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To my loving family

Husband: Che Mohd Hafizi Che Husin

Children: Muhammad Hazim Zhafran, Muhammad Hadif Zhafrin, and Che Muhammad Hud

With love and respect

Mother: Wan Nisah Wan Othman

Father: Salahuddin Abdullah

Mother in law: Zuaibidah Musa

Father in law: Che Husin Che Teh

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ABSTRACT

Hospital Information System (HIS) could potentially improve the quality of healthcare services and patient safety. Nevertheless, there is a number of growing evidence that show HIS can pose risk to patient safety when it is poorly designed, implemented, or adopted. Most of the preventive solutions have been focusing on improving the software design. Conversely, patient safety is not merely dependent upon HIS, but also influenced by its interactions with users, other technologies, and environment. Therefore, this research proposes a conceptual model for a safe use of HIS by considering the sociotechnical aspect. Exploratory mixed methods methodology was employed. The first phase involved qualitative exploration of the safe use of HIS and its antecedents. Interview transcripts from 31 medical doctors at three Malaysian government hospitals implementing Total Hospital Information System (THIS) were collected. A quantitative data collection followed as the second phase to evaluate the research model. A total of 450 medical doctors from the three hospitals participated in the questionnaire survey. Structural Equation Modelling (SEM) was used for quantitative data analysis. The findings showed that knowledge, system quality, and team work has a significant direct effect on vigilance, while task stressor has a significant direct effect on procedure compliance. Teamwork emerged as the most important factor in determining the safe use of HIS. In addition, vigilance has a significant direct effect on both patient safety and patient care quality, whereas procedure compliance has significant direct effect on patient safety. Besides that, vigilance mediates the effect of knowledge, system quality, and teamwork on patient care quality. Procedure compliance mediates the effect of task stressor on patient safety. The model has portrayed predictive capability and predictive relevance, implying that the model could effectively explain the safe use of HIS and its outcomes. Hence, this research concludes that healthcare organisations and practitioners should give attention to the sociotechnical aspect of the safe use of HIS antecedents in reducing error, as well as increasing the quality of patient care.

ABSTRAK

Sistem Maklumat Hospital (*Hospital Information Systems*, HIS) berpotensi meningkatkan kualiti perkhidmatan penjagaan kesihatan dan keselamatan pesakit. Namun begitu, semakin banyak bukti menunjukkan bahawa HIS boleh memberi risiko kepada keselamatan pesakit apabila ia tidak direkabentuk, diimplementasi, atau digunakan dengan baik. Kebanyakan usaha pencegahan memberi tumpuan kepada rekabentuk perisian yang lebih baik. Namun begitu, keselamatan pesakit tidak hanya bergantung kepada HIS tetapi juga dipengaruhi oleh interaksi dengan pengguna, lain-lain teknologi, dan persekitaran. Oleh itu, kajian ini mencadangkan model konseptual bagi penggunaan HIS yang selamat dengan mempertimbangkan aspek sosioteknikal. Kaedah penerokaan campuran telah digunakan. Fasa pertama melibatkan penerokaan kualitatif terhadap penggunaan HIS yang selamat dan faktor-faktor yang mempengaruhinya. Transkrip temu bual daripada 31 doktor perubatan di tiga buah hospital kerajaan Malaysia yang melaksanakan Sistem Maklumat Hospital Menyeluruh (*Total Hospital Information Systems*, THIS) telah dikumpulkan, diikuti dengan pengumpulan data kuantitatif sebagai fasa kedua bagi menilai model yang dicadangkan. Seramai 450 doktor perubatan dari tiga buah hospital tersebut mengambil bahagian dalam kajian soal selidik. Model Persamaan Berstruktur (*Structural Equation Modelling*, SEM) telah digunakan untuk menganalisis data kuantitatif. Hasil kajian menunjukkan bahawa pengetahuan, kualiti sistem, dan kerja berpasukan mempunyai kesan langsung yang signifikan ke atas aspek kewaspadaan, manakala tekanan kerja mempunyai kesan langsung yang signifikan ke atas pematuhan prosedur. Kerja berpasukan merupakan faktor yang paling penting dalam menentukan penggunaan HIS yang selamat. Di samping itu, kewaspadaan mempunyai kesan langsung yang signifikan ke atas keselamatan pesakit dan juga kualiti penjagaan pesakit, manakala pematuhan prosedur mempunyai kesan langsung yang signifikan ke atas keselamatan pesakit. Selain itu, kewaspadaan mempunyai kesan pengantara terhadap pengetahuan, kualiti sistem, dan kerja berpasukan ke atas kualiti penjagaan pesakit. Pematuhan prosedur mempunyai kesan pengantara terhadap tekanan kerja ke atas keselamatan pesakit. Model ini menunjukkan keupayaan ramalan dan relevan ramalan yang menunjukkan bahawa model ini dapat menjelaskan dengan efektif penggunaan HIS yang selamat serta hasilnya. Oleh itu, kajian ini menyimpulkan bahawa organisasi dan pengamal penjagaan kesihatan perlu memberi perhatian kepada aspek sosioteknikal bagi anteseden penggunaan HIS yang selamat untuk mengurangkan kesilapan serta meningkatkan kualiti penjagaan pesakit.

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LIST OF ABBREVIATIONS

CPOE	-	Computerized Provider Order Entry
CDSS	-	Clinical Decision Support Systems
CFA	-	Confirmatory Factor Analysis
D&M	-	DeLone and McLean
EFA	-	Exploratory Factor Analysis
EHR	-	Electronic Health Record
EMR	-	Electronic Medical Record
HFE	-	Human Factors and Ergonomics
HIS	-	Hospital Information Systems
IOM	-	Institute of Medicine
IS	-	Information Systems
IT	-	Information Technology
MOH	-	Ministry of Health
PLS	-	Partial Least Squares
SEIPS	-	Systems Engineering Initiative for Patient Safety
SEM	-	Structured Equation Modeling
SLR	-	Systematic Literature Review
THIS	-	Total Hospital Information Systems

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CHAPTER 1

INTRODUCTION

1.1 Overview

Healthcare refers to services received by individuals or communities to promote, maintain, monitor or restore health (Runciman *et al.*, 2009). The complex nature of the healthcare system makes it vulnerable to errors which are almost unseen or silent (Ash *et al.*, 2004). Errors are known as failure of planned actions to achieve the anticipated goal, which could potentially cause patient harm (Reason, 1995). Patient safety related to medical errors can be defined as the prevention of medical errors that could be harmful to patient (Aspden *et al.*, 2004; Kohn *et al.*, 2000). Reducing medical errors and improving patient safety are the focus of the primary quality improvement in the healthcare environment.

Hospital Information System (HIS) is a computerised integrated information system that manages hospitals' administrative, financial, and medical information (Abdullah, 2013). HIS is developed to support healthcare organisations in providing efficient, quality, and safe healthcare services. HIS may lead to a safer care by improving communication among healthcare practitioners, and facilitating shared decision making (IOM, 2011). Nevertheless, HIS involves interaction between healthcare practitioner and complex sociotechnical system (Meeks *et al.*, 2014; IOM, 2011). Hence, HIS may introduce new safety risks such as dosage errors, delay in detection of fatal illnesses, and delayed treatment (Castro *et al.*, 2016; Magrabi *et al.*, 2015; Odukoya *et al.*, 2014; IOM, 2011). The safety risks can lead to safety incidents

which could have resulted, or did result, in unnecessary harm to patient (Runciman *et al.*, 2009). The root cause of adverse event or medical error due to the implementation and use of HIS are multifaceted and may originate from numerous factors (Meeks *et al.*, 2014). This leads to the essential need to understand the root cause and criteria for the safe use of HIS in order to provide safer HIS.

The growing concern related to medical errors resulted from the implementation and usage of HIS has increased (Beuscart-Zéphir *et al.*, 2013). A number of national initiatives have been taken to comprehend the safety of HIS (Kushniruk *et al.*, 2013; Magrabi *et al.*, 2013). Recently, sociotechnical approach is frequently recommended for patient safety improvement efforts (Singh and Sittig, 2015; Middleton *et al.*, 2013; IOM, 2011). Safety incidents emerged from the interactions between people and the elements of technology, tasks, environment, and organisation in which they work (Carayon *et al.*, 2014; IOM, 2011). Evidently healthcare practitioners, healthcare organisations, and researchers need to discern the antecedents towards the safe use of HIS, particularly from the perspective of sociotechnical approach. As such, this can provide further insights into the safe implementation and the use of HIS as a tool to improve the quality of healthcare and patient safety.

1.2 Background of the Research

Healthcare system is a complex and high-risk system (Taib *et al.*, 2011). The complex activities require ad hoc and pragmatic response that are never completely predictable from patients' reaction (Berg, 1999). In critical care, the complexity of performing tasks is augmented by the constriction of time, inadequate or unavailable information, stress, and repeated and unpredictable interruptions (Alvarez and Coiera, 2005). Besides, healthcare practitioners perform multiple task simultaneously such as interpreting physical signs and diagnostic tests, and they are bound to organisational policies and patient's personal needs (Ash *et al.*, 2004). Healthcare work is also emergent in nature which involves a high degree of ambiguity and uncertainty, and

requires a high degree of coordination (Borycki *et al.*, 2012). It involves intersection and inter-reliant components such as various level of professional from various departments with multiple viewpoints required for specific treatment (Berg, 1999). The tasks are frequently context-dependent, unpredictable, interrupted, and dependant on coherent and timely communication among different healthcare practitioners (Ash *et al.*, 2004). Therefore, the interdependent nature facilitates the propagation of errors in such that any error created by one component may affect other components which is normally unpredictable (Taib *et al.*, 2011).

Since the publication of the Institute of Medicine (IOM) report entitled "To Err Is Human: Building a Safer Health System" (1999), paramount attention has been given by healthcare organisations and institutions at both the national and international level to create safe healthcare (Beuscart-Zéphir *et al.*, 2013). In their report, it is stated that 98,000 people die every twelve months in the United States (US) resulted from medical errors (Kohn *et al.*, 2000). Consequent to this report, the implementation of HIS has become a primary strategy to improve the safety of healthcare (IOM, 2000). Indeed, many developed countries such as the US, United Kingdom (UK), Australia, and Canada have proactively encouraged the implementation of HIS (Waterson, 2014; Morrison *et al.*, 2011; Rozenblum *et al.*, 2011).

HIS can prevent errors and adverse events (Bates and Gawande, 2003). Nevertheless, there are evidence indicating that HIS can cause patient harm, injury, disability, and death (Castro *et al.*, 2016; Magrabi *et al.*, 2015; Metzger *et al.*, 2010). A retrospective analyses of pre-CPOE (computerized physician order entry) and post-CPOE implementation were conducted. Results uncovered that mortality rate among children who are admitted to a children's hospital during an 18-month period significantly increased from 2.80% to 6.57% after CPOE implementation (Han et al., 2005). The unexpected increased of the mortality rate was due to the CPOE implementation profoundly altered patient care workflow processes as well as inadequate or unreliable computing capacity. Hence, caused delays in the delivery of life-saving medications, treatments, and diagnostic. Moreover, retrospective analysis of all safety events between September 2005 and November 2011, revealed that death were reported associated with the use of health IT (Magrabi *et al.*, 2015). Two of the

deaths were related to patient misidentification and failure to treat through software use errors. While the third linked to a delay in treatment following hospitalisation due to a pending test result from a preceding hospitalisation which was not accessible to the attending doctors.

A recent study has analysed 100 unique and closed investigations between August 2009 and May 2013 from 344 reported incidents, which revealed 74 of the safety concerns involving unsafe technology, whereas 25 involving the unsafe use of technology (Meeks *et al.*, 2014). In another study, types of e-prescribing errors and their potential consequences in five community pharmacies in the US were explored (Odukoya *et al.*, 2014). It was found that 75 e-prescribing errors were documented during 45 hours of observation. The factors that contribute to the errors include the technology incompatibility between pharmacy and clinic system, technology design issues, and inadvertently entering incorrect information. In a more recent study was conduct to analyse patient safety events associated with England's national programme for IT (NPfIT) (Magrabi *et al.*, 2015). It was also identified that the safety problems were predominately associated to technical problem (92%) rather than the human factor. The technical problems include errors in the display of clinical information, power failure, the slow or down of hardware, and non-accessible software. On the other hand, human factor problems were related to the interaction between humans and IT. Likewise, Castro *et al.* (2016) discovered that human-computer interface, workflow and communication, and clinical content–related issues are the most common contributing factors associated with health IT–related events. In general, the studies showed that the antecedents towards the safe use of HIS are not solely dependent on the technology, but also influenced by the sociotechnical aspects.

Despite its tag as a new developed country, Malaysian government has achieved significant progress in the development and utilisation of IT in the healthcare sector. The Ministry of Health Malaysia (MOH) under the Tele-health Flagship Application has embarked on introducing HIS in several government hospitals known as Total Hospital Information System (THIS) project (Mohan and Razali Raja Yaacob, 2004). The objective of the project is to establish a paperless hospital environment through a comprehensive information communication and technology (ICT) system,

which is subsequently expected to offer a quality healthcare service. Although THIS has been implemented, medical errors, particularly medication errors have resulted in patient harm (NPCB, 2012). Besides, there is paucity on studies related to HIS safety in the Malaysian context. Majority of the patient safety research in Malaysia were at the earlier stages that are concerned about identification of the risks and hazards (Yoelao *et al.*, 2014).

1.3 Statement of the Problem

The primary goal of HIS implementation is to improve the quality of patient care and patient safety (IOM, 2000). Even so, previous studies have shown that HIS can cause patient harm, injury, disability, and death (Magrabi *et al.*, 2010b; Metzger *et al.*, 2010). The US Food and Drug Administration (FDA) reported 42 reports of patient harm, and four deaths in 436 critical incidents involving health information technology (IT) over 30-months period, from January 2008 to July 2010 (Magrabi *et al.*, 2010b). In a more recent study carried out in 2015, 899 safety events associated with England's national programme for IT (NPfIT) managed by a dedicated IT safety team were analysed (Magrabi *et al.*, 2015). It was revealed that 3% of the safety events were associated to patient harm, specifically three recorded deaths. Likewise, Castro *et al.* (2016) identified over half of the health IT–related events reported to the Joint Commission between January 1, 2010, and June 30, 2013 resulted in patient death, 30% caused unanticipated or additional care, and 11% led to permanent loss of function. The three most repeatedly identified event types are i) medication errors, ii) wrong-site of surgery (including wrong side, wrong procedure, and wrong patient), and iii) delay in treatment.

The new safety risks that emerged have led to new types of errors, namely technology-induced errors or IT-related health errors. These errors may be attained during the design and development of a technology as well as its implementation, customisation, and adoption (Kushniruk *et al.*, 2013). In a large complex system, safety issues tend to rise from unexpected interactions between system components