EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2024

Expert Insights from ECRI's Device Evaluation Program www.ecri.org



The Most Trusted Voice in Healthcare

Top 10 Health Technology Hazards for 2024



Executive Brief

ECRI is providing this Executive Brief describing its 2024 Top 10 list of health technology hazards to inform the healthcare community about key safety issues involving the use of medical devices and systems.

The List for 2024

- 1. Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm
- 2. Inadequate or Onerous Device Cleaning Instructions Endanger Patients
- 3. Sterile Drug Compounding without the Use of Technological Safeguards Increases the Risk of Medication Errors
- 4. Overlooked Environmental Impacts of Patient Care Endanger Public Health
- 5. Insufficient Governance of AI Used in Medical Technologies Risks Inappropriate Care Decisions
- 6. Ransomware Targeting the Healthcare Sector Remains a Critical Threat
- 7. Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes
- 8. Infusion Pump Damage Remains a Medication Safety Concern
- 9. Poor QC of Implantable Orthopedic Products Can Lead to Surgical Delays and Patient Harm
- 10. Third-Party Web Analytics Software Can Compromise Patient Confidentiality

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Detailed descriptions of the hazards outlined in this Executive Brief, along with ECRI's stepby-step recommendations for addressing them, are provided in the <u>2024 Top 10 Health</u> <u>Technology Hazards Solutions Kit</u>. Members of ECRI programs can access the Solutions Kit through their membership web pages. For more information, contact <u>clientservices@ecri.org</u>; call +1 (610) 825-6000, ext. 5891; or visit <u>www.ecri.org</u>.

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The Purpose of the List

A Tool for Preventing Harm

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 risks and prevent harm. This 17th edition of ECRI's Top 10 Hazards list will help care providers do that.

Produced each year by ECRI's Device Evaluation group, the Top 10 Health Technology Hazards report identifies the potential sources of technology-related danger that we believe warrant the greatest attention for the coming year. The topics chosen are not necessarily 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 be given attention *now* to help care providers, as well as device manufacturers, prioritize their patient safety efforts.

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 (see the inset on page 2), the list serves as a tool to help technology managers and device users manage the risks efficiently and effectively.

THE IMPORTANCE OF PROBLEM REPORTING

The topics on our Top 10 Hazards list often derive from user-submitted reports of medicaldevice-related events and near misses. Effective reporting of such events by frontline healthcare workers and others who use or manage health technologies can help identify areas of risk, pinpoint causes, and prevent recurrence that could lead to patient harm.

ECRI encourages all care providers and device users to <u>send us reports</u> of medical-devicerelated events—adverse incidents and near misses—so we can share the findings with the rest of the healthcare community, whether through our <u>Alerts service</u> or through annual reports like this one.

A Challenge to Industry

Reducing preventable harm requires more than just vigilance on the part of technology managers and device users. The medical device industry also has a role to play. Several of the hazards outlined in this report could be mitigated—and possibly even eliminated—by improved device designs or manufacturing practices. We're challenging our industry colleagues to make those improvements. As a rule, an engineering solution that eliminates a hazard will always be preferable to a training solution that can only warn of a hazard.

ECRI has been in the business of making healthcare safer for more than 50 years, and our cooperative relationship with industry has been a key component of our success. ECRI—through its device evaluations, hazard reports, and other investigations—has identified shortcomings in thousands of individual models and systems, as well as many technology-wide hazards, that put patients and others at risk. Responsive manufacturers, then, have developed solutions to address those concerns and provide users with safer alternatives. In some cases, their work has yielded truly innovative technological advancements.

Together, we've driven significant improvements in medical technology, saving countless patients from preventable harm or even death. Continuing with that mission, we've highlighted in this report areas where we believe device manufacturers can advance the cause of patient safety through better product design.

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 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 and assessing hospital operations and 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 and the Institute for Safe Medication Practices PSO.

After the topic nomination phase, professionals from ECRI'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. Is the hazard likely to be experienced in many facilities or care environments? Or, if the hazard occurs, are the consequences likely to spread to affect a great number of people?

- Insidiousness. Is the problem difficult to recognize? Could the problem lead to a cascade of downstream errors before it is identified or corrected?
- Public 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 practical 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 within their own care environments.

Not all hazards on the list will apply to all healthcare facilities. Nor is every possible hazard included; the omission 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 those hazards persist, and healthcare organizations should continue working toward minimizing them. Rather, our experts determined that the topics listed here should receive greater attention in 2024.



Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm

The trend toward providing healthcare in the home has led to the increased use of medical devices in that setting. This includes devices that were originally intended for use in a clinical environment, such as infusion pumps and ventilators.

The use of medical devices in the home can support more comfortable and convenient patient care, but it is not without risk: Devices often are not designed with home users in mind, and patients and lay caregivers may lack the expertise needed to operate them properly. Plus, the home setting can introduce environmental limitations (e.g., space restrictions, unreliable power supply) that impact device operation. Severe harm can result if patients or their caregivers do not fully understand how to use a device and troubleshoot problems that arise.

Over the past decade, ECRI has encountered numerous examples of patient harm in this setting—from medication errors that resulted from a switch to an unfamiliar infusion pump to tragic fatalities that occurred when a ventilator alarm failed to activate, or when a venous needle became dislodged during hemodialysis. Minimizing the risk of harm requires selecting devices that are well matched to the patient and the environment of use, and providing the support that home users need to operate the device successfully.

Challenge to Industry. ECRI challenges manufacturers of devices that may be used in the home to consider the needs of users in this setting. Device operation should be intuitive, instructions should be written for a lay audience, and user support should be available.

Severe harm can result if patients or their caregivers do not fully understand how to use a device and troubleshoot problems that arise.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF



Inadequate or Onerous Device Cleaning Instructions Endanger Patients

Failure to properly clean and disinfect or sterilize reusable medical devices between uses can lead to the spread of infection, device damage, and other forms of harm. Successful reprocessing is made more challenging, however, by the wide variation in the content, quality, and feasibility of reprocessing instructions provided by product vendors.

ECRI is aware of numerous reusable medical devices and healthcare items that have incomplete, impractical, or onerous reprocessing instructions. As a result, healthcare workers who perform reprocessing may find it difficult or impossible to complete this task effectively—or they may suffer harm in the process (e.g., pain or fatigue from repeatedly performing onerous reprocessing procedures).

The best time for healthcare organizations to address this issue is *before* purchasing any reusable medical devices or healthcare items. That is, reprocessing considerations should be evaluated during the pre-purchase risk assessment of a product. Questions to consider include: (1) Will the vendor provide validated reprocessing instructions for the product? Validated reprocessing instructions have been shown to be effective and ensure the safe reuse of a product over its life. And (2) are the reprocessing steps practical to complete in your environment? If the answer to either question is "no," ECRI recommends considering alternative vendors and products.

Challenge to Industry. ECRI challenges manufacturers of reusable medical devices and healthcare items to provide practical, validated reprocessing instructions for their products. These instructions should adhere to relevant FDA guidance and should involve the use of common healthcare cleaning products.

Healthcare workers who perform reprocessing may find it difficult or impossible to complete this task effectively—or they may suffer harm in the process.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF



Sterile Drug Compounding without the Use of Technological Safeguards Increases the Risk of Medication Errors

Errors made during the compounding of injectable medications can have severe—sometimes deadly—consequences if they are not detected before the drug is administered to the patient. Unfortunately, such errors are exceedingly difficult for nurses or others who administer the preparations to detect. Consequently, errors that are not caught before the preparation leaves the pharmacy have a high likelihood of reaching the patient.

Drug compounding is required when a commercially available formulation does not come in a ready-to-administer form or does not otherwise meet patients' needs (e.g., dosing requirements). It involves combining, reconstituting, repackaging, or otherwise modifying a drug product to create a new preparation.

While accurate compounding is important for all preparations, injectable preparations are of particular concern because of their need to be sterile, the frequency with which compounding is required, the opportunities for error, and the potential for significant harm. Errors can include using incorrect or expired ingredients (e.g., medications, diluents), using an incorrect dose or concentration, using an incorrect volume, or mislabeling the medication. Both ECRI and the Institute for Safe Medication Practices (ISMP) recommend that pharmacy departments implement technological safeguards—like workflow management systems to minimize opportunities for human error in the sterile compounding process. These systems offer a range of capabilities (e.g., bar coding, gravimetric analysis) both to help prevent errors during the manual steps in the process and to help catch errors before they reach the patient.

> Drug compounding errors that are not caught before the preparation leaves the pharmacy have a high likelihood of reaching the patient.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF

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🖵 The 2024 List 🔰 e DeviceEvaluation@ecri.org 👘 🖬 🖸 🛛 7



Overlooked Environmental Impacts of Patient Care Endanger Public Health

Medical technologies play a lifesaving role in patient care, but the manufacture, use, and disposal of medical devices, systems, and supplies also have a cost. These activities consume energy, release contaminants, and generate waste, adversely impacting the environment. This in turn creates public health challenges causing or worsening numerous health problems—and it exacerbates health inequities, since many of the health risks associated with environmental stressors disproportionately impact disadvantaged communities.

As protectors of public health, healthcare organizations should be examining ways to minimize environmental harm. Consistent with the theme of top *health technology* hazards, for this article we focus on the selection, use, and disposal of medical technologies. Wise decisions in these areas can advance sustainability and improve a healthcare organization's bottom line.

The key for healthcare organizations is to identify areas where improvement is possible *without compromising patient care*. Sensible strategies include: reducing the amount of energy consumed by medical imaging equipment, choosing alternatives to anesthetic gases that have high global warming potential, and eliminating purchases of unnecessary single-use items (e.g., extraneous components in surgical kits) that contribute directly to waste volumes. Consider the three R's of sustainability: reduce, reuse, recycle.

Challenge to Industry. ECRI challenges medical device manufacturers to design products with sustainability in mind for example, by reducing the use of materials that contribute to environmental harm, by making reusable products easier to clean using minimally damaging processes, and by minimizing waste material (e.g., packaging) included with each product.

The key for healthcare organizations is to identify areas where improvement is possible without compromising patient care.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF



Insufficient Governance of AI Used in Medical Technologies Risks Inappropriate Care Decisions

Artificial intelligence (AI) functionality is being incorporated into a wide range of devices and systems in healthcare—from workflow aids (e.g., automated scheduling software) to diagnostic support systems that interpret medical images or analyze a patient's medical record. Some of these applications directly impact patient care and warrant careful scrutiny.

Al offers the promise of speeding up processes and assisting in clinical decisions. But AI systems are only as good as the algorithms they use and the data on which they are trained. Shortcomings in either area can lead to inappropriate responses. Instances have been reported of AI functionality contributing to harm, performing worse than advertised, or providing misleading results.

Complicating matters for care providers is that they have little visibility into the methodology that the application uses to reach decisions and the data on which the application was trained. This lack of transparency makes it difficult for healthcare professionals to judge system performance for their specific patient population. For these reasons, healthcare institutions need to establish a robust AI governance program that addresses all phases of technology adoption and use. When considering a system that incorporates AI functionality, this will involve assessing the risks and determining the potential impact on patient care. During procurement, it will involve testing whether the system will work as expected with your patient population and care practices. After implementation, it will involve monitoring performance, capturing problems associated with its use (e.g., decisions that providers find questionable), and maintaining the system over time.

AI systems are only as good as the algorithms they use and the data on which they are trained. Shortcomings in either area can lead to inappropriate responses.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF



Ransomware Targeting the Healthcare Sector Remains a Critical Threat

Healthcare providers continue to be targeted by hackers seeking to infiltrate IT networks in efforts to extract a ransom payment. Healthcare delivery organizations (HDOs) are attractive targets because of the value of their data, their critical need to restore operations quickly, and (often) their limited resources for hardening defenses.

During a ransomware attack, hackers may encrypt patient data, extract sensitive information, disable user access, or otherwise compromise system operation to gain leverage over the provider. These actions can disrupt the delivery of patient care—for example, by preventing clinician access to information needed for making care decisions, and possibly forcing the closure of medical offices and clinical units. Further, the cascading effects of an attack (e.g., cancellations, diversions) can overwhelm a community's healthcare resources.

HDOs can, and should, implement measures to manage cybersecurity risks. Specifically, they should deploy a framework for identifying risks, protecting against them, detecting and responding to ongoing threats, and recovering from an attack. These measures aren't foolproof, however. In this fight, HDOs are overmatched. They need help from policymakers and other stakeholders.

Challenge to Policymakers. HDOs need broad support to fend off and, when necessary, respond to ransomware attacks. Areas for policymakers to consider include incentives for implementing strong security programs, as well as HDOs' wherewithal to do so (in terms of funding and staffing); law enforcement tools for disrupting criminal networks; and the unintended consequences of existing penalty structures for being victimized by a ransomware attack.

In the fight against ransomware attacks, healthcare organizations are overmatched. They need help from policymakers and other stakeholders.



Top 10 Health Technology Hazards for 2024EXECUTIVE BRIEF

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두 The 2024 List 🔰 e DeviceEvaluation@ecri.org 🔰 🖬 🖬 🚺 🗍 10



Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes

Adult patients are placed at an unnecessary risk of burns during electrosurgery when single-foil conductive return electrodes are used instead of safer options. Alternatives include the use of dualfoil conductive return electrodes, capacitive return electrodes, or other treatment modalities. The issue is that single-foil conductive return electrodes do not engage a key electrosurgical unit (ESU) safety feature—the return electrode contact-quality monitor (RECQM).

RECQMs are designed to detect when contact between a return electrode and the patient is compromised. Return electrodes require a sufficiently large area of contact with the patient to safely disperse the electrosurgical current concentrated at the surgical site. When electrosurgery-related burns occur, insufficient contact of the return electrode with the patient is a common cause.

In 2023, ECRI received four reports of burns associated with the use of single-foil conductive return electrodes. In some of these cases, clinicians were not aware of the associated risks, nor that safer alternatives were available.

Such incidents could have been prevented if (1) commonly available dual-foil conductive return electrodes or capacitive return electrodes had been used or (2) an alternative treatment modality had been used (e.g., bipolar electrosurgery), if appropriate. (ECRI likewise recommends against the use of singlefoil return electrodes for neonatal and pediatric patients; however, fewer alternatives exist for these populations, which could make a transition impractical for some healthcare facilities.)

Challenge to Industry. ECRI challenges return electrode manufacturers to cease the manufacture and sale of single-foil conductive return electrodes, particularly for adult patients.

Adult patients are placed at an unnecessary risk of burns during electrosurgery when single-foil conductive return electrodes are used instead of safer options.



Top 10 Health Technology Hazards for 2024EXECUTIVE BRIEF



Infusion Pump Damage Remains a Medication Safety Concern

Damage to an infusion pump can affect its ability to accurately deliver fluids or medications, which may result in dangerous medication administration errors. Pump damage also can distract staff as they look for a replacement device and may ultimately delay therapy for the patient. Furthermore, if the damage goes unnoticed or uncorrected, multiple patients can be put at risk.

In one recent incident, a patient was harmed when a pump allowed an infusion to flow freely (under the force of gravity) to the patient. ECRI's investigation revealed that a key component of the pump—one that helps regulate the flow of medication had broken off, and that the absence of the component went unnoticed for several weeks.

Infusion pumps are routinely subjected to circumstances that can lead to damage, whether through mishandling, exposure to improper cleaning chemicals or methods, or normal wear and tear. Thus, staff need to be alert to the signs of damage. Unfortunately, infusion pump damage can be hard to identify. The recommendations in our full report can help care providers identify problems that might otherwise go unobserved, thereby reducing the likelihood of harm.

Challenge to Industry. ECRI challenges manufacturers to advance the technology by designing models that, for example, have fewer damage-prone components, can more reliably prevent gravity flow, and are made from materials that can withstand cleaning with a greater variety of chemicals. Further, we encourage manufacturers to simplify cleaning steps and develop means to help users adhere to validated cleaning and disinfection methods

If infusion pump damage goes unnoticed or uncorrected, multiple patients can be put at risk.



Top 10 Health Technology Hazards for 2024EXECUTIVE BRIEF

Poor QC of Implantable Orthopedic Products Can Lead to Surgical Delays and Patient Harm

In last year's Top 10 Health Technology Hazards report, ECRI expressed concern about the unacceptably high number of defective single-use medical devices present in the supply chain. That broad concern remains, but for the current year we've focused on one specific product group: implantable products intended for use during orthopedic procedures. The prevalence of quality control (QC) issues related to these products and the potential for significant harm warrant particular attention.

Implantable orthopedic products range from simple items—such as bone screws, rods, and plates—to complex ones, like knee and hip prostheses. Defects in these products can delay or prolong surgery and can lead to other harm, including persistent pain or infection, that may not become evident until long after the patient's surgery.

ECRI has received or investigated reports of:

 Incorrect labeling or packaging, which can lead to the selection of the wrong product, resulting in incorrect treatment and subsequent pain or injury

- Device-device incompatibility and missing components, which are most likely to cause delays in patient treatment or to prolong surgical procedures
- Breaks, cracks, and other defects, which can lead to implant failure, possibly requiring total revision surgery

Steps that healthcare organizations can take include instructing users to look for and report signs of defects before use, tracking defects that are reported, and holding manufacturers and distributors accountable, using the organization's leverage to push for improvements.

Challenge to Industry. ECRI challenges manufacturers of implantable orthopedic products—and all single-use medical devices—to strive for zero defects in their manufacturing and packaging processes.

Defects can lead to harm that may not become evident until long after the patient's surgery.

Top 10 Health

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF



Third-Party Web Analytics Software Can Compromise Patient Confidentiality

Third-party web analytics software can provide businesses with valuable statistics and insights about how customers use their websites. For healthcare organizations, though, these tools pose a hidden risk: Web analytics software installed on patient portals and other provider websites and applications can allow thirdparty companies (e.g., Meta, Google, Adobe) to collect information that could reveal details about the patient's medical condition.

This information—such as the patient's IP address, appointment scheduling details, or other data—might then be used for inappropriate purposes. For example, companies may use the data to track patients' online activity and target them with ads related to the medical conditions disclosed; these ads may promote unproven remedies and redirect patients from appropriate care. Additionally, the information might be used to discriminate against patients based on those conditions.

The US Department of Health and Human Services (HHS) is investigating HIPAA violations related to the use of these tools. However, not all parties agree that these practices present a risk. In November 2023, the American Hospital Association and several other organizations sued the federal government, challenging HHS's statutory authority over this issue.

Regardless, ECRI recommends that healthcare organizations remove third-party web analytics software from patient portals, as well as from "find a doctor" and medical library pages. In ECRI's view: Patients expect a provider's website to be a confidential safe haven for seeking medical information, treatment, and services. The collection and potential exploitation of private information could lead to patient distrust of the healthcare provider.

Information—such as the patient's IP address, appointment scheduling details, or other data—might be used for inappropriate purposes.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF

ECRI Resources for Addressing the Hazards

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

1. Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm

<u>Cybersecurity risks in the connected home healthcare environment. Hazard #7–2020</u> top 10 health technology hazards. Device Evaluation. September 26, 2019.

Gaps in recalls for at-home medical devices cause patient confusion and harm. Hazard #1—2023 top 10 health technology hazards. *Device Evaluation*. January 11, 2023.

The growing use of consumer-grade medical devices: advice for physicians and their patients. *Device Evaluation*. August 7, 2019.

<u>Home care ventilated patients face technological challenges</u> [ECRI Exclusive Hazard Report]. *ECRI Alerts*. September 21, 2023. Accession No. H0880.

Improperly set ventilator alarms put patients at risk for hypoxic brain injury or death. Hazard #4—2019 top 10 health technology hazards. *Device Evaluation*. September 26, 2018.

Incorrect key presses may cause Nutricia Flocare Infinity series enteral feeding. pumps to appear to be infusing even though an occlusion exists. *Device Evaluation*. 2011;40(5):170-171.

No-flow alarm disabled in Respironics EverFlo oxygen concentrators equipped with optional low-flow flowmeter. *Device Evaluation*. 2011;40(4):139-140.

<u>Unfamiliarity with differences in the way ventilators set pressure-control values may</u> <u>lead to lung injuries</u>. *Device Evaluation*. 2010;39(6):206-207.

2. Inadequate or Onerous Device Cleaning Instructions Endanger Patients

Biosense Webster—various cardiac cables: require uncommon steam sterilization parameters [ECRI Exclusive User Experience Network]. *ECRI Alerts*. June 8, 2021. Accession No. S0432.

"Clean" mattresses can ooze body fluids onto patients. Hazard #2—2019 top 10 health technology hazards. Device Evaluation. September 26, 2018.

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Confusion surrounding ventilator cleaning and disinfection requirements can lead to cross-contamination. Hazard #7—2023 top 10 health technology hazards. *Device Evaluation*. January 11, 2023.

Ease-of-reprocessing assessment tool. Device Evaluation. October 30, 2019.

<u>How improper cleaning can damage medical equipment</u>. *Device Evaluation*. August 16, 2017.

<u>Medical device pathways to market in the U.S. and the EU</u>. *Device Evaluation*. September 8, 2021.

<u>Olympus—Visera hysterovideoscopes: manufacturer updates IFU regarding</u> <u>reprocessing</u>. *ECRI Alerts*. September 6, 2023. Accession No. A41055.

Poor duodenoscope reprocessing ergonomics and workflows put healthcare workers and patients at risk. Hazard #8—2022 top 10 health technology hazards. *Device Evaluation*. January 12, 2022.

Smiths—DuraLife autoclavable extension sets and swivel connectors: instructions for cleaning and sterilization may be inadequate. *ECRI Alerts*. May 24, 2023. Accession No. A40665.

Teleflex—Pilling O'Reilly esophageal retractors and Pilling curved and straight. Lowsley prostatic tractors: IFU may contain incomplete pre-cleaning instructions. *ECRI Alerts*. June 9, 2023. Accession No. A40822.

3. Sterile Drug Compounding without the Use of Technological Safeguards Increases the Risk of Medication Errors

The following resources are publicly available from the Institute for Safe Medication Practices (ISMP), an ECRI affiliate:

Best practice 11. In: <u>2024-2025 ISMP targeted medication safety best practices for</u> <u>hospitals</u>. ISMP; 2024.

<u>Guidelines for sterile compounding and the safe use of sterile compounding</u> <u>technology</u>. May 4, 2022.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF

ISMP survey provides insights into pharmacy sterile compounding systems and practices. October 22, 2020.

ISMP survey provides insights into preparation and admixture practices OUTSIDE the pharmacy. November 4, 2020.

Maximize benefits of IV workflow management systems by addressing workarounds and errors. September 7, 2017.

Tragic error with neuromuscular blocker should prompt risk assessment by all hospitals. December 18, 2014.

4. Overlooked Environmental Impacts of Patient Care Endanger Public Health

Emergency preparedness: response and recovery. *Healthcare Risk Control*. December 19, 2018.

<u>Make your device donations count—use a medical surplus recovery organization</u>. *Device Evaluation*. March 9, 2022.

<u>Ready, set, go: emergency preparedness: response and recovery</u>. [Leadership Tool for a Learning Organization]. 2018.

Supply chain shortfalls pose risks to patient care. Hazard #2—2022 top 10 health technology hazards. Device Evaluation. January 12, 2022.

Sustainable medical imaging operations: recommendations for reducing energy consumption. Device Evaluation. May 24, 2023.

Taking action: strategies to achieve environmental sustainability. *Health System Risk Management*. April 11, 2023.

When to consider single-use endoscopes. Device Evaluation. Updated April 14, 2022.

5. Insufficient Governance of AI Used in Medical Technologies Risks Inappropriate Care Decisions

<u>Al-based reconstruction can distort images, threatening diagnostic outcomes. Hazard</u> <u>#7—2022 top 10 health technology hazards</u>. *Device Evaluation*. January 12, 2022. Artificial intelligence applications for diagnostic imaging may misrepresent certain patient populations. Hazard #8—2021 top 10 health technology hazards. *Device Evaluation*. January 28, 2021.

Artificial intelligence software for improving outpatient scheduling and patient chart. management. Clinical Evidence Assessment. May 2, 2023.

State of artificial intelligence: viewpoints from ECRI clinical and technical experts [webcast]. September 29, 2022.

6. Ransomware Targeting the Healthcare Sector Remains a Critical Threat

<u>Cybersecurity: The Essentials</u>. This web page features a collection of Device Evaluation resources on cybersecurity topics.

Related topics from previous editions of ECRI's Top 10 Health Technology Hazards report:

- 2018 (Hazard #1): <u>Ransomware and Other Cybersecurity Threats to Healthcare</u> <u>Delivery Can Endanger Patients</u>
- 2019 (Hazard #1): <u>Hackers Can Exploit Remote Access to Systems, Disrupting</u> <u>Healthcare Operations</u>
- 2021 (Hazard #7): <u>Vulnerabilities in Third-Party Software Components Present</u> <u>Cybersecurity Challenges</u>
- 2022 (Hazard #1): <u>Cybersecurity Attacks Can Disrupt Healthcare Delivery</u>, <u>Impacting Patient Safety</u>
- 2023 (Hazard #5): <u>Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions</u>

<u>Getting started with a cybersecurity incident response plan for your medical devices</u>. *Device Evaluation*. December 2, 2020.

Implementing the "Health Industry Cybersecurity Practices" (HICP) guidelines. *Device Evaluation*. Updated July 5, 2023.

Top 10 Health Technology Hazards for 2024 EXECUTIVE BRIEF

7. Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes

<u>Electrosurgery: The Essentials</u>. This web page features a collection of Device Evaluation resources on electrosurgical topics.

<u>Electrosurgical return electrodes: weighing the clinical and cost factors</u>. *Device Evaluation*. May 14, 2020.

Evaluation background: capacitive electrosurgical return electrodes. *Device Evaluation*. May 14, 2020.

Evaluation background: monopolar/bipolar electrosurgical units for general and specialty surgery. *Device Evaluation*. Updated April 27, 2022.

<u>Glossary of electrosurgical unit terms</u>. Device Evaluation. October 14, 2016.

8. Infusion Pump Damage Remains a Medication Safety Concern

Device Evaluation Resources

Be a T.R.A.C.E.R. not a RACER! [poster]. 2013.

Damaged infusion pumps can cause medication errors. Hazard #3—2022 top 10 health technology hazards. January 12, 2022.

Improper cleaning may cause device malfunctions, equipment failures, and potential for patient injury. Hazard #5—top 10 health technology hazards for 2018. November 1, 2017.

Inadequate or onerous device cleaning instructions endanger patients. Hazard #2—2024 top 10 health technology hazards. January 29, 2024.

Infusion errors can be deadly if simple safety steps are overlooked. Hazard #1—top 10 health technology hazards for 2017. November 4, 2016.

ECRI Alerts Resource

BD—Model 8100 Alaris pump modules: on very rare occasions, the platen door may be missing, potentially leading to undetected free-flow [ECRI Exclusive Hazard Report]. Updated October 26, 2023. Accession No. H0876.

ISMP Resources

The following resources are available from the Institute for Safe Medication Practices (ISMP), an ECRI affiliate:

Guidelines for optimizing safe implementation and use of smart infusion pumps. ISMP; 2020. (Membership required.)

Implement strategies to prevent persistent medication errors and hazards. *ISMP Medication Safety Alert! Acute Care.* 2023;28(6):1-4.

<u>Prevent uncontrolled, rapid infusion rates: confirm infusions are connected to pumps</u> <u>before opening the clamp!</u> *ISMP Medication Safety Alert! Acute Care*. 2022;27(15):1-3.

Pump up the volume: tips for increasing error reporting and decreasing patient harm. December 31, 2021.

9. Poor QC of Implantable Orthopedic Products Can Lead to Surgical Delays and Patient Harm

<u>Growing number of defective single-use medical devices puts patients at risk. Hazard</u> <u>#2—2023 top 10 health technology hazards</u>. *Device Evaluation*. January 11, 2023.

Supply chain shortfalls pose risks to patient care. Hazard #2—2022 top 10 health technology hazards. Device Evaluation. January 12, 2022.

10. Third-Party Web Analytics Software Can Compromise Patient Confidentiality

Third-party web analytic tools installed on provider websites may expose patient. data [ECRI Exclusive User Experience Network]. *ECRI Alerts*. October 31, 2022. Accession No. S0461.