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IN THIS ISSUE

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This is not a phantom pain: Liability risk grows for poor pain management

Provider sued after man dies in pain, CMS investigates fraud

A California nursing home is being sued for elder abuse and investigated for Medicare fraud after a resident died in terrible pain, with his family charging that clinicians ignored his pleas for medication despite charting his severe pain. A risk management expert says the case should be a shocking reminder that undertreatment of pain remains a serious liability risk, perhaps even a growing risk as the standard of care more firmly requires adequate pain treatment.

The case is almost a carbon copy of a case from two years ago in which a California doctor was ordered to pay $1.5 million for undertreating a dying man's pain. The hospital's records, dutifully maintained in compliance with standards on pain management, proved to be the doctor's undoing because they showed the patient was in terrible pain and that the doctor must have been aware of it.

Many of the facts are the same in the current case, says **Kathryn Tucker**, JD, director of legal affairs with the Compassion in Dying Federation in Seattle, an advocacy group that supported the plaintiff in both cases. In

SARS audio conference: Learning from Canada

Hospital clinicians in the United States are watching with grave concern as severe acute respiratory syndrome (SARS) — a rapidly emerging infection with unclear treatment options — strikes the health care system of their Canadian colleagues. Particularly beset is the city of Toronto, where nosocomial spread from unsuspected hospital patients set off an epidemic that has resulted in the quarantine of 9,000 people.

With sporadic, but increasing SARS cases appearing in the United States, the lessons learned in Toronto can provide critical guidance for U.S. clinicians.

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another case, a jury awarded $15 million, half of it punitive, from a nursing home where a patient had died in pain. The patient's family alleged that a physician had ordered morphine for the man's pain, but a nurse refused to administer it because she feared the patient would become addicted. She gave the man Tylenol instead.

In the current case, an 85-year-old man dying of lung cancer was denied adequate pain management despite his advance directive calling for all possible pain relief and his frequent reports to the nursing staff that his pain was intolerable.

The $1.5-million verdict of two years ago was a wake-up call to health care providers, proving that courts would hold health care providers accountable for inadequate pain management, Tucker says. There is even less doubt now, she adds.

"Two years have gone by and even more pain guidelines have been published," Tucker says. "A clinician in any of the 50 states who is just ignorant of modern pain practices is at risk of a lawsuit like this and the facility where it happens is going to be involved just as much."

Suit alleges pain reports were ignored

The lawsuit filed in the Superior Court of California, County of Contra Costa, is an action for elder abuse because state law does not allow recovery for pain and suffering after the patient dies. The family also alleges intentional infliction of emotional distress, fraud, unfair business practices, and other statutory violations. The suit is against Mt. Diablo Hospital Medical Center, the Bayberry Care Center (where the patient was transferred for long-term care), and three physicians. The defendants did not return *Healthcare Risk Management's* telephone calls seeking comment.

The complaint claims that "from Jan. 18, 2001, through the day of his death on Feb. 12, 2001, Lester Tomlinson's severe and constant pain was callously ignored, never effectively treated and allowed to progress by defendants without any intervention which would comply with modern concepts of pain management. Lester Tomlinson, who had gone to the effort of clearly expressing his wishes to live his last days with maximum control of his pain, nevertheless spent the last month of his life in agony, confusion, and indignity."

Nurses at the hospital and the nursing home assessed Tomlinson's pain level regularly but he did not receive adequate medications, according to the complaint. While Tomlinson was often unable to rate his pain either because he was hard of hearing or because of his confusion, he did rate his pain on many occasions and the pain level was almost always high. He frequently reported pain levels up to 9, and his initial assessment on admission indicated that he frequently experienced pain he rated as 10. The lawsuit alleges he sometimes received no medication or at other times wholly inadequate medication, despite his family member's pleas for better pain management.

Risk managers should take the current case as a warning and ensure that such an incident could not happen in their own facilities, says **Grena Porto**, RN, ARM, DFASHRM, a health care risk manager and principal with QRS Healthcare Consulting in Pocopson, PA, and past president of the American Society for Healthcare Risk Management. Pain

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management must be taken seriously or you can count on a major lawsuit, she says.

"Pain relief is the same as saying that the patient needs antibiotics or surgery," she says. "If the patient needs it, you provide it. You can't have a double standard about treatment that says there's real treatment and then there's pain relief."

Porto is particularly interested by the inclusion of the long-term care facility in the lawsuit. She says there may be plenty of blame to go around if the allegations are true, but she hypothesizes that, in particular, the nursing home's experience may illustrate a growing risk management problem. More seriously ill and dying patients are transferred to long-term care settings than in past years, she says, instead of staying in a hospital. That puts a greater burden on nursing homes to deal with issues such as pain management that they may not have handled much in the past.

"There are tons of ramifications in the long-term care setting," she says. "They need to do a lot of education and skill building for the staff in nursing homes, which is an area in which the staff might not have really studied before."

Tucker also says the allegations against the nursing home are especially troubling.

"Here's a patient who was discharged from an acute care facility to a nursing home and his chief complaint was excruciating pain associated with terminal lung cancer," she says. "Three and a half days go by before he receives pain medication of any kind, and then it's inadequate."

Porto also cautions risk managers not to be distracted by the fact that two of the major cases alleging undertreatment of pain have been brought in California. Such lawsuits can be brought anywhere, she says, and providers nationwide also have to consider the risk of committing fraud or violating accreditation requirements. Providers across the country have been accused of defrauding the federal government when patient care, including pain management, did not meet acceptable standards of care, she says.

"Pain management is part of the standard of care. If you're not providing the standard of care but you're billing for the standard of care, that's fraud," Porto says. "So you're risking not only civil liability but also charges of fraud and abuse."

The nursing home in question is being investigated by the Centers for Medicare and Medicaid Services for potential fraud related to the case. **Julie Sadovich**, manager of the long-term care operations branch at the CMS regional office in San Francisco, says the matter was referred to a state agency for investigation. The outcome of that investigation could lead to federal charges of fraud and abuse, she says, in addition to whatever sanctions the state may impose.

"The accusation is very inappropriate pain management," Sadovich says. "We consider that a very serious accusation and intend to investigate it fully."

Clinicians still not educated about pain

Tucker says the biggest hurdle to good pain management is that physicians and other clinicians are not well trained.

"In the 1990s, there was an explosion of information on pain management," she says. "If physicians don't take advantage of that then they're not adequately trained to care for patients. There's also the lingering problem of physicians who are concerned that if they treat pain aggressively they might be scrutinized and sanctioned by the authorities."

That worry is overblown, Tucker says, and there is not enough fear on the other side that physicians will be held accountable for undertreating pain. Compassion in Dying pursues these cases partly to show the real consequences for undertreatment, she says. Progress is being made, as illustrated by the fact that the Medical Board of California recently brought formal charges against one of the physicians involved in the current case. In the previous

landmark case, the board officially expressed disapproval for the undertreatment of pain but declined to take action against the physician.

If the case goes to trial, the defendants may have a hard time overcoming the paper trail they generated themselves. Tucker says both facilities documented the patient's pain but then didn't treat it, giving the plaintiff's attorney some strong ammunition.

"When the patient is being charted at a pain level of 8, 9, or 10, like Mr. Tomlinson, and then there isn't any response taken to bring that pain level down to a tolerable level, that's where the exposure lies," Tucker says. "If you see a complaint of pain and then the chart shows a prompt response to manage that pain, you've managed the risk."

Undertreatment of pain could be a problem that flies below the radar at many institutions, Porto cautions. It is all too easy for people to dismiss pain complaints as an inevitable part of health care, and risk managers also may rely too much on written policies and procedures. They don't do the patient any good if they're not used and they may only create a paper trail that will prove inadequate treatment. After all, she says, the hospital and nursing home being sued in California probably had policies on proper pain management; nearly everyone has developed policies in recent years.

Porto urges risk managers to review their organization's pain management programs to ensure not only that the right policies and procedures are in place, but that they are actually put into use. Meet with department managers and leading clinicians to discuss how pain management actually is delivered on the floors, and look for any signs that what happens in the real world is different from what you wrote in the policies, she says.

"The bottom line is you should not need the threat of liability to make you do something as decent and basic as giving a dying man some relief," she says. "That's pitiful." ■

With smallpox, don't over- or underreact

Seven health care workers with a history of heart disease have died after being vaccinated for smallpox, leading the federal Centers for Disease Control and Prevention (CDC) in Atlanta to add heart disease to the list of reasons to exclude individuals. The CDC says it is just being cautious until it determines if there is a connection between the deaths and the vaccine, but risk managers should follow the same path in their own institutions.

The deaths should not necessarily deter any risk manager from recommending continued participation in the nationwide smallpox vaccination plan, says **Jane McCaffrey**, director of risk management at Oconee Memorial Hospital in Seneca, SC. Risk managers should take note of the possible correlation and act accordingly, but don't overreact, she says.

"If you're already participating in the vaccination program, this is no reason to stop it. We knew there were risks involved from the outset, so this is one more risk that we didn't know about before, if it turns out to be a real risk," McCaffrey says. "It's not as if we thought this was risk-free and suddenly we found out that it's not."

The CDC took what it calls a "precautionary step" in adding a temporary medical deferral to the smallpox vaccination program for persons who have been diagnosed with heart disease. The CDC is investigating whether there is any association between smallpox vaccination and reports of heart problems in seven health care workers who have been vaccinated.

The CDC added the temporary measure to the existing list of deferral criteria based on information from its real-time monitoring system, which showed a small number of heart-related incidents among health care workers following smallpox vaccination.

"It is not clear whether this number is greater than would be expected normally in this population," according to a statement from the CDC.

CDC officials have received several reports of heart-related problems among the 25,645 people who have been vaccinated in the civilian program. The seven cases prompting the CDC's precautionary action include three cases of myocardial infarction, one of which resulted in death; two cases of angina; and two cases of myopericarditis (inflammation of the heart muscle or sac surrounding the heart). In each case, the individual's medical history — including risk factors for heart disease — is being studied.

Cases of heart inflammation following smallpox vaccination were reported in the 1960s and 1970s, the CDC reports. However, the information from these reports does not provide any information about the types of people who may be at higher risk for heart-related problems

following smallpox vaccination.

"We promised to closely monitor this program and to put safety first, so we are exercising exceptional caution," according to a statement from **Julie Gerberding**, MD, CDC director. "If our investigation shows this precautionary measure should become permanent or the need for other changes or enhancements in the civilian smallpox vaccination program, we will take immediate action."

The smallpox plan was initiated in recent months as a response to increased threats of bioterrorism, with the goal of vaccinating a number of front-line health care workers across the country. Vaccination is voluntary for both institutions and individuals, and significant numbers of both have declined to participate because of the perceived risk of the vaccine. About 25,645 civilians have been vaccinated already, the CDC reports. The seven deaths occurred seven to 17 days after vaccination.

The CDC already had recommended that some individuals be excluded, such as those with some types of skin disease. Now the CDC is recommends that people with known cardiac disease — such as cardiomyopathy, previous heart attack, history of angina, or other evidence of coronary artery disease — be temporarily deferred from receiving smallpox vaccination.

This is a prudent step and not especially surprising, McCaffrey says. She compares the situation to clinical research, in which you must inform participants about the known risks at the outset, but then more risks may be revealed as the research continues. Your consent process and any exclusion criteria must be revised in the light of new information. She urges risk managers to remember that the CDC has not definitively said that the smallpox vaccination had anything to do with the seven deaths.

"The CDC has been extremely sensitive to the issue of risk, so I'm sure they're being cautious," she says.

Cause and effect?

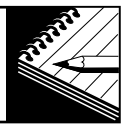
What about those health care workers who already have been vaccinated before the heart disease exclusion? McCaffrey wonders if those people may need some type of medical attention or monitoring, but the CDC so far says there is no answer to that question until it resolves whether the seven deaths actually were related to the smallpox vaccination.

It may turn out that there is no cause and effect between the vaccination and the deaths from heart disease, but in the meantime, risk managers must play it safe.

"This does mean that you want to be sure to exclude people with heart disease in a definitive way until we know more. That probably means you're going to have to screen every person for a history of heart disease, and you may have to examine participants for heart disease risk factors even if they don't know of any existing problems," she says. "If you're doing vaccinations tomorrow, you should be scrambling to get as much information on this one risk as you can."

CDC officials said they will provide states with simple questions about heart problems to use in screening people volunteering for smallpox vaccination. The CDC also asked the Advisory Committee on Immunization Practices' (ACIP) Smallpox Vaccine Safety Review Board to examine reports of heart-related adverse events occurring in connection with the smallpox vaccination program. ■

GUEST COLUMN



Preventing falls takes planning

By **Marva West Tan**, RN, ARM, FASHRM
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Patient falls continue to be one of the most common causes of hospital-related claims for damages. Although the severity of fall-related claims is typically not high, the frequency highlights a major patient safety concern and should make this problem a high priority.

The Centers for Disease Control and Prevention (CDC) considers falls among older adults (ages 65 and older) a serious public health problem because falls result in severe injuries, particularly hip fractures, increased mortality, decreased mobility, premature nursing home admission and significant health care costs. One of every three older adults falls each year. Fall rates within nursing homes and hospitals are even higher. With the aging

population, falls among older, hospitalized adults will likely pose an increasing patient safety and liability risk in the near future unless more aggressive steps in fall prevention are implemented.

Recognizing this problem, the third Institute of Medicine study on the quality of health care lists fall prevention for the frail, older adult as one of its priority areas for national action. Luckily, there are substantial data on patients at risk for falls and a number of environmental, behavioral, and clinical approaches to fall reduction and prevention are available. Health care risk managers should use this information to develop a fall prevention program or update your past work.

One of the first tasks is to identify patients at risk of falling. Major risk factors for falls include muscle weakness, history of falls, gait or balance deficit, use of an assistive device including a cane or walker, visual deficit, arthritis, impaired activities of daily living, depression, cognitive impairment, age older than 80 years, environmental factors such as lack of bathroom safety equipment or poor lighting, and polypharmacy (particularly involving psychotropic medications, Class Ia antiarrhythmic medications, digoxin and diuretics.) The risk of falling increases dramatically when multiple risk factors are involved.

Define falls and establish a reporting system

Fall prevention requires a well-coordinated facilitywide approach to be effective. Consider some of the following steps for implementing or updating a program:

- Form a multidisciplinary work group to develop and champion the institutional fall prevention program. Include representatives from nursing, medical staff, rehabilitative, social, pharmacy, and environmental services, risk manager and patient safety or performance improvement manager. The diversity of expertise will be invaluable due to the multifactoral causes of patient falls and needed interventions.
- Collect data on patient falls including facts about the fall incident, the patient's risk assessment, and any interventions in place. To assure that data are comparable, develop a definition of a patient fall that will be applied uniformly throughout the facility or health system.
- Decide if you want to include in your fall definition the "almost falls" — situations in which a staff member assists or controls the patient's unplanned descent to the floor.
- Determine whether unwitnessed falls, i.e., patient found on floor, will be counted separately from witnessed falls.
- Incorporate fall data collection in your institutional incident reporting policy and procedure. Collect adequate information so that you can analyze data by unit, shift, and other factors you deem important.
- If existing incident report forms are inadequate to collect needed data, you may want to develop a supplemental "fall data" form.
- Encourage complete reporting through creation of a blame-free atmosphere that emphasizes identifying opportunities to improve patient safety.
- Be aware that improvements in your institutional incident-reporting system may create the perception of an increased rate of falls when the rate of reported falls increases.
- Follow institutional confidentiality and privacy requirements in any data collection process.
- Analyze data on an ongoing basis — initially to identify a baseline for planning and action and periodically to evaluate the effect of interventions.
- Pay particular attention to falls that result in serious injuries, such as hip or pelvic fracture, and patients who fall more than once during the admission.
- Identify performance improvements suggested by these adverse events.
- Make sure all staff know to refer cases, as indicated, to the risk manager or patient safety officer.

While people are often interested in benchmarking the fall rate at their facility with other similar facilities, valid comparable data are difficult to locate in professional literature due to differences in definition of a fall, variations in thoroughness of incident reporting and different denominators used to calculate fall rates. One source for comparable data may be the facility's ORYX-approved quality indicator program if fall-related measures and data are available. For patient safety and risk management purposes, it is probably more useful to track your own facility's or health system's fall rate, rate of serious injury and frequency and severity of fall-related litigation over time to attempt to determine if your fall prevention program is having the desired impact.

Clinicians can and must be involved with preventing falls, so your program should include a fall risk assessment, using a risk-screening tool, on all older patients as part of the nursing admission process. Physicians should also ask their patients about the occurrence of falls. For patients

with a history of falls or an admission due to a fall, consider a more comprehensive medical evaluation of physical and other deficits, possibly including a physical therapy consultation. Use the fall assessment results to develop a fall prevention plan tailored to the patient's needs and medical condition. The combination of the assessment and planned interventions are the essential elements of a fall prevention approach.

Consider use of color-coded patient identification bracelets to identify patients at risk for falls. Because of confidentiality and privacy issues, it may be advisable to obtain the patient's specific written consent for this use of the bracelet.

Identify multifactoral interventions. There is a wide range of interventions that are being used to prevent falls. The fall prevention plan for an individual patient often includes several approaches. The major intervention categories include:

- Environmental adaptations that include grab bars and safety call signals in patients' bathrooms, use of nightlights, positioning beds in low position at night, using mats on floor near bed, decreasing clutter and electric cords on floor, and dry floors. Side rails can help prevent falls but also can be a factor in a fall if the patient tries to crawl over them. The evidence regarding the role of chair and bed alarms in preventing falls is not yet clear.
- Medication review to reduce the number of medications the patient is taking particularly those that may impact balance or alertness.
- Exercise training to improve strength, endurance, gait, and balance.
- Training in correct use of assistive devices such as canes and walkers.
- Visual interventions to correct deficits when possible. Encourage patients to use their prescription glasses and keep the lenses clean and smudge-free.
- Footwear interventions such as use of fitted slippers with a firm sole rather than paper slippers or flimsy slip-ons.

Restraints must be used carefully

Restraint use and the role of restraints in preventing or causing falls are a controversial area and one that is heavily regulated. Follow your institutional policy regarding restraint use and required documentation carefully. Many institutions are working to move to a restraint-free environment.

Anticipating the patient's behavior is an important part of designing a fall prevention plan. Patients often fall when they are attempting to fulfill a need, such as walking to the toilet, getting a drink of water or answering the phone. Patients who require assistance to ambulate should be placed on a defined toileting schedule whereby nursing staff, without waiting for a patient request, help patients to the bathroom or bedside commode upon their awakening, after meals and physical therapy and before bedtime. Patients on diuretics may require more frequent toileting. Phones, call bells, and water pitchers should be placed well within the patient's safe reach.

Some other potential interventions that are being considered to reduce falls are bone-strengthening medications to prevent or treat osteoporosis and appropriate use of cardiac medications or cardiac pacing to prevent syncope.

Ongoing patient and environmental monitoring by nursing staff is crucial to effective implementation of any intervention plan and is probably as important to fall prevention as the use of any other technique. But providing adequate nurse monitoring presents challenges in creative staff assignments and delegation of care in these times of nursing shortages.

Unfortunately, while there is much published information about fall prevention techniques, there is scanty scientific evidence on those approaches or combinations of approaches that are most successful in preventing falls in hospitalized patients. Also, interventions vary in costs, which complicates the decision of what approach to use.

Education, good documentation are key

Though a fall prevention program may be structured in different ways, be certain to include these elements:

- **Educate staff about the institutional fall prevention program.** Emphasize that success is dependent on participation by everyone. Refresh training on your incident reporting policy and procedures as part of this training. Repeat training twice a year, if possible, to keep people motivated. Use posters, newsletters, and other media to remind staff of fall prevention efforts and successes.
- **Educate patients and families on the risk factors for falls, the individualized plan to reduce the specific patient's falls in the hospital and suggestions for fall prevention in the home.** Involve the family, if possible, with creating a safe patient environment. A home assessment by occupational therapy could be very beneficial to increase home safety and prevent

future falls for the high-risk patient.

• **Manage falls that do occur as you would other adverse events.** Conduct an assessment of the patient's condition, obtain any needed clinical care, document the occurrence objectively and report as required by hospital policy. Disclose information to the patient and family in accordance with the hospital's disclosure of unanticipated outcomes policy. For falls that result in patient injury, risk management, after investigation and in cooperation with the facility's liability insurer, may decide to make an early offer of settlement.

• **Document the fall risk assessment, any planned interventions, patient and family education, and ongoing patient monitoring carefully.** While you may not be able to prevent all falls, be prepared to demonstrate that appropriate patient safety measures were taken. Flow sheets may simplify documentation of ongoing monitoring.

• **Provide feedback to administration, the fall prevention work group, medical staff, nursing units, and other involved services on the results of the fall prevention program.** Aggregate fall data analysis, injuries and fall-related litigation can be used to inform them of the successes in reducing falls and to keep everyone interested in participating in the program.

• **Consider piloting the fall prevention program on higher-risk units before rolling the program out to the whole facility and other age groups.** Revise the risk assessment and fall data collection tools and refine the program as indicated.

• **Keep assessing and updating the fall prevention program as more scientific evidence becomes available about the interventions that are most effective in preventing falls as well as those approaches which have been most successful in your facility.**

• **Ongoing feedback and periodic publicity about the program are essential to obtain buy-in and continued support for the program.** Sharing success stories can help build pride and staff participation as you strive to reduce falls in your facility.

Resources

• Best Practices: Analysis of Hospital Claims Trends and Information on Factors Driving Claims, *Health Care Update*, June 2002, The St. Paul.

• Centers for Disease Control and Prevention. *Falls and Hip Fractures Among Older Adults and The Costs of Fall Injuries Among Older Adults* at www.cdc.gov/ncipc/factsheets.

• American Geriatric Society, British Geriatric Society, and American Academy of Orthopedic Surgeons Panel on Fall Prevention, Guideline for the Prevention of Falls in Older Persons. *Journal of the American Geriatrics Society* 2001; 49:664-671.

• Institute of Medicine. *Priority Areas for National Action: Transforming Healthcare; Guideline for the Prevention of Falls in Older Persons.* Accessed at www.nap.edu.

• Fish J. *Using Nonclinical Evidence Practices to Face Complex Challenges; Guideline for the Prevention of Falls in Older Persons,* National Patient Safety Foundation. Accessed at www.npsf.org. ■

$50 million investment to improve patient safety

A California not-for-profit hospital is spending $50 million on new, advanced technology that promises fundamental changes in hospital ICU care and bedside medication delivery, all intended to improve patient safety. The huge outlay of funds is justified by the ability to reduce medication errors and other adverse events, say hospital leaders.

Sutter Health in Sacramento, CA, is implementing two high-tech solutions that promise to improve patient safety — an intensive care unit that allows specialists to view and treat patients remotely and a bar coding system for medications. The hospital is among the first to use technology from Baltimore-based VISICU Inc. to provide physician specialists with tools that will enable them to keep a close eye on critical care patients 24 hours a day, seven days a week. The solution uses telemedicine technology — early-warning software with advanced video and electronic monitoring — to connect off-site critical care specialists to ICU patients. The hospital studied the project for a year before deciding to go ahead with the investment, says **Mike Evans**, JD, chief risk officer and senior vice president. The $50 million covers the initial investment in technology, recruitment, software, and training.

The Sacramento facility is the first to employ the new technology. Sutter officials hope to have all of its 26 facilities tied in to the system in the next three years.

"This had to be weighed in with all the other capital requirements and demands placed on the system," he says, " but this one provided the greatest return for patient care."

Evans says one goal was to expand the availability of high-level care to patients in rural areas.

Patients in some areas served by the Sutter Health network have difficulty accessing certain specialists, such as intensivists, because the local facility does not have the volume to justify hiring additional staff.

Sutter is banking on high-tech, remote access for the solution. In the newly wired ICU, vital signs and laboratory data from the sickest hospital patients are fed to existing on-site doctors and nurse stations as well as to a new, remote, specially equipped electronic ICU, known as the eICU. The eICU serves as a high-tech and centralized patient safety net with additional, full-time physician specialists and critical care nurses. The additional critical care support team provides another set of watchful eyes, constantly checking early warning indicators for vital sign changes and looking for any sign of trouble, says Sutter Health chief medical officer **Gordon Hunt**, MD.

"Medical studies have shown time and again that full-time intensivist coverage for ICU patients can significantly improve patient outcomes," he says.

The intensivist shortage

The challenge has been the nationwide shortage of intensivists. Fewer than 6,000 intensivists are actively practicing in the United States. Many communities, especially those in rural areas, do not have access to intensivists at all.

"This innovative technology will enable us to extend intensivist talent to the more than 400 ICU beds throughout our entire hospital network, complementing the high-quality care already provided by existing ICU physicians and nurses," he says.

California law requires that the patient provide separate consent for the use of telemedicine. Evans says he considered the potential malpractice risk of having physicians work with patients through a remote hookup, but he is comfortable that any risk is justified by the improvements in patient care.

"This system provides a level of expertise that is not otherwise available on a timely basis for this class of patients," he says. "It's always after 5 p.m. and on the weekend when things go wrong. That's when there's no one around, the physician is home in bed, and he doesn't want to be disturbed. With this new technology, people are always monitoring the patient and can respond immediately."

Nurses are still present in person in the ICU, but the physician can be contacted immediately. Through the remote hookup, he or she has immediate access to the patient's data.

Here's how the system works: ICUs throughout the Sutter Health network are being equipped with a video camera in each patient room, and with connections to computerized remote monitoring systems. On-site physicians, nurses, and other staff continue to provide on-site care in the ICUs. Critical care physician specialists and highly trained nurses also will staff a new remote ICU monitoring center, the "eICU." The eICU staff are linked to hospital staff by voice, video, and data technology. They will serve as a high-tech safety net for the most critically ill patients, providing an additional layer of monitoring around the clock.

Sutter Health president and chief executive officer **Van Johnson** says he expects other hospitals to make the same kind of advance in the near future.

"Sutter hospitals already have stringent quality control guidelines, but these proven technologies will provide us the opportunity to take patient safety to the next level," he says. "These high-tech support systems are the future of health care."

Hospitals within the Sutter Health network also will begin applying advanced technology to administering patient medications at the bedside. A computer bar code on each patient's identification bracelet will be used to match and monitor the medication ordered by the doctor. Before administering medications, nurses and other caregivers will scan a bar code imprinted on the patient's armband, and on the medication, using a hand-held device. A bedside computer will then read these bar codes into a software application that uses expert databases to provide patient-specific information.

This new system helps ensure the right dose of the right medicine is given to the right patient at the right time. It also alerts the clinician to possible allergies, and lookalike/soundalike or high-risk drugs.

"Bar coding is going to significantly improve the checks and balances," Evans says. "The system identifies who is giving the drug, the patient, and makes sure you have a good match there. But it also has parameters that will flash warnings when it foresees a problem."

Evans says the nursing staff is excited about the new technology and eager to use it. He expects the bar coding to reduce medication errors and near misses. "This will take the burden off the nurses so they don't have to remember all the thousands of adverse interactions that can happen," he says. "It's not going to eliminate the decision to make medication decisions at the

SARS audio conference

(Continued from cover)

To prepare yourself and your facility, don't miss **SARS: What U.S. Hospitals Must Learn from the Canadian Outbreak** on May 6, 2003, from 2:30-3:30 p.m., EST, an audio conference program presented by Thomson American Health Consultants.

Transmission within hospitals to health care workers and patients has been clearly documented in eight Toronto hospitals. Two hospitals have been closed to all new admissions, with their staff, visitors, and patients quarantined. A Toronto long-term care facility also is under quarantine, a particular concern because the mortality rate of SARS rises with increasing age in the infected. Though numbers still were increasing, as we go to press, Toronto had some 160 SARS cases and nine dead.

The first speaker is a physician who is dealing directly with SARS patients in Toronto and leading hospital efforts to prevent further spread to workers and patients. **Andrew Simor**, MD, an infectious disease specialist at the University of Toronto and hospital epidemiologist at Sunnybrook and Women's College Health Sciences Centre, will describe the enormous impact on the city after SARS started with one case patient returning from Hong Kong. He will discuss both hospital transmission and infection control measures to prevent further spread.

Be prepared when a SARS patient walks into your emergency department. Learn the lessons of Toronto, and receive a comprehensive update on the U.S. situation from the program's second speaker, **Patti Grant**, RN, BSN, MS, CIC, director of infection control at RHD Memorial Medical Center in Dallas. A board member of the Association for Professionals in Infection Control and Epidemiology, Grant will detail the U.S. SARS situation and provide practical advice on implementing new Centers for Disease Control and Prevention guidelines to prevent transmission.

An apparent new corona virus that may well have made the leap from an animal host to man, SARS has rattled the health care community since its rapid emergence from China. Many of the first cases have been in health care workers. Get the latest information on the etiology, modes of transmission, respiratory protection, protecting household contacts, and possible treatment options.

At the conclusion of this program, participants will be able to:

- describe lessons learned by Canadian clinicians;
- employ measures to prevent transmission in health care settings;
- discuss the phenomena of "super-spreaders";
- summarize the most current information on the etiology and mode of transmission of this emerging pathogen.

Educate your entire staff for one low fee including 1 hour of CE, CME, or Critical Care credits for all attendees. You may invite as many participants as you wish to listen for the low fee of $299. Information on obtaining audio conference instructions and continuing education forms will be in the confirmation notice, which will be mailed upon receipt of registration. Your fee also includes access to a 48-hour replay following the conference and a CD recording of the program. For information or to register, call customer service at (800) 688-2421 or contact us via e-mail at customerservice@ahcpub.com. When ordering, please refer to effort code **80861**. ■

bedside, but it will help them remember that there are decisions to make." ■

Bar codes may help avoid the most common errors

The road has been paved for using bar codes on all medications to reduce errors, with the Food and Drug Administration (FDA) announcing recently that is proposing a rule requiring bar codes on all medication packages, a mandate that some say would significantly improve patient safety in the nation's hospitals.

But don't think the bar codes will be an immediate fix for medication errors. Implementing the system will take time.

The proposed rule, announced by Secretary of Health and Human Services Tommy Thompson, would require bar codes to include the National Drug Code (NDC), a system that contains the drug name, dosage form, and strength. But the proposed regulation stops short of mandating the inclusion of the medication's lot number and expiration date in the bar code, citing the cost as well as the need for more evidence of its value.

Pfizer Inc., a major medication manufacturer, also announced that it will print bar codes on

individually packaged pills used in hospitals, the most comprehensive move yet by a the pharmaceutical industry to address medication errors. Over the next year, Pfizer expects to have bar coding and text on all 30 medicines it sells in blister packs for hospital use that identifies the medicine, the dosage, lot number and expiration date.

ASHP applauds moves

The moves by the FDA and Pfizer were welcomed by the American Society of Health-System Pharmacists (ASHP) in Bethesda, MD. **Henri R. Manasse Jr.**, PhD, ScD, ASHP, executive vice president and chief executive officer, says it is clear that bar codes can improve patient safety. He hopes the FDA will go further to require that all manufacturers include the lot number and expiration date in addition to what the FDA has proposed.

"Requiring bar codes that include the NDC is an important first step, and we applaud the FDA for this proposal," he says. "But including the lot number and expiration date is a critical element to protect patients from medications that may have been recalled or are past their expiration date. We will continue to work with the FDA and other organizations to clearly demonstrate the value of including this vital information."

Manasse says there is substantial public support for these requirements. In its 1999 report, "To Err is Human: Building a Safer Health Care System," the Institute of Medicine noted that bar coding "is an effective remedy" for medication errors when used to ensure the right dose is administered to the right patient. The ASHP's **Kasey Thompson**, PharmD, director of the ASHP Center on Patient Safety, told the FDA at a hearing recently that medication bar codes are long overdue.

"Bar coding technology is entrenched throughout America in all types of venues — grocery stores, department stores, libraries. It is something that everyone expects, and it is found everywhere, except where it can do the greatest good — saving lives," she said. At that time, ASHP also called for bar codes to be placed on both the inner and outer wrap of all drug packages, including single-unit doses.

"Bar codes can be the last line of defense against making a dangerous medication error," Thompson added. "This technology can help hospitals ensure that the right medication is given to the right patient at the right time."

The bar codes could have a major impact in hospital emergency departments (EDs). The United States Pharmacopeia (USP) recently identified leading medication errors in EDs and offered tips for preventing medication errors in this critical setting. USP created recommendations after analyzing medication error data from its national databases containing more than 360,000 medication error reports since its inception in 1998. In 2001, hospitals reported more than 2,000 ED-related medication errors.

The combination of interruptions, intense pressure, and a fast-paced environment can lead to medication errors and fewer error interceptions in the ED than in other settings, the USP reports. In the ED, USP found that 23% of errors were intercepted before reaching patients as opposed to 39% intercepted in other areas of the hospital. ■

CE instructions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity each semester, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

COMING IN FUTURE MONTHS

- Need EMTALA on call 24/7/365?
- Cerebral palsy not likely caused by injury
- Using crew resource management to reduce risk
- Pelvic exams on unconscious patients criticized
- Putting patient safety goals to work

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

If you have any questions about the CE program, please contact customer service at (800) 688-2421.

17. Identify the true statement regarding the lawsuit filed against two facilities and three physicians for failing to the treat the pain of patient Lester Tomlinson.
A. The plaintiffs allege that the health care providers never assessed his pain level.
B. The plaintiffs allege that his pain levels were assessed but that he did not receive adequate pain medications.
C. The plaintiffs allege that the medical records are unclear as to whether his pain levels were assessed.
D. The plaintiffs allege that the pain levels were assessed but recorded inaccurately.

18. Choose the correct statement pertaining to pain management guidelines.
A. The publication of pain management guidelines surged in the 1990s.
B. The publication of pain management guidelines surged in the 1970s.
C. The publication of pain management guidelines surged in the 1960s.
D. The publication of pain management guidelines surged in the 1950s.

19. How much did Sutter Health in Sacramento, CA, has spent on a patient safety project that involves a high-tech ICU and bar coding technology?
A. $20 million
B. $30 million
C. $50 million
D. $70 million

20. According to the United States Pharmacopeia's most recent research, ___ of medication errors in the emergency department were intercepted before reaching patients, as opposed to 39% intercepted in other areas of the hospital.
A. 13%
B. 23%
C. 33%
D. 43%

Answers: 17-B; 18-A; 19-C; 20-B.

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

THOMSON
AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

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HIPAA compliance: Technology plus culture plus operations

Train-the-trainer approach saved money on consultants

For Baystate Health System, a $1 billion integrated health system operating in western Massachusetts, HIPAA compliance has been seen as more than a technology issue. It also is a major cultural and operational issue that has an impact on systemwide operations and the way the system and its staff interact with patients.

Baystate HIPAA project manager **Jim DiDonato** described the organization's compliance efforts in a presentation at the Sixth National HIPAA Summit in Washington, DC, saying that Baystate's approach to following the regulations includes technology solutions, new and revised policies and procedures, new and revised contracts, work force training, and ongoing maintenance and reinforcement.

Named one of the nation's 100 leading integrated health care networks, Baystate is based in Springfield, MA, and includes an academic medical center, two community hospitals, numerous outpatient facilities and programs, an ambulance company, home care and hospice services, an employed primary care provider group with multiple sites, and other support services.

Included in its HIPAA compliance planning were the medical practices and ambulatory care services, administrative support, the ambulance company, the three hospitals, Visiting Nurse Association and hospice, infusion and respiratory services, and the employee health plan. Not included were the for-profit HMO in which Baystate has a majority interest and other affiliated organizations that are joint ventures.

Assessment identified many gaps

DiDonato says a steering committee and project teams initially performed an assessment that compared the HIPAA regulations with their current practices and identified gaps. Their security and privacy assessment uncovered many items needing to be addressed, he says, such as contracts that were not compliant, patient consents and authorizations not compliant, patient information found in the trash, patient charts exposed on hospital hallway walls and counters, fax machines and printers left unattended, medical records not adequately secured, computer terminals pointing toward the public, employees and physicians not aware of existing policies, a need to designate a security officer and a privacy officer, a need to conduct

security certification, doors left unlocked (medical practices, hospital stairwells, and other "secure" areas), and a need for new policies for things such as passwords and workstation use.

Following the assessment, they agreed on a strategy to examine compliance options with a focus on costs, risks, and resource needs. They developed and implemented work plans to obtain compliance by specified dates, and established accountabilities and processes to ensure ongoing compliance.

Presentations to many groups

With more than 8,200 employees spread across four states, Baystate made a significant effort to help people become aware of HIPAA and the activities that would be undertaken. The purpose of administrative simplification under the HIPAA regulations was stated as "improving the efficiency and effectiveness of the health care system by standardizing electronic data interchange for administrative and financial transactions, and enhancing the security and privacy protections over patient information."

Presentations outlining the purpose, project organization, and schedule were made to boards of trustees and the board compliance committee, senior executives, management teams from operating units, the community hospital medical staffs, teaching hospital surgeons and residents, community practice managers, and others.

Consultants were brought in to train selected Baystate staff in a train-the-trainer approach that saved some money over making total use of consultants. A budget in excess of $1.6 million was set for both capital costs and operating costs related to necessary changes.

DiDonato shared with the Summit audience Baystate's security and privacy workplans and time charts showing completion dates. He also provided information on the approval process used for needed new privacy policies, and a listing of the policies and communications that were involved.

Training included an initial heads-up session that HIPAA was coming, followed by "HIPAA Lite," Phase I training that included a manager's guide, handbook for employees, quiz, and videotape. Phase II was specific training on privacy policies, and included a manager's guide, employee handbook, and use of the system intranet for policies and forms and other resources. Role-playing examples were built into the privacy training.

According to DiDonato, the group planned to assess the situation after its April 14 compliance date to see what had been missed and which procedures were not working as planned. An additional follow-up is scheduled for fall 2003, including compliance reviews by the system privacy workgroup and any necessary modifications or tweaking to policies, procedures, and processes.

[Editor's note: Contact DiDonato at (413) 784-8100.] ■

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CMS issues HIPAA checklist for provider compliance

Checklist addresses business associates

The Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) has issued a checklist to help health care providers who do business electronically

and their business partners to comply with the administrative simplification requirements of HIPAA.

HIPAA does not require a health care provider to conduct all transactions such as claims or equivalent encounter information, payment and remittance advice, claim status inquiry and response, eligibility inquiry and response, and referral authorization inquiry and response electronically. But any of these things that are done electronically must be done in the standard format outlined under HIPAA.

"Whether you contract a third-party biller or clearinghouse to conduct any of these transactions for you," the checklist says, "it is up to you as the health care provider to see to it that your transactions are being conducted in compliance with HIPAA."

Checklist items include:

• determining, as a health care provider, if you are covered by HIPAA because you conduct any of the typical transactions electronically;

• assigning a HIPAA point person to handle the remaining checklist items, having that person educate others on the office staff;

• familiarizing yourself with key HIPAA deadlines such as Oct. 16, 2003, the date providers must be ready to conduct transactions electronically in the standard HIPAA format with health plans and payers.

How HIPAA affects what you do — determine that software is ready, find out what needs to be done differently to comply for all electronic transactions, ask vendors how and when they will be making HIPAA changes and document the response.

Talk to health plans and payers you bill to see what they are doing to prepare for HIPAA and ask for trading partner agreements that specify transmission methods, volumes, and timelines as well as coding and transaction requirements that are not specifically determined by HIPAA. ■

Payment processes could be changed

Encryption requirements eliminated

Medical Banking Project founder **John Casillas** says that one of the changes in the final HIPAA security rule eliminated any requirement to encrypt electronically transmitted protected health information, even over the Internet or other open networks. Encryption now is an "addressable" implementation specification, which means that a provider or payer organization must determine if it is appropriate to use the technology. Encryption was one of many required procedures or technologies in the proposed rule that now are addressable as the Department of Health and Human Services seeks to make the final rule more scalable for health organizations of all types and sizes.

Casillas says that many providers implementing the security rule likely will decide encryption is a reasonable and appropriate way to protect data, but their trading partners may not agree. One area providers will have to consider is the electronic transmission of payment information — including protected health information — between providers, payers, and financial institutions.

For instance, an insurer may electronically transmit to its bank a payment file containing payment instructions for a batch of claims from multiple providers. The bank will transmit the file to the banking industry's automated clearinghouse network, which transmits the payments to the appropriate banks serving the providers listed in the payment file. The individual banks then will transmit electronic remittance advices that contain protected health information to their provider customers.

Technically, under the final security rule, none of these transfers of information need be encrypted. But to protect themselves from liability, providers will have to demand that their payers and financial institutions adequately encrypt the data. "That's inevitable," Casillas adds. "Providers are the ones on the line and will want to make sure their data is protected throughout the entire banking system." ■

Physician groups scared of HIPAA

Small groups have few resources available

San Francisco-area attorney **Steven Fleisher**, who is HIPAA consultant to the California Medical Association and provides compliance services to providers and employers, says that health care providers working in solo and small groups have the fewest resources available to deal with HIPAA compliance and are experiencing "fear

and loathing on the HIPAA trail."

Speaking at the Sixth National HIPAA Summit in Washington, DC, Fleisher described small physician practices as a "distressed cottage industry," noting that income is flat or even declining, while costs continue to grow. "Doctors are unhappy with their practice realities," he asserted.

Many providers are resisting HIPAA, according to Fleisher, viewing it as yet another unreimbursed government mandate and expressing concern about the changes it will bring about and how much they will cost. Physician fear has been made worse, he said, by "unscrupulous pandering and rumor mongering" by vendors and others, creating fear about penalties and enforcement.

Physicians who use electronic means to engage in covered transactions are considered covered entities under HIPAA, Fleisher said, noting that even use of a swipe card for eligibility determination could lead to being considered a covered entity. Most physicians who bill will be covered by HIPAA in the next several years, he indicated.

Because the Department of Health and Human Services' Office for Civil Rights has said that its enforcement of HIPAA will be complaint-driven and has very limited resources, Fleisher said that only those who are "really bad" will be going to jail for HIPAA violations. There may be a more significant problem with civil liability since consumer lawyers seem eager to file privacy lawsuits. He predicted that the HIPAA privacy and security regulations are likely to become the national standard of care for health care records over the coming months and years.

Practical help for small practices

"So far," Fleisher declared, "small and solo practitioners feel broke and besieged. They are afraid of HIPAA. Most will be covered despite some 'opt out of HIPAA' campaigns, and so the question now is how they can be helped."

Addressing the privacy rule, he said that confidentiality is a concept that providers understand, and what they need to do is enhance existing awareness, afford specific rights to patients, and increase staff training. Fleisher said his firm focuses on simple and practical steps that providers can take, helping them to realize that compliance simply involves work.

While technology, especially expensive or complex technology, can help a small practice, it can't be at the center of compliance strategies for most practices, he said. His practical privacy tips for providers include:

- put one person in charge of privacy and give that person training, authority, and time to do the job;
- inventory types, uses, and disclosures of protected health information;
- be aware of pitfalls in telephone, hallway, and office conversations;
- remove protected health information from easy patient access, looking at chart racks, chart holders, reception areas, exam rooms, hallways, and physicians' desks.

Clearance and training procedures need to be developed for practice staffs, Fleisher said, along with proper uses and disclosures, sanction procedures, and termination procedures. Attention should be paid to incoming materials such as faxes and other protected health information, and outgoing materials such as faxes and those sent with commercial couriers. He recommends that there be a written agreement with patients if e-mails are to be exchanged with the practice.

Document patient communications

All activities should be documented, he said, including any patient request, the practice response, and actions taken. Patient communications should be filed separately, especially complaints, and there should be only one request in place at a time to limit use of protected health information or alternative channels of communication.

A practice's Notice of Privacy Practices should be done last, he said, to assure consistency and conformity for specific practice issues such as questions of joint custody of children seen by pediatricians and treatment areas or support groups for oncology patients.

Fleisher advises practices to be sure that all their forms, policies, and procedures comply with state law as well as with HIPAA. "Pre-emption analysis and application to procedures and forms is a complex task," he cautioned, urging small medical groups to beg, buy, or borrow an analysis from another group such as a state medical association, bar association, hospital association, state agency, or academic privacy project.

Any materials that are borrowed from other sources still must be evaluated for their applicability to small provider issues, a check made of sources reviewed, and an inventory performed of state laws compared with HIPAA impacts, assumptions, and updates. Key areas to be aware

of, according to Fleisher, are highly confidential protected health information, access rights, application to minors, psychotherapy notes, and authorizations.

Several business associate agreements likely

Fleisher also discussed the need for business associate agreements with groups such as billing services, transcription services, collection agencies, software vendors, and outside practice managers. He said that typically practices can amend their existing agreements to include the provisions required under HIPAA. "Respond if you have any reason to believe that a business associate has breached the contract," he said. "And watch for any state law issues."

Turning to the HIPAA security rule, Fleisher said it is important to understand that the Department of Health and Human Services is concentrating on principles rather than details. "Risk assessment is critical and the place where security compliance must start," he declared. "This isn't rocket science. Use common sense."

He pointed out that industrial security, while commonplace in some other sectors, is a new concept in health care. Access restrictions can include office locks and keys, physical access to computers, chart racks, and supervision of visitors and patients. He recommended shredding paper waste.

Access to computers should be limited to authorized staff, according to Fleisher, and proper security arrangements should be made for storage of backups and removable media, as well as for home use and storage. He cautioned that the theft of personal digital assistants and laptop computers is not uncommon and must be addressed. Also needing to be addressed are lab and treatment devices that store or contain protected health information and chart racks.

Computer security techniques

He gave several suggestions for computer security, including examples of effective passwords that are a combination of letters, numbers, and symbols with no inherent meaning. Passwords should not be shared, he said, and should not be on Post-It notes stuck to a terminal. Passwords should be changed on a regular schedule.

Access rights to information stored on a computer should be assigned according to function, audit, and authorization, Fleisher said. He also recommended that protected health information be encrypted before being sent over the Internet.

Recognizing that it can be very difficult for physicians in smaller practices to organize compliance on their own, Fleisher suggested trying to secure help from local medical societies and private vendors for training and education, implementation planning, and policies, procedures, and forms that integrate state preemption analyses.

He shared examples of materials developed on CD-ROM by the California Medical Association for use by member practices that have policies, procedures, and forms customized for California law by association attorneys. The association also is providing training for physicians and staff, implementation planning, and regular updates.

Fleisher says that while most frontline physicians love high-tech equipment in the hospitals, they don't want a high-tech office, and thus "HIPAA compliance for most will be a low-tech affair." He urged focusing on the possibility that the rules actually will provide a benefit to small practices by forcing them to move closer to the 21st century.

[Editor's note: Contact Fleisher at (415) 882-5159 or e-mail fleisherassociates@att.net.] ■

5 ways to comply with HIPAA oral privacy regs

Consider simple design changes

When an orthopedic resident was paged repeatedly to assess a patient with an open fracture of the forearm, he failed to respond. The resident was paged multiple times and took more than an hour to get to the emergency department (ED). When he finally arrived, instead of apologizing for his delay, he began to loudly explain to the patient and his family that he was unaware of the urgency of the situation, recalls **Peter Alan Bell**, DO, FACOEP, FACEP, professor of emergency medicine at Ohio University College of Osteopathic Medicine in Columbus. "In a loud and clear voice, he criticized the staff's treatment and questioned their competency," Bell says.

Furthermore, the resident loudly discussed the extent of the injury, treatment, and potential complications, he adds. "His residency program director and I discussed this," he says. "Needless to say, his behavior was not condoned, and he received counseling." This is a potential violation of the Health

Insurance Portability and Accountability Act's (HIPAA) oral privacy requirements. **(To obtain the regulations, see "Resources," right.)** Penalties are severe, with civil penalties of up to $25,000 for each requirement violated, and criminal penalties of up to $50,000 and one year in prison for obtaining or disclosing protected health information.[1,2]

Consider another example of a potential HIPAA violation: When a thoracic-vascular surgeon suspected an aortic aneurism in an 89-year-old man, he discussed the plan of care, the risks, and the probability of success in full earshot of other patients. "He was loud enough for patients at a half dozen beds to hear, plus the staff at the adjacent nursing station," Bell says. When asked why he was speaking so loudly, he replied that this was a risky operation and he wanted witnesses. "I suggested he lower his voice," he says. The patient and his three children all had good hearing, he says. "The nurse would serve as his witness on the surgical consent form, and he could list the risks on the form for the patient to sign," Bell says. "If he was really concerned, he should ask the children to sign as well."

Don't ignore oral privacy

You may wrongly believe that it's impossible to give patients oral privacy in the hectic ED environment, says **David Sykes**, PhD, vice president and lead consultant for HIPAA compliance for Acentech, a Cambridge, MA-based consulting firm specializing in noise control. "ED managers often assume that it's too expensive a problem to solve, and therefore, they ignore it," Sykes says. That's a mistake, he says. "It's in the patient's best interest and your best interest to fix this," Sykes says.

Here are effective ways to comply with HIPAA requirements for oral privacy:

1. Encourage staff to be discreet.

Bell says, "I believe that we all could do a better job lowering our voices or stepping away from the bedside or main flow of people to discuss cases."

2. Consider simple design changes.

Remodeling the ED is *not* a HIPAA requirement, Bell stresses. "However, it certainly seems prudent that we take into consideration simple changes that would enhance confidentiality," he says. Bell gives these examples to improve oral privacy:

- using cubicles or screens in open areas;
- doing triage in a room adjacent to the waiting area;

Resources

For more information about compliance with oral privacy regulations, contact:

- **Peter Alan Bell**, DO, FACOEP, FACEP, Professor of Emergency Medicine, Ohio University College of Osteopathic Medicine, 1087 Dennison Ave., Columbus OH 43201. Telephone: (614) 297-4207. E-mail: bell@exchange.oucom.ohiou.edu.
- **David Sykes**, PhD, Vice President, Acentech, 33 Moulton St., Cambridge, MA 02138. Telephone: (617) 868-8866. Fax: (617) 499-8074. E-mail: david.sykes@remington-group.com.
- A guidance document for compliance with HIPAA's Medcal Privacy — National Standards to Protect the Privacy of Personal Health Information regulations is available, titled *Office of Civil Rights Guidance Explaining Significant Aspects of the Privacy Rule — Dec. 4, 2002.* The document can be accessed free at www.hhs.gov/ ocr/hipaa/privacy.html. The final rule was published in the Feb. 20, 2003, *Federal Register*, and can be downloaded at no charge at www.cms.hhs.gov. Click on "HIPAA," "HIPAA Administrative Simplification," and scroll down to "HIPAA Security Standards Final Rule Published."
- The Sonet Acoustic Privacy System includes a sound generator and two sound-masking emitters that can be placed on the wall, desk, or ceiling. Each sound generator can be expanded to cover a wide range of office and waiting room sizes. A variety of units ranging in cost from $144.95 to $999.95 can be ordered at http://store.yahoo.com/earplug store. Click on "HIPAA Products and Information," "Sonic Acoustic Privacy System."
- The Oasis System is a miniature, ceiling-mounted acoustical privacy system for health care facilities. The Oasis Master Control unit costs $375 each. For more information, contact Ergonomic Resources, 412 Long Cove Court, Allen, TX 75002. Telephone: (877) 474-3746 or (972) 678-2190. Additional information about sound masking products compliant with privacy regulations is available on the company's web site (www.ergo-2000.com). Click on "WhiteNoise/Soundmasking."
- Noise-reducing and sound-masking ceiling systems are available from Armstrong World Industries. A selection can be viewed on the company's web site (www. armstrong.com.) Click on "Commercial Ceilings," and under "Browse ceilings by . . . " click on "Performance Attribute," "Acoustics." For more information, contact Armstrong World Industries, Attention: BPO Customer Service Center, P.O. Box 3210, Lancaster, PA 17604. Telephone: (877) 276-7876.
- Sound Curtains are sound-absorbent barriers that can be installed with ceiling- or floor-mounted hardware. For more information, contact: Unger Technologies, 15370 Herriman Blvd., Noblesville, IN 46060. Telephone: (888) 213-4711. Web: www.enoisecontrol.com.
- A variety of sound control curtains, ceilings, and wall panels are available from Acoustical Surfaces, including portable enclosures and screens. For more information, contact: Acoustical Surfaces, 123 Columbia Court N., Suite 201, Chaska, MN 55318. Telephone: (952) 448-5300. E-mail: sales@acousticalsurfaces.com. Web: www.acoustical surfaces.com.

• using physician dictation cubicles to replace open desk areas that allow dictations to be overheard;

• placing clear plastic screens by nursing stations and desks.

3. Limit access of visitors.

Visitors pose the greatest risk of breach of confidentiality, but limiting access is not that difficult, Bell says. "Locked EDs are now the standard," he adds. "Defining how many visitors are allowed per patient and use of a visitors badge system can control flow." Security personnel can help by ensuring that a visitor's badge matches the patient he or she is visiting, and if not, asking visitors to leave, Bell points out.

4. Ask staff to put themselves in the patient's shoes.

It helps to remind staff to consider the issue of privacy from the ED patient's perspective, he says. "Patients put on a gown, lay down on a gurney, and subject themselves to a full work-up/evaluation," he says. "Add inadequate pain control, and the picture is almost complete." Consider the embarrassment of having the details of whatever brought you to the ED broadcast to others, he says. "It's not a pleasant feeling," Bell says.

5. Use sound-blocking tools to mask noise.

The following are effective and inexpensive solutions to block conversation in the ED waiting room, treatment areas, and hallways, says Sykes. (To obtain information about these tools and products, he recommends accessing www.google.com and doing a search using key words "HIPAA sound masking.")

• Use portable "white-noise" machines. "You can buy very useful, HIPAA-compliant sound-masking devices for as little as $100 that will take care of a waiting room, and they can simply be plugged into a wall," says Sykes. **(See "Resources," p. 22, for a list of manufacturers.)**

• Switch to ceiling tiles with a higher noise-reduction rating.

• Use sound-absorbent curtains or cubicle panels between beds. (**For more information, see "Resources."**)

• If you put a panel between two beds, you can prevent a patient from hearing a doctor talk to another patient in the next bed, Sykes says.

References

1. 45 CFR §160.306 and §160.312 (2000) for Civil Enforcement.
2. 42 USC 1320d-6 (HIPAA Sec. 1177) for Criminal Enforcement. ■

URAC accreditation standards out for comment

Standards to provide a guide for internal verification

URAC has released a draft set of HIPAA Security Accreditation standards for public comment. Once the program is completed, it will enable health care organizations to display a commitment to information security and demonstrate that they have adopted the necessary policies and procedures to ensure health information security in accordance with the HIPAA security rule, says URAC president **Garry Carneal**.

According to Carneal, the purpose of the accreditation program is to "verify that an organization has put in place the necessary infrastructure and implemented the necessary processes to comply with the HIPAA security rule. URAC supports fair information practices and recognizes the value that health information security adds to the health care process."

Source of due diligence

He says URAC HIPAA security accreditation will provide value to health care organizations by:

• providing a guide for internal verification of HIPAA security compliance efforts;

• providing a source of documented and demonstrated due diligence; providing a convenient source of industry security practices;

• facilitating collaboration with trade associations, government agencies, and the regulated industry in the compilation of security practices, threats, vulnerabilities, and advances in security technology;

• allowing organizations to treat the URAC accreditation as an evaluation by external reviewers; allowing accreditation by an independent, third-party organization; assuring customers/patients that appropriate steps are being taken to protect health information;

• demonstrating to current and potential business partners good-faith efforts to meet HIPAA security requirements; reducing potential penalties/sentences for organizations that have an effective compliance program; supporting organization risk management efforts;

• allowing an organization to demonstrate to regulators and other stakeholders that the

organization has taken reasonable steps to achieve compliance with the HIPAA security rule.

"This accreditation program is designed to be relevant to all health care organizations expected to comply with the HIPAA security rule," Carneal said. "That includes covered entities, business associates, and organizations that, while not legally subject to HIPAA, still wish to validate their HIPAA compliance program. Since different organization types need to comply with certain HIPAA requirements, we intend to take a situational approach in determining which of the HIPAA security accreditation standards apply."

URAC HIPAA security accreditation will last for two years, at which time an accredited organization can submit a reaccreditation application and be reviewed by URAC before accreditation is granted for another two years.

[Editor's note: Obtain a copy of the draft accreditation standards from www.urac.org. Contact URAC at (202) 216-9010.] ■

Time needed to document security compliance

The U.S. Department of Health and Human Services (HHS) says that the nearly four million covered entities that must comply with the final HIPAA security rule will spend 64.5 million hours documenting their compliance efforts.

HHS included the estimate in publication of the final rule. It said covered entities will spend about 99% of the time — some 64 million hours — documenting organizational security policies and procedures, which will take each entity an average of 16 hours.

The remaining time will be spent this way — 75,000 covered entities will have to document an average of three times why it is not reasonable and appropriate to implement a requirement, a 15-minute task that will require an aggregate 56,250 hours; 60,000 covered entities must document a contingency plan to secure electronic protected health information during a disaster or other emergency, an eight-hour task worth a total of 480,000 hours; and 15,500 covered entities will have to repair or modify physical components such as walls, doors, and locks, to secure data. Each repair or modification will take 10 minutes to document for a total burden of 2,583 hours, according to HHS. ▼

OCR pushes for voluntary compliance

U.S. Department of Health and Human Services Office of Civil Rights (OCR) director Richard Campanelli says that voluntary compliance with the HIPAA medical privacy rule is the best way to protect health information. He also told a HIPAA workshop that the federal government's enforcement of the regulation will be largely complaint-driven.

Campanelli added that most complaints about violations of the HIPAA privacy rule can be resolved easily. "OCR's goal is not to maximize enforcement," he said. "Our goal is to protect personal health information." Campanelli says he recommends that patients register complaints with their health care providers before turning to the government with privacy violations. ▼

Help available for employers

The U.S. Department of Labor's Employee Benefits Security Administration (EBSA) has started a HIPAA Compliance Assistance Program to help employers and other covered entities comply with new privacy regulations.

The program addresses many issues facing employers through nationwide compliance assistance workshops and a new section on the EBSA web site that has detailed compliance information. EBSA also will release several HIPAA compliance publications, including a self-audit checklist and tips for avoiding HIPAA pitfalls.

[Editor's note: For more information, go to www.dol.gov/ebsa.] ■

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Without proper language interpretation, sight is lost in Oregon and a $350,000 verdict is reached

By **Edward J. Carbone**, Esq., **Jan J. Gorrie**, Esq.,
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News: A Mexican laborer injured himself on the job when a piece of metal entered his eye. He did not seek medical attention until the next day. The day after that, he was referred to an emergency department (ED), where the eye was finally appropriately treated. The surgery was performed too long after the injury occurred to save the laborer's sight. The jury awarded the laborer $350,000, less 35% contributory negligence, for a net verdict of $250,000.

Background: The plaintiff was working as a general laborer in Oregon at the time of the accident. He was a native of Mexico whose native tongue was Spanish but spoke a limited amount of English. He was on a construction site using a nail gun when he was struck in the eye by a 6-mm piece of metal. At the time of the accident, the laborer advised his employer of his injury. However, it was not until the next day that he was taken to a freestanding urgent care center and examined by a physician. The clinic did not provide an interpreter on site and neither the physician nor her assistant spoke Spanish. An interpreter was made available through a phone service, but it was the physician who remained on the line and the three parties were not joined via speakerphone. The patient never spoke directly to the interpreter.

The plaintiff claimed that he tried to communicate that he had been using a nail gun at the time of the accident and that a piece of metal struck his eye. However, it was noted in the clinic's medical record that the patient had previously been hit in the eye by a wood chip. The clinic physician ultimately diagnosed the patient as having an abrasion to the eye and treated it accordingly.

By the next morning, the plaintiff's condition worsened and he returned to the clinic. After he was triaged, he was sent immediately to the neighboring hospital. Once seen in the ED, surgery was performed to remove a piece of metal lodged in his eye. The date was July 1, 1998. Subsequent surgeries were performed July 20, 1998, Sept. 15, 1998, and Feb. 23, 1999, but to no avail. The laborer's sight remains impaired.

The plaintiff brought suit against the clinic and the initial treating physician claiming that the lack of an interactive interpreter resulted in the impaired vision. The plaintiff averred that the standard of care required immediate referral to an ED if there was a history of using any sort of power tool at the time of injury, as was the case in this instance. The plaintiff maintained that had he been able to communicate directly with the interpreter, the details of the mode and extent of the injuries would have been conveyed to the practitioner. The plaintiff's expert testified that had the surgery been performed earlier, the man's sight could have been saved. The jury returned a

verdict in favor of the plaintiff of $350,000, less his contributory negligence of 35%, for a net verdict of $250,000.

What this means to you: For most clinicians, a good case history is the foundation upon which good care can be given. Incomplete or inaccurate information generally leads to spurious conclusions and often incomplete, inappropriate, or delayed care. Often this is to the detriment of the patient, as it was in this case.

While the physician attempted to seek assistance from an interpretive service, the patient was not concurrently interactive in the communication with the interpreter and physician. When the need arises to provide foreign language interpretive services in a medical environment, it is preferred that the interpreter is a certified medical interpreter, who understands the importance of the need for three-way communication. The interpreter should be just that — the middleman interpreting for both the patient and their caregiver, and the lines of communication, should be interactive so that each parties' questions and answers can be made known to the other. Further, a potential problem with using either family or staff as interpreters lies in the bias of the interpreter.

"A family member may interject their own desires into the patient's care plan or staff may perceive that the family is doing such and modify their treatment plan accordingly. Conversely, staff may bias the interpretation to suit the interests of the facility or physician. Use of a certified medical foreign language interpreter eliminates bias and the interpreter is able to balance the technical medical terminology in transference of information to the layperson. This service can be contracted on a case-by-case need. The contract should include a timeframe in which the interpreter must respond to a request for services. This is particularly important to facilities providing emergency or urgent care, where acute conditions may call for the delivery of more timely care. The contract also should specify the credentials of the individual interpreters to be provided," observes **Diane Giraudi Perry**, PhD, LHRM, senior risk manager at Bon Secours Venice (FL) Healthcare.

Should the patient's inability to communicate be related to a hearing deficit, additional considerations must be made. At minimum, an interpreter should always be made available during interactions between a hearing-impaired patient his or her physician.

"Not only can the lack of an interpreter result in medical errors and liability for such, but the failure to meet the needs of a hearing-impaired person in the delivery of medical care can also result in a lawsuit under the auspices of the Americans with Disabilities Act [ADA]. There are two basic interpretive services that should be available to the hearing-impaired and deaf populations: a manual interpreter (sign language) and an oral interpreter for patients who are not manual communicators. An oral interpreter rephrases the statements into words whose sounds are more easily heard by the severe to profoundly hearing impaired — those who generally use amplification such as hearing aids. The use of oral or manual interpreters who are certified medical interpreters is again recommended because the use of staff or family may result in the same pitfalls described above," states Perry.

Under the ADA, hospitals are required to provide qualified sign language interpreters to patients and the patients' companions who are deaf or hard of hearing whose primary means of communication is sign language and are to provide qualified oral interpreters to such patients and companions who rely primarily on lip reading, as necessary for effective communication. The following are examples of the circumstances when it may be necessary to provide interpreters: determination of a patient's medical history or description of the ailment of injury; provision of patient's rights, informed consent, or permission for treatment; religious services and spiritual counseling; explanation of living wills or powers of attorney; diagnosis of ailments or injuries; explanation of medications prescribed (such as dosage and side-effects); explanation regarding follow-up treatments, therapies, tests results or recovery; blood donations or apheresis; discharge instructions; provision of mental health evaluation, group and individual therapy, and counseling; explanation of complex billing or insurance issues that may arise; and, education presentations, such as classes concerning birthing, nutrition, CPR, and weight management.

Further, health practitioners also should be aware of the tools and techniques used to meet the needs of individuals with oral/speech communication deficits. The use of a communication board will assist the clinician in communicating with a patient with a verbal communication deficit, such as expressive aphasia. "Regardless of the patient's particular communication deficit whether the barrier is language- or hearing-related, if not

appropriately addressed, the inability to appropriately and effectively communicate with your patient makes it difficult to treat the patient. Pediatrics and emergency medicine practitioners experience these circumstances more frequently and routinely; however, all practitioners should have the means to address these circumstances," concludes Perry.

Reference

• *Martin N. Urbina v. Providence Health System and Lou Ann Goodrich, MD,* Mulnomah County (OR) Circuit Court, Case No. 0006-06026. ■

Two trials determine negligence in baby case

News: The mother of a premature infant who was placed in a hospital's neonatal intensive care unit (NICU) brought suit against the hospital and specifically against the NICU. The first trial resulted in a $2.4-million verdict against the NICU. This decision ultimately was overturned because instructions to the jury failed to specify which of the hospital's agents or employees were involved in the negligence alleged by the plaintiff and failed to differentiate between the varying standards of care applicable to those agents and employees. These technical deficiencies will likely be addressed on remand.

Background: The infant was born prematurely and was placed in the hospital's NICU. An umbilical arterial catheter (UAC) was inserted into his abdomen to monitor blood gases. When he was 2 days old, a nurse drew blood from the UAC and repositioned the child. Shortly thereafter, the boy was found bleeding from his umbilical artery because the UAC had become dislodged. The child lost approximately half his blood supply in the incident; however, no cardiac or respiratory alarm sounded.

According to the nurse, once she realized what had occurred, she immediately applied pressure to stop the bleeding, summoned a neonatologist, and paged a medical resident. The neonatologist ordered a push of 20 cc Plasmanate. The medical resident ordered another 10 cc Plasmanate and 20 cc packed red blood cells. The neonatologist did not recall the incident at trial.

The infant was transferred to another facility the following day. A cranial ultrasound showed the boy had suffered intracranial bleeding. He was later diagnosed with cerebral palsy and mild mental retardation.

The mother sued the hospital, alleging medical malpractice. The trial judge ruled a national standard of care applied to nurses and allowed for jury instructions that substituted the "hospital neonatal intensive care unit" for the specific professionals and specialists at issue.

On appeal, the court ruled that this instruction was improper because it failed to specify which of the hospital's nurses, physicians, and medical residents were involved in the care of the boy. Further, the instruction failed to differentiate between the varying standards of care applicable to those agents. The appellate court noted that the hospital could be held vicariously liable only for the negligence of its employees and agents, and that the NICU was neither. Further, there was no evidence presented by the plaintiff that the NICU acted independently or had any independent responsibilities. However, because the hospital may be directly liable for malpractice through claims of negligence in supervision of staff physicians and selection and retention of medical staff, or may be vicariously liable for its agents' negligence, if the arguments are repackaged, the hospital may ultimately be found liable in this instance.

The appellate court also rejected the court's use of a "general" statutory standard of care for nurses, which was the standard applicable to general practitioners as opposed to the specialty nurses used in the NICU. The court concluded that neither the general nor specialist standard of care applied to nurses, who do not engage in the practice of medicine. The court instead ruled that the common-law standard of care applied in medical malpractice actions against nurses, that being the skill and care ordinarily possessed and exercised by practitioners of the same profession in the same or similar "units."

What this means to you: We can expect claims of vicarious liability directed at hospitals to be on the rise as the media coverage expands on the issues of the nursing shortage, the malpractice crisis, and the increase in errors occurring in health care institutions. This case identifies legal arguments that were appropriately rejected at the appellate level. However, as mentioned, creative repackaging of these arguments by plaintiff's

counsel could create genuine exposure to the hospital in many areas.

"Staffing and nurse-patient ratios, particularly in high-acuity areas, will become critical in a climate where research studies are being conducted to attempt to correlate patient errors to the nursing shortage," notes **Melanie Osley**, RN, MBA, CPHRM, risk manager at St. Francis Hospital & Medical Center in Hartford, CT. In this particular case, the nurse-patient ratio would have been an important factor in identifying how much time might have elapsed before the nurse returned to this patient and discovered the dislodged catheter and the bleeding. Staffing issues also can effect how often routine safety checks of equipment are performed and whether alarms are functioning properly. If an argument of inappropriate staffing relative to patient acuity and maintaining patient safety prevails in court, the hospital can have significant liability.

Hospital training, supervision, and utilization of nursing staff also will come under scrutiny as a potential liability hazard. Cross training and floating are both commonly used methods for solving nursing staffing problems in particular patient care areas. Within a hospital system, similar nursing units may be under the supervision of one nursing director functioning under a specific nursing specialty division. Nurses in these units may be cross-trained to float among the similar units within the division. For example, neonatal intensive care, labor and delivery, postpartum, and pediatric nurses may be trained to float among all of their respective areas, or to float just within one or two of the areas. It is important to be certain that cross-training is adequate, ongoing, and properly documented. As cited in this scenario, the standard of care for malpractice actions against nurses refers to the skill and care ordinarily possessed by a practitioner in the same or similar "units." "Utilization of nursing staff in areas other than their "home" unit at a frequency rate that blurs the lines of nursing specialty skills, or that makes it difficult to properly maintain the skills for which the person was cross-trained, is fodder for liability exposure," Osley says.

Hospitals also could be held liable for inappropriate use of clinical staff in areas where the skill mix of the staff and the patient census and acuity do not match accurately enough. While the appellate court was correct in its ruling that a "unit" is not a specific employee or agent, the individual staff members within a particular unit *are* the agents, servants, or employees of the hospital. The training, education, and skills required of the personnel who work in certain units can and should come under scrutiny from a risk management perspective. Documents indicating the skill mix of unit employees can be discoverable, along with documents showing what specific staffing ratios were on any given date.

The publicity surrounding medical errors in health care institutions will, no doubt, create an increase in the numbers of medical malpractice claims. The malpractice crisis already has forced some providers to leave their private practices or continue their practice woefully underinsured in comparison to the settlements and verdicts that are occurring. This combination will force plaintiffs to look to the "deep pockets" of the hospital as a source of compensation. They will seek a variety of creative ways to find liability on the part of the hospital and its staff, whether it is physicians, physician extenders, or nurses. Osley contends, "the risk manager should be aware of how validation of staff skill is maintained, and how the staffing processes are utilized and documented."

Reference

• *Cox v. Board of Hospital Managers for the City of Flint,* No. 118110 (Michigan, July 25, 2002). ■