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Promotion of Patient Safety

Tatsuya FUKAMI
Medical Safety Division, Shimane University Hospital, Izumo, Shimane 693-8501, Japan
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It has been 20 years since patient safety in Japan was put in place after a patient mix-up accident at a university hospital in 1999. Based on the formulation of patient safety policies, system development and patient safety activities have been carried out at medical sites across the country. However, despite such on-site efforts, medical accidents continue. In 2016, several serious medical incidents occurred at special function hospitals, and in response to this outbreak, the requirements for patient safety systems at advanced treatment hospitals were significantly revised. This paper reports on the impact and prospects of patient safety, and the "Promotion of patient safety" for medical professionals, patients, and medical students through patient safety education.

Keywords: patient safety, patient engagement, psychological safety, shared decision making, education

INTRODUCTION

Medical care has made remarkable progress in recent years, as its sophistication and complexity accelerates. The goal of those of us involved in medical care is to ensure that patients receive good care and are satisfied with that care. Furthermore, once you are in the position of a patient, one might argue that what you want most is to safely receive medical care, whether it is very difficult treatment or standard care. However, medical accidents occur frequently in the real world of healthcare, and the importance of patient safety as a countermeasure is growing every year. To this end, I will outline the history of patient safety and the prospects for the future.

HISTORY OF PATIENT SAFETY IN JAPAN

Modern "patient safety" in Japan began with the 1999 Yokohama City University Hospital accident of mistaking patients for operations［1］. Since then, there were several serious accidents at various facilities（Table 1）causing public awareness of patient safety to rise. Japan's national policy started in 2001 and was triggered by media reports that heightened interest in medical accidents and safety measures. In approximately the last 20 years Japan has changed from the traditional person-based approach to thinking that "medical malpractice can be prevented by individual attention." Under this new so-called systems approach, the Japanese medical community recognizes that "medical accidents can happen," and aims to prevent accidents by improving the way teams and organizations work as a whole. Under this policy, in addition to developing patient safety guidelines at hospitals and clinics across the country, efforts were made to establish and staff departments specializing in patient safety. However, despite the thorough implementation of such measures, medical accidents have not yet decreased either in Japan or overseas, and there are reports that their frequency of occurrence is comparable to that of major diseases, with mortality rates［2］. Given this current situation, patient safety is

Corresponding author: Tatsuya FUKAMI, M.D., Ph.D.
Medical Safety Division, Shimane University Hospital, 89-1 Enya-cho, Izumo, Shimane 693-8501, Japan
Tel: +81-853-20-2066
Fax: +81-853-20-2405
Email: fukami@med.shimane-u.ac.jp

Table 1. Patient safety accidents which triggered national patient safety measures in Japan

- January, 1999: Yokohama City University Hospital
  Patients for heart surgery and lung surgery were mixed up, and operations were performed for different parts of the bodies.
- February, 1999: Tokyo Metropolitan Hiroo Hospital
  After a surgery, disinfectant, instead of anticoagulants, was administered intravenously by mistake, which resulted in the patient's death.
- February, 2000: Kyoto University Hospital
  Ethanol was put into a humidifier of a respirator/ventilator by mistake, instead of distilled water, and then the patient died of its toxicity.
- April, 2000: Tokai University Hospital
  Oral medication was administered intravenously, due to confusion with enteral nutrition route, which resulted in the pediatric patient's death.

attracting attention not only in Japan but also internationally as a social and medical problem that must be urgently resolved.

HISTORY OF THE ESTABLISHMENT OF THE PATIENT SAFETY DIVISION AT SHIMANE UNIVERSITY HOSPITAL

Even as patient safety attracted public attention, serious incidents related to patient safety have occurred at advanced treatment hospitals whose mission is to provide advanced medical care. Cases of death followed laparoscopic hepatectomy at Gunma University Hospital [3]. And at Tokyo Women's Medical University Hospital there was a case of death related to sedation due to the administration of off-label drugs to a child [4]. As a result of these incidents, the advanced treatment hospital approval for both hospitals was revoked. Intensive examinations were conducted simultaneously for advanced treatment hospitals. As a result, the approval requirements for advanced treatment hospitals, especially the patient safety system, were significantly revised (Table 2). As an overview, in addition to the enhancement of the patient safety management system and the establishment of a highly difficult new medical technology and unapproved drug review department, the appointment of a full-time doctor in the patient safety management department.

Table 2. Revised patient safety system for advanced treatment hospitals

1. Appoint patient safety manager
2. Incident/Accident Reporting
3. Establishment of a whistleblowing desk
4. Establishment of Patient Safety Audit Committee
5. Appropriate implementation of informed consent
6. Establishment of highly difficult medical technology/unapproved drug review department
7. A full-time doctor must be assigned to the patient safety management department.

ROLE OF THE PATIENT SAFETY DIVISION

1. Verifying the effects of assigning a patient safety specialist

The duties of a patient safety specialist include building a patient safety system, responding to medical accidents, and implementing patient safety education and training. We believe that providing safe medical care will lead to improved treatment outcomes and better quality of medical care. The most recent challenge is to raise physicians' awareness of patient safety in order to foster a culture of patient safety within the hospital. To help accomplish this, we have set an immediate goal of increasing the number of incident reports from physicians. We recognized that the current situation at our hospital was that doctors did not fully understand the significance and purpose of incident reporting, so we decided to focus on the following: 1) Ensuring patient safety: The hospital should intervene promptly. By doing so, the optimal treatment can be given to the patient after the event. 2) Diversification of risk: Once reported, the issue changes from an individual issue to a hospital management issue. 3) Ensuring transparency: Any report received helps demonstrate that the physician had no intention of hiding something. 4) Formal support: Full support can be obtained from the hospital regarding treatment of reported cases, compensation, etc. 5) Sys-

tem improvement: Reports can lead to preventive measures which reduce the risk of recurrence. We repeatedly made it known that the purpose is to prevent recurrence, and that reporting, rather than writing a letter of reflection or a letter of closure, is an important learning opportunity. In addition, as a concrete measure to increase the number of accident reports by physicians, 1) Clarification of accident reporting standards: reporting criteria were presented as surgery-related, non-surgical, and other, and expected complications were also included in the reporting criteria. We added this information to the manual and made it widely known. 2) Improving the reporting system: Due to the relocation of the hospital, the previously used electronic system was completely renovated to simplify reporting work, including using more check buttons. 3) Disclosure of the number of reports and reporting rate for each clinical department: In addition to the conventional reporting at the patient safety promotion committee, we started distributing and reporting the number of reports and reporting rate for each clinical department. As a recent result of the above measures, we have observed an increasing trend in the number of reports from doctors (Data not shown). However, most of the reports were made in response to reporting requests from the patient safety division, and we hope that in the future this will foster a culture of reporting and lead to an increase of voluntary reports. As for our next initiative, we will focus on diagnostic imaging, where patient safety issues have been reported nationwide. Describes countermeasures for insufficient confirmation of reports, etc. In order to prevent accidents due to insufficient confirmation of diagnostic imaging reports, etc., the Patient Safety Promotion Office of the General Affairs Division, Medical Policy Bureau, Ministry of Health, Labor and Welfare issued warnings on November 10, 2017 and June 14, 2018. In April 2019, the Japan Agency for Medical Safety released recommendations. Item 8, "Analysis of death cases related to image diagnosis in emergency medical care," is a warning aimed at preventing the recurrence of medical accidents [5]. As a countermeasure, our hospital has organized a series of procedures such as interpreting image diagnosis reports, opening and checking the contents of image diagnosis reports, and recording them in medical records, and we have required each medical department to open and report image diagnosis reports. The unopened document list was fed back to each clinical department, and the unopened document rate for each clinical department was disclosed at the clinical director's meeting. As a result, the unopened rate is decreasing, but the situation is still far from perfect. In addition, we strive to prevent important findings, such as suspected cancer in a site not intended by the referring physician, by having our patient safety experts directly check with the referring physician. In addition, we will build more reliable measures, including system improvements, by referring to the "Recommendations for the Utilization of Image Diagnosis Information from CT Examinations" published by the Japan Society for the Promotion of Science in September 2019 [6]. Regarding the unopened button, many people in the field wonder, "Are we really not checking it enough?" However, the original purpose is not to reduce the unopened rate to 0%. Our goal is to ensure that no reports are overlooked. It goes without saying that the number of patients who would be disadvantaged by this should be reduced to zero. We hope that these measures will increase awareness of patient safety and ultimately lead to the creation of a culture that values patient safety.

2. Future initiatives for patient safety measures

a. Patient engagement with psychological safety

Amy Edmondson is a renowned scholar and professor known for her work on psychological safety. She has highlighted the importance of leaders creating a safe space for people to speak up, make mistakes, and bring their full selves to work [7]. Edmondson's work on psychological safety has influenced academic research in management, healthcare, and education [7]. Her research has shed light on the importance of creating a psychologically safe environment for teams and organizations to thrive. Additionally, Project Aristotle, a research initiative by Google, aimed to discover the secrets of effective teams at Google [8]. The researchers found that the most successful teams shared five traits: Psychological safety, Dependability, Structure and clarity, Meaning and Impact. The disadvantage of a place with low psychological safety is that people have to

work with constant anxiety which leads to a decline in productivity and an increase in turnover [7,9]. If psychological safety is not ensured, the necessary information sharing and exchange of opinions will not be carried out due to fear of denial from those around them. Healthy conflict is an essential part of any workplace, as it can lead to improved outcomes, fresh perspectives, and growth for a business. It is therefore important to distinguish between healthy and unhealthy conflict [10]. Healthy conflict is based on mutual respect and trust, with participants being able to express thoughts without being bullied or put down for having a difference in opinion. To foster healthy conflict, it is important to encourage open communication, set clear expectations, embrace diversity, encourage healthy debate, and lead by example. By doing so, teams can experience more productivity, increased engagement, and improved innovation, creativity, and collaboration. Patients often come to the hospital with fear and anxiety and need psychological safety. Patient engagement is a process of involving patients in the care they receive, including providing them with information and resources to make informed decisions and allowing them to participate in care policy [11]. This process can be achieved through patient education and empowerment, patient-provider communication, and patient self-management [12]. It is an important part of patient-centered care, which focuses on understanding and meeting the needs and preferences of each patient. The goal of patient engagement is to improve health outcomes and patient satisfaction [13,14]. The theme of World Patient Safety Day 2023 is "Engaging patients for patient safety" [15]. It recognizes the crucial role patients, families and caregivers play in the safety of health care. Evidence shows that when patients are treated as partners in their care, significant gains are made in safety, patient satisfaction and health outcomes [13,14]. By becoming active members of the health care team, patients can contribute to the safety of their care and that of the health care system as a whole. World Health Organization calls on all stakeholders to take necessary action to ensure that patients are involved in policy formulation, are represented in governance structures, are engaged in co-designing safety strategies, and are active partners in their own care. This can only be achieved by providing platforms and opportunities for diverse patients, families, and communities to raise their voices, concerns, expectations, and preferences to advance safety, patient centeredness, trustworthiness, and equity [15]. Patient and family engagement were embedded in the Global Patient Safety Action Plan 2021–2030 [16] as main strategies for moving towards eliminating avoidable harm in health care. Psychological safety has been found to have a positive impact on patient engagement in healthcare settings [14]. Patients are more likely to feel comfortable and open up about their concerns when they perceive psychological safety in their interactions with healthcare providers [17]. In addition, psychological safety has been linked to patient safety, interprofessional collaboration, engagement in quality improvement work, learning from failures, and reporting adverse events [18]. To enhance psychological safety in health services, healthcare organizations can establish a council of patients and actively encourage family/career participation. Creating a psychologically safe environment in healthcare settings fosters a culture where individuals can speak up with new ideas, questions, and concerns in an effort to do better. This can lead to better communication and collaboration between healthcare providers and patients which ultimately improves the patient experience.

b. Psychological safety in shared decision making

Psychological safety between medical staff and patients is also key to successful shared decision making. Shared decision making is a process in which medical providers and patients work together to make decisions about their care. It allows for more collaboration and understanding between patients and providers, and helps to ensure that decisions are based on the patient's preferences and values [19–21]. For example, the implementation of a decision aid to encourage shared decision making may be difficult if clinicians do not have a good shared mental model with patients. Patient-Centered Care: Shared mental models can help healthcare professionals conceptualize patients as professionals, decision-makers, collaborators, and members of inter-professional healthcare teams. This can fa-

cilitate patient-centered care by enabling healthcare professionals to understand and respect the patient's perspective and preferences. Shared mental models are important between healthcare providers and they contribute shared decision making. Informed consent is an important aspect of patient-centered care and respects the autonomy and rights of patients. It ensures that patients are actively involved in their healthcare decisions and have a clear understanding of the risks, benefits, and alternatives. Healthcare providers have a responsibility to provide the necessary information and engage in open and transparent communication to facilitate informed consent [21]. Technically, we must distinguish between informed consent, informed choice and shared decision making (Figure) [22]. Informed consent consists with medical examinations and clinical evidence. Physicians explain and recommend the best care option(s) and the patient comprehends and accepts the policy of the physician. Informed choice also consists of medical examinations and clinical evidence with physicians explaining and recommending benefits and risks of care options. Shared decision making also consists of medical examinations and clinical evidence with physicians explaining and recommending benefits and risks of care options. Furthermore,

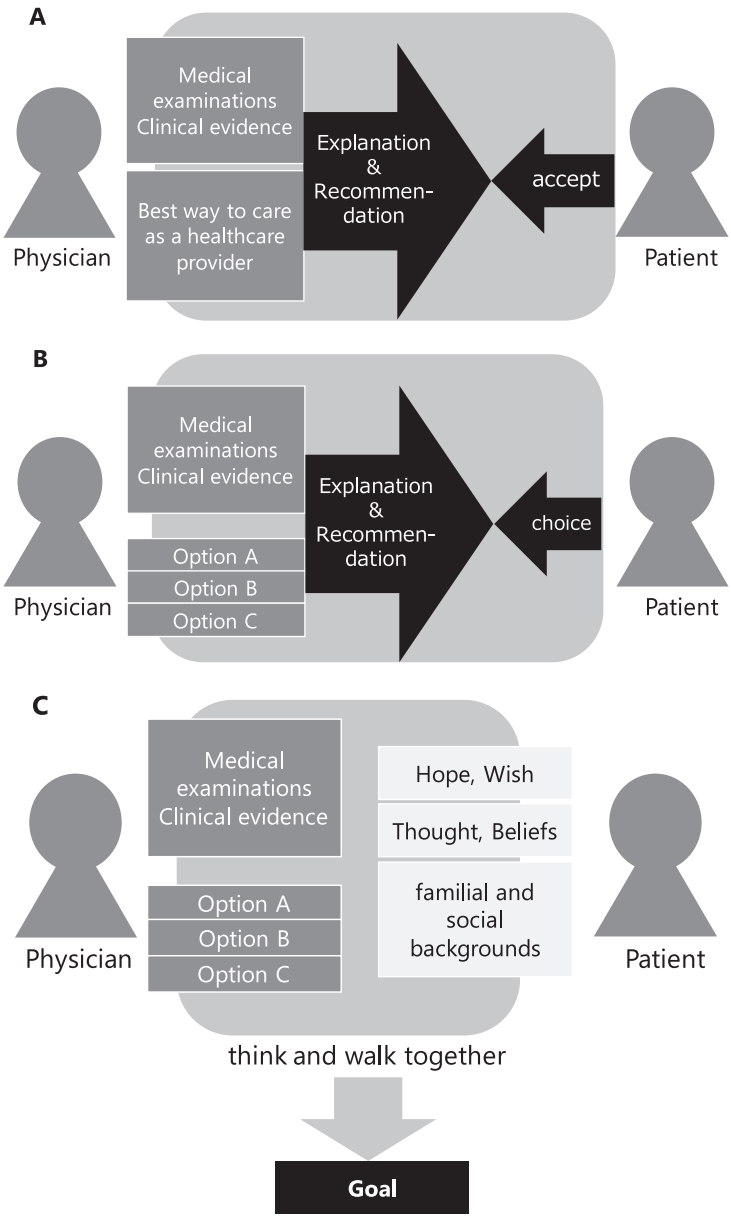

Figure. Typology of physician explanation for patient
A. Informed Consent, B. Informed choice, C. Shared decision making

Table 3. Patient safety education curriculum guide topics

Topic 1: What is patient safety?
Topic 2: Why applying human factors is important for patient safety
Topic 3: Understanding systems and the effect of complexity on patient care
Topic 4: Being an effective team player
Topic 5: Learning from errors to prevent harm
Topic 6: Understanding and managing clinical risk
Topic 7: Using quality-improvement methods to improve care
Topic 8: Engaging with patients and carers
Topic 9: Infection prevention and control
Topic 10: Patient safety and invasive procedures
Topic 11: Improving medication safety

patient and physician think together about many things including: patient's hopes, wishes, thoughts, beliefs, and their familial and social background.

c. Education of patient safety

The introduction of undergraduate education on patient safety is being promoted. In 2011, the WHO released a pre-graduate patient safety curriculum guide (Multi-professional Edition) for medical students [23]. Eleven topics in this table are presented (Table 3). One of its themes is the necessity of educating patient safety and improving the quality of medical care as "implementation science" for students who will be responsible for future medical care. In the team medical literacy workshop for fourth-year students of the Faculty of Medicine, lectures and practical training were given mainly on team medical care as part of the patient safety workshop. The educational value and significance of this was high as a very effective way to start the course soon after entering the medical field. We would like to contribute to cultivating and educating qualified medical professionals.

CONCLUSION

This article briefly reviewed some highlights of the history of patient safety in Japan and the role and prospects of the patient safety division of Shimane University Hospital. Both in Japan and internationally, patient safety education is improving. Yet appropriate educational content on patient safety, methods, educational effects, and staff who provide this kind of education and evaluate safety curriculum remain quite limited. Securing and training medical personnel remains an urgent issue, so I want to continue making an effort in this area.

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