



Healthcare Risk Management



Rogue nurse highlights dilemma over blame vs. root cause

When should you hold individual to blame rather than the system?

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It has been 10 years since the Institute of Medicine's report *To Err is Human* revolutionized patient safety by encouraging a focus on systemic flaws that allow errors to occur, rather than blaming the individual who actually made the mistake. From the start, however, risk managers have struggled with the idea of how to avoid a "culture of blame" without letting people get away with extraordinary negligence or deliberate misbehavior.

That dilemma surfaced again with the recent scandal at Broward General Medical Center in Fort Lauderdale, FL. In October, hospital officials announced that a 59-year-old nurse, Qui Lan, had reused IV bags when administering saline solution to patients who were at Broward undergoing cardiac chemical stress tests, a clear violation of infection control procedures that, according to the hospital's account, Lan committed knowingly. More than 1,800 patients were put at risk of infection.

Officials at the hospital said they learned that Lan was reusing catheter tubing and saline bags on multiple patients when a call came into the hospital's compliance hotline on Sept. 6, 2009. The caller reported seeing the

EXECUTIVE SUMMARY

A Florida hospital is testing more than 1,800 patients for potential infections caused by a nurse who allegedly improperly reused disposable equipment. The case is drawing attention to the quandary of how to hold employees accountable while avoiding a culture of blame.

- Hospital officials say the nurse knowingly and intentionally violated infection control procedures.
- The hospital has launched a major effort to contact all affected patients and test them.
- Experts say employees can be held accountable while also pursuing systemic flaws that allowed the transgression to occur.

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nurse use the same saline bag and a portion of tubing more than once, according to a statement released by Broward General Medical Center CEO James Thaw. The supplies were intended for one-time patient use during the cardiac chemical stress tests, with which Lan had been assisting since 2004.

The hospital's response was aggressive and public. Extensive information was posted on the hospital's web site and updated regularly, with a link on the home page to the special area set up for all information related to the potential exposures.

"We sincerely regret the actions of one employee, who acted on her own, and chose to disregard infec-

tion control standards in the delivery of intravenous fluids," Thaw said in a statement to the community. "We are thankful our compliance reporting system worked and that we were able to address this situation as soon as it was reported. We will take all action required to not only remedy the situation, but also to investigate and evaluate all details."

The hospital suspended Lan, who had a valid nursing license and a clean record, on Sept. 8, and she resigned the next day, the hospital reports. Broward General reported her to the Florida Board of Nursing and also requested a criminal investigation from the local police department. Fort Lauderdale Police spokesman Sgt. Frank Sousa issued a statement confirming the investigation and noting that authorities believe Lan has left the country. She grew up in Malaysia, earned her nursing degree in London, and came to the United States for a nursing job in 1976, according to personnel records released by Broward Health, the tax-assisted entity that owns Broward General.

Broward General is offering free testing for HIV/AIDS and hepatitis B and C to the 1,851 patients who underwent stress tests at its facility during the time in which Lan assisted with stress tests. (See p. 137 for more on how Broward General conducted the testing program.) The hospital also took several steps to assess the potential for infections and correct any systemic flaws that may have made it possible for Lan to violate infection control standards.

"We have consulted with expert physicians and a team of epidemiology and infection experts from the Centers for Disease Control and Prevention (CDC), the Florida Department of Health, and the Broward County Health Department," Thaw says. "Broward General Medical Center also informed the Agency for Health Care Administration, which has completed a site visit as part of their investigation."

After its own internal investigation, Broward General instituted the following corrective actions:

- Evaluated registered and licensed staff in the stress lab for adherence to infection control and intravenous therapy policies, and compliance was validated.
- Initiated opening all intravenous administration sets in the presence of the patient.
- Conducted an assessment of all outpatient procedural areas of intravenous therapy for compliance with infection control practices. Compliance was validated.
- Re-educated key staff on basic sterile procedures.

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Editorial Questions

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The Florida incident illustrates the ongoing need for vigilance and communication regarding patient safety, says **David Maxfield**, vice president of research at VitalSmarts, a corporate training company in Provo, UT. He is the leading researcher of "Silence Kills" — a study that exposes communication breakdowns in health care that lead to avoidable medical errors. (*Editor's note: For more information on that study, see www.silencekills.org.*) Maxfield says incidents such as these are often caused by health care workers' inability and fear to speak up when they see a colleague make a mistake.

According to his study, conducted by VitalSmarts and The American Association of Critical-Care Nurses in Alisa Viejo, CA, 80% of health care professionals regularly witness their co-workers break rules, make mistakes, or demonstrate incompetence. And yet less than one in 10 say anything about it. In addition, nurses are especially timid when the transgressor is a physician or superior.

Maxfield notes that the nurse was caught when someone, most likely a fellow health care worker, reported the problem through a compliance hot line. That is an endorsement of the use of anonymous help lines, he says, but they are not a panacea. Better is a culture that encourages people to speak up immediately when they see something wrong and removes the threat of retribution.

"Secondly, on a strong team, everyone holds everyone accountable. You don't have to be someone's boss to say that's wrong," Maxfield says. "You could be the housekeeper cleaning the room or the person delivering food to the patient, and when you see this, you know it's wrong. You need a culture in which the norm and expectation is that everyone holds everyone accountable."

Maxfield's research suggests that the health care industry is far from that ideal. When asked if they would speak up about a fellow health care worker failing to wash hands, only about 10% of those he studied said they would. While it is not known how long Lan may have reused supplies, the hospital's response indicates there is reason to fear her alleged misbehavior continued for years. That should be a concern for the risk manager, he says.

"It's a good thing that her behavior was finally reported — and it seems the hospital responded in a very proactive way to the information — but I would be concerned about why she could do this for so long. What does that say about the culture in my hospital?" Maxfield says. "She's been a nurse for more than 30 years. It's mind-boggling to think that she might have been doing some-

thing like this for so long."

Maxfield says the facts of the Florida case suggest that the violation of infection control procedures was intentional and possibly even malicious, though Lan's motivation is unknown. This sets the incident apart from other situations in which patient safety clearly was threatened inadvertently, through some fault in processes or procedures, and it brings up the longstanding debate over how to hold people accountable in a "no blame" culture. **(See p. 136 for more on accountability and willful misbehavior.)**

Cases of seemingly willful misbehavior are vexing, but Maxfield says risk managers must avoid the temptation to write them off as just an aberration, a wild outlier that never could have been anticipated or prevented. While there always will be some individuals who choose to harm others for their own pleasure or gain, in many cases the willful violation is spurred by more esoteric factors such as being overworked, working at too fast a pace, or being frustrated by conditions that make it difficult to follow proper procedures. In such cases, he says, the violation may be conscious and willful, but it still is spurred by a systemic flaw that should be corrected.

"Maybe there was a convenience factor about getting new supplies. Was it convenient or was it difficult to get what you needed?" he asks. "Did it require some level of red tape or human interaction that this person couldn't deal with? Maybe the solution is making getting rid of the old supplies easier and more visible, and getting the new supplies easier and more visible."

That question about the procedures involved should be a major part of the Broward General investigation into the incident, says **Susan Stinson**, RN, FACHE, vice president of professional services and clinical practice lead at AmerisourceBergen Drug Corp. in Chesterbrook, PA, and an expert on process improvement as it relates to patient safety. Even if the investigation determines that the nurse knowingly and intentionally deviated from proper procedures, the bigger question is still "Why?" she says.

"When the clinician has to go through 20 or more steps to complete a task for patient care, and then have four or five other patients that may require a similar task, multiply that times two or three times a shift, and you are talking about hundreds of steps that must be adhered to, without making a mistake," she says. "Blaming the individual doesn't help solve the real problem."

Stinson notes that since *To Err is Human*

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revolutionized patient safety philosophy, the health care industry has reached a better understanding of how important it is to put a support system in place that allows health care providers to do the best they can.

"We are seeing much more of a focus on standardization of processes, eliminating waste, and improving the workflow for the individuals on the front line," she says. "There is more attention now to looking at your processes and trying to anticipate what could go wrong. This is work that really never ends. You're always looking for vulnerabilities."

But what happens when a clinician just does something that seems crazy? Avoid relying on the "bad apple" explanation, Maxfield says. It is too convenient to simply say that the guilty employee simply was a bad apple who didn't follow hospital policies and procedures and there's nothing wrong with the system.

"Apples don't go bad on their own. There are forces in the system that allow them to go bad, provide motivation for them to go bad, or they aren't strong enough bulwarks against that happening," he says. "I would like to think that if I went into a hospital and tried to get away with something like this, just being a really bad apple, the system would catch me. Either the staff would speak up and say stop, or the inventory system would red flag the fact that I had X number of patients requiring IV bags and I only used Y number of bags today."

Even when the misbehavior is willful, there still is the very important question of why it is tolerated for any length of time.

"We have to ask what are the social and cultural norms within this group that could have allowed this to happen? Were there other people in her working group who either saw it or suspected it and somehow let it slide?" Maxfield says. "Did they allow that to become some sort of acceptable norm?"

Maxfield encourages risk managers to study the Florida case for clues about how an incident

would play out in their own facilities.

"Don't waste this crisis. Ask yourself what would happen if you had a rogue like this in your own hospital," he says. "How far could that rogue go? Could that rogue go on for 33 years, for a year, for a week? What would it take in my organization to catch someone like this?" ■

Hold people responsible, even when avoiding blame

Risk managers have struggled for years to reconcile the notion of a "no-blame" culture with incidents in which — systemic problems or not — one individual clearly committed a willful violation of procedure. Embracing the philosophy is easier when the evidence suggests the health care worker made a mistake, even a failure of attention or diligence, but willful and even malicious misbehavior seems to pose a dilemma. You don't want to abandon your "no blame" culture, but it seems just as wrong to let someone get away with brazen threats to patient safety.

You don't have to, says **David Maxfield**, vice president of research at VitalSmarts, a corporate training company in Provo, UT, and the leading researcher of "Silence Kills" — a study that exposes how communication failures can lead to medical errors. Focusing on the culture of the organization and the systemic problems that may have caused the incident or made it possible does not have to conflict with holding an individual responsible for willful violations of protocol, he says.

"We used to look at this as an either/or situation. Either we hold people accountable or we forgive them and hold the system accountable. In fact, we want to do both," he says. "The message should be that we expect employees to maintain safe practices, but at the same time, we want to make safety convenient, easy, logical, and sensible. We want to give them the easiest path to safety, but then we expect them to follow that path."

Striking the right balance is the key, Maxfield says. If the health care worker was in the wrong, you can hold that person accountable for violating policy and procedures, he says. But don't stop at blaming the last person to touch the patient. Look back further to see what may have spurred that violation and how it could be prevented in the future.

A "no-blame" culture also cannot be taken so far that people are not judged on their abilities to

perform given tasks and follow procedures, Maxfield says. At some point it can be reasonable to say that the problem is not with the system but with the individual who is not capable of following procedures. Risk managers should not feel this is a betrayal of the “no blame” culture, he says.

“In those cases, you move people to jobs where they are competent enough,” he says. “Nobody wants to create an organization where incompetent people are allowed to be incompetent because we’re afraid to hold them accountable for what they do, or what they prove themselves incapable of doing.” ■

Hospital quick to notify patients of infection threat

Once administrators at Broward General Medical Center in Fort Lauderdale, FL, discovered that a nurse had exposed patients to serious infections by reusing disposable tubing and IV bags, the hospital acted quickly to notify those affected and arrange testing.

Broward General immediately sent letters in English, Spanish, and Creole via certified mail to all 1,851 patients and their referring physicians, informing them of the incident and providing the hotline number, web site and details on follow-up screenings. The hospital arranged to have the patients tested for hepatitis B, hepatitis C, and HIV at no cost to them through a local testing facility not owned or operated by Broward General.

As of Oct. 26, 2009, Broward General had confirmation from 1,159 patients that they had received the notification letter. Of those known to have received the letter, 869, or about 75%, had been tested. Test results were available for 722 patients, and hospital spokeswoman **Cathy Meyer** says some of those patients did test positive for the bloodborne diseases, but she declined to release details. Positive results do not necessarily mean the patient was infected at the hospital, she notes, because the community has significant rates of infection for those diseases.

A second certified letter was sent to patients who did not respond to the first letter. Patients who had questions were encouraged to call a 24-hour hotline, with after-hours calls to be returned during the next business day.

The community outreach, and the extensive media coverage in Florida and nationwide, resulted

in significant use of the resources Broward General set up:

- number of total calls to the toll-free hotline by Oct. 26, 2009: 2,401;
- number of patients who requested and received follow-up calls from Broward General clinical staff: 1,656;
- number of walk-in patient visits to Broward General’s counseling center: 291;
- Number of visitors (page views) to the chemical stress test patient notice web site: 5,364. ■

Wi-Fi needs tight security to avoid problems

Free wireless Internet access, known as Wi-Fi, is offered in many retail establishments and public buildings, allowing customers and visitors to access the Internet with their laptop computers and cell phones. But as health care providers venture into offering this convenience, questions arise about network security and possible breaches of sensitive data.

The risks should not deter health care providers from offering Wi-Fi, but some precautions are necessary, says **Wade Williamson**, director of product management at AirMagnet, a Sunnyvale, CA, company that offers Wi-Fi security consulting. He recently studied Wi-Fi in hospitals around the country and found what he calls an “alarming” lack of security in some facilities.

Securing the Wi-Fi offered as a convenience is fairly simple, he says. Make it a completely separate network from any other Wi-Fi that is used in the facility — such as the wireless service used by employees to access any provider computer network.

EXECUTIVE SUMMARY

Providing wireless Internet access to patients and others in your facilities poses the risk of breaches in your computer network. Without specific precautions, Wi-Fi can allow users to access sensitive data.

- Wi-Fi offered to patients and visitors must be completely separate from the network.
- Security for a system that includes patient data must be extensive.
- Wi-Fi networks are popular with patients and visitors.

"We often see that there is a wireless network in the hospital that is used to track access badges or critical equipment, or to allow the staff to sign on to the system from a work station or the patient's bedside. There usually are extensive wireless systems in a health care facility, so when you want to provide a service to patients and visitors, there is a temptation to just branch off of that," he says. "That is a mistake."

Any system that carries patient data and other sensitive information must have extremely tight security, but the system, offered as a convenience, can be basic and provide no more than direct access to the Internet, Williamson says. That system should be no more capable of accessing the health provider's computer system than if the user were sitting at home working on his or her own PC.

Jörg Hirschmann, chief technical officer with NCP Engineering, a wireless network company in San Francisco, agrees that the key for a public access Wi-Fi system is to keep the user out of the provider's internal system.

"The benefit in this scenario is that you can offer a wireless network to your patients and visitors without this becoming a major challenge in terms of providing adequate security. The level of security needed for this system, if it is separate from any network that includes sensitive data, is not so substantial that it should be a deterrent to offering this service," Hirschmann says. "Once you have access in any way to the other network, security becomes a far more complex challenge. It can be done, but it is much more complex."

The details concerning exactly how to secure any Wi-Fi network, especially one with sensitive patient data, can be highly technical, but Williamson advises risk managers to consult closely with the IT department to ensure that there is an absolute separation — not just a firewall or some type of divide between the public side and the internal side of a network. The security necessary for the facility's internal wireless network, which includes patient information and other sensitive data, can be quite extensive and highly technical, whereas the security on a public network can be relatively simple, because there is no crossover with the sensitive data.

Offering Wi-Fi is popular with patients. In 2003, Crutchfield Dermatology in Eagan, MN, was the first dermatology clinic in the state to offer Wi-Fi in the reception area, and **Charles E. Crutchfield III**, MD, says he decided to offer it one day when he noticed while ordering coffee at a coffee shop that many of the patrons were using

SOURCES

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the Internet. Wi-Fi helps patients increase their productivity and increase their perception of value in attending the medical clinic, he says.

The primary concern was to make sure that when patients were on the Internet, they had no access to any of the practice's corporate information or medical records, so Crutchfield set up a completely separate network for Wi-Fi in the reception area. The cost was about \$1,000.

"Our patients are thrilled, and I receive compliments on a regular basis from patients, especially parents who are waiting for their children during appointments so they can maintain productivity in the reception area," he says. "Additionally, the Wi-Fi reaches into the exam rooms, so oftentimes when the patients are waiting a few minutes in the exam rooms to be seen, they can also continue their productive work." ■

Data mining can yield treasures for RM

Data are everywhere these days, and you can put it to work for you. Health care providers accumulate huge volumes of data, and some risk managers are learning that the strategic use of that information can improve patient safety, reduce costs, and reduce liability risks.

Administrators at Bancroft Neuro Health, with facilities in New Jersey and Delaware, recently learned the value of data mining. Bancroft serves more than 1,000 individuals and families annually, with a wide range of services to children and adults with autism, developmental disabilities, brain injuries, and other neurological impairments.

Toni Pergolin, CEO of Bancroft, tells *Healthcare Risk*

EXECUTIVE SUMMARY

Health care providers are finding that the data they already possess can be a treasure trove of information. Using that information properly can help improve your risk management efforts.

- Most health providers already have extensive data available for analysis.
- One provider slashed workers' comp costs through data mining.
- Data analysis requires first identifying your risks, then searching for metrics that lead to a solution.

Management that a thorough data analysis over the past two years is helping the company mitigate risk in its mental health facilities.

The focus on data yielded significant results for Bancroft:

- **Workers' compensation claims were cut in half.** Since implementing the on-site medical team and a more disciplined focus on accident prevention and claims management, Bancroft's number of workers' compensation claims has been cut in half for the year spanning July 1, 2008, to July 1, 2009, compared to the previous year.
- **The number of days lost due to injury was reduced by 80% over the same period.**
- **The cost of automobile liability claims cost was reduced by 78%.**
- **The number of automobile liability claims was reduced by 40%.**

Psychiatric and mental health settings provide unique challenges for engaging in risk management activities, especially when trying to understand where the potential issues are and where risk management needs to focus, Pergolin says. She had started at Bancroft as the chief financial officer, so she was strongly oriented to numbers and a data-driven approach. As CEO, she found that there was a real opportunity to use the company's data more productively in risk management.

"We had so much data, so we wanted to try to find the meaningful data and track it," she says. "As it got better or worse, we would know whether our actions were working."

Bancroft worked with The Graham Company, a Philadelphia-based insurance brokerage and risk management consultant specializing in high-risk businesses such as mental health organizations.

Scott Kegler, insurance producer at The Graham Company, helped Bancroft use data mining to reduce risk, and he says data analysis was the first

step in the process.

"The deep analysis of the data is the most critical thing to do when trying to reduce any type of risk, but for many risk managers it is the step that can be overlooked," Kegler says.

Like most health care providers, Bancroft already had plenty of data. The challenge, Pergolin says, was analyzing that data and presenting it in a way that illustrated where the organization's particular needs lie. Kegler says one of the first goals was to use the data to prioritize risk management goals.

"You can't solve everything at once, so we needed to know what our top priorities would be," he says. "It was a matter of digging through the data to find the metrics that were really meaningful in risk management."

For instance, the team's analysis of workers' comp claims started with the most obvious statistic on the number of claims, but then they dug deeper to determine what type of accidents and injuries were involved, and then deeper still.

"We wanted to see if the wrist sprains, for instance, could be categorized into what was happening when the sprain happened. We looked for trends that showed that when an employee was involved in a particular task or a specific scenario, that's when the wrist sprain is most likely to happen," Kegler says. "Then we had to ask why they were doing that task that way and if there might be alternative ways to do that."

The analysis also looked into factors such as how long the employee had been with Bancroft, how much training the employee had received, which work area was involved, and what type of claims were costing the most money.

Risks and solutions found

Pergolin says the data analysis revealed three primary risks:

1. Clinical safety

Bancroft's mission is to help individuals live more independent lives. Because of this, its staff are always balancing the desire to give independence with the need for safety. While they want to give each person as much independence as possible, it needs to be done in a way that keeps the individuals safe at all times. This is a delicate balancing act that requires focus, discipline, and attention every day.

2. Employee injuries

Injuries to employees are not only expensive; they also have a negative impact on morale and Bancroft's ability to provide service.

3. Automobile accidents

Bancroft has a large vehicle fleet. It is imperative that the organization operates those vehicles safely every day.

The data analysis also led the Bancroft team to strategies to address these risks:

- **Two safety committees**

One committee focuses on staff and environmental safety, including vehicle safety, and a second committee focuses on clinical safety. This has helped Bancroft target and prevent the specific circumstances that can lead to incidents.

Originally, Bancroft set up three safety committees, splitting the clinical safety into two groups with one focused on employee safety and one focused on patients. "But we found that there was so much interplay between the employees and the people they're serving that it made sense to bring those two groups together," Graham explains.

- **On-site medical care**

A nurse practitioner is on-site five days per week to help reduce the frequency and severity of employee injuries. In addition, a physician comes on-site to meet with individuals who require follow-up care. Prior to the data mining, injured employees were sent to a general practitioner's office down the street and, in most cases, would send the employee to a specialist. Now, the employee is examined and treated immediately by the nurse practitioner with a focus on occupational health. The focused care has sharply reduced the use of specialists and reduced down time.

"This has helped us reduce our costs by treating injuries immediately so they don't have more expensive complications down the line," Pergolin says. "It also helps with employee morale and service delivery. Healthy employees give better service."

- **Root-cause analyses**

Significant incidents, whether they result in injury or not, undergo a root-cause analysis.

- **Risk management report**

Every month, Bancroft reviews detailed information from every major part of the operation. This information is summarized and put into graphical reports so that administrators can quickly see whether indicators are getting better or worse in any given area.

"It's a huge spreadsheet of data," Pergolin says. "We have 23 different programs at Bancroft, so the spreadsheet has 23 worksheets. That allows us to track all the different risk management indicators for each program, and then there also is the summary sheet that brings it all together."

SOURCES

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- **William Graham**, CEO, The Graham Company, Philadelphia. Telephone: (215) 567-6300.
- **Toni Pergolin**, CEO, Bancroft NeuroHealth, Haddonfield, NJ. Telephone: (856) 348-1193.

Graham notes that the risk management report is largely proactive. Rather than tracking claims after the fact, the monthly report tracks unusual incidents or trends that could lead to liability if not corrected.

- **Quarterly employee injury reviews**

Injuries still occur no matter what preventive efforts are in place, so every quarter the Bancroft administrators meet to discuss the status of open workers' compensation claims. Bancroft is self-insured for workers' compensation, so a third-party administrator comes in every quarter to review the open claims, along with Pergolin, the nurse practitioner, an attorney, consultants from The Graham Company, and other involved Bancroft administrators.

"Our objective is to have a plan to resolve every open claim in the most effective way possible," Pergolin says. ■

Protect key data with digital security

With the Obama administration offering up to \$19 billion in incentives as part of the federal stimulus package for medical providers to go digital, and the goal for every American to have an electronic health record by 2014, the potential for data breaches dramatically increases.

Going digital raises new security concerns for any health care organization's risk management team, who must work with IT to ensure their organizations remain HIPAA-compliant. Some health care providers are finding that technological advances can help mitigate the risk of a data breach and ensure patient privacy. The Hanley Center, a drug and alcohol rehab center in West Palm Beach, FL, recently tackled the issue and chose to electronically monitor how sensitive data are transferred.

Michael R. Counes, BS, CAC, MCSE 2K3, director of information technology and education at the

EXECUTIVE SUMMARY

Increasing use of digital information technologies can mean a greater risk of data breaches. Some providers are turning to monitoring systems that can restrict and track access to sensitive data.

- The presence of a monitoring system can remind employees about protecting sensitive data.
- A monitoring system allows tracking of exactly how and when files were accessed or transferred.
- Risk managers can generate reports showing trends in data access that could highlight problems.

center, says the growing risk of a data breach led Hanley to use technology designed to monitor transfers of data to removable media to make sure patient data are not leaving the premises and ensure confidential charts are not being accessed by people without an express need. The provider's system, which cost Hanley about \$7,000, also monitors Internet usage and prevents some types of inappropriate access.

The Hanley Center has been using the monitoring software for two years, and Counes says it is primarily an educational tool for employees, rather than an enforcement tool.

"I find that 90% of our users are not the people going to look at things that are inappropriate or unethical," he says. "They just don't understand the impact of Internet use and accountability, especially with all the access to streaming movies, downloadable music, and social networking sites. They don't get how that kind of usage impacts our network."

Doug Taylor, marketing director for SpectorSoft, says the software works silently behind the scenes on the computer, recording a detailed description of any activity on that unit. The system even records screen shots of the computer usage so that, if the data report leaves any doubt about what happened, the screen shots can show exactly what the user saw at the time in question. The software can generate reports tailored to any particular concerns of the health care provider, he says. Some providers may want to monitor who is downloading the most files, for instance, or some may be concerned about who is accessing certain sensitive files.

The system also allows Counes to monitor USB downloads, which he says is critical in a health care setting. Without some type of monitoring, anyone with access to protected health information could easily download it onto a portable drive

with no record of the transfer. Counes had considered restrictions that would make it impossible to download onto a portable drive, or require passwords to do so, but some departments, such as marketing, download onto drives so often that such restrictions would be too cumbersome.

"Now, I can allow the download, but I can monitor it on a daily basis and see exactly who downloaded what," he says. "I can see exactly what goes in and out of that USB thumb drive, down to the individual keys they type in."

In addition, the system can provide reports on exactly what employees are doing with their time on the computer — what sites they visit, what files they transfer, whether they use chat or instant messaging, what programs are used, and the length and time that the computer or individual programs are used. Some software systems, including the one Counes uses, allow the option of setting key words that will trigger alarms to the person monitoring usage. For instance, the health care provider can set certain words to trigger the system if anyone searches for them in a patient's medical record.

"With HIPAA compliance, it is critical to know what documents are being accessed and how, and you really don't get that kind of documentation unless you use some type of software system that can monitor automatically and generate a report for you," he says. "If there ever is any question about a breach, you will be able to go to your records and either show that it didn't happen, or figure out precisely how it did." ■

Needlestick prevention still needs attention, diligence

Needlestick injuries were a hot topic in years past, when the health care industry took notice of the risk posed by exposure to hepatitis and HIV in the workplace, but now it is easy to assume that you've taken all the right precautions and lowered the risk as much as possible. But have you really?

Nurses still worry about sharps injuries, and there is some concern that the health care community is letting its guard down now that needlesticks are not the hot topic of the day, says **Rebecca M. Patton**, MSN, RN, CNOR, president of the American Nurses Association (ANA) in Silver Springs, MD. The most recent statistics from

EXECUTIVE SUMMARY

Some needlestick prevention experts and health care leaders are concerned that attention to sharps safety is on the wane. They suggest re-evaluating your needlestick prevention efforts.

- Nurses still express significant concern about needlesticks.
- Sharps safety does not get the attention now that it did several years ago.
- Education and training are just as important as needle safety devices.

the ANA indicate that nearly two-thirds (64%) of 700 U.S. nurses surveyed say needlestick injuries and bloodborne infections remain major concerns.

“An overwhelming majority of nurses, 87%, say safety concerns influence their decisions about the type of nursing they do and their continued practice in the field,” Patton says. “To enhance the safety climate of all health care workers, improvements need to be made to the workplace environment and staffing levels.”

The ANA research indicates that the vast majority of nurses, 89%, say increasing workloads and workplace stress levels (84%) affect workplace safety. The majority of nurses surveyed, 59%, say that when pressure mounts, they feel the need to work faster, even if it means taking shortcuts.

Those shortcuts, among other factors, can lead to sharps injuries. Sixty-four percent of the nurses surveyed report being accidentally stuck by a needle while working. Among those nurses reporting needlestick injuries, 74% have been stuck by a contaminated needle while working. When asked how nurses received their most recent needlestick injuries, the top three responses include: while giving an injection (28%); before activating the safety feature (19%); and during the disposal of a non-safety device (19%). (See p. 143 for more information on how needlesticks occur.)

Patton tells *Healthcare Risk Management* that reporting rates are reasonably high, but risk managers still may be in the dark about a significant number of needlesticks. The ANA survey revealed that while 91% said they were familiar with their workplace’s protocol regarding needlestick injuries, only 79% of those accidentally stuck by a needle while working say they reported the incident.

Attention to needlesticks is waning, and that could result in an increase in injuries, says **Angela Karpf**, MD, worldwide medical director of medical

affairs and an expert in needlestick safety with BD Medical — Medical Surgical Systems in Franklin Lakes, NJ, which manufactures needlestick safety devices.

“There is not a lot of talk now and not many studies being done lately on needlestick prevention,” she says. “The ANA survey shows that nurses are still worried about it, but I’m concerned that the health care community may have its focus on other concerns now and is not paying enough attention to needlestick prevention efforts.”

About 80% of acute care hospitals have adopted the use of needlestick prevention devices, regarded by the federal Occupational Health and Safety Administration (OSHA) and other agencies as a primary safety strategy, but there still is room for improvement, Karpf says.

“We also see that nurses do not feel there is enough information about needlestick prevention during training,” she says. “So, this is not just about using the proper safety-engineered devices. It also is extremely important that the health care providers train employees and continue the education and awareness strategies in the facility. This is a topic that needs ongoing attention.”

Karpf suggests that risk managers re-evaluate their needlestick prevention efforts, making sure that policies and procedures reflect the most recent advances in safety technology, but also to ensure that sharps education and training has not been minimized in recent years as other pressing needs came along.

Graham Reynolds, vice president of West Pharmaceuticals in Lionville, PA, which also offers products aimed at preventing sharps injuries, agrees that the health care community is at risk of sliding backwards in terms of

SOURCES

For more information on preventing needlesticks, contact:

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needlestick prevention.

"Unfortunately we may not see any real recognition, or response, to the problem until health care providers see the effects from the cost drivers associated with needlestick injuries or legislation that requires more attention to this issue," he says. "It is clear that there is concern among nurses about needlestick injuries, that their worries about this have not gone away, and it is imperative that health care employers not lose their focus. Clearly, the cost associated with needlestick injuries is only going to escalate." ■

Nurses, housekeeping staff at most risk from needles

The Centers for Disease Control and Prevention in Atlanta reports that data from 60 U.S. hospitals show health care workers suffer about 384,325 sharps and percutaneous injuries annually. These findings were presented recently at the International Conference on Nosocomial and Healthcare-Associated Infections in Atlanta.

The CDC estimates that 6% to 30% of health care workers who receive a needlestick injury from a patient positive with hepatitis B antigen will become infected. Nearly 12,000 health care workers contract work-related hepatitis B infections every year. From 500 to 600 of those workers require hospitalization; 250 will ultimately die from the infection or a related disorder. Between 700 and 1,200 will become chronic virus carriers.

Statistics from the federal Occupational Health and Safety Administration (OSHA) indicate that the risk of infection with HIV is small but still significant. A health care worker who sustains a single needlestick from a patient known to be infected with HIV has less than a five in 1,000 chance of becoming infected.

Studies and surveys from the CDC indicated that nurses have the highest frequency of needlestick injury reports, and housekeeping staff are second. Laboratory staff and phlebotomists also have high rates, as do nursing students and medical students. Other high-risk groups include pharmacists,

dialysis personnel, inhalation therapists, laundry workers, physicians and dietary staff.

Nursing needlestick injuries usually are associated with procedural problems and recapping, with a few sticks occurring because of stray needles. General use syringes account for most sticks because they are more abundant than other needles, but a greater risk of injury appears to come from those procedures that require several needles. Heparin flushes, for instance, produce at least three contaminated needles that are usually not disposed of until after the procedure. IV butterflies with entangled loops of tubing also pose a hazard. When nurses must exert force to counter resistance during the withdrawal of a needle, the risk of injury also increases.

Housekeeping, laundry and dietary staff needlestick injuries are always associated with improper disposal of needles by clinical staff and stray needles. Laboratory workers sustain needlestick injuries during procedures and recapping. One study found that vacuum tube phlebotomy was associated with an injury rate four times higher than the rate when disposable syringes are used. Recapping must be done because the needle has to be unscrewed from its reusable holder.

For more needlestick data and information on prevention strategies, see the OSHA web site at www.osha.gov/SLTC/bloodborne pathogens/index.html and the American Nurses Association site at <http://www.nursingworld.org/MainMenuCategories/OccupationalandEnvironmental/occupationalhealth/SafeNeedles.aspx>. ■

CME objectives

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

- **describe** the legal, clinical, financial and managerial issues pertinent to risk management
- **explain** the impact of risk management issues on patients, physicians, nurses, legal counsel and management
- **identify** solutions to risk management problems in health care for hospital personnel to use in overcoming the challenges they encounter in daily practice. ■

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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. **The semester ends with this 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.

21. According to information released by Broward General Medical Center, how was a nurse's alleged violation of infection control procedures discovered?
 - A. A call came into the hospital's compliance hotline, with the caller reporting seeing the nurse use the same saline bag and a portion of tubing more than once.
 - B. A nursing supervisor reported that she had witnessed the improper use.
 - C. A review of documentation pertaining to the supplies revealed that some items had been reused.
 - D. A surveillance camera caught the nurse reusing supplies meant to be disposable.
22. How did Broward General respond to news that a nurse may have exposed patients to bloodborne pathogens?
 - A. The hospital notified the health department and took no further action.
 - B. Broward General immediately sent letters in English, Spanish, and Creole via certified mail to all 1,851 patients and referring physicians, informing them of the incident.
 - C. The hospital refused all inquiries about the incident until faced with a lawsuit.
 - D. Broward General sent letters only to the patients treated on the day the nurse's misbehavior was reported.
23. How did Michael R. Counes, BS, CAC, MCSE 2K3, address security concerns about downloading information onto portable USB drives?
 - A. He prohibited all downloads to USB drives.
 - B. He implemented a system requiring special passwords for each download.
 - C. He used a monitoring system that details how and when files were downloaded to a USB drive.
 - D. He enacted large fines for improper use of USB drives.
24. At Bancroft Neuro Health, with facilities in New Jersey and Delaware, how often do administrators meet to discuss the status of open workers' compensation claims?
 - A. Monthly
 - B. Every quarter
 - C. Every six months
 - D. Annually

Answers: 21. A; 22. B; 23. C; 24. B.

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Failure to timely diagnose endometrial cancer results in death: \$1.1M PA verdict

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News: A woman presented at her gynecologist's office with complaints of post-menopausal bleeding. The gynecologist ordered a pelvic ultrasound, which displayed abnormal findings. A radiologist diagnosed the woman with endometrial cancer, but the gynecologist did not tell the woman. The gynecologist instead told the woman that she was worried about abnormal tissue and cancer, performed an office biopsy, and referred the woman to a specialist. The specialist performed a hysteroscopy and dilation and curettage, and concluded that the woman did not have cancer. The next year, the woman experienced post-coital bleeding and returned to the gynecologist, who told her that she had vaginal dryness. Ten months later, while on vacation, the woman experienced heavy bleeding and went to a gynecologist, who found worrisome tissue and told her to go to her gynecologist. The woman returned to the specialist, who performed an immediate hysterectomy. The woman was diagnosed with Stage II endometrial cancer, which spread to her lymph nodes. After two rounds of chemotherapy and radiation, the woman died. Her husband and son brought suit alleging medical malpractice. A jury returned a verdict of \$1,137,444.

Background: A 65-year-old retired woman presented at her gynecologist with complaints of post-menopausal bleeding. The gynecologist ordered a

pelvic ultrasound, which was read by a radiologist. The radiologist reported abnormal findings and a diagnosis of endometrial cancer. The gynecologist did not inform the woman of the findings; rather she told the woman that she was concerned about abnormal tissue and cancer. The gynecologist performed a biopsy in the office and referred the woman to a gynecologic oncology specialist.

The gynecologic oncology specialist performed a hysteroscopy and dilation and curettage. The specialist concluded that the hysteroscopy and dilation and curettage were negative for signs of cancer. The specialist informed the woman that she did not have cancer.

The following year, the woman began experiencing post-coital bleeding and returned to the gynecologist. The gynecologist informed the woman that she had vaginal dryness and recommended the use of topical estrogen and that the woman return to the office if the symptoms persisted.

Ten months later, while on vacation, after a period of heavy bleeding, the woman went to a different gynecologist. This gynecologist found worrisome tissue and directed the woman to return to her regular gynecologist.

The woman returned to the specialist. The specialist ordered an immediate hysterectomy. One month later, the woman was diagnosed with Stage II endometrial cancer that had spread to her lymph nodes. Over the next eight months, the

woman underwent two rounds of chemotherapy and radiation therapy. The treatment could not control the cancer, and the woman died.

The woman's husband and son brought suit on behalf of her estate against her gynecologist, the specialist, and their hospital employers, alleging medical malpractice. Plaintiffs' counsel alleged that the physicians failed to meet the standard of care in their treatment of the woman, by neglecting to tell her the results of the radiologist's pelvic ultrasound. By informing her of the results of the ultrasound, plaintiffs' counsel alleged that she would have been able to treat the cancer with a hysterectomy. Further, an oncology expert testified that had she had a hysterectomy following her first visit to her gynecologist, she would have had a 90% chance of surviving the endometrial cancer that ultimately resulted in her death.

Plaintiffs' counsel further contended that the amount of tissue obtained in both the office biopsy and dilation and curettage procedure was insufficient to reliably rule out cancer. They also alleged that the pathology report did not include an analysis of all of the tissue that was obtained in the dilation and curettage procedure. They further stated that the patient was never informed of this information and that the failure to inform her was a violation of the hospital's patient bill of rights.

Defendants' counsel alleged that the physicians met the standard of care in treating the woman, as the examinations of the office biopsy, hysteroscopy, and dilation and curettage procedure did not show any signs of cancer. Further, they contended that because they told her they were concerned about abnormal tissue and cancer, they were not obligated to inform her of the radiologist's ultrasound determination. They also argued that the cancer that the woman suffered from was a Type II aggressive cancer, which she developed after her initial visit.

Plaintiffs' counsel sought damages for the woman's pain and suffering during the final four months of her life, as she was treating her constant pain with morphine while experiencing nausea, vomiting, loss of appetite, and loss of weight. The woman's husband further sought damages for loss of society, as he was deprived of spending his retirement years with his wife. Plaintiffs also sought damages for loss of tutelage for the woman's five children. Defense counsel did not dispute the damages claimed by the plaintiff. The jury rendered a verdict of \$1,137,444 for the plaintiffs.

What this means to you: This case raises many

more questions than answers. Here we have a 65-year-old woman with a family who may have had her life expectancy shortened needlessly due to a lack of communication of test results. Had she been provided this omitted information, she may have made a different decision on how to proceed, which may have resulted in a more timely diagnosis and different outcome.

The sad aspect of a missed diagnosis of cancer is that often, when it is finally diagnosed, it has spread to the point where the treatment is much more drastic, and often the prognosis is not good and the patient's life expectancy is shortened.

One of the principles emphasized in today's health care climate of patient safety is partnering with patients. The ethics of medicine play a major role in the provision of health care services, as well. In some states, withholding material medical information from a patient that might impair a patient's ability to make a decision about his or her health care may be considered fraudulent concealment, which can toll the statute of limitations that runs on any claim the patient may have against the provider.

In this situation, the results of the first screening exam, the pelvic ultrasound, were positive. Yet the results were not shared with the patient. Even if the gynecologist questioned the radiologist's conclusion, the findings, along with the explanation — along with plans for further testing — should have been shared with the patient. Apparently, the results of the office biopsy were not shared with the patient, although the gynecologist did refer the patient to a gynecology oncologist. Even though further diagnostic testing turned out negative, the patient still should have been informed of the first ultrasound diagnosis. Had she had this information, she might have elected to seek a second opinion to verify the diagnosis of no abnormal cells against the ultrasound results.

The gynecologist had another chance to revisit the ultrasound results when the patient presented with post-coital bleeding a year later. He could have ordered another ultrasound to assess the current status of her endometrium compared to the previous exam results. Had this been done, it is possible that an appropriate diagnosis would have been made before it reached the Stage II level.

One would question why, 10 months later, when the patient returned to her initial gynecologist with another episode, he recommended an immediate hysterectomy. What were the results of the biopsy done in the office 10 months before?

One might question why ultrasounds of the uterus were not done at intervals between the initial exam and the 10-month return visit.

Testimony at trial indicated that the tissue sent for pathology review was inadequate for a diagnosis or a ruling out of cancer. Such information would have been a part of the report sent back from the pathologist. Had the gynecologist seen this report, it would have initiated a call to the patient to redo the dilation and curettage or order another diagnostic exam. The gynecologist also should have advised the patient that no definitive diagnosis of cancer had been made and that further follow was necessary. The failure of the gynecologist to follow up was not within the accepted standard of care. As a result, the patient was unable to seek proper, early treatment that may have prevented her death, or at least allowed for timely treatment to prolong her life.

This is a case that appears to be set entirely in the physician office setting. Many physicians do not employ risk management principles in their offices and do not utilize the services of a risk manager to assist them in this area. For instance, in this case, had a process been in place to monitor the receipt of reports of all specimens and orders for tests and consultations, the fact that the tissue sent from the dilation and curettage was insufficient might have been picked up. Verification of review of all test results and consultation reports by physician initial and date is a fail-safe procedure to identify abnormal results and to show that the doctor actually saw the report/results. Furnishing the patient with a copy of his or her test results is an aspect of the doctor-patient partnership. In addition, another redundancy to prevent things from “falling through the cracks” is to call or notify all patients in writing of their test results, whether positive or negative. Patients should be told that if they aren’t contacted by the physician’s office within so many days after the test that they should call in for the results.

In this case, there was testimony that the cancer that ultimately killed this patient occurred after the first dilation and curettage. However, because the tissue from that first procedure was inadequate for diagnosis, that is questionable.

While most physicians still maintain an independent practice, separate from the hospital setting, more hospitals are buying practices and employing physicians. Hospital-based risk managers should work with physicians’ offices that are part of the organization to assess and implement

systems to track the results of tests and consults ordered. When results are not returned within an appropriate time frame, steps should be taken to obtain the results. In addition, physicians always should initial and date reports to verify that they have actually reviewed the report. ■

Failure to timely diagnose results in \$5M verdict

News: A woman underwent a hysterectomy. During the procedure, an endotracheal tube was inserted, which resulted in a perforation of the woman’s esophagus. The woman complained of difficulty in swallowing and pain extending from her chest. Three days after surgery, the woman was diagnosed with a perforation of her esophagus. The woman underwent multiple corrective surgeries, but the injury resulted in a severe infection, pneumothorax, mediastinitis, and hypoxic damage ultimately resulting in permanent dementia. The woman brought suit against the hospital and the anesthesiologist for malpractice in inserting the tube and failing to timely diagnose her injuries. A jury awarded the woman \$5 million in damages.

Background: A 79-year-old homemaker underwent a hysterectomy at a local hospital. During the procedure, an endotracheal tube was inserted. The woman suffered a perforation of her esophagus during the insertion of the tube, which was not immediately discovered.

While the perforation was not immediately detected, the woman began to experience impairment in her ability to swallow, and she complained of pain extending from her chest. In the following days, the woman suffered a severe infection, a pneumothorax, which is a collapse of the lung, and mediastinitis, which is inflammation of the tissue of the middle portion of the chest. A test was performed, which showed that the woman’s blood contained an abnormally high concentration of white cells. The physicians finally discovered the perforation on the third day after surgery. The woman underwent multiple surgeries, including open surgery that repaired her injury, placement of an esophageal stent, and another surgery to remove the stent, but the injury resulted in hypoxic damage ultimately leading to permanent dementia.

The woman brought suit against the hospital, the surgical team's anesthesiologist, and the anesthesiologist's practice group, alleging that the hospital staff failed to timely diagnose the perforation and that this failure constituted compensable medical malpractice. Plaintiff's counsel argued that the anesthesiologist was not qualified to use the instrument that was used to insert the tube. Plaintiff's counsel further argued that, based on the woman's symptoms, a diagnosis could have been made in the 12 hours that followed the surgery. Counsel argued that a more timely detection would have minimized the woman's residual injuries.

Defendants proffered the testimony of an expert anesthesiologist. The expert contended that the intubation process involved several people and several instruments, and there was no way that plaintiff's counsel could have identified the instrument that caused the perforation. Defendants' counsel further argued that the injury that the woman suffered was a rare but known risk of intubation.

For seven months after the surgery, the woman was fed through a nasogastric tube and a gastric tube. She underwent seven months of rehabilitation and required assisted living care thereafter. The woman sought damages for past and future medical expenses and past and future pain and suffering. A jury determined that the defendants were liable and rendered a verdict of \$5 million in favor of the woman.

What this means to you: This case reflects the occurrence of an infrequent complication of a fairly frequent procedure, the process of inserting an endotracheal tube. While no one likes to see a complication occur, in this case the issue is the failure to follow up on the signs, symptoms, and complaints of the patient postoperatively, which, had they been addressed, might have led to an earlier diagnosis and intervention. Early diagnosis and intervention may have resulted in a different, more positive outcome for this patient.

Hospitals verify competency of employees to perform procedures and use equipment on an annual basis as a part of the employees' annual evaluations. But this case involved an anesthesia group, which is usually not directly employed by the hospital. Some anesthesia groups employ their affiliated anesthesiologists, while others contract with their staff. In either case, each physician is credentialed by the hospital. The contract between the hospital and the anesthesia group should be reviewed by the risk manager and legal counsel,

and by risk management to identify risk assumptions, risk exposures, appropriate insurance, and adequate limits of insurance, in addition to loss prevention activities. One such loss prevention technique, which may or may not be itemized in the contract but should be utilized by the group, is validation of competency of anesthesiologists and anesthesiologists in the group. Such a practice prevents the allegation that the anesthesiologist was not qualified to use a specific piece of equipment used to insert the endotracheal tube. One must take into consideration that all physicians may not have received training or used certain equipment during their residency. For example, the equipment may have come on the market after they finished their training. Even if certain equipment was on the market, it may not have been used in a certain facility or by a particular anesthesiologist (as in this case).

The risk manager must realize that mere language in a contract may not prevent the allegation of agency or ostensible agency from being asserted unless steps are taken to notify patients that the anesthesiologists are employees or agents of the anesthesia group, not of the hospital. This can be accomplished by including such language in the anesthesia consent and in the general admission consent. In addition, the hospital risk manager should take steps to be sure the anesthesiologists do not wear scrubs or other items identifying the hospital, such as white coats that have the name of the hospital stamped or embroidered on them. Collaboration with the anesthesia group's risk manager or risk management designee will assist in addressing this issue and in educating the physicians on why this is important.

A postoperative pain in the chest after a surgical procedure done in a completely different area of the body should be evaluated. The signs and symptoms and the patient's complaints should be reported to the surgeon to be evaluated. A sore throat is the most common postoperative complaint. Rarely is difficulty swallowing a complaint, especially when coupled with chest pain. This should have been evaluated promptly.

This was an untoward outcome that would benefit from a thorough root-cause analysis to identify first how the initial untoward complication, the esophageal perforation, occurred, and why the delay in the diagnosis occurred, which led to the more significant complications. Such a root-cause analysis would be a team effort, involving medical staff, surgeons, anesthesiologists, nursing staff, and risk management. ■



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CNE Evaluation

Please take a moment to answer the following questions to let us know your thoughts on the CNE program. Fill in the appropriate space and return this page in the envelope provided. **You must return this evaluation to receive your certificate.** Thank you.

CORRECT INCORRECT

1. If you are claiming nursing contact hours, please indicate your highest credential: RN NP Other _____

	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
After participating in this program, I am able to:						
2. Describe legal, clinical, financial, and managerial issues pertaining to risk managers in health care.	<input type="radio"/>					
3. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.	<input type="radio"/>					
4. 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.	<input type="radio"/>					
5. The test questions were clear and appropriate.	<input type="radio"/>					
6. I am satisfied with customer service for the CNE program.	<input type="radio"/>					
9. I detected no commercial bias in this activity.	<input type="radio"/>					
10. This activity reaffirmed my clinical practice.	<input type="radio"/>					
11. This activity has changed my clinical practice.	<input type="radio"/>					

If so, how? _____

12. How many minutes do you estimate it took you to complete this entire semester (6 issues) activity? Please include time for reading, reviewing, answering the questions, and comparing your answers to the correct ones listed. _____ minutes.

13. Do you have any general comments about the effectiveness of this CNE program?

I have completed the requirements for this activity.

Name (printed) _____ Signature _____
 Nursing license number (required for nurses licensed by the state of California) _____

OSHA enforcing N95 respirators for HCWs treating H1N1 flu patients

OSHA: 'We're looking for a good-faith effort.'

By **Gary Evans** and **Michelle Marill**
Editors

*Hospital Infection Control & Prevention
Hospital Employee Health*

Particulate respirators — a controversial step beyond common surgical masks — are now mandated by the Occupational Safety and Health Administration (OSHA) to protect health care workers from acquiring H1N1 pandemic influenza A from patients. With respirator shortages feared, “good-faith efforts” by health care employers will be recognized by OSHA, which nevertheless is warning that citations and fines may result from inspections that will be primarily prompted by employee complaints.

“Employers should do everything possible to protect their employees,” said **Jordan Barab**, acting assistant secretary of labor. He emphasized, however, that where respirators are not commercially available, an employer will be considered to be in compliance if the employer made every effort to acquire respirators. Health care employers will need to be able to show documentation of orders that have been placed or statements from a manufacturer that the respirators are on back order. N95 respirators — already used by many hospitals for the treatment of tuberculosis patients — are the minimum level acceptable for H1N1.

“We’re looking for some evidence that the employer has attempted to purchase N95 respirators,” Barab said. “We’re looking for a good-faith effort.”

OSHA is issuing a compliance directive to enforce the Centers for Disease Control and Prevention’s recently issued “Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel.” (Available at http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.)

The CDC disappointed infection preventionists in the guidance by reaffirming its stance that surgical masks are not sufficient to protect workers from

H1N1 patients. The CDC recommends the use of respiratory protection that is at least as protective as a fit-tested disposable N95 respirator for health care personnel who are in close contact (within 6 feet) with patients with suspected or confirmed 2009 H1N1 influenza. The president-elect of the Society for Healthcare Epidemiology of America said the CDC decision appeared to be made for reasons other than science, which has not shown burdensome, scarce N95s to be more effective in clinical studies.

“They are recommending a respirator that is not readily available, for transmission that has never been shown to be clinically relevant,” said **Neil Fishman**, MD. “It presents a hardship to health care workers and health care providers that is unnecessary and offers nothing in [additional] degree of protection.”

On the other hand, the CDC is under considerable pressure from health care unions and worker safety advocates since at least four nurses nationally have reportedly died of complications related to H1N1. Noting that H1N1 surveillance systems do not provide occupational data, the National Institute for Occupational Safety and Health (NIOSH) is asking for information from the public on health care worker H1N1 illnesses and deaths. (Information can be e-mailed to nioshh1n1data@cdc.gov.) NIOSH is asking for contact information so the agency can follow up on cases that have primarily been reported through the media.

“Once we get that information, we can make decisions about whether we want to do a more thorough investigation, whether it is a Health Hazard Evaluation or another kind of study,” says **Christina Spring**, health communications specialist with NIOSH in Washington, DC.

Meanwhile, OSHA inspectors will ensure that health care employers implement a hierarchy of

Supplement to *AIDS Alert, Critical Care Alert, Clinical Trials Administrator, Contraceptive Technology Update, Case Management Advisor, Discharge Planning Advisor, Drug Formulary Review, ED Nursing, ED Management, ED Legal Letter, Emergency Medicine Reports, Hospital Case Management, Hospital Peer Review, Hospital Medicine Alert, Hospital Home Health, Healthcare Risk Management, Infectious Disease Alert, IRB Advisor, Medical Ethics Advisor, Occupational Health Management, Patient Education Management, Primary Care Reports, Pediatric Emergency Medicine Reports, Same-Day Surgery, State Health Watch, and Travel Medicine Advisor.*

controls, including source control, engineering, and administrative measures, and to encourage vaccination and other work practices recommended by the CDC. Where respirators are required to be used, the OSHA Respiratory Protection standard must be followed, including worker training and fit testing. While the ruling clearly applies to hospitals, as this report was filed OSHA had not responded to a written request for clarification regarding other medical settings. Employee complaints from clinics and physician offices could potentially result in an inspection because OSHA's respiratory protection standards also apply to small businesses.

CDC casts wide net

The CDC clarified that the scope of its guidance includes a wide range of medical settings: "This guidance provides general recommendations for health care personnel in all health care facilities," the CDC stated. "For the purposes of this guidance, health care personnel are defined as all persons whose occupational activities involve contact with patients or contaminated material in a health care, home health care, or clinical laboratory setting."

Since a shortage of disposable N95 respirators is possible, employers are advised to monitor their supply, prioritize their use of disposable N95 respirators according to guidance provided by CDC, and to consider the use of reusable elastomeric respirators and facemasks if severe shortages occur, OSHA advised. Health care workers performing high-hazard, aerosol-generating procedures (e.g., bronchoscopy, open suctioning of airways, etc.) on a suspected or confirmed H1N1 patient must always use respirators at least as protective as a fit-tested N95, even where a respirator shortage exists. In addition, an employer must prioritize use of respirators to ensure that sufficient respirators are available for providing close-contact care for patients with aerosol-transmitted diseases such as tuberculosis.

Where OSHA inspectors determine that a facility has not violated any OSHA requirements but that additional measures could enhance the protection of employees, OSHA may provide the employer with a Hazard Alert Letter. OSHA will inspect health care facilities under the Respiratory Protection Standard "to ensure that health care workers are protected and that protection is in line with CDC [guidance]," Barab said.

The CDC guidance to use respirators has been controversial and hotly debated almost since the onset of H1N1 last spring. Many infection

preventionists argue that H1N1 is comparable to seasonal influenza in its virulence and transmission routes, and that droplet precautions (e.g., surgical masks) are sufficient. In fact, some state health departments diverged from CDC and called for surgical masks unless health care workers were performing aerosol-generating procedures.

The Healthcare Infection Control Practices Committee, a CDC advisory panel, endorsed the use of surgical masks rather than respirators. But an Institute of Medicine (IOM) panel charged with reviewing the available science concluded that surgical masks would not protect workers from airborne influenza particles. "[T]here is evidence that work-related exposures to patients infected with H1N1 virus result in health care workers becoming infected," the IOM report stated.

The answer, decided CDC director **Thomas Frieden**, MD, is to use respirators but to limit their use through other measures. "Use a scarce resource carefully," he said in a briefing on the guidance. "Follow a hierarchy of controls and limit the number of people who are potentially exposed and would need a higher level of protection."

The CDC is no longer recommending contact precautions — the use of gowns and gloves — but Frieden noted that influenza is spread through droplet, fomite, and aerosol transmission. "It is an unfortunate fact that we do not have definitive evidence on the portion of transmission that occurs from each of those three routes," said Frieden, noting that "the preponderance of belief" was that droplets were the most common route. "With that lack of knowledge and with the newness of H1N1 . . . we are recommending that N95s . . . would be clearly superior to surgical masks."

Still, CDC is providing some flexibility to hospitals. That means in some circumstances, health care workers may reuse respirators, continue to wear them while caring for more than one patient, or may even wear surgical masks as a last resort option. CDC states that extended use (in which the respirator is not removed while the health care worker cares for more than one patient) is preferred over reuse.

"We recognize that there may be shortage situations," said Frieden. "The need is for us not just to provide respiratory protection now, but the flu season lasts through May. We need to ensure we have a reliable supply."

The CDC guidance states that "when in prioritized respirator use mode, respirator use may be temporarily discontinued for employees at lower risk of exposure to 2009 H1N1 influenza or lower risk of complicated infection." ■