.**

18.	☐	All known HIV infected inmates must receive evaluation for signs and symptoms of TB disease; TST; and a CXR within 24 hours of their identification. They must also have a hepatitis screen and liver function tests drawn.
19.	☐	All close contacts must receive evaluation for signs and symptoms of TB disease; TST if previously negative; hepatitis screen; liver function tests; and a CXR within 7 working days of their identification.
20.	☐	Establish a list of exposed employees and deliver notification memos *(Attachment 23)* to Personnel within ten days of starting the investigation; note date delivered. Notification memo to include the date and place of employee testing/evaluation.
21.	☐	Refer employees requiring further evaluation and/or follow-up with Worker's Compensation to the HSO and/or RTW Coordinator.
22.	☐	Employees with new TST conversions will be assisted by the HSO or RTW coordinator to complete the State Compensation Insurance Fund (SCIF) form 3301, *Employer's Claim for Workers' Compensation Benefits,* and forward to their supervisor.
23.	☐	The HSO or RTW coordinate will complete the Cal/OSHA 200 log for new employee converters or those who have signs or symptoms of active TB.
24.	☐	Establish a list of inmates who paroled prior to TST/evaluation with notification letters sent to LCHOs and to the Chief Psychiatrist of Parole Region within two weeks of the exposure *(Attachment 19).*
25.	☐	Establish list of inmates who transferred prior to TST/evaluation with notification memos sent to CMO of receiving institutions and to the PHC, HCSD.
27.	☐	Phase I contacts are to be tested and evaluated within seven working days.
28.	☐	All close contacts of the index case, if there are no signs or symptoms of TB disease and if their CXRs are clear or stable, are offered preventive Rx, regardless of TSTs or prior TB therapy, within seven days of identification as a contact. All must be given medication information handouts. Treatment duration is nine months, except for patients in the following categories: *Negative TST*--all of the following criteria must be met before therapy may be stopped • Negative Initial TST • Negative repeat TST at 10-12 weeks • No signs or symptoms of TB disease • Negative HIV test Treatment may be terminated for TST negative close contacts who meet all of these criteria *Positive TST* – all of the following criteria must be met before therapy can be stopped • A previously positive TST documented in millimeters (mm) • An initial contact investigation TST less than 5mm larger than the previously documented TST • A repeat TST 10-12 weeks after the initial contact investigation, that is less than 5mm larger than the initial contact investigation TST • Contact has completed a course of treatment for LTBI • Contact is free of signs and symptoms of disease • Contact is HIV negative Treatment may be terminated for TST positive close contacts who meet all of these criteria

29.	☐	All close contacts to index case who refuse treatment must sign CDC Form 7225/7338 *(Attachment 7).* They must be evaluated monthly for at least for six months. An alternative plan can be discussed with the CMO, MPHP, DCHCS.
30.	☐	After CMO/HCM review, send a list of employees who are not compliant with Phase I investigation within two weeks of the exposure to the Warden.
31.	☐	Send a summary report of Phase I *(Appendix 26)* to PHC, CSSU, DCHCS within two weeks of the exposure, including copies of TB-related CXR reports, HIV-testing, and sputum smears, cultures and sensitivities.
32.	☐	Phase II is initiated 10-12 weeks after Phase I. Re-test and/or evaluate all employee and inmate contacts.
33.	☐	Send a list of employees who are not compliant with Phase II investigation within two weeks of notification to the LCHO of the jurisdiction where employee lives, and to the Warden.
34.	☐	Send a summary report of Phase II to CMO, MPHP, DCHCS *(Appendix 26)* by two weeks after Phase II is completed, and no later than four months after the initial exposure.
35.	☐	After a final discussion with CMO, MPHP, DCHCS, terminate the contact investigation, when there is a lack of evidence for ongoing TB transmission.

State of California **Department of Corrections and Rehabilitation**

Memorandum

Date :

To : Employee

Home Address

Subject : **POSSIBLE EXPOSURE TO TUBERCULOSIS**

During the performance of your duties as an employee for the California Department of Corrections and Rehabilitation (CDCR) you may have been exposed to an active case of tuberculosis (TB). The exposure took place during the time period between _____ to_____ . You have
(Date) **(Date)**

been identified as working in the area of exposure or having contact with the infectious inmate at:

_____
(Location)

You must be evaluated and/or tested within two weeks of receipt of this notice. Contact the health care staff to arrange for the evaluation and/or tuberculin skin testing (TST). If you have had a documented prior positive reaction to the skin test, please inform the health care staff of this fact when you report to them. After the TST is administered you must return in two days to have it read. It may be necessary for you to have a repeat evaluation and/or TST in 10 to 12 weeks.

If you test newly positive (5 mm or greater) or have signs and/or symptoms of TB, you will be scheduled for a CXR. You may elect to see the institution's health care provider (30-day treater) at no cost to you, or your private physician (at your cost). Please coordinate this with the institution's Health and Safety Office/Return to Work Coordinator to ensure proper documentation is completed.

Your cooperation in this manner is necessary to ensure that all concerned receive proper attention. Failure to report for evaluation or provide proper documentation of evaluation may be a basis for dismissal from CDCR employment.

If you have any questions, please contact: _____
Name of Contact Person and Phone Number

Public Health Nurse (Designee/Title): _____

Location/Institution: _____

cc: Original to Employee
Employee's Confidential Health Record

STATE OF CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION

TUBERCULOSIS CONTACT INVESTIGATION REPORT – EMPLOYEE CONTACTS

INDEX CASE INFORMATION					
CDCR NUMBER	INDEX CASE NAME	INSTITUTION	PREPARED BY	PHONE NUMBER	DATE

INDEX CASE MOVEMENT HISTORY							
INSTITUTION	ROOM#	ARRIVAL DATE	DEPARTURE DATE	INSTITUTION	ROOM#	ARRIVAL DATE	DEPARTURE DATE

EMPLOYEE CONTACTS INVESTIGATED								
EMPLOYEE NAME	JOB LOCATION	DATE 1ST TST	1ST TST RESULT	DATE 2ND TST	2ND TST RESULT	SYMPTOMS (Y OR N)	CXR (N OR ABN)	CLASS (0,1,2,3,4,5)

CDCR 7328B Rev. July 2005

TUBERCULOSIS CONTACT INVESTIGATION REPORT – EMPLOYEE CONTACTS

EMPLOYEE CONTACTS INVESTIGATED								
EMPLOYEE NAME	JOB LOCATION	DATE 1ST TST	1ST TST RESULT	DATE 2ND TST	2ND TST RESULT	SYMPTOMS (Y OR N)	CXR (N OR ABN)	CLASS (0,1,2,3,4,5)

CDCR 7328B Rev. July 2005

STATE OF CALIFORNIA **TUBERCULOSIS CONTACT INVESTIGATION REPORT – VISITORS** DEPARTMENT OF CORRECTIONS AND REHABILITATION

CDCR 7328A Rev.07/05 Page __ of _____

INDEX CASE INFORMATION					
CDC NUMBER	INDEX CASE NAME	INSTITUTION	PREPARED BY	PHONE NUMBER	DATE

INDEX CASE MOVEMENT HISTORY							
INSTITUTION	ROOM#	ARRIVAL DATE	DEPARTURE DATE	INSTITUTION	ROOM#	ARRIVAL DATE	DEPARTURE DATE

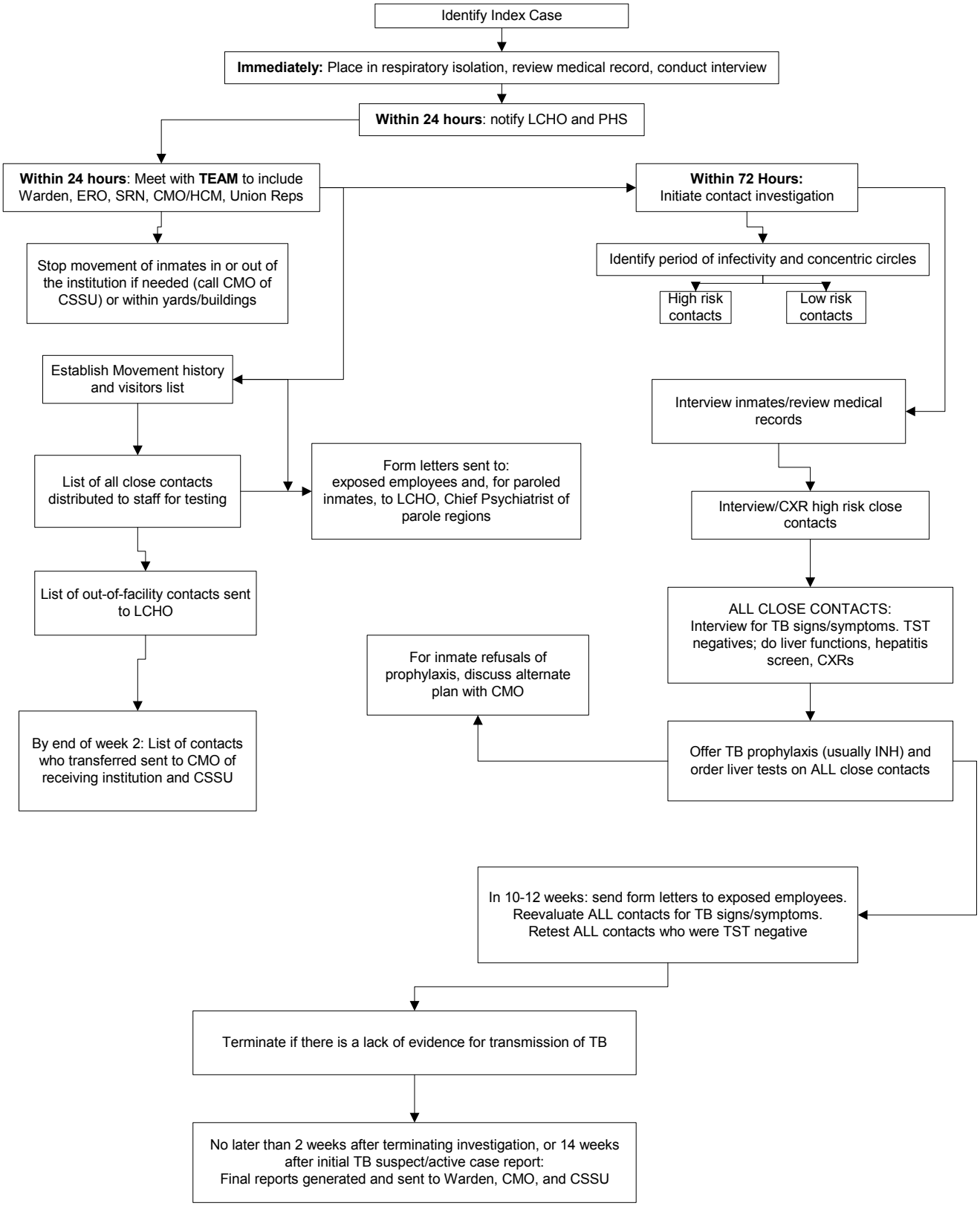
VISITOR CONTACTS INVESTIGATED			
NAME	HOME ADDRESS	DATE MEMO SENT TO LOCAL COUNTY HEALTH OFFICER	TB DISEASE CLASS (IF KNOWN)

STATE OF California **TUBERCULOSIS CONTACT INVESTIGATION REPORT – VISITORS** DEPARTMENT OF CORRECTIONS AND REHABILITATION

CDCR 7328A R07/05 Page __ of _____

VISITOR CONTACTS INVESTIGATED			
NAME	HOME ADDRESS	DATE MEMO SENT TO LOCAL COUNTY HEALTH OFFICER	TB DISEASE CLASS (IF KNOWN)

DIVISION OF CORRECTIONAL HEALTH CARE SERVICES
CLINICAL SUPPORT SERVICES UNIT CONTACT INVESTIGATION ALGORITHM



COUNTY HEALTH DEPARTMENT APPOINTMENT NOTIFICATION

From: _____ County Health Department

To: _____ Chief Psychiatrist of Parole Region _____
(name, if known) **Region 1, 2, 3, 4**

Street/Mailing Address, City, Zip: _____

_____

Phone Number: _____ FAX Number: _____

_____ _____ _____
Client Name **Date of Birth** **Social Security Number**

Appointment scheduled for (date): _____ at (time): _____

at _____ Local County Health Department. Clinic Phone Number: _____

Clinic address: _____

☐ Appointment kept Next Appointment scheduled (date and time) _____

☐ Appointment not kept. ***Please ensure client reschedules appointment immediately.***

Comments: _____

_____

_____

_____

Name: _____ Date: _____

Title: _____ Institution: _____

Phone Number: _____ FAX Number: _____

cc: ☐ Parole Agent (Name if known), Address, Phone No., FAX No.; or Regional Parole Office

☐ Inmate

☐ Chief Medical Officer, Medical and Public Health Programs, Division of Correctional Health Care Services, Department of Corrections and Rehabilitation, PO Box 942883, Sacramento, CA 94283-0001

State of California **Department of Corrections and Rehabilitation**

Memorandum

CONFIDENTIAL

Date :

To : Chief Medical Officer/Public Health Designee OR
Chief Psychiatrist of Parole Region, and
Local County Health Officer of Parole Region

Address

Subject : **POSSIBLE EXPOSURE TO TUBERCULOSIS DISEASE**

The inmate(s)/parolee(s) listed below was/were **transferred/paroled to your institution/region on** _____ (Date) . The individual(s) had: ☐ **close**, ☐ **moderate,** ☐ **casual exposure from** _____ (Date) **to** _____ (Date) to suspect/active tuberculosis with an **infectious period from** _____ (Date) **to** _____ (Date) **.** Please arrange to have the individual(s) evaluated/tested for tuberculosis infection. The individual(s) who are evaluated or test negative shall have a repeat evaluation or test in 10 to 12 weeks. Please notify us of the individual(s) initial and repeated evaluations/tests.

Last Name	First Name	Date of Birth	CDC #	Soc Sec #	Parole Office Address

For further information contact:
Name: _____ Phone Number: _____

Public Health Nurse or Designee: _____ Title: _____

Institution, Address: _____

Phone Number: _____ Fax Number: _____

PAROLE/DISCHARGE NOTIFICATION LETTER

Date: _____

To: ☐ Local County Health Officer (Name): _____

Address: _____

☐ Parole Agent (Name): _____

Address: _____

☐ Chief Medical Officer (CMO), Medical and Public Health Programs (MPHP), Division of Correctional Health Care Services (DCHCS): Fax: (916) 327-2476 Phone: (916) 324-7679

Inmate: _____
Full Last, First, Middle Name

AKAs:_____

CDCR Number: _____Date of Birth: _____

SSN: _____Parole/Discharge Date: _____

Address: _____

Phone Number: _____

Next of Kin/Address: _____

_____ Phone Number:_____

Medications have been supplied for ___ weeks. Total course to be completed by _____
(Date)

Medical Appointment scheduled at County Health Department on _____
(Date and Time)

If you have any questions regarding this information, please contact:

Name/Title:_____Phone No.: _____

Institution:_____FAX No.: _____

Street/mailing address: _____

City/State/Zip:_____

cc: Inmate
Inmate Medical Record

Enclosures: with LCHO & PHC copies: ***only*** ☐ *Correctional Facility Written Treatment Plan*

with LCHO, PHC, and Chief Psychiatrist of Parole copies ***only***
☐ *Notice of Requirement to Participate in Follow-UpTreatment*

NOTICE OF REQUIREMENT TO PARTICIPATE IN FOLLOW-UP TUBERCULOSIS TREATMENT

Date_____

_____ _____
Inmate Name CDCR #

If you are currently taking medications for active or suspected active tuberculosis (TB), you need to continue taking your medication and continue to be evaluated by health care professionals until they determine you are cured of TB disease. Failure to adhere to this mandate is a violation of *Penal Code* Section 3053* and may result in a revocation of your parole. You must:

☐ Take your anti-TB medication as ordered, and

☐ Keep all medical appointments for TB care until the local county health officer determines you are cured of TB disease.

The following appointment has been scheduled for you at the Local County Health Department. If you have any questions, please call the listed phone number.

Address: _____

Date and Time: _____ Phone Number: _____

Your Parole Agent will be notified of the date and place of this appointment.

It is your responsibility to keep the appointment to be evaluated and obtain your anti-TB medications.

The information above as initialed was discussed with me, and I understand I am being directed to keep the above appointment

_____ _____
Inmate Signature Date

_____ _____
Witness Signature Date

_____ _____
Name and Title Institution

_____ _____
Signature Date

cc: ☐ Inmate Medical File ☐ Inmate ☐ LCHO
☐ Chief Psychiatrist of Parole Region ☐ PHC, CSSU

*3053. (a) The Board of Prison Terms upon granting any parole to any prisoner may also impose on the parole any conditions that it may deem proper.
(b) The Board of Prison Terms may impose as a condition of parole that any prisoner granted parole undergo an examination or test for tuberculosis when the board reasonably suspects that the parolee has, has had, or has been exposed to, tuberculosis in an infectious stage.
(c) For purposes of this section, an "examination or test for tuberculosis" means testing and followup examinations or treatment according to the Centers for Disease Control and American Thoracic Society recommendations in effect at the time of the initial examination.

CALIFORNIA HEALTH AND SAFETY CODE
SECTIONS 121350–121460

121350 *The department shall maintain a program for the control of tuberculosis. The department shall administer the funds made available by the state for the care of tuberculosis patients.*

121355 *Notwithstanding any other provision of this chapter a county that has elected to come under Section 14150.1 of the Welfare and Institutions Code shall not receive any tuberculosis subsidy or reimbursement from the state under the provisions of this chapter.*

121357 *The state department shall be the lead agency for all tuberculosis control and prevention activities at the state level.*

121358 *(a) Notwithstanding any other provision of law, individuals housed or detained through the tuberculosis control, housing, and detention program shall not reside in correctional facilities, and the funds available under that program with regard to those individuals shall not be disbursed to, or used by, correctional facilities. This section shall not be interpreted to prohibit the institutionalization of criminals with tuberculosis in correctional facilities.*

(b) The department shall work with local health jurisdictions to identify a detention site for recalcitrant tuberculosis patients appropriate for each local health jurisdiction in the state. The department shall notify all counties of their designated site by January 1, 1998.

121360 *Pulmonary tuberculosis is an infectious and communicable disease, dangerous to the public health, and all proper expenditures that may be made by any county, pursuant to this chapter, are necessary for the preservation of the public health of the county.*

121360.5 *SECTION 1. It is the intent of the Legislature only to extend the authorization, as amended by this act, for local health departments to certify tuberculin skin test technicians to place and measure tuberculin skin tests.*

(b) It is not the intent of the Legislature to make tuberculin skin test technicians responsible for followup or completion of therapy for tuberculosis patients.

SECTION 2. Section 121360.5 of the Health and Safety Code is amended to read:

121360.5 *(a) Any city or county health department that elects to participate in this program shall provide for one-year certification of tuberculin skin test technicians by local health officers.*

(b) For purposes of this section, a "certified tuberculin skin test technician" is an unlicensed public health tuberculosis worker employed by, or under contract with, a local public health department, and who is certified by a local health officer to place and measure skin tests in the local health department's jurisdiction.

(c) A certified tuberculin skin test technician may perform the functions for which he or she is certified only if he or she meets all of the following requirements:

(1) The certified tuberculin skin test technician is working under the direction of the local health officer or the tuberculosis controller.

(2) The certified tuberculin skin test technician is working under the supervision of a licensed health professional. For purposes of this section, "supervision" means the licensed health professional is immediately available for consultation with the tuberculin skin test technician through telephonic or electronic contact.

(d) A certified tuberculin skin test technician may perform intradermal injections only for the purpose of placing a tuberculin skin test and measuring the test result.

(e) A certified tuberculin skin test technician may not be certified to interpret, and may not interpret, the results of a tuberculin skin test.

(f) In order to be certified as a tuberculin skin test technician by a local health officer, a person shall meet all of the following requirements, and provide to the local health officer appropriate documentation establishing that he or she has met those requirements:

(1) The person has a high school diploma, or its equivalent.

(A) The person has completed a standardized course approved by the California Tuberculosis Controllers Association (CTCA), which shall include at least 24 hours of instruction in all of the following areas: Didactic instruction on tuberculosis control principles and instruction on the proper placement and measurement of tuberculin skin tests, equipment usage, basic infection control, universal precautions, and appropriate disposal of sharps, needles, and medical waste, client preparation and education, safety, communication, professional behavior, and the importance of confidentiality.

(B) A certification of satisfactory completion of this CTCA-approved course shall be dated and signed by the local health officer, and shall contain the name and social security number of the tuberculin skin test technician, and the printed name, the jurisdiction, and the telephone number of the certifying local health officer.

(3) The person has completed practical instruction including placing at least 30 successful intradermal tuberculin skin tests, supervised by a licensed physician or registered nurse at the local health department, and 30 correct measurements of intradermal tuberculin skin tests, at least 15 of which are deemed positive by the licensed physician or registered nurse supervising the practical instruction. A certification of the satisfactory completion of this practical instruction shall be dated and signed by the licensed physician or registered nurse supervising the practical instruction

(g) The certification may be renewed, and the local health department shall provide a certificate of renewal, if the certificate holder has completed in-service training, including all of the following:

(1) At least three hours of a CTCA-approved standardized training course to assure continued competency. This training shall include, but not be limited to, fundamental principles of tuberculin skin testing.

(2) Practical instruction, under the supervision of a licensed physician or registered nurse at the local health department, including the successful placement and correct measurement of 10 tuberculin skin tests, at least five of which are deemed positive by the licensed physician or registered nurse supervising the practical instruction.

(h) The local health officer or the tuberculosis controller may deny or revoke the certification of a tuberculin skin test technician if the local health officer or the tuberculosis controller finds that the technician is not in compliance with this section.

(i) Each county or city participating in the program under this section using tuberculin skin test technicians, that elects to participate on or after January 1, 2005, shall submit to the CTCA a survey and an evaluation of its findings, including a review of the aggregate report, by July 1, 2006, and by July 1 of each year thereafter to, and including, July 1, 2011. The report shall include the following:

(1) The number of persons trained and certified as tuberculin skin test technicians in that city or county.

(2) The estimated number of tuberculin skin tests placed by tuberculin skin test technicians in that city or county.

(j) By July 1, 2008, the CTCA shall submit a summary of barriers to implementing the tuberculosis technician program in the state to the department and to the appropriate policy and fiscal committees of the Legislature.

(k) The local health officer of each participating city or county shall report to the Tuberculosis Control Branch within the department any adverse event that he or she determines has resulted from improper tuberculin skin test technician training or performance.

(l) (1) This section, except subdivision (i), shall remain operative only until January 1, 2011.

(2) This section shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date.

121361 *(a) (1) A health facility, local detention facility, or state correctional institution shall not discharge or release any of the following persons unless subdivision (e) is complied with:*

(A) A person known to have active tuberculosis disease.

(B) A person who the medical staff of the health facility or of the penal institution has reasonable grounds to believe has active tuberculosis disease.

(2) In addition, persons specified in this subdivision may be discharged from a health facility only after a written treatment plan described in Section 121362 is approved by a local health officer of the jurisdiction in which the health facility is located. Treatment plans submitted for approval pursuant to this paragraph shall be reviewed by the local health officer within 24 hours of receipt of the plans.

(3) The approval requirement of paragraph (2) shall not apply to any transfer to a general acute care hospital when the transfer is due to an immediate need for a higher level of care, nor to any transfer from any health facility to a correctional institution. Transfers or discharges described in this paragraph shall occur only after the notification and treatment plan required by Section 121362 have been received by the local health officer.

(4) This subdivision shall not apply to transfers within the state correctional system or to interfacility transfers occurring within a local detention facility system.

(b) No health facility shall transfer a person described in subparagraph (A) or (B) of paragraph (1) of subdivision (a) to another health facility unless subdivision (e) is complied with. This subdivision shall not apply to transfers within the state correctional system or to interfacility transfers occurring within a local detention facility system.

(c) No state correctional institution or local detention facility shall transfer a person described in subparagraph (A) or (B) of paragraph (1) of subdivision (a) from a state to a local, or from a local to a state, penal institution unless notification and a written treatment plan are received by the chief medical officer of the penal institution receiving the person.

(d) No local detention facility shall transfer a person described in subparagraph (A) or (B) of paragraph (1) of subdivision (a) to a local detention facility in another jurisdiction unless subdivision (e) is complied with and notification and a written treatment plan are received by the chief medical officer of the local detention facility receiving the person.

(e) (1) Any discharge, release, or transfer described in subdivisions (a), (b), (c), and (d) may occur only after notification and a written treatment plan pursuant to Section 121362 has been received by the local health officer. When prior notification would jeopardize the person's health, the public safety, or the safety and security of the penal institution, the notification and treatment plan shall be submitted within 24 hours of discharge, release, or transfer.

(2) When a person described in paragraph (1) of subdivision (a) is released on parole from a state correctional institution, the notification and written treatment plan specified in this

subdivision shall be provided to both the local health officer for the county in which the parolee intends to reside and the local health officer for the county in which the state correctional institution is located.

(3) Notwithstanding any other provision of law, the Department of Corrections shall inform the parole agent, and other parole officials as necessary, that the person described in paragraph (1) of subdivision (a) has active or suspected active tuberculosis disease and provide information regarding the need for evaluation or treatment. The parole agent and other parole officials shall coordinate with the local health officer in supervising the person's compliance with medical evaluation or treatment related to tuberculosis, and shall notify the local health officer if the person' s parole is suspended as a result of having absconded from supervision.

(f) No health facility that declines to discharge, release, or transfer a person pursuant to this section shall be civilly or criminally liable or subject to administrative sanction therefore. This subdivision shall apply only if the health facility complies with this section and acts in good faith.

(g) Nothing in this section shall relieve a local health officer of any other duty imposed by this chapter.

121362 *Each health care provider who treats a person for active tuberculosis disease, each person in charge of a health facility, or each person in charge of a clinic providing outpatient treatment for active tuberculosis disease shall promptly report to the local health officer at the times that the health officer requires, but no less frequently than when there are reasonable grounds to believe that a person has active tuberculosis disease, and when a person ceases treatment for tuberculosis disease. Situations in which the provider may conclude that the patient has ceased treatment include times when the patient fails to keep an appointment, relocates without transferring care, or discontinues care. The initial disease notification report shall include an individual treatment plan that includes the patient name, address, date of birth, tuberculin skin test results, pertinent radiologic, microbiologic, and pathologic reports whether final or pending, and any other information required by the local health officer. Subsequent reports shall provide updated clinical status and laboratory results, assessment of treatment adherence, name of current care provider if patient transfers care, and any other information required by the local health officer. A facility discharge, release, or transfer report shall include all pertinent and updated information required by the local health officer not previously reported on initial or subsequent reports, and shall specifically include verified patient address, the name of the medical provider who has specifically agreed to provide medical care, clinical information used to assess the current infectious state, and any other information required by the local health officer. Each health care provider who treats a person with active tuberculosis disease, and each person in charge of a health facility or a clinic providing outpatient treatment for active tuberculosis disease, shall maintain written documentation of each patient's adherence to his or her individual treatment plans. Nothing in this section shall authorize the disclosure of test results for human immunodeficiency virus (HIV) unless authorized by Chapter 7 (commencing with Section 120975) of, Chapter 8 (commencing with Section 121025) of, and Chapter 10 (commencing with Section 121075) of, Part 4, of Division 105. In the case of a parolee under the jurisdiction of the Department of Corrections, the local health officer shall notify the assigned parole agent, when known, or the regional parole administrator when there are reasonable grounds to believe that the parolee has active tuberculosis disease and when the parolee ceases treatment for tuberculosis. Situations where the local health officer may conclude that the parolee has ceased treatment include times when the parolee fails to keep an appointment, relocates without transferring care, or discontinues care.*

121363 *Each health care provider who treats a person for active tuberculosis disease shall examine, or cause to be examined, all household contacts or shall refer them to the local health officer for examination.*

Each health care provider shall promptly notify the local health officer of the referral. When required by the local health officer, nonhousehold contacts and household contacts not examined by a health care provider shall submit to examination by the local health officer or designee. If any abnormality consistent with tuberculosis disease is found, steps satisfactory to the local health officer shall be taken to refer the person promptly to a health care provider for further investigation, and if necessary, treatment. Contacts shall be reexamined at times and in a manner as the local health officer may require. When requested by the local health officer, a health care provider shall report the results of any examination related to tuberculosis of a contact.

121364 *(a) Within the territory under his or her jurisdiction, each local health officer may order examinations for tuberculosis infection for the purposes of directing preventive measures for persons in the territory, except those incarcerated in a state correctional institution, for whom the local health officer has reasonable grounds to determine are at heightened risk of tuberculosis exposure.*

(b) An order for examination pursuant to this section shall be in writing and shall include other terms and conditions as may be necessary to protect the public health.

121365. *Each local health officer is hereby directed to use every available means to ascertain the existence of, and immediately investigate all reported or suspected cases of active tuberculosis disease in the jurisdiction, and to ascertain the sources of those infections. In carrying out the investigations, each local health officer shall follow applicable local rules and regulations and all general and special rules, regulations, and orders of the state department. If the local health officer determines that the public health in general or the health of a particular person is endangered by exposure to a person who is known to have active tuberculosis disease, or to a person for whom there are reasonable grounds to believe has active tuberculosis disease, the local health officer may issue any orders he or she deems necessary to protect the public health or the health of any other person, and may make application to a court for enforcement of the orders. Upon the receipt of information that any order has been violated, the health officer shall advise the district attorney of the county in which the violation has occurred, in writing, and shall submit to the district attorney the information in his or her possession relating to the subject matter of the order, and of the violation or violations thereof. The orders may include, but shall not be limited to, any of the following:*

(a) An order authorizing the removal to, detention in, or admission into, a health facility or other treatment facility for appropriate examination for active tuberculosis disease of a person who is known to have active tuberculosis disease, or a person for whom there are reasonable grounds to believe that the person has active tuberculosis disease and who is unable or unwilling voluntarily to submit to the examination by a physician or by the local health officer. Any person whom the health officer determines should have an examination for tuberculosis disease may have the examination made by a physician and surgeon of his or her own choice who is licensed to practice medicine under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code under terms and conditions as the local health officer shall determine on reasonable grounds to be necessary to protect the public health. This section does not authorize the local health officer to mandate involuntary anergy testing.

(b) An order requiring a person who has active tuberculosis disease to complete an appropriate prescribed course of medication for tuberculosis disease and, if necessary, to follow required infection control precautions for tuberculosis disease. This subdivision does not allow the forceable or involuntary administration of medication.

(c) An order requiring a person who has active tuberculosis disease and who is unable or unwilling otherwise to complete an appropriate prescribed course of medication for tuberculosis disease to follow a course of directly observed therapy. This subdivision does not allow forceable or involuntary administration of medication.

(d) An order for the removal to, detention in, or admission into, a health facility or other treatment facility of a person if both of the following occur:

(1) The person has infectious tuberculosis disease, or who presents a substantial likelihood of having infectious tuberculosis disease, based upon proven epidemiologic evidence, clinical evidence, X-ray readings, or tuberculosis laboratory test results.

(2) The local health officer finds, based on recognized infection control principles, that there is a substantial likelihood the person may transmit tuberculosis to others because of his or her inadequate separation from others.

(e) An order for the removal to, detention in, or admission into, a health facility or other treatment facility of a person if both of the following occur:

(1) The person has active tuberculosis disease, or has been reported to the health officer as having active tuberculosis disease with no subsequent report to the health officer of the completion of an appropriate prescribed course of medication for tuberculosis disease.

(2) There is a substantial likelihood, based on the person's past or present behavior, that he or she cannot be relied upon to participate in or complete an appropriate prescribed course of medication for tuberculosis disease and, if necessary, follow required infection control precautions for tuberculosis disease. The behavior may include, but is not limited to, refusal or failure to take medication for tuberculosis disease, refusal or failure to keep appointments or treatment for tuberculosis disease, refusal or failure to complete the treatment for tuberculosis disease, or disregard for infection control precautions for active tuberculosis disease.

(f) An order for exclusion from attendance at the workplace for persons with infectious tuberculosis disease. The order may, also, exclude the person from any place when the local health officer determines that the place cannot be maintained in a manner adequate to protect others against the spread of tuberculosis disease.

(g) An order for isolation of persons with infectious tuberculosis disease to their place of residence until the local health officer has determined that they no longer have infectious tuberculosis disease.

(h) This section shall apply to all persons except those incarcerated in a state correctional institution.

(i) This section shall not be construed to require a private hospital or other private treatment facility to accept any patient without a payment source, including county responsibilities under Section 17000 of the Welfare and Institutions Code, except as required by Sections 1317 et seq. or by federal law.

121366 *The local health officer may detain in a hospital or other appropriate place for examination or treatment, a person who is the subject of an order of detention issued pursuant to subdivision (a), (d), or (e) of Section 121365 without a prior court order except that when a person detained pursuant to subdivision (a), (d), or (e) of Section 121365 has requested release, the local health officer shall make an application for a court order authorizing the continued detention within 72 hours after the request or, if the 72-hour period ends on a Saturday, Sunday, or legal holiday, by the end of the first business day following the Saturday, Sunday, or legal holiday, which application shall include a request for an expedited hearing. After the request for release, detention shall not continue for more than five business days in the absence of a court order authorizing detention. However, in no event shall any person be detained for more than 60 days without a court order authorizing the detention. The local health officer shall seek further court review of the detention within 90 days following the initial court order authorizing detention and thereafter within 90 days of each subsequent court review. In any court proceeding to enforce a local health officer's order for the removal or detention of a person, the local health officer shall prove the particularized circumstances constituting the necessity for the*

detention by clear and convincing evidence. Any person who is subject to a detention order shall have the right to be represented by counsel and upon the request of the person, counsel shall be provided.

121367 *(a) An order of a local health officer pursuant to Section 121365 shall set forth all of the following:*

(1) The legal authority under which the order is issued, including the particular sections of state law or regulations.

(2) An individualized assessment of the person's circumstances or behavior constituting the basis for the issuance of the order.

(3) The less restrictive treatment alternatives that were attempted and were unsuccessful, or the less restrictive treatment alternatives that were considered and rejected, and the reasons the alternatives were rejected.

(4) The orders shall be in writing, and shall include the name of the person, the period of time during which the order shall remain effective, the location, payer source if known, and other terms and conditions as may be necessary to protect the public health. Upon issuing an order, a copy of the order shall be served upon the person named in the order.

(b) An order for the detention of a person shall do all of the following:

(1) Include the purpose of the detention.

(2) Advise the person being detained that he or she has the right to request release from detention by contacting a person designated on the local health officer's order at the telephone number stated on the order and that the detention shall not continue for more than five business days after the request for release, in the absence of a court order authorizing the detention.

(3) Advise the person being detained that, whether or not he or she requests release from detention, the local health officer is required to obtain a court order authorizing detention within 60 days following the commencement of detention and thereafter shall further seek court review of the detention within 90 days of the court order and within 90 days of each subsequent court review.

(4) Advise the person being detained that he or she has the right to arrange to be represented by counsel or to have counsel provided, and that if he or she chooses to have counsel provided, the counsel will be notified that the person has requested legal representation.

(5) Be accompanied by a separate notice that shall include, but not be limited to, all of the following additional information:

(A) That the person being detained has the right to request release from detention by contacting a person designated on the local health officer's order at a telephone number stated on the order, and that the detention shall not continue for more than five business days after the request in the absence of a court order authorizing the detention.

(B) That he or she has the right to arrange to be advised and represented by counsel or to have counsel provided, and that if he or she chooses to have counsel provided, the counsel will be notified that the person has requested legal representation.

(C) That he or she may supply the addresses or telephone numbers of not more than two individuals to receive notification of the person's detention, and that the local health officer shall, at the patient's request, provide notice within the limits of reasonable diligence to those people that the person is being detained.

121368 *Notwithstanding any inconsistent provision of Section 121365, 121366 or 121367, all of the following shall apply:*

(a) A person who is detained solely pursuant to subdivision (a) of Section 121365 shall not continue to be detained beyond the minimum period of time required, with the exercise of all due diligence, to make a medical determination of whether a person who is suspected of having tuberculosis disease, has active tuberculosis or whether a person who has active tuberculosis disease has infectious tuberculosis disease. Further detention of the person shall be authorized only upon the issuance of a local health officer's order pursuant to subdivision (d) or (e) of Section 121365.

(b) A person who is detained solely for the reasons described in subdivision (d) of Section 121365 shall not continue to be detained after he or she ceases to be infectious or after the local health officer ascertains that changed circumstances exist that permit him or her to be adequately separated from others so as to prevent transmission of tuberculosis disease after his or her release from detention.

(c) A person who is detained for the reasons described in subdivision (e) of Section 121365 shall not continue to be detained after he or she has completed an appropriate prescribed course of medication.

121369 *For the purposes of Sections 121365, 121366, and 121367, all of the following shall apply:*

(a) If necessary, language interpreters and persons skilled in communicating with vision and hearing impaired individuals shall be provided in accordance with applicable law.

(b) Nothing in those sections shall be construed to permit or require the forcible administration of any medication without a prior court order.

(c) Any and all orders authorized under those sections shall be made by the local health officer. His or her authority to make the orders may be delegated to the person in charge of medical treatment of inmates in penal institutions within the local health officer's jurisdiction, or pursuant to Section 7. The local health officer shall not make any orders incorporating by reference any other rules or regulations.

121370 *No examination or inspection shall be required of any person who depends exclusively on prayer for healing in accordance with the teachings of any well recognized religious sect, denomination or organization and claims exemption on that ground, except that the provisions of this code regarding compulsory reporting of communicable diseases and isolation and quarantine shall apply where there is probable cause to suspect that the person is infected with the disease in a communicable stage. Such person shall not be required to submit to any medical treatment, or to go to or be confined in a hospital or other medical institution; provided, he or she can be safely quarantined and/or isolated in his or her own home or other suitable place of his or her choice.*

121375 *The department may inspect and have access to all records of all institutions and clinics, both public and private, where tuberculosis patients are treated.*

121380 *The department may advise officers of state educational, correctional, and medical institutions regarding the control of tuberculosis and the care of tuberculosis patients.*

121390 *The department shall lease any facilities it deems necessary to care for persons afflicted with active contagious tuberculosis who violate the quarantine or isolation orders of the health officer as provided in Section 120280.*

121395 *Whenever any person confined in any state institution, as provided in Section 120280, subject to the jurisdiction of the Director of Corrections, dies, and any personal funds or personal property of the person remains in the hands of the Director of Corrections, those funds may be applied in an amount not exceeding three hundred dollars ($300) to the payment of expenses relating to burial; provided, however, that if no such funds are available, the department shall reimburse the Director of Corrections for the expenses in an amount not exceeding three hundred dollars ($300).*

121400 *If the place of confinement of a person confined under the provisions of Section 120280 is in a county other than the county where he or she was convicted, upon release he or she shall be released in the custody of the sheriff of the county where he or she was convicted, and the sheriff shall forthwith return him or her to the place where he or she was convicted without the necessity of a court order or other process. The sheriff shall prior to the return of the person notify the health officer having jurisdiction of the area to which he or she will be returned of the date he or she will reach that area.*

121450 *The department may distribute for the purpose of tuberculosis control an annual subvention, paid quarterly, to any local health department that maintains a tuberculosis control program consistent with standards and procedures established by the department. This annual subvention shall be used primarily for the strengthening of tuberculosis prevention activities by local health departments. Further, the department may allocate additional funds to selected local health departments based on high disease incidence, or other standards established by the department. These additional funds shall be expended primarily for the cost of diagnosis, treatment, and followup services required for an effective tuberculosis control program. Services rendered under this section may not be made dependent on status of residence.*

121455 *The department may establish standards and procedures for the operation of local tuberculosis control programs. Such standards shall include, but not be limited to, the maintenance of records and reports relative to services rendered and to expenditures made that shall be reported semiannually to the department in a manner as it may specify.*

121460 *Of the annual appropriation made to the department for tuberculosis control, the department may expend a sum not to exceed 7.5 percent of the total, for administrative costs. In addition, it may, if it deems necessary, withhold a portion of the appropriation to pay for the cost of regional laboratory services and regional hospitalization facilities for patients whose care cannot be reasonably accomplished in facilities available within a local health department, or it may contract with physicians to supervise the medical care of tuberculosis patients in areas where the specialized care is not available. Further, the appropriation shall be available to purchase materials or drugs used in tuberculosis control for distribution to local health departments.*

SPUTUM COLLECTION FOR MYCOBACTERIUM TUBERCULOSIS

May be performed by:	**Effective Date: 1993**
Health Care staff educated in sputum collection; or respiratory therapists	**Revision Date: July 2005**

PURPOSE:

Collection of spontaneously produced sputum is indicated for diagnosing and monitoring pulmonary tuberculosis (TB). The best specimens are collected early in the morning, produced from deep in the lungs by vigorous cough. If the inmate-patient is unable to produce an adequate specimen, sputum induction may be necessary.

SUPPLIES/EQUIPMENT NEEDED:

- Sterile sputum collection kit with mailing carton and identification label.
- Laboratory requisition form (completed and ready to submit except for date collected).
- N-95 particulate respirators for health care and appropriate custody staff. An N95 respirator/mask has a filter efficiency level of 95% or greater against particulate aerosols free of oil when tested against a 0.3 micron particle
- Area with negative pressure ventilation and 100 percent exhaust to the outside, respiratory booth, or tent ventilated and serviced per manufacturer's instructions. (Sputum may be collected outdoors if a specially designed room, booth, or enclosure is not available.)
- Small volume nebulizer to provide aerosol mist.
- Hypertonic saline, 10 percent solution.
- Gloves.
- Biohazard bag.

LOCATION

Sputum induction must be performed in a designated room or booth with negative pressure relative to adjacent rooms or hallways. The room must be air exhausted outdoors, away from all windows and air intake ducts. Patients may leave the room after sputum induction, once coughing has ceased. Sputum samples may be obtained outdoors when an appropriate room or booth is not available.

Staff must wear an N-95 fit-tested respirator mask in the sputum collection room or area when, and shortly after, the patient has coughed up sputum. Sufficient time should be allowed between patients so that infectious droplet nuclei may dissipate and/or be removed by filters. This means that the filters shall be operated sufficient time, per manufacturer's instructions, to remove at least 99 percent of the room air.

PROCEDURE:

1. Obtain the physician's order and the appropriate number of laboratory requisition slips.
2. Confirm laboratory tests ordered and verify that the requisition slips are properly completed.
3. Gather equipment/supplies and proceed to the appropriate area for collection of sputum. Verify the correct inmate-patient, explain why and how to collect a sputum specimen. The early morning is usually the best time to raise sputum. Prior to producing sputum, the inmate-patient should rinse his/her mouth and/or brush his teeth with water. The inmate-patient should be instructed to breathe deeply, exhale, and cough deeply to bring up at least 5 milliliters (ml) of sputum from the lungs. Observe the procedure carefully throughout the collection. Do not collect saliva.
4. The sputum is deposited into the labeled container (identify inmate name, date, time of collection). Avoid contamination of the outside of the container with sputum.
5. If mailing sputum, follow specific lab instructions for packaging and mailing biologic specimens. If sputum cannot be mailed or taken to the laboratory on the date it is collected, it should be refrigerated.
6. If the inmate-patient cannot spontaneously produce a minimum of 5 ml of sputum, a specimen should be induced by a nebulized treatment with 5 ml of 10% sodium chloride solution.
7. If all attempts fail, written notification of the ordering physician is required.
8. **A portion of all sputum specimens shall be sent to the local county health officer (LCHO), mycobacteriology laboratory.** If required by contract, a similar portion shall be sent to the contract lab. Complete the requisition form for the LCHO, including the inmate-patient's name, date of birth, name of institution and place in the specimen container.
9. Unless used for screening an Human Immunodeficiency Virus-infected inmate-patient before placement, report the inmate-patient as a "suspect" using the *Correctional Facility TB Patient Plan (Attachment 9)* to the LCHO and to the Public Health Coordinator, Clinical Services Support Unit, Division of Correctional Health Care Services.

POSTURAL DRAINAGE:

If the specimen is not obtained after five minutes, instruct the inmate-patient to lean forward at a 30 degree angle, while continuing with the nebulized treatment; and then lean backwards at a 30 degree angle. These positions facilitate drainage from the upper lobes, the site of infection for a large percentage of patients with TB.

WHAT PRECAUTIONS SHOULD BE TAKEN WHEN TRANSPORTING A TUBERCULOSIS (TB) PATIENT?

TB TRANSMISSION:

TB disease is transmitted through the air. A person with TB disease of the lungs or larynx can, by coughing, sneezing, talking, or breathing, release droplets containing Mycobacterium tuberculosis (*M tb*) into the air. These droplets can cause TB infection if inhaled by anyone who shares air with the person with infectious TB.

During their stay in institutions such as hospitals, jails, and prisons known or suspected infectious TB patients should be placed, and should remain, in negative pressure isolation rooms until they are non-infectious to reduce the risk of TB transmission.

TRANSPORTING A KNOWN OR SUSPECTED INFECTIOUS TB PATIENT:

Occasionally TB patients may need to be transported elsewhere for medical or custodial reasons, or a negative pressure isolation room may not be available. This introduces the risk of TB transmission to others.

Patients are usually transported by:

- Car, bus, or ambulance, and
- Walking, wheelchair, or gurney through occupied rooms

Use the following checklist to ensure that all the steps that *should* be taken to reduce the likelihood of Tuberculosis (TB) transmission during transportation of a known or suspected TB patient *have* been taken.

TB PATIENT TRANSPORTATION CHECKLIST

PREPARING FOR THE TRANSPORT

- ☐ Provide and instruct the patient to wear a **surgical mask** over his or her mouth and nose, to help prevent particles from the patient's respiratory tract from being released into shared air. The patient should not wear a **respirator*,** (An N-95 filter respirator is used for employees; see below)**.**

- ☐ Surgical masks should be changed when they become wet or torn. Make sure that enough surgical masks are available for the entire journey.

- ☐ Notify the destination facility or department of the patient's planned arrival. Advise the facility or department in advance of the appropriate precautions and continuity of treatment needs of the patient. (To reduce the number of people that are potentially exposed to *Mtb*, schedule procedures for TB patients at times when they can be performed rapidly and when waiting areas are less crowded.)

TRANSPORTING WITHIN A FACILITY

- ☐ Provide an escort for the patient while he or she is walking or being wheeled through occupied areas. Having an escort will make it less likely that the patient will remove his or her surgical mask.

TRANSPORTING BETWEEN FACILITIES BY CAR, BUS, OR AMBULANCE

- ☐ Provide and require staff driving with a known or suspected TB patient to wear a respirator* during the entire journey. At a minimum, the respirator* should be an N-95 filter respirator approved by the National Institutes for Occupational Safety and Health.

- ☐ Transport additional passengers and staff members in a separate vehicle. This will reduce the number of people potentially exposed and also the number of people who are required to use respirators.

- ☐ Set ventilation controls to the fresh air or vent setting, rather than the recirculation setting.

- ☐ Set the fan to high.

- ☐ Open as many windows as possible.

- ☐ Leave the vehicle unoccupied with the windows open for at least an hour after the end of the journey. A sign should be placed on the vehicle indicating when the vehicle can be used again.

*A respirator functions in the opposite manner from a surgical mask. A respirator removes particles from the air and is worn by staff to remove any possibly infectious particles from the air that they inhale.

TITLE 17, *CALIFORNIA CODE OF REGULATIONS* (CCR), SECTION 2500
REPORTABLE DISEASES AND CONDITIONS*

§2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.

Section 2500(b) It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed below, to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.

Section 2500(c) The administrator of each health facility, clinic or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local health officer.

Section 2500(a)(14) "Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

URGENCY REPORTING REQUIREMENTS [17 CCR §2500 (h) (i)]

☎ = Report i**mmediately** by **telephone** (designated by a ◆ in regulations).

† = Report **immediately** by t**elephone** when **two (2) or more cases** or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a • in regulations).

FAX = Report by **FAX, telephone, or mail within one (1) working day of identification** (designated by a **+** in regulations).

All other diseases/conditions should be reported by FAX, telephone, or mail within seven (7) calendar days of identification.

SECTION 2500(j)(1): REPORTABLE COMMUNICABLE DISEASES

- Acquired Immune Deficiency Syndrome (AIDS)
- FAX Amebiasis
- FAX Anisakiasis
- ☎ Anthrax
- FAX Babesiosis
- ☎ Botulism (Infant, Foodborne, Wound)
- ☎ Brucellosis
- FAX Campylobacteriosis
- Chancroid
- Chlamydial Infections
- ☎ Cholera
- ☎ Ciguatera Fish Poisoning
- Coccidiodomycosis
- FAX Colorado Tick Fever
- FAX Conjunctivitis, Acute Infections of the Newborn, specify Etiology
- FAX Cryptosporidiosis
- Cysticercosis
- ☎ Dengue
- ☎ Diarrhea of the Newborn, Outbreaks
- ☎ Diphtheria
- ☎ Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
- Echinococcosis (Hydatid Disease)
- Ehrlichiosis
- FAX Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
- ☎ *Escherichia coli* O157:H7 Infection
- FAX Foodborne Disease
- Giardiasis
- Gonococcal Infections
- FAX *Haemophilus influenzae* Invasive Disease
- ☎ Hantavirus Infections
- ☎ Hemolytic Uremic Syndrome
- Hepatitis, Viral
- FAX Hepatitis A
  - Hepatitis B (specify acute case or chronic)
  - Hepatitis C (specify acute case or chronic)
  - Hepatitis D (Delta)
  - Hepatitis, other, acute
- Kawasaki Syndrome (Mucocutaneous Lymph Node Syndrome)
- Legionellosis
- Leprosy (Hansen Disease)
- FAX Leptospirosis
- FAX Listeriosis
- Lyme Disease
- FAX Lymphocytic Choriomeningitis
- FAX Malaria
- FAX Measles (Rubeola
- FAX Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
- ☎ Meningococcal Infections
- Mumps
- Non-Gonococcal Urethritis (Excluding Laboratory Confirmed Chlamydial Infections)
- ☎ Paralytic Shellfish Poisoning
- Pelvic Inflammatory Disease (PID)
- Pertussis (Whooping Cough)
- ☎ Plague, Human or Animal
- FAX Poliomyelitis, Paralytic
- FAX Psittacosis
- FAX Q Fever
- ☎ Rabies, Human or Animal
- FAX Relapsing Fever
- Reye Syndrome
- Rheumatic Fever, Acute
- Rocky Mountain Spotted Fever
- Rubella (German Measles)
- Rubella Syndrome, Congenital
- FAX Salmonellosis (Other then Typhoid Fever)
- ☎ Scombroid Fish Poisoning
- FAX Shigellosis
- ☎ Smallpox (Variola)
- FAX Streptococcal Infections (Outbreaks of any type. Individual Cases: Food Handlers/Dairy Workers only)
- FAX Swimmer's Itch (Schistosomal Dermatitis)
- FAX Syphilis
- Tetanus
- Toxic Shock Syndrome
- Toxoplasmosis
- FAX Trichinosis
- FAX Tuberculosis
- ☎ Tularemia
- FAX Typhoid Fever, Cases and Carriers
- Typhus Fever
- ☎ Varicella (deaths only)
- FAX *Vibrio* Infections
- ☎ Viral Hemorrhagic Fevers (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
- FAX Water-associated Disease
- ☎ Yellow Fever
- FAX Yersiniosis
- ☎ **OCCURANCE OF ANY UNUSUAL DISEASE**
- ☎ **OUTBREAKS OF ANY DISEASE** (Including diseases not listed in Section 2500). Specify if institutional and or open community

REPORTABLE NONCOMMUNICABLE DISEASES/ CONDITIONS (Section 2500(j)(2):

- Alzheimer's Disease and Related Conditions
- Cancer (except (1) basal and squamous skin cancer unless occurring on genitalia, and (2) carcinoma in-situ and CIN III of the cervix)
- Disorders Characterized by Lapses of Consciousness

LOCALLY REPORTABLE DISEASES (If Applicable):

*This form is designed to be used by health care providers to report those diseases mandated by Title 17, California Code of Regulations, §2500 (rev. 1996). (Cancer reporting is mandated by §2593.) Failure to report is a misdemeanor (Health & Safety Code §12095, formerly §3354). Punishable by a fine of not less than$50 nor more than $1,000, or by imprisonment for a term of not more than 90 days, or by both. Each day the violation is continued is a separate offense.

M.R.S.A.

California Department of Corrections and Rehabilitation
Division of Correctional Health Care Services
Methicillin-Resistant *Staphylococcus aureus* Policy

I. Purpose

The California Department of Corrections and Rehabilitation (CDCR) Division of Correctional Health Care Services' policy on the management of Methicillin-Resistant *Staphylococcus aureus* (MRSA) infections, adapted from the most recent Federal Bureau of Prisons clinical practice guidelines on the control of MRSA, is intended to provide direction on the prevention, treatment, and containment of MRSA infections within CDCR adult correctional facilities. The intended audience for this policy is for all correctional staff, especially infection control and public health practitioners, clinicians, nursing, laboratory personnel, and management.

II. Background

Staphylococcus aureus or "staph" is a common pathogen, which colonizes the noses of about 30% of the general population at any one time. "Staph" is frequently transferred by contaminated hands from the nose to the skin. MRSA is "staph" that is resistant to beta-lactam antibiotics (all penicillins and cephalosporins) and has variable susceptibility to other antibiotics depending on whether or not it is a healthcare-associated or a community-associated (CA) MRSA strain. At this time, most surveys show that less than 2% of the general population is colonized with MRSA. The *S. aureus* clinical spectrum ranges from colonization with no clinical evidence of infection to uncomplicated skin and soft-tissue involvement to more serious invasive disease including deep-seated abscesses, septic arthritis, pneumonia, and sepsis.

Colonized persons are more likely to develop staphylococcal infections; however, many colonized persons remain asymptomatic. Symptomatic MRSA infections most often present as a furuncle or superficial boil that occurs spontaneously and evolves to include multiple lesions. Patients commonly complain of "an infected pimple," "an insect bite," "a spider bite," or "a sore." There is no evidence that spiders or insects transmit MRSA; thus, vector control is not considered a part of MRSA control. Complicating medical conditions such as diabetes, HIV infection, chronic skin disorders, indwelling catheters, post-surgical wounds, and decubiti increase the risk of serious MRSA infection.

MRSA is transmitted from person to person by contaminated hands and by skin-to-skin contact. Transmission may also occur by sharing towels, linens, personal hygiene items, athletic equipment, through close-contact sports, personal items potentially contaminated by wound drainage, injection drug use, unsanitary tattoo practices, and inadequate hand and skin hygiene. Given the recent increase in infections due to CA-MRSA, a strain of MRSA with increased tissue virulence, transmission amongst healthy at-risk populations such as athletes in close-contact sports, military recruits, men who have sex with men, and inmate populations has become a significant public health concern.

III. Screening

A. Intake screening

All inmates undergoing intake medical screening and physical examinations should be carefully evaluated for skin infections. All inmates should be instructed to self-report any new onset skin infections or fever.

B. Recently hospitalized inmates

All inmates who are discharged from the hospital should be questioned about any new or previously existing skin infections or rashes in the Triage Treatment Area immediately upon return to the prison. This initial screening should be followed with a more detailed examination of the skin during the primary care follow-up visit (MRSA or other healthcare-associated infections may develop weeks after hospital discharge).

C. Inmates at greater risk of serious MRSA infections

Inmates with risk factors such as diabetes, immunocompromised conditions, open wounds, recent surgery, indwelling catheters, implantable devices, chronic skin conditions, or paraplegia with decubitus ulcers should be evaluated for skin infections during routine medical evaluations.

D. Observations by correctional workers

Inmates with visible or reported sores or wounds, or who self-report "boils" or "insect or spider bites" should be referred to health services.

E. Food handlers

All inmate food handlers should be advised on the necessity of self-reporting all skin infections, no matter how minor. Food handlers should be routinely examined for visible skin infections. Food handlers with suspected or confirmed contagious MRSA should be removed from their duties until the infections have healed.

F. Transfers

Inmates with skin and soft tissue infections should ordinarily not be transferred to other institutions until fully evaluated and appropriately treated.

G. Corrections Staff

Correctional workers (including health care workers) should report all skin infections and any confirmed MRSA infections to their supervisor. Supervisors should refer correctional workers with possible skin infections to their health care provider. If work-related infection is suspected, facilities are responsible for reporting immediately (no longer than 8 hours after notification of the employee's supervisor) by telephone or telegraph to the nearest District Office of the Division of Occupational Safety and Health any serious illness of an employee. Employees should be removed from direct inmate contact if they have staphylococcal infection that cannot be covered or contained.

IV. Diagnosis

A. Empiric diagnosis

An empiric (i.e., suspected, but not confirmed) diagnosis of a MRSA infection should be considered in inmates with clinical evidence of a staphylococcal infection.

B. Physical Examination

Correctional health care providers should consider MRSA infection in the differential diagnosis for all inmates presenting with skin and soft tissue infections or other clinical presentations consistent with a staphylococcal infection. A careful examination of the affected skin should be conducted to determine if there is fluctuance, crepitus, any evidence of a drainable infection, or cellulitis with or without streaking. Deep-seated MRSA abscesses may not be clinically apparent and only diagnosed through imaging studies.

C. Bacterial Culture

MRSA infections cannot be clinically distinguished from staphylococcal infections that are sensitive to beta-lactam antibiotics; therefore, routine aerobic bacterial cultures should be obtained whenever possible from purulent drainage from skin and soft tissue infections and aspirated material from potentially infected fluid collections. Blood cultures should also be obtained in febrile patients with suspected MRSA infections and whenever injection drug use or endocarditis is clinically suspected. Positive cultures from blood and sterile body fluids (e.g., joint fluid, pleural fluid, cerebrospinal fluid) are diagnostic of MRSA infections. Positive cultures of drainage from nonsterile sites (e.g., wounds) may indicate **bacterial colonization or infection**. Wound cultures obtained from expressed pus (avoiding skin contamination) are diagnostically meaningful; ***whereas positive cultures obtained directly from the surface of a wound are of limited value in detecting true infection***. **Obtaining bacterial cultures of the nares is not routinely indicated**, unless recommended by public health authorities in the context of a significant MRSA outbreak.

V. Reporting

All suspected or confirmed MRSA infections must be documented in the inmate's medical record and in surveillance logs maintained by infection control/public health staff. All suspected or confirmed MRSA outbreaks (two or more cases occurring amongst epidemiologically-linked individuals) should be documented per infection control protocol.

VI. Treatment

A. Warm soaks and compresses

A conservative, mechanical approach is the treatment of choice for minor skin and soft tissue infections, i.e., the lesion is localized and there are no signs of systemic illness. **Uncomplicated MRSA skin infections may resolve with warm soaks and/or incision and drainage, without antibiotics. Decisions about how to safely implement warm soaks**

and/or compresses in the correctional setting must be made on a case by case basis in consultation with the infection control officer. Consideration should be given to how and where to safely perform the soaks and safely dispose of bandages to prevent further transmission of MRSA.

B. Incision and Drainage & Antibiotic Therapy

CA-MRSA infections are frequently caused by isolates that are sensitive to a wider range of antibiotics compared to MRSA infections acquired in the hospital setting. The selection of oral antibiotics to treat skin or soft tissue MRSA infections should be based on bacterial cultures and antibiotic susceptibility results whenever possible. Treatment should also include aggressive drainage of accessible fluid collections, particularly loculated soft tissue infections in conjunction with the use of warm soaks or compresses.

Endocarditis and other endovascular infections, osteomyelitis, necrotizing fasciitis, pneumonia, and other deep-seated MRSA infections require intravenous antibiotic therapy for an extended period of time, i.e., 4-6 weeks or more. **Consultation with an infectious disease specialist is recommended for serious MRSA infections.**

VII. Infection Control - Primary Prevention

Controlling the transmission of MRSA infections in a confined setting, such as a prison, is extraordinarily difficult, time consuming, and resource-intensive. The majority of inmates with MRSA infection or colonization have acquired it from an external source; therefore primary infection control measures are critical. **All potential opportunities for inmates to have close skin-to- skin contact or share communal items should be carefully scrutinized within each correctional institution** to identify strategies to interrupt MRSA transmission. The following general interventions should be considered.

A. Education

Inmates and correctional staff should be provided information on the transmission, prevention, treatment, and containment of MRSA infections. Emphasis should be placed on the importance of regular hand hygiene, and of promptly referring inmates with skin infections for a medical evaluation. Training on methods to control the risk of occupational MRSA infections to employees and to reduce transmission of MRSA in the prison setting should be provided during new employee orientation and annual training. Regular hand hygiene should be emphasized as the most important intervention to prevent a MRSA outbreak.

B. Correctional standard precautions

These measures require correctional workers to assume that all inmates are potentially contagious and to take precautions whenever direct contact is anticipated with blood, body fluids (e.g., secretions, excretions, feces, and urine), nonintact skin, and mucous membranes. Correctional standard precautions have been adapted from hospital standard precautions, including increased emphasis on sanitation in housing areas and adaptation to recently identified modes of transmission of CA-MRSA, e.g., sharing of towels, use of exercise benches, etc. Standard precautions include adequate hand hygiene; routine use of

gloves whenever contact with body fluids or nonintact skin is anticipated; routine cleaning and disinfection of environmental surfaces; treating all linen as potentially infectious; safe disposal of needles and other sharp instruments and devices; and placement of inmates who may contaminate the environment in a private room (in consultation with medical staff).

C. Hand hygiene program

Hand hygiene is the simplest and most important infection control measure for preventing and containing MRSA infections and yet is the most difficult to implement. Correctional staff, health care workers and inmates should be periodically provided education on the importance of hand hygiene and effective hand hygiene techniques with soap and water or an alcohol-based hand rub during annual training and other venues. As part of the hand hygiene program, institutions should include the addition of hand washing sinks and alcohol-based hand rub stations to their plant improvement planning efforts.

D. Sanitation

MRSA is susceptible to most routinely used environmental cleaning agents. Sanitation measures are essential for preventing the spread of MRSA infections, and such measures should be regularly assessed, and any lapses rectified, in accordance with local policies and procedures.

E. Antibiotic prescribing practices

Clinical directors should monitor antibiotic prescribing patterns at their institutions in consultation with their pharmacy staff to ensure that antibiotics are being appropriately prescribed and not used in lieu of recommended conservative treatments for uncomplicated MRSA, e.g., warm soaks or compresses and I & D. The unnecessary use of antibiotics, particularly broad-spectrum antibiotics, should be strictly monitored and curtailed to reduce the development of antibiotic resistance among the inmate population.

VIII. Infection Control - Secondary Prevention:

When health care providers and correctional personnel have direct contact with inmates with suspected or confirmed MRSA skin and soft tissue infections, correctional contact precautions should be utilized. General infection control principles for managing an infected inmate are outlined below.

A. Inmate education

All inmates with MRSA infections should be instructed in regular hand hygiene, maintaining personal hygiene, including regular showers and clean clothing, and the importance of keeping wounds clean and covered.

B. Hand hygiene

Adequate hand hygiene should be reemphasized with staff working with inmates diagnosed with MRSA infections. Adequate hand hygiene supplies for the inmate diagnosed with MRSA and the staff in contact with them is critical. The availability of these supplies should be regularly assessed and remedied as necessary.

C. Housing

Inmates diagnosed with MRSA infections should be examined by a clinician to determine their risk of contagion to others. In general, inmates with non-draining wounds or wounds with minimal drainage, which can be contained by a simple dressing, can be housed in general population. Decisions about housing assignments should be made utilizing the guidelines outlined in (Appendix 3. MRSA Containment Guidelines). Factors entering into decisions about where to house inmates with MRSA infections include the degree to which wound drainage can be contained, the ability or willingness of an inmate to follow infection control instructions, and available housing options. Inmates with MRSA pneumonia should generally be housed in a single cell, utilizing droplet precautions in addition to correctional standard precautions.

D. Activities and visitors

Inmates with MRSA infections may be limited from certain activities on a case by case basis. For example, an inmate with a draining shoulder wound should be restricted from recreation activities, but not necessarily meals in the cafeteria if the drainage is contained. Visitor restrictions are rarely indicated and should be handled on a case by case basis in consultation with the infection control officer.

E. Discontinuing single cell housing

Criteria for discontinuing single-cell housing for an infected inmate are outlined in Appendix 3.

F. Wound management

Draining wounds must remain adequately dressed to prevent contamination of environmental surfaces, and dressings should be changed regularly. A plan should be developed to assure that dressings can be replaced if they are no longer effective. Clean, nonsterile gloves should be worn when contact with wound drainage is anticipated. Gloves must be removed and hands cleaned immediately before leaving the patient's room. For isolated patients with grossly draining wounds, a clean non-sterile gown should be worn whenever it is likely that a person will come into contact with wound drainage.

Unless bandages are saturated with or are leaking bloody drainage, they can be disposed of in a leak-proof container (e.g., plastic bag or wax paper) and placed in the regular trash. Bandages that are saturated with or leaking bloody drainage should be handled in accordance with regulated waste procedures. Inmates should be instructed in proper disposal of used bandages in accordance with local operating policies and procedures.

G. Sanitation

Sanitation measures used for primary prevention of MRSA infections should be strictly enforced. All rooms of infected inmates should be decontaminated ("terminally cleaned") prior to occupancy by another inmate.

H. Inmate transfers and releases

Inmates with contagious MRSA infections should ordinarily not be transferred to other correctional institutions or congregate living facilities until their infection has been adequately treated and the risk of contagion controlled.

- **Required transfers:** Inmates with contagious MRSA infections absolutely requiring transfer for security reasons or medical care should have draining wounds dressed the day of transfer with bandages that adequately contain the drainage. The following should occur prior to the transfer. Escort officers should be instructed to follow correctional standard precautions and educated on infection control measures including the importance of hand hygiene, protective measures, safe disposal of contaminated dressings, decontamination of security devices (e.g., handcuffs, leg irons, and other reusable restraints) and advised to use disposable restraints, when feasible. The clinical director of the sending institution or designee should notify the receiving institution's clinical director or health services administrator of pending transfers of inmates with suspected or confirmed MRSA infections.

- **Releases:** Inmates with skin and soft tissue MRSA infections who are scheduled for release should have draining infections bandaged to adequately contain drainage prior to release; be given enough antibiotics to complete treatment; be counseled on practical infection control measures to prevent transmission to household members and other anticipated close contacts; and should be given assistance with accessing follow-up medical services.

I. Surveillance

Upon the diagnosis of a single MRSA case, there should be a heightened awareness by health care staff to actively detect any additional MRSA cases. Once there is a confirmed case of MRSA infection, the patient's name, location, and diagnosis shall be logged by the infection control nurse once notified by the primary care provider or facility nursing staff. If an epidemiologic linkage (related by time and location) between cases is suspected, the Chief Medical Officer and Director of Nursing shall be informed, and infection control staff should initiate an investigation to identify potential close contacts. Implementation of the following procedures by medical staff will aid in the active surveillance for additional cases and therefore prevent unmitigated transmission.

- **Interview index case:** The index case should be interviewed by the primary care provider and/or nursing staff to identify close contacts. This information should be shared with the public health and infection control nursing staff.

- **Evaluate contacts:** Identified contacts should be instructed to self-report any signs and symptoms of infection.
- **History of food handling:** The inmate's work assignments should be reviewed to determine if he or she has been a food handler.
- **Increased surveillance at routine visits**: Health care providers evaluating inmates during sick call visits and chronic care visits should be on the alert for inmates with skin or soft tissue infections or other evidence of MRSA infections.
- **Microbiology:** Bacterial cultures should be regularly monitored to detect any additional MRSA infections among the inmate population.

IX. Outbreak Management

Detection of a cluster of MRSA infections (two or more cases related by time and location or other epidemiologic linkages) should prompt an investigation to determine if an outbreak has occurred. An outbreak is defined as an increase in the rate of MRSA cases or a clustering of new cases. Outbreak surveillance measures are not indicated if the MRSA infections are obviously unrelated (e.g., two inmates returning separately from a hospital where nosocomial MRSA infections are endemic or multiple MRSA infections separated in time without any epidemiologic linkage.) Once a MRSA outbreak is suspected the following measures should be taken.

A. Tracking

Inmates with suspected or confirmed MRSA infections should be systematically tracked in order to assess case clusters and help identify risk factors for transmission.

B. Containment

In the context of a large MRSA outbreak, cohorting of inmates with skin or soft tissue infections may be considered.

C. Inmate transfers

Guidelines for inmate transfers outlined above should be followed during an outbreak. **In addition, all inmates scheduled for transfer from an institution with a MRSA outbreak should be interviewed by a health care provider and have a targeted examination of the skin to determine if they have a previously undiagnosed skin or soft tissue infection**.

D. Infection control measures

In addition to the infection control measures described above, the following should be emphasized in the context of an outbreak.

- **Hand hygiene and the use of correctional contact precautions** should be strictly enforced for all health care providers and correctional workers.
- **The broader use of antimicrobial soaps, washes, or shampoos** in affected housing units, dormitories, or throughout the entire correctional facility should be considered on a case by case basis in the context of an outbreak.

- **More stringent infection control practices should be implemented**, i.e., routine cleaning and disinfection of patient care items, such as stethoscopes and blood pressure cuffs, after **all** patient contacts.
- **Diligently inspect and reinspect living, sleeping, bathroom, recreational, and all other areas within the correctional facility where close skin-to-skin contact or sharing of personal hygiene or communal items is likely to occur** in order to detect potential means of ongoing MRSA transmission. If the outbreak is confined to a certain housing unit or dormitory, all living, sleeping, and bathroom areas should be carefully inspected, including cell "shakedowns", when necessary, to identify potential sources of infection such as unsanitary conditions or ongoing injection drug use or tattooing.
- **Influenza prevention:** Persons with influenza are at higher risk of secondary, pulmonary infections with *Staphylococcus aureus* and other bacteria. Necrotizing MRSA pneumonias could occur during influenza outbreaks within the correctional setting.

E. Surveillance

Once an outbreak is suspected or confirmed, health care personnel should determine if inmates with MRSA infections have a common source of infection such as shared housing or work assignments, the same religious or recreational practices, the same social or gang affiliations, recent injection drug use activity, sexual contact with other inmates, new tattoos, hospitalization in the past 6 months, or a common primary health care provider. Surveillance physical examinations for previously undetected MRSA infections should be considered in accordance with the following:

- **Common source outbreak suspected:** All potential inmate contacts should be examined, e.g., dormitory inmates, for unidentified skin or soft tissue infections or other evidence of MRSA infections.
- **Surveillance of high risk inmates:** If the outbreak involves multiple inmates or is sustained over time, targeted examinations should be considered for inmates who may be at higher risk of MRSA infections (e.g., inmates with diabetes, renal failure, surgical wounds, indwelling catheters, chronic skin diseases, or immunocompromised conditions) for both surveillance and diagnostic purposes.
- **Health care worker is possible source:** If a health care worker is the potential common source of MRSA infections, the health care worker should be interviewed by the clinical director or designee to determine if the worker has had any recent skin or soft tissue infections and to review the worker's infection control practices such as hand washing and use of contact precautions. The health care worker should be referred to a physician for medical evaluation and clearance if a MRSA infection is suspected clinically or epidemiologically.
- **Environmental surveillance cultures** (i.e., swabbing medical equipment, clinical areas or living areas) to detect MRSA are normally of limited benefit in controlling a MRSA outbreak and should only be considered in consultation with public health authorities with expertise in outbreak control.

F. Decolonization of asymptomatic carriers

Nasal swab surveillance cultures for MRSA and decolonization of asymptomatic carriers with mupirocin are not routinely recommended in the context of an MRSA outbreak. **Mupirocin treatment does not eradicate colonization in all treated persons, does not prevent recolonization following future exposures to MRSA, and, when used broadly, can result in mupirocin-resistant MRSA strains.** MRSA decolonization of health care workers and patients may be of benefit in eradicating MRSA from certain confined settings, such as inpatient units. Decolonization of asymptomatic carriers should only be considered after consultation with public health authorities.

G. Education

Educational efforts should target inmates, correctional workers, and health care personnel in order to contain a MRSA outbreak.

- **Televised public service announcements and town hall meetings with inmates** to reinforce the importance of regular hand washing, good personal hygiene, routine showering, maintenance of a clean cell, regular laundering of bed linens, self-reporting of all skin lesions, importance of inmates keeping wounds covered, and refraining from any injection drug use, tattooing, and sexual contact with other inmates.
- **Recalls with correctional staff** to reinforce the importance of regular hand washing, correctional standard precautions when interacting with all inmates, the use of correctional contact precautions when interacting with inmates with MRSA infections, the routine inspection of inmate housing units for cleanliness, the examination of foodhandlers for visible skin infections, and the detection of prohibited tattooing practices, injection drug use, and sexual activity among inmates.
- **Meetings with health care personnel** to reinforce the importance of hand hygiene before and after every patient contact, decontamination of shared medical devices, as well as the appropriate use of correctional standard and contact precautions.

X. Inpatient Units

Inpatient units within correctional facilities should develop site-specific infection control practices to prevent the spread of resistant organisms. Infection control guidelines used for the hospital setting should be adapted to the correctional inpatient setting.

A. Primary prevention

The following primary prevention infection control measures should be considered for inpatient units:

- **Educating inpatient health care providers** on the importance of preventing the spread of antibiotic resistant organisms and the efficacy of control measures;
- **Strictly enforcing hand hygiene** before and after all patient contacts;
- **Avoiding inappropriate or excessive antibiotic usage** for inpatients (monitoring through the infection control and the pharmacy and therapeutics committees);

- **Dedicating noncritical patient-care equipment to a single patient** when contact or droplet precautions are indicated and when use of common equipment or items is unavoidable, adequately cleaning and disinfecting before use with other patients;
- **Strictly enforcing environmental disinfection of patient rooms**, including terminal cleaning at the time of patient discharge with a focus on environmental surfaces exposed to frequent hand contact (i.e., bed rails and door knobs);
- **Regularly monitoring bacterial cultures** of inpatients and recently discharged inpatients to detect clusters of MRSA infections; and
- **Appropriately assigning beds for new admissions with undiagnosed, potentially infectious conditions**, including MRSA, to avoid placement in rooms with other inmates at high risk for developing infections.

B. Secondary prevention

The following secondary prevention infection control measures should be considered for containing MRSA infections in inpatient units:

- **Aggressively evaluating, containing, and treating inpatients with suspected or confirmed MRSA infections** since these patients are at greater risk of serious disease (transmission of MRSA infections to others within the inpatient setting can occur easily and can cause serious illness to other medically compromised patients. Contact precautions and other recommended infection control practices should be strictly enforced);
- **Heightened MRSA surveillance of other inpatients**; and
- **Assigning specific staff to care for contagious MRSA patients (when staffing permits) in order to minimize the risk of cross-infection** (these staff members should not be assigned to care for inmates at high risk of developing infection).

C. Outbreak management

MRSA outbreaks within the inpatient setting can be extremely difficult to control and are affected by multiple factors that vary among inpatient units. The most effective methods to eradicate MRSA infections from the inpatient setting have involved the active surveillance and isolation of patients with MRSA infection and/or MRSA colonization along with the use of strict contact precautions when managing these patients. Public health authorities should ordinarily be consulted to develop a specific infection control strategy due to the difficulties in managing MRSA outbreaks in the inpatient setting and the inherent risks to the patient population. Strategies for controlling a MRSA outbreak in the inpatient setting beyond full implementation of primary and secondary infection control measures may include the following:

- **Careful and repeated examinations of all inpatients for undiagnosed MRSA infection.**
- **Aggressive culturing of all potential infections** and regular review of culture results.
- **Obtaining nares surveillance cultures for new inpatients and periodically, thereafter**, particularly for inmates at high risk of MRSA infection (persons at high risk of MRSA infection include persons with diabetes, immunocompromised conditions, open

wounds, recent surgery, indwelling catheters, implantable devices, chronic skin conditions, and paraplegia with decubiti).

- **Assign inpatients with MRSA infections and/or colonization to either single-cell housing or to cohorted housing** with other inpatients who are similarly colonized.
- **Decolonizing procedure: Decolonization of targeted groups of inpatients and/or health care providers is rarely indicated and should only be pursued in consultation with public health authorities.**

REFERENCES

Aiello AE, Lowy FD, Wright LN, Larson EL. Meticillin-resistant Staphylococcus aureus among US prisoners and military personnel: review and recommendations for future studies. Lancet Infect Dis. 2006 Jun; 6(6):335-41.

Bick J. Infection Control in Jails and Prisons. *Clin Infect Dis* 2007; 45: 1047-55.

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR* 2002; 51 (RR16):1-44.

Deresinski S. Methicillin-resistant *Staphylococcus aureus*: An evolutionary, epidemiologic, and therapeutic odyssey. *Clin Infect Dis* 2005; 40:562-573.

Federal Bureau of Prisons. Management of methicillin-resistant *Staphylococcus aureus* (MRSA) infection. http://www.bop.gov//news/PDFs/mrsa.pdf

Muto CA, Jernigan JA, Ostrowsky BE, et al. SHEA guideline for preventing nosocomial transmission of multi-drug resistant strains of *Staphylococcus aureus* and *Enterococcus*. *Infect Control Hosp Epidemiol* 2003; 24:362-386.

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007**.** http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf

Wenzel RP, Reagan DR, Bertino JS, et al. Methicillin-resistant *Staphylococcus aureus* outbreak: A consensus panel's definition and management guidelines. *Am J Infect Control* 1998; 26:102-110.

Wootton SH, Arnold K, Hill HA, et al. Intervention to reduce the incidence of methicillin-resistant *Staphylococcus aureus* skin infections in a correctional facility in Georgia. *Infect Control Hosp Epidemiol* 2004; **25:** 402–07.

Appendix 1A. Correctional Standard Precautions in the General Population

The following precautions should be observed by routinely by all correctional workers to prevent spread of disease.

Control Measure	Indicated	Notes:
Hand Washing	Yes	Hands should be washed with soap and running water for at least 15 seconds when hands are visibly dirty and when there has been contact with blood or other body fluids (even if gloves have been worn). Other than the situations listed above, alcohol-based hand rubs can be used for routine hand hygiene.
Personal Protective Equipment (PPE)	Not routinely	Personal protective equipment is indicated only if contact with blood/body fluids likely, i.e., gloves to protect hands from contact or mask, face/eye wear, gowns to protect from sprays and splashes.
Sharps	Yes	Dispose of in a leak-proof, puncture-resistant container. Never recap, bend, break or otherwise manipulate used needles by hand.
Single cell	Not routinely	Place potentially infectious inmates in a private room (in consultation with medical staff). Consider for inmates with poor hygiene practices.
Sanitation	Yes	Routine cleaning with an Environmental Protection Agency (EPA)-registered disinfectant. Use according to the manufacturer's instructions. All washable (non-porous) surfaces should be cleaned **during** and **after** (terminal) cell occupancy. Correctional workers should conduct sanitation inspections of living & bathroom areas to identify visibly dirty areas. Each institution should designate custody staff and supervisors to attend to this regularly.
Laundry	Yes	Collect at bedside. If wet or soiled, handle as little as possible and bag in a leak-proof bag at the location it was used, in accordance with local policy on management of contaminated linens. Machine wash and dry.
Activities	Yes	**Shared equipment**, weight benches or any other surface exposed to sweat should be disinfected *daily* and *routinely* wiped clean between users with a clean dry towel. Inmates should use barriers to bare skin, such as a clean towel or clean shirt while using exercise equipment. Inmate work crews should be assigned to do this task regularly after specific training is furnished.
Report Skin Infections	Yes	Correctional workers with possible skin infections should report them promptly to their supervisor. Inmates with possible skin infections should be sent promptly for a medical evaluation.

General Population refers to all correctional settings except health care settings.

Appendix 1B. Correctional Contact Precautions in the General Population

Observe the following precautions (in addition to routine Correctional Standard Precautions) when working with an inmate **known to have a skin infection.**

Control Measure	Indicated	Notes:
Hand Washing	Yes	Hands should be routinely washed with soap and running water for at least 15 seconds, or cleaned with alcohol based hand rubs. Perform hand washing BEFORE and AFTER every contact with an infected inmate, even if gloves were worn.
Personal Protective Equipment	As needed	Use gloves if touching contaminated items or contact with blood/infectious body fluids is likely. Use other personal protective equipment (mask, face/eye wear, gowns) if contact with sprays or splashes likely.
Sharps	Yes	Dispose of properly in a leak-proof, puncture-resistant container. Never recap, bend, break or otherwise manipulate used needles by hand.
Housing	Case-by-case	Medical determines the appropriate housing for an inmate with a skin infection. Inmates with skin infections may be housed in general population if the wound drainage can be contained in a dressing and the inmate is cooperative. Inmates with wounds that have significant drainage should generally be housed in a single cell. In an outbreak situation, inmates with MRSA may be housed together.
Sanitation	Yes	Routine cleaning with an Environmental Protection Agency (EPA)-registered disinfectant. Inmates are responsible for daily sanitation of cell. Instruct inmates to safely dispose of bandages in a leak-proof container according to local security policy. Remove trash *daily*. Clean all washable surfaces during and following (terminal) cell occupancy. Correctional workers should conduct sanitation inspections of living & bathroom areas.
Laundry	Yes	Change linens every other day (more often if visibly soiled). Linen bagged by the inmate in the cell. Change towels / wash cloths *daily*. Machine wash and dry.
Inmate Hygiene	Yes	Monitor inmate hygienic practices particularly if mentally impaired. Inmates with skin infections should shower daily.
Activities/ Visitors	Case-by-case	Medical will decide about any restrictions on activities or visitors for inmates with skin infections. Restrictions on visitors rarely indicated.
Equipment	Yes	Single-use disposable is recommended, e.g., security devices. Clean hand cuffs, etc., after use. Regular cleaning of security devices with alcohol based or chlorine bleach solution is necessary and should be done consistent with their daily use.
Transports	Only when essential	If transfer is **required** for security or medical reasons the following procedures should be followed: (1) wound should be dressed on the day of transfer with clean bandages; (2) use contact precautions as described above (hand-washing, gloves if touching wound drainage & safe disposal of dressings) - if soiling of security devices likely, use disposable restraints (if feasible), if not, decontaminate after use; and (4) place clean sheet on cloth seats in vehicle (not needed if vinyl) and decontaminate, if visible contamination occurs.

General Population refers to all correctional settings except for health care settings.

Appendix 2A. Correctional Standard Precautions in the Healthcare Setting

The following precautions should be observed routinely by all correctional workers and clinicians who work in healthcare (HC) settings.

Control Measure	Indicated	Notes:
Hand Washing	Yes	Perform BEFORE and AFTER every patient contact, whether or not gloves were worn. If not visibly soiled, clean hands with a small quantity, e.g., 2-3 mL, of an alcohol-based hand solution containing at least 60% alcohol (if permitted) or an antimicrobial soap. If visibly soiled, hands should be washed with soap (antimicrobial or regular) and running water using friction. Liquid soap dispensers at sinks preferred. Consider routine use of antimicrobial soap in clinical areas.
Personal Protective Equipment (PPE)	Yes	Access to single use, disposable gloves when contact with infectious body fluids or mucous membranes is anticipated. Latex-free gloves for latex-sensitivities. Gloves may be sterile or nonsterile, depending on the task. All HC staff should clean their hands before and after use of sterile/nonsterile gloves. Use other PPE if spray/splash is likely.
Sharps	Yes	Properly dispose in leak- & puncture-proof container per OSHA standards. Needles: Never recap, bend, break or manipulate by hand.
Room Assignment	Not routinely	Place potentially infectious inmates in a private room. Consider for those with poor hygiene.
Sanitation	Yes	Routinely clean all countertops, treatable surfaces in HC facilities per local schedule. Emphasis on frequently touched surfaces (i.e., door knobs, bed rails) & after any contamination with blood/body fluids. Use an appropriate quaternary ammonium (chloride containing) disinfectant. Ensure that patient care items and potentially contaminated surfaces are cleaned & disinfected after use. Barrier protective coverings, as appropriate, for surfaces that are touched frequently with gloved hands during patient care or may become contaminated with blood/body fluids or are difficult to clean.
Laundry	Yes	Collect & bag at bedside using standard precautions. Hot water, machine wash and dry regularly. Distribute when thoroughly dry.
Patient Care Equipment	Yes	Safely handle contaminated patient-care equipment to prevent skin and mucous membrane exposures, contamination of clothing & transfer of microorganisms to other patients & environments. Ensure that reusable equipment is decontaminated & reprocessed between each patient use. Discard all single-use items properly. Promptly decontaminate reusable equipment if contaminated with infectious body fluids or visibly soiled.
Report Skin Infections	Yes	HC staff should follow local procedures on reporting infections. Staff with suspected skin infections should report them to their supervisor.

"Healthcare Setting" refers to areas where health care is delivered such as: medical/observation room, ambulatory or chronic care clinics, dental offices or inpatient units.

Appendix 2B. Correctional Contact Precautions in the Health Care Setting

Observe the following precautions (in addition to Correctional Standard Precautions) when evaluating and treating inmates **with skin or soft tissue infections** in health care (HC) settings.

Control Measure	Indicated	Notes:
Hand Washing	Yes	Perform hand washing BEFORE and AFTER every contact with an infected inmate, in accordance with Standard Precautions.
Personal Protective Equipment (PPE)	Yes	Clean, non-sterile gloves for patient care. Change gloves after contact with infective material. Remove gloves before leaving the patient's room; immediately wash hands with an antimicrobial. After glove removal, avoid touching potentially contaminated surfaces/items to avoid transfer of germs. Other PPE if drainage contact, likely.
Sharps	Yes	Dispose properly in a leak-proof, puncture-resistant container. Never recap, bend, break or otherwise manipulate used needles by hand.
Room Assignment	Yes	Private, if extensive draining lesions (keep covered) or MRSA pneumonia.
Sanitation	Yes	Cleaned routinely per local schedule. Emphasis on high touch areas. Use quaternary ammonium. All patient care items & potentially contaminated surfaces must be cleaned & disinfected after use. Use barrier protective coverings, as appropriate, for surfaces that are frequently touched with gloved hands during patient care, or if likely to become contaminated with blood/body fluids, or if difficult to clean. Dispose of used bandages in accordance with local waste management policy.
Laundry	Yes	Use routine standard precautions. No separate "isolation linen".
Patient Care Equipment	Yes	Safely handle contaminated patient-care equipment to prevent skin and mucous membrane exposures, contamination of clothing & transfer of germs to other patients & environments. Ensure that reusable equipment is decontaminated & reprocessed between each patient use. Discard all single-use items properly. Promptly decontaminate reusable equipment if contaminated with infectious fluid or visibly soiled.
Report Infections	Yes	HC staff should follow local procedures on reporting MRSA infections. Staff with suspected skin infections should report to their supervisor.
Transfers	Case-by-case	**In general, do not transfer** inmates with MRSA infections. If transfer is required for security or medical reasons: (1) on day of transfer, securely dress draining wounds to prevent seepage; (2) use contact precautions (above) - if soiling of security devices likely, use disposable restraints (if feasible), if not, decontaminate after use; (3) place clean sheet on cloth seats in vehicle (not needed if vinyl) and decontaminate vehicle if visible contamination; and (4) the CMO or designee from the transferring institution will notify the CMO or designee of the receiving institution of pending transfer with MRSA infection.

"Healthcare Setting" refers to areas where health care is delivered such as medical/observation room, ambulatory or chronic care clinics, dental offices or inpatient units.

Appendix 3. MRSA Containment Guidelines

MRSA Status	Containment Guidelines	Precautions
Non-draining MRSA skin infections	**Single cell housing not required.** Instruct in personal hygiene and to report worsening of infection and draining wounds.	Correctional Standard Precautions
Small draining MRSA skin infections easily contained by simple dressing	**Single cell housing usually not required.** Single cell housing should be considered for mentally ill, cognitively impaired and uncooperative inmates. Visitor restrictions are generally not indicated.	Correctional Standard Precautions
MRSA skin infections with uncontained drainage (e.g., weeping cellulitis, purulent catheter-site infections, non-healing abscesses, infected surgical wounds, etc.)	**Single cell housing recommended.** In outbreak situations, cohorting inmates with MRSA infection is acceptable. Restrict from recreation and common areas. Visitor restrictions rarely indicated – handle on a case-by-case basis. Separate shower and toilet facilities preferred; priority for inmates with draining peri-rectal or thigh lesions.	Correctional Standard & Contact Precautions
MRSA pneumonia	**Single cell housing required.**	Correctional Standard & Droplet Precautions[1]

MRSA Status	Criteria for Discontinuing Containment
Healed wounds	Release 24 hours after wound drainage has ceased (even if antibiotic therapy incomplete).
Draining wounds	Release once wound drainage can be contained with a simple dressing OR after documenting clinical improvement.
MRSA pneumonia	Release after documenting clinical improvement.

[1]Droplet precautions include placing patient in a private room (negative pressure not required) or cohorting patients with same infection; wearing mask eye protection or face shield during activities likely to generate splashes; wearing masks when entering room or within 3 feet of patient (N-95 not required); allowing patients to leave room only for essential purposes, always wearing a surgical mask.

Hospice

Palliative Care

DNR

California Medical Facility
Vacaville, California 95696

ADVANCE HEALTH CARE DIRECTIVE

California Probate Code Section 4701

You have the right to give instructions about your own health care. You also have the right to name someone else to make health care decisions for you. This form lets you do either or both of these things. If you use this form, you may complete or modify all or any part of it. You are free to use a different form.

INSTRUCTIONS

PART 1 – POWER OF ATTORNEY

Part 1 lets you name another individual as agent to make health care decisions for you if you become incapable of making your own decisions or if you want someone else to make those decisions for you now even though your are still capable. You may also name an alternate agent to act for you if your first choice is not willing, able, or reasonably available to make decisions for you. (Your agent may not be an operator or employee of a community care facility or a residential care facility where you are receiving care, or your supervising health care provider or employee of the health care institution where you are receiving care, unless your agent is related to you.

Unless the form you sign limits the authority of your agent, your agent may make all health care decisions for you. This form has a place for you to limit the authority of your agent. You need not limit the authority of your agent if you wish to rely on your agent for all health care decisions that may have to be made. If you choose not to limit the authority of your agent, your agent will have the right to:

1. Consent or refuse consent to any care, treatment, service, or procedure to maintain, diagnose, or otherwise affect a physical or mental condition.

2. Approve or disapprove diagnostic, surgical procedures, and programs of medication.

3. Direct the provision, withholding, or withdrawal of artificial nutrition and hydration and all other forms of health care, including cardiopulmonary resuscitation.

PART 2 – INSTRUCTIONS FOR HEALTH CARE

You can give specific instructions about any aspect of your health care, whether or not you appoint an agent. Choices are provided for you to express your wishes regarding the provision, withholding, or withdrawal of treatment to keep you alive, as well as the provision of pain relief. You also can add to the choices you have made or write out any additional wishes.

PART 3 -- SIGNATURE

After completing this form, sign and date the form at the end.

YOU HAVE THE RIGHT TO REVOKE THIS ADVANCE HEALTH CARE DIRECTIVE OR REPLACE THIS FORM AT ANY TIME.

California Medical Facility
Vacaville, California 95696

ADVANCE HEALTH CARE DIRECTIVE
California Probate Code Section 4701

PART 1 – POWER OF ATTORNEY FOR HEALTH CARE

(1.1) DESIGNATION OF AGENT: I designate the following individual as my agent to make health care decisions for me:

Name of individual you choose as agent: _____

Address: _____

_____

Telephone: _____

(home phone) (work phone)

OPTIONAL: If I revoke my agent's authority or if my agent is not willing, able, or reasonably available to make a health care decision for me, I designate as my first alternate agent:

Name of individual you choose as alternate agent: _____

Address: _____

_____

Telephone: _____

(home phone) (work phone)

OPTIONAL: If I revoke the authority of my agent and first alternate agent or if neither is willing, able, or reasonably available to make a health care decision for me, I designate as my second alternative agent:

Name of individual you choose as second alternate agent: _____

Address: _____

_____

Telephone: _____

(home phone) (work phone)

(1.2) AGENT'S AUTHORITY: My agent is authorized to make all health care decisions for me, including decisions to provide, withhold, or withdraw artificial nutrition and hydration and all other forms of health care to keep me alive, except as I state here:

_____

_____

_____

_____

(use additional sheets if necessary)

(1.3) WHEN AGENT'S AUTHORITY BECOMES EFFECTIVE: My agent's authority becomes effective when my primary physician determines that I am unable to make my own health care decisions unless I mark the following box.

If I mark this box ☐ , my agent's authority to make health care decisions for me takes effect immediately.

(1.4) AGENT'S OBLIGATION: My agent shall make health care decisions for me in accordance with this power of attorney for health care, any instructions I give in Part 2 of this form, and my other wishes to the extent known to my agent. To the extent my wishes are unknown, my agent shall make health care decisions for me in accordance with what my agent determines to be in my best interest. In determining my best interest, my agent shall consider my personal values to the extent known to my agent.

PART 2 – INSTRUCTIONS FOR HEALTH CARE

If you fill out this part of the form, you may strike any wording you do not want.

(2.1) END-OF-LIFE DECISIONS: I direct that my health care providers and others involved in my care provide, withhold, or withdraw treatment in accordance with the choice I have marked and initialed below:

☐ Choice Not to Prolong Life

I do not want my life to be prolonged if (1) I have an incurable and irreversible condition that will result in my death within a relatively short time, (2) I become unconscious and, to a reasonable degree of medical certainty, I will not regain consciousness, or (3) the likely risks and burdens of treatment would outweigh the expected benefits, OR

☐ Choice to Prolong Life

I want my life to be prolonged as long as possible within the limits of generally accepted health care standards.

(2.2) RELIEF FROM PAIN: Except as I state in the following space, I direct that treatment for alleviation of pain or discomfort be provided at all times, even if it hastens my death:

_____

_____

_____

_____

(use additional sheets if needed)

(2.3) OTHER WISHES: (If you do not agree with any of the optional choices above and wish to write your own, or if you wish to add to the instructions you have given above, you may do so here.) I direct that:

_____

_____

_____

_____

(use additional sheets if needed)

PART 3 – SIGNATURE

(3.1) EFFECT OF COPY: A copy of this form has the same effect as the original.

(3.2) SIGNATURE: Sign and date the form here:

Date: _____

Name: _____ _____
(sign your name) (print your name)

(3.3) STATEMENT OF WITNESSES: I declare under penalty of perjury under the laws of California (1) that the individual who signed or acknowledged this advance health care directive is personally known to me, or that the individual's identity was proven to me by convincing evidence, (2) that the individual signed or acknowledged this advance directive in my presence, (3) that the individual appears to be of sound mind and under no duress, fraud, or undue influence, (4) that I am not a person appointed as agent by this advance directive, and (5) that I am not the individual's health care provider, an employee of the individual's health care provider, the operator of a community care facility, an employee of an operator of a community care facility, the operator of a residential care facility for the elderly, nor an employee of an operator of a residential care facility for the elderly.

FIRST WITNESS

Name: _____

Signature of Witness: _____

Date: _____

SECOND WITNESS

Name: _____

Signature of Witness: _____

Date: _____

(3.4) ADDITIONAL STATEMENT OF WITNESSES: At least one of the above witnesses must also sign the following declaration:

I further declare under penalty of perjury under the laws of California that I am not related to the individual executing this advance health care directive by blood, marriage, or adoption, and, to the best of my knowledge, I am not entitled to any part of the individual's estate upon his or her death under a will now existing or by operation of law.

Signature of Witness: _____

Signature of Witness: _____

DONATION OF ORGANS AT DEATH
(OPTIONAL)

Upon my death (mark applicable box):

☐ **(a)** I give any needed organs, tissues, or parts, OR

☐ **(b)** I give the following organs, tissues, or parts only.

_____

My gift is for the following purposes (strike any of the following you do not want):

(1) Transplant (3) Research
(2) Therapy (4) Education

EFFECT OF COPY: A copy of this form has the same effect as the original.

SIGNATURE: Sign and date the form here:

_____

(Print your name) (Address)

_____

(City) (State) (Zip Code)

_____

(Signature) (Date)

NOTARY SECTION
Part 3: To be filled out by Notary Public

State of California }
}ss.
County of _____ }

On _____, before me _____, Notary Public,
(date) (Notary name)

personally appeared _____, personally known to me
(Name)

(or provided to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her authorized capacity, and that by his/her signature on the instrument the person or entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

Signature_____ Official Notary Seal

Distribution: Original-UHR, Copy Inmate

DRAFT

CHAPTER 21
Palliative Care and Treatment

I. POLICY
The California Department of Corrections and Rehabilitation (CDCR) shall provide palliative care and treatment when the inmate-patient's terminal condition results in pain or disability to such an extent that the Primary Care Physician (PCP) and the inmate-patient determine that only palliation shall be provided.

II. PURPOSE
To provide comfort, relief from pain, and support when the inmate-patient has received a terminal diagnosis.

III. PROCEDURE
1. The PCP shall evaluate the inmate-patient and prescribe a treatment plan as warranted for palliative or comfort care. The ordered treatment shall be documented on a CDCR Form 7221, Physician's Order, and filed in the inmate-patient's Unit Health Record (UHR).
2. A pain control plan (including narcotics) will be developed with the assistance of a specialist, as appropriate.
3. If the inmate-patient meets the criteria for hospice care, the PCP shall complete a referral to CDCR's hospice at the California Medical Facility.
4. Hospice Admission Criteria are:
   a. The hospice has obtained written acceptance for hospice care from the Chief Medical Officer or designee.
   b. The hospice PCP and/or Chief Medical Officer or designee certifies a prognosis six (6) months or less if the disease follows its expected course.
   c. The inmate-patient and/or designated legal representative agrees to palliative goals/philosophy of hospice services.
   d. The custody level generally cannot be greater than a Close A and there cannot be any other precluding custody considerations (such as enemy situations).
   e. The hospice has the ability to meet the needs of the inmate-patient, according to the level and intensity of care required.
   f. There are adequate, cooperative efforts by the inmate-patient to follow safety measures and the plan for medical and non-medical emergencies.
   g. The hospice has adequate, suitable personnel and resources to provide the services required by the inmate-patient.
5. Inmate-patients receiving palliative care shall continue to receive medically necessary treatment for other medical conditions that may occur or coexist, such as injuries, infections, and chronic conditions (e.g., hypertension, diabetes).
6. Refusal of medically necessary care shall be documented on a CDCR Form 7225, Refusal of Examination and/or Treatment, and shall be filed in the inmate-patient's UHR.
7. Health Care Services staff shall inform inmate-patients that they may obtain a consultation with the Mental Health Services Department or Chaplain of their choice within the institution. Upon the inmate-patient's request, an appointment shall be made with the requested discipline.
8. The Health Care Manager shall request a "Compassionate Release" when appropriate.
9. Health care staff shall follow the Department's procedure for "Advance Directives."

Palliative Care for Prison Inmates

"Don't Let Me Die in Prison"

John F. Linder, MSW, LCSW; Frederick J. Meyers, MD

JAMA. 2007;298(8):894-901.

ABSTRACT

The number of older inmates in US correctional facilities is increasing and with it the need for quality palliative health care services. Morbidity and mortality are high in this population. Palliative care in the correctional setting includes most of the challenges faced in the free-living community and several unique barriers to inmate care. Successful models of hospice care in prisons have been established and should be disseminated and evaluated. This article highlights why the changing demographics of prison populations necessitates hospice in this setting and highlights many of the barriers that correctional and consulting physicians face while providing palliative care. Issues specific to palliative care and hospice in prison include palliative care standards, inmate-physician and inmate-family relationships, confidentiality, interdisciplinary care, do-not-resuscitate orders and advance medical directives, medical parole, and the use of inmate volunteers in prison hospice programs. We also include practical recommendations to community-based physicians working with incarcerated or recently released prisoners and describe solutions that can be implemented on an individual and systems basis.

THE PATIENT'S STORY

Mr L is an inmate in his early 40s, incarcerated in a state correctional facility where he is serving a 10-year sentence for manslaughter. In June 2005, he was transferred to a prison treatment setting after he complained of back pain and bloody sputum. His hemoptysis was evaluated with a chest x-ray, which was abnormal. A subsequent computed tomography (CT) scan showed a right upper-lobe mass; a biopsy confirmed adenocarcinoma. A magnetic resonance imaging scan to evaluate his back pain revealed metastatic invasion of T12 and L1, confirming stage IV disease.

Dr V, the prison physician, referred Mr L to a cancer center at a university medical center, where he completed a course of radiation and received first-line chemotherapy. Unfortunately, a reassessment of his disease by repeat CT after several months of chemotherapy showed tumor progression. A second chemotherapy regimen was undertaken, but it also failed to stop disease progression. Mr L was then referred to hospice inside the correctional facility. He was simultaneously referred for medical parole.

A Perspectives editor interviewed Mr L; the prison's internist, Dr V; and the prison's hospice caregiver coordinator, Dr S, in April and May 2006. Dr S suggested Mr L as a hospice patient who would be willing to talk about his own disease, and Mr L, Dr V, and Dr S all provided signed informed consent forms. Mr L's interview was conducted by telephone in the office of his caseworker on the prison staff. A student intern was

present when the interview took place; Dr V and Dr S were not present during Mr L's interview.

PERSPECTIVES

DR V (PRISON PHYSICIAN): *My role is to admit inmates from any of the 4 correctional institutions in the area into a local community hospital for medical treatment . . . [and] to supervise treatment of inmates . . . on our medical wing. While [Mr L] is here, I am his primary care physician. I'm not an oncologist, so I have to defer to the experts on the treatment of his cancer, but I take care of his primary medical needs, like any other internist would.*

MR L (PATIENT/INMATE): *I was supposed to have surgery done in September. It took the prison 2½ months to get me out to the doctors. By that time, it had turned malignant and gone into all of my body. . . . The cancer started in my lung and spread through my chest and into my spine. The cancer broke my back.*

DR S (PSYCHOLOGIST AND HOSPICE CAREGIVER COORDINATOR): *. . . The hospice caregivers are all inmate volunteers. . . . They visit [patients] as much as their schedules allow because they also have responsibilities such as jobs and school. . . . There is a bond between the inmates. . . . They share incarceration and separation from family members. . . . They understand the fear of dying in prison and the fear of dying alone.*

Federal, state, and local inmate populations across the United States are growing larger and older, primarily due to longer sentences and "three strikes" sentencing laws.[1] The needs of chronically ill and dying inmates include many of the challenges faced in the free-living community as well as several unique features. Successful prison hospice programs retain the best elements of community hospice applicable in this setting and integrate elements distinctive to the correctional system.

Using Mr L's story, this article provides correctional and noncorrectional physicians important contextual information and core medical knowledge needed to care for inmates or former inmates with advanced illness. A brief overview of the demographics, deficits in access to care, financing, and resources in correctional health care settings is presented. Issues specific to palliative care ethics, standards of palliative care, and hospice in prison follow. We also include practical recommendations to community-based physicians working with incarcerated or recently released prisoners.

HEALTH CARE IN CORRECTIONAL SETTINGS

Demographics

DR V: *There are an awful lot of 50-, 60-, 70-year-old inmates who come to prison with chronic illnesses. Even the younger inmates are not as healthy as typical*

Americans their age. We have a lot of inmates coming in with hepatitis C, untreated coronary disease, untreated or poorly treated diabetes, you name it.

Inmates are sicker than the general population.[2-5] The need for good general medical assessment and care, and especially for hospice and palliative care, logically follows the demographic patterns. To Dr V's list, we could add human immunodeficiency virus and AIDS, chronic obstructive pulmonary disease, end-stage renal and liver disease, hypertension, and numerous other conditions. Contributory factors include substance abuse and addiction, prior limited access to health care, low health literacy, poverty, homelessness, and undiagnosed or untreated mental illness.[6-8] The cycle of recidivism accentuates the lack of continuity of care between prison-based and community-based health care.

In the period 2001-2004, the state prisoner death rate nationwide was 19%, lower than that of the general adult population of the same age, although the composition of the populations differ by age bracket.[9] The black prisoner death rate was 57% lower than that of the same-age black adult population. Despite lower mortality rates, the absolute number of deaths among current inmates is climbing.[9] However, release from prison can result in sharply increased mortality risks.[10] Inmates and the free-living populations share 6 of the 10 leading causes of death: heart disease, cancer, cerebrovascular disease, respiratory diseases, influenza/pneumonia, and septicemia. Prisoners' remaining 4 leading causes of death are chronic liver disease, AIDS, intentional self-harm, and digestive diseases.[9, 11-14]

The other key demographic factor is the sharp increase in the absolute number of inmates,[15-18] placing even greater strains on the correctional health system.[19] In 2005, an estimated 1 in 491 US residents was in prison.[15] Health care costs in 2001, the most recent available, were approximately $7.41 per inmate per day, a total of $3.3 billion annually.[20-22]

Women constitute a small but rapidly growing segment of prisoner demographics.[15] Many enter the system with morbidity greater than age-matched peers.[23-25] Women often serve shorter sentences, limiting their opportunities for screening and chronic disease management.[26] A number of notorious inmate deaths have recently served to highlight deficiencies in end-of-life care for women in prison.[27]

Deficits in Prior Access to Care, Family Support, and Information

Physicians should recognize that for many inmates, prison is the first time in their adult lives that they have consistent access to health care. Nevertheless, with security a paramount concern in prisons, timely access to treatment can sometimes be impeded, as Mr L perceived. Inmates do not enjoy the benefit of family support during medical visits and have only limited access to health ombudsmen or patient advocates.

Approximately 20% of adults in the United States have limited literacy skills, meaning that they find it difficult to read and therefore understand and act on health information.[28] Although low health literacy affects persons of all age, race, educational achievement, and income groups, the prevalence is higher for adults in ethnic minorities and of lower socioeconomic status.[29] Incarcerated individuals are more likely to have both low literacy and low health literacy, often resulting in misunderstandings, frustration, and poorer health outcomes.[30] In this case, Mr L

misunderstood essential elements of his cancer pathogenesis and the effects of treatment and treatment delays on his prognosis.

Most free-living patients and caregivers can search the Internet for information, but access to the Internet for inmates is severely restricted. They also have very little say in choosing their clinicians. These deficits accentuate the physician's greater responsibility to communicate clearly, to provide information at an appropriate literacy level, and to allow time for questions when delivering an inmate's diagnosis and discussing treatment and palliative options.

Financing and Resources

Dr V: *From the standpoint of care of an individual patient,* [*prison physicians*] *don't have the kind of financial concerns that a community-based physician might. We do have a prior-approval process, but there are never any insurance issues. . . . If an inmate has a need for care to maintain life or health, the inmate gets that care.*

Correctional health services, including hospice, operate independently of Medicare, Medicaid, and all private insurers. Often, 1 or 2 prisons are designated as the central health care facilities for an entire state system or federal region. Designated facilities also house most of the nation's prison hospices. Contrary to Dr V's assertion, some data suggest that curative and life-prolonging approaches are limited for inmates.[31]

Innovative approaches can improve inmate health including palliative care. Examples include chronic disease management clinics,[32] use of telemedicine,[33-35] partnerships between academic medical centers and penal institutions,[32, 36] and the outsourcing of inmate health care.[37] These innovations and partnerships are increasingly implemented in correctional hospice programs, although only anecdotally reported.

Palliative Care and Hospice With Incarcerated Populations

Ethics and Standards of Care

Although many in free-living society assign a low priority to providing prisoners with high-quality health care, medical ethicists, provider organizations, and the judiciary see it as an ethical imperative.[38-40] This extends to palliative care as well.[41] Courts have generally affirmed that incarceration itself, not substandard health care, is the intended punishment for criminal acts. The judiciary does so by increasingly ruling against deliberate indifference,[42-44] affirming an inmate's constitutional right to health care,[45] and defining the community standard of care as the constitutionally protected minimum acceptable threshold for inmate health care,[45-46] although the judicial record is not uniform.[47] When the quality of care delivered falls below the acceptable threshold, the courts have not been timid about intervening.[48] For example, California is currently undergoing a court-ordered revamping of its inmate health care system,[49-50] estimated to cost hundreds of millions of dollars.

The National Commission on Correctional Health Care advocates for high-quality inmate health care, including palliative care, and has published clinical guidelines for health services in prisons.[51-52] The Centers for Disease Control and Prevention also has issued clinical guidelines for use in correctional settings.[53] Specific end-of-life care standards of practice for inmates in correctional settings[54] are adapted directly from the National Hospice and Palliative Care Organization standards of practice.[55]

Evaluation of the standards would be a valuable contribution to the research and quality improvement in prison hospice.

Providing hospice services in prison dates back to the early 1980s. In 2001, the most recent US-Canadian survey data available, hospice programs existed in 25 of the 49 jurisdictions reported on (including US territories and states and Canada). Twenty-two operate hospice as part of their infirmaries; 5 are free-standing hospice units.[20]

Descriptions of a number of these programs[20, 56-60] reveal both the strengths and vulnerabilities of prison hospice. Elements of best practice include staff and security personnel training in hospice philosophy; comprehensive symptom management training for medical personnel; dedicated staffing; inmate volunteers; bereavement services for inmates, volunteers, and staff; increased family contact and visitation; interdisciplinary care including psychosocial and spiritual services; community volunteers and community hospice involvement; and comprehensive care planning and advance medical planning

A comparison of prison and community hospices is shown in the Table. Prison physicians have greater flexibility in some respects, for instance, in being able to overlap dialysis with hospice care when patients or families are just learning of a terminal prognosis, or in offering hospice to patients with a prognosis of more than 6 months. Prisons are left to define which palliative services will be provided and how, as long as they abide by the judicial rubric of comparability with the community standard of care.

View this table:	Table. Not included

Despite these advantages, prison physicians confront challenges, including restrictions on inmate and staff movement; limited access to urgent care facilities; restricted pharmacy formularies; impediments to dispensing medications on an "as needed" basis; limited patient autonomy, as corrections department policies sometimes restrict the use of do-not-resuscitate (DNR) orders and advance medical directives; finding, training, and employing hospice volunteers; and defining patients' "families" and determining when and how to work with them.

Some policies or statutes may simplify palliative care treatment decisions for inmates. For example, laws intended to protect inmates from unethical research practices prevent prisoners from participating in clinical trials. Although this limits treatment options, it simplifies the decision to transition from disease-directed therapy to palliative care. Simultaneous care, providing concurrent disease-directed therapy and palliative or hospice care,[61-62] is more easily accomplished unencumbered by Medicare's conditions of participation criteria.

Symptom Management

DR V: *All medicines are given at pill call: 3 or 4 times a day, inmates line up, . . . and a nurse will pass them their medications, narcotics, or otherwise, with an officer sitting right there. . . . The whole process is observed. The medication is given in a cup. The inmate does not put the pill in his hands. The pill goes directly to the mouth, drink the water, and swallow. . . . Controlled substances, narcotics in particular, are crushed. The one exception to that are medicines that can't be crushed, like MS Contin, long-acting narcotics that need to be swallowed intact.*

Mr L gets MS Contin, I believe 90 mg every 8 hours. He can have Vicodin at pill call for breakthrough pain. . . . When I ask him about pain, he says it's fine. I have no reason to doubt him.

MR L: [*The pain*] *gets pretty out of hand sometimes. . . . If you can catch the right nurse or the right doctor, they can situate you where they can help you some. If you were to gauge my pain on a scale of 1 to 10 right now, it would be about 8.5. I've learned to deal with that kind of pain. I don't want to be totally out of pain because then I won't know what I'm really going through.*

In prisons and jails, pain management can be particularly vexing. Many inmates have addiction histories. The risks of drug diversion and abuse are real. As Mr L's case illustrates, there can be a mismatch between physician assessment and patient report of pain. Adherence can be an issue as well. Inmates are not forced to come to pill call. Inmates retain the right to consent and participate in or refuse treatment. In the general prison population, few options for intervention or relief exist between pill calls. Though the challenges of inmate symptom management are well-described, very little has been written in the United States about strategies for managing inmates' symptoms specifically[63] and virtually no research has been conducted. The paucity of research literature reflects both the historical abuses of inmates in research[64] and the resultant severe restrictions placed on inmate participation in research today.

Noncorrectional physicians providing prison patients with active treatment can independently assess a patient's pain and make recommendations directly to the correctional physician. Inmates may be more willing to discuss inadequate pain control with an outside physician. The community physician can also work with the inmate and the corrections physician to identify the level of care best suited to the inmate's symptom management needs; this in turn dictates which is the appropriate care unit.

The involvement of outside physicians with palliative care and hospice experience as trainers and consultants[65] can aid in corrections institutions' implementation and adherence to the published correctional hospice standards and helps ensure continuity of care between shifts and among clinicians inside the prison.

Prognosis and Site of Care

DR V: *If those of us that are treating an inmate agree that the inmate has a terminal condition, whether it's 6 months or not, we provide hospice care,* [*and*] *we can provide nursing care at the nursing facility, if that's appropriate.*

MR L: *I'm locked up in a medical wing with a lot of sick people. There's a lot of people in there that have cancer, too. They're all benign. They can recover from theirs and I can't.*

Moving Mr L to a medical unit within the prison affects his daily life dramatically. In this case, the medical unit is physically separated from the general prison population. Potential advantages to the inmate include increased security and fewer physical demands; frequent symptom assessment, medication titration, as-needed dosing and enhanced modes of delivery of medications; and perquisites like access to books or television, special diets, and smoking privileges or somewhat greater freedom in how one's time is spent.[1] These advantages may offset the disadvantages of being separated from friends, losing their prison "job," and having decreased opportunities for visitors from outside of the prison, because infirmaries are usually less readily accessible. Community physicians can ameliorate the emotional distress of these changes by actively discussing new goals that can be achieved in the face of advancing illness and facilitating decisions based on the benefits of choosing palliative care goals and hospice.

Patient-Physician Relationships

MR L: [*Doctors should*] *be honest with the people they're talking to. . . . If a person has cancer, like me, I wanted to know exactly what was wrong with me. You can deal with the honest truth a lot better. If you go to a doctor who tells you it might be a cyst or something else when there's a thought in his mind that it might be cancer, then he should tell the patient that it might be*.

Mr L emphasizes the importance of a trusting patient-physician relationship to him. Noncorrectional physicians are likely to see an inmate patient in a clinic or hospital setting with 1 or more security officers present, raising concerns of patient confidentiality. Privacy is not possible with outside observers to the clinical encounter,[66] potentially violating the Code of Medical Ethics.[67] Physical examination of inmates can be restricted because they are routinely shackled and may be in jumpsuits. Hands-on care of felons may raise personal safety considerations for physicians.

The financing of inmate health care and the inherent power imbalance between physicians and inmates[68] further impair a secure and trusting relationship. That mistrust is amplified during end-of-life care. Some recent mortality data comparing median survival with national cancer statistics for the same cancer diagnoses, adjusted for stage, support inmate skepticism about putting their faith in prison health care systems.[31] In this case, Mr L's poor understanding of his disease led him to conclude that the time spent waiting for approval of his care outside the prison made the difference between a benign or malignant disease and between cure and a terminal prognosis. Though inaccurate, he may share this perception with fellow inmates, deepening the atmosphere of mistrust.

Community physicians can build stronger relationships and overcome this mistrust by asking inmates about their health care access history; acknowledging (when applicable) the inmate's lack of experience with consistent care and providers; explaining their relationship and committing to follow-up with the inmate for the duration of treatment; acknowledging the awkwardness, stigma, and lack of privacy

of the current encounter; and listening attentively to questions and checking for understanding.

Family Relationships

MR L: *The worst thing to me right now is that I have 4 children. I'd like to see them before I die in a place like here. . . . My oldest daughter is 17, my youngest son is 7. . . . They live so far away that I don't get to see them. . . . That's the hardest part of it all, being away from my family, being away from my children.*

Many inmates are estranged from their families.[69-70] Other inmates' families have limited resources and thus transportation and accommodations for visits to the inmate are beyond their financial capabilities. Out-of-state placement of inmates can also exacerbate estrangement and impede visits from family members. In this case, Mr L does have family, including children; limited contact with them weighs heavily on him.

In prison, "family" may also mean other inmates.[54, 58, 71] This adds a layer of complexity to an ill inmate's decision to self-identify as having special health needs. Institutional policies may neither recognize nor support inclusion of other inmates as "family." Noncorrectional physicians can emphasize the integral role that interpersonal support plays in quality end-of-life care in their plan of care.

Interdisciplinary Team Care

DR V: [*W*]*e don't have a specific hospice nurse. . . .* [*S*]*taff nurses will take care of the hospice patients. Dr S, a psychologist who is deeply involved with the hospice program, would be the person who would deal with the psychosocial issues. We have chaplains from all the major religions. . . . Inmate hospice volunteers are available to provide whatever assistance they can. It's not that much different from the outside. It really isn't.*

DR S: *There isn't a clinical hospice team. At this time, that would just be me. It seems as though there would be a team, but there isn't a team approach to* [*hospice patients*].

The Institute of Medicine,[72] the World Health Organization,[73] and myriad palliative care and hospice organizations recognize the medical, psychological, social, and spiritual aspects of terminal illness and the impact these have on patients and their families. Medicare was quite intentional in defining the patient-family as the unit of care and designating the interdisciplinary team as the model of care delivery for hospice. The end of life from a disease process like Mr L's cancer is more than a medical phenomenon.

Many prison hospices have successfully established interdisciplinary teams, composed of health care professional and custody staff and a deputy warden, whose participation is essential to a successful prison hospice program.[20, 54, 56-58,74] In this example, there is a lack of coordination of care as evidenced by Dr V's and Dr S's contradictory reports about the existence of an interdisciplinary team and the provision of psychosocial care.

Poor communication and inadequate coordination of care can be reduced through formal training programs taught by interdisciplinary teams that emphasize the summative impact of integrated multidisciplinary teams. These programs are increasingly available, for example, from Education on Palliative and End-of-Life Care (EPEC),[75] the End-of-Life Nursing Education Consortium (ELNEC) curriculum, and the American Board of Hospice and Palliative Medicine's physician board certification in hospice and palliative medicine,[76] the Palliative Care Leadership Centers; state mandates for palliative care continuing education also assist in promoting such training.

Resuscitation Status and DNR Orders in Prison

DR V: [*T*]*he Department of Corrections rules say that there is no such thing as a "do not resuscitate" for inmates in the general population. . . .* [*A*] *lot of our wardens are of the opinion that it gives comfort to other inmates to see that somebody who is seriously ill is getting maximal treatment. They feel that it is important to get this message out to prevent unrest within the prison population. . . .*

Most of our guys are not real sophisticated folks, and I'd say the majority of them have the feeling that when they get sick, we ought to do something to cure them. . . . A better educated, middle-class American might realize sooner that this is a case where cure is not possible. These guys tend to come to that conclusion a little bit slowly. They tend also to be a little bit distrustful of you when you do say that. Their first thought is that the department just doesn't want to spend the money.

MR L: *If I die, I want them to leave me alone. . . . Dying doesn't scare me, which really puzzles most people. Most people are scared to death [of] the unknown. The loss. It would probably be different [if I were living outside] because I would be with my family. I'd be with my children.*

Advance care directives and DNR orders can carry added meaning in the criminal justice setting,[77] fueled by inmate distrust that the correctional system acts with their best interests in mind, administrative concerns that resuscitative efforts be highly visible and ubiquitous to avoid accusations of neglect or indifference, and clinicians' doubts that inmates who will not agree to a DNR do not fully understand the hospice philosophy.[20] In 2001, 35 of 49 jurisdictions reporting (71%) allowed inmates to issue advance medical directives, and 42 of 49 (86%) allowed DNR orders,[20] though research on inmate understanding and actual use of either instrument is lacking.

Mr L is atypical in that he has completed an advance directive and has a DNR order in place; most terminally ill inmates do not. Dr V states that prisons are likely to offer or provide more aggressive curative attempts (and perhaps even unwanted care) as they seek to dispel any impression of deliberate indifference or withholding treatment from inmates; this can translate into doing "everything possible" to revive a patient in extremis. Thus, the inmate's own wishes may run counter to those of prison administrators and to those of their family. Other inmates may interpret more invasive or burdensome care as better. Innovative approaches to overcome this misunderstanding in the setting of inmate health decision making, as well as the literacy concerns noted earlier, are few in number[78-79] and more are needed.

Given inmates' limited access to information noted earlier, community physicians can offer an inmate statements such as, "This course of action is what I recommend to

any patient I see whose disease and response to treatment is like yours." Helping the patient understand how his or her body changes throughout disease progression and that respiratory or cardiac arrest is the natural end point of disease progression may allay concerns about withholding interventions like cardiopulmonary resuscitation (CPR). A DNR order can thus be explained as consistent with the new goals of treatment: ensuring comfort and enhancing quality of life. Graphically explaining the process of CPR and the likelihood that the patient would die in transit to an outside hospital, in an emergency department, or in an intensive care unit, alone, separated from their biological and prison families, without a hospice volunteer sitting vigil, provides critical information inmates can use to decide what is best.

Volunteers

MR L: *It makes it pretty handy, him (the hospice volunteer) being a fellow inmate, because he can come in and talk to me fairly regularly. . . . We talk about different religious things. . . . How I feel about this disease I got, how I can cope with it, how I can handle it.*

DR S: *When the person* [*becomes*] *very ill or it looks like they are in their last hours of life, security will allow a hospice caregiver to come down from their dorm at whatever time of day or night. . . . Many times, the nurse will be in and out, but the hospice caregiver will be there at the end of their life, in the room, sitting with them*.

In the prison setting, a hospice program's most readily available supply of volunteers is other inmates. Volunteers in hospice programs provide companionship, emotional support, and practical assistance. In 2001, 26 of 49 jurisdictions indicated that inmate volunteers are used to assist chronically ill inmates; 3 of these indicated that volunteers are only used in their hospice programs.[20] No question specific to hospice inmate volunteers was included.

Mr L's prison does use inmates as hospice volunteers. Programs that involve inmate volunteers must deal with issues of selection, training, defining volunteers' scope of practice, ensuring security and patient confidentiality, and attending to volunteers' emotional and spiritual support needs. Inmate volunteers must be able to overcome differences of race, religion, and committal offense in order to be successful. Training is essential. Debriefing with the volunteers is often one of the duties of the inmate volunteer coordinator, who sometimes can then advocate more effectively on an inmate-patient's behalf. Little research has been conducted on the effects of participation on hospice inmate volunteers, but anecdotally, for many volunteers this work can be redemptive,[80-81] providing an opportunity to make reparations. One Angola (Louisiana) hospice volunteer said, "I did a lot of wrong and hurt a lot of people out there. When I heard about hospice, it was in my heart to join because this would be my way of giving back to society."[82] Research in this area would be quite valuable.

Medical Parole

DR S: *One of the things that I hear in the general population a lot is, "Of all the things that could happen, please don't let me die in prison."*

DR V: *If we are successful in obtaining his medical parole,* [*until release*] *we will try to control his pain. On 10 B (a medical housing unit), he is fairly functional and*

independent. If he gets to the point where he can't do that, we will move him to our nursing care facility. They will care for [*him*] *there and give him whatever assistance he needs with activities of daily living, and so on. If he doesn't get parole and he doesn't serve out the time, he will die in prison.*

MR L: *I'm hoping my doctor will put me in front of the medical parole board. The last time I spoke with the oncologist, he said I didn't have more than about 3 months left to live.*

Medical parole, or compassionate release, is the procedure for securing a terminally ill inmate's release from prison; the process varies by jurisdiction. Of the 49 agencies surveyed in 2001, 43 offered some form of compassionate release. The average number of annual requests was 18, and the average granted was 8.[20] A final decision is reached only after a long and cumbersome process, usually involving the warden and parole or review board, and even the state's governor.[20, 83] Given that the safety of society is the primary mandate of the corrections system, prison systems consistently err on the side of continued confinement of the inmate, even if this means death behind bars.[84] Inmates granted compassionate release are almost always in the final days of life.

Ideally, prisons have developed relationships with hospices in their area for the care of prisoners freed on compassionate release. Prisons and community hospices should work together to achieve a seamless transfer of care, facilitating placement if necessary, arranging insurance coverage, which often entails applying for Medicaid coverage, and if possible facilitating a successful return to family for home hospice care. Family and community reluctance to accept patients eligible for compassionate release heightens the importance of prerelease care coordination.[20] Occasionally, inmates are released to a residential hospice or skilled nursing facility with ties to a hospice program. Because such patients are usually bed bound or obtunded, such medically paroled prisoners pose almost no threat to society. Yet even in an advanced state of illness, the inmate's greatest fear, dying "inside," is relieved by compassionate release.

CONCLUSION

Correctional hospice challenges physicians to use all of their communications and palliative care skills. Collaboration between local correctional and community-based palliative care service providers through joint trainings, site visit exchanges, and funding initiatives that support continuity of care for released inmates who are terminally ill will transform prison end-of-life care and perhaps serve as a model for inmate health care overall. Evaluation studies of current correctional hospice programs and of the Standards of Practice for Inmates in Correctional Settings will move the cause of inmate palliative care forward. More rigorous research into the efficacy of specific palliative interventions would further refine the care standards.

Noncorrectional and correctional physicians are increasingly aware of systemic and demographic strains threatening the treatment of prisoners with advanced chronic illness and terminal conditions. The aging inmate population, their overall morbidity, and the mandate that they be provided the community standard of care means that community physicians will increasingly care for people like Mr L. Correctional and community physicians can do a great deal in partnership to relieve the pain and anguish of those inmates dying in prison who have paid for their crimes with loss of

freedom and who should not have a painful or poorly managed death as part of their sentence.

AUTHOR INFORMATION

Corresponding Author: Frederick J. Meyers, MD, Department of Internal Medicine, University of California, Davis, 4150 V St, No. 3100, Sacramento, CA 95864 (fred.meyers@ucdmc.ucdavis.edu).

Financial Disclosures: Mr Linder and Dr Meyers provide training to inmate volunteers and staff under a contract between the California Department of Corrections and the Regents of the University of California. This work is performed at the California Medical Facility, Vacaville. These duties are performed in the course of the authors' overall job responsibilities and neither receives compensation beyond regular salary and benefits for actual time spent preparing and delivering training.

Funding/Support: The Perspectives on Care at the Close of Life series is made possible by funding from the California HealthCare Foundation. Mr Linder is supported in part by grant DSW-06-218-010SW from the American Cancer Society, a training grant in oncology social work.

Role of the Sponsor: The California HealthCare Foundation and the American Cancer Society had no role in the preparation, review, or approval of the manuscript.

Perspectives on Care at the Close of Life is produced and edited at the University of California, San Francisco, by Stephen J. McPhee, MD, Michael W. Rabow, MD, and Steven Z. Pantilat, MD; Amy J. Markowitz, JD, is managing editor.

Other Sources: For a list of relevant Web sites, see below.

Resources for Correctional Hospice

National Committee on Correctional Health Care

http://www.ncchc.org

The mission of the National Commission on Correctional Health Care is to improve the quality of health care in jails, prisons, and juvenile confinement facilities.

Society of Correctional Physicians

http://www.corrdocs.org

The Society of Correctional Physicians was formed in 1993 to provide a forum for the support, education, and professional development of physicians delivering health care in a correctional setting. It aims to promote, improve, and if

necessary, defend the standards of care extended by its members.

Academy of Correctional Health Professionals

http://www.correctionalhealth.org/index.asp

The Academy of Correctional Health Professionals is the nation's community for correctional health care. Through publications, educational activities, and special events, the academy works to connect clinicians with peers from across the country.

The GRACE (Guiding Responsive Action For Corrections in the End-of-Life) Project

http://www.dyingwell.org/grace2001.htm

This is the forward for *A Handbook for End-of-Life Care in Corrections Facilities.* It summarizes the issues challenging health care and hospice in the corrections system and includes valuable links related to prison hospice.

End-of-Life Care Standards of Practice for Inmates in Correctional Settings

http://www2.edc.org/lastacts/archives/archivesMay00/standards.asp

Standards of Practice were developed by the GRACE (Guiding Responsive Action for Corrections in End-of-life) Project, a Robert Wood Johnson Foundation Promoting Excellence in End-of-Life Care initiative, administered by Volunteers of America. Included is Innovations in End-of-Life Care, an international journal of leaders in end-of-life care.

American Correctional Health Services Association

http://www.achsa.org

The American Correctional Health Services Association's mission is to be the voice of the correctional health care profession and to serve as an effective forum for communication addressing current issues and needs confronting correctional health care. The association holds annual multidisciplinary conferences designed to provide education on the latest developments in correctional health care, including continuing educational credits.

National Institute of Corrections

http://www.nicic.org

The National Institute of Corrections is an agency within the US Department of Justice, Federal Bureau of Prisons. The agency provides training, technical assistance, information services, and policy and program development assistance

to federal, state, and local corrections agencies.

American Correctional Association

http://www.aca.org

The American Correctional Association is the oldest and largest international correctional association in the world. It serves all disciplines within the corrections profession and is dedicated to excellence in every aspect of the field: from professional development and certification to standards and accreditation, from networking and consulting to research and publications, and from conferences and exhibits to technology and testing.

American Board of Hospice and Palliative Medicine

http://www.abhpm.org

The American Board of Hospice and Palliative Medicine was formed in 1995 to establish and implement standards for the certification of physicians practicing hospice and palliative medicine. It creates and administers the certifying examination, works to implement high standards for training, and contributes to setting the standards for excellence in palliative medicine.

American Academy of Hospice and Palliative Medicine

http://www.aahpm.org

The American Academy of Hospice and Palliative Medicine is an organization of physicians and other medical professionals dedicated to excellence in and advancement of palliative medicine.

National Prison Hospice Association

http://www.npha.org

The National Prison Hospice Association promotes hospice care for terminally ill prisoners. Its purpose is to assist corrections and hospice professionals in their continuing efforts to develop high-quality patient care procedures and management programs. It also provides a network for the exchange of information between corrections facilities, community hospices, and other concerned agencies about existing programs, best practices, and new developments in the prison hospice field.

Palliative Care Leadership Centers

http://www.capc.org

Palliative Care Leadership Centers is a national training and mentoring initiative supported by a consortium of funders, with direction and technical assistance

provided by the Center to Advance Palliative Care. Exemplary palliative care programs located at 6 different institutions, the center offers training and mentoring to help start and expand hospital palliative care programs in the United States.

Author Affiliations: Department of Internal Medicine, Division of Hematology and Oncology, UC Davis Cancer Center (Mr Linder), Department of Internal Medicine (Dr Meyers), Division of Hematology and Oncology and Smith College School for Social Work, UC Davis Cancer Center (Mr Linder), University of California, Davis, Sacramento.

REFERENCES

1. *Hospice and Palliative Care in Prisons: Special Issues in Corrections.* Longmont, CO: US Dept of Justice, National Institute of Corrections Information Center; September 1998.
2. Mitka M. Aging prisoners stressing health care system. *JAMA.* 2004;292(4):423-424. FREE FULL TEXT
3. Yorston GA, Taylor PJ. Older offenders: no place to go? *J Am Acad Psychiatry Law.* 2006;34(3):333-337. FREE FULL TEXT
4. Voelker R. New initiatives target inmates' health. *JAMA.* 2004;291(13):1549-1551. FREE FULL TEXT
5. Fazel S, Hope T, O'Donnell I, et al. Health of elderly male prisoners: worse than the general population, worse than younger prisoners. *Age Ageing.* 2001;30(5):403-407. FREE FULL TEXT
6. Falter RG. Selected predictors of health services needs of inmates over age 50. *J Correct Health Care.* 1999;6(2):149-175. FULL TEXT
7. Freudenberg N. Jails, prisons and the health of urban populations: a review of the impact of the correctional system on community health. *J Urban Health.* 2001;78(2):214-235. ISI | PUBMED
8. Harris F, Hek G, Condon L. Health needs of prisoners in England and Wales: the implications for prison healthcare of gender, age and ethnicity. *Health Soc Care Community.* 2007;15(1):56-66. ISI | PUBMED
9. Mumola CJ. *Medical Causes of Death in State Prisons, 2001-2004*. Washington, DC: US Dept of Justice; 2007:12. http://www.ojp.gov/bjs/pub/pdf/mcdsp04.pdf. Accessed July 25, 2007.
10. Binswanger IA, Stern MF, Deyo RA, et al. Release from prison: a high risk of death for former inmates. *N Engl J Med.* 2007;356(2):157-165. FREE FULL TEXT
11. Deaths, percent of total deaths, and death rates for the 15 leading causes of death. CDC/NCHS, National Vital Statistics System; 2001. http://www.cdc.gov/nchs/data/dvs/LCWK2_2001.pdf. Accessibility verified August 2, 2007.
12. Deaths, percent of total deaths, and death rates for the 15 leading causes of death. CDC/NCHS, National Vital Statistics System; 2002. http://www.cdc.gov/nchs/data/dvs/LCWK2_2002.pdf. Accessibility verified August 2, 2007.
13. Deaths, percent of total deaths, and death rates for the 15 leading causes of death. CDC/NCHS, National Vital Statistics System; 2003.. Accessibility verified August 2, 2007.
14. Deaths, percent of total deaths, and death rates for the 15 leading causes of death. CDC/NCHS, National Vital Statistics System; 2004. http://www.cdc.gov/nchs/products/pubs/pubd/hestats/finaldeaths04/finaldeaths04_tables.pdf#2. Accessibility verified August 2, 2007.
15. Harrison P, Beck A. *Prisoners in 2005*. Washington, DC: US Dept of Justice, Bureau of Justice Statistics; 2006:13.
16. Mumola C, Beck A. *Prisoners in 1996*. Washington, DC: US Dept of Justice, Bureau of Justice Statistics; 1997:15.
17. Beck A, Harrison P. *Prisoners in 2000.* Washington, DC: US Dept of Justice, Bureau of Justice

Statistics; 2001:16.
18. Beck A, Gilliard D. *Prisoners in 1994*. Washington, DC: US Dept of Justice, Bureau of Justice Statistics; 1995:15.
19. Cummings C. *Older Inmates: The Impact of an Aging Inmate Population on the Correctional System.* Sacramento: California Dept of Corrections; 1999:87.
20. Anno BJ, Graham C, Lawrence JE, Shansky R. *Addressing the Needs of Elderly, Chronically Ill, and Terminally Ill Inmates*. Middletown, CT: Criminal Justice Institute; 2004:162.
21. Stephan J, ed. *State Prison Expenditures, 2001: Bureau of Justice Statistics Special Report*. Washington, DC: US Dept of Justice; 2004:9.
22. Kinsella C. *Corrections Health Care Costs: Critical Information for State Decision-Makers*. Lexington, KY: Council of State Governments; 2004:38.
23. Smith BV, Dailard C. Female prisoners and AIDS: on the margins of public health and social justice. *AIDS Public Policy J.* 1994;9(2):78.
24. Reviere R, Young V. Aging behind bars: health care for older female inmates. *J Women Aging.* 2004;16(1-2):55-69. PUBMED
25. Maeve M. Adjudicated health: incarcerated women and the social construction of health. *Crime Law Soc Change.* 1999;31:49-71. FULL TEXT | ISI
26. Magee CG, Hult JR, Turalba R, McMillan S. Preventive care for women in prisons: a qualitative community health assessment of the Papanicolaou test and follow-up treatment at a California State women's prison. *Am J Public Health.* 2005;95(10):1712-1717. FREE FULL TEXT
27. Chandler C. Death and dying in America: the prison industrial complex's impact on women's health. *Berk Wom Law J.* 2003;18:40-60. PUBMED
28. Partnership for Clear Health Communication Steering Committee. Eradicating low health literacy: the first public health movement of the 21st century overview. http://www.aameda.org/MemberServices/Exec/Articles/sum03/EradicatingLowHealthcareLiteracy.pdf. Published March 2003. Accessed July 26, 2007.
29. Bennett IM, Kripalani S, Weiss BD, Coyne CA. Combining cancer control information with adult literacy education: opportunities to reach adults with limited literacy skills. *Cancer Control.* 2003;10(5)(suppl):81-83. PUBMED
30. Haigler K, Harlow C, O'Connor P. *Literacy Behind Prison Walls.* Washington, DC: US Dept of Education, Office of Educational Research and Improvement, National Center for Educational Statistics; 1994:187.
31. Mathew P, Elting L, Cooksley C, Owen S, Lin J. Cancer in an incarcerated population. *Cancer.* 2005;104(10):2197-2204. FULL TEXT | ISI | PUBMED
32. Raimer BG, Stobo JD. Health care delivery in the Texas prison system: the role of academic medicine. *JAMA.* 2004;292(4):485-489. FREE FULL TEXT
33. McCue MJ, Mazmanian PE, Hampton C, et al. The case of Powhatan Correctional Center/Virginia Department of Corrections and Virginia Commonwealth University/Medical College of Virginia. *Telemed J.* 1997;3(1):11-17. PUBMED
34. Brunicardi BO. Financial analysis of savings from telemedicine in Ohio's prison system. *Telemed J.* 1998;4(1):49-54. ISI | PUBMED
35. Nacci P, Turner CA, Waldron RJ, Broyles E, US Department of Justice–US Department of Defense. Implementing telemedicine in correctional facilities. http://www.ncjrs.gov/pdffiles1/nij/190310.pdf. Published May 2002:73. Accessed August 1, 2007.
36. Kendig NE. Correctional health care systems and collaboration with academic medicine. *JAMA.* 2004;292(4):501-503. FREE FULL TEXT
37. Zigmond J. Help from the outside: states use a variety of contractors to provide healthcare for prisoner populations. *Mod Healthc.* 2007;37(12):52-55. PUBMED
38. Watson R, Stimpson A, Hostick T. Prison health care: a review of the literature. *Int J Nurs Stud.* 2004;41(2):119-128. FULL TEXT | ISI | PUBMED
39. Dubler NN. The collision of confinement and care: end-of-life care in prisons and jails. *J Law Med Ethics.* 1998;26(2):149-156. ISI | PUBMED
40. Cohn F. The ethics of end-of-life care for prison inmates. *J Law Med Ethics.* 1999;27(3):252-259.

ISI | PUBMED
41. Byock I. Dying well in corrections: why should we care? *Correctcare.* 2002;16(4):18. PUBMED
42. *Ramos v Lamm*, 639 F2d 559 (10th Cir 1980).
43. *Casey v Lewis*, 834 F Supp 1477 (WD Ariz 1993).
44. *Gates v Cook*, 376 F3d 323 (5th Cir 2004).
45. *Estelle v Gamble*, 429 US 97 (1976).
46. *Wellman v Faulkner*, 715 F2d 269 (7th Cir 1983).
47. Weatherhead K. Cruel but not unusual punishment: the failure to provide adequate medical treatment to female prisoners in the United States. *Health Matrix Cleve.* 2003;13(2):429-472. PUBMED

48. Taylor M. Prisoners of the system. *Mod Healthc.* 2007;37(8):25-27. PUBMED
49. Udesky L. Court takes over California's prison health system. *Lancet.* 2005;366(9488):796-797. FULL TEXT | ISI | PUBMED
50. *Plata v Schwarzenegger*, C-01-1351 TEH (ND Calif 2005).
51. Puisis M, ed. *Clinical Practice in Correctional Medicine.* 2nd ed. Philadelphia, PA: Mosby Elsevier; 2006:608.
52. National Commission on Correctional Health Care. *Standards for Health Services in Prisons.* Chicago, IL: National Commission on Correctional Health Care; 2003.
53. *Health Issues in Corrections*. Atlanta, GA: Centers for Disease Control and Prevention; 2007. [Index of treatment and clinical practice guidelines relating to health issues in corrections].
54. End-of-Life Care Standards of Practice for Inmates in Correctional Settings. *Innovations in End-of-Life Care.* February 2000. http://www.edc.org/lastacts/archives/archivesMay00/standards.asp. Accessibility verified August 2, 2007.
55. Byock I, Twohig JS, Merriman M, Collins K. Promoting excellence in end-of-life care: a report on innovative models of palliative care. *J Palliat Med.* 2006;9(1):137-146. FULL TEXT | ISI | PUBMED
56. Ratcliff M. Dying inside the walls. *J Palliat Med.* 2000;3(4):509-511. FULL TEXT | PUBMED
57. Linder JF, Knauf K, Enders SR, Meyers FJ. Prison hospice and pastoral care services: California Medical Facility, Vacaville. *J Palliat Med.* 2002;5(6):903-908. FULL TEXT | PUBMED
58. Evans C, Herzog R, Tillman T. The Louisiana State Penitentiary: Angola Prison hospice. *J Palliat Med.* 2002;5(4):553-558. FULL TEXT | PUBMED
59. Boyle BA. The Maryland Division of Correction hospice program. *J Palliat Med.* 2002;5(5):671-675. FULL TEXT | PUBMED
60. Bauersmith J, Gent R. The Broward County jails hospice program: hospice in the jail. *J Palliat Med.* 2002;5(5):667-670. FULL TEXT | PUBMED
61. Meyers FJ, Linder J. Simultaneous care: disease treatment and palliative care throughout illness. *J Clin Oncol.* 2003;21(7):1412-1415. FREE FULL TEXT
62. Meyers FJ, Linder J, Beckett L, et al. Simultaneous care: a model to resolve conflict between investigational therapy and palliative care. Paper presented at: 38th Annual American Society of Clinical Oncology Meeting; 2002; Orlando, Florida. Abstract 1440.
63. Bick JA. Managing pain and end-of-life care for inmate patients: the California Medical Facility experience. *J Correct Health Care.* 2002;9(2):131-147. FULL TEXT
64. Hornblum AM. They were cheap and available: prisoners as research subjects in twentieth century America. *BMJ.* 1997;315(7120):1437-1441. FREE FULL TEXT
65. Linder JF, Enders SR, Craig E, Richardson J, Meyers FJ. Hospice care for the incarcerated in the United States: an introduction. *J Palliat Med.* 2002;5(4):549-552. FULL TEXT | PUBMED
66. AMA Council on Ethical and Judicial Affairs. Collective action and patient advocacy, amendment. June 2005. http://www.ama-assn.org/ama1/pub/upload/mm/38/a-05ceja.pdf. Accessed August 1, 2007.
67. *Code of Ethics, Policy Finder.* Chicago, IL: American Medical Association; 2007.
68. Parker FR, Paine C. Informed consent and the refusal of medical treatment in the correctional setting. *J Law Med Ethics.* 1999;27(3):240-251. FULL TEXT | ISI | PUBMED
69. La Vigne NG, Naser RL, Brooks LE, Castro JL. Examining the effect of incarceration and in-prison family contact on prisoners' family relationships. *J Contemp Crim Justice.* 2005;21(4):314-335. FULL

TEXT
70. King A. The impact of incarceration on African American families: implications for practice. *Fam Soc.* 1993;74(3):145-153. ISI
71. Bond GD, Thompson L, Malloy D. Lifespan differences in the social networks of prison inmates. *Int J Aging Hum Dev.* 2005;61(3):161-178. FULL TEXT | ISI | PUBMED
72. Foley K, ed, Gelband H, ed. *Improving Palliative Care for Cancer.* Washington, DC: National Cancer Policy Board (NCPB), Institute of Medicine and the National Research Council; 2001:344.
73. World Health Organization and WHO Expert Committee on Cancer Pain Relief and Active Supportive Care. *Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee*. Geneva, Switzerland: World Health Organization; 1990:75.
74. Ratcliff M, Craig E. The GRACE project: guiding end-of-life care in corrections 1998-2001. *J Palliat Med.* 2004;7(2):373-379. FULL TEXT | PUBMED
75. Education on Palliative and End-of-Life Care Web site. . http://www.epec.net/EPEC/webpages/index.cfm. Accessed July 26, 2007.
76. *Physician Board Certification in Hospice and Palliative Medicine.* Silver Spring, MD: American Board of Hospice and Palliative Medicine; 2007.
77. Anno BJ. Prison health services: an overview. *J Correct Health Care.* 2004;10(3):287-301. FULL TEXT
78. Enders SR. *Simple Answers to Difficult Healthcare Questions: Choice.* Carmichael, CA: Autumn Indigo Books; 2004:100.
79. Enders SR, Paterniti D, Meyers F. An approach to develop effective health care decision making for women in prison. *J Palliat Med.* 2005;8(2):432-439. FULL TEXT | PUBMED

80. Barnard J. Convicted murderers relearn compassion in Prison Hospice Oregon: with the spread of tough sentencing laws and HIV, more inmates are dying behind bars. Associated Press. August 1, 1999. http://www.aegis.com/news/ap/1999/ap990801.html. Accessibility verified August 2, 2007.

81. Head B. The transforming power of prison hospice. *J Hospice Palliat Nurs.* 2005;7(6):354-359. FULL TEXT
82. Barens E. *Angola Prison Hospice, Opening the Door* [video]. New York, NY: Open Society Institute; 1998.
83. Beck JA. Compassionate release from New York State prisons: why are so few getting out? *J Law Med Ethics.* 1999;27(3):216-239. ISI | PUBMED
84. Craig E, Ratcliff M. Controversies in correctional end-of-life care. *J Correct Health Care.* 2002;9(2):149-157. FULL TEXT

Perspectives on Care at the Close of Life Section Editor: Margaret A. Winker, MD, Deputy Editor.

Housing Issues

Program Matrix

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP																		
	CCCMS	EOP	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	60 Mo +	DPW	DPM	DPV	DPH	DPS	DD0	DD1 MSF Elig	DD1 CAM Elig	D1A DD2 MSF Elig	D1A DD2 CAM Elig	DD1 MSF Elig	DD1 CAM Elig	D1A DD2 MSF Elig	D1A DD2 CAM Elig	DD1 DD2 D1A SECURE	DD3	Applied	REVIEW	ESCAPE	Need Eval	Pregnant	CID	USINS	Felon yHold	Arson	VIO	LWOP	LIFER	Close A	Close B	SNY	Fac. Has A SAP Prog
ASP-II	✓		✓	✓	✓	✓	✓	✓	✓				✓											✓	✓	✓	✓			✓	✓	✓	✓		✓				✓
ASP-II(SNY)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓			✓	
CAL-I			✓	✓	✓	✓							✓																			✓							
CAL-IV(270)			✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
CAL-IV(SNY)			✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	
CCC-I			✓	✓	✓	✓	✓																		✓		✓			✓	✓	✓							
CCC-I(CAM)				✓	✓	✓																			✓		✓			✓									
CCC-II			✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓						
CCC-III			✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		
CCF			✓	✓																										✓		✓							
CCF(SNY)			✓	✓																										✓		✓						✓	
CCI-I	✓		✓	✓	✓	✓	✓						✓														✓			✓	✓								
CCI-II	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓				✓
CCI-IV(180)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
CCI-SHU	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
CCWF(SHU)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
CCWF-I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓		✓		✓	✓		✓		✓		✓	✓	✓	✓							✓
CCWF-II	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓		✓
CCWF-III	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓		✓
CCWF-IV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
CEN-I			✓	✓	✓	✓																										✓							
CEN-III			✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		
CEN-IV(270)			✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
CIM-C II(PWC)			✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓						
CIM-E-III(CID)	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓											✓	✓	✓	✓		✓	✓	✓	✓	✓		✓				
CIM-E-III(PWC)			✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓				

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP															
	CCMS	*EOP*	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	*60 Mo +*	*DPW*	*DPM*	*DPV*	*DPH*	*DPS*	*DD0*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	DD1 DD2 D1A SECURE	DD3	*RAplied*	*REVIEW*	ESCAPE	Need Eval	Pregnant	CID	USINS	Felony Hold	Arson	VIO	*LWOP*	*LIFER*	*Close A*	*Close B*	SNY	Fac. Has A SAP Prog
CIM-I	☑	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☐	☑	☐	☐	☐	☐	☐	☑
CIM-W II(PWC)	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☐	☑	☐	☑	☐	☐	☐
CIW-I	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑
CIW-I(CAM)	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐
CIW-II	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☐	☐	☑
CIW-III	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☐	☐	☑
CIW-PSU	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
CMC-E-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
CMC-E-III (EOP)	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
CMC-W-I	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☑	☐	☑	☐	☐	☐	☐	☑
CMC-W-II	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☐	☑	☐	☑	☐	☐	☑
CMF-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐
CMF-II	☐	☐	☑	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
CMF-III	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
CMF-III (EOP)	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
COCF	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☐	☑	☐	☐	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐
COR-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☑
COR-II(Gym)	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
COR-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☐
COR-III (EOP)	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☐
COR-III(SNY)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐
COR-IV(270)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
COR-PHU	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
COR-SHU	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
CRC-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☑	☑	☐	☐	☐	☐	☑	☐	☑	☑	☑	☑	☐	☐	☑	☑	☐	☑	☐	☐	☐	☐	☐	☑
CRC-II(SNY)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☑	☑	☐	☐	☐	☐	☑	☐	☑	☑	☑	☑	☐	☐	☑	☑	☐	☑	☐	☐	☐	☐	☑	☑
CTF-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
CTF-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☑	☐	☑

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP																		
	CCMS	EOP	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	60 Mo +	DPW	DPM	DPV	DPH	DPS	DD0	DD1 MSF Elig	DD1 CAM Elig	D1A DD2 MSF Elig	D1A DD2 CAM Elig	DD1 MSF Elig	DD1 CAM Elig	D1A DD2 MSF Elig	D1A DD2 CAM Elig	DD1 DD2 D1A SECURE	DD3	Rapplied	REVIEW	ESCAPE	Need Eval	Pregnant	CID	USINS	Felony Hold	Arson	VIO	LWOP	LIFER	Closed A	Closed B	SNY	Fac. Has A SAP Prog
CTF-S-I	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☑	☑	☐	☐	☐	☐	☐	☑
CVSP-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐
CVSP-II	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☑
CVSP-II(SNY)	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☑	☐
DVI-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐
DVI-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
FSP-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐
FSP-II	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
FSP-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
FSP-TTP	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☑
HDSP-I	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
HDSP-II(Gym)	☑	☐	☑	☑	☑	☑	☐	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
HDSP-III	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☐
HDSP-III(SNYG	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☑	☐
HDSP-IV(180)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
HDSP-IV(SNY	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐
ISP-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
ISP-III	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☑
KVSP(THU)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐
KVSP-I	☐	☐	☑	☑	☑	☑	☐	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
KVSP-II(Gym)	☑	☐	☑	☑	☑	☑	☐	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
KVSP-II(SNY-Gy	☑	☐	☑	☑	☑	☑	☐	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☑	☐
KVSP-III(Gym)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
KVSP-IV(180)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑
KVSP-IV(180SN	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐
LA-CCC	☐	☐	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☐	☑	☑	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
LAC-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
LAC-II(Gym)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP																	
	CCMS	*EOP*	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	*60 Mo +*	*DPW*	*DPM*	*DPV*	*DPH*	*DPS*	*DD0*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	DD1 DD2 D1A SECURE	DD3	*RAplied*	*REVIEW*	ESCAPE	Need Eval	Pregnant	CID	USINS	Felon yHold	Arson	VIO	*LWOP*	*LIFER*	*Close A*	Close B	SNY	Fac. Has A SAP Prog
LAC-IV(270)	✓		✓	✓	✓	✓	✓						✓									✓		✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
LAC-IV(270EOP		✓	✓	✓	✓	✓	✓						✓									✓		✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
MCCF			✓	✓																				✓	✓					✓	✓	✓	✓						
MCCF(SNY)				✓																				✓	✓					✓	✓	✓	✓					✓	
MCSP-II(SNY-G	✓		✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓		✓			✓	
MCSP-III(SNY)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	
MCSP-III(SNYE		✓	✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	
MCSP-IV(SNY)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	
MCSP-IV(SNYE		✓	✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	
MCSP-MSF(DP)			✓	✓	✓	✓							✓																	✓		✓							
NKSP-I			✓	✓	✓	✓							✓												✓		✓			✓		✓							
NKSP-III	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		
PBSP-I			✓	✓	✓	✓																			✓		✓			✓		✓							
PBSP-II(Gym)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓				
PBSP-IV(180)	✓		✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
PBSP-IV(180EO		✓	✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
PBSP-PSU		✓	✓	✓	✓	✓	✓						✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
PBSP-SHU			✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
PVSP-I			✓	✓	✓	✓		✓	✓				✓												✓		✓			✓		✓							
PVSP-II(SNY-Gy	✓		✓	✓	✓	✓	✓	✓	✓				✓											✓	✓	✓	✓			✓	✓	✓	✓		✓			✓	
PVSP-III	✓		✓	✓	✓	✓	✓	✓	✓				✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		✓
PVSP-III(SNY)	✓		✓	✓	✓	✓	✓	✓	✓				✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	
PVSP-IV(SNY)	✓		✓	✓	✓	✓	✓																	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	
RJD-I			✓	✓	✓	✓																			✓		✓					✓							✓
RJD-III	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		✓
RJD-III (EOP)		✓	✓	✓	✓	✓	✓						✓											✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓		✓
RJD-III(SNY-Gy	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓		✓	✓	✓	✓	✓		✓			✓	
RJD-IV(SNY)	✓		✓	✓	✓	✓	✓						✓											✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP																	
	CCMS	*EOP*	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	*60 Mo +*	*DPW*	*DPM*	*DPV*	*DPH*	*DPS*	*DD0*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	DD1	DD2	D1A	SECURE	DD3	*RAPPIED*	*REVIEW*	ESCAPE	Need Eval	Pregnant	CID	USINS	Felon Hold	Arson	VIO	*LWOP*	*LIFER*	*Class A*	Class B	SNY	Fac. Has A SAP Prog
SAC-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
SAC-II(Gym)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
SAC-IV(180)	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SAC-IV(180EOP	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SAC-PSU	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SATF-II	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☐
SATF-II(SNY)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☑	☐
SATF-III(SNY)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐
SATF-IV(180)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SATF-IV(SNY)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐
SATF-SAP	☑	☐	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☑	☑	☐	☐	☐	☐	☐	☑
SCC-I	☐	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☑	☑	☐	☐	☐	☐	☐	☐	☐
SCC-I(CAM)	☐	☐	☐	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☑
SCC-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐
SCC-III(SNY)	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑
SOL-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☐	☐	☑
SOL-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☐
SQ-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐
SQ-II	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☐	☑	☐	☐
SVSP-I	☐	☐	☑	☑	☑	☑	☐	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
SVSP-III(SNY)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐
SVSP-IV(180)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SVSP-IV(180EO	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
SVSP-IV(SNY)	☑	☐	☑	☑	☑	☑	☑	☑	☑	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐
VSPW-I	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☑	☐	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑
VSPW-II	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☑
VSPW-III	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☑
VSPW-IV	☑	☐	☑	☑	☑	☑	☑	☑	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑

			Time to Serve					DPP Cases					R/C DDP Cases					Mainline DDP Cases				Other DDP																		
	CCMS	*EOP*	6 to 7 Mo	7 to 18 Mo	18 to 36 Mo	36 to 60 Mo	*60 Mo +*	*DPW*	*DPM*	*DPV*	*DPH*	*DPS*	*DD0*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	*DD1 MSF Elig*	*DD1 CAM Elig*	*D1A DD2 MSF Elig*	*D1A DD2 CAM Elig*	DD1 DD2 D1A SECURE	DD3	*RAPPIED*	*REVIEW*	ESCAPE	Need Eval	Pregnant.	CID	USINS	Felony Hold	Arson	VIO	*LWOP*	*LIFER*	*Close A*	Close B	SNY	Fac. Has A SAP Prog
VSPW-SHU	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☐	☑	☑	☑	☑	☑	☑	☑	☑	☐	☐
WSP-I	☐	☐	☑	☑	☑	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☐	☑	☐	☐	☑	☐	☑	☐	☐	☐	☐	☐	☐	☐
WSP-III	☑	☐	☑	☑	☑	☑	☑	☐	☐	☐	☐	☐	☑	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☑	☑	☑	☑	☐	☐	☑	☑	☑	☑	☐	☑	☑	☑	☐	☐

Resources

- UC San Diego Tool Kit
- Maxor Clinical Guidelines

- Reading List

UC San Diego

Toolkit

CALIFORNIA DEPARTMENT OF CORRECTIONS & REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES

TABLE OF CONTENTS

Volume 1

A. ATRIAL FIBULLITATION
1. A-Fib Guidelines
2. A-fib Algorithm
3. A-Fib Powerpoint
4. A-Fib Bio

B. ANTICOAGULATION
1. Anticoagulation Guidelines
2. Anticoagulation Algorithm
3. Anticoagulation Powerpoint
4. Anticoagulation Bio

C. BREAST MASS
1. Breast Mass Guidelines
2. Breast Mass Algorithm
3. Breast Mass Powerpoint
4. Breast Mass Bio

D. CHEST PAIN
1. Chest Pain Guidelines
2. Chest Pain Algorithm
3. Chest Pain Powerpoint
4. Chest Pain Bio

D. COPD
1. CPOD Guidelines
2. CPOD Algorithm
3. CPOD Powerpoint
4. CPOD Bio

E. DIZZINESS
1. Dizziness, Syncope and Vertigo Guidelines
2. Dizziness, Syncope and Vertigo Powerpoint
3. Dizziness, Syncope and Vertigo Bio

F. DYSPEPSIA
1. Dyspepsia Guidelines
2. Dyspepsia Algorithm
3. Dyspepsia Powerpoint
4. Dyspepsia Bio

CALIFORNIA DEPARTMENT OF CORRECTIONS & REHABILITATION
DIVISION OF CORRECTIONAL HEALTH CARE SERVICES

TABLE OF CONTENTS

Volume 2

G. END STAGE LIVER DISEASE (ESLD)
1. End Stage Liver Disease Guidelines
2. End Stage Liver Disease
3. End Stage Liver Disease

H. HEART FAILURE
1. Heart Failure Guidelines
2. Heart Failure Algorithm
3. Heart Failure Powerpoint
4. Heart Failure Bio

I. KNEE AND ANKLE
1. Knee Injuries Guidelines
2. Knee Injuries Powerpoint
3. Selected Knee Injuries Bio

J. LOWER BACK PAIN
1. Evaluation and Management Guidelines
2. Lower Back Pain Algorithm
3. Lower Back Pain Powerpoint
4. Lower Back Pain Bio

K. SKIN
1. Folliculitis and Related Infections Guidelines
2. Cellutitis Guidelines
3. Pressure Ulcers Guidelines
4. Folliculitis Powerpoint
5. Cellutitis Powerpoint
6. Pressure Ulcers Powerpoint
7. Folliculitis, Cellutitis and Pressure Ulcers Bio

L. RED EYE
1. Red Eye Guidelines
2. Red Eye Algorithm
3. Red Eye Powerpoint
4. Red Eye Bio

M. THYROID
1. Thyroid Guidelines
2. Hypothyroidism Algorithm
3. Hyperthyroidism Algorithm
4. Thyroid Disease Powerpoint
5. Thyroid Disease Bio

CDCR Tool Kit
Practice Guidelines for End Stage Liver Disease

Background
End Stage Liver disease (ESLD) is the progressive deterioration of liver function which eventually results in metabolic decompensation. There are many causes of ESLD and it is essential to identify the cause(s), institute appropriate therapy and delay progression as well as its complications. However, in most patients, ESLD progresses and patients with ESLD develop similar complications.

The clinical manifestation of ESLD highlights the essential role of the liver in the normal physiology. This guideline will discuss on the most serious and common manifestations for ESLD: Cirrhosis, ascites, gastroesophageal bleed, spontaneous bacterial peritonitis, renal failure and encephalopathy. It is also important to recognize the many other clinical manifestations of ESLD: coagulopathy, pancytopenia, edema, malnutrition, chronic pain, depression, fatigue, muscle wasting, pruritis, and neuropathy.

Goals:
The management of these patients is challenging and rewarding. The main goals in treating patients with ESLD are:

1. Halt or slow disease progression
2. Reverse the disease whenever possible
3. To treat co-morbid conditions to improve outcomes
4. Prevent the complications of ESLD as long as possible and to treat them appropriately once they manifest
5. Improve patient's quality of life
6. Provide compassionate care and End of Life care to patients in the final stages of their illness

Causes of ESLD:

Most Common	Less Common
Hepatitis C	Autoimmune Hepatitis
Alcoholism	Wilson's Disease
Hepatitis B	Hemochromatosis
Non-alcoholic Steatohepatitis (NASH)	α -1 antitrypsin
Drug Induced	Galactosemia
Exposure to Toxins	Glycogen storage diseases
Hepatocellular carcinoma	

Evaluation of Patients with Liver Disease:
History: Obtain a full medical history

- Common symptoms: Fatigue, anorexia, weight loss, abdominal pain, abdominal distention, jaundiced, bruising, edema
- Risk factors: Alcohol intake, use of recreational drugs (snorting or IV), history of hepatitis C or B, +HIV status, toxin exposure

Perform a complete Physical exam.

- Look for stigmata of liver disease: Icteric skin or conjunctiva, spider angiomas, caput, bruising, ascites, edema, enlarged or small liver, gynecomastia, asterixis

Laboratory and Imaging studies:

- CBC with differential, INR and PTT, Complete Metabolic panel, Lipids, Hepatitis serologies, HIV test and Toxicology screen (if indicated). Abdominal US or CT
- In selected patients, refer for biopsy

Common and serious ESLD complications

Cirrhosis

- Cause: Results form chronic damage to the liver by toxins, inflammation, or metabolic derangement. The liver regenerates in an abnormal pattern forming nodules. Damaged and dead liver cells are replaced by fibrous tissue. This abnormal architecture leads to abnormal blood flow and disruption of sinusoids causing portal hypertension
- Diagnosis is best made with abdominal US or CT scan
- All patients with cirrhosis are at high risk for hepatocellular carcinoma and should be screened with a yearly abdominal US and α-1 antitrypsin every six months. If tests are indicative of cancer, patients should be referred for further evaluation.

Esophageal Varices Bleeding

As a result of portal hypertension, varices dilate and as the pressure increases they can burst causing this dreaded complication.

- About 60% of patients with cirrhosis have esophageal varices on endoscopy and the risk of dying with every bleeding episode is ~ 50%.
- The American College of Gastroenterology recommends:
    - Yearly endoscopy screening for patients with cirrhosis
    - Prophylaxis
        - Propranolol 10 mg tid or Nadolol 20 mg daily. It reduces the risk of bleeding from 45 to 22%
        - For patients not able to take β-blockers use Isosorbide mononitrate 20 mg bid
    - For patients with history of variceal bleeding, secondary prophylaxis by banding or sclerotherapy
- Acute management of esophageal bleeding
    - Hemodynamic resuscitation:
        - Two large IV accesses
        - STAT GI consult (patient may need sclerotherapy, banding)
        - Fluids, blood replacement, correct coagulopathy
        - Octeotride 50 micrograms IV load followed by 50 microgram/hr drip
        - Proton Pump Inhibitor IV
        - If unstable: Intubate, transfer to ICU ASAP. May need pressors

Ascites

The accumulation of fluid in the peritoneal cavity due to: Hepatic resistance to blood flow, portal hypertension, and local production of vasodilator, mainly nitrous oxide which causes significant splanchnic dilatation.

- Other factors contributing to ascites:
    - Malnutrition, hypoalbunememia, decreased oncotic pressure
- Diagnosis of Ascites:
    - It may be obvious on physical exam but the sensitivity and specificity of physical findings are poor
    - Best diagnosed by abdominal US or CT
- Not all ascites is due to liver disease. About 15% is due to heart failure, nephrotic syndrome, cancer, TB and other conditions
- Evaluation of ascitic fluid by paracentesis
    - Routine tests: CBC diff, albumin, total protein, and cultures
    - Optional tests: Glucose, LDH, Gram stain, and amylase
    - Special Tests: ABF smear and culture, cytology, triglycerides, bilirubin
    - Contraindication for paracenthesis: uncorrected coagulation
    - Determine the serum to ascetic albumin gradient (SAAG). Serum albumin minus ascetic fluid albumin. This value is the gradient and correlates well with the presence of portal hypertension.
        - SAAG > 1.1 indicates portal hypertension with 97% accuracy
        - SAAG < 1.1 indicates no portal hypertension
- Treatment
    - Diuretics. Start low and titrate up. Use combination drugs as needed.
        - Spironolactone 50 to 300 mg/day or Amiloride 5 to 10 mg/daily
        - Lasix 40 to 240 mg daily
        - Spironolactone + Lasix in a ratio of 100/40 mg/d. This ratio seems to maintain better K balance
            - Monitor K and other electrolytes closely
        - Caution: Excessive diuresis can lead to hepato-renal syndrome
        - Goal of diuresis as measured by weight loss
            - 300-500 mg/d if no peripheral edema
            - 800- 1000mg/d if peripheral edema
        - Sodium restriction: 2 gram/d
        - Fluid restriction only if hyponatremia
        - Therapeutic large volume paracentesis. Be cautious of hepatorenal syndrome. May need to give albumen to avoid intravascular depletion.
        - Refractory ascites: Transjugular intrahepatic portosystemic shunt
- Ascites significantly increases the risk of death during surgery.
    - The Child-Pugh score is use to assess potential surgical mortality. It is based on score system with three tier classification based on liver function. Three classes are defined as shown in the following table:

Modified Child-Pugh Score

	Parameters	Points Assigned		
		1	2	3
Lab Tests	Serum Bili (mg/dL)	< 2 mg/dL	2-3	> 3
	Serum Albumen g/dL	> 3.5	2.8-3.5	< 2.8
	INR	< 1.7	1.71-2.2	> 2.2
Signs	Ascites	none	controlled	Poorly controlled
	Encephalopathy	none	controlled	Poorly controlled

Spontaneous Bacterial Peritonitis (SBP)
SBP is the infection of the ascitic fluid without evidence of intra abdominal surgical treatable cause. It is due to the translocation of bacterial from the gut, usually by aerobic Gram negative bacteria.

- It is a serious complication of ascites
- Clinical Presentation: Fever (may be low grade), diffuse constant abdominal pain, anorexia, malaise and occasionally mental status changes.
- Diagnosis made by paracentesis
  - Evaluation of ascetic fluid showing:
    - 250 PMNs/ml is the fluid
    - Positive bacterial growth
- Treatment
  - Cefotaxime 2 gm IV q12 hrs for 5 days
  - Quinolone for patients with allergy to β-lactamase antibiotics
  - Avoid aminoglycosides (due to nephrotoxicity)
  - Prophylaxis: All patient with h/o pf SBP should be treated indefinitely
    - Norfloxacin 400 mg daily
    - Ciprofloxacin 750 mg once a week
    - DS Trimethoprim/sulfa 5 days a week

Hepatorenal Syndrome
The progressive deterioration of kidney function in the absence of kidney pathology

- It occurs in 30% of patients with SBP and carries very high mortality.
- Clinical Presentation and Diagnosis:
  - Oliguria, benign urine sediment, very low rate of sodium excretion, low urine output in the absence of diuretics and a progressive rise in plasma creatinine.
- Two types:
  - Type I. Progressive deterioration defined as a two fold increase in serum Cr to a level > 2.5mg/dl in < 2 weeks. Patients are rarely anuric.
  - Type II. Stable or slowly progressive deterioration of kidney function with refractory ascitis.

- Treatment: Goal Creatinine < 1.5 mg/dl
    - Albumin 1g/k IV on day 1 followed by 20- to 40 mg daily for 5-15 days
    - Vasoactive drugs:
        - Norepinephrine 0.5 to 3 mg/hr IV
        - Midodrine 7.5 mg po tid + Octeotride 100 microgram SQ tid
    - Hemodialysis if no response
    - Referral for transplant

Hepatic Encephalopathy

A complex neuropsychiatric syndrome that causes altered mental status. The cause is thought to be the accumulation of nitrogenous byproducts. Other theories suggest the creation of abnormal neurotransmitters, abnormal activation of receptors in the brain, alteration of ATPases in the brain and decrease activity of the urea cycle. The patho-physiology has not been fully elucidated.

- Evaluation: Thorough history, complete physical exam, laboratory tests and brain imagining. Other potential causes for altered mental status should be considered and ruled out.
- Clinical presentation varies from subclinical changes in mentation to deep coma. Patients may present with confusion, decreased attention, slowing of ability to perform mental tasks, irritability, sleep disorder, lethargy, asterixis and unresponsiveness.
- Precipitating factors for hepatic encephalopathy: Poor compliance with medications, GI bleed, infection, blood transfusion, excess protein intake, constipation, dehydration, drugs, porto-hepatic shunts.
- Treatment
    - Lactulose oral: It has a cathartic effect. It lowers the pH in the gut decreasing urease producing bacterial. Acidification of the gut causes movement of ammonia from blood into gut
    - Lactulose enemas
    - Water enemas are ineffective
    - Treatment with antibiotics
        - Neomycin 6 g a day. Caution: ototoxicity
        - Metronidazole 800 mg daily for one week. Caution: GI side effects
        - Rifaximin 1200 mg/d

Liver Transplant

As the patient's condition deteriorates and no "liver dialysis" is yet available, patients need to be evaluated for a possible liver transplant.

- Indications for transplant: Irreversible acute liver failure, refractory ascites, recurrent esophageal variceal bleeding, hepatorenal syndrome and encephalopathy
- Contraindications for Liver Transplant
    - Absolute: +HIV status, sepsis, malignancy, advanced non-hepatic disease, inability to comply with postransplant therapy, active alcoholism, active illicit drug use
    - Relative: Hepatitis B infection, previous abdominal surgery, advanced age

End Stage Life Issues

It is important to discuss prognosis with patients and their families. Refer for counseling and provide compassionate comfort care measures so that patients die with dignity.

Additional Recommendations

In addition to the recommendations presented under each condition, it is important to include the following additional recommendations for all patients with ESLD:

- Complete abstinence from alcohol and illicit drugs
- Vaccinations against Hepatitis A and B, Pneumovax every 10 years, and yearly influenza vaccine
- Avoidance of liver toxic and nephrotoxic drugs
- Avoid all NSAIDs
- Avoid iron containing multivitamins unless iron deficiency present
- Low sodium and low fat diet
- Regular exercise

This Clinical Guideline was developed by the faculty of the Quality Improvement in Correctional Medicine Program at the University of California, San Diego, March, 2006.

Algorithm for the Evaluation and Management of Patients with ESLD

Progressive deterioration of liver function which eventually leads to metabolic decompensation

Most Common Causes

Hepatitis C
Alcoholism
Non alcoholic steato hepatitis, NASH
Hepatitis B
Exposure to Toxins
Hepatocellular Carcinoma, Drugs

Symptoms: Fatigue, anorexia, nausea abdominal pain, weakness, wt. loss, pruritis
Risk factors: Alcoholism, h/o hepatitis, +HIV; Drugs: prescribed, recreational, supplements; Toxin exposure, hereditary conditions

Evaluation: Perform a complete H & P
Labs: CBC with diff, complete metabolic panel, lipids, INR, hepatitis serologies, HIV if indicated.
Imaging studies: Abdominal ultrasound or CT scan; In selected patients, refer for liver biopsy

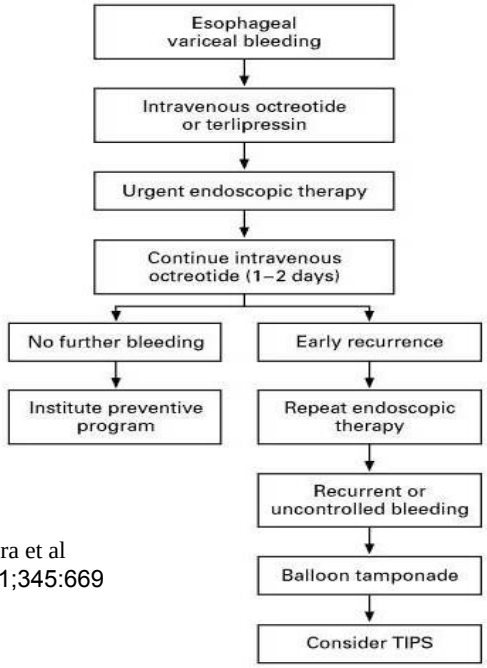
Cirrhosis: Damaged and dead liver cells are replaced by fibrous tissue which leads to fibrosis. Liver cells regenerate in an abnormal pattern forming nodules surrounded by fibrous tissue

- Yearly endoscopic screening for varices
- Patients with cirrhosis and no previous variceal hemorrhage

Prophylaxis to avoid variceal bleeding:

- Propranolol 10 mg tid or Nadolol 20 mg qd
- Isosorbide mononitrate 20 mg bid
- Secondary prophylaxis with esophageal banding or sclerotherapy

Esophageal Varices Bleed



From Sharara et al
NEJM 2001;345:669

Ascites

- Accumulation of fluid in the peritoneal cavity
- Confirm with US or CT scan
- **Perform paracentesis**, test for: CBC with diff, albumin, total protein and cultures. Optional Tests: Glucose, LDH, Gram stain, amylase. Special tests: ABF smear and culture, cytology, triglyceride, bilirubin
- Contraindication to paracentesis: Uncorrected coagulopathy

Treatment:

- Spironolactone 50-300 mg/d or Amiloride 5-10 mg/d
- Lasix 40-240 mg/d once or divided dose
- Spironolactone + Lasix in ratio of 100/40 mg/d
  Monitor electrolytes regularly
- Sodium restriction to 2 gram/d
- Fluid restriction only for patients with hyponatremia
- Therapeutic Paracentesis (large volume)
  Albumin only if concern for hepato-renal syndrome or intravascular volume depletion
- Transjugular intrahepatic portosystemic shunt

Algorithm for the Evaluation and Management of Patients with ESLD

Spontaneous Bacterial Peritonitis

Caused by the translocation of bacteria from the intestinal lumen to ascitic fluid

Diagnosis: Ascitic fluid has:

- 250 PMNs/ml
- Positive bacterial culture

Treatment:

- Cefotaxime 1-2 g IV q 8 hr x 5 days
- Third Generation Cephalosporin
- Quinolone for patients allergic to β-lactamase drugs
- **Prophylaxis:**
  Ciprofloxacin 750 mg a week
  Trimethoprim/Sulfa DS 5 days a week
  Norfloxacin 400 mg daily

Hepato-renal Syndrome

Progressive deterioration of kidney function in the absence of known kidney pathology

Diagnosis:

- Serum Cr > 1.5 mg/dL or 24 Cr Clear < 40 ml/min
- Absence of: shock, bacterial infection, fluid loss and nephrotoxic drugs
- No improvement of kidney function after discontinuing diuretics and trial of plasma expansion
- No proteinuria (<500mg/day) and no hematuria
- No obstructive or parenchymal nephropathy on US
- Urinary sodium concentration < 10 mmol/lt

Treatment:

- Albumin 1 g/k IV day one followed by 20-40 g daily
- Vasoactive drugs
  - Norepinephrine 0.50- 3.0mg/h IV
  - Midodrine 7.5 po tid + Octeotride 100ug SQ tid. Titrate up
  - Treat for 5-15 days. Goal Cr < 1.5 mg/dl
- Hemodialysis
- Referral for transplant

Encephalopathy

Altered Mental status due hepatic failure

Triggers:

- Poor compliance with lactulose
- GI bleed, Infection, Blood transfusion
- Excess dietary protein
- Constipation
- Dehydration, Fluid restriction, Excessive diuresis, Aggressive paracentesis
- Drugs:Benzodiazepines, Psychoactive drugs
- Portosystemic shunts
- Spontaneous, surgical

Treatment:

- Lactulose. Titrate to 3-4 BM/d
- Antibiotics against urease-producing bacteria reduce the production of intestinal ammonia
- Neomycin (6 g daily)
- Metronidazole (800 mg daily)
- Rifaximin 1200 mg daily

Hepatocellular CA

All patients with cirrhosis should be screened for:

- Alpha-fetoprotein q 6 months and liver US yearly
- If present, refer to Liver Center for treatment

Additional Recommendations for all Patients with ESLD

- **Complete abstinence from alcohol and IVDA**
- **Vaccinations: against hepatitis A and hepatitis B, pneumococcal vaccine and annual (autumn) influenza vaccine**
- **Avoidance of hepatotoxic medications**
- **No NSAIDs use**
- **Avoidance of iron supplements unless iron deficiency anemia is present; multivitamins without iron should be used**
- **Low-sodium and fat diet**

End Stage Liver Disease

Selected Bibliography

1. Runyon B. Management of Adult Patients with Ascites due to Cirrhosis. American Association for the Study of Liver Diseases. AALD Practice guidelines. Hepatology 2004, 39:1-16.

2. Gines P, et al. Management of Cirrhosis and Ascites. N. Engl J Med 2004;350:1646.

3. Sharara AI, et al. Diagnosis and treatment of gastrointestinal bleeding secondary to portal hypertension. N Engl J Med 2001;345:669.

4. Wolf D. Cirrhosis. e-Medicine. Nov 29, 2005. file://ESLD|eMedicine-Cirrhosis

5. Samonakis D, et al. Management of portal hypertension. Postgrad Med J 2004; 80:634-41.

6. Garcia N, Sanyal A. Minimizing Ascites. Postgrad Med 2001;109:91-103.

7. Yu A, Hu K. Management of Ascites. Clin Liver Dis 2001;5:541.

8. Saadeh S, Davis G. Management of ascites in patients with end-stage liver disease. Rev Gastroenterol Disorder 2004; 4:175.

9. Arroyo V. Pathophysiology diagnosis and treatment of ascites in cirrhosis. Ann Hepatol 2002;1:72.

10. Arroyo V. Pathophysiology, diagnosis and treatment of ascites in cirrhosis. Ann Hepatol 2002;1:72-79

11. Riley T, Bhatti A. Preventive Strategies in Chronic Liver Disease, Part I. Alcohol, Vaccines, Toxic Medications and Supplements, Diet and Exercise. Am Fam Physician 2001; 64:1555.

12. Riley T, Bhatti A. Preventive Strategies in Chronic Liver Disease, Part II. Cirrhosis. Am Fam Physician 2001; 64:1735.

13. Hegab A, Leketic V. Bleeding Esophageal Varices: How to treat this dreaded complication of portal hypertension. Postgrad Med. 2001;109:75-89.

14. Hillebrand D. Spontaneous Bacterial Peritonitis. Curr Treat Options Gastroenterol 2002;5:479.

15. Cardenas A. Hepatorenal syndrome: a dreaded complication of end stage liver disease. Am J Gastroenterol 2005;100:460.

16. Tong W, Hurley S, Hayashi P. Reconsidering hepatorenal syndrome: Throw in the towel? Not so fast. Postgrad Med 2004; 116:15-6, 21-4.

17. Gines P, et al. Hepatorenal syndrome. Lancet 2003;29:362.

18. Lizardi-Cervera J, et al. Hepatic Encephalopathy: a review. Ann Hepatol 2003; 2:12-30.

19. Abou-Assi A, Vlahcevic Z. Hepatic Encephalopathy. Postgrad Med 2001;109:52-70.

Maxor Clinical Guidelines

Acute Asthma

PEF = Peak flow (best or predicted)

ICS = Inhaled Corticosteroid

This pathway does not replace sound clinical judgement or apply to all patients

Initial Assessment

- Brief history –severity of symptoms, current medications, response to self treatment, time of onset, trigger, risk factors
- Physical Exam -peak flow, heart and respiratory rate, O2 saturation and breath sounds

LEVEL OF SEVERITY

Mild to Moderate Exacerbation

- PEF > 50% best or predicted
- Speech minimally impaired
- Respiration < 25 breaths/min
- Pulse < 110 beats/min

Severe Exacerbation

- PEF < 50% best or predicted
- Inability to complete sentence in 1 breath
- Respiratory rate ≥ 25 breaths/min
- Pulse > 110 beats/min

Life Threatening Exacerbation

- PEF < 25% best or predicted
- SpO2 < 92%
- Silent chest, cyanosis, week respiratory effort
- Bradycardia, dysrhythmia or hypotension
- Exhaustion, confusion or coma

TREATMENT

- Albuterol 2-6 puffs every 20 min for 3 doses
- Reassess response every 20 min for first hour

Good Response:

- PEF ≥80% & sustained response for 3-4 hours.
- Continue albuterol 2-4 puffs every 4 hours for 1-2 days, then PRN.
- Consider restaging and addition or step up of ICS
- Follow-up in 3-7 days

Incomplete Response:

- PEF 50-80%
- Continue albuterol 2-6 puffs every 20 min
- Prednisone 60mg po
- Oxygen
- Reassess response in 20-60 min.
- Start albuterol + ipratropium by nebulizer if no improvement.

- Oxygen
- Inhaled high dose albuterol and ipratropium by nebulization every 20min
- Prednisone 60mg po
- Reassess response every 20 min for first hour

- Arrange transport to nearest hospital
- Oxygen
- Prednisone 60mg po immediately
- Inhaled high dose albuterol + ipratropium every 20 min or continuously via oxygen driven nebulizer

Patient should be seen by PCP within 48 hours after hospital discharge

Good Response:

PEF ≥70%

No distress

Response sustained for 1 hour after last treatment

Albuterol 2-4 puffs every 4 hours x 2days, then PRN

Prednisone 60mg po QD x5days

Consider restaging and step up of ICS

Follow-up in 1-2 days

Incomplete Response:

PEF 50-70%

Mild to moderate symptoms

Individualized decision to discharge per good response or transfer to nearest hospital based on history and symptoms

Poor Response

PEF < 50% or

Signs of severe asthma

O2 < 90%

Consider transport to nearest hospital

References:

National Asthma Education and Prevention Program Expert Panel Report2: Guidelines for the Diagnosis and Management of Asthma http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm

NCCHC Clinical Guidelines for Correctional Facilities: Treatment of Asthma in Adults in Correctional Institutions. Apr 2006. http://www.ncchc.org/resources/clinicalguides/asthma.pdf

Approved by the CDCR Pharmacy & Therapeutics Committee May 2007.

Chronic Asthma

ICS = Inhaled Corticosteroid

PEF= Peak Flow

FEV1= Forced Expiratory Volume in 1 second

This pathway does not replace sound clinical judgement or apply to all patients

1.) Obtain history & physical
2.) Confirm diagnosis by spirometry
3.) Classify severity

Mild Intermittent:
- Symptoms ≤ 2 times / week
- Nighttime symptoms ≤ 2 times / month
- Asymptomatic and normal PEF between exacerbations
- Brief Exacerbations (hours to days)
- FEV1 or PEF ≥ 80% predicted and variability < 20%

1. No long term controller
2. Albuterol 2 puffs 4 times daily PRN

Controlled ?

No → Go to Mild Persistent treatment

Yes → Follow-up every 6 months with history & peak flow

Mild Persistent:
- Symptoms ≥ 2 times / week but not daily
- Nighttime symptoms 3-4 times per month
- Exacerbations with minor limitations
- FEV1 or PEF > 80% predicted and variability 20% o 30%

1. Low dose ICS
2. Albuterol 2 puffs 4 times daily PRN

Controlled ?

No → Go to Moderate Persistent Treatment

Yes → Follow-up every 3 months with history & peak flow. Spirometry every 1-2 years. For Moderate/Severe persistent, consider ICS step down therapy . 17

Moderate Persistent:
- Daily Symptoms
- Daily use of inhaled short acting beta-2 agonist
- Nighttime symptoms > 1 per week
- Exacerbations cause some limitations
- Exacerbations may last days
- FEV1 or PEF 60% to 80% predicted and variability > 30%

1. Medium dose ICS
2. Albuterol 2 puffs 4 times daily PRN

Controlled ?

Yes → Controlled ?

No → Go to Severe Persistent Treatment

No → 1. Medium dose ICS + Serevent 1 puff twice daily OR High Dose ICS 2. Albuterol 2 puffs 4 x daily PRN

Severe Persistent:
- Continual symptoms
- History of intubation or ICU admission
- ≥ 2 hospitalizations in past year
- Extreme physical limitations
- Frequent exacerbations
- Frequent nighttime symptoms
- FEV1 or PEF < 60% predicted and variability > 30%

1. High does ICS
2. Albuterol 2 puffs 4 times daily PRN
3. Serevent 1 puff twice daily

Controlled ?

Yes → Go to Box 17

No → Consider oral corticosteroid or nonformulary request for Singulair 10mg QD and referral to Respiratory Specialist. See acute pathway for acute exacerbation.

**Patient education on medical condition, goals of therapy, compliance, lifestyle modification, and inhaler technique should be provided at every encounter.

References:

National Asthma Education and Prevention Program Expert Panel Report2: Guidelines for the Diagnosis and Management of Asthma http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm

NCCHC Clinical Guidelines for Correctional Facilities: Treatment of Asthma in Adults in Correctional Institutions. Apr 2006. http://www.ncchc.org/resources/clinicalguides/asthma.pdf

Approved by the CDCR Pharmacy & Therapeutics Committee May 2007.

Directions for inhaler use:

1. Remove the cap and shake the inhaler.
2. Tilt head back slightly & breathe out.
3. Position the inhaler for closed (preferred) or open mouth technique.
4. Breathe in slowly through your mouth as you press down on the inhaler.
5. Keep breathing in slowly and deeply for 3-5 seconds.
6. Hold your breath for 10 seconds. Breathe out.
7. Repeat as instructed. Wait 1 minute between puffs. (Reliever medications should be administered before controllers.)
8. Place the cap back on the inhaler.
9. Rinse your mouth out with water.

Open Mouth Technique
Place mouthpiece 2 inches from your mouth and spray directly into open mouth

Closed Mouth Technique
Place mouthpiece between your teeth and gently close your lips around the mouthpiece.

What to do in an asthma attack?

1. Take your reliever inhaler immediately
2. Sit down and loosen any tight fitting clothing. Do not lie down
3. If no immediate improvement during an attack, continue to take one puff of your reliever inhaler every minute for five minutes or until symptoms improve
4. If your symptoms do not improve in five minutes seek medical attention.

Get Immediate Care if:

- Symptoms worsen despite reliever medications.
- Your lips and /or fingernails turn gray or blue.
- You are rapidly getting worse over a few hours.
- You can't say four or five words because you're so short of breath, wheezing, gasping for air, and hunched forward.

Sources
NHLBI. Diseases and Conditions. Asthma. Available at - http://www.nhlbi.nih.gov/health/dci/Diseases/Asthma/Asthma_WhatIs.html. Accessed March 2007.

AAFP. Asthma – Learning to Control Your Symptoms. Available at - http://familydoctor.org/online/famdocen/home/common/asthma/basics/014.html. Accessed March 2007.

Asthma UK. All About Asthma. Available at - http://www.asthma.org.uk/all_about_asthma/index.html. Ac-

Asthma Patient Education

What you should know

What is Asthma?

Asthma is a disease that affects the small tubes that carry air in and out of your lungs.

With asthma, your airways are super sensitive. If you come into contact with something that irritates the airways (an asthma trigger), the muscles around the walls of the airways tighten and become inflamed and swollen. The airways are made smaller, but air can still flow. Sometimes sticky mucus or phlegm builds up which can further narrow the airways.

Asthma Symptoms

The usual symptoms of asthma are:

- coughing
- wheezing
- shortness of breath
- tightness in the chest.

*Not everyone will get all of these symptoms. How often you have symptoms and how bad they are determine how severe your asthma is and how it should be treated.

Asthma Triggers

A trigger is anything that irritates the airways and causes the symptoms of asthma. It is possible to have one or several triggers, everyone is different. An important part of controlling your asthma is identifying and avoiding your triggers.

- Animal Dander
- Air pollutants
- Colds & illnesses
- Emotions including stress & laughter
- Exercise
- Dust mites
- Medications
- Molds & fungi
- Pollen
- Smoking
- Weather changes
- Food allergies

How do we treat asthma?

Relievers:

- Everyone with asthma should have a reliever inhaler with them at all times.
- The most common reliever inhaler is albuterol.
- Relievers are medicines that are taken to immediately relieve asthma symptoms. They act quickly to relax airway muscles allowing the lungs to open wider. This makes breathing easier again.
- You should use your reliever inhaler when you are having asthma symptoms.
- If you are using your reliever inhaler three or more times a week, your asthma may not be well controlled. Talk to your doctor.

Controllers:

- Controllers reduce swelling and inflammation of the air-ways. They keep your lungs from being so sensitive and reduce the risk of severe attacks.
- Not everyone with asthma will need a controller medicine.
- The protective effect builds up over time so they need to be taken every day even when you are feeling well.
- Controllers do not give immediate or quick relief when you are breathless.
- Controller inhalers usually contain a low dose of steroids.

When are controllers prescribed?

- Everyday activities cause you to be breathless, cough or have a tight chest.
- You use your reliever inhaler three times a week or more
- You have trouble sleeping due to cough or chest tight-ness on a weekly basis

Steroid tablets:

If you have severe asthma symptoms, your doctor may give you a short course (3-14 days) of steroid tablets. Steroid tablets are powerful reducers of airway inflammation.

- You must continue taking you controller medication (steroid inhaler) while taking steroid tablets.
- It is important to take the tablets exactly as directed and do not stop taking them until you talk to your doctor.
- Stopping steroid tablets abruptly can have serious side effects.

Medication side effects?

Relievers:

Relievers are a safe, effective and have very few side effects. They include increased heartbeat, nervousness and mild muscle shakes. The effects are usually only seen at high doses and wear off within a few minutes to a few hours.

Controllers:

The risk of serious side effects from taking your inhaled controller medicine is very low. The inhaled medicine goes straight to the airways with very little absorbed into the rest of the body.

There is a small risk of sore tongue, sore throat, hoarseness and a mouth infection called thrush. To help prevent this, rinse your mouth out and brush your teeth after inhaling.

It is possible that long-term use and high-doses of controller medicines (inhaled steroids) may cause some other side effects. Your doctor will try to keep you on the lowest possible dose.

Steroid tablets:

Short term use

Possible side effects from taking a short course of steroid tablets are mood swings and increased hunger.

There are very few other side effects from taking occasional (three to four) short courses of steroids per year. However it is important to keep the number of courses to a minimum by making sure you are using enough of your other regular inhaled medicines.

Long term use

A small minority of people with severe asthma need to take steroid tablets for a longer period. However, long term use (months to years) can cause serious side effects.

You should discuss with your doctor the risk of side effects versus the benefits of controlling your asthma. (Untreated, severe asthma can lead to permanent lung damage and death).

Some long term side effects include weight gain, heartburn, brittle bones, and increased risk of diabetes and cataracts.

Type 2 Diabetes

(see type 1 pathway for glycemic goals)

Initial Assessment

1. Complete medical history including medications
2. Physical Exam including fundoscopic, neurologic, and skin exam, thyroid palpitation, blood pressure, peripheral/deep vein pulses, and reflexes/sensation.
3. Labs – A1c, fasting lipid panel, serum electrolytes, LFT's, UA, Scr, TSH, microalbumin, ECG, fasting and postprandial serum glucose.
4. Nutritional and Lifestyle Counseling
5. Start aspirin if no contraindications
6. Start low dose ACE-inhibitor if no contraindication

"Pre-Diabetes"

- IFG = 100-125 mg/dl or
- IGT = 140-199 mg/dl
- Asymptomatic and no ketones

Manage other cardiovascular risk factors

Lifestyle Intervention:
weight loss
exercise
nutrition

At Goal

Continue lifestyle modifications

Re-evaluate annually

Not at Goal

Moderate

- FPG ≥ 126 mg/dl

or

- Symptoms of diabetes + CPG ≥ 200 mg/dl

or

- 2-hr plasma glucose ≥ 200 mg/dl during OGTT

Start Oral Hypoglycemic (OHG) & Lifestyle Intervention

1. Metformin is recommended first line for most. Initial dose 500mg daily. [Contraindications – Scr ≥ 1.4F/1.5M, hepatic disease, heart failure requiring treatment, metabolic acidosis]

or

2. May consider sulfonylurea, glyburide 2.5mg or glipizide 5mg, if nonobese

Monitor FBG at least 3 times a week and titrate dose every 2 weeks until at max.

Metformin: Increase by 500mg every 2 weeks. Doses below 1500mg are rarely effective. Maximum dose is 2500mg. Monitor LFT's & Scr at 1 & 3 months, then annually.
Glyburide: Increase by 2.5mg increments. Can be given once daily. Doses above 10mg often require twice daily dosing. Maximum dose 20mg/day
Glipizide: Increase by 2.5mg - 5mg increments. Can be given once daily. Doses above 30mg usually require twice daily dosing. Maximum dose 40mg/day

2 drug regimen
Metformin + Sulfonylurea if no contraindication.
Titrate dose and monitor as in previous box.

A1c above goal after 3 months at max doses?

3rd step depends on A1c

1. A1c < 8.5% - Consider triple oral therapy trial with TZD. Note, adding a 3rd agent is more costly and not as effective. TZD's may take 6 weeks for onset of action and 2-3 months for peak effects.
2. A1C > 8.5% - OHG Failure. Start PM insulin per severe pathway &
   On Metformin Regimen - Continue metformin, discontinue evening sulfonylurea dose, stop all other OHG
   On Sulfonylurea Regimen (no metformin) - continue SU and stop all other OHG.

[Metformin + Insulin = preferred regimen. Allows lower insulin dose, fewer hypoglycemic episodes, less weight gain.]

Severe (or OHG Failure)

- A1c > 10%
- FPG > 250 mg/dl
- RPG > 300 mg/dl

AND

- Significant symptoms

Start Insulin & Lifestyle Intervention

Begin HS NPH 10 units (0.1-0.2 units/kg)
Monitor FBG daily. Adjust dose every 2-3 days accordingly:
> 180 Add 6 units
141-180 Add 4 units
121-140 Add 2 units
100-120 add 1 unit
< 80 subtract 2 units
Or
Increase by 2 units every 3 days

OHG naïve: once A1c is at goal for 6-8 weeks, consider switch to OHG.

If A1c remains above goal for > 3 months, consider split-dose insulin or intensive insulin therapy based on A1c or referral to endocrinologist. (Sulfonylureas should be discontinued at this point.)

**Obtain A1c Q 3 months until stable then Q 6 months. Chem-10, UA, lipids, LFT's, foot & eye exam recommended annually.

This pathway does not replace sound clinical judgement or apply to all patients

IFG = Impaired fasting glucose; IGT = Impaired glucose tolerance; RPG = Random plasma glucose; FPG = Fasting plasma glucose; CPG = Casual plasma glucose; TZD = Thiazolidinedione (Actos)

Management of Hyperglycemia in Type 2 Diabetes: A conncesus algorithm for the initiation and adjustment of therapy. American Diabetes Association. August 2006.
Standards of Medical Care in Diabetes -2007. American Diabetes Association. Available at http://care.diabetesjournals.org/content/vol30/suppl_1/

Approved by the CDCR P&T Committee July 2007.

Type 1 Diabetes

Initial Assessment

1. Complete medical history including medications and cardiovascular risk assessment.
2. Physical Exam including fundoscopic, neurologic, and skin exam, thyroid palpitation, blood pressure, peripheral/deep vein pulses, and reflexes/ sensation.
3. Labs – A1c, fasting lipid panel, serum electrolytes, LFT's, UA, Scr, TSH, microalbumin, ECG, fasting and postprandial serum glucose.
4. Nutritional and Lifestyle Counseling
5. Start aspirin if no contraindications
6. Start low dose ACE-inhibitor if no contraindication

Begin Insulin NPH/Regular (0.5-0.6 units/kg/day)

Before Breakfast: 2/3 total daily dose as 2/3 NPH & 1/3 regular.
Before Supper: 1/3 total daily dose as 1/2 NPH & 1/2 regular.

Monitor FBG & 2 hour postprandial x 1 week

Not Controlled

Evaluate medication and lifestyle compliance

Before breakfast or bedtime reading high: ↑ NPH 1-2 units per 50 mg/dl above goal.
Before lunch or supper supper high: ↑ regular 1-2 units per 50 mg/dl above goal.

Continue daily FBG & 2 hour postprandial. Follow up at least weekly.

Controlled

Follow up monthly until stable, then every 3 months.

Obtain fingersticks twice daily

Obtain A1c every 3 months. Chem-10, UA, LFT's lipids, foot & eye exam recommended annually.

Options:

1. 3 shot regimen
   NPH before breakfast and at bedtime AND
   Regular insulin before breakfast and before supper per sliding scale
   (Note, this splits PM NPH/R single shot into NPH HS and Reg before supper. May consider 4th shot before lunch)
2. Intensive Insulin therapy (if practical)
   NPH QID + Regular before meals

Considerations for use of insulin glargine:

- Patient unable to achieve glycemic target because of frequent or severe hypoglycemia despite attempts with various insulin dosing regimens
- Patients receiving highly intensive insulin therapy with 4 times daily administration
- Rapid acting insulin analogs are used for meal-time blood glucose

Considerations for use of rapid acting insulin analogues (lispro/aspart) [Non-Formulary approval required]:

- Patient unable to achieve postprandial glycemic target despite attempts with various insulin dosing regimens
- Patient experiences frequent or severe hypoglycemia despite attempts with various insulin dosing regimens
- Insulin pump therapy

Management of Hyperglycemia in Type 2 Diabetes: A conncesus algorithm for the initiation and adjustment of therapy. American Diabetes Association. August 2006.
Standards of Medical Care in Diabetes -2007. American Diabetes Association. Available at http://care.diabetesjournals.org/content/vol30/suppl_1/
Standards of Medical Care in Diabetes -2007. American Diabetes Association. Available at http://care.diabetesjournals.org/content/vol30/suppl_1/
Approved by the CDCR P&T Committee July 2007

Diabetic Goals

Glycemic Goals

A1c	< 7%
Preprandial	90-130 mg/dl
Postprandial	< 180 mg/dl

Other Goals

Blood Pressure	< 130/80 mm Hg
LDL	< 100 mg/dl
Triglycerides	< 150 mg/dl
HDL	> 40 mg/dl

For those > 40 yo, statin therapy to achieve an LDL reduction of 30-40%, regardless of baseline LDL, is recommended

Key concepts

- A1c is the primary target for glycemic control
- Goals should be individualized.
- More stringent goals may further reduce complication at the cost of increased hypoglycemic episodes
- Less stringent goals may be indicated in patients with severe or frequent hypoglycemia.
- Post prandial glucose should be targeted if A1c goals are not met despite reaching preprandial goals .
- Always ensure compliance before adding additional medication.

Correlation between A1c and mean plasma glucose on multiple testing

A1c	mg/dl
6	135
7	170
8	205
9	240
10	275
11	310
12	345

Switching from NPH to glargine

On NPH once daily – May switch unit-for-unit (1:1).
On NPH twice daily – glargine dose should be 80% of total NPH dose.

What Makes Cholesterol High or Low?

Family History. High cholesterol can run in families. Your cholesterol may remain high despite doing the right things.

Diet. Too much saturated fat and cholesterol in the foods you eat is the main culprit of high cholesterol. Reducing the amount fat you eat is very important in reducing your cholesterol.

Limit high cholesterol foods such as dairy fats (ice cream, butter), oils, eggs, and organ meats. Avoid fried foods. Eat higher fiber foods such as fruits and vegetables. Eat more fish and skinless chicken breasts.

Weight. Excess weight tends to increase your LDL or "bad cholesterol". Losing weight can help lower your LDL, increase HDL, and lower your triglycerides.

Exercise. Even mild exercise can raise your HDL and lower LDL. It also helps you lose weight.

Age and Gender. Women tend to have lower cholesterol levels than men. As we age, cholesterol tends to rise.

How can I lower my cholesterol?

Exercise. You should try to by physically active for 30 minutes on most days of the week.

TLC Diet guidelines -- you should eat:

- Less than 7% of the day's total calories from saturated fat.
- Less than 200mg of dietary cholesterol per day
- 35% or less of the day's total calories from fat.
- Limit salt intake to 2400 milligrams a day.
- Just enough calories to achieve or maintain a healthy weight (Ask your doctor what is a reasonable calorie level for you.)

Cholesterol– Lowering Medications

If a low cholesterol diet, increasing physical activity, and losing weight have not lowered you cholesterol after about 3 months, your doctor may prescribe a cholesterol-lowering medication. You will need to :

1 - Continue to follow a low-cholesterol diet

2 - Continue to exercise

3 - Continue to lose weight (if overweight)

4 - Control all other risk factors for heart disease including smoking, high blood pressure and diabetes.

All of theses steps together will reduce the total amount of medication you take, help your medications work better, and reduce your risk of heart dis-

Sources
NHLBI. NCEP. High Blood Cholesterol. What You Need to Know. URL: http://www.nhlbi.nih.gob/health/public/heart/chol/wyntk.pdf. Accessed June 2007.
NHBLI. Coronary Heart Disease Explained. URL: http://nhlbisupport.com/chd1/chdexp.htm. Accessed June 2007.
AAFP. Cholesterol: What Your Level Means. URL: http://familydoctor.org/online/famdocen/home/common/heartdisease/risk/029.html. Accessed June 2007.

High Cholesterol

What does it Mean & Why You Should Care

What is Cholesterol?

Cholesterol is a waxy, fat-like substance that the body needs to function normally. It protects nerves, makes cell tissue and produces certain hormones. Most cholesterol is produced by the liver. The rest comes from foods such as eggs, meats, and dairy products.

Your body only needs a small amount of cholesterol. If you have too much cholesterol, the extra is deposited in your arteries (especially in the heart and brain) where it can cause narrowing and hardening of the blood vessels known as atherosclerosis. The higher your cholesterol, the greater your risk of having a heart attack or stroke.

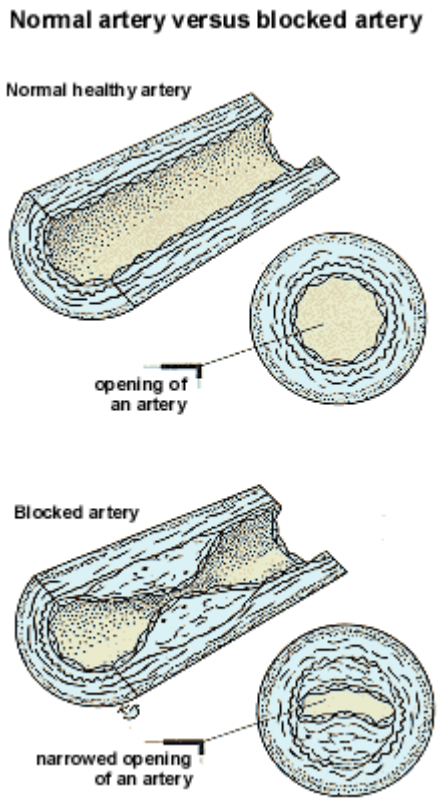
Why should I have my cholesterol checked?

High cholesterol does not cause any symptoms and therefore many people are not aware they have high cholesterol. It is important to find out what your cholesterol numbers are because lowering high cholesterol can reduce your chance for a heart attack, heart disease, and stroke. Cholesterol lowering is important for everyone, regardless of age or risk factors.

Everyone age 20 and older should have their cholesterol checked at least once every 5 years. Depending on your risk factors for heart disease and your cholesterol level, you may need to have your cholesterol checked more often.

Risk Factors for Heart Disease

- Cigarette smoking
- High blood pressure (above 140/90) or on high blood pressure medication
- Low HDL cholesterol (< 40 mg/dL)
- Family history of early heart disease
  - Father or brother before age 55
  - Mother or sister before age 65
- Age (men 45 and older, women 55 and older)
- Obese and / or physically inactive



What do Cholesterol Numbers Mean?

Total Cholesterol. The total of all types of cholesterol.

- Should be less than 200
- Between 200 & 239 is borderline high
- 240 or more is considered high

LDL Cholesterol. "Bad Cholesterol" The main source of cholesterol buildup and blockage in the arteries. LDL lowering is the main goal of treating high cholesterol. The higher you LDL, the greater your risk of heart developing heart disease.

- Less than 100 is optimal
- 100-129 is near optimal/above optimal
- 130-159 is borderline high
- 160-189 is high
- 190 and above is very high

HDL Cholesterol. "Good Cholesterol" Prevents cholesterol from building up in the arteries. Helps protect against heart disease. The higher the number the better.

- Above 60 is ideal
- Below 40 is low and increases your risk of heart disease

Triglycerides. Another form of fat that can increase your risk of heart disease.

- Below 150 is normal
- 150-199 is borderline high
- 200-499 is high
- Above 500 is very high

HYPERLIPIDEMIA

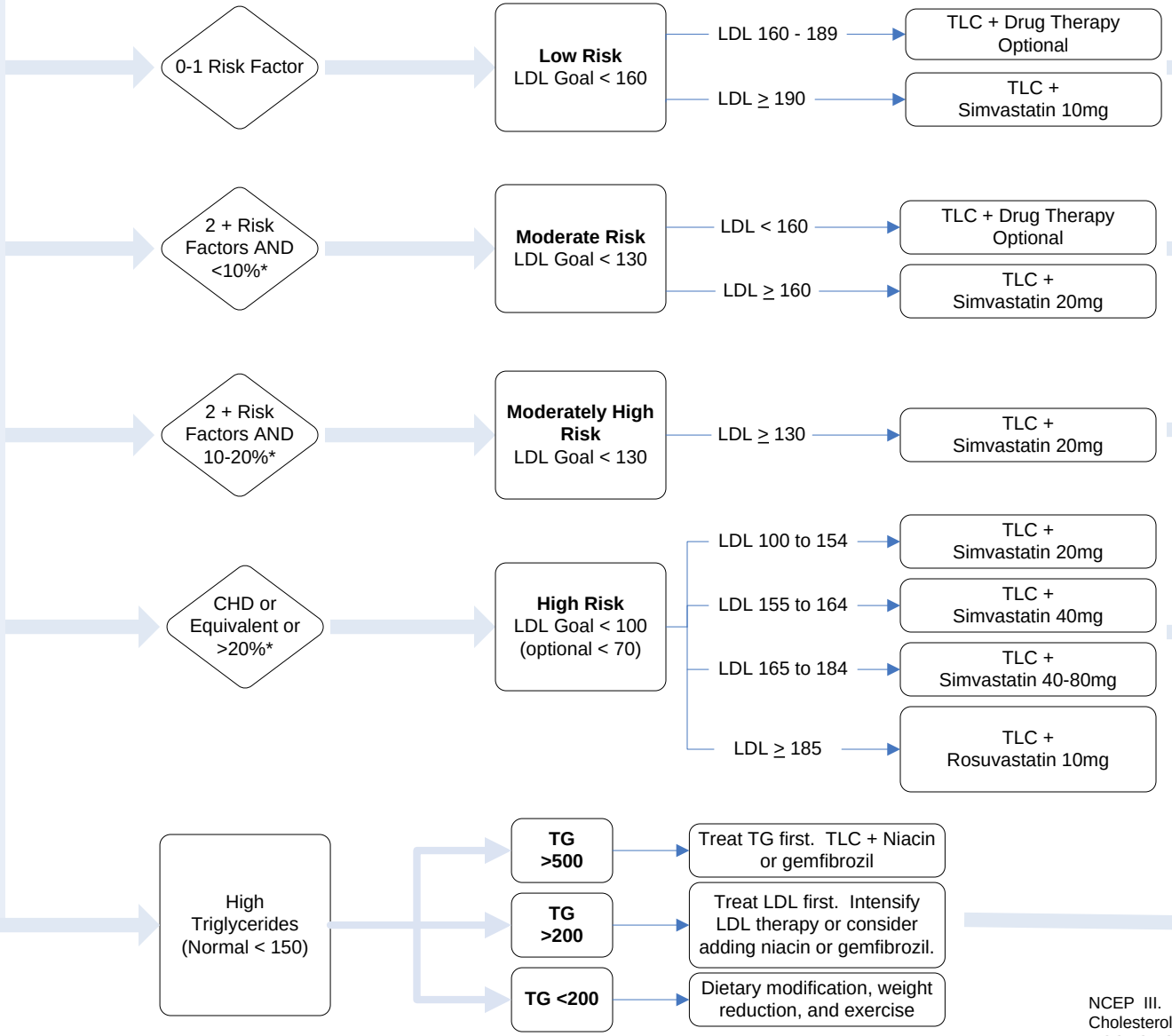
This pathway does not replace sound clinical judgement or apply to all patients

1. Initial Assessment

- H&P: rule out secondary causes (diabetes, renal disease, thyroid disorder, obstructive liver disease, drugs, and obesity).
- Baseline labs: UA, thyroid function, glucose, liver function, fasting lipid profile, Scr, BUN, CK.
- Evaluate for CHD or CHD risk equivalent
- Determine number of CV risk factors – if ≥2, assess 10 year risk of hard CHD. (*see Framingham tables).

2. Initial Therapy

All patients not at goal (except those with severe LDL elevations >220mg/dl) should be started on a 3 month trial of therapeutic lifestyle changes (TLC) first. If goal LDL is not achieved after 3 months, drug therapy should be considered.



3. Follow-Up

- Patients on TLC only should have a repeat lipid panel 3 months after TLC initiation.
- Once medication is started, the first follow-up should be at 2 months with lipid panel and LFTs. Therapy should be adjusted if indicated.
  - Therapeutic Options:
    - 1st line – increase statin dose
    - 2nd line – statin + cholestyramine OR statin + niacin
- After the initial follow-up visit, patients may be seen at 3 month intervals until target LDL goal is reached.
- Once at goal, lipids and LFTs should be monitored at 6 month intervals.

Patient Education at each encounter:

- Reinforce modifiable risk factors:
  - weight loss
  - exercise
  - smoking cessation
  - diet
  - control of comorbidities
- Reinforce compliance
- Review medications and side effects

*Pravastatin should be used if CYP450 drug interactions contraindicate the use of simvastatin. It is approximately ½ as potent as simvastatin.

NCEP III. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. 2002. http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf
NCCHC. Clinical Guideline for the Treatment of High Blood Cholesterol. 2005 http://www.ncchc.org/resources/clinicalguides/cholesterol.pdf

Approved by the CDCR P&T Committee June 2007

This pathway does not replace sound clinical judgement or apply to all patients

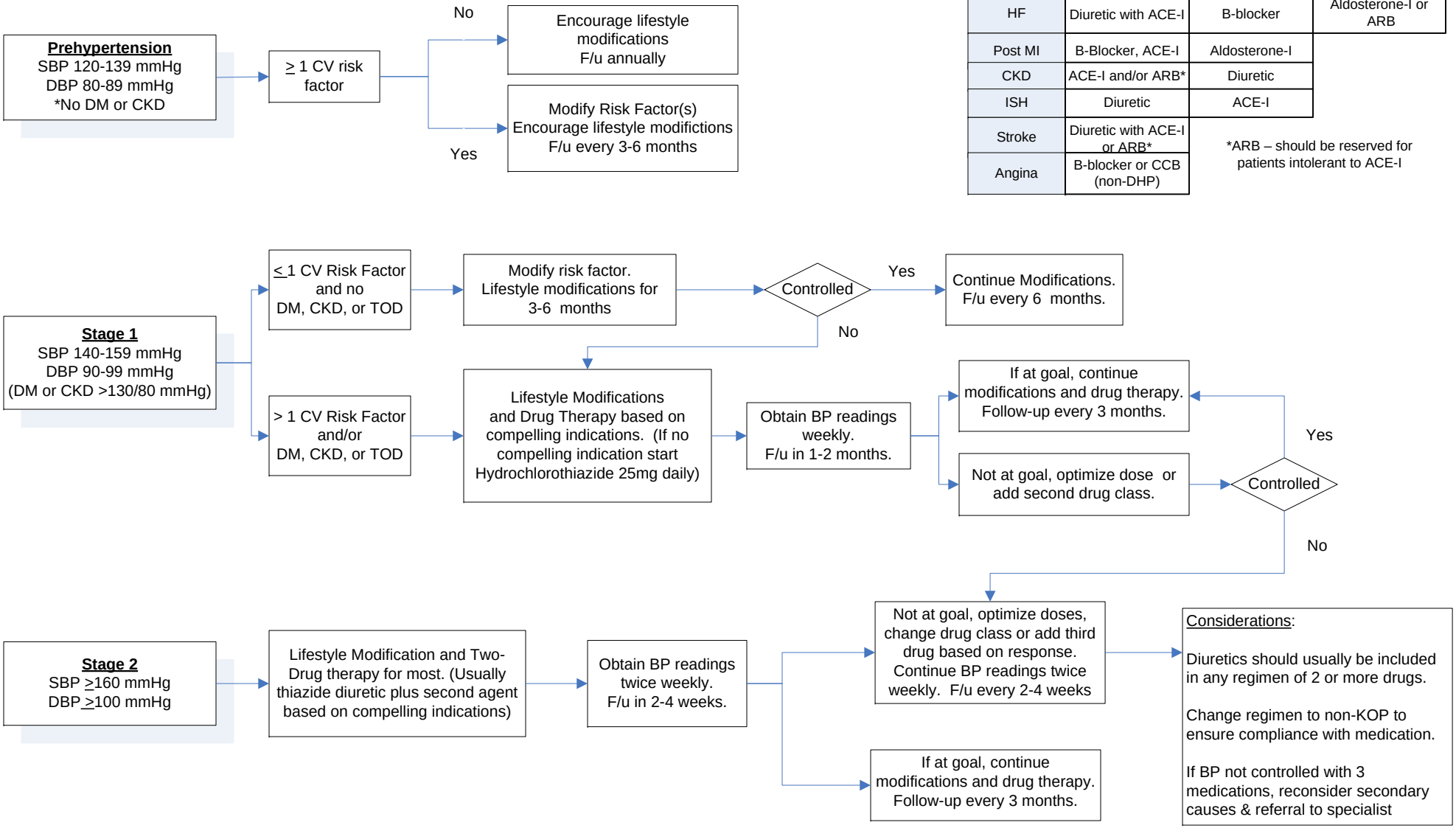
HYPERTENSION

1. Obtain History & Physical
2. Confirm Diagnosis and Rule Out Secondary Causes
3. Assess Cardiovascular Risk & Presence of Target Organ Damage
4. Obtain Initial Lab Work-up

Goal BP < 140/90 mmHg (Diabetics & CKD <130/80 mmHg)

Compelling Indications (CI)			
Indication	1st Line	2nd Line	3rd Line
No CI	Thiazide Diuretic	ACE-I, CCB, B-blocker	ARB
Diabetes	ACE-I or ARB*	Diuretic	B-blocker or CCB
HF	Diuretic with ACE-I	B-blocker	Aldosterone-I or ARB
Post MI	B-Blocker, ACE-I	Aldosterone-I	
CKD	ACE-I and/or ARB*	Diuretic	
ISH	Diuretic	ACE-I	
Stroke	Diuretic with ACE-I or ARB*		
Angina	B-blocker or CCB (non-DHP)		

*ARB – should be reserved for patients intolerant to ACE-I



SBP = systolic blood pressure, DBP = diastolic blood pressure, DM = diabetes mellitus, CKD = chronic kidney disease, TOD = target organ damage, CV = cardiovascular risk, ACE-I = angiotensin converting enzyme inhibotor, ARB = angiotensin receptor blocker, CCB = calcium channel blocker, MI = myocardial infarction, ISH = Isolated systolic hypertension, DHP = dihydropyridine, Aldosterone-I = Aldosterone antagonist

NCCHC Clinical Guidelines for Correctional Facilities: Treatment of High Blood Pressure in Adults in Correctional Institutions. April 2006. http://www.ncchc.org/resources/clinicalguides/HBP.pdf

The Joint National Committee. JNC 7 – Complete Version. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute. National High Blood Pressure Education Program, 2003;NIH Publication No. 03-5233. http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf

Approved by the CDCR Pharmacy & Therapeutics Committee May 2007.

American Heart Association Recommended Blood Pressure Levels

Blood Pressure Category	Systolic (mmHg)		Diastolic (mmHg)
Normal	Less than 120	and	Less than 80
PreHypertension	120-139	or	80-89
HIGH			
Stage 1	140-159	or	90-99
Stage 2	Above 160	or	Above 100

What do blood pressure numbers mean?

- The higher (systolic) number is the pressure while your heart is squeezing out blood.
- The lower (diastolic) number is the pressure when your heart is filling with blood.
- The systolic pressure is always stated first and the diastolic pressure second. For example: 118/76 (118 over 76); systolic = 118, diastolic = 76.

Other tests your doctor may recommend.

- Your doctor will recommend certain routine lab and blood tests before beginning treatment to determine if any damage has been done.
- These tests will also be done as a part of your yearly physical to monitor your treatment.
- Tests may include:

  - Urinalysis
  - Blood cell count
  - Blood sugar
  - Cholesterol check
  - Blood chemistry including potassium, calcium, and creatinine
  - EKG

Tips for Having Your Blood Pressure Checked.

- Do not drink coffee or caffeine products 30 minutes before your blood pressure is checked.
- Before your test, sit quietly with your feet on the floor for 5 minutes.
- Wear a short sleeve shirt.
- Go to the bathroom before your test.
- Have your blood pressure checked twice.
- Ask the doctor or nurse what your blood pressure reading was.

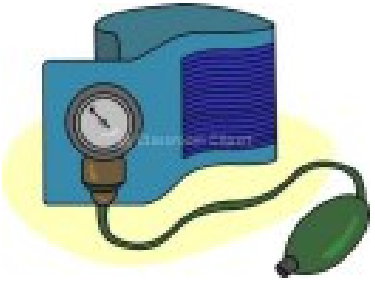
Blood Pressure Log

DATE	TIME	BLOOD PRESSURE

HIGH BLOOD PRESSURE

- *Stroke*
- *Heart attack*
- *Blindness*

- *Kidney Failure*
- *Heart Failure*
- *Silent Killer*



Why Should I Care?

What is High Blood Pressure?

- Blood pressure is the force of blood against your artery walls.
- Like air in a tire or water is a hose, a certain amount of pressure is required to push blood through your body.
- Just like too much pressure can damage a tire or water hose, too much blood pressure can damage your arteries and lead to life-threatening conditions.
- High blood pressure is the leading cause of cardiovascular disease, stoke, and heart attack.
- The medical term for high blood pressure is hypertension.
- Your blood pressure will rise and fall with changes in activity and emotional state. But when your blood pressure remains high, steps must be taken to reduce it.
- People with blood pressure above 140/90 (or above 130/80 for diabetics) on at least 2 separate occasions are said to have high blood pressure.

What Causes High Blood Pressure?

- In most people, the cause of high blood pressure is not known.
- High blood pressure is more likely in people who:
  - Have a family history of high blood pressure, diabetes, or heart disease
  - Are black
  - Are pregnant or take birth control
  - Are over 50
  - Are overweight
  - Are not physically active
  - Smoke
  - Drink excessively
  - Eat foods high in fat and salt

How Do I Know If I Have High Blood Pressure?

- The only way to know is to have your blood pressure checked
- There are no usually symptoms of high blood pressure. Over 30% of people with high blood pressure do not know they have it
- Testing is quick and painless and can be done anywhere.

Why should I care?

- High blood pressure over time forces the heart to work too hard and damages your blood vessels.
- High blood pressure is called "the silent killer" because people rarely have symptoms even as serious damage is done to the body.
- Left untreated, high blood pressure can lead to:
  - Heart attack
  - Stroke
  - Kidney failure
  - Heart failure
  - Blindness
  - Sudden cardiac death

Can High Blood Pressure Be Prevented?

You can help reduce you blood pressure and risk of heart disease by making a few changes in your lifestyle.

- Stop smoking
- Lose weight—weight loss can lower blood pressure and reverse some of the damage caused by high blood pressure
- Exercise—regular aerobic activity such as walking 3-4 times per week
- Eat right—stay away from salt. Eat lots of fruits and vegetables
- Limit alcohol
- Reduce stress

How Is High Blood Pressure Treated?

- In mild cases of high blood pressure, doctors may recommend lifestyle changes before medications are given.
- Most people with high blood pressure will have to take medications, usually for life.
- A number of drugs are used to treat high blood pressure and include:

  Diuretics– also called "water pills" they help your body get rid of excess sodium and fluid

  Beta-blockers– make your heart beat slower and with less force

  Calcium channel blockers– cause your blood vessels to relax decreasing pressure

  ACE inhibitors– decrease hormones that cause blood vessels to narrow. These drugs reduce the risk of kidney disease and are commonly given to people with diabetes and heart or kidney disease.

  Angiotensin Receptor Blockers– a newer type of medication that works in a similar way to ACE Inhibitors.

  Alpha-blockers, Vasodilators– work by different methods to relax blood vessels allowing blood to pass more easily

- It is important to remember to take your medication everyday, preferably at the same time each day.

HYPERTENSIVE URGENCY

- Hypertensive urgencies are those situations associated with severe elevations in BP without progressive target organ dysfunction. Examples include upper levels of stage II hypertension associated with severe headache, shortness of breath, epistaxis, or severe anxiety.
- The majority of these patients present as noncompliant or inadequately treated hypertensive individuals, often with little or no evidence of target organ damage.
- Blood pressure elevation alone rarely requires emergency treatment.
- These patients are often asymptomatic and can be observed for a brief period in the medical department to initiate or resume medication in the noncompliant patient or to increase dosages for those being inadequately treated.
- Some patients may benefit from treatment with oral agents (immediate release formulations) with fast onset of action followed by several hours of observation. However, caution should be advised as oral loading doses of antihypertensive agents can lead to cumulative effects causing hypotension after discharge from the medical department.

HYPERTENSIVE EMERGENCY

- Hypertensive emergencies are rare and are characterized by severe elevations in BP (>180/120 mmHg) complicated by evidence of impending or progressive target organ dysfunction.
- Patients require immediate BP reduction (not necessarily to normal) to prevent or limit target organ damage. Examples include hypertensive encephalopathy, intracerebral hemorrhage, acute MI, acute left ventricular failure with pulmonary edema, unstable angina pectoris, dissecting aortic aneurysm, or eclampsia.
- Patients should be immediately admitted to an intensive care setting.
- Most hypertensive emergencies are treated initially with parenteral agents. The initial goal of therapy is to reduce the mean arterial blood pressure by no more than 25% (within minutes to 1 hour), then, if stable, toward 160/100 to 110 mm Hg within 2 to 6 hours and then to normal within 24 to 48 hours. Excessive falls in pressure may precipitate renal, cerebral, or coronary ischemia.

This pathway does not replace sound clinical judgement or apply to all patients

SBP > 180 and/or DBP > 120

- Brief Histroy including duration & severity of HTN, symptoms, drug history, comorbidities, prior CV or renal disease, compliance
- Physical exam including BP in both arms, brachial/femoral/carotid pulses, abdominal, cardiovascular, neurologic and fundoscopic examination.
- Rule out secondary causes
- Baseline labs including chem-10, UA, EKG

Target organ damage
or
signs & symptoms indicate hypertensive emergency?

YES

Establish Intravenous line
and
Transfer immediately to nearest emergency room

Patient should be seen by PCP within 48 hours of hospital discharge.

NO

Noncompliant patient - resume medications immediately. If regimen includes only sustained release product(s), give labetolol 200mg, clonidine 0.1mg, or enalapril 5mg.

Newly diagnosed – start treatment immediately. Combination therapy recommended. (usually thiazide diurectic and second agent based on compelling indication.

Inadequately treated patient – administer extra dose of prescribed agent. If regimen includes only sustained release product(s), give labetolol 200mg, clonidine 0.1mg, or enalapril 5mg. Reevaluate and adjust regimen before discharge.

Multiple doses may be required over time.
Observe for at least 3 to 6 hours prior to discharge of clinically stable patient.
Follow-up BP in 24 hours

NCCHC Clinical Guidelines for Correctional Facilities: Treatment of High Blood Pressure in Adults in Correctional Institutions. April 2006. http://www.ncchc.org/resources/clinicalguides/HBP.pdf
The Joint National Committee. JNC 7 – Complete Version. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute. National High Blood Pressure Education Program, 2003;NIH Publication No. 03-5233. http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf

Approved by the CDCR Pharmacy & Therapeutics Committee May 2007

Reading List

Recommended Reading:

Textbooks:

Michael Puisis; Clinical Practice in Correctional Medicine. 1/2006

Journal Articles & Links:

1) Title: Preventive Strategies in Chronic Liver Disease - November 1, 2001 - American Family Physician
Link: http://www.aafp.org/afp/20011101/1555.html

2) Title: Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation - September 1, 2006 -- American Family Physician
Link: http://www.aafp.org/afp/20060901/756.html

3) Title: Cirrhosis and Chronic Liver Failure: Part II. Complications and Treatment - September 1, 2006 -- American Family Physician
Link: http://www.aafp.org/afp/20060901/767.html

4) Title: Practice Guideline 3/2001 American Family Physician March 1, 2001 (TB Test & Diagnosis Categories).
Link: http://www.aafp.org/afp/20010301/practice.html

5) Standards of Medical Care in Diabetes. Diabetes Care (Supplement) 30: S4-S41, 2007
Link: http://care.diabetesjournals.org

6) Diabetes Management in Correctional Institutions
Link: http://care.diabetesjournals.org/cgi/reprint/30/suppl_1/S77?eaf

7) Lauer GM, Walker BD Hepatitis C Infection New England Journal of Medicine 2001; 345:41-52
Link: www.nejm.org

8) National Heart Lung and Blood Institute ATP III Quick Desk Reference (For Lipid Management) 2001
Link: http://www.nhlbi.nih.gov/guidelines/cholesterol/dskref.htm

9) Longo LP, et.al. Addiction: Part II. Identification and Management of the Drug-Seeking Patient April 15, 2000 – American Family Practice
Link: http://www.aafp.org/afp/20000415/2401.html

Miscellaneous

Notes