SPECIAL REPORT

Top 10 Health Technology Hazards for 2023

Expert Insights from ECRI's Device Evaluation Program

EXECUTIVE BRIEF

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Voice in Healthcare

Top 10 Health Technology Hazards for 2023

Executive Brief

ECRI is providing this Executive Brief describing its 2023 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 2023

1. **Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm**
2. **Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk**
3. **Inappropriate Use of Automated Dispensing Cabinet Overrides Can Result in Medication Errors**
4. **Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death**
5. **Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions**
6. **Inflatable Pressure Infusers Can Deliver Fatal Air Emboli from IV Solution Bags**
7. **Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination**
8. **Common Misconceptions about Electrosurgery Can Lead to Serious Burns**
9. **Overuse of Cardiac Telemetry Can Lead to Clinician Cognitive Overload and Missed Critical Events**
10. **Underreporting Device-Related Issues May Risk Recurrence**

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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 2023 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 or call +1 (610) 825-6000, ext. 5891.

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 risk that adverse events will occur. This 16th 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 list 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.

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.

This year we're extending a challenge to our industry colleagues. We believe some 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. With the COVID-19 pandemic leaving healthcare facilities understaffed and healthcare workers overstressed, it's more important than ever that medical technologies be designed in ways that help ensure their safe use. And as always, ECRI is ready to help make this happen.

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 and death. Examples through the years have included:

- In the 1970s—Improvements to manual resuscitators to prevent inadequate lung inflation
- In the 1980s—Safer electrode connections for patient monitoring equipment to prevent accidental electrocution
- In the 1990s—Bed safety assessments to prevent entrapment and strangulation within bedrails, as well as free-flow prevention mechanisms for infusion pumps to prevent overmedication
- Since 2000—Drug libraries and infusion pump integration to prevent wrong-dose and wrong-drug errors; CT scanner dose-control technologies to protect patients from unnecessarily high radiation exposures; and improved endoscope reprocessing procedures and technologies to prevent cross-contamination

In this year's report, we've highlighted areas where we believe device manufacturers can advance the cause of patient safety through better product design. There's no better time to improve technologies to keep patients safe.

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 2023.

THE IMPORTANCE OF PROBLEM REPORTING

The topics on our Top 10 Hazards list 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.

Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm

1

ONE

Accurate and understandable information about medical device recalls often does not reach patients using those devices in the home; this information gap is growing every year as healthcare moves into the home setting.

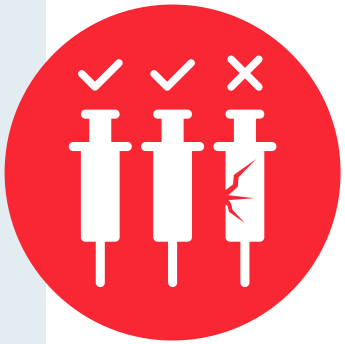
Device manufacturers seldom have direct communication with home care patients; and healthcare providers may not proactively contact patients about recalls. As a result, patients who use medical devices in the home may learn about a recall—and the steps needed to ensure safe use of the device—long after it was issued, and potentially from an unreliable source, such as a television commercial for a class-action lawsuit or through social media.

Even if patients do receive a notification, the language may be jargon-heavy and perplexing, and patients may have difficulty determining whether their device is affected or what to do about it. Without a clear understanding of the risks, patients may be harmed by continuing to use an unsafe device—or by inappropriately stopping use of a device whose benefits outweigh the risks.

All stakeholders—patients, healthcare providers, and manufacturers—have a role to play in building a recall process that meets the needs of home users.

Challenge to Industry. ECRI challenges manufacturers of medical devices that can be used outside the hospital environment to implement measures such as: providing users with easy-to-follow device registration instructions, writing simply worded recall notices, maintaining up-to-date databases of device distribution, and designating staff to ensuring that recalls reach home users.

Without a clear understanding of the risks, patients may be harmed by continuing to use an unsafe device—or by inappropriately stopping use.



Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk

2

TWO

An unacceptably high number of defective single-use medical devices continue to be present in the supply chain. Single-use medical devices—which include products that are used once and then discarded, as well as those that get consumed during use—play a role in virtually every patient encounter. As a result, defective products can have a broad, negative impact on patient care, causing delays and increasing costs—and most concerningly, contributing to patient harm or death in some circumstances.

ECRI has received reports of cracked tubing and connectors; compromised sterility of needles, catheters, and procedure kits; and incorrect product labeling. These are just a few examples of product defects that can lead to waste, delays, incorrect treatment, healthcare-acquired infections, or other patient harm.

ECRI is concerned that some device manufacturers are not making sufficient efforts to address the problem. In fact, rather than seeing improvements over time, we've noticed a continuing increase in problem reports. ECRI urges manufacturers to take decisive steps to improve their quality control (QC) processes.

Steps that healthcare organizations can take include encouraging users to report defective products; tracking device usage to identify potential waste due to defects; identifying functionally equivalent products for critical single-use items; and holding manufacturers and distributors accountable for defective products, using the organization's leverage to push for improvements.

Challenge to Industry. ECRI challenges manufacturers of single-use medical devices to revisit and improve their QC processes to prevent defective products from reaching the market.

> Product defects can lead to waste, delays, incorrect treatment, healthcare-acquired infections, or other patient harm.

Inappropriate Use of Automated Dispensing Cabinet Overrides Can Result in Medication Errors

THREE

3

Automated dispensing cabinets (ADCs) are used to provide controlled access to medications near the point of care. These cabinets typically incorporate locked or lidded pockets, drawers, or other drug storage options. During routine use, practitioners enter their credentials at the ADC and select patient-specific medications that have been reviewed and verified by a pharmacist.

In emergencies, an ADC's controls can be overridden so that medications can be accessed more rapidly. Overrides are occasionally necessary; but this is a risky practice that bypasses the pharmacist's review of the medication order. Pharmacist review is intended to identify contraindications, unsafe dosing, duplicate therapy, patient allergies, or other potential risks.

Some high-profile medication error events, including fatal incidents, have been associated with the inappropriate use of an ADC's override feature. Concerningly, the Institute for Safe Medication Practices (ISMP) has found that, too often, practitioners view the override process as a routine step, rather than a risky one.

Any deviation from safe ADC use practices could lead to the selection and removal of the wrong medication type, strength, or dose—errors that could lead to severe harm. For this reason, ADCs should be configured to require pharmacist approval prior to allowing access to a drug; the cabinet's override feature should be used only for its intended purpose (when even a short delay would put the patient at risk); and use of the override feature should be routinely tracked and monitored.

Any deviation from safe ADC use practices could lead to the selection and removal of the wrong medication type, strength, or dose—errors that could lead to severe harm.

Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death

4

FOUR

Potentially life-threatening hazards can occur during hemodialysis, including the venous needle becoming dislodged at the vascular access point or the central venous catheter becoming separated from the bloodline used for treatment. Either event can very quickly lead to a massive loss of blood, and thus severe injury or death. Often, such events cannot be detected by a hemodialysis machine's venous pressure monitor—and so will not produce an alarm.

Dislodgements or detachments can be caused by, for example, a person tripping on a bloodline, a line snagging on an object during patient movement, or someone pulling on the line (either knowingly or unknowingly). Such occurrences, which likely are underreported, are of particular concern if dialysis is being provided in the home or some other location where a trained caregiver is not available to respond immediately.

Protective measures include using a blood leakage detector at the vascular access site, particularly for home patients and for patients who may be restless or disoriented or are otherwise at higher risk of venous needle dislodgement (VND) or access-bloodline separation (ABLS). Other precautions include verifying that the needle and connections are secure and keeping these sites visible (e.g., not covered by clothing or blankets) to allow frequent examination.

Challenge to Industry. ECRI challenges manufacturers of hemodialysis machines to develop systems that minimize the risk of VND or ABLS going undetected (e.g., by incorporating blood leakage detection functionality) or that prevent such separations from happening in the first place.

> Dislodgements or detachments are of particular concern if dialysis is being provided in a location where a trained caregiver is not available to respond immediately.

Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions

5

FIVE

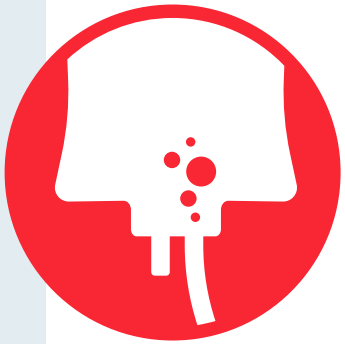
Accessing a clinical service such as an electronic health record (EHR) or a radiology system through the cloud can offer significant benefits compared with more traditional systems. This deployment model does not, however, eliminate a healthcare delivery organization's security considerations. It only changes them.

In a cloud deployment, much of the workload and control shifts to the cloud provider. Consequences of this shift are that the healthcare delivery organization must rely on the cloud company to ensure the security and reliability of its online operations and to remediate any security event and promptly restore service. Nevertheless, in most cases the liability for any failure remains with the healthcare delivery organization.

Organizations that do not both understand and plan for these differences will be at increased risk of a security event that could significantly disrupt patient care. Disruption of a cloud-based service in a healthcare environment could lead to loss of availability or integrity of that service, with the potential to cause lengthy delays in care and adverse patient outcomes. Potential breaches of patients' protected health information (PHI) are an additional concern.

To protect itself against a consequential security event, a healthcare delivery organization should evaluate how a cloud provider safeguards both the functionality of its system and the confidentiality and availability of patient data. In addition, the organization should implement appropriate internal security controls to reduce the risks.

> A cloud-based deployment model does not eliminate a healthcare delivery organization's security considerations. It only changes them.



Inflatable Pressure Infusers Can Deliver Fatal Air Emboli from IV Solution Bags

6

SIX

Inflatable pressure infusers (IPIs) are simple, mechanical devices that compress an IV solution bag to allow pressure-assisted infusions. In certain circumstances, using an IPI to administer fluids creates an increased risk of infusing air from the IV bag into the patient—specifically, if (1) the air is not purged from the bag before use *and* (2) the bag is allowed to be compressed completely flat by the IPI during use.

This could cause an embolism that, depending on its size and location, could lead to circulatory collapse, stroke, or death. Using IPIs to infuse through intracardiac catheters and sheaths is of particular concern.

Unlike infusion pumps, IPIs do not include any mechanism for detecting or eliminating air in the IV line, and thus cannot prevent air infusion. Therefore, it is incumbent on the user to purge as much air as possible from the IV bag before placing it in an IPI; to always hang the bag, not lay it flat (to keep any remaining air at the top of the bag); and to prevent the bag from being compressed completely flat by the IPI.

ECRI recommends avoiding the use of IPIs for continuous infusion through vascular sheaths and catheters that terminate in the left heart. Even small amounts of air introduced in this location can be fatal.

Challenge to Industry. ECRI challenges manufacturers to develop technical solutions that eliminate or minimize the risk of infusing air from an IV bag.

ECRI recommends avoiding the use of IPIs for continuous infusion through vascular sheaths and catheters that terminate in the left heart. Even small amounts of air introduced in this location can be fatal.

Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination

SEVEN

7

The importance of effectively cleaning and disinfecting ventilators is obvious: Ventilator components can become contaminated by exhaled gases and, potentially, by airway excretions. Unfortunately, the reprocessing instructions provided by ventilator manufacturers are, in some cases, incomplete or confusing; and even guidance from regulatory authorities is not always clear. The result is that reprocessing staff may be confused about which ventilator components need cleaning/disinfection, how to carry out the process, and how frequently it should be done.

Lack of clarity about the cleaning and disinfecting steps to be taken between patients can lead to ineffective reprocessing of ventilator components. This in turn increases the risk of cross-contamination, an otherwise preventable occurrence that can lead to the spread of infectious disease.

Areas of confusion include:

- Whether internal exhalation valves or other reusable ventilator components that come into contact with exhaled patient gas require high-level disinfection (or sterilization) between patients. ECRI believes they do.
- Whether use of a filter in the breathing circuit is sufficient to prevent contamination of ventilator components. ECRI believes it is not. The primary purpose of the filter is to limit the spread of pathogens through the atmosphere, not to protect ventilator components from contamination.

Challenge to Industry. ECRI challenges manufacturers to ensure that their instructions for cleaning and disinfecting ventilator components are complete, clear, well documented, and realistically achievable. The instructions should specify the frequency of cleaning and/or disinfection for all essential ventilator components.

> Reprocessing instructions provided by ventilator manufacturers are, in some cases, incomplete or confusing; and even guidance from regulatory authorities is not always clear.

Common Misconceptions about Electrosurgery Can Lead to Serious Burns

8

EIGHT

Electrosurgical units (ESUs) use concentrated electrical currents to cut and coagulate patient tissue at the site of application. These workhorses of the OR have been in use for decades. Nevertheless, misconceptions about their use persist, and the systems can—and sometimes do—cause unintended burns if operators do not fully understand the risks.

Misconceptions associated with monopolar electrosurgery include:

- That using multiple ESUs simultaneously on one patient presents no added risk. In reality, burn risks can increase exponentially when multiple ESUs are used.
- That the surgeon should activate the ESU's active electrode before its tip is in contact with the patient. In fact, doing so causes a high voltage to develop in the ESU circuit, increasing the likelihood of patient or clinician injury.
- That the return electrode pad can never be safely applied over an orthopedic metal implant, tattoo, or piercing—an assumption that may prompt users to place the return electrode over a less safe part of the anatomy (e.g., a bony prominence). In fact, ECRI's laboratory testing indicates that placing the return electrode over metal objects embedded in simulated surgical tissue does not heat or burn the surrounding tissue during ESU activation. (Note, however, that placement of the return electrode over a pacemaker or other electronic implant generally should be avoided.)

An incomplete understanding of the risks associated with any of the components involved in the electrosurgical circuit can lead to patient or clinician burns or other injuries.

> Electrosurgical units can cause unintended burns if operators do not fully understand the risks.

Overuse of Cardiac Telemetry Can Lead to Clinician Cognitive Overload and Missed Critical Events

9

NINE

Overuse of cardiac telemetry monitoring—specifically, its use on noncardiac patients—can lead to alarm fatigue, clinician cognitive overload, and ultimately unrecognized critical events.

Telemetry monitors are patient-worn devices that allow the patient's heart rate, heart rhythm, and other physiologic conditions to be assessed without restricting the patient to a bed. They are best suited for cardiac patients who are well enough to move around the facility, but who nevertheless need constant monitoring. However, there has been a trend toward using telemetry monitoring as a safety net for patients who do not have cardiac issues.

Paradoxically, this increased use of cardiac telemetry monitoring (for patients who do not require it) can lead to patients overall being less effectively monitored: It invariably leads to an increase in alarms—some of which will not require immediate action but nevertheless vie for the clinician's attention. This increased alarm load can overwhelm and distract care providers, creating the conditions that can lead to a critical alarm being missed and a patient's deterioration going unrecognized. ECRI is aware of incidents in which telemetry alarm events went unnoticed, in some cases resulting in patient harm.

To minimize the risk, healthcare providers should establish clear criteria defining when telemetry monitoring should be used, as well as when it should be discontinued. In practice, this means verifying that telemetry is being prescribed appropriately (i.e., to monitor the right patient populations) and regularly assessing each patient's need for continued telemetry monitoring.

Paradoxically, increased use of cardiac telemetry monitoring (for patients who do not require it) can lead to patients overall being less effectively monitored.

Underreporting Device-Related Issues May Risk Recurrence

10

TEN

Reporting medical-device-related problems is crucial for keeping patients and staff safe. Unfortunately, problems aren't always reported through appropriate channels, if at all. The reasons for this can vary:

- Device users may be focused on patient care and unable to interrupt a time-sensitive task to submit a report.
- They may be unfamiliar with the method for reporting.
- They may see little benefit to reporting, particularly if no harm was observed.
- They may fear disciplinary action or other personal consequences.

As a result, broken, malfunctioning, poorly manufactured, or poorly designed devices may remain in use.

Attempting to use faulty devices can, at the very least, waste clinician time as users try to effect workarounds or to quickly locate replacement equipment. More significantly, continuing to use deficient equipment can lead to patient harm.

In contrast, when problems are reported as soon as they are noticed, they can often be remedied before patient care is affected. To achieve this goal, healthcare organizations need to identify and eliminate barriers to reporting. Most importantly, they must make the reporting process as easy as possible in order to minimize disruptions to patient care tasks. Other measures include building a culture of safety (to encourage reporting), educating staff about how to identify device-related hazards, providing feedback to keep staff informed about the status of a report, and promoting the "wins"—that is, instances in which a report prevented significant harm or led to meaningful improvements.

> Continuing to use deficient equipment can lead to patient harm.

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. Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm

Helping patients with recalled Philips CPAP devices used in home [webinar recording]. 2022 Jun 24.

Medtronic—HeartWare ventricular assist device systems: welding defect in internal pump may cause pump malfunction [update] [MHRA FSN 2022/005/012/611/003]. *ECRI Alerts* 2022 Aug 4. Accession No. A39103 04. (To locate additional alerts related to this product, search *ECRI Alerts* using the search term "HeartWare Ventricular Assist Device Systems.")

2. Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk

Hospital Consumables and Supplies. A page describing ECRI's Supply Guide program, including the Utilization Analytics module and Functional Equivalents service.

Investigating overinfusions—award-winning joint effort by Lower Mainland Biomedical Engineering and Vancouver Coastal Health has a global impact. *Device Evaluation* 2020 Nov 11.

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

The following examples from *ECRI Alerts* illustrate the types of problems that occur, as well as the ubiquity of such reports; the examples are a sampling from just one four-week period near the end of 2022:

- 2022 Oct 20: Cardinal Health—Vistec x-ray detectable sponges: may be frayed [ECRI Exclusive Hazard Report]. Accession No. H0804.
- 2022 Oct 20: Medtronic—HeartWare ventricular assist device systems: may exhibit a delay or failure to restart; manufacturer develops alternative pump start algorithm [update]. Accession No. A36178 04.
- 2022 Oct 24: GlaxoSmithKline—BOOSTRIX DPT booster vaccine: syringes may be cracked. Accession No. A39763.
- 2022 Nov 3: Datascope/Getinge—LINEAR intra-aortic balloon catheters: balloon volume may be incorrectly labeled. Accession No. A39828.
- 2022 Nov 3: Teleflex—Iso-Gard filter S products: may split or detach during use [FDA Class I]. Accession No. A39636 01.
- 2022 Nov 11: BD—SafetyGlide shielding hypodermic needles (one lot): may be difficult to administer medication [ECRI Exclusive Hazard Report]. Accession No. H0808.
- 2022 Nov 14: BD—Insyte Autoguard catheters (one lot): may have surface irregularities and roughness [ECRI Exclusive Hazard Report]. Accession No. H0809.
- 2022 Nov 18: Baxter—SUB-Q-SET subcutaneous infusion sets: needle may not be beveled [ECRI Exclusive Hazard Report]. Accession No. H08011.

3. Inappropriate Use of Automated Dispensing Cabinet Overrides Can Result in Medication Errors

***Device Evaluation* Resources:**

- Pharmacy Technology and Medication Management: The Essentials. This web page features a collection of Device Evaluation resources on technologies used to manage medication preparation, storage, compounding, packaging, and dispensing.
- Medication distribution approaches and technologies. *Device Evaluation* 2018 Oct 3.

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

- Best practice 16. In: *Targeted medication safety best practices for hospitals.* 2022. [Access requires free registration.]
- *ISMP guidelines for the safe use of automated dispensing cabinets.* 2019 Feb 7. [Access requires free registration.]
- Over-the-top risky: overuse of ADC overrides, removal of drugs without an order, and use of non-profiled cabinets. 2019 Oct 24.

— Safety enhancements every hospital must consider in wake of another tragic neuromuscular blocker event. 2019 Jan 17.

4. Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death

Hemodialysis risks with central venous catheters—will the home dialysis push increase the dangers? Hazard #4—2020 top 10 health technology hazards. *Device Evaluation* 2019 Sep 26.

Hemodialysis venous catheter components may disengage during routine use, quickly causing patient harm or death [ECRI Exclusive Hazard Report]. *ECRI Alerts* 2019 Jul 11. Accession No. H0526.

Undetected venous line needle dislodgment during hemodialysis. *Device Evaluation* 1998 Nov;27(11):404-5.

Undetected venous needle dislodgment or access-bloodline separation during hemodialysis can lead to death [ECRI Exclusive Hazard Report]. *ECRI Alerts* 2022 Mar 31. Accession No. H0758.

5. Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions

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

Choosing cloud services for point-of-care ultrasound: what you need to consider. *Device Evaluation* 2019 Nov 27.

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

6. Inflatable Pressure Infusers Can Deliver Fatal Air Emboli from IV Solution Bags

Inflatable pressure infusers may infuse residual air from IV solution bags resulting in air emboli [ECRI Exclusive Hazard Report]. *ECRI Alerts* 2022 Apr 1. Accession No. H0706.

A case study describing this hazard is included in: ECRI. Healthcare Incident Management and Investigation Course, Module 4. 2022. (Purchase required; learn more at: https://www.ecri.org/healthcare-incident-management-investigation-course.)

7. Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination

Respiratory Assistance Technologies: The Essentials. This web page features a collection of Device Evaluation resources on ventilators and other respiratory assistance technologies.

Safe cleaning and disinfection of ventilators: ECRI's recommendations. *Device Evaluation* 2021 Oct 6.

8. Common Misconceptions about Electrosurgery Can Lead to Serious Burns

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

ECRI Institute provides 3 keys to safe return electrode use during monopolar radiofrequency ablation [ECRI Exclusive Hazard Report]. *ECRI Alerts* 2015 Sep 29. Accession No. H0248.

Evaluation background: active laparoscopic electrode shielding systems. *Device Evaluation* 2020 Oct 7.

General risks and protective measures during laparoscopic monopolar electrosurgery. *Device Evaluation* 2016 Oct 14.

Using electrosurgery on patients with jewelry, body piercings, and tattoos. *Device Evaluation* 2023 Jan 11.

Using multiple electrosurgical units on one patient: what to do when you can't avoid it. *Device Evaluation* 2018 May 30.

9. Overuse of Cardiac Telemetry Can Lead to Clinician Cognitive Overload and Missed Critical Events

Device Evaluation Essentials Pages—The following web pages feature a collection of Device Evaluation resources on the topics and technologies listed:

- Alarm Management: The Essentials
- Physiologic Monitoring: The Essentials

Clinical alarms. *Health System Risk Management* 2020 Mar 30.

Evaluation background: telemetry systems with integrated displays. *Device Evaluation* 2022 Jun 22.

Improper customization of physiologic monitor alarm settings may result in missed alarms. Hazard #7—2019 top 10 health technology hazards. *Device Evaluation* 2018 Sep 26.

Improving patient surveillance in telemetry: don't just rely on the monitor. *Device Evaluation* 2015 Sep 16.

Inadequate surveillance of monitored patients in a telemetry setting may put patients at risk. Hazard #4—top 10 health technology hazards for 2016. *Device Evaluation* 2015 Nov 7.

Integrated-display telemetry transmitters: key capabilities that can keep patients safe. *Device Evaluation* 2022 Apr 20.

Over-reliance on arrhythmia detection algorithms in physiologic monitoring systems puts patients on telemetry at risk [ECRI Exclusive Hazard Report]. *ECRI Alerts* 2015 Jun 12. Accession No. H0261.

Preventing the overuse of cardiac telemetry monitoring—Christiana Care Health System's award-winning project. *Device Evaluation* 2015 Jan 14.

10. Underreporting Device-Related Issues May Risk Recurrence

***Device Evaluation* Resources:**

- Don't lose the evidence—sequestering equipment after an incident. 2014 Mar 5.
- Evidence storage and recovery policies and procedures. 2014 Mar 5.
- Investigating overinfusions—award-winning joint effort by Lower Mainland Biomedical Engineering and Vancouver Coastal Health has a global impact. *Device Evaluation* 2020 Nov 11.
- Overwhelmed recall and safety-alert management programs. Hazard #10—top 10 health technology hazards for 2015. 2014 Nov 24.

ECRI Educational Resource:

- Healthcare Incident Management and Investigation Course. Online course from ECRI's Accident and Forensic Investigation Service.

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

- **Reporting:**
  - Pump up the volume: tips for increasing error reporting and decreasing patient harm. 2021 Aug 26.
  - Reporting and second-order problem solving can turn short-term fixes into long-term remedies. 2016 May 19.
  - Safety requires a state of mindfulness (part 1). 2014 Jul 31.
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