TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2014

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. AS YOU GO ABOUT PLANNING YOUR SAFETY INITIATIVES, IT'S VITAL TO KNOW WHICH RISKS TO TACKLE FIRST.

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

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.

Our annual Top 10 list 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 the technology landscape 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 one, 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.

Key Safety Threats to Manage in the Coming Year

The list is not comprehensive, nor will all of the hazards listed here be applicable at all healthcare facilities. We encourage facilities to use the list as a starting point for patient safety discussions and for setting their health technology safety priorities.

The List for 2014

As in previous years, the Top 10 list includes a mix of old and new topics. Alarm hazards and medication administration errors using infusion pumps, for example, retain the first and second positions on the list because of their prevalence and their potential to result in serious patient harm. New topics this year include hazards related to radiation exposure in hybrid ORs and complications arising from insufficient training in the application of robotic surgery. These are two rapidly evolving technology areas where, we believe, the inherent risks may not be fully appreciated.

We caution readers that the exclusion of a topic that was included on a previous year's list should not be interpreted to mean that the topic no longer warrants attention. Most of those hazards persist, and hospitals should continue working toward

minimizing them. Rather, our experts determined that other topics warranted greater attention for the coming year.

The hazards described here affect many departments (e.g., OR, radiology, sterile processing) and many professions, including clinicians and clinical department managers, patient safety, risk management and quality, administration, clinical engineering, IT, and materials management. We encourage you to alert staff in those areas to this list and its recommendations.

Criteria for Inclusion

This list focuses on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. It does not discuss risks or problems that pertain to specific models or suppliers. The hazards we discuss here reflect use errors that our research shows are being repeated by clinicians or that our experts determine may become more prevalent (e.g., as a technology becomes adopted more broadly). These trends point to the need for increased awareness, for remediating and harm-

GENERAL RECOMMENDATIONS

Specific advice for avoiding adverse incidents is provided within the section for each hazard in the Top 10 list. More generally, healthcare facilities that are well prepared to tackle these hazards will be able to state that:

▷ Technology-related safety is an organizational priority.

▷ All clinical staff are qualified (trained, licensed, or certified) for the equipment and treatments offered.

▷ A mechanism has been established for identifying and responding to technology-related hazard notices and other safety problems, such as those reported in ECRI Institute's *Health Devices Alerts*, for the devices in the facility's inventory. In addition, outstanding alerts are identified for any new equipment before it is put into service.

A well-prepared facility will also have an organization-wide adverse event reporting system for device problems and incidents, in which:

▷ Staff members are encouraged to report all events, including near misses, to the facility's adverse event reporting system. Consistent

with the ideals of establishing a culture of safety, the facility should take a nonpunitive approach toward problem reporting, encouraging reporting to help identify problems, work toward their resolution, and facilitate learning.

▷ A standard procedure has been instituted to assess reported events (and near misses), and criteria have been established for determining when events require further analysis, including root-cause analysis.

▷ Relevant events are reported to the manufacturer, to ECRI Institute, and to the appropriate regulatory agencies (e.g., FDA).*

▷ Trends of errors are examined to identify issues that might require increased awareness, process or technology changes, or other forms of remediation.

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* Problems can be reported to ECRI Institute using the "Report a Device Problem" link located in the banner at www.ecri.org.

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mitigation steps, or for improved design for a class of devices.

To identify the 10 topics that will be of greatest concern in the year to come, we start with a preliminary list of technology-related safety topics suggested by ECRI Institute engineers, scientists, nurses, physicians, and other patient safety analysts. When nominating topics for consideration, staff draw on the resources built up through ECRI Institute's 45-year history analyzing healthcare technologies, as well as their own expertise and insight gained through investigating incidents, observing operations and assessing hospital practices, reviewing the literature, and speaking with healthcare professionals, including clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators, and device suppliers. Another key source of information that staff consider are the thousands of health-technology-related problem reports that we receive through our Problem Reporting Network and through data that participating facilities share with our patient safety

organization, ECRI Institute PSO. (To report a medical device problem to ECRI Institute, use the "Report a Device Problem" link at the top of our home page, www.ecri.org. For more information about ECRI Institute PSO, refer to the box on page 369.)

After this topic-nomination phase, our professionals review the items on the preliminary list to select their top 10. When making this assessment, staff weigh 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?

While all the topics we select for the list must, to some degree, be preventable—that is, measures must exist that healthcare facilities can take to reduce the risks—the topics selected for inclusion need not meet all the rest of the criteria. Any of the other criteria can warrant including a topic on the list. We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities. (Members of several ECRI Institute programs can also use our Health Technology Hazard Self-Assessment Tool, which can help them gauge their risks of

experiencing any of the hazards on the list; see the box on page 367.)

For additional information about each hazard, including more detailed guidance for minimizing the risks, refer to the list of resources at the end of each section. In addition, the "General Recommendations" box on page 356 describes steps you should be taking throughout your facility to make your safety initiatives as effective as possible.

1. 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 one 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.

Discussion

Medical device alarms can make the difference between timely, life-saving interventions and serious injury or death: Physiologic monitors alarm when the patient's heart rate, blood pressure, or blood oxygenation falls outside specified limits or when an abnormal heart rhythm develops. Ventilators alarm when breathing circuits become disconnected or occluded. Infusion pumps alarm when air is in the line or a drug bag is empty. These are just a few examples of the devices and conditions that can 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 for conditions that could be prevented (e.g., poor contact between an ECG electrode and the patient's skin causing a leads-off alarm)—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 interrupting their thought processes or diverting their attention from other important patient care activities.

▷ They can become desensitized, possibly missing an important alarm because the sounds cease to be distinct in their minds or because too many previous alarms proved to be insignificant.

In addition, the noise from excessive alarms can hinder a patient's ability to rest and recuperate, it can increase anxiety among family members, and it can create a more stressful work environment for staff. Such factors may prompt caregivers to take unsafe actions, such as decreasing the alarm volume to an inaudible level or even turning off the alarm completely.

Beyond alarm fatigue, patients could be put at risk if any of the following occurs:

▷ An alarm does not activate when it should (e.g., the device is not configured correctly for the care area or patient, the patient is not connected to the device properly).

▷ The alarm signal is not successfully communicated to staff (e.g., nurses at one end of a long corridor are unable to hear or see alarms originating at the other end).

▷ The alarm signal does not include sufficient information about the alarm condition (e.g., an ancillary alarm notification system does not communicate the nature or priority of the alarm).

▷ The caregiver who receives the alarm signal is unable to respond (e.g., the nurse is unable to leave another patient, and no backup coverage has been established).

▷ Caregivers do not respond to the alarm for some other reason (e.g., staff are unclear about who has responsibility for responding to the alarm).

To compel healthcare organizations to work toward addressing these hazards,

* See www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.PDF.

ECRI INSTITUTE'S ALARM MANAGEMENT STARTER KIT

To coincide with its August 14, 2013, web conference on alarm safety, ECRI Institute released an Alarm Management Starter Kit to help hospitals meet the 2014 requirements of the Joint Commission's National Patient Safety Goal on alarm management (NPSG.06.01.01). The kit is intended to serve as a starting point from which hospitals can begin to create their own alarm management programs. It includes the following tools:

1. Sample announcement from leadership. This sample letter can serve as a guide to assist hospital leaders in announcing the alarm management effort and in communicating its importance to staff, particularly to clinical staff whose work may be affected by—and, as importantly, whose expertise may contribute to—the effort.

2. Alarm management team roster. One of the first steps in complying with the Goal—and, more broadly, in managing clinical alarms—is the creation of a multidisciplinary alarm management team. This document offers suggestions on who should be on the team and why.

3. Sample care area assessment form. This form suggests issues for members of the alarm management team to consider when assessing individual care areas for factors that can impede effective alarm management. The form directs the user to rate both the alarm load within the care area and any obstacles to effective alarm communication and response.

4. Sample nursing staff survey. Every alarm management effort should involve obtaining feedback directly from frontline caregivers, particularly from nursing staff. This tool solicits information from nursing staff about which alarm signals (within their care area) warrant the attention of the alarm management team.

5. Sample incident-report review. This document is intended to guide the team through some of the issues to think about during its review of the facility's previously submitted alarm-related incident and problem reports, helping to determine what degree of risk a particular alarm signal may present.

6. Alarm management resources. This tool directs the alarm management team to guidance documents, case studies, white papers, and other resources that serve as a starting point for research into alarm management best practices.

7. Starter list of alarm signals. This document lists those medical devices and associated alarm signals that ECRI Institute believes every hospital should consider when initiating an alarm management program. Even if your team eventually determines that managing other signals is more important, we recommend that you initially spend some time thinking about the items on this list.

8. Sample alarm review tool. This Excel spreadsheet is intended to serve as a repository for information obtained using tools 3 through 7 listed above. The spreadsheet allows the team to compile all the information collected and simultaneously review all the key alarm signals identified by the team. Once information is entered, Excel functions (e.g., filter, sort) can be used to facilitate simultaneous review of ratings that the team has assigned to all the unique alarm signals under consideration.

For information about ECRI Institute's web conference or to access the starter kit (available only to members or paid conference registrants), visit https://www.ecri.org/Conferences/AudioConferences/Pages/Alarm_Safety.aspx.

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the Joint Commission announced in June 2013 that alarm management would be established as a National Patient Safety Goal, with certain provisions taking effect during 2014. The new goal focuses on the management of "clinical alarm systems that have the most direct relationship to patient safety." During 2014, accredited organizations will be expected to establish alarm system safety as a priority and to identify the alarm hazards that they will address based on their individual situations. Organizations will then have until 2016 to develop and implement specific policies and procedures to combat identified hazards and to educate their staff accordingly. ECRI Institute has developed a series of articles (see the list of member resources below) and a collection of tools (see the

box on this page) to help hospitals address the Joint Commission's goal.

Recommendations

Addressing clinical alarm hazards is not simply a matter of making sure that alarms are turned on or that the alarm volume is set appropriately. It requires a comprehensive alarm management program involving stakeholders from throughout the organization. The facility must dedicate long-term effort to developing and implementing the program, to assessing and refining its functionality, and to adapting the program to changing clinical practices and medical technologies.

Goals for an alarm management program will include both (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. Following are some initial considerations for establishing such a program. For details and additional recommendations, refer to our series on alarm management published in *Health Devices*. (The first two articles appeared in the August and September 2013 issues. A third will appear in next month's issue.)

▷ Recognize that alarm hazards are not just a technology problem; issues of organizational culture and processes must also be examined. Leadership

must demonstrate a readiness to tackle the problem.

▷ Address the problem through a coordinated, multidisciplinary effort. Lasting improvements cannot be achieved by departments acting in isolation; thus, a key early step will be to form a multidisciplinary alarm management team.

▷ Invest the time to understand how alarms are used at your facility. A successful program will require identifying where your vulnerabilities lie and developing appropriate strategies to limit hazards.

▷ Consider the needs of each care area individually. Although reducing clinical alarm hazards will require an organization-wide effort, the risks will vary from one care area to the next, and the solutions will need to be tailored to each area individually.

▷ Involve frontline staff in identifying and implementing improvement strategies to help match the strategies to the needs of, and the workflow in, each clinical environment.

▷ Assess the effect of the strategies that are implemented, and revise or refine the program as needed.

▷ Promote your successes. Doing so can help staff see the value of any new approach and can keep the organization focused on this important patient safety program.

Member Resources

Health Devices alarm management series:

Alarm management as a patient safety goal: initial considerations, useful resources [guidance article]. 2013 Aug;42(8):242-7. (This article includes a list of additional resources—from ECRI Institute and other organizations and researchers—that hospitals may find useful as they seek to better understand and address clinical alarm hazards.)

The life cycle of an alarm: a conceptual model for understanding clinical alarm hazards [guidance article]. 2013 Sep;42(9):294-300.

The third article in the series, which will be published in the December issue, describes the steps involved in establishing an alarm management program.

ECRI Institute web conference and related materials:

Answering the call to alarm safety: getting ready for Joint Commission's National Patient Safety Goal [web conference]. 2013 Aug 14. Conference materials available from: https://members2.ecri.org/Components/HDJournal/Pages/Webinar_AlarmSafety0816-6617.aspx. (Nonmembers can view a description of the web conference at https://www.ecri.org/Conferences/AudioConferences/Pages/Alarm_Safety.aspx.)

Alarm Management Starter Kit of tools for addressing the Joint Commission's National Patient Safety Goal on alarm management. Available from: https://members2.ecri.org/Components/HDJournal/Pages/Webinar_AlarmSafety0816-6617.aspx. (For details about the starter kit, see the box on page 358.)

ECRI Institute. Physiologic monitoring systems: our judgments on eight systems [evaluation]. *Health Devices* 2013 Oct;42(10):310-40. (Alarm-related issues represented a major portion of our findings.)

Resource Center:

The "Alarm Safety" documents within the Safety Center section of the Health Devices Physiologic Monitoring Resource Center. Available from: https://members2.ecri.org/Components/HDJournal/Pages/ResourceCenter_PhysMon.aspx.

Additional Resources

Refer to the August 2013 Health Devices *for a more complete list of resources. Also see the box on page 373 for information about ECRI Institute's Alarm Management Safety Review service.*

Association for the Advancement of Medical Instrumentation (AAMI):

AAMI library of best practices. Available from: www.aami.org/htsi/alarms/library.html.

Monograph: Clinical alarms: 2011 summit—a siren call to action [report from the 2011 Medical Device Alarm Summit]. Arlington (VA): AAMI; 2011. Also available: www.aami.org/htsi/alarms/pdfs/2011_Alarms_Summit_publication.pdf.

Clinical alarm summit website: www.aami.org/meetings/summits/alarms.html.

Association for the Advancement of Medical Instrumentation (AAMI) Foundation Healthcare Technology Safety Institute (HTSI):

Clinical alarms white papers. Safety Innovation Series. Available from: www.aami.org/htsi/safety_innovation.html.

Clinical alarms webinars. Available from: www.aami.org/htsi/alarms/webinars/index.html.

ECRI Institute's alarm safety resource site (free access): https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Joint Commission:

Alarm safety [web conference]. 2013 May 1. Available from: www.jointcommission.org/alarm_safety_webinar. (Features an introduction from ECRI Institute's James P. Keller, vice president, health technology evaluation and safety.)

Medical device alarm safety in hospitals. *Sentinel Event Alert* 2013 Apr 8;(50):1-3. Also available: www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.pdf.

National Patient Safety Goal on alarm management [prepublication requirements online]. 2013 Jun 25 [cited 2013 Jul 18]. Available from: www.jointcommission.org/assets/1/18/PREPUB-06-25-2013-NPSG060101.pdf.

2. Infusion Pump Medication Errors

Infusion pumps are invaluable to health-care, 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.

Infusion devices are the subject of more adverse incident reports to FDA than any other medical technology (AAMI 2010). In addition, the consequences of such incidents can be severe: 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. Reports submitted to FDA from 2005 through 2009 include 710 deaths associated with infusion devices (AAMI 2010).

Discussion

A market in flux. The infusion pump market has changed considerably since our December 2012 Evaluation of large-volume pumps: Baxter's Sigma Spectrum and all of Hospira's pumps have become unavailable due to regulatory actions by FDA. In addition, Hospira has chosen to stop marketing its Symbiq model, and Fresenius recently received clearance to introduce a new pump into the U.S. market. (See the August 2013 *Health Devices* for a discussion of these changes.)

These and other changes in the market may lead healthcare facilities to switch to unfamiliar brands. To minimize the potential for use errors with new devices, be sure to consider usability issues and to involve frontline staff when evaluating pumps for purchase.

As we discussed in the December 2012 issue, some pumps have buttons that are not labeled in an intuitive manner or that involve user interfaces that are cumbersome to navigate—two factors that could contribute to use errors. Other devices, while user-friendly, can present "learning curve" issues for operators who have already become familiar with another pump and all the idiosyncrasies and workflow details associated with it. ECRI Institute's "Infusion Pump Test Criteria" list includes all the factors we assess when evaluating infusion pumps and can help facilities determine which factors to consider when assessing pumps for purchase. The criteria are available through our Large-Volume Infusion Pump Resource Center (see https://members2. ecri.org/Components/HDJournal/Pages/ InfusionPumpRC_TestCriteria.aspx).

The limits of "smart" technology. Infusion safety is often discussed in terms of the "Rights of Medication Administration," an expanding list that includes the five traditional "rights": the right patient, the right drug, the right dose, the right route, and the right time.

Pumps that are equipped with "smart" technology—onboard drug libraries that trigger alert limit warnings for gross misprogrammings (e.g., 10- or 100-fold overdoses)—do a good (but not perfect) job of helping to get the dose correct. However, they don't help ensure the other "rights." As we noted in the July 2013 *Health Devices*, many types of pump-related medication errors can't be addressed by using drug libraries alone. For example, wrong-drug selections, administering an order to the wrong patient, and mispro-grammed doses that do not exceed an alert limit (but that are still potentially harmful) are errors that can elude a smart pump's safety net.

Infusion pump integration—that is, connecting the servers for the infusion

pumps with other information systems—can help achieve a few of the other "rights." Integrated pumps can help verify that both the right patient and the right drug have been selected: A clinician could scan a bar code on the patient, the drug, and the pump, for example, and the system can automatically check that everything matches the electronic order. Also, pump integration can provide additional dose protection, either by autoprogramming the pump to match the order or by checking the pump programming against the order.

Reports to ECRI Institute PSO demonstrate the diversity of infusion-related errors and help make a safety case for integrating infusion pumps. A query of the PSO database revealed 468 infusion-related events reported between May 2010 and March 2012. We analyzed a random sample of 100 of these events, which we grouped into the 10 categories shown in the table on page 361. Smart pump drug libraries could potentially have averted 32% of the reported problems, but typically only if the entered values triggered alert limits. Successful pump integration, on the other hand, could potentially have averted 81% of the reported problems.

POTENTIAL ROLE OF PUMP INTEGRATION IN AVERTING INFUSION-RELATED EVENTS

Problem	Number reported	Addressed by smart pump drug libraries?	Addressed by pump integration?
Wrong concentration	29	No	Yes
Wrong entry of more than one parameter	19	Yes, if it triggers an alert	Yes
Secondary (piggyback) infusion setup error	15	No	No
Wrong weight	8	No	Yes
Wrong rate	8	Yes, if it triggers an alert	Yes
Pump is not turned on	6	No	Yes*
Wrong drug	6	No	Yes
Wrong units	4	Yes	Yes
Set is not connected to patient	4	No	No
Wrong dose	1	Yes, if it triggers an alert	Yes

* Integrated pumps may be able to address this using Integrating the Healthcare Enterprise's Point-of-Care Infusion Verification (IHE PIV) messaging, which, while not enabling a pump to be turned on automatically, includes the capability for the pump server to return an error message to the BPOC system indicating that the pump is not turned on.

Recommendations

▷ During the selection and purchasing process, assess the human factors of prospective infusion devices during trials. Be sure to get buy-in from staff members who will be using the system.

▷ When implementing a new infusion system, take advantage of vendor consulting programs and plan for these services in the initial purchase negotiations. Arrange for a vendor representative to provide training and troubleshooting assistance, both during the initial start-up and as future needs arise.

▷ Emphasize to clinicians the importance of infusion pump technology safeguards. Recognize that the introduction of new infusion technologies may necessitate some changes in workflow.

▷ Dedicate resources to regular training and assessment, not only for routine users, but also to ensure that incoming staff members receive adequate instruction and that infrequent users keep their skills fresh.

▷ Identify inappropriate practices by staff (e.g., failure to utilize smart pump drug libraries), and rectify them as soon as possible.

▷ When using smart pumps:

— Develop and maintain appropriate drug libraries for your pumps; do not rely on preloaded or outdated/non-optimized drug libraries. Often, this would be the responsibility of the pharmacy department, but in some facilities it is handled by nursing or even a dedicated staff position.

Drug libraries should have standardized concentrations of commonly used drugs and solutions. To determine appropriate concentrations, review the practices at your facility and also consult with other organizations to identify best practices.

The drug library should also accommodate changes in clinical practice. Pharmacy and medical staff should be directed to alert the drug library manager to changes in either formulary or clinical practice that could affect the drugs, concentrations, or dose limits in the library.

— Invest in resources to analyze infusion pump data (e.g., smart pump alert history) to improve work practices and policies. Develop a procedure that identifies the staff member responsible for data analysis and that describes how and when infusion pump data will be captured, analyzed, and disseminated.

▷ Begin (or continue) to implement infusion pump integration with information systems for checking orders and documenting administration.

— Implement a roadmap for integration, recognizing that this is a multistep, multiyear process. For guidance, refer to the July *Health Devices* article "Infusion Pump Integration: Why Is It Needed, and What Are the Challenges?" as well as the AAMI Foundation Healthcare Technology Safety Institute white paper on integration.

— When selecting new infusion pumps, consider the technology's ability to be integrated with electronic ordering, administration, and documentation systems (both those in place currently and those anticipated within the pumps' life span). Sample language that can be incorporated into a request for proposal is available at www.ihe.net/resources/upload/ihe_pcd_user_handbook_2011_edition.pdf.

Member Resources

Resource Center:

Large-volume infusion pumps. Available from: https://members2.ecri.org/Components/HDJournal/Pages/ResourceCenter_LVP0706-2471.aspx.

*Health Device*s:

Fluid situation: recent changes in the infusion pump market [guidance article]. 2013 Aug;42(8):263-4.

Infusion pump integration: why is it needed, and what are the challenges? [guidance article]. 2013 Jul;42(7):210-21.

Medication administration errors using infusion pumps [hazard no. 2]. In: Top 10 health technology hazards for 2013: key patient safety risks, and how to keep them in check [guidance article]. 2012 Nov;41(11):342-65.

Secure connections: IHE showcases interoperability certification at the 2013 Connectathon [guidance article]. 2013 Jun;42(6):194-7.

Which smart pumps are smartest? Ratings for six large-volume infusion pumps [evaluation]. 2012 Dec;41(12):378-91.

Web conference:

Building a safe framework for integrated infusion pumps. 2012 Aug 15. Conference materials available from: https://members2.ecri.org/Components/HDJournal/Pages/webinar_IntegratedPumps.aspx.

Additional Resources

Association for the Advancement of Medical Instrumentation (AAMI) Foundation Healthcare Technology Safety Institute (HTSI):

Best practice recommendations for infusion pump-information network integration [web conference]. Conference materials available from: www.aami.org/meetings/webinars/2013/012313_HTSI_Infusion_Pump_slides.pdf.

Best practice recommendations for infusion pump-information network integration [white paper]. Arlington (VA): AAMI; 2012. Safety Innovation Series. Also available: www.aami.org/htsi/SI_Series/Infusion_Pump_White_Paper.pdf.

Infusing patients safely. Priority issues from the AAMI/FDA Infusion Device Summit. Arlington (VA): AAMI; 2010. Also available: www.aami.org/publications/summits/AAMI_FDA_Summit_Report.pdf.

Infusion Systems Safety Initiative website: www.aami.org/htsi/infusion/index.html.

ECRI Institute PSO. *ECRI Institute PSO deep dive: medication safety*. Plymouth Meeting (PA): ECRI Institute PSO; 2011 Dec. (Available for purchase: https://eshop.ecri.org/p-142-pso-deep-dive-medication-safety-events.aspx.)

Integrating the Healthcare Enterprise (IHE). IHE patient care device user handbook. 2011 Aug. Also available: www.ihe.net/resources/upload/ihe_pcd_user_handbook_2011_edition.pdf.

Pennsylvania Patient Safety Authority. Smart infusion pump technology: don't bypass the safety catches. *PA PSRS Patient Saf Advis* 2007 Dec;4(4):139-43. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/dec4(4)/Pages/139.aspx.

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. (See the figure on page 363 for the estimated cancer risks to younger patients from a single scan.)

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.

Discussion

CT scans make use of ionizing radiation, which can damage DNA and other cellular structures. This in turn can lead to an increased risk of cancer. The potential for such damage is estimated by calculating the effective dose. The greater the effective dose, the greater the likelihood of harm. The effective dose delivered by CT is among the highest in diagnostic radiology. As mentioned above, radiation exposure is a particular concern for children, whose physiologic differences compared to adults puts them at a much higher risk of cancer.

The level of risk is subject to considerable debate, the calculations being largely based on data collected following the atomic bomb detonations during World War II. However, retrospective studies are now being published that indicate an increased risk of future cancers for children exposed to CT. In Australia, Matthews et al. (2013) looked at the records of 680,211 people who were exposed to CT at an age of 0 to 19 years. The authors found that cancer incidence, while low, was

24% higher compared to individuals who were not exposed to CT. In the United Kingdom, Pearce et al. (2012) looked at the records of almost 180,000 people who were younger than 22 when they were first examined with CT. They found a correlation between cumulative dose levels from previous CT scans and the risk of later developing leukemia or brain cancer; the higher the cumulative dose, the greater the risk.

Actions that healthcare providers can take to minimize a child's exposure to high doses of ionizing radiation include the following:

Using safer diagnostic options when appropriate. CT's ability to generate detailed images in a few seconds makes it an excellent choice for quickly diagnosing and treating imminently life-threatening injuries or illnesses. However, when time is not of the essence and the patient's condition does not specifically necessitate a CT scan, alternatives such as the following should be considered (a radiologist should be consulted to determine the best option):

▷ Magnetic resonance imaging (MRI). Though typically requiring more time and patient cooperation than CT, MRI generates excellent soft-tissue images without the application of ionizing radiation. In many cases, MRI can provide results comparable to those of CT, and it is considered the preferred choice for diagnosing problems such as ligament and tendon damage, spinal cord injuries, and brain tumors.

▷ Ultrasound. While it does not produce images of the same quality as CT, ultrasound is still effective at revealing the presence of soft-tissue abnormalities. Because ultrasound has difficulty imaging through bone and air-filled lungs, this technology is most commonly used for scanning abdominal organs.

▷ X-rays. Because radiography, including digital radiography, uses substantially lower radiation dose than CT, it should be considered as an alternative to CT when diagnosing children.

LIFETIME CANCER RISK—INCIDENCE AND MORTALITY FROM A SINGLE CT SCAN
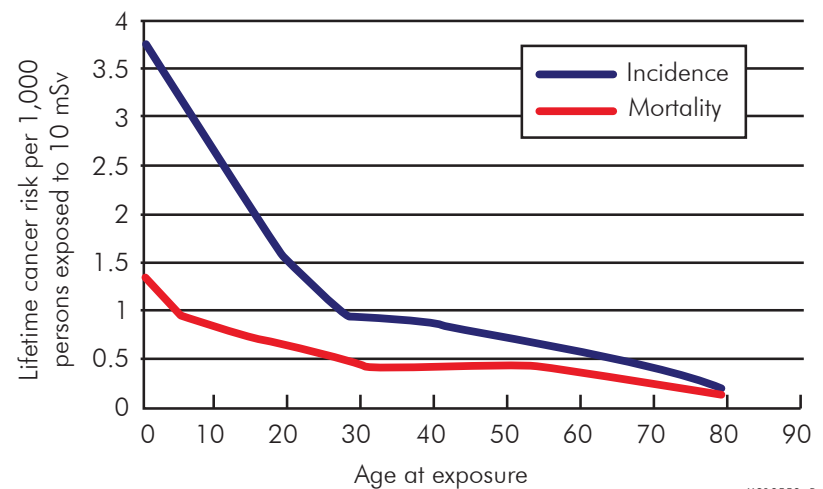
High cancer risk from pediatric CT. This graph of an individual's lifetime cancer risk based on a single 10 mSv CT exam shows a much higher likelihood of developing cancer for young patients. *Source:* BEIR 2005, Tables 12D-1 and 12D-2; sexes combined using 2005 estimates from the U.S. Census Bureau.

Furthermore, some new digital techniques, such as digital tomosynthesis, are becoming available that improve the amount of information available with radiography without greatly increasing the radiation dose.

Avoiding repeat scanning. In some instances, a patient who has already been scanned at one institution may be brought to a new facility by referral or by the parents seeking a second opinion. As discussed in an April 2012 *Health Devices* Safety Matters article, obtaining the existing images from the previous scan can greatly reduce the need for repeat scans, and thus decrease the amount of radiation pediatric patients are exposed to over the course of their diagnosis and treatment.

Following the ALARA principle. When it is determined that a child's healthcare would benefit from a CT scan, care must be taken to use a dose that is "as low as reason-ably achievable" (ALARA) to acquire the desired diagnostic information. This can include avoiding the use of "adult size" doses on children, as well as minimizing radiation exposures to parts of the body that are beyond the area of interest.

The Image Gently campaign, initiated by the Alliance for Radiation Safety in Pediatric Imaging, provides resources for healthcare providers, patients, and parents on topics related to radiation protection in the imaging of children.

Recommendations

▷ Because CT scans deliver a comparatively high radiation dose, implement appropriate use criteria for determining whether alternative methods—such as MRI, ultrasound, or x-ray—could be used when urgency or symptoms do not necessitate CT. (For example, refer to the American College of Radiology's

Appropriateness Criteria, available at www.acr.org/Quality-Safety/Appropriateness-Criteria.) A radiologist should be consulted to determine the best method.

▷ Before initiating a new CT study, try to identify whether a scan has already been performed on the patient, perhaps at another institution. Obtain the results of these scans if possible, and consider whether they are sufficient for diagnosis and treatment without the need for further scanning.

▷ When CT has been determined to be necessary:

— Use the ALARA principle to minimize radiation exposure.

— Customize scanning protocols to the needs of pediatric patients—that is, recognize that settings designed for adults are not appropriate for children.

— Take care to avoid beyond-boundary scanning (i.e., unnecessarily delivering the dose beyond the anatomical area of interest) and overexposure.

▷ Update your scanning protocols as necessary to reflect the latest guidance from professional organizations such as the American College of Radiology and the American Association of Physicists in Medicine.

Member Resources

Resource Center:

Computed tomography. Available from: https://members2.ecri.org/Components/HDJournal/Pages/Computed-Tomography-Resource-Center.aspx.

Health Devices:

Balancing radiation dose and contrast dose may reduce age-specific risk in abdominal CT [safety matters]. 2013 Apr;42(4):137.

CT radiation dose: understanding and controlling the risks [guidance article]. 2010 Apr;39(4):110-25.

Finding: importing outside images into PACS reduces repeat imaging [safety matters]. 2012 Apr;41(4):126.

Radiation dose in computed tomography: why it's a concern and what you can do about it [guidance article]. 2007 Feb;36(2):41-63.

Recent sources highlight need to control pediatric imaging dose [safety matters]. 2012 Aug;41(8):264-6.

Study: imaging beyond anatomical boundaries often occurs in chest and abdominal CT scans [safety matters]. 2012 Apr;41(4):126.

Top 10 health technology hazards, previous editions:

2013 list: Unnecessary exposures and radiation burns from diagnostic radiation procedures. Hazard no. 3. 2012 Nov;41(11):350-1.

2013 list: Inattention to the needs of pediatric patients when using "adult" technologies. Hazard no. 7. 2012 Nov;41(11):358-60.

Additional Resources

American College of Radiology (ACR). ACR appropriateness criteria [online]. 2013 [cited 2013 Oct 31]. Available from: www.acr.org/Quality-Safety/Appropriateness-Criteria.

Food and Drug Administration (FDA), U.S.:

Radiation-emitting products: what are the radiation risks from CT? [online]. 2009 Aug 6 [cited 2013 Sep 24]. Available from: www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm.

Radiation-emitting products: pediatric x-ray imaging [online]. 2012 May 14 [cited 2013 Sep 24]. Available from: www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm.

FDA's pediatric dose reduction efforts. Public meeting: device improvements for pediatric x-ray imaging, July 16, 2012 [slideshow online]. [cited 2013 Sep 24]. Available from: www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM313227.pdf.

Initiative to reduce unnecessary radiation exposure from medical imaging [online]. 2012 May 17 [cited 2013 Sep 24]. Available from: www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm.

Gislason A, Elbakri IA, Reed M. Dose assessment of digital tomosynthesis in pediatric imaging. In: *Proc SPIE* 7258. Medical Imaging 2009: Physics of Medical Imaging; Lake Buena Vista (FL); 2009 Mar 13; Conference volume 72585V.

Grady D. CT scans increase children's cancer risks, study finds [online]. *N Y Times* 2012 Jun 6 [cited 2013 Sep 24]. Available from: http://well.blogs.nytimes.com/2012/06/06/ct-scans-increase-childrens-cancer-risk-study-finds/.

Image Gently campaign website: www.pedrad.org/associations/5364/ig.

Image Wisely campaign website: www.imagewisely.org.

Matthews JD, Forsythe AV, Brady Z, et al. Cancer risk in 680 000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ* 2013 May 21;346:f2360. Also available: www.bmj.com/content/346/bmj.f2360.

National Research Council of the National Academies, Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2.* Washington (DC): National Academies Press; 2006.

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet* 2012 Aug 4;380(9840):499-505. Also available: www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60815-0/fulltext.

Also see "ECRI Institute Consulting Services" on page 373 for information about ECRI Institute's CT Radiation Dose Safety Review service.

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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. 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

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* Health information technologies: administration perspectives on innovation and regulation—statement of Farzad Mostashari, M.D., ScM., National Coordinator, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services. Testimony before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce, U.S. House of Representatives [online]. 2013 Mar 21 [cited 2013 Oct 1]. Available from: http://docs.house.gov/meetings/IF/IF02/20130321/100544/HHRG-113-IF02-Wstate-MostashariF-20130321-SD002.pdf.

much further than would have occurred with paper-based systems).

Discussion

Many care decisions today are based on data in an EHR or other information system. Incorrect data in these systems can lead to incorrect treatment, potentially resulting in patient harm. Furthermore, as EHR data flows through health information exchanges to other health systems, the inappropriate data can propagate to multiple areas and systems. Even once a problem has been discovered, the task of reviewing records and distinguishing good data from bad can be monumental.

Following are some of the mechanisms by which the information in an EHR or other health IT system could become compromised.

Patient/data association errors. In last year's Top 10 list (hazard number 4), we described some of the unexpected ways that data for one patient could be associated with—that is, could end up in—another patient's record (refer to the November 2012 *Health Devices* for details). For example:

▷ During our review of connectivity solutions,** we learned that, depending on the patient association method used when transferring data from a medical device to an information system, an event like moving a patient from one room to another could result in patient data being sent to the wrong patient's record (if, for example, the location information is not properly updated in the EHR).

▷ Safety notices published in our *Health Devices Alerts* database describe many

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** "Connectivity solutions" is a term we use to describe certain systems that enable data exchange between medical devices and EHRs. Refer to our April 2012 Guidance Article, "Making Connections: Integrating Medical Devices with Electronic Medical Records," for details.

instances of software flaws that have led to test results, radiologic images, image annotations, and other patient data being associated with the wrong patient.

Missing data or delayed data delivery. Caregivers are likely to expect that information in the EHR or other information system reflects the current state of the patient's care. However, a variety of factors can lead to delays between when an event occurs or a care task is completed and when the information is communicated to staff or reflected in the information system. This situation can result in caregivers initiating or withholding treatment based on non-current information. Causes of missing or delayed communication of data include:

▷ Delays in posting lab results or documenting medication delivery, or a failure to do so altogether.

▷ Delays in entering patient admission information into the facility's admission/discharge/transfer (ADT) system—a common occurrence in some facilities. These delays can prevent a connectivity solution from associating data with a patient, and thus prevent it from sending the latest patient data to the EHR.

▷ Network or system limitations or configuration errors. Such problems may lead to the delayed or failed delivery of data or alerts. For example:

— At one facility, improper setup of communications channels led to delays in clinical alarms reaching nurses on the phones they carried. In particular, when the alarms were broadcast to multiple phones simultaneously, the phones would occasionally "time out" while trying to retrieve the alarm message from the middleware server.*

— A disconnect between a member hospital's ancillary alarm notification system and the communication server prevented medical device alarms from reaching the nurses (via pagers).

▷ Latency of wireless networked telemetry systems—that is, a lag between when the physiologic parameters are captured by the telemetry unit and when they are displayed on the bedside monitor. The American Heart Association cautioned in a 2012 advisory that when used in certain clinical scenarios, some systems exhibit latency that lasts long enough to be clinically significant. Latency results from the time needed to transmit and process the data; see Turakhia et al. (2012).

Clock synchronization errors. Although discrepancies between the times kept by the internal clocks of different medical devices can be expected—one researcher showed an average clock error of 24 minutes among 1,700 surveyed medical devices (Goldman 2012)—such discrepancies should not be considered innocuous. Clock synchronization errors can present patient safety risks (Tahir 2012).

In one incident reported to the Pennsylvania Patient Safety Authority, a nurse discovered an eight-minute difference between the time displayed on a cardiac monitor and that recorded in the patient's electronic record. The difference meant that there was a time discrepancy between the caregivers' activities as recorded in the EHR and the patient's status as reported in the EHR by the monitor. While this incident did not result in patient harm, it is nevertheless troubling. For many short-acting vasoactive medications, for example, caregivers need to titrate the medication to result, which means that they will administer the medication and assess the patient's physiologic response. If the monitor and EHR are not synchronized, consequences could include (1) a caregiver providing inappropriate therapy based on misleading information from the EHR about the patient's current condition or (2) the EHR making it appear as if there was a delay in care, when in fact the caregiver had administered treatment at the appropriate time (Sparnon 2012).

Inappropriate use of default values. In another form of time-related error, the Pennsylvania Patient Safety Authority noted an instance in which a pharmacist entered the correct starting date for a drug administration, but the interface between the pharmacy system and an administration system caused the order to default to a start time on the next day. This error was not noticed by the nurse, and the patient missed one dose of medication (Sparnon and Marella 2012). Other incidents described by the Authority in a 2013 report include cases in which the user did not modify a prepopulated value, such as for dose, time, route, or other parameters in an order (Sparnon 2013 Sep).

Maintaining hybrid (paper and electronic) workflows. As more facilities transition from paper to electronic systems, the potential exists for failure-to-document errors, with some data being recorded in a paper system that hasn't been completely phased out and other data being recorded in a newly implemented electronic system. Consider the following incident, reported in ECRI Institute PSO's 2013 "Deep Dive" analysis of health IT** (see the box on page 369 for information about ECRI Institute PSO):

> Critical test results indicating possible transplant rejection were reported to the laboratory information system but not to the transplant surgery database; the interface between the two systems did not permit results reporting of that particular laboratory test. A paper-based workaround was employed, but staff forgot to enter an action item for the result in the transplant database. The patient later died of organ transplant rejection.

Additional examples, along with discussion and recommendations, are included in the June 2013 edition of the *Pennsylvania Patient Safety Advisory* (see Sparnon [2013 Jun] under Additional Resources, below).

Copying and pasting older information into a new report. With electronic systems, clinicians can easily copy and paste notes from a medical record into a new entry. One of the risks this practice poses is that outdated or incorrect older entries could be carried over into the new entry and mistakenly influence care and treatment decisions. (See "Safety Risks of Electronic Health Records" in the April 2013 *Health Devices* for additional information.) The issue has even caught the attention of a group of U.S. senators critical of the HITECH Act (Brino 2013).

Data entry errors. Events associated with data entry represented 24% of the safety issues identified in ECRI Institute PSO's Deep Dive analysis. The most common form of input error, not surprisingly, was a user simply entering incorrect information, such as the wrong weight, drug allergies, or identification number. Input errors can result not only from mistyping, but also from actions such as the following:

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* "Middleware" refers to hardware and software that can be used to coordinate the alarms from multiple devices and to support ancillary alarm notification.

** The Deep Dive analysis was based on a nine-week "snapshot" of health-IT-related adverse events and near misses reported by 36 participating healthcare facilities. (Available for purchase: https://eshop.ecri.org/p-140-pso-deep-dive-health-information-technology.aspx.)

As noted by the Pennsylvania Patient Safety Authority:

> Avoiding the challenges of a hybrid system may include preventing one from developing: instead of lingering in a hybrid transitional state, facilities may wish to focus on finishing the transition from a wholly paper to a wholly electronic workflow as completely and in as short a time frame as possible. The American Health Information Management Association considers a complete transition from a paper to EHR system to be best practice and offers practical advice for ensuring the quality and integrity of a facility's legal health record throughout the transition period, including factors to consider when developing policies and procedures for when electronic information can be printed out in a hybrid environment. (Sparnon 2013 Jun)

▷ Provide comprehensive user training. Users should complete training and demonstrate competence before being allowed to use the health information system. Training should address the frustrations of health IT adoptions (such as the fact that it will take time to learn the new system) and highlight how the system will ultimately improve patient care. A key point to emphasize during training is that automation is not a substitute for user vigilance.

▷ Provide support during and after implementation. Talk to users and seek their feedback on the system's ease of use and any problems they encountered. Have staff available to provide one-on-one support when problems arise. And provide new training when significant changes are made to the system.

▷ Facilitate problem reporting (a step that is common for medical devices but sometimes overlooked for health IT systems). Encourage users to promptly report any issues they encounter, and provide feedback, when relevant, so that users understand how event reporting leads to safer patient care.

▷ Selecting the wrong item from a drop-down menu, leading to entry of an incorrect order. *Incident:* A drug that was supposed to be delivered intravenously was instead ordered as an intramuscular injection.

▷ Entering information in the wrong field of the patient record, leading to caregivers subsequently missing an order. *Incident:* An order for heparin was incorrectly placed in the communication section of the record, not in the order-entry section, where the patient's nurse would have expected to find that information.

Recommendations

In addition to the following, we encourage readers to refer to the resources below for specific recommendations about the kinds of data integrity failures described above.

▷ Before implementing a new system or modifying an existing one, assess the clinical workflow to understand how the data is (or will be) used by frontline staff, and identify inefficiencies as well as any potential error sources.

▷ Test, test, and retest. Thoroughly test an EHR or any health IT system and the associated interfaces to verify that the system is properly and fully implemented and that it behaves as expected. For example, check that the right data flows into the right record for the various clinical workflows. A multiphase testing process may consist of testing with artificial cases, preferably in a simulated setting (ensuring that test scenarios are designed so as to avoid merging test data with real patient information), followed by a pilot implementation in one or a few areas before the full implementation. Be sure to include frontline staff in the testing process.

▷ Phase out paper. The need to document care in both paper charts and an electronic record can introduce errors.

Member Resources

Health Devices:

Bridging the data gap: reporting of health IT events is improving—gradually [guidance article]. 2013 Apr;42(4):110-3.

Device clock discrepancies may pose patient risks [safety matters]. 2013 Feb;42(2):70.

Making connections: integrating medical devices with electronic medical records [guidance article]. 2012 Apr;41(4):102-21.

Patient/data mismatches in EHRs and other health IT systems [hazard no. 4]. In: Top 10 health technology hazards for 2013: key patient safety risks, and how to keep them in check [guidance article]. 2012 Nov;41(11):342-65.

Safety risks of electronic health records [safety matters]. 2013 Apr;42(4):134-5.

Additional Resources

American Health Information Management Association. Managing the transition from paper to EHRs [practice brief online]. 2010 Nov [cited 2013 Apr 12]. Available from: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_048418.hcsp?dDocName=bok1_048418.

Brino A. Republican senators seek ways to improve HITECH implementation [online]. *Healthc IT News* 2013 Apr 18. Available from: www.healthcareitnews.com/news/repblican-senators-seek-ways-improve-hitech-implementation.

ECRI Institute. Crossing the connectivity chasm: pinpointing gaps in readiness to exchange health information [white paper]. Available from (registration required): https://www.ecri.org/Forms/Pages/Health_Information_Exchange_White_Paper.aspx.

ECRI Institute PSO. *ECRI Institute PSO deep dive: health information technology.* Plymouth Meeting (PA): ECRI Institute PSO; 2013 Jan. (Available for purchase: https://eshop.ecri.org/p-140-pso-deep-dive-health-information-technology.aspx.)

Goldman JM. Medical device interoperability ecosystem updates: device clock time, value proposition, and the FDA regulatory pathway. Presented at: NSF CPS Large Site Visit, PRECISE Center at Penn; 2012 Jan 31; Philadelphia. Presentation slides available at http://rtg.cis.upenn.edu/MDCPS/SiteVisit/MD%20CPS%20Meeting%20Goldman%20Jan%2031%202012.pdf.

Institute of Medicine. *Health IT and patient safety: building safer systems for better care.* Washington (DC): The National Academies Press; 2012. Also available: http://books.nap.edu/openbook.php?record_id=13269.

Sparnon E:

Potential hazards of clock synchronization errors. *Pa Patient Saf Advis* 2012 Dec;9(4):143-4. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/143.aspx.

Spotlight on electronic health record errors: errors related to the use of default values. *Pa Patient Saf Advis* 2013 Sep;10(3):92-5. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Sep;10(3)/Pages/92.aspx.

Spotlight on electronic health record errors: paper or electronic hybrid workflows. *Pa Patient Saf Advis* 2013 Jun;10(2):55-8. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Jun;10(2)/Pages/55.aspx.

Sparnon E, Marella WM. The role of the electronic health record in patient safety events. *Pa Patient Saf Advis* 2012 Dec;9(4):113-21. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/113.aspx.

Tahir D. Lack of device clock synchronization vexes physicians, hospitals [online]. *Gray Sheet* 2012 Jul 2 [cited 2013 Jan 23]. Available from (subscription required): www.elsevierbi.com/publications/the-gray-sheet/38/27/lack-of-device-clock-synchronization-vexes-physicians-hospitals.

Turakhia MP, Estes NA 3rd, Drew BJ, et al. Latency of ECG displays of hospital telemetry systems: a science advisory from the American Heart Association. *Circulation* 2012 Sep 25;126(13):1665-9. Also available: http://circ.ahajournals.org/content/126/13/1665.full.pdf+html.

Also see the box on page 373 for information about ECRI Institute's Readiness Assessment for Exchange of Health Information service.

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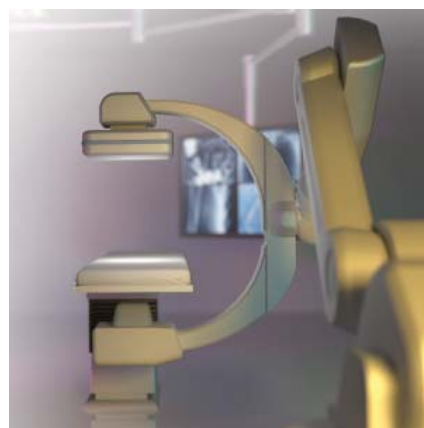
However, as these angiography systems are introduced into the OR, so too are the radiation exposure risks associated with the use of ionizing radiation. Patient exposure hazards are of course a concern. But perhaps less obvious are the risks to OR staff.

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.

Discussion

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. It educates them about the risks of ionizing radiation and the protective measures that should be taken—some of which may not be intuitive. For example, the angulation of the imaging system can affect the radiation dose received by the staff. An appropriate level of training should be provided to all hybrid OR surgical staff.

The second step in a radiation protection program is shielding. Lead aprons are the first line of defense for all staff working in the vicinity of the equipment. To be effective, an apron must provide a good fit. In addition, the apron must of course be worn—even though it can be uncomfortable and cumbersome and can contribute to musculoskeletal problems. New apron designs are available that provide more shielding and that relieve the strain on the clinician (Marichal et al. 2011). However, they are expensive, so an assessment should be carried out to determine whether such designs are a worthwhile investment. Shielding can also be provided by additional lead barriers, such as those

suspended from the ceiling. These barriers likewise will be effective only if they are actually used. However, staff may find them awkward to use, and the benefits are not easily quantifiable.

The third step is monitoring. Radiation monitoring badges are used to keep track of clinician exposure to radiation so that regulatory dose limits are not exceeded. (Employers are responsible for maintaining radiation records for those who are occupationally exposed.) Effective monitoring requires that the badges be properly worn, maintained, and reviewed, and employers must plan to assess and verify badge compliance. ECRI Institute has investigated reports in which misuse of the badges created the incorrect impression that exposure levels had been excessive.

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. Whereas traditional badges provide a cumulative radiation dose reading only when the badge is later analyzed, electronic badges allow dose rate readings to be instantly displayed and warnings to be provided when necessary. While real-time electronic badges do not replace traditional badges (because they lack traditional badges' ability to record a permanent radiation record), they can be used to aid

clinicians in immediately adjusting their behavior (e.g., repositioning themselves) to comply with occupational radiation safety procedures and reduce their exposure. The efficacy of the behavioral adjustment is immediately evident, thus providing positive reinforcement for safe practices. With traditional badges, on the other hand, a disconnect exists between the behavior that led to a high exposure and the badge analysis revealing the high exposure; thus, the causes of overexposure can be difficult to pinpoint and correct. As such, the use of traditional badges alone cannot immediately affect clinician behavior.

A recent study by Sandblom et al. (2013) showed that when staff were able to see their real-time exposure levels, they were able to take measures to reduce the dose they were receiving by 40% to 60%.

Recommendations

▷ Verify that all hybrid OR staff (including surgeons) obtain OR-specific radiation protection training and that they put this training into action. Consult with a medical or health physicist when developing your radiation protection and safety program.

▷ Nominate a member of the hybrid OR team to assume the day-to-day responsibility for verifying that radiation protection policies and procedures are being followed. This role is not to be confused with that of the radiation safety officer (who oversees procedures for the entire organization).

▷ Assess the adequacy of existing built-in radiation protection infrastructure. Consider implementing additional personal radiation safety equipment as needed, such as specialized radiation shield garments.

▷ Consider implementing real-time monitoring to ascertain the effectiveness of radiation safety training, particularly if the analysis of badges proves ineffective at determining the cause of—and steps needed to correct—clinician overexposure.

Resources

Berrington A, Darby SC, Weiss HA, et al. 100 years of observation on British radiologists: mortality from cancer and other causes 1897-1997. *Br J Radiol* 2001 Jun;74(882):507-19. Also available: http://bjr.birjournals.org/content/74/882/507.long.

ECRI Institute:

Employee radiation exposure. *Healthc Risk Control* 2012 Sep;4(Radiology 7):1-12.

Hybrid operating rooms: with a focus on endovascular hybrid ORs [infographic]. 2013.

Available from (registration required): https://www.ecri.org/Forms/Pages/Hybrid-Operating-Rooms.aspx.

Imaging and surgery: what imaging won't be done in an OR? In: *ECRI Institute's top 10 C-suite watch list: hospital technology issues for 2013.* Plymouth Meeting (PA): ECRI Institute; 2013.

Marichal DA, Anwar T, Kirsch D, et al. Comparison of a suspended radiation protection system versus standard lead apron for radiation exposure of a simulated interventionalist. *J Vasc Interv Radiol* 2011 Apr;22(4):437-42.

Also available: www.jvir.org/article/S1051-0443(10)01181-4/abstract.

Sandblom V, Mai T, Almen A, et al. Evaluation of the impact of a system for real-time visualisation of occupational radiation dose rate during fluoroscopically guided procedures. *J Radiol Prot* 2013 Jul 4;33(3):693-702. Also available: http://iopscience.iop.org/0952-4746/33/3/693/pdf/0952-4746_33_3_693.pdf.

Also see "ECRI Institute Consulting Services" on page 373 for information about ECRI Institute's Medical Radiation Safety Review service.

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, 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.

Discussion

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 these devices contact tissue or mucous membranes within the body, flexible endoscopes must be reprocessed between uses to reduce the risk of spreading infection among patients. However, because they are complex devices with narrow, hard-to-clean channels, flexible endoscopes can be particularly challenging to decontaminate.

Successful flexible endoscope reprocessing involves many steps—often model-specific—that need to be followed

diligently to ensure that the device is safe for subsequent use. Our October 2010 Guidance Article "Clear Channels" provides a detailed discussion of the problems that can occur and the steps to take to avoid them. Of particular concern are procedural failures, in which the same mistake is repeated on a consistent basis; such errors can ultimately affect thousands of patients. Several high-profile incidents discussed in our October 2010 article and in our previous Top 10 lists illustrate the harm to patients, and the damage to a facility's reputation, that can result from reprocessing failures. And such incidents continue to occur.

When examining the reprocessing function at your facility, it's important to note that endoscopes are not the only devices subject to such failures. Incidents reported to ECRI Institute PSO describe other instruments and devices that were used, or were presented for use, despite still being contaminated with potentially infectious biological matter (ECRI Institute PSO 2012). Examples include:

▷ During surgery, a foreign substance was found in an arthroscopy shoulder cannula.

▷ After a bronchoscopy was completed, it was discovered that the scope had not been reprocessed from the previous procedure.

- Bone and tissue were observed in an instrument tray for joint replacement surgery.

- Blood was observed on the instrument bin inside a surgical case cart before a procedure was started, contaminating the instruments and supplies within the cart.

In many instances, a thorough cleaning of the instrument or device before disinfection or sterilization could have removed the contaminant. The importance of this step is noted by the U.S. Centers for Disease Control and Prevention (CDC) in its *Guideline for Disinfection and Sterilization in Healthcare Facilities*; this guideline states: "Maximum effectiveness from disinfection and sterilization results from first cleaning and removing organic and inorganic materials." And as we discuss in the October 2010 *Health Devices*, it is not possible to fully decontaminate an endoscope, for example, without meticulous manual cleaning: Traditional automated endoscope reprocessing systems cannot remove gross contamination from the endoscope, and the germicidal agents used in these processes may not be able to reliably penetrate the debris to disinfect/sterilize the surfaces below.

One recent study examining various types of endoscopes highlighted the inadequacy of some facilities' manual cleaning processes. The study, conducted by the 3M Infection Prevention Division, found that 15% of the endoscopes examined at five healthcare facilities included markers suggesting that biocontamination remained in the scopes after they had been manually cleaned (Infection Control Today 2013). ECRI Institute notes, however, that the scopes had not yet been disinfected, so it is not known whether the biocontaminants would have ultimately put patients at risk.

A variety of factors can contribute to the improper reprocessing of instruments. These include:

- The intricacy of the instruments (e.g., devices with narrow channels or movable parts to disassemble)

- Lengthy manufacturer instructions for cleaning, or incomplete or missing instructions

- Time pressures placed on reprocessing staff

- After-hours requests for instrument reprocessing, possibly performed by insufficiently trained personnel

- The lack of standardization of processes among multiple reprocessing areas

- Coordination and cooperation issues between OR and reprocessing staff

Recommendations

We recommend the following to help ensure effective reprocessing of endoscopes and other instruments:

- Provide adequate space, equipment, trained staff, instructional materials, and resources for the reprocessing function to be performed effectively.

  This may include, for example, ensuring that ORs and other procedure areas have sufficient instruments to meet demand and allowing adequate time for instrument processing. (An insufficient inventory of devices, coupled with short turnaround times to have instruments available for scheduled procedures, could create an environment in which staff are tempted to take risky shortcuts.)

- Verify that an appropriate reprocessing protocol exists for all relevant instrument models in your facility's inventory. Refer to user manuals and consult device manufacturers to identify unique requirements (e.g., cleaning procedures, channel adapters) that need to be addressed.

- Develop a protocol to ensure that loaner instruments go through the same reprocessing processes as hospital-owned instruments before initial use and between uses (following manufacturer recommendations for each device).

- Ensure that current documented protocols are readily available to staff and that staff are trained to understand and follow them. Training should include new staff when they join the organization, should be periodically repeated for all staff to sustain competency, and should be supplemented to address new instruments or devices before they are put into service.

- Monitor adherence to protocols and quality of instrument cleaning.

- Periodically review protocols to ensure that they are clear and comprehensive and that they reflect the current environment (e.g., workflows and equipment/chemicals that are currently being used at the facility).

- When developing or reviewing protocols, ensure that all steps are addressed and documented in adequate detail—from precleaning of equipment at the site of use, when appropriate, to safe and aseptic transport of equipment back to that site for subsequent use.

  For a discussion of the typical steps in an endoscope reprocessing protocol, refer to the October 2010 *Health Devices*. Additional recommendations for facilities that reprocess endoscopy equipment using a reprocessing unit—such as an automated endoscope reprocessor, a liquid chemical sterilization system, or a gas plasma sterilizer—were included in last year's Top 10 list, available in the November 2012 *Health Devices* (hazard number 8).

- Seek input from reprocessing department staff when assessing instruments for purchase to identify devices that may require additional time, steps, or resources to reprocess effectively. Such factors may influence purchasing decisions.

- Foster communication and collaboration between reprocessing personnel and the departments they support (e.g., OR, endoscopy department, pulmonary lab) so that the groups understand each other's needs.

Member Resources

Health Devices:

Clear channels: ensuring effective endoscope reprocessing [guidance article]. 2010 Oct;39(10):350-9.

Inadequate reprocessing of endoscopic devices and surgical instruments [hazard no. 8]. In: Top 10 health technology hazards for 2013: key patient safety risks, and how to keep them in check [guidance article]. 2012 Nov;41(11):360-2.

Additional Resources

Centers for Disease Control and Prevention (CDC), U.S. *Guideline for disinfection and sterilization in healthcare facilities*, 2008. Atlanta (GA): CDC; 2008. Also available: www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf.

ECRI Institute PSO. Sterile processing department's role in patient safety. *PSO Navigator* 2012 Aug;4(3):1-9.

Infection Control Today. 3 out of 20 scopes harbor bioburden, study shows [online]. 2013 Jun 7 [cited 2013 Sep 24]. Available from: www.infectioncontroltoday.com/news/2013/06/3-out-of-20-scopes-harbor-bioburden-study-shows.aspx.

Pennsylvania Patient Safety Authority. The dirt on flexible endoscope reprocessing. *Pa Patient Saf Advis* 2010 Dec;7(4):135-40. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/dec7(4)/Documents/dec;7(4).pdf.

7. Neglecting Change Management for Networked Devices and Systems

The growing interrelationship between medical technology and IT offers significant benefits. However, one under-appreciated 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.

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.

Discussion

In today's hospitals, 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.

Consider the following examples:

▷ An ECRI Institute member hospital described an incident in which a facility-wide PC operating system upgrade caused the loss of remote-display capability for its fetal monitoring devices. The facility had configured its fetal monitoring system so that nurses could view the output on a PC located outside the patient's room. However, these displays became nonfunctional when the IT department pushed out a Windows 7 upgrade to the computers connected to the network. The PC application that allowed the display of the fetal monitor information was not compatible with Windows 7.

▷ Another member hospital likewise experienced problems displaying fetal monitor data on workstations at the nurses' station following an IT change. In this case, the problems began after the IT department moved the obstetrical data management system server off-site. No verification testing was performed to ensure continued performance after the change. (See *Health Devices Alerts* Special Report S0241, 2013 May 31.)

▷ An update to the firmware for the wireless access points at a member hospital caused the loss of wireless functionality for some of the facility's medical devices. Some physiologic monitors, for example, required a wired connection for months until a fix could be implemented.

▷ A recent article describes an incident in which 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. The fields remained in the screen display, so staff using the EHR system did not detect the change to the legal record. (See the June 2013 edition of ECRI Institute's *Risk Management Reporter* for details.)

Appropriate change management policies and procedures, as outlined in the recommendations below, 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.

Recommendations

Effective approaches to change management include the following:

▷ Facilitate good working relationships among departments that have a direct responsibility for health IT systems, medical technology, and change management. Involve the appropriate stakeholders (e.g., IT, clinical engineering, nursing) when changes are planned.

▷ Maintain an inventory listing the interfaced devices and systems present within the institution, including the software versions and configurations of the various interfaced components.

▷ Take steps to ensure that changes are assessed, approved, tested, and implemented in a controlled manner. ECRI Institute recommends that, when possible, the changes and associated system functionality be tested and verified in a test environment before the changes are implemented in a live clinical setting. Change management applies to a variety of actions, including hardware upgrades, software upgrades, security changes, new applications, new work processes, and planned maintenance.

▷ Evaluate the facility's policies and procedures regarding change management. Care should be taken to determine how technology decisions involving health IT systems, medical devices, and IT networks can affect current operations, patient care, and clinician work processes.

▷ Develop contract wording that is specific to change management. For example, contracts with vendors (e.g., information system vendors, device suppliers) should require the necessary documents (e.g., revised specifications, software upgrade documentation, test scenarios) to be provided to the appropriately designated staff member(s) to facilitate change management. Stipulating that vendors provide advance notice of impending changes can give healthcare facilities time to budget and adequately plan for those changes.

▷ Ensure that any system updates do not jeopardize processes to maintain the privacy of patients' protected health information and the security of records with that information.

▷ When making changes to interfaced systems, closely monitor the systems after the change is made to ensure their safe and effective performance.

INFORMATION-TECHNOLOGY-RELATED ALERTS BY YEAR

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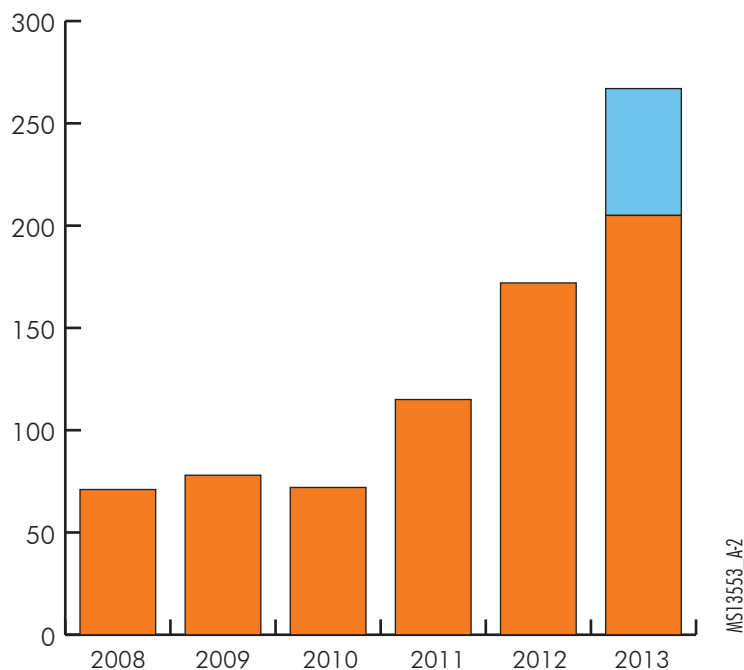
A search of the *Health Devices Alerts* database illustrates the growing role of information technology in a healthcare technology manager's job. The graph shows the number of alerts each year related to information technology. (The blue portion of the graph represents the projection for the remainder of 2013.)

▷ Provide frontline staff members a point of contact for reporting problems related to change management and health IT systems. Education, training, and good escalation procedures (so that reports reach someone who can respond if the first person is unavailable or lacks the necessary competence) can help to ensure that problems are addressed with the appropriate urgency.

In addition, consider applying risk management principles to change management as discussed in the IEC 80001-1 standard, *Application of Risk Management for IT-Networks Incorporating Medical Devices— Part 1: Roles, Responsibilities and Activities.* (Refer to our May 2010 Guidance Article "10 Questions about IEC 80001-1" for answers to some common questions about the standard.)

Member Resources

Health Devices:

10 questions about IEC 80001-1: what you need to know about the upcoming standard and networked medical devices [guidance article]. 2010 May;39(5):146-9.

Coping with convergence: a road map for successfully combining medical and information technologies [guidance article]. 2008 Oct;37(10):293-304.

Look who's talking: a guide to interoperability groups and resources [guidance article]. 2011 Jun;40(6):190-8.

Physiologic monitoring: a guide to networking your monitoring systems [guidance article]. 2011 Oct;40(10):322-45. See in particular the discussion of change management on pages 326 and 327.

Health Devices Alerts:

Biomed-IT collaboration critical to ensuring proper functioning of medical devices residing on hospital IT infrastructure [special report]. 2013 Jun 7. Accession No. S0241.

Additional Resources

American National Standards Institute/ Association for the Advancement of Medical Instrumentation/International Electrotechnical Commission (ANSI/AAMI/IEC). *Application of risk management for IT networks incorporating medical devices—part 1: roles, responsibilities and activities.* ANSI/AAMI/IEC 80001-1. 2010 Oct.

ECRI Institute. Risk managers' 10 strategies for health IT success. *Risk Manage Rep* 2013 Jun. Also available (member log-in required): https:// members2.ecri.org/Components/HRC/Pages/ RMRep0613_Focus.aspx.

ECRI Institute PSO. *ECRI Institute PSO deep dive: health information technology.* Plymouth Meeting (PA): ECRI Institute PSO; 2013 Jan. (Available for purchase: https://eshop.ecri.org/p-140-pso-deep-dive-health-information-technology.aspx.)

ECRI Institute web conferences:

Avoid risk with health information technology. 2011 Mar 16. Recording and CD-ROM toolkit available for purchase at www.ecri.org/ Conferences/AudioConferences/Pages/ Health_Information_Technology.aspx.

Avoiding the pitfalls of medical device connectivity. 2011 Oct 12. Recording available for purchase; for details, contact ECRI Institute at circulation2@ecri.org.

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.

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. (For additional discussion, refer to the August 2012 issue of ECRI Institute's *Health Technology Trends*, as well as the May 2013 article "Medical Devices Fall Short for Children" in the *New York Times* Well blog.)

Discussion

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

Radiation exposure hazards. Exposure to ionizing radiation such as that used in CT and x-ray imaging has been associated with an increased cancer risk. Because they are still developing, children are especially susceptible to long-term damage from radiation exposure. To compound this problem, using adult scanning techniques on children can expose them to an unnecessarily large "adult" dose and can potentially expose regions of the body outside the area of interest. We cover this topic at length as hazard number 3 in this year's list.

Electronic health records. 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, or may not allow both height and weight to be viewed on the same screen, which in turn can contribute to vital information being overlooked.

To bridge the gap between the functionality present in most currently available EHRs and that needed to better support children's healthcare, the Agency for Healthcare Research and Quality (AHRQ) recently announced the development of the Children's EHR Format. The Format provides information to help EHR developers optimize their systems for the care of children, as well as criteria to help facilities select an EHR that supports children's healthcare needs.

Medication dosing errors. Medication dosing errors can harm any patient. But children, because of their small size, are particularly susceptible to adverse consequences from incorrect dosing. This susceptibility to harm, coupled with the use of technologies that aren't optimized for pediatric patients, can lead to tragic results.
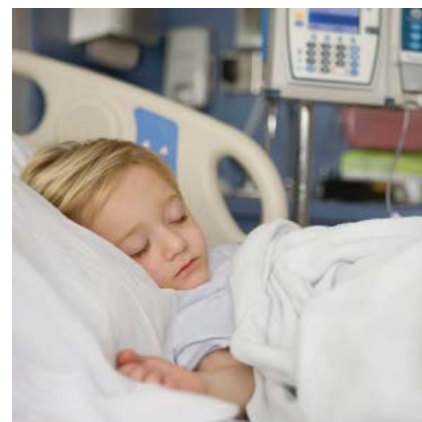
In fact, a device as simple as a scale can contribute to significant harm. In one report to ECRI Institute PSO, a mix-up involving the use of pounds versus kilograms to record weight contributed to the death of an infant. If the scale had been set to provide weights in kilograms only, as the American Academy of Pediatrics (AAP) and other organizations now recommend (AAP 2009), the mix-up could have been avoided.

A similar incident, but with a much less serious outcome, was reported in the March 2013 edition of AHRQ's *WebM&M*. In that case, a toddler's weight was measured to be 25 lb (11.3 kg), but was mistakenly recorded in the EHR as 25 kg. Calculating the dose using the incorrect weight led the physician to prescribe a drug at about twice the desired dose. Fortunately, the child's mother recognized the error before the child experienced significant adverse effects (Bokser 2013).

Even advanced technologies intended to help decrease medication errors are fallible. For example, the authors of a 2012 study identified CPOE systems as an enabler of tenfold medication errors in pediatric patients. The authors cited the "overriding of recommendations, ignoring of alerts, and the inability of CPOE to recognize certain tenfold underdoses" as contributing factors, and they noted the need for CPOE systems to be "designed in a standardized fashion that incorporates pediatric-specific dosing logic" (Doherty and McDonnell 2012).

Recommendations

▷ When assessing medical technologies and supplies for purchase or use, consider the extent to which the device, system, or accessory has been developed with the needs of pediatric patients in mind. For example:

— When selecting an EHR, consider the extent to which the system complies with AHRQ's Children's EHR Format. (For details on this format, see http://healthit.ahrq.gov/health-it-tools-and-resources/childrens-electronic-health-record-ehr-format.)

— Use electronic medication prescribing (e-prescribing)

systems that include such features as child-specific medication libraries, normative references, and child-specific weight-based dose calculations and alerts. Refer to AAP's article "Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management" for further details (full citation appears in resource list below).

— For infants and children, use scales that can be set to provide weights in kilograms only, and verify that the scales are clearly labeled as such.

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

▷ If obtaining pediatric-specific technology is not an option, investigate whether an available device can be safely and effectively used on children. Alternatively, ask if the vendor can refer you to current users of the technology who have implemented the system in a manner that addresses the needs of pediatric patients.

▷ Consider identifying a pediatric technology safety coordinator to assess both the adult-oriented technologies and the adult-pediatric hybrid technologies that are being used on pediatric patients at your facility. Responsibilities may include:

— Identifying devices, accessories, or systems that are appropriate for only a certain range of patients (e.g., adults but not children)

— Identifying devices, accessories, or systems that must be used in a specific configuration to safely accommodate pediatric patients (e.g., restricting the upper flow rate for infusion pumps)

— Where appropriate, clearly labeling any such devices

— Educating staff about unique safety considerations or methods of use that are required when working with pediatric patients

— Establishing protocols for setting medical device alarms to levels that are appropriate for pediatric patients and periodically verifying that these protocols are being followed

Member Resources

Health Devices:

Computerized decision support for pediatric meds—effectiveness uncertain [safety matters]. 2012 Dec;41(12):400-1.

No-flow alarm disabled in Respironics EverFlo oxygen concentrators equipped with optional low-flow flowmeter [hazard report]. 2011 Apr;40(4):139-40.

Program reduces need for sedation in pediatric MR [safety matters]. 2013 Jan;42(1):33.

Additional Resources

Agency for Healthcare Research and Quality, U.S.:

New children's electronic health record format announced [press release online]. 2013 Feb [cited 2013 Sep 24]. Available from: www.ahrq. gov/news/newsroom/press-releases/2013/childehrpr.html.

Children's electronic health record (EHR) format [online]. 2013 May [cited 2013 Sep 24]. Available from: http://healthit.ahrq.gov/health-it-tools-and-resources/childrens-electronic-health-record-ehr-format.

American Academy of Pediatrics:

Electronic prescribing in pediatrics: toward safer and more effective medication management. *Pediatrics* 2013 Apr;131(4):824-6.

Joint policy statement—guidelines for care of children in the emergency department. *Pediatrics* 2009 Oct;124(4):1233-43.

Bokser SJ. A weighty mistake [online]. *AHRQ WebM&M* 2013 Mar [cited 2013 Sep 24]. Available from: http://webmm.ahrq.gov/case.aspx?caseID=293.

Doherty C, McDonnell C. Tenfold medication errors: 5 years' experience at a university-affiliated pediatric hospital. *Pediatrics* 2012 May;129(5):916-24.

ECRI Institute. New strides for pediatric medicine: FDA grants support research to stimulate pediatric device innovation. *Health Technol Trends* 2012 Aug;24(8):5-6. Also available (member log-in required): https://members2.ecri.org/Components/Trends/Pages/13126.aspx.

Food and Drug Administration, U.S. Radiation-emitting products: pediatric x-ray imaging [online]. 2012 May 14 [cited 2013 Sep 24]. Available from: www.fda.gov/Radiation-EmittingProducts/Radiation EmittingProductsandProcedures/MedicalImaging/ucm298899.htm.

Institute of Medicine. *Safe medical devices for children.* Field MJ, Tilson H, eds. Washington (DC): National Academies Press; 2006.

Tarkan L. Medical devices fall short for children [online]. *N Y Times* 2013 May 6 [cited 2013 Sep 24]. Available from: http://well.blogs.nytimes.com/2013/05/06/medical-devices-fall-short-for-children/.

9. 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.

Discussion

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. Currently, Intuitive Surgical's da Vinci Surgical System is the only multipurpose robotic surgery system on the market. However, we expect that the issues raised in this report—specifically the need for hospitals to develop staff proficiency and expertise in using such a system—would apply to any similar system. In fact, such requirements would exist for any complex new technology.

The control console used with this type of system incorporates a video display on which the surgeon views 3-D video of the surgical site, as well as hand and foot controls that the surgeon uses to control the position and functions of the robot's arms, instruments, and endoscope.

Initial training provided by the device supplier is intended to help users become familiar with the system. In addition, the supplier suggests ways in which surgical staff can acquire procedure-specific training. However, the supplier's program 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

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* ECRI Institute published an analysis of the existing efficacy literature in the January 2013 *Health Devices*. At that time, we found that for most outcomes, the evidence wasn't strong enough to determine whether use of a multipurpose robotic surgery system was better or worse than the traditional methods. However, this is a rapidly evolving area of research, and newer, high-quality studies could lead to more definitive conclusions.

proficiency and expertise with a multipurpose robotic surgery system. The program should require that a specified number of proctored surgeries be performed (as determined by the hospital). And successful completion of the program should lead to credentialing within the hospital/system. Furthermore, maintaining competency will require maintaining a sufficient caseload so that the surgical teams' skills remain sharp. (However, the need to "practice" with the robot should never influence a decision to perform a particular case robotically. If a surgeon is credentialed for a specific surgical procedure, but the caseload is low, then consider ongoing simulation training to maintain the necessary skills to maneuver the robot arms and EndoWrists. Simulation training should never be a substitute for initial proctored training sessions.)

Recommendations

Currently, no widely recognized requirements exist for robotic surgery training and credentialing programs, so hospitals will need to make their own decisions. To help with that process, we present the following recommendations, which are based on the experiences of well-established robotic surgery programs:

▷ Before conducting unsupervised robotic surgery procedures, surgeons should do the following (note that the number of cases or sessions below are minimum values based on our discussions with large teaching hospitals; facilities should establish appropriate requirements to help ensure that surgical staff have the necessary procedure-specific skills):

— Complete initial training sessions provided by or recommended by the device supplier.

— Observe at least two cases, including room and instrument setup.

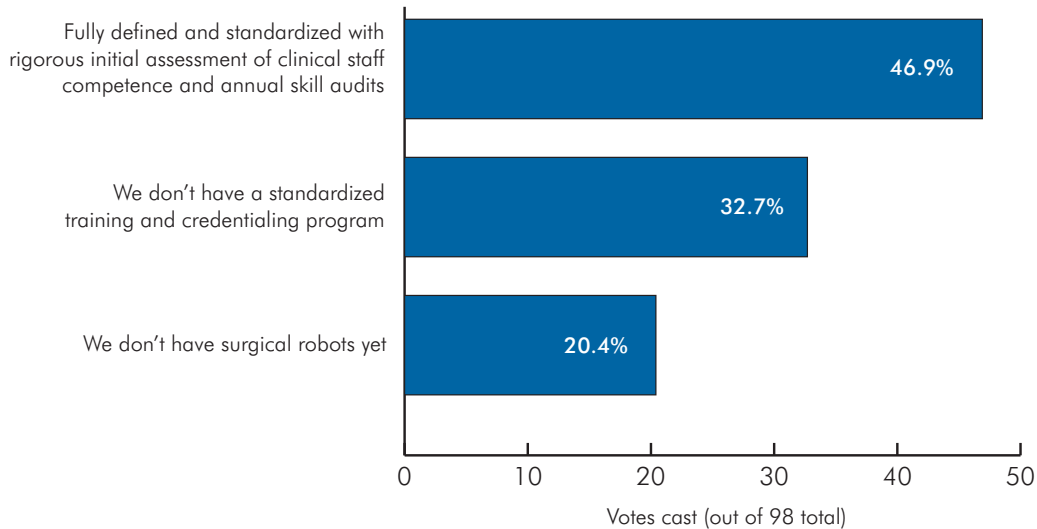— Serve as a bedside assistant for a minimum of five surgeries.
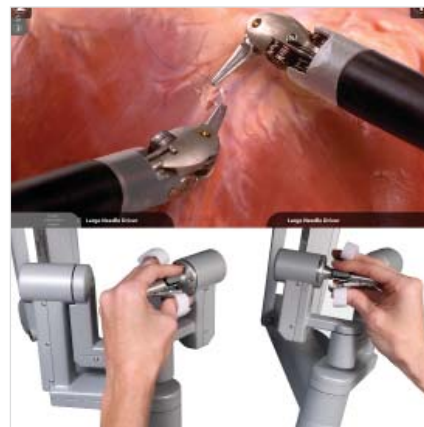
— Perform simulation training and training on appropriate inanimate or cadaver models.

— Complete a minimum of three proctored sessions. Note that if issues arise during the surgery that require the proctor's assistance, that session should not be counted as a completed, proctored session. Also be aware that if an external proctor is used—for example, if the hospital does not have an in-house surgeon who can serve as a proctor—the external proctor is unlikely to have surgery credentials within the hospital and thus would not be able to directly intervene in the procedure if there's a problem.

▷ In addition:

— Facilitate team training. Surgeons and nurses will each require their own training because of their different responsibilities. However, teamwork is essential during robot-assisted surgeries, and some users have found that the safest surgeries are those that have been performed by a team that has experience working together. Therefore, we recommend that joint training sessions also be conducted, including interdisciplinary dry lab,
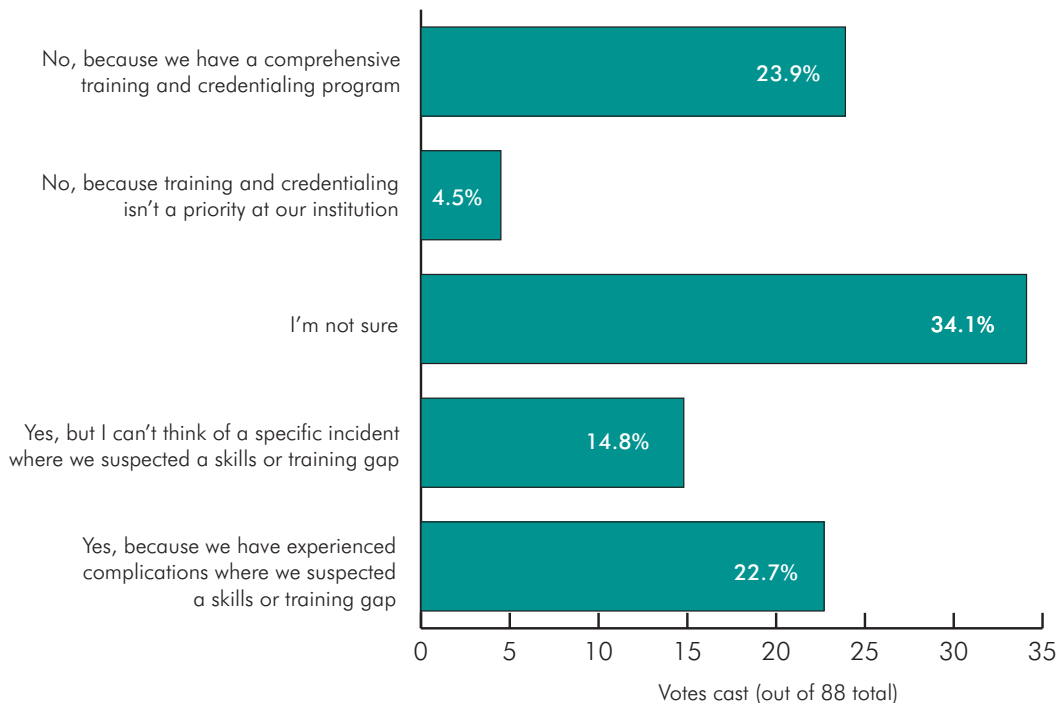

POLL RESULTS: ROBOTIC SURGERY TRAINING AND CREDENTIALING PROGRAMS

What Is the State of Your Training and Credentialing Program?

Category	%
Fully defined and standardized with rigorous initial assessment of clinical staff competence and annual skill audits	46.9%
We don't have a standardized training and credentialing program	32.7%
We don't have surgical robots yet	20.4%

Votes cast (out of 98 total)

If You Have a Robot, Do You Suspect That Surgeon Training and Credentialing Might Be an Issue at Your Institution?

Category	%
No, because we have a comprehensive training and credentialing program	23.9%
No, because training and credentialing isn't a priority at our institution	4.5%
I'm not sure	34.1%
Yes, but I can't think of a specific incident where we suspected a skills or training gap	14.8%
Yes, because we have experienced complications where we suspected a skills or training gap	22.7%

Votes cast (out of 88 total)

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In June 2013, ECRI Institute hosted a web conference to help healthcare providers understand the training and credentialing requirements for robotic surgery systems. During the conference, online attendees were asked two poll questions related to their programs. As indicated by the anonymous results shown here, many facilities still have work to do to verify staff proficiency and expertise in using these systems. For additional details about the web conference, see https://members2.ecri.org/Components/HDJournal/Pages/webinar_surgicalrobot.aspx.

cadaver, and simulation training that involves the OR nurses.

— Verify sustained proficiency. A surgeon's skill can decline with infrequent use; one premier robotic surgery hospital requires that surgeons perform 20 robot-assisted surgeries throughout the year. If the caseload for a particular procedure is insufficient to fulfill this requirement, consider whether simulation training would be adequate to maintain the necessary skills to maneuver the robot arms and EndoWrists.

For more detailed guidance, refer to the January 2013 *Health Devices,* as well as the ECRI Institute web conference and related materials listed below (including training and credentialing guides shared by the web conference participants).

Member Resources

Health Devices:

Da Vinci decisions: factors to consider before moving forward with robotic surgery [guidance article]. 2013 Jan;42(1):6-18.

Web conference:

The surgical robot invasion: training and safety. 2013 Jun 12. Conference video, training and credentialing guides shared by the web conference participants, and supplemental question-and-answer video available from: https://members2.ecri.org/Components/ HDJournal/Pages/webinar_surgicalrobot.aspx.

Additional Resources

American Urological Association. Standard operating practices (SOP's) for urologic robotic surgery [online]. [cited 2013 Sep 4]. Available from: www.auanet.org/common/pdf/about/ SOP-Urologic-Robotic-Surgery.pdf.

Kowalczyk L. Mass. cautions hospitals about robotic surgery: hospitals get advisory letter. *Boston Globe* 2013 Mar 26. Also available: www.bostonglobe. com/lifestyle/health-wellness/2013/03/25/

state-cautions-hospitals-about-patient-complications-during-robot-assisted-surgery/ xOAsxR80qH5mVENDdktjKL/story.html.

Rabin RC. Salesmen in the surgical suite. *N Y Times* 2013 Mar 25. Also available: www.nytimes. com/2013/03/26/health/salesmen-in-the-surgical-suite.html.

Sadler D. When your co-worker is a robot: how surgical robots have changed the operating room. *OR Today* 2013 Aug. Also available: http://ortoday.com/when-your-co-worker-is-a-robot.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). A consensus document on robotic surgery: prepared by the SAGES-MIRA Robotic Surgery Consensus Group [online]. 2007 Nov [cited 2012 Dec 19]. Available from: www.sages.org/publications/ guidelines/consensus-document-robotic-surgery.

Zorn KC, Gautam G, Shalhav AL, et al. Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of society of urologic robotic surgeons. *J Urol* 2009 Sep;182(3):1126-32.

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 one of the five 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 four years alone, ECRI Institute's Accident and Forensic Investigation Group has investigated nine retained surgical item (RSI) incidents.

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* NQF's 2011 revision of its SRE list includes 29 event types classified into seven categories: surgical events (5), product or device events (3), patient protection events (3), care management events (9), environmental events (4), radiologic events (1), and criminal events (4). For more information, see www.qualityforum.org/Topics/ SREs/List_of_SREs.aspx.

▷ A 2012 analysis of the Pennsylvania Patient Safety Reporting System data-base showed that healthcare facilities in the commonwealth reported 452 events involving RSIs in 2011—one-third of those events reportedly caused patient harm (Martindell 2012).

▷ A recently published analysis of 9,744 paid malpractice settlements and judg-ments associated with four types of surgical "never events" occurring between 1990 and 2010 ("never events" are now referred to as SREs) found that nearly half of the incidents that occurred involved the retention of a surgical item (Mehtsun et al. 2013).

▷ 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
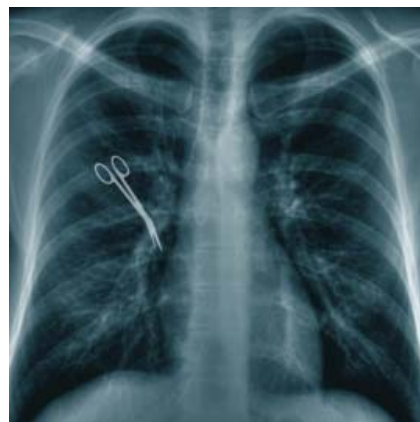
withholds payment for the treatment of this condition.

Discussion

Reports of surgical items unintentionally left inside patients following surgery or an interventional diagnostic procedure (which may take place outside the OR) 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. One example is the common practice of leaving epidural catheter fragments in place when it is clinically judged that they do not present an obvious risk of infection or neurological impairment.

In such cases, risks to the patient can include (1) prolonged or additional surgery, as would occur when an RSI is discovered and its removal is deemed appropriate, or (2) future complications, some potentially serious, as could occur when an RSI leads to infection or causes damage to the surrounding tissue. For example, retained metal could rotate if the patient undergoes a magnetic resonance examination; the result could be damage to internal tissue or structures.

Recommendations

To reduce the risk of object retention, we recommend that users:

▷ Visually inspect devices just before use. If a device appears to be damaged, immediately remove it from service.

▷ Be alert for significant resistance during device removal, which could indicate

that the device is trapped and at risk of breakage; consider what options are available (e.g., repositioning the patient) before continuing the removal process.

▷ Visually inspect devices as soon as they are removed from the patient. If a portion of the device appears to be missing, immediately take appropriate action (e.g., examine the treatment site, request radiologic evaluation).

▷ Adhere to accepted surgical count procedures. For guidance in reviewing your procedures or developing new ones, refer to the recommendations issued by the Association of periOperative Registered Nurses, as well as those listed in the Joint Commission's October 2013 Sentinel Event Alert (see Additional Resources, below).

▷ Consider whether adjunct technologies (e.g., surgical sponge detection systems) should be adopted.

In addition, cleaning and reprocessing staff should be cognizant of obvious damage to reusable instruments and devices and should pull suspect devices for evaluation.

Member Resources

Health Devices:

Radio-frequency surgical sponge detection: a new way to lower the odds of leaving sponges (and similar items) in patients [evaluation]. 2008 Jul;37(7):193-202. Also see the updated product information in the September 2008 issue, page 283.

Additional Resources

Association of periOperative Registered Nurses. Recommended practices for sponge, sharps, and instrument counts. *AORN J* 2006 Feb;83(2):418-33.

ECRI Institute: The case of the missing sponge: practice variation is culprit. *Risk Manage Rep,* June 2012. Available from (member log-in required): https://members2.ecri.org/Components/HRC/Pages/RMRep0612_Focus.aspx.

ECRI Institute PSO:

Retained foreign objects: it's not the robot's fault. *Patient Safety E-lerts* 2012 May 31. Available from (member log-in required): https://members2.ecri.org/Components/HealthcareGPS/Pages/E-lert_053112.aspx.

Retained guidewires. *Patient Safety E-lerts* 2010 Aug 31. Available from (member log-in required): https://members2.ecri.org/Components/HealthcareGPS/Pages/E-lert_083110.aspx.

Goldberg JL, Feldman DL. Implementing AORN recommended practices for prevention of retained surgical items. *AORN J* 2012 Feb;95(2):205-19.

Joint Commission. Preventing unretained foreign objects. *Sentinel Event Alert* 2013 Oct 17;(51): 1-4. Also available: www.jointcommission.org/assets/1/18/SEA_51_URFOs_10_17_13_FINAL.pdf.

Martindell D. Update on the prevention of retained surgical items. *Pa Patient Saf Advis* 2012 Sep;9(3):106-10.

Mehtsun WT, Ibrahim AM, Diener-West M, et al. Surgical never events in the United States. *Surgery* 2013 Apr;153(4):465-72. Also available: www.sciencedirect.com/science/article/pii/S003960601200623X.

NoThing Left Behind website: www.nothingleftbehind.org.

Pennsylvania Patient Safety Authority:

Beyond the count: preventing the retention of foreign objects. *Pa Patient Saf Advis* 2009 Jun;6(2):39-45. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Jun6(2)/Pages/39.aspx.

Epidural or subarachnoid catheter shear. *Pa Patient Saf Advis* 2009 Sep;6(3):84-6.

Preventing retention of surgical items website: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/rfo/Pages/home.aspx.

Preventing the retention of foreign objects during interventional radiology procedures. *Pa Patient Saf Advis* 2008 Mar;5(1):24-7.

Retained foreign object audit form: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/rfo/Documents/audit.pdf. (This sample auditing tool is designed to help staff assess events involving retained foreign objects.) /**D**