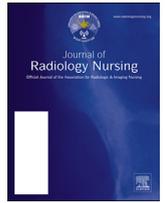




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2019 Top 10 Health Technology Hazards

A Brief Look at ECRI Institute's 2019 Top 10 Health Technology Hazards

The safe use of medical technologies requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood of adverse events. ECRI Institute's annual *Top 10 Health Technology Hazards* report is a useful tool for that effort. More than just an accounting of past incidents, this forward-looking list highlights problems that are likely to occur in the future—and offers recommendations for preventing harm.

The nonprofit healthcare research organization uses its experience investigating incidents, testing medical devices, and reviewing health-technology-related problem reports to identify topics that warrant priority attention. Factors considered when compiling the list include the likelihood that the hazard could cause serious injury or death, that it could affect a large number of people, or that it could lead to downstream errors. The full report also includes action steps to help healthcare organizations direct their time and energy toward activities that can have the greatest impact on patient safety.

The topics included on ECRI Institute's 2019 list are outlined below.

1. Hackers Exploiting Remote Access Vulnerabilities



Cybersecurity attacks that infiltrate a network by exploiting remote access functionality on connected devices and systems—or by any other means—remain a significant threat to healthcare operations. Attacks can render devices or systems inoperative, degrade their performance, or expose or compromise the data they hold, all of

which can severely hinder the delivery of patient care and put patients at risk.

Hackers commonly target remote access systems because these systems are, by nature, publicly accessible. Intended to meet legitimate business needs, such as allowing vendors to troubleshoot systems installed at the facility, remote access systems can be exploited for illegitimate purposes.

2. Mattresses Remaining Contaminated after Cleaning



Blood and other body fluids that remain on, or within, mattresses or mattress covers after cleaning can contact subsequent patients, posing an infection risk. Reported incidents include patients lying on an apparently clean bed or stretcher when blood from a previous patient oozed out of the surface onto the patient.

Mattress covers are intended to prevent body fluids and other contaminants from getting into mattresses. If a cover is not cleaned and disinfected effectively, or if its integrity is compromised in a way that allows the mattress underneath to become contaminated, subsequent patients could be exposed to infectious materials.

3. Retained Surgical Sponges



Surgical sponges that are unintentionally left inside the patient after the surgical site is closed can lead to infection and other serious complications, including the need for secondary operations.

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An Executive Brief version of the report is available as a free public service through www.ecri.org/2019hazards, ECRI Institute members can access the full report through their membership web page.

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Manual counts—in which the surgical team verifies that all sponges are accounted for before concluding the procedure—are standard practice, but they are prone to error. If such errors result in a retained sponge, complications can ensue, with consequences for both the patient and the healthcare facility.

Technologies that supplement the manual counting process are available and have been found to be effective when used correctly. ECRI Institute contends that broader adoption of these technologies could further reduce the risk that a surgical sponge will be unintentionally retained during a procedure.

4. Improperly Set Ventilator Alarms



Mechanically ventilated patients are at risk if user-adjustable ventilator alarms are not tailored to the patient's respiratory parameters. Leaks, disconnections, and other failures associated with a ventilator's consumable components are a fairly common occurrence and can quickly lead to harm if the condition is not identified and rectified promptly.

Ventilators rely on consumable components, such as plastic breathing circuits, to help convey respiratory gases between the ventilator and the patient. Loose connections, manufacturing defects, or other problems with these components can prevent adequate ventilation. Within minutes, inadequate ventilation can result in hypoxic brain injury or death.

Properly set alarms can prevent such consequences. Yet ECRI Institute continues to investigate deaths resulting from breathing circuit disconnections during which no alarm activated.

5. Recontamination of Endoscopes after Disinfection



Cleaning and disinfecting flexible endoscopes between uses is known to be a challenging process. Failure to precisely follow a robust reprocessing protocol can lead to debilitating or even fatal infections. Less well known is that improper handling and storage practices can recontaminate previously disinfected scopes, heightening the risk of patient infections.

If endoscopes are not completely dried after being subjected to high-level disinfection, any remaining viable microbes

can rapidly proliferate and colonize the instruments. Additionally, the disinfected status of endoscopes can also be compromised if the instruments are handled with unclean gloves—a practice that ECRI Institute has observed—or if the scopes come into contact with contaminants when being transported or stored.

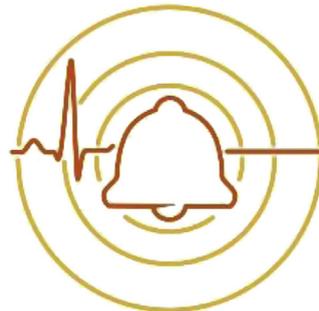
6. Wrong-Field Infusion Pump Programming Errors



Mistakes such as entering the intended flow rate into an infusion pump's dose rate field can lead to dangerous medication administration errors. Clinicians tells us that such wrong-field programming errors occur relatively frequently (though such errors often go unreported). Even “smart pumps” that incorporate a dose error reduction system can be misprogrammed in a way that could lead to patient harm.

Infusion pumps are designed to deliver medications and other solutions to the patient at a specified rate. If the rate programmed into the pump is incorrect, the patient will receive either too much or too little solution. Either situation can have grave consequences, depending on the solution being delivered.

7. Improper Customization of Physiologic Monitor Alarms



Improper customization of the alarms on a physiologic monitoring system could prevent staff from learning about significant changes in the patient's physiologic status or about problems with the medical device or system. Failure to recognize and respond to such conditions in a timely manner can result in serious patient injury or death.

Alarm customization involves selecting alarm values or settings based on the particular needs of a care area and the condition of the patient. When customization is done properly, alarms are less likely to activate for nonactionable conditions, thereby reducing the number of nuisance alarms that activate. But if done improperly, alarm customization can create opportunities for missed alarms, and thus patient harm.

8. Failures of Overhead Patient Lift Systems



Overhead patient lift systems are implemented as a safety technology, but are not without their own safety challenges. Significant injury or damage can occur if the system is designed, installed, used, or maintained improperly.

Overhead patient lift systems are fixed structures designed to lift and transfer patients, such as from a bed to a wheelchair. Safety challenges arise from the systems' installation requirements and from their reliance on weight-bearing and moving parts to function dependably, and be used correctly, when lifting and moving a patient. Lift components that fall from above or that fail during use can harm patients, care providers, and visitors.

9. Cleaning Fluids Damaging Electrical Components

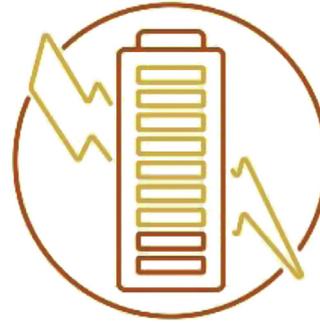


Overzealous or improper cleaning of electrical equipment can result in equipment malfunction, damage, or fire. The use of cleaning or disinfectant wipes that are dripping with excess fluid, or spraying liquids directly onto powered medical devices and equipment, can cause fluid to enter electrical components such as plugs, sockets, or power supplies. Repeated fluid ingress, and the residue it leaves behind, can create errant current pathways around the electrical component. These additional currents can eventually generate sufficient heat to cause a device failure, or worse.

ECRI Institute is aware of multiple instances in which cleaning fluid seeping into electrical components has led to equipment damage or fire. Incidents have involved infusion pumps, OR tables,

infant warmers, and electrical equipment such as light switches and power supplies.

10. Flawed Battery Charging Systems and Practices



Insufficiently charged batteries can affect the readiness and operation of medical devices that rely on rechargeable batteries to temporarily power the device. If no alternative device or source of power is readily available, serious injury or death could result, particularly if the equipment is needed for life-saving or life-sustaining therapy.

Staff failing to properly charge or maintain batteries is one concern. But often the fault lies with the equipment: A device's battery status indicators may not be sufficiently accurate or clear. A battery charger may malfunction. Or the battery itself may be defective or become exhausted.

An Executive Brief describing these topics is available from ECRI Institute for free download through www.ecri.org/2019hazards. The full report—including step-by-step recommendations for addressing the hazards and access to additional resources—is available to members of ECRI Institute programs.

Following are the complete titles for each of the topics:
ECRI Institute's 2019 Top 10 Health Technology Hazards

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death
5. Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
6. Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors
7. Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms
8. Injury Risk from Overhead Patient Lift Systems
9. Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires
10. Flawed Battery Charging Systems and Practices Can Affect Device Operation