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Meet NCCHC’s New President!

Thomas L. Joseph, MPS, CAE
A Career in Brief

Recent Positions
• Executive director, American Society for Blood and Marrow Transplantation
• Managing director, International Net Cord Foundation
• Associate executive director and director of marketing, Society of Critical Care Medicine
• Director, division of member services, American Academy of Pediatrics

Professional Activities
• Certified Association Executive since June 1996
• American Association of Medical Society Executives
• American Society of Association Executives
• Association Forum of Chicagoland
• Council on Medical Specialty Societies

Education
• DePaul University, Chicago – MS, public service management, with a concentration in association management
• Southern Illinois University, Carbondale – BS with a concentration in sports marketing

The NCCHC board of directors is pleased to announce the appointment of Thomas L. Joseph, MPS, CAE, as president and CEO. He succeeds Edward Harrison, CCHP, who announced his retirement last fall and will now assist in the transition process. (For a Q&A with Mr. Harrison, see page 5.)

“We are very pleased to welcome to our staff leadership a seasoned health care executive like Tom Joseph,” says NCCHC board chair Renee Kanan, MD. “Given Tom’s extensive background and experience, we are confident he will help the Commission move forward, building upon the foundation that currently exists.” Mr. Joseph has been in the medical association management field for more than 25 years.

A Passion for Public Service
It was his love of athletics that led Mr. Joseph to pursue an undergraduate degree in sports marketing. After he graduated and landed a job at the American College of Healthcare Executives, he developed a passion for public service and, specifically, health care.

“At ACEH, my aspirations were piqued. I was excited to find a profession where I can actually make a difference. By serving the medical community, it can potentially improve patient outcomes.” That passion prompted him to devote his career to health care association management, and during his time at ACEH he earned a master’s degree in public service management.

Mr. Joseph’s education, training and experience have given him well-rounded knowledge of association leadership and operations. He has extensive experience in strategic planning, international standards, continuing medical education and marketing. This expertise is highly valuable in the health care milieu, which he describes as an ever-changing target.

In his previous positions, Mr. Joseph’s strategy has been to build upon the organization’s foundation by enhancing its reputation and credibility, expanding its programs and services and strengthening its financial status. Reflecting on his accomplishments, he credits the many dedicated board leaders, staff members and volunteers who have supported his work.

At NCCHC, his approach will be similar. His first priority is to go through a discovery process so that he thoroughly understands the status quo, and then to establish a vision for the future.

Despite his long career in health-related associations, Mr. Joseph’s interest in sports has not waned. He and his wife have three children, and in his free time he coaches them in baseball, basketball and soccer. “I do this for purely selfish reasons,” he says. “It allows me the opportunity to spend more time with my children.” NCCHC welcomes this versatile coach to our team.

NCCHC Webinars Bring Learning to Your Desktop

Juvenile Health Intake Screening and Assessment: Critical Questions and Actions – July 16, 2 pm ET
Youth being received into juvenile detention settings often arrive from the community with many potential health risk factors. It is essential that an accurate screening process be in place for the protection of the receiving youth, other residents and staff. Specific screening and assessment questions and actions based on responses will be discussed, and policies and procedures that impact the effectiveness of an accurate screening and assessment program will be detailed. 60 minutes, 1 hour of CE credit available. $29.

This webinar will highlight the changes in the core areas covered by the standards: governance/administration, safety, personnel/training, health care services/support, patient care/treatment, health promotion, special needs/services, health records and medical-legal issues. Make sure your facility stays current in meeting these important national standards. 90 minutes, 1.5 hour of CE credit available. Free to individuals at accredited facilities; $29 for nonaccredited facilities.

Learn more and register at www.ncchc.org/distance-learning.
Firearm Injury Prevention: A Role for Correctional Health Providers

by John P. May, MD, CCHP

Your 28-year-old male patient sits on the examination table for his health assessment. He denies any medical problems or prior hospitalizations. He's physically active and does not smoke. He uses occasional marijuana and alcohol. As he raises his shirt, you notice a large laparotomy scar. "I thought you said that you did not have any medical problems or hospitalizations," you say. "Oh," he replies, "that's from when I got shot. I didn't think that counted."

Despite our best medications or clinical algorithms, we often fail to address what is the most likely cause of death for our patients: gunshot wounds.

Firearm injuries are a leading cause of death for persons passing through jails and prisons. In 2010, the latest year of data, gunshot wounds killed more men in the United States between the ages of 15 and 44 than any other cause. For young African-American men, firearm homicide rates are more than eightfold higher than for Caucasians, and 40 times higher than in the other high-income countries.

Many persons entering jails or prisons are not strangers to violence, whether as perpetrators, victims or often both. The evidence points to time in jail or prison as a risk factor for premature death from violence. In many urban areas, the majority of homicide victims have prior criminal records, suggesting that they were at one time our patients and perhaps a missed prevention opportunity.

While we traditionally focus on prevention of infectious and chronic disease, injury also can be prevented. Injury can be unintentional, such as a motor vehicle crash, or intentional, such as assault or homicide. In disease prevention, we commonly focus on environmental, social factors and behaviors. To reduce HIV/AIDS, for example, we focus on safe blood supplies, clean needles and reduction of sexual risk behaviors. To reduce injuries, the same model applies.

To reduce deaths from motor vehicle crashes, for example, we build safer roads and cars, discourage drunk driving and mandate seat belts. Similarly, we can reduce injuries from violence or firearms with attention to the environment, social factors and behaviors.

Risk Factors

What are factors associated with the risk of firearm injury or death? The majority of firearm deaths in the United States are suicides, followed by homicide and then unintentional injury such as a child playing with a loaded weapon. Most suicides are committed with firearms and few survive suicide attempts with guns. Fortunately, incarcerated persons do not have access to firearms, so their suicide attempts are less often lethal. But in an environment with easy access to a gun, such as home, the risk of suicide increases nearly fivefold.

Like suicide, most homicides in the United States are committed with firearms. Most homicides occur between people who know each other including domestic partners, in the context of an argument or fight, and in an environment of alcohol or drugs. The presence of a gun in a home increases the risk of homicide in that home nearly threefold. Patients can be educated about these risks and make decisions best for themselves and their family.

And while involvement in the criminal justice system may be one of the biggest risk factors for being a homicide victim, so too is having a prior violence-related injury. Data from trauma units suggests that violence behaves as a chronic disease, with nearly 20% of survivors of violence-related injury dying of a subsequent violence-related injury within five years. Many men entering jails or prisons have a history of prior gunshot wounds, as high as one in four in some areas. So our young male patient, with seemingly no significant health problems but a history of gunshot wound and incarceration, is at very high risk for becoming a future homicide victim.

Public Health Approach

The public health approach to injury prevention invites us to have an impact on our patients’ risk for violence. After identifying a patient at high risk, we can educate our patient about risk factors just as if we were to educate him about approaches to a high cholesterol level.

Our patients should know that their prior gunshot wound means that they are at risk for another gunshot wound; that environments of fighting, drugs, alcohol and easy access to guns increase their risk.

A simple mnemonic with the word "guns" can help to guide the discussion:

**G** – Do you have easy access to a gun? (Having a gun often invites more trouble than protection)

**U** – Are you around users of alcohol or drugs? (Most killings happen in these environments)

**N** – Do you feel a need to protect yourself? (What other strategies can keep you safer?)

**S** – Do any of these situations apply?

- School age children at home? (Risk for unintentional injury from guns)
- Sadness, depression or mental illness? (Risk for suicide with guns)
Enhance Your Skills and Advance Your Career

Leaders in correctional health care face unique challenges every day. You manage best practices, personnel, budgets, security concerns and patient advocacy in some of the toughest environments anywhere. You depend on tailored expert resources for support and guidance. Year after year, NCCHC delivers these resources. This exciting multifaceted event features a unique curriculum to help you develop and hone the critical skills needed to manage clinical and administrative operations in a correctional health care system. The conference will take place in a retreat setting where you will have plenty of time to meet peers and experts, learn from colleagues and go back to work energized and armed with new strategies and solutions. This program is supported by the Academy of Correctional Health Professionals and the Society of Correctional Physicians.

Essential and advanced tracks for physicians and health administrators provide the specialized knowledge and expertise you need. Attend your choice of two dozen sessions, including the following vital topics, all presented by some of the most widely respected experts in our field.

- The History of Correctional Health Care: Why It Matters More Than Ever
- Health Care in the Correctional Culture: Inmates as Patients
- Quality Improvement: Measuring Change, Outcome Measurement (2 sessions)
- Corrections: Where Health Care and Law Enforcement Leaders Meet
- The Appropriate Infrastructure for Quality Dental Services
- Avoiding Legal, Operational and Medical Problems
- Mental Health Services: Operating Expenses, Outsourcing (2 sessions)
- Infection Control Program Development
- Mechanics of Utilization Management for Physicians
- Developing Rational and Defensible Staffing Plans
- Strategies for Eliminating Diagnostic Errors
- Legal Dilemmas With Special Implications in Correctional Health Settings
- Creating and Sustaining a Healthy Work Environment
- What Correctional Health Will Need From Its Leaders in 2019 and Beyond

Continuing Education: Up to 14 hours of CE credit are offered for physicians, nurses, psychologists and CCHPs.

Conference Venue: All events will take place at the Omni Interlocken. Reserve your room online or call 303-438-6600.

Registration: Several options are available, including a package that includes the Correctional Mental Health Care Conference and discounts for members of the Academy of Correctional Health Professionals or the Society of Correctional Physicians.

Visit www.ncchc.org for complete details.

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2014 Correctional Mental Health Care Conference

Seeking Solutions, Making Connections

The growing number of incarcerated individuals with mental illness has become a crisis for correctional facilities. Patients in jails, prisons and juvenile facilities require treatment to meet health care standards and to improve their chances of successful reentry. This sharply focused gathering features two days of concurrent sessions, along with special networking events to enable participants to learn from each other. In a beautiful retreat setting, you will learn about best practices, emerging legal issues and practical approaches to mental health care delivery — and get actionable insights, techniques and tools you need to improve care in your facility. This program is supported by the American Psychiatric Association, the American Psychiatric Association and the Academy of Correctional Health Professionals.

The conference will feature 30 concurrent sessions in three educational tracks and special networking events to help participants make lifelong connections. Nowhere else will you see the critical intersection of correctional health care and mental health issues addressed so specifically.

- Involuntary Medication Hearings: Federal and State Due Process Requirements
- Managing Delayed Detoxifying Inmates
- Using a Big Picture Perspective to Fully Evaluate Inmate Suicide Risk
- Implementing PRTA Standards in the Context of Inmates With Severe Psychopathology
- Excess Morbidity and Mortality in Serious Mental Illness
- The Evolution of the DSM and Its Impact on Correctional Mental Health
- Creating an Evidence-Based Measuring Outcomes of Mental Health Treatment
- Treating the Adolescent Male Psychopath
- Applying the Adverse Childhood Experiences Research to Trauma-Informed Care
- Mental Illness, Aberrant Behaviors and Neurological Diseases in Aging Inmates
- Dealing With Fetal Alcohol Spectrum Disorders
- Gender Dysphoria: Clinical and Legal Aspects
- The Intersection of TBI, Substance Abuse, Mental Illness and Criminality

Continuing Education: Up to 15 hours of CE credit are offered for psychologists, physicians, nurses, social workers and CCHPs.

Conference Venue: All events will take place at the Omni Interlocken. Reserve your room online or call 303-438-6600.

Registration: Several options are available, including a package that includes the Leadership Institutes and discounts for members of the Academy of Correctional Health Professionals or the Society of Correctional Physicians.

Visit www.ncchc.org for complete details.
Edward A. Harrison: Reflections on a Career in Correctional Health Care

After 27 years at the National Commission on Correctional Health Care, Edward Harrison retires this summer. The correctional health care field, and the Commission itself, have evolved greatly since he joined NCCHC in 1987. When he started, NCCHC was a relatively small and young organization striving to fulfill a large and important mission. (For a time line of key events in NCCHC’s history, see www.ncchc.org/about.) Over the next several years, Harrison worked his way up to vice president, and in 1993 was appointed president. Here he reflects on his career and on the field in general.

What were you doing professionally before you joined NCCHC? I had just earned my MBA at Northwestern University. I went to grad school because I was looking for a challenging and stimulating career, and boy did I find it. Prior to that I worked in state government for several years, although my first job after earning my bachelor’s degree was in the marketing department of the Walt Disney Company.

Why did you agree to take the job as president? It was such a tremendous opportunity. I loved the pioneering work the Commission was doing and its rich history of support from major national organizations. Having a diverse board of directors with health care and corrections experience was unique and a big advantage for what we were trying to do, and my business and management experience and several years of experience at NCCHC would be an asset. Of course, having a personal relationship with NCCHC’s cofounders—B. Jaye Anno and my father, Bernard Harrison, who had retired years earlier—meant that a very strong network could come together to continue the efforts to define and improve the field as well as make it more professional.

What were some of the largest issues or concerns facing the correctional health care field at that time? Even a decade after Estelle and other court decisions, many correctional systems still lacked the wherewithal to organize adequate health care services. In those years local and state governments, as well as the federal government, were trying to grasp what makes correctional health care so important and different from other corrections or health care activities. I remember looking for people in the Justice Department and Health and Human Services Department to even have a conversation about correctional health care, and various agencies each pointed to the other department as the ones we should talk to.

A breakthrough moment occurred in about 1994. We were able to get an appointment with David Satcher, who was the director of the Centers for Disease Control and Prevention (he later became U.S. Surgeon General). Two of our board members, Doug Mack, a county health department director, and Carl Bell, who ran a community mental health center and knew Satcher, and I were to meet with him, but at the last moment Carl was unable to travel, which was unfortunate because he was instrumental in setting up the appointment. Doug and I met with Satcher and laid out the case as to why the CDC should be actively interested in correctional health care. Perhaps we were having some success but it didn’t seem quite enough to win Satcher over. Then, after about half an hour, Carl called and joined the conversation. Carl is very articulate and passionate about issues that are dear to his heart, and correctional health care is one of those issues. Well, at the end of the meeting Satcher was convinced. “Before you came in here I did not see a strong case for CDC to be involved in correctional health, but now I do,” he told us. He committed to assigning a corrections specialist to help coordinate the CDC’s involvement with corrections-related issues. (That specialist, by the way, was a young man named John Miles, who went on to do a number of great things within CDC and today serves as the editor of our Journal of Correctional Health Care.)

What were your objectives for NCCHC when you became president? I was the Commission’s third president and by that time the basic structure that we have today was pretty well-established, just much smaller. Accreditation, education, certification … the programs existed but hadn’t caught on as much as they have now. So there was still a lot of “sharing the vision” work to be done. We sought to raise awareness that the unique combination of corrections and health care presents an important public health opportunity as well as patient safety and risk management challenges that require attention at the highest levels of the correctional system. Operationally, the board’s highest priority was to make sure that NCCHC accreditation was as effective as possible. We focused on developing well-trained, highly experienced survey teams that could identify the many acceptable ways to meet the standards, and could educate facility staff members about successful, proven approaches.

Did your vision for NCCHC and its work change over time? Yes. Although the Commission had always taken on all issues of importance to correctional health systems and professionals, our work evolved to meet the opportunities and challenges that arose. For example, NCCHC has always promoted quality care and systems management, but we had to help change the old culture of corrections to embrace the concepts of performance improvement and patient safety, and then help them to adopt good, nonpunitive programs that improve quality and protect patients. Ever since our landmark study on the health status of soon-to-be-released inmates, our field has become much better at measuring patient outcomes and system performance in meaningful ways. Comparing our benchmarks with those of the free world can go a long way toward seamless care across correctional health, public health and free world health systems. It also shows our elected officials and the courts that correctional systems often provide necessary care at a level of quality and efficiency that is equal to or

continued on page 7
What’s New in the 2014 Jail and Prison Standards for Health Services

by Dianne Rechtine, MD, CCHP-A, and Tracey Titus, RN, CCHP

The National Commission on Correctional Health Care has published the 2014 editions of its Standards for Health Services in Jails and Standards for Health Services in Prisons. The revised standards are the product of a task force of experts representing all disciplines within correctional health care.

The Standards lay the foundation for constitutionally acceptable health systems and are the basis for NCCHC accreditation, which is a voluntary, ongoing process for continuing improvement. They address nine general areas: health care services and support, patient care and treatment, special needs and services, governance and administration, personnel and training, safety, health records, health promotion and medical-legal issues.

Each entry consists of the standard’s number and name, the standard itself, the compliance indicators, the definitions (if any) and the discussion. The “optional recommendations” from 2008 have either been eliminated or incorporated into the discussion section. The intent of the standard remains the first sentence of the discussion.

Each standard is designated as either essential (facilities must meet 100% of the applicable ones) or important (facilities must meet 85% of the applicable ones). Four standards that were classified as important in the 2008 manuals have been changed to essential in the 2014 editions:

- B-04 Federal Sexual Abuse Regulations
- D-05 Hospital and Specialty Care
- E-05 Mental Health Screening and Evaluation (jails only — already essential for prisons)
- G-06 Patients With Alcohol and Other Drug Problems

Nine standards were renamed or renumbered:

- B-01 Infection Prevention and Control Program
- B-04 Federal Sexual Abuse Regulations
- B-05 Response to Sexual Abuse
- C-01 Credentials
- E-12 Continuity and Coordination of Care During Incarceration
- G-06 Patients With Alcohol and Other Drug Problems
- G-07 Intoxication and Withdrawal
- H-03 Management of Health Records
- H-04 Access to Custody Information

Two standards were combined into one:

- G-09 Counseling and Care of the Pregnant Inmate contains elements previously found in G-07 Care of the Pregnant Inmate and G-09 Pregnancy Counseling.

One new standard was added:

- G-08 Contraception

Some changes to the standards were substantial, others were more subtle. These standards were extensively revised:

- A-06 Continuous Quality Improvement Program
- B-02 Patient Safety
- B-05 Response to Sexual Abuse
- G-02 Clinical Performance Enhancement
- G-08 Health Care Liaison
- D-02 Medication Services
- D-05 Hospital and Specialty Care
- E-04 Initial Health Assessment
- E-07 Nonemergency Health Care Requests and Services
- E-12 Continuity and Coordination of Care During Incarceration
- F-03 Use of Tobacco
- G-01 Chronic Disease Services
- G-07 Intoxication and Withdrawal (formerly G-06)
- G-09 Counseling and Care of the Pregnant Inmate (formerly G-07)
- G-11 Care for the Terminally Ill
- I-02 Emergency Psychotropic Medication

Snapshot of Notable Changes

The following are a few of the notable changes in the 2014 Standards. Future Spotlight columns will provide more detailed discussions of standards with important changes.

Many of the changes are designed to elaborate on the expectations for compliance. For example, Standard A-04 Administrative Meetings and Reports has added that health staff meetings must be documented in minutes or summaries and copies must be distributed. Standard A-08 Communication on Patients’ Health Needs now also includes suspected victims of physical or sexual abuse.

A-06 Continuous Quality Improvement Program has changed significantly. This standard no longer requires a basic or comprehensive CQI program based on average daily population in which facilities had to conduct one to two process studies and one to two outcome studies per year. Now, all facilities must establish a quality improvement committee. They must continue to study site-specific problems, but the type of study conducted is determined by the health care problem in question.

In the Personnel and Training section, C-02 Clinical Performance Enhancement was broadened to encompass all direct patient care clinicians, including RNs, LPNs and all qualified mental health professionals. C-06 Inmate Workers was changed to state that inmate workers may continue to assist with activities of daily living but not in the infirmary.

In D-05 Hospital and Specialty Care, a written agreement with the community hospital or off-site specialty services is no longer required, but it is recommended.
In Section E, Patient Care and Treatment, several standards have notable changes. E-04 Initial Health Assessment now requires that all positive findings are reviewed by a treating clinician no matter who conducts the health assessment, and for this standard, a treating clinician is defined as a nurse practitioner, physician assistant or physician. E-12 Continuity and Coordination of Care During Incarceration was almost entirely rewritten to be more patient-centered. Compliance indicator 2 states that deviations from standards of practice are to be clinically justified, documented and shared with the patient. E-13 Discharge Planning now requires a “reasonable supply” of medication, defined as sufficient for short-term continuity upon release.

In F-03 Use of Tobacco, compliance indicator 2 no longer requires that nicotine replacement products are available to all inmates.

G-01 Chronic Disease Services was changed to include monitoring disease control (poor, fair, or good) and patient status (stable, improving or deteriorating), as well as taking appropriate action to improve outcomes. G-05 Suicide Prevention Program redefined several terms; for example, “actively suicidal” was changed to “acutely suicidal.” New standard G-08 Contraception has a compliance indicator that requires that emergency contraception be available.

I-01 Restraint and Seclusion now specifies that health staff should order clinical restraints and seclusion only for patients exhibiting behavior dangerous to self or others as a result of medical or mental illness.

Complying With the New Standards
Accredited facilities may choose to follow either the 2008 or the 2014 edition of the standards until Oct. 1, when all programs must be in compliance with the 2014 edition. Facilities that are undergoing surveys before October and choose to be accredited under the 2008 standards must submit a transition plan to NCCHC by Oct. 1 outlining the changes that will be made to comply with 2014 standards.

Dianne Rechtein MD, CCHP-A, is a physician surveyor for NCCHC’s accreditation program and serves on the surveyor advisory committee. Tracey Titus, RN, CCHP is the manager of accreditation services. For more information, write to accreditation@ncchc.org. To purchase the Standards, visit our catalog at www.ncchc.org/publications.

About ‘Spotlight’
The articles in this series shed light on the nuances of NCCHC’s Standards for Health Services, exploring the rationale behind various standards, the intended outcomes, compliance concerns, the impact on the accreditation process and more. The complete series is available in the Standards and Guidelines section at www.ncchc.org along with an archive of questions from the Standards Q&A columns.

For more in-depth information about the standards, attend one of the preconference seminars at NCCHC’s annual spring and fall conferences.
Hepatitis C Treatment
Between a Rock and a Hard Place

by Jeffrey E. Keller, MD, CCHP

As you probably know, Sovaldi (sofosbuvir) is an important new treatment for hepatitis C infection that was released last December. The problem is that the going rate is $1,000 per pill. This translates into a minimum of $84,000 for Sovaldi alone for the simplest course of hep C treatment. Add on the other necessary drugs and take into consideration more complicated cases, and a single course of therapy for hepatitis C will cost between $100,000 and $250,000.

This has placed prison systems in a tough situation—and not just prisons, but also Medicaid, insurance companies and HMOs. On one hand, Sovaldi is a good drug that represents a significant advance in hepatitis C treatment. Lots of hepatitis C patients could potentially benefit from Sovaldi. On the other hand, treating every potential hep C patient using Sovaldi would bankrupt everyone. There is no good way out of this dilemma.

Historical Overview
Hepatitis C is an RNA virus transmitted almost exclusively via blood exposure. Most of the people who are infected with hepatitis C today contracted the disease prior to 1992 from a blood transfusion. That is why the Centers for Disease Control and Prevention issued a call for all baby boomers to be screened for hep C, since the majority of unrecognized hepatitis C cases are baby boomers. Since the blood supply was cleaned up in the early 1990s, the rate of new cases of hepatitis C has dropped dramatically. Almost all of the new cases are due to IV drug use and sharing needles. Hep C can also be transmitted inside a prison via tattoo needles.

Out of every 100 patients who are infected with hepatitis C, 75-85 will become chronically infected and 60-70 will develop chronic liver disease. Most chronically infected patients will remain asymptomatic; 5-20 will eventually develop cirrhosis (usually after 20 or 30 years) and 1-5 will die from hepatitis C, either from liver failure or cancer. The goal of treating hepatitis C patients is to stop progression of liver damage in those who have it.

The first antiviral drug used to treat hepatitis C was interferon, but only about 15% of the patients treated with interferon were able to completely clear the virus from their systems, which is called a sustained virologic response (SVR). Not very good. It was then found that attaching a polyethylene glycol (PEG) molecule to interferon markedly increased interferon’s effectiveness. This peginterferon increased virus elimination to the range of 30% of those treated. The next treatment advance was the development of ribavirin which, when added to peginterferon, increased the overall effectiveness of the treatment to around 50%.

Finally, in 2011, the protease inhibitors telaprevir and boceprevir were released. When one of these agents was added to peginterferon and ribavirin, even better SVR rates could be obtained in an even shorter amount of time, especially for genotype 1, the most common and hardest to treat subtype of hepatitis C. The three-drug regimen...
improved SVR rates in genotype 1 from around 40% to around 55% of those treated. SVR rates in genotypes 2 and 3 are closer to 85% to 90%.

However, there are significant problems with this triple therapy. First, it is hard for many patients to tolerate, the worst drug in this regard being peginterferon. Many patients with hepatitis C just cannot tolerate the vicious side effects of peginterferon. Second, it involves a lot of pills and shots, which is termed “the pill burden.” Of course, the more pills you have to remember to take, the more likely you are to forget doses or otherwise be noncompliant. Third, treatment lasts a long time—48 weeks. It is very hard for patients to tolerate the nasty side effects and remember to take all of the pills at the right time for that long. Finally, triple therapy is really expensive. At one conference on hepatitis C that I attended this comparison was made: “For every offender treated for hepatitis C (with triple therapy), that is one correctional officer that you cannot hire that year.”

**Game Changer**

The potential game changer is Sovaldi, which represents a new class of agents termed polymerase inhibitors. Sovaldi has many advantages over the old triple therapy.

1. Treatment times using Sovaldi are a lot shorter. The basic treatment course for genotype 1 is only 12 weeks compared to 48 weeks.

2. Sovaldi regimens seem to result in higher cure rates. For genotype 1, Sovaldi may boost the SVR to over 85%.

3. Sovaldi is dosed once a day, markedly cutting down the pill burden for hepatitis C, which should increase compliance.

4. Sovaldi regimens have fewer drug interactions and fewer side effects. In fact, those patients with genotype 1 who cannot tolerate peginterferon can instead combine Sovaldi and ribavirin and another new hep C drug, the protease inhibitor Olysio (simeprevir). This means that many patients who were ineligible for hepatitis C treatment before Sovaldi could now be treated. Examples include patients with concomitant diseases like HIV, advanced liver disease and hepatocellular cancer. This also means that all of the thousands of hepatitis C patients who failed peginterferon therapy due to side effects can now be retreated interferon-free.

5. Finally, the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases in January jointly issued new hepatitis C treatment guidelines that recommend Sovaldi as a first-line therapy for all genotypes. They do not recommend using telaprevir and boceprevir at all.

The result of all of this is a potential huge demand for Sovaldi. Liver specialists want to treat the thousands of patients who are ineligible for interferon. Patients who have failed interferon therapy want another shot at a cure. Some liver specialists are even advocating for the treatment of all patients with hepatitis C, even if they are asymptomatic. Advocacy groups are getting into the act and demanding free access to Sovaldi. The CDC recommends that everyone in the United States born between 1945 and 1965 be tested for hepatitis C infection. Those thousands found to be positive will want to be treated.

**At What Cost?**

The problem is the cost. A 12-week course of therapy is $84,000. With interferon and ribavirin, the total cost to treat genotype 1 is more than $110,000. Genotype 3 requires 24 weeks of therapy, so double the price. If you go peginterferon-free, add another $80,000 for Olysio. And we thought triple therapy was expensive!

Let’s do a little hypothetical number crunching for my home state of Idaho. As of a year ago, Idaho had nearly 8,000 inmates in the prison system. Let’s assume that 20% of them are infected with hepatitis C (a conservative estimate—it might be 30% or more). If we treat all of them with Sovaldi regimens, and taking into account the various genotypes, treatment could average $130,000 per patient for a total of $208,000,000. This number dwarfs the entire Idaho DOC budget! It is simply financially not doable.

But won’t we save money in the long run by reducing the incidence of liver failure and liver transplant? The Institute for Clinical and Economic Review analyzed this question in a paper titled "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection" and concluded that it would cost the state of California around $32 billion to treat half of the state’s hepatitis C patients. But even optimistically assuming optimal cure rates and no reinfection, only around 5% of that outlay would be recouped through lower expenditures for liver transplant and treating liver failure. They conclude that Sovaldi is of “low value” in treating most hepatitis C patients and recommend restricting its use to a small subset of patients.

This expense leaves those of us in corrections with few options. We simply cannot afford to use Sovaldi very much, if at all. The most obvious strategy is not to use Sovaldi and stick with the older regimens and the older protocols. Another is to authorize Sovaldi only for the sickest of the sick—those with advanced liver disease, for example, or those with comorbid conditions that preclude use of peginterferon. A variation of this strategy is the one recommended by the Institute for Clinical and Economic Review and has been adopted by many third-party payers. State Medicaid programs, like prisons, are still struggling with the issue of whom to treat.

What about the argument that since the IDSA and the AASLD have issued a guideline recommending Sovaldi for almost all hepatitis C patients, it now is the standard of care? In my opinion, this is simply not true. “Guidelines” do not a “standard of care” make.

First of all, there are many other published hepatitis C guidelines that do not recommend Sovaldi use. The Institute for Clinical and Economic Review paper itself can be viewed as one such guideline. Several others are listed within that paper.

continued on page 20
The focus on reentry as a component of juvenile justice reform has been paramount in recent years. Changes to legal systems and detention practices have decreased in the numbers of youth being detained in secure facilities for less serious and status-type offenses. Yet significant numbers of youth are still being detained within secure facilities, from a short-term predisposition basis to longer sentences for delinquent acts. No matter what the length of confinement, 100% of juvenile offenders will return to their community. Reentry efforts should be multidisciplinary with the ultimate goal of reducing recidivism. Plans for improving the health care continuum and improving the youth’s transition to community providers should be a critical component of the reentry process.

The Council of State Governments Justice Center website has posted an article titled “The Critical Elements of Juvenile Reentry in Research and Practice.” The authors, David Altschuler, PhD, and Shay Bilchik, JD, identified a reentry continuum consisting of three overlapping phases: 1) in facility, 2) the transition out of facility and into community and 3) in community. Using overarching case management, an approach that provides youth with a systemic continuity of care throughout the three phases, Altschuler and Bilchik identified six critical elements of juvenile reentry:

1. Assessment of risk for reoffending, strengths and needs
2. Cognitive-behavioral interventions
3. Family engagement
4. Release readiness
5. Permanency planning
6. Staffing and workforce competencies

This article will discuss how each of these six components relates to the provision of health care services and is incorporated into the reentry and reintegration continuum.

Facility Phase
Assessment of Risk for Reoffending, Strengths and Needs: It is essential to provide an adequate health screening process at the point of intake. The risk for reoffending is often related to factors identified in the health screening, such as substance abuse and mental health diagnoses. The screening process should be in compliance with the NCCHC Standards for Health Services in Juvenile Detention and Confinement Facilities. After completion of medical, dental and behavioral health screenings, full assessments in these areas should be made by their respective qualified providers. A system should be in place to address all urgent health needs and to process routine health care requests.

Cognitive-Behavioral Interventions: Screenings that identify youth with suicidal ideations or other behavioral risk factors must be addressed immediately. Policies and procedures should provide clear direction on how to maintain the safety of these identified youth. Treatment staff should be readily available to intervene, assess and meet the needs of youth with behavioral health disorders. These youth may or may not have been identified in the community. Even if they have been, there is often noncompliance to medication and other treatment regimens leading to behaviors that may promote detention.

Family Engagement: Contact with the family is important in order to obtain the youth’s health history such as medications, allergies, immunizations, previous hospitalizations and pertinent family history. Parental consents can be obtained at this point for care and treatment.

Release Readiness: Reentry efforts regarding health care should start at the point of admission to the facility. A plan of care should be made for all youth addressing their health needs. This is also a key opportunity for health care staff to determine whether the youth has been seen by health care providers in the community and how often.

Permanency Planning: Many youth who intersect with the juvenile justice system are eligible for Medicaid or the state-specific Children’s Health Insurance Program. There could also be coverage by a private insurer. A determination of insurance coverage should be made before or at the point of intake into the facility. The presence of insurance coverage does not indicate access in all cases.

Staffing and Workforce Competencies: Nonmedical staff should receive training from medical and behavioral health staff on how to conduct adequate assessment at intake, when to contact on-call health care staff and how to handle youth who present with health risks at intake, such as showing signs of infection. Facility health care staff must be fully credentialed and receive periodic training and competency assessments.

Transition Phase
Assessment of Risk for Reoffending, Strengths and Needs: Once health needs are identified, treatment should begin in the facility with the goal of transitioning that care back into the community. Youth should be identified with a community medical home to address health needs identified while in the facility.

Cognitive-Behavioral Interventions: Cognitive-behavioral interventions initiated in the facility can be continued in the community through linkages with community behavioral health providers. Ideally, these community providers should meet youth while they are still at the facility to facilitate continued care and follow-up upon release.

Family Engagement: Educating the youth and family on health problems identified in the screening and assessment process will prepare them for self-management. Adherence to medication and other treatment should involve the family in order to maximize compliance upon release. The youth’s home health care plan should be discussed, espe-
cially if the youth has a chronic health condition.**

**Release Readiness:** The plan of care initiated at intake should be continued and revised as appropriate in preparation for transition back to the community. It may be an acute need, such as follow-up for a positive sexually transmitted infection, or a health department referral for a positive tuberculosis test. Youth with chronic health conditions need a detailed plan that can be referred to a community provider. Communication between the facility and community providers is critical to a smooth transition. If possible, follow-up appointments should be set prior to the youth’s release from the facility.

**Permanency Planning:** If a youth’s health coverage is ineligable for use during the period of confinement, every effort should be made to suspend that coverage rather than to terminate. If youth are currently under the care of a community provider, every effort should be made to continue any current treatment plan through communication between the community and facility providers.

**Staffing and Workforce Competencies:** During the transition period, community health care providers for continuity of treatment should be identified. This is especially important when specialty care is required because these providers may be more difficult to locate.

**Community Phase**

**Assessment of Risk for Reoffending, Strengths and Needs:** Transition to aftercare requires ongoing assessments as the youth’s needs may change over the period of supervision in the community. Regular follow-up and reassessment in the community should be monitored for compliance.

**Cognitive-Behavioral Interventions:** These interventions should be continued in the community. Behavioral improvements may lower youths’ risk of reoffending and reduce overall recidivism rates.

**Family Engagement:** Family support is critical to youth with chronic health conditions. Families should be encouraged to become knowledgeable about the youth’s health problem and actively participate in receiving adequate health care. Families also need to be educated on the need for routine health care visits.

**Release Readiness:** Youth may need time to adjust to self-management of health conditions while in the community and not under direct supervision of facility staff. They must learn to become compliant with treatment regimens without facility staff there to monitor compliance.

**Permanency Planning:** Youth need to be able to continue medical coverage by compliance with medical plan requirements. Graduation and future employment will enable future health insurance coverage. Youth should begin the lifelong habit of seeking routine health care and managing chronic health conditions.

**Staffing and Workforce Competencies:** The availability of treatment staff in the community is essential for continuity of care. Limited availability, especially in rural areas, creates access issues. Lack of transportation to these providers is also a barrier to treatment. Every effort should be made to overcome these barriers to getting youth into community treatment. The use of telemedicine and the electronic health record may improve access.

**Essential for Success**

It is critical that health care reentry planning and implementation be incorporated throughout the reintegration continuum. Continuity of health care promotes success and well-being for each youth upon return to the community.

Michelle Staples-Horne, MD, MPH, CCHP, is medical director for the Georgia Department of Juvenile Justice, Decatur, GA.

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www.ncchc.org
Mental Health First Aid Training Enables Nurses to Prevent Crises

by Gwen Boyd, MA, MSN, CCHP

ental health disorders are the leading cause of disability in the United States and Canada, accounting for 25% of all years of life lost to disability and premature mortality, according to the World Health Organization. Furthermore, estimates suggest that 57 million Americans, or 1 out of 5 persons, suffer with a mental illness at any given time.

Healthy People 2020 identified the need to improve mental health in America as an important goal. (Healthy People is a federal initiative that provides science-based, 10-year national objectives for improving the health of all Americans.) Healthy People 2020 highlights the need for workplace educational programs on mental health as a way to increase the knowledge of employees on how to assist someone with a mental disorder and help to improve the person’s quality of life.

Many people lack sufficient information about mental health and would not know what to do in a mental health emergency. This is in part due to lack of education, but the bigger contributor is the societal stigma surrounding mental illness that causes people to avoid these situations. More education is needed to equip caregivers with the tools necessary to identify when someone is at risk and to get them the help they need.

What Is Mental Health First Aid?

Mental Health First Aid is a program that provides training designed to help a first aider recognize and respond to someone who may be experiencing a mental health problem. The MHFA program began in Australia in 2001, created by Betty Kitchener and Anthony Jorm as mental health’s answer to the traditional first aid (or CPR) that is provided for medical conditions. Since then this public education program has proliferated worldwide. The National Council for Behavioral Health brought MHFA to the United States in 2008 in collaboration with the Maryland Department of Health and Mental Hygiene and the Missouri Department of Mental Health. Moreover, the federal government now recognizes MHFA as an evidence-based program backed by solid research. As of 2012, more than 1,850 instructors had trained over 50,000 first aiders in the United States.

One of the hallmarks of this program is its five-step action plan, which can be remembered by the mnemonic ALGEE:

- Assess for risk of suicide or harm
- Listen nonjudgmentally
- Give reassurance and information
- Encourage appropriate professional help
- Encourage self-help and other support strategies

This helpful tool is taught during an eight-hour training course that covers illnesses such as depression, anxiety, suicidality, psychosis and substance use. Interactive activities like group discussions, role-playing and simulations are integrated into the training and a certificate is awarded to each participant who passes the course.

What Mental Health Nurses Want and Need

St. Louis Psychiatric Rehabilitation Center is a forensic mental health facility operated by the Missouri Department of Mental Health. It houses approximately 185 patients, many of whom are dually diagnosed with a severe mental illness and substance use disorder. Similar to a correctional facility, the patients live in a locked environment. Their predominant interaction is with the nursing staff that is on the front line and in the trenches.

A review of the nursing literature showed that forensic mental health nurses struggle with the need for safety. They typically want more skills and knowledge in mental health, and they want to know how to do their job more effectively. Importantly, they want to know how to manage violent patients and how to employ effective interventions of de-escalation.

This also is true at SLPRC, which recently hired a number of graduate nurses who lack mental health experience aside from what they learned during their brief psychiatric clinical rotation. Moreover, many have never worked in a locked environment with forensic patients. At times, these patients exhibit warning signs of impending aggression and violence, and are at risk of becoming a danger to themselves or to others. Mental health first aid would be an invaluable tool to use as an intervention before a crisis erupts.

Training Our Nurses

To become an instructor of the adult version of MHFA, I attended a five-day training course sponsored by Mental Health First Aid USA. The key benefits from this training were that I learned how to teach MHFA, the five-step action plan and self-help strategies according to the evidence-based model using adult learning principles. I also learned that MHFA can (and should) be taught to a variety of individuals in a variety of settings as there is both an adult and a youth version of MHFA. I could see how easy it would be to tailor MHFA to my facility.

After becoming certified to teach MHFA, I felt prepared to offer a lesson to the mental health nurses at SLPRC. Fifteen nurses (43%) participated in the first class. Participants were a mixture of new and seasoned nurses. The class began with a 13-question pretest on mental health. On average, the nurses answered 56% of the ques-
tions correctly. Next, we covered the ALGEE action plan as we discussed a variety of mental health disorders and interventions. Posttest results showed that 90% of the questions were answered correctly, on average. Mental health resources and handouts were also provided to the group.

During the group discussions, participants made comments such as, "These handouts are great, I can use them during my patient teaching." "I hope the aides get this training, too, because it is really needed," "My friend suffers with PTSD, now I know how to respond to her," and "Now I know that giving reassurance is not the same as giving patients false hope." One nurse even shared a personal account of a past traumatic event that left her feeling fearful and anxious, and how helpful it would have been to have had a first-aider in her life.

Surprisingly, the more experienced nurses were the most vocal and expressed a real appreciation for the training. Some stated that the information was a good refresher and that they also thought the five-step action plan was a helpful tool. Many commented that they thought the information would be useful not only with their patients, but also in their personal lives. One nurse said, "Nurses are the lifersavers … we need to recognize when someone is in distress and provide assistance whether we are at work, at home or in the community."

Expanding the Program
Since that first class, our administration has decided to continue offering MHFA to all of our nursing staff. We also will offer this class to the support staff such as our security guards, housekeepers and food service workers.

It is possible that one day MHFA will be as pervasive as medical first aid and CPR as a tool to help recognize and prevent a mental health crisis. Providing mental health education in the workplace will help reduce the stigma of mental illness by encouraging an open discussion on mental health and offering a useful tool that can be used by anyone who is willing to take the time to intervene.

Gwen Boyd, MA, MSN, CCHP, is a nurse educator with the St. Louis (MO) Psychiatric Rehabilitation Center. Contact her at Gwen.Boyd@dnh.mo.gov.

Helpful Resources
• Mental Health America – www.mentalhealthamerica.net
• Mental Health First Aid – www.mentalhealthfirstaid.org
• Missouri Department of Mental Health – dmh.mo.gov/docs/mentalillness/UnderstandingMentalIllness.pdf
• National Alliance on Mental Illness – www.nami.org
• National Council for Behavioral Health – www.thenationalcouncil.org
• National Institute of Mental Health – www.nimh.nih.gov
• World Health Organization – Mental Health – www.who.int/mental_health

2014 STANDARDS for Health Services in Jails or Prisons

Newly revised, the 2014 standards present NCCHC’s latest recommendations for managing health services delivery in adult correctional facilities throughout the nation.

The standards were updated to reflect the latest evidence and best practices in meeting professional, legal and ethical requirements in delivering correctional health care services.

Notable updated topics include continuous quality improvement, clinical performance enhancement, patient safety, pharmaceutical operations and women’s health. The new editions support facilities in achieving and maintaining compliance with NCCHC accreditation and constitutionally required correctional health care.

National correctional health care experts have spent thousands of hours researching, editing and evaluating feedback from the field to ensure that NCCHC standards remain the most authoritative resources for correctional health care services.

To order or to see a list of all NCCHC publications, visit www.ncchc.org.
Each year, an estimated 1 IN 7 PERSONS living with HIV pass through a correctional facility.

For many patients, KALETRA in combination therapy may offer long-term efficacy against HIV:

* Undetectable HIV-1 RNA (<50 copies/mL):
  * Study 730: At week 48, 77% of ARV-naive patients (N=664)1
  * Study 802: At 48 weeks, 54% of ARV-experienced patients (N=599)2
  * Study 720: At 7 years, 50% of ARV-naive patients (N=100)3

More than 12 YEARS of experience

* FDA approved September 2000
* Studied in clinical trials for 7 years in treatment-naive and for 2.5 years in treatment-experienced patients4

Some patients have discontinued clinical trials due to side effects or inadequate virologic suppression.

KALETRA®
(lopinavir/ritonavir)
Indication and Important Safety Information

Indication
KALETRA® (lopinavir/ritonavir) is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older). The following populations should be considered when initiating therapy with KALETRA:
- The use of other active agents with KALETRA is associated with a greater likelihood of treatment response.
- Genotypic or phenotypic testing and/or treatment history should guide the use of KALETRA. The number of baseline lopinavir resistance-associated substitutions affects the virologic response to KALETRA.

Important Safety Information

Contraindications
KALETRA is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, anaphylaxis, multiorgan, urticaria, angioedema) to any of its ingredients, including ritonavir.

KALETRA is a CYP3A inhibitor. Co-administration of KALETRA is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with severe or life-threatening reactions, and with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance. These contraindicated drugs include alprazolam, azithromycin, diltiazem, doxycycline, erythromycin, griseofulvin, indinavir, itraconazole, ketoconazole, nelfinavir, pimozide, prochlorperazine, quinidine, raloxifene, tacrolimus, telithromycin, and verapamil. Appendix 1 lists drugs to avoid when using KALETRA.

Drug Interactions
Because KALETRA is a CYP3A inhibitor, the potential for drug-drug interactions, including those that are severe or life-threatening, must be considered prior to and during therapy with KALETRA. Review of other medications taken by patients and monitoring of patients for adverse effects are recommended during therapy with KALETRA. Please see the Full Prescribing Information for a list of established and other potentially significant drug interactions.

KALETRA should not be administered once daily in combination with efavirenz, nevirapine, nelfinavir, ritonavir, saquinavir, or rifabutin.

Toxicity in Preterm Neonates
KALETRA oral solution contains alcohol and propylene glycol and should not be used in preterm neonates in the immediate postnatal period because of possible toxicities. A safety and effective dose in this patient population has not been established. Postmarketing data have been obtained in preterm neonates, including death, have been reported. Monitor infants closely for increases in serum osmolality and serum creatinine, and for toxicity related to KALETRA oral solution.

Pancreatitis
Pancreatitis, including fatalities, has occurred in patients receiving KALETRA, including those who developed marked triglyceride elevations. Suspend therapy as clinically appropriate.

Hepatotoxicity
Hepatotoxicity, including fatalities, has occurred in patients receiving KALETRA. Monitor liver enzymes before and during therapy, especially in patients with underlying hepatic disease, including hepatitis B and hepatitis C, or marked transaminase elevations.

OT/PR Interval Prolongation
OT interval prolongation and cases of torsade de pointes have been reported, although causality of KALETRA could not be established. Avoid use in patients with congenital long QT syndrome, those with hypokalemia, and with other drugs that prolong the QT interval. KALETRA prolongs the PR interval in some patients. Cases of second- and third-degree heart block have been reported. Use with caution in patients with pre-existing conduction system abnormalities, ischemic heart disease, cardiomyopathies, underlying structural heart disease, or who co-administer KALETRA with other drugs that may prolong the PR interval. Clinical monitoring is recommended.

Diabetes Mellitus/Hyperglycemia
New onset diabetes mellitus, exacerbations of diabetes mellitus, and hyperglycemia have been reported in patients receiving protease inhibitors.

Immune Reconstitution Syndrome
Immune reconstitution syndrome has been reported in patients receiving combination ARV therapy, including KALETRA. During the initial phase of ARV treatment, patients whose immune system responds may develop an inflammatory response to reactivation of latent or residual opportunistic infections, which may necessitate further evaluation and treatment. Autoimmune disorders have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment.

Lipid Elevations
Treatment with KALETRA has resulted in large increases in concentrations of total cholesterol and triglycerides. Monitor lipids prior to therapy and periodically thereafter.

Fat Redistribution
Redistribution/accumulation of body fat has been observed in patients receiving ARV therapy. The mechanism and long-term consequences of these events are currently unknown.

Patients with Hemophilia
Increased bleeding has been reported in patients with hemophilia types A and B treated with protease inhibitors. Additional factor VIII may be required.

Resistance/ Cross-resistance
HIV-1 cross-resistance among protease inhibitors has not been fully explored in KALETRA-treated patients; it is unknown what effect therapy with KALETRA will have on the activity of subsequently administered protease inhibitors.

Pediatric Use
The safety, efficacy, and pharmacokinetic profiles of KALETRA in pediatric patients below the age of 14 days have not been established. KALETRA once daily has not been evaluated in pediatric patients.

Special Dosing Considerations
Special attention should be given to accurate calculation of the dose of KALETRA, transcription of the medication order, dispensing information, and dosing instructions to minimize the risk for medication errors and overdoses.

The appropriate dose must be carefully calculated for each pediatric patient, based on body weight or body surface area and recommended in the full Prescribing Information, to avoid underdosing or exceeding the recommended adult dose.

Pregnancy
KALETRA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There are no adequate and well-controlled studies in pregnant women taking KALETRA. Mothers should be instructed not to breast-feed if they are receiving KALETRA.

Adverse Reactions
In KALETRA clinical trials, commonly reported adverse reactions in adult patients included diarrhea, nausea, vomiting, hyperglycemia, and hypercholesterolemia. In children receiving KALETRA oral solution, the most common adverse reactions were taste aversion, vomiting, and diarrhea.

Please see Brief Summary of Prescribing Information on the following pages.

1 Study MOS-730, Phase III, open-label, randomized, multicenter trial evaluating the safety and efficacy of KALETRA (LOP/RTV) in combination with tenofovir disoproxil fumarate (TDF) 300 mg QD and emtricitabine (FTC) 200 mg QD. BASELINE: 654 ARV-naive adults. Mean age 39 years, 75% Caucasian, 70% male. Mean viral load: 5.0 log10 copies/mL. Mean CD4 cell count: 216 cells/mm3.

2 PRIMARY EFFICACY ENDPOINT: Proportion of patients with HIV-1 RNA <50 copies/mL at week 24. All patients receiving soft-gel capsules were switched to tablets at week 24 while maintaining original dosing schedules.

3 PATIENT DISPOSITION: 10% of patients discontinued the study; 4% due to adverse events.

4 Study MOS-8052, Phase III, open-label, randomized, multicenter trial evaluating the safety and efficacy of KALETRA (LOP/RTV) in combination with 2 inhibitor-selected NRTIs. BASELINE: 599 ARV-experienced adults. Mean age 41 years, 51% Caucasian, 66% male. Mean viral load: 4.3 log10 copies/mL. Mean CD4 cell count: 254 cells/mm3.

5 PRIMARY EFFICACY ENDPOINT: Proportion of patients with HIV-1 RNA <50 copies/mL at week 24. All patients receiving soft-gel capsules were switched to tablets at week 24 while maintaining original dosing schedules.

6 PATIENT DISPOSITION: 23% of patients discontinued the study; 6% due to adverse HIV-related events.

7 Study M97-720, Phase II, blinded, randomized, dose-ranging, multicenter trial evaluating the safety and efficacy of KALETRA capsules at 3 dose levels within 2 groups (group I: 200/100 mg BID and 400/100 mg BID; group II: 400/100 mg BID and 400/200 mg BID) in combination with stavudine 40 mg BID and lamivudine 150 mg BID. All patients were converted to open-label KALETRA 400/100 mg BID between weeks 48 and 72. At year 6, 37% patients remained stavudine with TDF. BASELINE: 101 ARV-naive adults. Mean age 35 years, 70% Caucasian, 68% male. Mean viral load: 4.9 log10 copies/mL. Mean CD4 cell count: 338 cells/mm3.

8 PRIMARY EFFICACY ENDPOINT: Proportion of patients with HIV-1 RNA <400 copies/mL at week 24, extended to 360 week follow-up analysis. Proportion of patients with HIV-1 RNA <50 copies/mL was also analyzed.

9 PATIENT DISPOSITION: 9% of patients discontinued the study; 16% due to adverse events.

Reference:
KALETRA®

(lopinavir/ritonavir tablet, film coated)

(larinavir/ritonavir oral solution)

INDICATIONS AND USAGE
KALETRA is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older). The following points should be considered when initiating treatment with KALETRA:

- The use of other active agents with KALETRA is associated with a greater risk of resistance and cross-resistance. These drugs are listed in Table 1.
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### Laboratory Abnormalities

#### 2 Percentage of female population (N=574)

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td><em>Hypertension</em></td>
<td>47</td>
<td>1.8</td>
</tr>
<tr>
<td>Alopecia</td>
<td>10</td>
<td>0.4</td>
</tr>
<tr>
<td>Night sweats*</td>
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<tr>
<td><em>Dermatitis</em></td>
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<td><em>Erectile dysfunction</em></td>
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<td><em>Nephritis</em></td>
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<td><em>Hepatitis</em></td>
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<td><em>Headache</em></td>
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<td><em>Lipid abnormalities</em></td>
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<td><em>Convulsion</em></td>
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<td><em>Ageusia</em></td>
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<tr>
<td><em>Dizziness</em></td>
<td>45</td>
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<td><em>Musculoskeletal pain including arthralgia and back pain</em></td>
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<td><em>Myalgia</em></td>
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<td><em>Myoglobinuria</em></td>
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<td><em>Neuropathy and peripheral neuropathy</em></td>
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### Infections and Infestations

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<tr>
<td><em>Lactate dehydrogenase</em></td>
<td>166</td>
<td>6.2</td>
</tr>
<tr>
<td><em>Creatine</em></td>
<td>96</td>
<td>3.5</td>
</tr>
<tr>
<td><em>Calcium</em></td>
<td>11</td>
<td>0.4</td>
</tr>
</tbody>
</table>

### Metabolism and Nutrition Disorders

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Hypokalemia</em></td>
<td>52</td>
<td>2.0</td>
</tr>
<tr>
<td><em>Glucose</em></td>
<td>30</td>
<td>1.1</td>
</tr>
<tr>
<td><em>Weight increased</em></td>
<td>20</td>
<td>0.8</td>
</tr>
<tr>
<td><em>Tremor</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Ageusia</em></td>
<td>19</td>
<td>0.7</td>
</tr>
<tr>
<td><em>Convulsion</em></td>
<td>9</td>
<td>0.3</td>
</tr>
<tr>
<td><em>Tremor</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Central nervous system</em></td>
<td>6</td>
<td>0.2</td>
</tr>
</tbody>
</table>

### Psychiatric Disorders

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Anxiety</em></td>
<td>101</td>
<td>3.9</td>
</tr>
<tr>
<td><em>Depression</em></td>
<td>19</td>
<td>0.7</td>
</tr>
<tr>
<td><em>Blind decreased</em></td>
<td>19</td>
<td>0.7</td>
</tr>
</tbody>
</table>

### Renal and Urogenital Disorders

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Hematuria</em></td>
<td>31</td>
<td>1.2</td>
</tr>
<tr>
<td><em>Neutropenia</em></td>
<td>20</td>
<td>0.8</td>
</tr>
</tbody>
</table>

### Reproductive System and Breast Disorders

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Enucleation</em></td>
<td>34</td>
<td>1.7</td>
</tr>
<tr>
<td><em>Methotrexate</em></td>
<td>99</td>
<td>3.8</td>
</tr>
<tr>
<td><em>Peyronie's disease</em></td>
<td>54</td>
<td>2.0</td>
</tr>
<tr>
<td><em>Diabetes</em></td>
<td>50</td>
<td>1.9</td>
</tr>
<tr>
<td><em>Pustulosis</em></td>
<td>42</td>
<td>1.6</td>
</tr>
<tr>
<td><em>Aplasia</em></td>
<td>29</td>
<td>1.1</td>
</tr>
<tr>
<td><em>Capillitosis and vasculitis</em></td>
<td>10</td>
<td>0.4</td>
</tr>
</tbody>
</table>

### Vascular Disorders

<table>
<thead>
<tr>
<th>Medical Concept</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Hyperlipidemia</em></td>
<td>47</td>
<td>1.8</td>
</tr>
<tr>
<td><em>Deep vein thrombosis</em></td>
<td>17</td>
<td>0.7</td>
</tr>
</tbody>
</table>

* Represents a medical concept including several similar MedDRA PTs.

### Table 3. Grade 3-4 Laboratory Abnormalities Reported in ≥ 2% of Adult Antiretroviral-Naive Patients

<table>
<thead>
<tr>
<th>Variable Limit</th>
<th>Laboratory Abnormality</th>
<th>Study BMI (48 Weeks)</th>
<th>Study BMI (720) (N = 109)</th>
<th>Study BMI (360) (N = 238)</th>
<th>Study BMI (720) (N = 339)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>≥ 180 mg/dL</td>
<td>1%</td>
<td>3%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>SGPT/ALT</td>
<td>≥ 2.5 x ULN</td>
<td>7%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Creatinine</td>
<td>≥ 1.5 mg/dL</td>
<td>7%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Sodium</td>
<td>&gt; 140 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Potassium</td>
<td>&lt; 3.5 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

### Table 4. Grade 3-4 Laboratory Abnormalities Reported in ≥ 2% Pediatric Protease Inhibitor-Experienced Patients

<table>
<thead>
<tr>
<th>Variable Limit</th>
<th>Laboratory Abnormality</th>
<th>Study BMI (48 Weeks)</th>
<th>Study BMI (720)</th>
<th>Study BMI (360)</th>
<th>Study BMI (720)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>≥ 180 mg/dL</td>
<td>1%</td>
<td>3%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Creatine</td>
<td>&gt; 1.5 mg/dL</td>
<td>7%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Sodium</td>
<td>&gt; 140 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Potassium</td>
<td>&lt; 3.5 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

### Table 5. Grade 3-4 Laboratory Abnormalities Reported in ≥ 2% Pediatric Patients in Study 869

<table>
<thead>
<tr>
<th>Variable Limit</th>
<th>Laboratory Abnormality</th>
<th>Study BMI (48 Weeks)</th>
<th>Study BMI (720)</th>
<th>Study BMI (360)</th>
<th>Study BMI (720)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>≥ 180 mg/dL</td>
<td>1%</td>
<td>3%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Creatine</td>
<td>&gt; 1.5 mg/dL</td>
<td>7%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Sodium</td>
<td>&gt; 140 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Potassium</td>
<td>&lt; 3.5 mEq/L</td>
<td>4%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

### Postmarketing Experience

The following adverse reactions have been reported during postmarketing use of KALETRA. Because these reactions are voluntarily reported from a population of unknown size, it is not possible to reliably estimate their frequency or establish a causal relationship to KALETRA exposure. Body as a Whole: Rare. 

### Drug Interactions

See also Contraindications, Warnings and Precautions.

Potential for KALETRA to Affect Other Drugs

**Lopinavir/ritonavir** is an inhibitor of CYP3A and may increase plasma concentrations of agents that are primarily metabolized by CYP3A. Agents that are extensively metabolized by CYP3A and have high first-pass metabolism appear to be the most susceptible to large increases in AUC (> 3-fold) when co-administered with KALETRA. Thus, co-administration of KALETRA with drugs highly dependent on CYP3A for clearance and for which reduced plasma concentrations are associated with serious and/or life-threatening events is contraindicated. Co-administration with other CYP3A substrates may require a dose adjustment or additional monitoring as shown in Table 6.

In addition to KALETRA indicates immunosuppression.

**Potential for Other Drugs to Affect Lopinavir/ritonavir** is a CYP3A substrate; therefore, drugs that induce CYP3A may decrease lopinavir plasma concentrations and reduce KALETRA’s therapeutic effect. Although not observed in the KALETRA/ritonavir clinical drug interaction study, co-administration of KALETRA with other drugs that inhibit CYP3A may increase lopinavir plasma concentrations. **Established and Other Potentially Significant Drug Interactions**

Table 6 provides a listing of established or potentially clinically significant drug interactions. Alteration in dose or regimens may be recommended based on drug interaction studies or predicted interaction.
Table 6. Established and Other Potentially Significant Drug Interactions

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Other Drug Name</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>saquinavir</td>
<td>HIV-1 Protease</td>
<td>Increased rate of adverse reactions. Patients receiving KALETRA should be monitored for adverse reactions associated with saquinavir.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Clinical significance of this interaction is unknown. Patients receiving KALETRA and lopinavir should be monitored for adverse reactions associated with lopinavir.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and ritonavir should be used with caution. A decrease in the dosage or an increase in the dosing interval of ritonavir or lopinavir may be necessary for patients requiring co-administration with strong CYP3A inhibitors such as KALETRA.</td>
</tr>
</tbody>
</table>

Table 6 continued

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Other Drug Name</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>nevirapine</td>
<td>HIV-1 Protease</td>
<td>Combination of nevirapine and KALETRA should not be administered once in combination with nevirapine.</td>
</tr>
<tr>
<td>atazanavir</td>
<td>HIV-1 Protease</td>
<td>Clinical significance of this interaction is unknown. Patients receiving KALETRA and atazanavir should be monitored for adverse reactions associated with atazanavir.</td>
</tr>
<tr>
<td>fosamprenavir</td>
<td>HIV-1 Protease</td>
<td>Combination of fosamprenavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>indinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of indinavir and KALETRA should not be administered.</td>
</tr>
</tbody>
</table>

Table 6 continued

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Other Drug Name</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>saquinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of saquinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>oseltamivir</td>
<td>HIV-1 Protease</td>
<td>Combination of oseltamivir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>zidovudine</td>
<td>HIV-1 Protease</td>
<td>Combination of zidovudine and KALETRA should not be administered.</td>
</tr>
<tr>
<td>abacavir</td>
<td>HIV-1 Protease</td>
<td>Combination of abacavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>nel/fi navir</td>
<td>HIV-1 Protease</td>
<td>Combination of nel/fi navir and KALETRA should not be administered.</td>
</tr>
</tbody>
</table>

Table 6 continued

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Other Drug Name</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>saquinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of saquinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>oseltamivir</td>
<td>HIV-1 Protease</td>
<td>Combination of oseltamivir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>zidovudine</td>
<td>HIV-1 Protease</td>
<td>Combination of zidovudine and KALETRA should not be administered.</td>
</tr>
<tr>
<td>abacavir</td>
<td>HIV-1 Protease</td>
<td>Combination of abacavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>nel/fi navir</td>
<td>HIV-1 Protease</td>
<td>Combination of nel/fi navir and KALETRA should not be administered.</td>
</tr>
</tbody>
</table>

Table 6 continued

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Other Drug Name</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>saquinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of saquinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>ritonavir</td>
<td>HIV-1 Protease</td>
<td>Combination of ritonavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>oseltamivir</td>
<td>HIV-1 Protease</td>
<td>Combination of oseltamivir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>zidovudine</td>
<td>HIV-1 Protease</td>
<td>Combination of zidovudine and KALETRA should not be administered.</td>
</tr>
<tr>
<td>abacavir</td>
<td>HIV-1 Protease</td>
<td>Combination of abacavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>lopinavir</td>
<td>HIV-1 Protease</td>
<td>Combination of lopinavir and KALETRA should not be administered.</td>
</tr>
<tr>
<td>nel/fi navir</td>
<td>HIV-1 Protease</td>
<td>Combination of nel/fi navir and KALETRA should not be administered.</td>
</tr>
</tbody>
</table>
### Table 6 continued

<table>
<thead>
<tr>
<th>Concomitant Drug Class: Drug Name</th>
<th>Effect on Concentration of Lopinavir or Ritonavir</th>
<th>Other Agents</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac glycosides</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Captopril</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antihypertensives</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Angiotensin-converting enzyme inhibitors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lisinopril</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diuretics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Calcium Channel Blockers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Beta-blockers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adrenergic Agonists</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stimulants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Drugs with No Observed or Predicted Interactions with KALETRA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Drug Interactions**

KALETRA oral solution contains alcohol, which can produce effects similar to those observed with concomitant administration of other drugs that produce this reaction (e.g., metronidazole). Concomitant use of alcohol is not recommended in patients taking KALETRA.

**Special Populations**

**Pediatric Use**

Safety and efficacy in pediatric patients <6 months of age have not been demonstrated. In 160 pediatric patients, the clinical trial was an open-label, multicenter trial evaluating the pharmacokinetic profile, tolerability, and safety of KALETRA oral solution containing lopinavir 60 mg/mL and ritonavir 20 mg/mL. In 100 antiretroviral naive and experienced pediatric patients ages 6 months to 12 years, blood concentrations of lopinavir determined at steady-state were similar in patients taking these agents concomitantly. No data are available regarding the use of KALETRA in patients <6 months of age.

**Geriatric Use**

Clinical studies of KALETRA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, careful attention should be paid to the geriatric pharmacokinetic changes of lopinavir, ritonavir, and the combination of lopinavir and ritonavir and monitoring of vital signs and observation of the clinical status of the patient.

**Use in Patients with Renal Impairment**

Use of PDE5 inhibitors for pulmonary arterial hypertension (PAH) may be contraindicated. Other agents associated with adverse events and visual changes and vision disturbance. Use of PDE5 inhibitors for pulmonary arterial hypertension requires caution. It is recommended to avoid the use of PDE5 inhibitors in patients taking KALETRA due to the risk of increased lopinavir and ritonavir concentrations and the potential risk of drug interactions.

**Use in Patients with Hepatic Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with hepatic impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe hepatic impairment.

**Use in Patients with Renal Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with renal impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe renal impairment.

**Use in Patients with Cardiac Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with cardiac impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe cardiac impairment.

**Use in Patients with Renal Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with renal impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe renal impairment.

**Use in Patients with Cardiac Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with cardiac impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe cardiac impairment.

**Use in Patients with Renal Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with renal impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe renal impairment.

**Use in Patients with Cardiac Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with cardiac impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe cardiac impairment.

**Use in Patients with Renal Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with renal impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe renal impairment.

**Use in Patients with Cardiac Impairment**

The safety, efficacy, and pharmacokinetic profile of KALETRA in patients with cardiac impairment have not been established. In patients taking these agents concomitantly, no data are available regarding the use of KALETRA in patients with severe cardiac impairment.
**Drug Interactions**

• combination with /f_{l} uticasone propionate).

virus may become resistant to KALETRA and become harder to treat.

in their blood may increase if the medicine is stopped for even a short time. The

on Serevent® (salmeterol).

KALETRA, they should talk to their doctor about problems these two medications

together. The doctor may choose not to keep someone on Advair® (salmeterol in

combination with /f_{l} uticasone propionate) and KALETRA, they should talk to

their doctor about problems these two medications may cause when taken

• Do not share needles or other injection equipment.

• Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

• Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

• Do not breastfeed. We do not know if KALETRA can be passed to the baby through breast milk and whether it could harm the baby. Also, mothers with HIV-1 should not breastfeeding because HIV-1 can be passed to the baby in the breast milk.

**Drug Interactions**

**KALETRA** may interact with some drugs; therefore, patients should be advised to report to their doctor the use of any other prescription, non-prescription medication or herbal products, particularly St. John’s Wort.

**KALETRA Tablets** can be taken at the same time as didanosine without food. Patients taking didanosine should take didanosine one hour before or two hours after KALETRA oral solution.

If they are receiving avanafil, sildenafil, tadalafil, or vardenafil for the treatment of erectile dysfunction, there may be an increased risk of associated adverse reactions including hypotension, visual changes, and sustained erection, and should promptly report any symptoms to their doctor. If they are currently using or planning to use a non-prescription erectile dysfunction drug, patients should talk to their doctor about potential adverse reactions these medications may cause when taken with KALETRA. The doctor may choose not to keep them on avanafil, or may adjust the dose of tadalafil while initiating treatment with KALETRA.

If they are receiving estrogen-based hormonal contraceptives, additional or alternate contraceptive measures should be used during therapy with KALETRA.

They are taking or before they begin using Serenex® (salmeterol) and KALETRA, they should talk to their doctor about problems these two medications may cause when taken together. The doctor may choose not to keep someone on Serenex® (salmeterol).

If they are taking or before they begin taking Advair® (salmeterol in combination with fluticasone propionate) and KALETRA, they should talk to their doctor about problems these two medications may cause when taken together. The doctor may choose not to keep someone on Advair® (salmeterol in combination with fluticasone propionate).

**Potential Adverse Effects**

Skin rashes ranging in severity from mild to toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, erythema multiforme, urticaria, and angioedema have been reported in patients receiving KALETRA or its components iniparip and/or ritonavir. Patients should be advised to contact their healthcare provider if they develop a rash while taking KALETRA. The healthcare provider will determine if treatment should be continued or an alternative antiretroviral regimen used.

Patients should be advised that appropriate liver function testing will be conducted prior to initiating and during treatment with KALETRA. Pre-existing liver disease including hepatitis B or C can worsen with use of KALETRA. This can be seen as worsening of transaminase elevations or hepatic decompensation. Patients should be advised that their liver function tests will need to be monitored closely especially during the first several months of KALETRA treatment and that they should notify their healthcare provider if they develop the signs and symptoms of worsening liver disease including loss of appetite, abdominal pain, jaundice, and/or itchy skin.

New onset of diabetes or exacerbation of pre-existing diabetes mellitus and hyperglycemia have been reported during KALETRA use. Patients should be advised to notify their healthcare provider if they develop the signs and symptoms of diabetes mellitus including frequent urination, excessive thirst, extreme hunger or unusual weight loss and/or an increased blood sugar while on KALETRA as they may require a change in their diabetes treatment or new treatment.

KALETRA might produce changes in the electrocardiogram (e.g., PR and/or QT prolongation). Patients should consult their physician if they experience symptoms such as dizziness, lightheadedness, abnormal heart rhythm or loss of consciousness.

They should seek medical assistance immediately if they develop a sustained penile erection lasting more than 4 hours while taking KALETRA and a PDE 5 inhibitor such as Viagra, Cialis or Levitra.

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.

Patients should be informed that there may be a greater chance of developing diabetes with the once daily regimen as compared with the twice daily regimen.

KALETRA Tablets, 200 mg/50 mg ritonavir;
Manufactured by AbbVie Ltd., Barceloneta, PR 00617 for AbbVie Inc., North Chicago, IL 60064 USA

KALETRA Tablets, 140 mg/35 mg ritonavir and KALETRA Oral Solution;
Manufactured by AbbVie Inc., North Chicago, IL 60064 USA

Ref: 03-AB41-Revised November, 2013

036-1335406 MASTER

045-1403008

**Hepatitis C** (continued from page 9)

Second, the IDSA/AASLD guideline does not at all address the cost of using the drugs it recommends. When we are talking about potential bankruptcy if we follow these guidelines, cost is a critically important consideration.

Third, in their hepatitis C guideline, IDSA/AASLD said that some of the board members had a conflict of interest. When such a huge amount of money is at stake, potential conflicts of interest make me a little leery of accepting these guidelines without reservation, especially when it is not spelled out exactly who in the panel had conflicts of interest nor what those conflicts were.

Finally, in my opinion, “standard of care” is a legal term, not a medical term. It is loaded with undercurrent implications of “I’ll see you in court if you don’t prescribe this.” I think we are better off throwing out the term “standard of care” and evaluating Sovaldi on its medical merits, which includes its price.

In the end, Sovaldi is a good drug that we cannot afford, except maybe in a very small subset of patients.

Jeffrey E. Keller, MD, CCHP, is the chief medical officer of Centurion as well as the medical director of Badger Medical, which provides medical services to several jails and juvenile facilities in Idaho. This article is adapted with permission from a post on Keller’s blog at www.jailmedicine.com, and does not represent the official opinion of NCCHC.
Renal Transplantation for ESRD Patients With Hepatitis C Saves Lives and Money

Chronic kidney disease is a health issue of epidemic proportions with a dramatic economic impact, according to the authors of an article in the July issue of the Journal of Correctional Health Care. Panesar and colleagues write that $239 billion per year is spent on care for approximately 400,000 dialysis patients, and this case-load is projected to increase to 533,800 by 2020.

In comparison to dialysis patients, who have a five-year survival rate of about 34%, renal transplantation improves the quality and extends the life of patients with end-stage renal disease, who enjoy a five-year survival rate of 85% to 93%, depending on whether the donor was deceased or living. Of course, transplantable kidneys are in short supply and the wait list is long. To expand the donor pool, donor criteria have been extended, including in some cases accepting kidneys from donors who are HCV positive for use in HCV-positive ESRD patients.

Given the high cost, poor outcomes and security issues related to providing dialysis care to inmates, prisons might consider establishing a transplant program, Panesar and colleagues suggest. Their article describes such a program for ESRD patients at a maximum-security state prison for males and their findings from an assessment of its clinical and financial impact. The program began in 2003.

In this retrospective chart review, nine ESRD prisoners (average age 45 years) who were hep C antibody-positive received kidney transplants. These patients were selected based on their compliance with current treatment and their medical and psychiatric suitability. The article describes in detail the criteria and the evaluation protocol to identify patients who were eligible for the treatment. Data collected were from a seven-year period, 2003 through 2009.

Findings

Of the nine transplanted patients, three received (with their consent) kidneys from hep C antibody-positive donors. The average wait for a kidney was 66 months for those recipients compared to 49.6 months for the others.

The one-year patient and organ survival rate for all of the transplant patients was 100%. After five years, three grafts had failed; one of those was from an HCV-positive donor, but that graft had survived for 50 months. The other two grafts that failed had survived for 13 and 17 months. None of the failures was due to patient noncompliance. The average serum creatinine of the remaining six functioning allografts was 1.43 mg/dl. The authors concluded that transplanting HCV-positive kidney to HCV-positive recipient had no effect on survival or liver disease during the follow-up period of about 10 years.

A second major benefit of the program was financial. According to national averages, the annual cost of chronic hemodialysis for a patient aged 40-49 is $65,628. For transplant patients, the cost of care for the first year is $103,831 and then drops to $14,984 annually. Therefore, if the kidney remained functional for two years, there was a savings of $50,000 per year.

The authors identified four major outcomes from this transplantation program:

- Patients gained a potential survival benefit.
- It reduced the wait list time.
- Patient compliance was achieved.
- There appeared to be a substantial economic benefit.

The authors also speculate that recidivism would be reduced in those released from prison since they would be more employable.
WHO Predicts “Post-antibiotic Era”
Antimicrobial resistance is an increasingly serious threat to global public health that requires urgent, coordinated action across all government sectors and society, says the World Health Organization in a global surveillance report issued in April. Specific threats noted include the following:
- Gonorrhea: Treatment failure to the drug of last resort—third-generation cephalosporins—has been confirmed in several countries.
- E. coli: Resistance to fluoroquinolones, widely used for the oral treatment of urinary tract infections, is very widespread.
- Staphylococcus aureus: Resistance to first-line drugs to treat infections caused by S. aureus is also widespread.
- Intestinal bacteria: Resistance to carbapenem antibiotics—the last-resort treatment for life-threatening infections—has spread to all regions of the world.
- Tuberculosis: Globally, 6% of new TB cases and 20% of previously treated TB cases are estimated to have multidrug-resistant TB; extensively drug-resistant TB has been identified in 92 countries, in all regions of the world.

Unless this threat is brought under control, “common infections and minor injuries, which have been treatable for decades, can once again kill,” the report says.
- www.who.int/mediacentre/factsheets/fs194/en

Best Practices on Restraint Use With Pregnant Women
Among female prisoners, 4% of state and 3% of federal inmates said they were pregnant at the time of admission, and 5% of women in jails reported being pregnant at intake, according to data from 2006. To help criminal justice settings develop policy and practice relating to women and girls who are pregnant, in labor or delivery, or in the postpartum period, the National Task Force on the Use of Restraints With Pregnant Women Under Correctional Custody has issued best practices guidance. The statement elaborates on five principles with the intent to maximize safety and minimize risk for pregnant women and girls, their fetuses/newborns and correctional and medical staff.
- www cjinvolvedwomen.org

CDC Calls for HIV Prevention Pill for At-Risk Patients
Pre-exposure prophylaxis via a daily dose of an antiviral drug can reduce the risk of HIV infection by more than 90% if taken as directed, according to new clinical guidelines from the Centers for Disease Control and Prevention. Health care providers are advised to consider the use of PrEP in uninfected patients who are at substantial risk of infection.

Jail Populations Decline Significantly
After a peak in the number of inmates confined in county and city jails at midyear 2008 (785,533), the jail population was significantly lower by midyear 2013 (731,208), according to a recent report from the Bureau of Justice Statistics. The makeup by gender is shifting: Males have represented at least 86% of the jail population since 2000, but the female population increased 10.9% (up 10,000 inmates) between midyear 2010 and 2013, while the male population declined 4.2% (down 27,500 inmates). The jail incarceration rate fell between midyear 2012 (237 per 100,000 U.S. residents) and 2013 (231 per 100,000). This continues a downward trend from a high of 259 jail inmates per 100,000 residents in 2007. Jails operated at 82% of capacity at midyear 2013, the lowest percentage since 1984 (86%).
- www.bjs.gov/content/pub/press/jim13stprcfm

UConn Forms Center for Correctional Health Networks
The University of Connecticut’s School of Nursing, Medicine, and Pharmacy has launched a practice-based research center to support an interdisciplinary network of members who study and test health care innovations and quality improvement strategies in real world correctional practice settings. CCHNet is also sponsored by the Research Program on Global Health and Human Rights at the Human Rights Institute. The goal is to determine effectiveness, efficiency and equity of outcomes with people with incarceration experiences. The network currently has 25 members and invites others to join.
- http://cchnet.uconn.edu

PSYCHIATRIST

CFMG, the leader in correctional health care has an immediate opening for a Psychiatrist at the Monterey County Jail in Salinas, CA.

Salary is $310,000 per year.

Responsibilities include medication management, crisis intervention, and management of mental health treatment for incarcerated population. Board Certification preferred.

Please send Curriculum Vitae to: Elaine Hustedt
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Christopher Kent Finds Credibility and Excellence Through Advanced Certification

by Amy Graves

The CCHP-Advanced program recognizes CCHPs who have demonstrated excellence, commitment, and contribution to the field of correctional health care. Christopher Kent, CCHP-A, not only contributes by serving as a compliance auditor for Wexford Health Sources, Inc., but also goes above and beyond for the CCHP program. Volunteering his time and resources, Kent often proctors CCHP exams at Wexford facilities across the country and is a strong advocate that his colleagues become certified.

When encouraging others to take the exam, Kent says, "When I tell people that I'm a Certified Correctional Health Professional, it goes a long way. When I mention Advanced certification, it goes that much further. Certification has allowed me to achieve a certain level of integrity and trustworthiness with people who don't know who I am."

Kent began working in correctional health care in 2001 at the recommendation of a former coworker. He was hired as a medical assistant and worked at both a jail and a prison, but his assignments soon gave him experience in nursing care, long-term care, mental health, medical records, intake and more. He worked his way up to acting health services administrator, and then his manager gave him responsibility for accreditation, saying, "You like challenges. Get it done."

As senior corporate compliance auditor, Kent's responsibilities include assisting with start-ups of new contracts, implementing electronic health records and serving as accreditation specialist, educator, trouble-shooter and acting manager as needed.

**Certification = Credibility**

As soon as Kent learned of the CCHP program, he applied and was certified in July 2005. He became a CCHP-A on Jan. 1, 2011. A great proponent of CCHP certification, he says a chief reason he wanted to become certified was credibility. "In my line of work, it offers a great deal of credibility when I offer my services to a site whose goal is to meet federal requirements. Also, I always try to pursue and become the best. Certification offered this to me."

Kent says certification has benefited him professionally by increasing his responsibility in his work and allowing him to understand the bigger picture of the development of national accreditation standards. "Certification has strengthened my ability to review a system or process and pick out what's broken. I can then use my knowledge from CCHP requisites to provide solutions for those issues."

Though Kent enjoys working in corrections, he is not blind to the challenges it presents. "The word 'challenges' itself connotes a complicated work environment with challenges outside what others would view as the norm," he says. "The population is ever-changing: aging patients, intakes, end-of-life situations and the complications that come with mental health patients are just a few of such challenges." However, Kent maintains that the difficulty of the work makes the rewards that much sweeter.

Achieving CCHP-A certification has also benefited Kent personally. "Certification inspires me to set goals for myself and reach for those goals," he says. "The CCHP-A test was difficult. However, I was determined to pass and through the information provided by NCCHC, I was able to do just that." Kent's passion for the CCHP program is evident in his work and he is an excellent model of the type of professional the CCHP-A program strives to acknowledge.

Amy Graves is the certification specialist for NCCHC.

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**Step Up! Seeking Candidates for Board**

Serving on the Certified Correctional Health Professional board of trustees is a great way to "give back" to this important program and the thousands of people who participate in it. But the benefits go both ways: It also is a wonderful opportunity for leaders to continue their professional growth and build their network of colleagues.

If that piques your interest, step up! CCHPs in good standing are encouraged to seek nomination, or to nominate a fellow CCHP, to serve on the board. Elections are held every year to fill a three-year term. Comprised of 10 correctional health professionals, the board is charged with guiding the CCHP program and making it more responsive to the needs of the correctional health care community. Trustees also develop, score and evaluate the certification exams. Upon acceptance of nomination, candidates will be asked to submit a brief statement describing their ideas about the direction of the program.

Elections will be conducted online this summer. The new trustees' term will begin immediately after the board meeting in October. To review eligibility requirements and make a nomination, go to www.ncchc.org/program-governance. Nominations must be made by July 2.

**CCHP Exam Dates**

<table>
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<th>Date</th>
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<tr>
<td>July 19</td>
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<td>August 16</td>
<td>Regional sites</td>
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<td>October 19</td>
<td>Las Vegas, NV</td>
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We are seeking sites for regional exams as well as CCHPs to proctor the exams. To participate, contact the certification specialist at 773-880-1460 or cchp@ncchc.org. See the complete calendar at www.ncchc.org/cchp/calendar.
1. How would you classify your readership of CorrectCare?
☐ I read it cover to cover.
☐ I read most of the articles.
☐ I read one or two articles in each issue.
☐ I read some issues but not all.
☐ I never read it. (Please let us know why, and then skip to Question 4.) __________________________

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3. What do you do with your copy of CorrectCare?
☐ Discard without reading
☐ Discard after reading
☐ Share with others
☐ File for future reference
☐ Other: __________________________

4. Do you have any suggestions that could help us to improve the publication?

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5. Please rate your interest in the following topics for coverage in CorrectCare.

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6. How would you prefer to receive CorrectCare?

- [ ] In print
- [ ] In digital format
- [ ] Both
- [ ] No preference

7. How likely are you to read CorrectCare in the following formats?

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<th>Format</th>
<th>Very unlikely</th>
<th>Somewhat unlikely</th>
<th>Undecided</th>
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8. If CorrectCare were available in digital format ONLY, how likely would you be to read it?

- [ ] Very unlikely
- [ ] Somewhat unlikely
- [ ] Undecided
- [ ] Somewhat likely
- [ ] Very likely

9. CorrectCare currently is published quarterly. What frequency would you prefer?

- [ ] Weekly
- [ ] Monthly
- [ ] Every two months
- [ ] Quarterly
- [ ] Never

10. What other publications and resources do you use to stay informed about correctional health care?

________________________________________________________________________________________________________________

11. Please share any other comments or feedback.

________________________________________________________________________________________________________________
________________________________________________________________________________________________________________

One respondent will be chosen at random to win a two-night stay at the Paris Hotel in Las Vegas (excludes National Conference dates). If you would like to enter the drawing, please provide your name, phone number and email address. This information will not be used for any other purpose.

Name ____________________________________________________________
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Correctional Medicine Fellowship
Nova Southeastern University College of Osteopathic Medicine (NSU-COM) invites you to explore a growing career path for physicians by learning about its newly created Fellowship in Correctional Medicine. There are approximately two million people incarcerated in the United States who are mandated by federal law to have health care provided to them. If you are interested in an exciting, challenging, and growing field featuring regular hours, significant compensation, and built-in liability protection, then a career in correctional medicine may be just what you have been seeking.

NSU-COM has a two-year academically based Correctional Medicine Fellowship leading to a Master’s of Public Health degree, Board Certification and recognition by the field. It is currently approved by the American Osteopathic Association (DOs) as a specialty designation leading to a Certificate of Added Qualification and by 2016 it is expected to be accepted by the Accreditation Council for Graduate Medical Education (MDs). It involves the entire spectrum of correctional health care including requirements and opportunities to deliver hands-on care in private, State and Federal facilities. Besides honing skills with supervised hands-on care the Fellow will be exposed to all aspects of correctional leadership responsibilities including quality improvement, mortality reviews, data driven systems analysis and management, electronic informatics, pharmacy committee actions and drug selection, and other aspects of managing a complex correctional health delivery system. All Fellows are expected to perform a high quality Field Experience as a part of the MPH requirements in some aspect of correctional health care. At the end of the program Fellows are expected to be highly competitive for senior institutional, regional, and director level positions. Indeed, some of our partners have agreed to look at the graduates for these positions.

For additional program or application information, please contact
Carol Siu, MS
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College of Osteopathic Medicine
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email: casiu@nova.edu
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NCCCH Webinars
- The Juvenile Health Intake Screening and Assessment: Critical Questions and Actions – July 16, 2 pm ET. Topics to include policies and procedures that impact the effectiveness of an adequate screening and assessment program.

- NCHC Standards: What’s New for Jails and Prisons in 2014 – July 24, 11 am ET. Make sure your facility stays current in meeting these important national standards.

To learn more and to register, visit Education/Distance Learning at www.ncchc.org.

About CorrectCare®
CorrectCare is the quarterly magazine of the National Commission on Correctional Health Care. Its mission is to publish news, articles and commentary of relevance to professionals in the field of correctional health care.

Subscriptions: CorrectCare is mailed free of charge to members of the Academy of Correctional Health Professionals, key personnel at accredited facilities and other recipients at our discretion. To request a subscription, submit a request at www.ncchc.org or by email at info@ncchc.org. The magazine is also posted at www.nwncchc.org.

Change of Address: Send notification four weeks in advance, including both old and new addresses and, if possible, the mailing label from the most recent issue. See page 1 for contact information.

Editorial Submissions: Submitted articles may be published at our discretion. Manuscripts must be original and unpublished elsewhere. For guidelines, email editor@ncchc.org or call 773-880-1460. We also invite letters or correction of facts, which will be printed as space allows.

Advertising: Contact Carmela Barbara, sales manager, at sales@ncchc.org or 773-880-1460, ext. 298.

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Expert Advice on NCCHC Standards

by Tracey Titus, RN, CCHP

Forensic Information in Sexual Assault Cases

Q Standard I-03 prohibits health staff from participating in the collection of forensic information. However, the compliance indicators allow for exceptions, including in the case of sexual abuse, when health staff may gather evidence from the inmate-victim with his or her consent. In our facility, health staff collects forensic information in cases of sexual assault. Is there anything that needs to be in place to allow the health staff to continue this practice while remaining in compliance with the standard?

A Standard I-03 Forensic Information does allow for health staff to collect evidence from the inmate-victim with his or her consent. If evidence is collected on-site, then standard B-05 Response to Sexual Abuse elaborates more on the requirements for in-house procedures. One other standard to consider is B-04 Federal Sexual Abuse Regulations, which requires facilities to have written policies and procedures regarding the detection, prevention and reduction of rape consistent with the Prison Rape Elimination Act. [Note: This reply is accurate for both the 2008 and 2014 editions of the Standards, although the standard names used are from the 2014 edition.]

Nurse Staffing Ratios

Q Do the Standards have any requirements concerning how many inmates one nurse should be in charge of in a county jail?

A Standard C-07 Staffing requires that a sufficient number of health staff of varying types provide inmates with adequate and timely evaluation and treatment, consistent with contemporary standards of care. The responsible health authority must approve the staffing plan and the adequacy and effectiveness of the staffing plan should be assessed by the facility’s ability to meet the health needs of the inmate population. The number and types of qualified health care professionals required depend on the size of the facility, the types and scope of health services delivered, the needs of the inmate population and the organizational structure. It is not possible to specify exact ratios, but the number of staff must be sufficient to ensure that there are no unreasonable delays in patients receiving necessary care. [Note: This reply is accurate for both the 2008 and 2014 editions of the Standards.]

Response Time for Nonemergency Requests

Q In the 2014 Standards, E-07 Nonemergency Health Care Requests and Services says that oral or written requests for health care are picked up daily by qualified health care professionals and triaged within 24 hours. When a request describes a clinical symptom, a face-to-face encounter occurs within 48 hours (72 hours on weekends). Does this mean that we now have two days to see a patient once the request has been triaged?

A No. The 48-hour time frame begins upon receipt of the written or oral health care request. Triage is required within 24 hours and a face-to-face assessment (when the request describes a clinical symptom) by a qualified health care professional is required within the next 24 hours. This is applicable for all medical, dental and mental health requests.

Tracey Titus, RN, CCHP, is NCCHC’s manager of accreditation services. If you have a question about the NCCHC standards, write to accreditation@ncchc.org or call 773-880-1460. For an archive of past Standards Q&A columns, visit the Standards and Guidelines section at www.ncchc.org.

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