Winter **2009** | Volume **23** | Issue 1

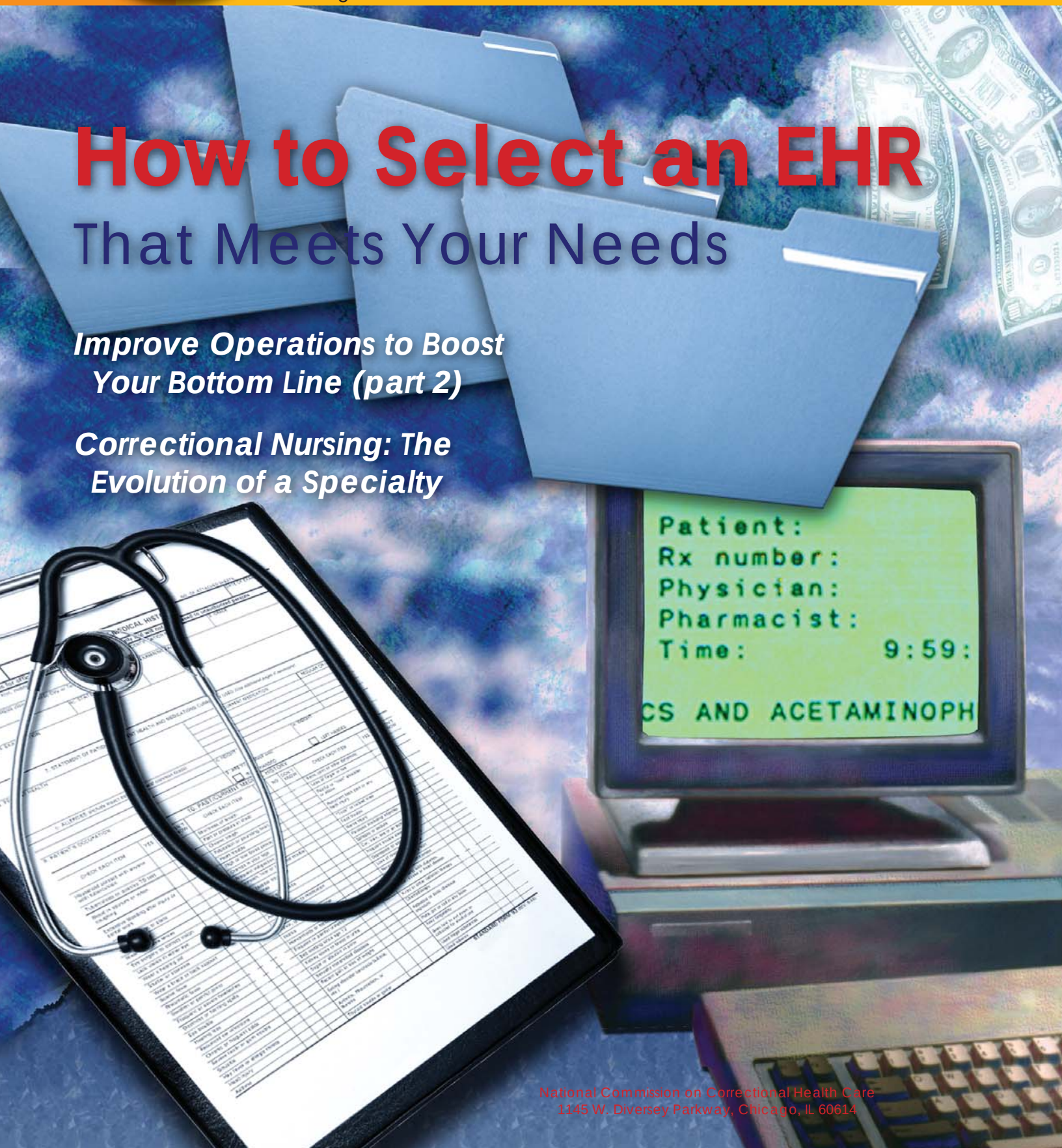
CorrectCare™

The magazine of the National Commission on Correctional Health Care

How to Select an EHR That Meets Your Needs

Improve Operations to Boost Your Bottom Line (part 2)

Correctional Nursing: The Evolution of a Specialty



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American Psychiatric Association

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CorrectCare™ is published quarterly by the National Commission on Correctional Health Care, a not-for-profit organization whose mission is to improve the quality of health care in our nation's jails, prisons and juvenile confinement facilities. NCCHC is supported by the leading national organizations representing the fields of health, law and corrections.

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CorrectCare™

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NCCHC news

As always, there's a lot going on at the National Commission. Here are some recent highlights.

JCHC Now Indexed on Medline

We are excited to report that the *Journal of Correctional Health Care* has been accepted for indexing by Medline. Operated by the U.S. National Library of Medicine, Medline is the largest component of PubMed, the free online database of biomedical journal citations and abstracts.

NCCHC's official, peer-reviewed journal, *JCHC* is published by Sage Publications. Acceptance in Medline "is a testament to the quality of the work and dedication of editor John R. Miles and the entire editorial team," said Nancy Olsen, executive editor of Sage's science, technology and medicine journals.

Approximately 5,200 journals are indexed for Medline, which has more than 16 million article citations. Journals undergo rigorous review by an advisory committee of experts to assess their scientific quality and other crtieria; the final decision is made by the NLM director.

"This is a wonderful accomplishment that underscores the quality and importance of *JCHC*," said NCCHC board chairman Joseph Penn, MD, CCHP, director of mental health services for University of Texas Medical Branch Correctional Managed Care. "Correctional health care is a vital, yet sometimes overlooked, aspect of public health. Now, the wide array of research and case studies featured in *JCHC* will be more accessible to a vast audience of researchers, practitioners, policy makers and others."

For information about submitting manuscripts or subscribing to the *Journal*, please visit http://jchc.sagepub.com.

ASTHO Becomes Supporting Organization

At the NCCHC board meeting last October, the Association of State and Territorial Health Officials became our newest supporting organization. ASTHO is a nonprofit membership association that represents the chiefs of state and territorial health agencies and the 120,000 individuals who work for them. Its mission is to transform public health within states and territories to help members improve health and wellness. The association brings together the nation's leading public health experts to address issues such as pandemic influenza, public health threats from natural disasters, dangerous trends in unhealthy lifestyles and access to health care. Learn more at www.astho.org.

Calendar of events

May 16 CCHP examination, Fairfax, VA

June 20 CCHP examination, Farmington, CT

June 26 Accreditation committee meeting

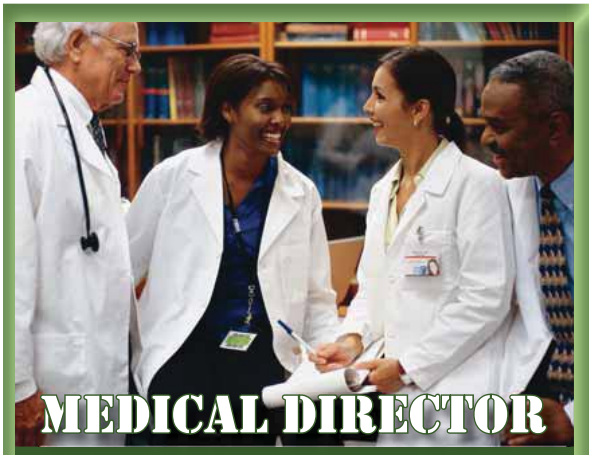
July 10-11 Medical Director Boot Camp, Seattle

July 12-13 Correctional Mental Health Seminar, Seattle

August 22 CCHP examination, multiple regional sites

October 17-21 National Conference on Correctional Health Care, Orlando

For a list of regional CCHP exam sites see www.ncchc.org.



July 10-11 • Seattle

Correctional health care is rife with unique challenges and requires esoteric knowledge and expertise. Designed by national experts from the Society of Correctional Physicians, this intensive program will provide essential training you won't find anywhere else.

Whether you are relatively new to the role or a seasoned professional, you will strengthen your understanding of the core elements of medical direction of inmate health care and explore contemporary practices. For two days, you will be immersed in a collegial, hands-on environment that will stimulate interaction, sharing and growth. The courses and exercises will delve into fundamentals such as…

- Roles and relationships
- Clinical practice oversight
- Quality assurance
- Finance
- Personnel
- Leadership
- Legal issues
- Pharmacy

Participants also will receive a take-home toolkit. For information about the meeting, visit www.ncchc.org, e-mail info@ncchc.org or call 773-880-1460.

Presented by the National Commission on Correctional Health Care and the Society of Correctional Physicians.

Juvenile Health Guidance

NCCHC has issued two new documents related to juvenile health care in correctional settings: a position statement on prevention of juvenile suicide and a clinical guideline on adolescent sickle cell disease. Both are available at the Resources & Links section of our Web site, www.ncchc.org.

Guest editorial

Correctional Nursing: The Evolution of a Specialty

by Mary V. Muse, MS, RN, CCHP-A

The field of correctional nursing is poised for its next big advance: specialty certification through NCCHC's Certified Correctional Health Professional program. This is an idea whose time has come. But how did we get here? Let's reflect on the evolution of this profession.

A Look at Our Past

The specialty of correctional nursing has been visible for more than 30 years. Although its early days are not well chronicled, it appears to have emerged largely in response to the forces that propelled correctional health care in general, such as the 1976 U.S. Supreme Court ruling in *Estelle v. Gamble*.

Before the 1970s, much inmate health care was provided by other inmates, correctional officers and the occasional physician. The first documentation of correctional nursing may be a 1975 article by Rena Murtha, a director of nursing for a large correctional system. In her account, nurses were "a tool of the warden, a slave of the physician and an unknown to the patient."

Since then, the literature on correctional nursing in this country has been limited. Some articles describe blurring boundaries between corrections and nursing, others found a lack of professional practice or lack of concern for inmate-patients. For many years, correctional nurses themselves felt they were viewed as substandard, as castaways who could not practice anywhere else. Similar perceptions existed of correctional physicians.

It is true that initially there were no real standards or expectations for nurses or physicians working in corrections. Because recruitment was often a challenge, it was easier to simply hire someone without relying on a systematic method of reviewing credentials or experience.

However, as standards for correctional health care emerged, such as those of the National Commission on Correctional Health Care, likewise standards for health professionals took hold. These standards guided provision of care in jails and prisons, helping to improve quality and to reduce negative stereotypes.

Despite these advances and the hiring of better qualified nurses, the perception persisted that good nurses would not work in corrections. In large part, this belief stems from the lack of knowledge about the environment and practice of correctional nursing, often coupled with fear and, occasionally, instances of nurses taking on aspects of their security counterparts. Consequently, some nurses left this field and others were reluctant to choose it.

It didn't help that many facilities lacked the leadership and structure for nurses that exist in traditional health care settings In years past, nurses usually reported to a corrections administrator or to a physician. In the absence of solid knowledge and expertise in nursing theory and standards, this reporting structure failed to optimize nursing practice in correctional health care.

A Critical Role

Correctional nursing has experienced considerable growth in the past 30 years. The complex health needs of patients entering our systems require nurses with specialized knowledge and skill. Today, correctional nurses play a critical role in ensuring inmates' access to care and in health care delivery. It is the nurse with whom the inmate interacts most frequently and whom the officer consults when an inmate has a health problem.

As in most health care settings, correctional nurses are the primary clinical providers of care. Registered nurses are necessary to lead care delivery, as well as to direct the licensed nurses who work under their guidance.

Correctional nurses must be clinically competent and well grounded in nursing practice. They must possess excellent skills in assessment and critical thinking. Their judgment is critical to the inmates' access to care.

It's also important to have a good understanding of the level of care that can be provided in their institutions. Correctional facilities can ill afford to have nurses who cannot or will not practice within the scope of their license or correctional nursing standards, or who have an aversion to the patient population they are expected to serve.

Thus, correctional nurses have a high degree of accountability and responsibility. The flip side, naturally, is that they also are highly subject to possible litigation.

Today, many facilities have added correctional nurse administrators to their staff. Under this structure, expectations for nursing practice are clearly defined and quality is strongly promoted. The growth in nursing leadership positions has contributed greatly to improvements in delivery of services and quality of care.

A Distinct Specialty

As the practice of correctional nursing has coalesced, it was natural that professional organizations would step up to foster professionalism in this specialty. The American Nurses Association, for example, promulgates standards for

continued on page 4

Correctional nursing is poised for its next big advance: specialty certification. To learn about this CCHP program, see page 24.

correctional nursing.

The ANA defines nursing as "the protection, promotion and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response, and the advocacy in the care of individuals, families, communities, and populations." Nurses' broad-based knowledge and holistic focus positions them as the logical network of providers on which to build health care systems with a focus on education, practice and facilitating patients' efforts to meet their fullest potential.

The ANA's *Corrections Nursing: Scope and Standards of Practice* was revised in 2006 with input from nurse leaders across the country. The standards state that "Matters of nursing judgment are solely the domain of the registered nurse." A major emphasis of this work is primary health care. These services include intake screening and evaluation, health screening, direct patient care, assessment and evaluation of an individual's health behavior, teaching, counseling and helping inmates to assume responsibility for their own health. The nurse also may identify and provide community linkages for inmates upon discharge.

Thanks to the increasing professionalism in correctional nursing, our colleagues in the correctional health care arena now understand and appreciate the value of this specialty. Beyond the walls, as well, negative perceptions are fading and enthusiastic interest in correctional nursing is growing, both in the community and from academic institutions.

It is not clear how many nurses work in correctional health care settings. However, several years ago a national study of the nursing workforce reported 18,033 RNs working in this field.

Opportunities Ahead

Clearly, correctional nursing is on a roll, and even greater opportunities lie ahead. Last spring, CCHP program leaders began to explore the development of specialty certification for correctional nursing. Given that 53% of the more than 2,000 active CCHPs are nurses, this only made sense.

Certification is the formal recognition of specialized knowledge, skills and experience that demonstrate competence and achievement of standards of a specialty that fosters and promotes optimal health outcomes. A key part of the CCHP program is a test designed to measure a candidate's mastery of the specialty.

Aided by a nurse consultant with expertise in test design and psychometrics, a CCHP task force of nurse leaders started by listing nursing task statements that describe correctional nursing and distilling this list to its key essentials. These statements were used to develop a job analysis survey tool, which was sent to a broad group of correctional nurses. The results guided and validated the development of a test for specialty certification.

Certification for correctional nursing helps to legitimize this specialty and validates that these professionals must possess a unique body of knowledge and skills. Just as important, it will certainly inspire others to pursue careers in correctional nursing and will stimulate scholarly research in this field.

Correctional nursing has reached a milestone. Our next challenges include expanding the knowledge of correctional nursing by seeking to more clearly define the profession, to identify the various levels of care delivered by nurses, to document the impact of nursing care on patient outcomes and to pursue research and evidence-based practice.

This is a wonderful time for correctional nurses, our patients and the field of correctional health care as a whole.

Mary V. Muse, MSN, RN, CCHP-A, is a correctional health care consultant based in the Chicago area. She is a surveyor for NCCHC, a frequent presenter at NCCHC conferences and immediate past chair of the Academy of Correctional Health Professionals. She also serves on the task force that is developing the CCHP-N program. To contact her, e-mail mvmuse@ameritech.net.

The ANA book Corrections Nursing: Scope and Standards of Practice *is available for purchase from NCCHC. See our catalog at www.ncchc.org or call 773-880-1460..*

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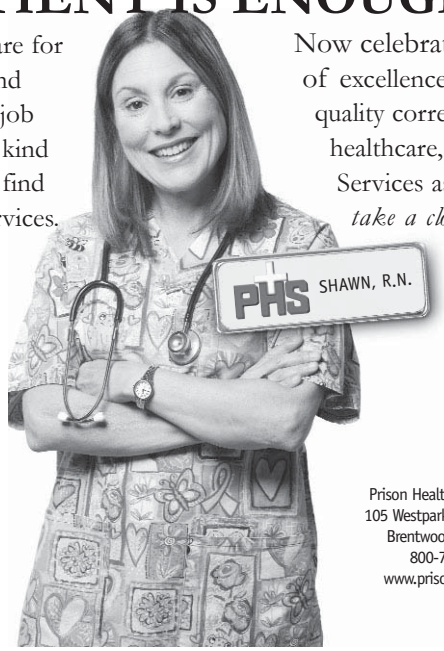

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Can Arrest Charge Inform Selective Screening for HIV in Jails?

With improvements in HIV care in the past decade, early diagnosis is highly important. To facilitate identification of previously undiagnosed HIV infections, in 2006 the Centers for Disease Control and Prevention issued a recommendation for routine, "opt-out" HIV screening in all health care settings, including correctional facilities.

However, to implement universal screening would be a challenge for many jail systems, especially those with insufficient resources or very large inmate populations, as Nina Harawa, MPH, PhD, and her colleagues point out. Their article in the latest issue of the *Journal of Correctional Health Care* note that one alternative is selective screening of higher-risk inmates, but approaches that rely on interviews or surveys have their own disadvantages, such as logistical difficulties or confidentiality concerns.

Thus, the researchers investigated whether arrest charge is associated with HIV risk and thus could be used as a screening criterion at intake. If so, this would "reduce the need to solicit sensitive risk behavior information ... and provide an alternative to selection based on more controversial factors, such as race/ethnicity."

Targeted testing would be more appropriate in areas with relatively low HIV prevalence rates. That includes California, where the proportion of *undiagnosed* infections was found to be relatively high.

The researchers examined data collected as part of a larger project to estimate HIV incidence among high-risk groups in two areas of Los Angeles County with high rates of AIDS. More specifically, they used data on 1,322 inmates newly admitted to two jails to evaluate whether certain types of arrest charges are associated with HIV risk.

Study Details

Trained interviewers collected data on inmates' demographic, socioeconomic, STD history and risk behavior during the prior two years or since their last negative HIV test. These same interviewers later gave the study participants the HIV test results as well as counseling. Arrest charge descriptions were obtained from the Los Angeles Sheriff's Department inmate information and grouped into six categories: drug charges, sex charges, violent charges, theft charges, parole violations and public disorder charges.

Undiagnosed HIV prevalence was found to be 2.7% among the male inmates in the study and 1.0% among females. No participants older than 44 years had undiagnosed infection. Recent STD diagnoses or high-risk behaviors for HIV were found among 32% and 45%, respectively, and men with such a history were far more likely to have undiagnosed HIV, although this relationship was not seen for the women.

Among the males, the highest rates of undiagnosed HIV infection were associated with parole violation and nonviolent sex and theft charges; these charges represented 30% of arrests but 60% of the infections detected. Among females with previously undiagnosed HIV, the most common charges were related to drugs, violent crimes and parole violations, although the relationships were not as strong.

This study results, along with a jail-based CDC demonstration project, suggest that relying on a history of high-risk behaviors would be inefficient in identifying HIV-infected inmates, particularly women. The researchers' discussion of findings makes an argument for selective screening based on arrest charge in jail settings where universal routine screening is not feasible. In Los Angeles County, the approach they advocate is projected to generate 54,000 HIV tests per year, compared to about 150,000 that would be done if universal screening were implemented.

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Predicting Medication Costs and Usage: Expenditures in a Juvenile Detention Facility — *Debra H. Tennyson, PhD, MBA*

Using Arrest Charge to Screen for Undiagnosed HIV Infection Among New Arrestees: A Study in Los Angeles County — *Nina T. Harawa, MPH, PhD, Trista A. Bingham, MS, MPH, PhD, Qiana R. Butler, MPH, Karen S. Dalton, DrPH, William E. Cunningham, MD, MPH, Stephanie Behel, MPH, and Duncan A. MacKellar, MA, MPH*

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Commentary: A Personal Retrospective: In the Eye of the Accreditation Storm (Part I) — *Judith A. Stanley, MS, CCHP-A*

Each issue of *JCHC* also has a self-study exam by which physicians, nurses, psychologists and CCHPs may earn continuing education credit.

Members of the Academy of Correctional Health Professionals receive *JCHC* (hard copy and online access) as a benefit of membership. To learn how to obtain *JCHC*, contact Sage Publications: 800-818-7243, ext. 7100; order@sagepub.com; http://jchc.sagepub.com.

Spotlight on the standards

by Jennifer E. Kistler, MPH

Correctional facilities house a significant number of inmates with chronic disease. While the goal of a chronic disease program is to decrease the frequency and severity of the symptoms, prevent disease progression and complication, and foster improved function, appropriate chronic disease care ultimately affects a patient's ability to work and lead a healthy lifestyle once returned to the community. Empowering patients to manage their own health and health care through education and involving them in taking better care of their disease is an important aspect of chronic disease management.

Standard G-01 Chronic Disease Services requires that the responsible physician establish and annually approve clinical protocols that are consistent with national clinical practice guidelines (those presented by national professional organizations and accepted by experts in the respective discipline) for the management of chronic diseases.

You may want to consider the clinical guidelines adopted by NCCHC, available at www.ncchc.org. These guidelines address the most problematic health issues seen among inmates (with distinct sets for adults and youth) and were adapted for correctional settings from nationally accepted guidelines prepared by organizations such as the National Institutes of Health; the American Diabetes Association; the National Heart, Lung, and Blood Institute; and the U.S. Department of Health and Human Services. While our guidelines take into account the unique barriers to appropriate treatment that are commonly found in correctional facilities, they do not replace individual clinical judgment based on a specific patient's presentation.

Total disease management is the best system for improving patient outcomes. Appropriate baseline laboratory and other testing data should be obtained and recorded in the health record. NCCHC highly recommends the use of flowsheets to track chronic care patients so that their history and progress can be monitored over time, rather than episodically. Regular clinic visits for evaluation and management are of obvious benefit to these patients. Total disease management requires clear indicators of the degree of control of disease and often the more subtle distinction as to whether the condition is stable, improving or deteriorating. NCCHC's Definitions of Disease Control and Clinical Status are also posted on our Web site. The purpose of the definitions of control is to help the clinician keep treatment goals in mind. Clinical status refers to more subtle subjective and objective changes since the previous visit.

People often ask why NCCHC considers HIV a chronic disease rather than infectious. We define chronic disease as an illness or condition that affects an individual's well-being for an extended interval, usually at least six months, and generally is not curable but can be managed to provide optimum functioning within any limitations the condition imposes on the individual. The HHS HIV/AIDS Bureau states that "…long-term complications have put HIV infection in the realm of chronic diseases rather than of infectious diseases, which usually respond to short-term clinical interventions" (see A Guide to Primary Care for People With HIV/AIDS, available at http://hab.hrsa.gov/tools/primarycareguide/PCGchap1.htm). NCCHC does recommend that patients enrolled in an HIV program be monitored by an HIV specialist who will initiate and change therapeutic regimens as medically indicated.

What's New?

Similarly, major mental illness is now categorized as a chronic disease in the 2008 Chronic Disease Services standard for jails and prisons. Clinical protocols for the management of chronic disease should include, but are not limited to, asthma, diabetes, high blood cholesterol, HIV, hypertension, seizure disorder, tuberculosis and major mental illness. Protocols are used to assist in decision making, assess the quality of care, control expenditures and reduce the risk and liability for negligent care.

The 2008 standard also states that a list of chronic care patients should be maintained and chronic illnesses noted on the master problem list. A properly completed problem list provides easy access to critical patient health information for clinicians and may improve patient safety.

The new standard also calls for more specific documentation that clinicians are following chronic disease protocols. Medical records should note the frequency of follow-up for medical evaluation; adjustment of treatment modality as clinically indicated; the type and frequency of diagnostic testing and therapeutic regimens; appropriate instructions for diet, exercise, adaptation to the correctional environment and medication; and clinical justification of any deviation from the protocol. Also available on the NCCHC Web site are forms for chronic disease initial baseline, clinic follow-up and a nursing flowsheet, along with instructions for their use. These forms may assist you in documenting chronic care visits. All NCCHC guidelines and forms are reviewed routinely and updated as necessary.

NCCHC also recommends that the management of chronic care patients be monitored through the continuous quality improvement process, and our guidelines suggest quality improvement monitors.

Aggressive management of chronic disease should significantly reduce morbidity and mortality. The concept of chronic disease care in correctional settings has been evolving; concentrating on total disease management with teamwork between clinicians and patients will help improve clinical outcomes.

Jennifer E. Kistler, MPH, is NCCHC's director of accreditation. To contact her, e-mail jenniferkistler@ncchc.org, call 773-880-1460 or write to NCCHC, 1145 W. Diversey Pkwy., Chicago, IL 60614. For an archive of Spotlight articles, visit the Resources section at www.ncchc.org.

G-01 Chronic Disease Services (essential)

Patients with chronic diseases are identified and enrolled in a chronic disease program to decrease the frequency and severity of the symptoms, prevent disease progression and complication, and foster improved function. —2008 *Standards for Health Services* for jails and prisons

7 Days in Restraints in Lieu of Mental Health Treatment Shows Deliberate Indifference

by William C. Collins, JD

Alan Payette was not a model inmate. He repeatedly destroyed jail property and repeatedly tried to injure himself. Over 10 days, he had to be taken to the hospital three times, once to remove a razor he had hidden in his anus, once because he swallowed a staple and the third time because he swallowed a piece of metal from his sink.

After one series of destructive behaviors, the jail administrator had Mr. Payette put in four-point restraints for five days. After he was removed from the restraints, Mr. Payette launched into his self-destructive phase and the spate of hospital visits mentioned above.

Several times during the self-destructive period, hospital staff told jail officials that Mr. Payette should be seen by a psychiatrist. For reasons that are not clear, the jail administrator's response was again to put Mr. Payette in restraints, this time for seven days, at which point he was transferred to another facility.

The lawsuit *Payette v. Hoenisch* (2008) raised various issues, but for this article, the issue of concern is the week-long period in restraints. The opinion does not specifically say if the inmate was let out of restraints for any reason, such as using the bathroom, but in the absence of any discussion about not being periodically let out of the restraints, it perhaps can be assumed that Mr. Payette was let up occasionally for short periods.

Defendants sought to rid themselves of the lawsuit via a motion for summary judgment but they offered very little by way of justification for the decision to deny mental health diagnosis or treatment for seven days. The only justification that the Court of Appeals mentions was the jail administrator-defendant's argument that he could ignore the recommendations of outside doctors because the jail's medical provider had said the inmate could live safely in his cell.

In some circumstances, this argument could carry the day but not here, where the context of the initial advice had completely changed. The jail doctor's assessment that Mr. Payette could live in a cell came "two months before [the inmate] slashed his arms, twice swallowed pieces of metal, and inserted part of a plastic razor into his anus" and obviously before the hospital doctors had been recommending mental health treatment for Mr. Payette.

Had the jail administrator asked his own doctor to reexamine the inmate in light of his self-destructive behavior and again been told "he's OK," perhaps the result would have been different. But to rely on old advice despite the recent self-destructive behavior and after other doctors were waving red flags about the inmate's mental health is almost a classic example of deliberate indifference: The jail administrator's own actions—putting the inmate in full body restraints for a week—showed he had rejected his doctor's earlier advice that the inmate could live safely in a cell. Reliance on the jail doctor's earlier assessment was nothing more than a vain grasp at a straw in the wind.

The combination of the extended period of time in restraints and recommendations from medical professionals that he needed mental health attention showed deliberate indifference to serious mental health needs. In discussing the week in restraints, the court noted that ACA standards and the policies of two departments of correction (Wisconsin and the Federal Bureau of Prisons) both call for close medical attention for any inmate in restraints for more than 12 hours. [See page 10 for information about NCCHC standards concerning inmate restraint. —*Editor*]

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THE MENTALLY DISORDERED INMATE AND THE LAW
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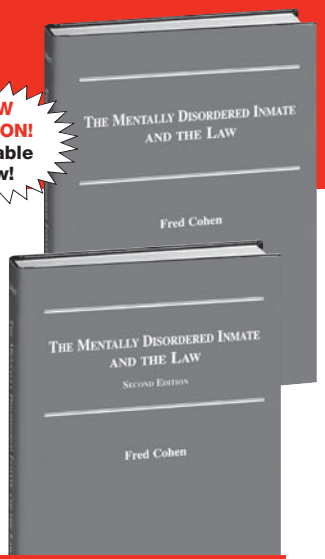

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Author's Comment

Boiled down to its essence, this case is one of delayed treatment. The correctional administrator who intentionally delays or denies an inmate medical or mental health treatment that has been recommended by a competent medical professional does so at his legal peril.

There are at least a couple of steps an administrator can take in a delayed treatment situation to make the legal situation worse, and both were taken in *Payette*. The first is to extend the period that treatment is delayed. A second is to see that the inmate is in as much discomfort as possible during that period. Putting a mentally ill inmate in full body restraints for seven days without medical attention accomplishes both of these steps.

Because the claim focused on the "deliberate indifference to serious medical needs" question, the court had no occasion to review whether the placement was initially proper or whether there was a justifiable need to continue the placement for a week. However, even had doctors not been telling the jail that the inmate was mentally ill, keeping him in full restraints for seven days without some medical/mental health review probably would have presented a claim for possible legal relief.

William C. Collins, JD, is the coeditor of Correctional Law Reporter. *This article was originally published in the October/November 2008 issue of* CLR, *©2008 Civic Research Institute, Inc., and is reprinted here in slightly abridged form with permission of the publisher. All rights reserved. For subscription information, contact Civic Research Institute, 4478 U.S. Route 27, P.O. Box 585, Kingston, NJ 08528; 609-683-4450; www.civicresearchinstitute.com.*

NCCHC Jail Standards Explain Health Staff Responsibilities for Inmates in Restraints

Standard J-1-01 addresses situations when restraints are ordered for clinical reasons as well as for custody reasons. In the *Payette* case, the latter situation seems to apply. Compliance Indicator 2 states the following:

a. When restraints are used by custody staff for security reasons, health services staff are notified immediately in order to: (1) review the health record for any contraindication or accommodations required, which, if present, are immediately communicated to appropriate custody staff, and (2) initiate health monitoring, which continues at designated intervals as long as the inmate is restrained.

b. If the restrained inmate has a medical or mental health condition, the physician is notified immediately so that appropriate orders can be given.

c. When health services staff note improper use of restraints that is jeopardizing the health of an inmate, they communicate their concerns as soon as possible to appropriate custody staff.

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Less Common Adverse Events

The following adverse events [defined as always serious by MedDRA-Preferred -(Critical)- Terms] occurred in <2% of SELZENTRY-treated patients. These events have been included because of their seriousness and either increased frequency on SELZENTRY or are potential risks due to the mechanism of action. Events attributed to the patient's underlying HIV infection are not listed.

Cardiac Disorders: unstable angina, acute cardiac failure, coronary artery disease, coronary artery occlusion, myocardial infarction, myocardial ischemia

Hepatobiliary Disorders: hepatic cirrhosis, hepatic failure, cholestatic jaundice

Infections and Infestations: Clostridium difficile colitis, viral meningitis, pneumonia, septic shock

Musculoskeletal and Connective Tissue Disorders: myositis, osteonecrosis, rhabdomyolysis, blood CK increased

Neoplasms benign, Malignant and Unspecified (including Cysts and Polyps): abdominal neoplasm, anal cancer, basal cell carcinoma, Bowen's disease, cholangiocarcinoma, lymphoma, metastases to liver, esophageal carcinoma, squamous cell carcinoma, squamous cell carcinoma of skin, tongue neoplasm (malignant stage unspecified)

Nervous System Disorders: cerebrovascular accident

Laboratory Abnormalities

Table 3 shows the treatment-emergent Grade 3-4 laboratory abnormalities that occurred in >2% of patients receiving SELZENTRY.

Table 3 Maximum Shift in Laboratory Test Values (Without Regard to Baseline) Incidence ≥2% of Grade 3-4 Abnormalities (ACTG Criteria) A4001027 and A4001028 (Pooled Analysis, Up to 48 Weeks)

Laboratory Parameter Preferred Term, %	Limit	SELZENTRY Twice daily + OBT N =421* (%)	Placebo + OBT N =207* (%)
Aspartate aminotransferase	>5.0x ULN	4.5	2.9
Alanine aminotransferase	>5.0x ULN	2.4	3.4
Total bilirubin	>5.0x ULN	5.7	5.3
Amylase	>2.0x ULN	5.5	5.8
Lipase	>2.0x ULN	4.9	6.3
Absolute neutrophil count	<750/mm^3	3.8	1.9

*Percentages based on total patients evaluated for each laboratory parameter

DRUG INTERACTIONS

Effect of Concomitant Drugs on the Pharmacokinetics of Maraviroc

Maraviroc is a substrate of CYP3A and Pgp and hence its pharmacokinetics are likely to be modulated by inhibitors and inducers of these enzymes/transporters. Therefore, a dose adjustment may be required when maraviroc is coadministered with those drugs [see *Dosage and Administration*].

Concomitant use of maraviroc and St. John's wort (hypericum perforatum) or products containing St. John's wort is not recommended. Coadministration of maraviroc with St. John's wort is expected to substantially decrease maraviroc concentrations and may result in suboptimal levels of maraviroc and lead to loss of virologic response and possible resistance to maraviroc.

For additional drug interaction information see *Clinical Pharmacology.*

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B

The incidence of fetal variations and malformations was not increased in embryofetal toxicity studies performed with maraviroc in rats at exposures (AUC) approximately 20-fold higher and in rabbits at approximately 5-fold higher than human exposures at the recommended daily dose (up to 1000 mg/kg/day in rats and 75 mg/kg/day in rabbits). During the pre-and post-natal development studies in the offspring, development of the offspring, including fertility and reproductive performance, was not affected by the maternal administration of maraviroc. However, there are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, SELZENTRY should be used during pregnancy only if clearly needed.

Antiretroviral Pregnancy Registry

To monitor maternal-fetal outcomes of pregnant women exposed to SELZENTRY and other antiretroviral agents, an Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling 1-800-258-4263.

Nursing Mothers

The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV infection. Studies in lactating rats indicate that maraviroc is extensively secreted into rat milk. It is not known whether maraviroc is secreted into human milk. Because of the potential for both HIV transmission and serious adverse reactions in nursing infants, mothers should be instructed not to breast-feed if they are receiving SELZENTRY.

Pediatric Use

The pharmacokinetics, safety and efficacy of maraviroc in patients <16 years of age have not been established. Therefore, maraviroc should not be used in this patient population.

Geriatric Use

There were insufficient numbers of subjects aged 65 and over in the clinical studies to determine whether they respond differently from younger subjects. In general, caution should be exercised when administering SELZENTRY in elderly patients, also reflecting the greater frequency of decreased hepatic and renal function, of concomitant disease and other drug therapy.

Renal Impairment

The safety and efficacy of maraviroc have not been specifically studied in patients with renal impairment, therefore maraviroc should be used with caution in this population. In the absence of metabolic inhibitors, renal clearance accounts for approximately 25% of total clearance of maraviroc. Maraviroc concentrations may be increased in patients with renal impairment, especially when CYP3A inhibitors are coadministered. Patients with a creatinine clearance of less than 50 mL/min who receive maraviroc and a CYP3A inhibitor may be at an increased risk of adverse effects related to increased maraviroc concentrations, such as dizziness and postural hypotension. Thus, patients with a creatinine clearance of less than 50 mL/min should receive maraviroc and a CYP3A inhibitor only if the potential benefit is felt to outweigh the risk, and they should be monitored for adverse effects.

Hepatic Impairment

The pharmacokinetics of maraviroc have not been sufficiently studied in patients with hepatic impairment. Because maraviroc is metabolized by the liver, concentrations are likely to be increased in these patients.

Gender

Population pharmacokinetic analysis of pooled Phase 1/2a data indicated gender (female: n=96, 23.2% of the total population) does not affect maraviroc concentrations. Dosage adjustment based on gender is not necessary.

Race

Population pharmacokinetic analysis of pooled Phase 1/2a data indicated exposure was 26.5% higher in Asians (N=95) as compared to non-Asians (n=318). However, a study designed to evaluate pharmacokinetic differences between Caucasians (n=12) and Singaporeans (n=12) showed no difference between these two populations. Only 14 Black subjects were included in the population pharmacokinetic analysis. No dosage adjustment based on race is needed.

OVERDOSAGE

The highest dose administered in clinical studies was 1200 mg. The dose limiting adverse event was postural hypotension, which was observed at 600 mg. While the recommended dose for SELZENTRY in patients receiving a CYP3A inducer without a CYP3A inhibitor is 600 mg twice daily, this dose is appropriate due to enhanced metabolism. Prolongation of the QT interval was seen in dogs and monkeys at plasma concentrations 6 and 12 times, respectively, those expected in humans at the intended exposure of 300 mg equivalents twice daily. However, no significant QT prolongation was seen in the studies in treatment-experienced patients with HIV using the recommended doses of maraviroc or in a specific pharmacokinetic study to evaluate the potential of maraviroc to prolong the QT interval.

There is no specific antidote for overdose with maraviroc. Treatment of overdose should consist of general supportive measures including keeping the patient in a supine position, careful assessment of patient vital signs, blood pressure and ECG.

If indicated, elimination of unabsorbed active maraviroc should be achieved by emesis or gastric lavage. Administration of activated charcoal may also be used to aid in removal of unabsorbed drug. Since maraviroc is moderately protein bound, dialysis may be beneficial in removal of this medicine.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term oral carcinogenicity studies of maraviroc were carried out in rasH2 transgenic mice (6 months) and in rats for up to 96 weeks (females) and 104 weeks (males). No drug-related increases in tumor incidence were found in mice at 1500 mg/kg/day and in male and female rats at 900 mg/kg/day. The highest exposures in rats were approximately 11 times those observed in humans at the therapeutic dose of 300 mg twice daily for the treatment of HIV-1 infection.

Mutagenesis

Maraviroc was not genotoxic in the reverse mutation bacterial test (Ames test in Salmonella and E. coli), a chromosome aberration test in human lymphocytes and rat bone marrow micronucleus test.

Impairment of Fertility

Maraviroc did not impair mating or fertility of male or female rats and did not affect sperm of treated male rats at approximately 20-fold higher exposures (AUC) than in humans given the recommended 300 mg twice daily dose.

17 PATIENT COUNSELING INFORMATION

See Medication Guide.

Patients should be informed that if they develop signs or symptoms of hepatitis or allergic reaction following use of SELZENTRY (rash, skin or eyes look yellow, dark urine, vomiting, abdominal pain), they should stop SELZENTRY and seek medical evaluation immediately [*see Warnings and Precautions*].

Patients should be informed that SELZENTRY is not a cure for HIV infection and patients may still develop illnesses associated with HIV infection, including opportunistic infections. The use of SELZENTRY has not been shown to reduce the risk of transmission of HIV to others through sexual contact, sharing needles or blood contamination.

Patients should be advised that it is important to:

- remain under the care of a physician when using SELZENTRY;
- take SELZENTRY every day as prescribed and in combination with other antiretroviral drugs;
- report to their physician the use of any other prescription or nonprescription medication or herbal products;
- inform their physician if they are pregnant, plan to become pregnant or become pregnant while taking SELZENTRY;
- not change the dose or dosing schedule of SELZENTRY or any antiretroviral medication without consulting their physician.

Caution should be used when administering SELZENTRY in patients with a history of postural hypotension or on concomitant medication known to lower blood pressure. Patients should be advised that if they experience dizziness while taking SELZENTRY, they should avoid driving or operating machinery.

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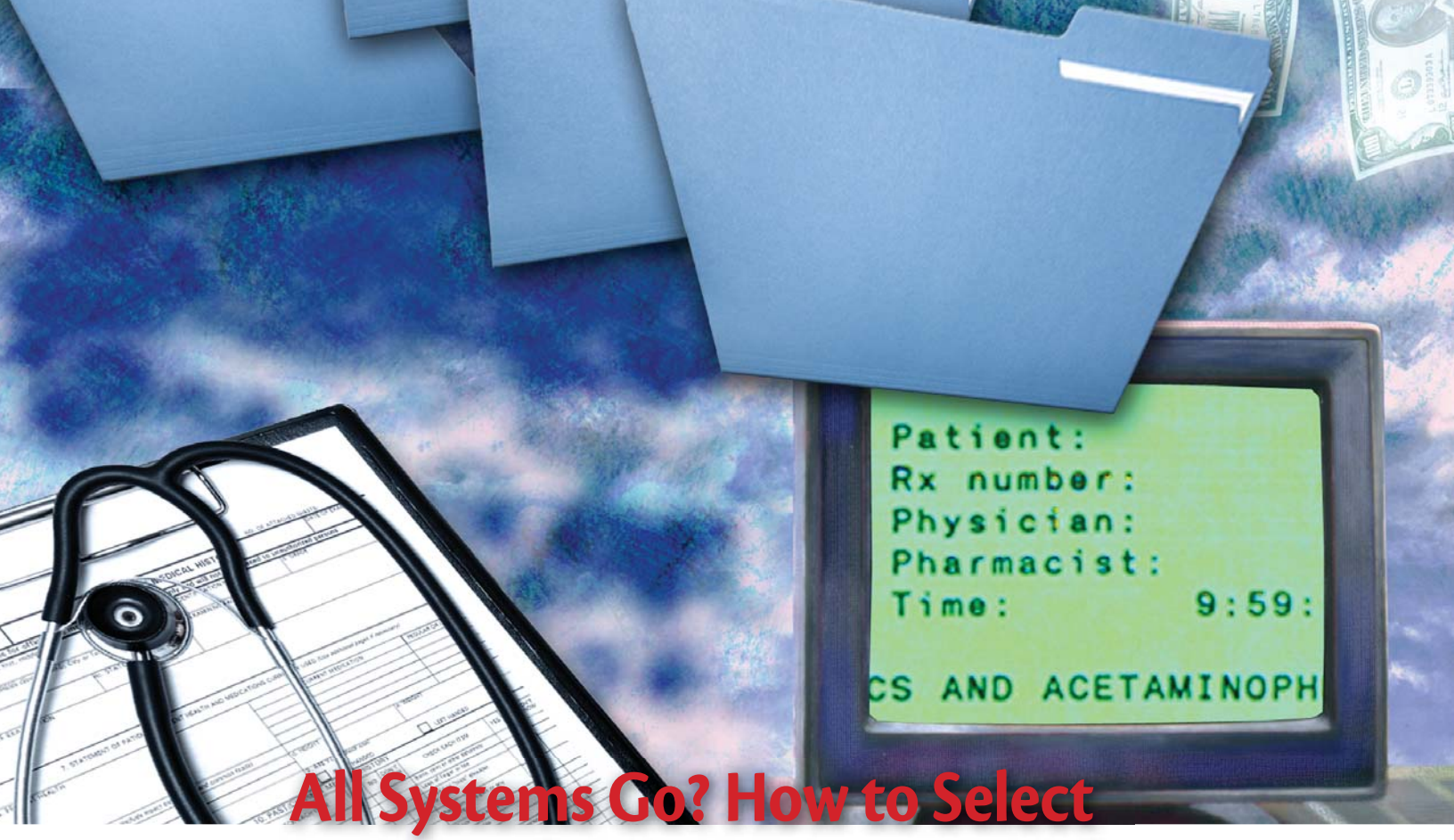

All Systems Go? How to Select an EHR That Meets Your Needs

It is critical to understand what you mean by EHR, your institutional needs, the type of system that fits best and the service you expect.

by Madison L. Gates, MS

Electronic health records are often pitched as a tool that will enhance health professionals' capability to provide and manage care, while also facilitating patients' ability to understand and participate in the management of their care. The U.S. Department of Health and Human Services, as well as primary care organizations such as the American Academy of Family Physicians, strongly advocate for EHRs as necessary if physicians are to improve the way they manage care and health outcomes. Many advocates also propose that EHRs will decrease health expenditures by making patient charts more integrated, shareable and secure, and making them less timely and labor intensive to manage.

These are compelling arguments, and if they hold true in the private sectors, then they are just as true in correctional health care systems, which face the additional complications of limited budgets, a patient population with few resources and the need to balance security and health care. While it's not the panacea for all of these problems, implementing a correctional electronic health record system often is proposed as a way to simultaneously control rising costs and improve outcomes.

Despite the many reasons why health professionals may want EHRs, the decision to adopt a system is difficult. And, once that decision is made, the selection of a specific EHR system is just as difficult. In fact, the success of the project ultimately is determined by the specific EHR that is chosen.

This article is based on a case study of a system successfully implemented and managed throughout the Kentucky Department of Corrections. The intent is to provide guidance for other DOCs interested in selecting an EHR that best meets their clinical, administrative and institutional needs. To make an informed selection, it is critical to understand what you mean by EHR, your institutional needs, the type of system that best fits your organization and the type of service you expect.

Defining EHRs

The first generations of EHRs are vastly different from the systems being implemented today. For example, some early EHRs were more document repositories than comprehensive tools to manage health and support clinical decision making. Today, EHRs come in many varieties. Thus, the first and most important question that any organization should ask is, "What do we mean by EHR?" The answer to this seemingly simple question establishes the criteria for evaluating prospective systems.

While organizations can begin to learn what an EHR is or can be via product demonstrations, the caveat to this approach is that not all EHRs are the same and different systems define the technology differently. Starting with a definition is advantageous even if you later must amend it.

Broadly defined, an EHR is an integrated data system to

document, analyze, manage and support clinical information and decision making, as well as a resource for patients to understand and participate in the management of their health. Using this definition, the essential components of an EHR can be categorized into four capabilities: documentation, order management, reporting and analysis, and communication. These capabilities should be seamlessly integrated and interrelated, which is to say that all features and functions should be accessible from every aspect of the system. The documentation function should support recording clinical encounters, making amendments, documenting in a structured manner, and relating and linking information to other aspects of health information, such as problems, procedures and medications.

Integrated within documentation, order management should support initiating, transmitting and managing orders, such as medications, labs, diagnostic tests, patient care, administrative and other directives. Structured data is preferable and should be used when possible. The key aspect of order management is the ability to track what has been requested, when the task has been completed, and who initiated, performed and reviewed the order. This capability also should minimize the potential for orders to "fall through the cracks" by not being completed or reviewed. An alert system and automatic messaging is fundamental to this function.

A system capable of documentation and order management is incomplete without a reporting and analysis component. Structured data for documentation and order management is critical to an effective and flexible reporting and analysis feature where the underlying information largely comes from databases. "Structured data" does not mean that there are no options for write-in text or that users must adapt the art of their practice to prearranged forms. However, structured data provides consistency for reporting and analyzing data.

The function common throughout any system should be communication, which is more than sending, receiving and managing messages like e-mail. Communication is the function that binds documentation, order management and reporting into a seamless system. This includes system-to-user and user-to-user communication, as well as alerts.

These four capabilities—documentation, order management, reporting and communication—broadly represent what an EHR system should be capable of doing and are important factors to consider in the selection process. Starting with a definition of an EHR and its components, an organization can evaluate realistically what is possible compared to what it wants. The next step of the selection process is to identify and evaluate its institutional needs.

Workflow and Operational Analysis

Identifying an organization's needs is important because not all EHRs are the same or appropriate for all types of institutions. But it is a difficult process and entails more than an evaluation of policies, procedures and guidelines. In a multiclinic organization, policies, procedures and guidelines often can be interpreted differently based on the particular clinic's culture, staffing mix and size, patient population and many other factors. Thus, too much reliance on these formal documents may not fully capture what is actually occurring.

This aspect of the EHR selection process entails examining how clinics operate, identifying the different types of encounters and evaluating the effectiveness of your paper system. You must define with some specificity what the EHR needs to do in order to build on your current workflow or to reorganize operations altogether.

When documenting workflow, no detail is too minor. For example, what are the many ways for a patient to get to clinic? What happens when the patient gets to clinic? What happens during the clinical encounter? What happens when the patient leaves the clinic? The best way to document these events is to follow a live example.

This analysis should produce a list of needs that can be ranked as either *critical* or as *wants*. The critical features and functions of an EHR are those essential to your clinic operations, such as the ability to document clinical encounters; everything else is a want. Of course, the rankings can be granulated further, but what you want to learn from this activity is what your EHR must be capable of doing. A primary reason for transitioning to an EHR is to improve the existing system, not to replicate it. An EHR that does not add value is not the right system for your organization.

Build or Buy?

Some organizations believe that the system most suitable for their operations is one they build. Regardless of whether you want to build or buy, you need to know what an EHR is and what is necessary to operate clinics. I propose that most organizations will, and should, want to buy. While there may not be a perfect system that meets all of your needs, building one is unlikely to meet your expectations, either. Also, building an EHR requires time, expertise and resources.

One way to think about the "build or buy" decision is that most organizations do not debate whether they should develop their own word processor, spreadsheet, presentation or database programs; they rely on companies with expertise in this type of software development. And these programs are far less complicated than a full EHR.

Medical informatics, the underlying discipline for most EHR systems, is not just a combination of medicine, information and technology, but a distinct field. Medicine, nursing, pharmacy, other health professions, computer science and project management are only some of the disciplines involved in the development of an EHR. Most EHR vendors specialize in developing these systems and devote the time and resources to the product.

My advice is to buy a system developed by experts. The remainder of this article assumes that your organization will make that decision.

Vendor Service

The range of EHR vendors is as diverse as the systems themselves. In the selection process, the services that the vendor provides is a critical factor.

continued on page 14

Some vendors are moving toward a hosted Web-based solution. There is much debate over whether such a system is better than a software-based one. Web-based systems are typically accessible anywhere with Internet access. Software-based systems can be housed on a server and be accessible remotely via a virtual private network. While there are advantages to Web-based systems—such as graphical user interface, lower learning curve and a smaller and less expensive technology footprint (hosted systems do not require an investment in servers)—the two types of systems can offer the same or similar features and functions. The primary difference is location. The hosted Web-based solution is often housed by the vendor, whereas the software-based solution tends to be housed internally.

Where the system is housed raises other issues and concerns, mostly related to service, with hosted solutions tending to provide more service. The extent of service your organization will require depends on the extent to which you want to invest time, expertise and resources to manage the system.

One of the most important services a vendor can provide is disaster recovery. It's not enough for a vendor to simply state that it has a disaster recovery plan. You should receive detailed and specific information about this service. Disaster recovery plans minimally should describe in detail how a vendor will secure, protect, backup and recover data. Disaster recovery should entail periodic backups, on-site and off-site storage, Internet service redundancy, mirrored servers in different locations and an estimated time for recovery. An organization that does not require a policy risks disaster without recovery.

Service also includes a range of options that will either enhance or impede the implementation, use and management of a system. Before selecting an EHR, you will want to know how the vendor will facilitate the transition from paper to electronic. Regardless of the type of system, service should include project management, training, support after implementation, technology and infrastructure guidance, and product enhancement. Although a good on-staff project manager can guide the EHR project to successful implementation, a vendor should have expertise in managing the adoption of its product and should provide the service.

There are many service questions that should be asked and discussed prior to selection. Who will train and support users? What is the product enhancement cycle? This is sometimes overlooked, but no technology is static, especially EHRs. No matter how carefully an organization evaluates its needs and how diligently a vendor develops its system, there likely will be a need for change. How often is the system updated and enhanced with new features? Are innovations included in the pricing model? What is the vendor's history in interfacing with other systems? How flexible is the system and vendor?

An organization can request a product enhancement history. Be cautious of too many enhancements in a short period of time, which may suggest a faulty system, and of too few innovations, which may indicate inattention to the product. Of course, many enhancements may mean that a vendor is highly motivated and active, and few innovations may suggest that the system was well-developed. The type and number of enhancements can be informative and may indicate the level of service that you can expect.

Flexibility vs. the 'Ideal'

In addition to the considerations discussed above, cost is a major deciding factor in selecting an EHR. Also, a vendor should be willing to provide an online demonstration site or environment to explore the product, or to facilitate a visit with an existing client. Both options demonstrate the vendor's level of comfort with its product.

But no matter how many demonstrations or site visits you make, your decision-making will be improved if you pay attention to the key factors described above. To identify an EHR that fits your organization's goals and objectives, you must know what you mean by EHR, what your needs are and what you expect from the vendor. However, many factors are organizationally specific. An EHR appropriate for one setting or organization may not necessarily be the best system for yours. A final word of advice: A system that is flexible but less than perfect is much more likely to be successful than one that is inflexible but more ideal.

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[1] Regent Medical Tests 050338-201 and HIB 3-107-10-1 [2] Jarvis WR. Selected aspects of the socioeconomic impact of nosocomial infections: morbidity, mortality, cost, and prevention. Infection Control and Hospital Epidemiology 1996;17:552-557. [3] Regent Medical Study #051120-201 [4] Independent Lab Test Time-Kill Study 5 Minutes S. epidermidis ATCC #12228. [5] 2006 HPIS data for antimicrobial skin cleansers. Regent Medical Study #040907-150, and Regent Medical Study #041101-201. [4] Regent Medical Study #040907-150 and #041101-201. [5] Third quarter HPIS data for antimicrobial skin cleansers.

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Examining Cost: How Improving Operations Can Boost Your Bottom Line *(part 2)*

by Rick Morse, MBA, CCHP

Editor's note: This is Part 2 of a two-part article. Part 1 appeared in the Fall 2008 issue of CorrectCare.

This two-part article discusses how to analyze a correctional health services program in order to improve quality and reduce costs. Part I focused on the financial component and the three primary cost drivers of the health unit: labor, off-site care and pharmaceuticals. Part II will look at the other two major components of the health program: operations and results. In addition, a case study will illustrate how to apply some of the basics.

Focus on Operations

There are three primary areas to look at when assessing your operational processes: (1) what's coming in the back door, (2) access to care and (3) follow-up and monitoring. From the big-picture perspective, these are the most important factors in ensuring a safe and cost-effective operation. I have proven time and again that doing what it takes to succeed in these areas justifies the expense and ultimately reduces overall costs.

• The back door (mostly for jails): Knowing what is coming in the back door refers to your intake/admission process. If you do too much screening and complete the physical exam too early, you may be inefficient with costly resources by focusing on admissions that may be gone in a matter of hours. Not enough screening and you may end up having to send an inmate to the hospital along with a security detail at the overtime rate. In NCCHC's 2008 *Standards for Health Services* for jails and prisons, standard E-04 Initial Health Assessment offers two options to allow for safe and cost-effective screening for your facility.

• Access to care: The ability for an inmate to access care is paramount. This happens primarily (although not exclusively) through the sick-call process. Significant attention should be paid to timely triage, scheduling and no-shows. Problems in any area will cue you to barriers to care. Litigation expense can be magnified if unresolved barriers to care exist and played a role in a negative outcome.

• Follow-up and monitoring: When a provider orders care, whether it's a lab, medication, x-ray or referral, there must be a system in place to ensure it happens. Letting ordered care fall through the cracks is unsafe, results in negative outcomes and increases grievances and risk for litigation. Also, when a lab or x-ray report is negative, make sure you have a process to notify the inmate. You'll be amazed at the overall improvement in inmate perception. If your staff can't stay on top of things, then take appropriate measures to address those problems.

Focus on Results and Satisfaction

This component also has three primary focus areas: a quality program, controlled grievances and litigation, and content staff.

A quality program has many components. Accreditation and a good CQI program are two you can put your arms around. High management interest in both of these areas will ensure a proactive approach to health care delivery and will identify costly concerns before they bleed your budget.

Grievances typically align with operational disparities whether or not they are recognized as significant by management. Even though grievances may be exaggerated, poorly described or inflammatory, cumulatively they provide a clear view of inmate perception of the overall health care program. There are exceptions, but litigation typically reflects the problems repeatedly reported by multiple inmates. Paying attention to inmate grievances is one of the best cost-saving measures you can take. You're less likely to get sued and you won't have to spend hours of your time responding to grievances.

Staff turnover is another expensive problem. Always know the condition of the troops. Manage by walking around, see firsthand what's going on. Take care of your people and your people will take care of the mission. Disinterested and problematic personnel not only drain your energy, they hurt your whole team. Think of the anti-tree hugger's slogan: "50 years to grow, 50 seconds to slash down."

Examining the Data

We've only highlighted the major points and barely scratched the surface, but it's time to move on. Let's look at a case study. (This is a high-level overview not intended to address every potential variable. It is not to imply that any particular employee classification is solely responsible or problematic.)

This scenario involves an 850-bed jail. The medical budget for the eight months ended August 31 is $3,731,900, but the actual year-to-date expenditure is $3,829,533—this is $97,633, or 2.62%, over budget (i.e., a negative variance). Let's examine the individual indicators (see page 17) to see if we can identify one of the major culprits.

Looking first at labor, the budget is on the high end of the benchmark average for a jail, and there is a significant negative variance between the budget and actuals. This reflects a 40% turnover of nursing staff, mostly LPNs, and the costs of using RNs and agency nurses to do LPN work, as well as overtime and the cost of orienting new hires.

Turning to off-site care, the financials are nearly on target, but are at a slight negative variance (1.87%). Actual emergency department trips and hospital days also exceed the budget. On-site care is budgeted adequately, but YTD costs are actually under budget. Some specialty clinics have been scheduled inconsistently. The orthopedic specialist now visits only about 50% of the time and doesn't want inmates coming to his office any longer. This is resulting in more ED trips. There is a direct correlation between the decreased on-site specialty care and the need for more off-site care

Case Study of an 850-Bed Jail: What's Wrong With This Picture?							
Budgetary Targets	**Benchmark (Jail)**	**Budget**	**Actual vs. Budget***	**Budget Variance**	**8 Mo. YTD Budget**	**8 Mo. YTD Actual**	**YTD Variance**
Labor/Payroll	53% – 65%	64.44%	67.21%	(4.30%)	$2,404,886	$2,508,352	($103,466)
Off-Site Care	15% – 25%	18.75%	19.10%	(1.87%)	$699,594	$712,655	($13,061)
On-Site Care	2% – 5%	2.57%	2.09%	18.94%	$96,000	$77,822	$18,178
Pharmacy	9% – 10%	10.56%	10.67%	(0.98%)	$394,219	$398,077	($3,858)
Other Line Items	5% – 10%	3.68%	3.55%		$137,201	$132,627	$4,574
YTD Total	—	100%	102.62%		$3,731,900	$3,829,533	($97,633)

**Actual vs. Budget was calculated as the line item actual amount divided by the budgeted total amount. This was done to highlight red flag percentages for this scenario. In reality, we calculate budget variances as a percentage of the line item budget amount divided by the line item actual amount.*

visits. This also has led to increased officer overtime associated with transportation and security details.

In pharmacy, the use of a capitated contract means there are no additional charges for medications ordered as long as they are on the formulary. There is an extra cost for nonformulary medications, but these are reasonably well-controlled. YTD pharmacy expenditures are just slightly over budget.

All other line items have produced an overall eight-month positive variance of $4,574.

Operationally, the medical intake process is very thorough and the jail tries to complete the entire screening and physical within 24 hours. But medical record filing is consistently four to seven days behind, and the clerks (3.0 FTEs) have a two-month backlog of medication administration records (MARs) waiting to be filed.

There are about 45 inmate grievances per month. About 75% of them concern medication issues, waiting for sick call or follow-up appointments, and missed treatments.

Applying the Principles

The jail administrator is not happy with this health services budget YTD or the department in general. No one can seem to get a handle on what's wrong. Why are they having problems?

If you focused on the medication numbers, you're on target. At a jail of this size you would expect to see 775 to 975 medications ordered each month (0.95 to 1.15 per inmate per month). But the actual number exceeds 2,400 medications per month (2.85 per inmate). This volume of work is

Budgetary Targets	Benchmark (Jail)	8 Mo. YTD Budget	8 Mo. YTD Actual
Hospital Days • Per Inmate Per Year	0.130 – 0.150	0.135	0.145
Emergency Department Trips • Per Inmate Per Year	0.075 – 0.100	0.085	0.104
Medications • Per Inmate Per Month	0.90 – 1.10	–	2.85

overwhelming the medical staff and has the residual effect of things falling through the cracks. This, in turn, leads to high LPN turnover and the labor costs discussed above.

How time consuming is medication administration? Time studies I've performed have found that one unnecessary med order three times a day for 30 days requires 104 minutes of nursing time to complete: 8 minutes to note the order and create or annotate the MAR, order the meds, receive the meds and place on carts; 90 minutes to pass the med 90 times; 3 minutes to transcribe the new MAR at the end of the month and pull the old MAR for filing; and add another 3 minutes per month to figure out one housing change per inmate. This is an eye opener for most people so time it yourself if you find it hard to believe!

For inmates admitted to the jail and then released in two to three days, it takes about 15 minutes of nursing time to note the order, make a couple of passes, return the meds to the pharmacy and pull the MAR. This is why I say that 23 unnecessary med orders tie up 40 hours of nursing time.

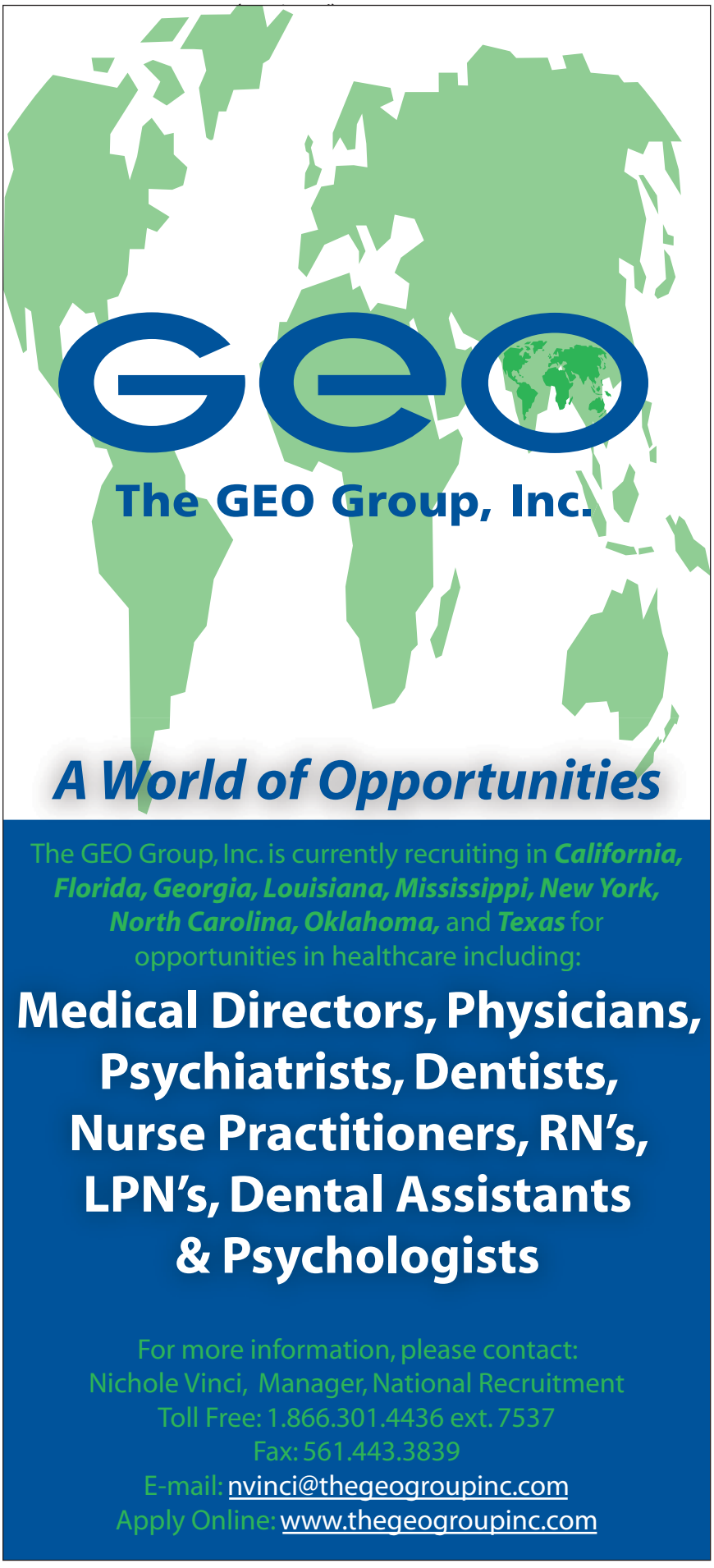
Clearly, overutilization of medication can become a big problem fast. The effects move down the line as the medical record clerks become inundated with documentation to file. Nurses are so busy passing meds and taking off orders that on some days there isn't enough time for blood pressure checks, treatments, seeing all sick-call requests or following up on no-shows. Housing changes also wreak havoc with inmates not receiving meds. Ultimately, the flurry of grievances reflects these problems.

There are many reasons for overutilization of meds, including practitioner preference. In this scenario, though, let's look at the intake process. At intake, the jail immediately performs receiving screening, health history, oral screening, mental health screening and evaluation, intake labs, and medical classification and disposition. This is a

continued on page 18

Clarification: On-Site Care Benchmark

A common question relates to the 2% to 5% benchmark for on-site care services. Typically, your professional on-site staff (physicians, psychiatrists, dentists and psychologists) are independent contractors and not employees. Regardless, these expenses are captured in the labor component of your budget. On-site care line items would include specialty clinic providers, x-ray, lab, telemedicine, etc. This should approximate 2%, but this figure will be higher if you provide on-site dialysis, have specialists that routinely perform surgical procedures on site, or use mobile units for surgery, mammography or other specialty services.



Examining Cost *(continued from page 17)*

good thing. But doing the physical examinations within 24 hours presents some complications to other routine medical operations at the jail.

These providers spent a great deal of time doing physicals on inmates who were out of the system within 72 hours. This is not the most efficient use of provider time. Providers also performed sick call during this exam, bypassing the normal triage process. This led to an overall slowdown during the physical exam that kept the providers from effectively handling the more pressing needs of the general population.

As a result of doing sick call at intake, many medications were ordered for inmates who, again, were released quickly. Too much nursing time was spent managing these meds and, consequently, other critical nursing needs were sometimes overlooked.

Because of the capitated pharmacy contract there is no financial downside to prescribing these meds, so looking at pharmacy cost data would have thrown you off the trail. However, heavy utilization might result in a price increase when the contract is up for renewal.

Commonsense Solutions

The jail took several measures to address these problems. They reevaluated the need to do all physicals within 24 hours and now do so only if the screening process indicates a clinical need for an urgent evaluation. I recommend timing routine physicals for 48 to 72 hours postadmission. (This also allows for the PPD test results to be read at that time.) The providers were coached to focus on the "mission" of the physical and to have the inmate submit a request for sick call. Now, with more people leaving the system before the physical must be performed and by eliminating sick call at intake, providers have more time to focus on inmate needs. This also has reduced the initial number of medication orders.

Pharmacy reports are now generated monthly to enable providers and management to review and analyze utilization. Providers strive to reduce prescribing of unnecessary medications and to order meds for once-a-day dosing (or twice a day when appropriate). A keep-on-person program was initiated to permit inmates to maintain limited amounts of certain medications, thus lessening the time spent in passing meds. In addition, temporary help was used to assist nurses with med pass and other activities until utilization was brought under control, as well as to get medical records caught up.

Finally, efforts were undertaken to stabilize on-site specialty care, which also reduced correctional officer overtime. for off-site care.

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Please see brief summary of Full Prescribing Information for SUSTIVA on the following pages.

Important Information about SUSTIVA® (efavirenz)

INDICATION:

SUSTIVA in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection. This indication is based on two clinical trials of at least one year duration that demonstrated prolonged suppression of HIV RNA.

IMPORTANT SAFETY INFORMATION:

- Coadministration with astemizole, bepridil, cisapride, midazolam, pimozide, triazolam, ergot derivatives, or standard doses of voriconazole is contraindicated. If SUSTIVA is coadministered with voriconazole, the voriconazole maintenance dose should be increased to 400 mg every 12 hours and the SUSTIVA dose should be decreased to 300 mg once daily using the capsule formulation. SUSTIVA tablets should not be broken.
- Concomitant use of SUSTIVA and St. John's wort *(Hypericum perforatum)* or St. John's wort-containing products is not recommended.
- Coadministration of SUSTIVA with ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is not recommended, since efavirenz is one of its active ingredients.
- Serious psychiatric adverse experiences, including severe depression (2.4%), suicidal ideation (0.7%), nonfatal suicide attempts (0.5%), aggressive behavior (0.4%), paranoid reactions (0.4%), and manic reactions (0.2%), have been reported in patients treated with SUSTIVA. In addition to SUSTIVA, factors identified in a clinical study that were associated with an increase in psychiatric symptoms included history of injection drug use, psychiatric history, and use of psychiatric medication. There have been occasional reports of suicide, delusions, and psychosis-like behavior, but it could not be determined if SUSTIVA was the cause. Patients with serious psychiatric adverse experiences should be evaluated immediately to determine whether the risks of continued therapy outweigh the benefits.
- Fifty-three percent of patients reported central nervous system symptoms, including dizziness (28.1%), insomnia (16.3%), impaired concentration (8.3%), somnolence (7.0%), abnormal dreams (6.2%), and hallucinations (1.2%), when taking SUSTIVA compared to 25% of patients receiving control regimens. These symptoms usually begin during Days 1-2 of therapy and generally resolve after the first 2-4 weeks of therapy; they were severe in 2.0% of patients and 2.1% of patients discontinued therapy. After 4 weeks of therapy, the prevalence of nervous system symptoms of at least moderate severity ranged from 5% to 9% in patients treated with regimens containing SUSTIVA. Nervous system symptoms are not predictive of less frequent serious psychiatric symptoms.
- SUSTIVA may cause fetal harm when administered during the first trimester to a pregnant woman. Women should not become pregnant or breast-feed while taking SUSTIVA. Barrier contraception must always be used in combination with other methods of contraception (eg, oral or other hormonal contraceptives). Because of the long half-life of efavirenz, adequate contraceptive measures are recommended for 12 weeks after discontinuation of SUSTIVA. If the patient becomes pregnant while taking SUSTIVA, she should be apprised of the potential harm to the fetus.
- Mild-to-moderate rash is a common side effect of SUSTIVA. In controlled clinical trials, 26% of patients treated with SUSTIVA experienced new-onset skin rash compared with 17% of patients treated in control groups. SUSTIVA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. Rash is more common and often more severe in pediatric patients.
- Liver enzymes should be monitored in patients with known or suspected hepatitis B or C, in patients treated with other medications associated with liver toxicity, and when SUSTIVA is administered with ritonavir.
- Use SUSTIVA with caution in patients with a history of seizures. Convulsions have been observed in patients receiving efavirenz, generally in the presence of known medical history of seizures.
- Redistribution and/or accumulation of body fat have been seen in patients receiving antiretroviral therapy. A causal relationship has not been established.
- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including SUSTIVA.
- Saquinavir should not be used as the only protease inhibitor in combination with SUSTIVA. **Please see the SUSTIVA Full Prescribing Information for complete list of drug interactions.**
- The most common adverse events (≥5%) observed in clinical studies with SUSTIVA include fatigue, pain, dizziness, headache, insomnia, impaired concentration, nausea, vomiting, diarrhea, depression, rash, and pruritus.

The dose of SUSTIVA is one tablet once daily taken orally on an empty stomach, preferably at bedtime, in combination therapy.
The increased concentrations following administration of SUSTIVA with food may lead to an increase in frequency of adverse events. Dosing at bedtime may improve the tolerability of nervous system symptoms.

Bristol-Myers Squibb

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SUSTIVA®

℞ ONLY

(efavirenz) capsules and tablets

Brief summary of Prescribing Information, 03-08. For complete prescribing information, please consult official package insert.

CONTRAINDICATIONS

SUSTIVA (efavirenz) is contraindicated in patients with clinically significant hypersensitivity to any of its components.

SUSTIVA should not be administered concurrently with astemizole, bepridil, cisapride, midazolam, pimozide, triazolam, or ergot derivatives because competition for CYP3A4 by efavirenz could result in inhibition of metabolism of these drugs and create the potential for serious and/or life-threatening adverse events (eg, cardiac arrhythmias, prolonged sedation, or respiratory depression). SUSTIVA should not be administered concurrently with standard doses of voriconazole because SUSTIVA significantly decreases voriconazole plasma concentrations. Adjusted doses of voriconazole and efavirenz may be administered concomitantly (see **CLINICAL PHARMACOLOGY**, Tables 1 and 2 in Full Prescribing Information; **PRECAUTIONS, Drugs That Are Contraindicated or Not Recommended for Use with SUSTIVA;** and **DOSAGE AND ADMINISTRATION: Dosage Adjustment** in Full Prescribing Information).

WARNINGS

ALERT: Find out about medicines that should NOT be taken with SUSTIVA. This statement is also included on the product's bottle labels. (See **CONTRAINDICATIONS** and **PRECAUTIONS: Drug Interactions**.)

SUSTIVA must not be used as a single agent to treat HIV-1 infection or added on as a sole agent to a failing regimen. As with all other non-nucleoside reverse transcriptase inhibitors, resistant virus emerges rapidly when efavirenz is administered as monotherapy. The choice of new antiretroviral agents to be used in combination with efavirenz should take into consideration the potential for viral cross-resistance.

Coadministration of SUSTIVA with ATRIPLA® (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) is not recommended, since efavirenz is one of its active ingredients.

Psychiatric Symptoms: Serious psychiatric adverse experiences have been reported in patients treated with SUSTIVA. In controlled trials of 1008 patients treated with regimens containing SUSTIVA for a mean of 2.1 years and 635 patients treated with control regimens for a mean of 1.5 years, the frequency of specific serious psychiatric events among patients who received SUSTIVA or control regimens, respectively, were: severe depression (2.4%, 0.9%), suicidal ideation (0.7%, 0.3%), nonfatal suicide attempts (0.5%, 0%), aggressive behavior (0.4%, 0.5%), paranoid reactions (0.4%, 0.3%), and manic reactions (0.2%, 0.3%). When psychiatric symptoms similar to those noted above were combined and evaluated as a group in a multifactorial analysis of data from Study 006, treatment with efavirenz was associated with an increase in the occurrence of these selected psychiatric symptoms. Other factors associated with an increase in the occurrence of these psychiatric symptoms were history of injection drug use, psychiatric history, and receipt of psychiatric medication at study entry; similar associations were observed in both the SUSTIVA and control treatment groups. In Study 006, onset of new serious psychiatric symptoms occurred throughout the study for both SUSTIVA-treated and control-treated patients. One percent of SUSTIVA-treated patients discontinued or interrupted treatment because of one or more of these selected psychiatric symptoms. There have also been occasional postmarketing reports of death by suicide, delusions, and psychosis-like behavior, although a causal relationship to the use of SUSTIVA cannot be determined from these reports. Patients with serious psychiatric adverse experiences should seek immediate medical evaluation to assess the possibility that the symptoms may be related to the use of SUSTIVA, and if so, to determine whether the risks of continued therapy outweigh the benefits (see **ADVERSE REACTIONS**).

Nervous System Symptoms: Fifty-three percent of patients receiving SUSTIVA in controlled trials reported central nervous system symptoms compared to 25% of patients receiving control regimens. These symptoms included, but were not limited to, dizziness (28.1%), insomnia (16.3%), impaired concentration (8.3%), somnolence (7.0%), abnormal dreams (6.2%), and hallucinations (1.2%). These symptoms were severe in 2.0% of patients, and 2.1% of patients discontinued therapy as a result. These symptoms usually begin during the first or second day of therapy and generally resolve after the first 2-4 weeks of therapy. After 4 weeks of therapy, the prevalence of nervous system symptoms of at least moderate severity ranged from 5% to 9% in patients treated with regimens containing SUSTIVA and from 3% to 5% in patients treated with a control regimen. Patients should be informed that these common symptoms were likely to improve with continued therapy and were not predictive of subsequent onset of the less frequent psychiatric symptoms (see **WARNINGS: Psychiatric Symptoms**). Dosing at bedtime may improve the tolerability of these nervous system symptoms (see **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** in Full Prescribing Information).

Analysis of long-term data from Study 006 (median follow-up 180 weeks, 102 weeks, and 76 weeks for patients treated with SUSTIVA + zidovudine + lamivudine, SUSTIVA + indinavir, and indinavir + zidovudine + lamivudine, respectively) showed that, beyond 24 weeks of therapy, the incidences of new-onset nervous system symptoms among SUSTIVA-treated patients were generally similar to those in the indinavir-containing control arm.

Patients receiving SUSTIVA should be alerted to the potential for additive central nervous system effects when SUSTIVA is used concomitantly with alcohol or psychoactive drugs. Patients who experience central nervous system symptoms such as dizziness, impaired concentration, and/or drowsiness should avoid potentially hazardous tasks such as driving or operating machinery.

Drug Interactions: Concomitant use of SUSTIVA and St. John's wort (*Hypericum perforatum*) or St. John's wort-containing products is not recommended. Coadministration of non-nucleoside reverse transcriptase inhibitors (NNRTIs), including SUSTIVA, with St. John's wort is expected to substantially decrease NNRTI concentrations and may result in suboptimal levels of efavirenz and lead to loss of virologic response and possible resistance to efavirenz or to the class of NNRTIs.

Reproductive Risk Potential: Pregnancy Category D. Efavirenz may cause fetal harm when administered during the first trimester to a pregnant woman. Pregnancy should be avoided in women receiving SUSTIVA. Barrier contraception should always be used in combination with other methods of contraception (eg, oral or other hormonal contraceptives). Because of the long half-life of efavirenz, use of adequate contraceptive measures for 12 weeks after discontinuation of SUSTIVA is recommended. Women of childbearing potential should undergo pregnancy testing before initiation of SUSTIVA. If this drug is used during the first trimester of pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential harm to the fetus.

There are no adequate and well-controlled studies in pregnant women. SUSTIVA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, such as in pregnant women without other therapeutic options. As of July 2007, the Antiretroviral Pregnancy Registry has received prospective reports of 373 pregnancies exposed to efavirenz-containing regimens, nearly all of which were first-trimester exposures (359 pregnancies). Birth defects occurred in 7 of 295 live births (first-trimester exposure) and 1 of 26 live births (second/third-trimester exposure). None of these prospectively reported defects were neural tube defects. However, there have been five retrospective reports of findings consistent with neural tube defects, including meningomyelocele. All mothers were exposed to efavirenz-containing regimens in the first trimester. Although a causal relationship of these events to the use of SUSTIVA has not been established, similar defects have been observed in preclinical studies of efavirenz.

Antiretroviral Pregnancy Registry: To monitor fetal outcomes of pregnant women exposed to SUSTIVA, an Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling (800) 258-4263.

PRECAUTIONS

General

Skin Rash: In controlled clinical trials, 26% (266/1008) of patients treated with 600 mg SUSTIVA experienced new-onset skin rash compared with 17% (111/635) of patients treated in control groups. Rash associated with blistering, moist desquamation, or ulceration occurred in 0.9% (9/1008) of patients treated with SUSTIVA. The incidence of Grade 4 rash (eg, erythema multiforme, Stevens-Johnson syndrome) in patients treated with SUSTIVA in all studies and expanded access was 0.1%. The median time to onset of rash in adults was 11 days and the median duration, 16 days. The discontinuation rate for rash in clinical trials was 1.7% (17/1008). SUSTIVA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. Appropriate antihistamines and/or corticosteroids may improve the tolerability and hasten the resolution of rash.

Rash was reported in 26 of 57 pediatric patients (46%) treated with SUSTIVA capsules. One pediatric patient experienced Grade 3 rash (confluent rash with fever), and two patients had Grade 4 rash (erythema multiforme). The median time to onset of rash in pediatric patients was 8 days. Prophylaxis with appropriate antihistamines prior to initiating therapy with SUSTIVA in pediatric patients should be considered (see **ADVERSE REACTIONS**).

Liver Enzymes: In patients with known or suspected history of hepatitis B or C infection and in patients treated with other medications associated with liver toxicity, monitoring of liver enzymes is recommended. In patients with persistent elevations of serum transaminases to greater than five times the upper limit of the normal range, the benefit of continued therapy with SUSTIVA needs to be weighed against the unknown risks of significant liver toxicity (see **ADVERSE REACTIONS: Laboratory Abnormalities**).

Because of the extensive cytochrome P450-mediated metabolism of efavirenz and limited clinical experience in patients with hepatic impairment, caution should be exercised in administering SUSTIVA to these patients.

Convulsions: Convulsions have been observed in patients receiving efavirenz, generally in the presence of known medical history of seizures. Caution must be taken in any patient with a history of seizures. Patients who are receiving concomitant anticonvulsant medications primarily metabolized by the liver, such as phenytoin and phenobarbital, may require periodic monitoring of plasma levels (see **PRECAUTIONS: Drug Interactions**).

Cholesterol: Monitoring of cholesterol and triglycerides should be considered in patients treated with SUSTIVA (see **ADVERSE REACTIONS**).

Fat Redistribution: Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The mechanism and long-term consequences of these events are currently unknown. A causal relationship has not been established.

Immune Reconstitution Syndrome: Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including SUSTIVA. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jiroveci* pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment.

Information for Patients: A statement to patients and healthcare providers is included on the product's bottle labels: **ALERT: Find out about medicines that should NOT be taken with SUSTIVA.** A Patient Package Insert (PPI) for SUSTIVA is available for patient information.

Patients should be informed that SUSTIVA (efavirenz) is not a cure for HIV-1 infection and that they may continue to develop opportunistic infections and other complications associated with HIV-1 disease. Patients should be told that there are currently no data demonstrating that SUSTIVA therapy can reduce the risk of transmitting HIV to others through sexual contact or blood contamination.

Patients should be advised to take SUSTIVA every day as prescribed. SUSTIVA must always be used in combination with other antiretroviral drugs. Patients should be advised to take SUSTIVA on an empty stomach, preferably at bedtime. Taking SUSTIVA with food increases efavirenz concentrations and may increase the frequency of adverse events. Dosing at bedtime may improve the tolerability of nervous system symptoms (see **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** in Full Prescribing Information). Patients should remain under the care of a physician while taking SUSTIVA.

Patients should be informed that central nervous system symptoms including dizziness, insomnia, impaired concentration, drowsiness, and abnormal dreams are commonly reported during the first weeks of therapy with SUSTIVA. Dosing at bedtime may improve the tolerability of these symptoms, and these symptoms are likely to improve with continued therapy. Patients should be alerted to the potential for additive central nervous system effects when SUSTIVA is used concomitantly with alcohol or psychoactive drugs. Patients should be instructed that if they experience these symptoms they should avoid potentially hazardous tasks such as driving or operating machinery (see **WARNINGS: Nervous System Symptoms**). In clinical trials, patients who develop central nervous system symptoms were not more likely to subsequently develop psychiatric symptoms (see **WARNINGS: Psychiatric Symptoms**).

Patients should also be informed that serious psychiatric symptoms including severe depression, suicide attempts, aggressive behavior, delusions, paranoia, and psychosis-like symptoms have also been reported in patients receiving SUSTIVA. Patients should be informed that if they experience severe psychiatric adverse experiences they should seek immediate medical evaluation to assess the possibility that the symptoms may be related to the use of SUSTIVA, and if so, to determine whether discontinuation of SUSTIVA may be required. Patients should also inform their physician of any history of mental illness or substance abuse (see **WARNINGS: Psychiatric Symptoms**).

Patients should be informed that another common side effect is rash. These rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. Patients should be advised that they should contact their physician promptly if they develop a rash.

Women receiving SUSTIVA should be instructed to avoid pregnancy (see **WARNINGS: Reproductive Risk Potential**). A reliable form of barrier contraception should always be used in combination with other methods of contraception, including oral or other hormonal contraception, because the effects of efavirenz on hormonal contraceptives are not fully characterized. Because of the long half-life of efavirenz, use of adequate contraceptive measures for 12 weeks after discontinuation of SUSTIVA is recommended. Women should be advised to notify their physician if they become pregnant while taking SUSTIVA. If this drug is used during the first trimester of pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential harm to the fetus.

SUSTIVA may interact with some drugs; therefore, patients should be advised to report to their doctor the use of any other prescription, nonprescription medication, or herbal products, particularly St. John's wort.

Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause and long-term health effects of these conditions are not known at this time.

Drug Interactions (see **also CONTRAINDICATIONS and CLINICAL PHARMACOLOGY: Drug Interactions** in Full Prescribing Information)

Efavirenz has been shown *in vivo* to induce CYP3A4. Other compounds that are substrates of CYP3A4 may have decreased plasma concentrations when coadministered with SUSTIVA. *In vitro* studies have demonstrated that efavirenz inhibits 2C9, 2C19, and 3A4 isozymes in the range of observed efavirenz plasma concentrations. Coadministration of efavirenz with drugs primarily metabolized by these isozymes may result in altered plasma concentrations of the coadministered drug. Therefore, appropriate dose adjustments may be necessary for these drugs.

Drugs which induce CYP3A4 activity (eg, phenobarbital, rifampin, rifabutin) would be expected to increase the clearance of efavirenz resulting in lowered plasma concentrations. Drug interactions with SUSTIVA are summarized in the following paragraphs and in Tables 5 and 6 in Full Prescribing Information. The following include potentially significant interactions, but are not all inclusive.

Drugs That Are Contraindicated or Not Recommended for Use With SUSTIVA: For clinical comment, please see Table 5 in Full Prescribing Information.

Antifungal: voriconazole at standard doses. When voriconazole is coadministered with SUSTIVA, voriconazole maintenance dose should be increased to 400 mg every 12 hours and SUSTIVA dose should be decreased to 300 mg once daily using the capsule formulation. SUSTIVA tablets should not be broken. (See **CLINICAL PHARMACOLOGY**, Tables 1 and 2 in Full Prescribing Information; **CONTRAINDICATIONS**; **PRECAUTIONS**, Table 5 in Full Prescribing Information; and **DOSAGE AND ADMINISTRATION: Dosage Adjustment** in Full Prescribing Information).

Antihistamine: astemizole; Antimigraine: ergot derivatives (dihydroergotamine, ergonovine, ergotamine, methylergonovine); Benzodiazepines: midazolam, triazolam; Calcium channel blocker: bepridil; GI motility agent: cisapride; Neuroleptic: pimozide; St. John's wort (*Hypericum perforatum*).

Established and Other Potentially Significant Drug Interactions*: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction

Antiretroviral Agents

Protease Inhibitors – *Amprenavir:* ↓amprenavir concentration. SUSTIVA has the potential to decrease serum concentrations of amprenavir. *Fosamprenavir calcium:* ↓amprenavir concentration. Fosamprenavir (unboosted): Appropriate doses of the combinations with respect to safety and efficacy have not been established. Fosamprenavir/ritonavir: An additional 100 mg/day (300 mg total) of ritonavir is recommended when SUSTIVA is administered with fosamprenavir/ritonavir once daily. No change in the ritonavir dose is required when SUSTIVA is administered with fosamprenavir plus ritonavir twice daily. *Atazanavir:* ↓atazanavir concentration. When coadministered with SUSTIVA in treatment-naive patients, the recommended dose of atazanavir is 300 mg with ritonavir 100 mg and SUSTIVA 600 mg (all once daily). Dosing recommendations for SUSTIVA and atazanavir in treatment-experienced patients have not been established. *Indinavir:* ↓indinavir concentration. The optimal dose of indinavir, when given in combination with SUSTIVA, is not known. Increasing the indinavir dose to 1000 mg every 8 hours does not compensate for the increased indinavir metabolism due to SUSTIVA. When indinavir at an increased dose (1000 mg every 8 hours) was given with SUSTIVA (600 mg once daily), the indinavir AUC and C_{min} were decreased on average by 33-46% and 39-57%, respectively, compared to when indinavir (800 mg every 8 hours) was given alone. *Lopinavir/ritonavir:* ↓lopinavir concentration. Lopinavir/ritonavir tablets should not be administered once-daily in combination with SUSTIVA. In antiretroviral-naive patients, lopinavir/ritonavir tablets can be used twice daily in combination with SUSTIVA with no dose adjustment. A dose increase of lopinavir/ritonavir tablets to 600/150 mg (3 tablets) twice daily may be considered when used in combination with SUSTIVA in treatment-experienced patients where decreased susceptibility to lopinavir is clinically suspected (by treatment history or laboratory evidence). A dose increase of lopinavir/ritonavir oral solution to 533/133 mg (6.5 mL) twice daily taken with food is recommended when used in combination with SUSTIVA. *Ritonavir:* ↑ritonavir concentration, ↑efavirenz concentration. When ritonavir 500 mg every 12 hours was coadministered with SUSTIVA 600 mg once daily, the combination was associated with a higher frequency of adverse clinical experiences (eg, dizziness, nausea, paresthesia) and laboratory abnormalities (elevated liver enzymes). Monitoring of liver enzymes is recommended when SUSTIVA is used in combination with ritonavir. *Saquinavir:* ↓saquinavir concentration. Should not be used as sole protease inhibitor in combination with SUSTIVA.

Other Agents

Anticoagulant – *Warfarin:*↑ or ↓warfarin concentration. Plasma concentrations and effects potentially increased or decreased by SUSTIVA. **Anticonvulsants** – *Carbamazepine:* ↓carbamazepine concentration, ↓efavirenz concentration. There are insufficient data to make a dose recommendation for efavirenz. Alternative anticonvulsant treatment should be used. *Phenytoin, Phenobarbital:* ↓anticonvulsant concentration, ↓efavirenz concentration. Potential for reduction in anticonvulsant and/or efavirenz plasma levels; periodic monitoring of anticonvulsant plasma levels should be conducted. **Antidepressant** – *Sertraline:* ↓sertraline concentration. Increases in sertraline dose should be guided by clinical response. **Antifungals** – *Itraconazole:* ↓itraconazole, ↓hydroxyitraconazole concentrations. Since no dose recommendation for itraconazole can be made, alternative antifungal treatment should be considered. *Ketoconazole:* ↓ketoconazole concentration. Drug interaction studies with SUSTIVA and ketoconazole have not been conducted. SUSTIVA has the potential to decrease plasma concentrations of ketoconazole. (See **PRECAUTIONS, Drugs That Are Contraindicated or Not Recommended for Use With SUSTIVA** and Table 5 in Full Prescribing Information for guidance on coadministration with adjusted doses of voriconazole). **Anti-infective** – *Clarithromycin:* ↓clarithromycin, ↑14-OH metabolite concentrations. Plasma concentrations decreased by SUSTIVA; clinical significance unknown. In uninfected volunteers, 46% developed rash while receiving SUSTIVA and clarithromycin. No dose adjustment of SUSTIVA is recommended when given with clarithromycin. Alternatives to clarithromycin, such as azithromycin, should be considered (see **PRECAUTIONS: Other Drugs** in Full Prescribing Information). Other macrolide antibiotics, such as erythromycin, have not been studied in combination with SUSTIVA. **Antimycobacterials** – *Rifabutin:* ↓rifabutin concentration. Increase daily dose of rifabutin by 50%. Consider doubling the rifabutin dose in regimens where rifabutin is given 2 or 3 times a week. *Rifampin:* ↓efavirenz concentration. Clinical significance of reduced efavirenz concentrations is unknown. Dosing recommendations for concomitant use of SUSTIVA and rifampin have not been established. **Calcium channel blockers** – *Diltiazem:* ↓diltiazem, ↓desacetyl diltiazem, ↓N-monodesmethyl diltiazem concentrations. Diltiazem dose adjustments should be guided by clinical response (refer to complete prescribing information for diltiazem). No dose adjustment of efavirenz is necessary when administered with diltiazem. *Others (eg, felodipine, nicardipine, nifedipine, verapamil):* ↓calcium channel blocker concentration. No data are available on the potential interactions of efavirenz with other calcium channel blockers that are substrates of the CYP3A4 enzyme. The potential exists for reduction in plasma concentrations of the calcium channel blocker. Dose adjustments should be guided by clinical response (refer to the complete prescribing information for the calcium channel blocker). **HMG-CoA reductase inhibitors** – *Atorvastatin:* ↓atorvastatin concentration, *Pravastatin:* ↓pravastatin concentration, *Simvastatin:* ↓simvastatin concentration. Plasma concentrations of atorvastatin, pravastatin, and simvastatin decreased. Consult the complete prescribing information for the HMG-CoA reductase inhibitor for guidance on individualizing the dose. **Narcotic analgesic** – *Methadone:* ↓methadone concentration. Coadministration in HIV-infected individuals with a history of injection drug use resulted in decreased plasma levels of methadone and signs of opiate withdrawal. Methadone dose was

increased by a mean of 22% to alleviate withdrawal symptoms. Patients should be monitored for signs of withdrawal and their methadone dose increased as required to alleviate withdrawal symptoms. **Oral contraceptive** – *Ethinyl estradiol:* ↑ethinyl estradiol concentration. Plasma concentrations increased by SUSTIVA (efavirenz); clinical significance unknown. The potential interaction of efavirenz with oral contraceptives has not been fully characterized. A reliable method of barrier contraception should be used in addition to oral contraceptives.

***Please see, in Full Prescribing Information, Tables 1, 2, 5 and 6 and PRECAUTIONS: Other Drugs for additional information.**

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term carcinogenicity studies in mice and rats were carried out with efavirenz. Mice were dosed with 0, 25, 75, 150, or 300 mg/kg/day for 2 years. Incidences of hepatocellular adenomas and carcinomas and pulmonary alveolar/bronchiolar adenomas were increased above background in females. No increases in tumor incidence above background were seen in males. In studies in which rats were administered efavirenz at doses of 0, 25, 50, or 100 mg/kg/day for 2 years, no increases in tumor incidence above background were observed. The systemic exposure (based on AUCs) in mice was approximately 1.7-fold that in humans receiving the 600-mg/day dose. The exposure in rats was lower than that in humans. The mechanism of the carcinogenic potential is unknown. However, in genetic toxicology assays, efavirenz showed no evidence of mutagenic or clastogenic activity in a battery of *in vitro* and *in vivo* studies. These included bacterial mutation assays in *S. typhimurium* and *E. coli*, mammalian mutation assays in Chinese hamster ovary cells, chromosome aberration assays in human peripheral blood lymphocytes or Chinese hamster ovary cells, and an *in vivo* mouse bone marrow micronucleus assay. Given the lack of genotoxic activity of efavirenz, the relevance to humans of neoplasms in efavirenz-treated mice is not known.

Efavirenz did not impair mating or fertility of male or female rats, and did not affect sperm of treated male rats. The reproductive performance of offspring born to female rats given efavirenz was not affected. As a result of the rapid clearance of efavirenz in rats, systemic drug exposures achieved in these studies were equivalent to or below those achieved in humans given therapeutic doses of efavirenz.

Pregnancy

Pregnancy Category D: See **WARNINGS: Reproductive Risk Potential.**

Nursing Mothers: The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV. Although it is not known if efavirenz is secreted in human milk, efavirenz is secreted into the milk of lactating rats. Because of the potential for HIV transmission and the potential for serious adverse effects in nursing infants, **mothers should be instructed not to breast-feed if they are receiving SUSTIVA**.

Pediatric Use: ACTG 382 is an ongoing, open-label study in 57 NRTI-experienced pediatric patients to characterize the safety, pharmacokinetics, and antiviral activity of SUSTIVA in combination with nelfinavir (20-30 mg/kg TID) and NRTIs. Mean age was 8 years (range 3-16). SUSTIVA has not been studied in pediatric patients below 3 years of age or who weigh less than 13 kg. At 48 weeks, the type and frequency of adverse experiences was generally similar to that of adult patients with the exception of a higher incidence of rash, which was reported in 46% (26/57) of pediatric patients compared to 26% of adults, and a higher frequency of Grade 3 or 4 rash reported in 5% (3/57) of pediatric patients compared to 0.9% of adults (see **ADVERSE REACTIONS, Percent of Patients with Treatment-Emergent Rash** below).

The starting dose of SUSTIVA was 600 mg once daily adjusted to body size, based on weight, targeting AUC levels in the range of 190-380 μM•h. The pharmacokinetics of efavirenz in pediatric patients were similar to the pharmacokinetics in adults who received 600-mg daily doses of SUSTIVA. In 48 pediatric patients receiving the equivalent of a 600-mg dose of SUSTIVA, steady-state C_{max} was 14.2 ± 5.8 μM (mean ± SD), steady-state C_{min} was 5.6 ± 4.1 μM, and AUC was 218 ± 104 μM•h.

Geriatric Use: Clinical studies of SUSTIVA did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other therapy.

ADVERSE REACTIONS

The most significant adverse events observed in patients treated with SUSTIVA are nervous system symptoms, psychiatric symptoms, and rash. Unless otherwise specified, the analyses described below included 1008 patients treated with regimens containing SUSTIVA and 635 patients treated with a control regimen in controlled trials.

Nervous System Symptoms: Fifty-three percent of patients receiving SUSTIVA reported central nervous system symptoms (see **WARNINGS: Nervous System Symptoms**). The following paragraph lists the frequency of the symptoms of different degrees of severity and gives the discontinuation rates in clinical trials for one or more of the following nervous system symptoms: dizziness, insomnia, impaired concentration, somnolence, abnormal dreaming, euphoria, confusion, agitation, amnesia, hallucinations, stupor, abnormal thinking, and depersonalization. The frequencies of specific central and peripheral nervous system symptoms are provided in Table 1.

Percent of Patients with One or More Selected Nervous System Symptoms (regardless of causality) in Study 006 and Three Phase 2/3 Studies: SUSTIVA 600 mg Once Daily (n=1008), Control Groups (n=635), respectively: Symptoms of any severity (52.7%, 24.6%); mild symptoms† (33.3%, 15.6%); moderate symptoms† (17.4%, 7.7%); severe symptoms† (2.0%, 1.3%); treatment discontinuation as a result of symptoms (2.1%, 1.1%).

† *"Mild" = symptoms which do not interfere with patient's daily activities, "moderate" = symptoms which may interfere with daily activities, "severe" = events which interrupt patient's usual daily activities*

Psychiatric Symptoms: Serious psychiatric adverse experiences have been reported in patients treated with SUSTIVA. In controlled trials, the frequency of specific serious psychiatric symptoms among patients who received SUSTIVA or control regimens, respectively, were severe depression (2.4%, 0.9%), suicidal ideation (0.7%, 0.3%), nonfatal suicide attempts (0.5%, 0%), aggressive behavior (0.4%, 0.5%), paranoid reactions (0.4%, 0.3%), and manic reactions (0.2%, 0.3%) (see **WARNINGS: Psychiatric Symptoms**). Additional psychiatric symptoms observed at a frequency of >2% among patients treated with SUSTIVA or control regimens, respectively, in controlled clinical trials were depression (19%, 16%), anxiety (13%, 9%), and nervousness (7%, 2%).

Skin Rash: Rashes are usually mild-to-moderate maculopapular skin eruptions that occur within the first 2 weeks of initiating therapy with SUSTIVA. In most patients, rash resolves with continuing SUSTIVA therapy within one month. SUSTIVA can be reinitiated in patients interrupting therapy because of rash. Use of appropriate antihistamines and/or corticosteroids may be considered when SUSTIVA is restarted. SUSTIVA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. The frequency of rash by NCI grade and the discontinuation rates as a result of rash are provided in the following paragraph.

Percent of Patients with Treatment-Emergent Rash (regardless of causality) in Study 006 and Three Phase 2/3 Studies: SUSTIVA 600 mg Once Daily Adults (n=1008), SUSTIVA Pediatric Patients (n=57), Control Groups Adults (n=635), respectively: Rash of any grade‡ (26.3%, 45.6%, 17.5%), Grade 1 rash – erythema, pruritus (10.7%, 8.8%, 9.8%), Grade 2 rash – diffuse maculopapular rash, dry desquamation (14.7%, 31.6%, 7.4%), Grade 3 rash – vesiculation, moist desquamation, ulceration (0.8%, 1.8%, 0.3%), Grade 4 rash – erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, necrosis requiring surgery, exfoliative dermatitis (0.1%, 3.5%, 0.0%), Treatment discontinuation as a result of rash (1.7%, 8.8%, 0.3%).

‡ *NCI Grading System*

As seen above, rash is more common in pediatric patients and more often of higher grade (ie, more severe) (see **PRECAUTIONS: General**).

Experience with SUSTIVA in patients who discontinued other antiretroviral agents of the NNRTI class is limited. Nineteen patients who discontinued nevirapine because of rash have been treated with SUSTIVA. Nine of these patients developed mild-to-moderate rash while receiving therapy with SUSTIVA, and two of these patients discontinued because of rash.

Pancreatitis has been reported, although a causal relationship with efavirenz has not been established. Asymptomatic increases in serum amylase levels were observed in a significantly higher number of patients treated with efavirenz 600 mg than in control patients (see **ADVERSE REACTIONS: Laboratory Abnormalities**).

Selected clinical adverse experiences of moderate or severe intensity observed in ≥2% of SUSTIVA-treated patients in two controlled clinical trials are presented in Table 1 below.

Table 1: Selected Treatment-Emergent[a] Adverse Events of Moderate or Severe Intensity Reported in ≥2% of SUSTIVA-Treated Patients in Studies 006 and ACTG 364

	Study 006: LAM-, NNRTI-, and Protease Inhibitor-Naive Patients			Study ACTG 364: NRTI-experienced, NNRTI- and Protease Inhibitor-Naive Patients		
Adverse Events	SUSTIVA[b] + ZDV/LAM (n=412) 180 weeks[c]	SUSTIVA[b] + Indinavir (n=415) 102 weeks[c]	Indinavir + ZDV/LAM (n=401) 76 weeks[c]	SUSTIVA[b] + Nelfinavir + NRTIs (n=64) 71.1 weeks[c]	SUSTIVA[b] + NRTIs (n=65) 70.9 weeks[c]	Nelfinavir + NRTIs (n=66) 62.7 weeks[c]
Body as a Whole						
Fatigue	8%	5%	9%	0	2%	3%
Pain	1%	2%	8%	13%	6%	17%
Central and Peripheral Nervous System						
Dizziness	9%	9%	2%	2%	6%	6%
Headache	8%	5%	3%	5%	2%	3%
Insomnia	7%	7%	2%	0	0	2%
Concentration impaired	5%	3%	<1%	0	0	0
Abnormal dreams	3%	1%	0	—	—	—
Somnolence	2%	2%	<1%	0	0	0
Anorexia	1%	<1%	<1%	0	2%	2%

[a] Includes adverse events at least possibly related to study drug or of unknown relationship for Study 006. Includes all adverse events regardless of relationship to study drug for Study ACTG 364. [b] SUSTIVA provided as 600 mg once daily. [c] Median duration of treatment. — = Not Specified. ZDV = zidovudine, LAM = lamivudine.

(continued)

Table 1: Selected Treatment-Emergent[a] Adverse Events of Moderate or Severe Intensity Reported in ≥2% of SUSTIVA (efavirenz)-Treated Patients in Studies 006 and ACTG 364 *(continued)*

	Study 006: LAM-, NNRTI-, and Protease Inhibitor-Naive Patients			Study ACTG 364: NRTI-experienced, NNRTI- and Protease Inhibitor-Naive Patients		
Adverse Events	SUSTIVA[b] + ZDV/LAM (n=412) 180 weeks[c]	SUSTIVA[b] + Indinavir (n=415) 102 weeks[c]	Indinavir + ZDV/LAM (n=401) 76 weeks[c]	SUSTIVA[b] + Nelfinavir + NRTIs (n=64) 71.1 weeks[c]	SUSTIVA[b] + NRTIs (n=65) 70.9 weeks[c]	Nelfinavir + NRTIs (n=66) 62.7 weeks[c]
Gastrointestinal						
Nausea	10%	6%	24%	3%	2%	2%
Vomiting	6%	3%	14%	—	—	—
Diarrhea	3%	5%	6%	14%	3%	9%
Dyspepsia	4%	4%	6%	0	0	2%
Abdominal pain	2%	2%	5%	3%	3%	3%
Psychiatric						
Anxiety	2%	4%	<1%	—	—	—
Depression	5%	4%	<1%	3%	0	5%
Nervousness	2%	2%	0	2%	0	2%
Skin & Appendages						
Rash	11%	16%	5%	9%	5%	9%
Pruritus	<1%	1%	1%	9%	5%	9%

[a] Includes adverse events at least possibly related to study drug or of unknown relationship for Study 006. Includes all adverse events regardless of relationship to study drug for Study ACTG 364. [b] SUSTIVA provided as 600 mg once daily. [c] Median duration of treatment. — = Not Specified. ZDV = zidovudine, LAM = lamivudine.

Clinical adverse experiences observed in ≥10% of 57 pediatric patients aged 3 to 16 years who received SUSTIVA capsules, nelfinavir, and one or more NRTIs were: rash (46%), diarrhea/loose stools (39%), fever (21%), cough (16%), dizziness/lightheaded/fainting (16%), ache/pain/discomfort (14%), nausea/vomiting (12%), and headache (11%). The incidence of nervous system symptoms was 18% (10/57). One patient experienced Grade 3 rash, two patients had Grade 4 rash, and five patients (9%) discontinued because of rash (see also **PRECAUTIONS: Skin Rash** and **Pediatric Use**).

Postmarketing Experience: *Body as a Whole:* allergic reactions, asthenia, redistribution/accumulation of body fat (see **PRECAUTIONS: Fat Redistribution**); *Central and Peripheral Nervous System:* abnormal coordination, ataxia, cerebellar coordination and balance disturbances, convulsions, hypoesthesia, paresthesia, neuropathy, tremor; *Endocrine:* gynecomastia; *Gastrointestinal:* constipation, malabsorption; *Cardiovascular:* flushing, palpitations; *Liver and Biliary System:* hepatic enzyme increase, hepatic failure, hepatitis; *Metabolic and Nutritional:* hypercholesterolemia, hypertriglyceridemia; *Musculoskeletal:* arthralgia, myalgia, myopathy; *Psychiatric:* aggressive reactions, agitation, delusions, emotional lability, mania, neurosis, paranoia, psychosis, suicide; *Respiratory:* dyspnea; *Skin and Appendages:* erythema multiforme, nail disorders, photoallergic dermatitis, skin discoloration, Stevens-Johnson syndrome; *Special Senses:* abnormal vision, tinnitus

Laboratory Abnormalities: Selected Grade 3-4 laboratory abnormalities reported in ≥2% of SUSTIVA-treated patients in two clinical trials are presented in Table 2 below.

Table 2: Selected Grade 3-4 Laboratory Abnormalities Reported in ≥2% of SUSTIVA-Treated Patients in Studies 006 and ACTG 364

		Study 006 LAM-, NNRTI-, and Protease Inhibitor-Naive Patients			Study ACTG 364 NRTI-experienced, NNRTI- and Protease Inhibitor-Naive Patients		
Variable	Limit	SUSTIVA[a] + ZDV/LAM (n=412) 180 weeks[b]	SUSTIVA[a] + Indinavir (n=415) 102 weeks[b]	Indinavir + ZDV/LAM (n=401) 76 weeks[b]	SUSTIVA[a] + Nelfinavir + NRTIs (n=64) 71.1 weeks[b]	SUSTIVA[a] + NRTIs (n=65) 70.9 weeks[b]	Nelfinavir + NRTIs (n=66) 62.7 weeks[b]
Chemistry							
ALT	>5 x ULN	5%	8%	5%	2%	6%	3%
AST	>5 x ULN	5%	6%	5%	6%	8%	8%
GGT[c]	>5 x ULN	8%	7%	3%	5%	0	5%
Amylase	>2 x ULN	4%	4%	1%	0	6%	2%
Glucose	>250 mg/dL	3%	3%	3%	5%	2%	3%
Triglycerides[d]	≥751 mg/dL	9%	6%	6%	11%	8%	17%
Hematology							
Neutrophils	<750/mm^3	10%	3%	5%	2%	3%	2%

[a] SUSTIVA provided as 600 mg once daily. [b] Median duration of treatment. [c] Isolated elevations of GGT in patients receiving SUSTIVA may reflect enzyme induction not associated with liver toxicity. [d] Nonfasting. ZDV = zidovudine, LAM = lamivudine, ULN = Upper limit of normal, ALT = alanine aminotransferase, AST = aspartate aminotransferase, GGT = gamma-glutamyltransferase.

Liver function tests should be monitored in patients with a history of hepatitis B and/or C. In the long-term data set from Study 006, 137 patients treated with SUSTIVA-containing regimens (median duration of therapy, 68 weeks) and 84 treated with a control regimen (median duration, 56 weeks) were seropositive at screening for hepatitis B (surface antigen positive) and/or C (hepatitis C antibody positive). Among these co-infected patients, elevations in AST to greater than five times ULN developed in 13% of patients in the SUSTIVA arms and 7% of those in the control arm, and elevations in ALT to greater than five times ULN developed in 20% of patients in the SUSTIVA arms and 7% of patients in the control arm. Among co-infected patients, 3% of those treated with SUSTIVA-containing regimens and 2% in the control arm discontinued from the study because of liver or biliary system disorders (see **PRECAUTIONS: General**).

Lipids: Increases from baseline in total cholesterol of 10-20% have been observed in some uninfected volunteers receiving SUSTIVA. In patients treated with SUSTIVA + zidovudine + lamivudine, increases from baseline in nonfasting total cholesterol and HDL of approximately 20% and 25%, respectively, were observed. In patients treated with SUSTIVA + indinavir, increases from baseline in nonfasting cholesterol and HDL of approximately 40% and 35%, respectively, were observed. Nonfasting total cholesterol levels ≥240 mg/dL and ≥300 mg/dL were reported in 34% and 9%, respectively, of patients treated with SUSTIVA + zidovudine + lamivudine; 54% and 20%, respectively, of patients treated with SUSTIVA + indinavir; and 28% and 4%, respectively, of patients treated with indinavir + zidovudine + lamivudine. The effects of SUSTIVA on triglycerides and LDL were not well characterized since samples were taken from nonfasting patients. The clinical significance of these findings is unknown (see **PRECAUTIONS: General**).

Cannabinoid Test Interaction: Efavirenz does not bind to cannabinoid receptors. False-positive urine cannabinoid test results have been observed in non-HIV-infected volunteers receiving SUSTIVA when the Microgenics CEDIA® DAU Multi-Level THC assay was used for screening. Negative results were obtained when more specific confirmatory testing was performed with gas chromatography/mass spectrometry.

Of the three assays analyzed (Microgenics CEDIA DAU Multi-Level THC assay, Cannabinoid Enzyme Immunoassay [Diagnostic Reagents, Inc.], and AxSYM® Cannabinoid Assay), only the Microgenics CEDIA DAU Multi-Level THC assay showed false-positive results. The other two assays provided true-negative results. The effects of SUSTIVA on cannabinoid screening tests other than these three are unknown. The manufacturers of cannabinoid assays should be contacted for additional information regarding the use of their assays with patients receiving efavirenz.

OVERDOSAGE

Some patients accidentally taking 600 mg twice daily have reported increased nervous system symptoms. One patient experienced involuntary muscle contractions.

Treatment of overdose with SUSTIVA should consist of general supportive measures, including monitoring of vital signs and observation of the patient's clinical status. Administration of activated charcoal may be used to aid removal of unabsorbed drug. There is no specific antidote for overdose with SUSTIVA. Since efavirenz is highly protein bound, dialysis is unlikely to significantly remove the drug from blood.

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Juvenile voice

by Jaime Shimkus

When Trudy shows up for duty at the Prince William County (VA) Juvenile Detention Center, the youth know it's going to be a good day. In fact, on mornings that she begins her work in the girls' unit, it's likely that those girls will have no sick calls for the day. Her bosses love Trudy, too. She never grouses about the job, seldom takes a day off and works pro bono. Such is life with a certified therapy dog on staff.

"She teaches the children a lot of lessons about how to interact with others, children and adults alike," says health services administrator Ellyn Presley, RN, CCHP, who owns Trudy. "They see that if you treat her with love and respect, she responds with love and respect. They learn to apply those principles to their own lives."

The four-year-old black labrador has been a near daily presence at the 73-bed JDC since she was just a few months old. But Trudy's career path was unusual in that she was not brought there initially for the children's sake. Rather, she had been assigned to Presley, a puppy trainer for Guiding Eyes for the Blind, who intended to use the facility setting to socialize the puppy.

Trudy returned to Guiding Eyes about a year later to become a service dog, but she didn't pass muster so the agency permitted Presley to adopt her. It's a good thing, too, because Trudy is perfectly suited to therapy work.

Positive Career Change

In that first year, after receiving an enthusiastic OK from the facility supervisor, Presley decided to turn Trudy's visits into a mutually beneficial experience for the youth under her care. She developed a program in which certain youth in the sentenced program (now disbanded) were taught to train the puppy.

About 10 children who had achieved the highest level of good behavior (measured through accumulation of points) would take part in daily structured activities. Following a protocol established by Guiding Eyes for the Blind, they taught the puppy commands and social skills. They also learned responsibilities of dog care such as grooming. This was a special privilege for these children, and they were the only ones who were allowed to call Trudy by name and to give her commands.

Presley relates an anecdote that is amusing, yet telling. At program start-up, one of the boys misunderstood the purpose of a seeing eye dog and thought it was to serve as a *guard* dog, protecting a blind person from victimization. The puppy training program also had a component to teach the youth about disabilities, including visits from guest speakers.

When Trudy returned to Presley, she joined the staff at the JDC but in a different capacity. She took classes and passed numerous tests to prove that she met the criteria to be a certified therapy dog. Disposition is very important: A dog must be highly obedient and gentle with people, and not become upset by devices, such as wheelchairs and crutches, common to health care settings.

As a graduate of Therapy Dogs International, Trudy wears a vest with a photo ID while on the job. "When I put her vest on, she is in working mode and she knows it," says Presley. "It changes her whole mindset: 'We've got stuff to do!'"

Trudy is free to roam around the facility but often can be found in the clinic, which is next to intake. "We have a lot of repeat offenders," Presley says, "and they all ask for Trudy right away." The dog also carries gear such as bandages and a blood pressure cuff in her vest pockets when making rounds with Presley. "The kids love it, and suddenly they all need Band-Aids."

Learning Life Lessons

Now that Trudy is a therapy dog, all of the youth are permitted to interact with her, and they do. Beyond enjoying the good feelings that come from petting and playing with a friendly, well-behaved dog, the youth internalize many positive lessons. In group discussions, a child will often make some observation that relates to personal behavior.

For example, when Trudy once stayed with a friend of Presley's for several days, the discipline she received was more lax and it took awhile to regain her focus. The youth recognized the harm done when rules were not enforced with consistency. Or if a child shows anger or speaks harshly, the dog will walk away, another valuable lesson. They also appreciate that she does not discriminate with regard to demographics or arrest charge.

Despite the troubled backgrounds of many detained youth, none at the Prince William County JDC has ever treated Trudy poorly, and just one made a threat to do so. That child was flagged and lost privileges to interact with her. Mostly, says Presley, "They just love on that dog."

Jaime Shimkus is the editor of CorrectCare. *To reach her, write to jaimeshimkus@ncchc.org or call 773-880-1460.*

We welcome your comments on this column or on other juvenile correctional health topics. Please write to NCCHC's juvenile health committee c/o Matissa Sammons at matissasammons@ncchc.org or by mail to NCCHC, 1145 W. Diversey Pkwy., Chicago, IL 60614.

CDC Guidance for HIV Testing in Corrections

In 2006, the Centers for Disease Control and Prevention changed its recommendation for HIV screening and now says that routine, "opt-out" screening is optimal in all health care settings. In January, it issued guidance for correctional facilities in implementing such a testing program. Along with statistical background, the document covers issues relating to inmate privacy and confidentiality, the components of HIV opt-out screening and testing procedures, overcoming obstacles and case reporting. Acknowledging the "logistics, security and financial demands" of routine opt-out screening in many correctional settings, it also offers alternative approaches to "efficiently identify the most previously undiagnosed cases of HIV ... while minimizing the burden to correctional staff and resources." These alternatives include screening based on risk factors, clinical indicators, demographics and custody information (for a preview of a *Journal of Correctional Health Care* article on arrest charges as HIV screening criteria, see page 6).
Source: HIV Testing Implementation Guidance for Correctional Settings, available at www.cdc.gov/hiv/topics/testing/guideline.htm

HIV Transmission Rates Drop Dramatically

The importance of HIV detection and prevention was highlighted in the February issue of the *Journal of Acquired Immune Deficiency Syndromes*. A letter by researchers at Johns Hopkins University and the CDC reports that the HIV transmission rate has declined by 89% since the peak of the epidemic, and by 33% in the decade prior to 2006. This decline is attributed to major successes in testing and prevention, as well as evidence-based behavioral interventions and the availability of highly active antiretroviral therapy. The cautionary corollary, however, is that as HIV becomes a chronic condition, the need for HIV prevention, medical care and HIV treatment will continue to grow. To help with prevention efforts, the CDC offers a compendium of "the strongest behavioral interventions in the literature that have been rigorously evaluated and have demonstrated efficacy in reducing HIV or STD incidence or HIV-related risk behaviors or promoting safer behaviors."
Resources: CDC podcast and fact sheet, available at www.cdc.gov/hiv/topics/surveillance; compendium at www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm

JEHT Foundation Victim of Madoff Fraud

One unfortunate casualty of the massive Ponzi scheme perpetrated by Bernard Madoff is the JEHT Foundation, a philanthropic organization whose name stands for Justice, Equality, Human Dignity and Tolerance. Established in 2000, JEHT supported programs that promote reform of the criminal and juvenile justice systems, giving away more than $26 million during that time. In 2003, JEHT funded NCCHC's three-year Searching for Common Ground project, which focused on prerelease discharge planning and continuity of health care for inmates. According to a statement from JEHT's president and CEO, "The issues the Foundation addressed received very limited philanthropic support and the loss of the foundation's funding and leadership will cause significant pain and disruption of the work for many dedicated people and organizations.... Hopefully others will look closely at this work and consider supporting it going forward."
More information: www.jehtfoundation.org

Certification for Nurses Coming in October!

As reported in the last issue of *CorrectCare*, the CCHP program is developing a specialty certification for nurses who work in the correctional setting. The task force behind this effort is making great progress. A nursing job analysis survey was conducted among CCHP RNs, and the results are being used to guide development of the test items. The first exam will be administered in October at the National Conference on Correctional Health Care.

The American Board of Nursing Specialties defines certification as the formal recognition of the specialized knowledge, skills and experience demonstrated by the achievement of standards identified by a nursing specialty to promote optimal health outcomes. The scope of correctional nursing practice requires competence in the application of specific principles and a unique body of knowledge to the care of the inmate-patient. Practicing correctional nurses who demonstrate that competence and knowledge now have the opportunity to receive recognition through certification. Eligibility requirements are as follows:

- Current CCHP certification
- Current, active RN license within a U.S. state or territory or the professional, legally recognized equivalent in another country, not restricted to corrections only
- Equivalent of two years of full-time practice as a registered nurse
- At least 2,000 hours of practice in a correctional setting within the last three years
- 30 hours of continuing education in correctional nursing within the last three years

The application includes the following elements:

- Professional development record (copies of continuing education certificates should not be submitted, but should be kept by the applicant in case of an audit)
- Licensure information and a copy of RN license
- Employment information
- Signed statement of understanding

Approved applicants participate in a proctored, examination composed of 60 to 80 multiple-choice questions. The exam must be taken within one year of the application approval date.

To obtain an application, visit www.ncchc.org or contact us at 773-880-1460 or cchp@ncchc.org.

CCHP Exam Dates

April 30	Lincoln City, OR
May 4	Wisconsin Dells, WI
May 16	Fairfax, VA
June 20	Farmington, CT
July 12	Seattle, WA
August 22	Multiple regional sites

For more information about the application process or the exams, please visit www.ncchc.org/cchp.

Also, we are seeking additional sites for the August. and future exams, as well as CCHPs to proctor the exams. If you would like to participate, contact the CCHP coordinator at 773-880-1460 or cchp@ncchc.org.

Board Update

The CCHP board of trustees is please to welcome the following new members:

JoRene Kerns, RN, BSN, CCHP (vice chair)
NCCHC board appointee
Executive Vice President, Correct Care Solutions
(2009 - 2011)

Thomas G. Lundquist, MD, MMM, CCHP
Public appointee
Vice President & Chief Medical Officer, Wexford Health Sources
(2009 - 2011)

Jacqueline M. Moore, PhD, RN, CCHP-A
Elected
President, Moore & Associates
(2009 - 2011)

Patricia N. Reams, MD, MPH, CCHP
NCCHC board appointee
Pediatrician, Access Now
(2008 - 2010)

In addition, Jayne Russell, MEd, CCHP-A, has become the board chair, having previously served as vice chair. Thanks to the outgoing board members: Ned Megargee, PhD, CCHP, who served since 2002 and was chair since 2005, as well as Margaret Collatt, RN, BSN, CCHP-A, and Joseph Marocco, MPA, CCHP, whose three-year terms have ended.

Physician Certification

Working in collaboration with the Society of Correctional Physcians, the CCHP program will next begin to develop a specialty certification for physicians. The first meeting of the task force will take place in April at NCCHC's Updates in Correctional Health Care conference. Stay tuned for more information!

Other Program News

The certification exams in October and November produced 90 new CCHPs. Those exams were held in Baltimore, Chicago, Hendersonville, NC, and St. Louis. Visit the CCHP Web site for a list of these individuals.

Special congratulations go to four CCHPs who recently achieved Advanced Certification status: Jane Grametbaur, RN, Laura Post, MD, PhD, JD, Michael Puerini, MD, and Judith Robbins, LCSW, JD.

Clinical briefs

Diabetes and Sleep Apnea

The International Diabetes Federation encourages physicians to assess their diabetes patients for sleep apnea symptoms and to screen sleep apnea sufferers for metabolic disease. This recommendation is based on strong preliminary evidence that linking the two disorders, according to the IDF's Task Force on Epidemiology and Prevention. Obstructive sleep apnea affects just 2% of women and 4% of men in the general population, but is much more prevalent among diabetics. A recent report in *Endocrine Practice* found that 36% of people with type 2 diabetes had obstructive sleep apnea, and that prevalence was particularly high among the men. Diagnosing sleep apnea is critical because "the prevalence of CVD increases progressively with the increasing severity of OSA and that people with diabetes and/or OSA face serious cardiovascular problems and earlier death," according to the task force.
Resource: Sleep Apnoea and Type 2 Diabetes, available at www.idf.org/home/index.cfm?node=1653

New Training Manuals From SAMHSA

The federal Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment has published two training manuals:

• Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs Inservice Training. Based on SAMHSA's Treatment Improvement Protocol (TIP) 43, the manual provides detailed information to introduce substance abuse treatment professionals to medication-assisted treatment in opioid treatment programs. The curriculum describes opioid use disorders; provides assessment, treatment planning, pharmacology and dosing information; and presents evidence-based best practices for treatment.

• Detoxification and Substance Abuse Treatment Training Manual. Based on TIP 45, this curriculum is for use by clinical supervisors to train staff members about detoxification of individuals with substance use disorders. Content includes the physiology of withdrawal, pharmacological management of withdrawal, patient placement, incorporating detoxification services into comprehensive systems of care, and instructions for providing inservice training.
Resources: www.kap.samhsa.gov/products/trainingcurriculums; hard copies may be ordered.

Serious Taser Injuries Rare: Study

Serious injuries occurred in fewer than 1% of 1,201 Taser uses by law enforcement officers, according to a study funded by the National Institute of Justice and published Jan. 22 in the *Annals of Emergency Medicine*. Overall, 41% of the subjects suffered mild injuries, mostly superficial puncture wounds from the probes. Of the three subjects who sustained significant injuries, two suffered from head injuries related to falls; the third developed rhabdomyolysis.
Source: www1.wfubmc.edu/News/NewsARticle.htm?ArticleID=2542

NCCHC Reference Set

Buy a Package and Save!

These specially priced packages are a popular resource for all types of institutions, as well as people who are studying to become Certified Correctional Health Professionals. For product descriptions, please consult the NCCHC Catalog (in print or online).

NCCHC Reference Set — Save 25%!

With the recent introduction of mental health standards, the NCCHC Reference Set was expanded to include this valuable resource.

- Standards for Health Services in Jails
- Standards for Health Services in Prisons
- Standards for Health Services in Juvenile Detention and Confinement Facilities
- Standards for Mental Health Services in Correctional Facilities
- Correctional Health Care: Guidelines for the Management of an Adequate Delivery System

A $319.75 value if purchased separately, the package is priced at only $239.80.

CCHP Study Package — Save 30%!

Planning to become a Certified Correctional Health Professional? The CCHP Study Package contains the essential materials for the CCHP exam.

- Standards for Health Services in Prisons OR in Jails (choose one)
- Standards for Health Services in Juvenile Detention and Confinement Facilities
- Correctional Health Care: Guidelines for the Management of an Adequate Delivery System

A $179.85 value if purchased separately, the package is priced at only $125.90.

NCCHC

To order, visit www.ncchc.org or call (773) 880-1460.

Fieldnotes

This department features news and information from NCCHC's supporting organizations and other partners that share our goal of promoting quality health care in correctional institutions. If your organization has news to share, please contact editor@ncchc.org, 773-880-1460.

Glenn Johnson, MD, CCHP-A

NCCHC surveyor Glenn Johnson, MD, CCHP-A, passed away March 16, succumbing to liver cancer at age 54. "Glenn was a good friend of the Commission and a respected leader in our field," says NCCHC president Edward Harrison. A senior physician surveyor, Dr. Johnson began his work for NCCHC in1991. He also was the first chair of the Survey Advisory Committee, leading efforts in quality improvement and surveyor training and mentoring. He aided the revision of NCCHC's 2003 *Standards for Health Services* and gave countless presentations on the prison standards at NCCHC conferences.

Glenn Johnson, MD, CCHP-A

Dr. Johnson grew up in Virginia, but stayed in Texas after completing his residency and internship at the University of Texas, Houston Health Science Center. He joined the Texas Department of Criminal Justice in 1981, rising to become deputy director for health services. "Glenn was an awesome leader and trailblazer," says Lannette Linthicum, MD, CCHP-A, director of the TDCJ Health Services Division. "Many of the Ruiz-related health care reforms came to fruition under his guidance and leadership."

Dr. Johnson later served as medical director for both the GEO Group and Maxor National Pharmacy Service Corp. In recent years he worked as an independent consultant.

Academy of Correctional Health Professionals

The Academy's education committee has planned several regional seminars on Managing Mentally Ill Inmates Through the Correctional System. Specific topics include mental health screening, diagnosis and referral; suicide prevention; substance abuse and co-occurring disorders; psychotropic medication management; behavioral management; and risk management. The program offers 6.4 hours of continuing education credit. For other details, please see www.correctionalhealth.org.

The following dates are planned so far:

- May 15: Fairfax, VA, at the Fairfax County Jail
- June 19: Farmington, CT, at UConn Health Center

If you would like to host a seminar in your facility or town, please contact academy@correctionalhealth.org or call 877-549-2247.

Robert Wood Johnson Foundation

RWJF has long been interested in correctional health care as part of the nation's public health. One exciting project that RWJF is funding is Community Oriented Correctional Health Services. Established in 2006, COCHS is a nonprofit organization that helps to connect health care provided in correctional centers with health care provided in the community. The goal is to provide quality care inside a correctional facility and to connect returning inmates to local community health centers for continued care after release. COCHS provides technical assistance and consulting services, as well as a variety of resources. In February, RWJF published an issue brief on linking reentry planning to community-based correctional care. To learn more about COCHS and to read the brief, visit www.cochs.org.

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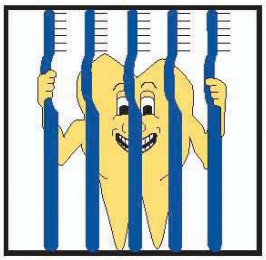

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TRUVADA is a once a day backbone for combination therapy in adults with HIV-1

Treat HIV confidently with TRUVADA in correctional facilities

#1 prescribed NRTI backbone in correctional facilities[1]

- Demonstrated efficacy and tolerability through 3 years in Studies 934 and 903*[2,3]
- TRUVADA is now the only DHHS-preferred dual NRTI[4]
- TRUVADA or its components have been partnered in long-term clinical trials with leading PIs[1,5-11]
  - Reyataz® (atazanavir sulfate)
  - Kaletra® (lopinavir/ritonavir)
  - Prezista® (darunavir)
  - Lexiva® (fosamprenavir calcium)

Depend on TRUVADA to be your partner with PIs

Truvada® 200 mg emtricitabine-tenofovir disoproxil fumarate 300 mg

Drug interactions have been observed between tenofovir DF and atazanavir or lopinavir/ritonavir. Atazanavir 300 mg should be boosted with ritonavir 100 mg and taken with food when administered with TRUVADA. Atazanavir without ritonavir should not be coadministered with TRUVADA. Patients on atazanavir or lopinavir/ritonavir plus TRUVADA should be monitored for tenofovir-associated adverse reactions. TRUVADA should be discontinued in patients who develop tenofovir-associated adverse reactions.[2]

Indications and usage[2]

TRUVADA, a combination of EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate), is indicated in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults. The following points should be considered when initiating therapy with TRUVADA for the treatment of HIV-1 infection:

- It is not recommended that TRUVADA be used as a component of a triple nucleoside regimen
- TRUVADA should not be coadministered with ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), EMTRIVA, VIREAD, or lamivudine-containing products†
- In treatment-experienced patients, the use of TRUVADA should be guided by laboratory testing and treatment history

WARNINGS

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, a component of TRUVADA, in combination with other antiretrovirals.

TRUVADA is not approved for the treatment of chronic hepatitis B virus (HBV) infection, and the safety and efficacy of TRUVADA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued TRUVADA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue TRUVADA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Dosage and administration

- Recommended dose: one tablet (containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) once daily taken orally with or without food
- Dose recommended in renal impairment: creatinine clearance (CrCl) 30-49 mL/min: 1 tablet every 48 hours. CrCl <30 mL/min or hemodialysis: do not use TRUVADA
- No dose adjustment is necessary for patients with mild renal impairment (CrCl 50–80 mL/min)

Warnings and precautions

- New onset or worsening renal impairment
  - Emtricitabine and tenofovir are principally eliminated by the kidney. Renal impairment can include acute renal failure and Fanconi syndrome
  - Assess CrCl before initiating treatment with TRUVADA. Routinely monitor CrCl and serum phosphorus in patients at risk
  - Dosing interval adjustment of TRUVADA and close monitoring of renal function are recommended in all patients with CrCl 30–49 mL/min. No safety or efficacy data are available in patients with renal impairment who received TRUVADA using these dosing guidelines, so the potential benefit of TRUVADA therapy should be assessed against the potential risk of renal toxicity.
  - Avoid administering TRUVADA with concurrent or recent use of nephrotoxic drugs
- Decreases in bone mineral density (BMD): consider monitoring BMD in patients with a history of pathologic fracture or who are at risk for osteopenia
- Redistribution/accumulation of body fat: observed in patients receiving antiretroviral therapy
- Immune reconstitution syndrome: may necessitate further evaluation and treatment
- Triple nucleoside-only regimens: early virologic failure has been reported in HIV-infected patients. Monitor carefully and consider treatment modification

Adverse reactions

- The most common (incidence ≥10%, any severity) and/or treatment-emergent (Grade 2–4, occurring in ≥5% of patients) adverse reactions occurring in Study 934 through 144 weeks include diarrhea, nausea, fatigue, sinusitis, upper respiratory tract infections, nasopharyngitis, headache, dizziness, depression, insomnia, abnormal dreams, and rash
- The following postapproval adverse reactions may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia
- Other adverse reactions that occurred in at least 5% of patients receiving EMTRIVA or VIREAD with other antiretroviral agents in clinical trials include anxiety, arthralgia, increased cough, dyspepsia, fever, myalgia, pain, abdominal pain, back pain, paresthesia, peripheral neuropathy (including peripheral neuritis and neuropathy), pneumonia, and rhinitis

Drug interactions

- Didanosine (ddI): tenofovir disoproxil fumarate increases ddI concentrations. Consider dose reductions or discontinuations of ddI if warranted
- Atazanavir (ATV): coadministration decreases ATV concentrations and increases tenofovir concentrations. Use ATV with TRUVADA only with ritonavir; monitor for evidence of tenofovir-associated adverse reactions
- Lopinavir/ritonavir: coadministration increases tenofovir concentrations. Monitor for evidence of tenofovir-associated adverse reactions

†Combivir® (zidovudine/lamivudine), Epivir® or Epivir HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine).

*In clinical Study 303, EMTRIVA and lamivudine (3TC) demonstrated comparable efficacy, safety, and resistance profiles as part of multidrug regimens, which supports the extrapolation of 3TC data to FTC.[2]

References: 1. Derived from patient chart audit, Synovate Healthcare Data, *US HIV Monitor.* 2008, Q2. **2.** TRUVADA® (emtricitabine/tenofovir disoproxil fumarate) Prescribing Information. Gilead Sciences, Inc. November 2008. **3.** VIREAD® (tenofovir disoproxil fumarate) Prescribing Information. Gilead Sciences, Inc. November 2008. **4.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. November 3, 2008; 1-139. Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed November 10, 2008. **5.** Molina J, Andrade-Villanueva J, Echevarria J, et al. CASTLE: atazanavir-ritonavir vs lopinavir-ritonavir in antiretroviral-naive HIV-1 infected patients: 96 week efficacy & safety. Presented at: 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting; October 25-28, 2008; Washington, DC. **6.** Johnson M, Grinsztejn B, Rodriguez C, et al. 96-week comparison of once-daily atazanavir/ritonavir and twice-daily lopinavir/ritonavir in patients with multiple virologic failures. *AIDS.* 2006;20:711-718. **7.** Riddler SA, Haubrich R, DiRienzo AG, et al, for the AIDS Clinical Trials Group Study A5142 Team. Class-sparing regimens for initial treatment of HIV-1 infection. *N Engl J Med.* 2008;358:2095-2106. **8.** Molina J-M, Podzadecki TJ, Johnson MA, et al. A lopinavir/ritonavir-based once-daily regimen results in better compliance and is non-inferior to a twice-daily regimen through 96 weeks. *AIDS Res Hum Retroviruses.* 2007;23:1505-1514. **9.** Young B, Smith K, Patel P, et al. Characterization of virologic failure over 96 weeks by drug resistance and antiviral response in ART naive patients receiving abacavir/lamivudine (ABC/3TC) or tenofovir/emtricitabine (TDF/FTC) each with lopinavir/ritonavir QD in the HEAT study. Presented at: 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting; October 25-28, 2008; Washington, DC. **10.** Mills A, Nelson M, Jayaweera D, et al. ARTEMIS: efficacy and safety of darunavir/ritonavir (DRV/r) 800/100 mg once-daily vs lopinavir/ritonavir (LPV/r) in treatment-naive, HIV-1-infected patients at 96 wks. Presented at: 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting; October 25-28, 2008; Washington, DC. **11.** US National Institutes of Health, Clinicaltrials.gov Web site. Available at: http://www.clinicaltrials.gov/ct2/showNCT00242216?term=PIQD&rank=1. Accessed November 10, 2008.

Please see brief summary of full Prescribing Information on following page, including **boxed WARNING** information about **lactic acidosis, severe hepatomegaly with steatosis**, and **exacerbations of hepatitis B upon discontinuation of therapy**.

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GILEAD

The following is a brief summary for TRUVADA® (emtricitabine/tenofovir disoproxil fumarate [DF]) tablets. Before prescribing, see full Prescribing Information, including boxed WARNINGS.

WARNINGS: LACTIC ACIDOSIS, SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, a component of TRUVADA, in combination with other antiretrovirals *[See Warnings and Precautions]*.

TRUVADA is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of TRUVADA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued TRUVADA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue TRUVADA. If appropriate, initiation of anti-hepatitis B therapy may be warranted *[See Warnings and Precautions]*.

INDICATIONS AND USAGE

TRUVADA, a combination of EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate), is indicated in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults.

The following points should be considered when initiating therapy with TRUVADA for the treatment of HIV-1 infection:

- It is not recommended that TRUVADA be used as a component of a triple nucleoside regimen.
- TRUVADA should not be coadministered with ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), EMTRIVA, VIREAD, or lamivudine-containing products *[See Warnings and Precautions]*.
- In treatment experienced patients, the use of TRUVADA should be guided by laboratory testing and treatment history.

DOSAGE AND ADMINISTRATION

The dose of TRUVADA is one tablet (containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate) once daily taken orally with or without food.

Dose Adjustment for Renal Impairment: Significantly increased drug exposures occurred when EMTRIVA or VIREAD were administered to patients with moderate to severe renal impairment *[See EMTRIVA or VIREAD Package Insert]*. Therefore, the dosing interval of TRUVADA should be adjusted in patients with baseline creatinine clearance 30–49 mL/min using the recommendations in Table 1. These dosing interval recommendations are based on modeling of single-dose pharmacokinetic data in non-HIV-1 infected subjects. The safety and effectiveness of these dosing interval adjustment recommendations have not been clinically evaluated in patients with moderate renal impairment, therefore, clinical response to treatment and renal function should be closely monitored in these patients *[See Warnings and Precautions]*.

No dose adjustment is necessary for patients with mild renal impairment (creatinine clearance 50–80 mL/min). Routine monitoring of calculated creatinine clearance and serum phosphorus should be performed in patients *[See Warnings and Precautions]*.

Table 1.
Dosage Adjustment for Patients with Altered Creatinine Clearance

	Creatinine Clearance (mL/min)*		
	≥50	30–49	<30 (Including Patients Requiring Hemodialysis)
Recommended Dosing Interval	Every 24 hours	Every 48 hours	TRUVADA should not be administered.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, a component of TRUVADA, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with TRUVADA should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

Patients Coinfected with HIV-1 and HBV: It is recommended that all patients with HIV-1 be tested for the presence of chronic HBV before initiating antiretroviral therapy. TRUVADA is not approved for the treatment of chronic HBV infection and the safety and efficacy of TRUVADA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of Hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued TRUVADA. In some patients infected with HBV and treated with EMTRIVA, the exacerbations of Hepatitis B were associated with liver decompensation and liver failure. Patients who are coinfected with HIV-1 and HBV should be closely monitored with both clinical and laboratory follow up for at least several months after stopping treatment with TRUVADA. If appropriate, initiation of anti-Hepatitis B therapy may be warranted.

New Onset or Worsening Renal Impairment: Emtricitabine and tenofovir are principally eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of VIREAD *[See Adverse Reactions]*.

It is recommended that creatinine clearance be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with TRUVADA. Routine monitoring of calculated creatinine clearance and serum phosphorus should be performed in patients at risk for renal impairment.

Dosing interval adjustment of TRUVADA and close monitoring of renal function are recommended in all patients with creatinine clearance 30–49 mL/min *[See Dosage and Administration]*. No safety or efficacy data are available in patients with renal impairment who received TRUVADA using these dosing guidelines, so the potential benefit of TRUVADA therapy should be assessed against the potential risk of renal toxicity. TRUVADA should not be administered to patients with creatinine clearance <30 mL/min or patients requiring hemodialysis.

TRUVADA should be avoided with concurrent or recent use of a nephrotoxic agent.

Coadministration with Other Products: TRUVADA should not be coadministered with ATRIPLA, EMTRIVA, or VIREAD. Due to similarities between emtricitabine and lamivudine, TRUVADA should not be coadministered with other drugs containing lamivudine, including Combivir® (lamivudine/zidovudine), Epivir® (lamivudine) or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine).

TRUVADA should not be administered with HEPSERA® (adefovir dipivoxil).

Decreases in Bone Mineral Density: Bone mineral density (BMD) monitoring should be considered for HIV-1 infected patients who have a history of pathologic bone fracture or are at risk for osteopenia. Although the effect of supplementation with calcium and vitamin D was not studied, such supplementation may be beneficial for all patients. If bone abnormalities are suspected then appropriate consultation should be obtained.

Tenofovir Disoproxil Fumarate: In a 144-week study of treatment naïve patients, decreases in BMD were seen at the lumbar spine and hip in both arms of the study. At Week 144, there was a significantly greater mean percentage decrease from baseline in BMD at the lumbar spine in patients receiving VIREAD + lamivudine (3TC) + efavirenz (EFV) compared with patients receiving stavudine + lamivudine + efavirenz. Changes in BMD at the hip were similar between the two treatment groups. In both groups, the majority of the reduction in BMD occurred in the first 24–48 weeks of the study and this reduction was sustained through 144 weeks. Twenty-eight percent of VIREAD-treated patients vs. 21% of the comparator patients lost at least 5% of BMD at the spine or 7% of BMD at the hip. Clinically relevant fractures (excluding fingers and toes) were reported in 4 patients in the VIREAD group and 6 patients in the comparator group. Tenofovir disoproxil fumarate was associated with significant increases in biochemical markers of bone metabolism (serum bone-specific alkaline phosphatase, serum osteocalcin, serum C-telopeptide, and urinary N-telopeptide), suggesting increased bone turnover. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in patients receiving VIREAD. The effects of VIREAD-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. For additional information, please consult the VIREAD prescribing information.

Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of VIREAD *[See Adverse Reactions]*.

Fat Redistribution: Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The mechanism and long-term consequences of these events are currently unknown. A causal relationship has not been established.

Immune Reconstitution Syndrome: Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including TRUVADA. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections [such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia (PCP), or tuberculosis], which may necessitate further evaluation and treatment.

Early Virologic Failure: Clinical studies in HIV-infected patients have demonstrated that certain regimens that only contain three nucleoside reverse transcriptase inhibitors (NRTI) are generally less effective than triple drug regimens containing two NRTIs in combination with either a non-nucleoside reverse transcriptase inhibitor or a HIV-1 protease inhibitor. In particular, early virological failure and high rates of resistance substitutions have been reported. Triple nucleoside regimens should therefore be used with caution. Patients on a therapy utilizing a triple nucleoside-only regimen should be carefully monitored and considered for treatment modification.

ADVERSE REACTIONS

Adverse Reactions from Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common adverse reactions (incidence ≥10%, any severity) occurring in Study 934, an active-controlled clinical study of efavirenz, emtricitabine, and tenofovir disoproxil fumarate, include diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash. See also full Prescribing Information for the frequency of treatment-emergent adverse reactions (Grade 2–4) occurring in ≥5% of patients treated with efavirenz, emtricitabine, and tenofovir disoproxil fumarate in this study.

Skin discoloration, manifested by hyperpigmentation on the palms and/or soles was generally mild and asymptomatic. The mechanism and clinical significance are unknown.

Study 934 - Treatment Emergent Adverse Reactions: In Study 934, 511 antiretroviral-naïve patients received either VIREAD + EMTRIVA administered in combination with efavirenz

(N=257) or zidovudine/lamivudine administered in combination with efavirenz (N=254). Adverse reactions observed in this study were generally consistent with those seen in other studies in treatment-experienced or treatment-naïve patients receiving VIREAD and/or EMTRIVA, including diarrhea, nausea, vomiting, fatigue, sinusitis, upper respiratory tract infections, nasopharyngitis, headache, dizziness, depression, insomnia, and rash event.

Laboratory Abnormalities: Laboratory abnormalities observed in this study were generally consistent with those seen in other studies of VIREAD and/or EMTRIVA.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of VIREAD: allergic reaction, lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, abdominal pain, hepatic steatosis, hepatitis, increased liver enzymes (most commonly increased AST, ALT, Gamma GT), rash, rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, acute renal failure, renal failure, acute tubular necrosis, Fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases), nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria, polyuria, asthenia. No additional adverse reactions have been identified during postapproval use of EMTRIVA. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions, listed above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia.

DRUG INTERACTIONS

No drug interaction studies have been conducted using TRUVADA tablets. Drug interaction studies have been conducted with emtricitabine and tenofovir disoproxil fumarate, the components of TRUVADA. This section describes clinically relevant drug interactions observed with emtricitabine and tenofovir disoproxil fumarate.

Didanosine: Coadministration of TRUVADA and didanosine should be undertaken with caution and patients receiving this combination should be monitored closely for didanosine-associated adverse reactions. Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. When tenofovir disoproxil fumarate was administered with didanosine the C_{max} and AUC of didanosine administered as either the buffered or enteric-coated formulation increased significantly. The mechanism of this interaction is unknown. Higher didanosine concentrations could potentiate didanosine-associated adverse reactions, including pancreatitis, and neuropathy. Suppression of $CD4^+$ cell counts has been observed in patients receiving tenofovir DF with didanosine 400 mg daily. In adults weighing >60 kg, the didanosine dose should be reduced to 250 mg when it is coadministered with TRUVADA. Data are not available to recommend a dose adjustment of didanosine for patients weighing <60 kg. When coadministered, TRUVADA and Videx EC may be taken under fasted conditions or with a light meal (<400 kcal, 20% fat). Coadministration of didanosine buffered tablet formulation with TRUVADA should be under fasted conditions.

Atazanavir: Atazanavir has been shown to increase tenofovir concentrations. The mechanism of this interaction is unknown. **Patients receiving atazanavir and TRUVADA should be monitored for TRUVADA-associated adverse reactions. TRUVADA should be discontinued in patients who develop TRUVADA-associated adverse reactions**. Tenofovir decreases the AUC and C_{min} of atazanavir. When coadministered with TRUVADA, it is recommended that atazanavir 300 mg is given with ritonavir 100 mg. **Atazanavir without ritonavir should not be coadministered with TRUVADA**.

Lopinavir/Ritonavir: Lopinavir/ritonavir has been shown to increase tenofovir concentrations. The mechanism of this interaction is unknown. **Patients receiving lopinavir/ritonavir and TRUVADA (emtricitabine/tenofovir disoproxil fumarate) should be monitored for TRUVADA-associated adverse reactions. TRUVADA should be discontinued in patients who develop TRUVADA-associated adverse reactions.**

Drugs Affecting Renal Function: Because emtricitabine and tenofovir are primarily excreted by the kidneys, coadministration of TRUVADA with drugs that are eliminated by active tubular secretion may increase concentrations of emtricitabine, tenofovir, and/or the coadministered drug. Some examples include, but are not limited to acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, and valganciclovir. Drugs that decrease renal function may increase concentrations of emtricitabine and/or tenofovir.

USE IN SPECIFIC POPULATIONS

Pregnancy Category B: Emtricitabine: The incidence of fetal variations and malformations was not increased in embryofetal toxicity studies performed with emtricitabine in mice at exposures (AUC) approximately 60-fold higher and in rabbits at approximately 120-fold higher than human exposures at the recommended daily dose.

Tenofovir Disoproxil Fumarate: Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to tenofovir. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, TRUVADA should be used during pregnancy only if clearly needed.

Antiretroviral Pregnancy Registry: To monitor fetal outcomes of pregnant women exposed to TRUVADA, an Antiretroviral Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-258-4263.

Nursing Mothers: The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV-1. Studies in rats have demonstrated that tenofovir is secreted in milk. It is not known whether tenofovir is excreted in human milk. It is not known whether emtricitabine is excreted in human milk. Because of both the potential for HIV-1 transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breast-feed if they are receiving TRUVADA.**

Pediatric Use: TRUVADA is not recommended for patients less than 18 years of age because it is a fixed-dose combination tablet containing a component, VIREAD, for which safety and efficacy have not been established in this age group.

Geriatric Use: Clinical studies of EMTRIVA or VIREAD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for the elderly patients should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Patients with Impaired Renal Function: It is recommended that the dosing interval for TRUVADA be modified in patients with creatinine clearance 30–49 mL/min. TRUVADA should not be used in patients with creatinine clearance <30 mL/min and in patients with end-stage renal disease requiring dialysis *[See Dosage and Administration]*.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Emtricitabine: In long-term oral carcinogenicity studies of emtricitabine, no drug-related increases in tumor incidence were found in mice at doses up to 750 mg/kg/day (26 times the human systemic exposure at the therapeutic dose of 200 mg/day) or in rats at doses up to 600 mg/kg/day (31 times the human systemic exposure at the therapeutic dose).

Emtricitabine was not genotoxic in the reverse mutation bacterial test (Ames test), mouse lymphoma or mouse micronucleus assays.

Emtricitabine did not affect fertility in male rats at approximately 140-fold or in male and female mice at approximately 60-fold higher exposures (AUC) than in humans given the recommended 200 mg daily dose. Fertility was normal in the offspring of mice exposed daily from before birth (in utero) through sexual maturity at daily exposures (AUC) of approximately 60-fold higher than human exposures at the recommended 200 mg daily dose.

Tenofovir Disoproxil Fumarate: Long-term oral carcinogenicity studies of tenofovir disoproxil fumarate in mice and rats were carried out at exposures up to approximately 16 times (mice) and 5 times (rats) those observed in humans at the therapeutic dose for HIV-1 infection. At the high dose in female mice, liver adenomas were increased at exposures 16 times that in humans. In rats, the study was negative for carcinogenic findings at exposures up to 5 times that observed in humans at the therapeutic dose.

Tenofovir disoproxil fumarate was mutagenic in the in vitro mouse lymphoma assay and negative in an in vitro bacterial mutagenicity test (Ames test). In an in vivo mouse micronucleus assay, tenofovir disoproxil fumarate was negative when administered to male mice.

There were no effects on fertility, mating performance or early embryonic development when tenofovir disoproxil fumarate was administered to male rats at a dose equivalent to 10 times the human dose based on body surface area comparisons for 28 days prior to mating and to female rats for 15 days prior to mating through day seven of gestation. There was, however, an alteration of the estrous cycle in female rats.

PATIENT COUNSELING INFORMATION

Patients should be advised that:

- TRUVADA is not a cure for HIV-1 infection and patients may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. Patients should remain under the care of a physician when using TRUVADA.
- The use of TRUVADA has not been shown to reduce the risk of transmission of HIV-1 to others through sexual contact or blood contamination.
- The long term effects of TRUVADA are unknown.
- TRUVADA tablets are for oral ingestion only.
- It is important to take TRUVADA with combination therapy on a regular dosing schedule to avoid missing doses.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Treatment with TRUVADA should be suspended in any patients who develop clinical symptoms suggestive of lactic acidosis or pronounced hepatotoxicity (including nausea, vomiting, unusual or unexpected stomach discomfort, and weakness) *[See Warnings and Precautions]*.
- All patients with HIV-1 should be tested for HBV before initiating antiretroviral therapy.
- Severe acute exacerbations of Hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued TRUVADA.
- Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported in association with the use of VIREAD. TRUVADA should be avoided with concurrent or recent use of a nephrotoxic agent *[See Warnings and Precautions]*. Dosing interval of TRUVADA may need adjustment in patients with renal impairment *[See Dosage and Administration]*.
- TRUVADA should not be coadministered with ATRIPLA, EMTRIVA, or VIREAD; or with drugs containing lamivudine, including Combivir, Epivir or Epivir-HBV, Epzicom, or Trizivir *[See Warnings and Precautions]*.
- TRUVADA should not be administered with HEPSERA (adefovir dipivoxil) *[See Warnings and Precautions]*.
- Decreases in bone mineral density have been observed with the use of VIREAD. Bone monitoring should be considered in patients who have a history of pathologic bone fracture or at risk for osteopenia *[See Warnings and Precautions]*.

*Calculated using ideal (lean) body weight.

Gilead Sciences, Inc. Foster City, CA 94404 November 2008

GILEAD

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Corrections, Mental Health, and Social Policy: International Perspectives. This book considers approaches and ideas beyond those generated in the domestic academic-practitioner community, including concerns that transcend national borders. This includes treatment and management of terrorists, immigrants, political prisoners, transnational gang members and drug traffickers, and those victimized by imprisonment. The unconventional approach will challenge intellectual complacency, stimulate fresh perspectives, and propose new ideas for correctional practice, research, teaching, advocacy and social policy. Edited by Robert Ax, PhD, and Thomas Fagan, PhD. C.C. Thomas Publisher (2007). Softcover, 446 pages, $63.95

About CorrectCare™

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ADVERTISER INDEX

Standards Q & A

Expert Advice on NCCHC Standards

by Jennifer E. Kistler, MPH, and
R. Scott Chavez, PhD, MPA, CCHP-A

Medical Diets and Confidentiality

Q *It was recently brought to my attention that inmates working in our kitchen have access to information about medical diets for other inmates; therefore, they may know about an inmate's medical condition. Do you have any suggestions on how to address this situation?*

A The most important consideration here is that an inmate who requires a medical diet actually receives the diet (see standard F-02 Medical Diets). Inmate workers perform a variety of duties in the kitchen, and it may not be possible to prevent knowledge of the fact that a particular inmate is receiving a special diet. However, the recipient's confidentiality can be protected to some degree by limiting the information on diet cards to the type of diet ordered (e.g., low sodium, bland) and the duration without specifying the inmate's condition or diagnosis. If your facility labels diet trays based on a diagnosis, we suggest you change the nomenclature so that the tray doesn't indicate labeled as a specific disease.

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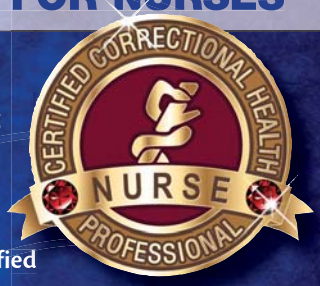

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To receive an application when it becomes available, contact us at cchp@ncchc.org or 773-880-1460. Also look for updates and announcements on our Web site at **www.ncchc.org/cchp.**

Clinical Performance Enhancement Review

Q *Is our obstetrician/gynecologist required to have a clinical performance enhancement review under the Clinical Performance Enhancement standard (C-02)?*

A This standard requires the clinical performance of a facility's primary care clinicians to be reviewed at least annually. Primary care clinicians are licensed practitioners (including medical physicians, psychiatrists, dentists, midlevel practitioners and PhD-level psychologists) who provide primary care on a regular basis. Therefore, this standard does not require an ob/gyn or any other specialist who is not considered a primary care clinician to receive a clinical performance enhancement review.

Sick Call and Medical Autonomy

Q *We have been holding sick call in the afternoons. Now the warden wants sick call held at 5 a.m. so that inmates can be screened before the workday starts. Isn't it a violation of the standard on medical autonomy for the warden to tell us to change our sick call time?*

A The standard on medical autonomy (A-03) covers clinical decisions. If a practitioner determines that a specific treatment is necessary, a nonmedical person may not countermand that order regardless of the security risk of the patient or the cost of the proposed treatment. However, a decision as to the time that sick call is held is not a clinical issue. These types of decisions should be made jointly by the administrative and the health staff.

Environmental Inspections

Q *Now that Environmental Health and Safety (former B-02) no longer appears in the* Standards *[2008 editions], are we still required to conduct inspections?*

A In the 2008 standards, Infection Control Program (B-01) now requires a monthly environmental inspection to be conducted of areas where health services are provided. This is to verify that equipment is maintained, that the unit is clean and sanitary and that measures are taken to ensure the unit is occupationally and environmentally safe. Please note that the 2003 Ectoparasite Control (B-04) standard is also addressed in the 2008 infection control standard.

Jennifer E. Kistler, MPH, is NCCHC's director of accreditation. R. Scott Chavez, PhD, MPA, CCHP-A, is NCCHC's vice president and liaison to the policy and standards committee. If you have a question about the NCCHC standards, please write to info@ncchc.org or call 773-880-1460.

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