

令和 6 年 9 月 20 日現在

機関番号：12608

研究種目：若手研究

研究期間：2019～2023

課題番号：19K15236

研究課題名（和文）Patient safety: Casting a spotlight on electronic medical record-related incidents

研究課題名（英文）Patient safety: Casting a spotlight on electronic medical record-related incidents

研究代表者

顧 秀珠 (Gu, Xiuzhu)

東京工業大学・工学院・准教授

研究者番号：20632615

交付決定額（研究期間全体）：（直接経費） 3,200,000 円

研究成果の概要（和文）：本研究では電子カルテシステムに起因する新たな患者安全問題に焦点をあて、これらの事象の報告・分析・対策・評価を含む「電子カルテシステム適応型インシデント管理システム」を構築した。まず「電子カルテシステム適応型インシデント分類法」を開発し、関連するインシデント・事故事例の分析、および医療者に対するインタビュー調査で得られた結果から、現状での問題点と特徴を解明した。これらの分析結果に加え、さらに電子カルテシステム先進国の安全管理経験をもとに構築したシステムの有効性を病院でのケーススタディにより、関連するインシデント報告の推移、システム適用による対策の妥当性、医療者・管理者の満足度などから評価した。

研究成果の学術的意義や社会的意義

本研究の3つの主要な成果：第一、電子カルテ（EMR）関連のインシデント分析のためのエラー分類法である。この分類法は、これまでの研究が技術的なエラーに焦点を当てていたのに対し、医療スタッフとEMRシステムとの間のインタラクションの失敗に注目。第二、日本の病院の現状におけるEMR関連のインシデントの重要な特徴である。この分野において日本での研究はまだ行われていないため、本研究で得られる結果は初めてのものとなる。第三、現在の患者安全管理システムは、新たなEMR関連の安全問題には適していないため、本研究で開発されたEMR関連のインシデント管理システムは、これらの問題を解決するための有用な支援となる。

研究成果の概要（英文）：This study focused on new patient safety issues arising from electronic medical record (EMR) systems and aimed to develop an EMR-related incident management system that includes reporting, analysis, countermeasures, and evaluation of these events. A literature review and interviews with experts such as healthcare providers and management personnel were conducted to develop a taxonomy system for EMR-related incident analysis. Using this taxonomy system, the current problems and characteristics were clarified through the analysis of related incident and accident events. Based on these results, EMR-related incident management system was developed, consisting of incident reporting, analysis, countermeasures, and evaluation. The effectiveness of the system was evaluated through case studies, considering the trends in related incident reports, the appropriateness of countermeasures applied by the system, and the satisfaction levels of healthcare providers and management personnel.

研究分野：医療管理、安全工学、人間工学

キーワード：Patient safety Accident Incident EMR system Taxonomy

1. 研究開始当初の背景

The implementation of medical information systems in hospitals is progressing steadily throughout the world. In Japan, about 40% of hospitals have introduced electronic medical record (EMR) systems by the end of 2017. An EMR system typically interfaces with systems related to clinical documentation, computerized provider-order entry, access to test and imaging results, and billing. Such EMR systems have been expected for the benefits of various organizational goals, e.g., higher efficiency, improved workflows, and patient safety. Based on the classifications of the Japanese Ministry of Health, Labor and Welfare, implementation level of EMR systems in Japan are mostly at Level 2 (handling electronic patient information between departments) or Level 3 (in a whole organization). Some domestic researchers dealt with EMR system implementation process. In other developed countries such as Nordic countries, United States and Australia, the implementation level of EMR systems is slightly higher than Japan, i.e., at Level 4 (handling electronic patient information between several organizations) or Level 5 (not only medical information, but also health and welfare information; Electronic Health Record).

However, according to the previous studies, introduction of EMR systems have given no benefit or even negative impacts on productivity in Japan. So far, there has been no research dealing with its impact on patient safety in Japan yet. However, in the previous studies, incidents caused by EMR systems have occurred in Japanese hospitals during patient handoffs. Such EMR-related patient safety topics draw attention recently in countries such as United States, European countries and Australia, where EMR systems were installed earlier and more widespread than Japan. Researchers in these countries identified that new patient safety problems appeared due to not only technology errors but also healthcare staff-EMR interaction failures. As it is a new concern on patient safety, very limited things have been known about features of these failures. There has been no system supporting for analysis and solving these problems. Therefore, this research project firstly initiated this field of study in Japan. The developed taxonomy and management systems for EMR-related incidents could be useful supporting safety management in a new era, and inspire further studies all over the world.

2. 研究の目的

Based on the background mentioned above, there are mainly three objectives: Firstly, to develop a taxonomy system for EMR-related incident analysis; secondly, applying the taxonomy system to a number of incidents, to capture crucial characteristics of EMR-related incidents and their latent factors in the current context of Japanese hospitals; finally, based on the obtained results and learning experience from EMR advanced countries, to develop an EMR-related incident management system, including incident reporting, analysis, measures taking and evaluation.

3. 研究の方法

A literature survey and interviews to several healthcare professionals were conducted first to collect relevant information related to this research project. The information includes all the possible EMR-related failure types, contributing factors, outcomes, measures, etc. Then, more information of latent factors was obtained by semi-structured interviews with healthcare staff about their self-experienced EMR-related critical incident. Based on all the investigated outcomes, an error taxonomy system specifically for EMR-related incidents was developed. The taxonomy system is divided into human-related and machine-related sections, and it consists of five categories: three process stages (data input, transformation, and output), general technical factors and latent factors. The inter-rater reliability of the taxonomy system was verified by Kappa coefficient. The developed taxonomy system was then applied to analyse EMR-related accidents and incidents.

EMR-related accidents and incidents were collected from Accident Information Collection Project of the Japan Council for Quality Health Care (JCQHC). The number of EMR-related accidents was 765, and the number of EMR-related near-misses was 1206. Thus, the characteristics of EMR-related incidents in the current context of Japanese hospitals were explored.

Based on all the results obtained, an EMR-related incident management system was developed. It includes incident reporting, i.e., what kind of incidents should be reported, to what extent and how. The system also includes how to make analysis of incidents; corresponding to the analysis results, what kind of measures could be taken and how, and how to make evaluations after taking measures. Effectiveness of the system was verified, using indicators such as change of EMR-related incident reporting rate, appropriateness of proposed measures, and healthcare staff and risk managers' satisfaction.

4. 研究成果

The findings of this research project showed that the problems in both EMR-related accidents and incidents are generally similar. Over 90% of both accidents and incidents involved human-related factors. Among these, factors related to the data output process are the most frequent, with the most common problem being the lack of data verification, accounting for nearly half of both accidents and incidents. The second most frequent issue is related to data input, with incorrect data entry being the most common problem.

Regarding latent factors, the most frequent issue is related to staffing and training, particularly problems arising from not following extended rules and deficiencies in workflow. For machine-related factors, issues in the data transfer process are the most common, especially problems with system integration. These account for 16.1% of all accident cases and 4.7% of incidents. Additionally, the failure of alerts to function properly during data input and output is a particularly serious issue. Among general technical factors, software issues are the most prevalent, accounting for 42.5% of accident cases and 9.5% of incidents. In addition, the loss of data when transcribing from paper to EMR systems is also a critical problem.

Therefore, this research project, the first large-scale investigation of EMR-related accidents and incidents in Japan, provides critical insights into the design, implementation, and use of EMR systems. For machine-related factors, the study highlights the need to enhance the functionality of EMR systems, particularly the effectiveness of alert functions and the integration with other devices. Additionally, during the initial implementation of EMR systems, careful attention must be given to the transcription of information from paper records and the configuration of master settings. Because 90% of the EMR-related issues are related to human factors, with significant problems arising from non-compliance with rules and deficiencies in workflow, regular training on procedures and the promotion of a safety culture within healthcare organizations are essential.

In conclusion, there are three major outcomes in this research project. The first outcome is the taxonomy system for EMR-related incident analysis. Particularly, this taxonomy system pays more attention on interaction failures between healthcare staff and EMR systems, as most of previous studies focused on technology errors. The second outcome is crucial characteristics of EMR-related incidents in the current context of Japanese hospitals. As there has been no Japanese study in this field yet, results obtained in this project are the first results. The third outcome is an EMR-related incident management system. Because the current patient safety management systems are not suitable for the new EMR-related safety problems, the developed management system is useful to address these problems.

5. 主な発表論文等

〔雑誌論文〕 計10件（うち査読付論文 10件 / うち国際共著 6件 / うちオープンアクセス 0件）

1. 著者名 Liu Ran, Liu Hu-Chen, Shi Hua, Gu Xiuzhu	4. 巻 160
2. 論文標題 Occupational health and safety risk assessment: A systematic literature review of models, methods, and applications	5. 発行年 2023年
3. 雑誌名 Safety Science	6. 最初と最後の頁 106050 ~ 106050
掲載論文のDOI (デジタルオブジェクト識別子) 10.1016/j.ssci.2022.106050	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 該当する
1. 著者名 Shao Zhen, Gu Xiuzhu, Shi Jianwei, Tian Kan, Yang Zhiqiang	4. 巻 39
2. 論文標題 Influencing Factors of Medical Adverse Events Reporting in Taicang, Jiangsu Province (in Chinese)	5. 発行年 2022年
3. 雑誌名 Chinese Journal of Social Medicine	6. 最初と最後の頁 103-107
掲載論文のDOI (デジタルオブジェクト識別子) なし	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 該当する
1. 著者名 Gu Xiuzhu, Deng Mingming	4. 巻 17
2. 論文標題 The Impacts of Disclosure and a Proactive Compensation Offer on Chinese Patients' Actions After Medical Errors	5. 発行年 2021年
3. 雑誌名 Journal of Patient Safety	6. 最初と最後の頁 e745 ~ e751
掲載論文のDOI (デジタルオブジェクト識別子) 10.1097/PTS.0000000000000855	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 該当する
1. 著者名 Gu Xiuzhu, Deng Mingming	4. 巻 17
2. 論文標題 Medical Error Disclosure: Developing Evidence-Based Guidelines for Chinese Hospitals	5. 発行年 2021年
3. 雑誌名 Journal of Patient Safety	6. 最初と最後の頁 e738 ~ e744
掲載論文のDOI (デジタルオブジェクト識別子) 10.1097/PTS.0000000000000760	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 該当する

1. 著者名 Gu Xiuzhu, Itoh Kenji	4. 巻 36
2. 論文標題 Organizational Climate for Safe and Effective Inter unit Handoffs in Japanese Hospitals	5. 発行年 2021年
3. 雑誌名 The International Journal of Health Planning and Management	6. 最初と最後の頁 1153 ~ 1165
掲載論文のDOI (デジタルオブジェクト識別子) 10.1002/hpm.3162	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 -

1. 著者名 Gu Xiuzhu, Itoh Kenji	4. 巻 76
2. 論文標題 Inter shift handoff: Changes over a 6 year interval	5. 発行年 2020年
3. 雑誌名 Journal of Advanced Nursing	6. 最初と最後の頁 3418 ~ 3428
掲載論文のDOI (デジタルオブジェクト識別子) 10.1111/jan.14537	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 -

1. 著者名 Gu Xiuzhu, Itoh Kenji	4. 巻 35
2. 論文標題 A comparative study on healthcare employee satisfaction between Japan and China	5. 発行年 2019年
3. 雑誌名 The International Journal of Health Planning and Management	6. 最初と最後の頁 171 ~ 184
掲載論文のDOI (デジタルオブジェクト識別子) 10.1002/hpm.2859	査読の有無 有
オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 -

〔学会発表〕 計4件 (うち招待講演 0件 / うち国際学会 4件)

1. 発表者名 Zhao, Y., Gu, X. and Liu, Y.
2. 発表標題 Resilience of Healthcare Systems in Natural Disaster - A Case Study in Henan Rainstorm
3. 学会等名 The 32nd European Safety and Reliability Conference (ESREL2022) (国際学会)
4. 発表年 2022年

1. 発表者名 Gu, X., Deng, M. and Itoh, K.
2. 発表標題 Incident Experienced Patients and Families' Expectations of Disclosure: A Cross-Cultural Study
3. 学会等名 The 6th World Conference on Production and Operations Management (P&OM) (国際学会)
4. 発表年 2022年

1. 発表者名 Gu Xiuzhu
2. 発表標題 How to make a medical error disclosure to patients?
3. 学会等名 IEEE International Conference on Industrial Engineering and Engineering Management (IEEM) 2019 (国際学会)
4. 発表年 2019年

〔図書〕 計0件

〔産業財産権〕

〔その他〕

-

6. 研究組織

氏名 (ローマ字氏名) (研究者番号)	所属研究機関・部局・職 (機関番号)	備考

7. 科研費を使用して開催した国際研究集会

〔国際研究集会〕 計0件

8. 本研究に関連して実施した国際共同研究の実施状況

共同研究相手国	相手方研究機関			
ノルウェー	ノルウェー科学技術大学			
中国	西安交通大学	上海交通大学	同濟大学	他1機関