SPECIAL REPORT

Top 10 Health Technology Hazards for 2020
Expert Insights from Health Devices

Executive Brief

ECRI Institute is providing this abridged version of its 2020 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report—including detailed problem descriptions and ECRI Institute’s step-by-step recommendations for addressing the hazards—is available to members of ECRI Institute programs through their membership web pages.

The List for 2020

1. Misuse of Surgical Staplers
2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards
3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices
4. Hemodialysis Risks with Central Venous Catheters—Will the Home Dialysis Push Increase the Dangers?
5. Unproven Surgical Robotic Procedures May Put Patients at Risk
6. Alarm, Alert, and Notification Overload
7. Cybersecurity Risks in the Connected Home Healthcare Environment
8. Missing Implant Data Can Delay or Add Danger to MRI Scans
9. Medication Errors from Dose Timing Discrepancies in EHRs
10. Loose Nuts and Bolts Can Lead to Catastrophic Device Failures and Severe Injury

For information about becoming a member of one of our programs, contact clientservices@ecri.org or call +1 (610) 825-6000, ext. 5891.
The Purpose of the List

The safe use of health technology—from simple devices to complex information systems—requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI Institute’s Health Devices Group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that we believe warrant the greatest attention for the coming year. The list does not enumerate the most frequently reported problems or the ones associated with the most severe consequences—although we do consider such information in our analysis. Rather, the list reflects our judgment about which risks should receive priority now.

All the items on our list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. With the additional content provided in the full report, the list serves as a tool that healthcare facilities can use to efficiently and effectively manage the risks.

How Topics Are Selected

This list focuses on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. It does not discuss risks or problems that pertain to specific models or suppliers.

ECRI Institute engineers, scientists, clinicians, and other patient safety analysts nominate topics for consideration based on their own expertise and insight gained through:

— Investigating incidents
— Testing medical devices in the ECRI lab
— Observing operations and assessing hospital practices
— Reviewing the literature
— Speaking with clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators, and device suppliers

Staff also consider the thousands of health-technology-related problem reports that we receive through our Problem Reporting Network and through data that participating facilities share with our patient safety organization, ECRI Institute PSO.
After the topic nomination phase, professionals from ECRI Institute’s many program areas, as well as external advisors, review these topics and select their top 10. We use this feedback to produce the final list, weighing factors such as the following:

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

All the topics we select for the list must, to some degree, be preventable. But any one of the other criteria can, on its own, warrant including a topic on the list. We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities.

Not all hazards on the list will apply at all healthcare facilities. Also note that the exclusion of a topic that was included on a previous year’s list should not be interpreted to mean that the topic no longer deserves attention. Most of these hazards persist, and hospitals should continue working toward minimizing them. Rather, our experts determined that the topics listed here should receive greater attention in 2020.

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**FOR MEMBERS ONLY: LOG IN TO ACCESS THE FULL REPORT AND SOLUTIONS KIT**

This Executive Brief helps raise awareness of critical health technology hazards—a key step in patient safety efforts. The next steps involve taking action to prevent the problems from occurring. The 2020 Top 10 Health Technology Hazards Solutions Kit—available online to members of ECRI Institute programs—will help with that effort.

The Solutions Kit provides a comprehensive discussion of each topic, actionable recommendations for minimizing the risks of harm, and lists of useful resources for more information about each topic. Log in to your membership web page to access this valuable content.
Misuse of Surgical Staplers

Surgical staplers are complex devices requiring meticulous technique to operate. Some models are used just to staple (seal) tissue, while others are designed to both staple and cut. Consequences of a staple line failing or staples being misapplied can be fatal. Patients have experienced intraoperative hemorrhaging, tissue damage, unexpected postoperative bleeding, failed anastomoses, and other forms of harm.

Although the overall adverse event rate is actually quite low relative to how frequently staplers are used, problems associated with the use and function of surgical staplers are regularly reported. In fact, a recent FDA analysis covered over 100,000 incident reports since 2011, including 412 deaths, 11,181 serious injuries, and 98,404 malfunctions. Most of these reports had not previously been accessible to the public.

In ECRI Institute’s experience, adverse consequences can most often be traced to how the surgical stapler was used. That is, the device itself typically is found to have functioned as intended. Errors in use include selecting an incorrect staple size, clamping on tissue that is too thick or too thin, and clamping on, or firing over, another instrument or clip.

Avoiding such errors, as we detail in our recommendations, requires effective training and familiarity. Specifically, we recommend hands-on practice with the specific model of stapler to be used.

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Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards

A lack of oversight regarding the use of point-of-care ultrasound (POCUS)—including when to use it and how to use it—may place patients at risk and facilities in jeopardy.

POCUS refers to the use of medical ultrasound by the treating clinician at the bedside. It is a powerful tool for diagnosis and for guiding interventional procedures in many clinical environments. POCUS scanners are typically highly portable, comparatively inexpensive, and easy to use—features that have fueled the technology’s rapid and broad adoption throughout medicine.

At many healthcare facilities, however, safeguards for ensuring that POCUS users have the requisite training, experience, and skill have not kept pace with the speed of adoption. The lack of sufficient oversight increases the potential that patients will be adversely affected by problems associated with use, or lack of use, of the technology.

Patient safety concerns include POCUS not being used when warranted, misdiagnoses, inappropriate use of the modality, and overreliance on POCUS when a more comprehensive exam by an imaging specialist is indicated.

Policies and procedures should address institution-wide concerns, including user training and credentialing, exam documentation, and data archiving. And they should address specialty-specific issues, such as developing exam protocols that conform to established guidelines and recommendations.

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Infection Risks from Sterile Processing Errors in Medical and Dental Offices

Insufficient attention to sterilization processes in medical offices, dental offices, and some other ambulatory care settings can expose patients to contaminated instruments, implants, or other critical items. As we’ve highlighted in previous editions of our Top 10 Hazards list, failure to consistently and effectively clean and disinfect or sterilize contaminated items before use can expose patients to virulent pathogens.

This concern exists in all healthcare settings where patients may come in contact with contaminated items, particularly those intended to enter sterile tissue or the vascular system. However, not all healthcare settings have similar resources for core infection prevention and control (IPC) practices. Settings that may lack the sterilization program resources commonly found in acute care facilities, for example, include medical offices (e.g., OB/GYN, dermatology), dental offices, and similar locations that are not serviced by a central sterile processing department.

During IPC consultations in these settings, ECRI Institute has observed numerous oversights and improper actions associated with sterilization processes. While the prevalence of such failures is unknown, the potential exists for this to be an insidious, widespread patient safety risk.

Key safety measures include designating a qualified staff member or contractor to support office IPC practices and providing appropriate training for, and conducting periodic competency testing of, benchtop sterilizer operators.

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For patients who receive hemodialysis through a CVC, the risks of home dialysis may outweigh the benefits.

Hemodialysis Risks with Central Venous Catheters—Will the Home Dialysis Push Increase the Dangers?

Here we examine the potential intersection of two ongoing developments in the treatment of end-stage kidney disease in the United States: Many hemodialysis patients receive treatment through a central venous catheter (CVC) well beyond the period when transition to another form of vascular access is recommended. And the U.S. federal government recently announced a push to increase the use of home treatment for kidney disease patients.

For appropriate patients, home hemodialysis can provide many long-term benefits. For patients who receive hemodialysis through a CVC, however, the risks of home dialysis may outweigh the benefits.

CVCs are typically placed through the jugular vein (or other large central vein), providing a pathway directly from the outside of the body to the patient’s heart. As a result, the consequences of infection, clotting, disconnection (with a potential for massive blood loss), and air embolism can be severe.

In a healthcare setting, clinical staff are available to properly care for the catheter and address any concerns. In a home care setting, though, family members or other caregivers may be ill-equipped to manage the risks or to respond when a CVC problem occurs. The possibility that an increasing number of patients with CVCs might receive hemodialysis in the home raises concerns.
Unproven Surgical Robotic Procedures May Put Patients at Risk

Surgical robotic systems are used to assist surgeons in performing a wide—and continually expanding—range of minimally invasive procedures. While the use of surgical robots in innovative ways or for new procedures can help advance clinical practice, such uses can also lead to injury or unexpected complications and the potential for poorer long-term outcomes.

With their mechanical wrists, surgical robots can offer the surgeon benefits such as improved dexterity, motion scaling, and tremor reduction. However, these systems also have limitations—they may not provide tactile feedback on forces exerted on tissue, for example—and adverse events do occur. In some cases, complications from a robotic procedure may not appear for years. (In a 2019 Safety Communication, FDA noted the potential for late-developing complications associated with surgical robot use for certain cancer-related surgeries.)

Healthcare facilities need robust processes for approving the application of surgical robots in new procedures, as well as comprehensive programs for training, credentialing, and privileging surgeons and OR staff for those procedures. For their part, prospective patients should recognize that robotic procedures are not inherently better or worse than traditional minimally invasive procedures. The various surgical options available are likely to have trade-offs in terms of risks and benefits.

Facilities need robust processes for approving the application of surgical robots in new procedures, as well as comprehensive programs for training, credentialing, and privileging surgeons and OR staff.
Alarm, Alert, and Notification Overload

More than ever before, clinicians have to divide their attention between direct patient care tasks and responding to prompts from medical devices and health IT systems. As the number of devices that generate alarms, alerts, and other notifications increases, so too does the risk that the clinician will become overwhelmed, creating the potential for a clinically significant event to go unaddressed.

The problem of alarm overload is well known. Just as important to consider, however, is the global notification burden—that is, the combination of alarms, alerts, and notifications from all sources, not just from a single medical device.

Patient care devices sound alarms and flash visual indicators. Phones buzz with calls or text notifications. EHR portals display pop-up clinical decision-support alerts. And nurse call systems beep and light up to indicate that a patient needs attention.

A global approach that considers all these sources is needed to prevent the kind of cognitive overload that can distract or desensitize clinicians or prompt them to use improper notification settings, all of which can lead to missed notifications and patient harm. In addition to implementing measures to reduce the overall notification burden, healthcare facilities should support activities that help clinical staff develop the critical thinking skills needed to mitigate cognitive overload.
Remote patient monitoring technologies are increasingly being used for at-home monitoring to help clinicians identify deteriorating patients before they require hospitalization. As network-connected medical technologies such as these move into the home, cybersecurity policies and practices that address the unique challenges involved must be instituted as well.

As with any networked medical device, connected devices used in the home must be protected against threats that could interrupt the flow of data, alter or degrade the device’s performance, or expose protected health information. A cybersecurity issue that interrupts the transfer of data to the healthcare provider, for example, could lead to misdiagnosis or a delay in care.

Challenges include: the deployment may rely on the patient’s home network, which the provider doesn’t control; physical access to the device is limited, which can complicate troubleshooting and installing updates; and patient compliance can be difficult to sustain, particularly if the patient lacks proficiency using the device or has unwarranted fears about cybersecurity risks.

Recommendations include assessing system security during device procurement and addressing security considerations during installation, both at the patient’s home and on the provider’s network. The goal is not just to get the monitoring system to function, but to get it functioning securely.
Missing Implant Data Can Delay or Add Danger to MRI Scans

Patients presenting for magnetic resonance imaging (MRI) studies must be screened for implanted devices to avoid harm. Some implants can heat, move, or malfunction when exposed to an MRI system’s magnetic field. Thus, MRI staff must identify and follow any contraindications or conditions for safe scanning prescribed by the implant manufacturer.

Unfortunately, information about patient implants is often scattered throughout various information systems or records of patient encounters, if it is captured at all. Without a single place within the electronic health record (EHR) to store implant information, care providers have no reliable means for determining the type and location of any implants. Even screening interviews can be unreliable, as patients may not remember details about implants or may not be in a condition to respond.

Direct harm to the patient is possible if a scan is, inappropriately, conducted in the presence of an unidentified implant. Also, the patient’s treatment can be adversely affected if a scan needs to be postponed while care providers search for implant information.

Healthcare facilities should work with their EHR provider to create an implant list stored within the patient record. Similar to an allergy list, an implant list collects all relevant information in one easy-to-access location.

Direct harm to the patient is possible if a scan is, inappropriately, conducted in the presence of an unidentified implant.
Medication Errors from Dose Timing Discrepancies in EHRs

Missed or delayed medication doses can result from discrepancies between the dose administration time intended by the prescriber and the time specified within the automatically generated worklist viewed by the nurse. Depending on the patient’s condition and the medication prescribed, these errors can have significant clinical consequences.

A combination of configuration and usability issues within the electronic health record (EHR) can contribute to such discrepancies. Consider the following scenario:

Late in the morning, a physician enters an order for a once-daily medication and assumes that the patient will be given the first dose that morning. At that facility, however, the default administration time programmed into the EHR for once-daily medications is 8:00 a.m. Because the order was placed later in the morning, the medication for that patient would not appear on the nurse’s worklist until the following morning, unless the prescriber was aware of the default administration time and had specifically changed the time within the order.

Dose timing errors can be made less likely if an EHR order-entry system prominently displays the scheduled medication administration time, allows prescribers to easily modify that time, and includes a “now” option for medications that need to be administered as soon as possible.

Depending on the patient’s condition and the medication prescribed, dose timing errors can have significant clinical consequences.
Loose Nuts and Bolts Can Lead to Catastrophic Device Failures and Severe Injury

The nuts, bolts, and screws that hold together medical device components can loosen over time with routine use. Failure to repair or replace loose or missing mechanical fasteners can lead to severe consequences: Devices can tip, fall, collapse, or shift during use—and any of which could lead to patient, staff, or bystander injury or death. Additionally, workflow can be impeded, compromising patient care, and devices can sustain significant damage.

Over the past two years, we have published nearly two dozen reports involving a wide variety of medical devices with loose fasteners. Affected equipment ranged from baby scale carts (putting newborns at risk) to massive angiography systems (which could cause devastating harm to anybody under a falling component).

This report illustrates how the failure of even simple components can have devastating consequences. As such, it serves as a reminder that device inspections are an important patient safety function. Clinical engineers should check the condition of all mechanical fasteners during such inspections, even if doing so is not explicitly stated in the instructions. Clinical staff, for their part, should alert appropriate personnel to any loose or missing fasteners, irregular device movement, or unusual noises coming from a device.

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ECRI Institute Resources for Addressing the Hazards

Members of certain ECRI Institute programs can access resources such as the following to learn more about the topics included on this year’s list:

1. Misuse of Surgical Staplers
   4 ways to prevent harm from surgical staplers. ECRI Blog 2019 Jul 15.
   Surgical stapler hazards (hazard #8). In: Top 10 technology hazards: high-priority risks and what to do about them. Health Devices 2009 Nov.
   Surgical staplers: recommendations to reduce the risk of commonly reported problems. Health Devices Alerts 2016 Mar 17 (Accession No. H0312).
   Using the wrong size surgical stapler cartridge can injure patients [hazard report]. Health Devices 2009 Apr.

2. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards

3. Infection Risks from Sterile Processing Errors in Medical and Dental Offices
   Health Devices resources:
   — Infection Reduction Technologies: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with infection reduction technologies.
   — For lists of previous Top 10 Health Technology Hazard topics that address sterilization failures, see:
     · Infection Risks—Topics include mattress contamination and infection risks with heater-cooler devices.
     · Reprocessing/Sterilization Failures—Topics address failures associated with cleaning, disinfecting/sterilizing, and storing/transporting endoscopes and other reusable instruments.
   Risk Management resources:
   — Failure to sterilize and clean equipment potentially exposed thousands at New Jersey facility to HIV, hepatitis. Healthcare Risk Control 2019 Jan 2.
   Product comparisons and technology assessments:

4. Hemodialysis Risks with Central Venous Catheters—Will the Home Dialysis Push Increase the Dangers?
5. Unproven Surgical Robotic Procedures May Put Patients at Risk

Relevant guidance from Health Devices:


Selected reports from ECRI Institute’s Health Technology Assessment Information Service:

- Da Vinci Xi robotic bariatric surgery (Intuitive Surgical, Inc.) for treating obesity. 2018 Dec 18.
- Da Vinci Xi robotic surgery (Intuitive Surgical, Inc.) for treating nonmalignant colorectal conditions. 2018 Nov 30.
- Da Vinci Xi robotic surgery (Intuitive Surgical, Inc.) for treating nonmalignant gynecologic conditions. 2018 Dec 18.
- Ion endoluminal system (Intuitive Surgical, Inc.) for minimally invasive peripheral lung biopsy. 2019 Jun 1.
- Mako robotic arm-assisted surgery system (Stryker Corp.) for total hip arthroplasty. 2018 Nov 13.
- Mako robotic arm-assisted surgery system (Stryker Corp.) for total or partial knee arthroplasty. 2018 Nov 13.
- Mazor X robotic guidance system (Mazor Robotics, Ltd.) for performing robotic-assisted brain and spine surgery. 2019 Jan 25.

Other resources:


6. Alarm, Alert, and Notification Overload

Collections of ECRI Institute alarm management resources:

- Alarm Management: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with magnetic resonance imaging technologies. Specific articles of interest include:
- The Alarm Safety Handbook and Workbook. ECRI Institute; 2014. These publications offer strategies, tools, and guidance for improving the management of clinical alarm systems.
- Alarm Management Resources List. A starter list of resources describing recommendations from trusted organizations and the experiences of other healthcare institutions.

Additional guidance from Health Devices:

- Improving patient surveillance in telemetry; don’t just rely on the monitor. Health Devices 2015 Sep 18.

7. Cybersecurity Risks in the Connected Home Healthcare Environment

- Cybersecurity: The Essentials. This web page features a collection of Health Devices resources on cybersecurity topics.

8. Missing Implant Data Can Delay or Add Danger to MRI Scans

MRI: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with magnetic resonance imaging technologies. Specific articles of interest include:

9. Medication Errors from Dose Timing Discrepancies in EHRs


10. Loose Nuts and Bolts Can Lead to Catastrophic Device Failures and Severe Injury

The following reports related to this topic were issued through ECRI Institute’s *Health Devices Alerts* notification service:

- A29621 01: Philips—CombiDiagnost image-intensified fluoroscopic x-ray systems: loose screws may cause collimator to fall and PE cable may cause electrical shock under certain circumstances. *Health Devices Alerts* 2018 Jan 16.
- A29828 01: Philips—Allura Xper systems: 7th or 8th extra monitors mounted on monitor ceiling suspension may fall. *Health Devices Alerts* 2018 Feb 15.
- A29848: Philips—Brilliance iCT, Brilliance iCT SP, and IQon Spectral CT computed tomography systems: screws securing reaction ring scanner’s main bearing may come loose. *Health Devices Alerts* 2018 Jan 25.
- A31543: Siemens—Biograph mCT and Biograph Horizon CT/PET scanners: system power connection screws may be loose, potentially causing the plug to overheat. *Health Devices Alerts* 2018 Nov 2.

Additional member resources:

- Health Technology Management: The Essentials. This web page features a collection of *Health Devices* resources on health technology management topics, including general departmental budgeting and planning, selection and purchasing, safe use, equipment maintenance and replacement, and overall policies and procedures.
- Caster failures. Hazard #4—top 10 health technology hazards: are you protecting your patients from these high-priority risks? *Health Devices* 2007 Nov 1.
About ECRI Institute

ECRI Institute is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. ECRI’s unbiased assurance in evidence-based research, medical device testing, and knowledge of patient safety are uniquely respected by healthcare leaders and agencies worldwide. Visit ecri.org and follow @ECRI_Institute to learn more.