EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2018

A Report from Health Devices
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Executive Brief

ECRI Institute is providing this abridged version of its 2018 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 certain ECRI Institute programs through their membership web pages.

The List for 2018

1. Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients
2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk
3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants
4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems
5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury
6. Unholstered Electrosurgical Active Electrodes Can Lead to Patient Burns
7. Inadequate Use of Digital Imaging Tools May Lead to Unnecessary Radiation Exposure
8. Workarounds Can Negate the Safety Advantages of Bar-Coded Medication Administration Systems
9. Flaws in Medical Device Networking Can Lead to Delayed or Inappropriate Care
10. Slow Adoption of Safer Enteral Feeding Connectors Leaves Patients at Risk

The Purpose of the List

The safe use of health technology—from beds and stretchers to large, complex imaging 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
- 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 members of some of our external advisory committees, 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 2018.
Ransomware and other types of malicious software programs (malware) can disrupt healthcare delivery operations, hindering the delivery of care and putting patients at risk.

These programs infiltrate a network, propagate through connected devices and systems, and encrypt data, disabling user access, software, and IT assets. Multiple variants of ransomware and other malware have infected healthcare facilities and other organizations throughout the world.

In a healthcare environment, a malware attack can significantly impact care delivery by rendering health IT systems unusable, by preventing access to patient data and records, and by affecting the functionality of networked medical devices. Further, such attacks can disable third-party services, disrupt the supply chain for drugs and supplies, and affect building and infrastructure systems.

Such disruptions can lead to canceled procedures and altered workflows (e.g., reverting to paper records). They can also damage equipment and systems, expose sensitive data, and force closures of entire care units. Ultimately, they can compromise or delay patient care, leading to patient harm.

Safeguarding against malware attacks requires a proactive approach involving senior management, clinical engineering, IT, and other individuals throughout the organization.
Failure to consistently and effectively reprocess flexible endoscopes—that is, failure to clean and disinfect or sterilize the instruments between uses—can lead to the spread of deadly infections. Studies highlighting the challenges of this process, along with continuing reports of patient exposures to contaminated instruments, underscore why this topic remains a critical concern. (We have included some version of this topic in eight of the 10 previous editions of our list.)

Areas that require particular attention include:

- The cleaning step, which is largely manual and technique-dependent. If biologic debris and other foreign material is not cleaned from the endoscope first, residual soil can harden, making subsequent disinfection ineffective.
- Instrument storage after reprocessing. Moisture trapped in the channels of an endoscope can promote the proliferation of any microbes not eradicated by reprocessing.

To achieve more reliable and effective endoscope reprocessing, ECRI Institute recommends that healthcare facilities: (1) establish processes for assessing the quality of the cleaning step—for example, through magnification-aided visual inspections and the use of biochemical testing—and (2) implement measures to dry endoscope channels after reprocessing. Additional, detailed recommendations are presented in our complete report.
Bed and stretcher mattresses can remain contaminated after cleaning, putting patients and staff at risk of exposure to body fluids or microbiological contaminants. Reported incidents include patients lying on an apparently clean bed or stretcher when blood from a previous patient oozed out of the support surface onto the patient.

A bed or stretcher’s support surface consists of a mattress along with a mattress cover that prevents the ingress of body fluids and other contaminants into the mattress. The mattress cover is cleaned and disinfected between patients, but the mattress is not. Hence, if the integrity of a mattress cover is compromised, the mattress underneath can become contaminated and remain so for subsequent patients.

To safeguard against this hazard, companies that sell or rent mattress covers must recommend cleaning and disinfecting materials and procedures that will successfully remove the likely contaminants without compromising the cover’s integrity (i.e., creating weak spots that could allow leaks). Unfortunately, this is not always the case.

For their part, healthcare facilities should use appropriate materials and procedures for cleaning and disinfecting mattress covers and should regularly inspect mattresses and mattress covers for signs of damage or contamination.
Secondary alarm notification systems are software solutions that send alarms and other relevant alerts from a medical device or IT system to a clinician’s smartphone or other communication device. The systems are intended to facilitate timely notification of the appropriate clinician, but configuration or management problems with the systems themselves can lead to alarm delivery delays or failures.

Delayed or failed delivery of a critical alarm or alert can lead to missed alarm conditions, delayed care, and avoidable patient harm.

Incidents that have been reported include:

- Alarm delivery delays and failures when a system became overloaded. The cause: Alarms were needlessly being broadcast to all users within a care unit.
- Dropouts and alarm delivery failures after installation of an antivirus software update. The cause: The update was incompatible with the secondary alarm notification system.
- Phones freezing or shutting down when the user switched between software applications. The cause: Conflicts between the secondary alarm notification system and other smartphone applications (e.g., text messaging, voice communications).

Avoiding such problems requires care during system configuration, verification and validation during implementation, and assessments of system integrity periodically during use.
Exposing medical devices and other equipment to incompatible cleaning agents or unapproved cleaning methods can result in:

- Premature deterioration of a device’s nonmetallic parts, which can lead to the often imperceptible weakening and ultimate breakage of the parts, as well as other associated damage or malfunctions
- Failure of device electronics or power supplies, resulting from component damage or fluid intrusion
- Adverse effects from residual surface debris or cleaning residue

All of these occurrences can lead to device performance and safety issues, such as equipment failure, power supply interruptions, excessive and often incorrect alarms, or unexpected motion or device operation.

In addition to having significant financial implications, device malfunctions and premature equipment failures can lead to patient or staff injury or compromised patient care.

The need to stock and use multiple cleaning products, along with the requirement to familiarize staff with device-specific cleaning methods, is a significant burden for hospitals. Nevertheless, the risk of harm to patients and staff, and the often substantial costs to replace damaged devices, outweighs the challenge of implementing safe and correct cleaning.
Electrosurgical unit (ESU) active-electrode pencils that are not safely holstered between activations can lead to burns or fires if the ESU is inadvertently activated.

Instances of injury or damage have occurred when OR staff placed the active-electrode pencil on, or near, the patient between activations, rather than placing it in a nonconductive safety holster. With the electrode tip exposed in this manner, a burn or fire could occur if the ESU is inadvertently activated—for example, if a staff member leans on the pencil or steps on the ESU footswitch.

For decades, ECRI Institute has received reports of, investigated, and published guidance on burns, arcing, and fires due to inadvertent activation of ESU pencils that were not placed in a nonconductive safety holster. Unfortunately, incidents continue to occur.

Proper and consistent use of the safety holsters that are typically supplied with active-electrode pencils can prevent such incidents. And as ECRI Institute’s PriceGuide data shows, the added costs associated with holster use are minimal.
Digital imaging tools that can help reduce and control radiation dose are often not used to their full advantage.

Imaging technologies that use ionizing radiation—computed tomography (CT), angiography, nuclear medicine, and others—play a vital role in modern medicine, but have inherent risks that must be managed. Exposure to high doses of ionizing radiation, whether from individual exposures or from the cumulative effect of multiple exposures, can increase a patient’s long-term risk of developing cancer. And excessively high doses during an individual procedure can cause radiation burns.

Digital imaging inherently provides the means and tools for users to reduce or control the amount of radiation by enabling image manipulation during procedures and allowing tracking of radiation dose.

However, such measures cannot protect patients and staff from unnecessary radiation exposures—and thereby help reduce the long-term risks—if users are not proficient with the tools at their disposal and do not use those tools when circumstances warrant.

Imaging departments and facilities need to investigate dose-control strategies and provide users with the training and support they need to gain confidence using newer tools and techniques.
**Bar-coded medication administration (BCMA) systems** help clinicians verify at the point of care that the medications to be administered match provider orders. Used correctly, these systems can prevent dangerous medication errors. Used incorrectly, BCMA’s safety advantages can be completely negated.

Improper practices include administering medications before using the bar-code scanner, scanning patient bar codes from a list of stickers on a clipboard instead of from the patient wristband, and preparing medications for more than one patient at a time.

Circumstances that may prompt staff to resort to such workarounds or other unsafe practices include:

- The system being configured in such a way that it does not support safe clinician workflow
- Staff not understanding how a BCMA system can improve patient safety
- Devices and systems being difficult to use, functioning unreliably, or not being well maintained

Maximizing the safety benefits of BCMA requires minimizing the circumstances that can lead to improper use. To do this, give careful thought to system implementation, verify that staff understand the importance of performing the multistep workflow correctly, and maintain the system so that all the component devices and systems function properly.
Inattention to best practices for implementing networked medical devices and information systems can lead to incorrect or incomplete data transfers and other data communication errors. Such errors can delay diagnosis or treatment or prompt a misdiagnosis, affecting patient safety.

Examples include:

- Lab results being delivered from a laboratory information system (LIS) to the electronic health record (EHR) with reference ranges but no lab values, leading to a delay in patient diagnosis and treatment
- Only partial information being forwarded from a ventilator to the physiologic patient monitor to which it was networked, leading to a delay in patient care and the potential to cause significant patient harm
- Data from a fetal monitor not being correctly displayed on the workstation at the nurse’s station, creating the potential for delayed response to a critical change in the patient’s condition

With more and more medical devices and information systems being connected through hardwired or wireless networks, it has become increasingly important for healthcare facilities to assess, approve, and implement changes to these networked medical devices and information systems in a controlled manner.
Enteral feeding tubing can be inadvertently connected to patient lines intended for other purposes, sometimes with fatal consequences.

In one deadly incident, enteral nutrition was delivered into a patient’s lungs when feeding tubing was misconnected to a ventilator suction catheter. In another, nutrition was delivered through an IV line directly into the bloodstream of a pregnant woman; neither the woman nor the fetus survived.

Severe incidents such as these are rare. However, enteral tubing misconnections with the potential to cause severe harm do occur (and are likely underreported).

A newly available, standards-based connector design for enteral feeding systems—known by its trademarked name, ENFit—can help prevent such misconnections. These new enteral connectors fit only with each other, not with other connector types.

To date, healthcare facilities have been slow to adopt enteral devices with ENFit connectors, primarily due to concerns over the availability of components bearing the new connectors. However, this situation has improved, and a successful transition is now possible. ECRI Institute and other organizations recommend that healthcare providers throughout the world transition to enteral devices with ENFit connectors as soon as practicable.
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. Ransomware and Other Cybersecurity Threats
   Cybersecurity: The Essentials—This web page features a collection of Health Devices resources on the topic.
   Fostering CE/IT/InfoSec collaboration for better medical device implementation. Health Devices 2017 Sep 20.
   Getting the most out of the MDS2 form. Health Devices 2017 Aug 23.
   Networked medical devices—get the answers you need for safe, secure acquisition and use. Health Devices 2016 Sep 14.
   Ransomware attacks: how to protect your medical device systems. Health Devices 2017 Jun 29.

2. Endoscope Reprocessing
   ECRI Institute has included the potential for cross-contamination from reusable medical devices and instruments in several previous editions of our Top 10 Hazards list:
   — The online cumulative subject index for the Top 10 Health Technology Hazards provides a complete listing.

3. Mattress and Mattress Cover Contamination
   Damaged or worn bed and stretcher mattress covers may allow fluid ingress. Health Devices 2014 Sep 11 (Accession No. H0237).
   Disinfectant concentrations for EPA’s list of products effective against Clostridium difficile. Health Devices 2017 May 10.
   Reducing the risks of fluid ingress and microbiological contamination in bed and stretcher support surfaces. Health Devices 2017 May 10.

4. Secondary Alarm Notification Systems
   Alarm Management: The Essentials—This page contains our complete collection of Health Devices guidance, tools, and other resources for improving clinical alarm safety.
   Alarm middleware vendor roundtable: cutting through the confusion [Health Devices web conference]. 2015 Apr 29.
   Inappropriately configured ancillary alarm notification systems may result in missing critical alarms. Health Devices Alerts 2014 Nov 20 (Accession No. H0242).

5. Improper Cleaning and Device Failures
   Guidance from Health Devices:
   — How improper cleaning can damage medical equipment. Health Devices 2017 Aug 16.
   Also: Cleaning/Disinfectant Wipe Compatibility (customizable chart, Microsoft Word).

   Incident reports published in Health Devices Alerts (January 2016 through September 2017):
   — Baxter—SIGMA Spectrum infusion pumps: improper battery contact may cause infusion to cease, potentially resulting in patient harm [ECRI Exclusive Hazard Report], Health Devices Alerts 2017 Sep 27 (Accession No. H0399).
— BD CareFusion—Model 8100 Alaris LVP modules: lower door hinge may crack [ECRI Exclusive User Experience Network] [Update]. Health Devices Alerts 2016 Dec 1 (Accession No. S0251 02).


— CareFusion—Model 8100 Alaris infusion system pump modules: cracked or broken upper platen hinge may result in drug overdelivery [ECRI Exclusive Hazard Report]. Health Devices Alerts 2016 May 13 (Accession No. H0319).

— Cook—various products: reprocessing instructions may be inadequate. Health Devices Alerts 2017 Jun 6 (Accession No. A28514 01).


— Haemonetics—various cell processor and collection system devices: improper cleaning may damage pump rollers, potentially leading to device malfunction [Update]. Health Devices Alerts 2016 Feb 23 (Accession No. A25476 01).


— Stryker—SmartLife large aseptic housings: failure to use recommended cleaning practices may cause deterioration; sections may separate. Health Devices Alerts 2017 Jun 8 (Accession No. A28506 01).

— Zimmer Biomet—Gender Solutions patello-femoral joint prosthesis milling handpieces: may be inoperable if preventive maintenance is not performed in accordance with IFU. Health Devices Alerts 2016 Dec 5 (Accession No. A27352).

### 6. Unholstered ESU Active Electrodes

Burns and fires from electrosurgical active electrodes [hazard update]. Health Devices 1993 Aug-Sep;22(8-9):421-2. (Free-access version; can be shared with nonmembers.)

Burns during electrosurgery. In: Top 10 health technology hazards: are you protecting your patients from these high-priority risks? Health Devices 2007 Nov 1.

Clamping electrosurgical unit electrode cables may result in burn risk and/or fire [ECRI Exclusive Hazard Report]. Health Devices Alerts 2016 Jun 24 (Accession No. H0329).

Electrosurgery checklist—Available through ECRI Institute’s Medical Device Safety Reports website.
Essentials pages—Web pages featuring collections of Health Devices resources on the following topics:

- Electrosurgery: The Essentials
- Surgical Fire Prevention: The Essentials


CT Dose Control: The Essentials—This web page features a collection of Health Devices resources on dose control issues, with a focus on CT.

8. Bar-Coded Medication Administration System Workarounds


9. Medical Device Networking Errors


Fostering CE/IT/InfoSec collaboration for better medical device implementation. Health Devices 2017 Sep 20.

GE CARESCAPE B850 monitor may fail to convey some ventilator alarms when equipped with GE compact airway module. Health Devices Alerts 2012 Apr 12 (Accession No. H0168).


Networked medical devices—get the answers you need for safe, secure acquisition and use. Health Devices 2016 Sep 14.

10. Enteral Feeding Misconnections

Implementing the ENFit initiative for preventing enteral tubing misconnections. Health Devices 2017 Mar 29.

The faster you respond to product safety alerts and hazards, the safer your patients

Our *Top 10 Health Technology Hazards for 2018* list is just a snapshot of how we can help you keep patients safe. ECRI Institute has trusted resources to help with your medical technology management challenges—including smart alternatives for recalled devices, and much more.

- **Alerts Tracker®** helps you streamline your recall management process by automatically distributing alerts to the appropriate staff within your organization.

- **Health Devices System** delivers exclusive product evaluations based on first-hand laboratory testing to help you make informed procurement decisions suited to your specific needs or budget.

- **ECRI Institute’s Accident Investigation Team** is on call to help you when an accident or serious adverse event occurs in your facility.

Turn to ECRI Institute for objective, evidence-based guidance for your most critical medical technology management needs. Explore our memberships and services at [www.ecri.org/technology](http://www.ecri.org/technology).

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**We’re here to help.**

Contact us today at (610) 825-6000, ext. 5891, or clientservices@ecri.org.
Objectives of the Health Devices System

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.