

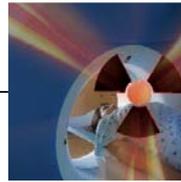
# *health.* **DEVICES**



## **TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2011**

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# TOP 10 TECHNOLOGY HAZARDS FOR 2011

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MOST ADVERSE INCIDENTS INVOLVING HEALTH TECHNOLOGY ARE PREVENTABLE. BUT THEY NEED TO BE CLEARLY UNDERSTOOD AND THOUGHTFULLY ACTED UPON. HERE ARE 10 SOURCES OF POTENTIAL DANGER THAT WARRANT PARTICULAR ATTENTION IN 2011, ALONG WITH RECOMMENDATIONS FOR PROTECTING PATIENTS AND STAFF.

Smarter choices, safer patients. That's the motto that appears on the front cover of every issue of *Health Devices*. The choices that affect patient safety cover a broad swath: Device selection decisions play a part, but just as critical are choices about what device settings are used, and how system interfaces are tested, and which ancillary technologies are employed, and when maintenance is performed. The list is long—encompassing all aspects of device management and use—and poor choices can adversely affect patient care. That's why well-focused patient safety initiatives are such a crucial component of any healthcare facility's technology management program.

With that in mind, we developed our annual list of the top 10 health technology hazards to be a tool that healthcare facilities can use to prioritize their patient safety efforts. Our list presents the potential sources of danger that we believe warrant the greatest attention to increase awareness and prevent risks for the coming year. Some of the topics reflect frequently reported problems, while others are less common. But all address problems that can adversely affect patient care—problems that can be

prevented, or at least made less likely, if effective risk-mitigation strategies are employed.

Note that our list does not reflect the problems reported most often in the past or enumerate the hazards with the most severe consequences—although we did consider such information in our analysis. Rather, it reflects our judgment about which risks should receive priority now, a judgment that is based on our review of recent recalls and other actions we've examined, our analysis of information found in the literature and in the medical device problem reporting databases of ECRI Institute and other organizations, and our experience in investigating and consulting on device-related incidents. Some topics remain from last year's list, and some are new.

The objective of this article is to increase awareness of these hazards and to stimulate action within healthcare facilities to formulate programs that succeed in minimizing the dangers. Thus, we present the guidance that leaders in hospital administration, clinical departments, and clinical engineering need in order to improve patient safety through the development and implementation of

*A Guide for  
Prioritizing Your  
Patient Safety  
Initiatives*



high-impact patient safety initiatives related to specific technologies.

For each topic in the list, we provide:

- ▷ A problem description that serves as an executive summary for the topic.
- ▷ Recommendations that provide a plan of action for addressing the hazard at your hospital; some of our recommendations specify policy and procedure improvements, while others outline actions that clinical staff can take.
- ▷ A list of resources that the clinical and technology experts in your hospital can reference to find the details they need to fully understand the extent of each problem and to develop concrete plans for having their staffs address the problems effectively.

We encourage you to incorporate this information into plans of action at your hospital and to find individuals in the relevant departments who can take the time to learn each hazard in depth and educate and influence their peers on an ongoing basis about these risks and the corresponding risk-mitigation strategies.

## **1. Radiation Overdose and Other Dose Errors during Radiation Therapy**

Radiation misadministration during radiation therapy can have devastating health consequences, from causing critical damage to normal tissue and organs, which can lead to severe morbidity and death, to creating an avenue for disease recurrence through improper or incomplete treatment of a tumor. The incidence of such errors appears to be low, but problems like these are likely underreported, and the issue nevertheless warrants particular attention for a variety of reasons. For one, the consequences of radiation dose errors are rarely immediately apparent, meaning that certain errors—such as those resulting from improper device setup or an inappropriate treatment plan—could lead to a patient being repeatedly exposed to an inappropriate dose before the error is noticed in a clinical review. And by that time, the damage has already been done (and can't be undone). For another, to increase the chances for success, treatment plans

are becoming more complex, leaving a very narrow margin for error; thus, even a small setup error can have serious effects.

The issue of radiation dose errors has begun to receive added attention from patient safety organizations and the press: In 2008, the World Health Organization (WHO) published its *Radiotherapy Risk Profile*, a document that assesses the risks of radiation therapy and identifies interventions that could reduce harm to patients. In 2009, the Pennsylvania Patient Safety Authority (PPSA) published its data on the incidence of reported radiation therapy errors along with guidance on risk-reduction strategies. And earlier this year, the *New York Times* published a series of articles that detailed several cases of the devastating consequences of radiation misadministration in specific patients (see the links listed in the Resources section, below).

Radiation dose errors can take the form of delivering the wrong dose, treating the wrong site on the patient, or treating the wrong patient. These “three wrongs” can be caused by a number of different factors:

1. Human error is one widely recognized cause. Examples from PPSA’s 2009 report include transcription errors and treatment of a patient with a similar-sounding name.
2. Software-related problems have also been cited as a cause. For example, with today’s technologies, computer-based systems from multiple vendors must now be integrated, which can lead to lost or corrupted data. A review of ECRI Institute’s *Health Devices Alerts* database revealed that, from July 2009 to July 2010, there have been over 40 reports of software errors, manufacturer-required software modifications, or dose calculation errors for radiotherapy systems, linear accelerators, and radiation treatment planning systems, including errors related to how data is transferred between these systems.

3. The pace of technological change is another factor. Inexperience with complex, newly introduced technologies can cause errors. These technologies often require extensive training and experience for equipment setup, treatment planning, and treatment administration. As a result, existing staff credentialing, professional society guidelines, and departmental policies and procedures may no longer be adequate for newer technologies that offer improved precision and thus make it possible to use higher doses—creating the potential for greater harm if a dose administration error were to occur. As roles and responsibilities change, the potential for errors can increase.

There is no simple fix to ensure safe and effective treatment. A comprehensive review of all aspects of radiation therapy operations and quality assurance is needed. ECRI Institute recommends the following:

- ▷ Ensure that clinical and technical staff responsible for radiation oncology services are qualified and have adequate training and support.
  - Check licensing, registrations, and board certifications (including effective dates of credentials) for all staff who will be working with and operating radiation therapy equipment.
  - Verify that personnel have training specific to each device and/or system used and each procedure performed in your program.
  - Determine whether staffing levels are adequate (e.g., to support equipment maintenance and patient load).
- ▷ Ensure that systems are properly installed, commissioned, and maintained.
  - Perform acceptance testing for new systems, as well as for system updates and modifications, and ensure that the integrated systems as a whole (simulation, treatment planning, delivery, and record and verify systems) meet device performance specifications.
- Before clinical use, verify that each system is properly commissioned by qualified personnel (e.g., a medical physicist). Commissioning involves measuring the delivered radiation dose so that the treatment planning system uses the correct data.
- Ensure that new treatment techniques are validated before use.
- Verify that an appropriate subset of key parameters (e.g., radiation beam output) is tested regularly and frequently as part of an ongoing quality control (QC) program.
- ▷ Ensure that standard patient treatment procedures are documented and followed, including performing independent double checks and conducting time-outs, as appropriate.
- ▷ Provide oversight of incident reporting and safety alerts management.
  - Encourage staff to be alert to any inconsistencies or problems and to raise concerns before delivering therapy.
  - Ensure that radiation oncology departments have a process for reporting problems and that this process is integrated with the hospital-wide medical device reporting system so that appropriate agencies and the

manufacturer can implement measures to reduce the risk of problems reoccurring at your own facility and other facilities.

- Assign responsibility within the radiation oncology department for oversight of safety alerts to ensure that the facility responds quickly to any radiation-therapy-related recalls and hazards.

▷ Implement corrective actions as needed, recognizing that there could be significant costs that will need to be budgeted for. For example:

- Assess whether existing testing equipment is adequate for today's advanced treatment systems.
- Examine the need for immediate or future investment in additional staffing, training, or professional development activities.
- Establish or modify policies and procedures as needed, and monitor compliance.

## Resources

### Health Devices Alerts:

"ECRI Institute Responds to Recent News Coverage of Radiation Therapy Overexposure Incidents" (Accession No. S0198, 2010 Jan 28)

ECRI Institute's Patient Safety Blog:

Inamdar R. "Radiation Therapy: A Double-Edged Sword" (2010 Jun 2); <https://www.ecri.org/blog/Lists/Posts/Post.aspx?ID=33>.

Additional resources:

Bogdanich W:

As technology surges, radiation safeguards lag. *N Y Times* 2010 Jan 26. Also available: [www.nytimes.com/2010/01/27/us/27radiation.html?emc=eta1](http://www.nytimes.com/2010/01/27/us/27radiation.html?emc=eta1).

Case studies: when medical radiation goes awry. *N Y Times* 2010 Jan 26. Also available: [www.nytimes.com/2010/01/27/us/27RADIATIONSIDEBAR.html](http://www.nytimes.com/2010/01/27/us/27RADIATIONSIDEBAR.html).

Radiation offers new cures, and ways to do harm. *N Y Times* 2010 Jan 23. Also available: [www.nytimes.com/2010/01/24/health/24radiation.html?pref=health](http://www.nytimes.com/2010/01/24/health/24radiation.html?pref=health).

Bogdanich W, Rebelo K. They check the medical equipment, but who is checking on them? *N Y Times* 2010 Jan 26. Also available: [www.nytimes.com/2010/01/27/us/27sideradiation.html](http://www.nytimes.com/2010/01/27/us/27sideradiation.html).

[www.nytimes.com/2010/01/27/us/27sideradiation.html](http://www.nytimes.com/2010/01/27/us/27sideradiation.html).

Pennsylvania Patient Safety Authority. Errors in radiation therapy. *Pa Patient Saf Advis* 2009 Sep;6(3):87-92. Also available: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Sep6\(3\)/Pages/Home.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Sep6(3)/Pages/Home.aspx).

World Health Organization (WHO). *Radiotherapy risk profile*. Geneva: WHO; 2008. Also available: [www.who.int/patientsafety/activities/technical/radiotherapy\\_risk\\_profile.pdf](http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf).

## 2. Alarm Hazards

Alarm hazards continue to rank highly on our list, and for good reason—alarm-related adverse incidents are all too common, and the consequences can be serious. Clinical alarm problems were once again in the news in 2010 when the *Boston Globe* reported the death of a patient whose treatment may have been delayed because a critical physiologic monitoring alarm had been turned off.

Many devices in the hospital incorporate alarms to help protect patients and thus are susceptible to alarm-related problems. However, ECRI Institute has seen the most reports of alarm problems with physiologic monitoring systems and ventilators.

Alarm-related adverse incidents typically involve one of the following:

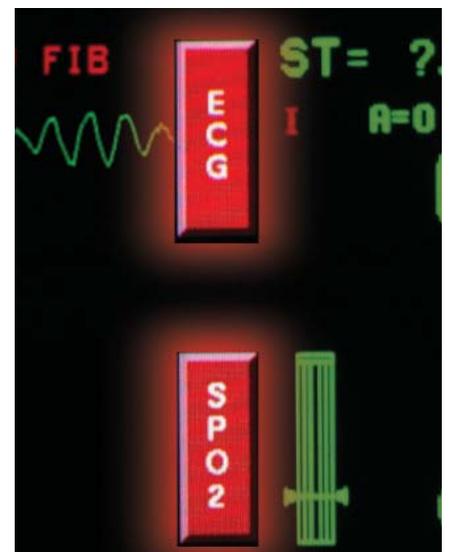
1. Staff becoming overwhelmed by the sheer number of alarms, with consequences that include:
  - a. Staff improperly modifying alarm settings in an attempt to reduce the alarm overload. If such modifications are made without careful consideration of the patient's condition and the alarm's function, the alarm may be set in such a way that it effectively becomes disabled.
  - b. Staff becoming desensitized to alarms, potentially leading to caregivers responding to alarms more slowly.

c. Staff being so busy responding to alarms that they are unable to perform other critical duties.

2. Alarm settings not being restored to their normal levels after being modified to accommodate temporary conditions—as in the example of a caregiver temporarily disabling an alarm while the patient is being washed.
3. Alarms not being properly relayed to ancillary notification systems (e.g., paging system, wireless phones), potentially leading to a failure to notify relevant staff.

To reduce the frequency of alarm-related adverse incidents, we recommend the following:

- ▷ Examine the entire alarm environment when setting up your facility's alarm-management program for each care unit, taking into account the following:
- The full array of equipment in use (e.g., bedside monitors, telemetry monitors, central station, ventilators, infusion pumps), as well as any associated ancillary notification technologies.



- Staffing levels, staffing patterns, and staff proficiency.
- The physical layout of the care unit (or facility).
- ▷ Establish protocols for alarm-system settings. These should include defining the default alarm settings for the specific care unit—that is, which alarms are active and what their limits are. Additionally, establish protocols to guide caregivers when the default settings need to be modified for a specific patient.
- ▷ Establish alarm-response protocols that ensure that each alarm will be recognized, delivered to an appropriate responder, and promptly addressed.
  - Clearly assign responsibilities, including: the staff person responsible for recognizing the alarm once it is issued by the device, the staff person responsible for delivering the necessary alarm information (e.g., existence of an alarm condition, identity of affected patient, reason for alarm, priority) to the responsible caregiver, and the person directly responsible for addressing the alarm.
  - Establish backup coverage protocols to ensure that someone responds promptly when the primary caregiver is not available.
  - Ensure that the correct pager/phone is assigned to the correct caregiver (e.g., that it is properly programmed to account for changes in staffing levels from shift to shift).
- ▷ Establish policies to control alarm silencing, modification, and disabling.
- ▷ Make sure these steps are implemented and compliance with established protocols is monitored for existing care areas and that an alarm-management program is considered from the earliest planning stages for new care areas.

## Resources

### Health Devices:

- “Alarm Notification for Physiologic Monitoring: Could You Benefit from a New Strategy?” (Guidance Article, 2007 Jan)
- “Alarm-Notification Problem Spotlighted in *Boston Globe* Is All Too Common” (Safety Note, 2010 Apr)
- “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)

### ECRI Institute’s Patient Safety Blog:

- Keller J. “Making Clinical Alarm Management a Patient Safety Priority” (2010 Jul 29); <https://www.ecri.org/blog/Lists/Posts/Post.aspx?ID=52>.

### PowerPoint presentations:

- “Alarm-Enhancement Systems for Ventilators”
- “Alarms—Critical Alarms and Patient Safety”

### Additional resource:

- Kowalczyk L. MGH death spurs review of patient monitors. *Boston Globe* 2010 Feb 21. Also available: [www.boston.com/news/health/articles/2010/02/21/mgh\\_death\\_spurs\\_review\\_of\\_patient\\_monitors](http://www.boston.com/news/health/articles/2010/02/21/mgh_death_spurs_review_of_patient_monitors).

## 3. Cross-Contamination from Flexible Endoscopes

Patient cross-contamination from improperly reprocessed flexible endoscopes has affected large groups of patients at hospitals large and small. At minimum, endoscope reprocessing problems, when discovered, can inconvenience patients and create anxiety; at worst, they can lead to life-threatening infections. The U.S. Department of Veterans Affairs (VA) has reported testing at least 10,000 patients in recent years after it was discovered that endoscopes and associated accessories weren’t being properly decontaminated at several of its medical centers. Also, in June 2010 two facilities reported contacting thousands of patients who might have been exposed to infection due to



endoscope contamination (Garrick 2010, Hennepin County Medical Center 2010).

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

With the scheduled removal of the Steris System 1 from the market, many healthcare facilities will be purchasing new devices to reprocess their endoscopes, and thus will be changing their endoscope reprocessing protocols and possibly purchasing new endoscope models. Therefore, this is a good time to remind healthcare facilities how crucial it is that they carefully develop model-specific protocols and implement strict adherence to these protocols—an effort that requires a strong emphasis on training.

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 and consult the endoscope or

reprocessor 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, endoscope reprocessor, or related equipment and accessories.

- ▷ Periodically review protocols to ensure that they are clear and comprehensive and that they reflect the current environment. For example, verify that they don't include obsolete 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 treatment site to safe and aseptic transport of equipment back to the treatment site for subsequent use. (Typical steps in a reprocessing protocol are described in our October 2010 Guidance Article “Clear Channels: Ensuring Effective Endoscope Reprocessing.”)
- ▷ If your facility reprocesses endoscopy equipment using a reprocessing unit—such as an automated endoscope reprocessor (AER), 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/connector combinations.
  - Staff are familiar with and adhere to appropriate reprocessor 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. Remember to periodically repeat training to ensure that staff remain familiar with the protocols and to address turnover. Also monitor adherence to protocols.

## Resources

### Health Devices:

“Clear Channels: Ensuring Effective Endoscope Reprocessing” (Guidance Article, 2010 Oct)

### Health Devices Alerts:

“Steris—System 1 Sterile Processing Systems and Accessories: U.S. Healthcare Facilities Should Begin Plans for Transition to Acceptable Alternatives” [Update] (Accession No. S0192 01, 2009 Dec 11)

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

### ECRI Institute online resource:

Steris System 1 Resource Center; <https://members2.ecri.org/Components/HDJournal/Pages/SterisSystem1ResourceCenter.aspx>

### Additional resources:

Food and Drug Administration, U.S. Preventing cross-contamination in endoscope reprocessing: safety communication from FDA, CDC, and the VA [online]. 2009 Nov 19 [cited 2010 Oct 5]. Available from Internet: [www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm).

Garrick D. PPH testing 3,400 patients when only 45 at risk of exposure. *North County Times* 2010 Jun 15. Also available: [www.nctimes.com](http://www.nctimes.com).

Hennepin County Medical Center. Error in manufacturer's disinfecting instructions prompts patient notification [news release online]. 2010 Jun 22 [cited 2010 Oct 5]. Available from Internet: [www.hcmc.org/Newsroom/pr2.asp?nrID=224](http://www.hcmc.org/Newsroom/pr2.asp?nrID=224).

## 4. The High Radiation Dose of CT Scans

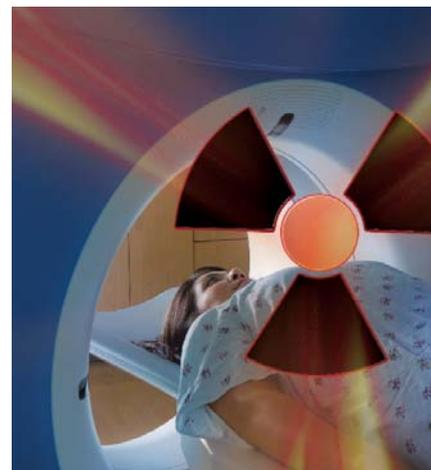
The high radiation doses generated during computed tomography (CT) are believed to increase a patient's risk of cancer. This hazard has received national attention

over the last few years and was again in the news this past July, when the *New York Times* reported that radiation overdoses during CT scans are larger and more widespread than previously estimated (Bogdanich 2010). Additionally, a 2009 study estimates that 29,000 cases of cancer could be related to CT scans that were performed in the United States during 2007 (Berrington de Gonzales et al. 2009).

Local and national regulators have been unable to determine how widespread the problem of excessive radiation dose from CT is. And while the increased risk of cancer cannot be reliably quantified, it clearly is a risk that healthcare facilities must take steps to mitigate. At the same time, concern exists that patients may decline CT scans that are necessary.

Compounding the challenge for hospitals is the fact that there is no regulatory dose limit in diagnostic radiology. The responsibility falls to radiologists to justify the radiation doses used, although many other professionals, including hospital management, have a part to play.

The crux of the problem is that a delicate balance must be achieved between keeping doses low and maintaining adequate image quality. Doses that are too high expose the patient to unnecessary radiation and increase the cancer



risk. And doses that are too low can result in poor-quality images that can lead to a patient being misdiagnosed or having to be rescanned, and therefore exposed to even more radiation.

A variety of new dose-saving technologies have been made available in recent years. Unfortunately, the most advanced technologies are generally available only on the latest, and most expensive, CT systems, and many healthcare facilities simply cannot afford to purchase top-of-the-line scanners. In time, these technologies will likely become more widely available. However, even at facilities where advanced dose-savings technologies are available, the following steps should be taken to avoid inappropriate levels of radiation during diagnostic radiology studies:

- ▶ Educate referring physicians regarding ordering the most appropriate diagnostic studies. Unnecessary imaging means unnecessary radiation dose, so it is important that the potential benefits of a CT study (or any radiology study) outweigh the radiation risk.
- ▶ Monitor and audit radiation levels used in routine CT exams. Seek expert assistance (e.g., from a medical physicist) in determining appropriate parameters to monitor.
- ▶ Ensure that your staff is adequately trained. Note that advanced systems often use innovative and proprietary technology, meaning that the equipment manufacturer is often the only source for training.
- ▶ Optimize and control x-ray parameters (protocols). The task of optimization, commonly undertaken when equipment is installed, should involve radiologists, medical physicists, and senior x-ray technologists. Access to equipment settings should be restricted so that these settings cannot be changed by unauthorized personnel after having been set.
- ▶ Investigate the applicability of technologies designed to reduce x-ray dose.

These include options available from the CT vendor and third parties. (Refer to our April 2010 Guidance Article “CT Radiation Dose: Understanding and Controlling the Risks” for details.)

## Resources

### Health Devices:

“CT Radiation Dose: Understanding and Controlling the Risks” (Guidance Article, 2010 Apr)

“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”

### ECRI Institute’s Patient Safety Blog:

Keller J. “CT Radiation Safety—Now It’s Personal” (2010 Aug 5); <https://www.ecri.org/blog/Lists/Posts/Post.aspx?ID=53>.

### Additional resources:

American College of Radiology. ACR appropriateness criteria [online]. [www.acr.org/secondarymainmenucategories/quality\\_safety/app\\_criteria.aspx](http://www.acr.org/secondarymainmenucategories/quality_safety/app_criteria.aspx).

Berrington de Gonzalez A, Mahesh M, Kim KP, et al. Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Arch Intern Med* 2009 Dec;169(22):2071-7.

Bogdanich W. After stroke scans, patients face serious health risks. *N Y Times* 2010 Jul 31. Also available: [www.nytimes.com/2010/08/01/health/01radiation.html?\\_r=1](http://www.nytimes.com/2010/08/01/health/01radiation.html?_r=1).

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 16 [includes link to 2009 Oct 15 statement from Thomas M. Priselac, president and CEO of Cedars-Sinai Medical Center; cited 2010 Oct 11]. Available from Internet: [www.npr.org/blogs/health/2009/10/cedarssinai\\_says\\_sorry.html](http://www.npr.org/blogs/health/2009/10/cedarssinai_says_sorry.html).

## 5. Data Loss, System Incompatibilities, and Other Health IT Complications

The convergence of medical technology and health information technology (HIT) is no longer a new phenomenon or purely a specialized concern. Technologies like medication management systems and processes like the incorporation of medical data from devices such as physiologic monitors and ventilators into electronic health records are just a few examples of how convergence is becoming more commonplace. While convergence presents many benefits, including improved standards of care and operational efficiencies, it also presents many risks. Ineffective convergence can adversely affect patient care in a wide variety of ways. It can, for example, lead to data being lost (e.g., overwritten, unsuccessfully transmitted) or being associated with the wrong patient, which in turn can lead to misdiagnosis, inappropriate treatment, or the need for repeat testing.

The number of HIT applications and integrations will likely increase dramatically, as efforts related to the U.S. federal Health Information Technology for Economic and Clinical Health (HITECH) Act quicken the pace. So it is vital that healthcare organizations take steps now to keep HIT problems from exploding at their facilities.

On February 25, 2010, the director of the U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) offered FDA’s testimony regarding its perspectives on HIT safety issues at the Health Information Technology Policy Committee Adoption/Certification Workgroup (FDA 2010). In its testimony, FDA noted that in the past two years there have been 260 HIT-related reports, with 44 reported injuries and 6 reported deaths. (Note, however, that FDA

and ECRI Institute consider it likely that such problems are underreported, since to date most reporting has been voluntary.) FDA stated that the reported adverse events largely can be grouped into the following four categories:

1. Errors of commission—for example, a confusing user interface led to the overwriting of one patient’s data with another patient’s study.
2. Errors of omission or transmission—for example, an improperly configured database caused manually entered patient data to be overwritten during automatic updates.
3. Errors in data analysis—for example, intravenous fluid infusion rates of greater than 1,000 mL/hr were printed as 1 mL/hr on the labels that were generated for a particular care area.
4. Incompatibility between multivendor software applications and systems—for example, results for the wrong patient were retrieved from a laboratory information system when the request was made through the facility’s emergency department management software.

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

- ▶ Carefully plan convergence-based projects. Seek input in the beginning stages from all involved parties—including nursing, pharmacy, risk management, IT, and clinical engineering, as appropriate—to ensure that clinical workflow, patient safety, and technology performance issues are all handled effectively.
- ▶ Develop wording for contracts that expressly states the healthcare facility’s needs and its expectations of the vendor (e.g., requesting system compatibility statements).
- ▶ Employ good project management, change management, and risk management processes. To aid in this effort, hospitals should consider applying the International Electrotechnical

Commission’s new IEC 80001-1 standard, *Application of Risk Management for IT-Networks Incorporating Medical Devices—Part 1: Roles, Responsibilities and Activities*. The expected publication date for the standard is November 15, 2010. (Refer to our May 2010 Guidance Article for answers to some common questions about the standard.)

- ▶ Educate staff to be alert to HIT-related problems, to report them, and to document them. Facilities should submit reports to regulatory bodies such as FDA or Health Canada and to organizations like ECRI Institute, as appropriate.
- ▶ Ensure good working relationships between IT and clinical engineering.
- ▶ Adhere to a robust software management program (e.g., requiring the careful administration of software upgrades). Many HIT errors are due to software anomalies, making adherence to a software management program essential.
- ▶ Ensure that cybersecurity is a priority.
- ▶ With each new interface (e.g., adding a new medical device’s data to an electronic health record), perform testing to ensure safe and reliable exchange of information.
- ▶ Remember that help desk calls regarding computer equipment and systems may now literally be a matter of life and death. Clinical engineering 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)
- “10 Questions about IEC 80001-1: What You Need to Know about the Upcoming Standard

and Networked Medical Devices” (Guidance Article, May 2010)

PowerPoint presentation:

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

Additional resources:

Food and Drug Administration, U.S. (FDA). Testimony of Jeffrey Shuren, Director of FDA’s Center of Devices and Radiological Health [online]. 2010 Feb 25 [cited 2010 Oct 11]. A PDF of the testimony can be downloaded from the “February 25, 2010 HIT Safety Hearing” section available at: [http://healthit.hhs.gov/portal/server.pt?open=512&objID=1473&&PageID=17117&mode=2&in\\_hi\\_userid=11673&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1473&&PageID=17117&mode=2&in_hi_userid=11673&cached=true).

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](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.htm).

## 6. Luer Misconnections

Tubing and catheter misconnections can be harmful to patients because they can allow gases or liquids to be introduced into the wrong lines or by unintended routes of administration. The risk of such misconnections is heightened when two functionally dissimilar devices each use Luer connectors. Serious patient injury or death can result when a connection is made to the wrong device, such as if fluid intended for an enteral feeding tube is instead delivered to an intravenous (IV) catheter.

Although misconnections have been recognized as a serious problem for years, incidents are still common. Between January 2008 and September 2009, the Pennsylvania Patient Safety Authority received 36 reports of tubing misconnections, with the incidents ranging from near misses to serious events (PPSA 2010). And in August 2010, a *New York Times* article described a death caused by the inadvertent delivery of nutrients intended for the gastrointestinal tract into the patient’s vein (Harris 2010).



Efforts at developing effective standards to eliminate or reduce the risk of Luer connector misconnections have been in development for years, but there has been little if any progress. Instead, prevention requires that hospitals implement effective policies and procedures and that clinicians exercise constant vigilance.

To prevent these kinds of misconnections, we recommend the following:

- ▷ Provide periodic training about misconnection prevention to all personnel working in patient care areas.
- ▷ Prohibit the use of adapters throughout the hospital. Adapters can permit the connection of two components that normally wouldn't mate—and that often shouldn't be connected (e.g., two female Luer connectors). Any exceptions should be carefully reviewed and justified, and measures should be implemented to ensure that the adapters will not be misused.
- ▷ Review purchasing policies to ensure that, whenever possible, only products that incorporate misconnection safeguards are purchased.
- ▷ Identify and manage conditions and practices that may contribute to healthcare worker fatigue, and take appropriate action.

- ▷ Require that clinical staff
  - trace all lines back to their origin before making connections, and
  - recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service as part of the handoff process.
- ▷ Label certain high-risk catheters—such as epidural, intrathecal, and arterial catheters—so that staff can clearly see that they are making a connection to one of these devices.

### Resources

#### Health Devices:

“Fixing Bad Links: Preventing Misconnections in Your Hospital” (Guidance Article, 2009 Jul)

#### PowerPoint presentation:

“Misconnections—Preventing Misconnections of Lines and Cables”

#### Additional resources:

Food and Drug Administration, U.S. (FDA). Letter from C. Foreman to manufacturers of enteral feeding tubes, healthcare professionals, and hospital purchasing departments [online]. 2010 Jul 9 [cited 2010 Oct 5]. Available from Internet: [www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf](http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf).

Harris G. U.S. inaction lets look-alike tubes kill patients. *N Y Times* 2010 Aug 20. Also available: [www.nytimes.com/2010/08/21/health/policy/21tubes.html?\\_r=1](http://www.nytimes.com/2010/08/21/health/policy/21tubes.html?_r=1).

Pennsylvania Patient Safety Authority (PPSA). Tubing misconnections: making the connection to patient safety. *Pa Patient Saf Advis* 2010 Jun;7(2):41-5. Also available: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7\(2\)/Pages/41.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/41.aspx).

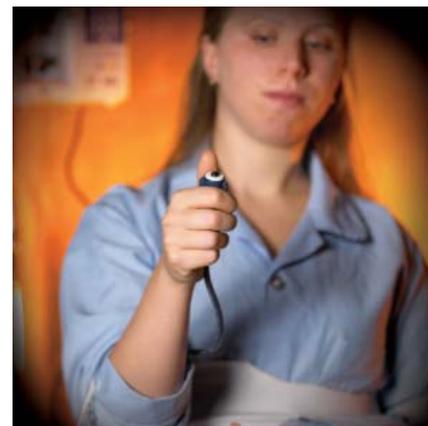
## 7. Oversedation during Use of PCA Infusion Pumps

This past April, the U.S. Food and Drug Administration (FDA) announced an initiative to address infusion pump safety, introducing a broad program covering large-volume, syringe, patient-controlled

analgesic (PCA), insulin, and enteral feeding pumps. While the FDA initiative addresses the potential dangers of all infusion technologies—certainly a worthwhile endeavor—for this year's Top 10 list we chose to focus more narrowly on PCA pumps because of the particular dangers associated with delivering opioids. Whereas other types of infusion pumps may be used to deliver anything from fluids to critical medications, PCA devices are used only with high-alert medications.

The most significant danger when using PCA pumps is oversedation, which can lead to potentially life-threatening narcotic-induced respiratory depression. Oversedation can result from misprogramming the PCA pump, but it can also occur when the pump is programmed as intended, since patients respond to opioids in different ways. For example, patients with certain medical conditions (e.g., sleep apnea) may be at higher risk for respiratory depression. For this reason, the Anesthesia Patient Safety Foundation (APSF) has been recommending that healthcare facilities monitor patients who are on PCA therapy (APSF 2007).

The trend toward monitoring patients who are using PCA pumps has led to an increased recognition of the frequency of oversedation. A study published in August 2007 reported that when postsurgical



patients undergoing PCA therapy were monitored with continuous oximetry and capnography, respiratory depression was identified in 41% of the patients (Overdyk et al. 2007). The authors compare this to the 1% to 2% incidence previously reported in the literature and conclude that the traditional method of assessing respiratory depression—retrospectively reviewing charts after data has been collected intermittently—significantly underestimates the true incidence. Thus, in addition to being underestimated in the literature, oversedation is underreported in clinical practice. One reason may be that improper assessment of patients on PCA therapy can mask the symptoms of oversedation (e.g., if the caregiver arouses the patient before checking the patient's vital signs). Another possibility may be that clinicians don't suspect oversedation as a root cause in patients who suffer cardiopulmonary arrest.

PCA therapy is often prescribed to patients in low-acuity wards where monitoring is not routinely performed and where clinicians may be less attuned to the risks. Thus, it is important that clinicians in these care areas know to always be on the lookout for symptoms of oversedation, particularly respiratory depression.

ECRI Institute recommends taking the following actions to help reduce the risks associated with the use of PCA pumps:

- ▶ Develop an action plan to implement effective physiologic monitoring of patients on PCA therapy. In addition to periodic nursing assessments of patient mental status and vital signs, monitoring might include pulse oximetry and/or capnography.
- ▶ Review how patients on PCA therapy are assessed by clinicians. For example, arousing a patient to ask a series of questions can defeat the purpose of the assessment since, when stimulated in this manner, an overly sedated patient may still be able to respond. That is, the stimulation can temporarily mask the signs of oversedation. Assessment

of patients should include checking respiratory rate in the absence of stimulation.

- ▶ Consider implementing a policy whereby all PCA orders and pump programming are double-checked by a second clinician.
- ▶ Consider implementing other forms of pain management, instead of PCA, where appropriate. Alternatives might include the administration of oral narcotics and local analgesic infusion.

## Resources

### Health Devices:

“Patient-Controlled Analgesic Infusion Pumps” (Evaluation, 2006 Jan); see in particular the “Safety Issues” discussion (p. 7) and the box article “Physiologic Monitoring during PCA Therapy” (p. 10)

“Someone to Watch Over Me: Monitoring Project That Won Health Devices Achievement Award Is Featured in *Anesthesiology*” (Spotlight, 2010 Mar)

### Additional resources:

Anesthesia Patient Safety Foundation (APSF):

Dangers of postoperative opioids: APSF workshop and white paper address prevention of postoperative respiratory complications. *Anesth Patient Saf Found News* 2006-2007 Winter;21(4):61, 63-7. Also available: [www.apsf.org/newsletters/pdf/winter2007.pdf](http://www.apsf.org/newsletters/pdf/winter2007.pdf).

Dangers of postoperative opioids—is there a cure? *Anesth Patient Saf Found News* 2009 Summer;24(2):25-6. Also available: [www.apsf.org/newsletters/pdf/summer2009.pdf](http://www.apsf.org/newsletters/pdf/summer2009.pdf).

Hospital coalition group endorses APSF recommendations for PCA monitoring. *Anesth Patient Saf Found News* 2010 Spring;25(1):17. Also available: [www.apsf.org/newsletters/pdf/spring\\_2010.pdf](http://www.apsf.org/newsletters/pdf/spring_2010.pdf).

Center for Devices and Radiological Health, U.S. Food and Drug Administration. Infusion pump improvement initiative [white paper online]. 2010 Apr [cited 2010 Oct 17]. Available from Internet: [www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm).

Institute for Safe Medication Practices. Patient-controlled analgesia: making it safer for patients [monograph online]. 2006 Apr [cited 2010

Oct 6]. [www.hospira.com/Files/ISMP\\_PCA\\_monograph.pdf](http://www.hospira.com/Files/ISMP_PCA_monograph.pdf).

Overdyk F, Carter R, Maddox RR, et al. Continuous oximetry/capnometry monitoring reveals frequent desaturation and bradypnea during patient-controlled analgesia. *Anesth Analg* 2007 Apr;105(2):412-8. Also available: [www.anesthesia-analgesia.org/content/105/2/412.full](http://www.anesthesia-analgesia.org/content/105/2/412.full).

## 8. Needlesticks and Other Sharps Injuries

The number of needlesticks and other sharps injuries that occur each year remains staggering, despite the implementation of safety devices and the emphasis on training over the past 15 to 20 years. Clinicians continue to stick themselves and one another, including when trying to activate needlestick-prevention devices. And clinicians and custodial staff—and sometimes even patients, as described in a recent CNN report (Batchelor 2010)—continue to get stuck while putting objects into or while handling sharps disposal containers. Consequences can include serious cuts and exposure to bloodborne pathogens, such as HIV or the hepatitis B or C viruses.

Most hospitals have ongoing programs to address sharps safety. But these programs may have been established some time ago and may no longer be



receiving adequate attention or achieving their expected level of effectiveness. It is easy to become complacent after initial efforts succeed in reducing the frequency of injuries. However, continuing injuries are a signal that additional attention is needed; it could be that clinicians are using poor technique, that the safety devices being used should be replaced with more effective models, or that gaps exist in the facility's sharps safety program.

An effective sharps safety program will include input from a variety of stakeholders. Thus, a typical sharps safety committee will include personnel from risk management, materials management, nursing, clinical laboratory, pharmacy, the patient safety committee, and housekeeping. Also, staff members such as the infection control officer, industrial hygienist, employee health officer, and medical director should be involved. Additional personnel—for example, operating room, emergency department, nuclear medicine, and home care staff—will likely be needed to address specific concerns. And when the identification, evaluation, and selection of sharps safety work practice and engineering controls are being considered, frontline healthcare workers need to participate in the process—in fact, in the United States the Occupational Safety and Health Administration (OSHA) requires that they be involved.

To achieve consistent success in preventing needlesticks and other sharps injuries, facilities should routinely review and refine all aspects of their sharps safety efforts. We recommend the following activities:

- ▷ Assess injuries and current practices—Analyzing information about needlesticks and other sharps injuries that have occurred in your facility is essential for designing or assessing a program. Such an analysis can help you identify where and when (e.g., during which procedures or applications) such injuries typically occur. For instance, if your hospital already has sharps safety devices in place, historical and current

data is helpful for deciding whether a particular safety device should be replaced with a new one.

- ▷ Define specific objectives—The data collected on injuries, devices, and current practices will help you define or refine the objectives of your program and prioritize your efforts.
- ▷ Establish an action plan—Within each action plan, each identified category of injury should have some plan for remediation or recommendation for action. The plan should also specify who is responsible for implementing particular aspects of the program, when specific milestones should be completed, and what results the facility expects to achieve.
- ▷ Implement the program—Some of the more challenging aspects include:
  - Ensuring that all personnel on all shifts are trained.
  - Obtaining supplier support for in-service training on the use of the protective devices that will be implemented.
  - Making supplies readily available and removing sharps that are to be replaced by protective devices.
- ▷ Periodically assess the program's effectiveness, using the first four steps above for guidance.

## Resources

### Health Devices:

“Needlestick-Prevention Devices: Disposable Syringes and Injection Needles” (Evaluation, 2007 Aug)

“Sharps Disposal Containers” (Evaluation, 2003 Jul); many of the containers rated in this Evaluation are still on the market, and the technology guidance is still valid

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

### PowerPoint presentation:

“Sharps Safety—Maintaining an Effective Sharps Injury Prevention Program”

### ECRI Institute Special Report:

*Sharps Safety and Needlestick Prevention*, 2nd edition (2003); this publication includes our evaluations of more than 90 protective devices, many of which are still on the market

### Additional resources:

Batchelor L. Toddler pricked by contaminated needles [online]. 2010 Oct 22 [cited 2010 Oct 26]. Available from Internet: [www.cnn.com/2010/US/10/22/us.child.needles/index.html?iref=allsearch](http://www.cnn.com/2010/US/10/22/us.child.needles/index.html?iref=allsearch).

Jagger J, Berguer R, Phillips EK, et al. Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation. *J Am Coll Surg* 2010 Apr;210(4):496-502.

## 9. Surgical Fires

ECRI Institute's research indicates that there are approximately 600 surgical fires in the United States each year, making them roughly as frequent as wrong-site surgery. Not all surgical fires result in patient injury, but when they do, the consequences can be severe, including potentially fatal airway burns and horrible facial disfigurement. To address this risk, last year new clinical practice recommendations for delivering oxygen during surgery were developed by ECRI Institute in conjunction with the Anesthesia Patient Safety Foundation (APSF). These recommendations—which focus on surgeries



to the head, face, neck, and upper chest, during which oxygen accumulation creates an enriched atmosphere—are discussed in detail in our October 2009 *Health Devices* Guidance Article “New Clinical Guide to Surgical Fire Prevention” and summarized in the second item in the list below.

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 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.

Formal training and drills are recommended by ECRI Institute and APSF. APSF recently commissioned ECRI Institute to produce a training video on surgical fires. The 18-minute video is available as a free download from the APSF website; the organization also offers DVDs of the video for a nominal fee.

We recommend the following:

- ▶ If you don’t already have one, implement a surgical fire prevention and management program, including training, based on the recommendations for preventing and extinguishing surgical fires presented in our October 2009 Guidance Article.
- ▶ 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. (Again, see our October 2009 Guidance Article for details.) The core point of these 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 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.

## 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)

### PowerPoint Presentation:

“New Clinical Guide to Surgical Fire Prevention”

### 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.lifefinetomodernmedicine.com/UploadedDoc/OR%20Fires%20Practice%20Guidelines.pdf](http://www.lifefinetomodernmedicine.com/UploadedDoc/OR%20Fires%20Practice%20Guidelines.pdf).

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

Joint Commission. Preventing surgical fires. *Sentinel Event Alert* 2003 Jun 24; issue 29. Also available: [www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea\\_29](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_29).

## 10. Defibrillator Failures in Emergency Resuscitation Attempts

Defibrillators are critical resuscitation devices. Their failure to perform effectively may result in the death of a patient who could have been saved. During emergencies, there is no time to troubleshoot or correct even minor difficulties, since every minute of delay significantly decreases the probability of a successful resuscitation attempt.

Measures are available that can help ensure that defibrillators are ready for use at a moment’s notice. These measures include performing regular preventive maintenance and conducting the routine (e.g., daily) checks recommended by the supplier. In addition, the devices



themselves perform automated self-tests. Nevertheless, achieving the required state of defibrillator readiness has proven to be a challenge for many healthcare facilities. The U.S. Food and Drug Administration’s Manufacturer and User Facility Device Experience (MAUDE) database and our own Problem Reporting System include many reports of incidents in which defibrillators didn’t discharge during resuscitation attempts for various preventable reasons (such as depleted batteries).

To reduce the risk of a defibrillator failing to operate correctly when needed, ECRI Institute recommends the following:

- ▶ Ensure that clinicians who are responsible for using the defibrillator during a resuscitation attempt
  - perform the supplier’s recommended checks at least daily,
  - verify that the installed battery is charged and that a charged spare battery is kept with the unit, and
  - verify that between uses the unit (or charger) is plugged in and batteries are charging.

Defective or discharged batteries are a primary reason for defibrillator failures.

- ▶ If the device does not pass the unit’s automated self-test or if performance

failures are found during routine manual checks, immediately replace the unit and arrange for repair of the original device, if needed. Ensure that users understand the outcomes that the self-test may yield and know the necessary corrective action(s).

- ▷ If any error codes are noted during routine checks or any other time, take any necessary corrective action or contact the clinical engineering department to investigate. Be aware that disappearance of an error code (for instance, after the power has been cycled) does not necessarily mean that the

underlying problem has been resolved. Clinical engineering will need to assess whether the device needs to be taken out of service.

- ▷ Ensure that the clinical engineering department performs the preventive maintenance recommended by the supplier.

### Resources

#### *Health Devices:*

“External Manual Defibrillators: Which Models Are Ready to Meet Your Needs?” (Evaluation, 2009 Nov)

“Insecure Connection between Zoll M Series Defibrillator Paddles and Cables Could Delay Therapy” (Hazard Report, 2009 Nov)

“Physio-Control Lifepak 20 Defibrillator/Monitor May Misrepresent Critical Failures as Incomplete Self-Test” (Hazard Report, 2009 May)

“Shift Checks and Semiannual Preventive Maintenance Are Important in Detecting Critical Failures in Zoll M Series Defibrillators” (Hazard Report, 2009 May)

“Upside-Down Insertion of Zoll M Series Multifunction Cable Connector into M Series Defibrillator Paddles Could Delay Therapy” (Hazard Report, 2009 Aug) **HD**



## 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.

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