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A Comparison of Two Principal Systems for Monitoring of Technology-Induced Errors in Electronic Health Records

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Abstract

Current methods for monitoring harm caused by health information technology (HIT) are minimal, even if there are known risks associated with the use of HIT. Monitoring is predominantly based on voluntary reporting using generic patient safety adverse events reporting systems. Another important means for monitoring technology-induced errors is a health authority reporting system. International oversight systems have medical devices´ related software´s adverse event and failure reporting models, but these systems differ due to differencies in the legislation. The protocol for this study included an electronic database literature search and the eliciting of information for study purposes from the literature. The purpose is to provide a scoping review focused on two types of systems and provide implications for monitoring technology-induced errors in the future. The analysis revealed not only differences, but also similarities between these systems which raises the question of these systems´ effectiviness due to overlapping goals in collecting data.

Keywords:

Electronic Health Records; Patient Safety, Medical Informatics

Introduction

A recent systematic review of eHealth technologies and their impact on the safety of healthcare showed that the problem of electronic health record (EHR) safety is an existing and possibly critical issue [1]. It is assumed that an increase in the implementation of information technology within healthcare systems will potentially lead to patient safety incidents by introducing novel vulnerabilities [2]. In 2012, the Institute of Medicine (IOM) [3] recommended that patient safety incidents which relate to the use of Health Information Technology (HIT) should be monitored and that this information be used to improve the safety of HIT. By detecting these errors, there is an opportunity to decrease risk for patients [4].

HIT related medical errors are defined in several ways. The concept of technology-induced error as defined by Borycki [4] has increasingly appeared in the literature during recent years. These errors result from 'the design and development of technology, the implementation and customization of a technology, and the interplay between the operation of a technology and the new work processes that arise from a use of technology' [4].

Existing methods for monitoring adverse events and harm caused by HIT systems rely mostly on voluntary reporting using generic patient safety adverse event reporting systems [5-6]. These adverse event monitoring systems have multiple functions, including: (a) the monitoring of levels of harm, and (b) identifying rare events and disseminating knowledge about patient safety issues arising during healthcare to avoid these incidents recurring [7]. These systems form a mechanism which also includes the analysis and triggering of an investigation of an incident [8] whether on a mandatory or voluntary basis. It is believed that voluntary adverse event monitoring systems are the most effective way of avoiding liability issues for providers, but there is also the belief that there is a need for greater accountability. Incident reporting systems generate numerators without denominators which has been regarded as a major problem [9-12].

HIT has not been strictly regulated over the past few decades [13]. Today, international healthcare systems have medical device related software adverse event and failure reporting models, but there are differences between these systems [13-18]. The differences originate from different legislation. In the United States (US), regulatory requirements that can be used to evaluate EHR system safety are insufficient [16-18]. Software has been regarded as a medical device according to European Union (EU) legislation for almost a decade. Medical device regulations apply to medical software in the EU [18]. The EU directive focuses on pre-market testing aiming for European conformity. In general, the regulatory oversight systems seek to gather data to help HIT developers and clinicians better understand and mitigate risks associated with HIT implementation and use [19, 21].

In this paper the authors provide: (a) review two of the most dominant reporting system types, (b) outline the implications of monitoring technology-induced errors in HIT and (c) provide insights into future research directions based on these analyses. More specifically, the authors answer the following research questions: (1)What are the main characteristics of the two dominant HIT related monitoring systems, (2) What are differences between these systems? and (3) What are the implications of this research for future analyses?

The scoping review presented in this paper is limited to the perspectives of healthcare organisations´ (i.e., the HIT vendors view is excluded). For the purpose of this paper the term patient safety incident reporting system is referred to as "IRS". Different types of software´s regulatory authority adverse event and failure reporting models and vigilance systems are referred to as "oversight systems".

Methods

A scoping review was conducted by the authors using Arksey's and O'Malley's approach [20]. The following steps were undertaken: (1) an electronic database was searched, and (2) information was elicited from downloaded articles to answer study questions. The database search was performed on

PubMed. Search results were restricted to those references published in English only. The search was performed on the two main topics associated with the theme of this work: HIT and monitoring. A combination of keywords were used: “HIT” OR “EHR”, OR “medical software” and “monitoring” OR ”patient safety reporting” OR “incident reporting system” OR “surveillance”, “regulation” OR “oversight” OR “vigilance” (Moreover, an additional search was based on these previous results which were combined with a keyword “technology induced error”, and this resulted in 3 citations of which one was a duplicate.)

Initially, the researchers reviewed the abstracts of the downloaded publications. Those abstracts that fulfilled the following criteria: patient safety incident reporting system and an authority surveillance perspective were downloaded and reviewed further. An additional type of non-scientific material collected contained legislation documents. Finally, the following data were extracted by two reviewers from the articles using the following criteria: the main objectives of reporting systems, nature, confidentiality aspects and reporting modes, who are the reporters, what is reported, and analysis of the incidents. The findings arising from our work are reported according to these data extraction criteria.

Results

In the next section of this paper, we report on our findings arising from the scoping review in the following areas: main objectives of reporting systems, nature, confidentiality aspects and reporting modes, who are the reporters, what is reported, and analysis of the incidents. Figure 1 illustrates the detailed steps of the literature search in PubMed. A total of 4966 citations were received of which 18 articles were included in the final review. We present our findings in terms of the two types of reporting systems described in the literature: oversight (ORS) and incident reporting systems (IRS).

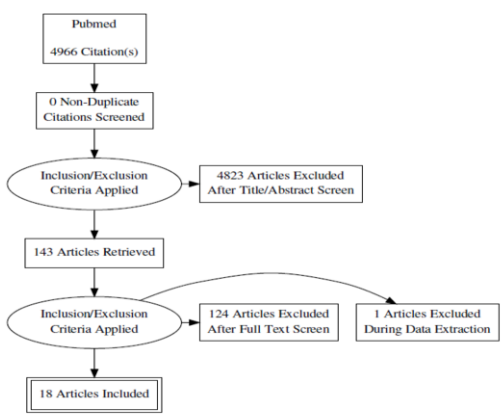

Figure 1. A PRISMA flow diagram of the review.

Main Objectives of Reporting Systems

Oversight system

The primary purpose of the EU Medical Device Vigilance System, which is grounded in the Medical Device Directive 93/42/EC, is to “improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incident elsewhere”. The Medical Device Vigilance System aims to facilitate an early and harmonised implementation of ´Field Safety Corrective Action´ across the Member States where the device is in use, in contrast to action taken on a country by country basis [18, 20].

Existing FDA databases for medical device errors are focused on collecting data about medical devices and have only recently been used to collect some data on reporting EHR-related incidents. The Office of the National Coordinator (ONC) has recently created a HIT complaint website; however, the form for entering complaints is basic with few specific HIT and error questions to answer limiting the usefulness of the resulting database. The regulatory oversight system´s intention is to gather data to help HIT developers and clinicians better understand and mitigate risks associated with HIT implementation and use [8, 15, 19].

Incident reporting system

The aims of a patient safety incident systems (IRS) are broad. IRS systems are intended to monitor levels of harm, identify rare events and disseminate knowledge about patient safety of care. Learning from errors is the main goal of IRS [7-8, 22].

Legislation

Oversight system

Directive 2007/47/EC1 amended the definition of the term "medical device" used in Directive 93/42/EEC, and stand alone software with medical purpose are subject to medical device directives [18].

The FDA currently considers clinical information systems to be medical devices, but to date their regulatory requirements are not enforced. The Office of the National Coordinator (ONC) is collecting data and attempting to resolve issues that have been submitted to their complaint system. In the US, no government agency is currently fully equipped to perform regulatory and legal authority functions where Medical software is concerned [15-17, 19].

Incident reporting system

EU Council Recommendation 2009/C151/012 [23] regarding reporting and learning about incidents recommends that Member States support the establishment or strengthen blame-free reporting and learning systems regarding adverse events, which provide information about the extent, types and causes of errors, adverse events and near misses. In the US the Patient Safety and Quality Improvement Act was launched in 2005. The core goals of the act are to encourage health care professionals to improve the safety of health care, to understand the underlying causes of hazards, and to share the results, thereby minimizing risks related to patient care [27].

Nature, Confidentiality Aspects and Reporting Modes

Oversight system

ORS in the EU are mandatory and failing to report an event may be punishable [e.g., 26]. The US databases supported by the FDA: Medical Device Reporting (MDR) cover mandatory reporting from 1984-1996 and voluntary reporting thru to June 1993. Manufacturer and User Facility Device Experience (MAUDE) contains voluntary reports starting in June 1993, and facility reports starting in 1991 [15]. The ONC Health IT Complaint system is newly active and posts information about how to address issues [20] The aspect of confidentiality does not apply to vigilance systems, when it comes to the principle of anonymity, and as is the case in the voluntary based IRSs, which are described in the next section of this paper. Vigilance systems are based on the traceability and accountability of the event and confidentiality would limit both traceability and accountability [19, 21, 25]. Paper-based reporting systems as well as electronic formulas are used, e.g., in Finland both are in

use, with the data structure of the report always remaining the same [26].

Incident reporting system

IRS reporting systems often contain anonymous data from both mandatory and voluntary systems. Closely connected to the issue of mandatory or voluntary reporting are the questions of reporting confidentiality. The discussion is focused around the aspect of preserving the reporter's anonymity. If healthcare personnel perceive that they will suffer judicial or legal consequences, when reporting patient safety incidents, they are less likely to report an incident [27]. To date the research suggests that the use voluntary IRSs continues to be the most effective way of encouraging reporting in a nonpunitive or "no blame" culture. The opposite view also exists, e.g, the public feels that mandatory reporting improves accountability [10-11].

There are big differences between these reporting systems in EU Member States. In the EU both mandatory and voluntary incident reporting systems exist across states; for example, in Finland**,** hospitals are required to have reporting systems (i.e., mandatory), but the reporting of adverse events (i.e., errors) by health professionals is a voluntary activity. In Finland, there is also a focus on reporting on near misses. In the Netherlands, healthcare professionals are obliged to report serious incidents to the Health Care Inspectorate. Yet, the reporting of incidents by health professionals is voluntary and recommended by professional organisations (EU). Three different types of national patient safety incident reporting systems are used to collect adverse event data: systems for sentinel events only, systems focusing on specific clinical domains (e.g. intensive care, emergency room) and healthcare system-wide, comprehensive reporting systems [27].

Traditional paper-based incident reporting systems as well as new forms of IT are used to enhance reporting. It has been suggested that elecronic health records could support new applications such as surveillance of patient safety events e.g., the integration of an IRS into an EHR used in operating theaters that has been implemented to allow for the reporting of accidents and preventable complications [28].

Who Are the Reporters?

Oversight System

Research suggests that health professionals need to be involved in reporting. For example, in the EU for a monitoring systems to be effective, user involvement is regarded important. There are differences between EU member states in the EHR user involvement [19, 29]. For instance, in Finland there is an obligation for the professional user of Medical software to report HIT related safety flaws but in most EU countries the user reporting is not mandatory [26].

Incident Reporting System

Reporting is typically done by frontline personnel where IRS are used. In recent years, patient involvement in reporting has increased, even though this involvement is voluntary in nature for organizations [27].

Reporting Criteria

Vigilance System

An incident in EU vigilance systems is defined as "any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, user or of other persons or has led to a serious deterioration in their state of health." [29]. In the EU, manufacturers must report medical device related serious adverse events and device failures, that might lead to or might have led to a death or serious injury, to the competent authority (CA) in the nation of their occurrence. There is no legal requirement within the directives obliging users to have an active role in a vigilance system, but this area may be reinforced by separate advice from national regulatory bodies, as is the case of Finland, where National Supervisory Authority has issued national regulations on reporting serious adverse incidents for users and manufacturers. The duty to report applies to manufacturers and professional users of medical devices in Finland. Medical device serious adverse incidents must be reported to the authority within ten days of the user or manufacturer first becoming aware of the incident. The case of a near miss should be reported within thirty days [19, 21, 26, 29].

The core FDA requirement to manufacturers in the US vigilance systems requires reporting within 30 days of an awareness of a problem with a device. Key criteria for inclusion are devices that: (1) may have caused or contributed to a death or serious injury; or (2) have malfunctioned (and this device or a similar device that was marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur) [17]. The ONC requires that issues be taken up with vendors and developers and only if the vendor has not resolved the issue or there is dissatisfaction with solution should an ONC complaint be submittted [20].

Incident Reporting System

Patient safety reports usually describe the key data categories used to understand what happened, why it happened, and what were the consequences and reactions to the incident [27].

Analysis of the Incidents

Oversight System

This goal of the EU vigilance system is to be achieved by the evaluation of a reported incident, and where appropriate, dissemination of information could be used to prevent other occurences of a similar event, or to alleviate the consequences of incidents. Suspected incidents are made known to the manufacturers and it is with their close involvement and co-operation that the implementation of the Field Safety Corrective Actions (FSCA) is made possible [19, 21, 26, 29].

In the US system there are no regulatory requirements to evaluate EHR system safety [17], and adverse outcomes associated with EHRs are not being systematically and consistently tracked. The regulatory data is stored in several databases supported by the FDA and ONC [19]. EHR certification alone does not guarantee that EHRs will be implemented and that they will work as planned [6, 14-18, 30]. If issues arise there is opportunity to: contact a vendor and this is followed by a formal complain with an ONC certification body [20, 31].

Incident Reporting System

Collected data is most commonly used for hazard identification and issuing of alerts, as well as for trends-cluster analysis. Risk, causal and systems analysis, are utilized in more mature US national reporting systems [27].

Summary

IRS are associated with voluntary reporting while oversight systems require that health professionals' are mandatory. Anonymity and confidentiality are important aspects of IRSs. Oversight systems do have usually more detailed HIT-specific

structures. Neither of these systems publically share data e.g., on a national level.

Discussion

This analysis provides a useful comparison between two types of reporting systems for technology-induced errors. The purpose and reporting criteria of IRS and ORS are not always clear for HIT users that are reporting these incidents. This paper may serve as guidance e.g., for clinicians by clarifying the major differences in these systems. In this context, our analyses reveal that there is a need for effective reporting about technology-induced errors. If there are multiple reporting systems with similar goals, health care professionals may become confused and this may negatively influence their willingness to report technology-induced errors. The issue of underreporting in both systems is a recognized phenomen which requires further consderation. For example, underreporting exists in the US regulatory system. In the US there are only a small number of EHR incidents in differring databases so the total number of reports requires a review and analysis of multiple differing databases [7, 16-18]. EU studies are scarce. To address this underreporting of technology-induced errors there is a need to encourage clinician reporting, to develop reporting criteria for health professionals when reporting to IRS and ORS (in such a way as to avoid duplicate reports), and to outline the process and provide information about how issues are resolved for health professionals to improve trust in the safety of HIT.

Specifically, in the EU the details of the medical software directive are relatively unfamiliar for EHR users and leaders. The application of the requirements of the directive have not been clear. Not all stand alone medical software qualifies as a medical device [21, 24, 29]. This complexity of criteria highlights the fact that resources are needed to strenghten the clinicians´ knowledge of reportable EHR-issues and consequently contributes to the reporting of incidents to improve the effectiveness of the regulatory system

When comparing oversight systems between the EU and US, there are challenges specifically with the US approach. Expert opinions of HIT oversight in the US and the HIT community should re-examine whether and how regulation of electronic health applications could foster patient safety [15]. Sittig and Singh proposed that in the US, there is a need to create a nationwide 'post-marketing' surveillance system to facilitate monitoring of HIT related safety events (i.e. technology-induced errors), and that methods and governance structures to support investigation of major HIT related safety events be developed [18]. Regarding both systems, there is an area still requiring consideration. Countries are at different stages of addressing technology-induced errors arising from HIT and there is considerable knowledge to be shared across the countries and internationally to improve HIT safety [32].

Conclusion

Criteria surrounding the types of reports that should be submitted to ORS and IRS systems are important so that health professionals know where to report such events and to avoid duplicate reporting (i.e., submitting one report across multiple databases). There is a need to provide informaton about HIT related safety events (and how they were resolved) to health professional users to encourage reporting of events and enhance their trust in the process of improving HIT safety.

References

[1] Agboola, S., Bates, D. and Kvedar, J. (2016). Digital Health and Patient Safety. JAMA, 315(16), p.1697. doi: 10.1001/jama.2016.2402.

[2] Denham, C.R., Classen, D.C., Swenson, S.J., Henderson, M.J., Zeltner, T. and Bates, D.W. (2013) 'Safe use of electronic health records and Health Information Technology systems', Journal Patient Safety, 9(4), pp. 177–189.

[3] IOM (Institute of Medicine) (2012) ´Health IT and patient safety: building safer systems for safer care. Opportunities to improve safety in the use of health IT´. Washington, DC, USA: The National Academies Press; 2012.

[4] Borycki, E. (2013) Technology-induced errors: where do they come from and what can we do about them? Stud Health Technol Inform, 194:20-6.

[5] Magrabi, F., Aarts, J., Nohr, C., Baker, M., Harrison, S., Pelayo, S., Talmon, J., Sittig, D.F. and Coiera, E. (2013) 'A comparative review of patient safety initiatives for national health information technology', International Journal of Medical Informatics, 82(5), pp. e139–e148.

[6] Magrabi, F., Ong, M.-S., Runciman, W. and Coiera, E. (2012) 'Using FDA reports to inform a classification for health information technology safety problems', JAMIA, 19(1), pp. 45–53. doi: 10.1136/amiajnl-2011-000369.

[7] Howell, A.-M., Burns, E.M., Hull, L., Mayer, E., Sevdalis, N. and Darzi, A. (2016) 'International recommendations for national patient safety incident reporting systems: An expert Delphi consensus-building process', BMJ Quality & Safety, pp. bmjqs–2015–004456.

[8] Benn, J., Koutantji, M., Wallace, L., Spurgeon, P., Rejman, M., Healey, A. and Vincent, C. (2009). Feedback from incident reporting: information and action to improve patient safety. Quality and Safety in Health Care, 18(1), pp.11-21.

[9] Brennan, T.A. (2000) 'The institute of medicine report on medical errors - could it do harm?', New England Journal of Medicine, 342(15), pp. 1123–1125.

[10] Flink, E., Chevalier, C.L., Ruperto, A., Dameron, P., Heigel, F.J., Leslie, R., Mannion, J., Panzer, R.J. (2005) Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems. In: Henriksen, K., Battles, J.B., Marks, E.S., Lewin, D.I., editors. Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb.

[11] Marella, W.M., Sparnon, E. and Finley, E. (2014) 'Screening electronic health Record–Related patient safety reports using machine learning', Journal of Patient Safety, p. 1.

[12] Warm, D. and Edwards, P. (2012) 'Classifying health information technology patient safety related incidents – an approach used in wales', Applied Clinical Informatics, 3(2), pp. 248–257.

[13] Chai, K.E.K., Anthony, S., Coiera, E. and Magrabi, F. (2013) 'Using statistical text classification to identify Health Information Technology incidents', JAMIA, 20(5),pp.980–985.

[14] Goodman, K.W., Berner, E.S., Dente, M.A., Kaplan, B., Koppel, R., Rucker, D., Sands, D.Z. and Winkelstein, P. (2011) 'Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: A report of an AMIA special task force', JAMIA, 18(1), pp. 77–81.

[15] Myers, R.B., Jones, S.L. and Sittig, D.F. (2011) 'Review of reported clinical information system adverse events in US food and drug administration databases', Applied

Clinical Informatics, 2(1), pp. 63–74. doi: 10.4338/aci-2010-11-ra-0064.
[16] De Moor, G,, O'Brien J,, Fridsma D,, Bean, C., Devlies J, Cusack CM,, Bloomrosen M,, Lorenzi N, and Coorevits P.(2011) Policy brief on the current status of certification of electronic Health Records in the US and Europe. Stud Health Technol Inform. 2011;170:83-106.
[17] Singh, H., Classen, D.C. and Sittig, D.F. (2011) 'Creating an oversight infrastructure for electronic health Record–Related patient safety hazards', Journal of Patient Safety, 7(4), pp. 169–174. doi: 10.1097/pts.0b013e31823d8df0.
[18] Sittig, D.F., Classen, D.C. and Singh, H. (2014) 'Patient safety goals for the proposed federal health information technology safety center', JAMIA.
[19] EU (2007) Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007. Archived at: http://www.webcitation.org/6lfm9YoLh.
[20] Health IT.gov (2016) Archived at: http://www.webcitation.org/6ms71VP9S.
[21] EEC (1993) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Archived at: http://www.webcitation.org/6lM7nIudx.
[22] Arksey, H. and O'Malley, L. (2005) 'Scoping studies: Towards a methodological framework', International Journal of Social Research Methodology, 8(1), pp. 19–32.
[23] Furukawa, M.F., Eldridge, N., Wang, Y. and Metersky, M. (2016) 'Electronic health record adoption and rates of in-hospital adverse events', Journal of Patient Safety , p. 1.
[24] EU (2009) Council Recommendation on patient safety, including the prevention and control of healthcare associated infections, 2009/C 151/012. Available at http://www.webcitation.org/6lp3DNpv4.
[25] AMA (American Medical Association) (2009). The Physician's Guide to Patient Safety Organizations. American Medical Association; 2009. pp. 1–24. Available at http://www.webcitation.org/6louKcZD4.
[26] National Supervisory Authority for Welfare and Health In Finland. Available: http://www.webcitaion.org/6lMAapqbN
[27] Doupi, P. (2009) National Reporting Systems for Patient Safety Incidents. A review of the situation in Europe. National Institute for Health and Welfare (THL), Helsinki, Finland: Yliopistopaino, Report 13/2009, pp. 59.
[28] Haller, G., Myles, P.S., Stoelwinder, J., Langley, M., Anderson, H. and McNeil, J. (2007) Integrating incident reporting into an electronic patient record system. JAMIA, 14(2):175-81. Epub 2007 Jan 9.
[29] EC (2016) European Commission MEDDEV 2.1./6.Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework on medical devices. http://www.webctation.org/6lp3WD4UA.
[30] Bowman, S. (2013) Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications. Perspectives in Health Information Management, 10(Fall):1c.
[31] HealthIT.gov Provider complaint process. http://www.webcitation.org/6msFcY6XH
[32] Kushniruk, A.W., Bates, D.W., Bainbridge, M., Househ, M.S. and Borycki, E.M. (2013) 'National efforts to improve health information system safety in Canada, the United States of America and England', International Journal of Medical Informatics, 82(5), pp. e149–e160. doi: 10.1016/j.ijmdinf.2012.12.006.

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