EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2025

Expert Insights from ECRI's Device Evaluation Team

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Voice in Healthcare

Top 10 Health Technology Hazards for 2025

Executive Brief

ECRI's 2025 Top 10 Health Technology Hazards report identifies potential sources of danger involving the use of medical devices and systems. Further, the report offers practical recommendations for reducing the identified risks, all with the goal of preventing harm. ECRI is providing this Executive Brief version of the report to inform the healthcare community about these key safety issues.

The List for 2025

1. **Risks with AI-Enabled Health Technologies**
2. **Unmet Technology Support Needs for Home Care Patients**
3. **Vulnerable Technology Vendors and Cybersecurity Threats**
4. **Substandard or Fraudulent Medical Devices and Supplies**
5. **Fire Risk in Areas Where Supplemental Oxygen Is in Use**
6. **Dangerously Low Default Alarm Limits on Anesthesia Units**
7. **Mishandled Temporary Holds on Medication Orders**
8. **Infection Risks and Tripping Hazards from Poorly Managed Infusion Lines**
9. **Skin Injuries from Medical Adhesive Products**
10. **Incomplete Investigations of Infusion System Incidents**

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Detailed descriptions of the hazards outlined in this Executive Brief, along with ECRI's step-by-step recommendations for addressing them, are provided in the 2025 Top 10 Health Technology Hazards Solutions Kit. Members of ECRI programs can access the Solutions Kit through their membership web pages. For more information, contact clientservices@ecri.org; call +1 (610) 825-6000, ext. 5891; or visit www.ecri.org.

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A Total Systems Approach to Safety

For more than 50 years, ECRI has worked to create safer healthcare environments by providing the guidance and tools that stakeholders need to reduce the incidence of preventable harm during patient care. ECRI's goal—a goal shared by healthcare professionals, administrators, device manufacturers, policymakers, researchers, and patients themselves—can best be achieved through a total systems approach to safety.

ECRI's total systems approach to safety, or TSS, moves organizations away from reactive, disconnected interventions by co-designing and implementing a more holistic, proactive, and sustainable safety system that achieves better results. TSS aligns leadership, governance, and culture priorities with workforce safety and wellness, along with patient and family engagement. By redesigning safety system elements, healthcare providers can deliver care more reliably and resiliently. Rooted in advanced safety science, clinically informed human factors engineering, safety management, and health equity, TSS aims to prevent errors, reduce harm, improve staff well-being, and enhance overall care quality.

Initiatives like the Top 10 Health Technology Hazards report show the total systems approach in action. ECRI's various teams—TSS, Human Factors Engineering, Device Safety, Medication Safety, Infection Control, and others—work collaboratively to identify device-specific safety concerns, to probe the underlying system issues that may have contributed to the risks, and ultimately to recommend system-wide safety solutions.

These efforts uncover potential sources of technology-related danger—using the methods outlined below—and they inform practical recommendations that organizations can take to reduce the risks and prevent harm.

Identifying the Top Hazards

The safe use of health technology—from simple medical devices and supplies 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. ECRI's Top 10 Health Technology Hazards report, now in its 18th year, identifies the potential sources of technology-related danger that ECRI's experts believe warrant the greatest attention for the coming year and offers practical solutions to safeguard patient care.

The topics included in the report 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 report reflects our judgment about which risks should be given attention *now* to help care providers, device manufacturers, and others prioritize their patient safety efforts. Further, this report 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.

To develop this report, 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 hazards we select for the report 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 of the hazards discussed will apply to all healthcare facilities. Nor is every possible hazard included; the omission of a topic that was included in a previous year's report 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 2025.

Hazard. A device or system fault, design feature, or method of use that might, under certain circumstances, place patients or users at risk.

Putting the Recommendations into Action

The topics we include in this report represent problems that can be avoided or risks that can be minimized through the careful management of technologies. However, 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.

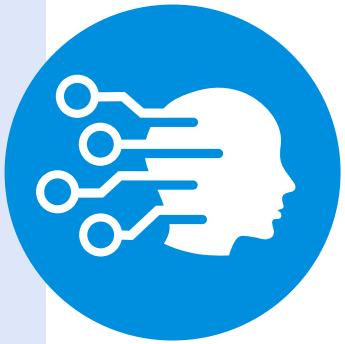
Several of the hazards outlined in this report could be mitigated—and possibly even eliminated—by improved device designs or manufacturing practices. As a rule, an engineering solution that eliminates a hazard will always be preferable to a training solution that can only warn of a hazard. In such instances, we challenge our industry colleagues to make those improvements.

With the additional content provided in the full report (see the inset on page 2), ECRI's Top 10 Health Technology Hazards report serves as a tool to help all stakeholders—from technology managers and device users to manufacturers and policymakers—to prioritize patient safety efforts and manage risk efficiently and effectively.

THE IMPORTANCE OF PROBLEM REPORTING

The topics included in our Top 10 Health Technology Hazards report often derive from user-submitted reports of medical-device-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 send us reports of medical-device-related events—adverse incidents and near misses—so we can share the findings with the rest of the healthcare community, whether through our Alerts service or through annual reports like this one.



Risks with AI-Enabled Health Technologies

1

ONE

Artificial intelligence (AI) offers the promise of increasing the efficiency and precision of medical diagnoses, treatments, and services—ideally improving clinical outcomes, reducing costs, and minimizing health disparities. Improvements are not guaranteed, however; and the potential for preventable harm exists.

Biases present in the data used to train the AI model—or mismatches between that data and the target patient population—can lead to disparate health outcomes or inappropriate responses. Additionally, AI systems have been known to produce "hallucinations" (false or misleading responses) and to exhibit changes in performance over time due to factors such as data drift and the "brittleness" of the AI model (an inability to appropriately adapt when confronted with novel conditions).

Further, AI solutions can yield disappointing results if organizations have unrealistic expectations, fail to define goals, provide insufficient governance and oversight, or don't adequately prepare their data for use by the AI application.

The bottom line? Placing too much trust in an AI model—and failing to appropriately scrutinize its output—may lead to inappropriate patient care decisions. AI offers tremendous potential value as an advanced tool to assist clinicians and healthcare staff, but only if human decision-making remains at the core of the care process. Preventing harm requires careful consideration when incorporating any AI solution into healthcare operations or clinical practice.

Leveraging AI to improve patient care requires that organizations define clear goals, assess and manage risks, evaluate options, develop effective implementation plans, manage expectations, and monitor performance for signs of degradation over time.

> Placing too much trust in an AI model—and failing to appropriately scrutinize its output—may lead to inappropriate patient care decisions.

Unmet Technology Support Needs for Home Care Patients

2

TWO

For many patients, healthcare at home is an attractive alternative to hospital-based treatment. But delivering care in the home has unique concerns, particularly when the patient or a family member is responsible for operating a complex medical device. Devices such as ventilators, dialysis machines, and infusion pumps traditionally have been used in acute care settings under clinical supervision but increasingly are being used in the home.

The safe and effective use of such devices requires adherence to key technology management practices. These include assessing device usability in the context of the user's abilities, mitigating any physical or structural limitations in the intended area of use, supplying the appropriate accessories, and providing sufficient training for proper device operation and maintenance.

Inattention to such practices can lead to events and errors going undetected, readings from the device being misinterpreted (creating either a false sense of security or unnecessary concern), or care delays and other harm from unresolved device malfunctions. ECRI has encountered numerous examples of patient harm from improper setup of or lack of familiarity with medical devices used in the home setting—from a hospitalization precipitated by a switch to an unfamiliar infusion pump to a tragic fatality that occurred when a ventilator alarm failed to activate.

Minimizing the risk of harm requires providing home users with the support they need to operate, maintain, and troubleshoot the device successfully. This involves anticipating challenges that the user may face and selecting devices that are well matched to the patient and the environment of use.

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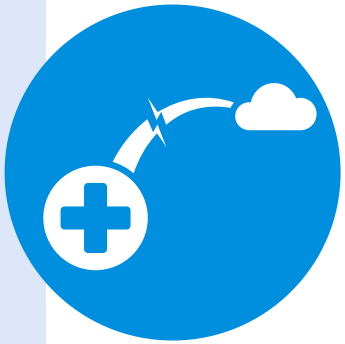


Vulnerable Technology Vendors and Cybersecurity Threats

THREE

3

The practice of healthcare depends heavily on the knowledge and skill of healthcare professionals, the availability and performance of in-house medical devices and systems, and—increasingly—the availability and performance of systems hosted by external (i.e., third-party) vendors. Essential tools ranging from scheduling and billing services to electronic health records and other clinical systems are frequently provided by third-party vendors.

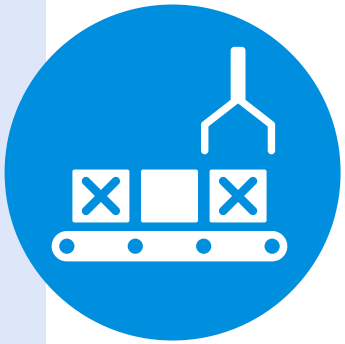
While there are many benefits to the use of third-party tools and services, a healthcare provider's operations can be jeopardized by an event that incapacitates or degrades operations at the third-party vendor. In several high-profile cases, instances of unauthorized access, service disruptions, or other adverse cybersecurity events that impacted a vendor had far-reaching implications for patient care—the 2024 attack on Change Healthcare and the resulting nationwide disruption to pharmacy and billing services being one example.

Such incidents can leave healthcare providers without access to critical services, reliable data, or effective communications channels with their partners. Any of those eventualities can put patients in harm's way, delaying, preventing, or degrading care and adversely affecting patient outcomes.

Measures that can help a healthcare organization mitigate third-party risks include thoroughly vetting vendors at the start of the service acquisition process, building in redundancy, conducting incident response testing, and developing recovery procedures.

Further, ECRI encourages government bodies, regulatory agencies, and others in industry to move away from "punish but not protect" approaches to cybersecurity challenges and third-party risks and toward fostering a collective approach to cybercrime and vendor risk.

> A healthcare provider's operations can be jeopardized by a cybersecurity event that incapacitates or degrades operations at a third-party vendor.



Substandard or Fraudulent Medical Devices and Supplies

4

FOUR

Supply chain challenges have created avenues for substandard and sometimes fraudulent (e.g., counterfeit) medical devices and supplies to reach the care setting, where patients or staff can be harmed if products do not function as intended. A few recent instances include:

- An FDA warning that plastic syringes made in China could be prone to failure, an action that could affect more than one billion products in US healthcare facilities
- ECRI's testing of isolation gowns, which continues to identify quality issues with products that have been distributed over the past four years
- The availability of counterfeit diabetes testing devices, infusion pump batteries, and other products through online marketplaces, drop-shipping websites, or unauthorized distributors

Large-scale instances of substandard or fraudulent products reaching the US market have become startlingly common, with widespread implications for patient care. Principally, such devices may be more susceptible to failure or malfunction, leading to misdiagnoses or injuries. Additionally, the disruptions and recalls that these products cause can stress the supply chain, leading to product shortages; and the need for corrective actions can cost time and money, as healthcare organizations must review inventories for affected items.

To minimize the risks, ECRI encourages healthcare organizations to carefully vet all suppliers; to trial new products before purchase; to establish processes for isolating, investigating, and reporting questionable products; and to develop response plans for supply chain challenges that may arise. Additionally, we challenge industry and policymakers to improve manufacturing quality control (QC) processes and to implement measures to curtail the distribution of substandard and fraudulent products.

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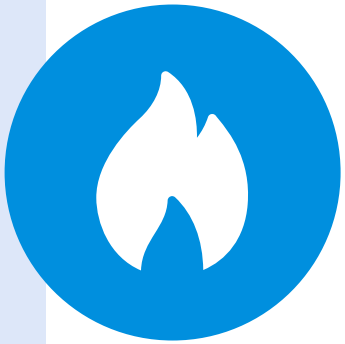


Fire Risk in Areas Where Supplemental Oxygen Is in Use

5

FIVE

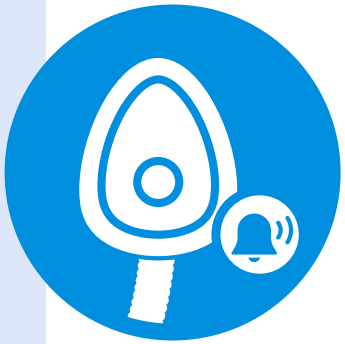
ECRI continues to investigate fires associated with the delivery of supplemental oxygen in a range of patient care areas, including the home.

The three elements needed for a fire—an oxidizer (any gas that can support combustion), a fuel (any object that can burn), and an ignition source—can be present wherever oxygen is delivered. Ignition sources can range from the obvious, such as the electrical current applied by an electrosurgical unit during surgery, to the unsuspected. ECRI has investigated fires that have occurred during defibrillation, as well as those associated with the use of heated humidifiers, fiberoptic light sources, and damaged electrical cords, to name a few examples.

Surgical staff in acute care facilities are likely well aware of fire risks in the OR, where the use of supplemental oxygen in the presence of ignition sources is common. However, ECRI's investigations suggest that increased attention is needed to prevent fires in areas *outside the OR* to protect patients, staff, and others from the potentially devastating consequences of a fire.

The key to preventing fires is to prevent the three elements of the "fire triangle"—an oxidizer, a fuel, and an ignition source—from coming together in the proper proportions and under the right conditions. Clinicians, caregivers, and even patients need to understand the risks associated with each element and take proper precautions. Additionally, those present where supplemental oxygen is in use should know how to respond in the event that a fire occurs.

> The elements needed for a fire can be present wherever oxygen is delivered; and ignition sources can range from the obvious to the unsuspected.



Dangerously Low Default Alarm Limits on Anesthesia Units

6

Anesthesia units are equipped with alarms to warn clinicians when problems arise. For alarm systems to be effective, the threshold values that trigger an alarm (i.e., the alarm limits) need to be set to clinically relevant levels.

Some anesthesia units can be configured such that the alarm limits that are active whenever a new surgical case is started—that is, the *default* limits—will be set to zero or a similarly unsafe lower limit. In effect, this disables the alarm at the start of the case.

Anesthesia providers can change the alarm settings as circumstances warrant; and at times during a procedure it may be appropriate to set the lower alarm limits to zero. What ECRI recommends against, however, is configuring the unit such that the lower limits' *default* setting is zero or some other unsafe lower limit.

ECRI has investigated numerous incidents in which inappropriate default alarm limits caused dangerous conditions to go undetected, leading to patient harm including patient awareness during surgery, brain damage, and even death. Alarms that warrant particular scrutiny are the low minute volume alarm, which alerts the provider to breaths that are too slow and/or shallow, and the low agent concentration alarm, which warns if the patient is not receiving a sufficient concentration of volatile anesthetic agent.

ECRI encourages anesthesia unit vendors to configure their units with safe lower default limits for critical alarms, and several already have done so. Healthcare organizations also are able to customize a unit's default settings; ECRI recommends they confirm that the defaults are set to appropriate values.

ECRI has investigated numerous incidents in which inappropriate default alarm limits caused dangerous conditions to go undetected, leading to patient harm.

SIX

Mishandled Temporary Holds on Medication Orders

SEVEN

7

The need to suspend (or hold) the administration of a drug based on clinical circumstances is a common—but sometimes problematic—requirement during the course of patient care. Errors can arise if organizations lack carefully vetted workflows for documenting medication hold order parameters in the electronic health record (EHR).

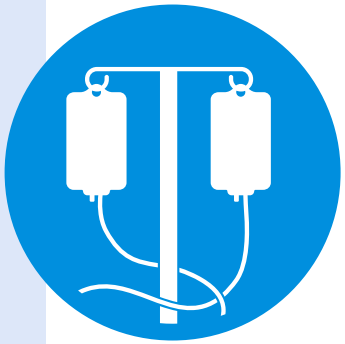
Medications may be held before or shortly after a patient undergoes a procedure, or when a patient's condition changes (such that the continued administration of a drug is inappropriate), or as dictated by clinical protocols. Failure to hold a medication when indicated, or neglecting to either restart or discontinue a held medication as circumstances require, can lead to patient harm.

The Institute for Safe Medication Practices (ISMP) has found that errors associated with hold orders often can be attributed to uncertainty about what a hold order means, how the order should be communicated, or what process should be followed.

One key concern is that the EHR configuration may prevent easy access to details about a hold order. For example, the EHR may require practitioners to scroll, browse, or search for information about whether and when to hold (or resume) a medication. Or prescribers may document this information where it is not easily visible to other practitioners.

Healthcare organizations need a well-defined, well-understood, and well-implemented process for holding or resuming medications. A thoughtful assessment of the EHR workflow for holding medications is critical for this effort; the EHR should allow practitioners to view held medication orders and associated parameters at all points of care, from the pharmacy to the bedside.

Failure to hold a medication when indicated, or neglecting to either restart or discontinue a held medication as circumstances require, can lead to patient harm.



Infection Risks and Tripping Hazards from Poorly Managed Infusion Lines

EIGHT

8

Failure to properly manage infusion lines and connectors can lead to severe patient harm. While medication errors and misconnections are perhaps the best-known risks, they aren't the only opportunities for harm. The potential for healthcare-associated infections (HAIs) and tripping hazards can be just as consequential.

Infections associated with improper line management may result from:

- Pathogens entering the connector and infusion line (e.g., if the connector is not cleaned and disinfected before access)
- Environmental contaminants contacting the insertion site or the outer surface of the infusion line (e.g., if a healthcare worker touches the insertion site or tubing with contaminated gloves)
- The drug, solution, or other infusate becoming contaminated (e.g., if sterile technique is not followed during preparation or if aseptic technique is not followed at the point of use)

HAIs can have severe consequences, including longer hospital stays and increased rates of patient morbidity and death. To minimize the risks, healthcare workers should follow infection control best practices, including employing aseptic technique when inserting, accessing, and maintaining lines, and using standard precautions or additional transmission-based precautions, as appropriate.

Another circumstance that can lead to harm is if infusion lines are allowed to dwell on the floor. This creates a tripping hazard that can lead to patient or staff injuries from a fall, as well as patient harm if the infusion line becomes dislodged. Staff should check infusion lines to ensure that they are not on the floor. Additionally, facilities may consider using a catheter securement product to decrease the risk of dislodgement.

> While medication errors and misconnections are perhaps the best-known dangers, infection risks and tripping hazards from mismanaged lines can be just as consequential.

Skin Injuries from Medical Adhesive Products

9

NINE

Medical adhesive products are used for a variety of applications—from dressing a wound, to securing an IV line, to attaching an electrode for an electrocardiogram. Tapes, dressings, and other adhesive products are intended to benefit patient care. But not all adhesives are the same, and not all patients will respond similarly to an adhesive product. Inappropriate choices can lead to skin tears, blisters, adverse reactions like contact dermatitis, or other forms of injury.

Factors that can contribute to medical-adhesive-related skin injuries, or MARSI, include:

- Patient risk factors, such as age, nutrition, or underlying medical conditions.
- The properties of the adhesive product. Stronger adhesives provide a more secure hold but also pose a higher likelihood of damaging the skin.
- Selection of an inappropriate product for the intended application.
- Errors when applying or removing an adhesive product.

MARSI can occur in any care setting, medical specialty, and patient population. While most skin injuries resolve within a few days, they nevertheless cause unnecessary discomfort and pain; additionally, they can leave patients susceptible to infection, which can lead to more severe consequences.

This hazard illustrates how purchasing decisions can impact patient care: Without access to appropriate products, staff may be forced to use one that is suboptimal for the situation. ECRI recommends purchasing—and providing staff with easy access to—an appropriate selection of adhesive products. For their part, clinicians should assess patients for MARSI risk factors and select an adhesive product with the lowest strength that still meets the requirements of the task.

> Inappropriate adhesive choices can lead to skin tears, blisters, adverse reactions like contact dermatitis, or other forms of injury.

Incomplete Investigations of Infusion System Incidents

10

TEN

Healthcare organizations will want to conduct a thorough investigation in the aftermath of any technology-related adverse event. Investigations involving infusion systems, however, can be particularly challenging due to the variety of potential contributing factors. Organizations that lack the expertise or resources to conduct a thorough investigation of such incidents will be poorly positioned to prevent future, potentially fatal infusion-related medication errors or other incidents.

Infusion therapy is an exceptionally common treatment, and the overwhelming majority of infusions are completed without incident—that is, with an infusion pump controlling delivery of the medications or solutions to the patient as intended. Nevertheless, adverse events and near misses do occur with some regularity. Pump-related incidents are frequently the subject of reports submitted to FDA, ECRI, and other patient safety organizations.

As ECRI has learned over its five decades of researching pump-related incidents, issues related to the pump hardware and software, the IV administration set and other accessories, and the actions of the user all must be examined. Furthermore, it's not uncommon for staff to take steps after an event that inadvertently hinder a future investigation.

The process of identifying root causes and implementing corrective measures starts with creating a culture in which incidents are immediately reported. Additional measures include educating staff about how to respond immediately following an incident and about the steps they should take to support an investigation—steps like documenting the incident and preserving the pump and any accessories and disposables used with it.

> Organizations that lack the expertise or resources to conduct a thorough investigation will be poorly positioned to prevent future incidents.

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. Risks with AI-Enabled Health Technologies

AI-based reconstruction can distort images, threatening diagnostic outcomes. Hazard #7—2022 top 10 health technology hazards. *Device Evaluation*. January 12, 2022.

AI in healthcare: an introduction. *Device Evaluation.* September 4, 2024.

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 2023.

Ethical use of AI in healthcare. *Device Evaluation*. August 23, 2024.

Incorporating AI into healthcare [ECRI position paper]. June 2024.

Insufficient governance of AI used in medical technologies risks inappropriate care decisions. Hazard #5—2024 top 10 health technology hazards. *Device Evaluation*. January 29, 2024.

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

Unintended consequences of technology adoption. Concern #4—top 10 patient safety concerns for 2024. *Health System Risk Management*. March 8, 2024.

Using AI-enhanced video technology to overcome staffing shortages and improve patient care: The Guthrie Clinic's award-winning initiative. *Device Evaluation*. Updated October 2, 2023.

2. Unmet Technology Support Needs for Home Care Patients

Cybersecurity risks in the connected home healthcare environment. Hazard #7—2020 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.

Home care ventilated patients face technological challenges [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.

Medical devices may pose usability challenges for home users, risking misuse and patient harm. Hazard #1—2024 top 10 health technology hazards. *Device Evaluation.* January 29, 2024.

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

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

3. Vulnerable Technology Vendors and Cybersecurity Threats

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

Cybersecurity attacks can disrupt healthcare delivery, impacting patient safety. Hazard #1—2022 top 10 health technology hazards. *Device Evaluation*. January 12, 2022.

Cybersecurity risks in the connected home healthcare environment. Hazard #7—2020 top 10 health technology hazards. *Device Evaluation*. September 26, 2019.

Emergency preparedness: response and recovery. *Healthcare Risk Control*. December 17, 2018.

Failure to manage cybersecurity risks associated with cloud-based clinical systems can result in care disruptions. Hazard #5—2023 top 10 health technology hazards. *Device Evaluation*. January 11, 2023.

Hackers can exploit remote access to systems, disrupting healthcare operations. Hazard #1—2019 top 10 health technology hazards. *Device Evaluation*. September 26, 2018.

Ransomware and other cybersecurity threats to healthcare delivery can endanger patients. Hazard #1—2018 top 10 health technology hazards. *Device Evaluation*. October 1, 2017.

Ransomware targeting the healthcare sector remains a critical threat. Hazard #6—2024 top 10 health technology hazards. *Device Evaluation*. January 29, 2024.

Third-party web analytics software can compromise patient confidentiality. Hazard #10—2024 top 10 health technology hazards. *Device Evaluation*. January 29, 2024.

Vulnerabilities in third-party software components present cybersecurity challenges. Hazard #7—2021 top 10 health technology hazards. *Device Evaluation*. January 28, 2021.

4. Substandard or Fraudulent Medical Devices and Supplies

[COVID-19] Cue Health—COVID-19 tests: FDA warns against use. *ECRI Alerts*. Updated May 23, 2023. Accession No. A42432.

[COVID-19] SD Biosensor—Pilot Covid-19 at-home test kits: may be contaminated with bacteria. *ECRI Alerts*. Updated May 26, 2023. Accession No. A40686.

Evaluation background: disposable AAMI Level 2 isolation gowns. *Device Evaluation*. Updated October 10, 2024.

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

Poor QC of implantable orthopedic products can lead to surgical delays and patient harm. Hazard #9—2024 top 10 health technology hazards. *Device Evaluation*. January 29, 2024.

Supply chain interruptions. Concern #4—top 10 patient safety concerns for 2021. *Health System Risk Management*. March 12, 2021.

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

Underreporting device-related issues may risk recurrence. Hazard #10—2023 top 10 health technology hazards. *Device Evaluation*. January 11, 2023.

Vetting nontraditional suppliers [self-assessment questionnaire]. *Health System Risk Management*. February 8, 2021.

5. Fire Risk in Areas Where Supplemental Oxygen Is in Use

While several of these resources focus on fires in the OR, much of the guidance applies to the risks associated with the use of supplemental oxygen in other locations as well.

Surgical Fire Prevention: The Essentials. This web page features a collection of Device Evaluation resources on preventing surgical fires.

Clinical Guide to Surgical Fire Prevention:

- Part 1. Surgical fire safety initiatives. *Device Evaluation.* February 8, 2017.
- Part 2. The team approach to surgical fire prevention. *Device Evaluation.* February 8, 2017.
- Part 3. Extinguishing a fire on the patient. *Device Evaluation.* February 8, 2017.

Posters (developed in collaboration with the Anesthesia Patient Safety Foundation):

- Surgical fire time-out. Before performing certain surgeries that involve an ignition source in the field, surgical teams should review the strategies on this poster to reduce the risk of surgical fires.
- Know your part when responding to a surgical fire. In the rare event of a surgical fire, a rapid and coordinated response is critical. This poster details what the anesthesia provider, scrubbed staff, and unscrubbed staff can do to extinguish the fire and tend to the patient.

Oxygen use outside the OR increases the risk of fires [ECRI Exclusive Hazard Report]. *ECRI Alerts.* April 1, 2022. Accession No. H0664.

6. Dangerously Low Default Alarm Limits on Anesthesia Units

Appropriately set inspired and end-tidal anesthetic agent alarms can help prevent intraoperative awareness [ECRI Exclusive Hazard Report]. *ECRI Alerts.* March 19, 2019. Accession No. H0501.

Awareness during anesthesia. *Health System Risk Management*. June 25, 2014.

ECRI Evaluation spurs anesthesia machine safety fix. *Device Evaluation*. June 16, 2021.

Evaluation background: anesthesia units for general-purpose and low-acuity/ambulatory surgery applications. *Device Evaluation*. Updated June 28, 2023.

7. Mishandled Temporary Holds on Medication Orders

The following resource is publicly available from the Institute for Safe Medication Practices:

Temporarily holding medication orders safely in order to prevent patient harm. *ISMP Medication Safety Alert! Acute Care*. 2023;28(21):1-4.

8. Infection Risks and Tripping Hazards from Poorly Managed Infusion Lines

Be a TRACER Not a Racer: This page provides access to meeting slides and a poster that cover risk-reduction strategies for preventing tubing misconnections.

Essentials pages—ECRI web pages that feature a collection of Device Evaluation resources on specific topics of interest:

- Infusion Pumps: The Essentials
- Ambulatory Surgery Centers / Outpatient Care Facilities: The Essentials
- Home-Based Health and Hospice Care: The Essentials
- Pharmacy Technology and Medication Management: The Essentials
- Health Technology Management: The Essentials

9. Skin Injuries from Medical Adhesive Products

Evaluation background: bordered foam dressings. *Device Evaluation*. February 23, 2024.

New evaluation: advanced wound care dressings [webcast]. November 15, 2023.

Polymer-cyanoacrylate skin protectants for prevention and treatment of incontinence-associated dermatitis. Clinical Evidence Assessment. August 2022.

Standard-of-care practices for managing skin tears. Clinical Evidence Assessment. March 2024.

Substandard or fraudulent medical devices and supplies Hazard #4—2025 top 10 health technology hazards. *Device Evaluation*. December 3, 2024.

Wound dressings for managing pressure injuries. Clinical Evidence Assessment. February 2023.

Wound dressings for preventing pressure injuries. Clinical Evidence Assessment. February 2023.

10. Incomplete Investigations of Infusion System Incidents

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

Device incident response [poster]. 2021.

Don't lose the evidence—sequestering equipment after an incident. *Device Evaluation*. March 5, 2014.

Incidents happen: are you prepared? [webcast]. April 28, 2022.

Infusion pump damage remains a medication safety concern. Hazard #8—2024 top 10 health technology hazards. *Device Evaluation*. January 29, 2024.

The following resources are publicly available from the Institute for Safe Medication Practices:

ISMP guidelines for optimizing safe implementation and use of smart infusion pumps. ISMP; 2020.

Smart infusion pump investigations after an unexplained over-infusion. *ISMP Medication Safety Alert! Acute Care*. 2023;28(10):1-3.