SPECIAL REPORT

Top 10 Health Technology Hazards for 2022

Expert Insights from ECRI’s Device Evaluation Program

EXECUTIVE BRIEF
www.ecri.org/2022hazards
Executive Brief

ECRI is providing this abridged version of its 2022 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’s step-by-step recommendations for addressing the hazards—is available to members of ECRI programs through their membership web pages.

The List for 2022

1. Cybersecurity Attacks Can Disrupt Healthcare Delivery, Impacting Patient Safety
2. Supply Chain Shortfalls Pose Risks to Patient Care
3. Damaged Infusion Pumps Can Cause Medication Errors
4. Inadequate Emergency Stockpiles Could Disrupt Patient Care during a Public Health Emergency
5. Telehealth Workflow and Human Factors Shortcomings Can Cause Poor Outcomes
6. Failure to Adhere to Syringe Pump Best Practices Can Lead to Dangerous Medication Delivery Errors
7. AI-Based Reconstruction Can Distort Images, Threatening Diagnostic Outcomes
8. Poor Duodenoscope Reprocessing Ergonomics and Workflows Put Healthcare Workers and Patients at Risk
9. Disposable Gowns with Insufficient Barrier Protection Put Wearers at Risk
10. Wi-Fi Dropouts and Dead Zones Can Lead to Patient Care Delays, Injuries, and Deaths

For information about becoming a member of one of our programs and accessing the full report, contact clientservices@ecri.org or call +1 (610) 825-6000, ext. 5891.
The Changing Landscape of Health Technology Hazards

Reflecting the volatility in healthcare during the COVID-19 public health emergency, this 15th edition of ECRI’s Top 10 Hazards list includes many first-time topics. Several of these expand on the key theme from our 2021 list: the need to progress from just trying to cope during the pandemic to building stronger and more resilient processes, leveraging the innovations developed and the lessons learned along the way. Other topics on this year’s list address emerging challenges, under-the-radar issues, or persistent hazards that require renewed attention.

The Purpose of the List

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

Produced each year by ECRI’s Device Evaluation 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 necessarily 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 manage the risks efficiently and effectively.

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.
Top 10 Health Technology Hazards for 2022

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 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 and the Institute for Safe Medication Practices PSO. ECRI encourages all organizations 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.

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, 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?

- **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 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, 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 to 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 2022.

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

This Executive Brief helps raise awareness of critical health technology hazards—a key step in patient safety efforts. The next steps involve taking action to prevent the problems from occurring. The **2022 Top 10 Health Technology Hazards Solutions Kit**—available online to members of ECRI programs—will help with that effort.

The Solutions Kit provides a comprehensive discussion of each topic, actionable recommendations for minimizing the risks of harm, and lists of useful resources for more information about each topic. Log in to your membership web page to access this valuable content.
Cybersecurity Attacks Can Disrupt Healthcare Delivery, Impacting Patient Safety

All healthcare organizations are subject to cybersecurity incidents. The question is not whether a given facility will be attacked, but when. Such incidents don’t just interfere with business operations—they can disrupt patient care, posing a real threat of physical harm.

A cybersecurity incident could threaten the network-connected medical devices and data systems that have become essential for safe and effective care delivery. Consequences may include rescheduling of appointments and surgeries, diversion of emergency vehicles, or closure of care units or even whole organizations—all of which could put patients at risk.

Many cybersecurity incidents can be thwarted—or their effects can be minimized—if appropriate measures are implemented before an incident, or in response to one. Managing cybersecurity risks in a healthcare environment, however, is uniquely challenging: Actions that might be commonplace in other IT environments could themselves cause problems if their potential impact on patient care is not assessed.

Responding to these risks requires not only a robust security program to prevent attacks from reaching critical devices and systems, but also a plan for maintaining patient care when they do.

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Supply Chain Shortfalls Pose Risks to Patient Care

The COVID-19 pandemic created a “perfect storm” for medical device supply chains: a crisis of international scale, with multiple product lines suddenly being in high demand, supported by insufficient supply chains designed around lean inventory models.

The vulnerability of supply chains, a problem that existed well before the pandemic, stemmed from several factors:

— Downward cost pressures have driven healthcare device manufacturers and distributors to source product from offshore manufacturers and have prompted healthcare organizations to maintain lean inventories that depend on just-in-time deliveries.

— Ongoing vendor standardization among healthcare providers has resulted in contracts with fewer manufacturers and distributors. This, combined with the fact that many manufacturers and distributors have been providing only a limited quantity of supplies, has affected product availability.

— The complexity of supply chains and vulnerabilities associated with raw materials coming from various sources created a blind spot for supply chain professionals, who were taken by surprise when manufacturers were unable or unwilling to provide supplies.

Unavailability of products could result in an inability to treat patients and protect staff, which could lead to injury, illness, or even death for both patients and clinicians. We explain measures you can take to help prevent product shortages, as well as strategies to maintain patient care if you are unable to get the supplies you need.
ECRI continues to receive reports of damaged infusion pumps being used during patient care, a situation that can lead to dangerous, and possibly fatal, medication administration errors. Pump damage can be hard to identify; it may not be visibly apparent or may not trigger an alarm. Too often, this leads to the use of a pump that should have been removed from service.

Causes of pump damage include wear and tear, mishandling, misuse, poor device design, or the use of improper cleaning agents or methods. Any of these could contribute to the failure of pump components during use.

ECRI has investigated several incidents in which damage to an infusion pump prevented the pump from regulating the flow of medication, leading to an overinfusion and patient harm. Use of a damaged infusion pump could also result in underinfusion or even total cessation of medication administration, which likewise can lead to patient harm, particularly if a critical medication was to be delivered.

Clinical staff need to be alert to signs of infusion pump damage, and they need to know how to respond if damage is suspected or observed. Nurse educators, central equipment distribution, clinical engineering, and pump manufacturers also have roles to play to avoid these problems and keep patients safe.

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Inadequate Emergency Stockpiles Could Disrupt Patient Care during a Public Health Emergency

Emergency stockpiles that are insufficient to meet the needs of the community can disrupt care in the event of a widespread health emergency, natural disaster, or other crisis, potentially harming patients and healthcare providers.

An emergency stockpile helps organizations continue operations when normal equipment inventories or supplies become depleted or when supply chains are disrupted. But if the stockpile is insufficient to meet the needs of the community during a crisis, healthcare organizations may be unable to care for the sick and the injured, or to protect their staff.

During the COVID-19 pandemic, medical supplies and equipment in local, state, and national emergency stockpiles have not always been ready for use. There have been numerous reports of inappropriate products for the expected uses; necessary products or accessories that had not been included in the stockpile; expired products; insufficient product quantities or supplies that had not been replenished; discharged or expired batteries in devices; and products physically damaged or not functional.

Shortcomings such as these can compromise the ability of healthcare organizations to provide care during a crisis. To the extent practical, organizations should work toward the development—and, importantly, the ongoing management—of an emergency stockpile that can better meet the needs of a future crisis.

If a stockpile is insufficient to meet the needs of the community during a crisis, healthcare organizations may be unable to care for the sick and the injured, or to protect their staff.
Telehealth Workflow and Human Factors Shortcomings Can Cause Poor Outcomes

Telehealth programs proved their value during the COVID-19 pandemic, allowing the continued delivery of many kinds of patient care at a time when in-person visits were difficult or impossible. However, some facilities and caregivers are now feeling the strain of using programs that were rapidly implemented during a crisis, without time for full consideration of workflow and human factors.

As facilities seek to optimize telehealth care-delivery models for the long term, they must address factors that could lead to poor outcomes, both for patients (e.g., misdiagnoses, delays in care) and for providers (e.g., cognitive overload, clinician burnout).

Factors to consider include:

- The extent to which the telehealth solution (1) meets the provider’s requirements for delivering appropriate patient care and (2) aligns with the patient’s capabilities and clinical needs
- Ease of use. Both the care provider and the patient must be able to use the communications technology effectively. Additionally, when a telehealth program involves the home use of health devices by the patient, the ease of use of those devices is crucial.
- The amount, quality, and relevance of the data that care providers receive. Large volumes of data that don’t serve a meaningful clinical purpose can overwhelm the provider, and inaccurate or incomplete data can lead to inappropriate care decisions.

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Failure to Adhere to Syringe Pump Best Practices Can Lead to Dangerous Medication Delivery Errors

Syringe pumps provide highly accurate fluid delivery and consistent flow for small volumes (≤60 mL) of pharmacologic agents. However, misconceptions persist about the practices required to accurately deliver low flows within the confines of the technology’s limitations. Both overinfusions and underinfusions can result.

One critical issue that may not be well understood is that, when syringe pumps are programmed at a low flow rate (e.g., <5 mL/hr), there may be a considerable lag between starting an infusion at the pump and actual drug delivery to the patient—often a critically ill child. The duration of the lag can exceed an hour, depending on the size of the syringe, the diameter and length of the tubing that carries the medication to the patient, and other factors.

As a result of the lag, the expected patient response will be delayed. Clinicians may believe the lack of response is due to inadequate dose, rather than delay of delivery. This may result in overinfusions of critical medications, which can have serious clinical consequences. Underinfusions may also occur, with similarly serious implications.

Key recommendations include: (1) adopting standardized drug concentrations that allow for reasonable flow rates for all patient groups, so that clinicians can avoid the dangerous combination of a low flow rate and a large syringe, and (2) reducing lag by using the pump’s priming feature instead of manually priming the administration set.

Misconceptions persist about the practices required to accurately deliver low flows within the confines of the technology’s limitations. Both overinfusions and underinfusions can result.
AI-Based Reconstruction Can Distort Images, Threatening Diagnostic Outcomes

Artificial intelligence is replacing the standard algorithms used to reconstruct images from data obtained during an MRI, CT, or other scan. One key benefit is AI’s ability to optimize the quality and speed of reconstruction. But as with any new technology in its early stages, AI image reconstruction has potential instabilities and limitations that can manifest in several forms. For example:

— Tiny, almost undetectable perturbations during image capture may result in severe artifacts, which may obscure a small structural change such as a tumor, or there may be a more subtle distortion or blurring of the features, which can hamper diagnostic interpretation.

— Current imaging devices are designed to reduce exam time and dose by optimally reducing the acquisition of redundant information contained in the raw data. However, depending on how this is done, the use of AI reconstruction may not improve image quality, and actually may degrade it.

Such problems are not rare. They can be triggered by factors such as normal anatomical variations, patient movement, and device malfunction. Plus, if a problem with an AI-reconstructed image is suspected, there is no way to verify that details have not been obscured.

Providers need to be acutely aware of the technology’s limitations—and its applicability to their specific patient population—before implementing AI for imaging applications.

AI image reconstruction has potential instabilities and limitations that can manifest in several forms.
Poor Duodenoscope Reprocessing
Ergonomics and Workflows Put Healthcare Workers and Patients at Risk

The failure to adequately reprocess contaminated duodenoscopes between uses is a well-known hazard, one that has led to the spread of deadly pathogens. Perhaps less well known are the risks of injury to the healthcare workers who perform this function, and the ways in which ergonomic and workflow factors can compromise reprocessing effectiveness, putting patients at risk.

A 2021 ECRI survey of healthcare workers who routinely perform duodenoscope reprocessing—that is, cleaning and disinfection (or sterilization)—identified several significant patient and worker safety hazards:

— Obstacles to effective reprocessing, potentially increasing patient infection risks. Survey respondents cited time pressures and poor work environment ergonomics (e.g., work surfaces at an uncomfortable height) as key concerns.

— The continued use of duodenoscopes with fixed distal endcaps, instead of scopes with single-use components. Duodenoscopes with fixed distal endcaps are more difficult to reprocess effectively, putting patients at increased risk of infection.

— A higher risk of healthcare worker musculoskeletal injuries due to poor workspace ergonomics

Correcting these problems requires facilities to take a close look at the workflow, the workspaces and surfaces, and the expected turnaround times for duodenoscope reprocessing, as well as reevaluating the use of reusable duodenoscopes.

Ergonomic and workflow factors can compromise reprocessing effectiveness, putting patients at risk.
Disposable Gowns with Insufficient Barrier Protection Put Wearers at Risk

Product selection errors and gown manufacturing flaws can lead to the use of medical protective gowns that do not adequately protect the wearer from body fluids and other potentially harmful substances. Gown wearers can be put at risk of cross-contamination if the wrong type of gown is purchased and worn for the intended application, or if the gown does not provide the level of protection that is claimed.

Selecting the appropriate gown (isolation, surgical, or cover) for any given application, however, is not as simple as looking at its labeling. The nomenclature used by suppliers to designate the gown type or protection level is not consistent. Terms may be used interchangeably, or in a manner that does not align with standards that define barrier protection levels. Additionally, ECRI’s testing of disposable gowns has raised concerns about manufacturing quality, particularly in gowns from nontraditional suppliers (i.e., new or non-U.S. manufacturers). Roughly half of the tested gowns failed to meet required protection levels.

Disposable gowns can’t be judged based solely on their appearance, labeling, or packaging, making it hard for purchasers or wearers to know the level of protection that a gown will provide. Healthcare facilities need to vet prospective suppliers and their products, and they need to educate wearers about which of the gowns in inventory are appropriate for various uses.
Wi-Fi Dropouts and Dead Zones Can Lead to Patient Care Delays, Injuries, and Deaths

Increasing numbers of medical devices depend on a facility’s wireless (Wi-Fi) network. Reliable Wi-Fi connectivity, as a result, now needs to be viewed as a patient care consideration.

Wi-Fi functionality can deliver significant workflow and patient safety improvements. It has become essential for transmitting clinical alarms to a nurse’s phone, for accessing the electronic health record (EHR), and for updating drug libraries on a fleet of infusion pumps, for example.

Realizing such benefits, however, requires reliable connectivity; and consistently achieving that level of connectivity throughout a facility can be a challenge. What’s more, failing to achieve it can create new avenues for harm, particularly if wirelessly connected devices lose communications at a critical moment.

Causes of connectivity issues include low signal strength in certain areas of the facility, inadequate or suboptimally allocated bandwidth to meet clinical needs, intentional outages during system maintenance, and poorly managed cybersecurity measures, to name a few.

Wireless communication failures or unreliable connections can lead to workarounds that circumvent a system’s safety features. They can also interrupt workflow, delaying patient care. They can even cause serious injury or death—for example, if critical alerts are not received.

Risks can be reduced by actively maintaining Wi-Fi systems, thoughtfully allocating bandwidth (e.g., to prioritize medical and communications devices), and monitoring the network on an ongoing basis.
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. Cybersecurity Attacks Can Disrupt Healthcare Delivery, Impacting Patient Safety

   - **Cybersecurity: The Essentials.** This web page features a collection of Device Evaluation resources on cybersecurity topics.
   - **Getting started with a cybersecurity incident response plan for your medical devices.** *Device Evaluation* 2020 Dec 2.
   - **Getting the most out of the MDS2 form.** *Device Evaluation* 2020 Mar 18.
   - **Including cybersecurity in a request for proposal.** *Device Evaluation* 2020 Mar 18.
   - **Software patches for medical devices: vendor validation is essential.** *Device Evaluation* 2020 Jan 22.

   Previous ECRI Top 10 Health Technology Hazards articles on this topic, including:
   - 2021, No. 7: [Vulnerabilities in third-party software components present cybersecurity challenges](#).
   - 2020, No. 7: [Cybersecurity risks in the connected home healthcare environment](#).
   - 2019, No. 1: [Hackers can exploit remote access to systems, disrupting healthcare operations](#).
   - 2018, No. 1: [Ransomware and other cybersecurity threats to healthcare delivery can endanger patients](#).

2. Supply Chain Shortfalls Pose Risks to Patient Care

   - **Outbreak Preparedness and Response: The Essentials.** This web page features a collection of Device Evaluation resources on COVID-19, including environmental cleaning and disinfection, safe and efficient vaccine practices, managing devices with FDA Emergency Use Authorization, and much more.
   - **Healthcare Recovery Center: COVID-19**—Selected resources spanning ECRI’s entire range of products and services.

   - [Alternate supplier list: personal protective equipment](#)—Comprehensive directory of go-to sources to supplement the usual suppliers.
   - “But we don’t have any”: when medication shortages hinder patient care. ECRI and the ISMP PSO 2018 Aug 14.
   - ECR/Association for Health Care Resources & Materials Management (AHRMM) collaborations to track nontraditional suppliers:
     - [Domestic suppliers](#)
     - [International suppliers](#)
   - [Medication safety. Health System Risk Management 2017 Nov 6.](#)
   - **Navigating the purchase of PPE from nontraditional suppliers**—from ECRI’s “COVID-19 and Medical Devices” lab webcast series. Includes recordings of the following webcasts:
     - [Navigating Nontraditional PPE Suppliers, and Key Findings from N95 Testing](#) (2020 Aug 5)
     - [Navigating Nontraditional PPE Suppliers, and Key Findings from Gown Testing](#) (2020 Jul 22)
     - Hazard #4: Supply chain interruptions
     - Hazard #5: Drug shortages
3. Damaged Infusion Pumps Can Cause Medication Errors

Infusion Pumps: The Essentials. This web page features a collection of Device Evaluation resources on various types of infusion pumps.


_Cleaning fluid seeping into electrical components can lead to equipment damage and fires. Hazard #9—2019 top 10 health technology hazards. Device Evaluation 2018 Sep 26.


4. Inadequate Emergency Stockpiles Could Disrupt Patient Care during a Public Health Emergency

Outbreak Preparedness and Response: The Essentials. This web page features a collection of Device Evaluation and other resources on responding to the COVID-19 pandemic.

_COVID-19 Technology Management Resources: free resources for combating the COVID-19 pandemic. This web page features a collection of Device Evaluation and other resources on responding to the COVID-19 pandemic. The page is publicly accessible; no subscription required.


5. Telehealth Workflow and Human Factors Shortcomings Can Cause Poor Outcomes

Telehealth: The Essentials. This web page features a collection of Device Evaluation resources on various aspects of telehealth, including Evaluations of RPM systems, purchasing advice, and safety guidance.


6. Failure to Adhere to Syringe Pump Best Practices Can Lead to Dangerous Medication Delivery Errors

*Infusion Pumps: The Essentials*. This web page features a collection of *Device Evaluation* resources on various types of infusion pumps.


7. AI-Based Reconstruction Can Distort Images, Threatening Diagnostic Outcomes

AI's potential as diagnostic aid continues to grow. *Strategic Insights for Health System* 2019 Feb 20.


Is your organization ready for emerging technologies? *Strategic Insights for Health System* 2018 Sep 5.

8. Poor Duodenoscope Reprocessing Ergonomics and Workflows Put Healthcare Workers and Patients at Risk

*Flexible Endoscopes and Endoscope Reprocessing: The Essentials*. This web page features a collection of *Device Evaluation* resources on endoscopes and reprocessing.


9. Disposable Gowns with Insufficient Barrier Protection Put Wearers at Risk

COVID is not the only concern: what you need to know about isolation gowns [webcast]. 2021 August 19.


10. Wi-Fi Dropouts and Dead Zones Can Lead to Patient Care Delays, Injuries, and Deaths

*Connectivity, Interoperability, and Health IT: The Essentials*. This web page features a collection of *Device Evaluation* resources on device integration and health IT topics, including Evaluations of consolidated health information platforms, hazard reports, purchasing guidance, and more.