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INSIDE

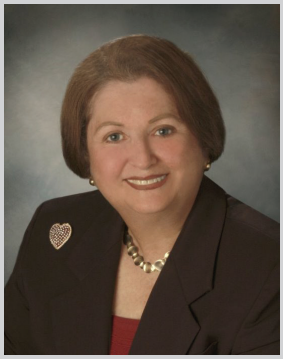
AHC Media

Adverse events can happen when staff try to maintain equipment

By Joy Daughtery Dickinson, *Executive Editor*

The incident at Silverton Health in Silverton, OR, started with good intentions. Halogen lights in the operating room (OR) had been cleaned with the wrong solution, and the light covers had been damaged and were affecting the light quality.

In the past, OR staff members had changed light bulbs in the surgical lights instead of calling engineers to do it because the employees thought they could do it in a timely manner without closing the OR. "They thought, we've changed light bulbs in past. We can change the plastic covers also," says **Ray Wille**y director of quality and risk services at Silverton Health.



WAS THERE OMISSION OR COMMISSION? "THAT'S WHERE A GOOD, OBJECTIVE INVESTIGATION COMES INTO PLAY." — LEILANI KICKLIGHTER, THE KICKLIGHTER GROUP

Some staff members probably didn't consider lights to be medical equipment that needed to be serviced by bioengineers, Willey says. "They're used to IV pumps and monitors [being considered medical equipment], but that thinking didn't carry through to surgical lights," he says.

A vendor previously had been contacted to replace the diffusers on the light covers. Staff members saw what was done and thought they could handle it forward. However, they didn't realize that the light covers had two pieces: a diffuser and a filter.

In September 2013, staff members at Silverton Health removed and replaced

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the diffusers, but not the filters. In June 2014, skin abnormalities began to be found on patients. Some patients had mild burns, but others had severe burns and will have permanent redness on the skin that was exposed to the lights.[1] Surgeons were updated.

Some of the patient burns were discovered in the recovery room, and others were found during follow-up visits with surgeons. Eventually six patients, but no staff members, were found to have burns. The surgical services staff looked at common causes of those types of injuries: cleaning solutions used on patients, adhesives on the drapes, and cauterizing devices. By November 2014, when those potential causes had been ruled out, a staff member recalled that the diffusers had been changed, and that action was brought forward as a potential root cause. Once it was determined that surgical lights were the cause of burns, the hospital notified surgeons and shut down the three ORs that had the halogen lighting systems. About 2,100 surgery patients underwent procedures in the ORs during the 14 months before the cause was determined and might have been at risk, Willey said. Since that time, the hospital has replaced the halogen lights with lamps that use LEDs (light-emitting diodes).

Leilani Kicklighter, RN, MBA, ARM, CHSP, CPHRM, LHRM, patient safety and risk management consultant with The Kicklighter Group in Tamarac, FL, says, "This situation happened in a hospital, not an ambulatory surgery center [ASC], but is a potential wake-up call for not only ASCs but also for office-based surgery centers. The issue is the same in any setting, other than the hospital setting is more likely to have an in-house biomedical department with trained biomedical engineers."

Jane J. McCaffrey, MHSA, CIC, DASHRM, independent consultant in healthcare risk and compliance in Easley, SC, agrees that this issue should get the attention of outpatient surgery managers. "There is liability here in that there was a failure to service the lights in a way they were intended," McCaffrey says.

Several years ago, another surgery program used a heat lamp that had a bulb burnout. "Staff did what they thought was easy and replaced the bulb with one they found on the unit," McCaffrey says. It "resulted in the wrong strength and severe burns to a patient."

Sharing these stories is important "because it is far too easy to become a DIY [do-it-yourself] person to expedite the flow of activity in a

EXECUTIVE SUMMARY

Silverton (OR) Health reports that six patients were burned when staff members changed diffusers on operating room lights but didn't know to change filters.

- Always contact bio-engineers for any equipment maintenance.
- Manufacturer's guidelines should be followed to maintain, clean, and repair technical, electronic, or electrical equipment and apparatus.
- When adverse events happen, involve your legal consultants and liability insurance carrier to advise you about early disclosure.

clinical situation," she says.

Lessons learned

Consider these lessons shared by Silverton Health and patient safety experts:

• Use experts to work with your medical equipment.

Involve your biomedical engineering department or contractors in any maintenance on any medical equipment, Willey says. Also, ensure your policies and procedures reflect that involvement, he says. "We had some in place that we thought addressed it, but we did modify and add clarifying language to be clear about engineering roles," Willey says. They also ensured that proper cleaning solutions are being used.

If you are a surgery center or office-based practice, have a contract/agreement with an individual or company that has knowledge of OR lights and their preventive maintenance, by company and model, and knows how to properly change the bulbs, Kicklighter says. "The cardinal rule in dealing with technical, electronic, or electrical equipment and apparatus is that manufacturer's guidelines should be followed to maintain, clean, and repair," she says.

The vendor for medical lights should provide guidance with regard to all maintenance to be performed, McCaffrey says. Care should be taken that this guidance comes from a qualified representative, not just a sales representative, she says.

• Examine your processes for equipment and preventive maintenance.

When lights need servicing, determine if the manufacturer provides a service manual that emphasizes use of filters, and ensure it is available and consulted, McCaffrey says. A copy of all manufacturer service manuals should be kept and maintained as up-to-date with any revisions or service alerts as long as you own or use the equipment, suggests **Mark Mayo**, CASC, executive director of Golf Surgical Center, Des Plaines, IL.

One gap in the process that Silverton identified concerns the preventive maintenance schedule for new equipment, rental equipment, borrowed equipment that is returned, and equipment returned from service. "Our process wasn't as tight as it should have been to make sure it was evaluated and to make sure the equipment was put in our preventive maintenance software system," Willey says. Now, any time equipment enters or re-enters the facility, it is evaluated in terms of what preventive maintenance needs to be performed going forward, he says.

Continually scrutinize your preventive maintenance processes, Willey advises. "Sometimes your employees think, we're working as best as we can," but it requires ongoing surveillance to make sure that they do, he says.

Don't necessarily focus on individuals, says **Bethany Walmsley**, executive director of the Oregon Patient Safety Commission in Portland. Silverton Health submitted a confidential report on the incidents to the Commission. "It's more important that the process used to maintain equipment is as reliable as possible," Walmsley says. "I want to emphasize the importance of having a systems-level view and a process view, rather than focus right away by saying, 'if we had someone with a much fancier title with a better background, this wouldn't have happened.'"

• Obtain help when you have adverse outcomes.

When patients are injured, it's a good idea to engage a healthcare attorney, Kicklighter advises. Also, call in biomedical engineering experts immediately, she says. Many universities have biomedical engineering programs that can be contacted for their expertise, she says. You also can hire certified, trained biomedical technicians from ECRI Institute in Plymouth Meeting, PA. (Web: https://www.ecri.org.)

Also report the incident to the manufacturer, Kicklighter advises. "Do not send the lights back to the manufacturer for evaluation," she says. "Remember the theory of 'chain of evidence.' Get risk management and legal advice before doing so."

In determining the cause, the industry standard is to perform a root cause analysis, Walmsley says. However, the process doesn't have to daunting, she adds. "There are ways to do a root cause analysis that are not overly burdensome in terms of time or bandwidth on your staff," Walmsley says. For example, you can use the five "whys" tool, which takes only five to 10 minutes. (*To access the tool, go to http://bit.ly/1DBRnS2.)*

Also, a Failure Mode and Effect Analysis (FMEA) can be helpful, Kicklighter says. *(For more information on FMEA, go to http://www.patientsafety.va.gov/professionals/onthejob/HFMEA.asp.)* Address these questions, she suggests: Were manufacturer's recommendations followed? Were staff trained and certified to perform the tasks? "Only the answers can tell how to prevent or what should have been done that wasn't done," Kicklighter says. Was there omission or commission?

"That's where a good, objective investigation comes into play," she says.

• Be transparent about your mistakes.

Willey says the hospital leaders discussed the incident with their legal resources and their liability insurance carrier to guide early disclosure. They notified all patients who were at risk for burns. They contacted the local newspaper to notify them of the incident. "We wanted to be completely transparent regarding the situation," Willey says.

They set up a dedicated phone line for other patients who might be concerned about burns.

Hospital representatives have met individually with patients who have suffered injuries related to this incident to go into more detail and to put them in contact with the insurance carrier for any assistance they might need with medical expenses.

No lawsuits have been filed, Willey says.

"There's a growing body of research in healthcare that early disclosure in adverse events does reduce litigation, as well as dollar value of claims, but that's not the reason we did it," he says. "We did it really because we felt responsibility to our service area."

The Oregon Patient Safety Commission has praised Silverton Health for its openness about the incident.

"We're glad to see any organization that is so open about what happened, what they learned, and how it could be applied in another ASC or hospital, so people can pay attention, so people can share the learning," Walmsley says.

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Trail of tears: Fired drug-diverting workers free to find another healthcare facility

By Gary Evans, *Executive Editor, AHC Media*

A nurse stealing morphine by replacing it with saline in a medication vial might not have realized she was colonized with *Serratia marcescens*, a gram negative bacteria that would soon find its way into the bloodstreams of a cluster of patients administered the contaminated solution. The insult of denied pain treatment was followed by the injury of infection, which proved fatal in one patient. That scenario is under investigation at a Wisconsin hospital, the latest in a series of outbreaks linked to drug-diverting healthcare workers. *(See second story that follows.)*

More often these cases involve hepatitis C virus, and it is particularly shocking to see how many patients can be endangered by a single healthcare worker. Over the past decade, outbreak investigations have documented more than 100 infections and nearly 30,000 potentially exposed patients stemming from drug diversion in U.S. healthcare facilities, a Centers for Disease Control and Prevention (CDC) study reveals.[1]

As disturbing as those numbers are, it should be noted at the outset that while protecting patients is paramount, nurses also emphasize the ethical obligation to try to get their addicted colleagues into treatment: "Drug diversion is a symptom of the disease of addiction … a treatable disease."[2] Encouraging healthcare workers with an addiction problem to seek treatment might be one of the best ways to save a caregiver's career before the disaster of an outbreak — the event that typically reveals the diverter.

"[Infection preventionists] would probably be the ones that would see an unusual cluster of infections and start investigating," says **Melissa Schaefer**, MD, co-author of the study and a medical officer in the CDC's Division of Healthcare Quality Promotion. "But ideally we don't want it to get to a cluster of infections or an outbreak. That brings up the need for a really strong detection surveillance system in place, a response mechanism so that when there's an abnormality, you can jump on it."

The reported outbreaks of infections related to drug diversion by healthcare workers represent only a small snapshot of what is occurring, as many healthcare-associated infections (HAIs) are not being tracked back to drug diversion activity that is apparently rampant in the healthcare system. **Joseph Perz**, PhD, co-author of the study and team leader of quality and safety in the CDC's Division of Healthcare

Quality Promotion, says, "Making the connection between unexplained or difficult-to-detect infections on the one hand, and illicit, concealed drug diversion activities on the other hand, is extremely difficult. Our review also does not in any way adequately reflect the frequency of diversion by healthcare personnel in the United States. It has been reported that more than 100,000 U.S. doctors, nurses, technicians, and other health professionals struggle with abuse or addiction. Prescription drugs and controlled substances such as oxycodone and fentanyl are often involved."

If you look hard enough for diverters, you are highly likely to find them, says drug diversion expert **Kim New**, RN, JD, an independent consultant who previously founded a program to detect diverters at the University of Tennessee Medical Center [UTMC] in Knoxville.

"Initially when I started the program [at UTMC], I was catching three or four per month, and then it leveled out to one to two per month and pretty much stayed there," she says. "I have no reason to believe that what I experienced in that medical center is any different than what [is happening] at similar institutions. In fact, I work extensively with hospitals and health institutions across the country on this topic, and I have heard from more than one academic medical center of approximately the same size that they were catching the same [number of diverters] when they had an aggressive program." *(See story on injection safety, below.)*

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Nationwide focus is growing on issues surrounding injection safety

There is an increasing focus on safe use of needles and vials, which was the subject of a *Sentinel Event Alert* from The Joint Commission last year, says **Vicki Allen**, MSN, RN, CIC, infection prevention coordinator at Beaufort (SC) Memorial Hospital.[1] *(For more information, see "TJC alert addresses unsafe injection practices,"* Same-Day Surgery, *August 2014, p. 87.)*

"The Joint Commission [Alert] was actually on the misuse of vials, but in talking about it, obviously diversion is one of the misuses of the vial," Allen says.

As a result, many healthcare facilities are emphasizing the proper use of single-dose vials and trying to limit access to multi-dose vials that could be contaminated. "The recommendation is to have single-dose vials whenever possible, and that's going to decrease the risk that you have multi-dose vials sitting around that can be accessible to those looking [to divert]," Allen says.

In addition, the common practice at her facility is for the pharmacy to provide the smallest dose possible for a given patient in the drug dispensing container, she adds.

"So if the patient is ordered morphine, the pharmacist is going to supply the lowest dose vials that they can, keeping the volume as low as possible," Allen says. "Decreasing the volume of the drug availability is one way we can control it. Then another part of that is an audit. Make sure you are doing audits on your units to look for open vials and any kind of red flag that would clue you in to some kind of diversion activity or patient exposure."

With patient safety advocates pushing for more involvement of patients and families in their medical care, there also are opportunities to assess pain levels that could raise the possibility of diversion, she adds. "Taking pain medication away from patients is essentially harming them," Allen notes. "By involving the patient and their families during rounding, this sort of thing can be addressed [by asking], 'Is your pain being controlled?' You may trigger something, and that's happening more and more."

While it does appear that incidents of drug diversion are increasing overall based on media reports and journal articles, that also might be a surveillance artifact of looking harder for signs of diversion activity, Allen adds. "It may be just that we are more aware," she says. "It's on the radar, so we are looking for it more. Patient safety is such a huge factor now. People are doing audits, more surveillance, mandatory reporting." Also, there is more oversight by the Centers for Medicare and Medicaid Services (CMS), Allen says.

In that regard, a recently finalized hospital infection control survey for CMS inspectors does not cite drug diversion specifically, but focuses a lot of attention on the proper use of needles, syringes, and single-dose and multi-dose vials. Surveyors are instructed to observe injection safety practices in two units of the hospital if possible.

The CMS conditions of participation to protect patients from harm are certainly applicable to drug diversion, which also is addressed in accreditation standards and is a felony in every state, says **Kim New**, RN, JD, an independent consultant who previously founded a program to detect diverters at the University of Tennessee Medical Center [UTMC] in Knoxville.

"The standards are out there. There is a regulatory aspect for hospitals to meet, but most of the time, unfortunately, the standards are not specific enough [to require] the hospital to have the 'ultimate' program and security measures," she says.

Regardless, healthcare facilities should have every incentive to establish strong diversion prevention programs because patients infected or exposed by drug diverters might be entitled to considerable compensation. Citing the huge sums some juries have awarded to patients infected through injection safety lapses and oversights, a drug diversion expert says similar results might be coming for diversion outbreaks.

"[C]onsider that every healthcare facility that handles divertible drugs is at risk for an unscrupulous healthcare worker not only diverting drugs, but doing so in a manner that could harm patients and others," **Keith Berge**, MD, an anesthesiologist at the Mayo Clinic in Rochester said in an editorial accompanying a CDC study.[2] *(For more information on that study, see previous story.)* "Then the question becomes not 'How can we afford a program to prevent and detect drug diversion by health care workers?' but instead 'How can we afford to not have such a program?'"

The risk of diversion could remain relatively constant in healthcare given the toxic combination of addiction, medication, and access. "Unfortunately, the plague of drug diversions cannot be fully exterminated because highly intelligent, desperate, and motivated addicts (e.g., addicted nurses and physicians training in or working in drug-rich environments) will continue to seek ways to obtain the highly desirable and abusable drugs housed within health care settings," Berge warned.

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Serratia outbreak linked to drug diversion

A former nurse at the University of Wisconsin (UW) Hospital and Clinics in Madison, who allegedly diverted pain medication for personal use, might be linked to a cluster of infections among patients in the units where she worked, UW officials say.

In May 2014, staff noticed a larger than average number of patients infected with the bacterium *Serratia marcescens*, the hospital said in a statement. "Further investigation showed that in five patients, the infectious agent was genetically identical. One of those patients died."

S. marcescens is a well-established source of healthcare infections and outbreaks. In the UW investigation, staff identified that four of the five patients with the genetically identical infection had received pain medication from units where ex-nurse Stefanie A. Jones worked. "Later, a connection between Ms. Jones and [a] fifth patient was identified, leading the hospital to contact the police, district attorney, licensing board and other regulatory agencies with their findings," UW Hospital said in the statement. "All patients or their families have been notified."

The hospital declined an interview request from AHC Media, publisher of *Same-Day Surgery*, but documents cited by a Wisconsin newspaper indicate that police took biological samples from the 31-year-old nurse looking for *S. marcescens*. Jones is accused of diverting morphine and hydromorphone from syringes intended for patients at the hospital more than 40 times between October and March 2014, the newspaper reported.[1] The drugs were replaced with water or saline. In a bizarre twist, one of the patients infected with *Serratia*, the "connection" cited by UW, is Jones' father.

According to police, Nasia Safdar, MD, medical director of infection control at UW Hospital, told police investigators that Jones was likely to have been the host of the *Serratia* and gave it to her father while caring

for him. Safdar said it was possible the nurse contaminated the syringes with *Serratia* while refilling them and placing them back into drug-dispensing machines.

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SDS Manager

Freestanding EDs and urgent care centers as new sources of surgical referrals

By **Stephen W. Earnhart**, *MS*
CEO
Earnhart & Associates
Austin, TX

One question I'm frequently asked is how to increase referrals to surgeons in the hospital or freestanding ambulatory surgery center (ASC) arenas.

Hospitals are easier due to their greater resources and patient capturing services and programs, including their primary care physician base. Freestanding ASCs, not so much. But you do have other resources available to you if you have the space and the money. Always the money!

A great source of referrals for hospitals is the emergency department (ED). Several states allow physicians to have their own EDs, just like hospitals. They typically are very profitable in their own right, but they also refer many potential surgical patients! In highest to lowest referrals, based upon our records, are orthopedic, ENT, GI, and general surgery. If your facility has a relationship with these facilities, you could be the recipient of a steady stream of patients after they have passed the acute phase of their ED treatment. ASCs cannot provide services for emergency cases. Care needs to be taken to make sure that the ED docs are not investors in the ASC, as their referrals to your facility can cause problems. However, these are very compartmentalized facilities with no overlap.

One nice feature of these EDs is that they can't continue to care for the patient after the emergency encounter, so they are very willing to pass the patient on to someone for follow-up care and surgical intervention if necessary.

How do you compete with the hospital's primary care network? Visit with all the local urgent care centers (UCC) in a radius around your ASC. Unlike EDs, these facilities can and do very much want to provide follow-up services to patients using their facility. Some UCCs don't hold on to a patient if another primary care doc recommends the UCC cover their patients after hours. But there are plenty of unfettered patients out there using UCCs who don't have a relationship with another doc, so they are up for grabs.

Developing a relationship with either of these providers is good business for everyone. Patients have a trusted referral to see someone after their episodic encounter. The ED has someone who can provide quality follow-up services. And the urgent care facilities only want to make sure the patients are taken care of after they leave, and they hope the patients will continue to come back for more non-emergency encounters.

Be alert to new EDs and UCCs opening in your area, but you also can approach a facility that has been open a long time. Like many relationships, they can erode over time, and they might be dissatisfied with their current arrangement.

Many of these freestanding EDs and UCCs have a corporate player behind them. If you don't have success with the individual approach, seek out the corporate owners and speak with them. Chances are they can see the bigger picture and can envision the benefit of such a relationship better than the local manager can.

But wait. There's more!

Can't find one to work with? They are all booked up?

Build your own! Neither is all that expensive, relatively, and if you have space available beside your ASC or in the immediate area, it can be a good investment for your surgeons. Discuss with your legal advisor the best way to structure such a venture, but they are very doable. In addition to being a good investment in themselves, they can benefit your ASC significantly. *[Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Earnhart & Associates is located in Austin, TX. Phone: (512) 297-7575. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.]* ■

Smaller outpatient facilities struggle to achieve regulatory compliance with HIPAA

An outpatient surgery facility gives a research organization a patient's protected health information (PHI) for recruitment, but it didn't have the patient's authorization or a signed waiver of authorization approved by the Institutional Review Board or privacy board.

In another case, an organization placed a patient's PHI, including demographic, financial, and clinical information, in a dumpster outside of a physician's office, according to a report on compliance with the Health Insurance Portability and Accountability Act (HIPAA) recently released by Stericycle in Northbrook, IL, a consulting firm that addresses employee and customer safety, regulatory compliance, and environmental impact.[1]

Stericycle reports that many privately owned and smaller providers struggle with HIPAA compliance.

"It's certainly a balancing act between having to do what all the requirements expect of a covered entity for HIPAA, and the balancing act of running a business and keeping things operating," says **Susan Stolz**, HIPAA compliance solution manager with Stericycle. Stolz points out that the regulations are complex. "The biggest challenge we see, oftentimes, is that there aren't appropriate resources, or the people responsible for compliance activities aren't necessarily subject matter experts."

These barriers have been witnessed firsthand by those working with smaller outpatient surgery providers. **Debbie Mack**, MSN, CASC, CNOR, is an independent healthcare consultant based in Nevada City, CA, who has visited three centers in the past six months. During her conversations with the managers, she just happened to bring up HIPAA. She found out those centers had only one or two HIPAA policies that offered basically "no security." "There was no risk assessment," Mack says. "They had nothing." Mack also is past president of the California Ambulatory Surgery Association.

Privacy/security is just one small piece of a manager's job at a smaller facility, says **Jan Kleinhesselink**, RN, BSHM, CPHQ, chief quality officer at Lincoln (NE) Surgical Hospital. "Time-consuming, laborious activities such as ensuring that compliance policies and procedures are updated, implemented, enforced, and audited can be very challenging," Kleinhesselink says. Leaders might be involved in the day-to-day activities, she says. "They may spend much of their day dealing with 'now' issues and putting out 'fires,'" Kleinhesselink says. "In this type of facility, there is an even greater chance that regulatory issues may fall through the cracks." In comparison, hospitals have entire compliance teams, Mack says.

Another issue is that managers at freestanding facilities might have difficulty finding time to attend national meetings where regulation changes are discussed, she says. The most important recent change was the security rule in 2013, Mack says.

Coupled with these demands is the thought prevalent among managers of smaller facilities that they won't have a breach, Stolz says. "That prevailing attitude can be a dangerous thing for the business," says Stolz, who points to severe financial repercussions as well as the publicity involved.

Resolving issues with HIPAA compliance boils down to policy development, IT security assessment, and employee training, Mack says. "And those all cost money, and then you have to have someone managing those," she says.

Consider these suggestions.

• Have a risk assessment conducted.

Kleinhesselink says, "Complete a risk assessment to identify potential failures, develop a mitigation plan, and assign staff specific responsibilities for essential components."

The risk assessment can help you see where you are and what deficiencies you have, Mack adds.

• Conduct audits and reviews.

Kleinhesselink says, "Put proactive

EXECUTIVE SUMMARY

Smaller facilities often find it difficult to maintain compliance with the Health Insurance Portability and Accountability Act.

- Have a risk assessment conducted, develop a mitigation plan, and assign specific responsibilities to staff members.
- Put proactive audits and reviews in place.
- Train all staff on accessing and communicating protected health information in all formats.

audits and reviews in place to reduce the ongoing day-to-day drain of reactive processes."

• Train staff.

Your staff must attend training on the HIPAA Security rule and patient rights, Mack says. Kleinhesselink says, "Keep in mind that privacy and security go together and that it will be essential to communicate with and train all staff regarding accessing and communicating PHI in all forms: electronic, paper, verbal, etc. It sounds like a lot of work, but putting sound processes and reviews in place will help reduce the stress of that person or persons wearing multiple hats."

You must maintain and sustain these activities, Stolz points out. "It's never a 'once and done," she says. "It's not a checklist to tick off, that 'we're completed and in compliance.'"

If you're audited, you'll have to produce six years of running documentation, Stolz says. HIPAA compliance requires continual and constant monitoring, training, risk assessment, and policy review, she says. "Anytime something changes in the organization, policies need to be updated," she says.

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FDA says to inform patients about risk of endoscopy linked to CRE infections

(The material in this story was contributed by Gary Evans, Executive Editor, AHC Media.)

ERCP (endoscopic retrograde cholangiopancreatography), an upper endoscopy procedure performed on some half a million U.S. patients annually, poses a risk of transmission of practically untreatable carbapenem-resistant Enterobacteriaceae (CRE).

After a series of outbreaks over the last few years, the Food and Drug Administration (FDA) issued a Feb. 19 alert that said patients should be advised of the benefits and risks associated with ERCP procedures, which typically involve the use of intricately designed duodenoscopes on the pancreas and biliary tract. Patients should report back to their providers after an ERCP procedure if they have symptoms such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools, the FDA advised. *(To access the alert, go to http://1.usa.gov/1JrNgeR.)*

The FDA is closely monitoring the association between reprocessed duodenoscopes and the transmission of infectious agents, including CRE and resistant strains of *Klebsiella* species and *Escherichia coli*. In total, from January 2013 through December 2014, the FDA received 75 medical device reports totaling some 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes.

The UCLA Health System in Los Angeles recently announced it has notified more than 100 patients that they might have been exposed to CRE during complex endoscopic procedures that took place between October 2014 and January 2015. The patients were being offered free home testing kits that will be analyzed at UCLA.

The endoscopes used at Ronald Reagan Medical Center were sterilized according to the standards stipulated by the manufacturer, but an internal investigation determined that CRE "may have been transmitted during a procedure that uses this specialized scope to diagnose and treat [pancreas and biliary tract] diseases and may have been a contributing factor in the death of two patients," UCLA stated. "A total of seven patients were infected. The two scopes involved with the infection were immediately removed and UCLA is now utilizing a decontamination process that goes above and beyond manufacturer and national standards."

A similar outbreak occurred in 2013 at Advocate Lutheran General Hospital in Park Ridge, IL, which halted transmission by going beyond standard practices to gas sterilize scopes used for ERCP with ethylene oxide.[1] A recurrent theme is that no breaks in cleaning and reprocessing protocols are identified, yet CRE might persist in the intricately designed duodenoscopes used in the procedures. The infection rate for ERCP is typically 1% or less, but the emergence of CRE threatens to change that number. Previous studies have shown an association between ERCP endoscopes and transmission of multidrug-resistant bacteria, as the complex design of the endoscopes might make them difficult to clean.[2,3]

Virginia Mason Medical Health System in Seattle recently reported that it had "discovered and addressed

a potential connection between endoscopes used in ERCP procedures and patients infected with a drug resistant bacteria in 2012 and 2013." Published reports said at least 32 patients were exposed or infected, including 11 who died.[4] However, the patient deaths were not definitively linked to the infections, at least some of which were caused by CRE.

Virginia Mason has now gone to a stringent system of withholding scopes from procedures until they test negative for bacterial pathogens. Virginia Mason posted information on its website that an internal review "determined the manufacturer's recommended guidelines for processing the scopes were less than optimal so we developed and implemented a much more rigorous cleaning process."

The FDA essentially recommended continued adherence to general endoscope reprocessing and consensus guidelines such as the *Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011*. Though some of the affected hospitals have clearly gone beyond the manufacturer's guidelines to stop transmission, the FDA said "it is important to follow specific reprocessing instructions in the manufacturer's labeling for each device. Even though duodenoscopes are inherently difficult to reprocess, strict adherence to the manufacturer's reprocessing instructions will minimize the risk of infection. Deviations from the manufacturer's instructions for reprocessing may contribute to contamination. The benefit of using cleaning accessories not specified in the manufacturer's instructions, such as channel flushing aids, brushes, and cleaning agents, is not known."

According to the FDA, additional general best practices include:

• Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor. Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides.

• Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.

• Consider taking a duodenoscope out of service until it has been verified to be free of pathogens if a patient develops an infection with a multidrug-resistant organism following ERCP and you suspect that there might be a link between the duodenoscope and the infection.

• Submit a report to the manufacturer and to the FDA if you suspect that problems with reprocessing a duodenoscope have led to patient infections.

The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) issued a statement that says in part: "Because duodenoscopes are more complex than other endoscope instruments, it requires meticulous attention to detail and step-by-step precision to render them safe for re-use."

The statement also emphasizes the role of infection preventionists (IPs) and healthcare epidemiologists (HEs) in hospital endoscopy departments. "After observing the cleaning and disinfecting processes and asking questions so that each step of the process is understood, the IP or HE may visit the department regularly to observe scope cleaning practices and reinforce the importance of the work being done," the statement says. "The IP or HE will evaluate human factors, including ensuring that the cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized."

The statement also points to factors that could negatively impact cleaning, including "distractions, interruptions in the process, or demands for rapid scope turn-around." The statement says staff might be pressured to turn around scopes quickly. It says, "IPs and HEs must lend their support to conscientious endoscopy staff who understand the importance of taking the time needed to do a thorough job. IPs and HEs must help promote a culture in which healthcare workers are empowered to speak up if they believe there is an issue that could impact patient safety."

REFERENCES

1. Centers for Disease Control and Prevention. Notes from the field:

COMING IN FUTURE MONTHS

- Quick way to figure out if your patient will have complications
- Should you substitute drugs during shortages?
- Bedside registration for outpatient surgery department
- Impact of sedatives before surgery

New Delhi metallo-ß-lactamase-Producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography — Illinois, 2013. *MMWR* 2014; 62(51):1051.
2. Muscarella LF. Investigation and prevention of infectious outbreaks during endoscopic retrograde cholangiopancreatography. *Endoscopy* 2010; 42:957–959.
3. Alrabaa SF, Nguyen P, Sanderson R, et al. Early identification and control of carbapenemase-producing *Klebsiella pneumoniae*, originating from contaminated endoscopic equipment. *Am J Infect Control* 2013; 41:562–564.
4. Aleccia J. Undisclosed superbug sickened dozens at Virginia Mason. *Seattle Times*. Jan. 26, 2015: http://bit.ly/1L252Ug. ■

CMS addresses lower relative humidity in ORs

The Centers for Medicare and Medicaid Services (CMS) has provided information on operating room (OR) relative humidity (RH) for ambulatory surgery centers (ASCs) and supplemental information for hospitals and critical access hospitals (CAHs) using the categorical waiver of *Life Safety Code (LSC) Anesthetizing Location RH Requirements*.

On Jan. 5, 2015, the Association for the Advancement of Medical Instrumentation coordinated a release, from multiple healthcare organizations, on how a RH of less than 30% in ORs might affect the performance of some sterile supplies and electro-medical equipment.

Survey and Certification Letter S&C: 13-25-LSC & ASC, previously issued by CMS, permits hospitals and CAHs to use an LSC categorical waiver to establish an RH level of less than 35% in anesthetizing locations. Before electing or continuing to use this categorical waiver, hospitals and CAHs are expected to ensure that the humidity levels in their ORs are compatible with the manufacturers' instructions for use (IFUs) for the supplies and equipment used in that setting, CMS says.

ASCs do not require a categorical waiver to use a lower RH level in their ORs, but they also need to ensure they comply with the IFUs for their OR supplies and equipment, CMS says. "Centers need to keep a daily log of relative humidity, so if they run below 35%, they need to have a plan of correction in place to maintain a proper RH level," says **Mark Mayo**, CASC, executive director of Golf Surgical Center, Des Plaines, IL. ■

ASCA: New quality measures are likely

The Measure Applications Partnership has issued a draft recommendation supporting two additional measures in the Ambulatory Surgery Center Quality Reporting Program. The Partnership guides the Centers for Medicare & Medicaid Services (CMS) on performance measures.

The two measures, Unplanned Anterior Vitrectomy and Normothermia, received conditional support from the group. This recommendation means there is a reasonable possibility that CMS will include the two measures in its proposed payment rule this summer, the Ambulatory Surgery Center Association (ASCA) says.

The intent of the Unplanned Anterior Vitrectomy measure is to determine the number of cataract surgery patients (based on certain CPT codes) who had an unplanned anterior vitrectomy. The intent of the Normothermia measure is to capture the number of patients who had general or neuraxial anesthesia of 60 minutes or more in duration and are normothermic (body temperature equal to or greater than 96.8 F/36 C) within 15 minutes of arrival in the postoperative care unit.

To download the measure specifications, go to http://bit.ly/1GOu31I. You may download a sample Normothermia collection log also on that web page. This collection log is not required. These resources are available to ASCA non-members (with registration) and members. ■

CNE/CME OBJECTIVES

After reading *Same-Day Surgery,* the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identifiy how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.

SAME-DAY SURGERY

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CNE/CME QUESTIONS

1. **At Silverton Health, what changes were made after patients received burns in the operating room?**

   A. The halogen lights were replaced with lamps that use LEDs (light-emitting diodes).
   B. The engineering department or contractors are involved in any maintenance on any medical equipment
   C. They ensured that proper cleaning solutions are used.
   D. All of the above.

2. **According to Joseph Perz, PhD, team leader of quality and safety in the Centers for Disease Control and Prevention's Division of Healthcare Quality Promotion, which drugs often are involved in drug diversion by healthcare providers?**

   A. Prescription drugs
   B. Controlled substances such as oxycodone and fentanyl
   C. Both A and B
   D. Neither A nor B

3. **In a Food and Drug Administration (FDA) alert regarding carbapenem-resistant Enterobacteriaceae, the FDA said that patients who have had endoscopic retrograde cholangiopancreatography should report which of the following symptoms to their providers?**

   A. Fever or chills, chest pain, or severe abdominal pain
   B. Trouble swallowing or breathing
   C. Nausea and vomiting
   D. Black or tarry stools
   E. All of the above

4. **According to Susan Stolz, HIPAA compliance solution manager with Stericycle, if you undergo an audit under the Health Insurance Portability and Accountability Act, how much running documentation will you have to produce?**

   A. One year
   B. Two years
   C. Six years