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ROOT CAUSE ANALYSIS TO IDENTIFY MAJOR BARRIERS TO THE PROMOTION
OF PATIENT SAFETY IN JAPAN

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Abstract

Objectives: Despite existing patient safety measures, both outside and inside hospitals, barriers to patient safety prevail. We aimed to identify the current contributory factors to patient safety in Japan.

Methods: This qualitative study included nine expert Japanese health care providers working both inside and outside hospitals. These participants, who included six physicians, one nurse, one pharmacist, and one physical therapist, work across a broad spectrum in government policy and public health, academia, and safety management. Root cause analysis using the online Kawakita Jiro method (KJ method or affinity diagram) was conducted. We labeled and summarized the classification in a fishbone diagram to elucidate barriers to patient safety in Japan.

Results: We identified specific factors in six main groups: the hospital system, education, law and policy, culture and society, patient centricity, and multidisciplinary cooperation. Quality of care, patient engagement, and shortage of patient safety specialists were crucial factors for multiple groups.

Conclusions: This study clarifies components of patient safety in Japan and provides basic data for promoting comprehensive patient safety in the future. Periodic root cause analysis of

comprehensive patient safety issues can help develop strategies to promote patient safety at both hospital and national levels.

Keywords: patient safety, root cause analysis, safety culture, health care quality improvement, fishbone analysis

Introduction

The publication of the report “To Err is Human,” by the Institute of Medicine in 1999, set patient safety as a global issue.^{1,2} In Japan, numerous serious medical accidents occurred in 1999, leading to the implementation of safety measures inside and outside hospitals.³ Given this social attention, the Japanese government established a department in charge of safety in 2001 and mandated the implementation of safety measures in all hospitals and clinics.³ In 2002, the Japanese council coordinated the “patient safety promotion comprehensive measures” report that described the barriers to and countermeasures for patient safety, such as education on patient safety, system factors to promote patient safety, and the necessity of scientific research on patient safety.^{3,4} Although various patient safety measures, including the national adverse event reporting and learning system and investigation system of death cases due to medical accidents, were enforced based on this report,³ barriers to patient safety remain.

Several factors, both outside and inside hospitals, lead to the failure in promoting patient safety.⁵ Careful consideration of all barriers and countermeasures against these barriers would strengthen the link between public health and hospital management, ensuring patient safety.

Therefore, we formed a multidisciplinary team of professionals involved in patient safety and conducted a qualitative root cause analysis to identify the current problems and contributory factors to patient safety in Japan. The team included those responsible for patient safety

policies in the Ministry of Health, Labour and Welfare, medical safety managers, and frontline health workers.

Methods

Nine Japanese health care providers attended an online meeting on July 7, 2021, to identify major barriers to promoting patient safety in Japan. This study group, which comprised six physicians (MK, TW, SK, SW, KN, and SK), one nurse (KT), one pharmacist (KE), and one physical therapist (TK), collected a wide range of opinions. In addition to the differences in job positions, we also paid attention to their roles inside and outside hospitals, such as government policy and public health, academia, safety management, and practitioners. KN has worked as a head officer at the Department of Patient Safety at the Ministry of Health, Labour, and Welfare in Japan; SK has worked as a key member of the Society for Patient Safety and supported patient safety from an academic perspective by holding a key position in the Japanese Society for Quality and Safety in Healthcare; SK and SW have been working as patient safety managers at their respective hospitals; and the other members have been engaged in patient safety activities, such as incident reporting triage and quality improvement, at their respective hospitals. This study involved no interaction or intervention with human participants and identifiable private information was not accessed; therefore, ethical approval was not required.

According to the Kawakita Jiro (KJ) method,⁶ we used an affinity diagram to list potential barriers to patient safety in Japan using Google Docs. The KJ method is used for identifying problems in a particular area and is a constituent of root cause analysis-related tools.⁷ In a 40-min session, we listed 100 foreseeable problems/barriers. After deleting duplicate items, we spent 20 min grouping the remaining problems/barriers. The possible barriers were then assigned to each group. After performing root cause analysis, we labeled and summarized the classification results in a fishbone diagram to elucidate the barriers to promoting patient safety in Japan. After an online discussion, we spent two weeks discussing contributory factors through email. Finally, all the participants agreed on the content.

Results

Figure 1 shows the six groups of contributory factors identified in our study.

Hospital System

We identified six factors belonging to the hospital system barrier. First, in Japan, a culture of patient safety has not fully developed, and incident reporting is typically not conducted because of the lack of penetrative reporting and improvement culture. Second, staff whose understanding of patient safety measures is limited may misunderstand incident reporting as a punitive measure.

Third, we identified a lack of scientifically validated data on patient safety that could be used in research and for comparison with other countries. Indeed, patient safety remains an under-researched and neglected area of study. Fourth, Japan also does not have enough patient safety specialists designated to provide patient safety leadership.

Fifth, an absence of continuity was also noticed because the person in charge of patient safety, in keeping with the conventions of their respective occupations, is often transferred periodically. The hospital rules about these decisions have not been sufficiently modified.

Last, we identified the weak authority of the hospital safety management department, exemplified by the need to generate proper patient safety leadership and the lack of encouragement among hospital staff to report safety issues. Hospital administrators do not fully understand medical safety and, therefore, are unable to promote patient safety activities.

Education

We identified several factors related to education. Factors that result in inadequate patient safety education include the shortage of relevant pre-and post-graduate education systems and the emphasis on diagnosis and treatment of diseases in medical education. Furthermore, qualifications and professional systems related to patient safety have not been established, research is scarce, and human resource training related to patient safety is lacking.

Consequently, Japan has not fostered an environment for the development of young patient

safety specialists. Finally, although quality indicators are measured for each hospital organization, those related to patient safety have not been fully investigated, and there is room for quality improvement in terms of collaborations within the field of health care.

Law and Policy

We determined several factors related to law and policy. First, data on medical accidents and patient safety are not widely shared. In addition, the continuum between the quality of care and patient safety is not well recognized. Investment in patient safety is lacking at the national and hospital levels, as well as from promoters and leaders of patient safety because of the dearth of national systems and programs to train professionals on the same. In Japan, instead of understanding the actual situation of patient safety in primary care and taking measures accordingly, discussions mainly focus on patient safety in hospitals, despite the fact that patient safety is important at all levels of health care, from primary care to hospital care. In addition, as the Japanese health care system is changing, such as with the promotion of home medical care, safety systems also need to be updated. Therefore, law and policy must be linked to safety measures in medical institutes. Consequently, the Japanese government appears hesitant to prioritize patient safety measures.

Culture and Society

Five factors related to Japanese culture and society were identified. The characteristics of the Japanese people include the pursuit of zero risks and a culture of shame and blame for failure, where individuals are heavily monitored and disincentivized punitively. Moreover, an understanding of patient safety as a science and scientific literacy on this issue is limited. Media coverage of patient safety including medical accidents tends to be sensationalized, attributable to hospitals' lack of relationship with the media. Medical practitioners are afraid of medical lawsuits which impact patient safety. Patient safety is often misconstrued as "medical" safety instead of being patient centered.

Patient Centricity

Five factors were identified as contributing to the lack of patient centricity. First, mechanisms encouraging dialogue between medical professionals and patients, such as open conferences and patient advisory boards, are absent. Second, the concerns of patients who have difficulties understanding the kind of medical care provided by medical teams are rarely reflected in medical care. Third, there is a need for greater transparency and information disclosure. Fourth, patients have few opportunities to voice their dissatisfaction and question medical care, and procedures for medical lawsuits are complicated. Finally, efforts to promote public understanding of patient safety are limited, and issues around patient literacy regarding health care quality and safety prevail.

Multidisciplinary Cooperation

We identified four factors related to multidisciplinary cooperation. Patient safety in hospitals involves various other medical professionals in addition to doctors and nurses, making it difficult to build a fully collaborative team. Moreover, opportunities for multidisciplinary collaboration are few. This creates a sense of stagnation and hierarchy among practitioners in each occupation. In addition, the mechanisms for patients to engage in medical care and improve safety through patient collaboration are deficient.

Discussion

We used qualitative analysis to examine issues related to patient safety in Japan, which included internal hospitals, individual patients, and law and policy issues. We divided them into six major groups using the fishbone diagram. This study clarifies the components of patient safety in Japan and serves as basic data for promoting comprehensive patient safety in the future.

Previous reports have categorized issues concerning patient safety, albeit using different methods. Wong and Beglaryan have categorized eight strategies for improving patient safety in hospitals,⁸ and recommend the following measures: improving communication within the clinical team, reporting adverse events, increasing patient involvement, developing

guidelines, managing human resources, setting management commitment to patient safety, disclosing adverse events, and implementing safety education for health care professionals.

Many of the above factors are similar to those identified in the present study. Therefore, the promotion of patient safety in Japan by referring to the measures adopted by other countries, should provide comprehensive solutions to these issues.

In our study, the following three issues were common across multiple groups: collaboration in the health care quality field, lack of patient collaboration, and lack of expertise and human resources in patient safety.

First, multidisciplinary collaboration in the medical quality field can improve patient safety, an important aspect of health care quality.⁹ Through proper measurement and evaluation of patient safety as part of health care quality, and by using research to improve and maintain safety, health care quality and patient safety can be ensured. Our study pointed to the inclusion of medical quality from the perspectives of education, medical policies, and law.

Moreover, the measured quality of medical care is ineffectively used for policy at the national level. In the United States, the Centers for Medicare & Medicaid Services measure safety as an indicator of the quality of care, which influences reimbursement.¹⁰ In addition, these indicators are scored so that they can be compared across hospitals. In Japan, all health care providers are required to undergo training on patient safety and hospitals are obliged to establish patient safety committees based on the medical care act.¹¹ However, this is

insufficient to ensure the quality of health care provision, since it is not possible to confirm whether safety has actually increased as a result. Therefore, Japan needs to strengthen institutions that can utilize an indicator for quality regarding patient safety at the national level and base its policy on feedback.

Second, promoting patient engagement is essential. Patient engagement refers to the significant role that patients play in their health care.¹² For this, hospitals should allow patients to participate in decision-making with health care professionals. The importance of patient engagement has also been highlighted in the Tokyo Declaration and has become a common issue worldwide.¹³ Australian and UK reports and the Global Patient Safety Action Plan 2021-2030 mention the need for patient engagement,^{2,14,15} and a Canadian report mentions several relevant initiatives.¹⁶ Only a few such reports are available in Japan.¹⁷ In this study, we noted poor patient engagement from the perspective of patient centricity and multidisciplinary collaboration. Patient engagement enhances patient centricity, and a high level of multidisciplinary collaboration promotes patient engagement.¹⁸ Patient centricity may be enhanced by strengthening multidisciplinary cooperation, increasing the number of activities that promote patient collaboration, and creating a culture wherein these activities are reported and shared.

Finally, we addressed the shortage of patient safety specialists who facilitate and implement projects and programs that encourage improvements in care quality and patient safety

promotion.¹⁹ These specialists are better aware of safety policies and systems than other health care professionals, and thereby occupy an important position in ensuring patient safety.²⁰ A National Health Service report also points to the shortage of patient safety specialists as a challenge.¹⁴ In Japan, although basic training courses on patient safety have been held nationally,³ the role and effectiveness of patient safety specialists and leaders have not been clarified, and the methods of training have not been established. To solve this problem alluded to by the National Health Service, the medical field should clarify the role of experts, establish patient safety training as a sustainable effort, clarify what experts need and what kind of training is useful for them, and facilitate basic patient safety education. It is necessary to promote the establishment and development of the role of patient safety specialists through medical education and practice in Japan.

Limitations and Future Research

This study has several limitations. First, although patient safety is recognized as an international issue, this study has focused on patient safety solely in Japan. Therefore, one should be cautious when adapting the methodology of this study to other settings. Second, this study used the KJ method and fishbone diagram to identify contributory factors in Japan. While the root cause analysis methodology can be applied across settings, the results of this study cannot be generalized to other contexts.

Despite these limitations, our study highlights the importance of a standard, scientifically comprehensive understanding of patient safety issues, as in the UK and Australia. In Japan, the current efforts to address patient safety remain limited. The Japan Council for Quality Health Care is the only institution that releases an annual report on collected incidents in English.²¹ The nation has not updated an exhaustive report on patient safety since 2005.^{4, 22} While some patient safety issues are universal, new ones are being identified amidst progress in the medical field.²³ To identify such problems in real-time, medical practitioners should proactively organize studies promoting comprehensive patient safety measures not only at the hospital level but also at the national level.

Conclusion

The study findings reveal problems regarding patient safety in Japan. In particular, the associations between quality of care, the practice of patient engagement, and the shortage of patient safety specialists are important from multiple perspectives. Periodic root cause analysis of these comprehensive patient safety issues, along with suggestions for improvement, implementation, and monitoring, could help formulate strategies for promoting patient safety at the hospital and national levels.

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The authors declare no conflicts of interest.

Author Contributions:

MK and TW contributed equally to the paper. TW conceived of the study. MK and TW developed the research protocol. All authors participated in the online session. TK, KT, KE, and SW performed the initial sorting of the data. MK drafted the first version of the paper. TW and SK made contributions to interpreting results and developing the conceptual findings of the paper. All authors contributed to the development of the manuscript content. All authors read and approved the final manuscript.

Data Sharing and Data Availability Statement:

This is a qualitative study, and there are no quantitative data available. However, the textual data collected online during discussions, a template for the Ishikawa Diagram, and several methods that support the findings of this study are available from the second author, TW, upon reasonable request.

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Figure Legend

Figure 1. Six types of barriers to promoting patient safety in Japan.

