



# Healthcare Risk Management™



## IN THIS ISSUE

- Good marks for industry's flu response ..... cover
- Home care ready for flu pandemic ..... 75
- Reporting test results requires oversight, vigilance ..... 76
- Unread X-ray prompts \$2.19 million verdict ..... 79
- Electronic credentialing may offer benefits ..... 79
- Wrong-site error leads to hospital review ..... 81
- Helicopter group supports night-vision goggles ..... 81
- New HHS secretary calls for action on HAIs ..... 82
- **Inserted in this issue:**
  - Legal Review & Commentary
  - 2009 Salary Survey

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## Flu scare shows strengths and weaknesses from providers

*Risk managers should assess response, prepare for next time*

The nation's most recent scare with the H1N1 flu virus showed both the good and the bad of health care providers' preparations for a serious pandemic, and the assessments are largely positive. Risk managers analyzing their own organization's response likely will find much to be proud of and a few areas that could use improvement, says **Maurice A. Ramirez, DO, BCEM, CNS, CMRO**, an emergency physician at Pascoe Regional Medical Center and president of the consulting firm High Alert, both in Kissimmee, FL.

There is no doubt that the H1N1 scare in the first half of 2009 gave American hospitals a test run for their epidemic readiness. Hospitals in Long Island, NY, reported a 50% surge in ED visits, forcing a scramble to find enough health care workers to handle the influx. The Hospital Association of California reported that hospitals in the Los Angeles area experienced a 12% increase in ED visits. A hospital in Galveston, TX, near the Mexican border, ran out of flu testing kits early in the season after being swamped with patients worried that they had the H1N1 flu. Loma Linda University Medical Center in San Bernardino, CA, set up a tent in the parking lot outside the ED to handle the sudden surge in patients

## EXECUTIVE SUMMARY

The current H1N1 flu season may be less severe than expected, but flu experts and hospital leaders say the effects may be more severe next time. In the wake of the experience of early 2009, risk managers can learn lessons from how the health care community and the general public responded.

- A key task for hospitals may be educating the public and discouraging overreaction.
- Some of the more prominent flu-response tactics have little value.
- The overall response by health care providers this time was good.

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fearful of the flu. Children's Memorial Hospital in Chicago saw 394 children in its ED one day, more than double the typical number. (**Some hospitals used a web-based system to keep track of flu cases and how providers were responding. See p. 76 for details on that system.**)

Almost all of the patients swarming EDs around the country turned out to have nothing more than a routine case of the sniffles or a less dangerous strain of the flu, and many were not sick at all but worried by the hype about H1N1. Most hospitals responded by isolating patients reporting flu symptoms, and handing out masks for them to wear while at the hospital. (**Home care providers also would be on**

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**the front lines of a pandemic. See p. 75 for more on their readiness.)**

Ramirez points out that, while it may seem the early 2009 flu scare is done or ending, that isn't necessarily the case. The flu could surge again and bring far more cases than the country saw earlier, either as a resurgence of the swine flu, the avian flu, or a combination of the two. Next year's flu season also could be more severe.

"The general pandemic scenario involves a pre-pandemic, a mini version if you will, that hits the season before the true pandemic really takes place," he says. "It keeps burning through the population worldwide and building the number of cases until the next season when it really takes off."

Risk managers should be sure that their organizations are not letting their guards down, Ramirez says. In particular, he says, remember how some providers handled the recent severe acute respiratory syndrome (SARS) scare.

"You must be certain that you are continuing your pandemic plans, particularly by continuing the surveillance," he says. "There are hospitals that stopped doing the tests to confirm it is H1N1 because they were afraid of being labeled a swine flu hospital, in the same way that hospitals in Toronto were labeled SARS hospitals and saw a dropoff in patronage as a result. You cannot let public relations, public image concerns, govern public health."

Without the surveillance, you may have flu spread to your staff, and you will quickly lose personnel, he notes. You also are unable to properly report flu cases if you are not vigilant about surveillance.

"Remember, they executed two people in China for not reporting SARS," he says. "You don't want people pointing fingers and deciding who to fire — the corporate equivalent of being executed — over having made a decision to not act in the public's best interest. That is a public relations nightmare that no one in this health care industry will want."

#### **Avoid flu hysteria**

Ramirez says he would give the health care community generally good marks for its response to the H1N1 flu, though there were instances of overreaction that fed the public's hysteria and led to overcrowding in EDs. He heard reports of some health care providers going "Tamiflu-crazy" with 10,000 prophylactic prescriptions for the anti-flu medication in the first 10 days of the flu scare, before there had even been 200 cases reported nationwide.

Some EDs acted with more paranoia than reason, Ramirez says. Activating a flu pandemic plan is justified, he says, but then the plan must be carried out in a reasonable manner. He saw some EDs putting masks on all children who showed up with a cough, which he says is overkill and counterproductive unless the masks are used properly — which they almost never are. Masks must be replaced every four hours, placed on the face whenever the wearer is near another person, and not removed for convenience when eating or drinking, among other rules.

"Masks on patients are supposed to be N95, not the little things with loops behind the ears. Those are useless," he says. "One of my colleagues at the CDC refers to those as 'tissues with handles.' Instead of throwing that tissue away, you keep it hanging on your face for 12 hours. I see health care workers take them off and let them hang from their neck. So now, they're just inhaling all the stuff that was on the outside of that mask."

On the positive side, Ramirez says most health care organizations saw an increase in good hand washing technique because of the flu. He suggests that risk managers push for a reasonable response to flu concerns, which may involve pulling back on some standard ways of operating in the health facility.

"There's been a big push for family presence in recent years, with the idea that we want those patients surrounded by family and friends," Ramirez notes. "That's all well and good in a normal situation, but the hospital has to be ready to say that in a Level 5 pandemic, having all those people around is not a good idea. The risk manager needs to be a voice of reason to say we can respond appropriately but without making it look like we're in a panic."

One of the lessons learned from the flu season was that you never know when a potential disaster will strike, and you must ensure that your organization is always ready, says **Carol Burkhart**, RN, MS, CNP, a senior vice president in Marsh's Health Care Consulting Practice in Denver.

"We always talk about preparation in health care, but we have to ask the hard questions about whether we have all the necessary equipment and whether our personnel are really prepared to respond effectively," she says. "In a situation like a pandemic flu, we find out very quickly whether we are or aren't."

The flu also highlighted the need for a good media response plan, Burkhart says. In the early 2009 flu season, the media hyped a lot of

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misinformation and led the greater fear among the general public than was warranted, she says. That, in turn, led to too many visits to EDs that, if flu really were present in the community, could have just spread the flu to the worried well who went and sat in the waiting room with the truly sick.

"There was a lot of confusion in the community, so it behooves risk managers to make sure their organizations can stem that tide and respond appropriately with information from your media department that counters some of the misinformation," Burkhart says. "Your people will be viewed as the local or regional experts, so they need to be ready and informed enough to be the voice of reason, the voice of fact — and not just worries and fears."

Burkhart says most of the health care operations she works with did operate their pandemic plans effectively.

"I think they could have been a little more aggressive in countering the misinformation from the media, but that would be my most serious criticism of the health care industry response," she says. "Overall, a good report for this experience, but we dodged a bullet this time. The next flu pandemic, in the fall or whenever it happens, may be much more severe than this one, and we will have to maintain a constant state of readiness." ■

## Most home care providers ready for flu pandemic

**B**e sure to include home care services in any pandemic response plans. Fortunately, more than half (53%) of the nation's home medical equipment and service providers have formal plans to respond to a pandemic flu, and another 23% have stockpiled N95 masks or other supplies

## SOURCES

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related to a flu pandemic, according to a survey of 1,500 providers conducted at the beginning of the most recent flu scare.

Eighteen percent said they were working on a formal plan and expected to have one in place within the week. Two-thirds said they were coordinating or communicating with other organizations in their communities to prepare for a pandemic.

The survey of approximately 1,500 home medical or durable medical equipment providers was conducted by the American Association for Homecare. The 147 home care providers that responded collectively serve more than 2.5 million patients through more than 1,000 branch locations across 50 states, explains **Tyler J. Wilson**, president of the association based in Arlington, VA.

"Home-based care is a centerpiece of the national pandemic flu response, and in a pandemic situation, home medical equipment personnel will be on the front lines," he says. "Our members have experience responding to weather-related emergencies and power outages, which present risks to patients who require oxygen through devices that require electricity. A pandemic flu presents a different set of challenges, but the home medical sector has prepared for them."

Wilson says home health care workers can expect to be called on to provide care for two main populations of patients:

- Those medical and surgical patients, not hospitalized because of the pandemic, who are well enough to be discharged early from hospitals to free up hospital beds for more severely ill patients.
- Patients who become or already are dependent on home health care services (predominantly elderly people with chronic disease) and will continue to need in-home care during the influenza pandemic, regardless of whether they become infected with the influenza virus.

The demand for home health care services during a pandemic influenza outbreak is likely to exceed the home health care industry's current capacity to respond, Wilson says. Indeed, the

overall surge capacity and preparedness levels of the home health care sector that will be necessary to respond effectively to a public health emergency, such as pandemic influenza, are significant unknowns, he notes.

Some home care providers have had pandemic flu plans and training dating back several years. **Pat Northheimer**, clinical director at Cole Care in Coudersport, PA, says his organization had a pandemic flu drill three years ago that involved hospitals and local EMS.

"Projections were made with a scenario that worsened each day," he says. "It was very helpful in showing us just how bad things could get if the projections were accurate. The drill went into great detail."

Two years ago, the American Association for Homecare participated, with the Centers for Disease Control and Prevention in Atlanta, other federal agencies, and other health care associations, in a two-day panel to advise the federal government about the role of home-based care during a flu pandemic. The chief result of that panel is the publication, *Home Health Care During an Influenza Pandemic: Issues and Resources*, prepared by the Agency for Healthcare Research and Quality, which contains useful links to resources and detailed discussion of key issues related to planning, patient care, community and business response, legal questions, and work force challenges.

"In the event of an influenza pandemic, because of anticipated shortages of health care professionals and widespread implementation of social distancing techniques, it is expected that the large majority of individuals infected with the influenza virus will be cared for in the home by family members, friends, and other members of the community — not by trained health care professionals," the report states.

(Editor's note: The publication is available online at [www.pandemicflu.gov/plan/healthcare/homehealth.html](http://www.pandemicflu.gov/plan/healthcare/homehealth.html).) ■

## Reporting test results requires vigilance

The reporting of critical test results and lab values is the kind of process that makes a risk manager nervous if you think about it too much. How do you really know if your organization is reporting test results promptly, efficiently, and

## EXECUTIVE SUMMARY

Critical test results must be reported efficiently and accurately every time to avoid threats to patient safety and potentially huge malpractice liability. Risk managers can improve reporting by working with laboratory managers and creating facilitywide policies and procedures.

- Each organization must define its own set of critical test results.
- Track key metrics to gauge your effectiveness with reporting results.
- Mislabeled specimens are a common cause of reporting errors.

effectively, every single time? After all, getting it right most of the time isn't good enough. Drop the ball just once, and a patient could suffer terribly, not to mention the resulting lawsuit.

All test results should be reported properly, of course, but it is the critical test results that pose the biggest risk management nightmare. A critical test result is defined as one that is sufficiently abnormal that the patient is potentially at risk of sudden death or immediate harm, explains **David S. Wilkinson, MD, PhD, FCAP**, a pathologist with the Virginia Commonwealth University (VCU) Health System in Richmond, chair of the Department of Pathology at VCU, and chair of the College of American Pathologists' Quality Practices Committee.

For risk managers, Wilkinson says a key step is for the organization to define its list of critical test results. Not every single test result can be handled as if it is of the utmost importance — Wilkinson's lab produces results on almost 3,000 different tests — so your organization must know which ones should be considered critical. That means not just which test, but which test results, he notes. In some cases, the results of a particular test will always be of critical importance. But in other cases, the results of the test will be critical only if they fall sufficiently outside the normal parameters. **(X-rays and other diagnostic results also must be performed and the results reported properly. For an example of how that process can fail, see the story on p. 79.)**

"The list will be different for each institution based on the type of care you provide and the patients you see, but you need to know which tests and results to watch out for. Get all the definitions on the table and make sure everyone understands what you mean when you say

critical test results," he says. "Then, it is a matter of having the right policies and procedures in place so that the workers, the medical laboratory technicians, or the licensed health care providers who may be receiving these critical results — or the physicians themselves — understand what to expect."

### **Track metrics to measure success**

That is a part of the process where risk managers can play a significant role, Wilkinson suggests. The risk manager can facilitate the communication between the parties and oversee the policies and procedures that must be followed when a critical test result is in play.

Tracking metrics regarding critical test results reporting also is important, Wilkinson says. There is no way to know how well you report results if you don't follow the data, he says. Risk managers should be directly involved in measuring the metrics and analyzing those data, then using the information to tweak the reporting policies and procedures.

Wilkinson notes that there are several ways the process of reporting critical test results can go wrong. Simply failing to pass on the information to the nurse or physician is only the most obvious way the process can fail; it actually is not the most common error. Reporting incorrect information because the patient or specimen was misidentified actually is a much more common way a critical result is miscommunicated, Wilkinson says.

"Probably by at least a factor of 10, that's far more common than other types of failure," he says. "You just got the wrong blood in the wrong tube somehow, and so the results you're reporting are not accurate for that patient. That is much more common than the situation in which all the actual testing went according to plan in the laboratory — and then somehow the result does not get communicated properly after that."

**Elizabeth A. Wagar, MD, FCA**, clinical laboratory manager at the University of California Los Angeles Clinical Laboratories with the David Geffen School of Medicine, says the most recent data on critical value reporting indicate that about 1% of specimens are mislabeled, and some of those results could involve critical values.

That means that any effort to ensure reporting of critical test results should encompass that potential error also, she says. The actual reporting process in the laboratory also must accommodate the real-world difficulty of getting a doctor on the

phone, she says. Laboratories have policies and procedures for calling physicians or nurses to report critical values, and they have computer programs to facilitate this; but research indicates that between 0.1% and 0.3% of those calls are not completed for technical reasons, or the person just cannot be reached, Wagar says.

"So, things do just fall through the cracks sometimes," she says. "There are scenarios where that can be very important."

Wagar's research has suggested that there are two practices that can improve the success rate for reporting critical values:

- Laboratories that report critical values only to health care professionals — not a receptionist or an answering service, for instance — have a better record of successful reporting.
- Critical value reporting is more consistent and effective when the laboratory does not make many exceptions for individual physicians when defining critical values.

Assuming the specimen was collected and tested properly, then the next concern should be whether the critical result was communicated properly. To make monitoring of that process possible, the computer system in Wilkinson's lab requires that the technologist attach a comment detailing the reporting process to the result in the clinical laboratory information system. Then the lab managers can periodically query the databases to compile all critical test results (as defined at VCU) and determine if there is a comment documenting that the technologist called that test result in to the caregiver.

"We check on a daily basis. Through a typical month, we may have a couple thousand critical results, and there may be one or two where that communication was not documented," he says. "Sometimes, we find out that the technologist did call the result in but didn't document it in the system. Occasionally, just because things are busy and you're depending on individuals, the result is just not communicated. Monitoring that on a daily basis minimizes the potential for harm."

Auditing the process is crucial to ensuring the proper reporting of critical test results, Wilkinson stresses. No matter how good your policies and procedures are, routine auditing will reveal room for improvement, he says.

## **Formalize reporting process**

Wilkinson also points out that reporting the critical test result to a physician is not always as simple as it sounds. Calling the doctor directly is the best

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option, but that can be a challenge when the physician who ordered the test is now off duty or has transferred care to another doctor. In many cases, the lab must report the result to a nurse, which creates a longer chain of communication, as the nurse then must report the result to a physician.

"I'd see that as an area where risk managers can have a lot of influence," Wilkinson says. "What happens in the lab is something that I can control, but what happens with that critical result once it is reported to the floor has to be directed by policies and procedures in the organization."

Accurate reception of the results is another concern. A common method for ensuring accurate communication is for the lab to use a standardized format for the report that includes stating the patient's name, medical record number, the test, the result, and the statement. "This is a critical value." The reporter then asks the receiver to read back the information. The caregiver reads back all of the information, including the patient's name and other identifiers, to ensure accuracy. Some organizations require the receiver to state "I understand this is a critical value" or words to that effect.

Properly identifying the patient is of utmost importance, Wilkinson notes. The exchange must include at least two patient identifiers, such as the name and medical record number. Risk managers should never allow a report with just the patient's name, or even worse, a casual reference to "that potassium level you wanted." Formalization of the reporting process is extremely important, Wilkinson says.

Wagar notes that risk management can be quite helpful to the laboratory manager when it comes to ensuring proper reporting and in the investigation of problems. She encourages risk managers to develop a personal relationship with the lab manager so that the two can collaborate on patient safety.

Wagar also points out that in many organizations, the risk manager overlooks the resources in the laboratory when investigating adverse events. Laboratories have detailed record-keeping systems that indicate how and when results were communicated, which often can be useful in a risk manager's investigation, she says.

"When I have looked into situations in which the reporting of critical values might have led to problems with patient management, I have worked as partners with risk management to do the investigation," she says. "They can go to the individual clinical services, and we can work together to find out what the issue was. I also highly recommend that the lab manager and the risk manager both be on the quality committee or the patient safety committee so that they can work together on these concerns." ■

## Unread X-ray prompts \$2.19 million verdict

Illustrating the potential liability when a test result falls through the cracks, a Philadelphia jury recently awarded a widow \$2.19 million in a malpractice suit against St. Joseph's Hospital and two ED physicians.

Testimony during the 10-day trial showed that 51-year-old Zachary James of Philadelphia died at the hospital when his heart stopped beating on April 20, 2006. The following day, his wife Rosalyn James, learned that a key X-ray had never been read before his death. Expert testimony in the trial indicated that the X-ray may have revealed information that could have prevented his death.

James had arrived at St. Joseph's by ambulance after suffering chest, arm, and leg pains. He was triaged within 10 minutes, and the attending ED physician, Thomas Powell, MD, assessed him within a half-hour, according to court documents.

Powell ordered lab tests, X-rays, and echocardiograms. Attorney **Stephen Pokiniewski**, JD, with the Philadelphia law firm of Anapol Schwartz, represented the James family. He told the *Philadelphia Daily News* that the doctor left the hospital at 10:20 a.m., just under two hours after the patient had arrived in the ED, to attend a corporate meeting in another city. The patient was left in the care of Emil Skobeloff, MD, who was working his first day on the job at St. Joseph's and was the only attending ED physician.

Pokiniewski says Powell was supposed to be orienting Skobeloff to the job, but instead the new doctor was left on his own. "Things fell through the crack with the changing of the guard," the attorney told the newspaper.

Court testimony and medical records indicated that hospital policy called for the emergency physician to review the patient's X-rays before they were sent to radiology, but neither physician did so. James died about 11 hours after admission from a dissecting aortic aneurysm. Court records indicate that the X-ray that could have revealed the aneurysm was not read until the following morning.

The jury found Powell 48% liable, Skobeloff 36% liable, and St. Joseph's 16% liable. ■

## Electronic credentialing may offer providers benefits

Every risk manager wants to believe that the credentialing process has properly vetted all the organization's health care professionals to ensure that they are qualified and have no known criminal record. But that is not always the case. Too often, risk managers get a phone call alerting them that one of their staff or physicians has a problem that did not show up in the credentialing process.

The reason for some problematic employees and physicians slipping through the system often comes down to the administrative burden of doing a thorough background check, suggests **Matthew Haddad**, president and CEO of Medversant Technologies, a company in Los

### EXECUTIVE SUMMARY

Some health care providers are using electronic credentialing services to improve and streamline their processes. The method is considered by some to be the 21st century way to complete a task that otherwise might take more time and yield less information.

- Software systems can automate most of the credentialing process.
- Electronic credentialing can offer more current information.
- Some liability insurers may offer discounts for improved credentialing.

Angeles that offers credentialing and other services for providers. Although risk managers understand the need for researching the background of any and all employees, credentialing can be a long, expensive, and grueling process, he says.

In the time when most methods are moving from paper to digital, the credentialing process is no different, and risk managers may want to consider a more modern version of credentialing than the systems that have been in place for years. Along with several other companies and nonprofits, Medversant offers a software tool that ensures information on all health care providers is centralized, up-to-the-minute, and accessible to appropriate parties, therefore enhancing patient safety and the quality of care.

The old way of credentialing involves gathering a great deal of information, usually on paper, about the individual and then trying to confirm much of it yourself. Health care providers in recent years have moved more and more toward utilizing electronic databases and other computer resources, but Haddad says there still are many that could automate the process much more.

"What has traditionally been a mostly manual process turns into an electronic process that is faster, but at the same time offers better, more reliable information," he says. "Even though most hospitals have some sort of software in use, the software acts like a filing cabinet for the information, so that you still have to go find the data, print it out or copy it to another location, and use multiple sources for a report."

Electronic credentialing software, such as that offered by Medversant, actually does much of that work for the provider, rather than simply acting as a storage site for the data, Haddad says.

"So, when you need to check various third-party sources to find information on an individual, the system automatically does that rather than a staff person having to go to each of those third-party resources and manually checking them," he says, "and it does that continuously. The system checks that information as often as those outside databases update, and you could never have enough staff to do that manually."

That constant updating provides a nearly real-time snapshot of the individual's information rather than relying on what might be outdated and incomplete information retrieved by hand at the beginning of the credentialing process, Haddad says.

Automating the credentialing process allows large health care organizations to move their credentials data from paper files to a more useful type

## SOURCES

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of information, says **Anthony D. Begando**, founder and CEO of Tenon Consulting Solutions, a health care consulting company based in Alpharetta, GA, that has used electronic credentialing on behalf of its health care clients.

"Automated credentialing provides organizations with a detailed inventory of the clinical skills across their enterprise," Begando says. "Automated credentialing substantially reduces the administrative burden placed on providers and greatly improves compliance."

In addition to services such as those offered by Haddad's company, Begando recommends the Universal Provider Datasource (UPD) offered by CAQH, a Washington, DC, nonprofit alliance of health plans and trade associations. (*Editor's note: For more information on the UPD, go to [www.caqh.org/ucd.php](http://www.caqh.org/ucd.php).*) The UPD allows risk managers to leverage existing provider credentials information and electronically monitor hundreds of sources of sanctions data for providers.

Begando says moving to an automated credentialing environment allows for centralization of credentialing activities across an entire enterprise while preserving local privileging and board review processes. By participating in an electronic credentialing system such as the UPD, providers benefit from an improved credentialing process that yields more reliable information, and they also encourage a more cooperative relationship among providers, he says.

Haddad says some malpractice insurers have indicated that they may offer discounts for using electronic credentialing.

"They're talking about offering discounts in the range of 8% to 10%," he says. "They see benefits in terms of the provider being better able to screen out potential sources of liability down the road, so they see it as cost-effective to offer the discount to their customers who use a service like this." ■

# Wrong-site surgery prompts hospital review

After an instance of wrong-site surgery that still defies explanation, officials at Rhode Island Hospital in Providence agreed to conduct an extensive examination of safety procedures in the surgery department.

**John B. Murphy**, MD, the hospital's vice president for medical affairs and chief medical officer, announced that the review was required under the terms of a consent agreement with the Rhode Island Health Department. In late May, surgery was suspended for at least two or three hours in each specialty to allow surgeons, anesthesiologists, nurse anesthetists, and nurses to review policies and consider how they apply to each type of surgery. The findings of the review, and any modifications to policy or procedures, were not made public.

The agreement with the health department required the hospital to focus on situations in which current policies may be insufficient. Examples included procedures for marking the correct site when surgery is performed on the mouth, vagina, or eye, or ensuring that the surgeon operates on the correct side of an internal organ.

In addition to staff meetings to review procedures, the agreement requires that the hospital take these steps:

- contract with a patient-safety consultant to establish a system for reporting near-misses.
- develop methods to regularly confirm that all surgical staff members understand the current policies and procedures.
- clarify and standardize its timeout procedure.

Rhode Island Hospital was the subject of an investigation by the health department after a May 11, 2009, incident in which a surgeon began operating on the wrong side of a child's face. The health department's investigation found that the procedure to repair a cleft palate involved removing a small piece of bone from the patient's hip and grafting it in the roof of the mouth. The left side of the mouth previously had been repaired, so the surgery was to address the right side.

Investigators determined that the consent form signed by the parents correctly indicated the surgical site. The surgical team also properly performed a timeout in which all members agreed that the right side of the mouth was the correct surgical site. Even so, the surgeon cut into the left side of the mouth, the health department found.

A surgical resident who was involved in harvesting the bone from the hip noticed the error and called it to the surgeon's attention. At that point, the surgeon stopped and proceeded with the surgery on the right side. The hospital and the health department report that the rest of the surgery was successful and the patient fared well.

**David R. Gifford**, director of the health department, says the investigation could not determine how the error was made because all the proper procedures were followed. He notes that the willingness of the resident to challenge the surgeon is a positive indicator of the hospital's patient safety culture.

Murphy told *The Providence Journal* that the error may have occurred, or was not stopped before the surgeon began cutting, because the surgery was intraoral and that limited the ability of everyone else in the room to see where the doctor was working. He also said the patient had some unique characteristics that may have complicated the situation further. Murphy says the hospital revamped its surgical policies and procedures in the past to try to accommodate all possible scenarios, but "we haven't anticipated the millions or billions of situations that may come up."

The consent agreement does not end the health department's investigation. The hospital placed the surgeon on administrative leave and referred him to the medical licensing board for possible disciplinary action. The hospital and the health department determined that the nurses and the rest of the surgical team were not at fault. ■

## Night-vision goggles endorsed by air group

Testifying before a crowded hearing in Washington, DC, on the oversight of helicopter medical services, the head of a leading air ambulance organization recently promised lawmakers that the dismal safety record of the industry can be improved.

Sandy Kinkade, president of the Association of Air Medical Services (AAMS) in Alexandria, VA, offered an overview of the medevac helicopter industry and discussed the need for greater funding for airport and low-altitude infrastructure improvements, among other initiatives aimed at making patient air transport safer. The hearing was called by the U.S. House of Representatives

Aviation Subcommittee after a sudden surge in crashes. Nine crashes killed 35 people, including six patients, from December 2007 to October 2008, prompting the National Transportation Safety Board to hold a public hearing to address the problem.

Kinkade told the committee that the industry was determined to improve safety.

Chief among the association's safety proposals is that all medical night-flight operations be required to either utilize night vision goggles (NVGs) similar enhanced-vision systems, or be conducted strictly under instrument flight rules (IFR). AAMS recommended that Congress further this process along by appropriating funds for the Federal Aviation Administration (FAA) to expand its capabilities surrounding the certification and approval of NVGs or similar enhanced-vision systems.

AAMS also supports improving the low-altitude aviation infrastructure by expanding the Airport Improvement Program to include private-use hospital helipads, regional airports, and other routinely utilized locations, and directing more FAA funding and research toward expanding the capacity of low-altitude, off-airport weather reporting. AAMS also is in favor of increasing the number of automated weather observation stations and utilizing other weather forecasting technologies.

In addition, AAMS has asked that funding and research be directed toward associated approach and departure procedures to facilitate a seamless transition from visual flight rules to IFR.

The AAMS testimony came on the heels of a report by the Flight Safety Foundation, a research group in Alexandria, VA. The analysis identifies eight "very high" risks within the industry and 18 "high" risks. (*Healthcare Risk Management* recently provided extensive coverage on the dangers and liabilities of medical helicopters. For more on safety issues related to air ambulances, see February 2009, p. 13, and March 2009, p. 29.) ■

## New HHS secretary calls for action on HAIs

*'I'm challenging hospitals to . . . fight infections.'*

**H**ealth care-associated infections (HAIs) are clearly on the radar of **Kathleen Sebelius**, the new Secretary of the Department of Health and

Human Services (HHS). She recently called for action to prevent HAIs in praising two new HHS reports on the quality of health care in America.

"Health care-associated infections can make illnesses worse, further debilitate patients who are already struggling, and sometimes lead to death," Sebelius recently said in Washington, DC, at a nursing conference.

Published by the Agency for Healthcare Research and Quality, the annual 2008 National Healthcare Quality Report and 2008 National Healthcare Disparities Report indicate that patient safety measures have worsened and that a substantial number of Americans do not receive recommended care. Upon issuing the reports, Sebelius also announced the availability of \$50 million in Recovery Act resources to fight health care-associated infections and improve patient safety. "Through the funding provided by the Recovery Act, we can help prevent these infections and improve the quality of care for all patients."

In a finding that will be no surprise to infection preventionists, the quality report underscored that central line-associated blood stream infections (CLABSIs) strike hundreds of thousands of patients each year. Patient safety has declined in part because of this rise in HAIs. Moreover, HAIs are among the top 10 leading causes of death in the United States, and drive up the cost of health care by up to \$20 billion per year, the HHS emphasized.

Sebelius announced that the HHS plans to make \$50 million in grants funded by the American Recovery Act available for states to help reduce HAIs. HHS plans to make \$40 million available through competitive grants to eligible states to create or expand state-based HAI prevention and surveillance efforts, and strengthen the public health work force trained to prevent HAIs. HHS also is allocating \$10 million in grants to states to improve the process and increase the frequency of inspections for ambulatory surgical centers.

### **Endorses use of Hopkins checklist**

Sebelius also called on hospitals across America to commit to reduce CLABSIs in intensive care units by 75% over the next three years. Research indicates that these infections strike hundreds of thousands of surgical patients and the percentage of patients acquiring those infections has steadily increased over the past six years, she noted. Sebelius challenged hospitals to make use of a proven patient-safety checklist (developed at Johns Hopkins) to significantly

reduce CLABSI.

"Patients expect to get better in a health care facility, not worse," added Sebelius. "The Recovery Act money will help protect patient safety, but we need hospitals to do more. Today, I'm challenging hospitals to take basic steps to fight infections that are weakening our health care system and threatening patient safety."

In a related development, the Association for Professionals in Infection Control and Epidemiology (APIC) applauded the Obama administration for proposing increases in the HHS fiscal year 2010 budget for public health programs.

"The 'HHS 2010 Budget for a Healthier America' is a fitting follow-up to recent funding bills which clearly show a strong commitment to improve the public's health," said **Christine J. Nutty**, RN, MSN, CIC, 2009 APIC president. "The FY09 Omnibus Appropriations Act provided \$22 million to address health care-associated infections and took much-needed steps toward addressing shortfalls in many chronic disease and environmental health programs. The proposed emergency supplemental bill that is under way would improve our nation's pandemic influenza preparedness."

The FY10 budget also includes a \$26 million increase in funding for the Strategic National Stockpile, increases for state and local health departments and hospitals to prepare for public

health emergencies, and an increase of \$30 million for the Biomedical Advance Research and Development Authority.

(Editor's note: The HHS reports are available at <http://www.ahrq.gov/qual/qrdr08.htm>. The HHS has posted the CLABSI checklist at <http://www.ahrq.gov/qual/clicklist.htm>.) ■

## State enacts tough law on reporting med errors

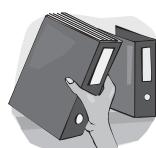
The Massachusetts Public Health Council recently implemented an aggressive new law that requires public reporting of hospital errors. Proponents say the tough standard will improve patient safety and keep the state at the forefront of health care improvement.

The council's action means that Massachusetts hospitals are now required to report all significant errors, including sentinel events and never events. In addition, the state will now publicize those errors.

The health council reports that the new regulations also prohibit hospitals from charging patients for care required as a result of a hospital error. Hospitals also must establish patient and family advisory councils by October 2010. ■

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### CME objectives

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

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

### COMING IN FUTURE MONTHS

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■ Preventing feeding tube mistakes

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## CNE Questions

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 semester's activity with the December issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

1. What does Maurice A. Ramirez, DO, BCEM, CNS, CMRO, recommend as a key way to ensure readiness for a flu pandemic?
  - A. Maintaining surveillance measures to detect incoming flu cases.
  - B. Distributing protective face masks widely to patients and staff.
  - C. Establishing a separate flu clinic to separate potentially infectious patients.
  - D. Encouraging physicians to use a low threshold for prescribing Tamiflu.
2. According to Carol Burkhart, RN, MS, CNP, how can the hospital's media relations department contribute during a flu pandemic?
  - A. By restricting information about the hospital's flu response.
  - B. By countering misinformation and panic in the community with more reasonable, accurate information about the flu.
  - C. By minimizing the true scope of the pandemic in order to protect the hospital's reputation.
  - D. By increasing the public's concern about the flu and encouraging more visits to the hospital at the first sign of possible flu symptoms.
3. According to Elizabeth A. Wagar, MD, FCA, what does research show is one factor that leads to more consistent and effective critical value reporting?
  - A. When critical values are reported only at certain set times of the day.
  - B. When critical values are reported by e-mail.
  - C. When the laboratory reports critical values only if requested by the physician.
  - D. When the laboratory does not make many exceptions for individual physicians when defining critical values.
4. In the wrong-site surgery incident that prompted a review of Rhode Island Hospital in Providence, which is true regarding the preoperative timeout?
  - A. There was no preoperative timeout.
  - B. The surgical team properly performed a timeout in which all members agreed that the right side of the mouth was the correct surgical site.
  - C. The surgical team performed a timeout and incorrectly identified the correct surgical site.
  - D. The surgical team performed a timeout but did not discuss the correct surgical site.

**Answers: 1. A; 2. B; 3. D; 4. B.**



Healthcare Risk Management's

# Legal Review & Commentary™

A Monthly Supplement

## Woman alleges negligence: \$4.3 million settlement

By Radha V. Bachman, Esq.  
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**News:** A woman presented at a hospital emergency department (ED) with abdominal pain. X-rays and a CT scan were performed. The emergency physician discussed the findings with a radiologist who noted the findings in his report. The emergency physician noted the CT as negative and ordered the woman to take morphine and fentanyl. Twelve hours later, the woman was seen by a different physician, who reviewed the previous record but did not mention the X-rays or the CT scan. The woman was given oxycodone and released with a prescription for Percocet. The next day, the woman saw her family physician, who scheduled her for an appointment with a vascular surgeon. The vascular surgeon advised that the woman see a hematologist within two months. The woman never saw the hematologist and, eventually, suffered from intestinal death, requiring intravenous feedings. A settlement was reached in the amount of \$4.3 million.

**Background:** A 37-year-old woman arrived at the ED of a hospital with complaints of severe abdominal pain. The ED physician ordered a CT scan and abdominal X-rays. The scan reportedly detected a "spleen with heterogeneous perfusion (possible infarct)" and a "filing defect in abdominal aorta." The ED physician discussed the results with a radiologist, who included this information in his report and also noted that the filing defect may "represent local thrombus formation and may be a source of distal emboli." Prior to sending the woman home,

the ED physician diagnosed the abdominal pain as arising from an unknown cause and determined that the CT scan was negative. The ED physician prescribed morphine and fentanyl and told the woman to return to the hospital 12 hours later.

When the woman returned to the hospital, she was seen by a different physician, who noted in her chart that he had reviewed the record but did not mention or explain the radiologist's findings. The physician prescribed oxycodone with a script for Percocet and an order to see her family physician the following day. During her visit with the family physician, the woman was told that she needed to see a vascular surgeon. The surgeon immediately scheduled a chest CT, echocardiogram, and blood clotting disorder study. An appointment was made for the woman to see a hematologist two months later. Due to transportation issues, the woman was unable to make her appointment. Less than one month later, the woman's abdominal aortic thrombus extended and blocked arterial blood flow to her intestines, resulting in intestinal death and requiring removal of all but 20 cm. of her intestines.

The woman sued the hospital and various physicians, alleging that she never was fully informed regarding the necessity of the hematology tests and that the defendants were negligent in allowing her condition to exacerbate to the point of complete loss of her intestines. The defendants denied negligence but did not proffer any alternate causes of the intestinal death. A \$4.3 million settlement was reached between the parties.

**What this means to you:** The major departure from a recognized standard of care most likely occurred in this case at the point when the first ED physician sent the patient home with a determination that the CT scan was negative. It can be assumed that there were substantial findings, and that the radiologist actually detected a medical issue that did indeed become the etiology of the patient's loss of her intestines.

Since the radiologist and the first ED physician did speak and one can only assume that the radiologist did discuss the positive findings of a possible splenic infarct and a filling defect in the abdominal aorta that represented the possibility of local thrombus formation and a source of distal emboli, the ED physician was negligent in not addressing these possibilities prior to discharging the patient.

The medications that were prescribed, morphine and fentanyl, are potent analgesics, which would call into question why he would release a patient who required such an intense level of pain control without first determining the source of the pain or at least continuing to observe the patient to assure that nothing further developed. His failure to properly diagnose is evident from the lack of attention that was paid to the radiology findings.

An ED is a frantic, volatile, and hostile environment that, by its very nature, is ripe for medical misadventure. Patients come and go over a 24-hour period. It is possible for a single patient to be seen by scores of staff and physicians of various specialties. It is equally likely that none of them has ever seen the patient before or will care for that patient again. The ED staff collectively see many patients at the same time. Emergent cases get priority over urgent ones. It is relatively easy to imagine how this woman could have been "lost," as that is exactly what happened.

The fact that two physicians did not note or mention the radiology report would indicate that it either was not in the chart or the chart was not reviewed in its totality. To assure quality and safety, it is imperative that hospitals have safeguard systems that ensure that the care provided is timely, accurate, and based on reasonable diagnostic testing appropriate to the patient's presentation. This patient again was discharged without any indication that the seriousness of her condition was recognized and properly dealt with.

Just as the first ED physician passed her on to a second, the second passed her off to her community-based physician. This physician obviously was not aware of the existing CT scan, nor did he or her family physician take an accurate history

from the patient. If they had, they would have known that her original complaint was abdominal in nature and that she had a CT scan in the ED two days previous.

In most communities, private practice physicians have near-instantaneous access to a patient's hospital record upon the authorization of the patient. In this case, if an accurate history had been obtained, both the family physician and the surgeon should have queried the hospital and obtained the ED records. Of course, that result would be dependent on the record actually containing her information and on the physicians appropriately requesting it.

In most health care settings, the information provided to the patient as to his or her condition and instructions for further care and the responsible use of prescribed medications is the responsibility of the provider. Patients treated in the ED are traditionally provided with an extensive synopsis of what has been done and recommendations for further testing and follow-up appointments. The patient must be instructed on the importance of information provided and the need to share those documents with referral sources to ensure continuity of care. This constitutes "patient handoff." Both patient education and handoff are significant standards in hospital accreditation processes and are recognized as one of the National Patient Safety Goals, which is amended yearly by The Joint Commission.

It is clear from the narrative and the horrific results that none of the providers paid due diligence to their respective obligations to this patient. The ED physicians saw her but did not truly treat her symptoms in an appropriate manner and passed her on to her family physician, who referred her to yet another specialist, who apparently did not solicit sufficient information to substantiate his tentative diagnosis. Time was wasted by testing that may not have been appropriate to the actual presentation, which now was lost to the ever-increasing chain of providers.

If this patient had been admitted at the time of the first ED visit, when a radiologist identified positive findings with serious consequences, this could have been avoided. A settlement of \$4.3 million seems reasonable for a 37-year-old patient who has been subjected to a seriously diminished quality of life with a greatly shortened life expectancy.

## **Reference**

- Anonymous. Case No. unknown. ■

# **Malfunctioning defibrillator results in \$5.3M award**

**News:** A woman suffered cardiac arrest while at home. Hospital paramedics arrived, but attempts to resuscitate her with a Lifepak 11 monitor and defibrillator failed. Forty minutes later, the woman was pronounced dead. The decedent's estate sued the hospital and was awarded \$5.3 million in damages.

**Background:** A 39-year-old woman employed as a security guard at a high school suffered cardiac arrest while at her home. Paramedics from a local hospital arrived within eight minutes of the call to 911 but were unable to find a pulse on the woman. The woman had no respirations and had a Glasgow Coma Scale score of 3. Attempts by the paramedics to resuscitate her with a Lifepak 11 monitor and defibrillator failed. Twenty minutes after the paramedics arrived at the woman's home, she was transported to the hospital, where she was pronounced dead.

Her husband brought suit against the hospital on behalf of the woman's estate. He claimed that the paramedics declared that the defibrillator was "not working" immediately after they placed the leads on his wife. According to the complaint filed, the Lifepak 11 had not administered a shock to the woman because of improper battery maintenance. While no malfunction was specifically noted by the hospital, the machine was removed from service after the call and left with an outside on-site service technician for complaints of "intermittent operation." The repairman testified, based on his records, that the machine was functional but that it had expired battery packs. Plaintiff's counsel also went on to point out the fact that electrocardiogram strips from the machine were missing. These strips would have been kept by the hospital for patients who had ventricular fibrillation and were shocked. The plaintiff further contended that even if the strips were not printed at the scene, they could have been printed at a later date from the machine's memory.

The paramedics' supervisor testified that a controversy had existed regarding whether the woman had actually been shocked by the Lifepak 11. Despite that, the machine had a limited memory and had been put back into service a few days later with no EKG strips being printed. The plaintiff claimed that this amounted to spoliation of evidence, because the defendant knew that the

machine had never turned on or had failed to render a shock. Based on the fact that only the battery pack for the machine's monitor was tested daily, the plaintiff's expert testified that the hospital had inadequate battery maintenance standards. He went on to opine that the hospital's failure to have an inventory system for batteries and a policy requiring the paramedics to keep spare batteries at all times violated industry standards regarding required paramedic equipment.

The defense relied on the fact that it had successfully shocked her twice, intubated her, injected her with medications, and given her cardiopulmonary respiration. The defense conceded that the machine had malfunctioned but that the malfunction occurred late in the rescue effort and only affected the monitor screen and not the treatment of the patient. Once the malfunction was realized, the woman was transferred to the ED, because the paramedics realized there was no other means by which to attempt resuscitation once all measures had been taken. Lending credibility to the defense was the argument that, had the machine malfunctioned, the paramedics would have utilized one of the other machines contained in the other emergency vehicles that arrived soon thereafter, including two other ambulances and at least two fire department vehicles.

The plaintiff's surgery expert testified that the woman would have had a 40% chance of survival if the shocks had been properly administered. Defense experts countered stating that at the time paramedics arrived, the woman had been in cardiac arrest for 10 minutes, making her chances of successful defibrillation and recovery slim. Along with the time frames, the defense introduced evidence of the woman's numerous medical conditions, including insulin-dependent diabetes, uncontrolled hypertension, high cholesterol, smoking, and morbid obesity.

The plaintiff introduced evidence that the woman earned an annual salary of \$30,000, and that, based on a life expectancy of 60, her past and future lost earnings, health insurance benefits for her family of eight children, and household services totaled \$1.3 million. The jury found the hospital negligent and awarded \$5,322,000.

**What this means to you:** The narrative would indicate that the patient's death would most likely have been the outcome even if the equipment had functioned properly. The paramedic squad did attempt resuscitation prior to the mechanical malfunction without success. The facts presented, if

accurate, would have precluded a successful outcome. Even if they did manage to restore cardiac function, the time that had elapsed from the onset of the event to the initiation of transport would have doomed this patient to an anoxic vegetative state.

It appears that the EMS team did all that was possible to effect resuscitation in the home and was unsuccessful. While there was an admission that the defibrillator had indeed failed, the failure was said to have occurred after several successful attempts to shock the patient. There also was evidence that backup equipment was available at the time, so the conjecture is that resuscitation was not possible and the ultimate malfunction by the defibrillator in use did not contribute to that failure and could have been readily overcome by the use of an available substitute.

The apparent issue was the failure of the defibrillator to provide adequate "shock intensity" given the use of expired battery packs. Generally, portable defibrillator units utilize rechargeable batteries, which have a diminishing ability to retain a charge as they age. The expiration date does not necessarily mean that the defibrillator will not operate, but rather that consecutive shocks would prematurely discharge the batteries and/or ultimately cause failure. The expiration date is the manufacturer's safeguard statement to the user that the battery unit is not reliable after that date and should be replaced. Unfortunately, the data stored in the machine's memory were not accessed in a timely fashion and were lost, so proof positive was not available to support the contentions that the woman had already received two shock attempts that had failed.

Now, on top of a failure to properly monitor and replace the batteries is the added failure to maintain the integrity of the effort by failing to follow manufacturer's directions for timely retrieval of data stored in the unit's electronic memory. Had the strips been printed simultaneously with each shock attempt, as recommended in the unit's instruction manual, there would have been proof positive that the unit had delivered sufficient energy to affect resuscitation or that it had not and required substitution.

All of this speaks to staff training and equipment maintenance. It is essential that all equipment be utilized and maintained as recommended by the manufacturer, including policy development, training records, and service logs. Electrical and mechanical equipment by nature is subject to wear and potential failure. Preventive maintenance

programs must be utilized and maintained in order to track required service and repairs. Such critical equipment as a defibrillator should have a daily inspection program and maintenance log.

Batteries, in particular, have expiration dates that need to be recorded and inspected. If a battery-powered unit is used more frequently than one would normally expect, the factory-estimated life of the battery may, in fact, be compromised, and the expiration date may need to be adjusted to assure that it still can maintain a charge.

In this case, the jury heard that essential equipment had failed not because of malfunction but because of user negligence. While there was no evidence that the battery life failure had actually contributed to the woman's death, juries are not trained medical professionals. They cannot separate the outcome from appropriate causation factors, such as the extended period of cardiac failure, her various comorbid conditions, and the generally anticipated success of a resuscitation effort in such patients.

The verdict amount also would speak to the fact that the jury was angry that the hospital, through what they had determined to be negligence, had allowed this to happen. Her comorbid conditions and their effect on her life expectancy were not given due consideration, nor was her income level reflective in the \$5 million-plus award.

Mediation is a controlled session designed to bring the parties together on a common ground instead of a volatile court room situation where six or more individuals must come to a consensus over two opposing parties. This certainly would be a case where risk management would dictate that the hospital consider mediation. The battery expiration alone was enough to establish liability. The effort should have focused on controlling the damages.

It would have been far easier and less costly to mitigate a more reasonable settlement in the interest of both the plaintiff and the defendant. Had a mediation been attempted, such issues as the patient's state of health, the realistic outcome of prolonged anoxia, and the fact that this family needed an immediate infusion of cash would have played more favorably in the final amount. The results would still have been tragic, but the monetary losses to the hospital not as damaging.

## **Reference**

- Case No. 23407/03, Supreme Court, 11th Judicial District, Queens (NY) County. ■