health. DEVICES

2010 TOP 10 TECHNOLOGY HAZARDS

MEDICAL TECHNOLOGY CAN SAVE LIVES, BUT IT CAN ALSO CAUSE HARM. FORTUNATELY, MOST RISKS ARE PREVENTABLE. HERE ARE 10 KEY SOURCES OF POTENTIAL DANGER, ALONG WITH RECOMMENDATIONS FOR PROTECTING YOUR PATIENTS AND STAFF.

Where do you start when trying to minimize the risks from healthcare technology?

For the past few years, we've been trying to help the healthcare community answer that question with our annual list of the 10 most crucial technology hazards. The list is derived from our experience in investigating and consulting on device-related incidents, as well as from information found in the medical device problem reporting databases of ECRI Institute and other organizations.

The choice of which hazards to include, and in what order, is based on the likelihood and severity of the reports we've received over the past year, the recalls and other actions we've reviewed, and our continuing examination of the published literature. Of course, any list like this one is arbitrary to a degree. Not only are relative risks impossible to define precisely, but the importance of any given hazard will depend on the circumstances of the individual hospital. So while we believe that this list represents the top 10 safety issues in healthcare overall, they may not be *your* top 10.

The purpose of this list isn't to establish a one-size-fits-all set of priorities for all hospitals everywhere. Rather, it's to identify the problems that we believe are the most crucial right now, and that hospitals should consider putting at the top of their to-do lists for keeping patients safe from technology-related risks.

1. Cross-Contamination from Flexible Endoscopes

Incidents of pathogen transmission related to flexible endoscopy continue to be reported in the media, and ECRI Institute continues to receive reports of potential endoscopy-related cross-contamination in facilities around the United States. Often in these cases, large numbers of patients must be notified of exposure to potentially contaminated endoscopic equipment.

Such incidents are almost always associated with failure to follow established cleaning and disinfection/sterilization guidelines, or with the use of damaged or malfunctioning equipment. Flexible endoscope reprocessing requires consistent adherence to a multistep process; failure to properly perform any step, including some necessary manual tasks, could compromise the integrity of the process. Unfortunately, ECRI Institute is aware of instances in which the required steps were not performed properly, putting patients at risk.

Staff need to recognize the importance of tailoring the process to the individual endoscope model (including newly acquired models). They also need to be aware that reprocessing just the endoscope is not sufficient to prepare equipment for safe patient use. A variety of accessories—such as those used for irrigation, insufflation, suctioning, or providing therapy to the treatment site—may also become contaminated during use and must be properly reprocessed or (if disposable) replaced. (See *Health Devices Alerts* Accession No. S0193 for an example of this point.) Even some items used in reprocessing, such as manual cleaning brushes, must themselves be reprocessed or disposed of.

The best defense against endoscopy-related cross-contamination continues to be careful development of and strict adherence to comprehensive, model-specific reprocessing protocols.

To minimize cross-contamination, ECRI Institute recommends the following:

- Ensure that a model-specific reprocessing protocol exists for each flexible endoscope model in your facility's inventory. Refer to the device's user manual or consult the endoscope manufacturer to identify unique requirements (e.g., cleaning procedures, channel adapters) that need to be addressed within each protocol document. Remember to repeat this review for each newly purchased endoscope model (or related equipment).
- Periodically review protocols to ensure that they are clear and comprehensive and that they reflect the current environment (e.g., that they don't include obsolete workflows or equipment/chemicals that are no longer in use at the facility).
- In reviewing or developing protocols, ensure that all steps—from precleaning equipment

at the treatment site to safe and aseptic transport of equipment back to the treatment site for subsequent use—are addressed and documented in adequate detail. (A list of steps is included in *Health Devices Alerts* Accession No. S0193.)

- If your facility reprocesses endoscopy equipment using an automated endoscope reprocessor (AER), ensure that:
  - Endoscopes (and related equipment) in your facility's inventory are compatible with the AER and its disinfecting/sterilizing agent.
  - The appropriate channel adapters are available to connect the endoscope to the AER, and staff are familiar with the correct endoscope/connector combinations.
  - Staff are familiar with and adhere to appropriate AER maintenance schedules, including the periodic replacement of particulate and bacterial filters.
- Ensure that documented protocols are readily available to staff and that staff are trained to understand and follow them. Training should be provided not only to reprocessing staff but also to clinicians who may be responsible for setup and precleaning or handling of equipment. Remember to periodically repeat training to ensure that staff remain familiar with the protocols and to address turnover.

RESOURCES

Health Devices:

"Ensuring the Effective Reprocessing of Flexible Endoscopes" (Guidance Article, 2007 Nov)

"The Steris Reliance EPS Endoscope Processing System: A New Automated Endoscope Reprocessing Technology" (Evaluation, 2007 Jan)

"Storage of Endoscopes in Shipping Cases Continues to Put Patients at Risk" (Hazard Report, 2007 Jun)

Health Devices Alerts:

"Review of Flexible-Endoscope Reprocessing Practices Needed to Prevent Patient Cross-Contamination" (Accession No. S0052, 2004 Nov 12)

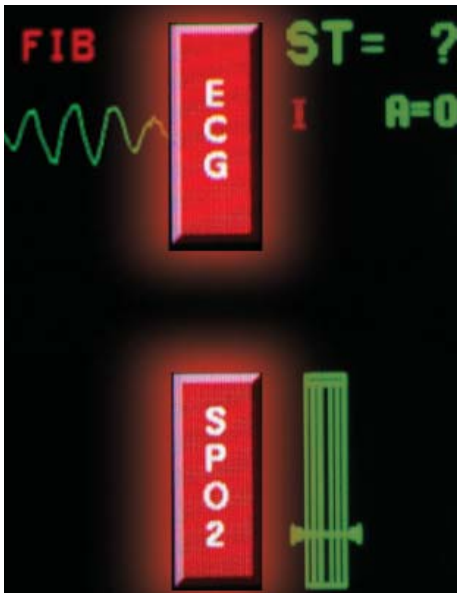
"U.S. Veterans Health Administration Announcements Highlight Need for Comprehensive Endoscopy-Reprocessing Protocols" (Accession No. S0193, 2009 Apr 16)

2. Alarm Hazards

Clinical alarms, which warn caregivers of hazards, can be instrumental in preventing patient injury or death—as long as caregivers get the message. But if alarm conditions aren't effectively communicated, or alarm limits aren't set appropriately, then patients are at risk.

Alarm issues are among the problems most frequently reported to ECRI Institute. The variety of affected equipment is considerable—reports involve patient monitoring equipment, ventilators, dialysis units, and many other devices. To reduce the frequency of alarm-related adverse incidents, we recommend the following:

- When evaluating a device for purchase, ask yourself whether the device handles alarms in a way that is logical, safe, and consistent with your facility's practice. Look for designs that limit nuisance alarms (that is, false or excessive alarms), which can desensitize your staff, possibly leading them to ignore true hazards. Some of our published Evaluations include test criteria covering alarm concerns, which may help you make safer choices.
- Make sure that staff members understand the purpose and significance of alarms and that they know how to set alarm limits to appropriate, physiologically meaningful values. We continue to learn of incidents in which staff unintentionally disable critical alarms by setting them far outside reasonable bounds. Low-saturation alarms on pulse oximetry monitors and low-minute-volume or high-peak-pressure alarms on ventilators are regular subjects of this sort of error.
- Ensure that alarm conditions are quickly and consistently conveyed to staff on the floor. Make sure that factors such as speaker volume, floor layout, and physical distance from the device aren't preventing staff from hearing audible alarms. Consider implementing an alarm-enhancement system, which can increase alarm volume or convey alarms remotely—for example, via pagers, mobile phones, or your



nurse-call system. But keep in mind that interfacing devices with these ancillary communication systems may result in alarm annunciation failures. For each interface connection, therefore, you'll need to pay close attention to the instructions for the specific makes and models involved, as well as verify proper function after installation. As for visual alarm indicators, make sure that devices are positioned so they can be easily seen.

RESOURCES

Health Devices:

"Alarm-Enhancement Systems for Ventilators" (Guidance Article, 2004 Jan); also see the follow-up article covering problems with physiologic monitoring interfaces in the October 2004 issue

"Alarm Notification for Physiologic Monitoring: Could You Benefit from a New Strategy?" (Guidance Article, 2007 Jan)

"The Hazards of Alarm Overload: Keeping Excessive Physiologic Monitoring Alarms from Impeding Care" (Guidance Article, 2007 Mar)

"A Lifesaving Reminder: Improper Use of Ventilator Alarms Places Patients at Risk" (Hazard Report, 2009 Apr)

"Physiologic Monitoring Systems" (Evaluation, 2005 Jan)

"Ventilator 'Vent Inop' Alarms May Not Be Communicated via Ancillary Notification Systems" (Hazard Report, 2008 Dec)

PowerPoint presentations:

"Alarm-Enhancement Systems for Ventilators"

"Alarms—Critical Alarms and Patient Safety"

3. Surgical Fires

Surgical fires don't happen often, but when they do, patients can be seriously injured, disfigured, or killed. Our latest estimates are that 550 to 650 surgical fires occur in the United States each year, making them roughly as frequent as other surgical mishaps like wrong-site surgery.

A component of most surgical fires is the presence of an oxygen-enriched atmosphere in or near the surgical site, which can lower the temperature at which a fuel will ignite, increasing the chances of a fire. To address this risk, new clinical practice recommendations for delivering oxygen during surgery have been developed by ECRI Institute in conjunction with the Anesthesia Patient Safety Foundation (APSF). The recommendations focus on surgeries to the head, face, neck, and upper chest, during which oxygen-enriched atmospheres can accumulate in the surgical site and electrosurgery, lasers, electrocautery, or other sources of ignition may be used.

The core point of these new recommendations is that, with certain limited exceptions, *the traditional practice of open delivery 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 a safe blood oxygen saturation without supplemental oxygen. If the patient cannot do this, secure the airway with a laryngeal mask airway or tracheal tube to prevent the excess oxygen from contaminating the surgical site.

Virtually all surgical fires can be avoided. But doing so requires that each member of the surgical team clearly understands the role played by oxidizers, ignition sources, and fuels (the classic fire triangle) in the operating room. Each team member should also make a point of communicating information on the risks to other team members—intraoperatively or in seminars, for example.

We recommend the following:

- If you don't already have one, implement a surgical fire prevention and management program, including training based on the October 2009 *Health Devices* Guidance Article "New Clinical Guide to Surgical Fire Prevention," which provides detailed recommendations on preventing and extinguishing fires.
- To minimize the risks posed by oxygen-enriched atmospheres, become familiar with and implement the new clinical recommendations on oxygen delivery from APSF and ECRI Institute described above (and discussed in more detail—including some notable exceptions—in the October 2009 Guidance Article).

RESOURCES

Health Devices:

"Improper Use of Alcohol-Based Skin Preps Can Cause Surgical Fires" (Hazard Report, 2003 Nov)

"New Clinical Guide to Surgical Fire Prevention: Patients Can Catch Fire—Here's How to Keep Them Safer" (Guidance Article, 2009 Oct)

"Surgical Fire Safety" (Guidance Article, 2006 Feb)

PowerPoint presentations:

"Surgical Fire Safety," which covers surgical fire risks and how to manage them

"Surgical Fire Safety—ECRI Audio Conference," which summarizes an ECRI Institute audio seminar on the surgical fire safety initiatives from various organizations

Additional resources:

American Society of Anesthesiologists Task Force on Operating Room Fires, Caplan RA, Barker SJ, et al. Practice advisory for the prevention and management of operating room fires. *Anesthesiology* 2008 May;108(5):786-801. Also available: www.asahq.org/publicationsAndServices/orFiresPA.pdf.

Anesthesia Patient Safety Foundation (APSF). Prevention and management of surgical fires [video]. APSF 2009. Forthcoming. Will be available from Internet: www.apsf.org/resource_center/educational_tools/video_library.mspx.

Joint Commission. Preventing surgical fires. *Sentinel Event Alert* 2003 Jun 24; issue 29. Also available: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_29.

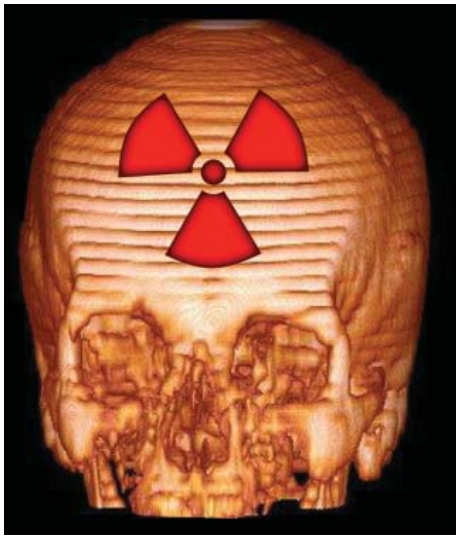
4. CT Radiation Dose

Computed tomography (CT) is fast, reliable, and convenient—so much so that only recently has its comparatively high x-ray dose begun to garner significant attention. That dose can pose a significant cancer risk: In the United States alone, CT is thought to be responsible for about 6,000 additional cancers a year, roughly half of them fatal.

With the publication in August of articles in the *New England Journal of Medicine* indicating that many CT studies expose patients to an unnecessary risk of cancer without a demonstrated benefit, along with a report in October that Cedars-Sinai Medical Center in Los Angeles accidentally used extremely high radiation doses during CT stroke scans on over 200 patients, the focus on this hazard will only increase.

To ensure that patients are not unnecessarily exposed to high dose levels, we recommend the following:

- Make sure the expected benefits of a CT study outweigh the radiation risks. This includes regularly reviewing your guidelines for CT referrals. (Your review should be referenced against the American College of Radiology's Appropriateness Criteria for imaging techniques—see Resources.) Such precautions are especially important for pediatric patients—for whom the cancer risk is as much as triple that for a 30-year-old—and for pregnant women.
- Minimize dose by optimizing your scanning protocols. Adjust your acquisition parameters to allow the required clinical information to be obtained with the lowest possible dose. Modern CT systems have dose-reduction technologies, some of which can reduce the dose by up to 80%. Make sure these are used as appropriate. At the same time, however, communicate to users that they must not rely on default settings provided by these systems on the assumption that they are the lowest possible dose settings. All protocols should be checked internally and certified by the chief radiologist and medical physicist. Technologists must check the dose against department norms before the scan begins. And a formal process must be followed when any changes are made to the standard protocols.



- Before a scan is prescribed, be sure that it has not already been performed.
- Ensure that technologists performing CT exams are trained specifically for CT and that they maintain their training and certification. In the United States, technologists should be registered with the American Registry of Radiologic Technologists.
- Monitor CT use and dose as part of your normal quality control and equipment maintenance efforts. Some suppliers are beginning to offer the ability to monitor patient dose. Participation in programs such as the American College of Radiology's CT Accreditation Program should be a high priority.
- Make sure referring physicians have easy access to information regarding the dose—and the cancer risk—associated with CT exams. This will allow them to make informed decisions and discuss the risks with patients as appropriate. Ensure that the expected effective dose for each exam protocol is calculated and readily available.

RESOURCES

Health Devices:

"Radiation Dose in Computed Tomography: Why It's a Concern and What You Can Do about It" (Guidance Article, 2007 Feb)

PowerPoint presentation:

"CT Radiation Dose Safety"

Additional resources:

American College of Radiology. ACR appropriateness criteria [online]. www.acr.org/secondarymainmenucategories/quality_safety/app_criteria.aspx.

Fazel R, Krumholz HM, Wang Y, et al. Exposure to low-dose ionizing radiation from medical imaging procedures. *N Engl J Med* 2009 Aug 27;361(9):849-57.

Lauer M. Elements of danger—the case of medical imaging. *N Engl J Med* 2009 Aug 27;361(9):841-3.

Mertens M. Cedars-Sinai apologizes for radiation errors. NPR Health Blog 2009 Oct 19 [online; includes link to 2009 Oct 15 statement from Thomas M. Priselac, President and CEO of Cedars-Sinai Medical Center; cited 2009 Oct 19]. www.npr.org/blogs/health/2009/10/cedarssinai_says_sorry.html.

5. Retained Devices and Unretrieved Fragments

ECRI Institute and the U.S. Food and Drug Administration (FDA) frequently receive reports of foreign bodies left inside patients following treatment. Reports typically describe one of two adverse events:

- **Retained devices,** in which an entire device is unknowingly left behind. This problem is most commonly associated with surgery, wherein objects intended to be placed temporarily in the surgical site (e.g., sponges, clamps) may become hidden from view by tissue.
- **Unretrieved device fragments,** in which a portion of a device (e.g., catheter tip, forceps jaw) breaks away and remains inside the patient. In some cases, the fragment isn't retrieved because clinicians don't notice the breakage. In other cases, clinicians may observe the breakage but decide that the fragment's location within the anatomy makes retrieval too risky. An example of the latter is the common practice of leaving epidural catheter fragments in place when they do not present an obvious risk of infection or neurological impairment. Retention of these objects can sometimes lead to serious infection or damage to the surrounding tissue. And if the patient later undergoes a magnetic resonance examination, retained metal can heat or migrate, resulting in burns or worse.

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

- Visually inspect devices just before use. If a device appears damaged, immediately remove it from service.
- Be alert for significant resistance during device removal, which could indicate that the device is trapped and at risk of breakage; consider what options are available (e.g., repositioning the patient) before continuing the removal process.
- Visually inspect devices as soon as they are removed from the patient. If a portion of the device appears to be missing, immediately take appropriate action (e.g., examine the treatment site, request radiologic evaluation).
- Adhere to accepted surgical count procedures. For guidance in reviewing or developing your own procedures, refer to the recommendations issued by the Association of periOperative Registered Nurses (see Resources).
- Make use of appropriate technology as it becomes available. Currently, three companies (ClearCount Medical Solutions, RF Surgical Systems, and SurgiCount Medical) offer systems to help reduce the risk of retained surgical sponges. Similar systems for locating other devices and fragments may eventually be introduced.

RESOURCES

Health Devices:

"Radio-Frequency Surgical Sponge Detection: A New Way to Lower the Odds of Leaving Sponges (and Similar Items) in Patients" (Evaluation, 2008 Jul); also see the updated product information in the September 2008 issue, page 283

Additional resources:

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

Pennsylvania Patient Safety Authority:

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

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

6. Needlesticks and Other Sharps Injuries

Accidental needlesticks and other sharps-related injuries keep happening, despite the common use of needles, intravenous administration sets, and other devices that include mechanisms to protect against such injuries. It's not only clinicians who are at risk: Patients, laboratory personnel, pharmacy staff, housekeeping personnel, and waste handlers can also be injured by an exposed needle or other sharp. Consequences can include serious cuts and exposure to bloodborne pathogens such as HIV or the hepatitis B or C virus.

To prevent these injuries, do the following:

- Ensure that staff are trained in operating all protective devices and that they correctly follow the procedures for disposing of them.
- Remind users that needlestick-prevention devices (NPDs) occasionally fail. Inform them that they should not assume that a sharp is shielded just because the safety mechanism appears to have been successfully activated. Also advise them that if an NPD fails to activate, they should not attempt to manually engage it, such as by applying greater force.

- Make sure the models you choose are effective, intuitive, and easy to operate. If injuries are still happening even with properly trained staff, the problem may be the device rather than the people using it. For instance, if a protective product is hard to operate, it could lead to injuries. What's more, not all protective devices are created equal—some models offer greater protection than others.
- Monitor sharps containers to make sure their contents do not pass the fill line, and replace them as appropriate.
- Monitor needlesticks and other sharps injuries and, as appropriate, implement corrective measures, possibly including implementation of new preventive technologies or practices.

RESOURCES

Health Devices:

"Needle Problems: Breaking, Coring, and Detaching" (User Experience Network Article, 2006 Mar)

"Needleless Connectors" (Evaluation, 2008 Sep)

"Needlestick-Prevention Devices: Disposable Syringes and Injection Needles" (Evaluation, 2007 Aug); also see our earlier Evaluation of these protective devices in the September 2003 issue

"Sharps Disposal Containers" (Evaluation, 2003 Jul)

"Sharps Safety Devices" (Evaluation, 2006 Sep)

"Sharps Safety: Five Steps for Maintaining an Effective Program" (Guidance Article, 2006 Sep)

"Still Getting Stuck—Protective Devices Alone Won't Always Prevent Needlestick Injuries" (Hazard Report, 2009 Sep)

PowerPoint presentations:

"Needleless Connectors and Catheter-Related Infections"

"Sharps Safety—Maintaining an Effective Sharps Injury Prevention Program"

"Sharps Safety—Products for Specialized Applications"

ECRI Institute Special Report:

Sharps Safety and Needlestick Prevention, 2nd edition (2003), which includes our evaluations of more than 90 protective products in 16 device categories

Additional resource:

Joint Commission. Preventing needlesticks and sharps injuries. *Sentinel Event Alert* 2001 Aug 1; issue 22. Also available: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_22.htm.

7. Problems with Computerized Equipment and Systems

Computers have become an increasingly integral and critical component of many medical devices—they read, analyze, display, disperse, and record patient data, and they facilitate the exchange and communication of medical information to and from different clinical and data systems. This convergence of medical technology and information technology (IT) is evident in many areas, including medication management systems, the routing of medical alarms to clinician-worn devices (e.g., cell phones and pagers), and the incorporation of medical data from devices such as physiologic monitors and ventilators into electronic medical records.

Convergence presents many benefits, but also many risks. If systems and interfaces are poorly planned, implemented, or managed, they can threaten patient safety and can lead to inefficiencies, significant interruptions in operations, and uncaptured or lost revenue. Over the last few years, ECRI Institute has learned of numerous instances of potentially dangerous data-communication errors. For example, problems involving picture archiving and communication systems (PACS) include images and related data being incorrectly transferred or processed, with effects ranging from inaccurate matching of patient data to delays in surgical procedures. And software anomalies have resulted in hazards such as alarm malfunctions and improper or failed delivery of therapy; if these problems escape detection, they can have serious or even fatal consequences.

In a December 11, 2008, Sentinel Event Alert, the Joint Commission advised providers to pay greater attention to the impact technology can have on the quality and safety of patient care. The report notes that, of the 176,409 medication error records for 2006—1.25% of which resulted in harm—43,372 (almost 25%) described some aspect of computer technology as at least one cause of the error.

To prevent these types of errors, we recommend the following:

- Be aware that, as the responsibilities of the clinical engineering (CE) and IT departments increasingly overlap, it's vital to foster effective collaboration between the two departments to ensure safe, meaningful, and accurate information exchange among systems and devices.
- Ensure that equipment purchases are planned properly to help avoid errors. The earlier CE and IT are involved in this process, the better.
- Develop contract wording that expressly states the hospital's needs for interoperability and information exchange.
- With each new interface put into place, perform testing to ensure safe and reliable exchange of information.
- Be aware that patient-related problems due to the improper exchange of medical data are most certainly

underreported. Ensure that your facility has good reporting systems, and forward reports to ECRI Institute, FDA, or other organizations as appropriate.

- Ensure that your facility has policies and procedures in place to handle technology management issues related to convergence—for example, how to manage software upgrades, cyber security, and recalls affecting converging technologies.
- Remember that help desk calls regarding computer equipment and systems may now be literally a matter of life and death. CE and IT will need to work together to ensure that all calls are responded to with the appropriate urgency.

RESOURCES

Health Devices:

"CE/IT Collaboration: Putting the Pieces Together" (Guidance Article, 2009 May)

"Coping with Convergence: A Road Map for Successfully Combining Medical and Information Technologies" (Guidance Article, 2008 Oct)

"Data-Transfer Problems between Imaging Devices and PACS Could Result in Misdiagnosis" (Hazard Report, 2008 Dec)

PowerPoint presentation:

"Coping with Convergence: A Road Map for Combining Medical and Information Technologies"

Additional resource:

Joint Commission. Safely implementing health information and converging technologies. *Sentinel Event Alert* 2008 Dec 11; issue 42. Also available: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.htm.

8. Surgical Stapler Hazards

Surgical staplers expedite surgical procedures by replacing tedious manual suturing. But like any medical device, staplers occasionally fail to perform as expected. Although not all failures harm the patient, ECRI Institute is aware of numerous instances that have resulted in prolongation of surgery, serious tissue injury, and even death.

Based on ECRI Institute's investigations, the following common user errors have been associated with surgical staplers:

- Failure to properly position the stapler jaws on the tissue to be stapled
- Improper matching of stapler cartridge size to tissue thickness
- Uneven distribution of the tissue in the stapler's jaws
- Clamping of the stapler on a nearby instrument
- Failure to correctly fire the stapler (e.g., not fully pulling the firing trigger, pulling too forcefully and breaking the stapler's interlocks)

To reduce errors that may lead to patient injury, ECRI Institute recommends the following:

- Before using a stapler, ensure that the users (e.g., surgeon, scrub nurse) are intimately familiar with how it should be used and how it might be misused.
- Before a procedure, ensure that an appropriate range of staple cartridges is available for use. That way, if the original staple size selection is inadequate, a more appropriately sized staple can readily be substituted.
- Be aware that tissue thickness varies not only from patient to patient, but also within the same patient (e.g., stomach); therefore, there is no "standard" staple cartridge for specific organs, tissues, or patients. Careful matching of stapler cartridge size to tissue thickness is essential to ensure a secure staple line and guarantee hemostasis. Follow the manufacturers' instructions for choosing the appropriate staple size.
- After securing tissue between the jaws, but before firing the stapler, pause to verify that the staples are sized appropriately for the task and to allow fluids in the clamped tissue to exit. Difficulty in grasping the tissue or a reduction in tissue thickness (as when fluids are forced out of the tissue) may indicate a need to resize.
- Once the tissue has been stapled, check the application site for secure closure and hemostasis. Make sure an alternative means of closure (e.g., manual sutures, another type of stapler) is readily available if needed. While this recommendation may seem obvious, we have investigated incidents in which serious patient harm or death occurred because an alternative closure method was not readily available or not employed.

RESOURCES

Health Devices:

"Using the Wrong Size Surgical Stapler Cartridge Can Injure Patients" (Hazard Report, 2009 Apr)

For relevant hazards and recalls, refer to the numerous reports from ECRI Institute's *Health Devices Alerts* service. (Members can access this service through their membership home page at www.ecri.org.)

REPORT MEDICAL DEVICE PROBLEMS TO ECRI INSTITUTE BY FILLING OUT THE ONLINE FORM AT WWW.ECRI.ORG/PROBLEMREPORT.

9. Ferromagnetic Objects in the MR Environment

The clinical literature and problem reporting databases continue to include numerous reports of injuries and equipment damage in magnetic resonance (MR) centers attributed to the presence of ferromagnetic devices and equipment, including implants, in the MR environment.

Ferromagnetic objects are those made from materials that can become magnetized in the presence of an external magnetic field. When brought too close to an MR scanner, seemingly harmless devices, like a wheelchair or gas cylinder, can become potentially deadly projectiles, hurtling with great force into the bore of the magnet. What's more, implanted objects, like ferromagnetic aneurysm clips, can migrate or move (e.g., rotate) within the patient, possibly leading to internal injuries. And patients can be burned—for example, by currents induced in electrically conductive materials, such as medical device cables or even parts of their own bodies.

In 2008 in Pennsylvania, there were 148 reports of problems related to inadequate screening that resulted in patients with implanted devices entering, or nearly entering, the MR scanner room. (See the Pennsylvania Patient Safety Authority reference in Resources.) The majority of reports involved MR scans ordered for patients with ferromagnetic implants, most of which were pacemakers.

The American Heart Association issued guidance in January 2008 to summarize and clarify issues regarding the safety of MR imaging in patients with cardiovascular devices (see Levine et al. in Resources).

Because of the risks in the MR environment, healthcare facilities must screen patients and equipment before MR procedures. A healthcare worker specially trained in MR safety must use one of two screening forms—one for patients and one for other individuals (e.g., caregiver, engineer)—to identify potential problems related to MR procedures or the MR environment. This is followed by a verbal interview to verify the content, address questions and concerns, and determine whether any implants are unsafe.

To reduce the risk for these types of injuries, ECRI Institute recommends the following:

- Consider installing ferromagnetic detectors to screen patients and equipment. These are handheld wands and walk-through/wheel-through or walk-by/wheel-by detector systems positioned before the entrance to the MR environment.
- Update all existing screening checklists to make sure they adhere to the most recent American College of Radiology guidelines. Have a documented protocol to determine the safety of devices and implants entering the room, and ensure that all personnel involved in MR screening understand all new recommendations.
- Do not allow equipment into the MR room unless it has been determined to be safe. Some equipment will have conditions regarding where it can be placed within the MR room. Allow only MR-safe or MR-conditional equipment beyond the area of public access—particularly if the equipment might be used in an emergency. That way, no ferromagnetic equipment (e.g., a ferromagnetic oxygen cylinder) will be placed where it might be grabbed in an emergency and brought into the scan room. Ensure that equipment is clearly labeled as to its usability in the MR environment.
- Provide formal MR environment safety training annually to all MR staff and other personnel who might enter the MR environment, and reinforce emergency procedures.
- If possible, restrict access to the MR area. All personnel working within the restricted area should be trained for MR safety.
- Make clear to everyone entering the MR scan room that the magnetic field of the MR scanner is always on. Stress the danger involved.
- Appoint a safety officer to ensure that MR environment safety procedures are in effect and enforced.

RESOURCES

Health Devices:

"Patient Death Illustrates the Importance of Adhering to Safety Precautions in Magnetic Resonance Environments" (Hazard Report, 2001 Aug)

"What's New in MR Safety: The Latest on the Safe Use of Equipment in the Magnetic Resonance Environment" (Guidance Article, 2005 Oct)

PowerPoint presentation:

"MR Safety"

Additional resources:

Joint Commission. Preventing accidents and injuries in the MRI suite. *Sentinel Event Alert* 2008 Feb 14; issue 38. Also available: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_38.htm.

Levine GN, Gomes AS, Arai AE, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices. *Circulation* 2007 Dec 11;116(24):2878-91.

Pennsylvania Patient Safety Authority. Safety in the MR environment: MR safety screening practices. *Pa Patient Saf Advis* 2009 Mar;6(1):20-6.

10. Fiberoptic Light-Source Burns

Fiberoptic light sources are designed to illuminate treatment sites through a number of devices, among them endoscopes, retractors, and headlamps. Frequently referred to as "cold" light sources, these devices are anything but. In fact, each year, ECRI Institute receives reports of burns to staff and patients resulting from use of these devices. The two burn hazards most commonly reported are:

- **Burns from the light itself.** This hazard is frequently presented when a clinician places the endoscope or the distal end of the fiberoptic cable (after disconnecting it from the instrument) on the patient without shutting off or otherwise suspending the light source. The light that is continually emitted can generate enough heat to burn objects in very close proximity, sometimes even resulting in fires.
- **Burns from heated cable connections.** This hazard can occur when the diameter of the light cable is too large for the light post on the connected device. Some of the light emitted from the cable can contact the metal portion of the light post (rather than the fibers within, which transmit light to the treatment site), heating the connection. If the connection contacts skin, a burn may result.

Many users believe that since LED fiberoptic light sources are marketed as generating less heat than other light-source designs, they can't heat up enough

to cause burns. However, testing by ECRI Institute reveals that these light sources can also cause burns. Therefore, the same precautions should be taken regardless of light-source type.

To reduce the risk of burns, we recommend the following:

- Ensure that fiberoptic cables are appropriately sized for the instrument in use. At minimum, visually compare the bundles in the two devices before use. If the cable's bundle is noticeably larger in diameter than the instrument's bundle, replace it with a smaller cable. Additionally, ensure that both the cable and the instrument are compatible with the light source, since some are intended for use only with moderate-power light sources. Refer to the device packaging or contact the suppliers if you're unsure.
- Instruct users to avoid placing illuminated instruments or fiberoptic cables on the patient or on flammable objects, particularly when the light source is active.
- Turn off the light source—or place it in standby mode, which temporarily suspends light output—before removing the cable from the light source or the instrument from the cable.
- Use only the minimum light output necessary to perform the procedure.
- Purchase only light sources that incorporate safety features, such as those that power up in standby mode or at very low output settings.

RESOURCES

Health Devices:

"Eye on Medical Errors: Endoscopic Light Sources and the Risk of Burns or Fire" (Evaluation box article, 2004 Apr)

"Reducing the Risk of Burns from Surgical Light Sources" (Hazard Report, 2009 Sep) HD