ECRI | The Most Trusted Voice in Healthcare

ECRI's Top 10 Health Technology Hazards for 2024

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MDEXPO

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I am not a Clinical Engineer/Biomedical Professional

Agenda

- About ECRI
- Purpose and Scope
- Identifying & Addressing Health Technology Hazards
- The 2024 List
- Questions

About ECRI

An independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings worldwide.

Nonprofit Advancing Effective, Evidence-based Healthcare Globally

Technology Decision Support

Capital, Supplies & Purchased Services Decision Support

Healthcare Device Evaluation & Alerts

Value Analysis Workflow

Cybersecurity

Medical Equipment Planning

Patient Safety

Patient Safety Organization

Infection Prevention

Healthcare Risk Assessments & Management

Safe Medication Practices

Accident & Forensic Investigation

Aging Services Care Delivery

Evidence-based Medicine

Clinical Evidence Assessments

Evidence-based Practice Center

Emerging Technologies Profiles & Forecasts

Genetic Test Assessments

Horizon Scanning

ECRI Guidelines Trust™

ECRI's Medical Device Evaluation Program > 50 Years!

Technology Decision Support

Independent Testing & Evaluation Lab

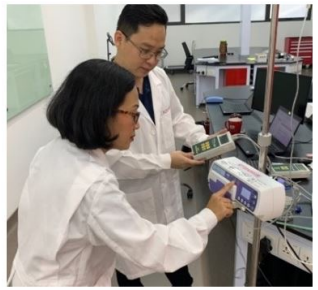
The only independent medical device testing and evaluation lab in North America and Asia Pacific

PROGRAM OBJECTIVES

To improve the **effectiveness, safety, and economy** of health services by:

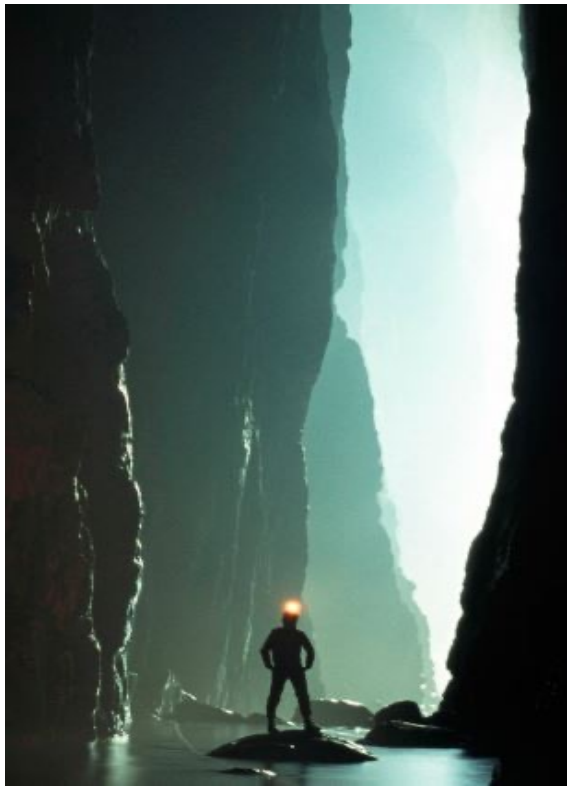
- Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
- **Functioning as an information clearinghouse for hazards and deficiencies in medical devices.**
- Encouraging the improvement of medical devices through an informed marketplace.



Purpose of the Top 10 Health Technology Hazards List

- The 2024 list is the 17th edition (first edition published November 2007)
- Motivation: Prevent harm by preventing hazards that have the clear potential to:
  - Cause death or serious injury
  - Adversely affect patient care
- Key features:
  - **Predictive**, not retrospective
  - Step by step recommendations for action
- Goal:
  - Shine a light on health technology safety issues
  - **Awareness → assurance**: Create a tool healthcare professionals can use to:
    - Set patient safety priorities
    - Implement effective changes



About ECRI

- Formed in 1968 by a Physician
- Non-Profit Worldwide Company with 550 Employees
- Designated as a PSO (Patient Safety Organization) by US Health & Human Services
- Acts as Clearing House for Pennsylvania Patient Safety Reporting System as Well as 17 Other States
- Employs Clinicians Including Physician, Nursing, Imaging, Laboratory, Respiratory and Cardiovascular Specialists
- All Research Staff are PhD.

The Max Cart – First Crash Cart – Invented by ECRI Founder

The Max Cart – First Crash Cart – Invented by ECRI Founder

Purpose & Scope

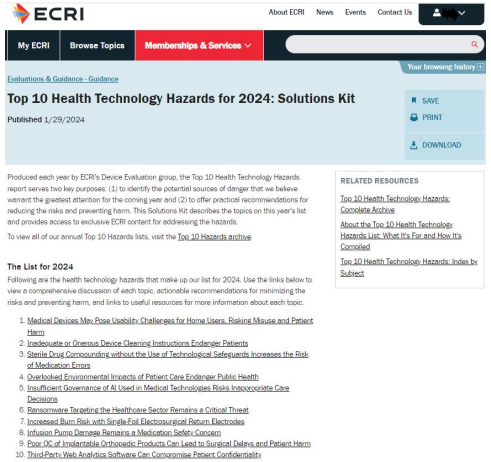
Why produce the list?

What is a “health technology hazard”?

How are topics selected?

Now Available: ECRI's Top 10 Health Technology Hazards for 2024

A tool for reducing preventable harm



Full Report

- ECRI members only
  - Detailed problem descriptions
  - Step-by-step recommendations
  - Helpful background to provide context
  - Resources for additional guidance

Executive Brief

- Free to the public (download)
  - One-page summary of each topic

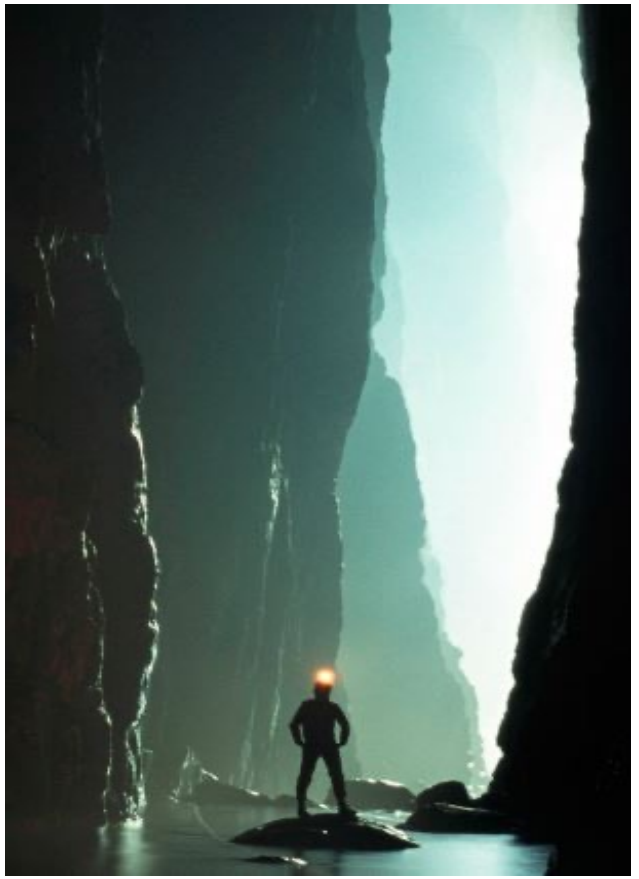
TO ACCESS THESE MATERIALS:

Non-members (Executive Brief): www.ECRI.org/2024hazards

Members (All content): https://ly.ecri.org/2024Top10Hazards

Purpose

- Motivation: Reduce harm by preventing hazards that have the clear potential to:
  - Cause death or serious injury
  - Adversely affect patient care
- Goal:
  - Shine a light on health technology safety issues
  - Provide healthcare professionals with a tool to help:
    - Set patient safety priorities
    - Implement effective changes
- Key features:
  - **Predictive**, not retrospective
  - Step by step recommendations for action



Scope: How Topics Are Identified and Selected

Definition

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

Sources: Insights gained . . .

- ✓ Investigating incidents
- ✓ Testing medical devices
- ✓ Analyzing problem reports
- ✓ Assessing healthcare practices
- ✓ Reviewing the literature
- ✓ Speaking with stakeholders

In Scope

- ✓ Generic
- ✓ Technology focus
- ✓ Preventable!
  Patient harm can be prevented if appropriate measures are taken

Criteria (one or more apply)

- ✓ Severity
- ✓ Frequency
- ✓ Breadth
- ✓ Insidiousness
- ✓ Public profile

Identifying & Addressing Health Technology Hazards

What are they?

Who needs to be involved?

Scope: Health Technology Hazards

"Hazards" defined as:

Device or system faults, design features, or methods of use that might, under certain circumstances, place patients or users at risk.

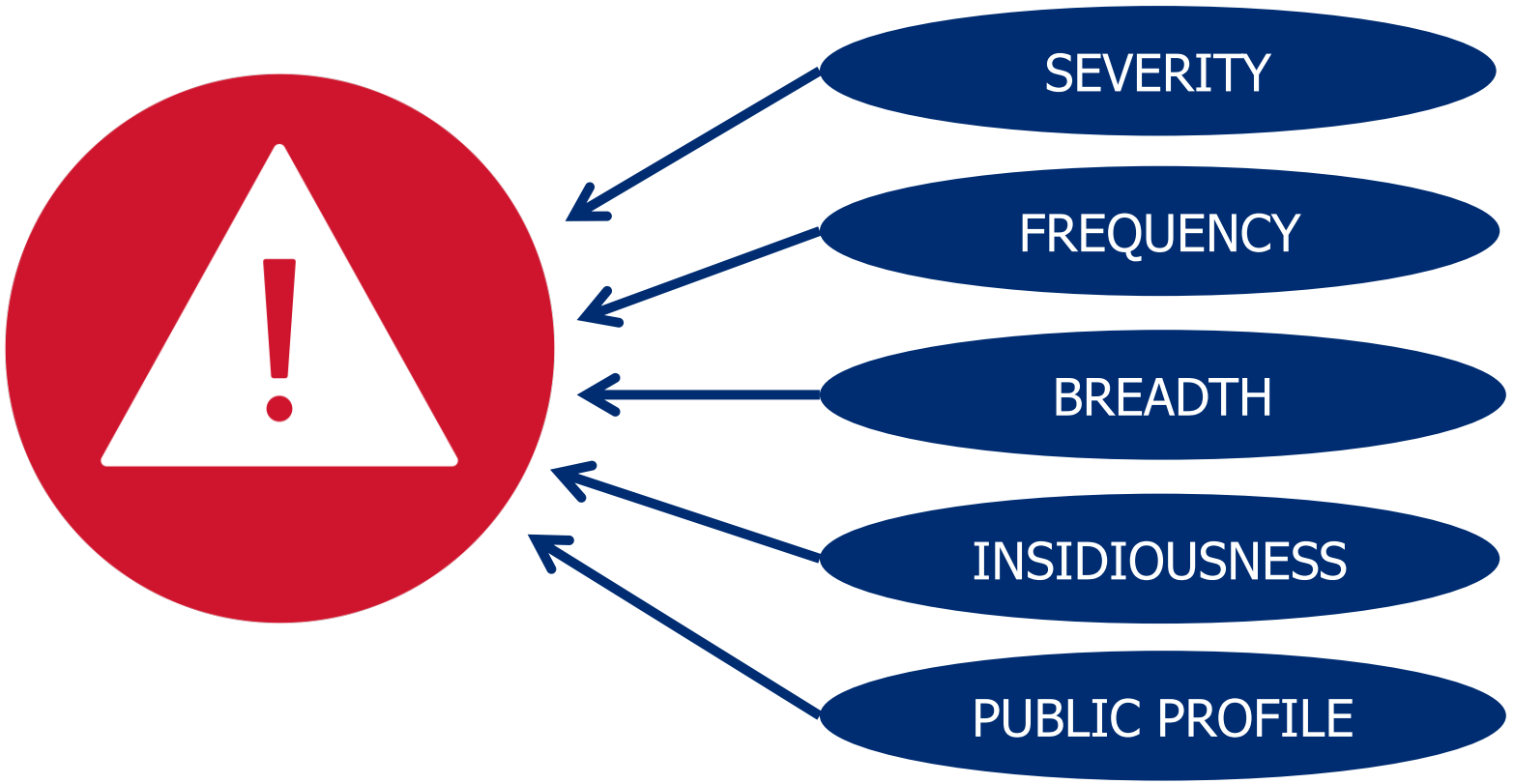
Topic Selection: Assessment Criteria

IN SCOPE

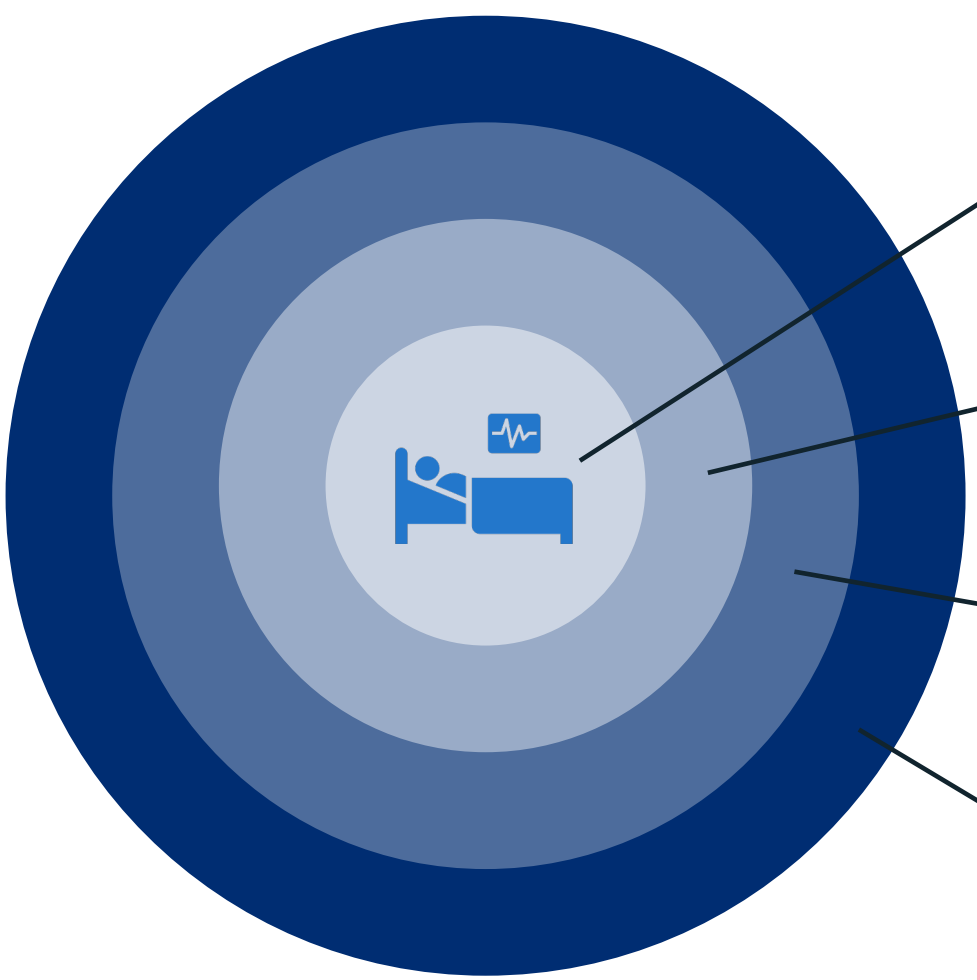
- ✓ TECHNOLOGY FOCUS
- ✓ GENERIC
- ✓ PREVENTABLE!

Patient harm **can be prevented** if appropriate measures are taken

ONE OR MORE APPLY



Identifying Hazards: Ways Technology Intersects with Patient Care



- At the bedside / manner of use
- Device design & manufacture
- Systems & processes associated with patient care
- Infrastructure supporting patient care

Improving Technology Safety: Who Should be Involved?

Investigate incidents & identify causes

Implement changes in an effective and sustainable manner

Champion the safety effort

Secure the resources to enact it

Procure safer products

Negotiate with suppliers for requested improvements

Provide clinical context

Offer real-world perspectives on the practicality of proposed solutions

The 2024 List

ECRI's Top 10 Health Technology Hazards for 2024

The 2024 List at a Glance

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

No. 1 Top 10 Health Technology Hazards for 2024

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

TREND

- Healthcare provided in the home – leads to:
- Medical devices used in the home

BENEFITS ☑

- Patient convenience and comfort
- Potential cost savings

SAFETY CONSIDERATIONS ☒

- Device usability challenges
  - Devices often not designed for home users
  - Users may lack expertise to operate device properly
- Home environment may impact device operation:
  - Space restrictions, cleaning & disinfection limitations
  - EMI, power supply reliability, electrical safety

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

RISKS

- User + Environment + Device = Interactions that can lead to:
  - Undetected events and errors
  - Misleading or misinterpreted results
  - Inappropriate response to a malfunction
- Result: Patient harm
- Examples:
  - Medication error: Mis-programming an infusion pump
  - Fatality: Ventilator alarm did not sound
  - Fatality: Venous needle dislodgment during dialysis

Photo. *Electrical safety risks in the home environment.*
Source. *ECRI webcast: Medical Device Usability Challenges for Home Users—ECRI's #1 Health Technology Hazard for 2024*

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

KEY RECOMMENDATIONS

Care Providers/Device Suppliers	Patients	Challenge to Industry
1. Select devices that are well matched to the patient and environment of use 2. Train users on proper device operation, and provide instructional materials 3. Assign a liaison within the facility to address questions patients may have while using the device	1. Discuss with your physician the risks and benefits of using the device 2. Read the instructions for use, and know who to contact if help is needed 3. Register the device with the manufacturer (to simplify communications in the event of a recall)	For devices that may be used in the home: 1. Strive for intuitive device operation 2. Create instructional materials intended for a lay audience 3. Conduct user testing to identify and address usability issues 4. Provide user support

No. 2 Top 10 Health Technology Hazards for 2024

Inadequate or Onerous Device Cleaning Instructions Endanger Patients

THE ISSUE

- Reusable devices must be reprocessed between uses (cleaning & disinfection)
- But—reprocessing instructions are often:
  - Incomplete
  - Impractical
  - Onerous
- Consequences:
  - Ineffective reprocessing & patient harm
    - Spread of infection
  - Healthcare worker injury
    - Pain/fatigue from onerous, manual tasks
  - Device damage
  - Legal & regulatory ramifications

2. Inadequate or Onerous Device Cleaning Instructions Endanger Patients

KEY RECOMMENDATIONS

- Assess reprocessing considerations for reusable medical devices and items *before* purchase
- Questions to consider:
  - Will the vendor provide validated reprocessing instructions for the product?
  - Are the reprocessing steps practical to complete in your environment?
- If not, consider alternative vendors & products

Challenge to Industry

Provide reprocessing instructions that . . .

- Are practical to complete in the intended environment of use
- Have been validated (i.e., shown to be effective and ensure safe reuse over the product's life)
- Involve the use of common healthcare cleaning products
- Otherwise adhere to relevant FDA guidance

No. 3 Top 10 Health Technology Hazards for 2024

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

THE ISSUE

- Compounding = Modifying a drug product to make a new formulation
- Errors can occur when compounding injectable medications—examples:
  - Incorrect or expired ingredients
  - Incorrect dose, concentration, or volume
  - Mislabeling the preparation
- Errors often can't be detected by those who administer the preparation—Thus:
  - They have a high likelihood of reaching the patient (if not caught in the pharmacy)
  - They can lead to fatal medication errors

3. Sterile Drug Compounding without the Use of Technological Safeguards

KEY RECOMMENDATIONS

- Pharmacy: Implement technological safeguards to minimize opportunities for human error
- Technology options range from:

- Recommended features: Look for systems that offer:
  - Bar-code verification of all source products
  - Tools for guiding users through essential steps in the compounding process
  - Remote verification of steps—via images, video, and/or gravimetric analysis
  - The ability to interface with the electronic health record (EHR)
  - Automated calculations and conversions . . . And more

No. 4 Top 10 Health Technology Hazards for 2024

Overlooked Environmental Impacts of Patient Care Endanger Public Health

THE ISSUE

- Healthcare activities have a substantial environmental impact—e.g.:
  - **Activity:** The manufacture, use, & disposal of medical technologies
  - **Impact:** These activities consume energy, release contaminants, & generate waste
- Environmental harm can:
  - Impact public health & the cost of care
  - Exacerbate health inequities
- Mission for healthcare organizations:
  - Fulfill role as stewards of public health
  - Work to reduce environmental harm

4. Overlooked Environmental Impacts of Patient Care Endanger Public Health

KEY RECOMMENDATIONS

Identify ways to minimize environmental harm *without compromising patient care*—Examples:

Reduce	Reuse	Recycle
1. Reduce energy consumption in the imaging suite 2. Limit anesthetic gas emissions 3. Curtail purchase of unnecessary single-use items	1. Define when reusable products can replace single-use ones 2. Carefully consider the risks of switching to reusables 3. Guide staff in making decisions	1. Consider options for recycling, composting, or donating 2. Review which items to designate as regulated medical waste, hazardous waste, etc.

Challenge to Industry

Design products with sustainability in mind—for example: Reduce the use of materials that contribute to environmental harm. Make products easier to clean using minimally damaging processes. Minimize waste material (e.g., packaging).

No. 5 Top 10 Health Technology Hazards for 2024

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

EXAMPLES of AI in healthcare:

- Workflow aids
  - Patient positioning for a CT or MR scan
  - Automated scheduling
- Diagnostic aids
  - Identifying problem areas in an x-ray
  - Analyzing a patient's EMR for trends

THE PROMISE of AI functionality:

- Speeding up processes
- Assisting in clinical decisions

BUT . . .

5. Insufficient Governance of AI Used in Medical Technologies

THE ISSUE

- AI results depend on . . .
  - The algorithm the AI system uses
  - The data on which it is trained
  - **Concern:** Shortcomings can lead to an inappropriate AI response
- Healthcare professionals have little . . .
  - Visibility into AI decision-making
  - Experience with this emerging technology
  - **Concern:** Users may not recognize when an AI response is inappropriate
- Inappropriate responses can impact patient care

KEY RECOMMENDATIONS

Establish an AI governance program

- When considering an AI system:
  - Assess the risks
  - Determine the impact on patient care
- During procurement—Test whether:
  - The system works with your population
  - The system works with your care practices
- After implementation:
  - Monitor performance
  - Capture problems (questionable decisions)
  - Maintain the system over time

No. 6 Top 10 Health Technology Hazards for 2024

Ransomware Targeting the Healthcare Sector Remains a Critical Threat

THE ISSUE

- Ransomware =
  - Hackers block access to IT networks
  - Apply pressure to extract a ransom
- Healthcare facilities are attractive targets:
  - Valuable data
  - Critical need to restore operations quickly
  - Limited resources for hardening defenses
- Affects on patient care:
  - Data unavailable for making care decisions
  - Delays, cancellations, diversions
  - Can overwhelm community-wide resources

6. Ransomware Targeting the Healthcare Sector Remains a Critical Threat

KEY RECOMMENDATIONS

- Deploy a framework for:
  - Identifying & protecting against risks
  - Detecting & responding to threats
  - Recovering from an attack
- Recommended practices include:
  - Configuring internet-facing systems securely
  - Implementing MFA, network segmentation, access control lists (where warranted)
  - Maintaining backup and recovery methods
  - Using the resources available from:
    - Cybersecurity Infrastructure Security Agency
    - Health Sector Coordinating Council

Challenge to Policymakers

Protective measures are not foolproof

HDOs need proactive, preventive policies to fend off and respond to attacks

Examples include funding/support for:

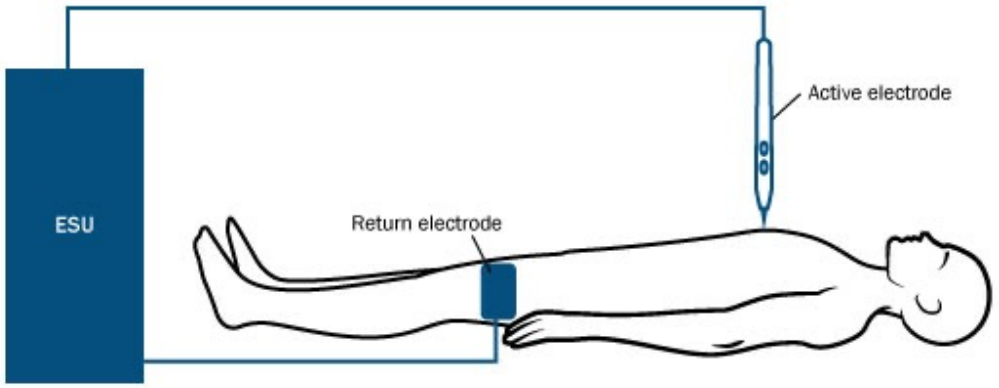
- Developing security programs
- Training and educating a security workforce
- Helping law enforcement agencies disrupt hacking operations

No. 7 Top 10 Health Technology Hazards for 2024

Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes

THE ISSUE

- Burns during electrosurgery:
  - 2023: ECRI investigated 4 incidents in which single-foil return electrodes were in use
  - Poor contact between the return electrode and the patient led to a burn



A conductive electrosurgical circuit

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

THE ISSUE (continued)

- Single-foil return electrodes do not engage a key ESU safety feature:
  - Return electrode contact quality monitor
  - Detects when contact is compromised
- Thus: Poor contact with the patient may go unrecognized
- Safer alternatives are available
  - Dual-foil conductive return electrodes
  - Capacitive return electrodes
  - Treatment modalities that do not require the use of a return electrode (e.g., bipolar electrosurgery)

KEY RECOMMENDATIONS

- For adult patients: Do not use single-foil conductive return electrodes; use an appropriate alternative
- For neonatal and pediatric patients:
  - Avoid the use of single-foil conductive return electrodes, if possible
  - Challenge: Fewer alternatives exist; a transition may be impractical

Challenge to Industry

Cease the sale of single-foil conductive return electrodes for adult patients

No. 8 Top 10 Health Technology Hazards for 2024

Infusion Pump Damage Remains a Medication Safety Concern

THE ISSUE

- Infusion pumps are used to accurately deliver fluids or medications over time
- Pumps can become damaged from:
  - Frequent handling or mishandling
  - Exposure to improper cleaning chemicals
  - Normal wear and tear
- Damage can lead to:
  - Dangerous medication administration errors
  - Delays in therapy (while staff look for a replacement pump)
- Challenge: Damage can be hard to detect

8. Infusion Pump Damage Remains a Medication Safety Concern

KEY RECOMMENDATIONS

- Clinicians: Do not use a pump if:
  - Damage is visible (e.g., door is cracked)
  - Any part of the setup seems abnormal
  - An unresolvable alarm condition occurs
- Nurse Educators: Train staff to identify:
  - Failure modes observed in your facility
  - Common signs of pump damage
- Central Equipment Distribution:
  - Follow cleaning & disinfection instructions
  - Visually inspect pumps before distribution
  - Send damaged ones to clinical engineering

Challenge to Industry

Facilitate proper cleaning & disinfection

- Verify that cleaning steps are realistic
- Provide job aids (e.g., posters)

Look for ways to advance the technology:

- Use materials that can withstand cleaning with a greater variety of chemicals
- Minimize the use of damage-prone exposed electrical interface connectors
- Minimize unnecessary hinges or moving parts
- Pursue designs that prevent gravity flow

No. 9 Top 10 Health Technology Hazards for 2024

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

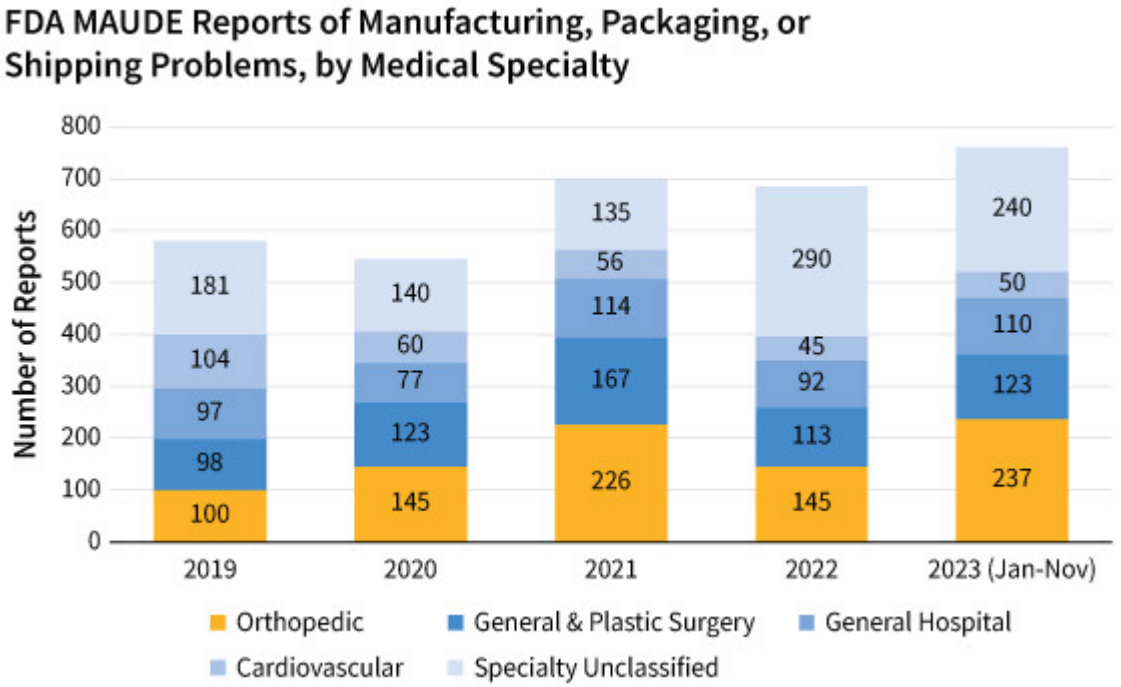
THE ISSUE

- Implantable orthopedic products include:
  - Knee and hip prostheses—plus:
  - Simple items like bone screws, rods, & plates
- Defects in these products can:
  - Delay or prolong surgery
  - Lead to infection or persistent pain, possibly long after surgery

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

THE ISSUE (continued)

- Concern:
  - Large number of device defect reports (compared with other medical specialties)
  - Points to deficient quality control (QC)
- Reports describe:
  - Breaks, cracks, and other defects
    - Harm: Implant failure, revision surgery
  - Device-device incompatibility, missing parts
    - Harm: Delay or prolong surgery
  - Incorrect labeling/packaging
    - Harm: Use of wrong product leading to incorrect treatment / pain



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

KEY RECOMMENDATIONS

For Purchasers

1. Establish a process for clinicians to report defective products
2. Track product usage – increases may indicate waste from defects
3. Identify functional equivalents
4. Use your leverage to push for improvements

For Frontline Staff

1. Check for signs of defects before use (e.g., broken components, the presence of debris or other signs of compromised sterility)
2. Report defective products
3. Sequester any product that could have contributed to an adverse incident (packaging too)

Challenge to Industry

1. Address deficiencies in QC practices!
2. Strive for zero defects in the manufacturing and packaging processes

Third-Party Web Analytics Software Can Compromise Patient Confidentiality

THE ISSUE

- Re: Web analytics software on patient portals and other provider sites
  - The good: Provides insight into website use
  - The bad: May allow third-party companies to collect patient information
  - The ugly: With that info, third parties may:
    - Learn a patient's medical condition
    - Track the patient's online activity
    - Target them with ads for unproven remedies
- Patient care consequences:
  - May redirect patients from proper care
  - May lead to distrust of healthcare provider

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

KEY RECOMMENDATIONS

- Develop policies governing the use of third-party web analytics software for sites containing patient information (e.g., patient portals):
  - Review usage agreements to determine how collected data may be used
  - Do not install third-party web analytics software unless you can:
    - Obtain a BAA (business associate agreement) with the vendor
    - Institute appropriate HIPAA-compliant settings protecting against the inappropriate use of patient data
- Audit customer-facing web applications for third-party web analytics software
  - Disable any such software that may collect patient data
  - If you learn that data previously had been shared, work with your legal team to achieve compliance with HIPAA breach notification requirements

Speaker Biography & Contact Info

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Mr. Schlessinger has BS and MBA degrees in Health Care Administration and is board certified in healthcare management by the American College of Healthcare Executives.

Mr. Schlessinger has held leadership positions in health care organizations in the Philadelphia area overseeing ancillary services including Respiratory Care, Cardiology, Neurology, Physical Medicine, Radiology, Wellness, and Pharmacy.

In his current role at ECRI, Mr. Schlessinger is the Principal Associate in the Accident and Forensics group, providing consulting services and assistance to hospitals and other healthcare institutions in matters concerning patient safety, alarm management, device integration, technology, strategic planning, operations, and capital planning.

Thank You