SMARTER CHOICES, SAFER PATIENTS

health. DEVICES

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2014

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ECRI Institute
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guidance
ARTICLE

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2014

THIS ABRIDGED VERSION OF ECRI INSTITUTE'S ANNUAL TOP 10 LIST OF HEALTH TECHNOLOGY HAZARDS IS PROVIDED AS A COURTESY OF ECRI INSTITUTE. A MORE COMPREHENSIVE DISCUSSION OF EACH HAZARD, ADDITIONAL RECOMMENDATIONS FOR MINIMIZING THE RISKS, AND A LIST OF USEFUL RESOURCES FOR MORE INFORMATION ABOUT EACH TOPIC ARE PROVIDED IN THE FULL ARTICLE, PUBLISHED IN THE NOVEMBER 2013 ISSUE OF *HEALTH DEVICES*.

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. We intend this list to be a starting point for patient safety discussions and for setting health technology safety priorities.

THE LIST FOR 2014

1. Alarm hazards
2. Infusion pump medication errors
3. CT radiation exposures in pediatric patients
4. Data integrity failures in EHRs and other health IT systems
5. Occupational radiation hazards in hybrid ORs
6. Inadequate reprocessing of endoscopes and surgical instruments
7. Neglecting change management for networked devices and systems
8. Risks to pediatric patients from "adult" technologies
9. Robotic surgery complications due to insufficient training
10. Retained devices and unretrieved fragments

About This List

This Top 10 list of health technology hazards, developed each year by ECRI Institute's Health Devices Group, highlights the technology safety topics that we believe warrant particular attention for the coming year. Some are hazards that we see occurring with regularity. Some are problems that we believe will become more prevalent, given the way technology is evolving. And some are well-known risks that periodically warrant renewed attention.

But all the items on the list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. For each hazard we describe the risk-mitigation strategies that are currently available, making this list a practical tool for identifying high-impact steps you can take to improve patient care at your facility.

We present here our list for 2014. Additional details about each topic—including our recommendations for addressing each hazard and a list of additional resources—are available in the November 2013 issue of *Health Devices*.

Criteria for Inclusion

ECRI Institute routinely addresses model-specific design, use, and maintenance issues through our

technology evaluation, problem reporting, accident investigation, and alerting services. For this Top 10 list, we focus only on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies.

When nominating topics for consideration, ECRI Institute staff—engineers, scientists, nurses, physicians, and other patient safety analysts—draw on the resources built up through the organization's 45-year history analyzing healthcare technologies, as well as their own expertise and insight gained through examining health-technology-related problem reports, evaluating medical devices and systems, investigating incidents, observing and assessing hospital operations and practices, reviewing the literature, and speaking with healthcare professionals and device suppliers. Staff then vote on the nominated hazards, weighing factors such as the following:

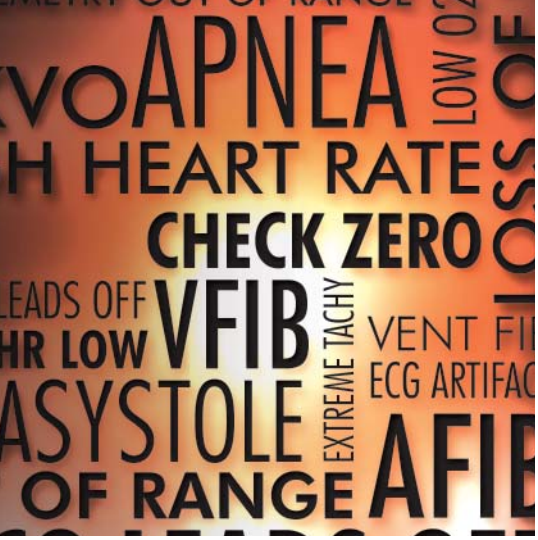
- Severity. What is the likelihood that the hazard could cause serious injury or death?
- Frequency. How likely is the hazard? Does it occur often?
- Breadth. If the hazard occurs, are the consequences likely to spread to affect a great number of people, either within one facility or across many facilities?
- Insidiousness. Is the problem difficult to recognize? Could the problem lead to a cascade of downstream errors before it is identified or corrected?
- Profile. Is the hazard likely to receive significant publicity? Has it been reported in the media, and is an affected hospital likely to receive negative attention? Has the hazard become a focus of regulatory bodies or accrediting agencies?
- Preventability. Can actions be taken now to prevent the problem or at least minimize the risks? Would raising awareness of the hazard help reduce future occurrences?

Any of these criteria can warrant including a topic on the list—although all selected hazards must, to some degree, be preventable; that is, measures must exist that healthcare facilities can take to reduce the risks.

For More Information

To access the full article, for questions about ECRI Institute's annual list of technology hazards, or for information about membership, contact ECRI Institute by telephone at (610) 825-6000, ext. 5891; by e-mail at clientservices@ecri.org; or by fax at (610) 834-1275.

Also see the box on page 13 to learn more about ECRI Institute's products and services and to find out how you can access our online self-assessment tool for gauging your facility's risks of experiencing the hazard on this list.



1. Alarm Hazards

Medical device alarms can make the difference between timely, life-saving interventions and serious injury or death. Physiologic monitors, ventilators, infusion pumps and many other devices generate clinical alarms to help caregivers keep patients safe.

However, it is possible to have too much of a good thing. Excessive numbers of alarms—particularly alarms for conditions that aren't clinically significant or that could be prevented from occurring in the first place—can lead to alarm fatigue, and ultimately patient harm. That is:

- Caregivers can become overwhelmed, unable to respond to all alarms or to distinguish among simultaneously sounding alarms.
- They can become distracted, with alarms diverting their attention from other important patient care activities.
- They can become desensitized, possibly missing an important alarm because too many previous alarms proved to be insignificant.

Beyond alarm fatigue, patients could be put at risk if an alarm does not activate when it should, if the alarm signal is not successfully communicated to staff or does not include sufficient information about the alarm condition, or if the caregiver who receives the alarm signal is unable to respond or is unfamiliar with the proper response protocol. In short, 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.

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 (www.jointcommission.org/sea_issue_50/). In June, the organization announced that alarm management would be established as a National Patient Safety Goal, with certain provisions taking effect during 2014.

Addressing clinical alarm hazards requires a comprehensive alarm management program involving stakeholders from throughout the organization. Goals for the program should include (1) minimizing the number of clinically insignificant or avoidable alarms so that the conditions that truly require attention can better be recognized and (2) optimizing alarm notification and response protocols so that the patient receives the appropriate care at the time it's needed.

For more information

ECRI Institute offers a free-access Alarm Safety Resource Site: https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Additional resources can be purchased from ECRI Institute; these include:

- The *Health Devices* alarm management series—a collection of articles to help healthcare facilities develop realistically implementable strategies to reduce clinical alarm hazards.*
- A recording of ECRI Institute's web conference "Answering the Call to Alarm Safety: Getting Ready for Joint Commission's National Patient Safety Goal"; for details, see: https://www.ecri.org/Conferences/AudioConferences/Pages/Alarm_Safety.aspx.*
- ECRI Institute's Alarm Management Starter Kit—a suite of tools for addressing the Joint Commission's National Patient Safety Goal on alarm management (available with purchase of the web conference described above).*

Customized, on-site assistance is available through ECRI Institute's Alarm Management Safety Review service. Our Applied Solutions Group can identify your alarm system vulnerabilities and provide realistic, implementable strategies to help improve alarm management at your facility.

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.

2. 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 incorrectly.

To minimize the risk of use errors, we recommend that healthcare facilities dedicate resources to regular training and assessment, both for routine users and incoming staff, so that all users receive adequate instruction and keep their skills fresh. And when purchasing new pumps, we recommend that facilities consider usability issues and involve frontline staff in the device evaluation process. These measures are particularly relevant in light of the recent changes to the infusion pump market, which have resulted in several popular models of pumps becoming unavailable because of regulatory actions or manufacturer marketing decisions. Such changes may lead healthcare facilities to switch to unfamiliar brands.

Another important consideration is to recognize the limits of safety technologies. Many pumps today are equipped with onboard drug libraries that trigger alert limit warnings for gross misprogrammings. Such "smart" technologies do a good (not perfect) job of helping to get the dose correct. This requires, however, that appropriate drug libraries are developed (and maintained) and that staff use the available safeguards appropriately. In addition, these technologies don't help prevent errors such as administering an order to the wrong patient or selecting the wrong drug.

Infusion pump integration—that is, connecting the servers for the infusion pumps with other information systems—can provide additional protections, such as helping verify that both the right patient and the right drug have been selected. Thus, we recommend that healthcare facilities begin (or continue) to implement infusion pump integration with relevant information systems.

For more information

Additional resources can be purchased from ECRI Institute; these include:

- Numerous *Health Devices* Evaluations and Guidance Articles, as well as product alerts, on infusion technologies.*
- A recording of ECRI Institute's web conference "Building a Safe Framework for Integrated Infusion Pumps"; for details, see: https://www.ecri.org/Conferences/AudioConferences/Pages/Integrated-Infusion-Pumps.aspx.*
- ECRI Institute PSO's *Deep Dive: Medication Safety*, published in December 2011; for purchase details, see: https://eshop.ecri.org/p-142-pso-deep-dive-medication-safety-events.aspx.**

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.
** Free to ECRI Institute PSO member organizations.

3. 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.

To minimize a child's exposure to high doses of ionizing radiation, healthcare providers can take actions such as the following:

- Using safer diagnostic options when appropriate. When time is not of the essence and the patient's condition does not specifically necessitate a CT scan, clinicians should consider lower-dose alternatives like x-rays, or technologies like magnetic resonance imaging (MRI) or ultrasound, which don't use ionizing radiation. (A radiologist should be consulted to determine the best option.)
- Avoiding repeat scanning. If a patient has already been scanned at another institution, the facility can try to obtain the existing images from the previous scan, rather than conducting a repeat scan.
- Following the ALARA principle. That is, using a dose that is "as low as reasonably achievable" to acquire the desired diagnostic information during any imaging procedure that uses ionizing radiation. In particular, healthcare providers should customize scanning protocols to the needs of pediatric patients—that is, recognize that settings designed for adults are not appropriate for children.

For more information

Additional resources can be purchased from ECRI Institute; these include numerous *Health Devices* guidance documents related to CT and radiation safety.*

Customized, on-site assistance is available through ECRI Institute's CT Radiation Dose Safety Review service. Our Applied Solutions Group can evaluate your facility's CT service and recommend measures to help you minimize the risks.

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.

4. Data Integrity Failures in EHRs and Other Health IT Systems

The adoption of electronic health records (EHRs) in U.S. hospitals has more than tripled from 2009 through 2012. This increase can be attributed to the quality and safety benefits that EHRs are expected to offer compared with their paper-based predecessors, as well as the financial incentives (and penalties) defined in the Health Information Technology for Economic and Clinical Health (HITECH) Act.* As the role of 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. The presence of incorrect data in such systems, however, can lead to incorrect treatment, potentially resulting in patient harm. And reports illustrate myriad ways that the integrity of the data in an EHR or other health IT system can be compromised. Contributing factors include:

- patient/data association errors—that is, one patient's data from a medical device or system mistakenly being associated with another patient's record;
- 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
- basic data-entry errors (which can be propagated much further than would have occurred with paper-based systems).

Key steps in safeguarding the integrity of electronic patient data include assessing the clinical workflow to understand how the data is (or will be) used by frontline staff; testing the system and the associated interfaces (preferably in a simulated setting) to verify that the system is functioning as intended; providing sufficient user training and support; and establishing a mechanism for users to report problems as they are discovered.

* From Farzad Mostashari's Testimony before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce, U.S. House of Representatives. 2013 Mar 21 [cited 2013 Oct 1]; see http://docs.house.gov/meetings/IF/IF02/20130321/100544/HHRG-113-IF02-Wstate-MostashariF-20130321-SD002.pdf.

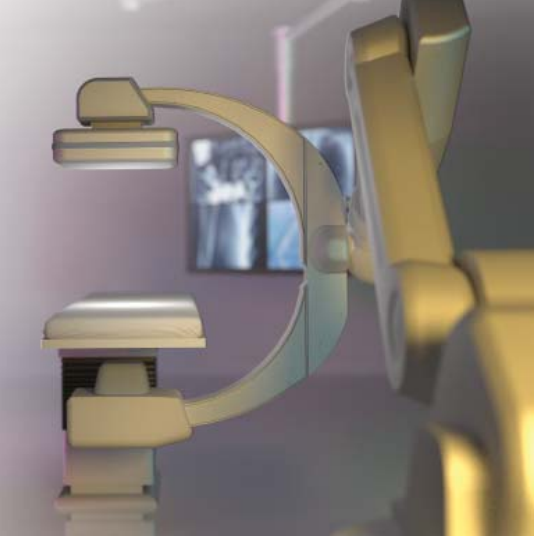
For more information

Additional resources can be purchased from ECRI Institute; these include:

- Numerous *Health Devices* articles on health IT and interoperability topics.*
- ECRI Institute PSO's *Deep Dive: Health Information Technology*, published in January 2013; for purchase details, see: https://eshop.ecri.org/p-140-pso-deep-dive-health-information-technology.aspx.**

Customized, on-site assistance is available through ECRI Institute's Readiness Assessment for Exchange of Health Information service. Our Applied Solutions Group can help you identify gaps that could affect the exchange of health information within your organization and with outside groups.

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.
** Free to ECRI Institute PSO member organizations.



5. 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 associated 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.

If a hybrid OR is to be implemented, healthcare facilities must have in place a radiation protection program that provides staff with the knowledge and technology they need to minimize occupational radiation exposures in this unique environment:

- The first step in any radiation protection program is training. An appropriate training program will address the specific needs of staff who may not have extensive experience with imaging technologies.
- The second step is shielding. Lead aprons are the first line of defense for all staff working in the vicinity of the equipment. Shielding can also be provided by additional lead barriers, such as those suspended from the ceiling. In either case, such protections are effective only if they are actually used.
- The third step is monitoring. Effective monitoring requires that radiation monitoring badges be properly worn, maintained, and reviewed. (These badges track clinician exposure to radiation by providing a cumulative radiation dose reading when the badge is later analyzed.) To augment the use of traditional badges, facilities may also choose to institute the use of electronic badges that provide real-time readings of the dose rate.

For more information

ECRI Institute's infographic "Hybrid Operating Rooms: With a Focus On Endovascular Hybrid ORs" is available, with registration, from: https://www.ecri.org/Forms/Pages/Hybrid-Operating-Rooms.aspx.

Customized, on-site assistance is available through ECRI Institute's Medical Radiation Safety Review service. Our Applied Solutions Group can assess your medical radiation services with the goal of reducing the likelihood of harm due to unnecessary and excessive radiation.

6. 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 (e.g., tissue, body fluids) 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.

Discussions of reprocessing failures frequently center on flexible endoscopes, devices that can be guided through narrow winding routes, such as the digestive tract, respiratory tract, and blood vessels, to allow physicians to view and access internal body structures less invasively than would otherwise be possible. Because flexible endoscopes are complex devices with narrow, hard-to-clean channels, they can be particularly challenging to decontaminate.

However, endoscopes are not the only devices subject to reprocessing failures. Incidents reported to ECRI Institute PSO describe other instruments and devices (e.g., arthroscopy shoulder cannulas, surgical instrument trays) that were used, or were presented for use, despite still being contaminated with potentially infectious biological matter.

Successful reprocessing of any device 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. Further, 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.

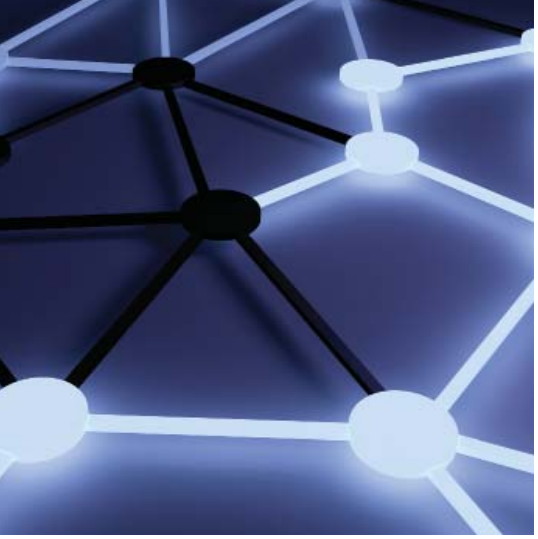
Consistent, effective reprocessing of endoscopes and other instruments requires that appropriate reprocessing protocols be developed, documented, and followed for all relevant instrument models in a facility's inventory. Staff need to be trained in these protocols, and they need adequate space, equipment, and instructional materials, as well as sufficient time to perform the procedure correctly.

For more information

Additional resources can be purchased from ECRI Institute; these include:

- The *Health Devices* Guidance Article "Clear Channels: Ensuring Effective Endoscope Reprocessing."*
- ECRI Institute PSO's article "Sterile Processing Department's Role in Patient Safety."**

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.
** Free to ECRI Institute PSO member organizations.



7. 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 one 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 one 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. For example:

- A facility-wide PC operating system upgrade caused the loss of remote-display capability for a hospital's fetal monitoring devices.
- Moving a facility's obstetrical data management system server off-site led to problems displaying fetal monitor data at the nurses' station.
- An EHR software upgrade resulted in changes to certain radiology reports, causing fields for the date and time of the study to drop from the legal record.

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. Initiatives that once may have been considered "IT projects" must instead be viewed as "clinical projects that require IT expertise." Software upgrades, security patches, server modifications, changes to or replacement of network hardware, and other system changes can adversely affect patient care if not implemented in a way that accommodates both IT and medical technology needs. Unfortunately, change management—a structured approach for completing such alterations—appears to be an underutilized practice.

Appropriate change management policies and procedures, as outlined in the recommendations in the full article, can help minimize the risks. Just as important, however, is to cultivate an environment in which IT, clinical engineering, and nursing/medical personnel (1) are aware of how their work affects other operations, patient care, and work processes—particularly clinical work processes—and (2) are able to work together to prevent IT-related changes from adversely affecting networked medical devices and systems.

For more information

Additional resources can be purchased from ECRI Institute; these include:

- Numerous *Health Devices* articles on health IT, medical and information technology convergence, and interoperability topics.*
- ECRI Institute PSO's *Deep Dive: Health Information Technology*, published in January 2013; for purchase details, see: https://eshop.ecri.org/p-140-pso-deep-dive-health-information-technology.aspx.**
- The *Risk Management Reporter* article "Risk Managers' 10 Strategies for Health IT Success"; freely available for a limited time at: https://www.ecri.org/EmailResources/PSRQ/RMRep0613-HIT.pdf.

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.
** Free to ECRI Institute PSO member organizations.

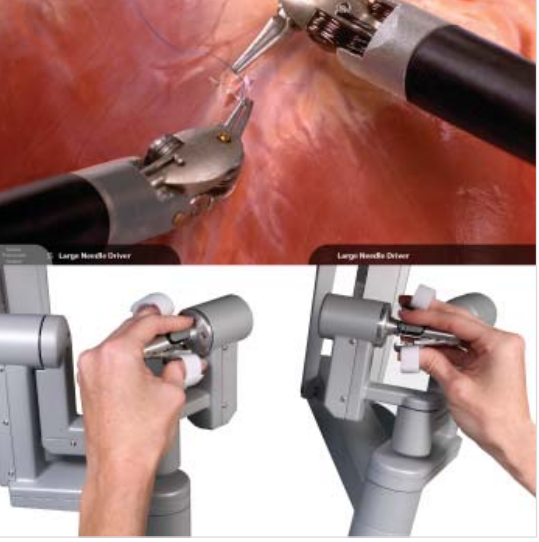
8. Risks to Pediatric Patients from "Adult" Technologies

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 due to their smaller size and ongoing physiologic changes, children may suffer adverse effects when subjected to adult-oriented healthcare techniques.

The following are just a few examples of how the care of pediatric patients can be compromised when applying "adult" healthcare technologies:

- Exposure to ionizing radiation, such as that used in CT and x-ray imaging, has been associated with an increased cancer risk. Because children are still developing, they are especially susceptible to long-term damage from such exposures. Using adult scanning techniques on pediatric patients can compound this problem, exposing children to an unnecessarily large "adult" dose and potentially exposing regions of the body outside the area of interest. We cover this topic as hazard number 3 in this year's list.
- A healthcare facility's EHR may not be configured to optimally support the care of children. For example, the system may not facilitate the recording and review of important pediatric-specific data, such as vaccinations.
- Medication dosing errors can be particularly harmful to children because of the patient's small size. This susceptibility to harm, coupled with the use of technologies that aren't optimized for pediatric patients, can lead to tragic results. Even a device as simple as a scale can contribute to significant harm: scales that report weights in both kilograms and pounds have contributed to errors in which the incorrect figure was used for weight-based dose calculations (e.g., the pounds value had been mistakenly recorded in the EHR as the kilogram value).

Whenever possible, healthcare providers should use pediatric-specific technologies, rather than using adult-oriented technology off-label or employing workarounds. 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.



9. Robotic Surgery Complications due to Insufficient Training

Robot-assisted surgery involves the use of robotic arms that are fully controlled by the movements of a surgeon, who is located at a control console several feet from the patient. The past decade has seen a rise in the implementation of such 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.

Initial training provided by the device supplier can help users become familiar with the system, but it does not teach trainees how to perform specific surgical procedures. Thus, it is up to the hospital to verify that surgical staff have the necessary procedure-specific skills. For this to happen, surgeons and staff will need to complete a multifaceted, detailed training program to develop proficiency and expertise with a multipurpose robotic surgery system. The program should require that a specified number of proctored surgeries be performed, and successful completion of the program should lead to credentialing within the hospital/system. Consideration must also be given to how the surgical team will maintain its competency with the system over time.

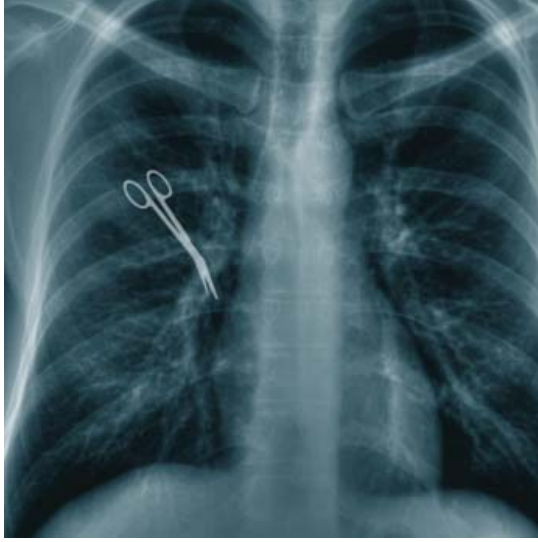
Currently, no widely recognized requirements exist for robotic surgery training and credentialing programs, so hospitals will need to make their own decisions. In the full article, we present recommendations that are based on the experiences of well-established robotic surgery programs to help hospitals that need to develop a program.

For more information

Additional resources can be purchased from ECRI Institute; these include:

- The *Health Devices* Guidance Article "Da Vinci Decisions: Factors to Consider Before Moving Forward with Robotic Surgery."*
- A recording of ECRI Institute's web conference "The Surgical Robot Invasion: Training and Safety," as well as training and credentialing guides shared by the web conference participants; for details, see: https://www.ecri.org/Conferences/AudioConferences/Pages/Surgical-Robots.aspx.*

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.



10. Retained Devices and Unretrieved Fragments

The unintended retention of a surgical item in a patient after surgery or after an interventional diagnostic procedure is the kind of medical error that can largely be prevented. But events that shouldn't happen sometimes do. For example:

- In the last four years alone, ECRI Institute's Accident and Forensic Investigation Group has investigated nine retained surgical item (RSI) incidents.
- A 2012 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 (http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Sep;9(3)/Pages/106.aspx).
- 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 our list. (It last appeared on our list for 2010.) 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.

Reports of surgical items unintentionally left inside patients following surgery or an interventional diagnostic procedure typically involve one of the following:

- A retained device, in which an entire device (including soft goods like a surgical sponge or towel) is unknowingly left behind.
- Unretrieved device fragments, in which a portion of a device (e.g., catheter tip, forceps jaw) breaks away and remains inside the patient. (Clinicians may be aware that a device fragment has been left in the patient, but decide that the fragment's location within the anatomy makes retrieval too risky.)

Risks to the patient can include prolonged or additional surgery, as would occur when an RSI is discovered and its removal is deemed appropriate, or future complications, some potentially serious, as could occur when an RSI leads to infection or causes damage to the surrounding tissue.

Visually inspecting devices before and after use and adhering to accepted surgical count procedures are key measures for preventing RSI incidents.

For more information

Additional resources can be purchased from ECRI Institute; these include:

- The *Health Devices* Evaluation "Radio-Frequency Surgical Sponge Detection."*
- ECRI Institute PSO *Patient Safety E-lerts* on retained foreign objects during robotic surgery (2012 May 31) and retained guidewires (2010 Aug 31).**
- The *Risk Management Reporter* article "The Case of the Missing Sponge: Practice Variation Is the Culprit."***

* Free to members of the Health Devices System, Health Devices Gold, and SELECTplus programs.
** Free to ECRI Institute PSO member organizations.
*** Free to members of the Healthcare Risk Control program.

KEY SAFETY RESOURCES FROM ECRI INSTITUTE

ECRI Institute is an independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care. Our unbiased, evidence-based healthcare research, information, and advice helps healthcare organizations:

- Assess and address patient safety, quality, and risk management challenges
- Select the safest, most effective medical devices, procedures, and drugs
- Procure healthcare technology in the most cost-effective manner
- Develop evidence-based health coverage policies
- Align capital investments with strategic technology needs

Following are a few of the products and services we offer to help healthcare organizations address the kinds of health technology hazards described in this report.

Online Hazard Self-Assessment Tool

As a complement to this report, ECRI Institute has developed an online Health Technology Hazard Self-Assessment Tool to help healthcare facilities gauge their risks of experiencing any of the hazards on the list. The Self-Assessment Tool enables users to invite multiple individuals and departments to respond to a short survey on any of the hazard topics; once the surveys are completed, the tool generates a report rating your level of risk for each hazard (from low to high) and identifying specific practices that could help reduce your risk.

Members of several ECRI Institute programs can access the Health Technology Hazard Self-Assessment Tool from their member home page at www.ecri.org. If you are not a member and would like to learn more about using the tool, see the contact information below.

Technology Management Services

More in-depth information on a wide range of medical technology issues is available through programs such as the following:

- The **Health Devices** program is best known for its comparative, brand-name evaluations of medical devices and systems. Based on extensive laboratory testing, ECRI Institute's evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.
- **SELECTplus**, ECRI Institute's industry-leading advisory service for supply chain and materials management professionals, assists with the safe, cost-effective procurement of capital medical equipment and health information technologies.

In addition, ECRI Institute's Applied Solutions Group provides customized services and on-site assistance to help healthcare facilities and health systems address challenges ranging from managing medical equipment needs for a major construction project to identifying and addressing patient safety vulnerabilities.

Patient Safety, Quality, and Risk Management

ECRI Institute also offers a variety of programs designed to meet the needs of patient safety, quality, and risk management professionals; these include:

- **ECRI Institute PSO**, a component of ECRI Institute dedicated to collecting and analyzing patient safety information and sharing lessons learned and best practices, operates under the Patient Safety and Quality Improvement Act. This act created a framework for healthcare providers to share data with PSOs, who in turn can provide analysis and feedback regarding patient safety matters in a protected legal environment. Additionally, PSOs can collect the information in a standardized format in order to aggregate the data and learn from it. For information about becoming an ECRI Institute PSO member organization, refer to www.ecri.org/pso.
- **Healthcare Risk Control (HRC)** is a membership program providing access to a wealth of practical resources, including more than 300 unbiased, in-depth risk analyses; dozens of self-assessment tools; more than 500 policies and procedures that can be tailored to your needs; ready-to-use education and training tools; standards and best practices; and bimonthly and online newsletters.

To Learn More

This executive briefing of ECRI Institute's annual Top 10 list of health technology hazards is provided as a courtesy of ECRI Institute. A more comprehensive discussion of each hazard, additional recommendations for minimizing the risks, and a list of useful resources for more information about each topic are provided in the November 2013 issue of *Health Devices*, available for purchase at a discounted rate at https://eshop.ecri.org/p-160-health-devices-journal-november-2013.aspx.

For more information about this report, the self-assessment tool, or any of our membership programs, contact ECRI Institute by telephone at (610) 825-6000, ext. 5891; by e-mail at clientservices@ecri.org; or by fax at (610) 834-1275. You can also visit us online at www.ecri.org.

STILL ALARMING.

Alarm events are accidents waiting to happen—the result of a perfect storm in an error-prone system. Patient deaths and other alarm-related events plague hospitals and make the news. And, they persist on ECRI Institute's annual list of Top 10 Health Technology Hazards.

ECRI Institute's **Alarm Management Safety Reviews** can help. Our experienced healthcare consultants come on site to assess your organization's culture, infrastructure, practices, and technology. Our approach identifies and addresses your patient safety vulnerabilities and provides implementable alarm management strategies.

▶ Don't wait for a perfect storm. Take steps now to improve alarm safety.

Visit www.ecri.org/alarmsafety

ECRI Institute

The Discipline of Science. The Integrity of Independence.

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OBJECTIVES OF THE HEALTH DEVICES SYSTEM

To improve the effectiveness, safety, and economy of health services by:

- Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
- Functioning as an information clearinghouse for hazards and deficiencies in medical devices.
- Encouraging the improvement of medical devices through an informed marketplace.

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