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TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2013

Reprinted from Volume 41
Issue 11

November 2012



TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2013

EACH YEAR, ADVANCES IN HEALTH TECHNOLOGIES PROVIDE NEW WAYS TO IMPROVE PATIENT CARE. BUT SOME ALSO CREATE NEW OPPORTUNITIES FOR HARM. THUS, HOSPITALS MUST REGULARLY EXAMINE THEIR HAZARD-CONTROL PRIORITIES IN ORDER TO REMAIN FOCUSED ON THE MOST PRESSING RISKS. OUR ANNUAL LIST WILL HELP YOU MAKE SMART DECISIONS ABOUT YOUR SAFETY INITIATIVES IN THE COMING YEAR.

THE LIST FOR 2013

1. Alarm hazards
2. Medication administration errors using infusion pumps
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures
4. Patient/data mismatches in EHRs and other health IT systems
5. Interoperability failures with medical devices and health IT systems
6. Air embolism hazards
7. Inattention to the needs of pediatric patients when using “adult” technologies
8. Inadequate reprocessing of endoscopic devices and surgical instruments
9. Caregiver distractions from smartphones and other mobile devices
10. Surgical fires

Ensuring the safe use of health technology requires identifying possible sources of danger or difficulty involving medical devices and systems—our definition of the term “hazards”—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 topics that periodically warrant renewed attention because of their potential to cause harm. 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.

*Key Patient Safety
Risks, and How to
Keep Them in Check*



Why a Top 10 List?

“Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous.”* That quote from the head of an academic health science system captures the essence of why a list like this one is needed.

The technologies and procedures we describe in this list all can contribute to effective patient care. However, most are also complex or their effective application relies on a complex interplay of factors. Thus, they can actually cause harm—to patients, staff, or others—if, for example, design flaws are not identified and rectified, equipment is not adequately maintained or otherwise prepared for use, or proper use procedures are not established and followed (e.g., to address risks that are inherent to the technology).

ECRI Institute routinely addresses *model-specific* design, use, and maintenance issues through our technology evaluation, problem reporting, accident investigation, and alerting services. For this

* Chantler C. The role and education of doctors in the delivery of healthcare. *Lancet* 1999 Apr 3;353(9159):1178-81.

Top 10 list, we focus only on what we call *generic* hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. 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 steps, or even for improved design for a class of devices.

What’s New on This Year’s List?

In the current healthcare environment, the interplay between complexity and either effectiveness or the potential for harm is perhaps most evident in the realm of healthcare information technology, or health IT. Thus, it shouldn’t be surprising that 3 of the 10 topics on this year’s list are associated with the still-maturing health IT field.

Health IT encompasses information systems such as electronic health records (EHRs), the hardware and software that support human interactions with such systems (e.g., laptops, tablet computers,

smartphones), and the interfaces that allow interactions between medical devices and these and other systems.

While many health IT implementations offer great promise for improving patient care, it must be recognized that these complex technologies also can create new paths to failure. As the Institute of Medicine points out in its 2012 report *Health IT and Patient Safety*,*

It is widely believed that health IT, when designed, implemented, and used appropriately, can be a positive enabler to transform the way care is delivered.

However, the report cautions that

Designed and applied inappropriately, health IT can add an additional layer of complexity to the already complex delivery of health care, which can lead to unintended adverse consequences, for example dosing errors, failure to detect fatal illnesses, and delayed treatment due to poor human-computer interactions or loss of data.

The inherent complexity of these technologies, their potential to introduce new failure modes, and the possibility that such failures will affect many patients before being noticed—combined with the increased usage that will likely result from the U.S. government’s incentivizing the implementation and meaningful use of effective health IT—leads us to encourage healthcare facilities to pay particular attention to health IT when prioritizing their safety initiatives for 2013.

Other topics on this year’s list are making repeat appearances: Alarm hazards and medication administration errors using

infusion pumps remain pressing issues, for example. Some topics are reappearing in this list in modified form: Narrowly focused past topics, such as the high radiation doses of computed tomography (CT) scans and cross-contamination risks associated with improper flexible endoscope reprocessing, were broadened for the current list to encourage healthcare facilities to extend their hazard prevention efforts to encompass additional applications or processes. Still other topics are making their first appearance on the list, signaling additional areas that warrant attention.

How Are Topics Selected?

Throughout the year, ECRI Institute engineers, scientists, and patient safety analysts examine health-technology-related problem reports; review the literature; and speak with clinicians, clinical engineers and technology managers, purchasing staff, health systems administrators, and device suppliers to identify the technology-related safety topics that will likely be of concern in the coming year. A list of potential topics is developed, and internal staff review each item on the list, along with relevant supporting material, to assess which topics warrant inclusion within the Top 10.

In narrowing down the list of potential hazards and ranking the topics, we weigh a number of factors, particularly those listed below.

- ▷ *Potential for harm.* How dangerous is it? Can the hazard kill someone or cause serious injury?
- ▷ *Frequency.* How likely is it? Does the hazard happen often?
- ▷ *Breadth.* How widespread is it? If the hazard occurs, is it likely to affect a great number of people, either at many facilities or within one facility?

- ▷ *Insidiousness.* Is the problem difficult to recognize or challenging to rectify once it occurs? Could the problem lead to a cascade of downstream errors before it is identified or corrected? Could addressing the problem, once it occurs, be time- or resource-intensive?

- ▷ *Profile.* Is it a high-profile problem? Has the hazard been reported in the media, and are you likely to be under pressure to deal with it quickly and conspicuously?

An affirmative answer for any single factor can warrant inclusion on the list. In addition, we consider whether including a topic can influence positive change. That is, can raising awareness of the hazard help reduce future occurrences?

We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities. (Health Devices members 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 page 349.) 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 346 describes steps you should be taking throughout your facility to make your safety initiatives as effective as possible.

Finally, we urge you to share this document with others throughout your facility. The hazards described here affect many departments and professions, including risk management, hospital administration, clinicians and clinical department managers, clinical engineering, IT, and materials management. We encourage you to alert staff in those areas to this list and its recommendations.

* 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.

1. Alarm Hazards

Medical device alarms perform an essential patient safety function. Physiologic monitors, medical telemetry units, ventilators, infusion pumps, dialysis units, and a host of other medical devices sound alarms or issue alerts to warn caregivers of potential problems with the patient. The sheer number of alarms, however, has itself become problematic. The result is that caregivers can become overwhelmed trying to respond to the alarms, or they can become desensitized, which can lead to missed alarms or delayed response, placing patients at risk.

Alarm hazards remain a high-impact, high-profile patient safety concern, leading us to again put this topic at the top of our list: The potential for alarm-related incidents leading to patient harm exists every minute of every day in virtually all health-care facilities. In truth, alarm issues may always warrant inclusion on a list of the most-pressing health technology hazards, as alarms are ubiquitous and the risks cannot fully be eliminated. What healthcare facilities can do, however, is continuously improve the manner in which alarms are managed.

This principle of measured, continuous improvement is illustrated by an initiative implemented at The Johns Hopkins Hospital—an initiative that earned the organization the 2012 Health Devices Achievement Award. (See page 365.) A team at Johns Hopkins analyzed alarm data on a unit-by-unit basis to gain an understanding of the type, frequency, and duration of alarms occurring in particular care areas. They then applied multiple small tests of changes to alarm settings and continued monitoring the alarm data, comparing pre- and post-change results. By making modest changes to default parameter settings, along with standardizing care and equipment and providing reliable ancillary alarm notification, the team was able to significantly reduce the number of non-actionable, clinically insignificant alarms (e.g., one clinical unit achieved a

43% reduction in alarms). Look for more details on the project in an upcoming issue of *Health Devices*.

What such initiatives can help a health-care facility achieve is balance between too many alarms sounding and too few. With too many alarms sounding—meaning frequent alarms for events that aren't clinically significant or for avoidable conditions (e.g., low-battery alarms)—staff may be more likely to experience alarm overload or “alarm fatigue.” These conditions can lead to ineffective responses or prompt unsafe actions. For example, caregivers may turn down the volume of alarms to an inaudible level, or they may improperly adjust alarm limits outside the safe and appropriate range in an attempt to reduce the number of alarms. Such modifications could possibly tip the scale too far the other way, resulting in caregivers not being warned of some conditions that require their attention. If alarm thresholds are set without careful consideration of the patient's condition and the alarm's function, for example, the alarm may be set in such a way that it effectively becomes disabled.

While it may no longer be necessary to include alarm safety on our list to raise awareness about the problem—our past Top 10 Hazards lists and increased media attention have done that—we nevertheless continue to shine the spotlight on alarm management to encourage healthcare facilities to build on the momentum that has been established following events such as the October 2011 Medical Device Alarms Summit. The summit—which was convened by ECRI Institute, the Association for the Advancement of Medical Instrumentation (AAMI), FDA, the American College of Clinical Engineering, and the Joint Commission—provided a strong impetus toward forming a consensus on alarm-safety problems and developing specific action plans.

Recommendations

The scope of the alarms hazard is broader than can be addressed in a few bullet



points, so we encourage you to refer to the resources listed below for more detailed guidance. The recommendations that follow can help you refine your alarm management program to reduce alarm-related adverse incidents. Recognize that this process requires a big-picture assessment of the organization as a whole, as well as more targeted assessments of each individual care area. Because so many factors influence alarm management, facilities are unlikely to find a one-size-fits-all solution that can be applied across all care areas.

- ▷ Evaluate the manner in which alarms are handled by devices and systems, including those in use at your facility and those that you are considering for purchase. (This may include ancillary alarm management technologies—those products that collect alarms and forward them to clinician-carried communication devices such as phones or pagers.) Factors to consider include:
 - How alarms are managed by the initiating medical device. For example: Is the priority level of each alarm made obvious (using visual and audible indicators)? Are alarms clear and unambiguous in their description? Can alarm configurations be customized in appropriate ways to meet patient needs?

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.

In addition, a well-prepared facility will 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 reporting system takes a nonpunitive approach, encouraging reporting to help identify problems, work toward their resolution, and facilitate learning.

- ▷ Relevant events are reported to the manufacturer, to ECRI Institute, and to the appropriate regulatory agencies (e.g., FDA).*
- ▷ A standard procedure has been instituted to assess reported events (including near misses), and criteria have been established for determining when events require further analysis, including root-cause analysis.
- ▷ Trends of errors are examined to identify issues that might require increased awareness, process or technology changes, or other forms of remediation.

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

- How alarms are managed by ancillary alarm management systems. For example: Is the ancillary alarm management system able to filter alarms so that only the desired alarms are forwarded to a clinician (based on well-thought-out protocols)? At what point can an ancillary alarm management system become saturated with alarms and either drop alarms or delay communication of the alarms?
- How alarms are handled by the clinician-carried communication devices. For example: Does the phone, pager, or other device provide adequate indication of the seriousness of the alarm and a clear description of the alarm?
- How alarms are managed in the overall system. For example: Can logs be retained showing that an alarm was received by a clinician-carried device and read or acknowledged by the clinician?
- ▷ Verify that your alarm management program addresses the following for each care unit:
 - The overall alarm load, considering the full complement of equipment in use—for example, physiologic monitoring systems (including telemetry), ventilators, infusion pumps, bed-exit alarms, and nurse call devices—and how the equipment is configured, as well as any associated ancillary alarm management technologies
 - The number of parameters monitored
 - Staffing levels, staffing patterns, and care model
 - The physical layout of the care unit
 - ▷ Assess your protocols and policies for the following, and modify them as necessary:
 - Setting alarm-system limits and priority levels. Protocols should define the default alarm settings for the specific care unit—for example, which alarms are active and what limits and priority levels should be used. Additionally, protocols should include criteria to guide caregivers in adjusting alarm settings (e.g., limits, priority levels) from their default values for individual patients to ensure that staff members are notified of clinically significant events.
- Alarm notification and alarm response. Effective protocols will ensure that the appropriate caregiver is alerted and that the alarm is promptly addressed.
 - For example, the facility should clearly assign responsibilities to staff, including who is responsible for alarm notification, who is responsible for responding to the alarm, and who is responsible for backup response in the event that the primary caregiver is unavailable. Layers of backup coverage may be required to ensure that someone responds promptly when the primary caregiver is not available.
 - Additionally, for care units that employ individually assigned devices (e.g., pagers, phones) as part of an ancillary alarm system, mechanisms should be established

to ensure that each device is assigned to the correct caregiver on a per-shift basis. Such mechanisms should also ensure that each nurse's patient assignments are programmed into the ancillary system and updated as assignments are changed and new patients are admitted.

- Controlling alarm silencing, modification, and disabling. This includes using the strongest password-protection techniques available on the medical devices and systems (e.g., changing passwords from the default values) to prevent unauthorized access to settings menus.

- ▶ For new care areas, be sure to consider the issues discussed above from the earliest planning stages.

For all these steps, it is important to solicit the perspectives of clinical staff, in particular the nurses and others who are responsible for the timely response to alarms. Having a clear understanding

of clinical needs and processes, ideally supported by alarm data (obtained, for example, from alarm logs or reports), can help you identify the issues that are causing the greatest difficulty and target the circumstances and patient care areas for which improvement is most needed.

Member Resources

Resource Center:

Physiologic monitoring. Available from: https://members2.ecri.org/Components/HDJournal/Pages/ResourceCenter_PhysMon.aspx. (See particularly the pages on managing alarm overload, alarm notification strategies, and alarm-enhancement technologies.)

Health Devices:

Alarm notification for physiologic monitoring: could you benefit from a new strategy? [guidance article]. 2007 Jan;36(1):5-21.

The hazards of alarm overload: keeping excessive physiologic monitoring alarms from impeding care [guidance article]. 2007 Mar;36(3):73-83.

Interfacing monitoring systems with ventilators: how well do they communicate alarms? [guidance article]. 2012 May;41(5):134-50.

Additional Resources

Association for the Advancement of Medical Instrumentation (AAMI). 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. Summit website: www.aami.org/meetings/summits/alarms.html.

Association for the Advancement of Medical Instrumentation (AAMI) Foundation Healthcare Technology Safety Institute (HTSI). Using data to drive alarm system improvement efforts—the Johns Hopkins Hospital experience [white paper]. Safety Innovation Series. Arlington (VA): AAMI; 2012. Also available: www.aami.org/htsi/safety_innovation.html.

ECRI Institute:

Alarm safety resource site: www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Don't kill the alarm: the time to improve alarm management is now [web conference]. 2011 May 18. Recording and CD toolkit available for purchase: www.ecri.org/Conferences/AudioConferences/Pages/Improve_Clinical_Alarm_Management.aspx.

2. Medication Administration Errors Using Infusion Pumps

ECRI Institute PSO* reports that medication mishaps—from any source—are among the most common errors in health-care (ECRI Institute PSO 2011); thus, such events warrant particular attention in any facility's patient safety efforts. While the broad topic of medication errors is beyond the scope of a list that focuses on technology-related hazards, the safe administration of medications using infusion pumps is an area in which technology

managers can play a vital role in preventing patient harm.

Infusion devices are the subject of more adverse incident reports to FDA than any other medical technology (AAMI 2010), and the consequences of infusion errors 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 during a five-year period from 2005 through 2009 include 710 deaths associated with infusion devices (AAMI 2010).

The careful implementation of “smart” pumps, as ECRI Institute has recommended for years, is one technology solution that can help reduce infusion errors. Smart

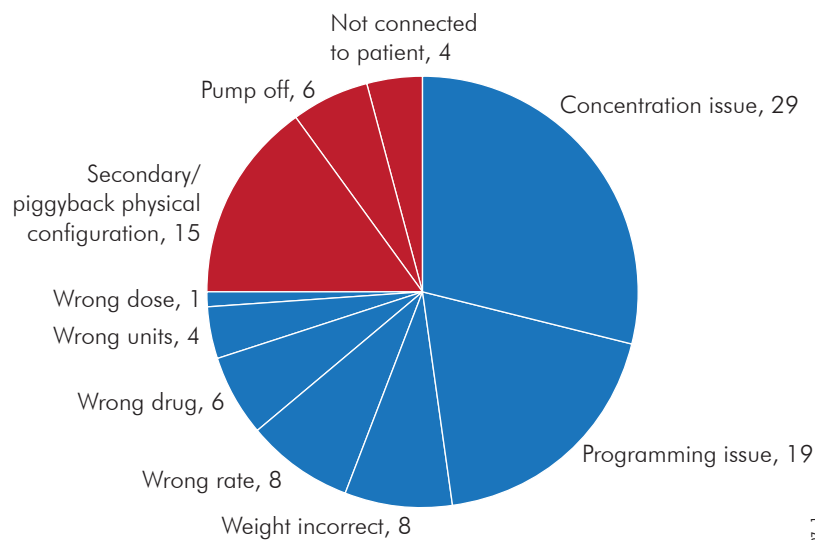
pumps can, for example, reduce gross misprogramming errors and provide a safer



* ECRI Institute PSO, which is a component of ECRI Institute, has been officially listed by the U.S. Department of Health and Human Services as a Patient Safety Organization under the Patient Safety and Quality Improvement Act. ECRI Institute PSO's mission is to achieve the highest levels of safety, quality, and cost-effectiveness of healthcare by collecting and analyzing patient safety information and sharing lessons learned and best practices.

SMART PUMP ISSUES REPORTED TO ECRI INSTITUTE PSO

Random Sample of 100 Reports (May 2010 to March 2012)



Seventy-five percent of the pump-related issues analyzed from ECRI Institute PSO's database (the blue regions of the graph) could be prevented with integration. Source: ECRI Institute/ECRI Institute PSO webinar: "Building a Safe Framework for Integrated Infusion Pumps" (August 15, 2012).

method of bolus administration. However, even these technologies are not foolproof.

The next step in infusion safety—and one that will require considerable involvement from clinical engineers, IT staff, and other technology managers—will involve integrating infusion pumps with electronic ordering, administration, and documentation systems. Successful integration can help reduce a significant portion of the errors that can occur even with smart pumps. For example: An analysis of a random sample of 100 pump-related events from ECRI Institute PSO's database (the sample was drawn from nearly 500 events covering May 2010 to March 2012) revealed the issues shown in the chart on

this page. With integration, which allows pump programming to be checked against medication orders, 75% of those events (the blue regions of the graph) could be avoided. Integration also has a convenience factor, eliminating many manual documentation tasks, for example.

Achieving integration, however, is a multistep, multiyear process. As described in ECRI Institute's August 2012 webinar (see Member Resources below), and as detailed in AAMI's white paper "Best Practice Recommendations for Infusion Pump-Information Network Integration," several infrastructure requirements must be in place before a healthcare facility can move forward with integration plans. This means

that most facilities will need to identify, budget for, and implement a variety of technologies (e.g., reliable and pervasive wireless coverage, electronic infusion orders, bedside bar-code scanning) to lay the groundwork for integration. However, as discussed below, we believe that healthcare facilities will need to start moving in this direction.

Recommendations

Moving forward, we recommend fostering a shift in mindset from viewing infusion pumps as stand-alone devices to viewing them as components of an integrated medication delivery system. Infusion pumps are likely to become integrated with pharmacy information systems, electronic medical records (EMRs), and other information systems. To best position your facility for integration, we recommend the following:

- ▷ Start developing a roadmap for integration, recognizing that this is a multistep, multiyear process. Refer to AAMI's Healthcare Technology Safety Institute white paper on integration for guidance (see the list of resources below).
- ▷ If you are in the market for new infusion pumps, continue to assess traditional factors such as vendor support, usability, and costs, but also be sure to 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). For example, consider requiring compliance with standard message formats developed and maintained by Integrating the Healthcare Enterprise (IHE). (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.) Also, request that pump vendors provide the names of other sites that have integrated the pumps with information systems from the major providers of EHRs and other information systems using IHE standard messaging.

- ▶ If you already own wireless smart pumps, start building the groundwork for integrating your infusion pump servers with electronic ordering, administration, and documentation systems that are currently in place.

Other steps that can help reduce infusion-related adverse events include the following:

- ▶ Develop appropriate drug libraries for clinical areas that use infusion pumps. The 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 and seek out best practices.
- ▶ When implementing a new infusion system, take advantage of vendor consulting programs. Consider requesting that a representative help the facility troubleshoot problems.
- ▶ Before and during purchasing, be sure to get buy-in from staff members who will be using the system, and emphasize to clinicians the importance of infusion pump technology safeguards. Also, recognize that the introduction of new infusion technologies may necessitate some changes in workflow. Involving clinicians in the process of defining workflows can help yield the most effective and efficient processes while minimizing staff resistance. Safety system noncompliance by staff (e.g., failure to acknowledge smart pump alerts) must be identified and rectified as soon as possible.
- ▶ Invest in dedicated resources to analyze infusion pump data (e.g., smart pump alert history) to improve processes and safety (including drug library updates). Develop a policy identifying a person responsible for data analysis, as well as how and when infusion pump data will be captured, analyzed, and disseminated.
- ▶ Read the Infusion Device Summit report (AAMI 2010), and consider how

WHAT'S YOUR RISK OF EXPERIENCING THESE HAZARDS? FIND OUT USING OUR SELF-ASSESSMENT TOOL

The 2013 edition of ECRI Institute's online Health Technology Hazard Self-Assessment Tool includes all-new functionality for gauging your risks of experiencing any of the hazards on our latest Top 10 list. The tool now allows you to invite multiple individuals and departments within your facility to respond to survey questions on any of the hazard topics. Also, for the first time the tool allows you to orchestrate distribution of surveys across your health system and pull together consolidated results covering all the surveyed facilities.

The Self-Assessment Tool processes the answers from all parties and generates a report that rates your level of risk for each of the hazards from low to high. The report also helps you identify specific practices that could help reduce your risk. Thus, you can use the Self-Assessment Tool to

- ▶ identify the hazards that are most relevant to your institution (i.e., where additional attention is warranted);
- ▶ raise awareness among administration and staff about those hazards;
- ▶ prioritize your response, targeting the areas of greatest vulnerability first and then working down the list; and
- ▶ formulate action plans based on the guidance provided.

Members can access the Health Technology Hazard Self-Assessment Tool from their Health Devices home page. If you are not a member and would like to learn more about using the tool, please contact ECRI Institute at clientservices@ecri.org or +1 (610) 825-6000, ext. 5891.

your facility is addressing the themes discussed in that report.

ECRI Institute has published extensively on infusion safety and the selection of infusion technologies; see the list of resources below.

Member Resources

Resource Center:

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

Health Devices:

General-purpose infusion pumps [evaluation]. 2007 Oct;36(10):309-36.

Large-volume infusion pumps: the evolution continues [evaluation]. 2009 Dec;38(12):402-10.

Patient-controlled analgesic infusion pumps [evaluation]. 2006 Jan;35(1):5-35.

Syringe infusion pumps with dose error reduction systems [evaluation]. 2008 Feb;37(2):33-51.

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):

Infusion Systems Safety Initiative:

Website: www.aami.org/htsi/infusion/index.html.

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.

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.

ECRI Institute PSO. *ECRI Institute PSO deep dive: medication safety*. Plymouth Meeting (PA): ECRI Institute PSO; 2011 Dec.

3. Unnecessary Exposures and Radiation Burns from Diagnostic Radiology Procedures

In diagnostic radiology procedures—procedures in which ionizing radiation is used to image structures within the body—the diagnostic quality of the image is affected by the amount of radiation, or dose, that is used. Image quality typically improves as the dose increases. As a result, there is a natural tendency to use higher doses. However, higher doses are associated with greater risks to the patient. Acute reactions to excessive radiation exposure, such as radiation burns or hair loss, occur only in extreme cases—but still too frequently, and such incidents can usually be prevented. The more common concern is that exposure to radiation increases the patient’s risk of eventually developing cancer—a risk that can’t be eliminated but that nevertheless should be controlled.

But controlling the risks can become more complicated—and more crucial—as technologies advance. Newer generations of imaging technologies can offer dramatically increased diagnostic capabilities compared with older technologies, but they often use higher doses. The higher dose per procedure is clearly a factor that contributes to higher cumulative doses for particular patients, but so too is the number of procedures performed. The advanced capabilities

of these technologies may lead to their increased use, resulting in a higher cumulative dose that a patient might receive. With so many factors pushing toward higher cumulative doses, concentrated efforts are required to reduce unnecessary radiation exposures whenever possible.

In previous Top 10 lists and in other *Health Devices* articles, ECRI Institute has addressed the topic of controlling dose during CT, a diagnostic imaging modality associated with a relatively high dose. For this year’s list, we are recommending that healthcare facilities look more broadly at the many factors that can contribute to unnecessary radiation exposures—or, in extreme cases, cause radiation burns—with any diagnostic imaging modality. Questions to consider include:

- ▷ Is the appropriate test being ordered? That is, could imaging techniques that don’t rely on ionizing radiation (e.g., ultrasound, MRI) be used to obtain the needed diagnostic information?
- ▷ Have acceptable images already been acquired recently, making a repeated exposure unnecessary? We discussed the issue of avoidable instances of repeat imaging—for example, the ordering of a new study when existing, acceptable images from another facility could instead have been used—in an April 2012 Safety Matters article.
- ▷ Are technologists using the ALARA principle—that is, using doses that are “as low as reasonably achievable” to acquire the desired diagnostic information? For example:
 - Do technologists consider the characteristics of each patient when planning a study? Settings designed for one patient may not be appropriate for another. One particular concern, which we address more directly in item

number 7 on this year’s Top 10 list, is the failure to adjust dose levels for pediatric patients. Using adult settings on pediatric patients exposes children to higher-than-necessary radiation levels.

- When selecting the anatomy to be imaged, are technologists careful to avoid unnecessarily delivering dose beyond the anatomical area of interest? We discussed the issue of beyond-boundary imaging in another April 2012 Safety Matters article.

- ▷ Are skin dose levels being tracked throughout the course of a procedure? This applies specifically to fluoroscopic procedures, in which real-time radiologic images are used to guide the physician. A warning of excessive accumulated dose can help reduce the chances of the patient experiencing an acute skin reaction. Interest in technologies that better track skin doses during fluoroscopically guided procedures is growing.

While no consensus exists on the extent of the cancer risk from diagnostic imaging, “there is uniform agreement . . . that steps should be taken to reduce unnecessary exposure to radiation” (FDA 2010 “Initiative to Reduce”). Since 2007, ECRI Institute has published numerous articles describing the risks and promoting measures to reduce unnecessary radiation exposures from radiologic imaging studies. And in 2010, FDA launched an initiative promoting patient safety through two principles of radiation protection developed by the International Commission on Radiological Protection: (1) that the procedure be justified—in other words, that it be “judged to do more good than harm to the individual patient”—and (2) that the dose be optimized such that “the lowest radiation dose that yields an image quality adequate for



diagnosis or intervention” be administered (FDA 2012 resource page).

The Joint Commission likewise has increased the focus on implementing measures to control the risks associated with diagnostic radiology. ECRI Institute worked with the Joint Commission in developing its August 2011 Sentinel Event Alert (Issue 47), “Radiation Risks of Diagnostic Imaging.”

In addition, the Image Wisely campaign—an initiative of the American College of Radiology (ACR), the Radiological Society of North America, the American Association of Physicists in Medicine (AAPM), and the American Society of Radiologic Technologists—was developed with the objective of lowering the amount of radiation used in medically necessary imaging studies and eliminating unnecessary procedures. Similarly, the Image Gently campaign, initiated by the Alliance for Radiation Safety in Pediatric Imaging, was developed with the goal of changing practice by increasing awareness of the opportunities to promote radiation protection in the imaging of children.

Recommendations

There is no simple fix to ensure that radiation for diagnosis is used safely and effectively. A comprehensive review of all aspects of operations and quality assurance is needed. ECRI Institute recommends the following:

- ▶ Maintain adequate staffing levels, and commit to a nationally recognized accreditation certification.
- ▶ Verify that appropriate quality assurance and quality control procedures are in place and documented. Oversight and peer review of these procedures should be conducted.
- ▶ Ensure that ionizing radiation systems are properly installed, commissioned, and maintained. This includes performing acceptance testing for new

systems, as well as for system updates and modifications, and ensuring that the integrated systems as a whole meet performance specifications.

- ▶ Ensure that radiologists and medical physicists are accessible to clinical staff for consultations and education regarding the appropriate use of diagnostic imaging.
- ▶ Emphasize to staff that radiation doses should be as low as reasonably achievable while maintaining acceptable diagnostic image quality.
- ▶ Monitor scan protocols for appropriateness.
- ▶ Validate all study protocols before routine clinical use.
- ▶ Customize all study protocols to specific patient needs (e.g., adult versus pediatric patients), and update protocols as necessary to reflect the latest guidance from professional organizations such as ACR and AAPM.
- ▶ Implement software to record and audit radiation doses.
- ▶ Investigate whether radiation dose mitigation technologies are available for the systems in use at your facility, and assess whether such technologies should be implemented.

Member Resources

Resource Center:

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

Health Devices:

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.

Optimizing CT dose: a look at the latest dose-monitoring, breast-protection, and noise-reduction technologies [guidance article]. 2012 Aug;41(8):238-49.

Radiation dose in computed tomography: why it's a concern and what you can do about it [guidance article]. 2007 Feb;36(2):41-2, 44-63.

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.

PowerPoint presentation:

CT radiation dose safety. Available from: <https://members2.ecri.org/Components/HdSlideShows/Pages/default.aspx>.

Additional Resources

Websites and online resource pages:

Food and Drug Administration (FDA), U.S. Initiative to reduce unnecessary radiation exposure from medical imaging [online]. 2012 May 17. Available from: www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm.

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

Image Wisely campaign website: www.imagewisely.org.

Articles and publications:

American College of Radiology. ACR appropriateness criteria [online]. 2012 [cited 2012 Oct 15]. Available from: www.acr.org/Quality-Safety/Appropriateness-Criteria.

Brody J. Medical radiation soars, with risks often overlooked. *N Y Times* 2012 Aug 20. Also available: well.blogs.nytimes.com/2012/08/20/medical-radiation-soars-with-risks-often-overlooked.

ECRI Institute. *Health Technol Trends* 2011 Feb;23(2):1-12. [special issue on pediatric imaging]

Food and Drug Administration (FDA), U.S. Initiative to reduce unnecessary radiation exposure from medical imaging [white paper online]. 2010 Feb [cited 2012 Aug 19]. Available from: www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM200087.pdf.

Joint Commission. Radiation risks of diagnostic imaging. *Sentinel Event Alert* 2011 Aug 24; issue 47. Also available: www.jointcommission.org/assets/1/18/SEA_47.pdf.

4. Patient/Data Mismatches in EHRs and Other Health IT Systems

The experience of the physician, the skill of the staff, the capabilities of the technology, the evidence supporting the procedure—all of that can be rendered meaningless if the procedure being performed on Mr. Smith was initiated because of test results that actually belong in the electronic health record (EHR) of Ms. Jones.

Mistakes leading to one patient's data ending up in another patient's record are not a new phenomenon: In traditional paper-based systems, a moment's inattention or carelessness certainly could lead to a printout being mistakenly placed in the wrong file. In addition, it's not possible to know whether patient/data association errors (i.e., mismatches) are more or less likely to occur with IT systems than with paper-based systems, since such errors are not consistently reported (and may not always be detected).

Nevertheless, ECRI Institute's research and testing show that patient/data association errors with health IT systems do occur. And with health IT systems, these errors are not necessarily a function of user mistakes or carelessness; they could, for example, result from system design flaws or software anomalies. If the problem is one that is not easily discoverable, many patients could be affected before the defect is found.

One particularly troubling aspect of patient/data association errors is that some of the capabilities that make health IT systems so powerful—their ability to collect data from and transmit data to a variety of devices and systems, for example—can serve to multiply the effects of such errors to a degree that would have been unlikely in a paper-based system. The result is that such errors can have far-reaching consequences, leading to a host of downstream effects that can be both difficult to identify and difficult to correct once they have been identified.

Many care decisions today are based on data in an EHR or other information system; and incorrect data can result in incorrect treatment, potentially resulting in patient harm. In addition, as EHR data flows through health information exchanges to other health systems, the inappropriate data can affect multiple areas and systems. Even once a problem has been discovered, the task of examining records and distinguishing which data belongs to which patient can be monumental.

Thus, we believe that healthcare facilities should be looking at this problem while in the planning and early implementation stages of health IT projects, to prevent more vexing problems down the road.

Adding to the challenge is the fact that these kinds of errors can occur in unexpected ways. Consider the following scenarios that we identified when examining connectivity solutions for our April 2012 Guidance Article (“connectivity solutions” is a term we use to describe certain systems that enable data exchange between medical devices and EHRs):

- ▷ Successful data transfer between a medical device and an EHR or other information system requires (1) that data from the device be associated with the correct patient's record in the information system and (2) that the device and patient record be correctly disassociated when the device is switched from one patient to another.

The functionality of the devices and systems involved, as well as the workflow employed, can be factors affecting whether data is associated with the wrong patient. To illustrate, a “location-centric” association method assumes that the patient and device are fixed within the room. If the patient is moved from one room to another and the patient's location is not updated



in the EHR, data may be sent to the wrong patient's record. A “patient-centric” association method, on the other hand, directly associates the data with a particular patient ID number. Association errors can still occur, however, if an incorrect ID is entered.

- ▷ Most connectivity solutions are designed to “store and forward” data in the event of a network outage. That is, they continue recording information from the device during a network outage and send it to the EHR once the network is up and running again. However, if a device is moved from one patient to another during the outage, and if the system is not designed to handle disassociation/association properly while offline, then the stored information could be sent to the wrong patient's record once the network comes back online.

Additionally, safety notices published in *Health Devices Alerts* demonstrate some of the problems that have been observed. Following are just some examples:

- ▷ A radiation oncology treatment planning system may use images from the wrong patient, posing a risk

of treatment to the incorrect area (Accession No. A17755).

- ▷ Software that aggregates data from different systems may incorrectly match patient data, potentially resulting in the incorrect patient data being displayed (Accession No. A17282).
- ▷ A software flaw in data servers would allow images from one patient to be put into another patient's study (Accession No. A18539).
- ▷ Annotation data from one patient may be displayed with the results for a different patient on a radiation therapy workstation (Accession No. A18336).

The incidence of patient/data association errors, and other health IT hazards, may increase as hospitals in the United States fast-track efforts to implement EHRs—initially to receive incentive payments made available through the Health Information Technology for Economic and Clinical Health (HITECH) Act, and eventually to avoid monetary penalties for failing to achieve meaningful use of EHRs. Well-implemented EHRs promise greater efficiency, more reliable data, and even improved patient safety. But making the switch from a paper-based system to an electronic system is difficult, and it may pose unanticipated risks to patients if the process isn't carefully thought through.

Recommendations

- ▷ When assessing health IT systems for purchase, when planning implementations, and when establishing workflows:
 - Consider how all the connected technologies facilitate placing the right patient data into the right record. Options may include choosing a patient from a pick list or scanning the bar code on a patient's wristband. To the extent possible, choose an association option that best fits the existing
- Consider both patient flow and device movement, planning for all anticipated types of transfers, not just the routine examples. If a patient is transferred from one care area to another, the goal, to the extent achievable, is to retain a continuous record for the entire stay with minimal or no gaps in the data. Also, recognize that devices that move from patient to patient, such as spot-check monitors and ventilators, may need different workflows or technologies (e.g., connectivity solutions) than devices that are permanently fixed to a patient care area (e.g., patient monitor affixed to Room 101).
- ▷ When implementing any project or software upgrade:
 - Before implementation, perform appropriate testing to verify that the system will behave as expected, with the right data

workflow—recognizing, however, that the workflow may need to be adjusted to ensure that the right patient data is included in the right record.

A patient-centric approach is typically preferred over a location-centric one, since the latter increases the burden on hospital personnel to maintain correct patient association. If, however, a location-centric approach is the only feasible alternative, make sure that staff are aware of the need for extra care when associating and disassociating patients and technologies. (Our April 2012 Guidance Article, “Making Connections: Integrating Medical Devices with Electronic Medical Records,” discusses these concepts in detail.)

flowing into the right record for the various clinical workflows.

- Design test scenarios in such a way as to avoid merging test data with real patient information. (“Health IT Hazard Manager Beta-Test: Final Report,” a document prepared for the Agency for Healthcare Research and Quality, describes a mock hazard scenario in which test orders, test lab results, etc., were entered using the word “Test” in place of the patient name. In the EHR, the orders were incorrectly associated with an actual patient with the surname of “Test.”)
- After implementation, verify that the system is working as planned.

Member Resources

Health Devices:

Connectivity and patient safety—perspectives from the HIMSS conference [safety matters]. 2012 Apr;41(4):123-4.

Data-transfer problems between imaging devices and PACS could result in misdiagnosis [hazard report]. 2008 Dec;37(12):381-3.

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

Additional Resources

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.

Walker JM, Hassol A, Bradshaw B, et al. Health IT hazard manager beta-test: final report. (Prepared by Abt Associates and Geisinger Health System, under Contract No. HHSA290200600011i, #14.) AHRQ Publication No. 12-0058-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2012 May. Also available: http://healthit.ahrq.gov/portal/server.pt/community/ahrq-funded_projects/654/projectdetails?pubURL=http://wci-pubcontent/publish/communities/a_e/ahrq_funded_projects/projects/health_it_hazard_manager.html.

5. Interoperability Failures with Medical Devices and Health IT Systems

Establishing interfaces among medical devices and information systems can facilitate functions such as automated clinical documentation, the delivery of data for real-time clinical support, data aggregation for retrospective review, and remote surveillance. This kind of integration has the potential to reduce errors associated with manual documentation and improve patient safety. However, interoperability allowing the appropriate exchange of data can be difficult to achieve, and patient harm can result if this is not done effectively.

In hazard number 4 on this year's list, we addressed one very specific type of interoperability failure—the association of one patient's data with another patient's record. However, we also recommend that safety efforts target broader interoperability issues, such as those outlined below:

Interfaces between medical devices. *Health Devices* research has shown that interfaces between medical devices may not work as intended. When testing connectivity between physiologic monitoring systems and ventilators, we found that most of the interfaces we tested did not function as desired—and some even allowed dangerous conditions to exist. For example, one monitoring system did not communicate audible or visual alarms from an interfaced ventilator to warn caregivers of a critical patient circuit disconnection, a condition that would result in the patient no longer receiving respiratory support. Some other monitoring systems did not sound an audible alarm to warn caregivers when the communication cables between the monitor and ventilator had become disconnected, severing communications between the two devices and potentially leaving clinicians unaware of life-threatening problems. (Refer to the May 2012 *Health Devices* for details.)

System incompatibilities. Reports received by ECRI Institute PSO and safety notices published in *Health Devices Alerts* illustrate the hazards that can exist when systems are not able to exchange data with one another or when the exchange goes awry (e.g., because of a software anomaly).

ECRI Institute PSO has received numerous reports in which lab results that were invalid (e.g., because a test was performed improperly) had been correctly removed from one system, such as a laboratory information system (LIS), but were still visible in another system (e.g., an electronic health record). The mismatches existed until the discrepancies were noted by staff and the results were manually removed from the second system.

Examples from *Health Devices Alerts* include blood gas analyzers transmitting incorrect results to a hospital information system (HIS) or LIS (Accession No. A18475); LIS software incorrectly flagging results transmitted from one brand of clinical chemistry analyzer (Accession No. A17287); and diabetes management software creating an erroneous high/low pattern report for results downloaded from a blood glucose meter (Accession No. A17444).

In all such instances, the risk exists that caregivers will act on the invalid results.

Change management. One consequence of interoperability is that changes to one device or system can have unintended effects on other devices or systems. For example: A facility's bar-code medication administration system, which was integrated with the facility's patient monitors, was brought down when a software upgrade to the facility's physiologic monitoring system was implemented. Avoiding such hazards requires effective change management. Change management is a structured approach for ensuring that



system modifications, such as software upgrades and scheduled maintenance, are performed in a controlled manner.

The challenges associated with medical device interoperability were the subject of an October 2012 summit convened by AAMI and FDA and supported by ECRI Institute and other organizations. The summit examined the complex issues surrounding interoperability and sought to identify steps that can be taken to improve device interoperability and enhance patient safety. For details, see www.aami.org/interoperability/index.html.

Recommendations

Despite the challenges associated with integrating medical devices and systems, healthcare facilities ultimately should be moving in that direction, though being mindful of both the benefits and risks. Careful planning and taking steps such as the following can help minimize the risks.

- ▷ Maintain an inventory of the interfaced devices and systems in your institution, including the software versions and configurations of the various interfaced components.

- ▷ Identify, assess, and prioritize risks associated with these interfaces. Follow best practices as described by the International Electrotechnical Commission's IEC 80001-1 standard, *Application of Risk Management for IT-Networks Incorporating Medical Devices—Part 1: Roles, Responsibilities and Activities*. Medical device integration with information systems creates a complex system consisting of many smaller systems. Risk management efforts, if executed properly, can facilitate successful examination of a hospital's entire system, allowing the facility to anticipate unintended patient consequences.
- ▷ Assess, approve, and implement changes to interfaced medical devices or information systems in a controlled manner. Software updates, hardware upgrades, the integration of new devices or systems, new work processes, and the like can affect other connected devices or systems. Thus, it is important to follow stringent change management practices and perform validation testing as necessary. We recommend measures such as the following:
 - Assessing your change management policies to ensure that they adequately cover how to handle changes that involve various interfaced devices and systems. For example, ensure that an IT department's change management policies incorporate how to deal with interfaced medical devices. Similarly, a clinical engineering department's change management policies should incorporate how to deal with changes that involve interfaces to information systems.

- Keeping good vendor relationships and leveraging contracts. Change management is easier when there is time to prepare for the change (i.e., be proactive rather than reactive). Include change management expectations in requests for proposals and purchasing agreements with IT suppliers, medical device vendors, and connectivity solution vendors. Language stipulating, for example, that vendors provide advance notice of impending changes can give healthcare facilities time to budget and adequately plan for changes.
- Involving the appropriate stakeholders (e.g., IT, clinical engineering, communications, nursing) when making changes to interfaced equipment to ensure the safe and effective performance of the system post-change.
- Performing the testing needed to verify that the system behaves as expected before any broad system modifications are implemented. For some interfaced systems, checklists can be developed to aid with such endeavors. For example, the May 2012 *Health Devices* includes our checklist for physiologic monitoring system and ventilator connectivity.

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.

Inattention to change management for medical device connectivity. Hazard no. 5. In: Top 10 technology hazards for 2012: the risks that should be at the top of your prevention list [guidance article]. 2011 Nov;40(11):358-73.

Interfacing monitoring systems with ventilators: how well do they communicate alarms? [guidance article]. 2012 May;41(5):134-50.

Look who's talking: a guide to interoperability groups and resources [guidance article]. 2011 Jun;40(6):190-7.

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

Physiologic monitoring: a guide to networking your monitoring systems [guidance article]. 2011 Oct;40(10):322-48.

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.

Association for the Advancement of Medical Instrumentation (AAMI). Medical device interoperability [white paper online]. 2012 [cited 2012 Oct 11]. AAMI MDI/2012-03-30. Available from: www.aami.org/interoperability/Materials/MDI_1203.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.

Joint Commission. Safely implementing health information and converging technologies. *Sentinel Event Alert* 2008 Dec 11; issue 42. Also available: www.jointcommission.org/assets/1/18/SEA_42.PDF.

6. Air Embolism Hazards

Intravascular air embolism is a potentially lethal complication of certain medical and surgical procedures.* Clinicians are generally aware of the risks of air embolism during such procedures, and the circumstances that can lead to patient harm are rare. Nevertheless, ECRI Institute occasionally receives reports and conducts investigations of fatal incidents.

In addition, data available through the Pennsylvania Patient Safety Authority likewise illustrates the dangers: Of the 59 confirmed or suspected air embolism adverse events reported to the Authority by Pennsylvania acute healthcare facilities from June 2004 through December 2011, 34 were reported as serious events resulting in harm, including seven cases of permanent harm and six deaths (PA Patient Safety Authority 2012).

Thus, periodic renewed attention within a patient safety program is warranted to ensure that caregivers are taking appropriate measures to minimize the risks.

An air embolism can occur when (1) there is a pathway for air to enter the vasculature and (2) the pressure gradient favors the entry of this air into the bloodstream—either from the active injection of air or the passive ingress of ambient air (PA Patient Safety Authority 2012). For instance: Air within IV tubing could be actively injected into the vasculature through the action of a device such as an infusion pump or contrast media injector. Also, circumstances in which the blood pressure in the vessel is lower than the ambient air pressure (e.g., if the opening to the vessel is above the level of the heart) can lead to the

passive formation of a pressure gradient that is conducive to atmospheric air flowing into an open vessel or cannula (Joint Commission Resources 2010).

The ingress of air into the vasculature during a variety of medical and surgical procedures is not necessarily a rare occurrence (Joint Commission Resources 2010). The consequences to the patient, however, can vary widely based on factors such as the amount of air entering the bloodstream, the rate at which the air enters, and the route of entry. Depending on these factors, effects can range from no symptoms and no harm to potentially fatal conditions such as heart attack or stroke.

As a potentially fatal complication of a variety of procedures, air embolism hazards warrant close attention as a patient safety concern. Additionally, as a preventable condition that the Centers for Medicare & Medicaid Services has labeled a serious reportable event with nonpayment for harm, air embolism hazards also represent a financial concern.

Broad initiatives to prevent air embolism events are complicated by the wide range of procedures and clinical specialties involved. For example, ECRI Institute has received reports and conducted investigations associated with the use of the following:

- ▷ Automatic contrast media injectors for radiologic procedures. In the first half of 2012, FDA received three reports of air embolism associated with the use of contrast media injectors, one of which required emergency medical intervention to resuscitate the patient.** In addition, ECRI Institute is aware of a fourth incident in that time frame that involved a patient death.
- ▷ Central venous access devices (CVADs) for intravascular catheterization. Adverse event reporting data received by the Pennsylvania Patient Safety



Authority shows that the largest percentage of reported embolism events and near misses (41%) were associated with the use of CVADs (PA Patient Safety Authority 2012).

- ▷ Pressurized spray devices for applying fibrin sealants (to facilitate blood clotting). The use of spray devices at higher-than-recommended pressures, or closer than recommended to the tissue surface, can lead to air embolism. This hazard has been the subject of numerous alerts over the years, including an FDA safety notification in 2010 and several new alerts issued in 2012 (see the list of member resources below).
- ▷ Sphygmomanometer or noninvasive blood pressure cuff tubing being erroneously connected to IV lines. Fortunately, most newer blood pressure devices offer non-Luer connectors to minimize the likelihood of such misconnections. However, a report of a near miss that we recently received illustrates that this particular connection hazard still requires vigilance (see *Health Devices Alerts* Accession No. H0171).

We are also aware of or have investigated air embolism incidents related to the use of extracorporeal blood circuits for hemodialysis and heart-lung bypass procedures, air

* An air embolism is a type of gas embolism. However, the term “gas embolism” is typically reserved for describing the introduction of a specific type of gas (e.g., carbon dioxide, nitrogen) into the vasculature. The potential for harm from a gas embolism depends on the gas involved. Nitrogen (the primary gas in air) is not very soluble in blood and so is more likely to impede blood flow than a much more soluble gas like carbon dioxide (Joint Commission Resources 2010). While we focus on air embolisms in this report, much of the guidance also applies to gas embolisms more generally.

** Source: FDA’s Manufacturer and User Facility Device Experience (MAUDE) database.

insufflators for gastrointestinal insufflation, and pressure infusers.

In *Preventing Air Embolism*, an e-book describing research on and strategies for preventing and mitigating the effects of air embolisms, the Joint Commission reports that the surgical procedures that place patients at a high risk for air embolism include, for example, surgery in the sitting position (including neurosurgery), surgeries involving cardiopulmonary bypass, cesarean section, hysteroscopy, orthopedic surgeries, and gastrointestinal endoscopy. (Laparoscopic surgery is mentioned as a procedure that places patients at risk of *gas* embolism, as opposed to *air* embolism; for such procedures, carbon dioxide instead of air is typically used as the distending agent.)

Medical procedures that put patients at greatest risk for air embolism, according to the Joint Commission, include the use of contrast injectors and CVADs, infusion therapies through peripheral or central venous catheters, the use of pressure bags for the infusion of fluids, mechanical ventilation, and hemodialysis (Joint Commission Resources 2010).

Recommendations

Specific air embolism prevention measures will vary depending on the procedure being performed. The list of resources below includes documents that present in-depth guidance on air embolism prevention or detailed recommendations for addressing air embolism hazards associated with some specific technologies or procedures. We encourage healthcare facilities to review these resources.

More generally, a healthcare facility can apply the following approach in any clinical area where embolism risks are determined to be high:

- ▶ Educate nurses, technologists, and other relevant personnel who participate in procedures (or use equipment) associated with the risk of air embolism about the hazards. Instruction can be provided by supervisors, nurse educators, or other appropriate personnel

through specific air embolism prevention initiatives or in the normal course of professional development.

- ▶ Have staff in these areas assess their practices for the risk of air embolism, and institute measures to minimize the risk, if needed. Policies and procedures should be revised accordingly during the next scheduled policy and procedure review. Depending on the procedures and technologies involved, measures might include, for example:
 - Instituting a time-out procedure for activities that present a high embolism risk. That is, before the start of the procedure, clinicians would review a predetermined list of risk factors and verify that predetermined risk-reduction measures are taken or that protective mechanisms are in place.
 - Reinforcing the appropriate procedures to follow for removing air from solution delivery systems (e.g., IV pumps, contrast injectors). Such procedures, which are intended to prevent delivery of air into a patient's vasculature in amounts that could be hazardous to the patient, will vary according to the clinical application and setting.
 - Requiring that clinicians trace any line to its source before connecting the line to a patient's IV access device. Clinicians should verify that the line is intended for IV administration before making the connection.
- ▶ When evaluating devices and technologies for purchase, favor devices that incorporate features designed to minimize the risk of introducing air into the patient's vasculature (e.g., air-in-line detection or elimination mechanisms). For procedures that require insufflating or distending the patient's anatomy and that present a risk that gas may be infused into the body, facilities may wish to consider devices that use carbon dioxide, instead of air, as the

insufflation gas. Carbon dioxide is far more soluble in blood than the major constituents of air (nitrogen and oxygen) and thus is less likely to result in a lethal embolism. The use of carbon dioxide is standard for laparoscopic insufflation, but less common for gastrointestinal endoscopic insufflation.

- ▶ Remind users that safety features, such as those designed to detect air in a line or otherwise help prevent air injection, are not foolproof. Vigilance—that is, checking for air bubbles, verifying connections, following evidence-based practices, etc.—is still essential.

Member Resources

Contrast media injectors:

Angiography contrast injector safety: visualizing the marketplace [evaluation]. *Health Devices* 2010 Jun;39(6):182-93.

Safety features on CT contrast injectors: enhancing patient protection [evaluation]. *Health Devices* 2010 May;39(5):150-65.

Tubing misconnections:

Fixing bad links: preventing misconnections in your hospital [guidance article]. *Health Devices* 2009 Jul;38(7):220-7.

Parks Medical redesigns vascular laboratory systems pressure/cuff tubing connectors to prevent misconnections [hazard report]. *Health Devices Alerts* 2012 Jun 11. Accession No. H0171.

Spray application of fibrin sealants:

FDA warns of risk of air or gas embolism during use of air- or gas-pressurized spray devices [hazard report]. *Health Devices Alerts* 2012 Jul 30. Accession No. H0119.

Additional Resources

American Society of Anesthesiologists. Practice guidelines for central venous access: a report by the American Society of Anesthesiologists Task Force on Central Venous Access. *Anesthesiology* 2012 Mar;116(3):539-73. Also available: <http://ngc.gov/content.aspx?id=36196&search=central+venous+access+device>.

Joint Commission Resources (JCR). *Clinical care improvement strategies: preventing air embolism*. Oak Brook (IL): JCR; 2010 Jul. PDF e-book.

Pennsylvania Patient Safety Authority. Reducing risk of air embolism associated with central venous access devices. *Pa Patient Saf Advis* 2012 Jun;9(2):58-64. Also available: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Jun;9\(2\)/Documents/jun;9\(2\).pdf](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Jun;9(2)/Documents/jun;9(2).pdf).

7. Inattention to the Needs of Pediatric Patients When Using “Adult” Technologies

We noticed a theme developing when reviewing topics for inclusion on our Top 10 list: Many of the topics included a pediatric component. That is, a given hazard posed particular risks of harm for pediatric patients, or a particular technology didn’t adequately address the needs of a pediatric population (e.g., infants, children), which could jeopardize the safety of these patients.

Often the issue is that a technology designed with adult patients in mind nevertheless needs to be used on children, in some cases because no alternatives exist. As reported in the August 2012 issue of ECRI Institute’s *Health Technology Trends*, pediatric-specific devices are slow to reach the market because of the small numbers of patients available to study, the devices’ high-risk nature, and high development costs.

In the absence of devices tailored exclusively for the pediatric population, healthcare personnel must exercise particular care when using technologies designed for adults on children. Following are just a few examples of how the care of pediatric patients can be compromised when applying “adult” healthcare technologies:

Radiology. The need to avoid unnecessary radiation exposures for *all* patients is addressed under hazard number 3 on our list. However, particular attention should be paid to the use of radiologic imaging equipment on pediatric patients.

Radiation dose settings designed for adults are usually inappropriate for children: The use of such settings exposes young, still-developing patients to excessive radiation—a significant concern because radiation-linked cancer risks are higher for pediatric patients. (We discussed pediatric imaging in an August 2012 Safety Matters column. Also refer to the study by Pearce et al. associating high cumulative

radiation doses from CT scans of children with increased risks of leukemia and brain cancers.)

Another practice that places pediatric patients at risk is the overuse of radiologic imaging technologies (which is likewise discussed under hazard number 3). In 2008, ECRI Institute honored the Children’s Hospital of Omaha, Nebraska, with the Health Devices Achievement Award for an initiative that reduced the number of x-rays for pediatric patients. By implementing evidence-based indicators within the x-ray order process, the hospital both reduced the number of imaging studies performed and streamlined the x-ray order process.

FDA recently released two resources related to pediatric radiation. One is a draft guidance document proposing that new imaging devices address dose in pediatric exams. (Refer to our August 2012 Safety Matters section for additional discussion.) The second is a website providing information on pediatric radiation safety. In addition, the Alliance for Radiation Safety in Pediatric Imaging has initiated an “Image Gently” campaign to promote radiation protection in the imaging of children. (See the list of resources below.)

Medication administration and computerized provider order-entry (CPOE) systems. As Palma et al. describe, children have been shown to be at higher risk for adverse drug events and their consequences “due to the importance of appropriate weight- and age-based dosing calculations”; thus, CPOE systems could offer significant safety benefits, particularly for critically ill neonates (2011).

However, CPOE systems are often designed with adult patients in mind. As a result, ensuring that this technology also serves the needs of pediatric patients requires “adaptation and modification of tools designed and acquired for use in

adults” (Kim et al. 2007). This sentiment was echoed in a 2012 study examining the circumstances and mechanisms that had led to 10-fold medication errors (i.e., errors that could lead to administering a medication at 10 times or 1/10 the intended dose) at a pediatric hospital. The authors noted that “blind implementation of CPOE will not adequately address pediatric 10-fold medication error until such time as CPOE systems are designed in a standardized fashion that incorporates pediatric-specific dosing logic” (Doherty and Mc Donnell 2012).

Oxygen concentrators. A *Health Devices Hazard Report* describes an oxygen concentrator design that could put pediatric patients at risk (see the list of member resources below). This particular unit requires the installation of an optional pediatric flow sensor if the device is to be used on pediatric patients. However, the installation of that component disables the unit’s no-flow alarm; thus, caregivers may not be warned if the flow of oxygen is interrupted. Whereas an adult patient might be expected to tolerate an extended interruption of supplemental oxygen, pediatric patients would be at greater risk because of their lower respiratory reserve. Additionally,



young children may be unable to inform caregivers if an interruption occurs.

Emergency care and pediatric emergency supplies. In a fact sheet titled “The Future of Emergency Care,” the Institute of Medicine noted that “many drugs and medical devices have not been adequately tested on, or dosed properly for, children.” The organization added that “more research is needed to determine the appropriateness of many medical treatments, medications, and medical technologies for the care of children” (IOM 2006).

In addition, data published by the Centers for Disease Control and Prevention (CDC) shows that, at the time surveyed, only 42% of the EDs in non-children’s hospitals or hospitals without pediatric intensive care units (PICUs) had at least 85% of the recommended emergency supplies for the care of pediatric patients. For comparison, almost three-quarters of the EDs in children’s hospitals and hospitals with PICUs had at least 85% of the recommended supplies (CDC 2012). It must be noted that the data reflects survey results from several years ago (2006). Similarly, in a 2009 policy statement, the American Academy of Pediatrics (AAP) noted that “published data have suggested that . . . many EDs in the United States and Canada still do not have some of the basic equipment and supplies needed to care for children of all ages” (AAP 2009).

Electronic health records. When caring for pediatric patients, the standard growth chart—showing height and weight curves—is an extremely important tool for physicians. However, some EHRs don’t allow caregivers to view the full height and weight charts at the same time, requiring scrolling or jumping back and forth between different screens. This is just one example of the usability challenges associated with EHRs when supporting pediatric care that were discussed at a May 2012 workshop hosted by the National Institute of Standards and Technology (NIST) and the Office of the National Coordinator for Health Information Technology (ONC). Materials from the workshop are available

online. In addition, in June 2012 NIST issued an EHR usability guide that highlights the user interactions that are unique to or especially salient for pediatric care. (See the list of resources for details.)

Recommendations

- ▶ Consider identifying a pediatric technology safety coordinator or champion to assess the technologies that are used on pediatric patients at your facility and to identify any associated risks. Responsibilities may include:
 - Identifying devices, accessories, or systems that are appropriate for only a certain range of patients (e.g., toddlers but not neonates).
 - Identifying devices, accessories, or systems that require some modification or must be used in a specific configuration for safe use on pediatric patients (e.g., restricting the upper flow rate for infusion pumps).
 - Wherever possible, clearly marking any such conditions on the devices, as appropriate.
 - Educating staff about unique safety considerations or methods of use that are required when working with pediatric patients.
 - When specific pediatric modes of operation are unavailable, establishing protocols for setting medical device alarms to levels that are appropriate for pediatric patients.
 - Verifying that supplies that are appropriate for pediatric patients are available in EDs and other areas where pediatric patients may be seen.
- ▶ When assessing medical technologies and supplies for purchase, consider the extent to which the device, system, or accessory is appropriate for use on the full range of patients that might be seen at your facility, including pediatric patients. For example, during

prepurchase assessments of CPOE systems, EHRs, and other health IT systems, ask vendors whether the needs of pediatric patients have been incorporated into the system design. That is, do the systems offer pediatric-specific applications or other functionality that can help reduce risks? Alternatively, ask if the vendor can refer you to current users who have implemented the system in a manner that addresses the needs of pediatric patients.

Member Resources

Health Devices:

Health Devices Achievement Award 2008: a look at the finalists [spotlight]. 2008 Dec;37(12):372-5.

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

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

Additional Resources

Alliance for Radiation Safety in Pediatric Imaging. Image Gently website and online resources: www.pedrad.org/associations/5364/ig.

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

Centers for Disease Control and Prevention (CDC), U.S. Availability of pediatric services and equipment in emergency departments: United States, 2006.

Natl Health Stat Report 2012 Mar 1;(47):1-21. Also available: www.cdc.gov/nchs/data/nhsr/nhsr047.pdf.

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

ECRI Institute:

Health Technol Trends 2011 Feb;23(2):1-12. [special issue on pediatric imaging]

New strides for pediatric medicine: FDA grants support research to stimulate pediatric device innovation. *Health Technol Trends* 2012 Aug;24(8):5-6.

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

Draft guidance for industry and Food and Drug Administration staff—pediatric information for x-ray imaging device premarket notifications

[online]. 2012 May 10 [cited 2012 Oct 11]. Available from: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm?source=govdelivery.

Pediatric x-ray imaging website: www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm.

Institute of Medicine (IOM). The future of emergency care: key findings and recommendations [fact sheet online]. 2006 Jun [cited 2012 Sep 5] Available from: www.iom.edu/~media/Files/Report%20Files/2006/Hospital-Based-

[Emergency-Care-At-the-Breaking-Point/EmergencyCareFindingsandRecs.pdf](#).

Kim GR, Miller MR, Ardolino MA, et al. Capture and classification of problems during CPOE deployment in an academic pediatric center. *AMIA Annu Symp Proc* 2007; 2007:414-7. Also available: www.ncbi.nlm.nih.gov/pmc/articles/PMC2655829.

National Institute of Standards and Technology (NIST):

A human factors guide to enhance EHR usability of critical user interactions when supporting pediatric patient care. 2012 Jun. NISTIR 7865. Also available: www.nist.gov/healthcare/usability/upload/NIST-IR-7865.pdf.

Creating usable electronic health records (EHRs): a user-centered design best practices workshop. Workshop resource page: www.nist.gov/itl/iad/creating-usable-ehrs.cfm.

Palma JP, Sharek PJ, Classen DC, et al. Neonatal informatics: computerized physician order entry. *Neoreviews* 2011;393-6. Also available: www.ncbi.nlm.nih.gov/pubmed/21804768.

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](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60815-0/fulltext).

8. Inadequate Reprocessing of Endoscopic Devices and Surgical Instruments

In several previous Top 10 lists, we addressed the cross-contamination hazards that exist when flexible endoscopes are not properly reprocessed. Several high-profile incidents described in those lists illustrate the consequences of failure to properly and consistently perform all steps in the endoscope reprocessing procedure, including some necessary manual tasks. At minimum, endoscope reprocessing problems (when discovered) can create anxiety when patients are told they may have been exposed to a contaminated endoscope. At worst, they can lead to life-threatening infections. In either case, such incidents can harm a facility's reputation.

While flexible endoscope reprocessing continues to require scrutiny, for 2013 we recommend that healthcare facilities address the reprocessing function more broadly in their patient safety initiatives. This recommendation was influenced both by incident reports obtained and analyzed by ECRI Institute PSO and by the results of a recent investigation that ECRI Institute conducted for a facility that was experiencing repeated reprocessing failures.

The incidents reported and the one we investigated involved "dirty" instruments being presented for use in surgery or other medical procedures. These were instru-

ments or devices that were not adequately decontaminated and cleaned before they underwent disinfection or sterilization or that otherwise were not properly reprocessed. In some cases, the contamination was not detected until after the item had been used on a patient.

Following are just a few examples of incidents reported to ECRI Institute PSO:

- ▷ "During surgery to repair a patient's rotator cuff, the surgeon found a foreign substance in the arthroscopy shoulder cannula."
- ▷ "A patient had to undergo bronchoscopy after normal working hours. The physician obtained a scope from the pulmonary lab. After the procedure was completed, it was determined that the scope had not been reprocessed from the previous procedure."
- ▷ "Bone and tissue were observed in the instrument tray for joint replacement surgery. The tray was removed, and a new sterile field and replacement instruments were set up in the room. The replacement instrument tray had fluid on several instruments and bone fragments."
- ▷ "When opening the OR supplies for a surgical procedure, [blood was observed] on the instrument bin inside

the case cart. All the instruments were contaminated, and the supplies in the cart had to be thrown away. The start of surgery was delayed." (ECRI Institute PSO 2012)

Data from the Joint Commission likewise suggests that the reprocessing function warrants attention in many facilities. The agency reports that 36% of accredited hospitals surveyed in 2011 were noncompliant with its standards to reduce the risk of infection associated with medical equipment, devices, and supplies. Failure to adhere to the standard, which includes measures to properly decontaminate, clean, disinfect, and sterilize medical equipment, was among the top 10 standards compliance issues for hospitals, ambulatory settings, and office-based surgery practices in 2011 (Joint Commission 2012).

As described in the August 2012 edition of ECRI Institute PSO's *PSO Navigator*, a variety of factors can contribute to the improper reprocessing of instruments. These include the complexity of the instruments (e.g., devices with narrow channels or movable parts to disassemble); lengthy and unclear manufacturer instructions for cleaning; 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; and 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, allowing for 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 within the protocol documents for particular device classes or models. Consider assembling all reprocessing protocols, policies, and



procedures into a comprehensive manual for use by relevant staff.

- ▷ Ensure that current documented protocols are readily available to staff and that staff are trained to understand and follow them:
 - Train new staff when they join the organization. Adequate orientation must be provided before new staff members are given responsibility for reprocessing instruments.
 - Periodically repeat training for all staff to ensure that they remain familiar with the protocols. Also, support competency-based ongoing education.
 - Educate reprocessing staff and others (e.g., relevant OR staff) on the proper care and handling of new instruments and equipment before they are put into service. Staff should be advised to alert management if they receive a new instrument for reprocessing but have not received instruction on the reprocessing procedure for that instrument.
- ▷ 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. That is, be alert to the need to revise protocols and training—for example, when new instrument models are added to your inventory or new reprocessing equipment is purchased. Verify that protocols don't include workflows or equipment/chemicals that are no longer in use 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 endoscopes and other lumened instruments, precleaning at the point of use—before organic material

has dried on the surface or in the channels and before transport to the decontamination area—is an important but sometimes overlooked step. For a discussion of the typical steps in an endoscope reprocessing protocol, refer to the October 2010 *Health Devices* Guidance Article “Clear Channels: Ensuring Effective Endoscope Reprocessing.”

- ▷ If your facility reprocesses endoscopy equipment using a reprocessing unit—such as an automated endoscope reprocessor, a liquid chemical sterilization system, or a gas plasma sterilizer—ensure that:
 - Endoscopes and related equipment in your facility's inventory are compatible with the reprocessor and its disinfecting/sterilizing agent.
 - The appropriate channel adapters are available to connect the endoscope to the reprocessor, and staff are familiar with the correct endoscope/adaptor combinations. Also ensure that staff have access to information on the correct combinations and know where this information is located if there are any questions.
 - Staff maintain daily checklists for equipment and appropriate logs for sterilization and disinfection, if applicable. Refer to user manuals and consult device manufacturers to identify the recommended logs and checklists.
 - Staff are familiar with and adhere to appropriate reprocessor maintenance schedules, including the periodic replacement of particulate and bacterial filters.
- ▷ Seek input from reprocessing department staff when assessing instruments for purchase to identify devices that may require additional time 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

Resource Center:

Steris System 1. Available from: <https://members2.ecri.org/Components/HDJournal/Pages/SterisSystem1ResourceCenter.aspx>.

Health Devices:

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

Additional Resources

ECRI Institute. Reprocessing in central service. *Health Risk Control* 2006 Jul;4:Infection control 4.

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

Joint Commission. Joint Commission identifies top standards compliance issues for 2011. *Jt Comm Perspect* 2012 Apr;32(4):1, 6-11.

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\(4\)/Pages/135.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/dec7(4)/Pages/135.aspx).

9. Caregiver Distractions from Smartphones and Other Mobile Devices

A lot has been written about the security considerations associated with the use of mobile devices like smartphones, tablet computers, and other handheld computing devices. Private patient information can too easily be exposed if appropriate policies aren't instituted and followed, and security breaches can be very costly for a healthcare facility. But a topic that is just starting to get attention, and one that may be more likely to lead to substandard patient care or even physical harm to patients, is the potential for caregivers to become distracted by their devices.

Consider the following often-cited case study written by Dr. John Halamka, chief information officer at Harvard Medical School: A resident physician (at an unnamed facility) was using her smartphone to enter an order in the facility's CPOE system. The order, as requested by the attending physician, was to stop anticoagulation therapy for a patient. Before completing the order, however, the resident received a personal text message. The resident responded to the message by text, but never went back to complete the order in the CPOE system. As a result, anticoagulation therapy continued unnoticed for several days, and the patient developed conditions that necessitated emergency open-heart surgery (Halamka 2011).

While the need for clinicians to multitask is nothing new—interruptions from pagers and other communication devices

have long been a part of the job—smartphones and other mobile devices now make it easier for clinicians to be interrupted for non-work-related reasons, as occurred in the above example.

What's more, these devices make it easier for clinicians to create their own interruptions. With the smartphone or other mobile device in their hands—and with Internet access or communication channels just a click or tap away—clinicians can easily succumb to the temptation to conduct personal business during patient care. For instance, half of the respondents to a 2010 survey of perfusionists acknowledged texting during heart-lung bypass procedures, with 15% further acknowledging that they accessed the Internet and 3% reporting that they visited social networking sites during procedures (Smith et al. 2011). Additional instances of digital distractions cited in a December 2011 *New York Times* article include a nurse checking airfares during surgery and a neurosurgeon using a wireless headset to make personal calls during surgery. In the latter case, the lawyer for a patient who was left partly paralyzed contends that cell phone use distracted the neurosurgeon during the procedure. The case was settled before the formal filing of a lawsuit (Richtel 2011).

If the results of a 2012 survey conducted by *OR Manager* are representative, the hazards of distraction may be

commonplace. More than half of the 112 survey respondents noted that they had received reports of an OR clinician being distracted by a mobile device during patient care. In addition, 41% report that they “have personally witnessed distracted behavior.” Furthermore, six of the respondents indicated that personal use of a mobile device was possibly linked to an adverse event during surgery at their facility. Of the events that were described, one was a wrong-site surgery (Patterson 2012).

Similarly, a study conducted at a university-affiliated public teaching hospital in New York described the prevalence of distractions from smartphones during patient care. The study specifically assessed the potential for smartphones to distract residents and faculty members during inpatient attending rounds. According to self-reports, 19% of residents and 12% of attending physicians believed they had missed important information because of distractions from smartphones. The authors noted that the attending physicians “strongly favored the institution of formal policies governing appropriate smartphone use during inpatient rounds” (Katz-Sidlow et al. 2012).

The potential to make mistakes or miss information is not the only concern. Caregivers who are focusing on a device's screen, rather than looking at the patient, may miss clues about the patient's condition. In addition, focusing on the device rather than the patient can lead patients to

question the quality of their care. Patients may wonder whether they are getting appropriate attention from the caregiver or whether the caregiver is instead engaged in some unrelated activity.

Organizations are starting to take notice of the hazards of distraction that mobile devices can create. For example, the American Association of Nurse Anesthetists issued a position statement in June 2012 stating, “Any inattentive behavior during a procedure, such as reading, texting, gaming or using mobile devices to access nonclinical content, should be considered a potential patient safety issue.”

Recommendations

- ▷ Refer to the October 2012 *Health Devices* Guidance Article on smartphone use in hospital settings and familiarize yourself with the risks associated with the use of mobile technologies in these environments.
- ▷ Educate staff members and independent physicians about the risks associated with the use of smartphones and similar devices. In particular, raise awareness about the potential for digital distractions to affect patient care.
- ▷ Develop a mobile device management strategy for the healthcare organization that addresses security considerations, such as the need to safeguard the privacy of patient data and protect the integrity of the facility’s information networks, but that also addresses the ways in which the use of mobile devices can compromise patient safety

(e.g., by diverting attention away from patient care tasks). The mobile device management strategy should specify

- the appropriate use of mobile devices while caregivers are on active duty,
 - what (if any) network resources the devices can access,
 - which mobile devices are supported, and
 - what measures users must take to ensure that mobile devices are used safely and securely.
- ▷ Obtain input from all stakeholders, including staff and independent physicians, when developing the mobile device management strategy and when formulating institutional policies regarding the appropriate and inappropriate use of mobile devices.
 - ▷ Consider whether to restrict personal uses of smartphones and similar devices during patient care activities. While such a policy would not eliminate all the distractions that can affect patient care, it can at least reduce the number of distractions that do not serve a clinical function.

Member Resource

Judgment call: smartphone use in hospitals requires smart policies [guidance article]. *Health Devices* 2012 Oct;41(10):314-29.

Additional Resources

American Association of Nurse Anesthetists (AANA). Position statement number 2.18:

mobile device use. Park Ridge (IL): AANA; 2012 Jun. Also available: www.aana.com/resources2/professionalpractice/Documents/PPM%20PS%202.18%20Mobile%20Device%20Use.pdf.

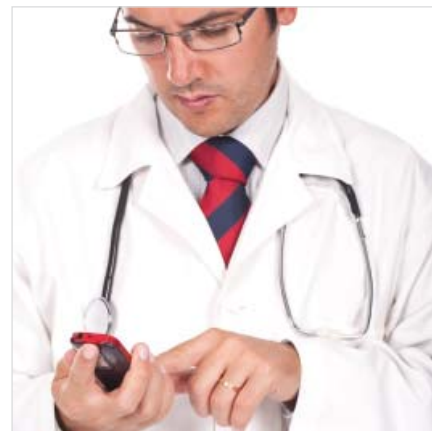
Halamka J. Order interrupted by text: multitasking mishap [online]. *WebM&M* 2011 Dec [cited 2012 Apr 9]. Available from: <http://webmm.ahrq.gov/case.aspx?caseID=257>.

Katz-Sidlow RJ, Ludwig A, Miller S, et al. Smartphone use during inpatient attending rounds: Prevalence, patterns and potential for distraction. *J Hosp Med* 2012 Oct;7(8):595-9.

Patterson P. Smartphones, tablets in the OR: with benefits come distractions. *OR Manager* 2012 Apr;28(4):1, 6-8, 10.

Richtel M. As doctors use more devices, potential for distraction grows. *N Y Times* 2011 Dec 15. Also available: www.nytimes.com/2011/12/15/health/as-doctors-use-more-devices-potential-for-distraction-grows.html?pagewanted=all&_r=0.

Smith T, Darling E, Searles B. 2010 survey on cell phone use while performing cardiopulmonary bypass. *Perfusion* 2011 Sep;26(5):375-80.



10. Surgical Fires

Fires that ignite in, on, or around a patient during surgery are extremely rare, occurring in only a minuscule percentage of the millions of surgical cases performed each year. Nevertheless, this hazard remains on our Top 10 list because (1) surgical fires are high-impact events that can have devastating consequences, and (2) surgical

fires continue to occur—more frequently than many people realize—despite the availability of effective guidance for fire prevention. ECRI Institute continues to receive at least one report of a surgical fire each week.

While not all surgical fires result in patient injury, the consequences of such a

fire clearly can be severe: Patients can be disfigured or killed, staff can be injured, and critical equipment can be damaged. Additionally, a surgical fire can result in reputational damage for the healthcare facility. A surgical fire is not the kind of adverse event that is quietly described in a medical journal or listed as a mere data

point in a problem reporting database. It's the kind of event that can make the local or national news.

Surgical fires are especially devastating if an open oxygen source is present on the face during surgery of the head, face, neck, and upper chest. Thus, ECRI Institute and the Anesthesia Patient Safety Foundation (APSF) collaborated to develop clinical practice recommendations that address the delivery of oxygen during such surgeries. The recommendations, which we published in our October 2009 Guidance Article, "New Clinical Guide to Surgical Fire Prevention," are intended to prevent the formation of oxygen-enriched atmospheres near the surgical site and thus reduce the likelihood of fires.

In the fall of 2011, FDA and several partner organizations, including ECRI Institute, launched the Preventing Surgical Fires initiative. The purpose of this initiative is to increase awareness of factors that contribute to surgical fires, disseminate surgical fire prevention tools, and promote the adoption of risk reduction practices throughout the healthcare community. For details, refer to the link included in the list of resources below.

The good news is that virtually all surgical fires can be avoided. For this to be possible, however, each member of the surgical team must clearly understand the role played by oxidizers, ignition sources, and fuels in the OR, and must communicate about the risks with other team members.

Recommendations

- ▷ If you don't already have one, implement a surgical fire prevention and management program, including training, based on the current recommendations for preventing and extinguishing surgical fires presented in our October

2009 Guidance Article (and summarized in the free posters available from ECRI Institute at www.ecri.org/surgical_fires).

- ▷ To minimize the risks posed by oxygen-enriched atmospheres, become familiar with and implement the clinical recommendations on oxygen delivery from APSF and ECRI Institute. (Again, see our October 2009 Guidance Article and educational posters for details.)

The core point of these recommendations is that, with certain limited exceptions, the traditional practice of open delivery to the face of 100% oxygen should be discontinued during head, face, neck, and upper-chest surgery. Only air should be used for open delivery to the face, provided that the patient can maintain safe blood oxygen saturation without supplemental oxygen. If the patient cannot do this, the airway should be secured with a laryngeal mask airway or tracheal tube to prevent the excess oxygen from contaminating the surgical site. For the exceptions to this recommendation, see our "Surgical Fire Prevention" educational poster at www.ecri.org/surgical_fires.

- ▷ Conduct a surgical team time-out before the start of each case to provide an opportunity for team members to assess any fire risks. An example of an effective and easily implemented surgical fire time-out procedure, which has been in use at many healthcare facilities, is available at www.christianacare.org/FireRiskAssessment.

Member Resources

Health Devices:

New clinical guide to surgical fire prevention: patients can catch fire—here's how to keep them safer [guidance article]. 2009 Oct;38(10):314-32.

PowerPoint presentation:

New clinical guide to surgical fire prevention. Available from: <https://members2.ecri.org/Components/HdSlideShows/Pages/default.aspx>.

Posters:

Emergency procedure—extinguishing a surgical fire. Available from: www.ecri.org/surgical_fires.


Surgical fire prevention. Available from: www.ecri.org/surgical_fires.

Additional Resources

Anesthesia Patient Safety Foundation (APSF). Prevention and management of operating room fires [video]. Indianapolis (IN): APSF; 2010. Also available: www.apsf.org/resources_video.php.

Christiana Care Health System. Surgical fire risk assessment [risk assessment tool online]. [cited 2012 Aug 13]. Available from: www.christianacare.org/FireRiskAssessment.

ECRI Institute. Surgical fire safety update: best practices for prevention [web conference]. 2009 Jul 22. Recording and CD toolkit available for purchase: www.ecri.org/Conferences/Pages/Surgical_Fires.aspx.

Food and Drug Administration (FDA), U.S. Preventing surgical fires: collaborating to reduce preventable harm [online]. 2012 Jun 14 [cited 2012 Aug 13]. Available from: www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/PreventingSurgicalFires. 



HEALTH DEVICES OBJECTIVES

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

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

This report appears in the November 2012 issue of ECRI Institute's monthly *Health Devices* journal, which is provided to members of ECRI Institute's Health Devices System, Health Devices Gold, and SELECTplus™ programs. Health Devices features comparative, brand-name evaluations of medical devices and systems based on extensive laboratory testing and clinical studies. ECRI Institute's evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.

For questions about ECRI Institute's annual list of technology hazards or for information about membership in any of ECRI Institute's programs, contact us by telephone at (610) 825-6000, ext. 5891; by e-mail at clientservices@ecri.org, or by mail at 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA.

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