Patient safety

Beware: ECRI Institute warns of 10 health technology hazards in 2017

As the use of technology in patient care increases, from electronic monitoring to specialized devices used in patient care to new ways to track potential complications, the risk to patients from hazards caused by this technology is also on the rise.

While infection control and technology recalls involving hard-to-clean endoscopes and endoscope processors have dominated the health care industry for months, more recently hospitals are scrambling to respond to CDC and FDA alerts on infections potentially linked to a common cardiothoracic surgical device. (see ECRI, p. 4)

Infection control

Infection control and EOC teams must join efforts to avoid critical RFIs

Make your environment of care specialists a key part of your infection control team as The Joint Commission (TJC) ramps up emphasis on infection prevention throughout a facility.

IC and EOC experts should conduct environmental rounds together to identify existing RFIs and infection preventionists must have a seat at the table from the beginning of planning and management of construction and renovation projects. (see EOC, p. 6)

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Look at ignition sources, ADA rules when placing hand-rub dispensers

Where to place alcohol-based hand rub (ABHR) dispensers and how many to have around to address continuing hand hygiene concerns continues to confound both hospital and Joint Commission leaders alike.

A hospital executive during The Joint Commission’s (TJC) Executive Briefing in New York Sept. 7 asked TJC’s infection control specialist Lisa Waldowski where ABHR dispensers were best put in an emergency department where patient treatment areas were not necessarily defined by walls, and specifically asked if dispensers were allowed on computer carts?

Waldowski admitted it was a tough subject because they need to be where they provided a visual reminder for clinicians to use them before and after caring for a patient, but not so prolific that they were regularly ignored.

“Overkill is not going to solve your problem,” she said.

And, she noted, there were several Life Safety concerns related to ABHR dispensers.

She recommended hospitals do a risk assessment for patient care areas, make use of hand-hygiene expertise developed through TJC’s Center for Transforming Healthcare, and consult with facilities managers to make sure placement met fire safety requirements.

**ADA also presents a challenge**

Making hospital compliance managers lives even harder is the final rule by CMS earlier this year, effective July 5, adopting the 2012 editions of the NFPA 101 Life Safety Code (LSC) and NFPA 99 Health Care Facilities Code.

In that rule, CMS noted that the NFPA code outlines what is and isn’t allowed with ABHR dispensers in hospitals, but that hospitals were required also to abide by other federal regulations, including the Americans with Disabilities Act (ADA).

In general, the LSC’s means of egress requirements have allowed ABHR dispensers as long as they did not protrude more than 6 inches into a corridor.

However, the ADA prohibits protrusions of more than 4 inches in all circulation paths, unless that protrusion goes all the way to the floor.

**All pathway protrusions ADA concern**

The ADA 4-inch standard is for any object — whether it is an ABHR dispenser or a drinking fountain — that extends out of a wall and is higher than 27 inches from the floor and below 80 inches. Items outside that range can protrude any distance.

“Objects mounted up on walls are not supposed to stick too far out into midair because, for people who are blind or have low vision, those objects are not cane-detectable,” points out Nancy Horton, a regional director.
Managing ABHR can be tricky

“Some of these dispensers are going to have to go on a diet,” says Joseph Gordon, founder of Survey Resources in Manchester, N.J.

Purchasing newer, shallower dispensers is the clearest way to ensure compliance. Until dispensers are replaced, however, there is little guidance so far on what action surveyors will take, notes Gordon. Both CMS and TJC surveyors began surveying to the 2012 editions as of Nov. 1.

Another solution is to use wall alcoves, even shallow ones, as a way to help mitigate excessive protrusion, Horton suggests.

Remember also that the 2012 LSC stipulates that “special consideration” be paid to the location of ABHR dispensers “with regard to adjacent combustible materials and potential sources of ignition, especially where dispensers are mounted on walls of combustible construction.”
The most common ignition sources are light switches and electrical outlets.

The LSC prohibits the placement of ABHR dispensers:
- Above an ignition source within a one-inch horizontal distance from each side of the ignition source.
- To the side of an ignition source within a one-inch horizontal distance from the ignition source.
- Beneath an ignition source within a one-inch vertical distance from the ignition source.
- Directly over carpeted floors unless in a sprinkler-equipped smoke compartment.

**TJC offers FAQ on ABHR**

Although the LSC and ADA standards differ, experts say the potential for conflict is low. At the same time, finding the ideal location for ABHR dispensers can pose a bit of conundrum for designers.

“You want those types of dispensers to be in a location that is convenient as you are going in and out of patient rooms,” Horton notes. “If you place it out of the way, you might reduce the use of them. But those high-traffic areas are where you find light switches, too.”

Over the years, The Joint Commission (TJC) has faced several queries on the location of ABHR dispensers and finally issued frequently asked questions (FAQ) guidance. Among other things, TJC expects ABHR dispensers to be:
- In corridors with a width of at least 6 feet or greater and with dispensers at least 4 feet apart.
- Each smoke compartment may contain a maximum aggregate of 10 gallons of ABHR gel in dispensers and a maximum of five gallons in storage.
- The maximum individual dispenser fluid capacity is 0.3 gallons for dispensers in rooms, corridors and areas open to corridors.
- The maximum dispenser size for individual dispensers in areas designated as suites of rooms is 0.5 gallons. — Scott Harris (ijc_editors@decisionhealth.com)

**Resources:**


**ECRI**

*(continued from p. 1)*

ECRI Institute, a patient safety organization in Plymouth Meeting, Pa., which often works with The Joint Commission (TJC) on patient safety initiatives, recently released its annual top 10 health technology hazards to watch for in 2017.

Here is an overview:

- **Infusion errors:** Safety mechanisms have reduced, but not eliminated errors related to infusion pumps. The safety mechanisms themselves can also fail. Errors that result in uncontrolled flow of medication to the patient are the biggest risk and could cause harm or even death. ECRI’s findings note that many of these errors can be averted by staff noticing signs of physical damage to infusion pumps, staff making appropriate use of the roller clamp in IV tubing and checking the drip chamber beneath the medication reservoir for unexpected flow.

  Hospital policies and procedures should specifically ensure staff focus on these steps, which are ironically often overlooked due to the advanced safety features of modern infusion pumps.

  TJC issued a Sentinel Event Alert on infusion pumps in 2000, but the alert has since been retired.

- **Infection control with reusable medical devices:** Inattention to the cleaning steps for complex instrumentation such as duodenoscopes, cannulated drills and arthroscopic shavers while being reprocessed between uses can be a potential cause of infections to patients, particularly as these devices become more complex, ECRI finds.

  Make sure that comprehensive reprocessing instructions are available to staff and all steps are followed, including precleaning of devices at the point of use, ECRI recommends.

  Both TJC and CMS have promised to step up focus on high-level disinfection and sterilization. Failures in these areas have led to several hospitals losing or almost losing accreditation in the last two years.

- **Missed ventilator alarms:** Ventilator alarm challenges include alarm fatigue, in which staff miss alarms due to becoming distracted or desensitized to the number and variety of alarms going off on the floor. Notification failures caused by alarms not being effectively communicated to staff are a second challenge.
Ventilator alarm data are hard to collect, making solutions more challenging for the hospital, according to ECRI.

TJC fully implemented clinical alarm management as a National Patient Safety Goal in 2016.

- **Undetected opioid-induced respiratory depression**: ECRI recommends that hospitals and other health care facilities implement processes to continuously monitor ventilation for patients receiving opioid therapy. Due to the risk of complications, including anoxic brain injury or death, spot checks are not considered to be adequate.

- **Infection risks associated with cardiothoracic heater-cooler devices**: It’s not fully understood how likely it is that a patient could be infected with a nontuberculous mycobacteria infection from a heater-cooler device during heart surgery. But at least one model has been found potentially to cause contamination. These devices are intended to warm or cool the patient during cardiothoracic surgery by circulating warm or cold water through a closed circuit. Water is not supposed to come into contact with the patient or with the patient’s circulating blood, but it is believed that aerosolized water from the exhaust vents of contaminated heater-cooler systems may be a source of these infections.

Both the CDC and FDA have issued warnings recently about certain devices and encouraged hospitals to advise patients to be on the lookout for possible symptoms of infection. For more information from the CDC, go to https://www.cdc.gov/HAI/outbreaks/heater-cooler.html.

- **Software management gaps**: Failing to maintain an up-to-date, easily retrievable set of information about updates to software versions used in medical devices makes facilities ill-prepared to manage these updates and alerts, and puts patients and patient data at risk, ECRI believes.

  Patient care is impacted because mismanagement causes downtime or affects the performance of such devices in patients, delays implementation of updates that may affect safety concerns and allows cybersecurity vulnerability to persist past the point at which it could be fixed.

- **Occupational radiation hazards**: Hospital workers in hybrid operating rooms that contain built in X-ray imaging systems should receive specific training on radiation protection steps, and the hospital should have its own policies to minimize exposure to radiation, especially for staff that might not be as aware of the risks of exposure as radiologists.

  Keep in mind that both CMS and TJC recently beefed up radiation and imaging safety requirements, and surveyors have been questioning hospital staff on policies and safety procedures.

- **Medication errors connected to automated dispensing cabinets**: Careful planning should be used with automated dispensing cabinets (ADCs) to ensure knowledge of which medications should be in a particular care area, where in the drawer to place medication to reduce instances of misidentification, and whether to use locked pockets to further restrict access to some medications.

  Among problems ECRI has seen with ADCs are the presence of a wrong drug or dose, high alert drugs in unsecured areas and unavailability of needed drugs.

- **Surgical staplers**: Thousands of adverse events related to surgical staplers are reported each year, including misapplied staples, misfiring or difficulty in firing, and tissue becoming jammed in the mechanism. Complications to the patient include hemorrhaging, tissue damage and unexpected post-operative bleeding.

  ECRI recommends paying close attention to device operation, selection of the appropriate staple size for the patient and signs the stapler may not be functioning properly.

- **Device failures caused by cleaning products and practices**: Hospitals should stock multiple cleaning products and provide training and information on which of these products are appropriate for the different devices used throughout the hospital, ECRI recommends.

  Use of incompatible cleaning agents can shorten the lifespan of devices, damage equipment services and degrade plastics, damage seals, lubricants, electronics, power supplies and motors. This causes devices to malfunction or fail prematurely, affecting patient care.

  TJC has repeatedly said it expects hospitals to follow manufacturer’s instructions for use on products and devices, or have documentation to show a risk assessment and why different instructions are being used.

— Scott Kraft (ijc_editors@decisionhealth.com) and A.J. Plunkett (aplunkett@decisionhealth.com)

**Resource:**

EOC
(continued from p. 1)

Hospitals that are succeeding at reducing their IC risks — including those involving high-level disinfection (HLD) and sterilization — “are ones who have brought everyone to the table,” said Lisa Waldowski, The Joint Commission’s (TJC) infection control specialist, during the Sept. 7 Executive Briefings session in New York.

Infectious outbreaks at hospitals have become high-profile headlines nationwide, she said. To avoid becoming one of those headlines, hospitals have to look at the overlap between infection control and the hospital environment of care (EOC).

“With mergers and with more ambulatory surgery settings, this has become even more critical that we get everyone to the table,” emphasized Waldowski.

IC begins, ends with assessing risk

TJC’s IC chapter begins with requirements for leadership to identify the individuals responsible for the hospital’s infection prevention and control program, to provide resources to make that program work and to identify risks for “acquiring and transmitting infections.”

Infectious risk assessment is at the heart of the chapter’s other requirements and ends with a final mandate for the hospital to evaluate the effectiveness of its IC program annually and “whenever risks significantly change,” according to the standard.

In a hospital, infection risks can change every day. “So what does that mean?” Waldowski asked the audience of hospital leaders. “That we’re not doing this annually, we’re doing this continually.”

To get that done, IC managers cannot work in a silo, she warned. IC and EOC managers must work in concert.

EOC and IC overlap in three critical areas: medical equipment, devices and supplies; utilities involving air and water; and construction and renovation, according to Waldowski and George Mills, TJC’s engineering director who spoke along with Waldowski. (For a rundown of what to look for in these three areas, see 7.)

EOC problems are IC problems

To emphasize the point, Waldowski noted that the two main drivers for TJC surveyors to call a problem an immediate threat to life (ITL) — a ruling that can threaten not only a hospital’s accreditation but also its ability to bill Medicare — are problems with the disinfection and sterilization of medical devices such as endoscopes and with improper ventilation and air pressure controls in areas such as surgical suites.

CMS surveyors also are increasing focus on those areas. Infection preventionists must establish and maintain a regular working relationship with the EOC team, not only to protect patients, staff and visitors from infection, but also to ensure that construction and renovation projects can move forward without delays, pointed out Mills.

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Include IC managers and other stakeholders from the clinical side on project planning to ensure that what is the most efficient engineering or design choice is also the best choice for patient care, he advised.

Moving a doorway may seem like a simple project, but if the noise, dust and vibration from construction compromises patient health, it can become complicated quickly, Mills noted. Better to know those problems from the beginning than having to stop work and redesign the project midway through.

Even quick jobs such as changing a ceiling tile can have IC implications if that tile has mold or other infectious materials that must be contained, Waldowski noted.

Head off costly project delays

Ensure that whenever maintenance orders are carried out in patient care areas, nurses or other care clinicians are kept informed of the work, she said, recalling the story of an immune-compromised patient who complained of being too cold.

Nurses put in a work order to fix the temperature controls in the room. But when maintenance responded, workers discovered that to do the repairs, part of a wall had to be removed. Work had already begun — and dust and other debris were already in the room — before nurses discovered what was happening.

By the time the patient was moved, his condition had gone from bad to worse, she said.

Having a process where the clinicians and maintenance sides were working together would have prevented what became a critical event, she observed. “There has to be more communication,” she said.

To encourage that, TJC is revising some EC requirements to emphasize infection control, Mills announced.

Most notably, to the EC requirement to inspect, test and maintain utility systems, TJC has added a requirement for hospitals during repairs or maintenance
to manage risks associated with air quality, infection control, noise, dust, vibration and other such hazards, Mills said. — A.J. Plunkett (aplunkett@decisionhealth.com)

**Infection control**

**Assess your risk in these critical areas where IC, EOC interlink**

Begin looking at the ways the environment of care (EOC) and infection control (IC) intertwine and view problem solving from that perspective because surveyors with The Joint Commission (TJC) will be doing the same, say TJC officials.

The IC issues that lead to a TJC call of immediate threat to safety and life (ITL) often are directly tied to EOC problems or solutions, warned Lisa Waldowski, TJC’s infection control specialist, during the Sept. 7 Executive Briefings session in New York.

Three critical areas in infection control concern medical equipment, devices and supplies; utilities involving air and water; and construction and renovation, said Waldowski, who spoke alongside George Mills, TJC’s engineering director.

Look for these common problems as you consider projects and do environmental rounds.

**Medical equipment, devices and supplies**

The IC risks associated with improperly cleaned duodenoscopes, endoscopes and other such medical devices, as well as the maintenance and testing of equipment used in the high-level disinfection and sterilization are drawing the attention of TJC Sentinel Event investigators and will remain a key focus of surveyors, Waldowski warned.

TJC has said it learns of Sentinel Events through voluntary reporting by hospitals, but also through patients, families and news reports. And the infectious outbreaks associated with poorly cleaned scopes and the resulting recalls has gotten major attention in the news media across the country, noted Waldowski.

IC risks must be addressed and continuously tweaked as those risks change, including as the FDA, the CDC and other agencies issue warnings and announce product recalls, she warned, noting that voluntary recalls associated with duodenoscopes, automated endoscope reprocessors and related cleaning products and equipment have numbered in the thousands in the past few years.

Among other things, review your process for dealing with recall notices and ensure that you have assigned backup personnel in case the chief person in charge is out of the office, Waldowski said.

Be sure to review how that information is passed along within your hospital and, if your facility is part of a larger group of hospitals and clinics, within the entire system.

As health organizations grapple with mergers and acquire ambulatory settings, “who has the latest and greatest information” on these high-risk devices, she asked. “Do you even know where all this inventory is in our organizations?”
To manage and maintain this inventory, you have to know where it is, Mills reiterated. “Talk to each other.”

Similarly, maintaining the equipment is not just the nuts and bolts of testing and repairs; it’s the outcome of ensuring that it is doing the job it is intended to do, Mills admonished.

The EC standard requiring hospitals to manage medical equipment risks includes EP 8, under which hospitals are required to monitor for and report incidents suspected of or implicated in deaths, serious injuries or illnesses, Waldowski pointed out. But it’s not just a TJC requirement. It’s an FDA regulation. Yet hospitals are still struggling with when to report information to the FDA and even who within an organization is in charge of reporting it, Waldowski observed.

“Aren’t we only waiting for the deaths? Are we only waiting for the confirmations? That is what burned us with lessons learned with duodenoscopes,” she said.

Rather than wait to see whether it becomes a bigger issue, “how about erring on the side of caution? Say, ‘hey we’re suspecting this and we’re going to report it. And have this be a little more timely,” she added. Organizations spend so much time asking, “what is this going to do to us?” that we are cautious and hesitant and nobody benefits from that, until obviously when there have been deaths and your hand has been forced.”

With the testing and maintaining of sterilizers and other automated devices and cleaning equipment — “and we do look at this very highly when we’re looking at your sterilization tracer processes” — surveyors will be checking how hospitals are cleaning and maintaining that equipment and whether it is being done according to manufacturer’s instructions. Surveyors will also be checking to see if that process is being documented.

Utilities: Air and water

Clean air and water are keys to proper infection control, and therefore the equipment and maintenance of those systems should be high on the list for assessing risk, noted Waldowski.

Outbreaks of Legionnaires’ disease are increasing. The majority of the time the Legionella bacteria is identified, it is at a hospital that lacks a water management plan or is not adhering to the plan it does have, said Waldowski.

IC and facilities management managers should look at the process for disinfection of water used in hot tubs and hydrotherapy units as well as maintenance of water towers, she said.

The team must also pay attention to their process for shutting down patient care areas if patient census drops, especially in organizations with older facilities, Waldowski stressed. When you close a unit down, it’s not just consolidating services in another area. No one will be using the water fountains or ice machines in the closed unit, shower heads are not being turned on and in general, the system is not regularly flushing itself out.

The biggest problem in engineering is when you have “a line that goes somewhere and then there’s something shut off,” added Mills. That can be in a whole unit or just one room — wherever changes are made so that a water pipe is capped and abandoned. “That is where we are growing and breeding all sorts of stuff,” he noted.

When you shut down an entire unit, those dead legs of water pipe are all over, he said. Plan for how the hospital is going to keep that water from just sitting, otherwise it will be “waiting to grow who knows what,” Mills said.

Construction and renovation

Water-related contaminations are an example of how aging infrastructure and facilities management can have a dramatic impact on infection control, Waldowski noted.

Changes made to deal with that aging infrastructure have to be looked at from a clinical as well as a physical environment perspective, said both Waldowski and Mills.

For instance, hospitals are required to monitor pneumonia rates and causes, which can be as much related to the environment of care as to a clinical connection.

Infection preventionists must be at the table before and during renovation projects, Waldowski said. And IC needs to be continually working with facilities managers to educate facility staff, not only on protecting patients but themselves. “Education needs to be upfront,” she added.

She told of her days as an IC manager at a hospital and walking through the hallway to see a maintenance staffer on a ladder changing a ceiling tile or in the middle of some other repair, and the look when he or she spotted her coming. The look said, “Oh, I should have had a mask on” or “I should have had a barrier [to contain dust and debris] up,” she recalled. “They think of that as soon as they see me coming — we want it before.” — A.J. Plunkett (aplunkett@decisionhealth.com)
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