HealthManagement
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ECRI’s Top 10 Health Technology Hazards Report: Key Safety Issues for 2024

The purpose of ECRI's 17th edition of the Top 10 Health Technology Hazards list is to aid care providers in identifying and mitigating potential sources of harm associated with health technology. The list, compiled annually by ECRI’s Device Evaluation group, highlights risks that require attention to prioritise patient safety efforts. It serves as a tool for both care providers and device manufacturers to manage risks effectively. Reducing harm involves not only vigilance from technology managers and users but also a commitment from the medical device industry to improve designs and manufacturing practices. ECRI challenges the industry to prioritise engineering solutions over training solutions to eliminate hazards whenever possible.

ECRI’s Generic Hazards Selection Process and Rationale

The selection process for topics on the list involves nominations from ECRI's experts based on incident investigations, device testing, literature review, and consultations with various stakeholders. Factors such as severity, frequency, breadth, insidiousness, public profile, and preventability are considered in determining the final list. The aim is to spotlight hazards that can be prevented or minimised through practical actions and awareness-raising efforts. The list focuses on generic hazards inherent to certain types or combinations of medical technologies rather than specific models or suppliers. It aims to address risks that could cause serious injury or death, occur frequently, have wide-reaching consequences, be challenging to recognise, garner significant publicity, or be preventable. Including a topic on the list signifies its importance for attention in the current year, but not all hazards may apply to every healthcare facility, and the absence of a topic from previous lists doesn't imply diminished importance.

Medical Devices Usability Challenges for Home Use

The shift towards delivering healthcare in the home has led to a rise in the use of medical devices outside clinical settings, including those initially designed for hospitals like infusion pumps and ventilators. While this transition offers more comfortable care, it comes with risks: Devices may not be user-friendly for home use, and patients or caregivers may lack the necessary expertise. Environmental factors like space constraints and power supply issues further complicate device operation. ECRI has witnessed instances of patient harm in home settings, from medication errors due to unfamiliar pumps to tragic incidents like ventilator alarms failing to activate. To minimise harm, it's crucial to select devices suitable for both the patient and the home environment and provide adequate user support. ECRI calls upon manufacturers to address the unique needs of home users by making device operation intuitive, providing lay-friendly instructions, and ensuring accessible user support.

Inadequate Device Cleaning Instructions

Failure to properly clean, disinfect, or sterilise reusable medical devices between uses can lead to infections, device damage, and other harm. ECRI notes the challenge of successful reprocessing due to variations in the quality and feasibility of reprocessing instructions provided by product vendors. Many reusable medical devices have incomplete or impractical reprocessing instructions, making it difficult for healthcare workers to perform effective reprocessing and potentially causing harm.

To address this issue, healthcare organisations should consider reprocessing factors during the pre-purchase risk assessment of a product. They should ensure that vendors provide validated reprocessing instructions and that the steps are practical for their environment. If not, alternative vendors and products should be considered. ECRI challenges manufacturers to provide practical, validated reprocessing instructions adhering to relevant FDA guidance and using common healthcare cleaning products for their reusable medical devices and healthcare items.

Drug Compounding Can Lead to Medication Errors

Errors in compounding injectable medications can have severe, even fatal, consequences if undetected before administration. These errors are challenging for nurses or administrators to catch, increasing the likelihood of reaching the patient. Compounding is necessary when commercially

available formulations aren't suitable, involving modifying drugs to create new preparations. Injectable preparations are particularly concerning due to their need for sterility, compounding frequency, error opportunities, and potential harm. Errors include incorrect ingredients, doses, concentrations, volumes, or mislabeling. ECRI and the Institute for Safe Medication Practices recommend implementing technological safeguards in pharmacy departments, like workflow management systems, to minimise human error. These systems employ features such as barcoding and gravimetric analysis to prevent and catch errors during compounding.

Environmental Impact of Patient Care Endangers Public Health

Medical technologies are vital in patient care but also have environmental costs in their manufacture, use, and disposal, contributing to energy consumption, contamination, and waste. This environmental impact leads to public health challenges and worsens health disparities, particularly affecting disadvantaged communities. Healthcare organisations should prioritise minimising environmental harm by making wise decisions in technology selection, use, and disposal, which can enhance sustainability and financial performance. Strategies include reducing energy consumption, opting for eco-friendly alternatives, and minimising single-use items. ECRI challenges medical device manufacturers to prioritise sustainability in product design by using environmentally friendly materials, facilitating easy cleaning of reusable products, and reducing waste.

Insufficient Medical AI Governance Could Lead to Inappropriate Care Decisions

Artificial intelligence (AI) is increasingly integrated into various healthcare devices and systems, ranging from workflow aids to diagnostic support systems. While AI can speed up processes and aid clinical decisions, its effectiveness depends on the quality of algorithms and training data. Instances of AI contributing to harm or providing misleading results have been reported. Moreover, healthcare providers often lack visibility into AI decision-making processes and training data, making it challenging to assess system performance. To address these challenges, healthcare institutions need robust AI governance programmes covering all stages of technology adoption and use. This includes assessing risks, testing system compatibility with patient populations and care practices during procurement, and ongoing monitoring and maintenance post-implementation.

Ransomware Attacks Remains a Critical Threat

Healthcare providers are increasingly targeted by hackers aiming to infiltrate IT networks and demand ransom payments. These attacks disrupt patient care by encrypting data, compromising system operations, and causing the closure of medical facilities. The cascading effects overwhelm healthcare resources, necessitating robust cybersecurity measures. Healthcare delivery organisations (HDOs) should implement frameworks for risk identification, protection, detection, response, and recovery. However, HDOs face challenges in managing cybersecurity risks and require support from policymakers. Policymakers should incentivise strong security programmes, provide resources, enhance law enforcement tools, and reconsider penalty structures for ransomware victims.

Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes

Using single-foil conductive return electrodes in electrosurgery poses a risk of burns to adult patients because they do not engage an essential safety feature, the return electrode contact-quality monitor (RECQM). ECRI received reports of burns associated with these electrodes in 2023, highlighting the need for safer alternatives such as dual-foil conductive return electrodes, capacitive return electrodes, or alternative treatment modalities. Clinicians may not be aware of these risks or available alternatives. ECRI challenges return electrode manufacturers to stop producing and selling single-foil conductive return electrodes, particularly for adult patients.

Infusion Pump Damage is a Safety Concern

Damage to infusion pumps can lead to inaccurate medication delivery and dangerous errors, as well as delays in therapy and risks to multiple patients if unnoticed. In one incident, a broken component went unnoticed for weeks, causing harm to a patient. Infusion pumps are vulnerable to damage due to mishandling, exposure to improper cleaning, or normal wear and tear. Identifying pump damage is challenging but crucial for patient safety. ECRI calls upon manufacturers to improve pump design with fewer damage-prone components, better prevention of gravity flow, and materials resistant to various cleaning chemicals. Simplified cleaning steps and support for validated cleaning methods are also encouraged.

Low-Quality Implantable Orthopaedic Products can Harm Patients

ECRI continues to express concern about the prevalence of defective single-use medical devices, with a specific focus this year on implantable products for orthopaedic procedures. These products, ranging from simple items to complex prostheses, have seen issues such as incorrect labelling, device-device incompatibility, and defects like breaks or cracks. Such defects can lead to surgery delays, prolonged procedures, and patient harm. Healthcare organisations are urged to educate users on detecting defects, track reported issues, and hold manufacturers accountable for improvements. ECRI challenges manufacturers to aim for zero defects in their manufacturing and packaging processes.

Patient Confidentiality at Risk from Third-Party Web Analytics Software

Third-party web analytics software used by businesses for website insights poses a hidden risk for healthcare organisations. Installed on patient portals and provider websites, these tools may allow companies like Meta, Google, or Adobe to collect patient data, potentially revealing medical conditions. This data could be misused to target patients with ads related to their conditions or discrimination. While HHS investigates HIPAA violations, disagreement exists over the risk. Regardless, ECRI advises healthcare organisations to remove such software from patient portals and other relevant pages to maintain patient trust in the confidentiality of their medical information.

Source: ECRI

Image Credit: iStock

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