"Evolving Patterns of Medical Device Hazards: A Comprehensive Study"

Zerin Ziaudeen[1], Selvam Jesiah[1*], Anusha Dakshinamoorthi[2], Tanima Chinnu Tomi[3]

[1] *Sri Ramachandra Faculty of Management Sciences, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, Tamil Nadu, India*
[2] *Department of Pharmacology, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, Tamil Nadu, India*
[3]*Department of Biomedical Engineering, SK Hospital, Trivandrum, Kerala, India*

***Correspondence:**
Dr. Selvam Jesiah
Sri Ramchandra Faculty of Management Sciences, Sri Ramachandra Institute of Higher Education and Research (SRIHER),Chennai-600116, Tamilnadu, India
Email : selvamjesiah@sriramachandra.edu.in

KEYWORDS

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ABSTRACT

Introduction: The "Emergency Care Research Institute's" (ECRI's) annual "Top 10 Health Technology Hazards (HTH) report" has been a reliable resource for healthcare providers, helping them prioritize patient safety. However, there is currently a lack of comprehensive HTH data assessment to aid hospitals in their decision-making.

Objective: This study seeks to bridge the existing knowledge gap of HTHs by conducting an analysis of hazard data spanning multiple years. The findings will equip hospitals with the necessary information to make strategic decisions on risk reduction, equipment management, MDAE prevention, and the acquisition of new technologies to enhance safety within healthcare settings.

Methods: Retrospective observational study using descriptive and analytical approach was conducted on secondary data of HTH report obtained from ECRI's website and other open access data repositories. The data was collected from the year 2010 to 2023 (spanning 13 years), and was subsequently organized, reviewed and analysed using Microsoft Excel and IBM SPSS Statistics to reveal any recurrent patterns and trends.

Results: According to the study, 7.7% of concerns were related to endoscope infections and while 4.6% were linked to medication errors from infusion pumps. Therapeutic devices were responsible for 22% of hazards, while diagnostic devices caused 5%. Alarm- related issues (7.7%), radiation-related hazards (4.6%), cybersecurity concerns (5.4%), and data integrity challenges (4.6%) were also significant contributors.

Conclusion: Tackling challenges such as therapeutic device hazards, infection control risks, radiation exposure, cybersecurity threats, and data integrity issues is crucial for improving patient safety and maintaining reliable operations in the rapidly evolving technological environment of healthcare facilities.

1. Introduction

The growing demand for medical devices in hospitals has been fuelled by various factors, including the aging population, the rise in chronic diseases, technological advancements, and increased healthcare expenditures [1,2]. Additionally, the trend of wearable devices in healthcare, driven by advances in data analysis techniques, should not be overlooked [3]. This increasing demand is a positive development for the healthcare industry as it encourages the development of advanced medical technologies that can enhance patient care and reduce costs. Nevertheless, this growing demand also increases the likelihood of adverse events related to medical devices (MDAEs) [4]. MDAEs are any "unintended" or "unexpected" events that occur during the use of a medical device and result in harm to the patient. Underreporting of adverse events, especially infectious complications, is a significant issue[5]. Examples of MDAEs include device malfunctions, device-related infections, and allergic reactions to medical devices[3]. MDAEs can be caused by various factors, including device complexity, user error, and device defects, and can range from minor to life-threatening incidents. To mitigate risks and create a safer healthcare environment, hospitals must be aware of the evolving patterns of health technology hazards(HTHs).

It is important that hospitals and healthcare providers are updated about these device related errors, so they can be prepared to mitigate the impact and develop strategies for operational stability and foster an environment of safety for both the staff and patient. The "Food and Drug Administration (FDA)", "Therapeutic Goods Administration (TGA)", "Central Drugs Standard Control Organisation (CDSCO)", and "ECRI Institute (ECRI)" are all organizations that play a vital role in evaluating MDAEs. These organizations contribute to the evaluation of MDAEs in a number of ways. They collect and analyse reports of MDAEs from manufacturers, healthcare providers, and patients, conduct research to identify the causes of MDAEs and develop strategies to prevent them, develop and disseminate guidelines for the safe use of medical devices and work with manufacturers to improve the safety of medical devices[6–9].

ECRI, originally founded as Emergency Care Research Institute, is an independent nonprofit organization that aims to improve the safety, quality, and cost-effectiveness of care across all healthcare settings worldwide[9]. Each year, ECRI releases a report on the top 10 health technology hazards. The list is created by ECRI's Device Evaluation group and identifies potential sources of danger that they believe warrant the greatest attention for the coming year. The list reflects their judgment about which risks should receive priority now[10]. The full report includes detailed problem descriptions and ECRI's step-by-step recommendations for addressing the hazards and is available to members of ECRI programs through their membership web pages. An abridged version of the report is provided as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems[10,11]. Despite the availability of this report, there is currently no comprehensive evaluation of hazard data to aid hospitals. This study aimed to address this gap in knowledge. The primary objective of this study was to systematically categorize and examine HTH based on their reported incidence over a 13-year timeframe. Examining hazard data from multiple years, will enable hospitals to implement evidence-based strategies for managing current equipment and preventing medical device adverse events (MDAE). By understanding the trend of hazards, hospitals can make informed decisions about purchasing new equipment and mitigating risks to create safer healthcare environment.

2. Methodology

2.1 Study design, data collection, inclusion & exclusion

This study adopted a retrospective observational design, leveraging secondary data sources and employing both descriptive and analytical approaches. The annual top 10 health technology hazards (HTH) compiled by ECRI were gathered from the organization's website and relevant open-access repositories, covering the period from 2010 to 2023. A comprehensive analysis of

130 hazards was conducted. The study excluded reports not published by ECRI, those outside the specified timeframe, incomplete reports lacking sufficient information, and content unrelated to HTH.

2.2 Data structuring

Phase 1: The first phase involved organizing the data on HTH chronologically and color-coding them for easy identification by medical device type using MS Excel.
Phase 2: During the second phase of the assessment, the identified medical devices, including endoscopes, ventilators, anesthesia machines, infusion pumps, syringe pumps, CT, MRI machines, fiber optic light sources, surgical staplers, defibrillators, surgical diathermy equipment, and point-of- care ultrasound, were prioritized according to the frequency of HTH occurrence to identify those that pose a significant risk to hospitals and warrant attention for risk mitigation. These devices were subsequently categorized into two groups: therapeutic devices (Endoscope, Ventilators, Anesthesia machine, Infusion pump, Syringe pump, Fiber optic light source, surgical stapler, Defibrillator, Surgical diathermy equipment) and diagnostic devices (CT, MRI, Point of care ultrasound), based on their respective functionalities to facilitate further analysis.
Phase 3: The third phase involved identifying recurring themes, such as "alarms-related issues," "radiation-related hazards," "cybersecurity concerns," and "data integrity challenges," through the assignment of colour codes for efficient categorization.
Phase 4: In the fourth phase, goodness of fit was assessed using SPSS to determine whether the reporting varied across the timeline based on the identified hazard themes or the device classification.[12]
2.3 Statistical Analysis
Descriptive analysis determined the frequency distribution and percentage of occurrences of HTH, Chi-square goodness of fit test was performed to check whether the hazard distribution fits the set of observations.[12] Data was entered and colour coded in Microsoft Excel and analysed using IBM SPSS Statistics, the data was reviewed and verified by a biomedical engineer, pharmacovigilance expert and healthcare management specialist during each of the four stages. STROBE checklist was used for reporting.

3. Results

3.1 Descriptive analysis:
Among the 130 hazards reviewed, 12 medical devices were identified to pose significant risks, and these devices were reported 36 times during the study period (Table 1). The descriptive analysis indicated that the primary concerns were focused around the risks of endoscope infections, accounting for 7.7% of the total hazards reported followed by medication errors associated with infusion pumps (4.6%) and ventilator usage (3.8%) (Table 1). To emphasize the enduring and significant nature of the issues at hand, it must be noted that these hazards have been consistently reported for over five years (Figure 1). Furthermore, the recent hazard reports have brought to light the issue of surgical stapler misuse and malfunction, the presence of ferromagnetic objects in MRI rooms, non-adherence to syringe pump best practices, and the absence of safeguards in point-of-care ultrasounds as per (Table 1).

Table 1. Description of the Medical device hazards

Medical device	Persistence over 13yrs (2010 - 2023)		Reported hazards	Year hazard reported
	Frequency	Percentage		
1. Endoscope	10	7.7%	Improper cleaning, disinfection, and handling of endoscopes, which posed risks of spreading pathogens and exposing patients to infection.[13–20]	2010,2011,2012,2013, 2014,2015,2016,2018, 2019,2022

2. Infusion Pump	6	4.6%	Errors associated medication administration using infusion pumps, damaged pump, overlook of safety steps.[15–17,20–22]	2012,2013,2014, 2017 2019,2022
3. Ventilator	5	3.8%	Ventilator disconnections, improper operation, missed alarms, confusing cleaning and decontamination requirements.[18,20,21,23,24]	2015,2016,2017,2019, 2023
4. CT	4	3.1%	High radiation doses from CT scans.[13–15,17]	2010,2011 2012,2014
5. Surgical stapler	3	2.3%	Improper positioning, uneven distribution, misuse, malfunction.[13,21,25]	2010,2017, 2020
6. MRI	2	1.5%	Ferromagnetic objects in the MR environment and the potential dangers of missing implant data during MRI scans.[13,25]	2010,2020
7. Fibre optic light	1	0.8%	Burns.[13]	2010
8. Defibrillator	1	0.8%	Failures during emergency resuscitation.[14]	2011
9. Syringe pump	1	0.8%	Failure to adhere to syringe pump best practices.[22]	2022
10. Anesthesia Machine	1	0.8%	Due to incomplete preuse inspection.[15]	2012
11. Surgical Diathermy	1	0.8%	Patient burns from unholstered electrosurgical active electrodes.[19]	2018
12. Point of care Ultrasound	1	0.8%	Point-of-care ultrasound outpacing safeguards.[25]	2020

Source : ECRI Top 10 Health Technology Hazard (2010 to 2023)
Notes: total hazards reported for 12 medical devices is 36, Total hazards reported for 13 years is 130

Identified devices were grouped into therapeutic (22%) and diagnostic devices (5%) (Table 3). Several consistent hazards emerged over time, beyond device-related issues. These hazards were categorized into broader themes and analysed to identify recurring patterns. The analysis revealed four prominent themes that persisted throughout the years, including: 1) Alarm-related issues (7.7%), 2) Radiation-related hazards (4.6%), 3) Cyber security concerns (5.4%), and

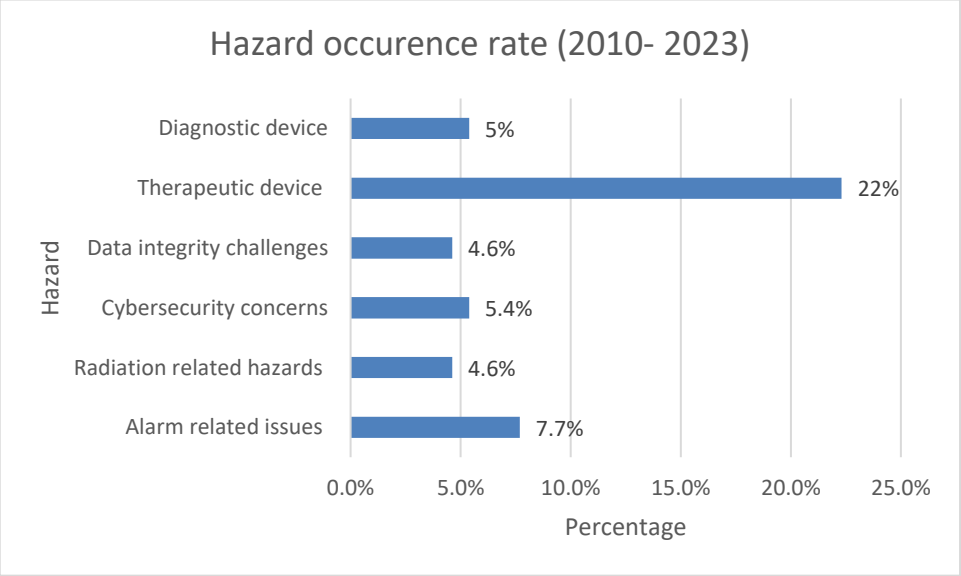
4) Data Integrity challenges (4.6%) (Table 2).

Table 2. Hazard themes

Hazard themes reported from 2010 to 2023				
Theme	**Frequency**	**Percentage**	**Year**	**Hazard**
1. Alarm-related issue	10	7.7%	2010,2011, 2012,2013,2014, 2015,2016,2018, 2019,2020	Alarm hazards (failure to communicate alarm conditions), inadequate alarm configuration policies and practices, missed alarms, improper customization of physiologic monitor alarm settings may result in missed alarms, alert, and notification overload.[13–20,23,25]
2. Radiation related hazard	6	4.6%	2011,2013,2014, 2015,2017,2018	Radiation overdose and other dose errors during radiation therapy, unnecessary exposures and radiation burns from diagnostic radiology

				procedures, occupational radiation hazards in hybrid operation rooms (OR), "Dose Creep": unnoticed variations in diagnostic radiation exposures, inadequate use of digital imaging tools may lead to unnecessary radiation exposure.[14,16–19,21]
3.Cybersecurity concerns	7	5.4%	2015,2018,2019, 2020,2021,2022, 2023	Insufficient protections for medical devices and systems, ransomware and other cybersecurity threats, hackers can exploit remote access to systems, cybersecurity risks in the connected home healthcare environment, vulnerabilities in third-party software components, cyberattacks, cybersecurity risks associated with cloud-based clinical systems.[18–20,22,24–26]
4. Data Integrity challenges	6	4.6%	2010,2011,2013, 2014,2015,2016	Problems with computerized equipment and systems, IT complications - data loss , system incompatibilities, Patient/data mismatches in EHRs and other health IT systems ,Interoperability failures with medical devices and health IT systems, inadequate surveillance of monitored patients in a telemetry setting may put patients at risk, errors arise when health IT configurations and facility workflow do not support each other.[13,14,16–18,23]

Figure 1. Hazard occurrence rate



Source: Author's own work

3.2 Inferential analysis

Chi-square goodness of fit test carried out to :

1. To check whether the therapeutic and diagnostic device hazards are reported in equal proportion.

H_0: Therapeutic and diagnostic devices hazards are reported in equal proportion ($p_t=p_d$)[1]

H_1: Therapeutic and diagnostic devices hazards are not reported in equal proportion

2. To check whether the hazard themes identified are reported in equal proportion.

[1] p_t = proportion of therapeutic hazards, p_d = proportion of diagnostic device hazards

H_0: The identified hazard themes are reported in equal proportion ($p_a=p_r=p_c=p_{di}$)[2]

H_1: The identified hazard themes are not reported in equal proportion

Table 3. Chi-square test for goodness of fit of distribution of device hazards

Hypothesis	Type of device hazards	Frequency	Percentage	Chi-square value	P value
1	Therapeutic device hazard	29	22%	13.44	<0.001**
	Diagnostic device hazard	7	5%		
2	Alarm related issues	10	7.7%	1.48	0.686
	Radiation related hazards	6	4.6%		
	Cybersecurity concerns	7	5.4%		
	Data integrity challenges	6	4.6%		

Note : ** denotes significant at 1% level

For hypothesis 1, as the p value is <0.05, null hypothesis is rejected and alternate hypothesis that the therapeutic and diagnostic device hazards are not reported in equal proportion is accepted, meaning that there is a significant difference between the reported cases for the two device categories. There are more cases of hazards due to therapeutic devices (22%) when compared to diagnostic devices (5%). Among all the hazards examined in the study, those related to therapeutic devices account for the highest proportion (Figure 1). Whereas for hypothesis 2, as P >0.05, null hypothesis is not rejected, meaning that the hazard themes are reported in equal proportion, and there is no significant difference between the reported hazard themes. All hazard themes require equal attention.

4.Discussions

This study emphasises the importance of medical device hazards due to therapeutic devices, this is supported by previous study indicating the declined reliability and increased maintenance cost of such equipment and the importance for hospitals to adopt risk-based maintenance.[27] This sheds light on the crucial requirement to address the reported hazards with the utmost urgency to minimize problems and reduce potential risks associated with the use of these technologies.

Endoscopes: As highlighted in our study the potential for endoscopes to transmit infections, particularly during the COVID-19 pandemic, necessitates careful consideration of proper reprocessing practices. Recent studies have shown that despite proper disinfection, endoscopes can still become contaminated, posing significant risks to patient safety. To prevent cross-contamination, it is essential to implement pre-cleaning, manual cleaning, and high-level disinfection. However, the success of these practices depends on the operator's competence, and continuous training of healthcare personnel is necessary to minimize risks and ensure safe patient care.[28,29]

Infusion pump: Similar to our study finding , research supports that parenteral drug administration via an infusion pump, although a common treatment, can be a complex process that may result in errors or discrepancies.[30] These issues can be addressed by regularly updating drug libraries in smart pumps, requiring the selection of drug names before operating the pump, providing standardized dosage regimens, using dosage calculation and dose error reduction

[2] p_a = proportion of alarm-related issue, p_r = proportion of radiation related hazard, p_c= proportion of cybersecurity concerns, p_{di}= proportion of data integrity challenges

software, and interfacing systems with central monitoring systems. Simulation-based training for staff can help recognize active orders and ensure compliance with health information technology. Additionally, electronic prescribing, double-check lists, and barcode-assisted administration can help proactively manage risks and reduce infusion-related errors by ensuring the five medication safety rights.[31,32]

Ventilators: Our study supports prior research emphasizing the importance of addressing ventilator issues. It aligns with findings indicating that human factors, ergonomic design, usability issues, alarm mismanagement, and other errors contribute significantly to ventilator-related adverse events.[33] Ventilator alarms make up 16-45% of clinical alarms in ORs, and a sizable portion of ventilator-specific alarms, as much as 73%, in adult ICUs are non-actionable. Understanding the characteristics of ventilator, including alarm rates, alarm proportion, and variations due to ventilator design, is critical for improving safety.[34,35] Mechanical ventilators play a vital role in the transmission of ventilator-associated pneumonia. Effective cleaning and disinfection of ventilators is vital, as demonstrated during the COVID-19 pandemic. This includes cleaning, disinfection recommendations, and guidelines, as well as post-disinfection microbiological cultures, to prevent healthcare-associated infections and adverse events.[36]

CT Scan: Our study concurs with recent research, indicating that certain procedures, including interventional, guided endoscopic procedures, radiation therapy, and computed tomographic examinations, pose a risk of higher radiation exposure for both patients and healthcare providers, reaching up to 16.4 mSv.[37] Periodic evaluations, including quality assurance (ALARA principle), continuous training of qualified medical professionals, TLD badge monitoring, are necessary to maintain control over the dose. Studies have shown that using a tin/Sn filter in CT scans and maintaining constant dose reduction parameters can result in a nearly 90% reduction in dose[38]. Additionally, artificial intelligence, including neural network and deep learning algorithms, has the potential to enhance patient safety without compromising image quality.[39]

Our analysis identifies four key themes in hazard assessment, namely alarms, radiation exposure, cybersecurity, and data integrity, which require equal attention from healthcare providers.

Alarm: The ECRI data identifies alarm fatigue, and notification overload as significant safety concerns. Alarm hazards arise due to various factors such as inadequate communication and response, improper customization of alarm settings, and insufficient configuration policies and practices. Implementing evidence-based strategies for safe alarm management systems and response processes can save more than 800 hours of nurses' time and over 100,000 USD, as suggested by recent studies. [40–42]

Radiation: As per our findings radiation-related issues, including exposure to high doses and other errors, have gained significant attention. It is important to reducing unnecessary exposures and occupational hazards, as well as patient exposure. Mobile shields can reduce radiation exposure by up to 90% when used correctly, lead aprons that wrap around the body provide better surface coverage, wearing lead glasses regularly can reduce lens exposure by 90%, and dosimeters can measure cumulative exposures. Effective radiation safety programs in healthcare facilities are essential to address these issues. [43,44]

Cybersecurity: Our research indicates that the significant growth in internet usage and digitalization in the healthcare sector has made it increasingly susceptible to cyberattacks, posing risks to patient data security, privacy, and accessibility. The widespread use of wireless communication technology like implantable devices, wearable health monitoring devices, and telemedicine services in open environments has exposed these areas to various cybersecurity threats. Regrettably, the preparedness of hospitals to confront cybersecurity breaches is inadequate. According to data from 2019, the healthcare sector experienced 24% of all reported cyberattacks, experts anticipate this percentage to rise even higher as medicine continues to rely more heavily on technology. Common forms of cyber threats in the healthcare industry include phishing, man-in-the-middle attacks, malware, and denial of service. Outdated security

in medical devices exposes them to new risks as cybercrime evolves rapidly.[45,46]

Data integrity: In alignment to our finding studies show that data integrity is a critical issue in healthcare, where accurate and reliable data is essential for quality care. The growing use of cloud-based computing, increases the risk of data loss and malicious threats. The multiplicity of interconnected devices creates more potential infiltration points, software programming errors, bugs, template default values, inconsistencies between data fields, and copying and pasting information also pose a threat to data integrity. To address these challenges, data integrity management techniques, including the use of blockchain technology, privacy-preserving data integrity verification models for healthcare cyber-physical systems, and lightweight data management and encryption techniques, can be employed.[47–49]

The study's results will significantly contribute to achieving the United Nations Sustainable Development Goal (SDG) 3 (Good health & wellbeing) and SDG goal 9 (Industry, Innovation, Infrastructure) by improving healthcare quality, patient safety, and fostering innovation while building resilient health technology infrastructure. [50]

4.1 Limitations

This study concentrated on the ECRI database, but expanding to more data sources would enhance our understanding of HTH. Further research is required to comprehend the reasons behind the therapeutic equipment errors. This may include obtaining user feedback and conducting tests in controlled settings. Moreover, examining the themes across diverse demographics and hospitals would provide a comprehensive strategy for hazard control and prevention.

5.Conclusion

This study stresses the urgent need for hospital administrators to address the technological hazards that pose significant risks. It provides a comprehensive overview of persistent hazards identified by ECRI, including therapeutic device hazards, infection control risks, radiation exposure, cybersecurity risks, and data integrity.

The study provides hospital management and quality teams with the HTH information to create a safer healthcare environment for patients and staff.

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Conflict Of Interest:

Authors declare no competing interest

Author's Contribution:

All authors contributed equally to the study

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Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by authors

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