REVIEW OF PATIENT SAFETY INCIDENTS AND THEIR ASSOCIATED FACTORS IN A MALAYSIA TEACHING HOSPITAL FROM 2018 TO 2022

DR SUHANA BINTI HASAN

UNIVERSITI SAINS MALAYSIA

2023

REVIEW OF PATIENT SAFETY INCIDENTS AND THEIR ASSOCIATED FACTORS IN A MALAYSIA TEACHING HOSPITAL FROM 2018 TO 2022

By

DR SUHANA BINTI HASAN

Research Project Report submitted in partial fulfilment of the requirement for the degree of

Master of Public Health

JUNE 2023

ACKNOWLEDGEMENT

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

x

LIST OF ABBREVIATIONS

Adj. OR   Adjusted Odds Ratio

CI   Confidence interval

df   degree of freedom

e-IR   Electronic Incident Reporting

IR   Incident Reporting

LR   Likelihood Ratio

MLR   Multiple Logistic Regression

MoH   Ministry of Health

PSI   Patient Safety Incident

OR   Odd Ratio

SPSS   Statistical Package for Social Sciences

WHO   World Health Organization

LIST OF SYMBOLS

=   Equal to

>   More than

<   Less than

α   Alpha

β   Beta

%   Percentage

n   Number of samples

m   Ratio between two groups

ABSTRAK

Latar Belakang: Sektor kesihatan mempunyai risiko yang lebih tinggi berbanding industri penerbangan dan nuklear kerana kebarangkalian untuk pesakit mendapat kecederaan semasa kunjungan ke fasiliti kesihatan adalah satu daripada 300. Pelaksanaan sistem pelaporan insiden keselamatan pesakit memberikan pengetahuan terperinci tentang bagaimana dan apa yang boleh membahayakan pesakit, dan ia bukan hanya berguna untuk menyelesaikan masalah dalaman sesuatu institusi, tetapi juga dapat disebarkan kepada orang lain sebagai pengajaran bagi mencegah insiden yang sama daripada berulang.

Objektif: Penyelidikan ini bertujuan untuk mengkaji kadar pelaporan, ciri-ciri insiden keselamatan pesakit, dan faktor-faktor yang menyebabkan kesan yang serius kepada pesakit yang terlibat dalam insiden berkaitan keselamatan pesakit di sebuah hospital pengajar di Malaysia dari tahun 2018 hingga 2022.

Metodologi: Data sekunder yang diperolehi daripada borang pelaporan dan sistem pelaporan insiden elektronik melalui laman web hospital telah digunakan untuk kajian keratan rentas ini. Kajian deskriptif digunakan untuk menghuraikan ciri-ciri insiden keselamatan pesakit dan model logistik digunakan untuk mengenal pasti faktor-faktor yang menyebabkan kesan yang serius kepada pesakit yang terlibat dalam insiden berkaitan keselamatan pesakit.

Keputusan: Sejumlah 263 kes insiden keselamatan pesakit dilaporkan dengan kadar pelaporan tertinggi 0.21 untuk setiap 1000 hari katil pesakit atau 0.18% setiap kemasukan ke hospital pada tahun 2021. Pelaporan insiden keselamatan pesakit didapati berlaku lebih tinggi dalam kalangan pesakit berusia lebih dari 60 tahun, pesakit lelaki, semasa syif petang, insiden daripada jabatan-jabatan pembedahan,

insiden yang melibatkan pesakit jatuh dan pesakit yang dirawat di dalam hospital. Kebanyakan kes dilaporkan oleh jururawat dan 82.9% daripada insiden keselamatan pesakit yang dilaporkan adalah kes sebenar. Insiden keselamatan pesakit berkaitan ubat merupakan faktor yang menyebabkan kesan yang serius kepada pesakit yang terlibat dalam insiden berkaitan keselamatan pesakit.

Kesimpulan: Keseluruhan kes yang dilaporkan telah meningkat selepas pelaksanaan sistem pelaporan insiden elektronik melalui laman web hospital pada tahun 2020. Namun, insiden keselamatan pesakit di hospital pengajar ini dilaporkan dengan kadar yang lebih rendah berbanding piawaian nasional dan global. Mengenal pasti dan menghapuskan faktor penghalang kepada pelaporan insiden keselamatan pesakit haruslah diberikan keutamaan. Proses-proses prespkripsi, penyediaan dan pemberian ubatan perlu dinilai semula bagi mencegah kesan yang serius kepada pesakit yang terlibat dalam insiden berkaitan keselamatan pesakit.

KATA KUNCI: keselamatan pesakit, pelaporan insiden, pengurusan keselamatan, kesilapan perubatan

ABSTRACT

Background: The healthcare sector poses a higher risk than the aviation and nuclear industries as the probability of a patient being harmed during a visit to a healthcare facility is one in 300 chances. The implementation of a patient safety incident (PSI) reporting system provides detailed knowledge on how and what harms the patient, and not only useful to manage the institutions' internal problems but the lesson gained can be disseminated to others as lessons to prevent similar incidents in the future.

Objective: This research aspires to study the reporting rates, characteristics of PSIs and the factors associated with the major outcome of PSIs in a Malaysia teaching hospital from 2018 to 2022.

Methodology: The secondary data obtained from paper-based reporting forms and the hospital's web-based electronic incident reporting (e-IR) system from a Malaysia teaching hospital were used for this cross-sectional study. A descriptive study was used to describe the characteristic of PSI and a logistic model was used to identify the factors associated with the major outcome of PSIs.

Results: A total of 263 PSIs cases were reported with the highest reporting rate of 0.21 for every 1000 patient bed-day or 0.18% per admission in 2021. The highest reported PSIs based on each category were patients more than 60 years old, male patients, incidents that took place during post meridiem (PM) shift, PSIs from the surgical-based department, incidents involving patient falls and inpatients. Nurses reported the majority of PSIs and 82.9% reported PSIs were actual cases. Drug-related PSI was significantly associated with major outcomes (Adj. OR 6.600; 95% CI: 1.364, 31.930, p-value= 0.019).

Conclusion: Overall reported PSI had increased after the implementation of the e-IR in 2020. However, the PSI in this teaching hospital was still underreported compared to national and global standards. Identifying and removing barriers to report PSI must be prioritised. The processes of prescribing until administering medication need to be re-evaluated to prevent future major PSIs outcomes.

KEYWORDS: Patient safety, incident reporting, safety management, medical errors

CHAPTER 1

INTRODUCTION

1.1   Background

As Hippocrates stated, *'primum non nocere'* or first, do no harm, more than 2000 years ago, it was intended for the health providers from harming or causing any needless injury or hardship to the patient. However, in this modern era, following multiple studies and reports, it is understood that some incidents are preventable whereas unfortunately some are inevitable and considered as by-products of the medical field (Wachter, 2012). Patient safety is defined as the prevention of errors and adverse effects on patients associated with health care (WHO, 2010). The evolution of the patient safety movement started in the late 20th century. Reports from the United States of America To Err is Human: building a safer health system and the United Kingdom of Great Britain and Northern Ireland, An organization with a memory, had served as major catalysts for the progression of this movement by scoping the subject, intriguing the globe to the scale of the problem, the parallels with other high-risk industries and the flaws of health systems in provoking a human error. Understanding that the fundamental step to reduce the risks associated with health care was to learn from the things that had gone wrong, lead to the acceleration of the establishment of patient safety incident reporting systems at the health care facility (WHO, 2020). Since then, the role of incident and adverse event reporting and the benefits that derive from it is still a work in progress (WHO, 2020).

In Malaysia, the Incident Reporting and Learning System has been established since 1999 as a quality assurance tool in Ministry of Health (MoH) hospitals (Bakar and Bakar, 2021). The national e-Incident Reporting system (e-IR) was introduced in

2015 to facilitate the process of reporting and is currently used by all healthcare facilities throughout the nation. The patient safety incident (PSI) reporting system provides detailed knowledge on how and what harms the patient, and it is not only useful to manage the institutions' internal problems, but the lesson gained can be disseminated to others as lessons to prevent similar incidents in the future (Bakar *et al.*, 2017a).

Globally, the healthcare sector poses a higher risk than the aviation and nuclear industries as the probability of a patient being harmed during a visit to a healthcare facility is one in 300 chances (*Patient Safety*, 2019). It was estimated that patient safety incidents lead to the deaths of at least 44,000 patients and probably more than 90,000 patients in United States American hospitals each year (Donaldson *et al.*, 2000). While receiving treatment four out of 10 patients were harmed in primary or ambulatory care settings worldwide and 80% of the incident is preventable (WHO, 2020). In another study, adverse events affect one out of 10 patients during hospital admission (De Vries *et al.*, 2008).

The reported actual incidents involving PSIs in Malaysia were 7928 cases in 2019, 9432 cases in 2019, 9427 cases in 2020, 7909 cases in 2021, and 8482 cases in 2022 (MOH, 2022). There was a decrement in the reported number of cases in 2020 and 2021 during the COVID-19 pandemic. In January 2020, a Myanmar refugee who suffered irreversible and severe brain damage was awarded RM1.7 million settlement by the Court of Appeal due to a medication error whereby he was given five times therapeutic doses of the anaesthetic drug, ketamine when receiving treatment at Hospital Universiti Kebangsaan Malaysia in December 2010. Meanwhile in Kelantan, a pair of twins were reunited after 19 years of being separated at birth when one of the twins was accidentally swapped with another baby that was born on the same day in

the state government hospital due to wrong patient identification (Bernama, 2021). After 12 years of battle in court against the Malaysia government, a 22-year-old man received RM3.1 million compensation for a reckless circumcision which cause a total amputation of his genitalia when he was 10 years old leading to a lifelong mental and emotional trauma (NSTP, 2022). These are some of the devastating events that reflected the grave repercussion of patient safety incidents and millions of other similar incidents in the healthcare industry worldwide.

Hence, to prevent and minimise these preventable errors in the future, recognizing the features associated with them will serve as a turning point for both patients and healthcare providers.

1.2   Statement of the problem

Harm in primary and ambulatory care often results in hospitalizations. Each year these may account for over 6% of hospital bed days and more than seven million admissions in Organization for Economic Co-operation and Development (OECD) countries - this is in addition to the 15% of acute care activity caused by harm occurring in hospitals alone (Auraaen *et al.*, 2018). A study was conducted in South Korea using 16,215 cases of PSIs extracted from the Korean Patient Safety Reporting and Learning system from 2017 to 2019 to determine the characteristics of PSIs that occurred in the hospitals (Shin and Won, 2021). Meanwhile, the first parallel research that was conducted Southeast Asia region was published in April 2022 by Khalid and Yamamoto (2022). It analysed the data reported in National e-Incidents Reporting System in 2019 involving reported incidents from 140 Malaysia MoH hospitals and institutions

including district hospitals, major specialist hospitals, minor specialist hospitals, institutes, and state hospitals (Khalid *et al.*, 2022).

However, in Malaysia, there is yet a published study that explores the characteristics and factors involved in the outcome of PSIs in a teaching hospital specifically in a single-centre. The governance of Malaysian hospitals varies depending on the type and size of the hospitals (MOH, 2018). Hence, a targeted single-centre study can spot distinct issues pertaining to that hospital and further assist in constructing suitable solutions relevant to the stakeholders within the structure and financial capability of the hospital itself.

1.3 Rationale of the Study

Identifying the factors associated with the outcome of PSIs will enable hospital administrator to intervene in a more targeted direction and further reduces the risks for future patients. Furthermore, the result of this study will also serve as a reminder and lesson to hospital staff to be more vigilant while handling a patient that has a higher risk to sustain poor PSIs outcomes. Indirectly it will also boost the stakeholder's trust and confidence in the hospital administrator's dedication to making the hospital a safe place for patients.

1.4   Research questions

1) What are the trend and rates of reported PSIs in a Malaysia teaching hospital from 2018 to 2022?

2) What are the characteristics of reported PSIs in a Malaysia teaching hospital from 2018 to 2022?

3) What are the factors influencing the PSIs outcome in a Malaysia teaching hospital from 2018 to 2022?

1.5 Objectives

1.5.1   General objective

To review the characteristics and factors involved in reported PSIs in a Malaysia teaching hospital from 2018 to 2022

1.5.2   Specific objectives

1) To describe the pattern and rates of reported PSIs in a Malaysia teaching hospital from 2018 to 2022

2) To describe the patient factor, environmental factor, category of incident, reporter factor, type of incident, and outcome of PSIs in a Malaysia teaching hospital from 2018 to 2022

3) To determine factors associated with the outcome of PSIs in a Malaysia teaching hospital from 2018 to 2022

1.6 Research hypothesis

There are significant factors associated with the outcome of PSIs in a Malaysia teaching hospital from 2018 to 2022

CHAPTER 2

LITERATURE REVIEW

Online search engines and databases such as Google Scholar, Science Direct, Springer Link, Scopus and PubMed were used for the search of papers in this study. Several search strategies were applied, including the use of Boolean operators, "AND", "OR" and "NOT". The keywords used were patient safety, incident reporting, medical error, safety management, unsafe medical care and factor associated with adverse events.

2.1   Terminology of Patient Safety Incidents

The lack of standardisation in the use of terminology related to PSIs has led to some confusion and hampering the process of data collection, analysis and evaluation (Rodziewicz and Hipskind, 2020). There are two specific features of healthcare-related incidents which are firstly when the adverse outcomes occurred due to underlying medical conditions which are unpreventable and secondly, when the incidents happened due to the medical care in the presence of errors which are preventable (Wachter, 2012). The term adverse event in patient safety used in Malaysia is defined as the harm that occurred due to complications or medical management instead of the underlying medical disease (Bakar *et al.*, 2017a). The idea of patient safety is gravitated towards preventable adverse events or preventable errors to focus more on the prevention of future incidents and improving the systems despite other opinion that thinks the use of "preventable adverse events" is rather inadequate and sounds like an understatement compared to words like "error" or "mistake" (McNutt *et al.*, 2002;

Wachter, 2012). The differences in the terminology used are summarised in a Venn diagram in Figure 2.1.
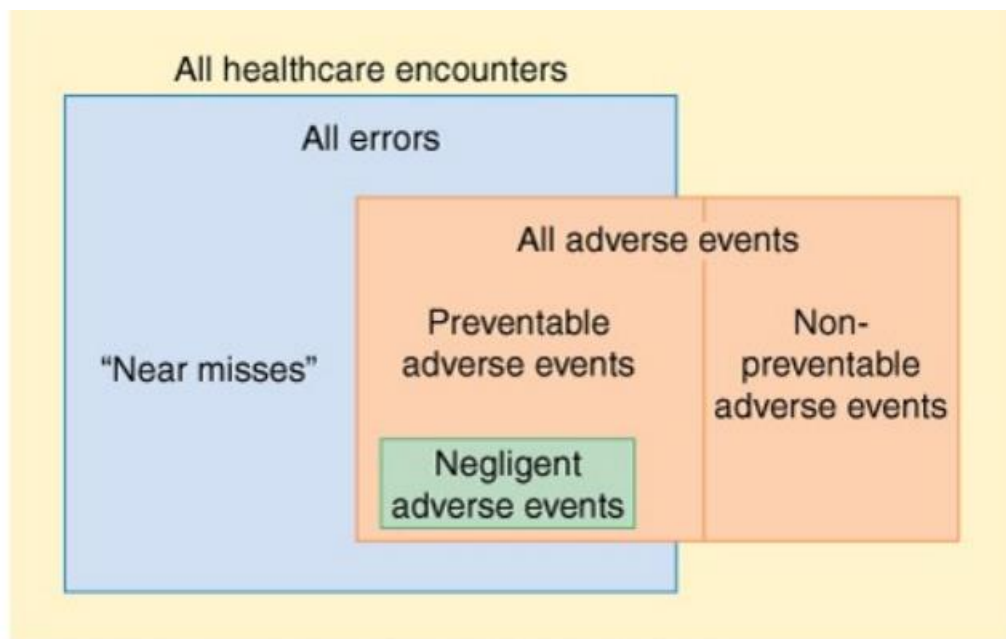
Source: Wachter RM: *Understanding Patient Safety, 2nd Edition:*

Figure 2.1: Venn diagram of patient safety terminology

The categorisation of PSIs that need to be reported based on Malaysia Guidelines on Implementation IR & Learning System 2.0 for MoH hospital 2017 includes wrong surgery/procedure, unintended retained foreign body inpatient after an operation/procedure, error in transfusion of blood/blood products, medication error, patient falls in the facility, obstetrics related incidents, adverse outcome of clinical procedure, pre-hospital care and ambulance service related incident, radiotherapy related incident, patient suicide/attempted suicide, patient discharged to wrong family members, assault/battery of patient, unanticipated fire and others (Bakar *et al.*, 2017a).

2.2   Swiss Cheese Model

In 1997, James Reason initially proposed The Theory of Active and Latent Failures or commonly referred to as the Swiss Cheese Model in his book, Human Error, to aid healthcare professionals to recognise the holes in each layer of cheese or identify the exact layer in the system that lead to PSIs and subsequently enabled them to address the issue from occurring in the future (Larouzee and Le Coze, 2020). The model illustrated the slice of cheese as a barrier of the system that safeguards it from errors, the holes represent the shortcomings of the process, and the arrow is the harm that is able to reach the patient by passing through the failures of each system when the holes line up (Stein and Heiss, 2015). The holes in the cheese have a dynamic characteristic which allows each hole to open and close at different rates and it is able to appear and disappear depending on the type of failure it represents (Wiegmann *et al.*, 2022). An active failure appeared during the active process of work and usually occurred nearby the PSIs in terms of location and time, for example, during performing surgery, dispensing medication, breach of standard operating procedure, failure to step up treatment, missing a diagnosis or exhausted healthcare professionals (Stein and Heiss, 2015; Wiegmann *et al.*, 2022). Meanwhile, latent failure took place much higher up in the system and remained undiscovered until PSIs happened, for example, inefficient policies or unsafe environmental factors that set the staff up for failures (Stein and Heiss, 2015; Wiegmann *et al.*, 2022). Unlike active failure, latent failure does not disappear immediately (Wiegmann *et al.*, 2022). In spite of facing criticism for being oversimplified and multiple attempts to improve the Swiss Cheese Model, the original model is still adequate to assist the healthcare provider to perform the root cause analysis for PSIs (Li and Thimbleby, 2014; Seshia *et al.*, 2018; Wiegmann *et al.*, 2022). The original Swiss Cheese Model is illustrated in Figure 2.2.
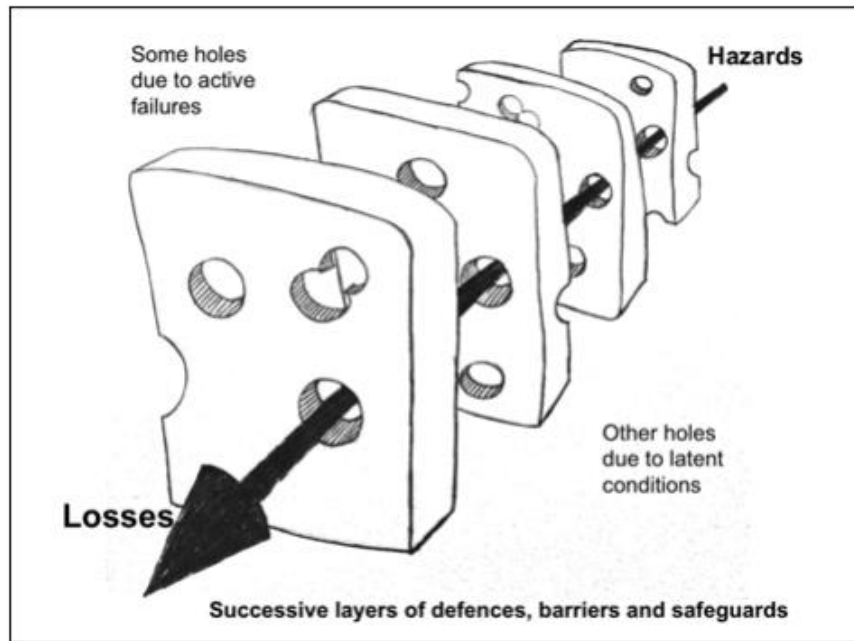
Figure 2.2: Swiss Cheese Model

2.3   Impact of medical error on healthcare providers

It is in the nature of a human to be imperfect and fallible, however regrettably, when discussing about PSIs, the fact that healthcare providers are also human are commonly forgotten. Dealing with unintended medical error affect the general, mental and emotional conditions of medical personnel causing deterioration of health, confusion, fear, guilt, anger, stress, shame, remorse, burnout, post-traumatic stress disorder, depression and even suicidal ideation which subsequently lead to poor work performance and allows more opportunity for errors (Schwappach and Boluarte, 2008; Abd Elwahab and Doherty, 2014; Robertson and Long, 2018; Rodziewicz and Hipskind, 2020). In addition, imminent legislative repercussions and worry about punishment induce the diminishing of clinical confidence and create hesitancy to report PSIs (Rodziewicz and Hipskind, 2020).

Robertson and Long (2018) highlighted four main issues regarding the impact of PSIs on healthcare providers which are the second victim, culture of perfectionism, individual against the system and absence of support. The term second victim was first coined by Wu (2000) as he noticed the under recognition of the immense and perpetual impact of medical error or adverse events on healthcare providers. On the contrary, another study stated that the use of the term second victim is insensitive to the suffering of the first victim who is the patient and depleted the professionalism of healthcare providers (Tumelty, 2021).

The culture of perfectionism was ingrained in young physician since they were in medical school, however, they were not prepared sufficiently to deal with medical errors and were taught to be the sole decision-maker rather than part of a decision-making healthcare team (Wu, 2000; Becher and Chassin, 2001; Classen and Kilbridge, 2002; Robertson and Long, 2018). Therefore, when PSIs happened, the blame was placed on the solo physician rather than analysing the error in the system (Robertson and Long, 2018).

To Err is Human was the first report that emphasised the flaws of the healthcare system in PSIs and it prioritised on eliminating the blaming culture on individuals as it diverted the focus to the needed improvement of the system (Donaldson *et al.*, 2000; Wu, 2000). The intervention to prevent future PSIs should be targeted towards improving the healthcare system, abolishing individual blame, adopting sportive training and boosting the personal well-being of healthcare providers which may reduce the impact of medical errors (Robertson and Long, 2018).

In order to tackle the issue of the second victim a survey had identified that emotional and peer support was the most desirable and effective approach (Edrees *et*

al., 2011). Implementing a support program for the second victim at John Hopkins Hospital, the RISE (Resilience in Stressful Events) peer support programme, had shown a promising and great response in helping the staff to overcome the negative impact of PSIs (Edrees *et al.*, 2016).

2.4 PSIs Reporting and national income status

The PSIs reporting has been recognised as a powerful learning tool to improve patient safety, hospital, and government policies. However, multiple studies and reports have shown that the initiatives and reporting rates of PSIs were found to correspond to the income status of the country (Wilson *et al.*, 2012; Auraaen *et al.*, 2018; WHO, 2020; Dhamanti *et al.*, 2021a). Malaysia is an upper middle-income country and had reported actual PSIs from 7900 to 9400 cases between 2018 to 2022 with reporting rates of 2.1 incidents for every 1000 patient bed-days in 2019 (Rashid, 2016; Khalid *et al.*, 2022; MOH, 2022). Whereas advanced-high-income countries like Taiwan reported 489,768 PSIs between 2005 to 2016 and despite establishing the incident reporting system almost at the same time, Indonesia, which is a lower middle-income country only reported 668 PSIs in 2016 (Dhamanti *et al.*, 2021a). South Korea, which is also a high-income country showed an increment in PSIs reporting from 3864 incidents in 2017 to 11,953 incidents in 2019 (Shin and Won, 2021). As the majority of PSIs studies and reports were from developed countries, there is an immense limitation to assessing the scale of the issue at a global level (Wilson *et al.*, 2012). The complexities of the requirement to establish a full fledge incident reporting system such as financial resources, information technology infrastructure, skilled personnel, confidentiality and data security policies, analysis and interpretation, protocols for dealing with clinical governance concerns, reporting rules, channels and feedback, and

release of information, may be the reasons for underdeveloped PSI reporting system in lower and middle-income countries (WHO, 2020). Furthermore, the reporting rates were found to be lower in certain fields such as primary care and mental health as stated by (Auraaen *et al.*, 2018).

2.5   PSIs Reporting in Malaysia

After the establishment of the e-IR system in 2015, the PSIs reporting system further underwent extensive improvement in 2018 with the aim to make a much simpler and more effective system in response to the feedback from MoH staff (MOH, 2022). The total number of reported PSIs from 2018 to 2022 was 43178 cases with Selangor, Johor and Wilayah Persekutuan showing the highest number of reporting which can be attributed to the number and type of hospitals available in the state (MOH, 2022). The number of reported PSIs in MoH e-IR for each year from 2018 to 2022 is illustrated in Figure 2.3.
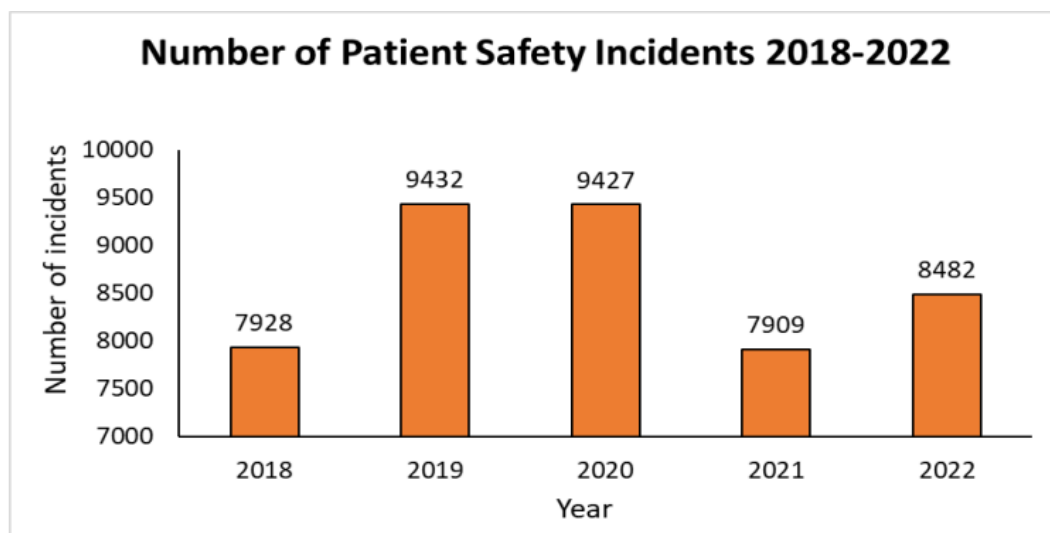
Figure 2.3: Number of reported PSIs in MoH e-IR from 2018-2022

In 2022, the department with the highest PSIs report was the medical department with 2426 cases, the highest reported PSIs was patient falls in facility and almost half (49.4%) of the PSIs outcome was no harm (MOH, 2022). The number of PSIs based on patient outcomes in 2022 is illustrated in Figure 2.4.
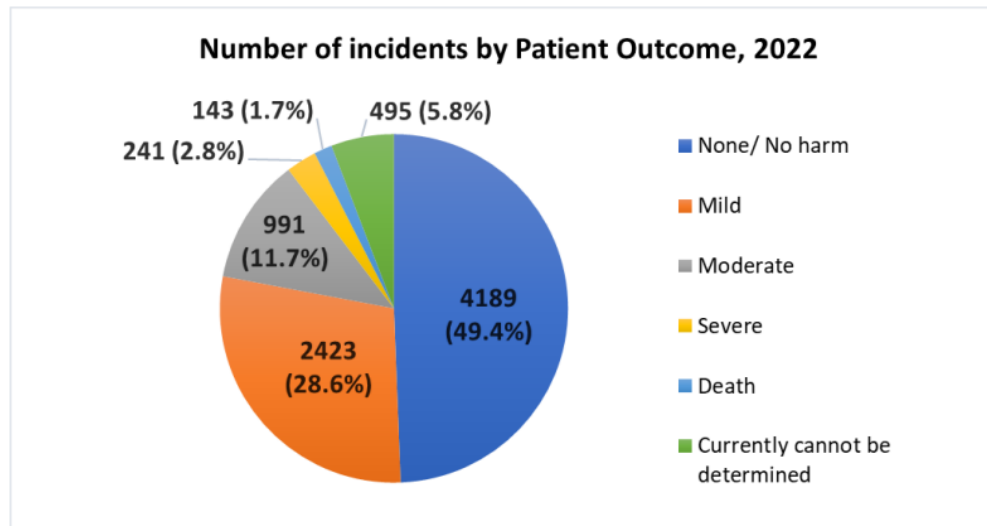
Figure 2.4: Number of PSIs by patient outcome in 2022 (n=2426)

2.6 The factor associated with PSIs

Despite the implementation of the PSI reporting system more than two decades ago, there were limited studies that explored the factors influencing the outcome of PSIs. The only published study from Malaysia was by Khalid and Yamamoto (2022) which was also the first study in Southeast Asia and another latest study around this region was by Shin and Won (2021) from South Korea. Meanwhile, the neighbouring country, Indonesia was facing a problem of underreporting of PSIs due to inadequate knowledge, understanding and accountability of reporting, incompetent leadership and institutional culture of reporting PSIs, poor perception of reporting, inadequate feedback and training, inefficient confidentiality mechanism in the healthcare system and unavailability of policy to prevent any punishment against the reporting healthcare facility (Dhamanti *et al.*, 2021b).

2.6.1   Age

Two separate studies from Australia stated that the elderly aged more than 64 years old were more likely to be involved in PSIs (Haller *et al.*, 2011; Ghosh *et al.*, 2022). Khalid and Yamamoto (2022) reported that in 2019, the majority of PSIs that occurred in Malaysia were among the elderly aged 61 years and above with 26.8% of total cases. Simultaneously, more than half PSIs reported in Shin and Won (2021) study comprised of elderly more than 60 years of aged.

2.6.2   Gender

One of the commonest types of PSI is patient falls. Studies from Japan and Australia found that male patients had a higher risk of falls compared to female patients (Toyabe, 2016; Ghosh *et al.*, 2022). Similarly, the studies from Malaysia and South Korea showed that male patients involved in more PSIs (Shin and Won, 2021; Khalid *et al.*, 2022).

2.6.3   Time of incident

Acute care activities usually take place during the day and the number of working healthcare personnel was much higher during the day. A study from Malaysia stated that PSIs were mostly reported during the daytime which was 67.2% compared to at night which was 32.8% (Khalid *et al.*, 2022). Similarly, Toyabe (2015) also described that patient falls incidents were reported more during the daytime. Whereas Shin and Won (2021) study found a significant association when PSIs took place during the daytime with sentinel events. So, it can be concluded that PSIs are more likely to happen during the day.

2.6.4 Medical Discipline

Another factor involved in PSIs is the discipline or location where the incidents took place. Generally, internal medicine had the most patients and the highest number of hospital admissions. In Malaysia, the field with the most gazetted number of specialists was internal medicine and had remained in the top ranking consecutively from 2014 to 2018, followed by anaesthesiology (MOH, 2018). More than 60% of PSIs were reported from internal medicine department, obstetrics and gynaecology department and surgical department (Khalid *et al.*, 2022). Meanwhile, a study from South Korea also concluded that the internal medicine was the leading department in reporting PSIs (Shin and Won, 2021). A systematic review comprising eight studies from the USA, Canada, UK, Australia and New Zealand established that the highest number of PSIs were reported from the general surgery department (De Vries *et al.*, 2008).

2.6.5 Category of Incidents

A near-miss incident must not be ignored as it holds beneficial knowledge to prevent harm in the future (Auraaen *et al.*, 2018). Unfortunately, several studies showed that near-miss cases were less likely to be reported compared to actual incidents (Hwang *et al.*, 2012; Shin and Won, 2021; Khalid *et al.*, 2022). This situation directly reflects the patient safety culture among healthcare staff. Reporting near-miss cases served as an invaluable lesson to galvanize the effort to improve the quality of healthcare facility, thus healthcare providers must be more vigilant in reporting near-miss cases (Crane *et al.*, 2015).

2.6.6   Reporter's designation

In most healthcare facilities, the majority of the workforce comprises of nurses. Hence, it was expected when studies from Japanese and United Kingdom teaching hospitals concluded that most PSIs were reported by nurses (Nakajima *et al.*, 2005; Kreckler *et al.*, 2009). A study from Malaysia also produced the same result (Khalid *et al.*, 2022). On the contrary, a study by the Johns Hopkins University School of Medicine United States of America found that physicians would report more PSIs if they received financial incentives for the action (Addo *et al.*, 2020). Therefore, it was concluded that incentives can be an effective intervention to help in improving the sense of ownership and further enhance patient safety culture (Addo *et al.*, 2020).

2.6.7   Type of incident

As the income status of a country affects the advancement of the medical field such as the quality of infrastructure, number and expertise of health personnel, access to knowledge and others, thus, it also influences the type of PSIs that are commonly reported (Auraaen *et al.*, 2018; WHO, 2020). A study that included eight developing countries which were Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia, and Yemen found that 34% of reported adverse events were from therapeutic errors in relatively non-complex clinical situations (Wilson *et al.*, 2012). Nakajima *et al.* (2005) reported a total of 2815 drug-related cases from 2001 to 2004 which was 46.6% of total cases. On the contrary, a study from Malaysia found that operation-related, patient falls, procedure-related and therapeutic-related PSIs were significantly associated with severe or death outcomes (Khalid *et al.*, 2022). Whereby, operation-related PSIs had the highest number of reports in five developed nations (De Vries *et al.*, 2008). Another

study concluded that patient falls was significantly associated with the sentinel event outcome of PSIs (Shin and Won, 2021).

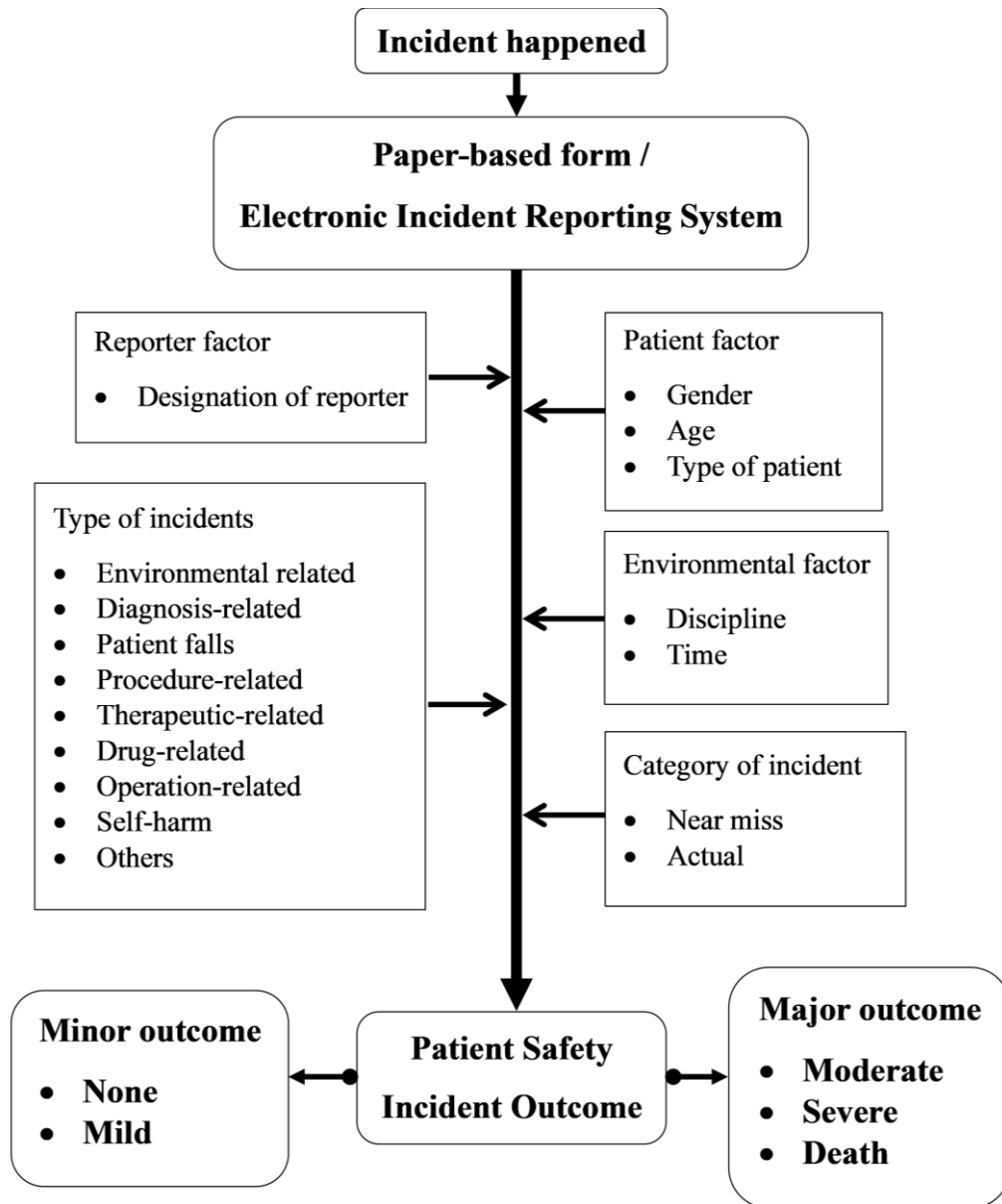## 2.7 The factor associated with PSIs outcome

A study from Malaysia found three factors that were associated with severe or death PSIs outcomes. Khalid and Yamamoto (2022) stated that male patients, PSIs that occurred in the internal medicine, obstetrics and gynaecology, emergency and surgical departments and types of PSIs such as operation-related, patient falls, procedure-related and therapeutic-related had significant associations with severe or death PSIs outcomes. On the other hand, a study from South Korea concluded eight factors that were highly associated with sentinel events; these factors were female patients, patients age more than 60 years old and between 20 to 59 years, PSIs occurring in special wards, incidents involving internal medicine, surgical and clinical support division patients and type of PSIs which were patient falls, operation related, infection, equipment disorder and others (Shin and Won, 2021). On top of that, healthcare providers were significantly more likely to report more adverse and sentinel events (Shin and Won, 2021).

2.8 Conceptual framework

Based on literature reviews, several factors were identified to be associated with the outcome of PSIs. They were categorised into patient factor, environmental factor, category of incident, reporter factor and type of incidents. Patient factors that were listed are the patient's age, patient's gender, type of patient, diagnosis, educational background, financial status, and behaviour. Characteristics of

environmental factors listed were discipline, time of incidents, location of the incident, staff manpower and availability of caretaker. Whereas categories of incidents reported were near-miss cases and actual cases. Reporter factors listed were the designation of the reporter, working experience, staff education background, knowledge, attitude, and practice of health care provider and patient safety culture. Lastly, the types of incidents listed in the study were environmental-related, drug-related, diagnosis-related, operation-related, patient falls, procedure-related, self-harm, therapeutic-related, and others.

Unfortunately, due to time constraints and limitations of the availability of secondary data, only several variables in each factor were included in this study. All variables in the type of incident and category of incidents were included. For the patient factor, only patient's age, patient's gender, and type of patient were included. Whereas for environmental factors, only discipline and time of incidents were included. Finally, for the reporter factor, only the designation of the reporter was included. The summary of the conceptual framework is depicted in Figure 2.5.

Figure 2.5: Conceptual framework of factors associated with PSIs outcome
Factors with "**" were not included in the study

CHAPTER 3

METHODOLOGY

3.1 Study design

This study was a cross-sectional study using a retrospective record review of anonymous data from a Malaysia teaching hospital.

3.2 Study duration

This study was conducted between December 2022 and May 2023.

3.3 Study location

This study was conducted in a Malaysia teaching hospital with a total of 816 beds available in 2018 and 829 beds in 2019 until 2022. It possessed a manpower of 623 doctors from house officers to clinical specialists, 1500 nurses, 86 medical assistants and more than 700 other clinical staff. In addition to that, there were approximately 1200 clinical master students from both MoH and other countries currently providing services to the hospital.

3.4 Reference population

The reference population were the PSIs in Malaysia teaching hospitals and government hospitals with 500 or more hospital beds.

3.5   Source population

The source population were the PSIs that were reported to the hospital administrator of a Malaysia teaching hospital.

3.6   Study population

The study population were the PSIs that were reported to the hospital administrator of a Malaysia teaching hospital from 2018 to 2022.

3.7   Sample frame

The sampling frame was PSIs that were reported to the hospital administrator of a Malaysia teaching hospital from 2018 to 2022 that fulfilled the inclusion and exclusion criteria.

3.8   Study criteria

In this study, the criteria for sample selection can be categorised as follows:

3.8.1   Inclusion criteria

The inclusion criteria were all cases of PSIs reported to the hospital administrator of a Malaysia teaching hospital using the paper-based reporting form and web-based e-IR system from 2018 to 2022.

3.8.2 Exclusion criteria

The exclusion criteria were duplicate data entered via web-based e-IR, duplicate data that was reported both using paper-based reporting form and web-based e-IR and unrelated cases that were wrongly entered via web-based e-IR.

3.9 Sample size determination

The sample size was calculated based on the study objective as follows:

3.9.1 Objective 1

The sample size was not calculated in Objective 1 because it was a descriptive study. There was a total of 331 PSIs cases reported to the hospital administrator with 74 cases reported using paper-based reporting forms and 259 cases reported in web-based e-IR. However, only 263 cases that fulfilled the criteria were included to answer Objective 1.

3.9.2 Objective 2

There was no sample size calculation done for Objective 2 because it was a descriptive study. As per Objective 1, only 263 cases that fulfilled the criteria were included to answer Objective 2.

3.9.3   Objective 3

The sample size calculation for Objective 3 was calculated for each variable of factors associated with PSIs outcome in a Malaysia teaching hospital from 2018 to 2022 using two proportion formula by using Power and Sample Size calculation software. Some of the variables of factors associated with PSIs outcome are shown in Table 3.1. The parameters used for sample size calculation were P0, P1, n, 2n, m, significant level, and power of test.

The sample size was calculated for each variable including an allowance of an additional 10% possibility of duplicate data for PSIs reporting. Description of each of the parameters are as follows:

P0   = proportion of non-exposure among PSIs reporting (from literature)

P1   = expected proportion of exposure among PSIs reporting

α = value of standard normal distribution cutting off probability α (1.96 for α = 0.05 (two-tailed))

β = value of standard normal distribution cutting off probability β (0.8 for 80% power)

m   = ratio of the size of the exposed population to the unexposed population

n   = sample size of PSIs reporting

2n   = sample size of PSIs reporting (two-tailed)