Overview of Challenges Concerning Patient Safety Issues in Malaysia: A Scoping Review

Izzaty Dalawi, Nurjuliana Noordin, Zatil Z. Mohd S., Mohammad H. Suhairi, Mohd H. Mohd A., Leny S. Suddin*

Department of Public Health Medicine, Faculty of Medicine, Universiti Teknologi MARA

***Corresponding Address**

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ABSTRACT

Damage is never the intention in healthcare delivery; unfortunately, it is often the result. To ensure patient safety in healthcare services, concerns must be addressed to tackle issues and potential challenges. Thus, this study aims to examine the current situation and challenges in enhancing patient safety in Malaysia. A review of the published abstracts and articles on the current situation and challenges of patient safety issues in Malaysia was performed using the PubMed and Google Scholar databases. In addition, The Malaysian Ministry of Health (MOH) Annual Reports and Health Plan were reviewed. The "fall" case with 191 cases followed by medication error 86 cases and adverse outcome of clinical procedure 62 cases reported in 2017 was the top incident recorded in Malaysia. The Patient Safety Council Malaysia was established to promote systemic improvement in healthcare safety and quality, which has 13 patient safety goals, and various guidelines have been published, including incidence reporting guidelines, save surgery and save lives, prevention of falls, transcription error, management of suicide risk, hand hygiene protocol, and others. The Malaysia Society for Quality in Health (MSQH) has developed standards and accreditation programs to improve the quality of hospital care; however, they are voluntary. Several challenges were identified, including a lack of resources, patient safety system technology availability, healthcare organizations' positive safety culture, the culture of punitive organizations, lack of understanding and participation of senior leadership, limited amount of research, and disclosure responsibility. The challenges related to patient safety issues are the gaps that should be addressed and taken positively by healthcare organizations to ensure quality and safer services delivered to patients.

Keywords- patient safety, challenges, Malaysia, issues, healthcare

INTRODUCTION

In healthcare delivery, harm is never the intention. However, this is often the result [1]. One of the greatest fears of patients is that a mistake will occur and that the error will affect them, in addition to fears of a terminal diagnosis, serious illness, and pain. Amid surgical operations, horror stories of patients waking up or getting the wrong limb amputated, although uncommon, instill fear in entering the healthcare system. Fear of such incidents also plays on healthcare practitioners' minds, who worry about allegations of malpractice, loss of license, and, worst of all, the shame of causing harm instead of delivering treatment and healing [1]. While the principle of "First, do no harm" is followed by all healthcare practitioners, patients are sometimes affected by caregivers' actions (or inactions).

The report To Err Is Human: Building a Safer Health System by the Institute of Medicine (IOM) [2] estimated that 44,000 to 98,000 Americans die each year as a result of preventable medical errors [3]. In terms of lost revenue, disability, and healthcare expenses, IOM estimated the expense of medical errors at around $29 billion a year, not to mention the priceless emotional cost of losing a loved one due to medical errors. The publication sparked a public uproar that contributed to increased attention to patient safety. Between 2016 and 2018, in both public and private hospitals in Malaysia, the number of accidents involving incorrect surgery,

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accidental retention of foreign objects (URFOs), transfusion and drug errors, and patient falls have almost doubled increased [4]. Therefore, this study aimed to examine the existing situations and challenges in enhancing patient safety in Malaysia.

MATERIALS AND METHODS

An analysis of the literature was conducted for a month in January 2021 by reviewing all related studies. The search was carried out using online databases for related literature dated between 2001 and 2021: PubMed and Google Scholar. The following key terms were used to search for articles: "Challenges", "patient safety", and "Malaysia". Keywords were mixed using the Boolean operator. Studies that met the inclusion criteria were published in English between 2001 and 2021 and addressed or contained information regarding patient safety, issues, and challenges in Malaysia. All types of study designs were considered. Additional searches through websites for country reports and progress were also included to look for Malaysia's current patient safety data. The review flow is shown in Figure 1.

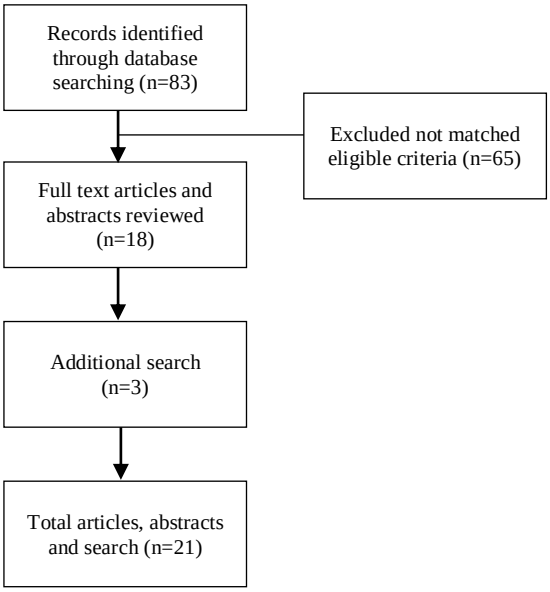

Figure 1 Flow of review

RESULTS & DISCUSSION

Statistics of Patient Safety Issues

In October 2004, in response to the World Health Assembly Resolution (2002), the World Health Organization (WHO) initiated a patient safety program to encourage the WHO and the Member States to pay the greatest possible attention to patient safety issues. Its establishment stressed the importance of patient safety as a global healthcare problem. Patient safety is the absence of preventable harm to a patient and is reduced to an acceptable minimum risk of unnecessary injury associated with health care [5]. An acceptable minimum refers to the collective notions measured against the likelihood of non-treatment or other treatments provided by existing information, services available, and the context in which care was delivered. Patient safety discipline is a concerted attempt to avoid harm to patients caused by the healthcare process itself. Patient safety has increasingly been recognized as a topic of global significance.

Malaysia current situation on patient safety

In 2017, Malaysia showed a remarkable increase in the number of reported incidents, with a total of 5,689 incidents compared to previous years, 2,769 incidents with a total of 1,427 mandatory cases increased in 2016 to 1923 in 2017 and a total of 1,342 voluntary cases in 2016 to 3,766 in 2017 [6]. Selangor recorded the highest number of incidents in 2017 (366 cases), followed by Johor (267 cases) and Perak (179 cases). Total number of reports (mandatory) based on case category in emergency department: 556 cases were registered in

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the red zone (28.9%), 262 in the yellow zone (13.6%), and 1,105 in the green zone (57.5%). The highest incident recorded was "fall" with 191 cases, followed by medication error with 86 cases and adverse outcome of clinical procedure with 62 cases reported in 2017 [7].

Factors contributed to patient safety issues

Errors in the administration of medicine are a universal problem in healthcare. A study conducted at a government hospital in Malaysia found that the most contributing factor to medication errors was a heavy workload, and complicated orders accounted for 95.8% of cases. This was followed by 81.2% of cases due to new staff and 66% due to personal neglect [8]. An investigation on near-miss transfusion medicine incidents showed that all mislabeled and mis collected samples and incidents of their location were identified [9] as 66.3% and 33.7%, respectively, were mislabeled and mis collected samples. The largest number of mislabeled and mis collected samples originated from the accident and emergency unit and medical ward. An important point for improving the safety and quality of patient treatment is measuring safety risks, the occurrence of adverse events, and patient harm [10]. It helps clinicians, patients, funders, regulators, and policymakers understand the magnitude, impact, and variability of patient harm, track performance over time and across environments, and assess the efficacy of safety improvement measures.

Current Program for Patient's Safety in A Malaysian Hospital

Quality assurance activities have been introduced in Malaysian hospitals since 1985, when the focus and priorities of our healthcare policy shifted from obtaining equity to consolidation and improvement of quality performance. The National Quality Assurance Program (QAP) was initiated in a government-owned hospital using quality indicators to monitor performance [11]. A Quality Assurance Committee was established at various levels in the Ministry of Health (MOH) to ensure the smooth running of the program. It was chaired by the Director-General of Health Malaysia, and its members comprised various program directors who periodically reviewed performance and facilitate training activities [12]. Currently, the MOH has 141 indicators at the national level and approximately 500 indicators at the hospital and district levels. Malaysian QAP has become among the best in the region and was invited to provide consultation at other countries such as Brunei, Papua New Guinea, and Vietnam [13].

In 2003, the Patient Safety Council Malaysia was established following a Malaysia Cabinet directive to promote systemic improvement in the safety and quality of healthcare in Malaysia. The council developed the Malaysian Patient Safety Goal in 2013 through discussions with various stakeholders, including the MSQH, university hospitals, hospital directors, and clinicians, as well as expert opinions from Sir Liam Donaldson, the WHO advisor on strategic issues in patient safety. There were 13 patient safety goals with 19 KPI's to guide and challenge our healthcare organization to improve patient safety issues in Malaysia. These goals apply to both public and private healthcare facilities in Malaysia. Data collected via the online "e-goal patients' safety" website will be reviewed and evaluated by the council every five years.

Various guidelines have been published by the Patient Safety Council, including incidence reporting guidelines, safe surgery and saves lives, fall prevention, transcription error, suicide risk management, and hand hygiene protocol [14]. Quality improvement activities in medical care programs can be generally classified into technical and interpersonal aspects. These activities can be assessed through the indicator approach (national indicator approach, hospital-specific/district-specific indicator approach, patient safety goals indicator, and incidence reporting), internal peer review (perioperative mortality review, perinatal and maternal mortality review, intensive care unit audit, and nursing audit), and external peer review through a hospital accreditation program. The practice of incidence reporting and learning from the analysis of the incidence reports are among the widespread improvement strategies used in healthcare. The program has been in existence since 1999; however, the number of incidents reported to the MOH was minimal due to under-reporting. Based on the three main elements of "Report, Respond and Share" this program aims to educate people on the importance of a holistic improvement of the system and not about finding an individual to be blamed. Every incident related to a patient's safety must be reported, investigated, and reviewed. Appropriate actions must be taken to prevent similar incidents from occurring, and they must be shared with others as lessons to be learned. Incidence reporting was made available under the online reporting and learning system

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e-IR2.0, which was recently updated in 2018. In addition to e-IR 2.0, another tool is used to report medication errors, known as the Medication Error Reporting System (MER-S), which has been available since 2009. Like e-IR 2.0, the national Medication Error Reporting System (MER-S) is a voluntary and non-punitive system that is mainly used as a surveillance program to report any error related to the medication process, including prescribing, dispensing, and administration. However, most users or reports are from pharmacists, and only minimal reports come from doctors. This is because pharmacists are trained to look for medication errors, and the Pharmacy Division of MOH provides various training. Therefore, reporting medication errors is part of the pharmacist's professional duty, whereas many doctors are reluctant to report [15].

To complement the MOH's quality improvement activities, a voluntary patient-led network was established in 2014. This organization works closely with the Patient Safety Council Malaysia through the Malaysian Society for Quality in Health (MSQH) accreditation program. The MSQH has developed standards and accreditation programs to improve the quality of hospital care. MSQH's accreditation is needed as it is a tool to prove that hospital performance achievement is evidence-based in terms of its accessibility, affordability, efficiency, quality, and efficacy in delivering care to patients. However, this accreditation program is not mandatory and is voluntary. In Malaysia, this is the first accreditation standard available for quality assurance in healthcare service delivery. In other countries, accreditation is seen as an important mechanism to preserve and improve quality, especially in low-and middle-income countries [16]. A study on the impact of accreditation on quality performance conducted in a multispecialty hospital in Abu Dhabi showed that preparation for accreditation significantly improved the quality of care; however, there was a transient slope immediately after the survey, and the performance was maintained for three years until the next accreditation survey [17]. In Japan, newly accredited hospitals have a significant impact on infectious control infrastructure and quality performance compared to non-accredited hospitals [18]. In the surgical field, bariatric surgery performed in accredited hospitals has significantly fewer complications, lower mortality, and shorter length of stay than that performed in non-accredited hospital [19]. This shows that hospitals that have been accredited and follow quality standards for patient care have better performance in terms of quality and patient outcomes. Figure 2 summarizes the chronology of quality assurance in Malaysian hospitals since 1985.

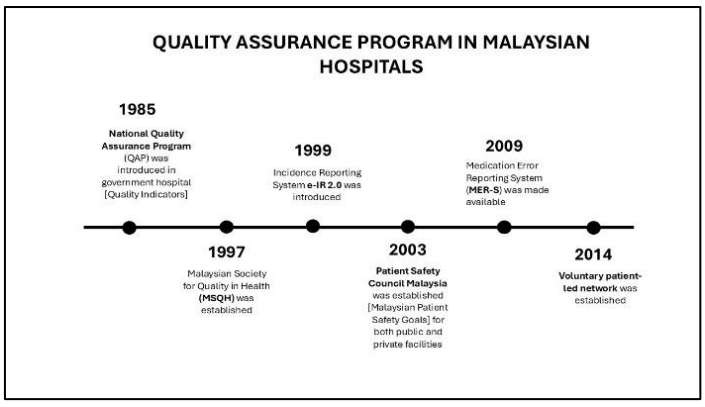

Figure 2 QA in Malaysian hospitals

Challenges Concerning Patient Safety Issues

To ensure high quality and patient safety in healthcare services, several challenges that may inhibit success should be considered by healthcare organizations. The most common challenges that the organization faces are lack of resources, such as inadequate staffing, which may compromise the quality of care given to patients [20]. This shortage of staff, especially in busy and critical departments such as the intensive care unit or emergency department, creates an error-prone environment, and high workloads cause stress and burnout among staff. Subsequently, the staff could not focus on their work and may endanger patient safety [20-21]. Conversely, increasing staff will lower staff burnout, increase job satisfaction, improve patient care [22], and improve communication between patients and providers which leads to better compliance with discharge instruction [23].

Challenges may also arise in ensuring the availability of patient safety system technology. Investing in

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improving patient safety can result in significant financial savings and better patient outcome [24]. Automated systems using programmable machines or computerized hospital information systems have been proven to minimize patient safety issues, although errors may sometimes be inevitable [25]. The availability of a system that can improve communication, understanding, and transparency in patient care is crucial. Unfortunately, such a system is costly. When there is a competing priority for scarce resources in the organization, and patient safety is not considered a top priority, the system may not be employed. In addition, the lack of synchronization in the health system between primary and tertiary care in prescribing patient's medication with a dual record system also created challenges to patient safety, as confusion may occur when they are not tally which is prone to medication error and interactions [26]. Apart from the availability of the patient safety system, there is also a need to have a safeguard system including the regular monitoring, calibration, maintenance services scheduled to be in place to ensure the quality of the systems and care provided to patients.

Another major challenge related to patient safety issues is cultivating an effective and positive safety culture in healthcare organizations [27]. This can occur when there is resistance to change from the leaders and the care team due to the strong assumption of already providing high-quality and safe care. Continuous training and retraining should be conducted to ensure that all staff adhere to patient safety. Inexperienced and newly appointed staff should be trained to work in interdisciplinary teams and improve quality to deliver best practices [23]. Hospitals should maintain adequate employees, sufficient equipment, strategies for continuing education, training, upgrading, and improving interprofessional collaboration to maintain a positive clinical work environment and deliver the best care practices [23]. Healthcare organizations should also aim for accreditation to sustain a healthy work environment, provide excellent care services, and retain and attract skilled employees [23].

The healthcare culture is also familiar with the culture of blame, or sometimes people refer to the term punitive organization culture. The biggest challenge in moving toward a safer healthcare system is changing the culture from blaming individuals for errors to one in which mistakes are not treated as personal failures but as opportunities to improve the system and prevent harm [24]. The disadvantage of this culture, on top of can moral down the staff, it makes the safety issues less likely to be identified and discourage the incident reporting action [20]. Therefore, a healthcare organization must change the culture of blaming an individual to one-off blaming of broken systems to improve the quality of care and patient safety [23]. Besides, the culture of 'cover-up' also another negative culture that should be avoided to stay in our system. Such a culture can also discourage reporting. Hence, ensuring accountability in the organization must be clearly defined and separated from the process of obtaining information for system improvement. Patient safety may also be included as a performance measure to ensure accountability for patient safety issues rather than blame. The organization also needs to prepare a training program for example to ensure a skilled, trained, educated and empowered staff belong to the organization to maintain the healthy work environments [23].

In addition, a lack of senior leadership understanding and involvement with patient safety issues also poses a challenge to patient safety [28]. Good leadership styles, such as transformational leadership, may increase executive effectiveness, empower employees, and lead to improved quality and control of expenses. In addition, it can develop interdisciplinary teamwork, learning culture, and involve staff to improve patient safety and enhance patient outcomes. Leaders of healthcare organizations should transform work environments to create high-functioning interdisciplinary teams, a learning culture, and engage all staff to improve quality and patient safety [23]. A patient safety committee from each department in an organization could be established as part of the Quality Assurance Program to cultivate a patient safety culture in every department.

Notably, the limited number of studies on patient safety issues is also a challenge in improving patient safety locally. This is especially true when investigating staffing levels, shift lengths and work environment [23]. Research is one way to generate evidence-based data that can be used to improve patient safety in an organization. Future research should focus on examining multiple domains affecting the quality of care and patient safety so that a comprehensive model of sustainable quality and safety can be developed [23]. Research related to patient safety can also be conducted to identify areas for improvement and benchmarking for the organization to refer to and improve on [29].

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Finally, disclosure responsibility is another challenge in our healthcare organization, especially when a blaming culture is in place. It is challenging to make disclosures and encourage every error as a learning opportunity at the same time. A study has shown that disclosure communication is still less practiced in retail pharmacy setup [30]. Furthermore, organizations should be encouraged to provide detailed instructions on how disclosure responsibility can be done [31]. Patients and their families should also be made aware of the importance of participation in safety risk and safety procedures by informing the healthcare provider of any of their concerns, paying attention to the care they receive, being educated on their illness and medicine that they receive, getting an advisor from a trusted family member, familiarizing themselves with the health care institution from which they seek treatment, and participating in all decisions. Thus, disclosure can be part of patient participation and their right to know the mistakes that occurred or were about to occur.

This review had several limitations. This review did not formally address the quality of evidence in every study included, and the information was gathered from a wide range of study designs and methods. In addition, we only retrieved literature from two online databases without contacting the original authors to identify other sources. In addition, the article does not provide a synthesized result or answer to a specific question but rather provides an overview of the available literature. The number of studies included in the review process can be large by design. Therefore, a large research team is required to screen a large number of studies and other sources for possible inclusion in future reviews.

Despite these limitations, this review has several strengths. First, this study provides a summary of the state of evidence in the field of patient safety. In addition, the analysis included a systematic approach that was replicable, transparent, and comprehensive. Finally, it serves as a reflection of patient safety research activities rather than the quality of literature.

Future research should incorporate qualitative insights from healthcare professionals or patients to deepen and contextualize the understanding of the knowledge gap related to patient safety issues. In addition, employing mixed method approaches to combine quantitative outcomes with stakeholder perspectives can enhance the validity of the findings.

CONCLUSION

The challenges concerning patient safety issues are the gaps that healthcare organizations should fulfil and take positively, although overcoming them is easier said than done. All applicable goals and requirements, including acceptable alternatives, should be vigorously considered. Public disclosure of compliance with the plans and guidelines should be clear, visible, and transparent. The patient-provider relationship should be enhanced to achieve a good rapport between both parties, thus improving the patient's trust, satisfaction, quality of care, and minimizing patient safety issues. Moreover, because accreditation of a healthcare organization can be costly, leaders should plan resources intelligently. Accreditation should be encouraged periodically for all healthcare services to ensure compliance with quality and safety standards. Investment in health systems and technology, training, and programs related to patient safety culture should also be considered by leaders. In addition, clear patient safety legislation and patient safety organizations should be established and act as reference points and guides for healthcare organizations.

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