Know the health technology hazards that pose possible patient risk

Hospitals depend on countless medical devices and systems when diagnosing, treating, and monitoring patients. Overall, the use of health technology has led to safer, more reliable care. But from time to time, technology actually causes harm.

When planning your safety initiatives, it’s vital to know which risks to address first. ECRI Institute’s newly released Top 10 Health Technology Hazards for 2014 is a comprehensive report published annually to raise awareness of the potential dangers associated with the use of medical devices and systems. Facilities can use this list to prioritize 2014 patient safety efforts.

Ensuring the safe use of health technology requires identifying possible sources of danger or difficulty involving medical devices and systems and taking steps to minimize the likelihood that adverse events will occur. With the vast array of technologies in use at a modern healthcare facility, however, deciding where to commit limited resources is a continual challenge.

ECRI Institute’s annual Top 10 list highlights some hazards that regularly occur; some problems that will become more prevalent, given the way the technology landscape is evolving; and some that are well known but periodically warrant renewed attention.

All of the items on the list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. The full report describes the risk mitigation strategies currently available, making the list a practical tool for identifying high-impact steps you can take to improve patient care at your facility.

The following is an excerpt from the 2014 list, originally published in November 2013 in ECRI Institute’s Health Devices journal.

Alarm hazards

Many medical devices incorporate alarms to warn caregivers of relevant changes in the patient’s condition or of circumstances that could adversely affect the patient. These warnings have doubtless saved many lives. But alarm-related adverse incidents do occur, and they can lead to significant patient harm. In an April 2013 Sentinel Event Alert, the Joint Commission cited 98 alarm-related events over a three-and-a-half-year period, with 80 of those events resulting in death and 13 in permanent loss of function.

Alarm fatigue—in which caregivers can become overwhelmed by, distracted by, or desensitized to the numbers of alarms that activate—is a commonly cited concern. However, clinical alarm hazards can take many forms. Any circumstance that results in the failure of staff (1) to be informed of a valid alarm condition in a timely manner or (2) to take appropriate action in response to the alarm can be considered a clinical alarm hazard.

Infusion pump medication errors

Infusion pumps are invaluable to healthcare, delivering specified doses of fluids and medication directly into a patient’s bloodstream over an extended period of time.
However, these devices also represent a large technology management burden: A hospital may have hundreds or even thousands of these devices in its inventory, and device failures—or failures to use the devices properly—are not uncommon and can cause significant patient harm.

Patients can be highly sensitive to the amount of medication or fluid they receive from infusion pumps, and some medications are life-sustaining—or life-threatening if administered in the wrong amounts or to the wrong patient.

CT radiation exposures in pediatric patients
Computed tomography (CT) systems have proven to be a valuable tool for diagnosing serious injuries and illnesses. However, this diagnostic imaging technology is not without risk—especially to pediatric patients, who are inherently more sensitive to the effects of ionizing radiation than are adults.

While the risk has always been hard to quantify, newly published empirical studies add to the evidence that exposure to ionizing radiation from diagnostic imaging at a young age can increase a person’s risk of developing cancer later in life. As a result, efforts should be made to minimize a child’s exposure to high doses of ionizing radiation.

Practices that can place children needlessly at risk include the inappropriate use of any technology that uses ionizing radiation, as well as the failure to properly control the radiation dose during such procedures—which can occur, for example, if an adult protocol is used for pediatric patients. However, CT scans are of particular concern because they deliver a comparatively high dose of radiation and are widely used.

Data integrity failures in EHRs and other health IT systems
As the role of electronic health records (EHRs) and other IT-based systems in patient care increases, the integrity of the data within (and passed among) those systems becomes an increasingly critical patient safety concern.

When designed and implemented well, an EHR or other IT-based system will provide complete, current, and accurate information about the patient and the patient’s care so that the clinician can make appropriate treatment decisions. However, these complex systems also can create new paths to failure.

Reports illustrate myriad ways that the integrity of the data in an EHR or other health IT system can be compromised, resulting in the presence of incomplete, inaccurate, or out-of-date information. Contributing factors include patient/data association errors, missing data or delayed data delivery, clock synchronization errors, inappropriate use of default values, use of dual workflows (paper and electronic), copying and pasting of older information into a new report, and even basic data-entry errors (which can be propagated much further than would have occurred with paper-based systems).

Occupational radiation hazards in hybrid ORs
The implementation of hybrid ORs is a growing trend in healthcare facilities. These operating suites bring advanced imaging capabilities into the surgical environment via built-in, full-scale angiography systems, which can be used to guide complex minimally invasive procedures that may need to transition to open procedures.

However, as these angiography systems are introduced into the OR, so too are the radiation exposure risks associated with the use of ionizing radiation. Patient exposure hazards are of course a concern. But perhaps less obvious are the risks to OR staff.

Personnel in radiology departments and catheterization labs, where imaging devices have a long history, are generally well versed in the occupational risks associ-
ated with ionizing radiation and well educated in the safety precautions that must be taken. Outside those more controlled environments, however, the knowledge of the risks and the experience in executing precautions may be lacking—a situation that could lead to unnecessary radiation exposures to those clinicians working in a hybrid OR on a daily basis.

**Inadequate reprocessing of endoscopes and surgical instruments**

Every day, healthcare facilities clean and disinfect (or sterilize) thousands of reusable surgical instruments and devices so that they can be used for subsequent procedures. When performed properly, this reprocessing removes residue and potentially infectious materials (eg, tissue, body fluids, other organic material) and disinfects or sterilizes the instrument so that it can be safely used on the next patient.

When reprocessing is not performed properly, however, patient cross-contamination is possible, potentially leading to the transmission of infectious agents and the spread of diseases such as hepatitis C, HIV, and tuberculosis. In addition to directly affecting patient safety, incidents involving improperly reprocessed instruments can damage an organization’s reputation, reduce patient satisfaction, prompt review by accrediting agencies, and lead to citations and fines from regulatory bodies or lawsuits from patients.

Successful reprocessing requires consistent adherence to a multistep procedure. Failure to properly perform any step, including some necessary manual tasks, could compromise the integrity of the process and lead to significant patient harm.

**Neglecting change management for networked devices and systems**

The growing interrelationship between medical technology and IT offers significant benefits. However, one underappreciated consequence of system interoperability is that updates, upgrades, or modifications made to 1 device or system can have unintended effects on other connected devices or systems. ECRI Institute is aware of incidents in which planned and proactive changes to 1 device or system—relating, for example, to upgrading software and systems, improving wireless networks, or addressing cybersecurity threats—have adversely affected other networked medical devices and systems.

To prevent such downstream effects, alterations to a network or system must be performed in a controlled manner and with the full knowledge of the personnel who manage or use the connected systems. Unfortunately, change management—a structured approach for completing such alterations—appears to be an underutilized practice.

**Risks to pediatric patients from “adult” technologies**

Healthcare technologies are often developed with the needs of adult patients in mind, leaving clinicians with little choice but to rely on “adult” technologies in the diagnosis and treatment of pediatric patients. But because of their smaller size and ongoing physiologic changes, children may suffer adverse effects when subjected to adult-oriented healthcare techniques.

Unfortunately, pediatric-specific devices can be slow to reach the market because of the small numbers of patients available to study, the devices’ high-risk nature, and high development costs. Thus, healthcare providers are often put in the position of having to use a technology designed for adults to diagnose or treat conditions in children. Healthcare personnel must exercise particular care when this is necessary.
Robotic surgery complications due to insufficient training

The past decade has seen a rise in the implementation of robotic surgery systems to replace open surgery and traditional minimally invasive surgery (MIS) techniques for certain procedures. The past year, however, has seen a rise in the number of media reports that are critical of robot-assisted surgery. Some of the reports, which describe complications that individual patients have experienced, suggest that robotic systems are being used for a greater number of cases or for additional kinds of procedures without adequate consideration of the surgical team’s proficiency in using the system for the procedures performed.

These reports don’t speak to the efficacy of robot-assisted surgery: The articles do not meet the standards of evidence-based research studies, and proponents of these systems can point to many successful outcomes. However, the reports do draw attention to the critical need for appropriate training, detailed credentialing, and ongoing surgical team competency assessments to minimize patient risk.

Retained devices and unretrieved fragments

The unintended retention of a surgical item in a patient after surgery or after an interventional diagnostic procedure is 1 of the 5 surgical serious reportable events (SREs) currently classified by the National Quality Forum (NQF). SREs are medical errors that NQF has determined are serious, unambiguous, and largely preventable.

But events that shouldn’t happen sometimes do. For example:

• In the last 4 years, ECRI Institute’s Accident and Forensic Investigation Group has investigated 9 retained surgical item (RSI) incidents.

• An analysis of the Pennsylvania Patient Safety Reporting System database showed that healthcare facilities in the commonwealth reported 452 events involving RSIs in 2011—one-third of those events reportedly caused patient harm (Pennsylvania Patient Safety Advisory, September 2012).

• In October 2013, the Joint Commission issued a Sentinel Event Alert on the unintended retention of foreign objects, noting that 772 such incidents were reported to its Sentinel Event Database from 2005 to 2012, including 16 that resulted in death.

These reports have prompted us to again include the topic on the list. In addition to being a patient safety concern, RSIs are classified by the Centers for Medicare & Medicaid Services (CMS) as a hospital-acquired condition; thus, CMS withholds payment for the treatment of this condition.

Spread the word about ECRI Institute’s 2014 Top 10 Health Technology Hazards, and let it help your facility focus its patient safety efforts. If you haven’t seen it already, a free Executive Brief version of the report can be downloaded at www.ecri.org/2014hazards.

This article is based on the report that appears in the November 2013 issue of ECRI Institute’s Health Devices journal, available to members of the Health Devices System. To learn more about the Health Devices System or any ECRI Institute services, visit www.ecri.org or call 610.825.6000, ext. 5891.