A BAHASA MELAYU VERSION (HSOPSC-BM) EVALUATION OF PATIENT SAFETY CULTURE IN PUBLIC HOSPITALS IN MALAYSIA: A MULTICENTRE ASSESSMENT

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THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PUBLIC HEALTH

FACULTY OF MEDICINE
UNIVERSITY OF MALAYA
KUALA LUMPUR

2019

UNIVERSITY OF MALAYA
ORIGINAL LITERARY WORK DECLARATION

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Matric No: MHC 130003
Name of Degree: Doctor of Public Health
Title of Project Paper/Research Report/Dissertation/Thesis ("this Work"):

A Bahasa Melayu version (HSOPSC-BM) evaluation of patient safety culture in public hospitals in Malaysia: A multicentre assessment

Field of Study: Health Management

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ABSTRACT

A BAHASA MELAYU VERSION (HSOPSC-BM) EVALUATION OF PATIENT SAFETY CULTURE IN PUBLIC HOSPITALS IN MALAYSIA: A MULTICENTRE ASSESSMENT

Introduction: Implementation of patient safety culture in an organization with the aim to improve patient safety outcome has received worldwide attention. Patient safety also reflects quality care in general. As patient safety continues to be a concern especially in hospital care, safety culture is a target for patient safety improvements as recommended by the Institute of Medicine. In this study, Hospital Survey on Patient Safety Culture questionnaire was used to evaluate patient safety culture in public hospitals in Malaysia. **Methodology:** This study was divided into two phases. **Phase one** was testing the validity and reliability of HSOPSC-Bahasa Melayu (HSOPSC-BM). It was a cross sectional survey with purposive sampling and involved 700 participants. The original HSOPSC which has 12 dimensions and 42 items underwent a thorough process of validation. Confirmatory and exploratory factor analyses were assessed using Statistical Package of Social Science (SPSS version 21) and Analysis of Moment Structure (AMOS version 22). **Phase two** assessed patient safety culture among staff in public hospitals in Malaysia using validated HSOPSC-BM. It was a cross sectional study with 700 participants who were selected from four hospitals using quota sampling. Descriptive analysis was done followed by inferential analysis using SPSS. Three outcome measures which were patient safety score, patient safety grade and number of events reported were investigated for its relationship with safety culture dimensions using regression analysis. **Result:** The Content Validity Index was excellent (CVI-0.9). A final 9 dimensions and 30 items were retained in the hypothetical model of HSOPSC-BM. Results of goodness of fit for the hypothetical model were of $\chi 2$ (df) of =770(369) with p value of <0.005, CFI=0.8, RMSEA=0.7 and P ratio=0.85.The overall Cronbach's

Alpha for the new construct is 0.88. In Phase two of the study, 89% of participants gave valid responses. Among safety culture dimensions, Organizational Learning scored the highest with 87% positive response rate whilst Non-Punitive Response to Error scored the lowest with 4.3%. In regression analysis testing mean patient safety score showed that medical officers are 4.9 times more likely to practice safety culture compared to other profession and socio-demographic and job related characteristics [OR 4.87 (95% CI: 1.31, 18.15, $p<0.05$)] Similarly, medical officers were 2.3 times more likely to report 1-2 incidence reporting compared to other groups (OR 2.33 [1.23,4.41], $p<0.05$) **Discussion/Conclusion**: In the Phase 1 study, HSOPSC-BM didn't replicate similar construct as the original HSOPSC. However, it was considered appropriate for use in the Malaysia healthcare setting. In phase two, it was noted patient safety practice requires a lot of improvements. Medical officers are practising safety culture better than other profession or socio-demographic and job-related characteristics. In conclusion, patient safety culture should be introduced into medical curriculum to educate students before they embark into their real career. Implementation of remedial measures based on findings from patient safety surveys using HSOPSC-BM could improve the quality of health services in Malaysia.

Keywords: patient safety culture, validation, assessment, public hospitals

ABSTRAK

PENILAIAN VERSI BAHASA MELAYU (HSOPSC-BM) UNTUK MENCERAP BUDAYA KESELAMATAN PESAKIT DALAM HOSPITAL AWAM DI MALAYSIA: KAJIAN BERBILANG PUSAT

Pengenalan: Pelaksanaan budaya keselamatan pesakit dalam sesebuah organisasi bagi tujuan meningkatkan keselamatan pesakit telah mendapat perhatian di seluruh dunia. Secara amnya, keselamatan pesakit juga mencerminkan kualiti penjagaan kesihatan sesebuah organisasi. Menurut saranan *Institute of Medicine*, budaya keselamatan pesakit harus menjadi matlamat dalam meningkatkan keselamatan pesakit terutama dalam perawatan pesakit di hospital. Dalam kajian ini, borang kaji selidik Keselamatan Pesakit di Hospital (HSOPSC) telah digunakan untuk menilai budaya keselamatan pesakit di hospital-hospital awam di Malaysia. **Kaedah**: Kajian ini dibahagikan kepada dua fasa. Fasa pertama menguji kesahan dan kebolehpercayaan HSOPSC-Bahasa Melayu (HSOPSC-BM). Ia merupakan kaji selidik silang dengan persampelan purposif dan melibatkan 700 peserta. Versi asal kajian ini mempunyai 12 dimensi dan 42 item dan telah menjalani proses pengesahan yang menyeluruh. Di dalam fasa ini perisian Pakej Statistik untuk Sains Sosial (SPSS versi 21) dan Analisis Struktur Moment (AMOS versi 22) telah digunakan. Fasa dua menilai budaya keselamatan pesakit di kalangan kakitangan di hospital awam di Malaysia menggunakan HSOPSC-BM yang disahkan. Ia merupakan kajian keratan rentas dengan 750 peserta yang dipilih dari 4 hospital menggunakan persampelan kuota. Perisian SPSS digunakan untuk analisis deskriptif diikuti dengan analisis statistik inferens. Skor keselamatan pesakit, gred keselamatan pesakit, bilangan laporan insiden dan kaitannya dengan dimensi keselamatan pesakit merupakan hasil akhir dari kajian menggunakan model analisis regresi. Kajian korelasi digunakan untuk melihat apakah kaitan antara dimensi keselamatan pesakit dan hasil akhir. **Keputusan:** Indeks Kesahan Kandungan adalah

sangat baik (CVI-0.9). Hasil akhir model hipotetikal bagi HSOPSC-BM ialah 9 dimensi dan 30 item. Keputusan *goodness of fit* untuk model hipotetikal ialah $\chi 2$ (df) = 770 (369),$p<0.005$, CFI=0.8, RMSEA=0.7 dan p=0.85. Manakala, Cronbach Alpha keseluruhan adalah 0.88. Dalam Fasa dua kajian ini, 89% peserta dikira sebagai memberi jawapan yang sahih. Dimensi *Organizational Learning* mencatatkan kadar respon positif tertinggi dengan kadar sebanyak 87% manakala dimensi *Non-Punitive Response to Error* pula paling rendah dengan 4.3%. Ujian analisis regresi skor keselamatan pesakit menunjukkan bahawa pegawai perubatan adalah 4.1 kali lebih berkemungkinan untuk mengamalkan budaya keselamatan berbanding faktor sosio-demografik dan ciri-ciri berkaitan pekerjaan yang lain [OR 4.87 (CI 95%: 1.31, 18.15, $p<0.05$)]. Pegawai perubatan juga adalah 2.3 kali lebih cenderung melaporkan 1-2 laporan insiden dibandingkan dengan faktor lain (OR 2.33 [1.23,4.41], $p<0.05$) **Perbincangan / Kesimpulan**: Dalam Fasa 1, HSOPSC-BM tidak membentuk model yang sama seperti HSOPSC asal. Walau bagaimanapun, ia dianggap sesuai untuk digunakan dalam sistem penjagaan kesihatan di Malaysia. Dalam Fasa 2, didapati pegawai perubatan mengamalkan budaya keselamatan lebih baik daripada faktor sosio-demografik dan ciri-ciri berkaitan pekerjaan yang lain. Kesimpulannya, budaya keselamatan pesakit perlu diperkenalkan di dalam kurikulum pelajar-pelajar perubatan sebelum mereka memasuki alam pekerjaan. Pelaksanaan langkah-langkah penambahbaikan berdasarkan dapatan dari kajian keselamatan pesakit menggunakan HSOPSC-BM mampu meningkatkan kualiti perkhidmatan kesihatan di Malaysia.

Kata kunci: Budaya keselamatan pesakit, validasi, penilaian, hospital awam

ACKNOWLEDGEMENTS

First and foremost, my most grateful thanks to Allah The Almighty for providing His guidance throughout the completion of this thesis.

My deepest gratitude goes to my supervisor, Professor Dr. Tin Tin Su. I am indebted to her for the ideas, guidance and encouragement that she had shown to me and the long hours that she has spent in reading and correcting my manuscripts. I have learned a lot under her supervision.

Special thanks to Professor Dr. Sanjay Rampal for his kind support and encouragement for me to finish this thesis in the stipulated time. Also, my appreciation to all the lecturers in Social and Preventive Medicine for their teaching and guidance duirng my DrPH journey.

My appreciation to the Public Service Department for giving me scholarship to further my studies in DrPH. My special thanks to my dear colleagues for their continuous moral support for me to finish my theses.

My deepest appreciation to my parents, Anuar bin Maimon and Zabedah bt Hj Abdul Rahman for their unconditional love and prayers for me to complete my studies and always be the best in my life. To the person I love most, Ahmad bin Berahim for always be my side in my ups and downs and always supported me in any ways he can. Thank you dear, for your time, understanding and love that you have shown me all these years. Not forgetting to my 5 little children. Some of you turn to different phases of life from small kids to teenagers during my journey. My apologies if I haven't given enough attention to all of you. Thank you for the understanding you've given as I am concentrating to the studies.

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LIST OF SYMBOLS AND ABBREVIATIONS

AHRQ	-	Agency for Healthcare Research in Quality
AMOS	-	Analysis of Moment Structure
ANOVA	-	Analysis of Variance
AGFI	-	Adjusted Goodness of Fit Index
AMO	-	Assistant Medical Officer
CFA	-	Confirmatory Factor Analysis
CFI	-	Comparative Fit Index
CI	-	Confidence Interval
CME	-	Continuous Medical Education
CO	-	Communication Openness
CVI	-	Content Validity Index
EFA	-	Exploratory Factor Analysis
ESBL	-	Extended spectrum β lactamase
FCE	-	Feedback and Communication about error
FER	-	Frequency of Event Reporting
GFI	-	Goodness of Fit Index
HCAI	-	Healthcare Associated Infection
HMSPS	-	Hospital and management support on patient safety
HNT	-	Hands-off and Transition
HRO	-	Highly Reliable Organization
HSOPSC	-	Hospital Survey on Patient Safety Culture
HSOPSC-BM-		Hospital Survey on Patient Safety Culture (Bahasa Melayu)

ICC	-	Intra-class Correlation Coefficient
I-CVI	-	Item Content Validity Index
IOM	-	Institute of Medicine
IT	-	Information technology
MaPSAF	-	Manchester Patient Safety Assessment Framework
MO	-	Medical Officer
MOH	-	Ministry of Health
MRSA	-	Methicillin Resistant *Staphylococcus aureus*
MSQH	-	Malaysian Society for Quality in Health
NHS	-	National Health Service
NRE	-	Non punitive response to error
OL	-	Organizational Learning
OPPS	-	Overall perception on patient safety
PIS	-	Participant Information Sheet
PSCHO	-	Patient Safety Culture in Healthcare Organization
PSCoM	-	Patient Safety Council of Malaysia
RMSEA	-	Root Mean Square Error of Approximation
SAQ	-	Safety Attitude Questionnaire
SPSS	-	Statistical Package for the Social Science
S-CVI	-	Scale Content Validity Index
SD	-	Standard deviation
SEAAPPS	-	Supervisor expectation and action promoting patient safety
TAU	-	Teamwork across unit
TWU	-	Teamwork within unit

UA	-	Universal Agreement
UMMC	-	University Malaya Medical Centre
VRE	-	Vancomycin Resistant *Enterococcus faecum*
WHO	-	World Health Organization

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

The aim of this chapter is to briefly introduce readers to the subject of patient safety culture in medical and health services and to provide a general overview of my study. Patient safety culture has become a sub-topic of medical tourism due its emerging significance in the health industry more generally. This chapter explains the background to the research topic including the evolution and efforts to achieve patient safety culture. This is then followed by the definition of the terminology used in this study, the problem statement, the rationale for the study, the aims and objectives of the study and the research hypotheses. The structure of the thesis is presented at the end of this chapter.

1.1 Background of the Study

Patient safety is a fundamental principle of healthcare and it has become an important domain in maintaining high-quality healthcare services. In providing services to patients there is a certain degree of inherent risk that an unsafe act will be undertaken by health staff in the performance of their duties.

Patient safety has been defined simply as the prevention of harm to patients (Aspden, Corrigan, Wolcott, & et.al, 2004). The World Health Organization (WHO) extended this definition to the prevention of errors associated with healthcare and the consequent adverse effects on patients (World Health Organization [Europe], 2016). On the other hand, medical errors are the consequence of safety being compromised. The resultant errors cause injury to every party involved, but primarily affect the patients as the victims (Baker et al., 2004). Healthcare providers have been described as secondary victims because they suffer the indirect impact of such errors, which can be considerably damaging (A Wu, 2000).

Patient safety and medical errors are inversely related. Medical errors can be subdivided into near misses and adverse events, which can be seen as analogous to the absence or presence of harm, respectively. The difference between these two types of error is that adverse events cause harm to the patient, whereas near misses are usually stopped before harm occurs. While near misses might go unnoticed, adverse events result in a certain degree of loss, morbidity or even mortality in patients. Whenever an organization has an excellent patient safety culture, the rate of medical errors is minimal (Morello et al., 2013).

Equally important is the adverse economic impact of medical errors on health institutions that arise due to increased length of stay or increased treatment cost which result in a greater burden on these organizations, as evidenced in the United States of America (US) where the total financial losses due to medical errors in the region of US$17,000 million and US$29,000 million for disability and medical expenses, respectively (World Health Organization., 2002). Meanwhile, adverse events in the United Kingdom (UK) result in additional costs due to longer hospital stays, litigation to claim compensation and other potential liabilities totalling approximately £4,800 million per year (World Health Organization., 2002). The financial impact of safety failure is considerable. In a recent study by Organisation for Economic Co-operation and Development (OECD), it was approximated that around 15% of total hospital activity and expenditure is a direct result of adverse events (Slawomirski, Auraaen, & Klazinga, 2017).

The WHO estimated that millions of patients worldwide were still enduring disabling injuries or death each year that could be attributed directly to unsafe medical practices and care (World Health Organization, 2019). Efforts to improve patient safety have flourished remarkably since the release of the landmark report by the Institute of

Medicine (IOM) in the US, entitled *To Err is Human: Building a Safer Health System* in 1999. In this IOM report, it was estimated that 44,000–98,000 people died in US hospitals each year because of medical errors (L. T. Kohn, J. M. Corrigan, &, & M. S. Donaldson, 2000). The figures generated responses from various stakeholders in healthcare, including the general public because the media also played a role in promoting the issue. Hence patient safety came to the attention of policymakers, administrators and researchers, who began to work on this issue more seriously. The IOM report also made some recommendations and suggested several strategies to improve the healthcare system with the aim of achieving a 50% reduction in medical error cases in five years' time (i.e., by 2004), one of which was to improve patient safety culture as a means to reduce medical errors. With the continuous support of the US government and governments in other countries, more research into patient safety has been conducted and published since that first report by the IOM.

Subsequently, a report from IOM in 2001, entitled *Crossing the Quality Chasm: A New Health System for the 21st Century* proposed six dimensions of quality that every stakeholder in the healthcare system could commit to in order to provide continuously high-quality services to the population (Institute of Medicine (US) Committee on Quality of Health Care in America., 2001).

The first dimension of quality healthcare is that it must be ***safe***. The word safe can be regarded as an extension of the ancient maxim, "First, do no harm" because it not only requires the individual caregiver to be extra careful, but insists that the healthcare system itself makes safety a priority. The second dimension of quality healthcare is that it should be ***effective***, which means that the provision of health services must be based on scientific knowledge and offered to all patients who can benefit from the service. For example,

every elderly heart patient who would benefit from beta-blockers should get them, and no child with a simple ear infection should get advanced antibiotics.

The third dimension concerns ***patient-centred or acceptable*** means of providing care that is tailored to patient needs and also respects their values and preferences. Patients must be actively involved in decision-making about their care plan. This is particularly important at present because more people require chronic rather than acute care. The fourth dimension involves providing care in a ***timely*** manner and avoiding unnecessary delays which can produce harm to both patients and caregivers. Unintended waiting that does not provide information or time to heal is seen as a system defect. Prompt attention benefits both the patient and the caregiver.

The fifth dimension of quality care relates to ensuring that services are ***efficient***. All resources should be utilized so as to avoid waste in every aspect of care, which ultimately relates to the financial perspective of care and covers, for example, supplies, equipment, space, capital, ideas, time, and opportunities. The sixth and final dimension concerns the aim of providing ***equitable*** care, which means that care is provided to the patient without bias and irrespective of the patient's characteristics such as gender, age, income, race and ethnicity.

Following the two abovementioned IOM reports, the US Agency of Healthcare Research in Quality was identified as the government agency that would act as the coordinator responsible for the realization of various targets and the achievement of national goals regarding the safety and quality of care in general. In addition, the WHO, at its 55th World Health Assembly in 2002, passed Resolution 55.18 urging member states to pay the closest attention possible to the problem of patient safety (World Health Organization., 2002). Since then, activities to improve patient safety have evolved

tremendously with the support of governments, policymakers and administrators around the world.

Moreover, the emphasis on patient safety was further strengthened by the launching of the World Alliance for Patient Safety in October 2004. The alliance regards patient safety as a global issue that affects all levels of the healthcare system and that it is a hidden phenomenon, especially in developing countries. The alliance serves as a coordinator and supports the development of patient safety policy and practice especially in countries that have problems in implementing a culture of patient safety (World Health Organization., 2016).

Patient safety and quality improvement activities both fall under the umbrella of quality care, therefore these two dimensions must be considered in parallel to achieve excellence in the healthcare system. Although it is argued that patient safety is something of a fad and not as important a priority as other dimensions of quality, investment in patient care should be aimed at improving quality because patient safety will follow from such efforts (Brennan TA, Gawande A, Thomas E, & D., 2005). Accordingly, it is believed that separating patient safety from healthcare quality represents a false dichotomy because patient safety is a first step in providing quality care, and both are valuable. A quality programme in a health system is carried out to improve the quality of services. It can range from a hospital-level quality programme to an external review conducted by an accreditation body to a national quality strategy at the other end of the spectrum.

Shortell et al., in a study published in 1995, found that quality improvement implementation is positively associated with greater perceived patient outcomes (Shortell, 1995). Accreditation is a method of certifying an organization as competent in providing

quality services based on certain standards of quality (Malaysian Society for Quality in Health, 2016a). In a healthcare system, it is important for a health institution to be recognized as safe and certified as practising safe and quality care in order to gain the trust and desire of people to come and seek treatment.

1.2 Accreditation as a Proxy Indicator for Quality Healthcare

Accreditation can be defined as recognition given by a national or international body to an organization which indicates that the organization adheres to a set of quality standards (Dictionaries, 2018). In the context of this study, accreditation is awarded in recognition that the health organization maintains quality and safe care, thus protecting patients and family rights. A systemic review of the impact of accreditation on the quality of healthcare services concluded that accreditation programmes improve the process of care and clinical outcomes of a wide spectrum of clinical conditions. Hence an accreditation programme should be viewed as a tool to improve the quality of healthcare services (Pomey et al., 2010). By definition, accreditation carries the meaning of an action or process of officially recognizing someone as having a particular status or being qualified to perform a particular activity (Dictionaries, 2018). Several well-known organizations conduct accreditation, including Joint Commission International which is responsible for conducting surveys in the US and internationally, the Accreditation Association of Ambulatory Healthcare (AAAHC) and the American Association for Accreditation of Ambulatory Surgery Facilities (AAASF) in the US, the Health Quality Service (HQS) in the UK, and the Australian Council on Healthcare Standards (ACHS), and many more.

Similarly, in Malaysia, the Malaysian Society for Quality in Health (MSQH) is responsible for conducting surveys for the accreditation of both public and private healthcare sector organizations, including those involved in delivering primary care services (Malaysian Society for Quality in Health, 2016a). The MSQH is a national body that offers and coordinates accreditation activities in Malaysia. Its main functions are to advocate and facilitate quality improvement activities by means of conducting accreditation programmes in the country. To date, a total of 99 hospitals have received accreditation from the MSQH (Malaysian Society for Quality in Health, 2016b). Malaysian Society for Quality in Health has been awarded International Society for Quality in Healthcare (ISQua) accreditation certification for its Organisation and MSQH Surveyor Training Programme from August 2016 until July 2020 (Malaysian Society for Quality in Health, 2016a). This certification means that the MSQH is accredited as a prestigious and authoritative body that adheres to international standards in executing the accreditation process in Malaysia.

During an accreditation process, performance in several areas needs to be assessed before a facility can be accredited. To receive accreditation the facility is obliged to adhere to and meet a certain set of agreed standards. These standards are developed to reflect current accepted practices and are widely accepted by all the parties involved. Moreover, these standards and their associated measurements are dynamic because they must be routinely reviewed and updated in order to remain in sync with advances in medical care. Although measurement does not assure quality, it can be used to identify the extent to which a facility and providers actually deliver quality care. The major areas covered by these standards include governance, resources, quality activities, policies and procedures, facilities and safety. In Malaysia, it is compulsory for a facility to meet the

safety requirement standards. Failure to adhere to the safety requirement means that the facility will not be awarded an accreditation certificate.

1.3 Patient safety and medical tourism

In response to the evolving interest in seeking treatment outside one's country in order to be treated at a lower cost but with a presumably similar quality of care in the receiving country, issues around the safety of patients in receiving country have come to the fore in order to find ways to protect patients' rights. Therefore, patient safety is an important component that needs to be addressed in the domain of medical tourism. Historically, in the late nineteenth century, people from less-developed countries travelled to Europe or the US which offered the necessary resources for treatment or diagnostic evaluation that were not readily available in their home country. However, this trend has shown a remarkable shift. Nowadays, citizens of highly developed nations seek medical treatment in less-developed countries mainly for economic reasons. This shift is mainly due to patients being uninsured or underinsured in their home country, which makes it difficult for them to afford the medical services offered in their country. Medical tourism, which is classed as sub-category of health tourism, is defined as people who travel to another country to receive medical, dental and surgical care while at the same time receiving equal to or greater care than they would have in their own country, and are traveling for medical care because of affordability, better access to care or a higher level of quality of care. as opposed to health tourism, the definition of which does not have the connotation of medical intervention (Medical Tourism Association, 2019).

Medical tourism has become an important commodity in generating economic revenue for developing countries. This is particularly true in the case of Thailand, Malaysia and Singapore because Southeast Asia has emerged as a main regional hub for

medical tourism. Undoubtedly, governments play a strong role in promoting this niche market because it offers an attractive potential economic advantage for a country. The potency of medical tourism in Southeast Asia is remarkably appealing. To give an idea of the number of individuals taking this route, it was projected in 2016 that about 1.4 million US citizens would seek medical treatment outside their own country (Carrera & Bridges, 2006). Further, the size of the global medical tourism market in 2016 was estimated at US$45.5–72 billion globally and an average of US$3,800–6,000 was spent per visit (which includes the direct and indirect costs of treatment) (Woodman, 2016).

While medical tourism has its attractions for both the patient and the receiving country and provider, certain issues in relation to the quality and safety of patient need to be tackled. Understandably, travellers will go to a less-developed country for medical treatment because cost is the main driver in medical tourism. As many treatments carry certain risks and complications, it is questionable as to whether the treating facility is properly equipped should anything goes wrong in view of the different treatment regulations and practice guidelines which can be of a lower standard compared to those in the patients' home country.

The language barrier can also pose a significant problem in carrying out treatment if the receiving country does not use the same language as the patient, especially if that language is English. Also, patients might have problems when they are back in their country because treatment usually stops when the patients go back to their country. Likewise, patients may contribute to the spread of infection in their home country, especially with respect to resistance to antibiotics when the treating country does not properly adhere to antibiotic guidelines/protocols (T. Ballantyne, 2016; Lunt, Machin, & Green, 2011). This is where accreditation becomes important in an effort to safeguard the

quality of care provided to medical tourists because accreditation is an important component in patient safety, although as yet there is limited evidence on its effectiveness in this regard (Hinchcliff et al., 2012).

1.4 Definition of Terminology

In the discussion of patient safety it is inevitable that certain terminology is used with which one must become familiar. There are several important terms that are related to patient safety. The terms used in this thesis were chosen from the various definitions available and they are those that are most often quoted in patient safety articles worldwide. The key terms are defined below.

An *error* is the failure of a planned action to be completed as intended. An error may also be the use of a wrong plan to achieve an aim. By extension, a *medical error* is an error related to medical practices by the provider (Reason, 2000). The definition of a medical error will be discussed in detail in chapter 3. *Patient safety* is the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare (Institute of Medicine, 2000).

Culture is the values, beliefs, rituals, symbols and behaviours that are shared with others (J. B. Sexton, Thomas, & Helmreich, 2000). On the other hand, *safety culture* is defined as the product of individual and group values, attitudes, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management and programmes (Agency for Healthcare Research Quality, 2012). Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures (Commission, 1993).

As multiple factors contribute to medical errors there is a need to understand these influencing factors, especially *human factors*, which are defined as the interrelationships between humans, the tools they use, and the environment in which they live and work (L.T Kohn et al., 2000). *Human errors* are the failure of planned actions to achieve their desired ends without the intervention of some unforeseeable event (Reason, 2000). The end products of errors can be classified into two main types: *adverse events* are injuries caused by medical management rather than the underlying condition of the patient (Institute of Medicine, 2000), whereas *near misses* are an unplanned event that did not result in injury, illness, or damage, but which had the potential to do so (Institute of Medicine, 2000).

1.5 Problem Statement

The occurrence of adverse events was estimated to be around 3–17% of all hospital admissions globally, and about 10% of these resulted in the death of the patient of which almost half could have been preventable (Brennan et al., 1991). A study on the frequency and preventability of adverse events across 26 hospitals in eight low and middle-income countries, showed the adverse event rate to be around 8%. Of these events, 83% were preventable, while about 30% were associated with death of the patient (Slawomirski et al., 2017). Most studies on patient safety and medical errors have been conducted in developed countries particularly in North American and Europe (World Health Organization, 2011). While research on patient safety is growing in developing countries, generally data on said issue is still lacking (Salmasi, Khan, Hong, Ming, & Wong, 2015).

It has been proposed that medical errors happen when safety in the system is compromised. Diagrammatically, the Swiss Cheese Model explains how an unsafe act can pass through layers of barriers/defence and form a linear trajectory to result in error. Hence error happens as a result of a break in the system rather than an individual flaw. Thus individuals and organizational factors are more essential factors when focusing and discussing patient safety. (Reason, 2000).

Near misses and adverse events are two important outcomes of medical errors and often require extensive investigation and inquiry from various perspectives. However, it is equally important to detect and analyse both types of medical error for the purpose of learning and improvement. Hence a reporting system is an important tool for improvement in any organization. A good reporting system has often been demonstrated to be useful and resulted in the detection of areas that need to be improved and enables measurement of the actual magnitude of safety in an organization. (Kaldjian et al., 2008).

Also, a non-blame culture is vital in an organization to encourage healthcare providers to report every incident and grasp each learning opportunity that arises. Administrators and policymakers are in a position to take advantage of all the information available from the reporting of errors because they can use the reports as a feedback mechanism, making changes to ameliorate weaknesses and evaluating the effectiveness of the changes made in order to achieve quality excellence in the organization . In a culture of safety, open communication facilitates reporting and disclosure among stakeholders and is considered the norm (Wolf & Hughes, 2008)

The availability of information technology (IT) makes the reporting of errors much easier for staff. However, most importantly, a breakdown in communication predisposes a team or individuals at a devastating impact of error. Therefore, reducing the

communication gaps between the disciplines involved in patient care and among profession will enhance the teamwork thus improves patient safety. The use of IT in developed countries has been shown to improve patient safety. However, to date, many of the research studies on the impact of IT use on the healthcare system have been conducted in highly developed countries such as the US and UK. In contrast, there is a significant lack of research on this issue in developing countries, which requires the attention of policymakers. This is an issue that needs further study because IT may reinforce existing barriers or introduce new barriers to error, for example, by preventing specific unsafe actions (active failures). Similarly, IT may be effective in ensuring that certain information is uniformly available or in reducing the time required to complete certain tasks, and as such IT tools can actively address latent failures (Huckvale et al., 2010).

In developed countries and several developing countries, patient safety activities are coordinated by an agency appointed by the government. For instance, the Agency of Healthcare Research in Quality (AHRQ) is responsible for providing coordination and support for healthcare institutions implementing, monitoring and evaluating patient safety in the US (Agency for Healthcare Research Quality, 2012). Similarly, in Malaysia, the Patient Safety Council of Malaysia (PSCoM), which was launched in 2003, shows the country's commitment to improving safety culture and reducing medical errors. It serves as a national body for policy-making, implementation and monitoring of patient safety activities and its board is chaired by the Director General of Health and composed of key persons from various bodies, including universities and private sector organizations (Patient Safety Council of Malaysia, 2010).

The measurement of patient safety culture has been made possible by the development and availability of various tools. Examples include the Hospital Survey on

Patient Safety Culture (HSOPSC) ((Agency for Reasearch and Healthcare in Quality, 2012), Manchester Patient Safety Framework (MaPSaF) (Manchester, 2006), the Safety Attitude Questionnaire (SAQ) (J. Sexton, Helmreich, et al., 2006) and others. Knowledge of the magnitude of safety culture is essential in enabling the identification of the strengths and weaknesses of an organization (V. Nieva & J . Sorra, 2003). Many of these questionnaires have been translated into various languages or have been adapted for use in the context of different countries in order to assess patient safety culture. One of the commonly used tools is the HSOPSC, which was developed by the AHRQ (Sciences, 2001). It is psychometrically sound and has been translated into numerous languages for use around the world (Agency for Healthcare Research and Quality, 2014.).

Motivated by the successful application of the HSOPSC, this study aims to establish a psychometrically sound patient safety measurement tool for general use in Malaysia. This study consists of two phases. Phase 1 tests the validity and reliability of the adopted and adapted questionnaire on patient safety culture. Phase 2 involves the use of the questionnaire on patient safety validated in Phase 1 to assess the level and practice of patient safety in public hospitals in Malaysia. For these purposes, the HSOPSC was selected as the measurement tool with the permission of the AHRQ, which was received by email (see appendix D).

It is hoped that the findings of this study will enable policymakers and healthcare professionals especially hospital managers, to have more understanding of the actual practice of patient safety culture in the Malaysia and their organization. The ultimate goal is to identify the strengths and weaknesses in the implementation of patient safety culture in the Malaysian healthcare system and to facilitate the establishment of a benchmark for patient safety culture in Malaysia.

1.6 Rationale for the Study

In Malaysia, research on patient safety culture in the country's hospitals is scarce despite the many initiatives and efforts by the authorities since the 1980s to achieve quality in healthcare services. Therefore, it is hoped that this study will serve as one of the initial steps to achieve better and eventually outstanding services in healthcare delivery in the country.

Even though quality improvement initiatives have been extended and expanded in recent decades, to the knowledge of the researcher, research that especially pertains to patient safety culture is still in its infancy. Therefore, in this study, the researcher used a standard, validated tool to investigate how organizations practice patient safety culture in their organization as a whole and as a team in a unit. An examination of the various factors related to patient safety culture in an organization can help to identify both strong and weak areas and consequently find ways to improve the quality of services provided in public hospitals in Malaysia.

1.7 Research Objectives

1.7.1 General objectives

The general objectives of this study are to test whether the Bahasa Melayu version of Hospital Survey on Patient Safety Culture tool is appropriate for use in the Malaysian healthcare system and to assess the safety culture in public hospitals in Malaysia.

1.7.1 Specific objectives

This study has five specific objectives:

i. To explore the factor structure of the original Hospital Survey on Patient Safety Culture and examine the validity and reliability of the Hospital Survey on Patient Safety Culture-Bahasa Melayu (HSOPSC-BM) questionnaire.

ii. To assess the patient safety culture and medical error reporting behaviour among health staff in public hospitals in Malaysia.

iii. To assess the possible differences in patient safety culture among staff in public hospitals Malaysia according to socio-demographic and work-related factors.

iv. To identify the practice of medical error reporting in different type of hospital in Malaysia.

v. To measure the relationship between patient safety culture and medical error reporting practices.

1.8 Research Hypotheses

Three hypotheses were formulated in relation to the above objectives:

i. The Hospital Survey on Patient Safety Culture-Bahasa Melayu (HSOPSC-BM) is psychometrically sound for use in Malaysia.

ii. Health staff in the Malaysian healthcare system has adopted a good patient safety culture.

iii. There are differences in patient safety culture and medical error reporting practices that are caused by the demographic factors of staff.

1.9 Structure of the Thesis

This thesis is divided into six chapters. The current chapter, Chapter 1, is the introduction to the study. This chapter provides the background to the research and outlines the structure of the thesis.

Chapter 2 presents a review of the literature on patient safety culture and the factors that affect patient safety culture. The background, history and theories that underlie the concept of patient safety culture are discussed in detail in this chapter.

Chapter 3 provides details of the methodology applied in conducting the two phases of this research study, which took place in four different types of public hospital in Malaysia from 1 December 2014 to 31 May 2016. Phase 1 (validation study) and Phase 2 (actual study) are described in detail separately in this chapter.

Chapter 4 presents a comprehensive report of the statistical analysis of the two phases of the study. The analysis of the Phase 1 study entailed the use of the Statistical Package for the Social Sciences (SPSS) software version 21 and the Analysis of Moment Structure (AMOS) software version 21. On the other hand, the analysis of the Phase 2 study mainly involved the use of SPSS version 21. The analysis of Phase 1 entailed the use of descriptive statistics and factor analysis. The analysis of Phase 2 involved the use descriptive statistics and inferential analysis.

Chapter 5 discusses the findings of this research and compares them with those of other studies conducted in developed and developing countries. The implications of the findings are also highlighted.

Chapter 6 is the concluding chapter of the thesis. It summarizes the study and made some recommendations for policymakers and programme managers involved in the making and the implementation of patient safety initiatives and activities.

CHAPTER 2: LITERATURE REVIEW

This chapter discuss patient safety culture in further detail. It starts with an overview of the history of safety culture in general, and then focuses specifically on patient safety culture confined to the healthcare organization context.

As safety culture in healthcare has been learned very much from other industries such as the aviation and chemical industries, collectively known as high reliability organization (HRO), a brief discussion of HRO follows the section on the history of medical errors and safety culture in healthcare. The epidemiology of errors and a detailed discussion of patient safety culture including the mechanism and types of medical errors can be found later this chapter.

Then, the various patient safety measurement tools currently available are discussed and because the Hospital Survey on Patient Safety Culture (HSOPSC) was used in this study, summary of the HSOPSC validation studies conducted in various countries is also provided in which a comparison of the findings between countries is made in terms the positive response rate by dimension and the final structure post validation in each country. That summary is followed by a discussion of the important domains of patient safety such as incident reporting, blame-free culture, leadership and communication. Then, medical errors particularly medication errors and healthcare associated infections (HCAI) which are considered key medical errors are explained in greater details. This is followed by a brief explanation of impact of error as it is quite important to discuss the healthcare staff perspective on the commission of medical errors.

2.1 History of Safety Culture

The medical profession and especially physicians are considered highly trained personnel who are carefully selected and exercised a high level of cognitive skills

throughout their daily routine at work. They are expected not to make mistakes in their work because a mistake, even a minor one is considered a failure and the physician will be considered incompetence or lacking knowledge. It is the duty of healthcare professionals (HCPs) and institutions to ensure patient safety in order to improve treatment outcomes and reduce adverse events (AEs). Failure to adhere to patient safety may result in serious negative outcome such as death, disabilities, poor health outcomes and ultimately increased costs and legal issues.(Kim, Park, Park, Yoo, & Choi, 2013)

In 1995, a famous health reporter for the Boston Globe, Ms. Betsy Lehman, 39, died following four repeated overdoses of chemotherapy (Altman, 1995). Earlier, it was reported by the same newspaper that, a devastating incident happened when a surgeon in the US amputated the wrong leg of Willie King (Altman, 1995). These two terrifying stories were quoted in the introduction of the famous report "To Err Is Human: Building A Safer Healthcare System" (L. T. Kohn, J. M. Corrigan, & M. S. Donaldson, 2000).

Just a few years before, in the late 1980s, the Bristol Royal Infirmary in the UK shocked the healthcare industry when the quality of care imposed by the institution was questioned by the staff. The higher mortality in paediatric cardiac surgery in the hospital compared to similar units elsewhere led to an inquiry on the issue that resulted in various recommendations for improvements (Kennedy, 2001). The findings of the investigation showed that the problem was not due to a single factor but was multifaceted. Understaffing, undertraining, poor facilities and equipment and managerial issues were among the factors highlighted in the report. One of the main recommendation in the inquiry report was that the patient should be the centre of everything that National Health Service (NHS) does and that the safety of the patient must be the foundation of the NHS commitment to quality services (Kennedy, 2001).

Perhaps it is not an exaggeration to say that patient safety has long been a priority in medicine because one of Hippocrates principles of medical ethics is *"Prium, no nocere*" meaning "First, do no harm". The principle was further stressed by the founder of modern nursing and a statistician, Florence Nightingale, who, over 150 years ago, pondered the issue of patient safety, as exemplified by her famous phrase " The very first requirement in a hospital is that it should do the sick no harm" (Nightingale, 1863).

2.2 Highly reliable organization (HRO)

Hazardous industries such as the nuclear industry, aviation, chemical industry, are considered as high reliability organizations (HRO) because these industries operated in a very hazardous environment but have a lower rate of adverse events. Discussion on patient safety in healthcare organizations needs to be seen in the context of the achievement of HRO. In 1986, a massive explosion at a nuclear plant in Chernobyl, Ukraine was deemed to have occurred due to a flawed reactor design and inadequately trained personnel. As a result, a major movement to improve safety culture in the industry was led by the government of Ukraine (World Nuclear, 2016).

These HROs face the challenge to avoid failures that would destroy their organization while at the same time maintaining high performance. They share similar characteristics with healthcare organization in that they are complex in structure, dynamicity, use of highly modern technologies that keep on evolving and have to meet the high expectation of stakeholders yet maintain a very low incident of error (Weick. Karl, 1987).

The beauty of HROs in terms of safety is that they practiced an open line of communication which enables the sharing of information that it is unaffected by

demographic factors (when safety is of great concern) such as seniority, job title, rank or grade (Gamble, 2013). In other words, when the situation is critical, the line of command starts with a highly trained member of staff irrespective of other factors. The practices that HROs have employed to achieve such a commendable safety performance should be learned by the healthcare industry. The spirit will continue as emergency occur, the mitigation of responsibility to the experts continue to enable a better control of the acute situation. The normal hierarchical mode will resume as the crisis resolved (Reason, 2000). Unfortunately, the scenario is yet to be observed in healthcare system especially in our Malaysian healthcare system.

It is important for an organization to learn as to what extent it has instilled a safety culture among their workers. Therefore, periodic or regular assessments need to be performed by the management. Assessments of safety culture have been incorporated into many industries other than healthcare industry. The aviation industry, for instance, has developed a very well established set of procedures and guidelines concerning safety and has regularly evaluated the safety attitudes of its employees and its own organizational safety culture for decades (J. B. Sexton et al., 2000). Furthermore, more than two decades ago, the safety expert, Lucian Leape (1994) stated his belief that safety exist as the culture is cultivated in the system itself (Leape, 1994). This view was further re-emphasized by Vincent, Taylor-Adams and Stanhope (1998) who believed that safety culture should be the foundation of any organizational safety system (Charles. Vincent, Taylor-Adams, & Sanhope, 1998).

The high incidence of mortality and morbidity in healthcare organizations indicates that healthcare is a high hazard industry. Thus the industry must learn from other HRO industries and strongly embrace safety culture. The enhancement of patient safety in

the organizational culture and structure is mandatory especially considering the risk of committing error in medicine. As mentioned above, HRO industries make safety a priority in every system and process. Therefore, in benchmarking HRO principles, the healthcare industry needs to build systems and processes to enhance the mindfulness of various stakeholders. Carayon and Wood (2010) delineated five HRO principles that influence mindfulness namely tracking small failures, resisting oversimplification, sensitivity to operations, resilience and deference to expertise. These five principles not only encourage error reporting and learning from them, it can also trigger a better understanding of system processes and furthermore allow the anticipation of potential failures and the redesigning of the system.

2.3 Epidemiology of Medical Errors

The occurrence of adverse events has been estimated at around 3-17% in all hospital admissions globally. Brennan et al., in his qualitative study published in 1991, it was observed that 10% of adverse events resulted in the death of patients, and sadly, almost half of these deaths were preventable (Brennan et al., 1991). A few years later, The Institute of Medicine (IOM) published its first report (*To Err Is Human: Building a Safer Health System*, 2000) which triggered an extensive response from the healthcare industry to improve the safety of patients. The report stated that from 40,000 to almost 100,000 cases of death due to medical errors were reported in the US as well as millions of injuries. The report suggested several strategies to improve the healthcare system and aimed for a 50% reduction in medical error cases in five years following publication of the report. Recently, WHO has made a statement that the risk of patient death occurring due to a preventable medical accident, while receiving health care, is estimated to be 1 in

300.(World Health Organization, 2019). Since 2000, with the continuous support from various stakeholders more research on patient safety has been conducted and published (Aiken et al., 2012; Kim et al., 2013).

Further, according to a 1991 landmark study, the *Harvard Medical Practice Study* which used secondary data, injuries occur in 3.7% of all admission (Brennan et al., 1991). Similarly, an Australian study recorded permanent disability in 13.7% of adverse events of which 4.9% resulted in the death of patients. The study also estimated that more than 50% of the events were actually preventable and the research also concluded that medical errors and adverse events increased the length of stay and the cost of treatment (Wilson et al., 1995).

2.4 Patient safety

Patient safety has been defined as the prevention of harm to patients (2000). World Health Organization extended the definition to include prevention of errors and adverse effects on patients associated with healthcare (World Health Organization [Europe], 2016). Before discussing patient safety in more detail, it is important to understand where patient safety resides in terms of delivery of quality care in a health system. The IOM in one of its publications in 2004 considered patient safety as indistinguishable from the delivery of quality care because the definition of quality has been described as conceptual rather than having an explicit meaning in terms of the terminology (Aspden et al., 2004).

The IOM, in its second key report titled '*Crossing the Quality Chasm: A New Health System for the 21st Century'* proposed six dimensions of quality namely safe, effective, patient centred, timely, efficient and equitable (refer to figure 2.1 on page 28). These dimensions can be viewed as commitments for every stakeholder in the healthcare

system needs to make in order to provide a continuously high quality services to the population. Each of these six dimensions is explained on page 24 (Institute of Medicine (US) Committee on Quality of Health Care in America., 2001)

First, a healthcare system must be *safe*. Although the ancient maxim "First, do no harm," already dictates the importance of safety, a commitment to safety means much more than that especially for individual caregivers because they need to do their utmost to ensure the safety of patients. Here, safety must be a property of the system with the aim that no one should ever be harmed by the healthcare they received.

Second, healthcare must be *effective*. Patient care must be evidence based in order to avoid underuse or wasting of available techniques. Adherence to available clinical practice guidelines must be encouraged so that optimum treatment is provided to patients. For example if an elderly patient with a heart problem would benefit from beta blockers, the patient should be prescribed the drug or if a patient has a viral infection, the patient should not be given antibiotics as a first- line treatment.

Third, healthcare should be *patient-centred*. Patients must be involved in the decision making about their own care. Patient and family rights are important aspects to stress during patient care especially now a growing number of patients require chronic care rather than acute care. The individual patient's culture, social context, and specific needs deserve respect.

Fourth, care should be *timely*. Patient care should avoid unnecessary waiting without proper information. Unintended waiting that does not provide information or time to heal is a system defect. Prompt attention benefits both the patient and the caregiver.

Fifth, the healthcare system should be *efficient*. A healthcare system should actively and constantly seek ways to reduce waste and hence the cost of resources such as supplies, equipment, space, capital, ideas, time, and opportunities.

Sixth and finally, healthcare must be *equitable*. Patients should be provided with the best available care regardless of race, ethnicity, gender, and income. Advances in healthcare delivery need to match advances in medical science so the benefits of that science may reach everyone equally.

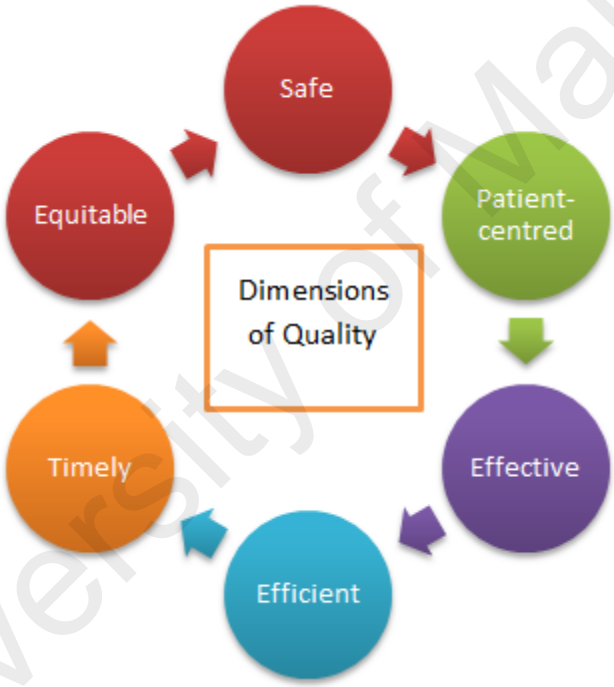

Fig 2.1 Dimensions of healthcare quality (Institute of Medicine., 2005)

Achievement in these dimensions will benefit patients because they will experience better care that is safer, reliable and meets the need. On the other hand, healthcare providers benefit from the achievement in this regard by increasing satisfaction and self-esteem of staff. This in turn, will be of advantage to the organization in the sense of making it more productive and achieving a level of excellence.

As far as adverse events are concerned, they can occur at any level of the healthcare delivery system, starting from the primary to the tertiary level of care. Safety, as part of the quality agenda, is important in maintaining high-quality healthcare delivery. It requires broad commitment from all stakeholders from policy makers, organizations and providers to patient and their families. It is not uncommon to relate patient safety and medical errors. Both patient safety and medical errors are inversely related; wherever an organization has embraced a positive patient safety culture, the incidence of medical error has decreased. A shared goal of patient safety among employees influences their behaviour in terms of how they view patient safety and make patient safety their top priority in whatever decision they make in relation to patients (Mardon, 2008; Navon, Naveh, & Stern, 2005).

The definition of medical errors has been evolving since the 1950s, when the term medical error was initially defined as a disease of medical progress, which is an outcome-based definition. Another definition of medical error was proposed by Schimmel (1964), who described it is a noxious episode (a term that covers all untoward events, complications and mishaps that resulted from acceptable diagnosis or therapeutic measures deliberately instituted in the hospital) proposed by Schimmel in 1964 (Schimmel, 1964). On the other hand, Grober and Bohnen (February 2005) state that the definition of medical error must by itself include all unintended events that result from any act of commission or omission in the planning or execution of a plan that contribute or could contributes to error. It has been agreed that although the term error carries negative connotation or can be seen as antagonistic, it is important to retain such a term as a motivation to learn from mistakes because errors can act as a powerful tool in improving

a system, in learning, in shaping behaviours and ultimately in achieving organizational goals (L.T Kohn et al., 2000).

Medical errors can be subdivided into near misses and adverse events, terms which can be seen as analogous to the absence or presence of harm, respectively. The IOM defined adverse drug event as an injury caused by medical management rather than the underlying condition of the patient. On the other hand, near misses are an unplanned event that did not result in injury, illness, or damage, but which however, had the potential to do so. The difference between these two subcategories of medical errors is that adverse events produce harm to the patient where near misses usually stop before harm is produced. While near misses might go unnoticed, adverse events produce a certain degree of loss, morbidity or even mortality to patients(Weingart, R, Gibberd, & Harrison, 2000) .Morello et al (2013) in his article concluded that whenever an organization has an excellent patient safety culture, the rate of medical errors is minimal. (Morello et al., 2013)

In a healthcare organization, a near misses and adverse events are both two important outcomes of medical errors and often require an extensive investigations or inquiry that takes into account from various aspects. It is also important that both types of outcome are detected and analysed for the purpose of learning and improvement. Hence an error reporting system in an organization is an important tool for improvement. A good reporting system has often been demonstrated to be useful and in the detection of areas to be improved and enable the measurement of a safer system (Barach & Small, 2000). Patient safety initiatives should be applied to every stage of work processes to avoid medical error from happening and ultimately to improve the overall quality of care Figure 2.2 below illustrates how medical errors arise in a safe environment and the important role

of patient safety initiatives in all stages of patient care because these initiatives can inhibit an error from becoming hazardous to the patient.

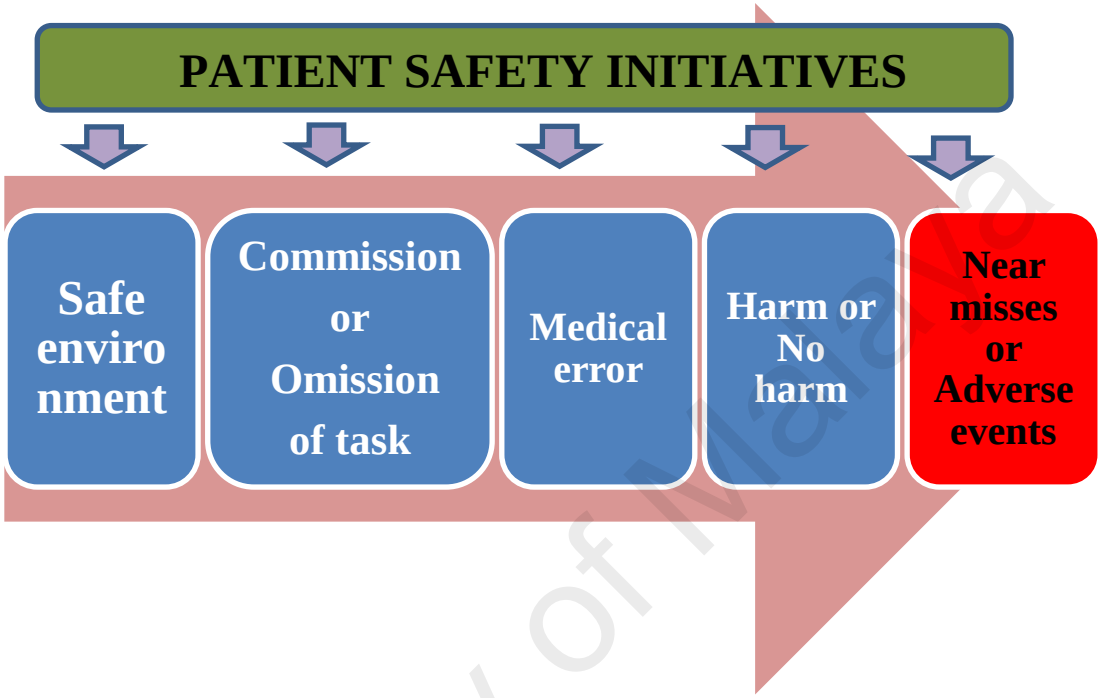

Figure 2.2: Evolution of the two types of medical error and how patient safety initiatives need to be applied in every step of the work process. (Barach & Small, 2000)

In order to establish a patient safety culture in healthcare organizations, the National Patient Safety Agency in year 2004 outlined seven steps to achieve patient safety (National Patient Safety Agency, 2004). The first step is **to build a safety culture**. A safety culture is established when staff in an organization are constantly and actively aware of the potential gaps in the system that predispose the system to error. Also, errors are accepted as learning points where each error is acknowledged and discussed in order to make things right. Moreover, open and free communication about errors when incidents happen is practiced so that all individual staff who are involved in the production of error

are treated fairly. This is vital for both the safety of patients and the well-being of those who provide their care.

Furthermore, a system approach to treating errors looks into the system factors that contribute to the development of errors. The blaming of individuals does not help in remedying of error, rather, it requires an examination of what is wrong in the system and it is this type of approach that will help organizations to learn lessons that can prevent the incident from recurring.

The second step mainly concerns to the role of **leadership** in promoting patient safety. Leaders must show full commitment to change to improve patient safety. Top management and leaders throughout the service need to assist in and show commitment to change in culture and support their subordinates especially when they report incidents. Also, they need to show and practise the safety principles through examples or more colloquially, they should walk the walk. Again, communication and feedback are vital in managing patient safety issues. Staff must be involved in the discussion of errors and communication must be made feely among staff so that they perceive error as areas for improvement.

The third step is to **integrate risk management activities in the organization**. Risk management should not be managed at the individual level or in functional silos. As the core of risk management is intermingled with healthy and safety issues, the integration of risk in both clinical and administrative areas will expose more room for learning and improvement in the organization. A central administrative team should be responsible for pulling the system and processes of risk management together and for disseminating such information to all staff across the organization. Integration also promotes compliance with

all the assurance standards including clinical governance and at the same time ensures that information is spread across the organization.

Much has been said about the importance of reporting in patient safety. Therefore, the p**romotion of error reporting** is the fourth step in establishing a safety culture. Reporting provides learning opportunities and the execution of remedial measures to prevent similar occurrences in the future. To encourage staff to report patient safety incidents, they must first know what to report. Continuous support and encouragement from the leadership is vital to ensure staff that staff self-report any incident. Therefore, it is important to break the barriers to reporting such as not meting out punitive treatment to the staff involved, providing an easy and friendly reporting system, explaining clearly the benefits of reporting and providing psychological support to the staff involved because errors are often perceived as failure by staff and this demotivates them.

The fifth step is to **involve and communicate with patients and the public**. It is important to involve and communicate openly with patients, their relatives, and their carers about their treatment plan. Many patients know their disease well and this knowledge can help them to identify risks and solutions to patient safety problems. Healthcare staff need to include patients in reaching the right diagnosis, deciding on the appropriate treatment, discussing the risks and ensuring that treatment is correctly administered, monitored and adhered to. Open communication about error and discussing the problem promptly, fully and compassionately can help patients cope better with the after effects when things have gone wrong.

The sixth step in cultivating a patient safety culture in an organization is to **learn and share safety lessons**. The reporting of errors is not enough. Errors must be investigated and remedial measures discussed openly among staff and administrative staff.

Often the underlying causes are many and in the majority of cases extend beyond the individual staff member or team involved. Thorough investigation often reveals other systemic factors that contribute to the development of errors. These findings can be shared with other units as areas for improvement.

To prevent harm from continuously being committed, the implementation of solutions is vital. Active learning from patient safety incidents should be through implementing changes incorporated into the standard operating procedures at all levels. However, it is important to ensure the sustainability of such changes.

Therefore, the seventh and final step is in establishing a patient safety culture is **implementing solutions to prevent harm**, which calls on organization to learn from mistakes and to take mistakes as an opportunity for learning. Also, a good practice implemented locally can be shared with other organizations. Solutions need to be realistic, sustainable and cost effective. Moreover, before implementation they must undergo risk assessment and evaluation.

An established patient safety culture in an organization can be characterized as a culture in which staffs actively anticipate and are aware of any potential room for things to go wrong. An organization that speaks about safety freely and that has an environment in which staff can openly share and gives opinions for improvement is vital (Agency., 2004). An open and fair culture should involve all stakeholders involved in care delivery. Patient safety is a priority for everyone and affects every aspect of care and every decision that is made should be tailored to the safety of patient.

2.5 Safety culture

It has been stated that safety culture is typically defined as 'the shared attitude, beliefs, perceptions, collective behaviours of employees that determines the commitment of organization's management (V. Nieva & J . Sorra, 2003). On the other hand, safety culture also has been defined as collection of attitudes, beliefs, perceptions and values that is shared by the employees pertaining to safety (Cox & Cox, 1991).

Topics on patient safety culture are merely discussion of quality and culture from the healthcare provider's perspective. It is a complex framework which involves multidimensional approach and consideration and tailored to behavioural discretionary of patient safety (J. Sexton, Helmreich, et al., 2006). An established culture in an organization connects employees and the employer with the vision, mission and organizational goals. The embracement of the culture leads and tailor employees towards achieving the organizational goals (Okunola, Ikuomola, & Noun).

Both parties, employer and employees are very much aware that incidents can happen at any time and can be committed by anybody. In addition, they perceive error as a fact and take it as a lesson to be learnt. Open communication is where individuals are free to speak up on safety issues and errors, seek assistance when there is problem or when the care delivery is jeopardized by the erroneous acts or decisions of anyone else. In addition, there should be administrative support that promote a 'just culture' where, staff are accountable for any of their action during care delivery and are not blamed when system failure occur (National Patient Safety Agency, 2004).

2.5.1 Mechanism of error

The presence of various factor in a healthcare institution contribute to its complexity. The various administrative controls, guidelines and protocols that are meant to safeguard and protect patients from becoming victim of medical error add to the complexity.

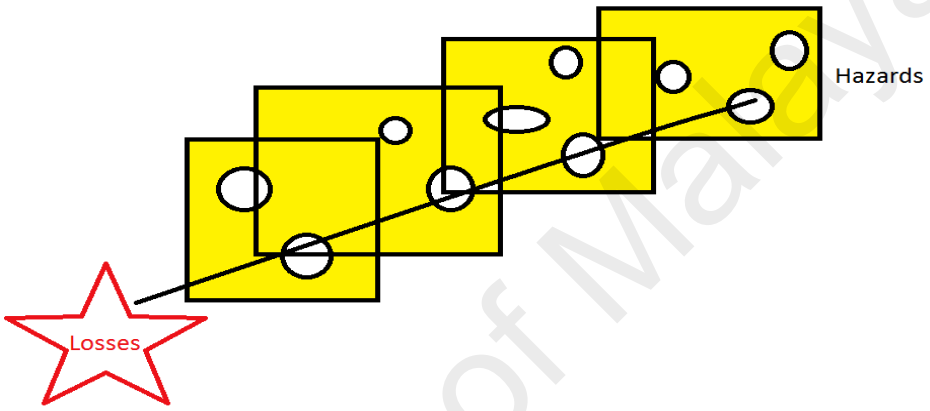

Figure 2.3: Swiss Cheese Model showing how hazards passes through defence in a system (Reason, 2000)

James Reason proposed the Swiss Cheese Model to describe how errors occur as a result of gaps in a system and how hazards can pass through layers of barriers or defences in a system (Reason, 2000). Figure 2.3 above illustrate this model. Each layer of cheese acts as a defence or barrier and there should be a mechanism to detect errors and prevent them from passing through the layer. The holes in each layer represent active failures and latent conditions. The active failures are due to slips, lapses or other forms of potential failures and usually involve people who have direct contact with patients during healthcare delivery.

On the other hand, latent conditions are failures resident in the system. They can take the form of understaffing, inadequate equipment, inexperience staff or permanent

weaknesses such as faulty design or construction or substandard procedures and guidelines. When these latent failures are combined with active failures and are assisted by chance or local triggers, they produce an accident opportunity. When hazards or failures are able to pass through every defensive layer, they are said to form a trajectory or become aligned to reach and breach the final layer, which results in the occurrence of errors.

Individual active errors are more difficult to predict than latent conditions. Therefore remedial action is easier to take to address latent condition because it is more predictable and manageable. Effective and proactive risk management is able to detect and correct such failures before they reach the patient and cause an adverse events (Sciences, 2001).

Active failures and latent failures can be seen as analogous to the sharp end and the blunt end of an organizational structure approach. Traditionally, in the person approach, individuals at the sharp end are to blame when errors occur. The measures that can be applied to them include disciplinary actions, threats, shaming and blaming. This approach is so predominant that we often forget to consider the blunt end i.e the procedures, guidelines and directives from leadership, among others. If we take another analogy, active failures are like mosquitoes, but it is the breeding site (latent failure) that is in need to be destroyed rather than the individual mosquitoes.

2.6 Measurement of Patient Safety Culture

In order to quantitatively measure safety culture, there is a need to have an established tool to assist in the exercise. To date several tools have been developed and widely used in individual countries or which have been extended for use in other

countries. A tool that is designed for one country and then used in another country should undergo validation in order to ensure that the language used in the tool is culturally acceptable in the other population. Here, only a few survey tools that are often used in safety culture assessment and monitoring are discussed, in no particular order or preference.

2.6.1 Safety Attitude Questionnaire (SAQ)

The Safety Attitude Questionnaire (SAQ) was developed by Sexton and colleagues in 2006. This questionnaire is a two part questionnaire that has a section to collect demographic information and a section consisting of 30 items to cover six dimensions has 6 dimensions covering 'Teamwork Climate', 'Safety Climate', 'Perception of Management', 'Job satisfaction', 'Working condition' and 'Stress recognition'. Responses to the items are made using five-point Likert scale ranging from 1 (strongly disagree) to 5 for strongly agree. Some items are negatively worded. Respondents are expected to be able to complete the questionnaire in 15 minutes. Psychometric assessment of the SAQ has revealed that it is a sound tool for use in the assessment of the safety climate in an organization (J. Sexton, Helmreich, et al., 2006).

2.6.2 Patient Safety Culture in Healthcare Organization (PSCHO) questionnaire

The Patient Safety Culture in Healthcare Organization (PSCHO) questionnaire (PSCHO) was developed by Singer et al (2009) and is a 45-item measure that assesses safety culture in healthcare organizations. Six close-ended demographic items are also included. The PSCHO is comprised of 12 subscales that assess different aspects of the safety climate. These subscales are grouped into four categories: hospital contributions to

safety climate, work unit contributions to safety climate, interpersonal contributions to safety climate, and other aspects of safety climate. The hospital contribution to safety climate is composed of senior managers' engagement, organizational resources for safety, and overall emphasis on patient safety subscales. The work unit contribution to safety is composed of the unit managers' support, unit safety norms, unit recognition and support for safety efforts, collective learning, psychological safety, and problem responsiveness subscales. The interpersonal contribution to safety climate is composed of the fear of shame and fear of blame and punishment subscales. Finally, the other aspects of safety climate section examines the provision of safe care (Singer et al., 2009).

2.6.3 The Manchester Patient Safety Assessment Framework (MaPSaF)

The Manchester Patient Safety Assessment Framework (MaPSaF) was developed in 2006 and is a tool that was designed to help NHS organizations and healthcare teams assess their progress in developing a safety culture. The tool uses critical dimensions of patient safety and for each of these describes five levels of increasingly mature organizational safety culture. The dimensions relate to areas where attitudes, values and behaviours about patient safety are likely to be reflected in the organization's working practices. These practices include, for example, how patient safety incidents are investigated, staff education, and training in risk management. It works as a tool for organizations to qualitatively work with nine dimensions of patient safety culture in five organizational levels of safety; 'pathological', 'reactive', 'calculative', 'proactive' and 'generative' (Parker, 2009).

The MaPSaF is based on Westrum's typology of organizational communication, which describes how different types of organizations process information (Westrum,

2004). This typology was later expanded by Parker and Hudson to describe five levels of increasingly mature organizational safety culture, as follows (Parker, 2009):

When an organization put less or no effort on patient safety, it is regarded as **pathological** i.e it is an organization with a prevailing attitude of 'why waste our time on safety' and, as such, there is little or no investment in improving safety. The next level is **reactive** which covers an organization that only think about safety after an incident has occurred. The c**alculative** level is where an organization is very paper-based and safety involves ticking boxes to prove to auditors and assessors that they are focused on safety. A better level is described as p**roactive** when organizations place a high value on improving safety, actively invest in continuous safety improvements and reward staff who raises safety-related issues. The highest level of safety attitude is **generative** when safety is an integral part of everything that an organization does. In a generative organization, safety is truly in the hearts and minds of everyone, from senior managers to frontline staff.

2.6.4 Hospital Survey on Patient Safety Culture (HSOPSC)

The HSOPSC was developed by the AHRQ and was released in November 2004. Since then it has been used by numerous studies on patient safety culture (sometimes referred to as PSC) all over the world to investigate and examine patient safety culture in a country and to compare the similarities and differences between the obtained data with those for other countries. The HSOPSC was developed due to the need for a tool to assess patient safety culture in healthcare organization. The survey was pretested and underwent validation and reliability testing as appropriate. It was piloted across the US in a test that involved 21 hospitals and 1400 staff. The final survey is comprised of 42 items covering

12 dimensions. Apart from assessing safety dimensions, it also includes demographic questions.

The 42 items mostly use the five-point Likert response scale of agreement from 1 to 5 ("strongly disagree" to "strongly agree") or frequency ("never" to "always"). Seventeen of the items are negatively worded which means that the responses to these items must be reverse coded for analysis purposes as to give similar response as in positively worded items. The survey measures the following 12 dimensions: Supervisor/manager expectations and actions promoting safety (four items), Organizational learning-continuous improvement (three items), Teamwork within units (four items), Communication openness (three items), Feedback and communication about error (three items), Non-punitive response to error (three items), Staffing (four items), Hospital management support for patient safety (three items), Teamwork across hospital units (four items), Handoffs and transitions (four items), Overall perceptions of safety (four items) and Frequency of event reporting (three items).

Out of these 12 dimensions, two are outcome measures namely Overall perceptions on patient safety and frequency of events reporting. Apart from that, there are two questions that require respondents to give an overall grade for patient safety culture (section E) in their own area or working unit and to indicate how many events they have reported during the past 1 year (section G). Table 2.1 presents the dimensions and the distribution of the items arranged in those dimensions.

Table 2.1: The 12-dimension and 42 items in HSOPSC

	Dimensions	No. of items	Items
1	Teamwork across unit	4	F2r F4 F6r F10
2	Teamwork within units	4	A1 A3 A4 A11
3	Hands Off and Transitions	4	F3r F5r F7r F11r
4	Frequency of events reporting	3	D1 D2 D3
5	Non-Punitive Response to Error	3	A8r A12r A16r
6	Communication Openness	3	C2 C4 C6r
7	Feedback and Communication on error	3	C1 C3 C5
8 .	Organizational Learning	3	A6 A9 A13
9	Supervisor expectation and action on patient safety	4	B1 B2 B3r B4r
10	Hospital management support on patient safety	3	F1 F8 F9r
11	Staffing	4	A2 A5r A7r A14r
12	Overall Perception on patient safety	4	A10r A15 A17r A18

2.6.4.1 Validation study of HSOPSC

As mentioned above, the HSOPSC survey tool was tested in its origin country using a large population from across the country. It underwent various validation steps to ensure that it fit the purpose of measuring patient safety culture. It was found to have

good, sound psychometric properties. Since then, the tool has been translated into various languages and validated in various countries across the globe such as The Netherlands, Japan, Taiwan and China to suit native languages and cultures. It has also been tested for validity and reliability before being used for research (Sorra JS & VF., 2004) . Other countries that have implemented HSOPSC include Belgium , Singapore, Germany, England, Ireland, Saudi Arabia, Serbia, Australia and many more (2014.) .

Although the findings vary, overall it is regarded as a valid tool for the measurement of patient safety culture. For instance, the HSOPSC has been rated as better than to other established questionnaires on safety culture such as the SAQ in terms of collecting accurate data on medical error reporting and overall perception of patient safety (Etchegaray & Thomas, 2012). This tool was selected for use in the study because it has been used internationally including countries in the Western Pacific region. Hence the HSOPSC is considered an appropriate tool for measuring safety culture in Malaysia. This will also allow further comparison among countries in the region in the future.

Table 2.2 on page 45 provides a between countries comparison of the use of the HSOPSC as a measurement tool in the assessment of patient safety culture. As the HSOPSC was developed by the AHRQ, which is based in US, the findings from the US are used as benchmark scores for comparison among countries (Sorra & Dyer, 2010).

From table 2.2 it can be seen that Taiwan scored the highest in four of the dimensions: Teamwork within unit, Teamwork across unit, Overall perception on patient safety and Manager and supervisor expectations and actions in promoting patient safety. Generally, Taiwan scored better than other countries in terms of teamwork and administrative support (Chen & Li, 2010).

Table 2.2: Comparisons of positive response rate to Dimensions in different countries

PSC Dimensions	US (338607)	Netherland (3779)	Norway (358)	Turkey (309)	Iran (145)	China (1160)	Taiwan (788)
TWU	80	84	57	70	65	84	94
MSEAPS	75	62	65	44	61	63	83
OL	72	47	46	41	62	88	84
HMS	72	32	22	40	54	69	62
OPPS	65	52	57	62	60	55	65
FCE	63	49	32	38	56	50	59
CO	62	69	58	38	53	65	58
FER	62	38	31	15	58	-	57
TAU	58	28	32	40	53	66	72
ST	56	62	52	44	47	45	39
HNT	44	40	31	54	60	-	48
NPE	44	67	72	24	44	60	45
Mean	**62.75**	**52.5**	**46.25**	**42.5**	**56.1**	**64.5**	**63.8**

TWU-Teamwork within unit, MSEAPS-Manager and Supervisor Expectation and Action Promoting Patient Safety, OL-Organizational Learning, HMS-Hospital Management Support on Patient Safety, OPPS- Overall Perception on Patient Safety, FCE-Feedback and Communication on Error, CO-Communication Openness, FER-Frequency of Event Reporting, TAU-Teamwork Across Unit, ST-Staffing, HNT- Hands Off and Transitions, NPE-Non Punitive Response To Error)

In contrast, the US scored higher in the dimensions of Hospital management support, Feedback and communication on error and Frequency of event reporting. The practice of event reporting is much better in the US than in other countries especially when compared to countries such as Norway and Turkey (Bodur & Filiz, 2010; Olsen, 2008). On average, Frequency of event reporting had the lowest score among all countries in comparison with the US which scored highest in this dimension with a score of 62%. Turkey scored the lowest in this dimension (15%), followed by Norway with 31%.

Among all the countries compared above, Turkey scored the lowest in terms of mean score of positive response with 42.5% followed by Norway with a mean score of 45.25%. China had the highest mean score of positive response with 64.5%. Thus, from this comparison, it can be concluded that event reporting (or, as it is often called, incident reporting), communication and leadership support are the dimensions that need to be seriously considered in relation to patient safety. Therefore, these three areas will be discussed in further details later in this chapter.

In some nationwide studies, some dimensions achieved higher marks than the others. For example, a nationwide study in Taiwan showed that Teamwork within units, Organizational learning and Manager and supervisor expectations and action promoting safety scored higher than other the other domain in HSOPSC (Chen & Li, 2010).

In contrast, in a Japanese nationwide study (Fujita, 2013) and an Australian intensive care unit (ICU) nationwide study, hospital management is viewed as a problem in many ICU in Australia and is consequently associated with poorer patient outcomes (Wendy C, 2013). On the other hand, Non punitive responses to error, Communication openness and Teamwork across units were the dimensions that were identified as in need of improvement in Saudi Arabian hospitals (Alahmadi, 2010).

2.6.4.2 Comparison of final structure of the HSOPSC in different countries

Researchers in several countries have validated the HSOPSC so that it fits the culture and population and can consequently be implemented in their respective countries. In some cases, a different number of dimensions and/or items appeared in the final country-specific version of the HSOPSC. Table 2.3 provides some examples.

Table 2.3: Comparison of final dimensions and items after validation of HSOPSC in different countries

Country	Year	Final Dimension	Final Items
Netherland	2008	11	40
Norway	2008	12	42
Taiwan	2010	12	Not mentioned
United Kingdom	2010	7	27
Turkey	2010	10	40
Palestine (Arab)	2012	11	38
Iran	2012	Unable to construct factors	Use original structure
Sweden	2013	14	48
French	2013	10	40
China	2013	8	29

2.7 Medical Error Reporting

Medical errors reflect the presence of problems in a system. In order to improve, a mechanism is necessary to identify these problems to avoid repetition of the same mistakes or worse putting the patients in more danger in the future. Systems problems can be detected through reporting of errors that have harmed patients (true errors), errors that occur but do not result in patient harm, and errors that could have caused harm but were mitigated in some manner before they ever reached the patient (near misses) (Mudur, 2004). Due to fears about potential lawsuits and the self-perception of incompetence, often medical errors go unnoticed. Hence a voluntary and mandatory reporting system coupled with a non-blame culture is vital to promote open communication and feedback about errors and ultimately to provide room for improvement from lessons learned. Three principal conditions need to be met in order to create an effective reporting system: staff awareness about patient safety (attitude), how to report incidents (knowledge) and ability to recognize risky situations (skills).

Therefore, patient safety education plays an important role in achieving these principle conditions to stimulate an active reporting culture (Varkey P, Karlapudi S, Rose S, & S., 2009). Medical staffs are key figures in delivering healthcare, hence they are an important target group for education. Also, rather than punishing the staff, they should be encouraged to report any error in their unit to allow open discussion about the error and to encourage a learning environment. In a controlled study, after repeated intervention in the intervention group, the members of the group showed a positive attitude and knowledge about error reported and reported errors voluntarily that were registered by the hospital reporting system (Jansma, Wagner, Kate, & Bijnan, 2011).

Incident or event reporting allows the detection and analysis of both near misses and adverse events or actual events. Detailed investigation of the error allows discussion between staff and administrative personnel who can then figure out how the error happened and look for ways to mitigate or obviate weaknesses. Having said that, even where staff have a positive attitude towards event reporting , there are incidents where staff fail to report adverse events for several reasons such as lack of time in a busy clinic and the perception that error reporting lacks usefulness (Kousgaard, Joensen, & Thorsen, 2012). Hence there is a need not only to encourage incident reporting through continuous awareness programmes or continuous medical education (CME) at the hospital level, but also for policy maker and administrators to develop a better and easier way to report errors so as to encourage health staff to report any incidents.

An organization with a positive safety culture usually puts patient safety at the top of its priority list. Such an organization usually promotes open and fair discussion of mistakes or errors with their staff, enables the staff and the relevant committees to learn from mistakes (V. Nieva & J . Sorra, 2003) and seek ways to improve rather than blaming individuals involved in the error process and taking punitive actions against them. Organizational or system error or faults are also taken into consideration in the discussion. In an organization that permits error reporting without subjecting staff to any punitive action, the number of reports increases and free communication between employer and employees eventually results in a measurably safer system. The harmonious combination of voluntary reporting and free communication further improve patient safety in the healthcare setting (Emslie, Knox, & Pickstone, 2002).

2.8 Risky behaviour

Often, health staff have developed and engaged in risk-taking behaviour in their daily practices. Short-cuts and risky behaviours are often adopted by staff because the rewards are immediate and the risk of patient harm seems remote, making it difficult to motivate people to always choose the safest way to work (National Coordinating Council For medication error Reporting and Prevention, 2014). Such actions are indicative of a system based problem that opens up the opportunity for staff to create or practise forms of risk-taking behaviour (Geller, 2001). Examples of system-based errors include complexity of processes, or problems with technology.

There are organizations that have an attitude of tolerant to risk, where a risk behaviour practice is often rewarded and safe behaviours are punished (A Train Education, 2018). By way of example, a staff member who does his/her work carefully is often regarded as a slow and inefficient worker whereas a staff member who can finish and complete multiple tasks on time is considered efficient even if she/he bypasses certain steps and takes short-cuts to overcome the problems in the system. The latter member of staff is actually compromising patient safety to achieve organizational goals. Just a few of the examples of risky behaviours that are commonly practiced by health staff include preparing multiple drugs at the same time, rushing communication during patient transfer/ hand off , borrowing medication prescribed for one patient to administer it to another patient, failure to adequately supervise/orient staff, inadequate orientation of new/agency staff and illegible handwriting (Institute Of Medication Safety Practice, 2004). Ironically, some staff who practised risky behaviour in their daily practice are often regarded as efficient and competent and some are rewarded with organizational excellence awards whereas other staff who are highly committed to safety practices are treated the opposite.

2.9 The role of leadership in safety culture

Leadership plays an important role in initiating, promoting and sustaining a culture of safety in an organization. Leaders inspire their team or employees to achieve higher level safety and productivity. In doing so, a leader must apply good attributes daily in order to be an exemplary role model for their subordinates. In order to cultivate a safety culture, it is very important for leaders to be well trained in their key role as safety leaders and that they are free to implement their safety skills at every level. The implementation of safety practices in organization need to be monitored by the leadership.

In the process of establishing a positive safety culture, several safety principles must be practised. Firstly, safety must be made a priority in every decision especially when the patient becomes the primary concern. Leaders must lead by example. In doing so, senior management must repetitively and visibly demonstrate their commitment to safety at every level. Then the vision of safety is commonly shared by everybody in the organization. A simple way to demonstrate visibility is by doing walkabouts. This practice gives the impression to staff that managers are serious about cultivating safety apart from providing an environment for open discussion with staff especially regarding problems concerning safety practices (Manchester, 2006).

Open communication about errors provides room for improvement. A leader must show empathy and care in handling errors. They must demonstrate care and concern towards employees in managing them. There is no doubt that staff involve in errors sustain a psychological impact. Guilt, demotivation, stress and other feeling will impede them from performing as well as they normally would (A Wu, 2000). Managers must show empathy and justice to their staff so that staff will willingly report errors without the fear that some form of punitive treatment awaits them. Sharing the same organizational

mission and vision helps in motivating staff to cultivate and practice patient safety. The Joint Commission's Sentinel Event Database reveals that leadership's failure to create an effective safety culture is a contributing factor to many types of adverse events from wrong site surgery to delays in treatment ("Sentinel Event Alert.," 2004)

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2.10 The Role of Communication In Safety Culture

Apart from leadership, communication also plays an important role in mitigating medical error. Many medical errors occurred when messages were not conveyed properly between individuals and/or teams. By definition, communication means the imparting or exchanging of information from one party to another by speaking, writing, or using some other medium (Press, 2017). On the other hand, communication breakdown occurs when there is a partial communication or an absence of communication between parties resulting in incomplete information being transferred (Vermeir et al., 2015).

In a healthcare system, information is communicated between healthcare members or between healthcare providers and patients and/or their family members (caregivers). Information exchanged between healthcare providers mainly relates to decision making, planning of treatments, performing interventions, or hand overs of patients. Information is also transferred between healthcare providers and patients or family members especially during the discussion of treatments or procedures suggested by the managing team, news breaking and other patient-related matters. Thus, the patient and their relatives (caregivers) are a crucial part of patient management.

In patient care, a high level of communication is vital. Information must be complete and detailed enough for correct interpretation and proper management. Loss of information during the process of care might predispose a patient to harm due to

incomplete, inadequate or inappropriate information. During the process of care, communication is used to establish the staff-patient relationship, exchange information with the patient/family, ensure accuracy in delivering the correct treatment regime, exchange information with other health-care providers, transfer (handover) the responsibility of care of the patient from one department to another and ensure accuracy in interpreting information. Open communication means information is freely communicated between parties. In the context of patient safety, it also encompasses the communication of errors in their organization. This practice stimulates a positive culture of event reporting which in turn provides room for active and free discussion of the error that ultimately promotes improvement to the existing process of care. This will eventually benefit the patients the most because potential errors can be detected and avoided long before they could occur (Sutcliffe, Lewton, & Rosenthal, 2004).

2.11 Common types of medical error

There are many types of medical errors. Medication errors, diagnostic errors, infection, surgical errors, equipment failure, patient fall and transfusion error are examples of medical errors.(Anees Alsaadi, 2003). Among these medical errors, medication errors and healthcare associated infection were among the commonest error committed in healthcare system and they are largely preventable (La Pietra, Calligaris, Molendini, Quattrin, & Brusaferro, 2005)

2.11.1 Medication errors

Medication errors are the most common type of error and the most common preventable cause of medical errors. According to one study in the US, medication errors occurred approximately one in five dose .(Barker, Flynn, Pepper, Bates, &

Mikeal, 2002). Medication error is a significant cause of morbidity and mortality during hospitalization. Ironically, however, it is the one adverse event that is largely preventable. As individual and systematic factors are usually involved in this type of error, strategies to reduce the occurrence of medication errors should be aimed at all various levels or factors that could possibly be involved (Anne -Marie Bradie, 2009).

A medication error has been described as a deviation from a physician's order (Mayo & Duncan, 2004). It has also been defined as a preventable mistake in prescribing or delivering medication to patients (Lasseter & Warnick, 2003). In Malaysia, in 2009, 2572 cases of medication errors were reported and it was identified as the main adverse event issue that impacted patient outcomes (Ministry of Health, 2012b). It has serious direct and indirect results and is usually the consequence of a breakdown in a system of care.

In practice, drug administration is predominately a nursing responsibility. However, medication management involves a few other steps before the administration of the medication itself. Other stages of medication process include the selection, procurement, storage, prescribing, ordering and transcribing of drugs (Carrera & Bridges, 2006). Alternatively, medication error may occur as a consequence of or be influenced by individual or systems issues including the type of drug administration system, the quality of the prescription, deviations from procedures, workload, staffing and shift patterns and the knowledge and mathematical skills of nurses (Doyle, Lennox, & Bell, 2013).

2.11.2 Healthcare associated infection (HCAIs)

Healthcare associated infections are the most frequent adverse events in healthcare delivery worldwide and lead to significant mortality and to financial losses in the

healthcare system. It has been estimated that about 7% of patients in developed countries and 10% in developing countries will contract with HCAIs during their hospital stay (Haque, Sartelli, McKimm, & Abu Bakar, 2018; Pittet, 2005). Previous study have shown that patient to patient transmission is largely the result of the suboptimal hand hygiene of healthcare workers which permits transfer of infection and spread of various organisms for example methicillin –resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus faecium* (VRE) which in particular poses a huge challenge to physicians in terms of choosing the most appropriate anti-microbial therapy best suited to affected patients.(Albrich & Harbarth, 2008; Duckro, Blom, Lyle, Weinstein, & Hayden, 2005; Khan HA, Baig FK, & R., 2017)

While MRSA and VRE are among the commonest gram-positive bacteria affecting patients in healthcare, *Eschericiae coli (E. coli), Klebsiella pneumonia* and *Pseudomonas aeruginosa* are examples of gram-negative bacteria that commonly affect patients during their treatment course in healthcare settings. Other groups of pathogens that are also responsible for HCAI include *Aspergillus* sp, Hepatitis B, Hepatitis C, Human Immunodeficiency virus (HIV) etc.

The WHO had launched its Global Patient Safety Challenges in response to the world's need for specific patient safety issues enabling the congregation of experts, political and social involvement in the urge to raise awareness on patient safety. The first global challenge in patient safety was launched in 2005 and focused on infection control implementation global campaign (Emslie, Knox, & Pickstone, 2009). Failure to maintain cleanliness particularly hand hygiene predisposes patients to cross infection and harm during their hospital stay. Eventually it increases the disease burden on the organization

and also increases the cos of treatment ("Guidelines on Hand Hygiene in Health Care," 2009)

Hand hygiene compliance, which is basically the practise of hand washing by individuals, is considered a vital practice in order to reduce the spread of infection. Hand washing, whether using an anti-septic or simply a domestic soap can reduce the chance of an epidemic. In a healthcare setting, hand hygiene plays an important role in preventing HCAIs. By definition, HCAIs (also referred to as “nosocomial” and “hospital” infections), affect patients while in a hospital or other healthcare facility. It is absent at the time of admission. They also include infections acquired by patients in a hospital or facility but which appear after discharge, and occupational infections among staff ("IBEAS: a pioneer study on patient safety in Latin America. Towards safer hospital care," 2011).

The WHO hand hygiene programme has five components. The first of which is system change. This component primarily concerns the access of health staff to an alcohol-based hand rub at the point of patient care. The second component is the training of healthcare workers particularly on hand hygiene. This training must be continuous and constant but a particular focus on new staff is vital. The practices and regular feedback on staff performance should be monitored. Audits and schematic scoring on the practices help in identifying and improving such practice. Wherever possible, visual reminders can be put in strategic places in the workplace. Finally, the organization as a whole must instil good practice and ensure that there is a climate of safety within the institution (2019).

In a study on the effectiveness of the WHO hand hygiene strategy across five countries (Costa Rica, Italy, Mali, Pakistan, and Saudi Arabia), the extent of staff compliance (the first outcome measure) , was measured by direct observation, and the results showed an increase in staff compliance in respect of hand hygiene after

implementation of the WHO hand hygiene program from 51% before intervention to 67.2% after intervention (Allegranzi et al., 2013).

Consequently, the WHO also introduced the Five Moments Hand Hygiene as a standard guideline for health staff to help them practise hand hygiene in the workplace. The Five Moments Hand Hygiene campaign emphasized the prevention of the transmission of infection by using hand rub and hand wash at five critical points in patient care namely, before patient contact, before an aseptic task, after body fluid exposure risk, after patient contact and after contact with patient surroundings.

In 2006, Malaysia has developed its own national guidelines on infection control which were adopted primarily from the WHO. Various campaigns at national and state level have been conducted to improve staff knowledge and compliance with regards to hand hygiene. Data from the Patient Safety Committee of Malaysia (PSCOM) in 2010 showed an improvement in compliance from 59% in June 2008 to 65.9% in Oct 2009 (2010).

The Ministry of Health (MOH) in Malaysia has made HCAIs as an important patient safety goal. Patient safety goal no. 2 which is "who is Safer Care" focus on hand hygiene compliance whereby, hand hygiene action performed by healthcare staff must be at least achieve 75% compliance during audit. The audit should be held at quarter yearly interval. Tackling anti-microbial resistance is the fourth patient safety goal in Malaysian MOH Patient Safety Goals. In these goals there are 3 Key Performance Indicators: The Incidence rate of MRSA (target $\leq 0.4\%$), incidence rate of ESBL *Klebsiella Pneumoniae* (target $\leq 0.3\%$) and Incidence rate of ESBL *Eschericiae coli* (target $\leq 0.2\%$).

A local study conducted in 2009 that compare 2 ICUs using direct observation showed that compliance among staff with regards to hand hygiene was quite low and staff

did not adhere completely to the guidelines (Katherason et al., 2009). However, as compared to different studies at different settings, findings showed better compliance with hand hygiene practices in the nurses group compared to the physician group (Allegranzi et al., 2013).

2.12 Impact of error

Undoubtedly, an error in any variant will produce some degree of impact on the person involved in the process. Although we often talk about the patient and family as the victims, we often neglect the effects on the healthcare providers themselves (Bernhard, 2013). The patient and family are direct victims in the case of medical error and could face mild consequences in the case of a near miss or extensive ones that result in the disability or even death of their loved ones in the case of a serious event/error. On the other hand, the staff involved in the process was often reported to have varying degrees of psychological impact. Demotivation, frustration, loss of confidence, fear of medical litigation, anxiety and depression are among the negative impact of medical error on staff. There have also been reported cases of suicide among physicians due to the inevitable and unbearable guilt. Also, to some degree, the institution might incur increasing costs due to lower productivity, loss of trust from patients and financial losses due to the prolonged stay of a patient after an error has occurred (*To Err Is Human: Building a Safer Health System*, 2000; C Vincent, Neale, & Woloshynowych, 2001).

Free communication about error and the reporting of errors carry psychological threats to healthcare providers. It is therefore important that staff are ready to seek help for, communicate about or confess to errors without being worried about being blamed, punished and rejected over errors they have committed when they speak up. Psychological

safety, whereby staff feels confident about speaking up about errors, is an important safety dimensions that need to be instilled in an organization. A system with good psychological safety and thus a good safety culture will encourage staff to stand up and speak up about the mistakes they have committed because they feel secure in the knowledge that they will receive support from colleagues and leadership.

2.14 Framework of Patient Safety Culture

The WHO produced a comprehensive framework on patient safety in 2009, which is illustrated diagrammatically in figure 2.4 below.

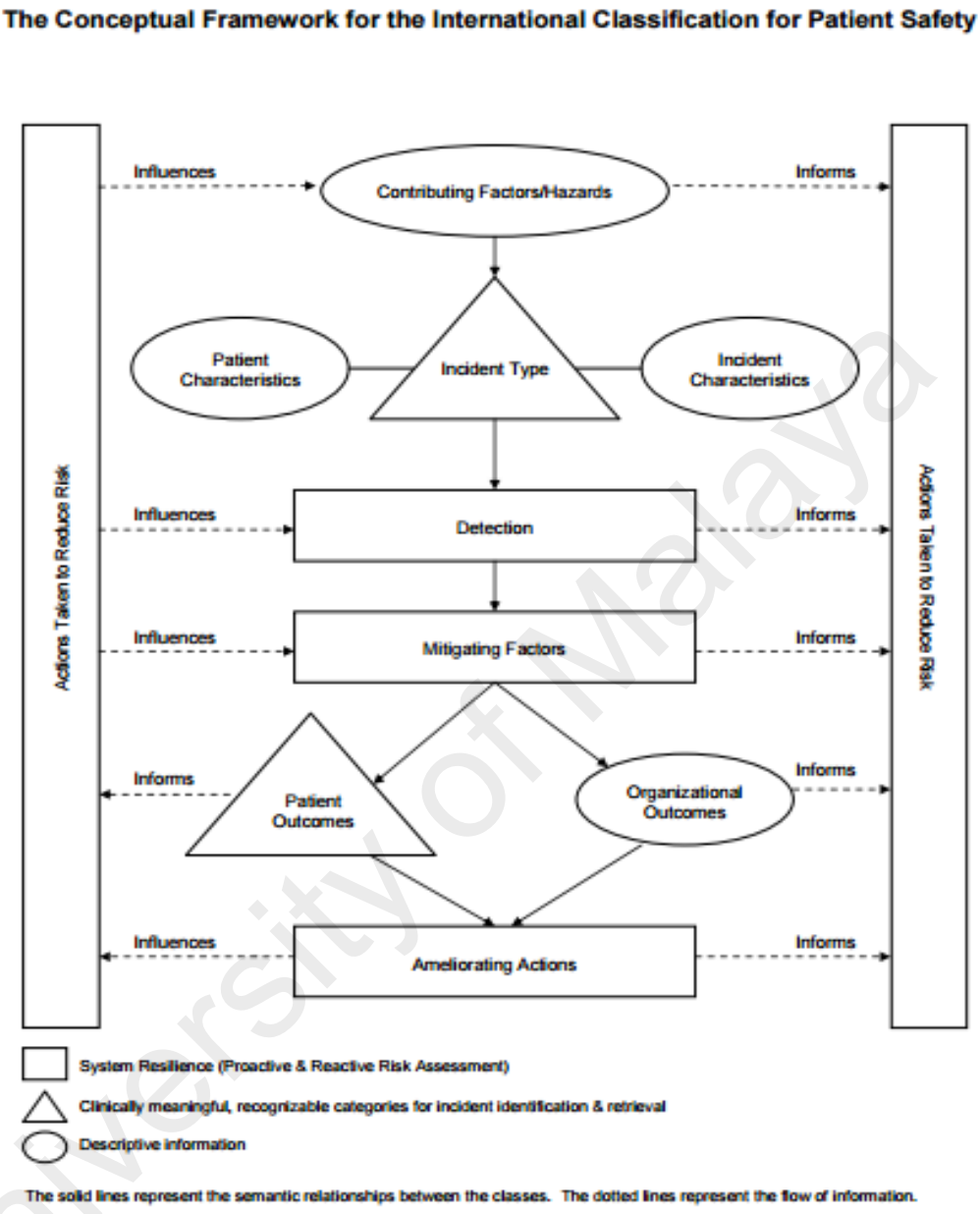

Figure 2.4: The WHO conceptual framework for the international classification for patient safety. (Source: WHO (2009)

This comprehensive model represents a continuous learning and improvement cycle that emphasizes the identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience; all of which occur throughout and at any point within the conceptual framework. The 10 high level classes are incident type, patient outcomes, patient characteristics, incident characteristics, contributing factors/hazards, organizational outcomes, detection, mitigating factors, ameliorating actions and actions taken to reduce risk.

The discussion about the conceptual framework is lengthy. Therefore, here, the focus is on detection, mitigating factors and actions taken to reduce risks. A conceptual model proposed by Moray (2000) will be used in this study which will focuses on the human factors involved in patient safety.("Human Factors in Patient Safety: Review of topics and tools," 2009; Moray, 2000)

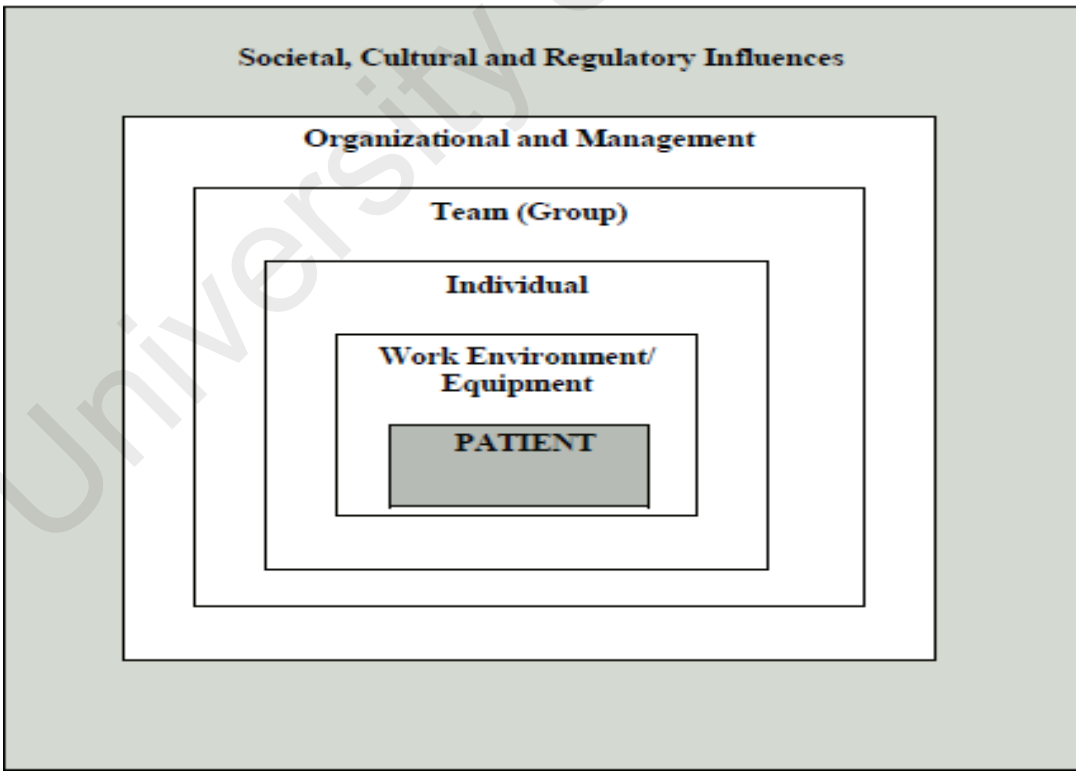

Figure 2.5 A conceptual framework on factors related to patient safety culture by Moray (2000)

The framework proposed by Moray was used by the WHO in its publication entitled *Human Factors In Patient Safety: Review Of Topics And Tools* ("Human Factors in Patient Safety: Review of topics and tools," 2009). It puts the patient at the centre of patient safety. The framework also includes organizational, cultural, human (staff) and technical factors. However, in this study, the patient and the societal, cultural and regulatory influences are not discussed in detail as they are considered as external factors ("Human Factors in Patient Safety: Review of topics and tools," 2009).

Generally, the above-mentioned report outlined four main categories that contain 10 key human factors that are relevant to patient safety. The four categories and their factors are Organizational, Team, Individual and Work environment. These four categories are sub divided into several other categories. A brief discussion of each category follows.

Starting with the outer layer and working inwards, the organizational and managerial factor makes up the first layer of the framework. It is vital to have a strong outer layer. There are three factors in an organization that can influence patient safety: i) safety culture, ii) senior/ middle management safety leadership, and iii) workplace communication procedures (e.g. briefings, handovers). As mentioned earlier, the establishment of safety culture is the most important aspect in patient safety. An attitude of 'Doing the right things' must be cultivated in all staff. A safety culture essentially reflects managerial and worker attitudes and values related to the management of risk and safety. Safety in an organization must be freely communicated among staff at every level. As discussed earlier, lack of communication is a key factor in the occurrence of error. In fact, it is the leading cause of inadvertent patient harm (Leonard, Graham, & Bonacum, 2004). Healthcare delivery requires effective communication between individuals with

different roles, perspective on care and experience. A breakdown in communication results in loss of information, near misses and worst-case scenario, medical errors.

The second layer is the team or group. In a healthcare organization the delivery of care requires the cooperation of an interdisciplinary group of workers comprising, for example ward staff, operation room staff and clinical staff, among others. A team has been defined as 'a distinguishable set of two or more people who interact, dynamically, interdependently, and adaptively toward a common and valued goal/objective/mission, who have each been assigned specific roles or functions to perform (Salas, Burke, & Stagl, 2004). The factors that influence team performance include the size of the team, psychological composition of the group and what happens when they work together.

There are two aspects to the team layer namely teamwork and team leadership. From the patient safety point of view, good teamwork means that the team members are able to minimize patient safety problems by working together and this improves the morale and motivation of the team members as well as the team's viability (Bower, Campbell, Bojke, & Sibbald, 2003). Schaefer, Helmreich, and Scheideggar (1994) estimated that 70-80% of medical errors are contributed by human factors specifically poor team communication and understanding (Schaefer, Helmreich, & Scheideggar, 1994). Hence, manager or leadership must understand how the teamwork in order to ensure patient safety.

In healthcare, the team leader or supervisor plays a critical role in the maintenance of patient safety in the unit they manage. A good leader coordinates functions of team members so that they work better together. Edmondson (2003) proved that the team leader's behaviour affect the behaviour of the team members and improves

communication between team members because the leaders monitors, emphasizes and reinforces safety behaviours among team members. (Edmondson, 2003)

The individual category is the next third layer in the framework. There are multiple factors in this layer including psychological and physiological attributes that might impede favourable safety outcomes. This individual factor is comprised of several sub- factors such as situation awareness, decision making, stress and fatigue. In the context of healthcare services, an individual need to be proactive rather than reactive to expected or unexpected events during their daily job routine. Thus, in regard to the situation awareness sub-factor, an individual is expected to be alert to critical cues from her/his surroundings. In relation to patient care, an individual need to be more alert to any change in the patient's vital signs, and to the sounds from the monitor attached to patient. Any signal should trigger the individuals understanding and comprehension about what the signal should mean in relation to the patient. Next, she/he needs to have some idea and to be able to make some projections about what steps should be taken when things goes wrong. In situational analysis, these three steps are known as perception, comprehension and projection or anticipation.

As regards decision making, for most of healthcare professionals, this is the key skill needed especially in the diagnosis stage and later in the treatment of the patient. Decision making in the diagnosis and treatment stages is more critical compared to decision during task execution or in emergency settings. In order to train individuals to think critically under high pressure condition, there is an increasing trend of using clinical simulators which are intended to prepare individuals to make good decision (Riley, 2008).

Another sub-factor is stress. Often, occupational stress is reported by healthcare staff. Among the factors that contributed to stress at work are high workload, inadequate

staffing, restricted autonomy and inadequate rest or time off. Various factors can result in distraction at work, poor attention and concentration which ultimately might result in medical errors. Hence, it is vital for managers or team leaders to recognize and take the necessary measures to overcome such issues in order to avoid stress and thus and thus reducing the risk of errors affecting patients (Biaggi, Peter, & Ulich, 2003).

The final sub factor in the individual layer is fatigue which has been defined as " the state of tiredness that is associated with long hours of work, prolonged periods without sleep, or requirements to work at times that are "out of synch" with the body's biological or circadian rhythm' (Caldwell & Caldwell, 2003). Obviously, poor sleep that eventually cause fatigue can result in poor concentration as shown by the findings in a study, 41% of junior doctors admit that fatigue contributed to their most serious mistakes and even worse, 31% of these mistakes resulted in patients' death (A. Wu, Folkman, McPhee, & Lo, 1991). Even so, in contrast, doctors were noted to perform effectively in critical situation as compared to routine and repetitive daily jobs where they are prone to make mistakes after a period of deprivation. (Samkoff & Jacques, 1991). This finding was supported by Helmreich and Meritt (1998) who showed that 60% of doctors are able to perform effectively in critical surgeries even after a period of sleep deprivation. As healthcare requires the provision of a continuous 24 hour service, it is important for leadership to identify the risk of working long hours among staff. Administrative control can be implemented to overcome the problems that arise due to lack of sleep.

The fourth and final innermost layer of the patient safety framework addressed in this study is the work environment. In healthcare delivery, there are not only complex series of interactions between patients and healthcare workers, but also between patients and their environment. Therefore, these interactions must be systematically inspected and

examined. Identification of the embedded risks and hazards is necessary to reduce the risk of error to patient and ultimately improve patient safety (Battles, Dixon, Borotkanics, Rabin-Fastmen, & Kaplan, 2006) .

2.11 Summary

Patient safety is a crucial aspect of healthcare delivery and must be a priority in all the decision made in regard to treatment. Indeed, instilling safety culture among healthcare staff is a prerequisite for patient safety. A combination of factors affects the practice of a safety culture in an organization. In particular, strong leadership is needed to promote safety culture among employees as well as effective communication, error reporting and teamwork.

The quantification of safety culture can be achieved by using many available tools. In this research, HSOPSC was selected for this purpose due to its extensive use internationally. Having said that, other tools are comparable they capture several similar dimensions of safety culture such as leadership, teamwork, communication and error reporting. The repeated measurement of safety culture using a standard tool is the best way to monitor the safety practices of staff in healthcare institution. Moreover, using a standard tool enables an extensive comparison of patient safety culture all over the world.

CHAPTER 3: METHODOLOGY

This research was divided into two phases, namely, Phase 1 and Phase 2. The Phase 1 study was a study to validate the suitability of a Bahasa Melayu (BM) version of the HSOPSC for use in Malaysia. This was followed by the Phase 2 study, which assessed the safety culture among staff in Malaysia public hospitals using the validated version of the HSOPSC-BM.

The details of each phase are described separately in this chapter. The discussion of each phase follows a similar flow, covering aspects such as the study area, study population and duration of the study, sample size calculation, sampling procedure, operational definition, method of data collection, study instrument, ethical consideration, data management, data analysis, and interpretation of the results.

3.1 Phase 1: Validity and Reliability of the BM Version of the HSOPSC Questionnaire

The Phase 1 study followed the guidelines suggested by the AHRQ ("Translation Guidelines For The Survey On Patient Safety Culture," 2010). The study began with a process of linguistic validation, which was followed by face validation, content validation and lastly construct validation. Figure 3.1 illustrates this process in a diagrammatic manner.

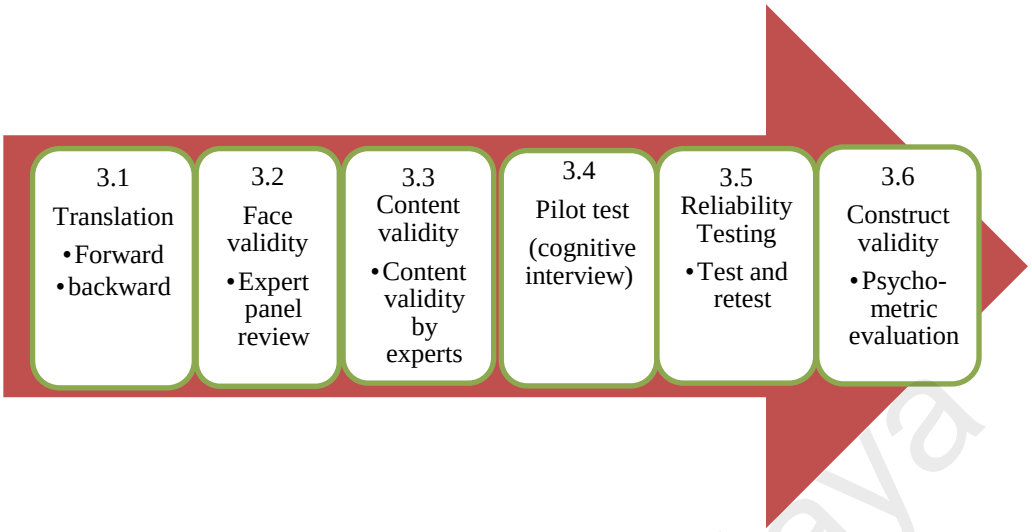

Figure 3.1: Steps of the Phase 1 study.

This part of the research was designed to test whether the HSOPSC survey was fit for use among the Malaysia population. The process of validation followed the guidelines outlined by the AHRQ (Martínez Agulló et al., 2010). A request was made to the AHRQ to use the questionnaire in Malaysia, and the AHRQ gave official permission to do so (refer to appendix 3).

3.1.1 Translation of original HSOPSC into Bahasa Melayu

Translation of the original HSOPSC was done by an independent professional translator with a background in medicine. The translated version was checked by two independent reviewers who were medical personnel, whose native language was BM and who were fluent in English. Some necessary amendments were made based on the reviewers' comments to produce a final draft version of the HSOPSC-BM. Direct translation was avoided and as much as possible the translation was fitted to the Malaysian context, syntax and culture. The translation was made in such a way so that it

would be understandable to a variety of staff categories in the Malaysian healthcare population.

The final draft was then sent to another independent translator who was an expert in English and BM for back-translation into English. The back-translated copy of the questionnaire was compared with the original English version to determine whether it was the same as the original version. This was done to ensure that the BM version of the questionnaire carried the same meaning and was as close as possible to the original.

3.1.2 Expert panel review

Six individuals who were experts in medicine and patient safety were chosen to assess the final version of the translated HSOPSC. The experts were either quality managers, administrators, clinicians or public health physicians and they were all Malaysian citizens whose native language was BM, were well versed in English and involved in patient safety activities to various degrees in their organization.

Each expert was approached personally by a friendly visit to their office, telephone call or email. When they had agreed to participate, the questionnaire was sent to them via email together with a consent form. They were asked to read the questionnaire in its entirety and comment on whether the words, sentences and phrases would be understood by future participants. They were also asked to consider whether the meaning in English suited the culture and context of Malaysian healthcare providers. They were also made aware that they were welcome to make amendments or suggestions about any words or sentences that they felt would better fit the English meaning.

The experts were asked to return their reviewed draft to the researcher within a week. Gentle reminders via email were sent to improve the response rate. A small token gift was given to each expert after they had returned the reviewed questionnaire. The

questionnaire was then improved based on the comments and suggestions received from the experts.

3.1.3 Content validity

The revised version of the questionnaire was sent to another five experts who were engaged in patient safety at the national or international level. The experts were chosen from various organizations dealing with quality and safety in health in Malaysia. They were the Chief Executive Officer of the MSQH; the Chief Surveyor of the MSQH; the Deputy Director (Medical) of the Health Department of Pahang State; a researcher from Institute of Health Service Research (IHSR), who was an expert in patient safety; and a quality manager from the Health Department of Selangor State.

The experts were approached and given information regarding the research and what they were expected to contribute to this part of the study. Then, they were asked if they would agree to participate as part of an expert panel on content validity. The expert reviewers were asked to rate each item for its relevancy, for which there were four possible responses: very relevant, relevant, irrelevant and very irrelevant (Lynn, 1986). The experts were asked to assess whether each item was relevant for the survey to be implemented in Malaysia. In addition, it was made clear to the experts that they were most welcome to make comments or suggestions about any of the words, phrases or sentences that would improve the understandability of the questionnaire. The experts were asked to return the survey within a week. However, another a week was allocated for late responders to improve the response rate. The experts were gently reminded via email or telephone call to return their ratings and comments on the survey. At the end of this process, each expert was given a small souvenir as a token of appreciation.

3.1.4 Pilot test (cognitive interview)

The next of the process was to pilot test the questionnaire on a group of participants. Healthcare staff with various job title were selected randomly to represent the various positions available in the Malaysian healthcare system. Eight staff from the following job categories (medical officer (MO), nurse, assistant medical officer (AMO), attendant, pharmacy dispenser and a lab technician) from different health settings were chosen to participate in the pilot test, which took the form of a cognitive interview.

A similar procedure to that described above for the panels of experts was applied to approach the potential participants for the pilot study. The participants were sent an email with a number of attachments, namely, the HSOPSC (English version), pre-test draft of the BM version, participant information sheet (PIS) and consent letter. Since this part of the study involved various health organizations in Malaysia, it was considered important to inform these participants that this research had received permission from national bodies responsible for coordinating research in Malaysia, namely, the University Malaya Medical Research Ethical Committee (UM-MREC) and the National Medical Research Registry (NMRR) and that researcher would abide by the guidelines imposed by these bodies.

Before the participants started their task, they were expected to read the PIS and sign the consent form. They were also made aware about the confidentiality of the research in the email. The participants were required to read the BM version of the questionnaire and compare it with the English version. After that they were required to take notes and make comments on any words, items or particulars that they thought need to be discussed further.

The participants also were reminded to have the questionnaire available for reference during the interview. One day prior to the interview, participants were contacted to remind them about the interview and the interview requirements. The interviews took place about one week after the distribution of the email. Since the participants were from different organizations located across a wide geographical area, the interviews were conducted either face to face or via telephone, based on whichever mode was thought by the researcher to be the most practical ("Translation Guidelines For The Survey On Patient Safety Culture," 2010).

Before the interview started, the researcher read out the important points on patient information sheet and once again encouraged participants to sign the consent letter. Also, the issues of confidentiality and the right to withdraw were re-emphasized by the researcher. Only upon the agreement of the participant did the interview then proceed.

During the interview, every item was read by the researcher one after another. Any comments from the participants were jotted down. A fruitful discussion was established with each participant to ensure the best outcome of each interview. It should be noted that the last two participants in this component of the research gave similar inputs to those of the other interviewees and no new ideas emerged from those discussions. A total of eight participants took part in the cognitive interview.

3.1.5 Test and retest (reliability testing)

The test retest procedure is a form of reliability testing. This study used the test retest technique to assess whether the questionnaire remained consistent when tested at different points in time. A questionnaire is said to be reliable if it measures what it is supposed to measure (Collin Phelan & Wren, 2005). In this component of the research, the questionnaire was assessed by the same participants twice at two different time points

at an interval of 1-week. A total of 40 staff from various clinics and wards was purposively chosen for this part of the study.

Appropriate approval from the organization by means of ethical approval and formal permission from the respective heads of department was gained prior to the conduct of the test retest survey. A point of contact/liaison officer was also established where it was deemed necessary. Several briefing sessions were conducted in the selected departments or units to explain the research and provide instructions on how to complete the survey. Alternatively, some participants were approached either individually or in groups to explain the test and retest. Upon the receipt of organizational approval, participants were encouraged to sign the consent form and were given the survey to complete. Each participant was given a package that contained the survey questionnaire, the participant information sheet and an envelope for completed survey.

After one week, the researcher collected the completed form from each individual participant or collected them from a point of contact in the respective ward/unit. The collection of the test component of the test retest was immediately followed by the distribution of the retest component. Similarly, the retest component was collected 1 week after distribution either from points of contact or from individual staff members. The participants were contacted promptly if they had omitted to answer any item. This was to ensure a good response rate and was feasible because the sample size for this test was small.

The data entry for the completed test and retest surveys was performed as soon as the surveys had been collected. The data were initially entered into Microsoft Excel and then transferred to SPSS software for analysis. A composite score was created for the data

collected from each participant. Both Pearson's correlation and intra-class correlation were used to ascertain the reliability of the test and retest.

3.1.6 Psychometric analysis

To complete the validation process, the questionnaire underwent a construct validity analysis. This validation component of the research was conducted from December 2014 and was completed in June 2015 after several follow-up sessions. This part of the study was designed to test the construct validity of the translated version of the HSOPSC using appropriate statistical analysis.

3.1.6.1 Study design

The Phase 1 study to validate the use of the HSOPSC-BM in Malaysia employed a cross-sectional study design.

3.1.6.2 Study area

The validation study was conducted in three hospitals in Malaysia. The hospitals were selected using convenience sampling. The choice of hospital depended on logistical feasibility and prompt hospital management approval to conduct the study at the hospital. The three selected hospitals were the University Malaya Medical Centre (UMMC), Hospital Raub and Hospital Cameron Highlands. A brief overview of each of the hospitals can be found below and Figure 3.2 shows their location:

- **UMMC** is located at Pantai Dalam, in the southwest corner of Kuala Lumpur, Malaysia. It is a hospital organization that falls under the purview of the Ministry of Education. This hospital is a teaching hospital with more than 1,000 beds and about 4,000 staff (Universiti, 2010). The Centre is equipped with the latest medical technology and offers specialties enabling it to serve the population with currently the best resources in the country.

- **Hospital Raub** is a district hospital without specialist and is located in the Raub District, northwest of the capital of the state of Pahang. It is about 100 km south of Kuala Lumpur. This hospital has about 80 beds and more than 300 staff (K. Ghazali, Hospital Director, Personal Communication, November 2014).
- **Hospital Cameron Highlands** is a small district hospital without specialist serving the Cameron Highlands. It is about 200 km north of Kuala Lumpur. Generally, it has about 50 beds and fewer than 300 staff. (S. Badiuzzaman, Hospital Director, Personal Communication, November 2014).

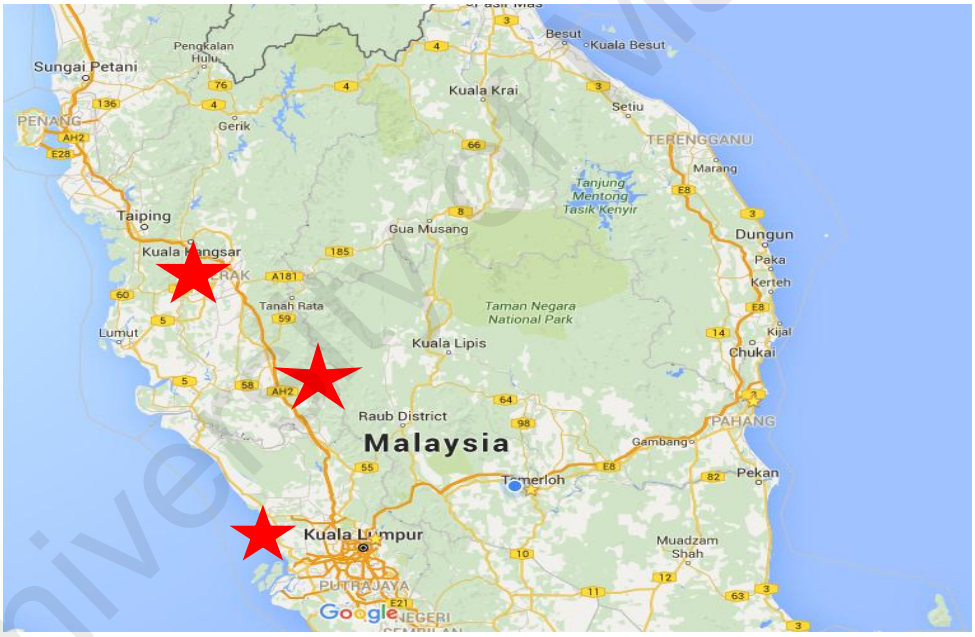

Figure 3.2: Map of the three hospitals selected for the Phase 1 study.

3.1.6.3 Study duration

The Phase 1 study started on 1 December 2014 and ended on 30 April 2015 (5 months). A further 2 months from 1 May 2015 to 30 June 2015 was needed for follow-up and recalling non-responders. Data entry was performed simultaneously with data

collection and the former extended into another 1 month (July 2015). Data analysis commenced as soon as data entry finished, and maximum efforts were made to obtain any missing data.

3.1.6.4 Study population

All staff in public hospitals in Malaysia constituted the study population involved in this component of the research. The participants from the three preselected hospitals mentioned above were considered as the study sample. The participants were chosen using purposive sampling and held various posts including MOs, nurses (of different ranks), pharmacists, pharmacy dispensers, technicians (radiographers, medical lab technologists), rehabilitation therapists and others. As much as possible, the participants were staff who had direct contact with patients and they all met the following inclusion and exclusion criteria:

- Inclusion criteria:
    i. Malaysian nationality
    ii. Able to read, write and communicate in BM.
    iii. Has been working in the department for more than 1 month.
- Exclusion criteria:
    i. Undergraduate student on a posting in the department
    ii. Permanent staff on long-term leave of more than 1 month.

3.1.6.5 Sample size estimation

The sample size was calculated using a formula that employed a standard value for the confidence interval (CI) of (95%) and a power of (0.8) and an estimated total health

staff population of 20,000, as well as an anticipated response rate of 50% (Bodur & Filiz, 2010):

$$x = Z\left(\frac{c}{100}\right)^2 r(100 - r)$$

$$n = \frac{Nx}{(N-1)E^2 + x}$$

$$E = \sqrt{\left[\frac{(N-n)x}{n(N-1)}\right]}$$

Where:

Z = critical value of the chosen CI of 95%

N = population size

r = response rate

n = sample size

E = margin of error (5%)

The above calculation resulted in an estimated sample size of 375, which was increased to almost doubled to 700 to ensure an adequate pool of data (Sorra & Dyer, 2010) .

3.1.6.6 Sampling Procedure

In the case of UMMC, only two departments were conveniently selected to participate in the validation study, namely, the Nursing Department and Medical Department. Universal sampling was used in these two departments to capture the population of doctors and nurses in UMMC. In the two district hospitals (Raub and Cameron Highlands), universal sampling was used due to the limited number of staff, and thus all staff who had direct contact with patients were included in the study.

3.1.6.1.1 Operational definitions of the independent variable

The independent variables were based on the literature review (refer to chapter 2). The variables were grouped into socio-demographic (age, ethnicity and gender), socio-economic (years of experience, profession and academic level) and job characteristics (working unit, working hours and interaction with patients) as follows:

- Socio-demographic characteristics:

    i. Age: The participants were categorized into 10-year group categories. Four categories were developed which are less than 30, 31 to 40, 41 to 50 and above 50 years. The aim is to capture the specific age group that is more prone to error in daily practice.(Sauerbrei & Royston, 2010)

    ii. Gender: Male or female.

    iii. Ethnicity: The participants were placed in one of three categories: Malay, Chinese or Indian.

- Work related characteristics:

    i. Profession: In phase 2 study, only 5 categories of healthcare staff were chosen to participate in this study as they are considered as having the most direct contact with patients in their daily routines. The 5 job categories are registered nurses, doctors, pharmacists, assistant medical officers and rehabilitation therapists. The details on the staff in each hospital that participated in the study are provided in Table 3.3 on page 96.

    ii. Academic level: The participants were categorized into one of three academic levels based on their highest qualification upon entry into their

profession, namely, diploma, Bachelor's degree and advanced degree (Master's and above).

iii. Years of experience: This category was subdivided into less than 1 year, 1 to 5 years, 6 to 10 years, 11 to 15 years, 16 to 20 years, 21 years and above. These categories were chosen mainly because the similar categories were used in the original questionnaire (Agency for Reasearch and Healthcare in Quality, 2012).

iv. Working unit: The participants were employed in a variety of places of work which they identified themselves.

v. Working hours: The working hours were based on the cumulative hours of work per week. This category was divided into less than 20 hours, 20 to 39 hours, 40 to 59 hours, 60 to 79 hours, 80 to 99 hours, 100 hours and above. The working hours were divided in such a way to enable the researcher to capture which category or categories are at higher risk of committing error or if they are overworked. Furthermore, these categories follows the categories used un original questionnaire (Agency for Reasearch and Healthcare in Quality, 2012)

vi. Interaction with patients: This variable indicated the type of contact that the participants had with patients, which was classed as either direct contact or indirect contact.

3.1.6.7 Data collection

Figure 3.3 below showed the flow of process in data collection for phase 1 study.

3.1.6.7.1 Data collection protocol/survey distribution

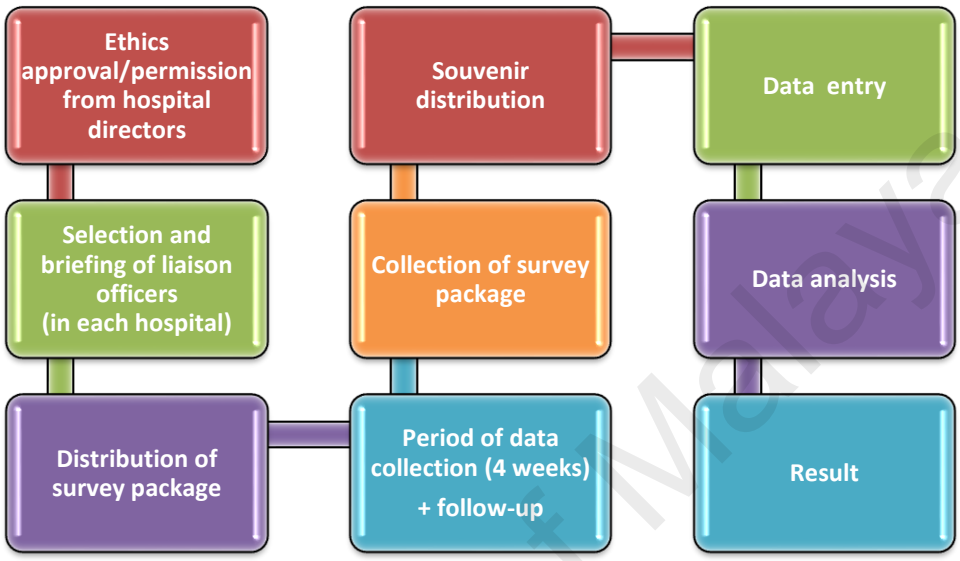

Figure 3.3: Data collection protocol for psychometric analysis of HSOPSC in Malaysia study.

3.1.6.7.2 Participant recruitment

The participants for the validation study were selected by using convenient sampling. Not all units were provided with a briefing session because a debriefing session with all the participants was considered impractical at that point in time due to the low probability of being able to gather most of them together at the same time. Hence, liaison officers were selected where appropriate in order to assist the researcher in the conduct of the study. The liaison officers were required to list the names of the staff who could potentially participate in the study. They were also required attended a short briefing on the research and the method of data collection, in case they needed to respond to questions from the participants in the absence of the researcher. However, if the participants have any enquiries about the study, they could also contact the researcher via email or by

telephone. When the researcher was satisfied that the liaison officers understood the process, the distribution of the survey questionnaire took place.

All the potential participants were supplied with an envelope containing the BM version of the HSOPSC questionnaire, the PIS and a consent form. The participants were required to read the PIS first. They also had to sign the consent form to signify that they agreed to participate in the study. The participants were also encouraged to ask the researcher any questions by telephone or email, and the telephone number and email address were provided in the PIS. Alternatively, they could address their questions directly to their respective liaison officer in their ward or unit.

The questionnaires were collected after 4 weeks had passed. The participants were advised to send the completed questionnaire to their respective liaison officer or put it in a bag in the management office. A total of 700 questionnaires were distributed and 554 were returned. About 75 questionnaires were excluded from the analysis because they were less than 70% complete or the participants had given the same response to all the questions.

3.1.6.7.3 Follow-up and exclusion

Non-responders were identified through the staff lists compiled by the liaison officers of each department and they were approached again personally and reminded about the survey. Two follow-ups on the survey were conducted via email and telephone within the 4-week period following the first deadline for collection in order to improve the response rate.

3.1.6.8 Study instrument

As mentioned in chapter 1, this study used a survey tool, the HSOPSC, which was developed by the AHRQ and released in November 2004. It was created due to the need for a tool to assess patient safety culture in healthcare organizations. The survey was pretested and underwent a series of validation and reliability tests. It was subjected to a pilot test in the US that involved 21 hospitals and 1,400 staff. The final survey comprised 42 items covering 12 dimensions. Apart from assessing the safety dimensions, it also includes some demographic questions. The outcome variables included an overall rating of patient safety and the number of events reported.

The 42 items were mostly scored using a five-point Likert response scale ranging from 1 to 5 for agreement ("Strongly disagree" to "Strongly agree") or frequency ('never' to 'always'). Seventeen of the items were negatively worded, which means that the responses to these items had to be reverse-coded to give a similar response to the others. The survey measured the following dimensions:

(1) Teamwork across unit (four items)

(2) Teamwork within unit (four items)

(3) Hands off and transition (four items)

(4) Frequency of events reported (three items)

(5) Non punitive response to error (three items)

(6) Communication openness (three items)

(7) Feedback and communication about error (three items)

(8) Organizational learning – Continuous improvement (three items)

(9) Supervisor/manager expectations and actions promoting patient safety (three items)

(10) Management support for patient safety (three items)

(11) Staffing (three items)

(12) Overall perceptions of patient safety (four items)

Apart from that, there are two questions that require respondents to give an overall grade for patient safety culture (section E) in their own area or working unit and to indicate how many events they have reported during the past 1 year (section G).

The HSOPSC survey tool has been tested in on a large population across the country of its origin. It has also undergone various validation tests to ensure that it fit the purpose of measuring patient safety culture. As a result, this survey tool has been found to have good and sound psychometric properties (Sorra & Dyer, 2010). Since then, the tool has been translated into various languages and validated in various countries across the globe (Hedskold et al., 2013a; Moghri et al., 2012; Occelli et al., 2013; Shahenaz Najjar et al., 2013). Though the findings vary, overall it is regarded as a valid tool of patient safety culture. The dimensions of safety culture measured by the HSOPSC are described in more detail.

Independent variables:

1) **Teamwork across hospital units (four items):** This dimension evaluates whether the units of the hospital cooperate and coordinate with each other to provide high-quality care for patients.
2) **Teamwork within units (four items):** This dimension relates to how staff within a unit work as a team, treat each other with respect and support each other in a good manner. This item needs participant to indicate how staff of different ranks work together as a team in a unit.

3) **Hospital handoffs and transitions (four items):** This dimension enables staff to rate the unit or hospital performance in relation to continuity of care especially with regards to information loss when a patient is transferred to another unit or organization or it can be a measure of whether important information about patient care is transferred throughout hospital units and during shift changes (which is, in effect, a prerequisite for continuity).
4) **Frequency of event reporting (three items):** This dimension evaluates the commitment of staff to reporting errors whether they are true errors or near misses and whether they perceive reporting as an important thing to do following an error.
5) **Non-punitive response to error (three items):** The questions in this dimension are used to measure whether any error that is reported implicates the staff in terms of their performance record or is documented in the staff's personal file.
6) **Communication openness (three items):** The questions in this dimension are designed to ascertain whether staffs in a unit or organization communicate well with each other vertically or horizontally in every aspect, especially concerning medical errors and patient safety.
7) **Feedback and communication about error (three items):** This dimension is aimed at determining how staff perceive how an error is communicated from the time the error happens, through discussion of the error, to ways in which to implement changes and the monitoring of the implementation of those changes so as to avoid similar mistakes from happening ever again.
8) **Organizational learning** – continuous improvement (three items): This dimension assesses how the organization is providing trainings and continuous

education in an effort to improve the quality of care and patient safety at the same time. Continuous medical education as practised in most hospitals in Malaysia is an example of organizational learning.

9) **Supervisor/manager expectations and actions promoting safety (four items):** This dimension measures how much supervisors/managers (or higher authority) look at patient safety initiatives or implement plans for improving patient safety in their organization. Also, it is intended to identify how managers actually respond to staff suggestions for promoting patient safety and whether or not they overlook safety issues in their unit

10) **Hospital management support for patient safety (three items):** This dimension concerns the assessment of managerial support for patient safety in the organization and whether they provide a work climate that promotes patient safety and shows that patient safety is a priority in the process of care in the organization

11) **Staffing (four items):** This dimension assesses whether staff in a unit or workplace can handle their workload and working hours and whether there is an adequate number of staff in relation to the workload. This dimension also measures whether the available staff are able to provide the best care for patients.

12) **Overall perceptions of safety (four items):** This dimension concerns whether the organization/working unit has good and acceptable patient safety initiatives for preventing errors.

Dependent variables:

13) Patient safety grade (one item): This single outcome dimension requires the participant to self-grade their hospital with regard to patient safety. This dimension consists of only an item and responses were divided
14) Number of events reported (one item): The participants need to declare their reporting behaviour to adverse events in the past 1 year in terms of the number of events they themselves have reported.

3.1.6.9 Data management

To determine face validity and content validity of the questionnaire, all the data were entered into Excel and tabulated for ease of comparison. For construct validity (psychometric analysis), the data were first entered into Microsoft Excel before being transferred into SPSS version 22 for further analysis. Table 3.1 on page 82 provides the dimensions and the numbers and codes of the items for each dimension studied.

Table 3.1: Dimensions and Items for Each Dimension.

	Dimensions	No. of items	Items
1	Teamwork across unit	4	F2r F4 F6r F10
2	Teamwork within units	4	A1 A3 A4 A11
3	Hands Off and Transitions	4	F3r F5r F7r F11r
4	Frequency of events reporting	3	D1 D2 D3
5	Non-Punitive Response to Error	3	A8r A12r A16r
6	Communication Openness	3	C2 C4 C6r
7	Feedback and Communication on error	3	C1 C3 C5
8	Organizational Learning	3	A6 A9 A13
9	Supervisor expectation and action on patient safety	4	B1 B2 B3r B4r
10	Hospital management support on patient safety	3	F1 F8 F9r
11	Staffing	4	A2 A5r A7r A14r
12	Overall Perception on patient safety	4	A10r A15 A17r A18

Note: The items with an r suffix are negatively worded and need to be reversed coded.

3.1.6.10 Data analysis and interpretation of results

3.1.6.10.1 Face validity

The responses of the experts in face validity were analysed qualitatively via a thorough inspection and noted down. Since each expert gave different opinions, all the responses were collected and analysed simultaneously for each item. Finally, a decision was made by the researcher so as to produce the best words/sentences/phrases.

3.1.6.10.2 Content validity

For this part of the research, the original five-point Likert scale of agreement was minimized into a four-point Likert scale of relevancy. The four points were as follows:

1. Very irrelevant
2. Not relevant
3. Relevant
4. Very relevant.

Obviously, the scores 1 and 2 indicate that the item is irrelevant, whereas the scores 3 and 4 indicate that the item is relevant. Hence, to quantitatively measure the relevancy of each item, the four-point Likert scale was collapsed into a dichotomous response scale of relevant and irrelevant (Lynn, 1986).

For this research, upon consensus with the other co-researcher, a content validity index (CVI) in the form of an item CVI (I-CVI) and a scale-CVI (S-CVI) were considered appropriate as quantitative measurements for describing this component of the validation. This decision is supported by a research study that validated the Osteoporosis Risk Assessment Tool (ORAT), where the researcher used the S-CVI as proposed by Lynn (Lynn, 1986) to measure the CVI (Wynd, Schmidt, & Schaefer, 2003).

All the responses were tabulated in an Excel spread sheet. The I-CVI score for each item was calculated. Then, an overall S-CVI score was determined. For the purpose of reporting, as suggested by Polit and Beck, both methods of computing the S-CVI were documented (Pollit & Beck, 2006). The S-CVI value of 0.8 was used as the cut-off point in this research, although a more stringent value of 0.9 has been suggested by CVI experts especially when using the S-CVI/Average as the composite score in CVI (Davis, 1992; Waltz, Strickland, & Lenz, 2005).

The scale-CVI/average (S-CVI/Ave) was defined as the average proportion of items rated as relevant by all raters. According to Polit et al (2006), there are three ways of calculating the S-CVI/Ave: the researcher (1) can simply average the relevant responses across the raters, which means that the researcher calculates the average of the proportion of items rated as relevant for each expert; (2) can sum the responses rated as relevant for each item and later divide the composite sum score by the number of items in the questionnaire; or (3) can count the total number of responses rated as relevant out of the expected relevant responses. These three methods will always give a similar finding (Pollit & Beck, 2006).

Another way to compute the S-CVI is to calculate the proportion of items achieving total agreement (100% relevant responses among experts divided by the total number of items). This method is called S-CVI/UA (Universal Agreement). However, the author of this formula stated that this method will yield a lower S-CVI/UA when more experts are involved (Pollit DF., Bect CT., & SV., 2007)

3.1.6.10.3 Test retest

A reliability value (Cronbach's alpha) of more than 0.6 carries the meaning that a tested questionnaire is reliable (Nunnaly. JC & Bernstein. IH, 1994). The demographic

patterns of the staff and the agreement of the raters in the test retest were expressed using the average measure of intra-class correlation coefficient (ICC) for each item. The ICC was used to test the agreement computed by two-way ANOVA. Values ranging from 0.4 to 0.75 were considered acceptable, while the preferred value was more than 0.75(Weir, 2005). However, only the ICC (composite score) was used in the final decision on the test and retest component.

3.1.6.10.4 Psychometric testing

Before proceeding to the psychometric testing of the whole dataset, a descriptive analysis of the demographic data collected via the questionnaire was performed. All the questions in section H and the earlier part of section A provided information on the participants' years of experience in the service, current unit and workplace. All 17 negatively worded items were reverse coded prior to analysis to ensure the responses were similar in terms of the magnitude of scoring. The outcome dimensions were reported as positive response rate whereas, the single outcome dimension were reported in mean and Standard Deviation (SD).

The responses made to each item were first analysed within the 12 dimensions of the original version and the percentages of positive responses were calculated. Scores of 4 and 5 were considered to denote a positive response and to be equal to a percentage score of 75% and above (Samsuri, Pei Lin, & Fahrni, 2015). The original version was later tested as a whole using exploratory factor analysis and (EFA) and confirmatory factor analysis (CFA) to assess the overall level of fit. The data were analysed using SPSS version 22 and AMOS version 23.

Following that, the sample was tested to determine whether it was constructed an optimal model and whether it differed from the original version. For that purpose, the

sample was split randomly into two sets. The first set was named the 'exploratory set' and was used to construct a hypothetical construct of the items in the Bahasa Melayu version. The other set, named the 'confirmatory set' was used to test the hypothetical construct using CFA. The finalized optimal model was then analysed for reliability (P Waterson, Griffiths, C Stride, J Murphy, & Hignett, 2009).

To test the Bahasa Melayu version, the researcher first tested it using EFA. The acceptable factor loading was set at ≥ 0.4 (Stevens, 1992). The analysis of construct validity, which involved assessing the links between the items and the relations between the items and an underlying dimension, was performed using CFA to determine the degree of fit of the hypothesized construct. Three fitness measures were used: the comparative fit index (CFI), goodness of fit index (GFI) and adjusted goodness of fit index (AGFI). These measures range from 0 (poor fit) to 1 (perfect fit) and 0.9 was chosen as the acceptable level of fit. The root mean square error of approximation (RMSEA) was also applied with the limit for an acceptable fit set at below 0.09 (Farrell, 2009).

The composite scores of the final dimensions were established to later determine the correlation between groups and between the final dimensions and the single outcome dimensions, i.e., the Patient safety grade and Frequency of event reporting. For the correlation assessment, Pearson's correlation was used, where the correlation should not exceed 0.5 in order to indicate that the dimensions are actually measuring different perspectives of the same concept (divergent validity). Finally, internal consistency was established by using Cronbach's α as a measurement to reliability, where the criterion was set as ≥ 0.6 for each dimension (Sorra & Dyer, 2010).

3.1.6.11 Ethical consideration and confidentiality

Similar to many other studies, ethics approval needed to be obtained from the relevant MREC of the appropriate bodies. In this study, ethics approval was sought and obtained from two different bodies, namely, the University Malaya Medical Research Ethics Committee (UM-MREC) MEC ID No 201402-0763 and the MREC Ministry of Health (MOH), Malaysia (NMRR-14-1174-19801). This study was also registered with the NMRR to enable the conduct of the study in Malaysia.

Apart from the obtaining the approval from authorized bodies, which is compulsory, formal written permission was also sought and obtained from the hospital directors and relevant heads of department of each hospital participating in the study.

In the case of the UMMC, special approval and permission was also sought and obtained from the Head of Nursing as a courtesy to the nursing profession and to improve responses through fostering better coordination and cooperation from nurses through leaders and senior management.

Every participant was assured of the confidentiality of the information they would provide in the questionnaire. They were informed that only the researcher and the research supervisors would have access to the information and that the information would be used solely for the purpose of this research.

3.2 Phase 2 The Evaluation of Patient Safety Culture in Public Hospitals in Malaysia: A Multi-Centre Assessment Using the Hospital Survey on Patient Safety Culture-Bahasa Melayu Version (HSOPSC-BM)

Phase 2 of the study started on 1 July 2015 and was completed on 28 February 2016. It commenced upon completion of the validation study and on the gaining of approval from the State Health Director of Health and the respective hospital directors and local ethics boards.

3.2.1 Study design

The Phase 2 study used a cross-sectional study design. This design was considered appropriate to observe data from a population at specific set times.

3.2.2 Study area

The state of Pahang was purposively chosen as the study area for this research. Pahang is the largest state in Peninsular Malaysia and the economic distribution varies among the districts across the state. Hence variations in patient safety practices between hospitals in the state were expected.

In Malaysia, the public healthcare system is divided into several hierarchical layers (Hamidy, 2012), which can be illustrated in the form of a pyramidal structure, as shown in Figure 3.4 on page 87. Primary care lies at the foundation of the system and includes pre-hospital care. Above this level are district hospitals without specialists, district hospitals with specialists (minor) and district hospitals with specialists (major), where the distinction between minor and major depends on the number of resident specialists. Hospital care is then considered secondary and tertiary care.

The state hospital, which is usually located in the capital city of the state, is the largest public hospital in a state and offers the widest scope of specialties. As shown in Figure 3.4 on page 90. Hospital Kuala Lumpur sits at the top of the healthcare system as the National Referral Centre. Hospital Kuala Lumpur serves as the ultimate referral hospital for public health services and it offers specialties and subspecialties that are not available in other public hospitals.

Apart from general hospitals that offer general institutionalized care, the MOH also provides specialized care institutions, including the Institute of Respiratory Medicine, Institute Tun Hussein Onn National Eye Hospital, and National Heart Institute, to name but a few.

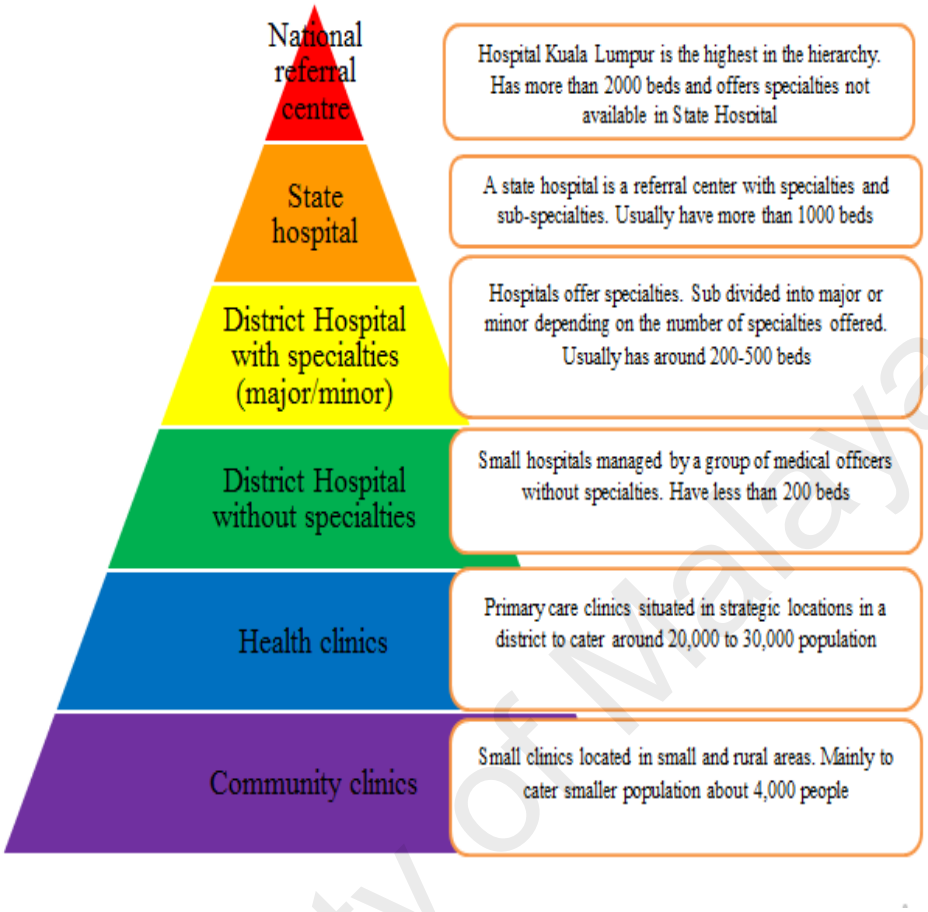

Figure 3.4: Hierarchy of healthcare organizations in Malaysia (adopted from Powerpoint presentation by Dr Mahani bt Abdul Hamidy, 2012 (Hamidy, 2012)).

3.2.2.1 State of Pahang

Pahang is the third largest state in Malaysia and the largest in Peninsular Malaysia. This state is bordered by Kelantan to the north, Johor to the south, and Terengganu and the South China Sea to the east. Selangor, Negeri Sembilan and Perak lie to the west of Pahang. The state of Pahang encompasses a total area of 36,137 km^2 and has a total population of about 1.6 million at a density of 45 persons/1 $km^{2.}$

In Pahang there are eleven public hospitals serving the population. These hospitals can be classed into different levels based on their facilities and other resources. There is only one state hospital (Hospital Tengku Ampuan Afzan) located in the capital of Pahang (Kuantan). Three of the hospitals are district hospitals with specialists (a major and two minor). The remaining six hospitals are district hospitals without specialists.

Four hospitals were purposively chosen with discussion with the state director and hospital directors to participate in this research namely, Hospital Tengku Ampuan Afzan (the state hospital), Hospital Sultan Haji Ahmad Shah [a district hospital with specialties (major)], Hospital Kuala Lipis [a district hospital with specialties (minor)] and Hospital Jengka (a district hospital without specialties). Note that, in this thesis, the term 'hospital' is used to describe all levels of hospital in order to avoid confusion. A brief overview of each hospital is provided below and their locations are illustrated in Figure 3.5 on page 93. These 4 hospitals were chosen due to their type, logistically feasible and good support from their leadership for the study conduct.

- **Hospital Tengku Ampuan Afzan, Kuantan (HTAA)** is located near the Kuantan River in Kuantan District. It is a state hospital with more than 700 beds and offers various disciplines and specialties and has around 5,000 staff in various categories. It also serves as a referral centre for the state, and because it is equipped with

modern technologies it is often the final referral hospital in the state (Ministry of Health, 2014).

- **Hospital Sultan Haji Ahmad Shah (HOSHAS)** is a district hospital with specialists (major) and is situated in Temerloh District. It has 500 beds and around 2,000 staff and serves as a referral hospital for West Pahang. This hospital offers the majority of major and minor specialties, including Internal Medicine, Obstetrics and Gynaecology, Surgery, Orthopaedics, Paediatrics and Orthorhinolaryngology among others (Malaysia Ministry of Health, 2017b).
- **Hospital Kuala Lipis (HKL)** is located in Kuala Lipis District about 120 km from HOSHAS (Temerloh) and 222 km from HTAA (Kuantan). The hospital is situated in remote West Pahang so it is equipped with facilities offering basic specialties such as Obstetrics and Gynaecology, Internal Medicine and Orthopaedics. This type of hospital is classed as a district hospital with specialties (minor) because it offers very few specialty services. This hospital also serves as a referral centre for other district hospitals in West Pahang, namely, Hospital Cameron Highlands and Hospital Raub, both of which are situated further away from HOSHAS and HTAA (Pahang, 2015).
- **Hospital Jengka (HJ)** is a district hospital without specialists. It is located nearer to HOSHAS than HTAA (60 km vs 120 km). It also serves as referral hospital for ambulatory care in Maran District. However, like other hospitals in the same category, it receives regular weekly visits from specialists from major departments in HOSHAS, e.g., Internal Medicine, Obstetrics and Gynaecology, Surgery etc. (Malaysia Ministry of Health, 2017a).

Figure 3.5: Map of the four hospitals involved in the Phase 2 study in the State of Pahang.
Source: Tourism Pahang, Malaysia (https://www.pahangtourism.org.my)

3.2.3 Study duration

Overall, the Phase 2 study lasted a total of 8 months (6 months for data collection and 2 months for follow-up). The initial steps of data collection started on 1st December 2015 and were completed on 1st June 2016. An additional 2 months were required for follow-up.

3.2.4 Study population

All health staff who had contact with patients were identified as the study population, which equated to an estimated 15,000 healthcare workers in the state of Pahang. According to Malaysia Health Facts 2017 (reference data for 2016), about 270,000 health staff from different job categories serve in Malaysia healthcare system (public and private) A large proportion of the staff are nurses (about 40%) followed by doctors (about 20-30%) and assistant medical officers (about 10%) (Malaysia. Ministry of Health, 2017). In this study, only staff with certain job titles were selected to participate in the study, namely, MOs, AMOs, nurses, pharmacists, and rehabilitation officers. These five job categories were chosen because they are heavily and directly involved in patient care. The inclusion and exclusion criteria for this sample were as follows:

3.2.4.1 Inclusion criteria:

i. Malaysian nationality

ii. Able to read, write and communicate in BM

iii. Have been working in the department for more than 1 month.

3.2.4.2 Exclusion criteria:

i. Undergraduate student on a posting in the department

ii. Permanent staff on long-term leave of more than 1 month.

It is important to note that the participants work in different workplace in different organization. The differences in environment, leadership support, communication will have effect on the patient safety culture practiced by staff. The process of care involved individuals from various workplace in an organization from the casualty, ward, prescription of medicine, delivery of medication and monitoring. As

noted in the Swiss Cheese Model, multiple factors affect the development of error until the alignment of barriers to produce error. In this research the various factors will be studied to give a better picture on factors affecting the practice of patient safety culture in public hospitals in Malaysia.

3.2.5 Sample size calculation

The sample size calculation was done using several fixed parameters. Based on an estimated population size of 15,000 for the whole state of Pahang, a CI of 95%, margin of error of 5% and an expected response rate of 50%, the recommended sample size was calculated using the following formula:

$$x = Z\left(\frac{c}{100}\right)^2 r(100 - r)$$

$$n = \frac{Nx}{(N-1)E^2 + x}$$

$$E = \sqrt{\left[\frac{(N-n)x}{n(N-1)}\right]}$$

Where:

Z = critical value of the CI chosen (c = 95%)

N = population size

r = response rate

n = sample size

E = margin of error (5%).

The above calculation produced a sample size of 375. Following the recommendation of the AHRQ (Culture, 2007), this figure was doubled to give a final sample size of 700.

3.2.6 Operational definitions of the independent variable

The independent variables were based on the literature review (refer to chapter 2). The variables were grouped into socio-demographic (age, ethnicity and gender), socio-economic (years of experience, profession and academic level) and job characteristics (working unit, working hours and interaction with patients) as follows:

- Socio-demographic characteristics:
    iii. Age: The participants were categorized into a 10-year group categories. Four categories were developed which are less than 30, 31 to 40, 41 to 50 and above 50 years. The aim is to capture the specific age group that is more prone to error in daily practice.(Sauerbrei & Royston, 2010)
    iv. Gender: Male or female.
    v. Ethnicity: The participants were placed in one of three categories: Malay, Chinese or Indian.
- Work related characteristics:
    i. Profession: In phase 2 study, only 5 categories of healthcare staff were chosen to participate in this study as they are considered as having the most direct contact with patients in their daily routines. The 5 job categories are registered nurses, doctors, pharmacists, assistant medical officers and rehabilitation therapists. The details on the staff in each hospital that participated in the study are provided in Table 3.3 on page 96.

ii. Academic level: The participants were categorized into one of three academic levels based on their highest qualification upon entry into their profession, namely, diploma, Bachelor's degree and advanced degree (Master's and above).

vii. Years of experience: This category was subdivided into less than 1 year, 1 to 5 years, 6 to 10 years, 11 to 15 years, 16 to 20 years, 21 years and above. These categories were chosen mainly because the similar categories were used in the original questionnaire.(Agency for Reasearch and Healthcare in Quality, 2012)

viii. Working unit: The participants were employed in a variety of places of work which they identified themselves.

ix. Working hours: The working hours were based on the cumulative hours of work per week. This category was divided into less than 20 hours, 20 to 39 hours, 40 to 59 hours, 60 to 79 hours, 80 to 99 hours, 100 hours and above. The working hours were divided in such a way to enable the researcher to capture which category or categories are at higher risk of committing error or if they are overworked. Furthermore, these categories follows the categories used un original questionnaire (Agency for Reasearch and Healthcare in Quality, 2012)

x. Interaction with patients: This variable indicated the type of contact that the participants had with patients, which was classed as either direct contact or indirect contact.

In view of the involvement of four study sites across the state, convenience sampling was used, according to the size of the hospital and logistic issues. The higher the rank or level of a hospital, the bigger is the sample size. Details on the distribution of the sample by hospital are given in Table 3.2 below.

Table 3.2: Distribution of Sample Size in Each Selected Hospital Using Quota Sampling.

Name of Hospital	Type	Quota (%)	Sample Size
Hospital Tengku Ampuan Afzan (HTAA)	State Hospital	40	300
Hospital Sultan Haji Ahmad Shah (HOSHAS)	District Hospital with Specialties (Major)	30	225
Hospital Kuala Lipis (HKL)	District Hospital with Specialties (Minor)	20	150
Hospital Jengka (HJ)	District Hospital without Specialties	10	75

Further, taking the state hospital as a benchmark, the proportions of staff that needed to be included in the sample from each of the five job title categories were also calculated. Thus, it was determined that nurses would account for 40% of the study sample, followed by MOs (20%), AMOs (15%), pharmacists (15%) and rehabilitation therapists (10%). This proportions of staff also adhered to those in the Malaysia Health Facts report (Ministry of Health, 2013). However, due to the limited number of rehabilitation therapists, all therapists were included in the study. The details on the staff in each hospital that participated in the study are provided in Table 3.3.

Table 3.3: Distribution of Participants by Profession and Hospital Based on Proportion Allocated for Each Hospital.

Job title	Percentage	No of participants in each hospital				Total no. of participants
		HTAA	HOSHAS	HKL	HJ	
Nurses	**40**	120	90	60	30	300
Medical Officers	**20**	60	45	35	15	155
Assistant Medical Officers	**15**	45	34	23	13	115
Pharmacists	**15**	45	34	23	13	115
Rehabilitation Therapists	**10**	30	23	15	8	75

From a total sample size of 700 determined earlier, a percentage was set to each hospital to estimate sample size from each hospital. The weightage of percentage depends on the type of hospital. Using the percentage, the number of staff who will involve in the study were determined. For example, for State Hospital 120 registered nurses will be chosen as participants, 60 Medical Officers 45 Assistant Medical Officers, 45 Pharmacists and 30 Rehabilitation Therapists. The same percentage were applied to each participating hospital. At the micro level, the choice of participants was made using systematic random sampling or universal sampling, whichever was the most appropriate and feasible for each study site. For a larger hospital or department with a large number of staff, systematic random sampling was used. In contrast, in a smaller hospital, where the number of staff was relatively smaller, universal sampling was used. Similarly, in order to obtain a better response rate from MOs, different sampling techniques were used. In larger hospitals, only three departments were purposively selected to participate, namely, Medical, Obstetrics/Gynaecology and

Ophthalmology, whereas in smaller hospitals universal sampling was applied to capture more responses from MOs.

3.2.6 Methods of data collection

3.2.6.1 Participant recruitment

Prior to the distribution of the questionnaires, permission from the respective hospital directors and heads of department was applied for and received. Following that, a main liaison officer from the administrative office was identified within each hospital. A list of sub-main contact points according to job title was obtained from each liaison officer. These contact points were the individuals who had the most authority in each job title category in the hospital. However, due to the expected low response rate from MOs, every head of department that had MOs who had been selected to participate in the study were also assigned the role of contact person.

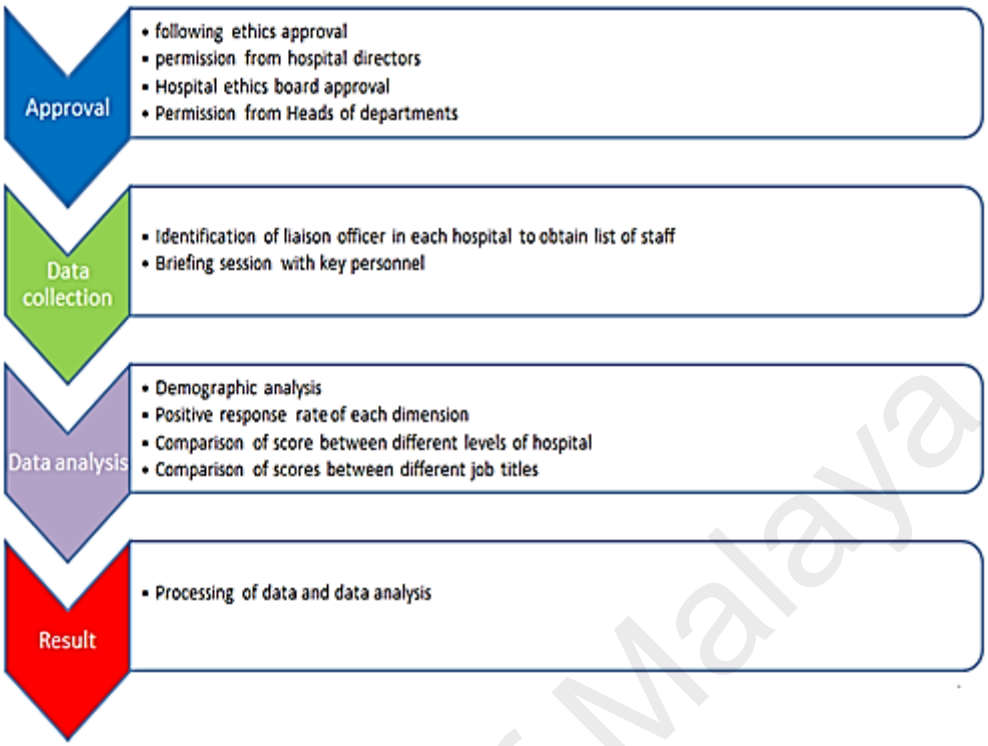

Figure 3.6: Data collection steps for Phase 2 study.

A briefing session was conducted in each hospital. It involved a single session in the two smaller hospitals, but more sessions were needed in the two bigger hospitals. In these sessions, participants who consist of several key persons of the department were told about the nature of the study, confidentiality declaration, and how researcher would collect the survey forms. Simple instructions were used in order to improve the response from the participants. Contact persons were encouraged to bring up any queries or problems or misunderstandings related to the survey in order to enable them to answer any questions that their subordinates might raise later during the survey.

All the potential participants were supplied with a package consisting of the BM version of the HSOPSC questionnaire, the PIS and consent form in an envelope. The

participants were required to read the PIS first. They then needed to sign the consent form provided together in the envelope to signify that they had agreed to participate in the study. The participants were encouraged to ask the researcher any questions by telephone or email, the number and address for which were provided in the PIS.

The questionnaires were distributed to each participating hospital according to the percentage assigned earlier. In each hospital, the questionnaire was distributed among the five job title categories, namely, MOs, nurses, AMOs, pharmacists and rehabilitation officers (physiotherapists, occupational therapists, speech therapists, audiologists etc.) according to the proportion described earlier.

For that purpose, a staff list for each hospital was obtained through the kind cooperation of the administrative staff. The staff lists were sorted according to the five job title categories that had been selected to participate in the study. Following that, the exact proportion of participants was calculated for each job title based on the proportion of the staff in these categories in each hospital. When the number of potential participants in each hospital was determined, the participants were chosen by referring to the staff list and by using systematic random sampling. As mentioned above, universal sampling was used to select the participants in the smaller hospitals.

The completed survey forms were collected 8 weeks after their distribution. The participants were advised to send the completed questionnaire to their respective liaison officer or to put in a bag in the respective management office. Non-responders were identified through the staff list for each department and were approached again personally and reminded about the survey. As a lower response rate was expected from the MOs due to their mobility within the hospital, a stamped, addressed envelope was provided to

facilitate their response. The participants who submitted the survey were given a small souvenir as a token of appreciation. A period of 4 weeks was allocated for follow-up and recalling participants and non-responders. However, most departments needed a shorter follow-up period because they were administrated by a dedicated manager, which made the collection of the questionnaires more systematic. However, for MOs, the follow-up period was extended for a short amount of time because their work was distributed across several units and departments in the hospital.

3.2.7 Study instrument

In the Phase 2 study, the HSOPSC-BM version was used as the study instrument. In its final version it had nine dimensions and 30 items as a result of some redistribution of items among the dimensions. However, the instrument had been tested in the Phase 1 study and proven to be fit and suitable for use in the Malaysian context. An explanation of the original HSOPSC can be found in section 3.1.6.8 in this chapter. Table 3.4 on page 104 provides details of the items and dimensions o of the final HSOPSC-BM.

Table 3.4: Items and dimensions of the final HSOPSC-BM.

Hypothetical dimension	Name of dimension	Item
Aa1	Teamwork Within Unit	A1 A2 A3 A4
AA2	Organizational Learning-Continuous improvement	A13 A6 A9 A15
AA3	Non-Punitive Response to Error	A8 A12 A16
AA4	Overall Perception of Patient Safety	A14 A17
B	Supervisor/manager Expectations and actions in promoting Patient Safety	B1 B2 B4
C	Feedback and Communication on Error	C3 C5
D	Frequency of Event Reporting	D1 D2 D3
F1	Handoffs and Transition	F11 F3 F5 F6 F7 F9
F2	Teamwork Across Units	F1 F4 F10
Total	9 dimensions	30 items

3.2.8 Data management

The data were entered into Microsoft Excel on a personal computer before being transferred to specialist statistics software, namely, SPSS version 22.0. The entered data were double-checked immediately against the raw data to avoid typing errors. In addition, duplicate entries were identified manually and eliminated. Data were also checked for

outliers for all variables. After that, data transformation was performed using SPSS version 22.0 by creating new variables using the Transform, Recode or Compute commands where necessary. Data cleaning procedures such as validation, editing and tracing the missing data were carried out before commencing the data analysis. For the purpose of safekeeping, all the files were backed up regularly.

3.2.8.1 Descriptive analysis

Data exploration was undertaken mainly to acquire descriptive statistics to describe all the variables and to examine the distribution of the data graphically. Following data exploration, data tables were constructed. In the descriptive analysis, all the categorical variables were summarized using counts and percentages (%). After examining the data, some categories of some variables were collapsed due to the small numbers in the sample. Negatively worded items in the questionnaire were reverse coded to reflect the actual response of the participants towards the items.

For Sections A to G of the questionnaire, the positive response rate was calculated using percentages. Responses of 4 (agree) and 5 (strongly agree) were considered positive responses. In other words, a score of 75% or more was considered a positive response (Samsuri et al., 2015). An analysis of each hospital was performed as well as an analysis of the whole dataset (VF Nieva & J Sorra, 2003).

3.2.8.2 Inferential analysis

To meet the objectives of this research, simple linear regressions were used to assess the relationships between the independent variables and the dependent variables. Comparison of each independent variable was done using a sample t-test for the gender variable and using ANOVA for the other independent variables (type of hospital, years of experience, profession, age and ethnicity).

There are three types of t-test, namely, the one sample t-test, paired t-test and independent t-test. In this study, the independent t-test was used for data analysis. The independent t-test is a statistical test used to compare the means of two groups. It is performed when there is one nominal variable and one measurement variable with the following assumptions: dependent variables must follow a normal distribution in a population (if the sample size is 30 or more in each group, the need for normality is reduced), there is equality of variances (if the sample sizes are equal, this assumption may be ignored) and there is independence of observations (Statistics, 2016).

In the next stage of an ANOVA, which involves comparing the differences between groups, the following six assumptions must be met. The assumptions are where the dependent variable must be continuous. The independent variable should consist of 3 or more categorical, independent groups. Examples in this data include ethnicity (3 categories ie Malay, Chinese, Indian). The observation should be independent which means that there is no relationship between the observations in each group or between the groups themselves. There should be no significant outliers. Outliers are simply single data points within the data that do not follow the usual pattern. The dependent variable should be approximately normally distributed for each category of the independent variable. Lastly, Levene's test was used to test homogeneity of variance (Laerds Statistics, 2016). A p value of more than 0.05 is expected to indicate that the variance is equal across the groups.

Multiple linear regression analysis was used to test the impact of the independent and controlling variables on the patient safety score of public hospitals in Malaysia. First, the mean score was calculated for every dimension in order to construct a composite

value. All the independent and controlling variables were then regressed using multivariate linear regression analysis to ascertain the impact of these variables on patient safety culture in Malaysia. Before proceeding to conduct this analysis, all the independent variables were tested to determine whether they met the assumptions of multiple linear regressions: (1) there is a linear relationship between the independent and dependent variables; (2) the error between the observed and predicted values should be normally distributed; (3) there needs to be little or no multi-collinearity in the data; and (4) the data also need to have minimal or no autocorrelation and homoscedasticity (Statistic Solution, 2016).

The crucial limitation of linear regression is that it cannot deal with dependent variables that are dichotomous and categorical. Many interesting variables are dichotomous: for example, consumers make a decision to buy or not buy, a product may pass or fail quality control, there are good or poor credit risks, an employee may be promoted or not. Therefore, a variety of regression techniques have been developed for analysing data with categorical dependent variables, including logistic regression. Hence in this study, multiple logistic regressions was used for the further analyses. The continuous dependent variable that was tested was the mean patient safety score (composite). Later on, this variable was subcategorized into high and low to enable analysis through multiple logistic regressions. Binary logistic regression was deemed to be a suitable analysis technique for a dichotomous outcome such as the mean patient safety score (Laerd . Statistics, 2017). A mean score of 3.0 and more was considered a high score, whereas a mean lower than 3.0 was considered a low score ("LeapFrog Hospital Safety Grade:

Explanation on Patient Safety Grades," 2017). The low category was used as the reference category.

Multiple logistic regressions also allow the testing of the association between independent variables and categorical dependent variables that have more than two subcategories. A set of assumptions need to be complied with before an analysis is performed using multiple logistic regression. First, logistic regression does not assume a linear relationship between the dependent and independent variables. In addition, the dependent variable must consist of two or more categories. Also, the independent variables need not be interval, normally distributed, linearly related, nor of equal variance within each group. Next, the categories (groups) must be mutually exclusive and exhaustive; a case can only be in one group and every case must be a member of one of the groups. Moreover, larger samples are needed than for linear regression because maximum likelihood coefficients are large sample estimates. A minimum of 50 cases per predictor is recommended (Laerd . Statistics, 2017).

There are two main uses of logistic regression. The first is the prediction of group membership. Since logistic regression calculates the probability of success over the probability of failure, the results of the analysis are in the form of an odds ratio. In addition, logistic regression also provides knowledge of the relationships and strengths among the variables (e.g., marrying the boss's daughter gives a person a higher probability of job promotion than undertaking five hours' unpaid overtime each week) (Robert Burns & Burns).

In this study, for the Number of events reported variable was divided into three categories, namely, no report, one to two reports and three or more reports. The reference

category was no report. These categories were tested against independent variables that were similar to those tested by linear regression, namely age, gender, profession, years of experience, ethnicity and academic level.

In addition, the model was tested using goodness of fit to ascertain whether the data fit the model well. For the binary regression, the Hosmer-Lemeshow goodness of fit was used (Laerd. Statistics, 2017) On the other hand, Pearson's chi-square goodness of fit was used to test whether the data fit the model in the multinomial regression (Laerd . Statistics, 2017). A cut-off point of a p-value of more than 0.05 indicated that the data fit the model (Stevens, 1992).

Finally, the Pearson's product-moment correlation coefficient was assessed to determine whether there was any correlation between the safety culture dimensions and the dependent variables (Patient safety grade and Number of events reported). In addition, the correlation between both of those dependent variables was tested and sorted according to type of hospital.

3.2.9 Ethical consideration and confidentiality

The Phase 2 study shared common approval with the Phase 1 study, which was granted by both the UM-REC and the NMRR via the Ministry's MREC (refer to section 3.1.6.11). It is important to note that before commencing the Phase 2 study, formal approval from the Director of the Health Department of Pahang State was sought. Only on receipt of that approval, and prior to the distribution of the questionnaires, permission from the respective hospital directors, local ethics boards (wherever applicable), heads of department and head of units were applied for and obtained. Liaison officers were then

identified for each hospital and each department that were chosen to participate in the study.

3.2.10 Summary

This chapter provided details on the study design and work conducted to extract the data for the two phases (Phase 1 and Phase 2) of this research. The data collection process took longer than expected due to various logistical documentation issues. Data cleaning, recoding and analysis were performed as described above.

In the Phase 1 study, the data were divided into two components. The first component was used to test whether the HSOPSC-BM was a similar construct to the original version. The second component was used to ascertain whether the HSOPSC-BM possessed a different structure of domains compared to the original HSOPSC.

In the Phase 2 study, the resultant new construct of the HSOPSC-BM from Phase 1 was used to assess patient safety culture in Malaysia. Four public hospitals from different levels of the Malaysian healthcare system were preselected for this study. The participants were those staff who had direct contact with patients and were employed in one of five job title categories namely, MOs, pharmacists, nurses, AMOs and rehabilitation therapists.

The descriptive analysis preceded inferential statistics as is the norm. Then, simple linear regression and simple logistic regression were followed by multiple linear regressions and multiple logistic regressions, respectively.

CHAPTER 4: RESULT

The results of this study are presented following the sequence of the objectives as stated in Chapter 3. This chapter is generally divided into 2 sections representing Phase 1 and Phase 2. Each section consists of several subsections to allow for in-depth discussion of each phase. For instance, in Phase 1, which was a validation study of the original HSOPSC, the results of each step in the validation process would be initially explained with face validation, content validation and construct validation. In the construct validation section, the results would be further subcategorized into several other smaller sections to explain in detail the steps involved in the construct validation process.

On the other hand, phase 2 discussed the assessment of patient safety culture in public hospitals in Malaysia using the HSOPSC-BM version. The subsections discussed the demographic features, descriptive analysis of each dimension and the single outcome dimensions such as 'Patient Safety Score' and 'Number of Event Reporting.' The analysis continued with the comparison of the mean between the dimensions. Regression analysis would be presented later in this chapter.

4.1 Phase 1: Validity and Reliability of the BM Version of the HSOPSC Questionnaire

4.1.1 Translation process

The translation process was uneventful, straightforward and the final translation was brought to the expert panel for review. The final draft is attached in Appendix (see appendix B)

4.1.2 Expert panel review

Almost half of the experts agreed that the word '*laporan kejadian'* needed to be changed to '*laporan insiden'* to enhance the translation of 'incident reporting'. Wordings

for item A10 were also commented by a few experts and necessary changes were made to the item. A few of the experts commented that the translation in item A12 needed to edited to avoid direct translation. Even though the initial translation was comprehensible, it did not fit the syntax of BM. After a few amendments, the final phrase became '*apabila sesuatu kejadian dilaporkan, seolah-olah kakitangan yang terlibat menjadi fokus dan dipersalahkan, bukannya mencari punca dan penyelesaian kepada masalah tersebut.'*

4.1.3 Cognitive interview

Section A: Among the few items that had been commented on by participants during the interviews were A 7 and A10. In A7: 'We use more agency/temporary staff than is best for patient care' was initially translated into '*Kami menggunakan lebih banyak kakitangan/agensi sementara daripada yang sepatutnya untuk rawatan pesakit'*. The term *agensi sementara* was confusing as this kind of employment is not common in the Malaysian public health services. However, it would be better understood if the sentence included the word contract staff. The finalized version of the item was *'Kami menggunakan ramai kakitangan sementara/kontrak dari yang sepatutnya untuk rawatan pesakit'.*

In A10, the original English version were '*It is just by chance that more serious mistakes don't happen around here'.* It was translated into '*Kesilapan yang lebih serius tidak berlaku di sini hanya kerana kebetulan'*. However, following the suggestion from experts, the phrase was added to include *'... around here not because a good system or procedures'* so the BM version became '*Kesilapan yang lebih serius tidak berlaku di sini hanyalah kerana kebetulan atau bernasib baik bukan kerana prosedur atau sistem yang baik'*. During the interviews, the added phrase was considered confusing by the majority of

Table 4.1: Content Validity Index in expert panel reviews of HSOPSC-BM

Item	Expert 1	Expert 2	Expert 3	Expert 4	Index
A1			/	/	0.5
A2	/	/	/	/	1
A3	/	/	/	/	1
A4	/		/		0.5
A5	/	/	/	/	1
A6	/	/	/	/	1
A7		/	/	/	0.75
A8	/	/	/	/	1
A9	/	/	/	/	1
A10	/	/			0.5
A11	/	/	/	/	1
A12		/		/	0.5
A13	/	/	/	/	1
A14		/		/	0.5
A15	/	/	/	/	1
A16		/	/	/	0.75
A17		/	/	/	0.75
A18	/	/	/		0.75
B1	/	/	/	/	1
B2	/	/	/	/	1
B3		/	/	/	0.75
B4		/	/	/	0.75
C1		/	/	/	1
C2	/	/	/	/	1
C3	/	/	/	/	1
C4	/	/	/		0.75
C5	/	/	/	/	1
C6		/	/	/	0.75
D1	/	/	/	/	1
D2	/	/	/	/	1
D3	/	/	/	/	1
F1	/	/	/	/	1
F2	/	/	/	/	1
F3		/	/	/	0.75
F4	/	/	/	/	1
F5		/	/	/	0.75
F6			/	/	0.5
F7		/	/	/	0.75
F8	/	/	/	/	1
F9		/	/	/	0.75
F10	/	/	/	/	1
F11		/	/	/	0.75
Mean					**0.87**

the participants, and they suggested that the added phrase be withdrawn from the sentence. The finalized sentence for the item was '… *Kesilapan yang lebih serius tidak berlaku disini hanyalah kerana kebetulan atau bernasib baik'.* The word '*bernasib baik'* (good luck) was suggested by a few participants to enhance the meaning of '*kebetulan'*.

Section B: There was minimal comment for Section B. All the items could be well understood by the participants during interviews.

Section C: For item C6, there was a disagreement about a few phrases for example in the BM version the sentence is '*...sekiranya mendapati ada sesuatu yang tidak kena'*. Only one participant commented on this as he suggested that the phase 'tidak betul' should be added to accurately translate the phrase 'not right'. However, upon the consensus of other participants, it was agreed that the initial translation was adequate and understandable. Therefore the suggested addition was not included. The final phrase became '*kakitangan takut untuk menyuarakan persoalan sekiranya mendapati ada sesuatu yang tidak kena'.*

Section D: All the items were considered understandable and acceptable

Section E and G: This section deals with the grading of the patient safety culture in the hospital. No problem was encountered in relation to the sentences or the word 'grade'.

Section F: No significant comments on this section needed to be amended

Section G: All the items were agreed upon by the participants

4.1.4 Content validity

Only 4 experts responded to the invitation to participate in the process of content validity. It was noted that the average I- CVI was 0.87 and was considered good (Lynn, 1986) . The method for calculating the average CVI was suggested by Pollit et al. (Pollit DF. et al., 2007). In this study, as illustrated by Table 4.1, 22 items are rated as relevant by all the evaluators (rated as 3 or 4 for each item). Only 6 items are scored 0.5 and rated as relevant by 2 out of 4 evaluators. The rest which is about 13 items have an index of 0.75 (rated as relevant by 3 out of 4 evaluators). The rest of the items are rated as relevant by all the evaluators. However, the lower score item is not removed and is included in further analysis.

4.1.5 Test and Retest Reliability

Based on 40 staff who were approached for this test, 32 of them completed both components (test and retest). The total response rate for these test and retest were 80%. The staff nurses contributed about 50% of the sample. The rest were medical officers from various units in the UMMC and health clinics. In the test and retest, the participants' agreement about the items were calculated and compared from the two-time frames. Apart from that, each item used in the test and retest was tested for reliability. A composite score were generated from each time frame.

Table 4.2: Correlation (Pearson's Correlation) of two composite scores from 32 observations in the test and retest.

	Test 1	Test 2
Pearson Correlation	1	0.544**
Sig. (2-tailed)		0.001
N	32	32

Table 4. 3: Correlation of each item in reliability testing between test(T1) and retest (T2)

No.	Item	R
1	A1	0.919
2	A2	0.842
3	A3	0.748
4	A4	0.778
5	A5	0.806
6	A6	0.522
7	A7	0.475
8	A8	0.163
9	A9	0.436
10	A10	0.462
11	A11	0.602
12	A12	0.634
13	A13	0.400
14	A14	0.638
15	A15	0.535
16	A16	0.256
17	A17	0.446
18	A18	0.533
19	B1	0.533
20	B2	0.628
21	B3	0.716
22	B4	0.668
23	C1	0.634
24	C2	0.598
25	C3	0.410
26	C4	0.687
27	C5	0.747
28	C6	0.649
29	D1	0.469
30	D2	0.340
31	D3	0.329
32	F1	0.368
33	F2	0.656
34	F3	0.732
35	F4	0.587
36	F5	0.768
37	F6	0.696
38	F7	0.740
39	F8	0.633
40	F9	0.502
41	F10	0.702
42	F11	0.638

Pearson's Correlation was used to assess how well the values from the 2-time frames correlated with each other. The correlation shows that the results from Time $_1$ (test) and Time $_2$ (retest) are moderately correlated with $R = 0.544$ ($p<0.05$). Finally, a

composite score was created to test the overall correlation between the 2 time frames. A high degree of reliability between the 2 tests is found. An average measure of 0.704 with 95% confidence interval from 0.394 to 0.856 F (31,31) = 3.381, p <0.01 give an impression that there is a good correlation between these 2 tests where 70% of participants agree on the same scales repeatedly.

Table 4.4: Correlation (Intra Class Correlation) between two composite scores in test and retest reliability

	Intraclass Correlation	95% Confidence Interval	
		Lower Bound	Upper Bound
Average Measures	0.704*	0.394	0.856

4.1.6 Psychometric Analysis

For the purpose of psychometric analysis, about 700 sets of questionnaires were distributed to selected health facilities. These facilities were purposively chosen. Participants were chosen based on convenience sampling. . In phase 1 study, participants were chosen as convenient sampling without any specific preference except being healthcare staff having direct contact with patients. About 600 participants responded to the study. Each questionnaire was checked. When there was no entire section completed; fewer than half items answered; or all the items answered the same the questionnaire is discarded. Following face validation to the responses only 479 of them answered the questionnaire correctly and acceptable with the response rate of about 68% which is considered as a sufficient response rate compared to other studies.

4.1.6.1 Descriptive analysis

The demographic analysis which was part of Section H and the initial part of section A were analysed using descriptive statistics Based on Table 4.5, most of the respondents are from the Medical Department (50%), and 76% of them comprise registered nurses. About half of the respondents are junior staff with1 to 5 years of experience working in the current unit, current job title or the total years of experience working in the health sector. Among the respondents, 89% have direct contact with patients. This percentage can be due to the sampling method where these departments were purposively chosen, and the participant selection was using convenient sampling. A major proportion of staff has less than 5 years of working experience. About 41% work less than 5 years in the hospital whereas 50% of them have been working in the current unit for less than 5 years. The majority of the participants work for more than 40 hours per week.

Table 4.5: Demographic patterns of participants (N=479)

VARIABLES	N	%
JOB TITLE		
Registered Nurse	364	76
Health Assistant	24	5
Medical/House Officers	24	5
Others	14	2.9
Assistant Medical Officer	11	2.3
Pharmacist	9	1.9
Clerk/Secretary	9	1.9
Technician (Lab/Radiographer)	8	1.7
General worker	8	1.7
Rehabilitation Therapist	3	0.6
Specialist/Consultant	2	0.4
Dietician	1	0.2
Administrator/Manager	1	0.2
Driver	1	0.2
WORKING UNIT		
Medicine	268	55.9
Many different units/no specific unit	64	13.4
Anaesthesiology	47	9.8
Obstetrics & Gynaecology	21	4.4
Paediatric	20	4.2
Emergency Department	13	2.7
Pharmacy	13	2.7
Laboratory	11	2.3
Intensive Care Unit	8	1.7
Rehabilitation	5	1
Radiology	4	0.8
Others	3	0.6
Surgery	1	0.2
Psychiatry	1	0.2
WORKING EXPERIENCE		
Less than 1 year	91	19
1-5 years	196	40.9
6-10 years	77	16.1
11-15 years	43	9
16-20 years	23	4.8
21 years an above	49	10.2
YEARS WORKING IN CURRENT UNIT		
Less than 1 year	117	24.4
1-5 years	238	50
6-10 years	72	15
11-15 years	29	6.1
16-20 years	13	2.7
21 years an above	9	1.9
YEARS OF WORKING EXPERIENCE IN CURRENT SPECIALTY		
Less than 1 year	75	15.7
1-5 year	211	44.1
6-10 years	80	16.7
11-15 years	53	11.1
16-20 years	20	4.2
more than 20 years	39	8.3

Table 4.5 cont

VARIABLES	N	%
HOURS OF WORKING PER WEEK		
less than 20 hours per week	9	1.9
20-39 hours per week	55	11.5
40-59 hours per week	333	70
60-79 hours per week	62	12.9
80-99 hours per week	7	1.5
more than 100 hours	13	2.7
CONTACT WITH PATIENTS		
Yes, I have direct contact with patients	424	88.5
No, I don't have direct contact with patients	55	11.5

An analysis of the positive responses was conducted using this set of data. Though this phase of study was meant mainly for validation purposes, the authors felt that it was commendable if an effort was made to analyse the data for its descriptive properties to ascertain whether HSOPSC-BM carries the same factor structure as the original HSOPSC or there is a possibility that the new HSOPSC-BM do not have a similar factor structure. The average of each HSOPSC-BM dimension was calculated and compared with the US version. A positive response rate was defined as participants responded '5-agree' and '4-somewhat agree' on the Likert scale. The items with a negative coding were reverse coded before the analysis. The result for each item was established, and the mean for each dimension was calculated. A table of comparison with the US data is shown in Table 4.6.

In general, the average score of this study shows a remarkably lower score compared to the US data. However, each dimension needs to be interpreted individually to capture the actual picture. In this study, it shows that there are rooms for improvement awaiting the public health services. This study was treated as a benchmark for the later phase of the study using the validated tool in Malaysia. Overall, the data shows that there are differences between the positive responses from the US data. Eight of the 12 dimensions in our data show that the mean positive response is lower than the US data

(teamwork within the unit, supervisor's expectation, manager and supervisor's action promoting patient safety, overall perception on patient safety, communication openness, the frequency of event reporting, teamwork across the unit, and staffing). Staffing scores the lowest among all the scores with a score of 30% signifying that majority of staff think that their workplace is understaffed and that contributes to a reduced level of safety. Another dimension that scores low is the 'Communication Openness' dimension which scores slightly higher with a score of 33% which indicate that the opportunity for staff to openly discuss errors or mistakes with their superiors is considerably limited.

` On the other hand, 'Organizational Learning' scores the highest with 85.3%. Undoubtedly, there are various methods and opportunities for learning, provided by the institutions such as Continuous Medical Education (CME), Hands-On Courses, seminars, and workshops. Other dimensions show a better response than the US data. The scores for the single outcome measure, i.e., Patient Safety Grade and Number of Event Reported were analysed individually according to their individual category (Table 4.8). A cumulative percentage of 52.6% is attained in the Patient Safety Grade by participants who have been voted for excellent and good Patient Safety Grade of their workplace. More than half of participants admit that they never report any incident reporting for the past 12 months.

Table 4.6: Comparison of positive response rate with US (AHRQ) data (N=479)

Item	Description	Positive Response (%)	Mean	
1. Teamwork Within Unit			**Malaysia**	**US**
A1	People support one another in this unit	83.5	74	80
A3	When a lot of work needs to be done quickly, we work together as a team to get the work done	79.7		
A4	In this unit, people treat each other with respect	76.4		
A11	When one area in this unit gets really busy, others help out	54.7		
2. Manager and Supervisor Expectation on Patient Safety				
B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	60.9	71.3	75
B2	My supervisor/manager seriously considers staff suggestions for improving patient safety	71.4		
B3	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts	69.6		
B4	My supervisor/manager overlooks patient safety problems that happen over and over	83.3		
3. Organizational Learning				
A6	We are actively doing things to improve patient safety	84.9	85.3	72
A9	Mistakes have led to positive changes here	87.1		
A13	After we make changes to improve patient safety, we evaluate their effectiveness	83.9		
4. Hospital and management support for Patient safety				
F1	Hospital management provides a work climate that promotes patient safety	70.1	64	72
F8	The actions of hospital management show that patient safety is a top priority	73.9		
F9	Hospital management seems interested in patient safety only after an adverse event happens	47.6		
5. Overall Perception on Patient Safety				
A15	Patient safety is never sacrificed to get more work done	90.2	51	65
A18	Our procedures and systems are good at preventing errors from happening	70.3		
A10	It is just by chance that more serious mistakes don't happen around here	24.6		
A17	We have patient safety problems in this unit	17.1		
6. Feedback and Communication About Error				
C1	We are given feedback about changes put into place based on event reports	55.8	65	63
C3	We are informed about errors that happen in this unit	67.7		
C5	In this unit, we discuss ways to prevent errors from happening again	72.2		
7.Communication Openness				
C2	Staff will freely speak up if they see something that may negatively affect patient care	60.1	33	62

Table 4.6 cont

Item	Description	Positive Response (%)	Mean	
C4	Staff feel free to question the decisions or actions of those with more authority	29.5		
C6	Staff are afraid to ask questions when something does not seem right	8.3		
8. Frequency of Event Reporting				
D1	When a mistake is made but is caught and corrected before affecting the patient, how often is this reported?	24.3	25	62
D2	When a mistake is made but has no potential to harm the patient, how often is this reported?	21.5		
D3	When a mistake is made that could harm the patient, but does not, how often is this reported?	30.4		
9. Teamwork Across Unit				
F4	There is good cooperation among hospital units that need to work together	65.1	52	58
F10	Hospital units work well together to provide the best care for patients	77.2		
F2	Hospital units do not coordinate well with each other	3.3		
F6	It is often unpleasant to work with staff from other hospital units	61.8		
10.Staffing				
A2	We have enough staff to handle the workload	32.4	30	56
A5	Staff in this unit work longer hours than is best for patient care	37.4		
A7	We use more agency/temporary staff than is best for patient care	11.9		
A14	We work in "crisis mode" trying to do too much, too quickly	34.8		
11.Hands off and Transition				
F3	Things “fall between the cracks” when transferring patients from one unit to another	54.9	61	44
F5	Important patient care information is often lost during shift changes	61.8		
F7	Problems often occur in the exchange of information across hospital units	52.4		
F11	Shift changes are problematic for patients in this hospital	74.4		
12. Non Punitive Response to Error				
A8	Staff feel like their mistakes are held against them	67.6	53	44
A12	When an event is reported, it feels like the person is being written up, not the problem	30.7		
A16	Staff worry that mistakes they make are kept in their personnel file	61		
		Mean Score	**55.4**	**62.75**

Table 4.7: Scores of single items outcome in mean (SD) and percentage of each category (N=479)

Dimension - mean (SD)	%
Patient Safety Grade - 3.04 (±1.563)	
Excellent	4.2
Good	48.4
Acceptable	26.1
Poor	1.9
Failing	0.4
No answer	18.4
Number of Events reported - 1.70 (±1.100)	
No Incident Reporting	54.9
1-2 Incident Reporting	32.2
3-5 Incident Reporting	7.9
6-10 Incident Reporting	2.3
11-20 Incident Reporting	0.6

The descriptive findings of Phase 1 were meant as a bench mark for Phase 2 of the study. More importantly, the results from Phase 1 study, namely the factor analysis, were to be used in continuum in Phase 2 of the study.

4.1.6.2 Testing the original construct

An initial testing of the survey was done using the original factor structure in HSOPSC. Internal consistencies of the BM version using the original factor structure were analyzed. Out of the original 12 dimensions, the translated BM version show 4 dimensions having the Cronbach Alpha scores that are lower than 0.6 compared to the rest of the 8 dimensions (Sorra & Dyer, 2010). The 4 dimensions are:

i. Manager and Supervisor expectation on patient safety (0.38)

ii. Communication openness (0.40)

iii. Overall perception on patient safety (0.30)

iv. Non-punitive error on patient safety (0.53)

These results were then tested using CFA to test if the model fits. Structural equation modelling was used to test the model fit using AMOS software. After a few series of modelling, the final 8 dimensions with 24 items were constructed in the HSOPSC/BM version. The model of fit shows the chi-square score of (df)=730.322(224), p value<0.005, relative chi-square=3.260, CFI=0.865, P ratio=0.747, RMSEA= 0.069 showing an acceptable fit to the original model of construct. The final overall reliability is good where the overall Cronbach's Alpha is 0.78. All the dimensions show a Cronbach's Alpha of more than 0.6.

The Chi-square (df) of 730.322 with a p-value of <0.005, P ratio of 0.747 and RMSEA of 0.07 show a good fit of the original model in the BM version after the deduction of the 4 dimensions and a total of 18 items removed. The model of fit collectively gives an impression that the original US HSOPSC is considered good to be accepted for use in Malaysia. The final construct is left with 8 dimensions and 24 items. The reliability test of the remaining 8 dimensions shows good reliability. However, since the items are cut to almost half of the initial number of items, it is therefore thought that an exploration of the dataset is appropriate to enable the optimisation of the factor structure of the HSOPSC-BM.

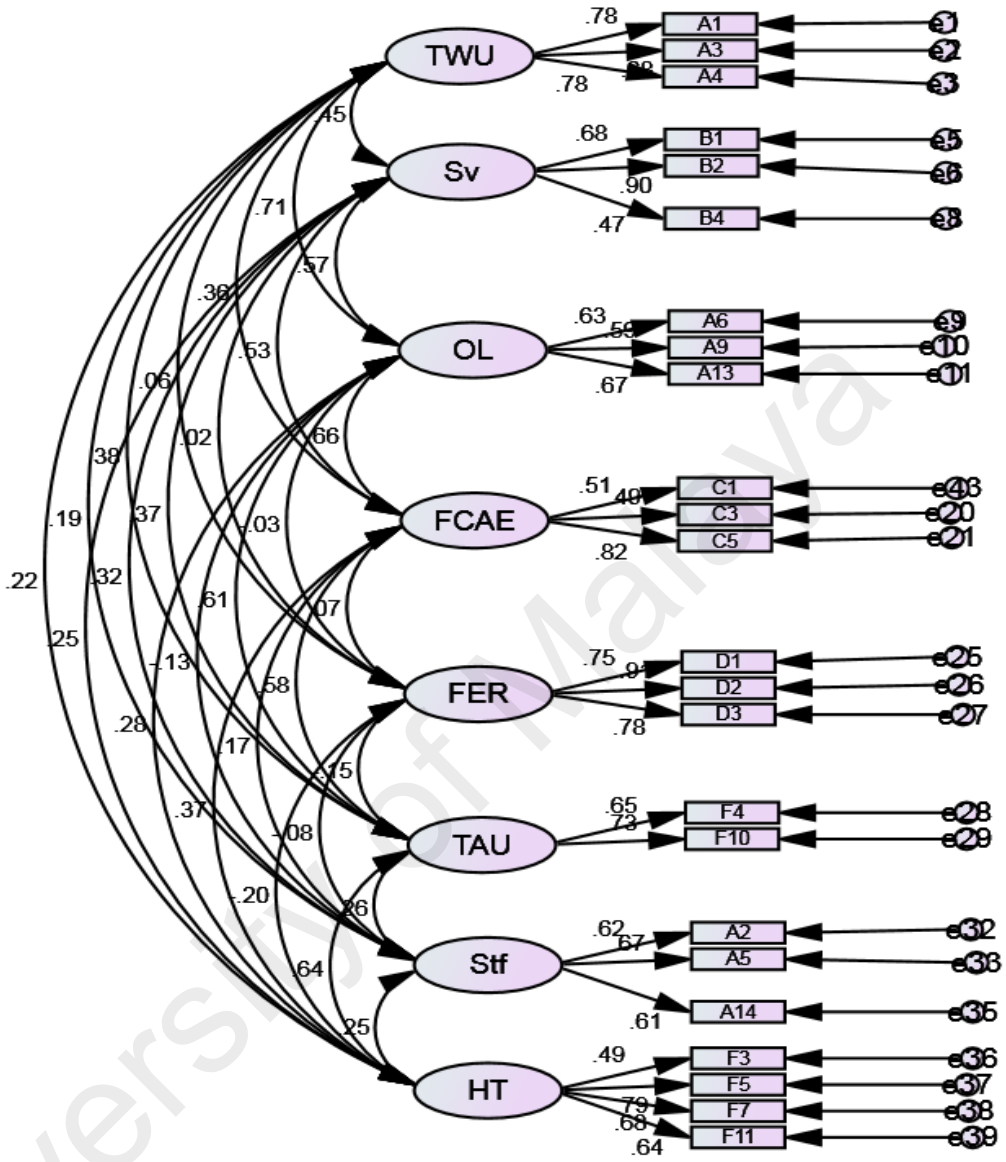

Figure 4. 1: The final Model of fit of the original structure of HSOPSC

4.1.6.5 Developing a hypothetical construct

The data set was tested using the Exploratory Factor Analysis to assess if it provides different structures in the BM version and to investigate if the BM version gave an optimised structure in comparison to the original factor structure. For this purpose, the dataset was divided into 2 subsets. About 210 samples were grouped into the first set meant to be used for EFA (exploratory set). The next 269 samples were used for CFA (confirmatory set). The first dataset was used to test if the BM version creates a different construct compared to the original version.

i. Exploratory Factor Analysis

A subset of 210 samples from the total sample size was used for EFA. Kaiser-Meyer-Olkin (KMO) measure of sampling is 0.756. The Bartlett's Test of sphericity is 3288.30 with a degree of freedom of 861 and level of significance of 0.000. From the EFA, upon compliance with the cut off points of 0.6, a total of 10 factors with 39 items are extracted (Table 4.9). The findings were underwent the confirmatory analysis using another subset of samples from the total sample size.

ii. Confirmatory Factor Analysis

Following the findings in the EFA, the structure was forwarded to the next step of the analysis. The hypothesized structure was tested with the Structural Equation Modelling using AMOS Software version 21. The second subset of 269 samples from the total sample was used in this test. The final 10 factors with 39 items were tested, and the results show an acceptable fit of the model after further deduction of the factor and items. The final 9 dimensions with 30 items are retained (Figure 3).

Table 4.8: Final reliability test of original construct

Dimension	Item	Cronbach's Alpha if Item Deleted	Cronbach's Alpha	No of Items
Teamwork Within Unit	A1	0.7	0.79	3
	A3	0.75		
	A4	0.7		
Supervisor expectation and action promoting patient safety	B1	0.6	0.7	3
	B2	0.41		
	B4	0.76		
Organizational Learning	A6	0.54	0.67	3
	A9	0.6		
	A13	0.57		
Feedback and Communication about error	C1	0.6	0.63	3
	C3	0.56		
	C5	0.42		
Frequency of event reporting	D1	0.82	0.84	3
	D2	0.71		
	D3	0.82		
Teamwork across unit	F4		0.64	2
	F10			
Staffing	A2	0.61	0.66	3
	A5	0.49		
	A14	0.59		
Hands off and transition	F3	0.74	0.73	4
	F5	0.61		
	F7	0.65		
	F11	0.69		

Table 4.9: Factor loadings of the hypothetical construct of HSOPSC-Bahasa Melayu version following Exploratory Factor Analysis (EFA)

Item	AA1	AA2	AA3	AA4	AA5	BB1	CC1	DD1	FF1	FF2
A1	0.75									
A2	0.73									
A3	0.71									
A4	0.65									
A18		0.55								
A13		0.56								
A6		0.58								
A9		0.66								
A15		0.7								
recoded_A8			0.67							
recoded_A12			0.71							
recoded_A16			0.77							
recoded_A10				0.57						
A5				0.65						
recoded_A7				0.79						
recoded_A14					0.49					
recoded_A17					0.62					
A11					0.85					
B1						0.75				
B2						0.85				
recoded_B3						0.6				
recoded_B4						0.71				
C1							0.65			
C2							0.62			
C3							0.64			
C4							0.47			
C5							0.71			
D1								0.85		
D2								0.91		
D3								0.87		

Table 4.9 cont.

Item	AA1	AA2	AA3	AA4	AA5	BB1	CC1	DD1	FF1	FF2
recoded_F11									0.48	
recoded_F3									0.6	
recoded_F5									0.63	
recoded_F6									0.64	
recoded_F7									0.7	
recoded_F9									0.71	
F1										0.65
F10										0.79
F4										0.82

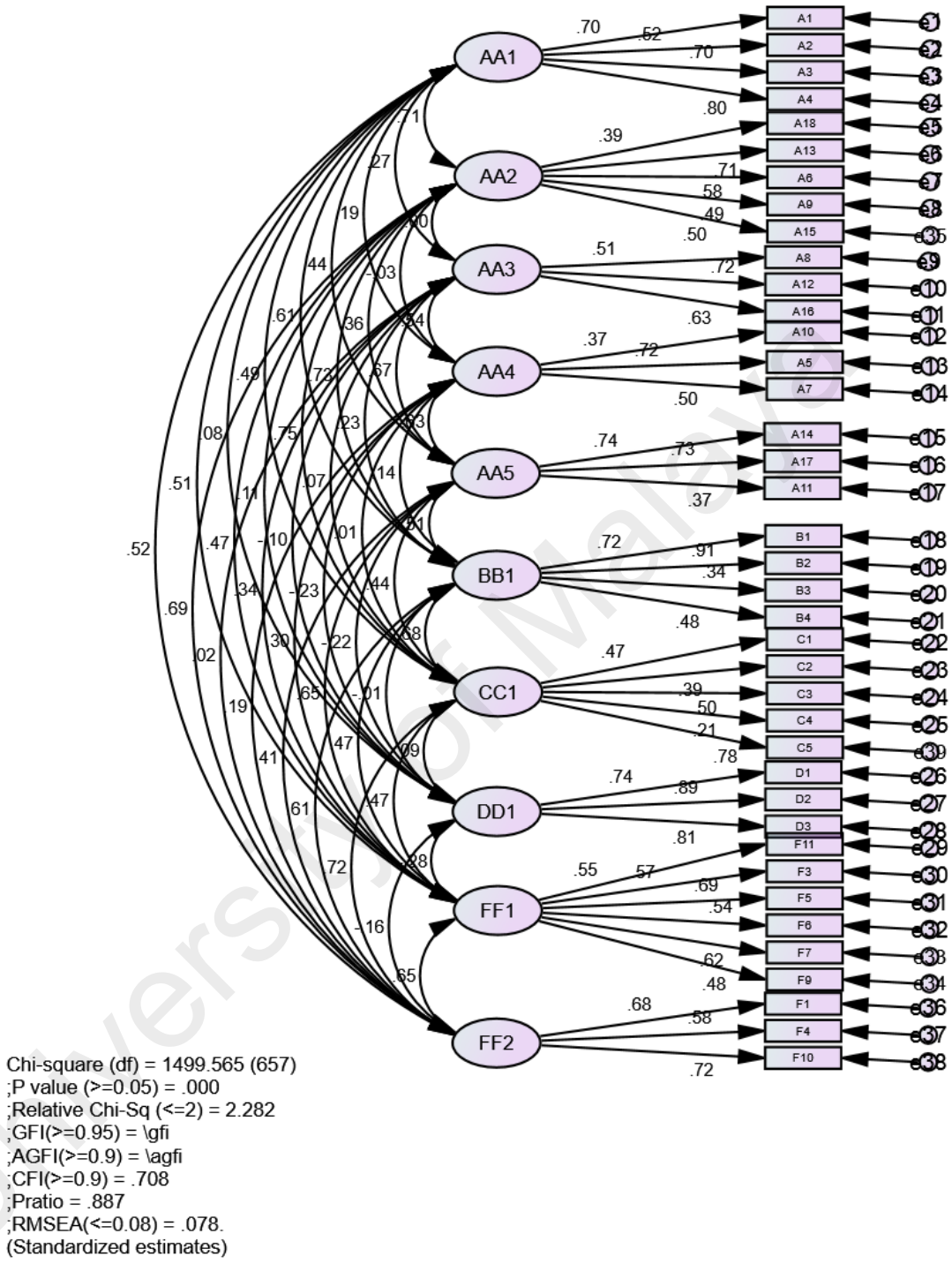

Figure 4.2: Confirmatory Factor Analysis of new factor structure of HSOPSC-BM (Model 1)

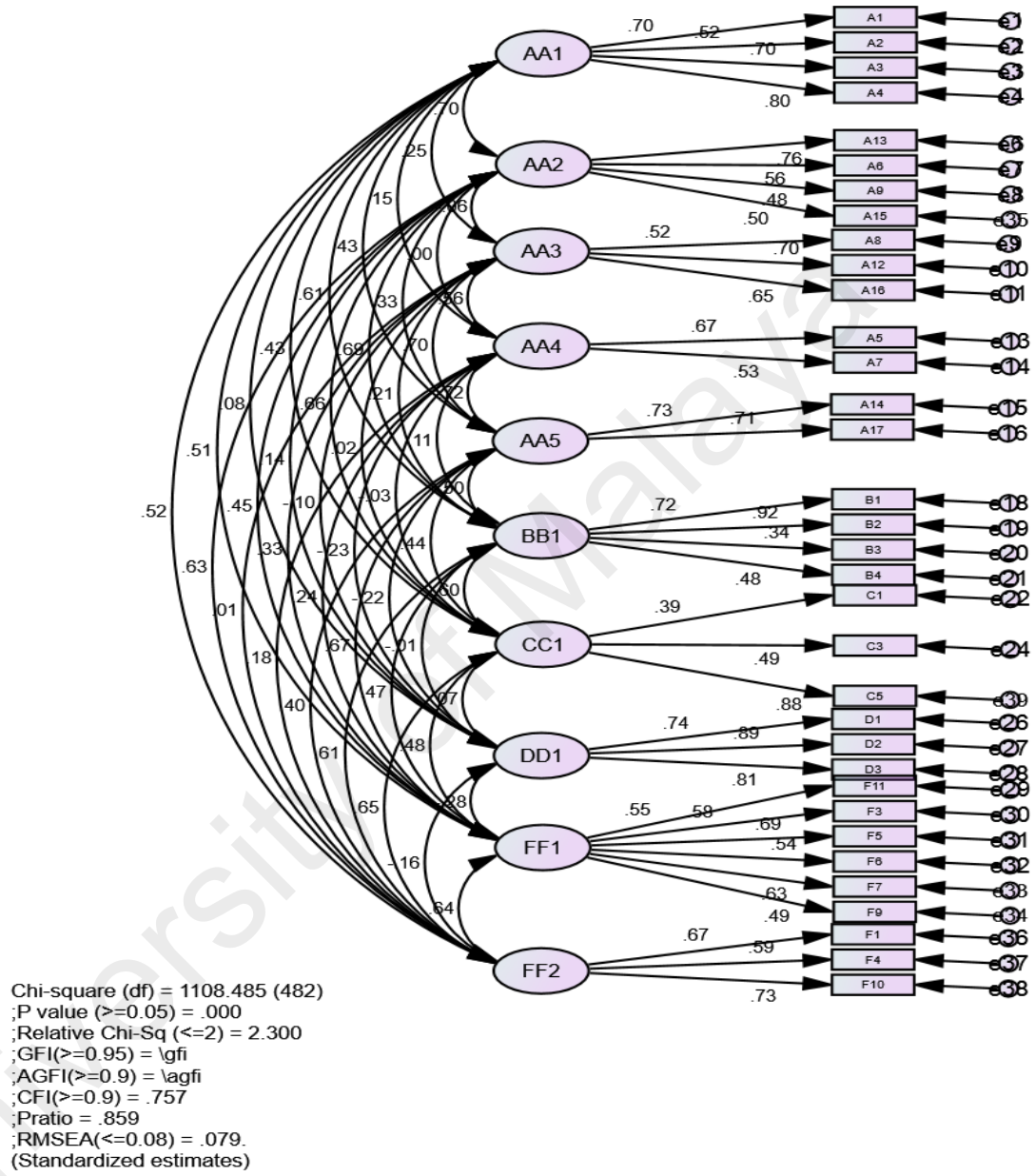

Figure 4.3: Confirmatory Factor Analysis of new factor structure of HSOPSC-BM (Model 2)

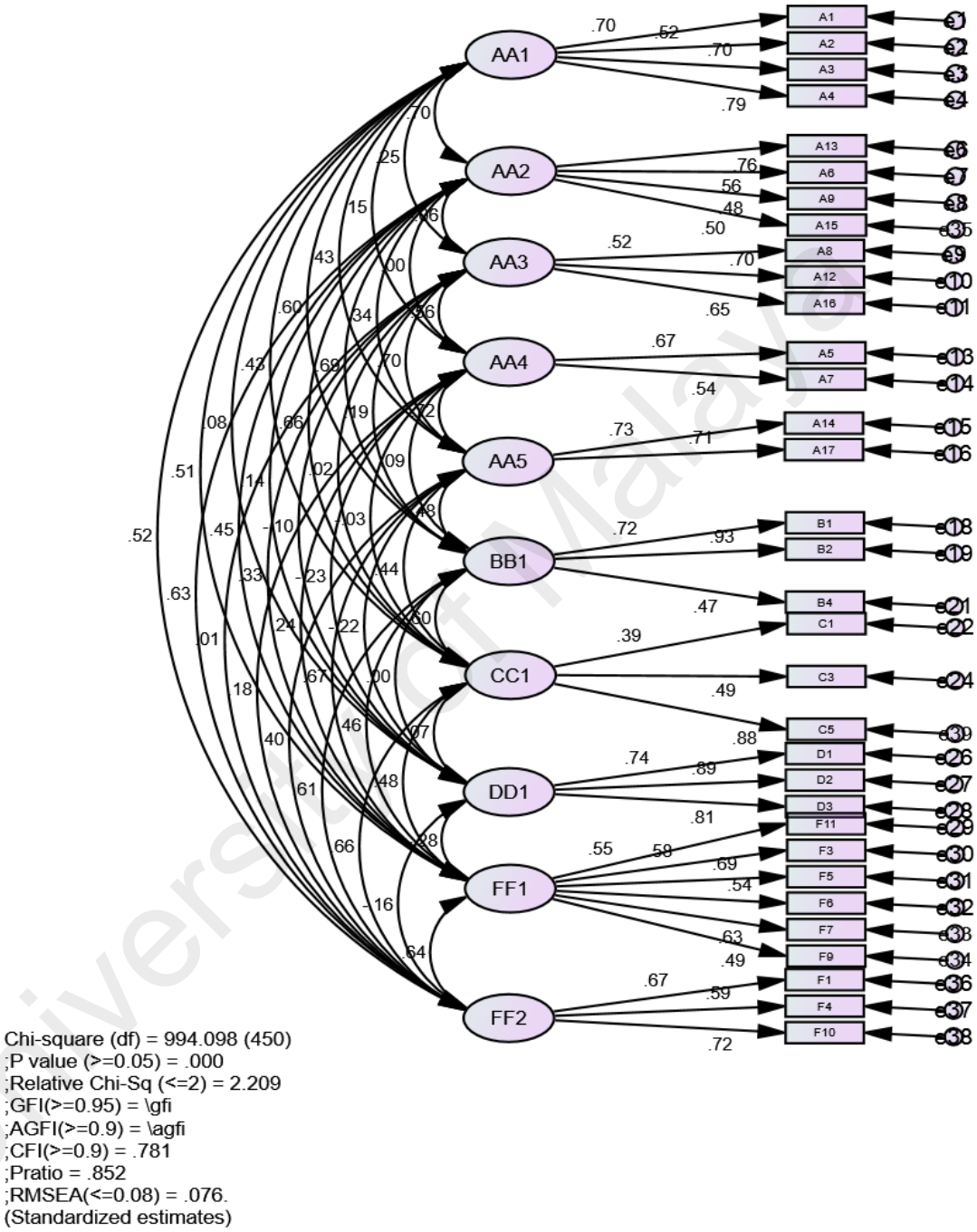

Figure 4.4: Confirmatory Factor Analysis of new factor structure of HSOPSC-BM (Model 3)

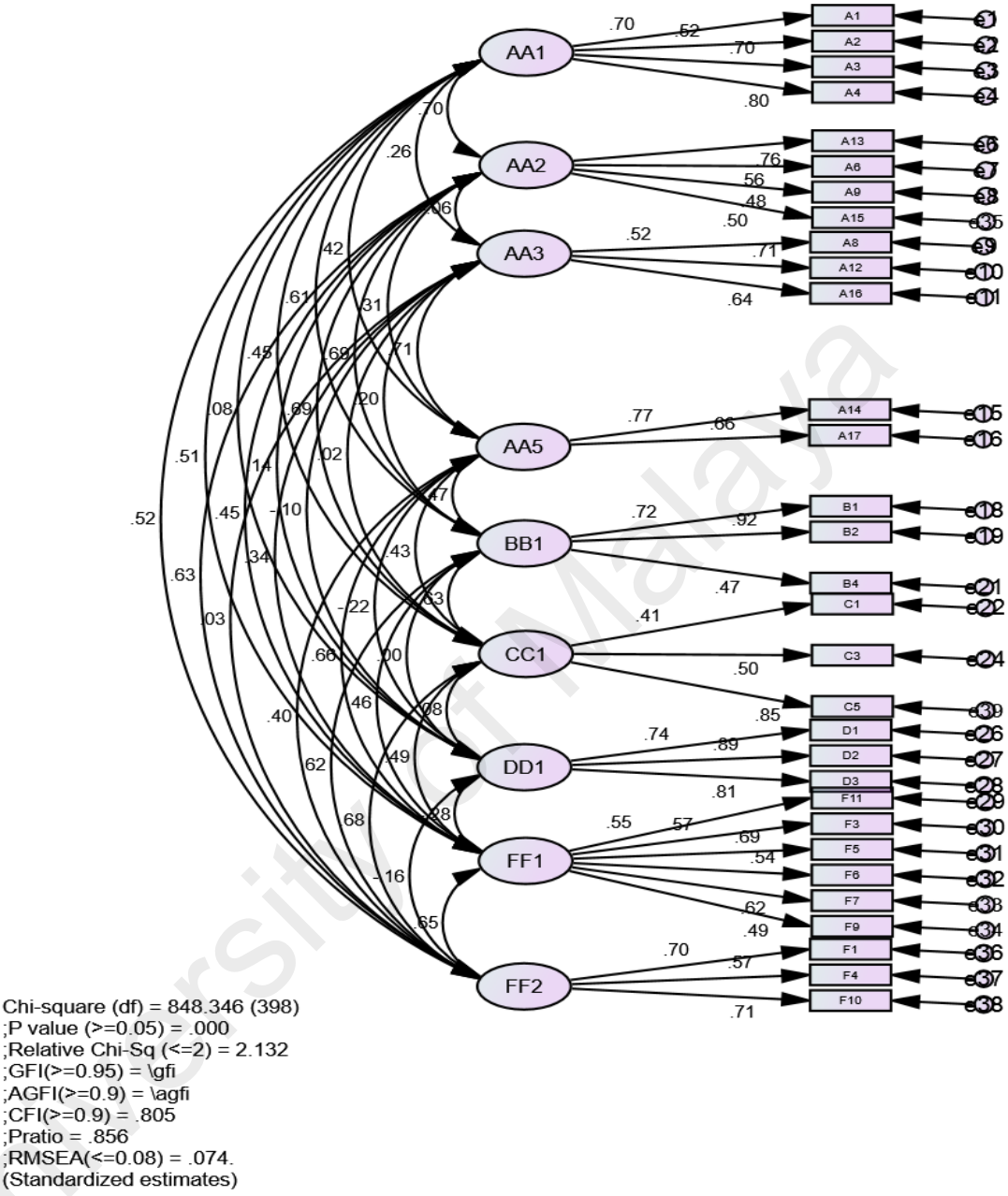

Figure 4.5: Confirmatory Factor Analysis of new factor structure of HSOPSC-BM (Model 4)

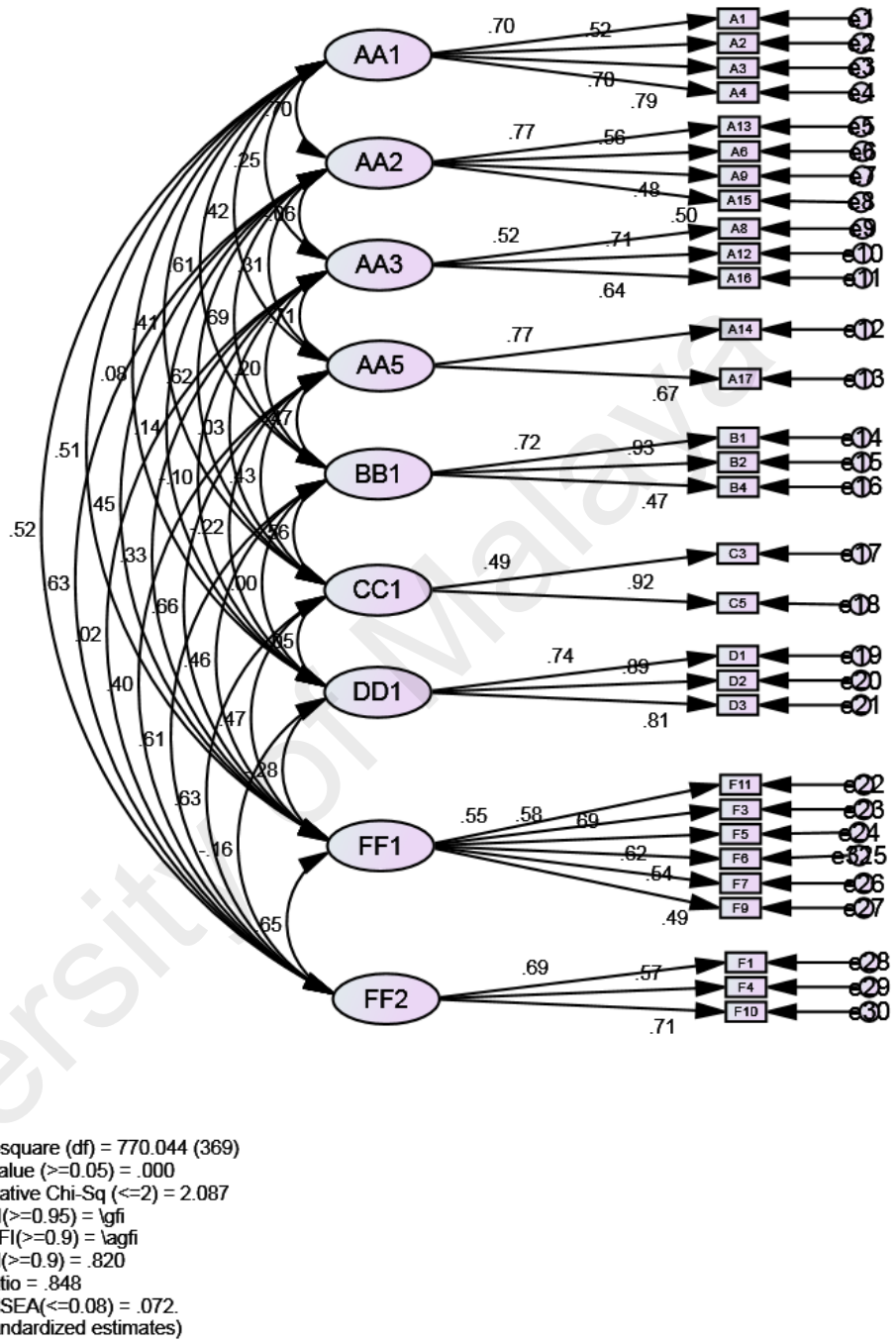

Figure 4.6: Confirmatory Factor Analysis of new factor structure of HSOPSC-*BM* (Final model).

Table 4.10: Summary of Goodness of fit model comparing from initial to the final model

Model	Chi-Sq. (Df)	p Value	Relative Chi-Sq.	CFI	P-ratio	RMSEA	Dimension	Items
1	1499.56(657)	0.005	2.282	0.708	0.887	0.078	10	39
2	1108.49(482)	0.005	2.3	0.757	0.859	0.079	10	34
3	994.1(450)	0.005	2.209	0.781	0.852	0.076	10	33
4	848.35(398)	0.005	2.132	0.805	0.856	0.074	9	31
5	770.04(369)	0.005	2.087	0.82	0.848	0.072	9	30

Table 4.11: Final items, dimensions, and reliability of the final hypothetical construct of the HSOPSC-BM

Hypothetical Dimension	Name of Dimensions	Items	Factor Loadings	Cronbach's Alpha
Aa1	TWU	A1	0.7	0.77
		A2	0.52	
		A3	0.7	
		A4	0.8	
AA2	OL	A13	0.8	0.7
		A6	0.6	
		A9	0.5	
		A15	0.5	
AA3	NPE	A8	0.52	0.7
		A12	0.7	
		A16	0.64	
AA4	OPPS	A14	0.8	0.7
		A17	0.7	
B	SEAPPS	B1	0.7	0.7
		B2	0.9	
		B4	0.5	
C	FCE	C3	0.5	0.6
		C5	0.9	
	FER	D1	0.74	0.85
		D2	0.9	
		D3	0.81	

Table 4.11 cont.

	Name of Dimensions	Items	Factor Loadings	Cronbach's Alpha
F1	HNT	F11	0.55	0.75
		F3	0.6	
		F5	0.6	
		F6	0.62	
		F7	0.64	
		F9	0.5	
F2	TAU	F1	0.7	0.75
		F4	0.6	
		F10	0.71	
	9	30		0.88

Legend: TWU-Teamwork Within Unit, OL- Organizational Learning, NPE- Non Punitive Response to Error, OPPS – Overall Perception on Patient Safety, SEAPPS – Supervisor Expectation and Action in Promoting Patient Safety, FCE- Feedback and Communication about Error, FER – Frequency of Event Reporting, HNT- Hands Off and Transition, TAU –Teamwork Across Unit

Repetitive testing of the construct was done to enable the researcher to come out with the optimized factor structure. It was only successful after the fifth attempt where the final construct was established (Table 4.6). The results of the model of fit must be seen as a whole and together with the reliability testing. Hence, the value of Cronbach's Alpha as a measure of internal consistencies was used for reliability testing. A value of more than 0.6 is used as the lower limit (Sorra & Dyer, 2010). Items with the lower value were dropped to enhance the findings. Finally only 9 dimensions and 30 items are left.The overall internal consistency of the new construct is 0.88 which is considered good. All except for one dimension achieve the Cronbach's Alpha value of less than 0.6 (feedback and communication about errors) (Table 4.9)

Table 4.12: Inter-dimensional correlation analysis matrix of the final construct of HSOPSC-BM

Correlations									
	TAU	TWU	HNT	FER	NPE	FCE	OL	SEAPPS	OPPS
TAU	1								
TWU	.270**	1							
HNT	.198**	.657**	1						
FER	.062	-.130**	-145**	1					
NPE	.139**	.091*	.163**	.006	1				
FCE	.222**	.386**	.239**	.042	.009	1			
OL	.345**	.412**	.189**	.010	-.172**	.392**	1		
SEAPPS	.386**	.326**	.260**	.006	.069	.365**	.379**	1	
OPPS	.200**	.216**	.341**	-,070	.368**	.161**	.004	.353**	1

****. Correlation Is Significant at the 0.01 Level (2-Tailed).**
***. Correlation Is Significant at the 0.05 Level (2-Tailed)**

The correlations using Pearson's Correlation are used to determine that the dimensions correlated to each other. Among these dimensions, the highest correlation is seen between 'Teamwork within unit' and 'Organizational learning' while 'Overall perception of patient safety' and 'Organizational learning' showed the lowest correlation. No dimension is highly correlated with each other in the questionnaire.

4.2 Phase 2: The Evaluation of Patient Safety Culture in Public Hospitals in Malaysia: A Multi-Centre Assessment Using the Hospital Survey on Patient Safety Culture-Bahasa Melayu Version (HSOPSC-BM)

In this phase, the survey used the Malay version of the HSOPSC tool which is validated in Phase 1. A final total of 9 dimensions with 30 items were included in the final validated tool. Since the factor analysis resulted in a redistribution of the items, all the items were renamed accordingly to avoid preventable confusion during the analysis.

All the analysis was conducted after the necessary pre-analysis workout. After receiving the completed questionnaires, a pre-processing step was applied to remove incomplete or invalid data (Hellings, Schrooten, Klazinga, & Vleugels, 2007). Validation of responses was done by the researcher by face validation. Each questionnaire was checked. When there was no entire section completed; fewer than half items answered; or all the items answered the same the questionnaire is discarded. The negatively worded items were recoded accordingly. All the dimensions were categorized and presented with the Likert Score. A composite score was created for all the dimensions to reflect the true Patient Safety Culture score.

4.2.1 Demographic characteristics

Table 4.13 represents a summary of the demographic characteristics of the participants in this part of the study. A total of 625 questionnaires were considered valid for further analysis from a total of 700 questionnaires delivered (about 89% response rate). Generally, the distribution of participants in each hospital was followed as proposed. Based on Table 4.11, the percentages of participants from the State Hospital is 40.2%, the District

Hospital with Specialties (major) is 32.8%, the District Hospital with Specialties (minor) is 15.7%, and the District Hospital without Specialties contributes 11.4%. This distribution is considered appropriate compared to the quota sampling proposed earlier in the study which are 40%, 30%, 20% and 10% respectively. Of all the participants, the registered nurses contribute 45.4% which reflects their considerable presence in the public hospitals. The group is followed by the pharmacists (17.3%), medical officers (15.0%), assistant medical officers (12.8%) and therapists (9.4%). The majority of the participants are diploma holders as it is the minimum entry requirement to the healthcare service for registered nurses, assistant medical officers and rehabilitation therapists in Malaysia.

Almost half of the participants are of the age that is less than 30 years old (47.7%), and the Malays represent 82.9% of the population with reference to ethnicity. From the demographic findings, it is noted that 71.5% of the participants are female, and they have 5 years of working experience or less which contribute to 50.8% of the overall population. In terms of working hours per week, the majority of the staff claims that they work more than 40 hours per week. However, comparing the result of this study (using HSOPSC-BM) to the original version is considered unacceptable because of the derangement of the items in the tool.

Table 4.14 on page 143 represents the positive response rate for all the items in the HSOPSC-BM and the mean scores of each dimension of the tool. The results of all the dimensions varied between 92.8% to as low as 4.3%. Among all the items, the item coded as 2d (previously as A15R), 'Patient safety is never sacrificed to get more work done' from the dimension of "Organizational Learning-Continuous improvement" (OL) scores the highest with 92.8%. On the other hand, item 3a 'Staff feel like their mistakes are held

against them' from the dimension of "Non-Punitive Response to Error" (NPE) scores the lowest with a score of 4.3%.

Table 4.13 Distribution of participants according to socio-demographic and work-related factors (n=625)

Variables		N	(%)
Type of hospital	State hospital	251	40.2
	District hospital with specialties (major)	205	32.8
	District hospital with specialties (minor)	98	15.7
	District hospital without specialties	71	11.4
Profession	Registered nurse	284	45.4
	Assistant medical officer	80	12.8
	Medical officers	94	15
	Pharmacist	108	17.3
	Rehabilitation Therapist	59	9.4
Education level	Diploma	420	67.2
	Degree	189	30.2
	Advanced degree	16	2.6
Age	30 years old and below	298	47.7
	31-40 years old	206	33
	41-50 years old	100	16
	Above 50 years old	21	3.4
Ethnicity	Malay	518	82.9
	Chinese	75	12
	Indian	32	5.1
Gender	Female	447	71.5
	Male	178	28.5
Years of experience	Less than 1 year	60	9.7
	1-5 years	255	41.1
	6-10 years	139	22.4
	11-15 years	70	11.3
	16-20 years	51	8.2
	More than 21 years	46	7.4
Working hours per week	Less than 20 hours	4	0.6
	20-39 hours	71	11.4
	40-59 hours	443	71.1
	60-79 hours	70	11.2
	80-99 hours	28	4.5
	100 hours or more	7	1.1

"Organizational Learning-Continuous improvement" (OL) scored the highest mean score (87.8%) and "Non-Punitive Response to Error" (NPE) score the lowest among all the dimensions with 17.43%. For the dimensional mean score, a score of more than 75% is

considered as a strength, scores between 50% to 75% is considered as having room for improvement whilst a score of less than 50% is considered a weakness in the organization.

Table 4.14 Positive response rate of each item and average of the positive response of each dimension (N=625)

Dimensions	Item	Description	Positive response (%)	Average of positive response (%)
Teamwork Within Unit	A1	People support one another in this unit	83.04	
	A2	We have enough staff to handle the workload	23.44	
	A3	When a lot of work needs to be done quickly, we work together as a team to get the work done	79.68	
	A4	In this unit, people treat each other with respect	78.21	66.15
Organizational Learning	A6	We are actively doing things to improve patient safety	88.78	
	A9	Mistakes have led to positive changes here	85.6	
	A13	After we make changes to improve patient safety, we evaluate their effectiveness	83.49	
	A15R	Patient safety is never sacrificed to get more work done	92.79	87.8
Non-Punitive Response to Error	A8R	Staff feel like their mistakes are held against them	4.33	
	A12R	When an event is reported, it feels like the person is being written up, not the problem	41.64	
	A16R	Staff worry that mistakes they make are kept in their personnel file	5.95	17.43
Overall Perception on Patient Safety	A14R	We work in "crisis mode" trying to do too much, too quickly	38.04	
	A17R	We have patient safety problems in this unit	57.28	47.6
Supervisor Expectation and Action Promoting Patient Safety	B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	66.35	
	B2	My supervisor/manager seriously considers staff suggestions for improving patient safety	78.21	
	B4R	My supervisor/manager overlooks patient safety problems that happen over and over	84.3	76.23
Feedback and Communication on Error	C3	We are informed about errors that happen in this unit	58.33	
	C5	In this unit, we discuss ways to prevent errors from happening again	70.63	64.65
Frequency of Event Reporting	D1	When a mistake is made but is caught and corrected before affecting the patient, how often is this reported?	24.56	
	D2	When a mistake is made but has no potential to harm the patient, how often is this reported?	22.15	
.				
	D3	When a mistake is made that could harm the patient, but does not, how often is this reported?	28.46	25.1

Table 4.14 cont.

Dimensions	Item	Description	Positive response (%)	Average of positive response (%)
Hands Off and Transition	F3R	Things "fall between the cracks" when transferring patients from one unit to another	46.62	
	F5R	Important patient care information is often lost during shift changes	59.94	
	F6R	It is often unpleasant to work with staff from other hospital units	51.77	
	F7R	Problems often occur in the exchange of information across hospital units	47.6	
	F9R	Hospital management seems interested in patient safety only after an adverse event happens	23.04	
	F11R	Shift changes are problematic for patients in this hospital	59.16	48.03
Teamwork Across Unit	F1	Hospital management provides a work climate that promotes patient safety	63.62	
	F4	There is good cooperation among hospital units that need to work together	70.35	
	F10	Hospital units work well together to provide the best care for patients	75.12	69.7

Apart from "Organizational Learning", "Supervisor Expectation and Action Promoting Patient Safety" scores 76.23% and identified as a strength whilst others such as "Teamwork within Unit" (66.15%), "Teamwork Across Unit" (69.7%) and "Feedback and Communication on Error" (64.65%), score more than 50%. Hence, they considered as areas that need improvements. Four dimensions score less than 50% which are "Hands Off and Transition" (HNT), "Overall Perception on Patient Safety" (OPPS), "Frequency of Event Reporting" (FER) and "Non-Punitive Response to Error" (NPE) with scores of 48.03%, 47.6%, 25.1% and 17.43% respectively and they are considered as a serious weakness of the organization (Table 4.14).

4.2.2 Single item Outcome Dimensions

The majority of the participants (55.6%) grade their hospital as acceptable in terms of patient safety grade. Only 2.3% of them grade their hospitals as excellent and very good. The rest (42.1%) claim their hospitals as having a poor grade and failing in patient safety grade (Table 4.15). It is documented that more than half of the participants declare that they have never reported any incident reporting for the past one year of their service (56.6%). About 32.3% of them report 1 to 2 incident reporting for the past one year whilst another 10.9% of them report more than 2 reports per year.

Table 4.15 Patient Safety Grade as perceived by participants (N=625)

Grades	N	%
Excellence	3	0.5
Very good	11	1.8
Acceptable	346	55.6
Poor	234	37.6
Failing	28	4.5

4.2.3 Patient Safety Culture Dimensions

The mean patient safety score from each dimension were used to compare demographic characteristics of participants, namely the type of hospitals, age, ethnicity, profession, years of experience and education level. A p-value of less than 0.05 was used as the cut off point for a statistically significant result. Table 4.16 on page 146-147 showed the mean patient safety score of each item and dimensions in HSOPSC BM, Out of the 9 dimensions in HSOPSC-BM, 6 show significant results when the p-value is less than 0.05. The dimensions are “Organizational Learning”, “Overall Perception on Patient Safety”, “Supervisor Expectation and Action in Promoting Patient Safety”, “Frequency of Event Reporting”, “Hands Off and Transition” and “Teamwork Across Unit”.

Two items scored the lowest which were item A8R with a score as low as 2.13±0.72 and item A16R with a score of 2.15±0.80. Two of the dimensions "Organizational Learning" (OL) and "Supervisor Expectation and Action in Promoting Patient Safety" (SEAPPS) scored high with the mean±SD of 4.05±0.43 and 3.87±0.57 respectively. "Frequency of Event Reporting" and "Non-Punitive Response to Error" are among those with the lowest mean±SD with 2.69 ±0.88 and 2.44±0.6 respectively.

Table 4.16 Mean Patient Safety Score of each item and dimension in HSOPSC-BM (N=625)

Dimensions (Means ± SD)	Item	Description	Mean	SD
Teamwork Within Unit (3.63 ±0.53)	A1	People support one another in this unit	4.00	0.67
	A2	We have enough staff to handle the workload	2.67	0.98
	A3	When a lot of work needs to be done quickly, we work together as a team to get the work done	3.92	0.69
	A4	In this unit, people treat each other with respect	3.92	0.68
Organizational Learning (4.05 ± 0.43)*	A6	We are actively doing things to improve patient safety	4.06	0.61
	A9	Mistakes have led to positive changes here	4.02	0.67
	A13	After we make changes to improve patient safety, we evaluate their effectiveness	3.95	0.58
	A15R	Patient safety is never sacrificed to get more work done	4.18	0.63
Non Punitive Response to Error (2.44 ± 0.6)	A8R	Staff feel like their mistakes are held against them	2.13	0.72
	A12R	When an event is reported, it feels like the person is being written up, not the problem	3.03	1.07
	A16R	Staff worry that mistakes they make are kept in their personnel file	2.15	0.80
Overall Perception on Patient Safety (3.24 ± 0.88)	A14R	We work in "crisis mode" trying to do too much, too quickly	3.00	1.09
	A17R	We have patient safety problems in this unit	3.48	1.07

Table 4.16 cont

Dimensions (Means ± SD)	Item	Description	Mean	SD
Supervisor Expectation and Action Promoting Patient Safety (3.87 ± 0.57)*	B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	3.68	0.72
	B2	My supervisor/manager seriously considers staff suggestions for improving patient safety	3.83	0.65
	B4R	My supervisor/manager overlooks patient safety problems that happen over and over	4.08	0.84
Feedback and Communication on Error (3.61 ± 0.67)	C3	We are informed about errors that happen in this unit	3.50	0.82
	C5	In this unit, we discuss ways to prevent errors from happening again	3.73	0.76
Frequency of Event Reporting (2.69 ± 0.88)*	D1	When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	2.70	0.99
	D2	When a mistake is made, but has no potential to harm the patient, how often is this reported?	2.70	0.99
	D3	When a mistake is made that could harm the patient, but does not, how often is this reported?	2.66	1.14
Hands Off and Transition (3.36 ± 0.5)*	F3R	Things "fall between the cracks" when transferring patients from one unit to another	3.33	0.98
	F5R	Important patient care information is often lost during shift changes	3.64	0.98
	F6R	It is often unpleasant to work with staff from other hospital units	3.64	0.98
	F7R	Problems often occur in the exchange of information across hospital units	3.36	0.92
	F9R	Hospital management seems interested in patient safety only after an adverse event happens	2.69	1.06
	F11R	Shift changes are problematic for patients in this hospital	3.66	0.94
Teamwork Across Unit (3.77 ± 0.56)*	F1	Hospital management provides a work climate that promotes patient safety	3.63	0.75
	F4	There is good cooperation among hospital units that need to work together	3.77	0.73
	F10	Hospital units work well together to provide the best care for patients	3.91	0.73

* statistically significant at $p<0.05$

4.2.3 Patient safety dimension scores according to demographic and work-related factors

As patient safety can be determined by various factors, analysis of patient safety dimensions in relation to demographic and work related factors were done using mean and SD. District Hospital With Specialties (minor) showed higher scores in dimensions of Organizational Learning, Hands Off and Transition whereas State Hospital showed highest score in Frequency of Event Reporting (see Table 4.17) .analysis of dimensional mean patient safety score for other factors were also analysed. Table 4.18 on page 146 showed that female staff scored higher than males with significant findings in dimensions such as Organizational Learning (4.1±0.42), Supervisor Expectation And Action Promoting Patient Safety(3.93±0.55) , Feedback And Communication On Error (3.65±0.66) , Hands Off And Transition (3.41±0.50) and Teamwork Cross Unit (3.83±0.50).

Table 4.17: Mean patient safety score dimensions at different levels of hospitals (N=625)

Dimensions	State Hospital	District Hospital with Specialties (Major)	District Hospital with Specialties (Minor)	District Hospital Without Specialties
Teamwork within unit	3.56 ±0.48	3.67 ±0.55	3.65 ±0.6	3.72 ±0.57
Organizational learning*	4.01±0.41	4.02 ± 0.44	4.17 ±0.44	4.12 ±0.45
Non punitive response to error	2.47 ± 0.56	2.42 ± 0.62	2.5 ± 0.65	2.28 ± 0.64
Overall perception on patient safety	3.11 ± 0.89	3.26 ± 0.81	3.38 ± 0.89	3.42 ± 0.98
Supervisor expectation and action promoting patient safety*	3.81 ±0.55	3.84 ± 0.58	3.97 ± 0.53	3.99 ± 0.60
Feedback and communication on error	3.67 ± 0.65	3.61 ± 0.67	3.53 ± 0.66	3.52 ±0.75
Frequency of event reporting*	2.77 ± 0.93	2.73 ± 0.8	2.54 ± 0.92	2.45 ± 0.82
Hands off and transition*	3.31 ± 0.45	3.31 ±0.49	3.51 ±0.57	3.51 ± 0.51
Teamwork cross unit*	3.66 ± 0.51	3.78 ± 0.55	3.98 ± 0.57	3.83 ± 0.64

*Statistically significant at $p<0.05$

Table 4.18 Mean Score of Patient Safety Dimensions according to gender

	Gender	(Mean±SD)
Dimension	Female	Male
Teamwork within unit	3.64±0.53)	3.59±0.5
Organizational learning*	4.1±0.42	3.95±0.44
Non punitive response to error	2.42±0.60	2.49±0.62
Overall perception on patient safety	3.25±0.90	3.19±0.83
Supervisor expectation and action promoting PS*	3.93±0.55	3.7±0.58
Feedback and communication on error*	3.65±0.66	3.51±0.68
Frequency of event reporting	2.66±0.90	2.74±0.83
Hands off and transition*	3.41±0.50	3.24±0.470
Teamwork cross unit*	3.83±0.50	3.62±0.55

*Statistically significant at $p<0.05$

In an analysis of mean patient safety score according to profession, it was found that registered nurses scored highest in the dimensions of Organizational Learning, Supervisor Expectation and Action Promoting Patient Safety and Teamwork Across Unit. The lowest

score was from the dimension of Frequency of Event Reporting. However, in this dimension, pharmacists and medical officers are among profession practising better event reporting compared to other professions (Table 4.19 on page 148).

Table 4.19 Mean score of patient safety dimension according to profession

Dimension	Profession (Mean±SD)				
	Registered Nurses	Assistant Medical Officer	Rehab Therapist	Medical Officer	Pharmacist
Teamwork within unit	3.66	3.69	3.52	3.62	3.56
Organizational learning*	4.17	3.98	4.03	3.97	3.91
Non punitive response to error*	2.31	2.36	2.45	2.8	2.52
Overall perception on patient safety	3.18	3.28	3.53	3.28	3.16
Supervisor expectation and action promoting patient safety*	3.99	3.75	3.62	3.99	3.64
Feedback and communication on error*	3.67	3.51	3.43	3.75	3.5
Frequency of event reporting*	2.58	2.54	2.31	2.98	3.02
Hands off and transition*	3.54	3.3	3.22	3.29	3.09
Teamwork cross unit*	3.89	3.74	3.77	3.62	3.6

*Statistically significant at $p<0.05$

Table 4.20 Mean score of patient safety dimensions according to age group

Dimension	Age (Mean±SD)			
	<30 y.o	31-40y.o	41-50 y.o	51-60 y.o
Teamwork within unit	3.58±0.53	3.66±0.58	3.66±0.44	3.75±0.54
Organizational learning*	3.99±0.42	4.10±0.42	4.14±0.43	4.07±0.59
Non punitive response to error	2.47±0.61	2.38±0.58	2.46±0.58	2.49±0.82
Overall perception on patient safety	3.22±0.83	3.25±0.95	3.24±0.93	3.31±0.83
Supervisor expectation and action promoting patient safety*	3.80±0.57	3.90±0.57	4.02±0.49	3.76±0.66
Feedback and communication on error	3.58±0.65	3.61±0.71	3.73±0.60	3.45±0.77
Frequency of event reporting	2.72±0.87	2.59±0.90	2.78±0.88	2.75±0.92
Hands off and transition*	3.30±0.51	3.41±0.48	3.43±0.46	3.41±0.58
Teamwork across unit*	3.71±0.54	3.77±0.56	3.91±0.54	3.98±0.71

Statistically significant at $p<0.05$; y.o = year old

Staff in the age group between 41-50 years old scored highest in patient safety dimensions of Organizational Learning (4.14±0.43), Supervisor Expectation and Action in Promoting Patient Safety (4.02±0.49) and Hands Off and Transition(3.43±0.46) On the other hand, staff in age group of more than 50 years old scored highest in Teamwork Across Unit. (3.98±0.71) (Table 4.20)

4.2.4 Comparing the mean patient safety score according to the demographic characteristics and other factors.

Later, a mean score of all dimensions was computed to come out with a single value. In Analaysis of variance (ANOVA), a descriptive analysis when comparing the mean patient safety score with the demographic data is presented as mean±SD. District Hospitals with Specialties' (major) score is slightly higher than the State Hospital (3.42±0.30 from 3.40±0.30). The best score is obtained by the District Hospital with Specialties (minor)

(3.50±0.34) followed by the District Hospital Without Specialties (3.47±0.36). In terms of profession, the pharmacists show the lowest mean of PS (n=108, 3.33±0.30) compared to registered nurses (n=284,3.49±0.32). As the largest group of according to profession, the registered nurses have the highest mean among the professions It is observed in this study that the staff within the range of 41-50 years old and those who have been working for more than 21 years have better mean patient safety score compared to other groups with 3.51±0.30 (n=100) and 3.53±0.32 (n=46) respectively. Mean Patient Safety Score is statistically significant for different levels of hospitals $F(3,621)=3.175$ ($p<0.05$) (Table 4.21 on page 153). Comparison between the mean patient safety score (revised) and socio-demographic and work-related factors reveal that there are differences depicted when comparing the types of hospital, profession, age and years of experience (Table 4.22 on page 154)

Tukey post hoc test analysis reveals that the differences between the State Hospital and District Hospital with Specialties (minor) is statistically significant, but no other group differences are statistically significant (Table 4.23 on page 155-156). The same analysis shows that there is a statistically significant difference ($p<0.05$) between groups differences that lies between pairwise comparison in terms of profession between the registered nurses, assistant medical officers, rehabilitation therapists and pharmacists, as well as between the medical officers, pharmacists and rehabilitation therapists. The pairwise Tukey post hoc test show a statistically significant difference that lied between the age of less than 30 years old and the age group between 41-50 years old. Similarly, there is also a statistically significant difference when pairwise comparison between mean patient safety score and

years of experience in staff with less than 1 year of experience, and staff with 21 years and more of experience.

Table 4.21 Differences in mean patient safety score (revised) according to socio-demographic and work-related factors

	N	Mean	SD	95% Confidence Interval for Mean	
				Lower Bound	Upper Bound
Types of hospital					
State Hospital	251	3.40	0.30	3.36	3.43
District Hospital with Specialties (Major)	205	3.42	0.30	3.38	3.46
District Hospital with Specialties (Minor)	98	3.50	0.34	3.44	3.57
District Hospital Without Specialties	71	3.47	0.36	3.38	3.55
Profession					
Registered Nurses	284	3.49	0.31	3.45	3.52
Assistant Medical Officer	80	3.37	0.34	3.30	3.45
Rehabilitation Therapists	59	3.33	0.30	3.25	3.41
Medical Officer	94	3.48	0.28	3.42	3.53
Pharmacist	108	3.34	0.30	3.28	3.39
Education level					
Diploma	420	3.44	0.33	3.41	3.47
First Degree	189	3.40	0.30	3.36	3.44
Advanced Degree	16	3.44	0.17	3.35	3.52
Ethnic Group					
Malay	516	3.44	0.33	3.41	3.47
Chinese	75	3.37	0.27	3.31	3.44
Indian	33	3.43	0.22	3.35	3.51
Age Group					
Less than 30 years old	298	3.39	0.30	3.36	3.43
31-40 years old	206	3.44	0.34	3.39	3.48
41-50 years old	100	3.51	0.30	3.45	3.57
more than 50 years old	21	3.47	0.33	3.32	3.63
Years of Experience					
less than 1 year	60	3.33	0.36	3.24	3.43
1-5 years	255	3.40	0.30	3.36	3.43
6-10 years	139	3.45	0.31	3.40	3.50
11-15 years	70	3.48	0.35	3.40	3.56
16-20 years	51	3.49	0.30	3.41	3.58
More than 21 years	46	3.53	0.32	3.41	3.62

Table 4.22: Differences of mean patient safety score (revised) in each socio demographic and work-related factors (N=625)

Mean Patient Safety Score and dimension	Sum of Squares	Df	Mean Square	F
Patient Safety Score and Hospital Type				
Between Groups	0.942	3	0.31	3.18*
Within Groups	61.44	621	0.1	
Total	62.38	624		
Patient Safety Score and Profession				
Between Groups	2.91	4	0.73	7.57*
Within Groups	59.47	620	0.1	
Total	62.38	624		
Patient Safety Score and Education Level				
Between Groups	0.26	2	0.13	1.31
Within Groups	62.12	622	0.1	
Total	62.38	624		
Patient Safety Score and Age				
Between Groups	1.09	3	0.36	3.69*
Within Groups	61.29	621	0.1	
Total	62.38	624		
Patient Safety Score and Ethnicity				
Between Groups	0.28	2	0.14	1.38
Within Groups	62.1	621	0.1	
Total	62.38	623		
Patient Safety Score and Experience				
Between Groups	1.77	5	0.36	3.62*
Within Groups	60.21	615	0.1	
Total	61.99	620		

*statistically significance $p<0.05$

Table 4.23: Pairwise comparison among socio-demographic and work-related variables (Tukey Post Hoc Test) (N=625)

		Mean Difference	Std Error	95% Confidence Interval	
				Lower Bound	Upper Bound
TYPE OF HOSPITAL					
State Hospital	District Hospital with specialties (Major)	-.026	.030	.102	.050
	District Hospital with specialties (minor)	-.109*	.037	.205	-.012
	District Hospital (without specialties	-.070	.042	.179	.039
District Hospital with specialties (major)	District Hospital with specialties (minor)	-.083	.038	.182	.017
	District Hospital (without specialties	-.045	.043	.156	.067
District Hospital with specialties (minor)	District Hospital (without specialties)	.038	.049	.088	.164
PROFESSION					
Registered Nurses	Assistant Medical Officer	.111*	.039	.004	.219
	Rehabilitation Therapist	.157*	.044	.036	.279
	Medical officer	.010	.037	.091	.110
	Pharmacist	.150*	.035	.055	.246
Assistant Medical Officer	Rehabilitation Therapist	.046	.053	.099	.191
	Medical officer	-.102	.047	.231	.027
	Pharmacist	.039	.046	.086	.164
Rehabilitation Therapist	Medical officer	-.148*	.051	.289	.007
	Pharmacist	-.007	.050	.144	.130
Medical officer	Pharmacist	.141*	.044	.021	.260
EDUCATION LEVEL					
Diploma	Degree	.045	.028	.020	.110
	Advance Degree	.008	.081	.182	.197
Degree	Advance Degree	-.037	.082	.231	.156
ETHNICITY					
Malay	Chinese	.065	.039	.027	.157
	Indian	.008	.057	.125	.142
Chinese	Indian	-.057	.066	.212	.098

Table 4.23 cont

		Mean Difference	Std Error	95% Confidence Interval	
AGE RANGE					
Less than 30 years old	31-40 years old	-.041	.028	.115	.032
	41-50 years old	-.117*	.036	.211	-.024
	more than 50 years old	-.081	.071	.263	.102
31-40 years old	41-50 years old	-.076	.038	.174	.023
	more than 50 years old	-.039	.072	.225	.146
41-50 years old	more than 50 years old	.037	.075	.158	.231
YEARS OF EXPERIENCE					
less than 1 year	1-5 years	-.063	.045	.192	.065
	6-10 years	-.120	.048	.258	.019
	11-15 years	-.148	.055	.305	.010
	16-20 years	-.160	.060	.331	.010
	more than 20 years	-.197*	.061	.373	-.022
1-5 years	6-10 years	-.056	.033	.151	.038
	11-15 years	-.084	.042	.205	.036
	16-20 years	-.097	.048	.234	.040
	more than 20 years	-.134	.050	.278	.009
6-10 years	11-15 years	-.028	.046	.159	.103
	16-20 years	-.041	.051	.187	.106
	more than 20 years	-.078	.053	.230	.074
11-15 years	16-20 years	-.013	.058	.177	.152
	more than 20 years	-.050	.059	.220	.120
16-20 years	more than 20 years	-.037	.064	.219	.145

*Statistically significant at $p < 0.05$

4.2.5 Factors influencing patient safety score and incident reporting (Multivariate Analysis)

A further investigation of the relationship between the dependent and independent variables using regression analysis was conducted. The continuous dependent variable (mean patient safety score (revised) which was a continuous variable was tested against the independent variables using multiple linear regression. Later, the revised mean patient safety score was further categorized into 2 categories, namely high and low score. Logistic regression (binomial logistic regression) was used to assess the relationship between the independent variables and the score grade. The other dependent variable was the number of incident reporting reported in the past 12 months which was subcategorised into 3 categories (no report, 1-2 reports and 3 and more reports). The analysis was done using the multinomial logistic regression to see if there was any relationship between the dependent variables with the independent variables.

4.2.5.1 Multiple Linear Regression

A multiple linear regression was run to predict the patient safety score towards factors such as age, ethnicity, years of experience, gender, hospital type, professions, and education level. Before a regression analysis could proceed, it is important to meet the assumptions set in multiple linear regressions. The initial two assumptions were easily met which required the dependent variables to be continuous and independent and can be of continuous or categorical variables. Durbin-Watson statistics which shows the presence of independence of residuals gave a reading of 1.807 which is near to 2 indicating that there is no correlation between the residuals. A linear relationship between the dependent and independent variables are shown by the scatter plot. A collective linear relationship is

shown by the unstudentized predicted (PRE) chart vs. the studentized residuals (SRE). Apart from identifying linearity, the scatter plot can also detect homoscedasticity. It simply means that the plots exhibit no specific pattern and approximately constantly spread. Proof of homoscedasticity in this analysis fulfill the fifth assumption of multiple linear regressions. As none of the correlation exceeds 0.85 and the tolerance is more than 0.1, it is deduced that there is no problem with multi-collinearity in the data which settles the sixth assumptions of multi-collinearity. There are no studentized deleted residuals greater than ±3 standard deviations, no leverage values greater than 0.2, and values for Cook's distance that are above 1.0. The assumption of normality is met, as assessed by a curved histogram and P-P Plot.

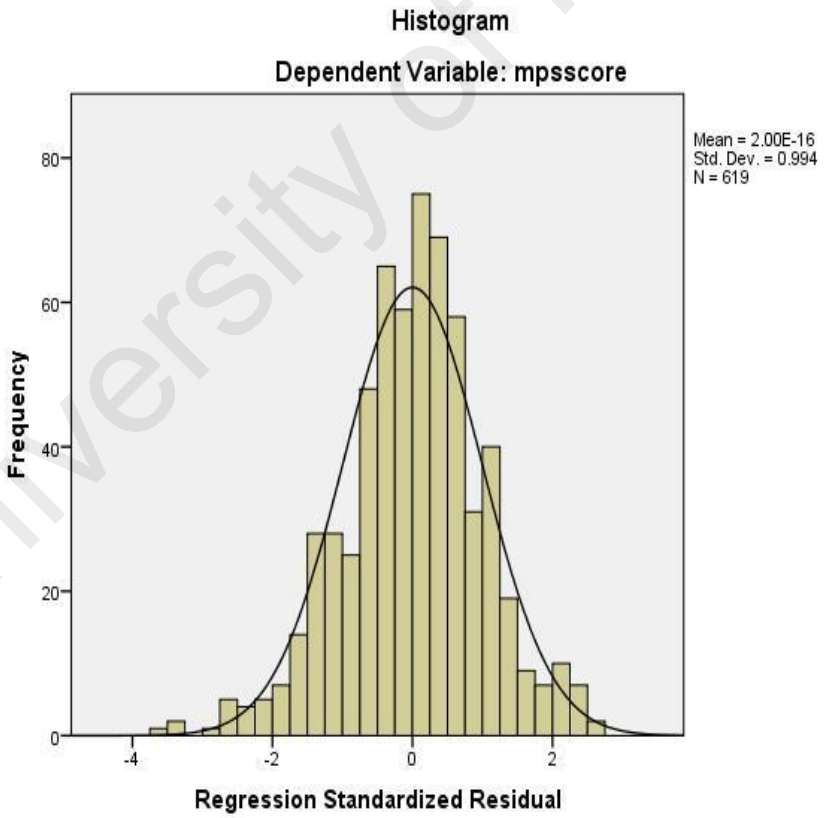

Figure 4.7: Histogram with normal curve showing normally distributed data between Standardized residuals and frequency

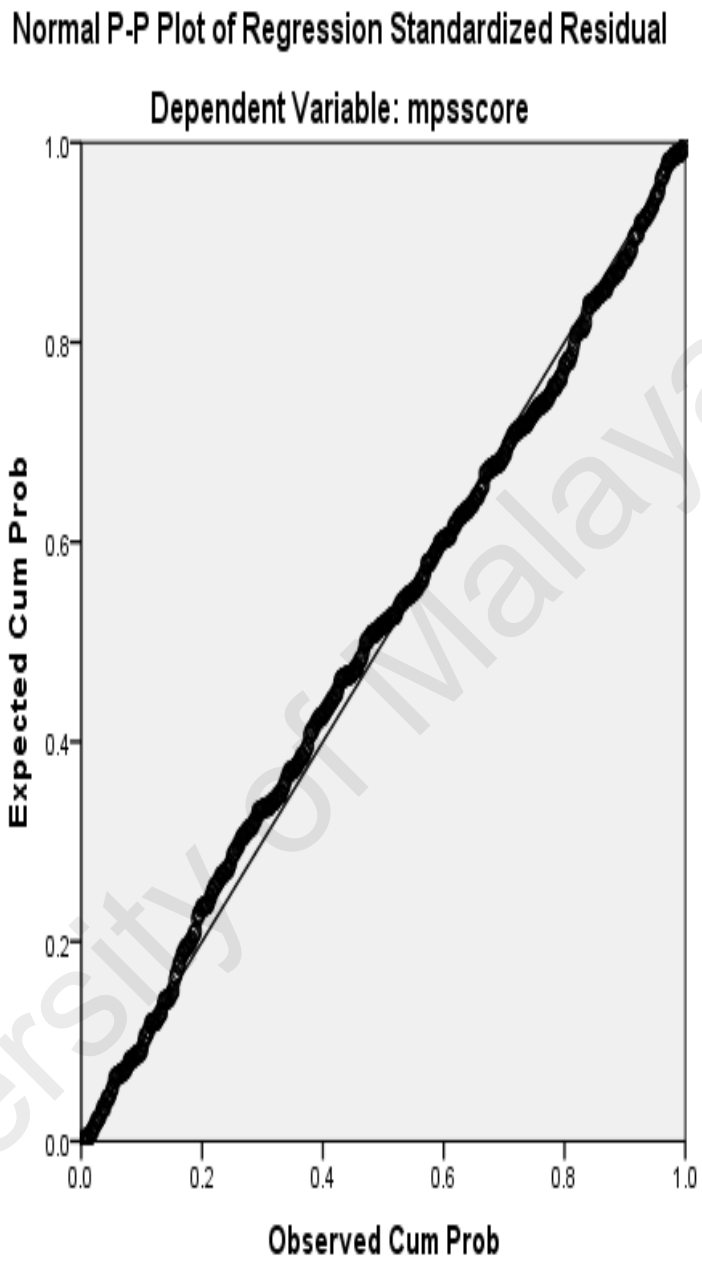

Figure 4.8: A P-P plot between observed and expected axis showing a linear relationship

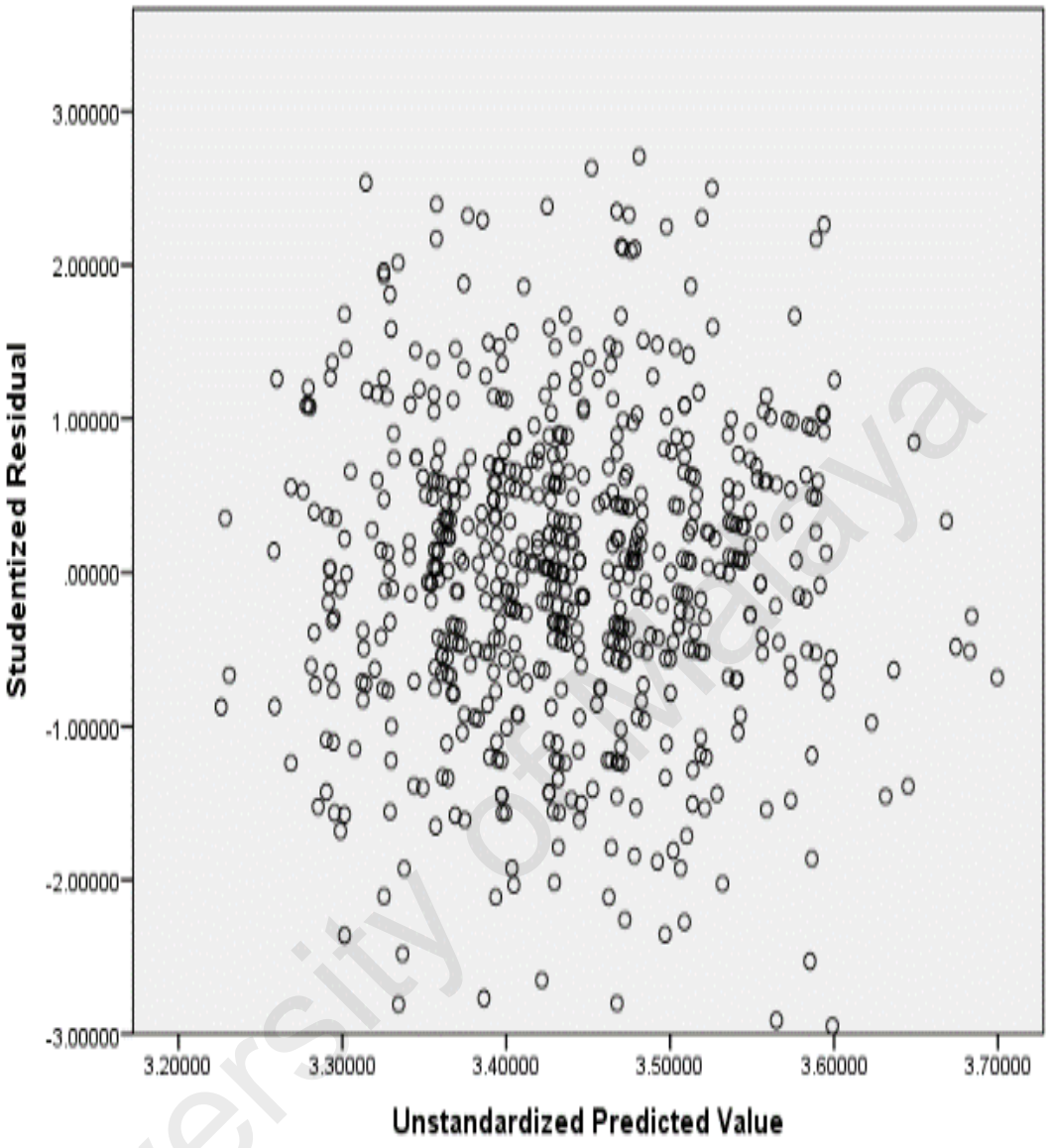

Figure 4.9: A horizontally distributed residuals between independent and dependent variables suggesting a linear relationship between these two variables.

A multiple linear regression model was calculated to predict the patient safety score based on socio-demographic and work-related independent variables namely the type of hospitals, profession, education level, age, ethnicity, gender and years of experience. Based on the univariate analysis of each variable (Table 4.18), it has already been mentioned that when the patient safety score has regressed with independent variables, only

hospital type, profession, age, gender and years of experience show that there is at least one of the categories in the variables that shows a significant difference with the other categories. However, all the independent variables are included in the multivariate analysis since all of them are considered important in determining the patient safety score.

All categorical variables were dummy-coded to allow the analysis using multiple linear regressions to be conducted. All the variables have been tested in terms of the dependent variable namely the patient safety score. In this analysis, a stepwise regression analysis was adopted (see Table 4.19). From the model summary in the stepwise regression technique, the variable 'Registered Nurse' was entered first, followed by variables of age, Medical Officer, State Hospital, and gender. All the other independent variables are excluded from the analysis.

The first variable illustrates 3.4% of variation in the patient safety score. As the second variable was entered, about 2% addition to the variation is observed in the patient safety score. Finally, as the 4th modelling was approached, the variation increases to 8.8% of the variation. The p-value for the change is 0.001, and the Adjusted R square is 8.2 %. The Durbin-Watson statistics is 2.163 which is near to 2.00.

Table 4.24: The relationship between Mean Patient Safety Score and independent variables in a step-wise regression (N=625)

Variables entered in step wise manner		Unstandardized Coefficients		Standardized Coefficients	95% Confidence Interval for B		Collinearity Statistics	
		B	Std. Error	Beta	Lower Bound	Upper Bound	Tolerance	VIF
Model 1	(Constant)	3.34	.020		3.35	3.42		
	Registered Nurse	.11	.024	.18**	0.07	.16	1.00	1.00
Model 2	(Constant)	3.22	.051		3.12	3.32		
	Registered Nurse	.10	.025	.15**	.05	.14	.95	1.05
	Age	.01	.00	.14**	.002	.008	.954	1.049
Model 3	(Constant)	3.18	.05		3.076	3.279		
	Registered Nurse	.13	.03	.21**	.078	.182	.822	1.217
	Age	.01	.00	.14**	.003	.008	.953	1.049
	Medical Officer	.13	.04	.15**	.058	.199	.851	1.174
Model 4	(Constant)	3.19	.05		3.085	3.286		
	Registered Nurse	.12	.03	.20**	.073	.176	.818	1.222
	Age	.01	.00	.17**	.003	.009	.926	1.080
	Medical Officer	.13	.04	.15**	.057	.197	.851	1.175
	State Hospital	-.08	.02	-.13**	-.128	-.032	.971	1.030

**statistically signifant at p<0.01

From the model summary, an R^2 value of 8.8 % with an adjusted R2 of 8.2 %, a statistically significant regression equation was found with probability score F (4,614)=14.832 ($p<0.05$). In the final model, only four variables are included namely Registered Nurse, Medical Officer, age and State Hospital. An equation of 3.185 + 0.124 (Registered Nurse) + 0.006 (Age) + 0.127 (Medical Officer) – 0.080 (State Hospital) were constructed upon completing the analysis.

There was no multi-collinearity noted from the variance inflation factors (VIF) value as all value were less than 5. In addition, no residuals falls more than ± 3.00 and is supported by the residual plots with all the plots were in random distribution. The assumption of normality is met by observation of curved histogram. Using the GLM Univariate procedure, the State Hospital partial eta squared is 0.33 (>0.15), and the power

is 91.2% (>80%). Similarly, all the parameters tested for effect size in this modelling showed each partial eta squared of less than 0.15 and power of more than 80%.

4.2.5.2 Binomial Logistic Regression (Logistic Regression)

In binomial logistic regression, the mean patient safety score (revised) is categorized into 2 groups. Score less than 3.0 were considered as having low patient safety score. Alternatively, the scores of 3 and more are considered as having high patient safety score. ("LeapFrog Hospital Safety Grade: Explanation on Patient Safety Grades," 2017). The low score is made as the reference category, and the demographic characteristics are tested against the patient safety score.

In order to proceed with this test, there are seven assumptions that needed to be met. Firstly, the dependent variable must be dichotomous. The second assumption requires the independent variable to be either continuous or nominal in nature. As applied to the study dataset, the first two assumptions are easily met. There is independence of observation in the conduct of the study and both dependent, and independent variables were both exclusive and exhaustive. The next assumption is met by the large sample size in this study. A minimum requirement of 15 samples per independent categories is a prerequisite in this assumption. In this part of the analysis, the continuous variable (age) is treated as the nominal variable to precisely identify which group is associated with higher patient safety score. Therefore, the test for linearity was skipped in this analysis. The other two assumptions would be presented later in the interpretation of results. The Hosmer and Lemeshow goodness of fit test shows a non-statistically significant result of 0.687 indicating that the model is a good fitting model.

Univariate binomial analysis preceded the multivariate analysis to determine the variables to be selected for the multivariate analysis. According to Hosmer-Lemeshow, the

variables with a p-value of less than 0.250 can be considered for the multivariate analysis although variables that have higher values can also be reconsidered for further analysis.

Table 4.25: Predicted score of each independent variable towards Mean Patient Safety Score (revised) in Univariate Analysis (N=620)

			95% C.I. for EXP(B)	
	OR	Sig.	Lower	Upper
HOSPITAL		.95		
State Hospital	1.04	.94	.43	2.51
District Hospital with specialties (Major)	1.21	.69	.48	3.05
District Hospital with specialties (Minor)	1.23	.70	.43	3.57
District Hospital without Specialties (constant)	9.14	.00		
PROFESSION		.01		
Registered Nurses	2.53	.01	1.22	5.27
Assistant Medical Officer	0.83	.65	.37	1.86
Rehabilitation Therapist	1.20	.71	.46	3.13
Medical Officer	3.63	.03	1.16	11.40
Pharmacist (constant)	6.20	.00		
EDUCATION				
Diploma	1.06	.85	.59	1.90
Degree/Advanced degree (constant)	9.79	.00		
AGE RANGE		.54		
Less than 30 years old	1.74	.40	.48	6.31
31-40 Years old	1.47	.56	.40	5.40
41-50 years old	2.61	.20	.60	11.41
More than 50 years old (constant)	6.00	.00		
ETHNICITY		.51		
Malay	.31	.25	.04	2.28
Chinese	.30	.27	.040	2.57
Indian (constant).	32.00	.00		
GENDER				
Male	.38	.00	.22	.66
Female (constant)	14.48	.00		
EXPERIENCE				
Less than 1 year	.31	.09	.08	1.19
1-5 years	.74	.64	.21	2.58
6-10 years	.90	.88	.24	3.42
11-15 years	.74	.69	.18	3.14
16-20 years	1.12	.90	.21	5.83
More than 20 years (constant)	14.33	.00		

From the univariate analysis, only profession, gender, and experience show a p-value of less than 0.25. Therefore, those variables are compulsory to be included in the multivariate analysis. This finding is supported by findings from the cross-tabulation to identify the significant variables related to patient safety score (see Table 4.22). However,

in this study, all the variables were treated as potential covariates to determine the patient safety score. Thus, all of them were included in the next analysis.

Table 4.26: Initial identification of relevant variables to be included in the multivariate analysis of mean patient safety score (revised) (N=620)

Variables	X^2	Df	P	Decision
Hospital	1.08[a]	3	.78	Excluded
Profession	21.86[a]	4	.00	Included
Education	.58[a]	2	.75	Excluded
Age Range	2.64[a]	3	.45	Excluded
Ethnicity	1.93[a]	2	.38	Excluded
Gender	46.99[a]	1	.00	Included
Experience	17.07[a]	5	.00	Included

A binomial logistic regression (multivariate) was performed to assess the relationship between the independent variables (the type of hospital, profession, gender, age, ethnicity, education level and years of experience) and a dichotomous dependent variable (Mean Patient Safety Score revised). Continuous variable in this analysis (age) was treated as a nominal variable hence the test for linearity was omitted. All the outliers and residuals were treated accordingly, and at the point of analysis, no residuals were included. The logistic regression model is statistically significant with a χ^2 (20) = 36.694, $p<0.05$. The model explains 12.4% (Nagelkerke R^2) of the variance in patient safety score and correctly classifies 91.1% of the cases. Of the seven variables, only three exhibit significant relationship in predicting the patient safety score. Medical officers are 4.87 times higher odds than the other professions with the [OR 4.87 (CI 95% 1.31, 18.15,

p<0.05)]. There is also a relationship between the age of staff in predicting the patient safety practice. It was noted that staff who are aged within 41-50 years are 7 times more likely to practice patient safety in a hospital with an OR of [7.24 (CI 95% 1.04,50.47, p<0.05)]. On the other hand, staff with less than 1 year of experience are 98% less likely to practice safety culture compared to other experienced staff with [OR 0.12 (CI 95% 0.02, 0.93, p<0.05)].

4.2.5.3 Relationship between the number of incident reporting with socio-demographic and work-related factors.

The next analysis examined the relationship between socio-demographic and work-related factors in determining the practice of incident reporting. The dependent variable (number of incident reporting) is initially a multiple responses variable (5 responses) which is then collapsed into 3 responses to optimize the number of responses per category in the variable.

Table 4.28 on page 168 illustrates the distribution of responses in the actual categories. It is clearly documented that more than half of staff do not report any event in the past year. Only about 10% of staff report 3 or more incident reporting which contributed to about 10% of total staff. About 30% of the staff claimed to report 1-2 reports in the past 12 months of the year.

Table 4.27: Prediction of Socio-demographic and work-related factors on mean patient safety score (revised) in multivariate analysis (N=620)

	Adjusted OR	Sig	95% CI Lower	95% CI Upper
Hospital				
State Hospital	.96	.93	.37	2.46
District Hospital with specialties (Major)	1.51	.43	.54	4.17
District Hospital with specialties (Minor)	1.03	.96	.33	3.22
District Hospital without specialties	Ref			
Profession				
Registered Nurses	3.11	.32	.34	28.36
Medical Assistant	1.49	.73	.16	13.61
Rehabilitation Therapist	1.94	.57	.20	18.97
Medical Officer	4.87	.02	1.31	18.15
Pharmacist	Ref			
Education				
Diploma	.79	.83	.10	6.44
Degree/Advanced degree	Ref			
Age Range		.10		
Less than 30 years old	7.18	.06	.95	54.57
31-40 Years old	3.86	.18	.55	27.26
41-50 years old	7.24	.05	1.04	50.47
More than 50 years old	Ref			
Ethnicity				
Malay	.24	.18	.03	1.96
Chinese	.42	.43	.04	3.73
Indian	Ref			
Gender				
Male	.50	.07	.231	1.06
Female	Ref			
Experience				
Less than 1 year	.12	.04	.015	.93
1-5 years	.24	.15	.034	1.70
6-10 years	.54	.54	.077	3.85
11-15 years	.32	.28	.042	2.53
16-20 years	.38	.36	.048	3.05
More than 20 years	Ref			
Constant	15.25	.04		

*p<0.05, Nagelkerke R^2 0.124 , Reference category : Last category

Table 4.28: Description on number of incidents reported in last 12 months [N=625]

Number of reports	N	%
No incident reporting	352	56.6
1-2 incident reporting	201	32.3
3 -5 incident reporting	55	8.8
6-10 incident reporting	5	0.8
11- 20 incident reporting	5	0.8
21 or more incident reporting	3	0.5

Table 4.29: Description of number of events reported according to socio-demographic and work-related factors (N=625)

Variable	No report (%) (n = 352)	1-2 report (%) (n=256)	>3 reports (%) (n=13)
Hospital (mean ± SD)	2.11 ± 1.02	1.84 ± 0.95	1.54 ± 0.97
State Hospital	33.8	47.3	69.2
District Hospital with Specialties (major)	34.4	31.3	15.4
District Hospital with Specialties (minor)	19	11.7	7.7
District Hospital without Specialties	12.8	9.8	7.7
Profession (mean ± SD)	2.41 ± 1.55	2.45 ± 1.60	3.38 ±1.88
Registered Nurse	44.6	47.7	30.8
Assistant Medical Officer	14.2	11.3	7.7
Rehabilitation Therapist	13.9	3.9	0.1
Medical Officer	9.7	22.3	15.4
Pharmacist	17.6	14.8	46.2
Education (mean ± SD)	1.28 ± 0.46	1.42 ± 0.59	1.77 ± (0.73)
Diploma	71.9	62.9	38.5
First Degree	27.8	32	46.2
Advanced degree	0.3	5.1	15.4
Age range (mean ± SD)	1.64 ±7.64	1.80 ± (0.90)	2.02 ± (1.12)
Less than 30 years old	52	43.4	15.4
31-40 years old	33.2	72.4	38.5
41 -50 years old	13.4	19.5	15.4
> 50 years old	1.4	4.7	30.8
Ethnicity (mean ± SD)	1.22 ±0.52	1.22 ± 0.52	1.46 ± 0.66
Malay	83.2	82.8	61.5
Chinese	11.4	12.1	30.8
Indian	5.1	5.1	7.7

Table 4.29 cont.

Variable	No report (%) (n = 352)	1-2 report (%) (n=256)	>3 reports (%) (n=13)
Gender (mean ± SD)	0.71 ± 0.46	0.70 ± 0.44	0.69 ± 0.48
Male	29.3	25.8	30.8
Female	70.7	74.2	69.2
Experience (mean ± SD)	2.73 ± 1.24	3.08 ± 1.49	4.0 ± 1.63
Less than 1 year	11.1	7.8	0.1
1-5 years	42.6	39.5	23.1
6-10 years	22.4	21.9	23.1
11-15 years	13.1	8.2	15.4
16 -20 years	6.3	10.9	7.7
More than 20 years	4.0	10.9	30.8

Before further analysis can proceed, a simple analysis was conducted to identify the variables that can potentially to be included in the next analysis. Using the likelihood ratio test, several variables have been depicted to have a statistically significant chi-square value thus indicating the potential variables in the multivariate analysis (Table 4.30). Those variables are the types of hospital, profession, education level, age and years of experience. These findings are supported in the univariate multinomial regression as it shows similar findings (Table 4.29). It was decided that all the variables will be included in the next analysis

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Table 4.30 Identification of significant variables to be included in the multivariate analysis (N=620)

	Likelihood Ratio Tests	
Variables	Chi-Square	Df
Hospital	18.18*	6
Profession	42.67*	8
Education	25.98*	4
Age	26.71*	6
Ethnic	3.41	2
Gender	0.95	2
Years of Experience	28.96*	10

Reference category: no report. *p<0.05, **p<0.01 level of significance

The Pearson chi-square significant level is 0.568 which shows that the model fits the data well. In the univariate analysis, the number of events are reported as the dependent variable, it is noted that there is a statistically significant finding related to the type of hospital. It is found that the State Hospital is 1.83 times more likely to report 1-2 reporting per year compared to the District Hospital Without Specialists (reference category) with [OR of 1.830, CI 95% (1.055,3.174)]. Medical Officers are 2.74 times more likely to report 1-2 incidents reporting in the past 12 months compared to the reference category (pharmacist) with [OR 2.735, CI 95% (1.522,4.915)]. Rehabilitation therapists, on the other hand, are 0.33 times less likely to report 1-2 incidents compared to the reference group, [OR 0.333, CI 95% (0.151,0.734)]. In the reporting of 3 or more categories, the registered nurses are 0.26 times less likely to report 3 or more incidents per 12 months compared to the pharmacists with [OR 0.263, CI 95% (0.072,0.965)]. Generally, when the age group and years of experience are compared, the younger age group and lack of experience and practice are linked to incident reporting (see Table 4.31 on page 171). All pseudo R^2 value in each category are very small.

Table 4.31: Univariate analysis in predicting the relationship between variables and the number of incidents reported in 12 months (N=620)

Variables	Number of IR 1-2 report vs. No report OR (95% CI)	Number of IR 3 or more reports vs. No report OR (95% CI)	Nagelkerke pseudo R^2
Hospital type			0.04
State Hospital	1.83 (1.06,3.17)*	3.40 (0.42,27.63)	
District Hospital with specialties (Major)	1.19 (0.68,2.09)	0.74(0.07,8.40)	
District Hospital with specialties (Minor)	0.80 (0.42,1.55)	0.67 (0.04,11.02)	
District Hospital without Specialties (constant)	1.0	1.0	
Profession			0.09
Registered Nurse	1.27 (0.79,2.02)	0.26 (0.07,0.97)*	
Assistant Medical Officer	0.94 (0.51,1.74)	0.21 (0.02,1.77)	
Rehabilitation Therapist	0.33 (0.15,0.73)**	1.27 (1.27,1.27)	
Medical Officer	2.74 (1.52,4.92)**	0.61 (0.12,3.18)	
Pharmacist (constant)	1.0	1.0	
Education level			0.5
Diploma	0.05 (0.01,0.38)*	0.01 (0.00,0.13)*	
Degree	0.06 (0.01,0.50)	0.03 (0.00, 0.39)*	
Advance degree (constant)	1.0	1.0	
Age			0.05
Less than 30 years old	0.25 (0.09,0.74)*	0.01 (0.00, 0.09)	
31-40 years old	0.30 (0.10,0.87)*	0.05 (0.01, 0.26)	
41-50 years old	0.44 (0.14, 1.35)	0.05 (0.01,80.37)	
>50 years old (constant)	1.0	1.0	
Ethnicity			
Malay	1.00 (0.48,2.09)	0.49 (0.06, 4.15)	0.1
Chinese	1.07 (0.46,2.52)	1.80 (0.19,17.26)	
Indian (constant)	1.0	1.0	
Gender			0
Male	0.84 (0.59,1.21)	1.07 (0.32,3.577)	
Female (constant)	1.0	1.0	
Years of experience			0.04
Less than 1 year	0.26 (0.11,0.60)*	6.09 (6.09,6.09)	
1-5 years	0.34 (0.17,0.67)*	0.07 (0.01,0.35)*	
6-10 years	0.35 (0.17,0.75)*	0.13 (0.03, 0.66)*	
11-15 years	0.23 (0.10,0.52)*	0.15(0.030, 0.92)*	
16-20 years	0.64 (0.27,1.49)*	0.16 (0.02, 1.57)	
>20 years (constant)	1.0	1.0	

Statistically significant p<0.05.

Table 4.32: Predicting the number of incident reporting according to socio-demographic and wok related factors in multivariate multinomial regression analysis (N=620)

Variables	Number of Incident Reporting	
	1-2 reports vs no report Adjusted Odds Ratio (95% CI)	3 or more reports vs no report Adjusted Odds Ratio (95% CI)
Intercept		
Hospital type		
State Hospital	1.72 (0.95,3.11)	3.57 (0.34,37.63)
District Hospital with specialties (Major)	1.15 (0.62,2.13)	0.77 (0.05, 12.13)
District Hospital with specialties (Minor)	0.70 (0.35,1.40)	0.85 (0.04,18.91)
District Hospital without specialties	1.0	1.0
Profession		
Registered Nurse	0.84 (0.22,3.18)	0.04 (0.00,2.55)
Assistant Medical Officer	0.58 (0.15,2.31)	0.04 (0.00,2.86)
Rehabilitation Therapist	0.18 (0.04,0.78)*	0.00 (0.00,0.00)
Medical Officer	2.33 (1.23,4.41)*	0.00 (0.00,0.00)
Pharmacist	1.0	1.0
Education level		
Diploma	0.15 (0.01,1.73)	0.00 (0.00,0.00)
Degree	0.12 (0.02,1.03)	0.00 (0.00,0.00)
Advance degree	1.0	1.0
Age range		
Less than 30 years old	0.38 (0.10,1.49)	0.01 (0.00,0.19)
31-40 years old	0.47 (0.13,1.74)	0.03 (0.00,0.63)
41-50 years old	0.51 (0.14,1.79)	0.05 (0.00,0.65)
>50 years old	1.0	1.0
Ethnicity		
Malay	1.70 (0.72,4.04)	1.63 (0.12,21.70)
Chinese	1.45 (0.56,3.77)	1.81 (0.10,33.02)
Indian	1.0	1.0
Gender		
Male	0.95 (0.57,1.56)	0.52 (0.09,3.24)
Female	1.0	1.0
Years of experience		
Less than 1 year	0.42 (0.13,1.29)	0.00 (0.00,0.00)
1-5 years	0.43 (0.16,1.15)	0.88 (0.04,18.00)
6-10 years	0.40 (0.16,1.02)	0.39 (0.02,6.91)
11-15 years	0.23 (0.08,0.61)*	0.71 (0.04,13.37)
16-20 years	0.70 (0.27,1.80)	0.68 (0.03,12.29)
>20 years	1.0	1.0

Reference category: no report, *statistically significant p<0.05. ……Nagelkerke pseudo R2 =0.231

In a further analysis using the multivariate multinomial logistic regression, only the medical officers exhibit higher odds than the other categories [OR 2.33, CI 95% (1.232, 4.410)] in 1-2 reports. Rehabilitation therapists are 0.18 time less likely to practice incident reporting compared to the reference group [OR 0.175, CI 95% (0.040, 0.775)]. Staff with experience between 11-20 years are 0.23 times less likely to practice incident reporting compared to the staff with more than 20 years of experience [OR 0.226, CI 95% (0.084, 0.608)]. No significant finding is depicted in the 3 or more reports category. The pseudo R^2 value is 23.1% which is rather small. Table 4.32 on page 172 showed the prediction for the number of event reporting in the past 12 months according to socio-demographic and work related factors using multivariate multinomial logistic regression.

Finally, a correlation between "Mean Patient Safety Score" and "Number of Events Reported" was tested and sorted according to the type of hospital. Table 4.33 shows that there is a statistically significant positive correlation seen in the State Hospital with Pearson Correlation ($r=0.26$, $N=625$, $p<0.05$).

Table 4.33: Correlation of "Mean Patient Safety Score" and "Number of Events Reported" according to the type of hospitals.

Types of hospitals	Pearson Correlation	p-value
State Hospital	0.26*	0.05
District Hospital with Specialties (major)	0.12	.1
District Hospital with Specialties (minor)	-0.12	.23
District Hospital without Specialties	-0.04	.73

4.2.6 Summary

This chapter presents the result of the study from the validation process of HSOPSC until the use of the validated HSOPSC in Bahasa Melayu among staff in public hospital in Malaysia. A total of nine dimensions and thirty items were constructed in HSOPSC-BM. The validation phase employed a thorough process from translation to psychometric analysis as recommended by AHRQ. The final construct was brought to the second phase in order to assess patient safety culture among staff in public hospitals in Malaysia. In phase 2 study, Registered Nurses scored the highest mean of Composite Patient safety Score followed by Medical Officers, Assistant Medical Officers, Pharmacists and Rehabilitation Therapist. Further, in Tukey Post Hoc Test it was found that the practice of patient safety among registered nurses and medical officers showed no significant difference compared to other profession. In regression analysis for mean patient safety score,

The mean patient safety culture score was further sub divided into 2 to represent low and high score. Binomial Logistic Regression was used to assess the patient safety score. It can be concluded from the findings in univariate analysis that registered nurses and medical officers are more likely to give a better score on patient safety practices. However, in multivariate analysis only medical officers showed significant findings in patient safety culture practice compared to other socio-demographic and work related factors.

In univariate analysis of incident reporting practice state hospital, registered nurses and medical officers are more likely to report 1-2 reports per year compared to other factors. All junior staff are less likely to report incident reporting compared to staff with

more than 20 years of experience. In multivariate analysis only medical officers significantly report 1-2 reporting per year whereas rehabilitation therapists are less likely to report incident compared to other socio-demographic and work-related factors. However, no significant findings noted in 3 or more reports among health care staff. In contrast to 1-2 reporting, 3 or more reporting are less likely being practiced among healthcare staff in reference to the pharmacists.

It is very important to note that patient safety culture is a process involving individuals in the process of care. Medical officers, nurses, assistant medical officers, pharmacists and rehabilitation therapists have their own function and task in ensuring safe care. As noted in the Swiss Cheese Model, error will happen when barriers or defences are passed and become aligned to result in error. Hence it is important to ensure that every single individual involved in the delivery of care to embrace and practice patient safety culture in their daily practice.

CHAPTER 5: DISCUSSION

Chapter 5 discusses the findings that were initially presented in the previous chapter and compared the results of the current study with other studies worldwide. In addition to that, the strengths and limitations in this study are also discussed. The discussions chapter is divided into Phase 1 and Phase 2. This study utilised the Hospital Survey on Patient Safety Culture (HSOPSC) to measure the patient safety culture in Malaysia. The use of HSOPSC in Malaysia was preceded by the assessment of reliability and validity of the tool to determine whether the HSOPSC is an appropriate tool to be used in the context of the Malaysia healthcare system.

5.1 Phase 1: Validity and Reliability of the BM Version of the HSOPSC Questionnaire

Embracing the safety culture environment is probably the most challenging part of improving patient safety where there are too many hurdles and challenges to make such culture a norm. In Malaysia, many programmes concerning patient safety have been implemented by the relevant department in the Health Ministry and the related organisations in the country. Thus, the starting point in the evaluation of patient safety culture in an organization and the country require an appropriate instrument. Not only will it function as an evaluation in the short and long-term by diagnosing the perception of such a culture, it can also be a benchmark for future programmes concerning patient safety.

Given the logistic issues and a considerable number of participants, a self-reporting instrument was the most suitable choice for this study. Despite being a simple method, it is able to capture which important domains of patient safety were employed by the participants. Hospital Survey on Patient Safety Culture (HSOPSC) was finally chosen due

to its extensive use internationally and the fact that it has undergone various validation processes in many countries. To date, about 32 countries had translated and validated the document for use in their own country and there were about 71 countries that reported the use of HSOPSC to measure patient safety culture (Agency for Healthcare Research and Quality, 2014.).

The method of HSOPSC was considered appropriate due to its robustness and the fact that it has been widely used in other countries around the world. Among the countries that had participated in the validation of this tool included United Kingdom, Germany, The Netherlands, China and Palestine (Nie et al., 2013; Pfeiffer & Manser, 2010; Shahenaz Najjar et al., 2013; M. Smits, Christiaans-Dingelhoff, Wagner, Wal, & Groenewegen, 2008; Waterson, Griffiths, Stride, Murphy, & Hignett, 2010). This questionnaire had undergone the process of validation thus it is considered a reliable tool. However, for use in the individual country, it has been recommended that the tool should be revalidated to determine whether it is appropriate and suitable for the local population. This is particularly important even in countries where English is the native language (United States English versus British English). It had been proven in many studies that there are differences in the validity and reliability findings in these countries due to differences in the health care system itself and the perceived meaning of certain terminologies that are specific to each country's cultural context. Therefore, it is considered important for the researcher to proceed with the validation of HSOPSC in this country in consideration of these possible variations (Hedskold et al., 2013b; Waterson et al., 2010).

Even though several studies concerning patient safety had been conducted in Malaysia, to the knowledge of the researcher, this study was the first to conduct a

validation study of HSOPSC and this phase was followed by the application of the validated tool to assess the perception of patient safety in public hospitals in Malaysia. A validation study was conducted in the Johor state in 2015, and based on the result, the researcher decided to conclude that the original HSOPSC is a reliable tool for use in the country (Sandars & Esmail, 2003). However, considering the variations that might occur in different hospitals due to the state's vast geographical area and possible distinct cultural behaviour contributed by the socioeconomic demography, a validation of HSOPSC was deemed appropriate at that point of time. Hence, a proper validation process was conducted in the Pahang state which is the largest state in Peninsular Malaysia. Therefore, in conducting this study, the researcher had applied almost every step recommended by the Agency of Healthcare Research in Quality (AHRQ). AHRO is the organisation that is responsible for monitoring and compiling the use of HSOPSC not only in the United States of America but worldwide.

This study was conducted in public hospitals in Malaysia which comprise different levels of hospitals with varying degrees of facilities, number of staff, expertise, and location of the hospitals including a well-established university hospital in Kuala Lumpur. In the Malaysian healthcare system, public hospitals captured about 60% of the health services nationwide including primary care services (Ministry of Health, 2012a). The complex nature of the health care system in Malaysia, had increased the possibility for medical errors to occur. Therefore, it is crucial for the programmes currently executed at the national level to be adequately assessed to reduce the errors from transpiring. The programmes may indirectly improve the quality of healthcare.

5.1.1 Face and Content Validity

Not many countries diligently followed the AHRQ steps in the validation of HSOPSC. Out of the many published papers on psychometric properties; only a few provided information on the translation and adaptation processes (Hedskold et al., 2013b; Shahenaz Najjar et al., 2013). Most authors described a forward-backward translation process of the HSOPSC from the original English version into their native language (Lunt et al., 2011). In this study, a vigorous process of forward and backward translations was conducted to ensure a good and acceptable tool was constructed in term of the structure, context, and syntax of the tools when translated to another language. Apart from Malaysia, the validation of HSOSPC to the Arabic language in Palestine employed similar steps as recommended by AHRQ. A comprehensive step by step process (from translation to psychometric assessment) that it adhered to was particularly different from other studies validating HSOPSC (Shahenaz Najjar et al., 2013).

In addition, at the stage of content validity, the scale-content validity index (S-CVI) also showed an acceptable result which indicated that the 42 items were relevant to be included in the questionnaire. It is important to note that the content validity scales were reviewed by a group of experts in patient safety. Hence, the availability of CVI is as crucial as the other steps in the validity testing of a tool as it required experts to rate if an item is relevant to the local context (Tom Ballantyne, 2016). Not many changes were made following this step. A few words were identified to be potentially problematic if used in the questionnaire as it might introduce confusion to the participants especially when the questionnaire was to be used among the lower category of staff for example words like '*incidents',* '*error'*, and '*by chance'*. In this study, a conclusive result of 0.87 indicated that

the tool is relevant for use in the country. Therefore, all the items were brought forward to the next step in the validity testing. However, a proper comparison of the content validity with other countries was limited in this study making it a striking component of the research to be highlighted. Next, the questionnaire was tested among a few selected healthcare workers in hospitals in Pahang to validate further the suitability of the language to the local population.

In test and retest, a few methods were employed to assess the reliability of the inter-rater agreement including Intra Class Correlation (ICC), Structural Equation Modelling (SEM), Pearson Correlation and Bland-Alman Plots. Since participants were tested with the same questionnaire twice in this study, it was more meaningful to have a score that measured the correlation between the 2-time frames. Intra Class Correlation was also mentioned in a previous study, but only the itemized ICC was reported (Occelli et al., 2013). In the current study, ICC was chosen as it was considered sufficient to measure the reliability of the test and retest (Weir, 2005). As mentioned before, ICC gives a score between 0 to 1.0 reflecting poor to very good correlation. Five items showed a low correlation between the first and second tests which were A8, A16, B4, D2, and D3. Seven other items showed a high correlation between the 2-time frames which were A1, A2, A3, A4, A5, C6 and F6. However, for the purpose of decision making, a composite score was generated to express the overall impression. A score of 0.704 in Intra Class Correlation (ICC) meant that 70.4% of the reviewers agreed on the scales when the items tested on them repeatedly. This indicated that the tool is reproducible and can be used to proceed to the next step.

5.1.2 Construct Validity

The dimensions in the original construct of HSOPSC were used to compare the positive response rates between the dimensions with the positive response rate in the original US study (Wagner, Smits, Sorra, & Huang, 2013). It was considered appropriate to use the data from the validation study for such comparison as the factor structure might have deranged after the final modelling in the validation study. It was found that seven of the 12 dimensions scored lower than the US findings. The dimensions with the lowest score were "Communication Openness", "Frequency of Event Reporting" and "Staffing" where each of these dimensions scored less than 50%, indicating that they needed to be further evaluated to be improved. These findings signify the weaknesses in the Malaysia healthcare system pertaining to patient safety. Medical errors were not communicated freely in the Malaysia Healthcare sector despite various patient safety activities conducted. Special emphasis should be stressed upon improving the communication among staff when it comes to disclosing errors since errors opened ample space for improvement in the organization. Understaffing is also an issue that needs to be urgently tackled in the Malaysian healthcare system. Apart from predisposing an organization to error, it also inhibits staff from reporting an error due to time constraints. However, it is crucial to note that this finding was meant as a comparison with the benchmark data from other countries since the findings in Malaysia exhibited a certain degree of difference with the original tool because some items and dimensions were moved from its original construct.

As mentioned earlier, this study utilised every step as suggested by AHRQ in the validation process. In addition, to ensure that the findings the database was not over-estimated, it was divided into 2 for the purpose of exploratory and later confirmatory

analysis. This procedure was practiced by studies in UK and Palestine but not in the validation of the original HSOPSC. It was argued that the use of the same database for 2 different analyses might expose researchers to overestimation of the results particularly concerning the factor structure (Shahenaz Najjar et al., 2013; Sorra & Dyer, 2010; Waterson et al., 2010).

Acceptable factor loading was set at >0.4 to indicate that these items were correlated with each other and grouped as a factor or dimension (Stevens, 1992). The lowest factor loading was seen from item F11, and the highest was from item D2. The dimension of 'Frequency of event reporting' was maintained as a dimension in this validation.

Several items were moved from its original dimension for instance item F6 which was originally from the dimensions of "Teamwork Across Unit". In the Malaysian setting, this item was moved into the dimension of "Hands Off and Transition". Together in the HNT dimension was item F9 which was from the "Hospital and Management Support in Patient Safety" item. Another item from HMSPS (item F1) was transferred into the TAU dimension. This indicated the perceived meaning of items F1 and F9 were somewhat different from the original version. All items in relation to communication were lumped into one single dimension indicating that staff in Malaysia regarded communication as a large entity capturing various perspectives that need not be separated. A few of the other studies also reported rearrangement of items between dimensions for example in UK where item F9 in the HMSPS was also transferred into the Dimension of HNT (Waterson et al., 2010).

The dimensions of 'Feedback and Communication about Error' and 'Communication Openness' were grouped into one single dimension. This finding showed that in Malaysia, these two communication aspects were accepted as having correlated with each other. In contrast to the findings from France where Communication Openness (C2, C4, C6) were maintained in one dimension whilst ' Feedback and Communication about Error' were moved into the dimension of 'Organizational Learning' which deviated from the communication perspectives (Occelli et al., 2013). Similarly, the FCE dimension was grouped with MEAPPS as one dimension in a study in Turkey (Bodur Said & Emel., 2010).

In short, our CFA was replicated differently from the proposed factor structure compared to other international use of HSOPSC. In HSOPSC-BM, only 9 dimensions were retained, and some of the items were rearranged or combined in a dimension. The final construct which contained 9 dimensions and 30 items were in line with other research that adapted HSOSPC into their local population such as in the Netherlands where only 11 factors were replicated (M. Smits, ., Christiaans-Dingelhoff, Wagner, & al, 2008), Only 9 factors with only 27 items were left in the UK version (Waterson et al., 2010) Kosovo (8 dimensions) (Lunt et al., 2011; Nie et al., 2013) and only 8 factors with 29 items were left in China (Nie et al., 2013). Though the comparisons with the original version shall be conducted with care, these findings enable the Malaysian healthcare system to assess and evaluate the patient's safety culture in the organizations. Thus in long-term, a longitudinal comparison can be made possible in the presence of a valid tool. The findings in Malaysia showed differences in the arrangement of dimensions in HSOSPC compared to the original version. Though some items were redistributed to other dimensions, and some were

dropped from the questionnaire, the final result was expected to capture the main elements that were deemed essential to assess the safety culture in the Malaysian context.

5.2 Phase 2 - The evaluation of patient safety culture in public hospitals in Malaysia: A multi-centre assessment using the Hospital Survey on Patient Safety Culture-Bahasa Melayu version (HSOPSC-BM)

In Phase 2 of the study, four public hospitals were selected in the Pahang State to become part of the study. Among the participants, 40% were selected from the State Hospital followed by the District Hospital with specialties (major) contributed 30%, the District Hospital with specialties (minor) formed 20% and the District Hospital without specialties (DHWOS) added the 10%. This proportion was somewhat similar to the proposed proportion but only differed due to the rate of response in the individual hospital. If we were to look into the distribution of staff in this study, the same picture was captured according to the Malaysian Health Facts 2012 (Ministry of Health, 2013). In Phase 1 of this study, only 5% of the participants comprised doctors compared to Phase 2 where about 15% of doctors responded to the questionnaire. The low response rate among the doctors was also reported in other studies and was alerted by Olsen (Olsen, 2008). Despite the seemingly low response, this figure can be considered a success partly due to the efforts made prior and during the study. The efforts included conducting a debriefing session with the head of departments, approaching key people in the departments especially the head of departments in person and the regular follow up undertaken. About 71% of the participants

were female partly and the significant numbers were contributed by the higher percentage of registered nurses in the system.

It was noted that the majority of the participants were young aged less than 30 years old and had less than 5 years of working experience. This can be due to senior staff doing managerial work as they had been promoted to a higher rank in the service. The majority of the participants claimed that they worked more than 40 hours. In Malaysia, the normal working hours for government staff are 40 hours, 5 days a week. However, it was only applicable to certain professions and cannot be applicable to some professions such as healthcare workers. Since most healthcare workers work in a shift, they are prone to have extra working hours especially when there is understaffing or when a disaster occurred. The need for them to be in on standby mode and overnight call predisposed them to overworked.

Four dimensions scored lower than 50% namely the "Hands Off and Transition", "Overall Perception on Patient Safety", "Frequency of Event Reporting" and "Non-Punitive Response to Error" with scores of 48.03%, 47.6%, 25.1% and 17.43% respectively. Scores below 50% signified areas for improvement in the organizations (VF Nieva & J Sorra, 2003). According to the findings, there were problems with the passing over of the patient that usually involved inter-unit coordination (hands off and transition). Aspects such as the loss or incompleteness of the patient's information during the transfer of the patient, poor coordination of the patient's transfer workflow and timing of the transfer were often seen as problems in this dimension. These aspects were reflected in the findings. Hands off and transition which primarily referred to the transfer of information during patient care occurred during shift changes in the unit and the transfer of patients to

other units or specialty area (transfer of responsibility) within the complex organizational systems and cultures. Undeniably, sub-standard or ineffective practice during the hand overs contributed to the gaps and breaches in patient care that might expose the patients to medical errors (WHO, 2016).

The dimension of the "Overall Perception on Patient Safety" consisted of 2 items; only one of them was the original item and the other was from the dimension of "Staffing" which was aborted during Phase 1 of the study. Cumulatively, only 47.6% of participants agreed on this dimension. The majority agreed that they worked in a rush as there was way too much work to be completed in a short period of time, through more than 50% of them agreed that they did not have patient safety problems in the organization. This indicated that the organization was understaffed such that they had to catch up trying to finish their daily jobs on time. On the other hand, staff might be burdened with considerable tasks contributed by a large number of patients beyond the acceptable ratio. According to Malaysia Health Facts 2016, the proportion of nurses to patient serving in both the public and private sector was about 1:305. In a local study in Malaysia's private hospitals, it was shown that there is a negative impact on patient safety if the numbers of patient served by a staff nurse increased, though this has not been proven to affect the quality of care (Makeham, Dovey, County, & Kidd, 2002). Having known that patient safety is an important indicator of the quality of care, a serious effort must be taken to tackle this issue at the ministry level.

The frequency of event reporting and Non-Punitive Response to Error scored very low in this study especially indicating how errors were treated in the system. This score was in line with the fact that more than 50% of participants admitted that they never

reported any adverse event in the past 12 months. The staffs was worried about being punished if they committed an error as it affected their performance, recorded in the service book and later might implicate their promotion and seniority. However, it is important to cultivate the culture of reporting in a healthcare organization as it opens rooms of improvements and shall be regarded as 'information-rich' data for learning and system upgrades if taken positively. Undoubtedly the support from the leadership and management are vital to motivate staff to embrace safety culture in their daily practice (Crutchfield & Roughton, 2014). However, it was noted that FER and FCE in this study did not correlate with each other. The low score of FER did not sync with the findings in FCE which received considerably more positive responses which can be cited as complementary to each other. The fact that the errors were freely informed and communicated in the organization does not reflect the practice in the error reporting practice. Probably, the punitive treatment for staff who committed errors hindered the positive practice of error reporting. This assumption was supported by the low positive response in item A16 which depicted the worrying facts that errors are being kept in the staff's personal file. Moreover, staff did admit that whenever an error was reported, the staff were to be blamed instead of discussing the problem and finding solutions.

Among dimensions with the highest score, "Organizational Learning" scored 87.8% with the item 'Patient safety is never sacrificed to get the work done' reflected the organization's vigorous effort to improve patient safety. Generally, most public hospitals in Malaysia cultivated continuous learning as their weekly or monthly agenda. Patient safety is part of the learning activities during the continuous medical education apart from periodic campaigns and directives from the ministry. Therefore, it was quite convincing to

say that the staff from the Malaysian Health Care system were adequately equipped with knowledge on patient safety (Patient Safety Council of Malaysia, 2010).

Six of nine dimensions showed statistically significant findings between the hospitals namely "Organizational Learning", "Overall Perception on Patient Safety", "Supervisor Expectation and Action Promoting Patient Safety", "Frequency of Event Reporting", "Hands Off and Transition" and "Teamwork Across Unit". These findings were supported by ANOVA when the test showed that the mean PS Score of the hospital types was statistically significant. It was somehow proven that the different levels of hospitals behaved differently in practicing the safety culture as previously mentioned in another study (Jacobs et al., 2004). Though all the hospitals are under the directives of the Malaysia Ministry of Health, there were some differences in its execution; the execution was particularly influenced by the environment, the organizational culture and not forgetting leadership support in patient safety initiatives. Each hospital or work-place has their own culture in practicing patient safety.

A hospital is usually associated with a complex system in structure and the way they communicate with each other across discipline and units, the larger the hospital, a more complex system is expected. In this study, the State Hospitals and District Hospitals with Specialties (major) are located in a more urban area in the 2 most populated districts. Whereas, the location of the District Hospital with Specialties (minor) and District Hospital without Specialties was quite distance from the two. In the ANOVA testing, factors such as the types of hospital, age, profession and years of experience influenced the patient safety culture in public hospitals of the Pahang State. Further analysis using post hoc test revealed that there was a significant difference in patient safety culture practice in the State Hospital

and District Hospital with Specialties (minor). Even though The District Hospital with Specialties (minor) is a minor specialist hospital, other factors such as geography, local culture, facilities, manpower, leadership support, funding, number of the patients also contribute to the attitude of the staff towards patient safety culture. Doctors and nurses shared commonalities in the practice of safety compared to other professions. This could be attributed to the fact that they always work together in-patient care in the ward as well as on administrative matters. Hospital management in Malaysia is led by medical doctors who have been trained in administrative processes and supported by other heads from other non-medical administrative staff. Since nurses are the largest group of staff in the Malaysia Healthcare system, nurses are often regarded as the backbone of the implementation programs in any healthcare institution. Their hierarchical structure and leadership are commendable whereby the implementation of programmes among nurses in Malaysia can be considered as straight-forward and more practical than those from other professions. Though the entry qualification for a registered nurse is diploma, there is an increasing trend of nurses pursuing their studies to a higher degree. Policymakers are beginning to recognize their degrees provide opportunities for carreer enhancement in nursing. This can be a positive contributory factor to improve patient safety in public hospitals despite the fact that in the current study, no difference was found between patient safety cultures' mean with the education background of the staff.

There was a difference between junior staff and those with less than 1-year working experience with the more senior group of staff. The differences supported the fact that experience counts in the assessment of patient safety culture. Apart from the findings indicating that doctors and nurses practiced patient safety culture more than the other

healthcare professions, it was also noted that staff with experience of 5 years and below were less likely to practice safety culture compared to those with more experience. Younger staff lacked experience and training compared to their senior counterparts. It is questionable if they were able to recognize error if those incidents were to happen in front of them since patient safety was not routinely communicated during their training. Close supervision from the senior staff is considered mandatory in order for them to develop sufficient knowledge and competencies to ensure patients receive safe care (A. Wu et al., 1991).

Even though the protocol is already in place, the implementation was somewhat difficult due to other barriers limiting its effectiveness. For example, a houseman doctor in a ward was assigned to a senior medical officer or specialist. It is to ensure close monitoring and hands-on learning for the junior doctors. But with other unexpected circumstances such as excessive workload, short of staff, clinic days or involvement in administrative activities, the seniors were indirectly hindered from closely monitoring them. This situation opened possibilities for error as the junior doctors were allowed to make decisions with minimal direct supervision or sometimes none at all. Careful supervision of the junior medical, nursing and allied health staff is critical to the provision of safe care to all patients. There is a need for a defined and transparent process of supervision from the senior to junior doctors. It is active surveillance rather than passive surveillance that is important for them to ensure competencies of these doctors (L. T. Kohn et al., 2000).

On the other hand, there was no significant relationship observed between the education level, race and patient safety score. Continuous education in an institution is

more beneficial in improving patient safety among staff as it can consistently instill the understanding and practice in a long-term compared to formal education in college or university as limited time is often allocated to patient safety in the curriculum (Rahman, Jarrar, & Don, 2015). However, different findings were concluded in another study (Aiken et al., 2012). For instance, Tourangeau et al. (2007) discovered that a 10% increase in the proportion of bachelorette nursing staff significantly decreased the mortality rate among a thousand discharged patients which amounted to nine cases (Tourangeau et al., 2007).

It was depicted that there was a statistically significant relationship between patient safety score and 4 categories, namely the state hospital (from the variable of the type of hospital), age, registered nurses and medical officers (both from the variable of the profession). Further analysis confirmed that medical officers were 4.8 times more likely to exhibit higher patient safety score as opposed to the other categories. Senior staff aged 41-50 years old practiced patient safety with a more likely odd of 6 times compared to the other categories which indicated that the role of experience were combined with the increase in the age of the staff in public hospitals. This interesting finding was supported by the fact that junior staff with experience of less than a year was 0.12 times less likely to practice high patient safety grade compared to other categories. The exposure to various scenarios might strengthen their views about the importance of patient safety in their daily practice.

Such findings are considered surprising especially when patient safety initiatives and activities have been routinely communicated and implemented among all levels of staff. The question that arises at this point is whether the efforts are effective enough to make an impact on the level of patient safety practiced by all the staff. Is there a possibility

that the initiatives implemented by the Ministry of Health or other organizations benefitted a certain profession more than others? Similar pictures were seen when the number of events reported could be linked to some demographic patterns. In the descriptive analysis, it was revealed that more than 50% of the staff admitted that they had never reported any incident reporting for the past 12 months. It was interesting to establish the reason behind the refusal to report.

Furthermore, only medical officers had positively reported 1-2 incident reporting where they were 2.73 times more likely to report 1-2 reports in 12 months. The reason behind this finding was probably contributed by the fact that medical officers were the first to see the patient and doing a close observation of the patient. In addition, they were the person consulted by paramedics should the paramedics encountered any problem. Staff with less than 20 years of experiences was generally less likely to report an incident compared to their seniors. Similarly, junior staff was also less likely to report 3 or more incident reportings compared to the other categories. The fear of punitive treatment for reporting might contribute to the phenomena. Thus, it is about time for a healthcare institution to cultivate a culture of no-blame so that the staff feel free to report a medical error and see the medical error as a learning opportunity. It will be a great wastage if the golden opportunity is overlooked as it hinders improvement

Again, as all the covariates had regressed towards the number of incident reporting, only the medical officers showed a significant contribution to prediction. This group was 2.33 times more likely to report 1 to 2 events in the past one year compared to other groups. The result was probably contributed by the choice of participants where they consisted of the different ranks of doctors from housemen to consultants in various fields. In certain

areas of specialties, patient safety was put on the top of the list and supported by the supervisors of the unit who are mainly specialists and consultants for example in units such as the Intensive Care Unit and surgical based departments (Wendy C, 2013). In 2016, Patient Safety Awareness Course for Junior Healthcare Professionals was launched for doctors undergoing houseman-ship in the Malaysian public hospitals (*Summary of the Evidence on Patient Safety: Implications for research*, 2008). The main aim was to improve awareness for patient safety among junior doctors. At the end of the course, an exam will be held, and participants were required to achieve scores of more than 80% to be considered a pass. Undeniably, this strategy has improved patient safety culture among junior doctors and further engrained the practice as part of the way they conduct their services in the future.

In a correlation study, the findings showed that all the safety culture dimensions in HSOPSC-BM correlated with the "Patient Safety Score". This may imply that dimensions in HSOSPC-BM were fundamental aspects to look into when discussing patient safety in the Malaysia public health services. More importantly, it allowed specific dimensions for the administrative or leadership to be focused on. In other words, it enabled the identification of areas for improvement. In contrast, only a few dimensions were positively correlated to "Number of Events Reported" which included "Non-Punitive Response to Error", "Feedback and Communication about Error" and Frequency of Event Reporting". All these dimensions were positively correlated with the "Number of Events Reported".

These findings might indicate that when errors are freely communicated in the organization without the fear of being punished by any means, staff will be less reluctant to report any event as they understand that free discussion of errors can open more

possibilities for improvements. It is vital that the positive culture of safety be instilled in any organization as already applied in other HRO organizations. It is important to note that event reporting will include all events namely near misses and true adverse events, so the dimension of "Number of Events Reported cannot be treated as a proxy to an actual number of adverse events. The advantage is that earlier detection of near misses, will benefit the organizations as we can identify any procedural weaknesses, make improvements and later avoid true adverse events. In a qualitative study that assessed pharmacists' attitudes regarding event reporting revealed that they were more positive on event reporting as they could see improvements brought about by the process or system change in the organization (Runciman et al., 2009).

In this study, only State Hospital had a positive correlation between the "Patient Safety Score" and "Number of Event Reported" which might indicate that the State Hospital practiced a more positive safety culture in the organization. Though these four hospitals were located in the same state and head by a State Director, variations in the practice of safety culture can be seen across different institutions, settings, departments, and leadership at the micro level. These findings were supported by other studies in other countries including in Malaysia itself (Huang et al., 2007; Samsuri et al., 2015; J. Sexton, Holzmueller, et al., 2006).

The distribution of staff in these studies determined the overall outcome in this study. In the aimed to capture responses from staff with direct contact a variety of healthcare staff from different work-place and job description were chosen. Among the 5 job professions registered nurses and medical officers devoted most of their time in patient care along the delivery of care. Whereas, assistant medical officers mainly in pre-hospital

care of a hospital discharged patients to outpatient or inpatient care. On the other hand, pharmacists and rehabilitation therapists work in their own department and in contact with patients during dispensing medications and rehabilitation follow up. Although patient safety is the responsibility of all health care workers, it is generally believed that nurses are the cornerstone in the implementation of the patient safety initiatives (RigobelloI et al., 2012). Moreover, nurses, who comprise the greatest number of health care professionals in the hospital involved in providing nursing services to patients, are extremely important to maintain the safety culture. Being in an organized supervisory system, the nurses are expected to perform any directives especially pertaining to patient safety culture under close supervision from their immediate supervisors. (Alshammaria et al., 2019).

Medical officers, on the other hand are considered as person in charge in the management of patients. The directives are from consultants, specialists, medical officers and house officers. They are responsible in the success of treatment and therefore avoidance of medical error along the process of care. Communication about medical error and patient safety are routinely communicated in the organization using several mediums such as Continuous Medical Education (CME) which usually held once a week, meetings, seminar and conferences.

Managerial and supervisory supports are important elements in the success of patient safety culture in an organization. The need to know factors influencing such practices is vital to all leaders and managers. Crucial issues such as understaffing and heavy workload must be seen seriously, and action must be taken as soon as possible. Delayed in tackling such issue will burden existing staff and subsequently become stressors to the staff. In this situation, in order to complete their daily tasks shortcuts happens. Even

a small mistake needs to be tackled and get it fixed. A good procedural guideline adhered is the best in avoiding medical errors.

5. 3 Strengths of the study

This research was conducted in 2 different phases in public hospitals in Malaysia. Public hospitals were chosen as the study site due to its abundance across the country and the fact that provided about 60% of total health service in Malaysia. (Ministry of Health 2012). It enabled this research to capture patient safety culture in a broader range of healthcare staff in Malaysia. This study was conducted timely in tandem with the Ministry of Health, Malaysia that is currently promoting aggressively and implementing patient safety initiatives in Malaysia.

Phase 1 of the research was mainly a validation of HSOPSC. In this study, the recommended AHRQ guidelines for the validation were fully applied. The use of content validity which was less frequently seen in another validation study of HSOPSC was somewhat valuable in the sense that Content Validity Index (CVI) ensured that the translated items were semantically and culturally equivalent to the original English questions. The pilot testing of the translated questionnaire went through different types of providers including those not included in the study such as technicians, administrative staff, dispensers and other categories of staff who did not have direct contact with patient care. The reason was to prepare the questionnaire to be used in a broad range of staff in the future and to enable a wider assessment of patient safety culture involving every category of staff in Malaysia. In construct validity, the Exploratory Factor Analysis (EFA) was accomplished and followed by the Confirmatory Factor Analysis (CFA). The use of the

split half validity where the database was split into 2 was used to analyze the EFA and CFA. The final construct of HSOPSC-BM showed a trimmed version of the original HSOSPC had evolved to only 9 dimensions, and 30 items with the rearrangements of some items into certain dimensions. This version was better accepted by the Malaysia healthcare provider since it was simpler and better suit the Malaysian population. Overall, HSOPSC-BM had undergone a detailed process for it to be finalized. Hence, it is the best version for the use in the Malaysian context.

Our findings highlighted the variation in safety culture between different levels of hospitals available in public healthcare in Malaysia especially in the same state, the Pahang State, Malaysia which is the largest state in Peninsular Malaysia. There are 11 hospitals in Pahang State and consisted of different levels of hospitals. Only 4 hospitals were selected to be the study site which covered the State Hospital, District Hospital with Specialties (major), District Hospital with Specialties (minor) and district Hospital without specialties. The location and differences in the organizational structures of these hospitals were representatives of the patient safety culture practiced in the state since each hospital was separated about 100 to 200 km apart.

The identification of strengths and weaknesses of patient safety dimensions in Malaysia public hospitals enable the policy makers to plan and execute actions to improve the practice of patient safety culture. As in this research it was noted that Organizational Learning, Supervisor Expectation and Action in Promoting Patient Safety, Feedback and Communication About Error and Teamwork Across Unit are the dimensions that considered as strength. Therefore, further plans should be on how to empower these dimensions to staff. Whereas, the weak factors such as Non-Punitive Response to Error and

Frequency of Event Reporting must be reassessed to determine the root cause to the problems. These findings are very much consistent with other findings using HSOPSC as measuring tool (Reis, Paiva, & Sousa, 2018)

In comparison to other similar studies using HSOPSC to assess patient safety culture in the country, the findings in Malaysia showed similarities in the patient safety score dimensions for instance Non Punitive Response to Error, Frequency Of Event Reporting, Organizational Learning and Communication and Feedback About Error. Such findings can be seen in studies conducted in China, Palestine and United Kingdom (Nie et al., 2013; P Waterson et al., 2009; Shahenaz Najjar et al., 2013). There were significant advantages using one common instrument for patient safety culture measurements in the Malaysian healthcare system. At the hospital level, it allowed the identification of problems and targeted actions on weaker dimensions while further improve the strong dimensions. Not only was the process of measurement simplified, but it also provided an opportunity for comparison and learning within the system. Having a single and uniform assessment tool in the country can allow a continuous assessment of policies on national programmes to be undertaken to ensure quality and patient safety improvements.

5.4 Limitations

There are a few limitations to be considered in this study. It was conducted in the State of Pahang only which is located in the center of Peninsular Malaysia, and the state can be considered as the most rural state in Peninsular Malaysia. However, the result from this study may not be able to be generalised to the whole of Malaysia. In addition, this study noticed only staff with direct contact with the patient which means that the responses

of staff from other categories were subsequently ignored including the administrative staff who had relatively indirect contact with patients. It is also important to assess the safety culture of other personnel (e.g., pharmacy technicians) in the organization in order to have a proper insight about dimensions like communication, teamwork and overall picture of safety culture in the organization and the Malaysian healthcare system in general. Such information was deemed necessary so responses of staff from another profession that might differ from each other and later affect the organizational culture as a whole can be identified. Apart from that, in HSOPSC, participants were required to self-grade their hospital's patient safety culture. This might contribute to the bias of information since it is expected that the participants may have some degree of preference about their workplace.

An extension to the quantitative studies is important to capture actual picture of patient safety practice in the organizations. As biases in the responses to questionnaire can be expected, a qualitative approach is considered as comparative or complementary to quantitative studies in assessing patient safety culture. Observations to their daily practices, interviews (semi structured), focus group discussions, review of medical notes are methods to be considered in qualitative studies in complementary to quantitative studies. It was evidenced in a mixed method study that interviews can depict challenges rather than positive findings thus identify specific areas for improvements (Listyowardojo et al., 2017)

CHAPTER 6: CONCLUSION

This final chapter summarizes the major findings in this thesis, proposes the likely implications of the findings, offers recommendations and finally makes suggestions for future research based on the data analyses in this thesis. As patient safety is becoming increasingly crucial in healthcare settings, a large number of movements and research had been conducted to study patient safety culture. It was also noted that there is a need to have more standardized terms and greater understanding of how the safety culture is measured and how other factors in healthcare are related and have contributed to the patient safety practice.

6.1 Review of the main findings

Phase 1 of the study resulted in a more concise questionnaire to assess patient safety culture in Malaysia compared to the original HSOPSC. However, it is believed that the final construct was able to capture the main elements of patient safety as discussed earlier. The use of an extensive questionnaire validation technique in this study was considered important to extract salient elements in PSC in Malaysia. Nevertheless, the findings in HSOPSC BM looked somewhat different from the original HSOPSC. The final factor structure was not identical and showed lower consistencies compared to the original HSOPSC. However, it is crucial to note that an optimal model becomes more acceptable and reliable by removing weak items and shifting others. Modification in HSOPSC-BM reflected the differences in Malaysian Healthcare system in terms of perception and practice of such culture among staff particularly in public hospitals in Malaysia compared

to various other countries. The final 9 dimensions with 30 items were considered suitable for use in Malaysia as an assessment tool for patient safety culture.

The importance of having an accurately validated tool allows for the tool to be confidently applied to measure the safety culture in an organization or health system within or across countries that share the same language. Having said that, there is a need to be extra cautious when comparing findings of similar dimensions between countries especially when there are differences in the cultural and the healthcare system themselves. In Malaysia, disparities between different types of hospitals, rural and urban, public and private may be taken into consideration if the comparison of the findings is expected to be made.

In Phase 2 of the study, the dimension of staffing was lumped together with the dimension of HMSPS indicating that staffing was considered an administrative issue in public hospitals in Malaysia. Generally, dimension related to event reporting and management response towards error scored among the lowest. Feedback on error and openness of communication were acknowledged as dimensions reflecting the perceived idea of staff in Malaysia when discussing errors. Open communication and discussion about errors encourage staff to give feedback and comments when an error happens. The fear of a punitive treatment on an error committed by the staff will diminish substantially once there are active and open discussions on the problem rather than pointing fingers to identify the responsible person. Staff who deemed as guilty often was given punitive treatment such as disciplinary action and mistakes being recorded into the individual service book. Such action further hinders a good reporting habit among staff as they fear of the punishment that might jeopardize their service.

It was also noted that registered nurses and medical officers scored among the highest in term of patient safety score. These groups of profession are among the largest in health care system. Their daily practice and close adherence to guidelines by the ministry have instilled good values in patient safety practices. Direct contact with patient during the delivery of care makes them more susceptible to error. It is deemed necessary for policy makers to implement measure in order to empower the patient safety culture among health staff in public health care services.

In addition, medical officer was also predicted to have a better attitude towards event reporting compared to other profession assessed. Understaffing, punitive response to error and lack of managerial commitment in empowering patient safety are main factors hindering a better event reporting practice.

Certain hospitals have better patient safety practices than the other. Strong leadership and supervision, open communication between management and staff stimulates a positive environment to patient safety culture. Though it takes years to improve a small step is important for the good change.

6.2 Implications

The use of a proper assessment tool in patient safety will enable patient safety to be measured quantitatively. In the long term, proper monitoring of patient safety and policies can be made possible. Further assessment of the effectiveness or impact of programs or activities related to patient safety can be accomplished by using the validated tool.

6.2.1 Implications for hospital/clinical care

A standard measurement tool will enable hospital administration to evaluate and identify the practice of patient safety culture in the organization. It is essential to distinguish between the weaknesses and strengths of the organization in order to administer remedial actions to address the weak area of a unit/department. As we noted in this study, the low scores particularly referred to the aspects of communication and error reporting practice among staff in the Pahang State, Malaysia. There were many significant issues highlighted by this study despite various efforts by the ministry to empower patient safety culture in the country.

The communication aspects pointed at how errors are communicated in the organization. Staff in Pahang admitted that they were not willing to report adverse events in fear of punitive action taken by their supervisors and the hospital administration. The idea might have also been instilled among the healthcare staff in other parts of Malaysia since similar policies and guidelines were used all over the country. As determining the patient safety culture is ideally a continuous process, the administrative support is vital especially in assuming the non-punitive approach in error reporting. Any barriers to report medical errors must be identified and addressed.

By knowing an exact level of patient safety culture in one's organization, administrators will be able to re-strategize programs and actions to improve patient safety culture in their own hospitals. A fine-tuned strategy aiming at enhancing improvements in the identified areas of weakness, in a particular organization, is better than aimless strategies in dealing with the dimensions of patient safety culture.

6.2.2 Implications for patients and family

Assessment of patient safety culture will lead to the identification of weaknesses and strengths of safety culture dimensions. As communication and error reporting were among the dimensions needed, further strengthening, actions towards improving these dimensions will ultimately improve patient safety by addressing the weaknesses found in the organization. Empowerment of the safety dimensions in an organization will eventually enhance the quality of care as staff become more aware of potential problems and take the necessary precautions and actions to prevent any possible medical errors. Staff awareness on patient safety is crucial in determining good quality patient care. The patients' safety will be better assured that when they obtain their treatment in health facilities, they are not being subjected to a possible medical error committed by the medical staff. Ultimately, following safer care, quality health care can be achieved. Recent movements involving patients and family rights in patient care and accreditation process in health care reflect the importance for the stakeholder to determine quality care.

6.2.3 Implications for policymakers

The final outcome of this research is considered remarkable in capturing information about patient safety culture in Malaysia's public hospitals, bearing the fact that it underwent a tedious process of translation and validation. Having a survey tool in the national language, *Bahasa Melayu* enabled the extended use of the survey tool involving non-professional staff in public hospitals as their ability to understand English in writing and comprehension may not be as good as other staff with higher ranks.

Acknowledging patient safety as a priority is mandatory for each staff who is involved in health care delivery. The policymakers are obliged to ensure that patient safety is well cultivated in the system. In doing so only will a safe medical practice be guaranteed. The more the number of younger doctors engaged in the ward, the more difficult for the monitoring to be established. Medical errors may be hindered, and ultimately patient safety may be compromised.

6.3 Recommendations

It is important to have leadership support in the implementation and practice of patient safety in a hospital. Thus, a leadership with good insight and understanding of patient safety is crucial to achieve such an aim. Therefore, it is worth considering advanced training in the institutionalization of patient safety for hospital directors or managers. An in-depth and better understanding of patient safety will gain considerable support from the top management in cultivating patient safety culture in an organization. Policies are easier to be executed with the leadership's support.

The use of an information system can potentially reduce the rate of medical errors contributed by human fallibility, environmental influences, and vulnerability to fatigue. Wrong dosage, wrong prescriptions, wrong timing and other prescription-related errors can be reduced to a minimum or eliminated. Although the cost of installation is high, it is worth the investment. There must also be a good communication flow in the system. Top-down information and vice versa must be acknowledged and fine-tuned to minimize the loss of information, especially during patient transfer and discharge. Staff would be more willing to report error voluntarily if the fear of being punished is negligible. It is wise to have an

accessible reporting system in a hospital enabling staff to report errors. The practice of punitive treatment once the an error is committed should be reserved for those who have been proven to practice pure negligence as other factors are ruled out. It is a loss of learning opportunity if errors or any kind of misconduct are left unattended simply due to fear of reporting. Improvements and upgrading of service quality are often initiated by deficiencies.

Patient safety from patient and family perspectives are largely contributed by their own understanding of their rights. Patients and their family members must educate themselves on their rights in seeking treatment. The right to be informed on the treatment received and information on the disease are vital for the patient to gain insight about what is going on and ultimately enable them to comply better in the process of care. Care providers must explain to patients in layman terminologies to improve their understanding of the treatment. The mode of information relay can use various methods. Undeniably, the use of social media can play a substantial role in communicating patient safety to end users particularly the patients and their families. However, printed tools are probably more effective in relaying messages about patient safety to older citizens and those living in the rural areas. They must be made readily available and easy to understand.

Undeniably, the government through the corresponding ministry has implemented several measures to improve patient safety, especially in public hospitals. A number of guidelines and references have been published by the Malaysia Patient Safety Council, and the efforts are commendable. But certain areas need to be improved in order to fine-tune the situation so excellence in patient safety culture can be achieved. Communication between healthcare providers and between providers and patients must be strengthened.

Good command and understanding from both sides will allow better flow of perceived information and ultimately spare patients from medical errors.

Introduction to patient safety must start from as early as possible in the carrier pathway of medical staff. Hence, it is thought wise to teach them especially during their clinical years as they can inculcate the habit of incorporating the principles of patient safety in their learning process. To establish this protocol, a collaboration between the relevant ministries is necessary.

6.4 Future Research

The original HSOPSC used an extensive database made up of heterogeneous participants ranging from many different healthcare organizations and level of staff. Therefore, in future research, it is worthwhile to consider involving other health care providers which might include staff who do not have direct contact with patients and administrative staff. Apart from measuring the culture per se, the survey needs to capture the interaction between organizational and individual factors thus providing a better understanding of attitudes and dynamics of the groups in cultivating patient safety culture.

A multidirectional approach is seen as a better way to assess patient safety culture among healthcare staff which should include qualitative component to the research methodology. Observation, focus group discussion and medical record review are among methods that can depict the actual practice of patient safety culture among healthcare staff in Malaysia public hospitals. The findings will enable researcher to come out with better solution and the quality improvement activities mainly to improve the quality of health delivery system in the country.

Primary care is a component of public health care services provided by the government. They outnumbered public hospitals and are distributed all over the country to provide first line service to the people. Future research can also consider the assessment of patient safety culture in primary health care to give a more holistic picture of patient safety practice in the country. An extensive assessment of patient safety involving private hospitals and private general practice will be a bonus to the patients and the country's health system as a whole.

Lastly, it is very much hoped that Malaysia health care staff to cultivate the patient safety culture in their daily practice. Ultimately the effect will be on the patient safety and improving quality of care in the country's health care system. Though it will be a long way to go, initial steps are mandatory.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

Poster presentation: 5th AHLA Conference (Kuala Lumpur, Malaysia) 12-14th November 2017

Title: The evaluation of patient safety culture in public hospitals in Malaysia: A multi-center assessment using Hospital Survey on Patient Safety Culture –Bahasa Melayu version (HSOPSC-BM)

Oral presentation: 6th International Public Health Conference (Kuala Terengganu, Malaysia) -31st May-1st June 2016.

Title: The psychometric properties of the Bahasa Melayu version of Hospital Survey On Patient Safety Culture (HSOPSC-BM)