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Our Independence Matters

The National Commission on Correctional Health Care has no membership or dues. NCCHC does not require any affiliation to be considered for accreditation, certification or employment as a consultant or surveyor, or to serve on committees or the board of directors. NCCHC staff and spouses are not allowed to accept gifts or consulting fees from those we accredit or certify. NCCHC is impartial, unbiased and expert. And dedicated only to recognizing and fostering improvements to the field of correctional health care.
NCCHC President Announces Retirement

Edward Harrison, CCHP, president and CEO of the National Commission on Correctional Health Care, announced he was stepping down after 27 years of service with the organization. The announcement was made at the Oct. 27 meeting of the NCCHC board of directors. Mr. Harrison intends to retire in 2014 after the board names a successor for his position.

Mr. Harrison joined NCCHC in 1987 and became its president in 1993. During his tenure the Commission grew significantly as the nation’s leader in the movement to improve health care in correctional settings. Among the notable achievements during this period are the great expansion of services and improved linkages with correctional and public health systems. NCCHC programs now reach tens of thousands of health professionals responsible for the care of millions of incarcerated patients.

"With Ed Harrison at the helm, NCCHC has led the way in improving health care in our nation’s jails, prisons and juvenile facilities," said Renee Kanan, MD, MPH, who chairs NCCHC’s board of directors. "We will miss his visionary leadership and steady guidance, and will be forever grateful for all of his contributions to our field."

"Correctional health care is a unique field that, despite its remarkable advances in the past 35 years, will always require advocacy and attention," Mr. Harrison said. "It has been an honor to serve in such a worthy effort and in collaboration with so many extraordinarily dedicated professionals over the years."

Mr. Harrison plans to work to ensure a smooth transition to the new president, both before and after stepping down.

New! 2014 Standards for Health Services

Newly revised by a task force of leaders in health, law and corrections, the NCCHC standards have been updated to provide our latest recommendations for managing health services delivery in jails and prisons. The Standards address nine general areas: health care services and support, inmate care and treatment, special needs and services, governance and administration, personnel and training, safety, health records, health promotion and medical-legal issues. New areas of emphasis include the following:

- Continuous quality improvement, an important element of the NCCHC accreditation process. Among other requirements, all accredited facilities, regardless of size, must now have a quality improvement committee.
- Clinical performance enhancement. The new standards include more types of health care professionals to improve patient safety and clinical outcomes.
- Prison Rape Elimination Act. The standards provide detailed guidance on how medical and mental health staff should prepare for and respond to allegations of sexual abuse and comply with PREA.
- Patient safety. Succinct patient safety tips provide immediately useful guidance to accredited facilities without increasing their compliance burden.

Take advantage of the field’s top experts and stay current, meet constitutional requirements and be better prepared for the challenges you face every day. Standards will be shipped in first quarter 2014. Order at 773-880-1460.

Welcome (Back!) to New Director of Education

NCCHC welcomes Deborah Ross as its director of education and meetings, a position she held with NCCHC from 1998 through 2010. For the past three years, she served as account director of sales for the Toronto Convention and Visitors Bureau. Contact her at deborahross@ncchc.org or 773-880-1460, ext. 286.

2014 Mental Health Conference Call for Proposals

NCCHC invites leaders and practitioners to submit abstracts for the Correctional Mental Health Care Conference, to take place at the Omni Interlocken near Denver on July 20-21, 2014. The submission deadline is Jan. 10. This conference brings together mental health professionals to share innovative solutions and network with colleagues facing similar challenges. It will feature a broad range of content areas and interactive instruction. Expert presentations and posters are being sought on critical issues such as behavioral and mental health disorders and treatment, administrative issues, best practices, emerging legal issues, substance abuse and treatment, special populations, segregation, reentry and more. Submit your abstract online at www.ncchc.org/correctional-mentalhealth-2014.

Calendar of events

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<th>Date</th>
<th>Event</th>
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<tr>
<td>Feb. 22</td>
<td>CCHP exam, multiple regional sites</td>
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<tr>
<td>April 5-8</td>
<td>Spring Conference on Correctional Health Care, Atlanta, GA</td>
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<tr>
<td>April 6</td>
<td>CCHP exam, Atlanta, GA</td>
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<tr>
<td>June 7</td>
<td>CCHP exam, regional sites</td>
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<tr>
<td>July 18-19</td>
<td>Correctional Health Care Leadership Institutes, Broomfield, CO</td>
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<tr>
<td>July 20-21</td>
<td>Correctional Mental Health Care Conference, Broomfield, CO</td>
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For the complete list of CCHP exam dates and sites, see www.ncchc.org/cchp/calendar.
New Board Chair Renee Kanan Advocates for Quality and Connections

When Renee Kanan, MD, MPH, took the stage at the 2013 National Conference opening ceremony, she shared with the audience her belief that quality health care is a basic human right for all persons. Although she, like many correctional health professionals, did not set out to work in this field, it was a natural continuation of her work caring for vulnerable populations. For Kanan, this work is her calling. “To paraphrase a few philosophers, ‘You can tell how civilized a society is by how they treat their most vulnerable people, including prisoners,’” she says.

But Kanan is no starry-eyed idealist. Armed with training and experience in public/population health, health administration and quality management, she is spreading the word that quality health care is also an economic issue, and that providing good care is good business because it yields the best value.

As chief quality officer for California Correctional Health Care Services—the organization established as a result of the state prison system being placed in a receivership due to inadequate health care—Kanan has been deeply involved in efforts to reinvent prison health care in the state. It’s a big job: CCHCS provides care to roughly 125,000 inmates at 34 adult institutions and oversees more than 9,000 medical care positions. This effort has involved implementing systems to measure, track and improve performance in key metrics within an environment of transparency, disclosure and accountability.

Making Connections

Looking at the bigger picture, Kanan says that U.S. health care reform offers great opportunities to raise the quality and value of patient care both within correctional settings and as inmate-patients reenter their communities. This can be achieved by creating a seamless system of cost-effective care that realizes the quality improvement vision of “triple aim”: better care for individuals, better health for populations and better value for everyone.

To take advantage of these opportunities, Kanan urges that all parties strive to connect. “Connect to each other, connect our patients as they transition through different settings within corrections and connect our patients and ourselves to the non-correctional world.”

As Kanan takes the helm at NCCHC, she sees the Commission as a leader in helping the field to make these connections. Some are based on technology and other tools, such as electronic health records systems, sharing of standardized quality data and delivery models that guide patients across the continuum of care.

But it is equally important that health care professionals make and strengthen connections with their colleagues in corrections—and with the larger community. “NCCHC and each one of us is an ambassador and a teacher to the outside world,” Kanan says. In part this is to raise public awareness of the excellent work being done in our field. But this outreach has even greater potential benefit, she says.

“Best practices and innovative models of care are happening within correctional health care systems that should be shared beyond the walls so that the national health care system keeps evolving, too. And by connecting in all these ways, we will increase the likelihood that our patients, the people who work in corrections, our communities and the public will be better off for the work that we do.”

In Other Board News...

• Patricia Reams, MD, CCHP, has been elected chair-elect; her term as chair will begin in October 2014. She has served on the board since 2002 as the liaison of the American Academy of Pediatrics. Reams is a pediatrician with Cumberland Hospital for Children and Adolescents, New Kent, VA. She also is a physician surveyor for NCCHC’s accreditation program.

• The American College of Obstetricians and Gynecologists has become a supporting organization of NCCHC. A 501(c)(3) organization, ACOG was founded in 1951 and has more than 55,000 members. Chief activities include education, research, practice and advocacy aimed at quality health care for women.

ACOG’s liaison on the board is Carolyn Sufkin, MD, assistant professor in the department of obstetrics, gynecology and reproductive sciences at San Francisco General Hospital and a women’s health specialist for San Francisco Jail Health Services.

• The new liaison to the American Nurses Association is Mary Muse, RN, CCHP-RN, CCHP-A, director of nursing for the Wisconsin Department of Corrections. Muse is an NCCHC surveyor and serves on the task force for CCHP-RN specialty certification. She replaces Patricia Voermans, MSN, CCHP-RN, who has retired.
NCCHC’s annual awards pay tribute to leaders and innovators that have enriched the correctional health care field. We applaud this year’s recipients of the most prestigious awards in this field. The awards were bestowed Oct. 28 at the opening ceremony of the National Conference on Correctional Health Care in Nashville.

**Bernard P. Harrison Award of Merit**

NCCHC’s highest honor, this award is presented to an individual or group that has demonstrated excellence and service that has advanced the correctional health care field, either through an individual project or a history of service. The award is named after NCCHC’s cofounder and first president.

**The Robert Wood Johnson Foundation and Risa Lavizzo-Mourey, MD, MBA, President and CEO**

*For visionary efforts that have improved correctional health care*

The mission of the Robert Wood Johnson Foundation is pure simplicity: to improve the health and health care of all Americans. Established in 1971, RWJF is the nation’s largest philanthropy devoted solely to the public’s health, investing in projects that improve health status, and more. These projects have had a major impact by addressing everything from infectious disease screening to chronic care, drug treatment, juvenile populations, reentry and more. These projects have had a major impact by shedding light on deficiencies in correctional health systems, providing research to drive improvement in health care delivery systems and fostering environments that promote health and prevent disease and injury.

For the past 10 years RWJF has been led by Risa Lavizzo-Mourey, MD, MBA, who in 2013 was named, for the eighth time, one of the 100 most influential people in health care by *Modern Healthcare* magazine. Dr. Lavizzo-Mourey asserts that good health should be a fundamental expectation for all and not an accident of geography or socioeconomic status.

Correctional populations have long been a target of the Foundation’s work, with dozens of projects and reports addressing everything from infectious disease screening to chronic care, drug treatment, juvenile populations, reentry and more. These projects have had a major impact by shedding light on deficiencies in correctional health systems, providing research to drive improvement in health care delivery and bringing correctional health care into the mainstream of public health concerns.

In the early 1980s, RWJF provided critical support that laid the groundwork for profound transformation of correctional health services, an evolution that continues today. A grant was awarded to sustain the American Medical Association’s successes in developing standards and accreditation for our field. With that support, the AMA project became the National Commission on Correctional Health Care.

Most recently, RWJF supported publication of Health and Incarceration—A Workshop Summary, which synopsizes a 2012 roundtable convened by the National Academy of Sciences and the Institute of Medicine to discuss the challenges and opportunities for improving health and health care of incarcerated populations. This discussion will inform a National Research Council committee that is examining the causes and consequences of high rates of incarceration in the United States, including physical and mental health and substance use disorders.

Teletechnology can connect rural health settings with academic medical centers to enhance primary care doctors’ knowledge and to deliver high-quality specialty care to underserved populations. Project ECHO is a model for collaborative practice that originated at the University of New Mexico and now, through the RWJF-supported ECHO Institute, is spreading throughout the country. Through this project, participating jails and prisons have been able to provide inmates with expert specialty care and peer education programs.

Because of the importance of community support when an inmate is released from incarceration, reentry and continuity of care have been the focus of many RWJF-funded projects, including coordinated assistance with housing, employment, health care and community support. Since 2006, RWJF has championed Community Oriented Correctional Health Services, a nonprofit organization that builds partnerships between jails and community health care providers in order to establish medical homes for former inmates in their communities.

Importantly, the Foundation is not content to produce research and conduct evaluations for their own sake. Rather, the aim is to produce evidence that both policy makers and practitioners in the field can use. With a 42-year history of bold, wide-ranging projects that have advanced policy and practice, the Robert Wood Johnson Foundation has, indeed, benefitted the health and health care of all Americans—incarcerated individuals among them.

**B. Jaye Anno Award of Excellence in Communication**

This award pays tribute to innovative, well-executed communications that have had a positive impact on the field of correctional health care, or to individuals for bodies of work. The award is named after NCCHC’s cofounder and first vice-president.

**Lorry Schoenly, PhD, RN, CCHP-RN**

*For a body of published work and digital communications that have advanced the field of correctional health care*

If you happen to be a Facebook friend of Lorry Schoenly, PhD, RN, CCHP-RN, you know that she peppers her page with posts about the joys and travails of writing—and the incredible willpower it takes: “Writing this morning—even though I don’t feel like it. Do I get an extra star?”

Happily, Dr. Schoenly subscribes to the philosophy that “writers write” and she musters the self-discipline to do so with impressive frequency. Long a nurse educator by vocation, she has always relied on the printed word to assist with
staff development and other educational activities. Her works were also published in textbooks and peer-reviewed journals somewhat regularly. But it was after she found correctional health care that her writing really blossomed.

Some background: After earning an associate’s degree in nursing, Dr. Schoenly worked as a critical care nurse, but after a few years was promoted to staff development instructor. Professional education has been her passion ever since. Her career path led her to serve as assistant vice president of education and development at a two-hospital system, and then as director of education for the National Association of Orthopaedic Nurses. Along the way she advanced her own education, earning a doctoral degree. In 2005, she joined a large correctional health care contract management firm and soon became its clinical education manager.

Dr. Schoenly retired from 9-to-5 employment in 2009 and now enjoys her considerable energy to educate others through writing, teaching and consulting, with a primary focus on correctional health care. She continues to write for traditional print media. Most notably, last year saw the publication of Essentials of Correctional Nursing: a much-lauded text that she coedited with Catherine M. Knox, MN, RN, and for which she wrote seven chapters. She also contributed to the American Nurses Association’s second edition of Correctional Nursing: Scope and Standards of Practice. She frequently writes for CorrectCare and other periodicals.

But Dr. Schoenly also embraces the new media outlets. Among her many activities, she writes the CorrectionalNurse.net blog; produces Correctional Nursing Today podcasts; is a health care columnist for CorrectionsOne.com and has a lively presence on Twitter, Facebook and LinkedIn. As a consultant, she was instrumental in NCCHC’s early social media efforts.

Dr. Schoenly finds writing to be rewarding because it can reach so many people, and her prolific output shows no signs of abating. Just check her Facebook page: She is sure to be giving herself a pep talk to tackle the next chapter in her forthcoming book on the principles of patient safety.

NCCHC Facility of the Year Award
This prestigious award is presented to one facility selected from among the nearly 500 prisons, jails and juvenile facilities accredited by NCCHC.

Essex County Juvenile Detention Center
Newark, New Jersey
A prom? In a juvenile detention center? The warden of the Essex County Juvenile Detention Center was skeptical when he first joined the facility, but this event for youth in their junior and senior years of high school has proven to be a great success. Proposed by one of the educators as a way to motivate the residents and open their minds to a better life, prom is now a regular event, with security, medical, mental health, social services, food service and volunteers all pitching in. Participants must earn the privilege of attending, and they receive coaching in etiquette, grooming and ballroom dancing—skills that fill the adolescents, and their invited parents, with pride.

Prom is but one example of the exceptional caring and dedication demonstrated by the staff. The inner-city facility houses nonadjudicated youth, primarily males, aged 10 to 18. The daily population is approximately 100 and average length of stay is 30 days. Health staff are on-site 24 hours a day, seven days a week. Staffing includes a health services administrator, physician, RNs, LPNs, psychiatrist, psychologist, mental health worker, dentist, dental assistant and medical records clerk. The facility has been accredited since 2004 and during its latest survey achieved 100% compliance with the NCCHC standards.

The programming focuses on providing services to address chronic behavioral problems and criminal behavior, and strives to divert the youth into detention alternatives, such as in-home monitoring, when appropriate. Those who remain residents receive schooling that emphasizes personal responsibility, mentoring, job training and other assistance to help them function well in society.

The accreditation surveyor who nominated the facility—and attended the prom—said that some parents of former residents are so grateful for the staff’s hard work and devoted attention to their sons and daughters that they volunteer at the facility. She added, “I can’t think of any more deserving group to receive this award.”

NCCHC Program of the Year Award
This award recognizes programs of excellence among the thousands provided by accredited prisons, jails and juvenile facilities.

Harris County Downtown Central Jail, Houston, Texas
Mental Health and Medical Security Unit
The largest mental health institution in Texas is the Harris County Downtown Central Jail. Situated in central Houston, the facility has an average daily population of about 9,300 inmates, of whom 25% to 30% are prescribed psychotropic medication. To better serve those who need the most intense treatment, several years ago the jail created a four-pod, 188-bed mental health unit designed to provide more efficient, effective care.

This award recognizes the program in which specially trained sheriff’s deputies are assigned exclusively to this mental health unit as well as the jail’s medical security unit. To be eligible to join this elite team, the officers must undergo rigorous training in skills such as crisis intervention, use of force, de-escalation techniques and suicide detection, and must obtain certification as a mental health peace officer. A visible symbol of this novel approach is the team members’ uniform, which includes blue polo shirts rather than patrol deputy shirts, designed to appear less intimidating to inmates. These deputies are cross-trained to work in both the mental health and medical security units, and they receive incentive pay.

The team members work in close cooperation with medical and mental health staff—including the two psychiatric technicians who are in the mental health unit at all times—to ensure the inmates’ well-being. This approach has decreased use-of-force incidents and has eliminated the need for clinical or custody-ordered restraints for the last two years, demonstrating the success of this innovative, practical program.

Representatives of Harris County Downtown Central Jail
Health-Compromised Detainee Dies: Oklahoma Jail Likely Deliberately Indifferent

by Fred Cohen, LL.M.

Wishing will not make it so. The Oklahoma County Jail was the subject of so many negative federal and state reports that were simply ignored, we can only imagine that the sheriff prepared a wish list and hoped that the health care fairy would deliver. But the elusive health care fairy was too busy to visit this jail.

Charles Holdstock visited the jail as a detainee and left as a corpse. The narrative of the medical care and oversight errors in the case of Mr. Holdstock, who arrived with serious medical issues, is stunning. Equally stunning is the federal district court’s grant of summary judgment for the sheriff and the county. In Layton v. Board of County Commissioners, the district court is reversed and the case remanded.

**Facts**

Mr. Holdstock was booked into the Oklahoma County jail on Sept. 5, 2006. He suffered from preexisting medical conditions, including congestive heart failure, diabetes and hypertension. He had a pacemaker, and part of his treatment regimen included taking the medication digoxin. Digoxin is filtered through the kidneys, and, if the kidneys are not functioning properly, digoxin can build up to toxic levels in the body.

Jail staff contacted the University of Oklahoma Medical Center out of concern for Holdstock’s pacemaker. While there was no immediate issue, there was to be follow-up treatment every 12 weeks and there is no evidence of any testing or treatment thereafter.

On April 28, 2009, Mr. Holdstock was found unresponsive on the floor of his cell. His skin was cool and clammy. He was taken to the infirmary by Correctional Healthcare Management of Oklahoma, where he was evaluated and treated. The treating physician issued an “[o]rder to continue to monitor [Mr. Holdstock and] call if [his] condition worsen[ed].” The next day, Mr. Holdstock was found in his cell, having difficulty breathing and unable to verbalize what was wrong. He was again taken to the infirmary, where the staff performed tests and drew blood for analysis. When his condition stabilized, he was returned to his cell.

Two days later, CHMO received the blood analysis results from the lab. The lab work indicated that Mr. Holdstock’s white blood cell count, neutrophils, glucose serum, BUN count, creatine serum and potassium serum were all in the high range. The appellants’ medical expert testified that the test results “indicate[d] that acid was piling up in his blood; that his kidney failure had gone from a chronic, stable state to ... a downward spiral.” Based upon the test results, the appellants’ expert “would [have been] very concerned that the digoxin level was toxic,” which would have prompted him to check Mr. Holdstock’s digoxin level, conduct further testing on his kidneys and consider hospitalization.

However, CHMO took no action following receipt of Mr. Holdstock’s test results. No further intervention occurred until May 15—the day of Mr. Holdstock’s death—when he was found unresponsive in his cell and sent to the emergency room. The appellants’ expert testified that Mr. Holdstock’s death could have been prevented had Mr. Holdstock been treated for kidney failure, and that there was a reasonable probability that the kidney failure resulted from Mr. Holdstock’s pacemaker failing, which could have been prevented had the pacemaker been checked.

On this record to this point, you are likely wondering how in the world did the trial judge decide that no reasonable jury could find for plaintiff? The court of appeals also wondered—and reversed.

Deliberate indifference, of course, is the crucial factor here: Who knew what, when, and then failed to act accordingly. As it develops, evidence of systemic failure in the jail’s
medical care and observation practices proved overwhelming. There is a damming Department of Justice report of July 2008, seven reports on death investigations and two complaint investigations by the Oklahoma State Department of Health. In sum, patients were not seen in a timely manner; there were ongoing problems with prescription medication; medical follow-up care was lacking; adequate safety, security and supervision did not exist; visibility was limited.

The Oklahoma report on Holdstock’s death supported the claim of a lethal failure to monitor and properly provide medications. “Change must occur” was the regular call in these reports. No change occurred was the melancholy result.

**Deliberate Indifference**

Pretrial detainees are entitled to at least the same level of care as convicted inmates. The source for detainees is the 14th Amendment, the Eighth Amendment for the convicted, but the underlying principles are the same.

There first must be a serious medical condition—clearly met here—and then deliberate indifference to the condition. This requires actual knowledge of an excessive risk to the detainee’s health, which is disregarded to the detriment of the detainee.

Deliberate indifference may manifest itself in a variety of ways: ignoring a medical condition, failure to properly treat it or preventing an inmate from gaining access to needed care.

Plaintiffs submitted evidence that tends to demonstrate long-standing, systemic deficiencies in the medical care that the jail provided to detainees—specifically, that the detainees were not being seen for medical care in a timely manner; that medications were not being administered as directed, that follow-up care was not being provided to seriously ill detainees and that the jail’s design prevented effective monitoring and supervision of detainees with serious medical needs. Despite this ample evidence indicating constitutionally inadequate conditions at the jail, the district court reasoned that somehow officials did not and could not know Holdstock faced death on April 28.

That, of course, is not required. It is risk of serious harm of which officials were aware and not that death would occur on a specific date. The record is loaded with knowledge of risk and the risk being ignored.

Reversed.

**Comment**

I am struck by the weight accorded the numerous, negative reports on medical care in this case. They provided the all-important actual knowledge basis required for deliberate indifference. The care afforded in this case is obviously disgraceful and how the lower court entered judgment for defendants amazes me.

Fred Cohen, LLM, is the editor of the Correctional Law Reporter. This article is in press for a future issue of CLR, ©2013 Civic Research Institute, Inc., and is reprinted here in slightly abridged form with permission of the publisher. All rights reserved. For subscription information, contact Civic Research Institute, 4478 U.S. Route 27, PO Box 585, Kingston, NJ 08528; 609-683-4450; www.civicresearchinstitute.com.
As health care providers and as consumers of the American health care system, we are aware of the initiatives and the drive to increase health care safety in all settings. Consumers and government demand that health care professionals “do no harm” and that they decrease the number of medical mistakes. Correctional facilities place high value on safety, but how do correctional facilities define “safety”—and where does patient safety fit into a correctional system’s mission of safety?

In 2009, a group of correctional professionals met at John Jay College in New York City to select a number of patient safety standards already present in community health care settings and tailor them to correctional settings. The workgroup used evidence-based resources such as the National Quality Forum and HEDIS measures to develop 47 corrections-specific standards that focus on patient safety (see For Further Reading on page 10).

Elements of a Patient Safety Culture

It has been determined that an environment that promotes a patient safety culture requires the six key elements described below.

Leadership

Engaged leadership is critical to successful development of a culture of safety—and lack of leadership is a barrier.

Communication

Poor communication among health care providers has been found to be a root cause of a majority of adverse events. As we advance in our knowledge, ability and skill, we can become overwhelmed with the responsibilities, legalities and stressors of having so much to do with so few resources, and this can result in workplace incivility. Incivility manifests itself in behaviors that range from eye-rolling and sarcastic remarks to rudeness, intimidation and, ultimately, workplace violence. Take a look at your environment. What do you see? Even when we follow policies and standards to guide our care, this type of behavior becomes a barrier to successful communication and teamwork. When unchecked, feelings of anger result in increases in absenteeism and grievances, high staff turnover and even destabilization of the organization. The final result is that patients suffer from fragmented and lower quality care.

Evidence-Based Practice

There is significant evidence that patient safety culture very much relies on the design of health care units and the use of technology to improve and support patient safety mea-
sures. Reliable health care practices that support patient safety are user-centered, decrease reliance on memory and vigilance and are automated whenever possible. Practices that support patient safety include the following:

- Make information accessible. Health care staff should not have to search for needed information about a patient or decision support information.
- Standardize room setups. Every patient care room contains the same equipment, preferably in the same place so staff always know what is available and where it is located.
- Decrease the need to remain vigilant. Nurse are continually pushed to maintain high vigilance, but it is impossible for humans to remain totally vigilant for extended periods of time. Mitigating strategies include using checklists and protocols to reduce the need to memorize everything, simplifying processes to minimize problem-solving and ensuring adequate staff breaks.
- Decrease distractions. Create “quiet zones” where physician’s orders are being transcribed and where medications are being prepared and administered.

Teamwork

It is well known that people make fewer errors when they work in teams. The process of teamwork starts with the relationships between staff members. Workplaces that support patient safety build team relationships that are safe and respectful, where staff members look out for each other to help detect potential errors before they happen. Health services administrators set the tone for relationships among staff by treating their staff with respect and consideration, then setting the expectation that the rest of staff will treat each other the same way.

Two concepts have been shown to profoundly affect teamwork. First, the traditional medical hierarchy places the physician in an unquestionable position, so that other health care professionals may hesitate to ask questions or share observations. Staff may speak up but be easily convinced that their contribution is invalid because of their rank in the pecking order. Flattening the traditional medical hierarchy so that the opinions and views of all staff are valued can promote the second concept, that of a “high index of suspicion.” A high index of suspicion takes into account everyone’s input. All viewpoints are evaluated. A low index of suspicion exists in organizations that maintain a compliant culture, where team member concerns go unspoken or unaddressed. Red flags include sayings such as “We don’t do things that way here” and “There’s the correct way and the correctional way.”

Teamwork also is important to allow the patient to be part of the team and care process. Health care staff need to provide patients with adequate education on conditions, symptoms, medications, diagnoses and testing processes. Health care staff should consider that patients who are properly informed about their medical care can provide an important “safety check” against error.

Patient-Centered Practice

Central to patient safety culture is placing the patients at the center of care. Here are several ways that patient-centered practice can be implemented in correctional settings:

- Patients participate in health care planning. Inmates are informed about the treatments prescribed for them and the consequences of refusing the treatment.
- The correctional environment is adjusted for identified special needs.
- Patients are notified of test results within a defined time period.
- Advance directives are available.

Just Culture

Just culture is a system of error evaluation that attempts to distinguish between acceptable and unacceptable behavior in the workplace. It uses a systems approach to determine how a health care unit’s systems and procedures may have contributed to an error rather than just seeking to assign blame. Just culture is, however, a nonpunitive or blame-free system—errors and mistakes are evaluated in a manner that identifies contributing factors first and then identifies accountability in relation to actions. It uses a stepwise system to evaluate four behaviors:

- Human error vs. misconduct: Was the error deliberate? Was there substance use involved; was the substance prescribed or an abused substance?
- Negligence: Were there acts of omission or commission that violated the standard of care?
- Intentional rules violations: Were procedures available, correct and workable? Did the staff member receive proper training? Is there evidence of work-arounds or policies routinely not followed?
- Reckless conduct: Does the staff member have a history of unsafe acts?

How Do We Get There?

Assess your staff, look at your present culture. Does your staff think that their patients receive safe care? Are staff members supportive of each other, or does lateral violence exist? Do they think that other staff (health care and/or security) “has their backs”? Unit staff can be assessed using tools developed specifically for assessing patient safety, or the assessment can be as simple as interviewing staff members individually about their perceptions of patient safety.

Open Communication

Staff members have an absolute responsibility to clearly point out actual and potential safety problems. One approach involves the use of standardized/structured communication techniques:

- Read-backs: whenever telephone or verbal patient orders are used
- Structured shift reports: to ensure all needed information is given
- Standardized language: use of an approved list of abbreviations, symbols and acronyms
- Structured communication: use of techniques like SBAR (situation, background, assessment, recommendation)

continued on page 10
(continued from page 9)

For Further Reading

Prison-Specific Patient Safety Standards

Just Culture

Staff Competency
Correctional health care is a specialty with specific duties and procedures not commonly practiced in other medical settings. Staff must be trained for their new responsibilities and evaluated for competence before they are permitted to function independently, and regularly thereafter.

Again, design and use checklists and protocols to decrease the reliance on memory. Anticipate errors and be ready to track them. Plan and execute drills for staff to participate in scenarios that prepare them to respond to real incidents. Look for error-prone practices and intervene to prevent them. Keep the pharmacy and other entities involved as providers of education and part of the multidisciplinary health team. Encourage staff to participate in continuing education and encourage professionalism through attainment of certification.

Medication Management
Since medication errors are known to be a significant factor in patient morbidity and mortality, medication management procedures are of particular importance. Medication management starts at admission into the system; a complete and accurate medication history is needed on all inmates and needs to be available to all professional staff providing care for inmates. Safe medication handling procedures are also important and should include the following:
- Observe state mandates about medication dispensing and administration.
- Follow the “8 rights”: The “5 rights” of medication administration have been expanded and now include right documentation, right reason and right response.
- Identify “look-alike, sound-alike” situations with medications and patients.
- Properly label medications, containers, medication administration records, etc.
- Provide access to medication reference resources: allergy information, up-to-date medication information—whatever will ensure that health care staff can get information quickly and easily.

Unit Design
Patient safety culture in health care units very much relies on the design of the unit itself. User-centered designs create systems that make it easier to do the right thing and difficult (or impossible) to do the wrong thing. Some of these designs rely on technology and have a cost, but some could be implemented at low or no cost.
- Increased visibility: Clearly written directions on equipment (e.g., AED design)
- Simplified processes to minimize problem-solving
- Standardized room setups
- Creation of “quiet zones”
- Use of protocols and checklists to serve as reminders of steps to be followed

Finally, remember that staffing patterns, such as mandatory overtime, rapid staff turnover, frequent use of agency staff and even shift work, can compromise patient safety. Conditions that lead to staff fatigue and burnout need to be monitored and corrected because they are a known source of error. The health unit’s staffing plan needs to be adequate for the facility needs.

Patient Safety: A Right and an Obligation
The Institute of Medicine has declared that patient safety is the right of all patients and the obligation of all health care staff. In corrections, we have the additional challenges of providing health services to patients who may demonstrate hostility and where health care needs may need to be balanced against legitimate security concerns. However, it remains unacceptable for inmate-patients to be harmed by medical errors and mistakes. Perhaps it would help if it were fully recognized that staff safety is tied to patient safety; that efforts invested in patient safety measures will result in lower health care costs, improved patient outcomes and an environment in which staff feel safe.

Sue Smith, MSN, RN, CCHP-RN, is a correctional nurse educator based in Ohio. Carol E. Smith, MSN, BC, CCHP, is quality assurance coordinator at Ohio State Penitentiary – Youngstown.
Sunovion Pharmaceuticals Inc. is dedicated to developing new treatment options for patients and their families living with mental illness.
Part One of this article appeared in the Summer 2013 issue and discussed best practices in nursing sick call.

**Case Study**

A 46-year-old state prisoner is involved in an altercation with other inmates and is immediately taken to the nurse to assess his injuries.

She documents using a preprinted form that allows her to clearly outline and describe all injuries to the patient. They are all superficial and cleansed and dressed.

She notes that his gait is normal and that he denies any pain, and documents his statement, “I just want to go back to my unit.”

No follow-up care is ordered and the patient is advised to return to care, if necessary.

One week later, the same patient walks up to the pill-call window and demands to see a physician for the injuries he sustained a week ago in a fight. He is angry and abusive, and states that he wasn’t given anything for pain or any X-rays to determine if anything was broken. The nurse schedules him for physician sick call the next week, but does not write a progress note.

The physician sees the patient one week later and orders an X-ray of the knee, which shows a bipartite patella with mild arthritis. An MRI later shows an ACL tear of unknown age. Over the next year the patient is seen multiple times by orthopedics and eventually has a surgical ACL repair with full recovery.

The issues that ultimately resulted in this settlement came down to documentation, both good and bad. This actual case was settled out of court for $1,500.

Although this settlement to the prisoner was small in comparison to many we read about in the media, this settlement is only a small fraction of the costs associated with defending the case; attorney fees, expert witnesses, depositions and the entire discovery process. The issues that resulted in this settlement were the following:

- **Documentation:** The physician failed to document anything about the patient’s gait, pain, or any injuries. The nurse failed to document the patient’s statement and that no follow-up care was ordered.
- **Communication:** The patient failed to communicate his pain and injuries to the nurse at the pill-call window.
- **Follow-up Care:** The nurse failed to follow up with the patient and order any X-rays or other tests to determine if anything was broken.

The nurse was not prepared to refer the patient to an advanced level of care. The physician was not prepared to refer the patient to an advanced level of care.

**Diagnostic Errors**

Diagnostic errors are, of course, errors in determining what the patient’s problem is. One way to classify them is as Type 1 or Type 2 errors; these are just statistical terms applied to the diagnostic process.

Type 1 errors are those where the practitioner decides there is a problem when, actually, there is no problem—the old “better to be safe than sorry” approach.

Type 2 errors are those where the practitioner decides there is no problem when, in fact, there is. Needless to say, these are the most dangerous kind of errors because a missed diagnosis can have lethal consequences. Common causes of type 2 errors include the following:

- **Trivializing patient complaints:** This patient (or group of patients) is never truthful and their complaints can always be discounted because they give the wrong information on purpose. As discussed previously, this is a dangerous game to play.
- **Tunnel vision:** Experience is a wonderful thing, but experience can lead us to using some mental “shorthand,” looking for certain visual or physical cues to a diagnosis or making the signs and symptoms “fit” a selected protocol. An example of this is the overweight male with a big belly who is demonstrating pallor and diaphoresis and holding a fist to his chest versus a small person with a trim or athletic build giving atypical symptoms. Both may be having a myocardial infarction, but some very good ER physicians have missed this diagnosis by having tunnel vision.

The way to prevent both types of diagnostic errors is...
the same: Always start from square one with every patient encounter. Try to clear your mind of preconceived ideas and biases—even if you have seen this patient many times for similar complaints that lacked objective physical support—and always do a thorough assessment that includes a worst-case scenario.

**Failure to ‘Connect the Dots’**

“Connecting the dots” refers to taking the various pieces of assessment data gathered in the subjective and objective assessments and putting them together, sorting and analyzing them to come up with the appropriate nursing diagnosis and subsequent treatment plan. It is like a jigsaw puzzle: Put together properly, all of the pieces fit and the picture is clear and makes sense; but put together wrong, the picture makes no sense at all.

Failing to connect the dots in patient encounters is troubling because it points to lapses in nursing judgment. One possible cause for this is inadequate training. The need for adequate training in NSC procedures was discussed in Part One of this article. Nurses in mainstream nursing jobs are generally not accustomed to the very independent nature of NSC practice and need training in how to use and implement nursing protocols, how to conduct an efficient NSC patient assessment and, often, additional training in the more advanced subjective/objective assessment techniques used in NSC. Nurses who are inadequately trained may not put the puzzle together properly, are often are reluctant to carry out protocol provisions, may conduct inadequate assessments and burn out quickly.

Additionally, not all nurses are created equally with respect to critical thinking and clinical decision-making—some nurses just struggle with the type of clinical decision-making required of nurses in NSC.

**Legal Pitfalls**

Remember that most claims or lawsuits will come years after you see the patient. Your memory of the event or encounter will never be as clear as the thorough documentation you make as close as possible to the time you see each patient. You might even find that you have absolutely no recollection of the patient, so your written note will be your only defense when you have to explain what happened. Be clear and concise in your documentation and remember to carefully document what your patients tell you about their condition, in their own words if possible.

In our case study, the first nurse who saw this patient did an excellent job recording her findings, both subjective and objective. Her clear description of his many superficial injuries accompanied by her notation of his desire to return to his housing unit as his only complaint helped to refresh her recollection of this encounter. Although many years had passed, she was able to review her note and based on that, and her usual practice for providing care to patients, she was able to clearly describe in deposition testimony the events surrounding the treatment she provided.

The second nurse in our case had some challenges. Due, in part, to the situation of the patient consultation at the pill-call window, she did not document anything about her encounter with this patient, and later (many years later) testified in deposition that she recalled this patient and remembered he did not show any sign of having difficulty walking or any pain. Not only was her testimony suspect in its credibility, but she also had trouble convincingly describing her encounter when asked on multiple occasions what she remembered from the pill-call window discussion. She also had difficulty explaining why she documented nothing in the chart when the facility’s policy and procedure required it.

If you find that you need to make a late entry in the medical chart, make sure you do so as soon as possible. Specific policies and procedures should guide clinical care providers on how to correctly make a late entry in the health record. The author should document within the entry that it is a late entry.

Addressing an issue quickly with an over-the-counter medication might seem the best solution for the patient, but if it is not within your scope of practice, do not do it! Too many nurses have learned the hard way this very important lesson. Please call the on-call physician when these situations occur; do not take this risk upon yourself or jeopardize the health of your patient. Be sure to research the scope of practice for your license in your state. Not all nursing boards are the same.

Protocols can change often and our memories might not fully recall the steps and interventions. It is OK to look things up if you are not absolutely sure. Many facilities have printed protocol manuals in every nursing clinic or online access for the most up-to-date versions. Use the resources at your facility, or insist that they be available. There are too many depositions where the nurse explained that the protocol manuals were locked in the supervisor’s office when she was treating a patient.

Other problems include inadequate assessment, skipping steps and scanty documentation in the health record. If the protocol requires you to collect certain data before providing an intervention, make sure you collect all of the data and thoroughly document your findings. It is difficult to explain at a deposition or in trial why you did not follow the protocol and made a decision without the required assessment.

Finally, you have to address issues with nursing competence in a timely manner. Work closely with your nursing supervisors and physicians to identify when improper use of protocol occurs, and address these with focused training and reinforcement. If the problems do not resolve with training, additional measures might be necessary.

**Key Takeaway Points**

Since nursing sick call is a primary means of access to health care for the inmate population, we must be sure that it is

*continued on page 25*
The Current State of HIPAA in Corrections

by Deana Johnson, JD

When the Health Insurance Portability and Accountability Act was enacted in 1996, one aim was to standardize a set of privacy rules to apply to all patients’ protected health information. However, for many of us working in correctional health care, HIPAA’s applicability is still far from clear even now, 17 years later.

One main reason for this confusion is the varying positions taken by the government in applying HIPAA to corrections. The U.S. Department of Health and Human Services, the government department charged with interpreting and regulating HIPAA, has taken inconsistent positions on the issue over time.

A second major source of confusion lies in the application of HIPAA’s electronic transmission provision to correctional institutions. Not only does the application seem counterintuitive, but the result is that HIPAA applies to some correctional systems and not others. It all depends on whether the system electronically transmits certain specific types of data, explored in detail below.

History of HIPAA

HHS was charged with creating standards for the privacy of medical information. In doing so, HHS released several versions over time. The competing versions of the regulations generated misunderstanding among many correctional officials and medical providers alike.

The original draft regulations, issued in 1999, specifically provided that inmates’ health information was not protected under HIPAA. Many people continue to operate under the misunderstanding that this original interpretation is still in place. It is not.

HHS later revised this aspect of the regulations and found that “individually identifiable health information about inmates is protected health information under the final rule.” As such, certain correctional institutions have been required to comply with HIPAA since April 2003. So why, almost a decade later, is it still unclear which information is protected and which correctional institutions are impacted?

The Text of HIPAA Does Not Easily Translate for Correctional Institutions

To determine whether HIPAA applies to corrections, the natural starting point is the statute itself. HIPAA applies to covered entities, which are defined as (1) health plans, (2) health care clearinghouses and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards.

HHS has determined that correctional institutions are not health plans or health care clearinghouses. What about the last choice? HHS now classifies correctional institutions as health care providers. So the remaining question is whether your institution electronically transmits health information for one of the specific transactions regulated by HHS.

Of course, most electronic transmission of health information concerns billing and payment for services or a determination of insurance coverage and rates: for example, hospitals sending patient information in order to be paid by Medicaid or private insurance. However, the electronic transmission provision is broader than that.

There are eight standard electronic transactions regulated by HHS. Although a correctional institution is unlikely to engage in many of these, the three that could apply are (1) transmission of encounter information for the purpose of reporting health care, (2) requests for the review of health care in order to secure an authorization for the health care and (3) payment of health care claims from a private/public health plan. It is important to note that contracting out the transmission of this information, the provision of health care or both to private entities does not exempt the correctional institution from HIPAA.

So what are the most likely scenarios that would fall under these three types of electronic transmissions? One of the most common is sending patient information to request approval for a nonformulary medication or a nonstandard procedure. If your institution electronically sends these requests to the person or oversight committee with authority to approve the request, it just became a covered entity under HIPAA. Another example would be electronically transmitting health information for purposes of conducting quality control, audits or other oversight activities. Less likely in the correctional environment is seeking payment of claims from private health insurance, but it does occur in some systems and, when the expansion of Medicaid under the new health care law goes into effect, even more inmates will have inpatient hospital care covered by public insurance, necessitating this type of electronic communication.

So If HIPAA Does Apply, What Are the Obligations of Your Institution?

For the average covered entity, HIPAA requires:

- Notifying patients about their privacy rights and how their information can be used
- Adopting and implementing privacy procedures
- Training employees so that they understand the privacy procedures
- Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed
- Securing patient records containing individually identifiable health information so that they are not readily available to those who do not need them

In creating its privacy rules, HHS recognized that corrections

continued on page 25
Beyond a reasonable doubt...

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Critical Commandments in Correctional Health Care (Part 3)

by Todd Wilcox, MD, MBA, CCHP-A

Correctional systems are rife with difficult institutional problems that impact health care services. To help correctional medical directors and administrators deal with these problems, Todd Wilcox, MD, MPH, CCHP-A, has prepared a list of “critical commandments.” The aim is to identify potential areas of risk that are frequently part of litigation and to offer long-term strategies to address these problem areas. This three-part series presents these commandments, some of which are relevant mainly to jail settings, along with a brief discussion of each.

Thou Shalt Scrutinize All Documentation Practices
Review of documentation practices looks at sick-call requests, completeness of lab reports and X-ray reports, handling of verbal orders and integration of data based on the treatment plan. With regard to diagnostic studies, look at time lines, policy and procedure for critical values and the process for nursing-derived diagnostic data (blood sugar checks, blood pressure checks, withdrawal scores, etc.).

Thou Shalt Establish Good Wound Care Education and Modern Practices
Wound care policy must address scope of licensure concerns, documentation of contemporary wound care practices by all staff and appropriate follow-up for wound management. All splints, casts, dressings, bandages and the like should be removed for assessment and care. Wound types include chronic, ischemic and colonized, and there are many possible wound care solutions and dressings, including vacuum-assisted closure. Note that wet-to-dry is not a universal dressing.

Thou Shalt Review and Practice Medical Emergency Response
Nurses must be trained in how to respond to emergencies. The facility should have the equipment necessary to respond appropriately. Specific documentation is necessary to respond to and record an emergency. Restocking and refreshing emergency supplies is critical. Staff need to be taught how to prepare patients for transport.

Thou Shalt Develop a Special Needs Plan and Communication Strategy
It is essential to have a reliable method for clinical staff to communicate to custody staff. This requires that all custody staff have access to this communication. As always, confidentiality of patient information must be maintained.

Thou Shalt Develop An Excited Delirium Policy and Procedure
Excited delirium is a medical emergency masquerading as a custody problem. Improper response has led to death and litigation. It is incumbent upon medical to develop institutional policies and procedures for dealing with this syndrome. Rapid capture and treatment of the inmate is critical, so this is the only time to move straight to the top of the use-of-force continuum. To improve the chances of survival, it is critical to send these patients to the ER.

Thou Shalt Develop a Follow-Up Plan for Less-Than-Lethal Force Evaluations
Health services needs to develop a method to assess patients for complications of less-than-lethal force. This plan also involves decontamination methods, including for pepper spray, and wound assessment and complications.

Thou Shalt Deal With Pain in a Reasonable, Modern Way
Good faith management of pain requires a good history and an excellent physical exam. The Joint Commission standards for pain management may be useful. The “no opiates in custody” policy is unreasonable and out of sync with current medical standards of care. It is important to distinguish between addiction and pseudoaddiction. Acute pain management may involve Tylenol, nonsteroidal agents and short-acting opiates such as Lortab. For chronic pain management, methadone is the preferred opiate for these syndromes; short-acting opiates are inappropriate.

Thou Shalt Develop Infectious Disease Protocols Before You Need Them
Infectious disease protocols should address tuberculosis, methicillin-resistant Staph aureus, chickenpox, influenza, scabies, lice and foodborne illnesses such as E. coli.

Thou Shalt Develop Chronic Care Clinics and Treatment Pathways
Chronic conditions to address include diabetes, hypertension, seizure disorders, metabolic syndrome, anticoagulation needs, pregnancy and women’s issues. This category also includes infectious disease issues and mental illnesses such as schizophrenia and bipolar disorder.

Thou Shalt Associate With Advocacy Groups
Community advocacy groups such as the American Civil Liberties Union, the National Alliance on Mental Illness, disability groups and others can cause a lot of problems for correctional facilities. They are mandated to try to resolve issues using all nonlitigative techniques first. So meet with them, develop collaborative relationships and open the channels of communication.

Todd Wilcox, MD, MBA, CCHP-A, is the medical director for the Salt Lake County (UT) Jail System and a frequent speaker at NCCHC educational conferences.
Correctional mental health professionals face unique challenges. They must provide effective, efficient care to a high-acuity population while facing strict security regulations, crowded facilities and myriad legal and public health concerns. Specialty certification recognizes dedication to quality service delivery. Eligibility is extended to qualified mental health professionals as defined by NCCHC’s Standards for Mental Health Services.

CCHP-MH Correctional mental health professionals face unique challenges. They must provide effective, efficient care to a high-acuity population while facing strict security regulations, crowded facilities and myriad legal and public health concerns. Specialty certification recognizes dedication to quality service delivery. Eligibility is extended to qualified mental health professionals as defined by NCCHC’s Standards for Mental Health Services.

CCHP-RN Specialty certification makes a difference—to the patients whose care is provided by certified correctional nurses, to employers who desire top-notch nurses on staff and to the nurses who attain the credential. CCHP-RN certification recognizes registered nurses who have demonstrated the ability to deliver specialized nursing care in correctional settings.

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*Undetectable HIV-1 RNA (<50 copies/mL):
- Study 730: At 48 weeks, 77% of ARV-naïve patients (n=664)†
- Study 802: At 48 weeks, 54% of ARV-experienced patients (n=599)‡
- Study 720: At 7 years, 59% of ARV-naïve patients (n=100)§

Some patients have discontinued clinical trials due to adverse events or inadequate viral suppression.

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Models for illustrative purposes only.
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 years and older). The following points 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.

Resistance/Cross-resistance

HIV cross-resistance among protease inhibitors has not been fully explored in KALETRA-treated patients; it is unknown what effect 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 overdose. The appropriate dose must be carefully calculated for each pediatric patient, based on the body weight or body surface area recommendations 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, the most common adverse reactions reported in >5% of adult patients were diarrhea, nausea, abdominal pain, asthenia, vomiting, headache, and dyspepsia. In children receiving KALETRA oral solution, the most common adverse reactions were taste aversion, vomiting, and diarrhea.

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Please see Brief Summary of Prescribing Information on the following pages.
Drug Interactions - CYP3A Enzyme Inhibition

WARNINGS AND PRECAUTIONS

Drug Interactions - CYP3A Enzyme Inhibition

KALETRA® (lopinavir/ritonavir tablet, film coated) (lopinavir/ritonavir oral solution)

INDICATIONS AND USAGE

KALETRA® is a CYP3A-inhibitor. Initiation treatment with KALETRA in patients receiving medications metabolized by CYP3A or including medications metabolized by CYP3A in patients already maintained on KALETRA® may result in increased plasma concentrations of concurrent medications. Higher plasma concentrations of concurrent medications can result in increased or prolonged therapeutic or adverse effects, potentially leading to signs, life-threatening effects or fatalities. The potential for drug-drug interactions must be considered prior to and during therapy with KALETRA. Review of other medications taken by patients and medications. Higher plasma concentrations of concomitant medications metabolized by CYP3A may result in increased plasma concentrations of concomitant medications in patients already maintained on KALETRA® (see Drug Interactions).

Toxicity in Preterm Neonates

KALETRA® is contraindicated in patients sensitive to any excipients (42% w/v) and propylene glycol (15.2% w/v). When administered concomitantly with propylene glycol, ethylene glycol competitively inhibits the metabolism of propylene glycol, which may lead to metabolized by patients who are already maintained on KALETRA® may result in increased plasma concentrations of concurrent medications. Higher plasma concentrations of concurrent medications can result in increased or prolonged therapeutic or adverse effects, potentially leading to signs, life-threatening effects or fatalities. The potential for drug-drug interactions must be considered prior to and during therapy with KALETRA. Review of other medications taken by patients and medications. Higher plasma concentrations of concomitant medications metabolized by CYP3A may result in increased plasma concentrations of concomitant medications in patients already maintained on KALETRA® (see Drug Interactions).

Table 1. Drugs That are Contraindicated with KALETRA®

Table 2. Percentage of Adult Patients with Selected Treatment-Related Adverse Events as Compared to Placebo

Lipid Elevations

Treatment with KALETRA has resulted in large increases in the concentration of total cholesterol and triglycerides (see Adverse Reactions). Triglyceride and cholesterol testing should be performed prior to initiating KALETRA® therapy and at periodic intervals during therapy. Lipid disorders should be managed as clinically appropriate, taking into account any potential drug-drug interactions with KALETRA® and HIV-2COA Inducers (see Contraindications and Drug Interactions).

Fat Redistribution

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

Patients with Hemophilia

Increased bleeding, including spontaneous skin hematomas and hemorrhage have been reported in patients with hemophilia type A and B treated with protease inhibitors. In some patients additional factor VIII was given. In more than half of the reported cases, treatment with protease inhibitors was continued or reintroduced. A causal relationship between protease inhibitor therapy and these events has not been established.

Resistance/Cross-resistance

Because the potential for HIV 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 subtherapeutically administered protease inhibitors.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Hepatitis B virus reactivation
- Immune reconstitution syndrome
- Lactic acidosis and severe hepatomegaly with steatosis
- Progressive multifocal leukoencephalopathy
- Hematological abnormalities
- Drug-induced lupus erythematosus
- Hypogonadism
- Pancreatitis
- Hypersensitivity reactions
- Rhabdomyolysis
- Methemoglobinemia
- Autoimmune disorders
- Guillain-Barré syndrome
- Eosinophilia
- Hypoglycemia
- Transaminase elevations
- Myopathy
- Diabetes Mellitus/Hyperglycemia
- Pancreatitis
- Steatorrhea
- Abnormal liver function tests
- Autonomic nervous system disorders
- Nephrotic syndrome
- Interstitial nephritis
- Cytomegalovirus infection
- Mycobacterium avium infection, cytomegalovirus, Pneumocystis jirovecii pneumonia (PCP), or tuberculosis which may require further evaluation and treatment.

Table 1. Drugs That are Contraindicated with KALETRA®

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Hepatitis B virus reactivation
- Immune reconstitution syndrome
- Lactic acidosis and severe hepatomegaly with steatosis
- Progressive multifocal leukoencephalopathy
- Hematological abnormalities
- Drug-induced lupus erythematosus
- Hypogonadism
- Pancreatitis
- Hypersensitivity reactions
- Rhabdomyolysis
- Methemoglobinemia
- Autoimmune disorders
- Guillain-Barré syndrome
- Eosinophilia
- Hypoglycemia
- Transaminase elevations
- Myopathy
- Diabetes Mellitus/Hyperglycemia
- Pancreatitis
- Steatorrhea
- Abnormal liver function tests
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- Mycobacterium avium infection, cytomegalovirus, Pneumocystis jirovecii pneumonia (PCP), or tuberculosis which may require further evaluation and treatment.

Table 2. Percentage of Adult Patients with Selected Treatment-Related Adverse Events as Compared to Placebo

See Drug Interactions, Table 7 for co-administration of sildenafil in patients with erectile dysfunction. See Drug Interactions, Table 7 for parenterally administered midazolam.
Table 2.

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</table>
pancreatitis, vomiting, alanine aminotransferase increased, dry skin, common adverse reactions of any severity reported in pediatric patients

Dysgeusia (22%), vomiting (21%), and diarrhea (12%) were the most common adverse reactions in 31 pediatric patients 14 days to 6 months of age. The adverse reaction had additional predisposing conditions such as electrolyte abnormalities, pre-existing cardiac abnormalities.

KALETRA oral solution dosed up to 300/75 mg/m² has been studied in combination with drugs highly dependent on CYP3A for clearance and for which elevated 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 7.

Table 7. Established and Other Potentially Significant Drug Interactions

<table>
<thead>
<tr>
<th>Concomitant Drug Class</th>
<th>Drug Name</th>
<th>Effect on Concentration of Lopinavir or Concomitant Drug</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 Inhibitor Inactivator</td>
<td>nelfinavir</td>
<td>↓</td>
<td>Increase in lopinavir concentration; reduction in nelfinavir concentration.</td>
</tr>
<tr>
<td>HIV-1 Inhibitor Inactivator</td>
<td>indinavir</td>
<td>↓</td>
<td>Increase in lopinavir concentration; reduction in indinavir concentration.</td>
</tr>
<tr>
<td>HIV-1 Protease Inhibitor</td>
<td>fosamprenavir/ ritonavir</td>
<td>↑</td>
<td>↑ in fosamprenavir; ↓ in ritonavir.</td>
</tr>
<tr>
<td>HIV-1 Protease Inhibitor</td>
<td>nelfinavir</td>
<td>↓</td>
<td>↓ in lopinavir.</td>
</tr>
<tr>
<td>HIV-1 Protease Inhibitor</td>
<td>indinavir</td>
<td>↓</td>
<td>↓ in lopinavir.</td>
</tr>
<tr>
<td>HIV-1 Protease Inhibitor</td>
<td>saquinavir</td>
<td>↑</td>
<td>↑ in ritonavir.</td>
</tr>
</tbody>
</table>

Drug Interactions

Table 7 provides a listing of established or potentially clinically significant drug interactions. Alteration in dose or regimen may be recommended based on drug interaction studies or predicted interaction.

KALETRA tablets 400/100 mg twice daily should not be administered with rifapentine or rifampin. KALETRA tablets to 500/125 mg twice daily may reduce rifapentine plasma concentrations compared to KALETRA tablets 400/100 mg twice daily without rifapentine. KALETRA tablets should not be administered once daily in combination with rifapentine or rifampin.

KALETRA tablets 400/100 mg twice daily may not be adequately inhibited by KALETRA tablets 400/100 mg twice daily co-administered with efavirenz. KALETRA and efavirenz should be co-administered with KALETRA tablets 600/150 mg twice daily.

KALETRA tablets 400/100 mg twice daily may increase plasma levels of maraviroc. KALETRA tablets 400/100 mg twice daily should not be co-administered with maraviroc.

KALETRA tablets 400/100 mg twice daily may decrease plasma levels of maraviroc. KALETRA tablets 400/100 mg twice daily should not be co-administered with maraviroc.

KALETRA tablets 400/100 mg twice daily may increase plasma levels of nelfinavir. KALETRA tablets 400/100 mg twice daily should not be co-administered with nelfinavir.

KALETRA tablets 400/100 mg twice daily may reduce plasma levels of ritonavir. KALETRA tablets 400/100 mg twice daily should not be co-administered with ritonavir.

KALETRA tablets 400/100 mg twice daily may increase plasma levels of tipranavir. KALETRA tablets 400/100 mg twice daily should not be co-administered with tipranavir.
### Table 7.

**Anticancer Agents:**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Concomitant Drug</th>
<th>Effect on Concentration of Anticancer Agents</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>dasatinib, vinblastine, vincristine</td>
<td>Lopinavir or ritonavir</td>
<td><strong>↓</strong></td>
<td>The concentration of antineoplastic agents is decreased when co-administered with Lopinavir or ritonavir. This effect should be considered.</td>
</tr>
<tr>
<td>rivaroxaban warfarin</td>
<td></td>
<td><strong>↑</strong></td>
<td>The clinical significance of this interaction is unknown. Additional clinical studies are warranted.</td>
</tr>
</tbody>
</table>

**Clinical Comments:**

- **Antifungals:**
  - Ketoconazole (may be given as 0.3 mg twice a day)
  - Voriconazole: patients on KALETRA:
    - Followed by 0.3 mg (half a tablet) once a day.
    - The regimen should be adjusted to 0.3 mg once a day.

- **Anticonvulsants:**
  - Lamotrigine or valproate may cause decreases in hepatic metabolism. A dose increase of lamotrigine or valproate may be needed when co-administered with KALETRA and therapeutic concentration monitoring for lamotrigine may be indicated particularly during dosage adjustments.

- **Antidepressants:**
  - Trazodone: co-administration of trazodone and ritonavir has not been studied. However, co-administration may result in decreased voriconazole concentrations and the potential for decreased voriconazole effectiveness should be considered. Additional clinical studies are warranted.

- **Anticoagulants:**
  - Rivaroxaban: rivaroxaban and KALETRA do not alter the international normalized ratio (INR) while combining KALETRA with rivaroxaban.

- **Antimycobacterial:**
  - Itraconazole: KALETRA contains two CYP3A4 inhibitors (ritonavir and saquinavir) which may lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co-administered antiretroviral agents. A study evaluated combination of rifampin 600 mg once daily, with KALETRA 800/200 mg twice daily or KALETRA 400/200 mg + ritonavir 300 mg twice daily. Pharmacokinetic and safety results from this study do not allow for a dose recommendation. Additional clinical studies are warranted.

- **Benzodiazepines:**
  - Because contraceptive efficacy may be altered when KALETRA is co-administered with oral contraceptives or with the contraceptive patch, the contraceptive patch, oral contraceptives or with the contraceptive patch, the contraceptive should be considered in these patients.

- **Corticosteroids:**
  - Prednisone, dexamethasone, e.g. budesonide, considered in these patients.
  - The contraceptive patch, oral contraceptives or with the contraceptive patch, the contraceptive patch should be considered.

- **Dihydropyridine calcium channel blockers:**
  - Omeprazole: the interaction has not been studied. However, co-administration may result in decreased voriconazole concentrations and the potential for decreased voriconazole effectiveness should be considered. Additional clinical studies are warranted.

- **Dipyridamole, metformin:**
  - KALETRA contains two CYP3A4 inhibitors (ritonavir and saquinavir) which may lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co-administered antiretroviral agents. A study evaluated combination of rifampin 600 mg once daily, with KALETRA 800/200 mg twice daily or KALETRA 400/200 mg + ritonavir 300 mg twice daily. Pharmacokinetic and safety results from this study do not allow for a dose recommendation. Additional clinical studies are warranted.

- **Other Agents:**
  - Clarithromycin: co-administration of clarithromycin and KALETRA is not recommended.

### Table 8.

**Anticoagulants:**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Concomitant Drug</th>
<th>Effect on Concentration of Anticoagulants</th>
<th>Clinical Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>rivaroxaban</td>
<td></td>
<td><strong>↑</strong></td>
<td>The concentration of anticoagulant agents is increased when co-administered with KALETRA.</td>
</tr>
<tr>
<td>warfarin</td>
<td></td>
<td><strong>↑</strong></td>
<td>The concentration of anticoagulant agents is increased when co-administered with KALETRA.</td>
</tr>
</tbody>
</table>

**Clinical Comments:**

- **Antifungals:**
  - Voriconazole: patients on KALETRA:
    - Followed by 0.3 mg (half a tablet) once a day.
    - The regimen should be adjusted to 0.3 mg once a day.

- **Anticonvulsants:**
  - Lamotrigine or valproate may cause decreases in hepatic metabolism. A dose increase of lamotrigine or valproate may be needed when co-administered with KALETRA and therapeutic concentration monitoring for lamotrigine may be indicated particularly during dosage adjustments.

- **Antidepressants:**
  - Trazodone: co-administration of trazodone and ritonavir has not been studied. However, co-administration may result in decreased voriconazole concentrations and the potential for decreased voriconazole effectiveness should be considered. Additional clinical studies are warranted.

- **Anticoagulants:**
  - Rivaroxaban: rivaroxaban and KALETRA do not alter the international normalized ratio (INR) while combining KALETRA with rivaroxaban.

- **Antimycobacterial:**
  - Itraconazole: KALETRA contains two CYP3A4 inhibitors (ritonavir and saquinavir) which may lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co-administered antiretroviral agents. A study evaluated combination of rifampin 600 mg once daily, with KALETRA 800/200 mg twice daily or KALETRA 400/200 mg + ritonavir 300 mg twice daily. Pharmacokinetic and safety results from this study do not allow for a dose recommendation. Additional clinical studies are warranted.

- **Benzodiazepines:**
  - Because contraceptive efficacy may be altered when KALETRA is co-administered with oral contraceptives or with the contraceptive patch, the contraceptive patch, oral contraceptives or with the contraceptive patch, the contraceptive patch should be considered in these patients.

- **Corticosteroids:**
  - Prednisone, dexamethasone, e.g. budesonide, considered in these patients.
  - The contraceptive patch, oral contraceptives or with the contraceptive patch, the contraceptive patch should be considered.

- **Dihydropyridine calcium channel blockers:**
  - Omeprazole: the interaction has not been studied. However, co-administration may result in decreased voriconazole concentrations and the potential for decreased voriconazole effectiveness should be considered. Additional clinical studies are warranted.

- **Dipyridamole, metformin:**
  - KALETRA contains two CYP3A4 inhibitors (ritonavir and saquinavir) which may lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co-administered antiretroviral agents. A study evaluated combination of rifampin 600 mg once daily, with KALETRA 800/200 mg twice daily or KALETRA 400/200 mg + ritonavir 300 mg twice daily. Pharmacokinetic and safety results from this study do not allow for a dose recommendation. Additional clinical studies are warranted.
Co-administration of bosentan with Kaletra is not recommended. Cases of severe hypotension have been reported in patients who have been receiving Kaletra for at least 10 days and who had not previously received bosentan at doses of 62.5 mg once daily or every other day based upon individual tolerability. Co-administration of Kaletra with bosentan is not recommended in patients in whom there is a history of hypotension at least 36 hours prior to initiation of Kaletra. After at least 10 days following the initiation of Kaletra, bosentan may be reinitiated at 62.5 mg once daily or every other day based upon individual tolerability.

Concomitant Drug

Intranasal sirolimus e.g. cyclosporine, glucocorticoids

↑ Lopinavir or ritonavir

↑ bosentan

↓ Concentration of lopinavir when used with Kaletra

↓ Concentration of bosentan when used with Kaletra

Use of PDE5 inhibitors is contraindicated.

Drugs with No Observed or Predicted Interactions with Kaletra

Narcotic Agonist: methadone

Avoid use of ADCIRCA during the first 24 hours of starting Kaletra. After at least one week following the initiation of Kaletra, use ADCIRCA at 20 mg once daily. Increase to 40 mg once daily based upon individual tolerability.

Concomitant use of ADCIRCA with Kaletra should be avoided.

Diuretics: furosemide, hydrochlorothiazide, indapamide

Long-acting beta-adrenoceptor antagonists (e.g. tamsulosin)

Drugs with No Observed or Predicted Interactions with Kaletra

Drug interaction or clinical studies reveal no clinically-significant interaction between Kaletra and dapagliflozin, diapizine, tirilazad, sulfasalazine, azathioprine, entecavir, or furosemide.

Use of PDE5 inhibitors is contraindicated.

Use of PDE5 inhibitors is contraindicated.

Use of PDE5 inhibitors is contraindicated.

Animal Data:

No treatment-related malformations were observed when lopinavir in combination with ritonavir was administered to rats. Embryonic and fetal developmental toxicities (early/late pregnancy death, decreased fetal viability, decreased fetal body weight gain, and litter size and maternal toxicity-based on AUC measurements. Based on AUC measurements, low dose of the ataxic doses were approximately 0.7 to 4-fold for lopinavir and 1.5 to 3-fold for ritonavir in the plasma and fetal tissues and for increases in the exposure in humans at the recommended therapeutic dose (400/100 mg twice daily). In a peri- and postnatal study in rats, a developmental toxicity is decrease in survival in pups between birth and postnatal day 21 occurred.

No embryonic and fetal developmental toxicities were observed in rats at a maternally toxic dosages. Based on AUC measurements, low dose of the ataxic doses were approximately 0.7 to 4-fold for lopinavir and 1.5 to 3-fold for ritonavir in the plasma and fetal tissues and for increases in the exposure in humans at the recommended therapeutic dose (400/100 mg twice daily). In a peri- and postnatal study in rats, a developmental toxicity is decrease in survival in pups between birth and postnatal day 21 occurred.

In the chronically treated young rat model, treatment-related histopathological changes were observed in the gastrointestinal tract of both lopinavir and ritonavir. No treatment-related malformations were observed when lopinavir in combination with ritonavir was administered to rats. Embryonic and fetal developmental toxicities (early/late pregnancy death, decreased fetal viability, decreased fetal body weight gain, and litter size and maternal toxicity-based on AUC measurements. Based on AUC measurements, low dose of the ataxic doses were approximately 0.7 to 4-fold for lopinavir and 1.5 to 3-fold for ritonavir in the plasma and fetal tissues and for increases in the exposure in humans at the recommended therapeutic dose (400/100 mg twice daily). In a peri- and postnatal study in rats, a developmental toxicity is decrease in survival in pups between birth and postnatal day 21 occurred.

In the chronically treated young rat model, treatment-related histopathological changes were observed in the gastrointestinal tract of both lopinavir and ritonavir.

The Centers for Disease Control and Prevention recommend that HIV-1 infected mothers not breastfeed their infants to avoid risking postnatal transmission. If HIV-1-infected women choose to breast-feed, they will need to undergo frequent monitoring of therapeutic and toxicological endpoints. If the infant has a severe primary immunodeficiency, it may be necessary to discontinue breastfeeding at an earlier age than is recommended for healthy infants. If the infant is not severely affected, breastfeeding should be continued until at least 6 months of age.

Breastfeeding is not recommended unless it is judged to be of potential benefit to the infant and the mother has concluded that she will not breastfeed. Healthcare providers should be alert to the potential for severe adverse reactions in nursing infants. Mothers should be instructed not to breastfeed if they are receiving Kaletra. Pediatric use of Kaletra was not studied in clinical trials in infants younger than 16 years of age. Safety and efficacy of Kaletra in children younger than 16 years of age have not been established. Treatment of overdose with Kaletra should consist of general supportive measures. In cases of overdose, where toxic exposure is confirmed or strongly suggested, priority should be given to specific therapeutic interventions as indicated. Overdoses with Kaletra oral solution have been reported. One of these reports described fatal cardiac arrest in a 2 1/2 year old infant who received a single dose of 6.5 of Kaletra oral solution (300 mg lopinavir, approximately 10-fold above the recommended lopinavir dose) nine days prior. The following events have been associated with overdose in patients with unintended overdoses in preterm neonates: complete All block, cardiomyopathy, ischemic acidosis, and acute renal failure (seeWARNINGS and PRECAUTIONS). Healthcare professionals should be aware that Kaletra oral solution is highly concentrated, and therefore should exercise special attention to accurate calculation of the dose of Kaletra, transcription of the medication order, dispensing information and dosing instructions. Kaletra should not be administered to patients receiving concomitantheated, renal, or cardiac function, and of concomitant disease or other drug therapy.

Hepatic Impairment

KALETRA is principally metabolized by the liver; therefore, caution should be exercised when administering this drug to patients with hepatic impairment, because lopinavir concentrations may be increased (see WARNINGS and PRECAUTIONS). A prospective multicenter, open-label trial evaluated the pharmacokinetic profile, tolerability, safety and efficacy of high-dose Kaletra with or without concurrent NRTI therapy Group 1 400/100 mg/m² twice daily (2+ 2 NRTIs, Group 2 480/120 mg/m² twice daily + 1 NRTI + 1 NNRTI) in 256 children and adolescents ≥ 2 years to < 18 years of age who had failed prior therapy. Patients also had saquinavir mexitil added to their regimen. This strategy was intended to assess whether higher than approved doses of Kaletra could overcome protease inhibitor cross-resistance. High doses of Kaletra exhibited a safety profile similar to those observed in previous trials; changes in HIV-1 RNA were less than anticipated, three patients had HIV RNA ≥ 4000 copies/ml at 48 weeks (see ADVERSE REACTIONS).

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, appropriate caution should be exercised in the administration and monitoring of Kaletra in elderly patients reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
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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.

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.

Drug Interactions

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, light-headedness, abnormal heart rhythm or loss of consciousness.

Patients should be advised that appropriate liver function testing will be conducted prior to initiating and during therapy with KALETRA.

Skin rashes ranging in severity from mild to toxic epidermal necrolysis (TEN) have been reported in patients receiving KALETRA or its components lopinavir 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.

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County Jail’s Restoration of Competency Program Saves Money, Improves Care

Lack of adequate mental health services in the community has led to high numbers of people with severe and persistent mental illness landing in county jails, which must assume the cost and services burden of managing these inmates. A related problem is the practice of jailing individuals with severe mental illness who are incompetent to stand trial for long periods because state hospital systems lack enough forensic beds. As Kevin Rice, LCSW, and Jerry Jennings, PhD, explain in their article in the latest issue of the Journal of Correctional Health Care, a jail-based restoration of competency model offers a cost-effective way to evaluate, treat and stabilize persons with severe mental illness when they are first arrested and detained, and restore them to competency in the jail setting. Their article describes the model as used in San Bernardino County, CA, and presents evaluation findings after 29 months of ROC program operation.

Inmates who meet the criteria for placement in the ROC program are restored to competency including deficit remediation and alleviation of acute symptoms. Besides enabling the patient to regain general thinking abilities, a second goal is to educate the patient in the court process so that he can cooperate in mounting a defense. Treatment combines the use of psychiatric medications, motivation to participate in rehabilitative activities and multimodal cognitive, social and physical activities that address competency in a holistic fashion. Involuntary medication is not used.

The interdisciplinary ROC treatment team includes a forensic psychiatrist, forensic psychologist, psychiatric nurse, social worker, rehabilitation therapist and clerk to coordinate scheduling, court dates, transports and forensic reports. The direct care staff are specially trained security officers who are trained in treatment functions.

Program Outcomes

Treatment services were provided to 192 incompetent-to-stand-trial patients in a jail setting. For the 168 patients who have reportable outcomes, the ROC restored competency for 55% in an average of 57 days compared to the state hospital average of 180 days. Findings varied by gender, with 88% of the females restored compared to 51% of the males and in a shorter average time (48.8 days compared to 59.2).

Although the 55% restoration rate may appear to be modest, the authors note that the program is based on the presumption that patients admitted to the ROC program could be restored within a 70-day time frame, and that those who require longer treatment will be transferred to a psychiatric hospital. This conserves the use of ROC beds for those who can be effectively treated and restored in a short-term setting.

The average cost of treatment/restoration per admission was $15,568 compared to the state hospital average of $81,000. A state agency report found a cost differential of $278 per day for a ROC bed compared to $450 per day for a state hospital bed, and a combined savings to the state and county of $1.4 million from the pilot project.

According to Rice and Jennings, the benefits of the ROC model are many. It accelerates needed treatment for mentally ill defendants, cuts demand for costly state hospital forensic beds and assists jails in better managing inmates with severe psychiatric disorders—yielding major cost savings and improved care. In addition to preventing readmissions and negative behavioral episodes, the ROC expanded the broader forensic system by eliminating the state hospital waiting list, accelerating access to psychiatric services, promoting local access for lawyers and family and gaining stakeholder satisfaction.
NCCHC Issues Guideline on Adolescent ADHD

When attention-deficit/hyperactivity disorder goes undetected or untreated among youth in detention, they are at greater risk of maladaptive behavior. NCCHC has issued a new guideline to help correctional clinicians care for youth with ADHD. Find the complete guideline online at www.ncchc.org/guidelines.

An evaluation for ADHD should be considered for any youth who has academic or behavioral problems along with symptoms of inattention, hyperactivity or impulsivity. The diagnosis should be guided by the new, fifth edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. ADHD criteria in the DSM-5 differ somewhat from the previous edition.

In addition to formal assessments, information should be gleaned from a variety of sources—past treatment providers, juvenile justice system staff, parents, etc.—and alternative causes of problem behaviors should be ruled out.

When a youth reports past diagnosis or treatment of ADHD upon intake, it is important to assess and verify this history. The treatment team should reassess the need for previously prescribed ADHD medications based on current symptoms, level of functioning and treatment needs.

Clinicians should follow the principles of the chronic care model. NCCHC recommends ongoing assessments of the severity of the disorder and response to treatment based on patient evaluation and validated questionnaires filled out by correctional and educational staff. When patient status is listed as worsened in the assessment, the treatment plan includes a strategy for improving the status. This may include reevaluation of the diagnosis, confirmation of medication compliance, clarification of side effects, change in medication dosing or schedule and behavioral strategies.

**Treatment Concerns**

Treatment of ADHD is complex. Medications should be used with caution and only after an intake history and physical and medical evaluation to rule out medical and cardiac contraindications and after reviewing the potential risks, benefits, side effects and alternatives with the youth and the youth’s parent or legal guardian.

If ADHD medications are used, they should be combined with behavioral approaches and education. Newly detained youth on one or more ADHD medications require careful assessment and monitoring, and attempts should be made to gradually reduce the need for multiple medications.

When conducting a behavioral assessment, it is important to understand that the youth is likely highly vulnerable to interactions and conflict in the unit, family communication, legal and disciplinary issues and other stressors. Behavioral management should be informed by an understanding of these vulnerabilities as well as the challenges that these youth are likely to face. Referral to mental health staff may be more appropriate than disciplinary action.

Postrelease planning should ensure that a provider is identified to continue medication treatment and that parents have resources and medical and/or mental health services to support ongoing care, supervision and follow-up.
CCHP Board of Trustees Welcomes Charles Lee

by Amy Graves

The CCHP board of trustees welcomes Charles Lee, MD, JD, CCHP, who was elected to the board this fall and will serve a three-year term. The board of trustees is charged with, among other things, developing policy, writing examination questions and analyzing exam results.

In addition to his MD, Lee also has law and business degrees, which are what first generated his interest in working in corrections. He had been working as a practicing physician for more than 30 years and as a medical director with a medical management company for two years when the office he worked in closed. He applied for a management position in the California Department of Corrections and Rehabilitation, recognizing that the job offered him “the opportunity to use all the knowledge, experience and education I possessed.”

Lee is now retired but worked as a health care manager for the CDCR at Salinas Valley State Prison from 2001 to 2010. In that position he supervised the medical department, which included medical, dental, mental health, pharmacy, medical records, nursing and administration.

Commitment and a Sense of Pride

Lee passed the CCHP exam in 2004. He wanted to become certified because it “shows my commitment to and knowledge of correctional health care. It gives me a sense of pride in the correctional community.” He is excited about his election to the board of trustees and looks forward to providing input into the CCHP program, helping to make “a good program better.”

A benefit of certification is that it enabled Lee to become a physician surveyor for NCCHC’s accreditation program. He enjoys being a surveyor because it has allowed him to travel to correctional facilities all over the country, to tour their medical facilities and to offer assistance to improve the health care of inmates.

Lee believes that the most challenging part of working in corrections is developing an understanding of inmates, of their needs, personalities and behavior. An understanding of these goes a long way in providing appropriate medical care, he says. Another big challenge is the restrictive environment of a correctional facility. To successfully treat inmates, Lee says, there must be friendly collaboration between medical and correctional staff, which can come only through understanding the role and purpose of correctional staff.

Despite these challenges, Lee also points to several great rewards of working in correctional settings. Foremost is the sense of accomplishment he feels when these challenges are met. He also says it is professionally satisfying to feel that one has been an instrumental part of providing compassionate medical care that not only meets constitutional requirements, but also sometimes surpasses community standards of care. A third great reward is interacting with the community of other correctional health care providers.

When he is not surveying or, now, working on CCHP board activities, Lee has many other interests to keep him busy. He is an avid collector, seeking out coins, American Brilliant period crystal, sterling silver, pocket watches, Navy clocks and artwork. He is also reconditioning a 1995 BMW.

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

**Society of Correctional Physicians**

SCP has named Michelle Staples-Horne, MD, MPH, CCHP, as the 2013 recipient of its Armond Start Award of Excellence. The award was established in 1997 in honor of one of SCP’s founding members and recognizes individuals who attain the high ideals that Start advocated for correctional medicine. The nomination for Staples-Horne says that for “nearly two decades, she has been a national leader in clinical care and public health for vulnerable youth who are involved in the legal system. She is an outstanding advocate of troubled youth who brings dignity to our field.”

Staples-Horne is medical director for the Georgia Department of Juvenile Justice, responsible for the provision of care to more than 2,000 youth in 28 secure long-term and short-term facilities. In her “off hours” she works in the Fulton County (GA) adolescent health clinic. She has provided correctional health care consultation and training for numerous agencies and organizations, including NCCHC, and participates in research aimed at expanding the evidence base for best practices. She has served four terms on the SCP board, including one as its president, and is a member of NCCHC’s juvenile health committee.

**American Public Health Association**

The APHA adopted 17 policy statements at its annual meeting in Boston on Nov. 5. Three of the statements deal with corrections or criminal justice issues.

- **Addressing solitary confinement as a public health issue**—Noting that solitary confinement of inmates can cause significant mental health problems and create barriers to needed health care, this policy urges correctional officials to discontinue solitary confinement as a punishment and to create alternatives for inmates with mental and chronic illness. It encourages officials to limit solitary confinement to the most extreme cases, with appropriate monitoring for health issues. It also calls for excluding all juveniles from solitary confinement.

- **Support for people released from jails, prisons**—This policy calls on the Department of Labor to support policies that offer stable housing for people reentering the community and that link them to primary care providers. It proposes policies that require stable housing and employment to avoid jail. It encourages an increase in incarceration alternatives for people with mental illness and substance use disorders.

- **Public health response to drug use**—Noting that substance use treatment is often inaccessible and unaffordable for those who need it, this policy recommends that federal officials and agencies convene stakeholders to review current drug policy and discuss the core components needed for a health-based drug policy. It encourages federal, state, and local policy makers to implement evidence-based prevention and intervention strategies, such as expanding access to treatment programs and redirecting resources from criminal justice programs to public health programs.

For brief descriptions of the statements, go to www.apha.org/advocacy/policy. Upon finalization, the full policy statements will be posted in early 2014.
Who Attended in 2013?
- Nurse: 35%
- Physician/physician assistant: 24%
- Psychiatrist/psychologist: 14%
- Administrator: 12%
- Social worker, therapist, counselor: 5%

Decision Makers With Authority
- State medical director: 7%
- Medical director, director of nursing, other directors: 13%
- Health services administrator: 17%
- Department manager/supervisor: 22%
- Health services, dental or mental health staff: 35%

Who Do Attendees Represent?
- Jail facility: 46%
- Prison facility: 16%
- Private corporation: 19%
- State DOC/agency: 10%
- Juvenile detention or confinement facility: 6%
- Federal agency: 3%

Categories Attendees Recommend or Buy
- Dental care and supplies
- Disaster planning
- Electronic health records
- Health care staffing
- Information technology
- Medical supplies
- Mental health services
- Pharmaceuticals
- Safety equipment
- Suicide prevention
- Telecommunications
- Transportation services
- Training
- Travel
- Uniforms

Exhibitor Benefits
- Three days of exhibit hall activities
- Two free full conference registrations per 8’ x 10’ booth
- Discounted full registration for up to 3 additional exhibit personnel (per company)
- Direct access to attendees for premium face time
- 50-word listing in the Final Program (deadline applies)
- Electronic attendee lists for pre- and postshow marketing
- Ad discounts for the meeting programs and CorrectCare
- Opportunity to participate in raffle drawings
- Priority booth selection for upcoming conferences
- Opportunity to attend sessions and earn CE credits
- Exclusive opportunity to become a sponsor or advertiser

Sponsorship Opportunities
Your brand will take center stage with these sponsorship opportunities. These high-profile options ensure branding and recognition throughout the event and are orchestrated to provide maximum exposure for your company. Plus, you gain extra exposure when attendees return home with these meeting mementos. Ask your sales representative to help you maximize your marketing exposure!

Stand Out in the Conference Proceedings
- Exhibit hall reception, lunch or refreshment breaks
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- CCHP lounge host or sponsor
- Conference bags
- Badge holders
- Show bag inserts
- Exhibit hall aisle drop

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The Spring Conference is the premier event where you can meet with key contacts and raise your profile, so reserve your space now. Standard booth sizes are 8’ x 10’, double-size and premium spaces are available. For more information and a reservation form, email sales@ncchc.org or call 773-880-1460, ext. 298. Don’t forget to ask about sponsorships and advertising.
Academy CareerCenter
The #1 Career Resource for Professionals in the Correctional Health Community
Looking for a job? This benefit is free to job seekers. Post your resume online and showcase your skills and experience to prospective employers to find the best job opportunities.
Hiring? Receive member discounts on job postings and access the most qualified talent pool to fulfill your staffing needs.
Hosted by the Academy of Correctional Health Professionals. For information or to access listings, visit http://careers.correctionalhealth.org.

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New! 2014 Standards for Health Services for Jails or Prisons
Newly revised by a task force of leaders in health, law and corrections, the NCCHC standards have been updated to provide our latest recommendations for managing health services delivery in adult correctional facilities. The Standards address nine general areas: health care services and support, inmate care and treatment, special needs and services, governance and administration, personnel and training, safety, health records, health promotion and medical-legal issues. New areas of emphasis include continuous quality improvement, clinical performance enhancement, the Prison Rape Elimination Act, pharmaceutical operations, women’s health and patient safety. Take advantage of the field’s top experts and stay current, meet constitutional requirements and be better prepared for the challenges you face every day. Standards will be shipped as soon as they are printed in first quarter 2014. Order yours now! $79.95

New! CCHP-MH Study Package
This discounted package contains the essential materials for the CCHP-Mental Health specialty certification exam:
- Correctional Mental Health: From Theory to Best Practice
- How to Identify Suicidal People—A Systematic Approach to Risk Assessment
- Standards for Mental Health Services in Correctional Facilities
Save 16%! A $164 value if purchased separately, the package is only $137.
Learn more about CCHP specialty certification at www.ncchc.org/CCHP.

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Tap into the incredible network of the National Commission on Correctional Health Care with the NCCHC Buyers Guide. Powered by MultiView, the Guide is the premier search tool for correctional healthcare practitioners. Find the suppliers and services you need, within the network of the association you trust.
SimplifiedFind your search today at www.ncchc.org.
Language Assistance During Intake Screening

**Q** What is NCCHC’s position on using corrections officers or deputies for language assistance during the receiving screening process? We do a complete receiving screening of each inmate upon intake and determine acceptance to jail or need for medical clearance. We have deputies who speak other languages and work in our intake area. In lieu of calling an interpreter to come in, which could take several hours, can we use a deputy to be the interpreter between the new inmate and the nurse who is completing the receiving screening process with that inmate?

**A** There are two standards to consider regarding the use of security personnel for language assistance during receiving screening. The first is J-E-02 Receiving Screening. This standard allows health-trained correctional officers to conduct the entire screening; however, in this case, the security officer is not doing the screening and so would not need to be health trained. The other standard is J-A-09 Privacy of Care, which requires that security staff and interpreters are given instruction in maintaining confidentiality when a health encounter is observed or overheard. The scenario you described would not violate either of these standards as long as the correctional officer is given instructions on maintaining confidentiality.

Communication on Patient Health After a Fight

**Q** How much information can health staff give jail administration concerning an inmate when he or she has been involved in an incident or altercation?

**A** There is no problem with certain information on health matters being communicated between health staff and custody staff. In fact, standard A-08 Communication on Patients’ Health Needs requires that inmates’ significant health needs be considered in classification decisions in order to preserve the health and safety of that inmate, other inmates or staff. After an altercation, it is appropriate and expected that health staff prepare a summary of how the injury and subsequent treatment may affect work assignments, recreational programming, cell assignment and availability for follow-up appointments (as examples).

HIV Tests After Officer Blood Exposure

**Q** Health services was asked to obtain blood samples for HIV testing from detainees who were involved in a significant blood exposure with an officer prior to arrest. Once the detainee was booked into the jail, the workman’s comp manager and the local community infectious disease office asked that health services obtain the samples. If health staff were to obtain blood samples from detainees for HIV testing, would there be a conflict of interest with compliance indicator 1a of standard I-03 Forensic Information?

**A** This answer assumes the worker’s comp manager and community infectious disease office wanted the health staff to collect the blood sample with the intention of sharing the results with the officer involved. If so, then the standards that would be involved are J-H-02 Confidentiality of Health Records and J-I-05 Informed Consent and Right to Refuse. The collection of a blood sample to test for HIV is a medical procedure and the results are confidential. Therefore, the inmate would need to consent in writing to the procedure and sign a consent allowing the release of the information to the requesting parties. Standard J-I-03 would apply only if the information being collected may be used against the inmate in disciplinary or legal proceedings.
We founded MHM in 1981 to provide acute care hospitals a better management solution for their inpatient psychiatric units. In the 1990's we transitioned into the corrections market, and became the leading national provider of correctional behavioral health services. Today, we see needs in the broader correctional healthcare spectrum for a better managed care solution.

The Changing Landscape of Correctional Healthcare
National healthcare reforms and continued budget pressures will make the challenge of staffing and efficiently managing correctional healthcare programs more difficult than ever before. Correctional agencies will need a healthcare system that delivers the level of expertise and proven results in staffing, clinical operations, and client satisfaction that MHM is known for, coupled with a new level of managed care resources to contain costs - a level historically unavailable in correctional settings.

Introducing Centurion
MHM formed Centurion in 2011 in partnership with Centene Corporation, a Medicaid managed care company with over 3 million covered lives in 18 states. Centurion offers elements of managed care perfected in state Medicaid programs. Combined with some of the correctional industry’s most experienced healthcare managers.

A Winning Solution
The marketplace is responding favorably to our Centurion model. We are proud to announce new correctional medical contracts in Massachusetts, Minnesota, and Tennessee. We look forward to demonstrating the “Centurion difference” in the coming months.
We discover, develop & deliver innovative medicines that help patients prevail over serious diseases.

Around the world, our medicines help millions of people in their fight against serious diseases.

Bristol-Myers Squibb would like to thank The NCCHC National Conference on Correctional Health Care for all its support in 2013.

For more information, please visit www.bms.com