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Ebola prompts changes, creates new risk management challenges

EMTALA, employment among the most difficult issues

The nation's healthcare system was challenged by the recent cases of Ebola in the United States, but the clinical treatment and infection control were not the only difficult issues to emerge. Risk management issues regarding potential liability, staff training, and regulatory compliance continue to complicate Ebola care, and hospitals not yet affected by the disease are urged to review their capabilities while they can.

As the first day of Ebola response for U.S. healthcare workers unfolded on Sept. 24, 2014, it soon became clear

that those responsible for helping the infected were the most at risk. Seventy-six healthcare workers who helped treat Liberian Ebola patient Thomas Eric Duncan at Texas Health Presbyterian Hospital Dallas were monitored for potential Ebola exposure. Two contracted the disease but recovered. Duncan died. Amid nationwide concern about the adequacy of the nation's response to the Ebola infections, healthcare workers involved in Duncan's treatment complained that inadequate education, training, and equipment put them at risk of infection.

Special Report on Ebola Response

This month's *Healthcare Risk Management* includes a special report on the healthcare industry's response to the first cases of Ebola in the United States and the risk management issues that have arisen. Risk managers are advised to consider some of the difficult decisions that would be necessary when treating Ebola patients and also to remember that other infectious diseases could create the same dilemmas.

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EDITORIAL QUESTIONS
Questions or comments?
Call **Greg Freeman**,
(770) 998-8455.

The Centers for Disease Control and Prevention (CDC) confirmed claims that the Dallas nurses and physicians had to learn on the fly how to control the deadly virus, initially using CDC protocols that left the caregiver's neck exposed to the patient's copious amounts of highly infectious vomit and diarrhea. The nurses treating Duncan worked for days without proper protective gear and faced constantly changing protocols, according to a statement released by National Nurses United, the largest U.S. nurses' union. Nurses were forced to improvise improvements, using medical tape to secure openings in their flimsy garments, the union claims. The hospital soon changed its protocol to include more extensive gear that completely covered the clinician. (*See the story on p. 124 for a timeline of Duncan's treatment and the subsequent infections.*)

Quarantines, or the lack thereof, became a heated issue. U.S. nurse Kaci Hickox was quarantined at a hospital by the state of New Jersey upon returning from hands-on treatment of Ebola patients in Sierra Leone. She was released to self-quarantine at home in Maine after she publicly derided the precaution and obtained a high profile attorney to sue the state. President Barack Obama also criticized the quarantine as unnecessary. Hickox flagrantly violated the home quarantine and

convinced a federal judge to overturn the order.

Texas Health Presbyterian Hospital Dallas confirmed that it settled with Duncan's family regarding the delayed diagnosis. The settlement was for a "substantial amount," says the family's attorney, **Les Weisbrod, JD**, of the Dallas law firm of Miller Weisbrod. In addition, Texas Health Resources Foundation agreed to create a charitable trust in Duncan's memory intended to eventually create a state-of-the-art treatment facility for Ebola patients in Africa. The hospital also agreed not to charge Duncan's family for his medical care.

The hospital still could be facing lawsuits related to the nurses' infections and the emotional stress suffered by not only those two healthcare workers who were infected, but everyone else involved in Duncan's care or exposed to him after his initial visit to the hospital.

Duncan began experiencing symptoms on Sept. 24, 2014, and he arrived at the Texas Health Presbyterian Hospital emergency room (ER) at 10:37 p.m. on Sept. 25. A nurse recorded a fever of 100.1 degrees F but did not inquire as to his travel history, as this was not triage protocol at the time. Another nurse later asked about his travel history, but she did not follow through when the electronic health record (EHR) indicated that

EXECUTIVE SUMMARY

The recent cases of Ebola in the United States have revealed significant risk management concerns for the treatment of this disease or any other infectious disease. Because the potential liability is so high, risk managers should consider their hospitals' readiness for such an emergency.

- Complying with EMTALA could be challenging.
- Proper training and education of employees is a key concern.
- The hospital treating the first Ebola patient has settled with his family.

information should be reported to the physician. Early the next morning, Duncan was diagnosed with sinusitis and abdominal pain. He was sent home at 3:37 a.m. with a prescription for antibiotics.

Duncan returned to the hospital on Sept. 28 and was diagnosed with Ebola. The delay between those hospital visits could prompt lawsuits from anyone exposed in the interim, says **R. Stephen Trosty**, JD, MHA, ARM, CPHRM, president of Risk Management Consulting in Haslett, MI, and a past president of the American Society for Healthcare Risk Management (AHRM) in Chicago. “There was a clear misdiagnosis or missed diagnosis in the ER when the patient first went there. This raises potential liability issues for the hospital relative to the family and others who came in contact with him between the time he was improperly discharged from the ER until he was readmitted,” Trosty says. “But you would have to show some damage resulting from this, although it could be any expense incurred, any lost wages, any resulting mental anguish. They might also have to show some accompanying actual loss, injury, or damage.”

Trosty notes that Duncan’s family would have found it difficult to prove that the delay in diagnosis made a difference in the outcome. “The plaintiff would have to prove that medical malpractice occurred by showing that some standard of care existed, that it was not met, there was some injury, and the resulting injury was the proximate result of the failure to adhere to standard of care,” Trosty explains. “In order to do this, it probably would be necessary to establish that his death was caused by the failure to admit him from the ER. With a disease that has a fatality rate of at least 50%, there would be a

strong defense to that claim.”

The exposure of the medical staff is another potential source of litigation. CDC protocols were changing rapidly, and the initial instructions to the Dallas clinicians – plus the gear that was available – proved inadequate.

“There is the potential issue of whether adequate protective gear and isolation policies existed, whether staff was adequately trained, and were [policies] adhered to,” Trosty says. “This can directly relate to the issue of the percent of the body that was and was not covered by the protective gear. I believe that in this case, not all of the body, neck, and/or face were covered. This raises a potential issue of whether the proper policies existed.”

Was hospital liable?

Because the protective gear later changed to cover the body more completely, and the CDC guidelines subsequently changed on this issue, it is difficult to know if a liability existed for the hospital relative to its existing policies and procedures and if it complied with existing CDC guidelines, Trosty notes.

This situation opens up the issue of whether the hospital should have known better, if there were other places using more complete protective gear, and if hospitals can look to the CDC as the final word on protection.

“This issue could arise for staff personnel who contracted the disease as a result of treating the patient but who were not given the complete protective gear that should have been and subsequently was worn,” Trosty says. “This could be a new area of actual or potential liability for the hospital and maybe even the CDC, but this is specifically, as of now, some uncharted legal territory.”

Still another worry for risk managers is how Ebola could complicate efforts to comply with the Emergency Medical Treatment and Labor Act (EMTALA). A potential Ebola patient still must be stabilized even if transfer to a more capable hospital is appropriate, yet the extreme isolation needed could strain the abilities of some smaller emergency departments. (*See the story on p. 126 for more on the EMTALA challenge.*)

Another concern that has arisen is the potential for environmental liability. Transport companies that manage the disposal of hazardous waste for your hospital might be alarmed at the exposure and liability, says **Maureen Archambault**, RN, MBA, HRM, CPHRM, FASHRM, managing director and west zone healthcare practice leader for Marsh Risk and Insurance Services in Los Angeles. As a result, they might refuse pick up, or there might be delays while they consider options and establish a protocol.

“This is an area that can be easily overlooked in the planning stage,” Archambault says. “Environmental services flies under the radar for most people, but it becomes a very important issue when you have highly infectious waste piling up in your hospital. The hospital is ultimately responsible for what happens to that waste, so it is important to work with your contractor beforehand to make sure they are capable of responding and that they won’t be caught off guard if this scenario develops.”

The risk manager’s response to Ebola should follow the principles of enterprise risk management, Archambault suggests. Look at every potential outcome and assess your contingency plans, reaching far into the more mundane aspects of

treatment and infection control that can determine a successful response. For example, when assessing your hospital's ability to respond to Ebola or another infectious disease, don't stop with confirming that you have an adequate supply of gloves, gowns, masks, and other gear, Archambault says. What will happen if you suddenly start going through that disposable gear at 10 or 20 times the normal rate? Do you have an adequate supply chain that can respond?

Even though Ebola is unlikely to hit any particular hospital, many of the same concerns apply to other

infectious diseases. Taking the proper steps to prepare is akin to having good contingency plans for a fire, flood, or tornado, Archambault notes. The plans might never be used, but the consequences of not planning for that event are too great to allow complacency.

Liability will not arise until you actually have an Ebola experience and someone is damaged in some way, but even then the claimant would have to prove negligence, notes **Gigi Norris**, managing director with Aon Risk Solutions' Western Region Healthcare Practice in San Francisco. What constitutes negligence with Ebola

still is unclear because negligence is relative to the standard of care, she notes, and that situation has been changing from day to day.

"Even a lot of what we call negligence is really just bad luck. This poor hospital in Dallas was first, and everybody was caught short — not just the hospital, but the CDC, everyone," Norris says. "They were the unlucky first hospital, and we have to hope that everyone else learns from what they went through. It's kind of black swan situation where you're not going to see it very often, but if it happens to you, it's a very serious issue." ■

Delayed diagnosis, then workplace infections

This summary of Texas Health Presbyterian Hospital Dallas' experience with the first Ebola patient in the United States is compiled from statements and data provided by the hospital and the Centers for Disease Control and Prevention (CDC):

Liberia native Thomas Duncan arrived at the Texas Health Presbyterian Hospital Dallas emergency department at 10:37 p.m. on Sept. 25. Fifty-nine minutes later, a triage nurse asked Duncan about his symptoms, and he reported "abdominal pain, dizziness, nausea and headache (new onset)." The nurse recorded a fever of 100.1 degrees F. The nurse did not ask about his travel history because the Ebola screening protocol did not yet require that inquiry.

Duncan was admitted at 12:05 a.m. to a treatment room where a physician accessed the electronic health record (EHR) and visited Duncan, but he did not yet examine the patient. At 12:33 a.m., an emergency department nurse continued Duncan's assessment and

asked about his travel history. She noted "came from Africa 9/20/14." The EHR prompted the nurse to verbally relay the travel information to the physician, but she did not. The physician began examining Duncan and accessed the EHR, which included the travel information (contrary to original reports, which said the EHR did not convey that information). The record also showed that Duncan rated his pain as 8 on a scale of 1 to 10.

The EHR indicates that the attending physician asked Duncan and his companion about Duncan's personal history and health information. The patient identified himself as a "local resident" and said he had not been in contact with any sick people and claimed he had not experienced diarrhea, vomiting, or nausea.

Documenting nasal congestion, a runny nose, and abdominal tenderness, the physician provided an extra strength pain reliever at 1:24 a.m. A computed tomography scan revealed nothing of concern, but lab

results showed a slightly low white blood count, low platelets, increased creatinine, and a mild elevation in the liver enzyme AST. His temperature was noted at 103.0 degrees F at 3:02 a.m. and 101.2 degrees F at 3:32 a.m. The physician diagnosed sinusitis and abdominal pain and sent Duncan home at 3:37 a.m. with a prescription for antibiotics.

Duncan's condition worsened, and he returned by ambulance on Sept. 28 at 10:07 a.m. with diarrhea, abdominal pain, and fever. Fifteen minutes later, a doctor noted that Duncan recently had come from Liberia and ordered a test for Ebola. At 12:58 p.m., the doctor called the Centers for Disease Control and Prevention (CDC) directly. By 9:40 p.m., Duncan was experiencing explosive diarrhea and projectile vomiting.

On Oct. 10, 26-year-old nurse Nina Pham, who had treated Duncan at the hospital, reported a low-grade fever and was placed in isolation. On Oct. 11, she tested positive for the Ebola virus, becoming the first person

to contract the virus in the United States.

On Oct. 14, 29-year-old Amber

Vinson, a nurse who also had treated Duncan, reported a fever and was isolated within 90 minutes of

reporting the fever. She tested positive for Ebola the next day. Both nurses recovered. ■

Ebola: What You Need to Know Now

- **Lawsuits stemming from the care of Ebola patients are possible, but the plaintiff's burden of proof would be daunting.**

Employees, patients, or others who contract Ebola can sue the hospital for not preventing transmission, but the plaintiff would have to prove that the provider failed to meet the standard of care. For Ebola, the standard of care is changing daily, and the hospital would have a reasonable defense in proving that it followed the infection control standard at the time of treatment. However, some plaintiffs' attorneys will be eager to take on even cases with little viability, just for the publicity.

- **If a staffer refuses to come to work or care for a potential Ebola patient, tread carefully.**

You probably can discipline the employee, but doing so might not be the best choice. Ebola is no different than other infectious diseases that pose a hazard to healthcare workers: If the employee refuses to report to work, then the standard attendance policies that typically include progressive discipline can be followed. However, you should use caution and avoid termination if the employee has a specific concern about the safety of a situation. The National Labor Relations Act protects employees who engage other employees about the terms and conditions of employment, which includes workplace safety.

- **Expect a workers' comp claim if an employee is infected with**

Ebola.

Most state workers' comp laws will apply to healthcare workers who contract the disease in the course of their jobs. If the infection occurs because the employee didn't follow the prescribed infection control protocol, the hospital could have grounds to deny the workers' comp claim. However, workers' comp laws require you prove willful misconduct to support disqualification. Even gross negligence isn't enough. You would have to prove that the employee knowingly and willfully did something egregious, which is not likely with Ebola.

- **Reinforce with employees the importance of complying with the Health Insurance Portability and Accountability Act (HIPAA).**

Even staff well trained in HIPAA compliance can let their guard down when a patient is the subject of sensational news coverage and reporters are pestering everyone for information. Remind staff that HIPAA applies.

- **Consider an all-volunteer Ebola strike team.**

Some hospitals use this strategy to avoid the concerns about employees who don't want to care for Ebola patients. The volunteers can undergo much more training than you are able to provide for all staff, and they can be compensated for serving on the strike team.

- **Some hospitals are limiting the type of care they will provide to suspected Ebola patients.**

To limit exposure of healthcare workers, particularly when their

efforts might be futile, several hospitals have stated that they won't perform CPR on patients suspected to have Ebola. Others have said they will restrict minimally invasive procedures on these patients because their hospitals aren't adequately equipped to provide that care with extreme isolation measures. The Centers for Disease Control and Prevention (CDC), as well as the American College of Surgeons, recommends that patients with suspected or confirmed Ebola not have elective surgical procedures.

- **Quarantines for people who might have been exposed to Ebola are the responsibility of government officials.**

A hospital is free to tell employees to take 21 days off work to ensure no Ebola infection, but enforcing any quarantine falls to the local health department and law enforcement.

- **Ebola might change the standard of care.**

A "crisis" standard of care applies during declared emergencies, which allows for legal adaptation to the changing circumstances and increased demands. Ebola can prompt a crisis standard of care.

Source: Mark W. Peters, JD, Waller Lansden Dortch & Davis, Nashville, TN; George B. Breen, JD, Epstein Becker Green, New York City; The Network for Public Health Law; CDC's Public Health Law Program; the American Health Lawyers Association. ■

Workers' comp, quarantines will be difficult

Relying on the authority of the Centers for Disease Control and Prevention (CDC) for infection control procedures should be safe, even if the CDC later proves to be wrong, suggests **Jane J. McCaffrey**, MHSA, CIC, DASHRM, a risk management consultant in Easley, SC, and a past president of American Society for Healthcare Risk Management. However, that statement does not diminish the hospital's obligation to properly train staff on protocols and provide the necessary equipment, she says.

"One key thing each organization needs to get on board with is that

there will be set protocols and no shortcuts," McCaffrey says. "Every facility will need to have a 'junior guru' with the clipboard and a checklist who observes strict compliance with the recommended protocol and documents that compliance."

Quarantines might require digging deep into little-used hospital policies and the fine print of insurance policies, McCaffrey notes. Consider the following questions: Is a quarantined employee on paid leave? Will it matter if the infection was acquired at work or in the community? Will workers' comp

apply for the expenses?

Workers' compensation costs could be contested by insurers, particularly if they claim that the hospital did not take adequate precautions. At the same time, however, some insurers are offering specific policies for losses related to Ebola. (See the stories on p. 127 and p. 128 for more on employment issues and insurance coverage.)

SOURCE

- **Jane J. McCaffrey**, MHSA, CIC, DASHRM, Consultant, Easley, SC. Telephone: (864) 751-3092. Email: jjmccaffrey49@gmail.com. ■

EMTALA more difficult with suspected Ebola

If a patient shows up at your emergency department (ED) with risk factors for Ebola, are you ready to fulfill your obligations under the Emergency Medical Treatment and Labor Act (EMTALA)? Complying might not be a simple task.

Many states are designating certain hospitals as the sites where Ebola patients will be treated, which acknowledges that not every hospital is capable of providing adequate care under extreme isolation measures. Some hospitals also have announced that they are not capable of providing the spectrum of care Ebola patients might need and will transfer them to more capable facilities.

Those are legitimate strategies, but those patients still might present at your ED, notes **George B. Breen**, JD, an attorney with the law firm of Epstein Becker Green in New York City. He is in the Health Care and Life Sciences and Litigation practices and chair of the firm's National Health Care and Life Sciences Practice Steering Committee.

If a potential Ebola patient arrives at the ED, the hospital cannot just turn that person away or direct him or her to another facility, he explains.

"YOUR
RESPONSE WILL
BE SCRUTINIZED
FOR THE
SLIGHTEST
ERROR OR
FAILURE TO
PLAN."

"If yours is not the appropriate facility because you don't have the capacity or the capability to take care of this patient, what practice or policy do you have in place to make sure this person is transported to

an appropriate facility?" Breen asks. "First, you have the obligation to stabilize this patient to the best of your ability, as with any other patient in your ED. You may not have to prepare your entire hospital for Ebola care, but your emergency department should have a plan for fulfilling EMTALA."

Once the patient is stabilized, then it is a matter of exactly how you are going to transfer this person. Protocols for the transfer must include infection control procedures to protect others, Breen says.

Planning for such an eventuality can seem like an overreaction or even discrimination against people from Africa, notes **Kathleen M. Williams**, JD, also with Epstein Becker Green in New York City. The alternative would be worse, she says.

"Everyone is going to be accused of underreacting when that Ebola patient comes forward," Williams says. "Your response will be scrutinized for the slightest error or failure to plan." ■

Employment law will protect exposed staff

Clinicians deal with plenty of dangerous substances and infectious diseases, but the idea of caring for an Ebola patient can make even the most dedicated nurse waver. When employees are reluctant to take on that task, risk managers must ensure that the hospital is not violating employment laws that might apply.

In that situation, hospital leaders should avoid a knee-jerk reaction, says **Mark W. Peters**, JD, partner with the labor and employment practice group of the Waller Lansden Dortch & Davis law firm in Nashville, TN.

“What I’ve heard from clinicians in the past weeks is ‘we have sick patients, so employees must care for them, period, end of story,’” Peters says. “It’s an absolute for clinicians, as well as a licensing issue and an ethical issue. But there are some employment considerations to walk through before you declare it’s that simple.”

For example, is a nurse critical of the infectious disease protocol or the hospital’s compliance? The nurses caring for Liberian Ebola patient Thomas Eric Duncan at Texas Health Presbyterian Hospital Dallas expressed concern initially about the inadequate protective gear available and prescribed under the then-current protocol. If one of the nurses refused

to care for the patient because of those concerns, he or she could be considered a whistleblower, and any disciplinary action would be seen as retaliatory, Peters explains.

That is not to say disciplinary action, even termination, is out of the question if the clinician refuses assigned tasks without good reason, Peters says. Just take your time and consider what workplace law might apply. At the same time, remember that the hospital is obligated to protect employees under the Occupational Safety and Health Act.

CDC guidelines endorsed

The Occupational Safety and Health Administration (OSHA) has endorsed the guidelines issued by the Centers for Disease Control and Prevention (CDC) as procedures for dealing with the threat from Ebola, Peters notes. OSHA also will apply the Bloodborne Pathogens standard (1910.1030), which provides guidance for employees at risk of coming into contact with blood or other potentially infectious materials. Hospitals must establish a written Exposure Control Plan designed to minimize employee exposure to the virus that meets the requirements of the standard, including identifying at-risk employees and job functions.

Other applicable standards include the Respiratory Protection standard (1910.134), the Personal Protective Equipment standard (1910.132), and the Hazard Communication standard (1910.1200). The General Duty Clause also requires employers to provide a safe work environment against known threats, which now include Ebola.

Peters cautions that the hospital could be sued even without any clear violation of labor law or applicable standards. The sensational nature of Ebola will appeal to some people seeking publicity.

“Plaintiffs’ attorneys could come up with a number of ways to allege liability, whether it’s related to failure to dispose of infectious waste properly or letting a nurse who just came back from Africa care for patients the next day,” Peters says. “It only takes \$350 to file a lawsuit in federal court. There are lots of good, creative lawyers out there who will pursue a case on its merits or they will pursue a case for another agenda. We’ve all dealt with those folks.”

SOURCE

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MERS at hospital revealed Ebola lessons

One hospital’s experience with another deadly infectious disease revealed lessons for how hospitals can respond to Ebola, say two healthcare attorneys who helped that facility through the incident. The key is preparation.

Laura D. Seng, JD, partner with the law firm of Barnes & Thornburg in South Bend, IN, and **Heather F.**

Delgado, JD, a partner with Barnes & Thornburg in Chicago, were part of the response team working with Community Hospital in Chicago when it treated the first patient in the United States with the potentially fatal Middle East Respiratory Syndrome (MERS). The patient recovered and was released from the hospital in May 2014.

Healthcare risk managers should participate in assessing the hospital’s planned response to an infectious disease such as MERS or Ebola, they say, and don’t shy away from concluding that your facility is not capable.

Seng says, “Many hospitals are not going to be prepared for a patient with Ebola because all the

demands of caring for a patient like this – the supplies needed, the isolation procedures, the training, the infectious waste disposal – are incredibly resource-intensive, on just the chance that you might get an Ebola patient. The first thing to think about is whether you can handle these patients. Most hospitals have isolation rooms, but they might not have the antechambers necessary for donning and removal of protective equipment or enough staff for the buddy system in which staff watch each other and help with donning and removing the equipment.”

The key lesson from the MERS incident is that hospital risk managers must plan their response before the patient shows up, Delgado says. Because Community Hospital had a response plan already, it was able to treat the patient with a minimum of disruption, she says.

“It really is the right time for risk managers to make sure they are up to date on all their training for infectious diseases and that all your policies and procedures are updated,” Delgado says. “Drills are important too, just so people can practice what you expect them to do in this

situation. Risk managers can play a big role in ensuring that, if an Ebola patient walks through your doors, you’re ready.”

SOURCES

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Insurers respond: New Ebola coverage, exclusions

Insurers are quick to see the needs and the danger in a problem such as Ebola care, and some already are responding with coverage options for potential losses. Some also are looking for ways to avoid paying for those losses.

The response of the insurance industry shows that the potential for financial losses related to Ebola are significant, notes **Maureen Archambault**, RN, MBA, HRM, CPHRM, FASHRM, managing director and west zone healthcare practice leader for Marsh Risk and Insurance Services in Los Angeles. Her company is one of several offering new coverage options.

“All the insurance companies are scrambling to respond, with some offering additional coverage for losses from business interruption and other effects,” she says. “Some others are declaring an Ebola exclusion, and then you have some offering policies specifically for Ebola coverage, which could help with the costs of cleanup or having to close your facility for a while.”

Archambault suggests that the Ebola concern is a good reason to

review all insurance coverage for losses related to infectious diseases. Check everything from professional liability to workers’ compensation, property losses, and directors and officers, she says. Look for exclusions that could apply in an infectious disease scenario, and consider any new insurance products that could fill gaps.

A good first step is to sit down with your insurance broker and go over all the potential losses that could be related to Ebola or a pandemic, suggests **Gigi Norris**, managing director with Aon Risk Solutions’ Western Region Healthcare Practice in San Francisco, which also is offering insurance products for Ebola exposures. “Your pandemic plan can be a good place to start, even though it’s different because a pandemic will result in a very high degree of absenteeism,” Norris says. “But it might give you a framework to think about planning for an event like this: where the challenges are, what losses you might face, what coverage you have or don’t have.”

Miller Insurance Services and William Gallagher Associates

(WGA), insurance brokers in Boston, jointly announced the availability of their Pandemic Disease Business Interruption Insurance, which responds to loss of income arising directly out of shutdowns of healthcare facilities as well as diminished revenues in the aftermath of a quarantine. Insurance for lost revenue arising out of a non-physical damage event such as a voluntary or involuntary quarantine of facilities and medical professionals is not available on most Business Interruption coverage forms, the brokers noted.

Marsh provides these points to consider when assessing insurance coverage and new policy options:

- Even within an organization that has a thorough understanding of pre-loss measures, it is possible that an accident, a breach in procedures, or other event could cause an employee to contract Ebola. The risk also exists for on-site contamination or for the government to require a facility to close.

- If a healthcare worker contracts Ebola during the course of employment, workers’ compensation

insurance likely would provide coverage for costs related to treatment of the illness, lost wages, and, in a worst-case scenario, death benefits. Such an event could be expensive: Full isolation protocols, for example, can cost \$1,000 per hour. Long-term complications from Ebola could require kidney dialysis and other treatments. In addition, local and state public health officials using Centers for Disease Control and Prevention (CDC) guidelines — rather than the employer and its insurer — likely will dictate dispensation of medication and other treatments.

- An insured employee might choose to file suit against an employer for negligence rather than collecting

statutory workers' compensation benefits, in which case employers' liability insurance could apply. But an employers' liability policy typically includes a limit per accident, disease per employee, and disease per policy limit. If an underlying primary employers' liability policy is properly scheduled to an umbrella and excess insurance policy, it should provide additional protection to insureds.

- Infection control procedures could cause providers to shut down or restrict access to all or part of their facilities in an actual or suspected case of Ebola, or due to potential contamination after treating a patient. The resulting disruption of normal operations could lead to reduced admissions and a loss of revenue.

- Property and business interruption (BI) policies are typically triggered only in the event of direct physical damage to or loss of an insured's property as a result of a covered peril. Most healthcare organizations' policies also contain communicable disease contamination sublimits that require an order of an authorized governmental agency prohibiting access as a result of a law or ordinance regulating the actual, not suspected, presence of a communicable disease. This wording means that without special provisions — for example, wording to broaden coverage — healthcare providers' property insurance and BI policies likely would not be triggered based solely on the presence of Ebola. ■

EHR failures can be dangerous without having a contingency plan

Electronic health records (EHRs) can be a boon to clinical care, until the system goes down or the power goes off. Then the clinicians might be flummoxed by how to do things “the old-fashioned way” with paper and pen, or they might not have the resources necessary.

For that reason, risk managers should ensure their hospitals have contingency plans for an EHR failure, says **Dean Sittig**, PhD, faculty member at the University of Texas Health Science Center at Houston, who specializes in clinical information systems and clinical decision support. He was the lead author of a recent paper that quantified how often EHRs go down and how hospitals are prepared to respond.

The numbers were not good. Sittig and his colleagues surveyed 50 U.S.-based healthcare institutions that were members of a professional

“IT WAS A LITTLE SHOCKING TO ME HOW MANY OF THESE ORGANIZATIONS HAD THESE LARGE DOWNTIMES.”

organization that focused on collaboration and sharing of best practices related to health information technology (HIT) among its members. All members were large integrated health systems.

Nearly all (96%) institutions reported at least one unplanned

downtime (of any length) in the last three years, and 70% had at least one unplanned downtime greater than eight hours in the last three years. Three institutions reported that one or more patients were injured as a result of either a planned or unplanned downtime.

“It was a little shocking to me how many of these organizations had these large downtimes. Most people would say that can't happen to us,” Sittig says. “If you asked them what they would do if the computer were down for eight hours, they would be hard pressed to imagine how they would carry on. The point of our paper is that you have a very good chance of being in that situation.”

The survey also revealed that most institutions had only partially implemented comprehensive contingency plans to maintain safe and effective healthcare during

unexpected EHRs downtimes. (*An abstract of the study is available online at <http://tinyurl.com/kfm8z43>.*)

Risk managers can take the lead in ensuring that contingency plans are in place, possibly acting as a liaison between clinicians and the hospital's IT department, Sittig suggests. Even highly skilled and motivated IT professionals might not fully understand the ramifications of even a brief EHR failure, he says. Risk managers, especially those with clinical backgrounds, will be able to explain, Sittig says.

IT professionals and clinicians can assume that a brief EHR failure will be easily handled with a temporary return to the pre-EHR work flow, he says. However, they often find that going back is not so easy.

"We were able to afford those nice EHR systems by eliminating the runners we used to employ for taking medication orders to the pharmacy, and we got rid of all the

fax machines," Sittig says. "Plus, there will be some employees who never worked under that system and don't have any idea how to manually accomplish these tasks. In our hospital, at least a third or maybe half of the nurses have never worked in an environment where they didn't have a computer system."

Sittig suggests these strategies for EHR downtime contingencies:

- Have a binder in each room with the forms necessary for ordering medications and recording treatment notes that normally would be handled in the EHR.

- Ensure that each unit has at least one computer plugged into the emergency generator supply (usually the red plug) so that it will continue functioning in a power outage. Hospitals often have elaborate plans to keep their servers and the network operational in a power outage, but units still are helpless if they don't have a computer on the dedicated

power supply.

- A "read-only" computer terminal in each unit can serve as a backup for all current patient data in the event of an EHR crash. When the EHR goes down, clinicians still can access this computer terminal for patients' medications, lab values, and treatment notes.

Sittig cautions that the risks from EHR downtimes are easily overlooked.

"In my experience the risk managers are not really worrying about the computer so much because they have to worry about falls, medication errors, and all kinds of things," Sittig says. "But it's getting to be so that the computer is driving a lot of what we do in healthcare, and if the computer isn't working, that can open all kinds of potential for patient harm. And one of the things that can happen is the computer doesn't work at all. No screen. No data. Nothing." ■

Centers for Medicare and Medicaid Services releasing hospital mistake data, after all

Your hospital's mistakes will be public again, as federal regulators reverse course to resume publicly releasing data on errors.

Officials with the Centers for Medicare and Medicaid Services (CMS) stopped publicly reporting life-threatening mistakes recently, after criticism from hospital leaders and associations that claimed the data were misleading. The data were removed from CMS' hospital comparison site. They still were available on a public spreadsheet that could be accessed by the public.

CMS will make the data on eight hospital-acquired conditions (HACs) available on its website,

<http://tinyurl.com/nhly2tf>. The eight conditions are:

- foreign object retained after surgery;
- air embolism;
- blood incompatibility;
- pressure ulcer stages III and IV;
- falls and trauma;
- vascular catheter-associated infection;

- catheter-associated urinary tract infection;
- manifestations of poor glycemic control.

Before the data were removed, the Hospital Compare website listed how often many hospital-acquired conditions occurred at thousands of acute-care hospitals in the United States. ■

COMING IN FUTURE MONTHS

- What is the actual role of a compliance officer?
- Liability risks from Google Glass?
- The emergency doctrine in malpractice cases
- Defending against a cyber attack

Study assesses cost of the overuse of medical tests and procedures

About 28% of the orders for three services at three hospitals were at least partially defensive by the physicians who ordered them, according to a recent study by Michael B. Rothberg, MD, MPH, a researcher with the Center for Value-Based Care Research at the Cleveland (OH) Clinic.

Rothberg and his research colleagues studied allegations about the overuse of medical tests and procedures being driven by a fear of malpractice lawsuits, which is commonly known as defensive medicine. The cost of defensive medicine has been estimated at \$46 billion annually in the United States, although those costs have been measured indirectly.

The authors estimated the cost of defensive medicine on three services –

tests, procedures, or hospitalizations – by asking physicians to estimate the defensiveness of their own orders. The authors invited 42 hospitalist

physicians to complete a survey. Thirty-six physicians did. The researchers then rated 4,215 orders

for 769 patients in the research letter.

Of the orders, 28% were rated as defensive. The mean cost was \$1,695 per patient, of which \$226 (13%) was defensive. Completely defensive orders represented about 2.9% of costs, mostly because of additional hospital days.

Rothberg and his colleagues concluded that although a large portion of hospital orders had some defensive component, “our study found that few orders were completely defensive and that physicians’ attitudes about defensive medicine did not correlate with cost. Our findings suggest that only a small portion of medical costs might be reduced by tort reform.”

Access to the full study is available online at <http://tinyurl.com/mvoh5ov>. ■

THE COST OF DEFENSIVE MEDICINE HAS BEEN ESTIMATED AT \$46 BILLION ANNUALLY IN THE UNITED STATES....

Revisions to safe harbors proposed by the HHS Office of Inspector General

The Department of Health and Human Services’ Office of Inspector General (OIG) has issued a proposed rule that would amend the safe harbors to the anti-kickback statute and the civil monetary penalty (CMP) rules to protect certain payment practices and business arrangements from criminal prosecution or civil sanctions.

Many of the revisions reflect statutory changes in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010. In addition, the rule would revise the definition

of “remuneration” added by the Balanced Budget Act of 1997 and ACA, and it would add a gainsharing CMP provision.

Included in the CMP changes are proposals OIG said are “intended to protect certain arrangements that offer beneficiaries incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care, including

better care coordination.” The rule states, “As hospitals move towards using objective quality metrics, we recognize that a change in practice does not necessarily constitute a limitation or reduction of services, but may in fact constitute an improvement in patient care or reduction in cost without reducing patient care or diminishing its quality.” ■

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. describe the legal, clinical, financial, and managerial issues pertinent to risk management;
2. explain the impact of risk management issues on patients, physicians, nurses, legal counsel, and management;
3. identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.



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CNE QUESTIONS

1. **What is one reason that Liberian patient Thomas Eric Duncan was not recognized as a potential case of Ebola when he first went to the ED at Texas Health Presbyterian Hospital?**
 - A. A nurse recorded a fever of 100.1 degrees F but did not inquire as to his travel history, as this was not triage protocol at the time.
 - B. Duncan did not have a fever and did not mention having been in Africa.
 - C. The hospital immediately performed an Ebola test that came back negative.
2. **Why does R. Stephen Trosty, JD, MHA, ARM, CPHRM, say it might be difficult for Duncan's family to sue the hospital for delayed diagnosis?**
 - A. There is no evidence that the clinicians could have diagnosed Ebola on the first visit.
 - B. It probably would be necessary to establish that his death was caused by the failure to admit him on his first visit to the hospital.
 - C. Judges and juries are likely to give hospitals the benefit of the doubt when treating Ebola patients.
3. **According to George B. Breen, JD, with Epstein Becker Green, how does EMTALA apply when treating potential Ebola patients?**
 - A. Because of the highly infectious nature, Ebola patients might not be transferred to another hospital.
 - B. EMTALA requirements for stabilization are waived because the staff might be unable to care for the patient without infecting themselves or others.
 - C. EMTALA requirements for stabilization before transfer still apply, even to Ebola patients.
4. **What is one requirement under the Bloodborne Pathogens standard (1910.1030), which provides guidance for employees at risk of coming into contact with blood or other potentially infectious materials?**
 - A. Hospitals must establish a written Exposure Control Plan designed to minimize employee exposure to the virus that meets the requirements of the standard, including identifying at-risk employees and job functions.
 - B. Hospitals must designate a specific room for the donning and removal of protective gear.



LEGAL REVIEW & COMMENTARY

EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Appellate court affirms verdict of \$20.6 million in birth injury case

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News: The patient, an adult woman, was admitted to a hospital in early September 2002, approximately two months before her due date. She was diagnosed with preeclampsia by an obstetrician, and the obstetrician decided to induce labor rather than perform a caesarean section. While the patient was in labor the following day, a fetal heart rate monitor revealed that the baby was low on oxygen; however, the obstetrician allowed labor to continue for an additional three hours. When the child finally was born, the umbilical cord was wrapped around his neck, which deprived him of oxygen and resulted in spastic diplegic cerebral palsy. The patient, individually and

on behalf of her son, brought suit against the obstetrician and hospital. She alleged that both were negligent in her treatment. The defendants denied that any malpractice had occurred. The jury found the obstetrician and hospital negligent and awarded the patient and her son \$20.6 million in damages.

Background: The patient was an adult woman who was 32 weeks pregnant in early September 2002. She suffered from preeclampsia, a dangerous pregnancy complication that is characterized by high blood pressure and signs of damage to other organ systems. Despite this finding, the obstetrician in charge of the patient's care decided to continue with a vaginal delivery rather than perform a caesarean section. The following day, the woman was given Pitocin (oxytocin) to induce labor, and the fetus was externally monitored. After this monitoring, a physician ruptured the woman's membrane to speed the labor and delivery process, and the monitoring was switched to internal monitoring. Eventually, the heart monitor indicated that the fetus was extremely low on oxygen, but the obstetrician did not opt for caesarean

section. The physician allowed labor to continue for an additional three hours. When the child finally was delivered, he was born with a nuchal cord: the umbilical cord was wrapped tightly around his neck. This situation caused the infant to be deprived of oxygen. He later was diagnosed with periventricular leukomalacia (PVL), which is the death of white matter in the brain due to softening of the brain tissue caused by lack of oxygen or blood flow to the area. He subsequently developed spastic diplegic cerebral palsy. Experts stated that the child is not mentally impaired, but he has difficulty moving his legs and arms and will always require a wheelchair along with numerous surgical and other medical treatments related to his conditions.

The patient, individually and on behalf of her child, brought suit against the obstetrician and hospital. She claimed that the obstetrician was negligent for failing to perform a caesarean section, which was necessitated by the low oxygen signs, and that the hospital was responsible for the obstetrician's behavior. The plaintiffs' experts, including an obstetrician/gynecologist specializing in high-risk pregnancies and deliveries

and a neonatologist, explained the series of events that led to the fetus' deprivation of reserves that normally protect fetuses during labor. The defense relied on an umbilical cord gas analysis that reportedly was within the normal range. They attempted to counter by arguing that the baby was not injured at birth based on this evidence and a blood gas analysis from blood taken shortly after birth. Furthermore, the defense argued that the PVL occurred as a result of his prematurity and magnesium that the mother received at the hospital to prevent seizures related to preeclampsia. The jury found the obstetrician and hospital jointly and severally liable and awarded a total of \$21 million in damages: \$18 million for future medical expenses, \$2 million for future lost wages, and \$1 million in non-economic damages. After the verdict, the judge reduced the \$1 million in non-economic damages to \$605,000 based on Maryland's medical malpractice damage cap. On appeal, the court found that the injury was foreseeable as a result of a healthcare provider's failure to respond to severe non-reassuring fetal heart tracing data and a nuchal cord and that the plaintiff's evidence was sufficient to sustain the jury verdict.

What this means to you: First, note that this case, like many medical malpractice cases before it and many that will follow, came down to a "classic battle of the experts," according to the Court of Special Appeals of Maryland. In many medical situations, there is no clear, definitive answer or one single correct approach. This situation can be particularly evident when there are tests that must be interpreted, such as the fetal monitoring in this case. Where there can be multiple

interpretations, plaintiffs and defense can have experts who appear in court and vigorously support their respective positions on why their side's interpretation was the correct one. Thus, a physician or hospital's defense might rest completely upon an expert's testimony in the eyes of the jury.

Having an expert who is more credible or believable (or even likeable) than the other side is essential. It is extremely important to select a strong expert or team of experts, and this selection should be done with competent counsel early in preparation for trial.

There are many factors to consider when selecting an expert, and choosing the most published or most famous expert is not always the best decision. An expert with a balanced resume, rather than one who only works as an expert, is an important consideration. Anyone in the field with a deep understanding of the subject matter and a strong ability to communicate can be a suitable candidate, and the more the jury can understand the expert, the better.

Secondly, a major issue in this case was related to causation: whether the obstetrician's failure to perform a caesarean section resulted in the injuries or they were caused by a different condition. Causation is a necessary element of any medical malpractice claim, and the plaintiff must prove that the defendant's wrongful acts factually and proximately caused the injury. Proximate cause is a tricky legal issue, and defendants can be protected if other events occur between their actions and the injuries to some extent. However, here the defendants attempted to argue against cause-in-fact. They claimed that the infant's injuries after birth were not caused by the delivery, but rather were caused

by his prematurity and magnesium that the mother received at the hospital to prevent seizures related to preeclampsia.

Causation can be an extremely valuable and effective defensive tool if it applies and if the jury can be convinced of its application. If a physician or hospital does not meet the standard of care and the patient gets injured, the physician or hospital still might avoid liability if the injury actually was caused by something else. Discovery and investigation are thus crucial to proving causation. If the defense can find a different source that actually caused the injury rather than the defendant's wrongdoing, then the defendant will not be held liable. This situation means that if a patient becomes injured, it is not necessarily medical malpractice, as there might be one or a number of other things that caused the injury rather than a physician's or hospital's actions.

This case additionally raises some important procedural notes. First, many states, including Maryland in this case, have maximum amounts awardable for medical malpractice cases. Most of these damage caps affect "non-economic damages," which are the part of the jury award that compensates plaintiffs for pain and suffering, anxiety, discomfort, loss of enjoyment of life, etc. These are types of damages that are not easily calculated in a specific dollar amount, unlike medical bills, which are economic damages. These caps are statutory in nature, and some allow for inflation by increasing the cap each year or a period of years. For physicians and hospitals, if liability is found but an exorbitant amount of non-economic damages are awarded, it is important to research these statutes. There might be a possibility for reducing the amount of damages

based on such, and this reduction can be significant as juries might award runaway damages for vague items such as “pain and suffering.” In this case, the reduction was almost \$400,000, which is not an insignificant amount.

Second, courts of appeal apply varying levels of review based on what specifically is being challenged in the case. If the appellant is challenging an issue of law, the appellate court can review such issues “de novo,” meaning anew, and the court addresses the

concern with no deference to the trial court’s decision. However, if the appellant is challenging a factual issue or the sufficiency of the evidence, appellate courts give the trial court a far higher level of deference. They will review for “substantial evidence,” which is actually a misnomer because the appellate court only looks to see if there is a reasonable basis for the jury for concluding how it did. It is thus far more difficult to challenge a jury finding based on the sufficiency of the evidence, and defendants who

lose at the trial level must consider this standard of review when deciding whether to appeal, as the appellate process (like the trial process) is highly involved, time-consuming, and expensive. Be sure to work closely with counsel to understand damages caps and standards of review as they might impact your litigation matters.

REFERENCE

Court of Special Appeals, MD. Case No. 1805. Sept. 25, 2014. ■

Botched cataract surgery yields \$1.5M verdict

News: The patient, an adult man, was scheduled for a standard cataract surgery in 2008 on his left eye. During the procedure, the ophthalmologist ordered a dye named VisionBlue that is used to stain the cataract in the eye so that it can be more easily visualized and removed during the surgery. However, although the ophthalmologist ordered the correct dye, the nurse who fulfilled the request instead brought methylene blue rather than the correct VisionBlue.

The nurse told the surgical technician that she was handing him methylene blue, and the surgical technician then relayed this same information to the ophthalmologist. The ophthalmologist claimed that he did not hear this and, believing the solution to be the correct VisionBlue, he applied it to the patient’s eye during the surgery, which caused serious permanent damage, including blindness in the eye. The patient brought suit against the ophthalmologist and hospital, and he claimed that their negligence brought about his injuries. The defendants denied any wrongdoing. The jury found the ophthalmologist and the hospital liable and awarded the

patient \$1.5 million in damages.

Background: The patient was an adult man who suffered from a cataract on his left eye and scheduled surgery to fix the problem in 2008. During the procedure, which is routine and uncomplicated, the ophthalmologist ordered a dye named VisionBlue that is used to stain the cataract in the eye so that it can be more easily visualized and removed during the procedure. The nurse who received the order from the ophthalmologist, however, fulfilled the request as methylene blue rather than VisionBlue.

Methylene blue, a completely different chemical compound, is extremely toxic to human eyes and can cause severe damage. The nurse who filled the order then passed the methylene blue to the surgical technician and announced that it was methylene blue. After this step, the surgical technician handed the methylene blue to the ophthalmologist, again stating that the solution was methylene blue. Neither the nurse nor surgical technician stated that the solution was VisionBlue. The ophthalmologist claimed that he did not hear the

nurse or the surgical technician state the solution was methylene blue, and thus he believed it to be the correct VisionBlue dye.

After applying the methylene blue to the patient’s eye, the ophthalmologist became aware that it was the incorrect solution, and the patient’s eye became severely damaged. Corrective surgery was attempted at the same hospital, but the damage from the methylene blue was too serious. A full corneal transplant also was attempted, but the patient’s body rejected it. As a result, the patient became blind in his left eye and suffers from glaucoma due to the multiple corrective surgeries.

The patient subsequently brought suit against the ophthalmologist and hospital, and he alleged that both were negligent during the procedure that resulted in the patient’s injuries. According to the plaintiff, the ophthalmologist’s use of the incorrect solution constituted negligence because the ophthalmologist had a duty to the patient, and by administering the incorrect drug to the patient, he breached that duty. Similarly, the hospital was liable on the basis of respondeat superior, which is a legal theory where an

employer is legally responsible for the actions of its employees. It was unclear whether the ophthalmologist was considered an employee, but the nurse and surgical technician were employees for which the hospital was responsible. Ultimately, the jury found the defendant ophthalmologist and defendant hospital jointly and severally liable, and it awarded \$1.5 million in damages.

What this means to you: In this case, the primary issue was to what degree, if any, the ophthalmologist was negligent for administering the incorrect drug to the patient, and whether the hospital was liable for the ophthalmologist, nurse, and/or technician, who all played a role in the incident.

As the primary physician in charge of the procedure, the ophthalmologist owed the patient a duty to perform in accordance with the appropriate standard of care. There are many different ways medication errors can occur, as there are many steps between the initial prescription or order and the administration of the drug. A physician who prescribes the wrong medication to a patient can be liable for medical malpractice, but there are many other situations that might give rise to a medical malpractice claim as related to a medication error.

For example, look-alike, sound-alike (LASA) medication errors are common. The hospital pharmacy has the responsibility to put caution labels on LASA drugs such as methylene blue and VisionBlue. In addition, the pharmacy stocks medications in the operating suites and should take steps to separate LASA medications from each other to prevent staff from inadvertently choosing the wrong one. All regulatory and accreditation organizations require hospital staff

and physicians to read medication labels before administration of any drug, even in the operating room. If medication is removed from the original container and not used immediately, a new label must be made and placed on the syringe or other delivery device. Physicians and hospitals must exercise caution throughout the entire process to ensure that there are no mistakes. In this case, the ophthalmologist ordered the correct drug to be used, so the error originated after this initial involvement. Because the physician holds ultimate responsibility for the patient's medical care, the physician should be cautious when other individuals act as intermediaries or are required to perform duties delegated by the physician.

It is important to note that this situation could have been prevented by having additional measures relating to communication. Oral communications can inherently be unreliable. If the communication is one-way, it is impossible to know whether the other party actually has heard the message. This situation is exactly what happened here more than once. The nurse and surgical technician claimed to have announced that the solution was methylene blue, but the ophthalmologist never heard those words.

The situation potentially could have been prevented if the hospital had a policy requiring confirmation in this context. (*Editor's note: Confirmation bias leads people to see or hear what they expect to see or hear, regardless of the actual information. For more information on confirmation bias and solutions to this problem, see package of stories in Healthcare Risk Management, November 2014.*)

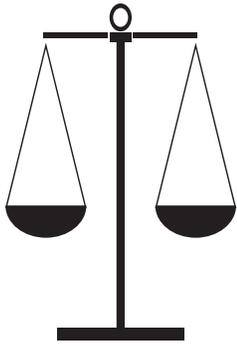
Note also that the surgical technician should not have been

involved in the confirmation process, as the technician is not trained to administer medication. Certainly the technician can pass medication from the hand of the nurse into the hand of the physician, but that involvement is the only one that the technician should have. Communications involving medications must be between physicians and staff trained in medication administration unless the physician is directly supervising the untrained individual and not involved in another activity such as performing surgery.

To prevent oral communication errors in emergency departments, operating rooms, and even over the phone, "read-backs" or "repeat-backs" are used in most hospitals. When a physician orders a medication verbally, the receiver repeats the name of the drug and the dose to the physician and the physician confirms it. Had this practice been carried out, the physician would have said, "VisionBlue" and the nurse would have said "methylene blue," which would have given the physician the opportunity to correct the error. Requiring this important oral communication process is a simple solution that provides extra defense for physicians and hospitals, and in this case, could have prevented injury and litigation. Written communications are inherently even clearer than oral communications; however, the realities of an operating room don't allow for everything to be done in writing, so it is not the case that oral communication is forbidden.

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Superior Court of Durham County, NC.
Case No. 11-CVS-1525. Aug. 19,
2014. ■



HEALTHCARE

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