Current Status and Reflections on Information Technology-Related Healthcare Adverse Events at Home and Abroad (Postprint)

Authors: Zeng Ke, Wang Yu, Zhu Weiguo

Date: 2019-11-15T00:00:00+00:00

Abstract

With the deepening application of information technology in healthcare, information technology-related medical adverse events have been continuously increasing. This paper systematically reviews the terminology, concepts, and research status of such events both domestically and internationally, classifies them from three perspectives: event manifestation patterns, system component elements, and root causes, and provides corresponding definitions and case illustrations. Drawing upon relevant research at home and abroad, it further explores response strategies for information technology-related medical adverse events, proposing solutions that include raising awareness, encouraging reporting, and establishing a standardized prevention system. The objective is to enhance the healthcare industry' s understanding of and attention to these adverse events, thereby providing references for related research.

Full Text

Current Situation and Considerations Regarding Information Technology-Related Medical Adverse Events

Ke Zeng[1], Yu Wang[2], Weiguo Zhu[1,2]

[1]Department of Information Management, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100730, China
[2]Department of General Internal Medicine, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100730, China

Corresponding author: Weiguo Zhu, Department of General Internal Medicine and Information Management, Peking Union Medical College Hos-

pital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100730, China; Email: zhuwg@pumch.cn

Abstract

With the deepening application of information technology in healthcare, information technology-related medical adverse events have been increasing continuously. This paper reviews and organizes the terminology, concepts, and research status of IT-related medical adverse events both domestically and internationally, classifying them from three perspectives: manifestation patterns, system components, and root causes, with corresponding definitions and case illustrations provided. Building upon relevant research, the paper further explores countermeasures for IT-related medical adverse events, proposing solutions that emphasize raising awareness, encouraging reporting, and establishing standardized prevention systems. The aim is to enhance the healthcare industry' s understanding and attention to such adverse events and to provide references for related research.

Keywords: Health Information Technology; Information System; Medical Adverse Events; Medical Error; Technical Hazards

Funding: Chinese Academy of Medical Sciences Medical and Health Science and Technology Innovation Project "Medical Big Data Information Collection and Analysis Evaluation" (Project No. 2016-I2M-2-004); Chinese Academy of Medical Sciences Rare Disease Research Center: Construction and Application Demonstration of HLH Precision Medicine System (2016ZX310174-4).

Conflict of Interest: None

1. Definition of Information Technology-Related Medical Adverse Events

Medical adverse events refer to any factors and incidents in clinical diagnosis and treatment activities and hospital operations that may affect patient outcomes, increase patient suffering and burden, potentially trigger medical disputes or medical accidents, and impact the normal operation of medical work and the personal safety of medical staff [1]. In the United States, approximately 400,000 to 440,000 patient deaths annually are attributed to medical adverse events, making them the third leading cause of death [2][3]. With the widespread application of Health Information Technology (HIT), leveraging IT to reduce adverse events and enhance medical safety has become an important strategy. Studies show that Computerized Provider Order Entry (CPOE) systems can prevent 17.4 million clinical medication errors annually, reducing the error rate by 12.5% [4]. Barcode technology can reduce errors in the prescription transcription and administration processes by 41.4% while decreasing the incidence of

potential adverse events by 50.8% [5]. However, while extensive IT applications reduce medical errors, they have gradually become a significant factor causing medical adverse events. When not properly designed, implemented, and used, IT itself threatens healthcare quality and patient safety. Research indicates that approximately one-sixth of medical safety incidents are related to HIT [6], making HIT-related adverse events a non-negligible threat to medical safety [7]. Recently, incidents have been reported where artificial intelligence applications may endanger medical safety. For example, IBM Watson recommended chemotherapy and bevacizumab for a lung cancer patient with severe bleeding, despite bevacizumab being a cancer drug that can cause serious hemorrhage [8]. While AI holds great value for assisting medical decision-making, its reliability and safety should not be overlooked.

Research on IT-induced medical adverse events began in the early 21st century. With the modernization of global healthcare, HIT such as Electronic Health Records (EHR), CPOE, and Clinical Decision Support Systems (CDSS) have significantly improved healthcare quality and efficiency while reducing industry burden, making IT a crucial driver for healthcare [9]. However, as IT applications became widespread, researchers discovered that IT creates a new type of medical adverse event that endangers patient and healthcare worker safety [7]. Currently, there is no unified definition for IT-related medical adverse events, with common terms including "Technology induced errors" [10][11], "System related errors" [12][13][14], "E-iatrogenic" [15], "Technological iatrogenesis" [16], and "Health Information Technology Events" [17]. Borycki EM et al. [18] define IT-induced medical adverse events as errors occurring during system design and development, implementation and customization, and the interaction between technology application and new workflows. Such errors typically occur in complex clinical environments and are difficult to detect through traditional software testing methods. In some cases, users may notice and correct these errors in time—for instance, when a physician discovers and corrects a medication entry error. Weiner JP et al. [15] coined the term "E-Iatrogenesis" to define safety hazards to patients caused by HIT applications. Palmieri PA et al. [16] proposed the concept of "Technological Iatrogenesis," representing new types of medical errors arising from integrating technological innovations into complex healthcare systems, warning users to enhance management awareness of such emerging risks.

---

2. Research Status of IT-Related Medical Adverse Events

Since 2005, international research reports on HIT-related medical adverse events have increased significantly [9], while domestic policies, regulations, and literature reports on such events remain scarce.

The Emergency Care Research Institute (ECRI) in the United States publishes an annual "Top 10 Health Technology Hazards" report [19], identifying safety

issues in medical device and system usage to help healthcare organizations recognize potential technological hazards. Table 1 summarizes IT-related content from ECRI' s "Top 10 Health Technology Hazards" reports over the past six years.

Table 1 IT-Related Hazards in ECRI' s "Top 10 Health Technology Hazards" 2014–2019

Year	IT-Related Hazards
2014	Incomplete or unreliable data in EHR and other healthcare information systems
2015	Inadequate change management for networked devices and systems
2016	Incorrect or incomplete data in EHR and other healthcare information systems
2017	Inadequate protection of networked medical devices and systems
2018	Mismatch between HIT configuration and workflows
2019	Defects in medical device software management settings affecting patient data security; Ransomware and other information security threats in healthcare services may endanger patient safety; Failure to strictly use barcode scanning medication administration systems prevents realization of safety benefits; Hackers can exploit remote access to hospital information systems to disrupt healthcare services

Between 2014 and 2018, the Joint Commission in the United States documented 170 reports related to alarm management and alarm fatigue, 101 of which resulted in patient deaths. False alarms from EHR and medical device alerts accounted for 85%-99% of all alarms [20], creating significant medical safety risks. Healthcare workers experiencing burnout from excessive unnecessary warnings may occasionally overlook meaningful alerts, leading to medical errors.

In 2011, Canadian scholar Bellwood Paule [21] analyzed factors influencing HIT-related adverse events, categorizing them into nine aspects: system development lifecycle, knowledge/training, workflow, human-computer interaction, policy, user participation, etc., and further grouped these factors into four themes: individual, vendor, institution, and government, which have complex interrelationships.

The Manufacturer and User Facility Device Experience Database (MAUDE), maintained by the U.S. Food and Drug Administration (FDA), collects medical device adverse event reports since 1991, including numerous HIT-related incidents. Table 2 lists typical cases of IT-related patient deaths from the past decade [22].

Table 2 IT-Related Patient Death Events in MAUDE Database (Past 10 Years)

Date	Event Description	Cause
2008/12/18	Patient' s aortic balloon catheter ruptured with blood above the pneumatic drive line, but the system did not alarm.	System alarm message failure
2009/8/11	During X-ray examination, insufficient disk space prevented Windows system operation; patient died of myocardial infarction during multiple system restarts.	Software programming error
2009/12/5	Software programmed to administer morphine at 1ml/hr at 1mg/ml concentration, causing overdose; alarm sounded after approximately one hour when patient had already died.	Software programming error
2010/1/24	Patient under cardiac and oxygen saturation monitoring; critical alarm volume on bedside monitor was turned off; staff failed to detect cardiac event in time, resulting in death.	Software control setting error
2014/12/6	Patient' s hemodynamic information displayed distorted during surgery; patient died on operating table.	Application abnormal exit
2015/3/23	Patient experienced ventricular fibrillation; monitor alarmed but nurse did not notice. Investigation revealed alarm tone had 5-second delay (default is 0 seconds).	Software control setting error
2015/7/1	Emergency myocardial infarction case; system shut down spontaneously in examination room; two restart attempts failed; patient died during transfer to another hospital.	Operating system problem

U.S. scholars Kang Hong et al. [7][23][24] developed an HIT event identification strategy to better understand the nature of adverse events caused by current HIT systems. Using structured feature-based filters and unstructured feature-based classifiers, they identified HIT events in the MAUDE database and established a dedicated HIT event database by extracting adverse event report data.

3. Classification of IT-Related Medical Adverse Events

Currently, there is no unified classification method for HIT-related medical adverse events domestically or internationally. Drawing upon foreign research clas-

sification methods and practical experience, this paper categorizes IT-related medical adverse events from three perspectives: manifestation patterns, system components, and root causes.

3.1 Classification by Manifestation Pattern Based on manifestation, information system medical errors can be classified as: selection errors, usage errors, documentation errors, and system errors [25].

Table 3 Manifestation Patterns of Adverse Events in Information Systems

Error Type	Description	Example
Selection Error	Incorrect selection from dropdown menus (medication/formulation/route/frequency, etc.)	Incorrectly selecting epidural injection of 0.9% sodium chloride instead of intravenous injection
Usage Error	Incorrect use of medication/formulation/route/frequency, etc.; contradictory prescriptions and medication instructions	Prescribing nitroglycerin as 10mg/24h, 1 patch, while medication instructions specify 50mg/24h
Documentation Error	Content documentation errors	Writing daily dose of 150ug Stalevo as 37.5 tablets
System Error	Prompt errors, default time/date errors, auxiliary information-related errors, etc.	After patient admission, doctor ordered urgent blood tests; barcode printed and blood drawn same day, but system default time for urgent tests was next morning; nurse reprinted barcode and repeated blood draw next day

3.2 Classification by System Components At each critical node of information systems, adverse events can occur due to system or user factors. Based on information system components, errors can be categorized as: information

input, information transmission, information output, general technology, and user-related factors [26].

Table 4 Classification by System Components

Component	Category	Description	Example
Information Input	System: Data collection failureUser: Data entry or recording problems	Registration staff entered patient name incorrectly during record creation, affecting medical insurance reimbursement	
Information Transmission	System: Network paralysis or delay, software interface issues	Oral medication orders from CPOE system not transmitted to packaging machine system in time, causing missed medication doses	
Information Output	System: Input device shutdown, unavailable records, output/display errorsUser: Data query or recording errors	Patient retrieving head MRI report at radiology department; self-service kiosk incorrectly printed another patient' s CT report	
General Technology	Computer system failure, access issues, software problems, data loss, etc.	Computer failure causing delayed reporting of critical lab values	
User Factors	Personnel training, cognitive load, failure to perform duties, occupational issues	Users unfamiliar with system functions and operations, leading to usage problems	

3.3 Classification by Root Causes Referencing the classification method used in the FDA' s MAUDE database, adverse events can be categorized as computer problems, data problems, alarm problems, communication problems, human-computer interaction problems, and application system problems, with each category further subdivided into multiple error types.

Table 5 Root Cause Classification of HIT-Related Adverse Events

Category	Subcategories	Example
Computer Problems	Hardware, operating system, software, system security issues	Data backup issues, data integrity problems
Data Problems	Data integrity, data loss, data security issues	System malicious intrusion and attack disrupting medical supply chain
Alarm Problems	Alarm system failure, inability to generate error or warning messages	Paper and electronic data used concurrently, causing partial patient data loss
Communication Problems	Wireless communication issues, network problems	System not setting daily maximum medication dose alerts, leading to patient overdose
Application System Problems	Program abnormal exit, calculation errors, parameter setting errors, version/upgrade issues, software security	Network failure causing remote operation failure, data loss

Human-Computer Interaction Problems	Human factors, interface issues, usage problems, etc.	Outpatient high-value system and inpatient high-value consumables system not linked, causing some consumables not to be billed; User opened multiple HIS interfaces simultaneously and inadvertently operated in wrong interface

In 2016, Canadian scholar Borycki E et al. [27] proposed the "Cyclic Process of Improving HIT Safety" model to summarize solutions for HIT safety incidents (see Figure 1 [Figure 1: see original paper]).

Figure 1 [Figure 1: see original paper] "Cyclic Process of Improving HIT Safety" Model

4. Countermeasures for IT-Related Medical Adverse Events

Based on relevant research, we propose several strategies for addressing IT-related medical adverse events:

4.1 Enhancing Awareness of IT-Related Medical Adverse Events Hospitals as HIT users, vendors as HIT providers, and administrative agencies as regulators should all attach great importance to IT-related medical adverse events. For HIT applications, safety hazard management should be strengthened, employing various techniques and methods to predict potential errors and prevent and correct problems proactively. Root cause analysis of HIT adverse events should be conducted to develop effective solutions. As AI technology penetrates deeper into healthcare, AI applications should undergo strict review by domain experts, with robust testing mechanisms and deployment models established to ensure safe and reliable medical AI applications.

4.2 Encouraging Reporting of IT-Related Medical Adverse Events Healthcare institutions should implement positive incentive measures to encourage reporting of HIT-related adverse events. These events should be incorporated into reporting systems, and a dedicated HIT adverse event database should be established to provide data support for statistical analysis. This will

help researchers analyze associations and commonalities among HIT events and develop standardized classification systems for HIT incidents.

4.3 Establishing a Prevention System for IT-Related Medical Adverse Events **(1) System Design:** Patient safety should be considered from the initial design phase. All programming involving critical medical processes must be validated by clinical experts. System controls, default values, automatic calculations, prompts, and warnings must strictly adhere to medical principles. Interface and operational design are critical and should ensure system usability, friendliness, and safety.

(2) System Testing: Establish standardized software testing mechanisms covering communication networks, browsers, operating environments, system functions, load capacity, and fault recovery capabilities. Core business systems should undergo not only software security certification but also medical safety certification in the future.

(3) System Implementation: Strengthen user training and assessment. Training should cover not only new modules and functions but also emergency response mechanisms and strategies for handling HIT-related adverse events.

(4) System Operations and Maintenance: Enhance monitoring of hardware and software availability, conduct regular inspections, establish mechanisms for identifying problems from operational events, and regularly organize emergency drills for users.

(5) System Security: Develop robust data backup mechanisms and emergency management strategies, and construct comprehensive information security assurance systems.

(6) User Operation: Value user feedback for continuous optimization and improvement. Pay close attention to user-reported system usage burden and burnout. Simplify repetitive operations and optimize human-computer interaction.

(7) Information Sharing: Best practices for system operation, safety hazards, and response strategies should be shared among users, establishing communication mechanisms between users and technical personnel.

In conclusion, information technology plays an increasingly important role in medical activities, while IT-related medical adverse events have emerged as a consequential threat that may cause medical errors and even endanger lives. Therefore, we must emphasize IT-related medical adverse events, raise awareness of safety risks associated with HIT and emerging technologies like AI, and introduce safety management concepts throughout all stages of system design, development, implementation, usage, and maintenance to ensure patient safety and fully realize the tremendous value of medical information technology.

References

[1] Definition and classification of medical adverse events[J]. Chinese Health Quality Management, 2014, 21(04): 28.

[2] Schreiber M, Klingelhfer D, Groneberg DA, et al. Patient safety: the landscape of the global research output and gender distribution[J/OL]. BMJ Open, 2016, 6: 8322.

[3] Makary MA, Daniel M. Medical error—the third leading cause of death in the US[J]. BMJ, 2016, 353: 2139.

[4] Radley, David C & Wasserman, Melanie R & Olsho, et al. Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. Journal of the American Medical Informatics Association: JAMIA, 2013, 20(3): 470-476.

[5] Poon EG, Keohane CA, Yoon CS, et al. Effect of bar-code technology on the safety of medication administration. N Engl J Med, 2010, 362(18): 1698-1707.

[6] Cheung KC, van der Veen W, Bouvy ML, Wensing M, van den Bemt PM, de Smet PA. Classification of medication incidents associated with information technology[J]. J Am Med Inform Assoc, 2014, 21(e1): e63-70.

[7] Kang H, Yu Z, Gong Y. Initializing and Growing a Database of Health Information Technology (HIT) Events by Using TF-IDF and Biterm Topic Modeling. AMIA Annu Symp Proc, 2017, 1024-1033.

[8] Casey Ross, Ike Swetllitz. IBM' s Watson supercomputer recommended 'unsafe and incorrect' cancer treatments, internal documents show [EB/OL]. https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments/, 2018-07-25

[9] Borycki E. Trends in Health Information Technology Safety: From Technology-Induced Errors to Current Approaches for Ensuring Technology Safety. Healthcare Informatics Research, 2013, 19(2): 69-78.

[10] Kushniruk AW, Triola MM, Borycki EM, Stein B, Kannry JL. Technology induced error and usability: the relationship between usability problems and prescription errors when using a handheld application. Int J Med Inform, 2005, 74(7-8): 519-26.

[11] Borycki E, Kushniruk A. Identifying and preventing technology-induced error using simulations: application of usability engineering techniques. Healthc Q, 2005, 8: 99-105.

[12] Brushwood DB, Winterstein A. Manufacturer warnings of system-related medication errors. Am J Health Syst Pharm, 2002, 59(11): 1110-2.

[13] Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. J Am Med Inform Assoc, 2004, 11(2): 104-12.

[14] Voight PE. Using safety tools to prevent system-related errors. AORN J, 2009, 89(6): 969-70.

[15] Weiner JP, Kfuri T, Chan K, Fowles JB. "e-Iatrogenesis": The Most Critical Unintended Consequence of CPOE and other HIT. Journal of the American Medical Informatics Association: JAMIA, 2007, 14(3): 387-388.

[16] Palmieri PA, Peterson LT, Ford EW. Technological iatrogenesis: new risks force heightened management awareness. J Healthc Risk Manag, 2007, 27(4): 19-24.

[17] Abramson EL, Kern LM, Brenner S, Hufstader M, Patel V, Kaushal R. Expert panel evaluation of health information technology effects on adverse events. J Eval Clin Pract, 2014, 20(4): 375-82.

[18] Borycki EM, Kushniruk AW, Keay L, Kuo A. A framework for diagnosing and identifying where technology-induced errors come from. Stud Health Technol Inform, 2009, 148: 181-187.

[19] Top 10 Health Technology Hazards for 2018[EB/OL]. [2018-08-12]. https://www.ecri.org/Pages/2018-Hazards.aspx

[20] Fred Schulte, Erika Fry. Death By 1,000 Clicks: Where Electronic Health Records Went Wrong[EB/OL]. https://www.physicianspractice.com/article/death-1000-clicks-where-electronic-health-records-went-wrong, 2019-04-01

[21] Bellwood, Paule. Qualitative Study of Technology-Induced Errors in Healthcare Organizations. M.Sc. University of Victoria (Canada), 2011.

[22] MAUDE - Manufacturer and User Facility Device Experience [EB/OL]. [2018-10-10]. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[23] Kang H, Yu Z, Gong Y. Initializing and Growing a Database of Health Information Technology (HIT) Events by Using TF-IDF and Biterm Topic Modeling. AMIA Annu Symp Proc, 2018, 2017: 1024-1033.

[24] Yao B, Kang H, Wang J, Zhou S, Gong Y. Exploring Health Information Technology Events from FDA MAUDE Database. Stud Health Technol Inform, 2018, 250: 187-191.

[25] Westbrook JI1, Baysari MT, Li L, Burke R, et al. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals. J Am Med Inform Assoc. 2013, 20(6).

[26] Magrabi F, Ong MS, Runciman W, et al. Using FDA reports to inform a classification for health information technology safety problems. J Am Med Inform Assoc. 2012, 19(1): 45-53.

[27] Borycki E, Dexheimer JW, Hullin Lucay Cossio C, et al. Methods for Addressing Technology-Induced Errors: The Current State. Yearbook of Medical Informatics, 2016, (1): 30-40.