A Study of Adverse Events in Chinese Hospitals

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Submitted in fulfillment of the requirements for the degree of
Doctor of Philosophy

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January, 2014

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ABSTRACT

Adverse events (AEs) have negative impacts on patients, and may sometimes cause severe harm to patients and even death. This thesis aimed to investigate AEs in Chinese hospitals. Two studies had been designed and conducted in order to meet the aim.

The first study, a systematic review, was designed to collect relevant evidence about the prevalence, consequence, classifications of AEs in the past 7 years. Seven studies were included in the systematic review (Figure 0.1), which were sub-grouped to studies carried out in developed countries and developing countries. The research conducted in developed countries identified higher prevalence rates of AEs than in developing countries, but a higher proportion of AEs were considered to be preventable in developing countries. In addition, higher proportion of AEs in developing countries were found to cause patient mortality. The review showed that no studies measured AEs in China from a hospital-wide level.

The second study of this thesis aimed to determine the prevalence, preventability, consequence and risk factors of AEs in Chinese hospitals. A medical record audit was conducted based on a two-stage retrospective medical records review protocol. In total, the records of 1,897 patients (Figure 0.2) were randomly selected from two Chinese hospitals. Both of the hospitals were public secondary-level hospitals, located in a major city in China, with around 550 beds in each hospital. Each medical record was screened by a nurse according to 17 explicit screening criteria. If one or more criteria were satisfied, the medical record was forwarded to a panel of doctors for further review. Two doctors reviewed each medical record independently. There were 16 nurses involved in screening process and 40 doctors participated in the review process. A summary of the study process appears in Figure 0.2.

Figure 0.1 Systematic Review Study Process

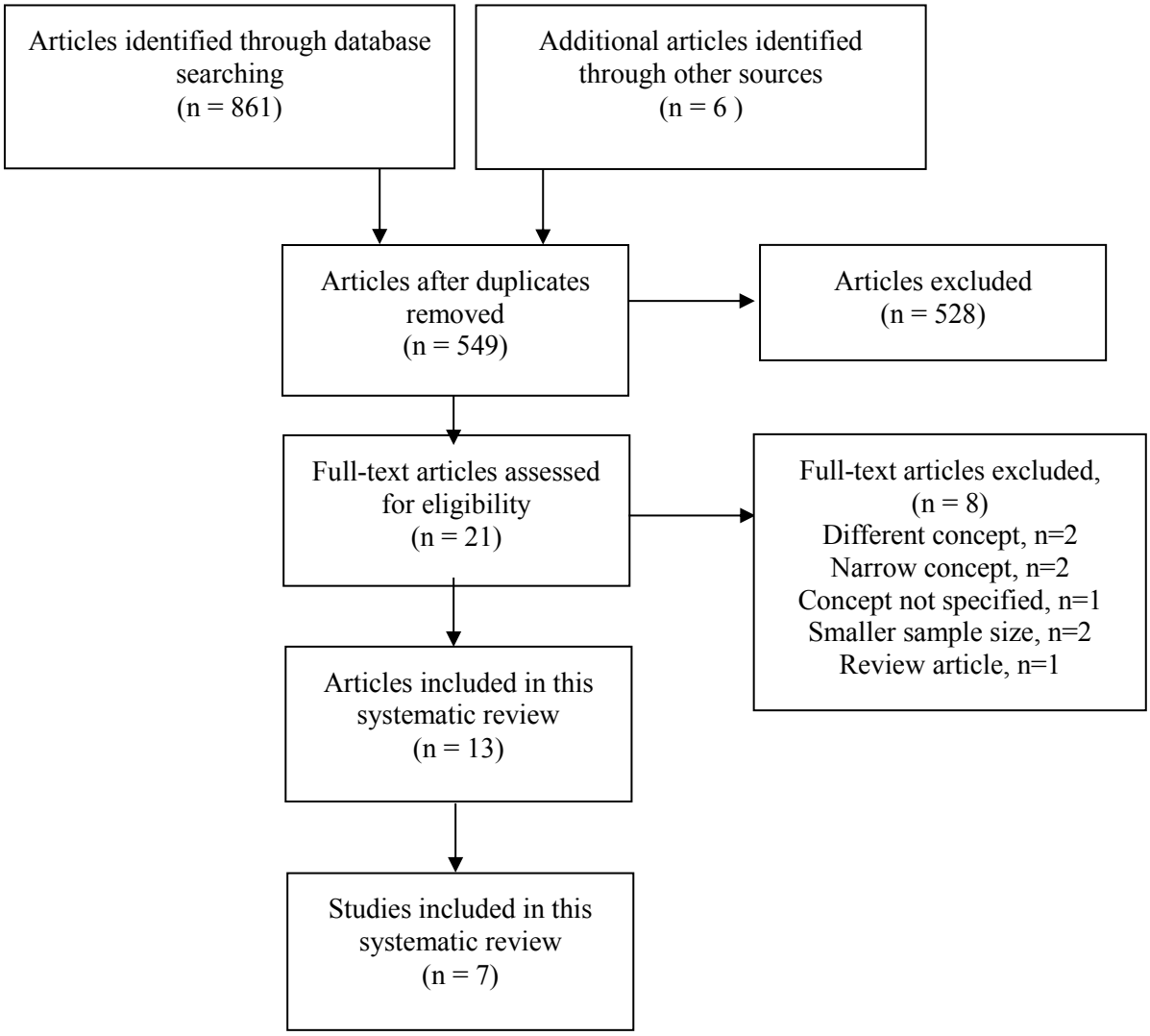
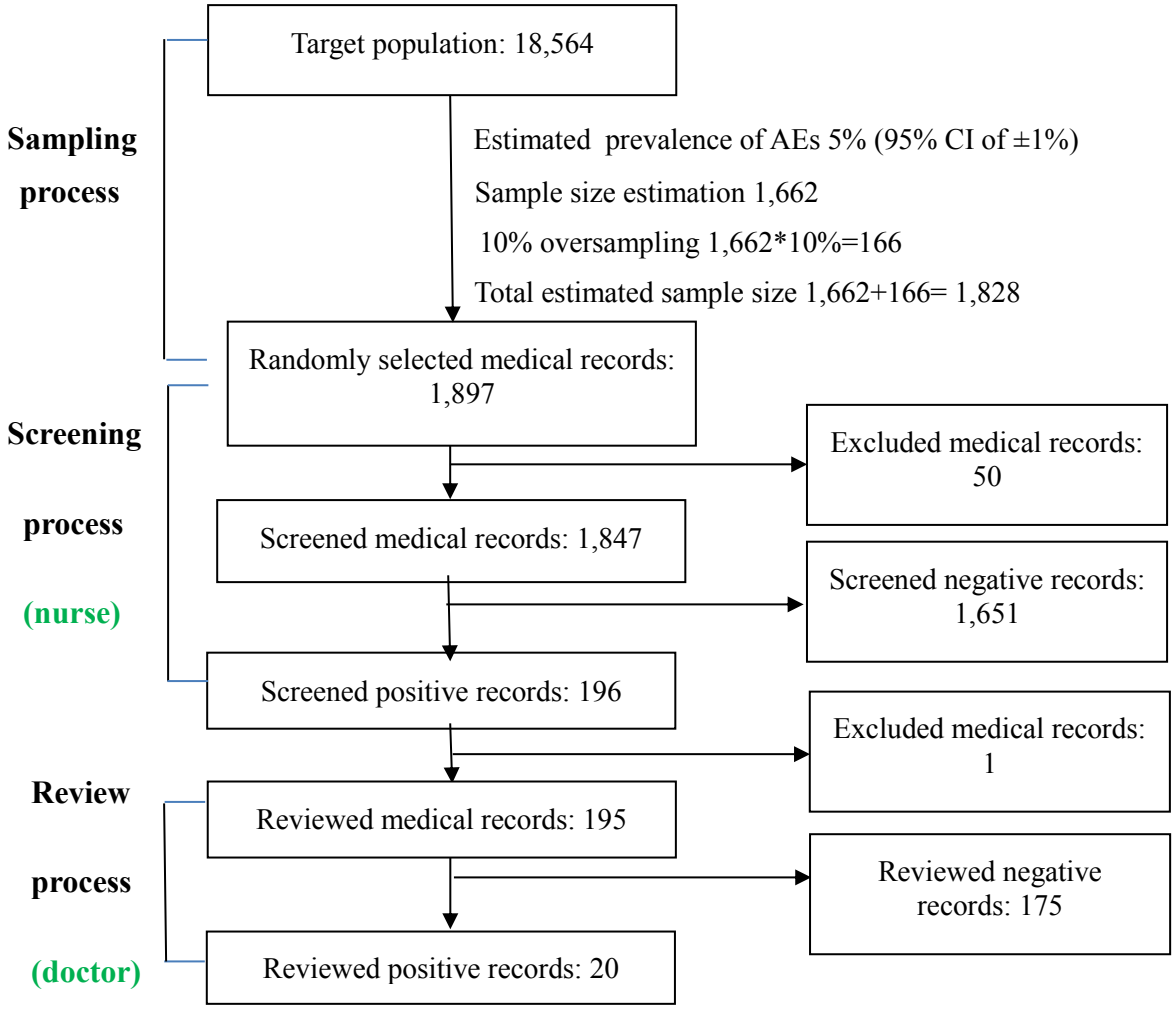


Figure 0.2 Medical record audit study process



The medical records were screened by nurses, with a screening positive rate of 10.6% (9.3%-12.1%, 95% CI). Older patients (≥65 years) who were admitted to non-surgical departments and stayed in hospital longer than 14 days had more risk of being screened as positive for AEs. After review by doctors, the review positive rate (prevalence) of AEs was dramatically reduced to 1.14% (0.69%-1.68%, 95% CI). Surprisingly, all the AEs were judged as preventable by doctors, and 85% were highly preventable. Forty percent of detected AEs caused temporary disability to patients, but no permanent disability or deaths caused by AEs were found based on doctors' judgments. Patients with longer hospital stays, in particular longer than 24 days, had more risk to be judged as AEs case by doctors.

The unexpectedly low screening positive rate and review positive rate (prevalence) of AEs based on the nurses' and doctors' decisions were found to be remarkably lower than previous studies. The results may have been significantly influenced by the quality of medical records in China. However it is very likely that the reviewers' judgments, especially the doctors', had a major impact on the study results. The results generated by the nurses in the screening process were considered to be more credible and consistent with other studies.

The thesis concludes with a discussion of the implications of the study findings for future policy and practice in Chinese hospitals as well as the implications for future research in this area. From policy and practice level, the implications include establishment of governance for patient safety, nurses' crucial role on reduction of AEs, improvement of the quality of medical record, and protection of healthcare professionals' safety. From the research level, this thesis could be a base study for further exploration on methodologies about detection of AEs and localised screening criteria. In addition, more and upgraded training is recommended for future medical record audit study.

DECLARATION

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other institution and affirms to the best of my knowledge that this thesis contains no material previously published or written by another person, except where due reference is make in the text of the thesis.

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PUBLICATION AND CONFERENCE

PRESENTATIONS

The following publication and conference poster were produced during my PhD candidature.

Chen, N., S. Thomas, C. Browning and H. Yang (2009). "International research on adverse drug events and implications for Chinese hospital quality improvement." Chinese Health Quality Management **16**(6): 1-6.

Chen, N., S. Thomas, and H. Yang (2012). The study of adverse events in Chinese hospitals. Paper accepted as Presentation at the Hospital Quality Improvement Forum, Beijing, 15 April, 2012.

Chen, N., S. Thomas, and H. Yang (2012). The study of adverse events in Chinese hospitals. Paper accepted as Poster Presentation at the International Forum on Quality and Safety in Healthcare, Paris, 17-20 April, 2012 (accepted, unable to attend).

Chen, N., S. Thomas, and H. Yang (2013). A Study of adverse events in Chinese hospitals: the perception gap between doctors and nurses. Paper accepted as Poster Presentation at the International Forum on Quality and Safety in Healthcare, London, 16-19 April, 2013.

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to a number of people who have enabled me to complete this journey. First of all, I am indebted to my supervisors, Professor Shane Thomas and Dr. Hui Yang, for their supervision, support, encouragement, advice, understanding, tolerance, and most importantly, friendship during my candidature. I appreciate their patience with my learning, and the many hours they spent explaining things to me and correcting my mistakes. Their wisdom and knowledge in the area of patient safety always inspired me and motivated me. Their constant words of encouragement always came at the time I needed them.

In addition, I would like to acknowledge the support of the hospital managers in the two participating hospitals, and the hard work of all nurses and doctors who participated in this study, although I cannot name them for reasons of confidentiality. Their dedication and commitment to achieve patient safety encouraged my hope of improving patient safety in China. I am also grateful to all staff at the Primary Care Research Unit who helped me in different ways during my candidature. In addition, I would like to thank Dr. Alex McKnight for assistance by proofreading a draft of the thesis for grammatical errors.

I would like to express the warmest appreciation to my parents, Qiusheng and Chune, who always love me, encourage me, comfort me, and be there for me. Their belief that I would be able to achieve this was one of the main reasons I decided to pursue a doctorate. As their only child, I appreciate their sacrifice for everything.

Finally, very special thanks to my husband and lifetime best friend, Jingwei, for his continued and unfailing love. Without his support, encouragement and understanding, I would not have been able to go this far. I also thank our lovely daughter, Amy, who joined us when I was writing up this thesis. She gives me unlimited happiness and pleasure. Her smiles helped me to efficiently overcome all the difficulties I encountered in my pursuit of the doctorate. This thesis is dedicated to both of you, Jingwei and Amy.

GLOSSARY OF ABBREVIATION AND ACRONYMS

AE	Adverse Event
AIDS	Acquired Immunodeficiency Syndrome
ALOS	Average Length Of Stay
AMI	Acute Myocardial Infarction
AUD	Australian Dollar
BMI	Basic Medical Insurance
UE-BMI	Urban Employees' Basic Medical Insurance
UR-BMI	Urban Residents' Basic Medical Insurance
CBD	Central Business District
CDM	Clinical Decision-Making
CHQIS	China Healthcare Quality Indicators System
CNKI	China National Knowledge Infrastructure
CNY	Chinese Yuan
CVA	Cerebrovascular Accident
EMR	Electronic Medical Record
G&O	Gynecology & Obstetrics
GDP	Gross Domestic Product
GHI	Government Health Insurance
GTT	Global Trigger Tool
HQMS	Health Quality Monitor System
ICD-10	International Classification of Diseases-10th Revision
ICU	Intensive Care Unit
IQR	Inter-Quartile Range
LOS	Length Of Stay
MOH	Ministry Of Health
NCMS	New Rural Cooperative Medical Scheme
OOP	Out Of Pocket
PAE	Preventable Adverse Event
PE	Pulmonary Embolism
RF	Review Form
RMRR	Retrospective Medical Record Review
SPSS	Statistical Product and Service Solutions
THE	Total Health Expenditure
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

CHAPTER ONE: INTRODUCTION

This chapter will provide background information and rationale of studying adverse events (AEs) from different perspectives. Firstly, the definitions of AEs adopted by research will be summarised and compared. In addition, necessity to study AEs and prevalence of AEs is stated. Thirdly, the nature and cost of AEs will be discussed. The aims, scope and structure of this thesis will be provided at the end of the chapter.

1.1 Definitions of adverse events

The definition of AEs is a conditional and contextual concept which can be defined in different ways. To date, there is no universal definition of adverse events (AEs). The table below lists some existing definitions (Table 1.1) in the research literature. Although the definitions differ, each has three common elements to some degree: ***undesirable events***, ***impacts on patients*** and ***causation***.

Table 1.1 Definitions of AEs

Study citation	Definition of AEs
Wilson, Runciman et al. (1995)	An unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused by health care management rather than the patient's disease
Department of Health (2002)	An event or omission arising during clinical care and causing physical or psychological injury to a patient.
Walshe (2000)	An untoward or undesirable occurrence in the healthcare process which has or potentially has some negative impact on a patient or patients and results or may result from some part of the healthcare process
	An event that was unfavourable for the patient, and was consequent to medical management (treatment planning and treatment, diagnosis, prevention or rehabilitation) rather than being an inherent part of the pathological process.
Michel, Quenon et al. (2007)	Unfavourable events were included if they were: ●Associated with death or life-threatening conditions; ●Liable to lead to an extension by at least 1 day of the hospitalisation period; ●Liable to lead disability or handicap at the end of hospitalisation in the unit involved in the study.
Sari, Sheldon et al. (2007)	An unintended event resulted in patient harm (prolongation of hospital stay, disability at discharge and/or extra cost of treatment), and it was caused at least partly by healthcare rather than by disease process alone.
Griffin and Resar (2009)	Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.
Wilson, Michel et al. (2012)	An unintended injury that resulted in temporary or permanent disability or death (including increased length of stay or readmission) and that was associated with healthcare management rather than the underlying disease process.

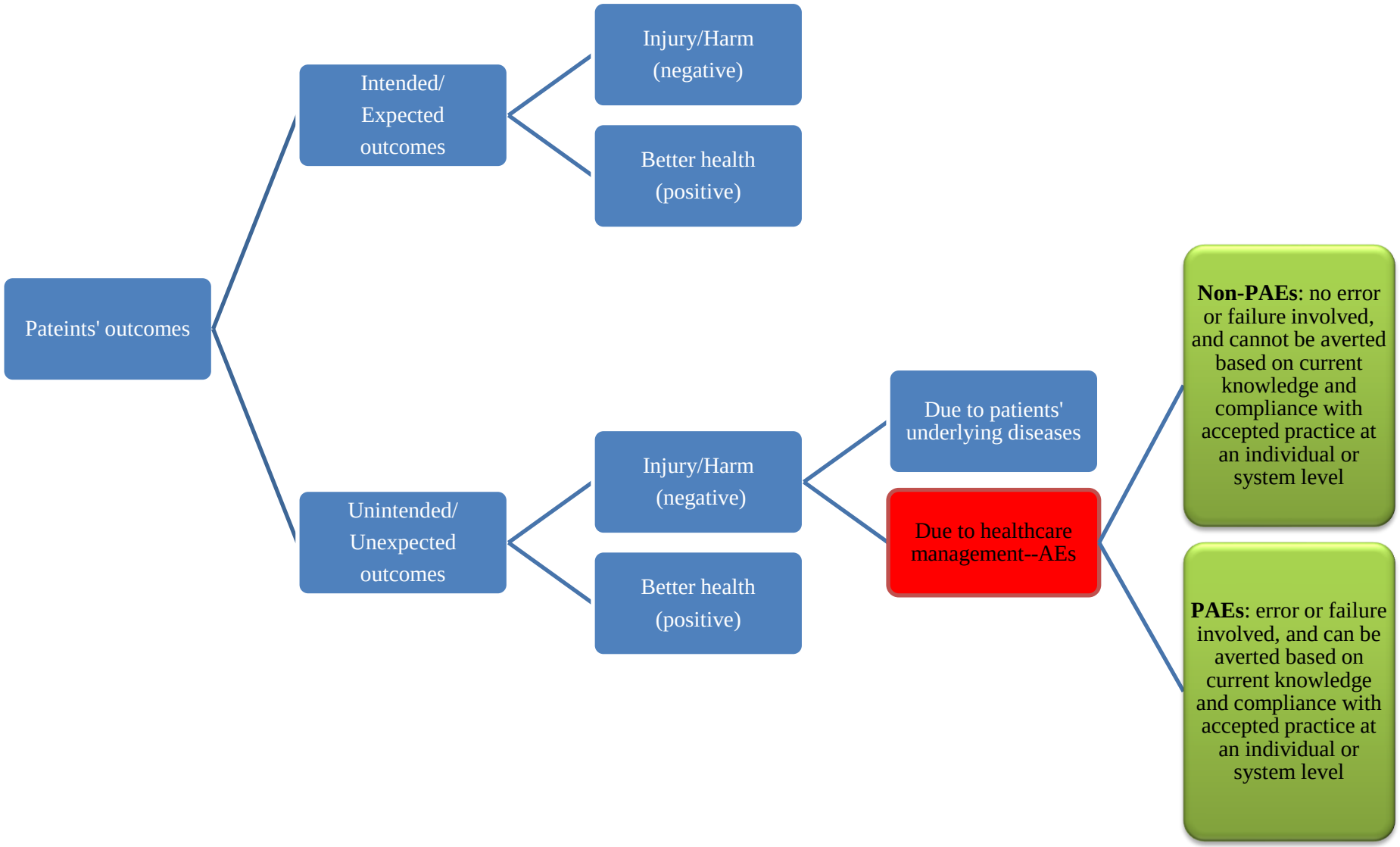
First of all, AEs are described as unintended or unfavourable events, which emphasises their negative nature. This is a common component in every definition of AEs. However, the impact on patients is defined differently between definitions. The impact may be either physical injury or both physical and psychological injury (Department of Health 2002); it could be either an occurred impact or a potential impact (Walshe 2000). In terms of the severity of the impact, most of definitions include patients' disability, death or prolongation of hospital stay (Wilson, Runciman et al. 1995; Michel, Quenon et al. 2007; Griffin and Resar 2009; Wilson, Michel et al. 2012). However, in the definitions stated by Sari, Sheldon et al. (2007) and Griffin and Resar (2009), the impact to patients have a boarder scale. Unintended events results in additional monitoring or treatment to patients are also recognised as AEs. Thirdly, the causation of AEs may be defined differently. Some definitions state that an AE is an undesirable injury caused by healthcare management (Wilson, Runciman et al. 1995; Sari, Sheldon et al. 2007), while other definitions describe it is as being caused by medical management (Michel, Quenon et al. 2007). Compared with medical management, healthcare management also includes non-medical aspects, such as logistics service, system factors, hospital design etc (Zegers, De Bruijne et al. 2007). Nevertheless, the common point about causation in all definitions is that AEs are not caused by the patient's underlying disease. Consider the differences of definitions of AEs, studies have used different definitions, applied different boundaries and captured different numbers of AEs, which have consequently contributed to different results of the prevalence of AEs.

A widespread accepted definition of an AE is "*an unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused by health care management rather than the patient's disease*" (Wilson, Runciman et al. 1995). Many countries employ this definition to guide research on AEs, including Australia, New Zealand, Canada, Brazil and the Netherlands (Wilson, Runciman et al. 1995; Davis, Lay-Yee et al. 2002; Baker,

Norton et al. 2004; Mendes, Martins et al. 2009; Zegers, de Bruijne et al. 2009). Some examples of AEs are provided by Wilson, Runciman et al. (1995).

There are two major categories of AEs: preventable AEs (PAEs) and non-preventable AEs (non-PAEs) (Figure 1.1). Generally, PAEs are resulted from a failure or an error in treatment and/or management, and they could be averted by applied different treatment or management based on current knowledge and compliance with accepted practice at an individual or system level (Zegers, De Bruijne et al. 2007; Wilson, Michel et al. 2012). However, the boundary between PAEs and non-PAEs is normally not a clear cut due to the nature of uncertainty of medicine.

Figure 1.1 The definition of AEs



1.2 Necessity of studying adverse events

In 1999, the Institute of Medicine of USA announced a report entitled "To err is human: Building a safer health system". In this report, safety is described as the first dimension of quality (Institute of Medicine 1999). 'First do no harm' is considered a motto by health care professionals (Hurwitz and Sheikh 2009). Like the aviation and nuclear industries, healthcare is a high-risk industry. However, it was the last industry to take note of human factors and safety issues, and now, patient safety as an important component of quality is widely recognised as a priority in the healthcare industry (World Health Organisation 2006).

The intervention to improve patient safety needs to be evidence-based (Bucknall 2011). In patient safety research and practice, the first step is to measure harm. The World Health Organisation (WHO) provides a five-step research model to guide research in this field (WHO 2009). Measuring harm as the initial step will direct an understanding of the extent, causes and effects, which could assist in identifying solutions, followed by translating research evidence into interventions for safer care. Unfortunately, existing information about patient safety, especially the incidence and causation of harm is insufficient. It is impossible to introduce any relevant and evidence-based intervention to reduce and prevent harm to patients unless policy makers and hospital managers are informed where, why and to what extent patient harm occurs (WHO 2008).

Performance indicators could be inclusive of patient safety, such as unplanned re-admission, surgical site infection, patients' falls, etc. However, the prevalence of adverse events (AEs) is recommended as the most important indicator of patient safety (Baker, Norton et al. 2004; Steering Committee for the Review of Government Service Provision 2012), because it provides a comprehensive understanding of harm in healthcare setting instead of focusing on a specific safety problem. Unfortunately, information about the prevalence of AEs is deficient, and this is considered as the main obstacle to the achievement of the goal of "safety" in

healthcare (WHO 2008).

By measuring the prevalence of AEs, the process of healthcare could be evaluated. Generally speaking, the evaluation of the quality of healthcare can be conducted from either a "process" or an "outcome" perspective (Lilford, Mohammed et al. 2003). During the investigation about prevalence of AEs, the severity, natures, causations, consequences and preventability of AEs are evaluated as well, which could reflect the process of healthcare (Liang, Jiao et al. 2010). In addition, according to Mant and Hicks (1995), if two hospitals have only small differences in comparisons of outcomes (such as prevalence of AEs), this could be attributed to measurable and remarkable differences in clinical processes. For example, some AEs have a high potential to cause severe damage but very rarely happen, such as wrong site surgery, so are unlikely to affect outcomes from an organisational level. On the other hand, if an AE happens frequently but with less severe impact, this also hardly influences outcomes. Overall, more gains could be achieved through the investigation to the prevalence of AEs by measuring process, which could be used for continuous quality improvement. In addition, the quality of healthcare could be measured more objectively and comprehensively by AEs-related indicators (Ma 2007).

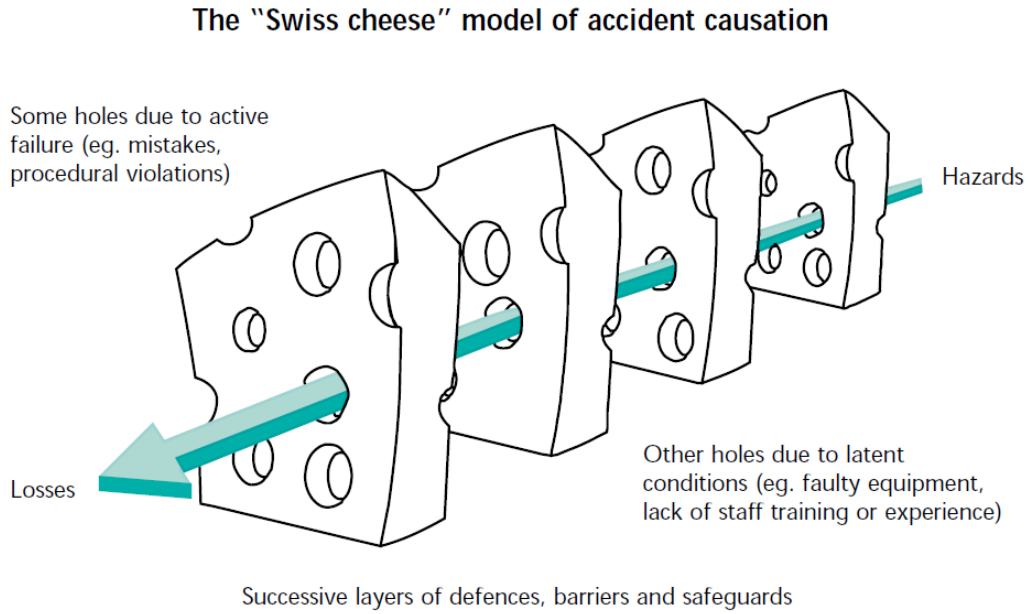
Brennan, Leape et al. (1991) conducted a pioneering study to investigate the incidence of AEs. This study had a profound impact on this research area. Firstly, this study focused the attention of the public and policy makers on patient safety problems. Secondly, the methodology of this study, a retrospective medical record review (RMRR), is considered as a main streams and has been utilised widely all over the world for similar research studies (Baker 2004). RMRR involves two stages. In the first stage, each medical record is screened according to a list of explicit screening criteria. Positive cases are forwarded for second-stage review by physicians to identify any AEs (Hiatt, Barnes et al. 1989). More detailed description about RMRR will be provided in Chapter 4.

1.3 Nature of adverse events

It appears that human errors are the main contributor to AEs, because the predominant causation of AEs is related to human causes (61%-82%) (Wilson, Harrison et al. 1999; Smits, Zegers et al. 2010). In fact, AEs are more commonly related to organisational factors, because most of the human causes were caused by organizational factors (Institute of Medicine 1999). Almost all preventable AEs (93%) are associated with organisational factors, such as lack of protocols, failures of equipment and poor hospital constructed design (Smits, Zegers et al. 2010).

The nature of AEs can be understood systematically by applying the "Swiss cheese" model (Figure 1.2), which was developed to explain how unintended events happen in the real world (Reason 2000). This model has been widely accepted and implemented for risk management in many fields, including in medicine. WHO adopted this model to explain the occurrences of AEs in healthcare environment (World Health Organisation 2008).

Figure 1.2 The "Swiss cheese" model



Source: World Health Organisation (2008)

Ideally, hospitals should build up defences to separate organizational problems (hazards) and AEs (losses). However, in reality, there are “holes” in each layer of defence, and the “holes” keep opening, shutting and changing locations (Reason 2000). The appearance of an AE is a cumulative act effect of faults in defences. The hazard passes through “holes” in different layers and finally becomes a loss, which is represented as an AE.

The “holes” in the defences consist of two types, active failures and latent conditions. Active failures are unsafe acts which are committed by healthcare professionals in hospitals, such as mistakes and violations of procedures. Because people who commit active failures normally have direct contact with patients, they are recognised as at “the sharp end” of an AE (Reason 2000; Department of Health 2001). In contrast, latent conditions are at “the blunt end” of an AE (Reason 2000; Department of Health 2001), and hidden in the system. Some of them cannot be foreseen until they combine with active failures and become an AE. Latent conditions may include holes in the system, such as low staffing levels, poorly written prescriptions, lack of training etc.

As a response to AEs, hospitals traditionally blame the individual(s) directly involved, which is called the “personal approach”. Healthcare professionals, in particular, doctors and nurses, are blamed most frequently and considered the cause of AEs because they are at the “sharp end”. It is human nature to blame someone rather than some organisation, and people find it more satisfactory (Reason 2000; World Health Organisation 2008). However, the personal approach does not emphasise latent conditions. Once unsafe acts are identified and target individuals are blamed, the case is closed. In fact, the application of this approach is a major obstacle to patient safety development, because, in reality, everyone can make mistakes, and the best and most experienced people may make the worst mistakes. In addition, the same mistakes tend to have a repeat pattern if the conditions remain the same (Reason 2000).

In contrast, the "system approach" believes to err is human. As the "Swiss cheese" model illustrates, people are led to make mistakes or fail to prevent mistakes because of the different system holes. When AEs happen, the hospital needs to deeply investigate latent failures rather than simply blaming someone. The most important questions to ask are why and how the defences failed. Ideally, if the whole system can be designed to be safer and better, people will be guided to do something right rather than wrong (Institute of Medicine 1999). From the patient safety improvement perspective, the system-level interventions are essential (Bucknall 2011).

1.4 Consequences of adverse events

AEs may have enormous impacts on patients' lives from both finances and other non-financial aspects. It was estimated around 43 million AEs occur all over the world in only 1 year and lead to approximately 23 million associated disability-adjusted life years (Adhikari 2013). AEs kill more people per year than breast cancer or acquired immunodeficiency syndrome (AIDS) in the USA, and it is one of the top 10 leading causes of death (Institute of Medicine 1999). Each year in the USA, 44, 000-98,000 preventable deaths happen due to AEs (Institute of Medicine 1999). In Australia, about 18,000 deaths and more than 50,000 disabilities result from AEs annually (Weingart, Wilson et al. 2000). A Dutch study noted that 10.7% of deaths in hospital were associated with AEs, and 4 deceased patients out of 100 were killed by AEs directly (Zegers, de Bruijne et al. 2009). The estimation is even more shocking in Brazil, where 34% of deceased patients were related to AEs, and 26.6% of hospital deaths involved preventable AEs (Martins, Travassos et al. 2011).

From a financial perspective, an estimated cost of $36 billion was due to AEs in the USA, equivalent to 4% of the annual national health expenditure (Thomas, Studdert et al. 1999). In Australia, AEs result in 3.3 million bed days annually, which incur a cost of over $2 billion (The Australian Commission for Safety and Quality in Health Care 2004; Commonwealth of

Australia 2010). A huge expenditure is also attributed to AEs in the UK, where the expenditure due to increased hospital stays alone is over £2 billion per year (Department of Health 2000).

Apart from the above direct financial costs, AEs cause pain and anxiety to patients, consequently increasing dissatisfaction with the healthcare service or causing loss of trust and confidence in the healthcare system (Brady, Redmond et al. 2009). Health professionals suffer frustration and low job satisfaction when they think they do not provide the best service, and lower levels of health status, lost work productivity, and lower school attendance are burdens on the whole society (Institute of Medicine 1999).

1.5 Aims of the thesis

This thesis includes a systematic review and a medical record audit study. The objective for a systematic review to literature is to identify the difference of prevalence, consequence, preventability and classifications of AEs between developed countries and developing countries. In addition, by conducting systematic, the published articles about AEs in China would be identified. Finally, the research questions for medical records audit study would be able to generate after the systematic review to previous literature.

The second part of this thesis is a medical record audit study, which will be the first comprehensive epidemiological study of AEs in Chinese hospitals. The aim of this study is to measure the prevalence and other characteristics of AEs from hospital-wide level. Patients who are more vulnerable to suffer AEs would be explored as well. Ideally, this study could inform healthcare quality managers to develop further patient safety initiatives and arouse policy-makers' attention, and provide suggestions on clinical contents changes.

1.6 Scope of the thesis

The systematic review included in this thesis only searched the articles published from January 2007 to July 2013, since a previous systematic review had included articles published before 2007 (de Vries, Ramrattan et al. 2008). All the included studies should be designed to investigate the prevalence of AEs from a hospital-wide level, and published in either English or Chinese. The studies were not included in this systematic review if sample size smaller than 1,000 in order to maintain consistence with the previous review (de Vries, Ramrattan et al. 2008).

The medical record audit study focuses on an investigation of the prevalence of AEs in Chinese hospitals by applying the retrospective medical record review (RMRR) method. AEs in other settings (community health centres, out-patient services) were not included in this thesis. AEs identified through other methods are beyond the scope of this study, such as reporting systems, interviews and observations. In addition, strategies to prevent and/or reduce AEs will not be discussed in detail.

1.7 Structure of the thesis

As stated previously, the fundamental aim of this thesis is to determine the prevalence of AEs in Chinese hospitals. This chapter**, Chapter 1**, has provided the rationale of this thesis. Concepts and theories of AEs have been reviewed.

In **Chapter 2**, a systematic review was conducted to investigate and analyses the evidence for AEs, in particular the prevalence of AEs, in the research literature. The methods, results and discussion of the systematic review are described and discussed in details.

Chapter 3 introduces background information about China and the Chinese health system, in particular hospital system. The hospital system is introduced from 5 angels: administrative management, facility, finance, human resource, and information management. In addition, the

current indicators system to evaluate patient safety and AEs in China is described. In order to gain further understanding about AEs in Chinese context, the status of medical disputes and the doctor-patient tension in China is briefed introduced.

Chapter 4 encompasses the details of methodology of the medical record audit study to investigate the prevalence of AEs in Chinese hospitals. Definitions related to this study are classified at the beginning. The study design, sample selection, the review process, the development of review forms, reliability test and other issues related to data collection are described in detail.

Chapter 5 presents the results generated from this study. The characteristics of the sample and general results are reported at the first part of Chapter 4. Then, followed by a detailed analysis of the results of the screening and reviewing process.

Chapter 6 compares this study with similar studies conducted in other countries before, especially with developing countries. For a better understanding and interpretation of the results, factors influencing reviewers' clinical decision-making and the quality of medical records will be discussed. In addition, based on the findings of this thesis, further implications for policy, practice and theory will be proposed.

CHAPTER TWO: STUDIES OF ADVERSE EVENTS:

A SYSTEMATIC REVIEW

A systematic review about the previous literature to investigate the AEs from a hospital-wide level is conducted, which could effectively identify related publications in this field, synthesis the published results and generate the research questions for the medical record audit study in China.

2.1 Introduction

AE research dates from about 30 years ago, and a number of countries have conducted research into the prevalence or incidence of AEs, while there is very little literature in developing countries. A systematic review was conducted 6 years ago to investigate the incidence of AEs in 8 studies (de Vries, Ramrattan et al. 2008). In order to explore the development and findings of AEs studies in recent years (2007-2013), the present systematic review is designed to provide updated information about AEs studies. The objective of this systematic review is to explore the latest development of AEs studies, especially in developing countries.

2.2 Methods

In order to maintain consistency, the search strategy, inclusion and exclusion criteria of this systematic review were adopted from a previous systematic review published by de Vries, Ramrattan et al. (2008), which is a comprehensive and detailed systematic review about AEs.

2.2.1 Search strategy

A computer-based literature search of MEDLINE, EMBASE and Cochrane Library was conducted in August 2013. The author used “adverse events” and “preventable” as keywords. Published studies that reported the prevalence of AEs and were conducted in representative population samples were included in this review. The search was restricted to studies published from January 2007 through July 2013. A cross-reference search of retrieved articles was conducted manually. The year 2007 was used as the cut-off point was because de Vries,

Ramrattan et al. (2008) included research published from January 1966 to February 2007.

Another computer-based database search was performed in September 2013 for articles published in Chinese language in China. Wangfang Data[1] and CNKI[2] were searched using " 负性事件" ("adverse events" in Chinese, literally means negative events) as the keyword. A cross-reference search was conducted as well.

2.2.2 Study selection

As with the search strategy, the inclusion and exclusion criteria for this systematic review were the same as the previous study (de Vries, Ramrattan et al. 2008). All included articles define AEs the same as, or similar to the following: an unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused by health care management rather than the patient's disease. Sample sizes of included studies were not smaller than 1,000 patients or medical records. All the studies investigated the in-patient hospital-wide situation of AEs across hospitals with no restriction on types of AEs and types of patients. The consequences of the AEs needed to be described and classified according to their severity.

Studies which focused on specific populations (eg. patients in intensive care unit (ICU)) or specific types of AEs (eg. diagnostic AEs) were excluded. In addition, if the AEs screening was carried out simply on the basis of computerised screening process, those studies were excluded (de Vries, Ramrattan et al. 2008). Because most of the computerised programs were normally designed to capture specific key words in medical records, and the findings were only limited to those designed key words. Studies which investigated AEs in out-patient settings only were not included. Disagreements about inclusions were reconciled through discussion between the author of this thesis (NC) and one of her supervisors (HY).

[1] E-resources provided by Institute of Scientific and Technological Information of China
[2] CNKI is the abbreviation of China National Knowledge Infrastructure. The database is called as China Knowledge Resource Integrated Database.

2.2.3 Data extraction and analysis

All data were extracted by the author of this thesis. The extracted data included:

- characteristics of studies: citations, country of origin, purpose of study, time of setting, number of hospitals, sample size, study design, definitions of AEs, population, oversampling, number of reviewers in the second stage, reliability test, and Kappa value.
- prevalence and preventability of AEs: number of medical records, number of patients with at least one AE, prevalence of AEs, number of AEs, rate of preventable AEs, and number of AEs per 1,000 hospital days.
- consequences of AEs: proportion of AEs with no disability, temporary disability, permanent disability, death, or prolonged hospital stay to patients, and extra hospital days due to AEs.
- Classifications of AEs: proportion of drug related AEs, diagnostic related AEs, procedure related AEs (surgical-related and medical-related), and nosocomial infection.

Reported prevalence, preventability rate, consequence results and classifications of AEs were recalculated for medians and inter-quartile ranges (IQRs).

2.3 Results

The MEDLINE, EMBASE and Cochrane Library searches yielded 861 potential articles, with 339, 516 and 3 articles from each database, respectively. Additional 6 articles were identified by a cross-reference search and added manually (Figure 2.1). After the removal of duplications, 549 articles were screened by title initially, which eliminated 496 articles of the remaining 51 articles, another 32 articles were excluded after reviewing abstracts. The most common reasons to exclude articles during the title and abstract scanning round were that they were review

studies, focussed on specific populations or events, and had sample sizes smaller than 1,000.

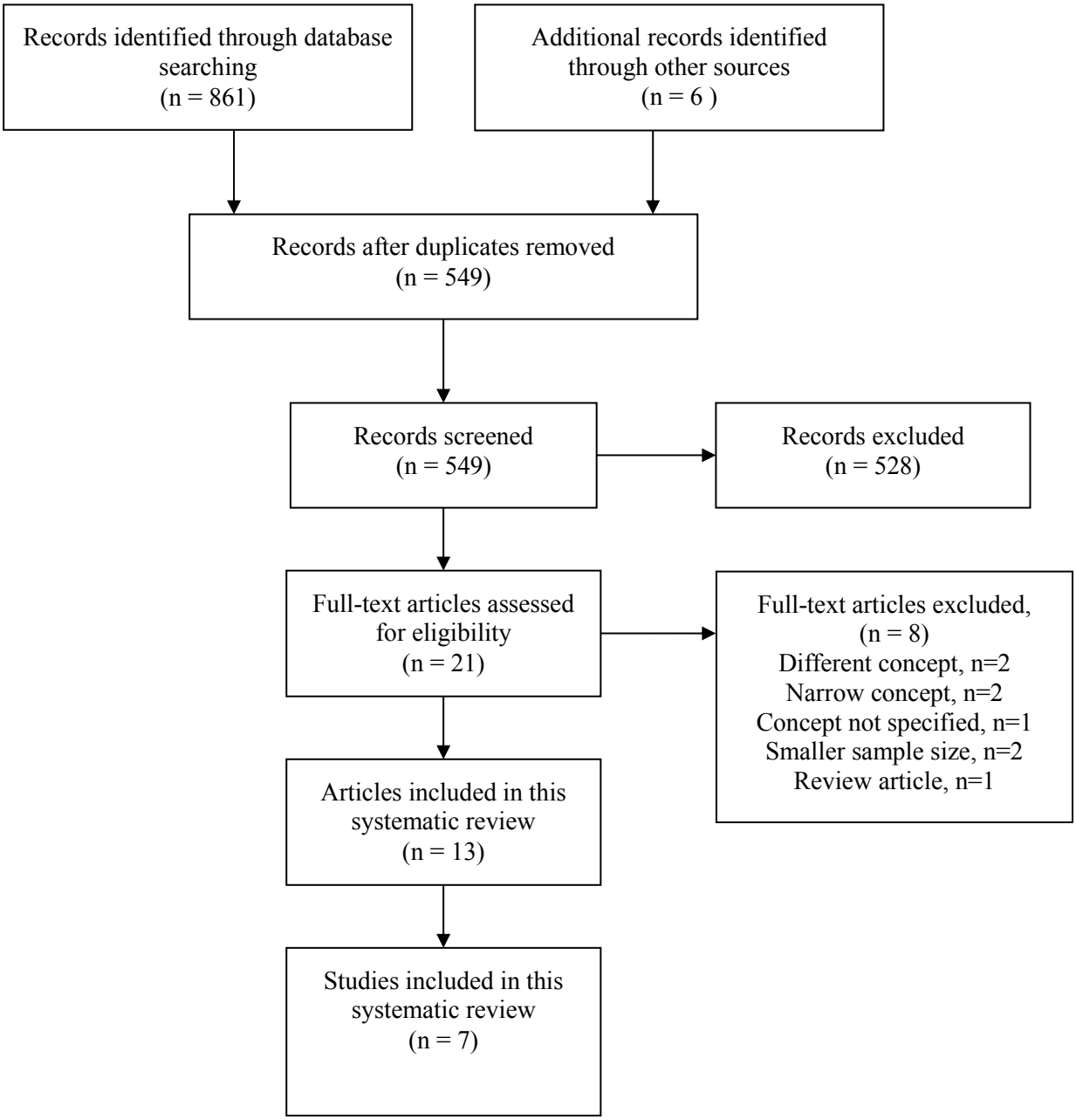
The Wangfang Data and CNKI databases search retrieved 301 Chinese articles in total. And there is no extra articles were identified through cross-reference search. After title screenings, there were only 2 articles left for abstract review. After read abstract, those 2 articles were eliminated, based on the same exclusion criteria as the English articles.

The full texts of the remaining 21 papers were separately screened by two reviewers (NC and HY), and 8 were eliminated. Two studies used different terms (incidents and harms) other than AEs (Nuckols, Bell et al. 2007; Landrigan, Parry et al. 2010). Two studies applied a narrow concept of AEs and were consequently eliminated as they focused on AEs resulting from medical management (Michel, Quenon et al. 2007; Fowler Jr, Epstein et al. 2008). One study applied different definition of AEs and only focused on four specified clinical departments (Forster, Worthington et al. 2011). Two studies applied Global Trigger Tool (GTT) to investigate AEs, and were excluded due to their small sample sizes (Asavaroengchai, Sriratanaban et al. 2009; Classen, Resar et al. 2011). The last elimination was a review article (Galadanci 2013).

2.3.1 Included studies

After a comprehensive and systematic search, 13 papers of seven studies were included. Four studies published more than one article, and the later published articles provided additional and complementary results to previous articles for the same or partly the same populations. The study published by Sari, Sheldon et al. (2007) about the AEs in UK was included in a previous systematic review; however, more data and results were published to make complements since 2007. Therefore, this study was included again in this systematic review.

Figure 2.1 Flow diagram of study selection



2.3.2 Study designs

Study design and features of the included studies were summarised in Table 1.2-1.7. The seven studies included 4 studies from developed countries and 3 studies from developing countries (Table 2.1). Five of the studies focused on a single country's situation, while two studies were performed across several developing countries (Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). Six of the studies investigated the prevalence of AEs in particular countries (Sari, Sheldon et al. 2007; Aranaz-Andrés, Aibar-Remón et al. 2008; Mendes, Martins et al. 2009; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Wilson, Michel et al. 2012), while one study measured "point prevalence" of AEs, which means patients presented AEs on the day of observation, in Latin American countries (Aranaz-Andres, Aibar-Remon et al. 2011).

The definitions of AEs for all included studies were the same or similar to the definition stated in the inclusion criteria (Table 2.2). The sample size of each study was between 1,103 and 15,548 with a median of 5,624 (IQR 1,103-11,379). The hospitals included in each study ranged from 1 to 58. All data were collected by using a two-stage RMRR protocol. A standard RMRR, which were developed in 1980s (Hiatt, Barnes et al. 1989), contains two stages. In the first stage, records are screened according to a list of explicit screening criteria, normally by nurses. If one or more criteria are found, the record is then forwarded to doctors for second stage reviewing. In addition, Sari, Sheldon et al. (2007) and Christiaans-Dingelhoff, Smits et al. (2011) compared the rate of AEs identified using a review-based method with thorough incident reporting systems.

In the reviewing process, the number of doctors to review each record varies according to different study designs (Table 2.3). This number is not specified by Aranaz-Andrés, Aibar-Remón et al. (2008). Two out of four studies in developed countries had two doctors to review each record independently (Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009), while

other studies arranged one physician for each record (Sari, Sheldon et al. 2007; Mendes, Martins et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012).

It is a crucial question for reviewers to consider whether an event was caused by healthcare management (the causation of an AE). All of the included studies used the same 6-point scale to measure whether an AE was caused by healthcare management or the underlying disease. At least score 4 was required, which means management causation was more likely than not, more than 50-50 but close call. Two studies adopted a double standard as a threshold (at least score 2: slight-to-modest evidence for management causation and score 4: management causation more likely than not, more than 50-50 but close call) for causation (Sari, Sheldon et al. 2007; Wilson, Michel et al. 2012). Another 6-point scale was used to judge whether an event was preventable (preventability). If the preventability of an AE was at least more likely than not, more than 50-50 but close call (scores 4), this AE was considered preventable in all seven studies.

2.3.3 Prevalence and preventability of AEs

For the purpose of comparison, this systematic review only discusses the prevalence of AEs yielded by causation scores ≥4. The prevalence of AEs ranged from 5.7% to 12.3% with a median percentage of 8.6% (IQR 7.7%-10.5%) (Table 2.4).The median prevalence of AEs in developed and developing countries were 9.0% (IQR 8.5%-10.8%) and 7.7 (IQR 6.1%-10.5%), respectively. In addition, the percentage of preventable AEs (PAEs) ranged from 31% to 83% with a median of 59% (IQR 39.6%-70.0%). The proportion of PAEs was higher in developing countries, with 67% of AEs considered as preventable in developing countries, compared with 41.5% in developed countries (Table 2.4).

Other than representing AE rates in traditional prevalence format (numbers of medical records with AEs / 100 admissions), two studies also examined the rate of AEs per 1,000 hospital days (Aranaz-Andrés, Aibar-Remón et al. 2008; Mendes, Martins et al. 2009). It is also necessary to

point out that two of the seven studies reported only the most serious AE, even if more than one event was identified for a patient (Soop, Fryksmark et al. 2009; Wilson, Michel et al. 2012).

2.3.4 Consequences of AEs

The consequences of AEs could be interpreted from level of severity and prolonged length of stay in hospital. The level of severity of AEs could fall into 4 categories: no disability, temporary disability (resolved within 12 months), permanent disability (not resolved within 12 months), and death. Prolonged hospital stays could co-exist with any of the severity category. The data extracted from the included articles are listed in Table 2.5. Mendes, Martins et al. (2009) discuss the incidence of AEs in deceased patients. However, they do not clearly stated whether the patients' deaths resulted from AEs. In the Latin American study, only 28.8% of AEs were identified to lead to any kind of disability but the authors did not specify the types of disability (Aranaz-Andres, Aibar-Remon et al. 2011). Hence, when calculating the median percentage for the relative consequence categories, these two studies were not included.

Overall, about half of the patients with AEs did not have a disability (55.15%, IQR 42.8%-56.9%) in the 7 included studies. There were 22.0% (IQR 16.0%-29.8%) of patients had temporary disability due to AEs, and 10.9% (IQR 7.9%-12.5%) of patients suffered permanent disability. The median percentage of patient deaths associated with AEs was 6.8% (IQR 4.4%-9.0%). Prolongation of hospital stay was identified in 64.7% (IQR 31.4%-88.0%) of patients with AEs, with an average 7.4 extra days (IQR 6.2 days-12.6 days) in hospital per patient.

Studies conducted in developed countries reported higher medians of no disability and temporary disability than the overall median (developed and developing countries), while the medians for permanent disability, death, prolongation of hospital stay and extra hospital days were lower than the overall median. Higher proportion of AEs in developing countries resulted in patients' deaths (17.9%). The extra hospital stay was two times longer than that in developed

countries (12.6 days vs. 6.3 days).

2.3.5 Clinical classifications of AEs

AEs were classified into different types in different studies. However, there were three most common classifications of AEs: drug-related, diagnostic-related and procedure-related. These were found in all included studies, although under different terminology (Sari, Sheldon et al. 2007; Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Martins, Travassos et al. 2011; Wilson, Michel et al. 2012). In some articles, procedure-related AEs were sub-divided into surgical procedure-related and medical-procedure related. In general, procedure-related AEs accounted for the greatest proportion of all types of AEs (44.9%, IQR 25.0%-65.8%), especially surgical procedure-related (36.8%, IQR 26.8%-51.8%). Three studies listed nosocomial infection as a separated classification of AEs, with a median of 25.3% (IQR 14.0%-37.1%), followed by drug-related AEs (14%, IQR 5.6%-30.1%) and diagnostic-related (6.3%, 5.1%-11.3%). Only these four classifications are listed in Table 2.6. Please refer to Appendix A for detailed classifications for all included studies. In contrast with developed countries, more diagnosis-related AEs while fewer drug-related AEs were identified in developing countries. Although developing countries had lower proportions of AEs related to surgical procedures, medical procedures contributed to more AEs.

Table 2.1 Included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Country	Purpose of study	Time of setting	Number of hospitals	Sample size	Study design
			Developed countries			
Sari, Sheldon et al. (2007)	UK	Quality improvement	1/2004-5/2004	1	1,006	Retrospective medical record review Reporting system
Aranaz-Andrés, Aibar-Remón et al. (2008)	Spain	Quality improvement	4/6/2005-10/6/2005	24	5,624	Retrospective medical record review
Soop, Fryksmark et al. (2009)	Sweden	Quality improvement	10/2003-9/2004	28	1,967	Retrospective medical record review
Zegers, de Bruijne et al. (2009)	Netherlands	Quality improvement	2004	21	7,926	Retrospective medical record review Reporting system
			Developing countries			
Mendes, Martins et al. (2009)	Brazil	Quality improvement	2004	3	1,103	Retrospective medical record review
Aranaz-Andres, Aibar-Remon et al. (2011)	Argentina, Colombia, Costa Rica, Mexico and Peru	Quality improvement	One week in late 2007	58	11,379	Retrospective medical record review
Wilson, Michel et al. (2012)	Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa and Yemen	Quality improvement	2005	26	15,548	Retrospective medical record review

Table 2.2 Definitions of AEs in included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Definition of AEs
	Developed countries
Sari, Sheldon et al. (2007)	An unintended event resulted in patient harm (prolongation of hospital stay, disability at discharge and/or extra cost of treatment), and it was caused at least partly by healthcare rather than by disease process alone.
Aranaz-Andrés, Aibar-Remón et al. (2008)	Any accident which caused health care-associated harm to a patient. Accident was defined as any event causing an injury that can result in a longer hospital stay, disability at the moment of discharge, death or any combination of these.
Soop, Fryksmark et al. (2009)	An unintended injury or complication, which results in disability at discharge, death or prolongation of hospital stay, and is caused by healthcare management (including omissions) rather than the patient's disease.
Zegers, de Bruijne et al. (2009)	An unintended injury that results in temporary or permanent disability, death or prolonged hospital stay, and is caused by healthcare management rather than by the patient's underlying disease process.
	Developing countries
Mendes, Martins et al. (2009)	An unintended injury or harm resulting in death, temporary or permanent disability or dysfuntion, or prolonged hospital stay that arises from health care.
Aranaz-Andres, Aibar-Remon et al. (2011)	Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.
Wilson, Michel et al. (2012)	An unintended injury that resulted in temporary or permanent disability or death (including increased length of stay or readmission) and that was associated with healthcare management rather than the underlying disease process.

Table 2.3 Characteristics of included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Population	Oversampling	Number of reviewers in 2nd stage	Reliability test	Kappa value
	Developed countries				
Sari, Sheldon et al. (2007)	Hospital patients stayed in longer than 24h from eight departments	No	One physician	Screening Reviewing	0.68 (screening) 0.64 (identification) 0.44 (preventability)
Aranaz-Andrés, Aibar-Remón et al. (2008)	Hospital patients stayed in hospital longer than 24 hours	No	N/A External	N/A	N/A
Soop, Fryksmark et al. (2009)	Hospital patients except psychiatric, rehabilitation, palliative care and day-only admissions	10%	Two physicians	Screening Reviewing	0.53 (screening) 0.80 (identification) 0.76 (preventability)
Zegers, de Bruijne et al. (2009)	Hospital patients except obstetric, psychiatry and children under 1 year old Stayed in hospital longer than 24 hours No time limit for deceased patients	100 medical records	Two physicians	Screening Reviewing	0.62 (screening) 0.25 (identification) 0.40 (preventability)
	Developing countries				
Mendes, Martins et al. (2009)	Hospital patients (include obstetric) except patient under 18 years old, stay in hospital less than 24 hr and patients with psychiatric diagnoses	20%	One physician	Screening	0.55 (screening)
Aranaz-Andres, Aibar-Remon et al. (2011)	Hospital patients with no other restriction	No	One physician	N/A	N/A
Wilson, Michel et al. (2012)	Hospital patients from medical, surgical, paediatric, and obstetric departments Same day admissions excluded	20%	One physician	Screening	0.33-0.88 (screening)

Table 2.4 Reported prevalence and preventability of AEs in included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	No. of records (1)	No. of patients with at least one AE (2)	No. AEs	Percentage of PAEs %	Prevalence of AEs (1)/(2)%	AEs/ 1,000 days
		Developed countries				
Sari, Sheldon et al. (2007)	1,006	87	107	31	8.6	-
Aranaz-Andrés, Aibar-Remón et al. (2008)	5,624	525	655	43	9.3	12
Soop, Fryksmark et al. (2009)	1,967	241	N/A	70	12.3	-
Zegers, de Bruijne et al. (2009)	7,926	663	744	40	8.4	-
Median	3,796 (1,487-6,775)	383 (164-594)	655 (107-744)	41.5 (35.5-56.5)	9.0 (8.5-10.8)	-
		Developing countries				
Mendes, Martins et al. (2009)	1,103	84	103	67	7.7	8
Aranaz-Andres, Aibar-Remon et al. (2011)	11,379	1,191	1,349	59	10.5	-
Wilson, Michel et al. (2012)	15,548	949	N/A	83	6.1	-
Median	11,379 (1,103-15,548)	949 (84-1,191)	726 (103-1,349)	67 (59-83)	7.7 (6.1-10.5)	-
Overall Median	1,103 (1,103-11,379)	525 (87-949)	655 (105-1,047)	59 (40-70)	8.6 (7.7-10.5)	10 (8-12)

Table 2.5 Reported consequences of AEs in included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Categories of severity				Prolong hospital stay	
	No disability	Temporary disability	Permanent disability	Death	Prolong hospital stay	Extra hospital stay
Developed countries						
Sari, Sheldon et al. (2007)	57%	22%	11%	9%	88%	7.4 days
Aranaz-Andrés, Aibar-Remón et al. (2008)	-	-	-	4.4%	31.4%	6.1 days
Soop, Fryksmark et al. (2009)	53.5%	29.8%	10.8%	4.1%	-	6.3 days
Zegers, de Bruijne et al. (2009)	56.8%	-	5.0%	7.8%	-	-
Median	56.8% (53.5%-57.0%)	25.9% (22%-29.8%)	10.8% (5.0%-11.0%)	6.1% (4.3%-8.4%)	59.7% (31.4%-88.0%)	6.3 days (6.1 days -7.4 days)
Developing countries						
Aranaz-Andres, Aibar-Remon et al. (2011)	-	-	-	5.8%	64.7%	16.1 days
Wilson, Michel et al. (2012)	32%	16%	14	30%	-	9.1 days
Median	-	-	-	17.9% (5.8%-30.0%)	-	12.6 days (9.1 days -16.1 days)
Overall Median	55.2% (42.8%-56.9%)	22.0% (16.0%-29.8%)	10.9% (7.9%-12.5%)	6.8% (4.4%-9.0%)	64.7% (31.4%-88.0%)	7.4 days (6.2 days -12.6 days)

Table 2.6 Reported classifications of AEs in included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Drug related	Diagnostic related	Procedure related		Nosocomial infection
			Surgical	Medical	
Developed countries					
Sari, Sheldon et al. (2007)	14.0%	5.1%	36.8%	44.9% 8.1%	14.0%
Aranaz-Andrés, Aibar-Remón et al. (2008)	37.4%	2.8%	-	25.0% -	25.3%
Soop, Fryksmark et al. (2009)	30.1%	11.3%	49.4%	63.6% 14.2%	-
Zegers, de Bruijne et al. (2009)	15.3%	6.3%	54.2%	71.2% 17.0%	-
Median	22.7% (14.7%-33.8%)	5.1% (1.4%-8.8%)	49.4% (36.8%-54.2%)	54.3% (35.0%-67.4%) 14.2% (8.1%-17.0%)	19.7% (14.0%-25.3%)
Developing countries					
Mendes, Martins et al. (2009)	5.6%	10.2%	35.2%	65.8% 30.6%	-
Aranaz-Andres, Aibar-Remon et al. (2011)	8.2%	6.1%	-	28.5% -	37.1%

Study citation	Drug related	Diagnostic related	Procedure related		Nosocomial infection
			Surgical	Medical	
Wilson, Michel et al. (2012)	5.0%*	19.1%	24.4%* 18.4%	6.0%*	-
Median	5.6% (5.0%-8.2%)	10.2% (6.1%-19.1%)	28.5% (24.4%-65.8%) 26.8% (18.4%-35.2%)	18.3% (6.0%-30.6%)	-
Overall Median	14.0% (5.6%-30.1%)	6.3% (5.1%-11.3%)	44.9% (25.0%-65.8%) 36.8% (26.8%-51.8%)	14.2% (7.1%-23.8%)	25.3% (14.0%-37.1%)

2.3.6 Impact factors to adverse events

Several contributors to AEs were noted by the included studies, which can be categorised into "supply side" and "demand side". Factors from the "supply side" included type of hospital and patient's length of stay (LOS). The factors from "demand side" were determined by patients, such as demographics, pre-existing comorbidity, admitting departments and main diagnosis.

From the "supply side", higher proportions of AEs were detected in large hospitals and university hospitals, which could be related to more complexity clinical practice (Zegers, de Bruijne et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011). However, Aranaz-Andrés, Aibar-Remón et al. (2008) found more AEs in small hospitals. In terms of LOS, Aranaz-Andrés, Aibar-Remón et al. (2008) and Wilson, Michel et al. (2012) stated longer hospital stay was a risk factor for AEs. The study conducted in Latin American countries also showed an association between longer hospital stay and occurrence of AEs (Aranaz-Andres, Aibar-Remon et al. 2011).

From the "demand side", age was recognised as a crucial factor. Four out of seven of the included studies stated that older patients (65 years and over) had more risk of suffering AEs during their hospital stay (Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Wilson, Michel et al. 2012). Furthermore, pre-existing comorbidity was identified as a contributor to AEs by three studies (Aranaz-Andrés, Aibar-Remón et al. 2008; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). In regards to admitting departments, more AEs were identified in surgical departments (Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011). However, only Aranaz-Andrés, Aibar-Remón et al. (2008) found the incidence of AEs in non-surgical departments was higher than in surgical departments, probably due to the high proportion of AEs related to medications. In addition, two studies analysed the impact of main diagnosis (case mix) on prevalence of AEs; both studies suggested that patients admitted for

predominantly obstetric reasons had lower risk of AEs (Mendes, Martins et al. 2009; Wilson, Michel et al. 2012).

2.3.7 Timing of AEs

Four studies investigated the timing of AEs and found that most AEs occurred and/or were detected during the index admission period. Aranaz-Andrés, Aibar-Remón et al. (2008) indicated 80% of AEs occurred in index admission. Mendes, Martins et al. (2009) reported 84.5% and 91.3% of AEs occurred and were detected during index admission, respectively. In addition, Zegers, de Bruijne et al. (2009) also revealed most AEs (63%) occurred and were detected during index admission. The only exception was found in the study conducted in Sweden, where around 30% of AEs occurred and were detected during index admission, in contrast with 45% of AEs which occurred before patients were admitted to hospital (Soop, Fryksmark et al. 2009).

2.4 Discussion

This systematic review investigated the results of large-scale AE projects since 2007. The information extracted from the included articles contained study characteristics, prevalence of AEs, preventability, impact of AEs, classifications, contributors and timing. The review was organised into developed and developing countries groups for the purpose of comparison. This systematic review has generated a brief picture of recent research trends and outcomes in AEs, and provides insights into differences in developed and developing countries.

2.4.1 Principal findings

This systematic review included 7 studies, of which 4 were from developed countries and 3 from developing countries. The four studies from developed countries were from the UK, Spain, Sweden and the Netherlands. The three studies conducted in 14 developing countries included one article from Brazil, one article from Latin America (Argentina, Colombia, Costa Rica, Mexico and Peru), and one study conducted in 8 countries (Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa and Yemen).

The medical record-based method to investigate AEs has acknowledged disadvantages, such as underestimation of AEs and overestimation of preventability (Zegers, De Bruijne et al. 2007; Zegers, de Bruijne et al. 2009). The RMRR method was adopted by all of the 7 studies. It is recognised as the mainstream and first preference for large-scale studies of AEs. Overall, the median of prevalence of AEs is 8.7%, and around 60% are preventable. Six point eight per cent of AEs result in death. Generally, the most common classifications of AEs are procedure-related, nosocomial infection-related and drug-related. However, diagnostic-related AEs have a greater proportion in developing countries. As the previous research has shown, older patients, longer hospital stays, pre-existing comorbidities, and admission to surgical departments are identified as risk factors for AEs. Obstetric patients have less chance of suffering AEs than other patients, while deceased patients have higher risk of having AEs. In terms of timing of AEs, most occur and/or are detected during the index admission period.

In order to insight an overall view of AEs, it is necessary to combine the result of this review with the previous one. The previous systematic review included 8 studies in USA, Australia, UK, New Zealand and Canada (de Vries, Ramrattan et al. 2008). And there were several articles were recognised as “classic studies” in the field of AEs, such as the Harvard medical practice study (Brennan, Leape et al. 1991), the Australian health care study (Wilson, Runciman et al. 1995) and the Canadian adverse events study (Baker, Norton et al. 2004). All

the studies were designed based on the protocol of RMRR. As it stated before that one UK study (Sari, Sheldon et al. 2007) was included in both systematic reviews. Therefore, the author of this thesis removed the data extracted from this UK study from the previous systematic review (de Vries, Ramrattan et al. 2008) when calculate the relevant medians for studies published before 2007.

The median prevalence of AEs was 7.5% (IQR 3.8%-12.9%) in those 7 studies conducted before 2007, which was a bit lower than the result of the present review, 8.6% (IQR 7.7%-10.5%). However, a remarkable difference was noticed in terms of preventability. There were 59.0% (IQR 40.0%-70.0%) of AEs were considered preventable in this review, while 43.5% (IQR 39.4%-49.6%) in the previous review. Two reviews found similar trends of the consequences of AEs; in general, the proportions were decreased with the severity of consequences increased (Table 2.7). Over half of AEs resulted to no or minor disability to patients. The present review identified slightly more AEs led to temporary disability and permanent disability. The proportions of death caused by AEs were similar in the two reviews. In regards to the classifications of AEs, the similarities could be found between the two reviews. de Vries, Ramrattan et al. (2008) identified operation-related (39.6%), drug-related (15.1%) and diagnostic-related (7.5%) were top 3 classifications in the previous review. The same pattern of classifications was detected in this review, although with slightly different proportions.

Table 2.7 The comparison of reported consequences of AEs between the previous review and present review

	No or minor disability	Temporary disability	Permanent disability	Death
The previous review (de Vries, Ramrattan et al. 2008)	56.3% (51.4%-62.8%)	19.1% (15.5%-30.3%)	7.0% (6.1%-11.0%)	7.4% (4.7%-14.2%)
The present review	55.2% (42.8%-56.9%)	22.0% (16.0%-29.8%)	10.9% (7.9%-12.5%)	6.8% (4.4%-9.0%)

There were several impact factors to AEs detected in the 7 studies, which were also revealed in the previous systematic review (de Vries, Ramrattan et al. 2008). First of all, the prevalence of AEs in teaching hospitals was higher than other types of hospitals (Baker, Norton et al. 2004). In addition, older patients had more chance to have AEs during their hospitalisations. On the other hand, obstetric patients had less chance to suffer AEs (Brennan, Leape et al. 1991; Wilson, Runciman et al. 1995; Vincent, Neale et al. 2001).

2.4.2 Interpretation of results

Although all included studies in this review were designed using the same standard method protocol and employed the same or similar definition of AEs, the results have to be interpreted with caution due to the variations. One study was designed to investigate point prevalence, and may have captured different patterns and numbers of AEs than others (Aranaz-Andres, Aibar-Remon et al. 2011). In addition, as it has been shown by previous research that slight differences in study design can have major influences on result (Runciman, Webb et al. 2000; Thomas, Studdert et al. 2000).

Firstly, different studies applied different time-frames and settings for included AEs. For instance, two studies included AEs which occurred in non-hospital settings, such as primary health care, which were detected in index admission or contributed to index admission (Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009). In contrast, some studies included only AEs which happened in hospital settings (Mendes, Martins et al. 2009; Zegers, de Bruijne et al. 2009).

Secondly, the populations of each study varied. Two studies did not include obstetric patients (Sari, Sheldon et al. 2007; Zegers, de Bruijne et al. 2009), who have been shown to have lower risk of AEs (Mendes, Martins et al. 2009; Wilson, Michel et al. 2012). In contrast, in the Dutch study 50% of included medical records were selected from deceased patients although this group is likely to have higher prevalence of AEs than other patient groups (Zegers, de Bruijne et al. 2009). The different proportions of samples from obstetric and deceased patients potentially influence the prevalence results (Mendes, Martins et al. 2009; Wilson, Michel et al. 2012). Although Sari, Sheldon et al. (2007) and Zegers, de Bruijne et al. (2009) did not report higher prevalence of AEs compared with others, it may result from other study design factors, quality of medical records, etc.

Furthermore, there were other differences from a methodological perspective. For example, there were different numbers of reviewers for each record, different reviewer backgrounds, and different causation thresholds. Also, two studies used two causation thresholds for AE identification (≥2 and ≥4) (Sari, Sheldon et al. 2007; Wilson, Michel et al. 2012), while the others used ≥4 as the standard.

Not all of the included studies specified the standards for clinical classification of AEs. When different standards applied, an AE could be classified into different classifications in different studies. For example, pressure ulcers were presented as an individual classification of AEs by Sari, Sheldon et al. (2007), and Wilson, Michel et al. (2012) considered fractures as an

individual classification parallel to drug-related AEs. However, pressure ulcers and fractures were combined and categorised into care-related AEs by Aranaz-Andrés, Aibar-Remón et al. (2008), along with burns and respiratory failure. In addition, nosocomial infection appeared as an important individual classification in a few studies, but it may have been included under procedure-related or another classification in other studies. Furthermore, some classifications, such as therapeutic errors (Wilson, Michel et al. 2012) and system events (Mendes, Martins et al. 2009) were only reported in one study. Hence, the results presented in this review must be read with caution. The differences in findings may be due to different study designs instead of true differences.

2.4.3 The study of AEs in developing countries

In this section, the necessity and importance to study AEs in developing countries will be stressed at the beginning. In addition, the reported prevalence of AEs in developing countries is generally lower than developed countries. The lower prevalence is probably due to the under-estimation of the actual situation in developing countries. Therefore, in the second part of this section, the reasons could lead to under-estimate of the prevalence of AEs will be discussed. Finally, the preventability of AEs in developing will be compared with that in developed countries.

2.4.3.1 The necessity of studying AEs in developing countries

To study AEs in developing countries is necessary. Relatively, there is sufficient evidence available to understand the scale of AEs problems in developed countries, while there are three reasons to continue this kind of research in developing countries.

First, the conduct of this kind of research reflects the importance of patient safety and it could be an opportunity for improvement of patient safety in developing countries. To conduct the AEs research in developing is not simply repeating the same research which had been done in

developed countries. The study about AEs could have profound impact on improvements of hospital practice (Michel 2003). For instance, several national policies and initiatives were issued after the study about AEs in five developing countries, and most of policies and initiative were promoted and led by participants in the AEs studies (Aranaz-Andres, Aibar-Remon et al. 2011). In addition, the study of AEs has educational value for participating doctors and nurses, since it provides new knowledge to doctors and nurses and that knowledge can be applied in daily clinical activities to increase patient safety (Michel, Quenon et al. 2007).

Second, the evidence about AEs in developing countries is severely inadequate, such as the extent, nature and influence etc. (World Health Organisation 2004). A clear and serious research gap has been identified, while in order to set up a global understanding about AEs, more data from developing countries is required (Wilson, Michel et al. 2012). A number of studies have been conducted in developing countries to investigate AEs. However, most of them focus on a specific AE only (e.g. adverse drug events (dos Santos and Coelho 2006)) or specific hospital service (e.g. ICU patients (Rosenthal, Maki et al. 2006)) rather than from a comprehensive hospital-wide viewpoint (Carpenter, Duevel et al. 2010). To date, only three large-scale studies were conducted in developing countries in the past, in contrast with 12 studies in developed countries.

Third, the AEs in developing countries may be different from that in developed countries. Due to different healthcare contexts, different results may be yielded. This systematic review has provided a detailed comparison of prevalence, preventability, consequences and clinical classifications of AEs between developed and developing countries, which has indicated different patterns. Therefore, the evidence from developed countries is not consistent with that from developing countries.

In this systematic review, three studies were included from developing countries. This indicates that in the past few years, the necessity of studying AEs has arisen in some developing countries, compared with the previous systematic review, in which all articles were from developed countries (de Vries, Ramrattan et al. 2008). Those three studies conducted in 14 developing countries also showed that the use of RMRR to conduct research into AEs may be feasible in developing countries (Wilson, Michel et al. 2012).

2.4.3.2 Reasons for underestimation of AEs in developing countries

Considering healthcare resources, infrastructure, education level of health professionals and other factors, it is reasonable to assume that more AEs would occur in developing countries than in developed countries. However, as previous sections have shown the median prevalence of AEs is 7.6% in developing countries, slightly lower than in developed countries (9.0%) (see Table 2.4). Most AEs were considered preventable (see Table 2.4). In addition, a larger proportion of AEs contributed to patients' deaths in developing countries (see Table 2.5). The lower prevalence may reflect that fewer AEs happen in developing countries, or an underestimation of the real problems. The latter is almost certainly, and three possible reasons were discussed below.

First of all, using medical record reviews to investigate quality problems has the acknowledged drawback of underestimation, since reviewers' judgements are based on the information provided in records (Hiatt, Barnes et al. 1989; Donabedian 2003), although RMRR is still considered a valid method to investigate the prevalence, nature and consequence of AEs (Michel 2003).

One possible scenario could lead to underestimation of AEs is a larger proportion of medical records may be unavailable for screening and reviewing. Those unavailable or missing records could "hide" AEs, which could not be identified until records are available for review. The Harvard medical practice study have found AEs in the initial unavailable or missing records,

and the frequency and severity of those AEs were similar to the AEs detected before (Brennan, Leape et al. 1991). According to Wilson, Michel et al. (2012), 14% of medical records were not available due to being unable to identified, unable to be located, unavailable or duplicated. In Brazil, even worse, over 30% of medical records were excluded (Mendes, Martins et al. 2009). In other words, it could be assumed that 14% of AEs and over 30% of AEs were unable to be detected in those two studies.

If the medial records are available for review, lack of completeness in medical records could be another reason contributed to underestimation of AEs (Michel 2003). As Wilson, Runciman et al. (1995) stated in the literature, there were some cases were highly suspected to be AEs cases, but could not be confirmed due to the incomplete documentation. Given the fact that the quality of medical records is questionable in developing countries (Michel 2003), the previous literature detected fewer AEs in developing countries, possibly because fewer could be identified from less detailed and comprehensive records. For example, nursing progress notes and procedure notes were found to be the two most important sources to identify AEs in an Australian study (Wilson, Runciman et al. 1995). Unfortunately, this information was found to be not sufficient or absent in developing countries (Wilson, Michel et al. 2012).

Second, the screening criteria have an impact on underestimating AEs in developing countries. The screening criteria in the three studies (Mendes, Martins et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012) were all adopted from previous similar studies in developed countries, such as Australia, Canada, and Spain, although some modifications were made based on the local context. In fact, the screening positive rate was between 22% and 41% in developing countries by contrast with 32% to 54% in developed countries. This phenomenon could result from the screening criteria being not fully localised, and therefore not being suitable to an individual country's healthcare context. For example, according to Wilson, Michel et al. (2012), readmission criteria had a remarkably lower rate than previous studies in

developed countries (Wilson, Runciman et al. 1995; Baker 2004; Zegers, de Bruijne et al. 2009), because most of the participating hospitals would start a new medical record for each admission. On the other hand, some of medical records with AEs were probably incorrectly screened as negative, because of the sensitivity and validity of the screening criteria. Hence, a lower screening positive rate means more medical records were excluded for reviewing, which would consequently influence the results for the prevalence of AEs (Wilson, Michel et al. 2012). However, none of the three studies from developing countries measured the sensitivity of the screening tool.

Third, the "human factor" is another unignored reason contributed to underestimation. The performance of reviewers may influence study results, since judgements were made based on the reviewers' knowledge of, and perceptions and attitudes towards AEs (Mendes, Martins et al. 2009; Soop, Fryksmark et al. 2009). Since AEs may be a relatively new concept in developing countries, training plays a profound role in this kind of research project. Reviewers could build up knowledge and clarify confusions. However, the confusions might be still existed. For example, the reviewers may have experienced confusion between causation and preventability (Wilson, Michel et al. 2012), which could influence the results for both lower prevalence rate and higher preventable rate of AEs. More detailed analysis about "human factor" in studies about AEs will be discussed in section 6.3.1 "Factors influencing nurses' and doctors' clinical decision-making" of this thesis.

2.4.3.3 The preventability of AEs in developing countries

One of the significant parts of studying AEs is to gain an insight into preventable AEs, especially highly preventable AEs. They are called preventable AEs because they are changeable and avoidable through healthcare improvement. In other words, averting these kinds of AEs could help to reduce the prevalence of AEs and increase patient safety. In contrast with developed countries, more AEs were considered preventable in developing countries

(41.1% vs. 66.7%), which indicates that reducing AEs probably has substantial room for improvement. In terms of classifications of AEs, more diagnostic-related AEs were found in developing countries, which tend to be more preventable compared with operative-related events (Sari, Sheldon et al. 2007).

2.4.4 Limitations

Each included study had limitations and contributions to the AE research field, and these are summarised in Table 2.8. In addition, a tool for assessing risk of bias was adopted from the work by Hoy, Brooks et al. (2012). Each included study was evaluated according to 10 items (Table 2.9) and the results of evaluation of bias were listed in Table 2.10.

This systematic review has several limitations. First of all, the results presented in this review must be interpreted with caution due to the variations of methodology, which have been discussed above in "interpretation of results" section. Second, despite the fact that a comprehensive and systematic search was conducted, there is a possibility that this systematic review did not capture some studies. This review only focused on peer-reviewed literature published since 2007 in either English or Chinese. Several very relative papers had to be excluded because they were published in other languages, such as a Danish AEs study (Schiøler, Lipczak et al. 2001). In addition, a few of interesting studies both from developed and developing countries were excluded because of the restrictions of the inclusion criteria of this systematic review. However, these excluded studies may also have effects on the development of AE studies from different perspectives. For example, in order to explore different methodologies to investigate AEs, Weissman, Schneider et al. (2008) compared the medical record review method and patient interviews on the identification of AEs. They found patients reported more AEs, which were not documented in medical records, and numbers of the AEs were related to severe outcomes and preventable. Another study conducted by Classen, Resar et al. (2011) reported around 33% of hospital patients experienced AEs during their

hospital stay. This study used a global trigger tool as a screening tool instead of screening criteria. Three studies from Thailand, Tunisia, and Jordan were excluded due to small sample size, but they provided valuable information for a better understanding of research situation in developing countries(Asavaroengchai, Sriratanaban et al. 2009; Hayajneh, AbuAlRub et al. 2010; Letaief, El Mhamdi et al. 2010).

2.5 Conclusion

AEs do exist in hospitals, whether in developed or developing countries. They cause harm to patients, and are more preventable and leading to severer consequences to patients in developing countries. The importance of the measurement of the prevalence of AEs cannot be over-emphasised. It was excited to find out that research about AEs has been conducted in few developing countries. This systematic review has shown the differences in prevalence, preventability, consequences and classifications of AEs between developed and developing countries. However, an obvious research gap is that to date there has been no comprehensive study which investigates AEs in Chinese hospitals with a relatively large-scale sample size. To achieve the goal of patient safety, it is necessary to conduct a similar study in China. There are two research questions that will be answered by the following medical record audit study in this thesis:

- Determine the prevalence, consequence, classifications and preventability of AEs among hospitalised, discharged and/or deceased patients in Chinese hospitals.
- Identify patients' risk factors for AEs in Chinese hospitals.

Table 2.8 Limitations and quality considerations of included studies in chronological order, sub-divided into developed countries and developing countries

Study citation	Limitations and strengths
	Developed countries
Sari, Sheldon et al. (2007)	***Limitations acknowledged in article:*** Overestimation of PAEs and death. Limit on generalising of findings. ***Other limitations:*** Limits related to retrospective medical record review (RMRR), such as underestimation of AEs, and quality of medical records. ***Strengths:*** Compared two methods: RMRR and reporting system. False negative cases were measured in order to assess sensitivity of the screening tool, although without detailed data of it.
Aranaz-Andrés, Aibar-Remón et al. (2008)	***Limitations acknowledged in article:*** Poor quality of medical records. External reviewers may have difficult to understand circumstances in each hospital, which could influence their decisions to identify AEs. ***Strengths:*** Categorised risk factors to extrinsic and intrinsic and investigated the association between them and AEs.
Soop, Fryksmark et al. (2009)	***Limitations acknowledged in article:*** RMRR related limits, such as underestimation on AEs, and totally relay on medical records to collect data. Hindsight bias could result to overestimation on preventability. ***Strengths:*** Measuring the sensitivity of screening criteria on detecting PAEs. High reliability on reviewing process than previous studies because of comparisons of review results between physicians.

Study citation	Limitations and strengths
Zegers, de Bruijne et al. (2009)	***Limitations acknowledged in article:*** Low reliability in reviewing stage. Subjective judgement on preventable deaths and life expectancy. Hindsight bias results to overestimation on preventability. ***Strengths:*** Compared two methods: RMRR and reporting system (including reports from healthcare professionals and patients). Detailed description on how to match patients' information in reporting incidents. Have more information about AEs occurred on deceased patients than other studies.
	Developing countries
Mendes, Martins et al. (2009)	***Limitations acknowledged in article:*** Quality of medical records and validity of reviewing process. ***Other limitations:*** Reliability test for screened nurses was conducted by fixed pairs. The result of reliability was presented in simple agreement form rather than in kappa value. ***Strengths:*** Detailed description of translation and adoption screening tool from previous study in Canada. Four nurses completed screening process. Small numbers of group is relatively easier to do training. Only one physician did review for this study, which could maintain consistent and reliability. However, it could be a bias on the other hand. The agreement between nurses and physicians on screening process was measured.
Aranaz-Andres, Aibar-Remon et al. (2011)	***Limitations acknowledged in article:*** Quality of medical records. Limit on generalising result. Data-collection tools used in this study might be not adequacy to measure point prevalence. ***Other limitations:*** Two step training could lead to potential reliability problems. The researchers provide training to the representatives from each country first. After the initially training, these representatives provided trainings to data collectors at each country. Result of this study did not have comparability with others due to different study aim. This study was designed to measure point prevalence of AEs, and identified different patterns of AEs than studies measured the prevalence of AEs. ***Strengths:*** Reviewers were allowed to ask ward staff for more information or data, which could not been documented.

Study citation	Limitations and strengths
Wilson, Michel et al. (2012)	***Limitations acknowledged in article:*** Underestimation of AEs because of the RMRR study design. Quality of medical records in developing countries had significant influence to study result. ***Other limitations:*** Convenience sample of hospital could have impact on generalisation result to large scale. Challenges to conduct research in developing countries: language diversity, organisations and logistics problems. ***Strengths:*** Review forms were well designed and could be used for further study in developing countries with modifications.

Table 2.9 Risk of bias assessment tool for observational studies

Risk of bias item	Answer Yes (Low risk of bias)/ No (high risk of bias)
External validity	
1. Was the study's target population close representation of the national population in relation to relevant variables?	
2. Was the sampling frame a true or close representation of the target population?	
3. Was some form of random selection used to select the sample, OR was a census undertaken?	
4. Was the likelihood of nonresponse bias minimal?	
Internal validity	
5. Were data collected directly from the subjects (as opposed to a proxy)?	
6. Was an acceptable case definition used in the study?	
7. Was the study instrument that measured the parameter of interest shown to have validity and reliability?	
8. Was the same mode of data collection used for all subjects?	
9. Was the length of the shortest prevalence period for the parameter of interest appropriate?	
10. Were the numerator(s) and denominator(s) for the parameter of interest appropriate?	
11. Summary item on the overall risk of study bias	

Source: Hoy, Brooks et al. (2012)

Table 2.10 Assessment of risk of bias of included studies in chronological order, sub-divided into developed countries and developing countries

Studies	Risk of bias item										
	External validity				Internal validity						
	1	2	3	4	5	6	7	8	9	10	11
Developed countries											
Sari, Sheldon et al. (2007)	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Aranaz-Andrés, Aibar-Remón et al. (2008)	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Soop, Fryksmark et al. (2009)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Zegers, de Bruijne et al. (2009)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Developing countries											
Mendes, Martins et al. (2009)	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Aranaz-Andres, Aibar-Remon et al. (2011)	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Wilson, Michel et al. (2012)	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

CHAPTER THREE: BACKGROUND

A brief introduction to the Chinese healthcare system and the current situation in China will assist the understanding of the context and enable a better interpretation of the results of this study. This chapter will start with a general introduction to China and the Chinese healthcare system, in particular hospital system, followed by a discussion of the present indicators system of patient safety and AEs research in China. At the end of this chapter, the status of medical disputes and the doctor-patient tension will be described, which are important factors to be born in mind for a better understanding of the study of AEs in China.

3.1 General introduction to China

The People's Republic of China is located in East Asia. As the world's most populous country, the total population in 2010 was 1.37 billion. Ageing is an increasingly urgent threat, as 9% of the population is 65 years and older (National Bureau of Statistics of China 2011). Administratively, there are 23 Provinces, 5 Autonomous regions, 4 Municipalities, and 2 Special Administrative Regions. According to the Chinese Academy of Social Science (2009), around 45.7% area of China is recognised as urban. According to the sixth national population census 2010, about half of the Chinese population (49.7%) were urban residents (National Bureau of Statistics of China 2011).

3.2 Hospital system in China

There are significant differences in hospital system between urban and rural areas. The inequity of distribution of all kinds of resources, such as numbers of hospitals, government funding, and numbers of doctors and nurses, is associated with health service outcomes (Ministry of Health 2012). Compared with rural areas, more resources concentrated in urban areas, and more intensively in big cities, such as Beijing and Shanghai (Ministry of Health 2012). A general description about hospital systems in China will be discussed from five views: administrative management and regulation, facility, finance, human resource and information management.

3.2.1 Administrative management and regulation

Chinese public hospitals are administrative governmental institutions, and vertically and horizontally fragmented administrated by different levels of governments. All levels of government (central, provincial, prefectural, county and township) own and manage hospital facilities, while multiple government departments run hospitals in each level. There are three levels of public hospitals "accredited" in the Chinese hospital system: community, secondary, and tertiary hospitals. In recent years, community hospitals in urban were restructured to community health center. The three level hospitals are administrated by different levels of governments:

- Community hospitals: street governments or township governments,
- Secondary hospitals: district governments or country governments, and
- Tertiary hospitals: city governments or higher level of governments.

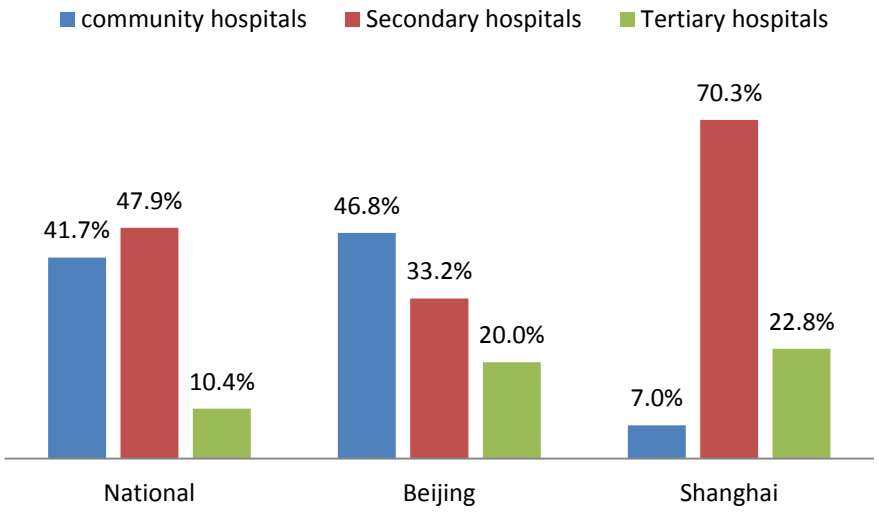
The public hospitals were regulated by government through different ways, such as budgeting and financing, human resources administration, capital asset investment, and legislation and regulation. The hospital managers are appointed and evaluated by governments. In addition, public hospitals are taking almost fully responsibility for profit and cost, and hospitals are allowed to keep the profit they generated (self-financing). In addition, hospitals also have more autonomy on setting bonus for staff, and majority autonomy in purchase of drugs, equipment etc (The World Bank 2010).

3.2.2 Facility

In China, many organisations provide healthcare services, such as hospitals, community health centres, township health centres etc. There are 21,979 hospitals in total in 2011, and 13,539 of them are public hospitals. The total number of beds in hospitals is 3,705,118 in 2011, and 3,243,658 beds (87.6%) are in public hospitals (Ministry of Health 2012). There is a significant

imbalance of hospitals resource in urban and rural area. Even in urban area, big hospitals, such as tertiary hospitals, have more intense resource (Shi and Du 2011). Compared with the distribution of different levels of hospital from national level, there are higher proportion of tertiary hospitals located in developed cities, such as Beijing and Shanghai (Figure 3.1). The number of beds in hospitals per 1,000 populations is 3.5 in 2011 from national level, while 6.8 and 6.2 in Beijing and Shanghai, respectively (Ministry of Health 2012).

Figure 3.1 The distribution of different levels of hospitals in China, Beijing and Shanghai



Each hospital normally provides both outpatients and inpatients services. Ministry of Health (2012) report 6.27 billion outpatient visits in 2011 and 36% of the visits (2.26 billion) in outpatient departments of hospitals. The total inpatient number in 2011 is 152.98 million, and 70% of them (107.55 million) are hospital admissions. The mortality rate for patients admitted in hospitals is 0.7% (Ministry of Health 2012). The average length of stay (ALOS) in hospitals is 10.3 days, and it varies in different level of hospitals. The ALOS in community, secondary and tertiary hospitals is 9.1, 9.3 and 12.0 days, respectively (Ministry of Health 2012).

3.2.3 Finance

Since the 1980s, public hospitals receive less funding from government, constituting 8% of the total revenue of public hospitals in 2011. Over 90% of hospital revenue comes from the provision of healthcare services to patients, such as drug fees, surgery fees, examination fees, and treatment fees (Zhao 2010; Ministry of Health 2012). Because of the self-financing policy (keep the profit), hospitals have the incentives to increase revenues from patients. However, the price for medical services was set by the state, which is below the cost in order to achieve widest accessibility to basic health services. On the other hand, the drug sale in hospitals is allowed to have a maximum 15% profit margin. Due to these pricing policies, medical services results to net loss to hospitals, in contrast, drug sale leads to net gain (The World Bank 2010). Therefore, the income from drug sales normally takes a big proportion on overall revenue of hospitals.

The average expenditure for each separation[3] was 7027.7 Chinese Yuan (CNY) in 2011 (equivalent to 1,232 Australian Dollar (AUD)), which composed of 41.8% of expenditure for drug fee, 26.7% for examination and treatment fee, and another 8.2% for surgery fee (Ministry of Health 2012). The cost for hospitalisation was paied by medical insurances, or co-payments, or out-of-pocket. Because there is no universal insurance in China to every residence and the eligibility to medical insurance rely upon social class, nature of employment, and residency condition.

Currently, there are two main health insurance programs to cover different groups of people. In urban areas, the dominant insurance scheme is Basic Medical Insurance (BMI), which includes Urban Employees' Basic Medical Insurance (UE-BMI) and Urban Residents' Basic Medical Insurance (UR-BMI) (Ministry of Health 2012). Rural residents are mainly under the cover of the New Rural Cooperative Medical Scheme (NCMS) (Barber and Yao 2010). The deduction,

[3] Separation includes patients who are discharged from hospitals (including discharge against medical advice), transferred, and died. Australian Institute of Health and Welfare (2012). National Health Data Dictionary Version 16 2012. Canberra, AIHW..

reimbursement rate and ceilings for different insurance schemes are variable and are listed in Table 3.1 (Barber and Yao 2010). About 30% of the urban population are uninsured, and are called “out-of-pocket” (OOP) patients (Ministry of Health 2012). Before 2010, around 3% of the population was covered by Government Health Insurance (GHI), and it was merged with BMI in 2010.

Table 3.1 Types of insurance and reimbursement characteristics in China

	NCMS	**UE-BMI**	**UR-BMI**
Population	Rural residents	employees	children, unemployed, disabled, and elderly residents
Coverage rate	97.5%	67%	
Inpatient deduction	100-800 CNY	10% of the local average payroll	0-2700 CNY
Inpatient reimbursement rate	41%	65%	45%
Inpatient reimbursement ceiling	30,000 CNY	4 times average payroll	25,000-100,000 CNY

Source: Barber and Yao (2010)

From the total health expenditure (THE) perspective to understand the expenditure, the THE in China is growing every year. In 2011, the THE was 2,426.9 billion CNY, equivalent to 425.8 billion AUD, comprising 5.15% of the gross domestic product (GDP) (Ministry of Health 2012). The THE per capital was 1,801.2 CNY, equivalent to 316.0 AUD. The difference of THE per capital in urban and rural area was significant (2,695.1CNY in urban area Vs. 871.6 CNY in rural area). In addition, The THE per capital was much higher in the developed cities in China. For example, the THE per capital was 4,147.2 CNY in Beijing. Government funded 30.4% of THE, while 34.7% was from society and 34.9% from individuals. In recent years, government expenditure in THE increased from 15.5% in 2000 to 30.4% in 2009 (Ministry of Health 2012). The social health expenditure also has been increasing slightly from 25.6% in 2000 to 34.7% in 2012. While individual health expenditure was gradually decreased from 59.0% in 2000 to 35.3% in 2012, correspondingly (Ministry of Health 2012).

3.2.4 Human resources

In China, there are 8.6 million health professionals by 2011, with more doctors than nurses. The total number of doctors is more than 2.5 million, while about 2.2 million nurses (Ministry of Health 2012). The ratio of doctors and nurses is 1: 0.91. In terms of the density of health professionals, there are 1.82 doctors per 1,000 populations, while 1.66 nurses per 1,000 populations. The density of doctors in urban areas is two times than that of rural areas, while the nurse density difference is more than three times (Anand, Fan et al. 2008). Therefore, the shortage of nursing staff is a significant threat in China. About 80% of doctors have undergraduate or diploma qualifications and majority of nurses (87%) have only completed training in nurse schools or have a diploma.

In China, doctors are employed by hospitals and they are the salaried staff of hospitals. The relationship between doctors and hospitals is administrative rather than cooperative in Australia (Xue, Xiang et al. 2011). The nature of Chinese doctors is "unit persons" rather than "independent persons". In fact, they must rely on hospitals to a certain extent for personnel, career development, professional title promotion, superannuation etc (Lin and Geng 2011; Ke and Jia 2012). Both doctors and hospitals need to take responsibility for medical disputes and/or medical incidents (Xue, Xiang et al. 2011). A doctor normally can only practice at one hospital. But after 2009, a pilot of multi-cited practice has been conducting; however the progress is at a slow pace with great difficulties (Xue, Xiang et al. 2011).

3.2.5 Information management

Information management could involve all aspects of activities in hospitals, such as register, asset managements, healthcare service, quality control etc. The dominant source of information about the process of inpatients service comes from medical records in hospitals. The medical records managements is one of the most important part of information management in hospitals

settings (Wu 2008). According to the Chinese regulations for medical records management, medical records should be stored and managed in records-keeping offices by professional staff (Ministry of Health 2002). The quality of medical records and medical records management could influence the accreditation of hospitals (Ministry of Health 2011).

The function of medical records is to summarise medical activities. These medical activities include the examinations the patient undergoes, diagnosis and treatment. The information contained in medical records covers the lifetime of the diseases from occurrence, development, prognosis and outcome (Ji 2010). Medical records could provide crucial information for medical service quality control and improvement, education and research, and rational hospital management. In the recent years, the legal effect of medical records has been increasing, and medical records had an important role on medical disputes, medical lawsuits and medical malpractice evaluation (Ji 2010).

Medical records need to be documented followed rules and regulations. In 2010, the new guideline for documentations of medical records was issued by the Ministry of Health (MOH) (2010). An inpatient medical record is supposed to include: an abstract of medical record, admission note, progress note, consent form for operation, consent form for anesthesia, consent form for blood transfusion, consent form for particular examination/treatment, critical condition notice, medical advices, reports of examinations, chart of vital signs, documents about imaging, pathological reports, etc (Ministry of Health 2010). A few parts could be not existed in a medical record, which is subjective to different patients. For example, a patient with stable conditions normally would not receive a critical condition notice. According to the guideline (Ministry of Health 2010), almost all the information in medical records needs to be documented by doctors. Nurses are required to record patients' vital signs and nursing notes for patients with critical conditions.

The abstracts of medical records summarise key information throughout patients' hospitalisations, which have profound role on statistics analysis, hospital management, education and research etc. (Qi and Cui 2005; Gao and Sun 2009; Su 2009). The current version of abstract (see Appendix B) was modified by MOH in 2011 and was official utilised in all medical organisations across China from 2012. The information collected through the abstract of medical record includes demographic, medical and expenditure information of the patient (Ministry of Health 2011). As one of the most important component of a medical record, the abstract is required to be reported to MOH compulsorily. By the middle of 2013, all the tertiary hospitals in China had achieved the goal to report abstracts of medical records to Health Quality Monitor System (HQMS, www.hqms.org.cn) of MOH electronically in real-time, which has become one of the determinant criteria to the accreditation of tertiary hospitals (Ministry of Health 2012).

To date, with the development of technology, medical records could be either paper-based or electronic-based. In the past decade, the electronic medical records (EMRs) has been developing rapidly in Chinese hospitals, especially in big cities and tertiary hospitals. A survey was conducted in 91 large-scale hospitals in 2010 to investigate the application of EMRs, which reflect that EMRs is utlised widely in resource-intensively hospitals, such as tertiary hospitals (Cui 2011). According to the government's blue print (Tang and Wu 2012), EMRs will be applied in all tertiary and secondary hospitals in Beijing by 2014. However, there is insufficient data about applications of EMRs in small hospitals, or from national levels.

Although the flourishingly development of EMRs, the goal to set up a network to share patients' information is not achieved yet from a large scale level, even in resource-intensive cities and hospitals. In the most developed cities of China (Beijing and Shanghai), the information sharing system only set up in a few hospitals. The shared information is limited to outpatient and emergency records, abstracts of inpatient medical records, and a part of

radiology report (Zhao, Yuan et al. 2010; Tang and Wu 2012). Therefore, detailed information in medical records, in particular inpatient records, could not be shared between hospitals, and every hospital is still an information silo.

Either paper-based medical records or electronic-based medical records, the quality of information contained needs to be improved, and it has the obvious gap compared with medical records in developed countries (Feng, Li et al. 2008; Wu 2008). A huge amount of research has conducted to investigate the information defects of medical records. The reported rate of medical records with information defects in varying degrees ranged from 5% to 77%. The most common components of medical records to detect information defects are from progress notes and abstracts (Chu, Wang et al. 2001; Chen, Chen et al. 2011; Hu and Su 2011; Li 2013; Luo, Shen et al. 2013; Wang, Shang et al. 2013). The defects could be caused by missing information, incorrect information, and undetailed information. In addition, around 65% of death notes have defects in the medical records of deceased patients.

3.2.6 Summary

In conclusion, the background information about Chinese healthcare system, in particular, the hospital system in China has been discussed from five angels: administrative management, facility, finance, human resource and information management. The Lancet published a series of articles about the Chinese healthcare system in 2008 (Anand, Fan et al. 2008; Hu, Tang et al. 2008; Liu, Rao et al. 2008; Tang, Meng et al. 2008). Inequity, low accessibility and high cost were all identified as urgent issues, which could be more aggravated in hospital system. In 2009, the Chinese government launched a three-year reform plan, with 850 billion Yuan funding (148 billion AUD). However, escalation of costs, inequities of access and high-level out-of-pocket payments are still complained of by the public (Hu, Tang et al. 2008; Hu, Zhang et al. 2012).

3.3 Indicators system for patient safety and AEs in China

The development of quality indicators in China started fairly late. The initial incentive to set up the indicator system was for hospitals' accreditation (Ministry of Health 1989; Ministry of Health 2005; Ministry of Health 2008). However, these previous indicator system was considered to be incomplete, subjective, and non-evidence-based (Ma 2008). It did not fully reflect the concept of quality and did not fully cover all dimensions of quality, such as patient safety. A couple of widely-accepted safety indicators are not included in the Chinese indicator system, such as readmissions, unplanned returns to theatre, and urinary catheter-related infections in ICUs (Ma 2008). Some of the existing indicators have been shown to be not directly related to quality of healthcare, such as documentation of medical records, average cost for examination and average length of stay before operation. In addition, some of indicators were subjective and based on personal judgments, such as clinical cure rate (Ma 2008). Due to the accreditation incentive, these indicators were mainly management-oriented.

In 2005, the MOH initiated a nation-wide hospital quality improvement program, which focused attention on the establishment of a systematic, evidence-based, and internationally-comparable indicator system in China. In 2009, the Chinese Healthcare Quality Indicators System (CHQIS) was set up. The CHQIS includes 11 first-level indicators and 33 second-level indicators, which are classified into three main categories: inpatient death-related, unplanned return-related, and adverse event- related (Zhao, Liang et al. 2009) (see Appendix C).

A large proportion of the indicators in CHQIS measure safety from different perspectives, especially the 13 indicators under the AE-related category, and patient safety is clearly emphasised by CHQIS. It is noteworthy that the prevalence of AEs is considered as the first first-level indicator under AE-related categories (Zhao, Liang et al. 2009). Unfortunately, this has not attracted much attention. Several journals have published articles about AEs in Chinese hospitals, but these have been limited to introducing the concept of AEs (Zhu and Pei 2006; Hu

and You 2011) or only focused on specific groups of people or events (Liang, Jiao et al. 2010; Hu, You et al. 2013), rather than setting up a hospital-wide understanding of AEs. One research was conducted to detect AEs from medical disputes cases. However, the analysis of AEs only focused on classifications of AEs (Zhang, Li et al. 2012).

As a relatively new concept, the concept of AEs was firstly introduced to China by Zhao, Sun et al. (2005). Until 2009, the definition of AEs was clarified for the first time at a national level in CHQIS. Adverse event is *an unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused by health care management rather than the patient's disease* (Wilson, Runciman et al. 1995; Zhao, Liang et al. 2009). However, in practice, doctors and nurses are more familiar with the concepts of medical dispute, medical incident, medical error and medical accident, which may include AEs in some cases (Box 3.1).

In addition, safety culture in China remains lacking. Hospital managers and healthcare professionals do not have a clear and sufficient understanding on how to build up and maintain safety culture (Cao 2007). Instead, most hospitals in China still have a dominant punitive culture, and blaming allegedly responsible individuals is still considered the main strategy to resolve AEs (Cao 2007; Li and Liu 2009; Liu, Zhang et al. 2011). For self-protection, doctors and nurses are concerned about being punished (financial or administrative), receiving negative performance evaluations, and causing medical dispute or litigation, and often have negative attitudes to the disclosure of errors or mistakes (Li and Liu 2009; Wang and Zhang 2009; Li and Shi 2011).

Box 3.1 Other safety concepts in China

Medical dispute (医疗纠纷): a disagreement between patients and health professionals about negative outcomes due to the health service. The patient lodges a complaint with the hospital's administrative department or conducts a prosecution to ascertain legal responsibility and demand compensation from the hospital, or requests the hospital to refund the medical expenses.

It may involve a negative outcome or prolong hospital stay and increase expense. A negative outcome could occur during or after hospitalization. A medical dispute is not necessarily a medical incident. Although there is a disagreement between patients and health professionals, it may be reconcilable in some situations (Zhang and Zhang 2006).

Medical incident / medical malpractice （医疗事故）: an event which leads to harmful effects on patients. The event represents a marked negative deviation from the standard of care, which violates the law, administrative and department regulations and standards. There is malpractice involved either by health professionals or other staff in the hospital, such as administrative or logistic staff.

The malpractice may be either omission or commission. There must be causality between malpractice and harmful outcomes. The harmful outcomes include death, disability, injury to organ and tissue, impairment and other negative outcomes (State Council (PRC) 2002).

Medical error （医疗差错）: an event in which health professionals violate the law, administrative and department regulations and standards, but it does not result in injury or death to patients.

Patients may suffer prolongation of hospital stay, extra economic expense and extra physical suffering (Zhang and Zhang 2006).

Medical accident（医疗意外）: an unplanned, unexpected and undesired event normally with a negative outcome to the patient, which is caused by abnormal disease condition or idiosyncrasy during "standard care".

Generally, there is no malpractice involved. This kind of event is not predictable or preventable according to current medical knowledge and technique (Zhang and Zhang 2006).

3.4 The doctor-patient tension in China

The doctor-patient relationship, in particular the tension, in China cannot be ignored to set up a brief understanding of health services in China. It also has significant impacts on patient safety research, especially on the study of AEs, often not in a positive way. With the increase number of medical disputes in China, the tension between doctors and patients are getting more and more intensive.

The reported number of medical disputes is increasing every year. According to Luo and Wang (2013), there were only 2 reported medical disputes in 2005 in a tertiary-level hospital with 1500 beds in Sichuan Province. By 2011, the number of medical disputes jumped to 38. However, the total number of medical disputes at the provincial or national level is normally unavailable. Most of the disputes end with hospitals providing financial compensation in exchange for a settlement with patients. Because there is no medical indemnity insurance for doctors and nurses, healthcare professionals need to take the majority of responsibility to medical disputes and pay for the compensation from their own savings.

Around 30% of medical disputes deteriorate to medical disturbance, often with violence involved (Yangcheng Evening News 2003). Because of concerns about the reputation of hospitals, staff safety and other factors, even though there may be no fault on the part of hospitals, hospitals reluctantly pay compensation in order to settle disputes as soon as possible (He and Sun 2012). So far, there is a law blank in China to regulate and punish medical disturbance in hospitals.

The status of medical disputes is partly a cause, and at the same time a consequence, of the current doctor-patient tension in China. Healthcare professionals and patients are expected to be cooperative and interactive; however, they have more and more hostile attitudes, and the tension is becoming more and more intense (Zhou 2009). Patients and healthcare providers (especially doctors and nurses) are described as “enemies” (Chen 2006).

A Chinese survey found the current doctor-patient tension to be heavily influenced by the health system in China according to the perceptions of both doctors and patients (Le, Wei et al. 2011), including difficulty of access and high out-of- pocket costs. The average 30.4% growth of healthcare costs each year far exceeds the 5.2% growth of revenue (Zhou 2004). Patients probably already have many complaints about accessibility and affordability before they are admitted to hospitals. When in hospital, giving gifts ("red-envelope money") to doctors in exchange for better quality of treatment has become customary, and patients are frequently over-treated and over-prescribed (Hougaard, Osterdal et al. 2011) in Chinese hospitals in pursuit of profit, which only makes the tension more intensively.

In conclusion, an investigation of AEs is actually regarded as the "shame" of healthcare, although the ultimate goal is to provide safer healthcare with high quality to patients. In the context of the present situation in China this kind of study may encounter many barriers, especially from healthcare professionals and hospitals. That may be a reason why there has been no comprehensive study of AEs in China to date, although the importance of understanding and measuring AEs has been emphasised in CHQIS since 2009. In the following chapters of this thesis, a medical record audit study to investigate the prevalence of AEs in two Chinese hospitals will be described. This brief outline and background information of the Chinese context will be helpful in interpretation of the study results.

CHAPTER FOUR: METHOD

The purpose of this chapter is to provide details of study design related to the medical record audit. There are two research questions to be answered in this study:

- Determine the prevalence, consequence, classifications and preventability of AEs among hospitalised, discharged and/or deceased patients in Chinese hospitals.
- Identify risk factors of patients suffer AEs.

The key terms and their definitions used in this study are clarified as follow:

Adverse event (AE): an unintended injury or complication which results in disability, death, or prolonged hospital stay, and caused by health care management rather than the patient's disease (Wilson, Runciman et al. 1995; Davis, Lay-Yee et al. 2002; Baker, Norton et al. 2004; Wilson, Michel et al. 2012).

A preventable adverse event (PAE): an adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level (Zegers, de Bruijne et al. 2009; Christiaans-Dingelhoff, Smits et al. 2011).

Disability: temporary or permanent impairment of physical function (including disfigurement) or mental function or prolonged hospital stay (even in the absence of such impairment) (Wilson, Runciman et al. 1995).

Temporary disability (暂时性功能损失): including AEs from which complete recovery occurred within 12 months (Wilson, Runciman et al. 1995).

Permanent disability(永久性功能损失): includes AEs which cause permanent impairment or which result in permanent institutional or nursing care or death (Wilson, Runciman et al. 1995).

4.1 Study design: retrospective medical record review

Retrospective medical record review (RMRR) was applied in this study. It was first established by a Harvard study in 1984 (Brennan, Leape et al. 1991), and it has been widely used to investigate the prevalence of AEs in both developed and developing countries. Some scholars support this method as the best way to do epidemical studies of AEs (Lilford, Mohammed et al. 2003; Baker, Norton et al. 2004).

The RMRR was described as:

> *"Nurses and medical-records administrators who were trained in our methods first applied the criteria to all the records in the study sample… Physicians on the research team… trained them in the use of the Adverse Event Analysis Form to analyze records...Each record was reviewed independently by two primary physician-reviewers… Records in which the reviewers identified different adverse events, or in which only one reviewer found an adverse event, underwent a third independent review by a physician-supervisor" (Hiatt, Barnes et al. 1989, p.482).*

Many other methods are available to investigate AEs. For instance, a French study compared three methods, cross-sectional, prospective and retrospective, to estimate the incidence of AEs and preventable AEs (Michel, Quenon et al. 2004). The researchers found prospective and retrospective methods found similar numbers of AEs, but the prospective method is more sensitive for the identification of preventable AEs. However, the prospective method requires more work and financial funding (Michel, Quenon et al. 2004). Other methods for studying AEs are observation (Andrews, Stocking et al. 1997) and self-reporting (Thomas and Petersen 2003). Those methods could identify some AEs not found by review-based methods, but these are not reliable methods, highly subject to personal judgements and requires more human resource (Thomas and Petersen 2003).

This study is the first comprehensive epidemiological study of AEs in Chinese hospitals. RMRR was manageable for this study, and RMRR had proven to be feasible in other developing countries (Mendes, Martins et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). In addition, it is possible to compare Chinese AE data with other countries' if a similar research protocol is used.

4.2 Setting (hospital selection)

Two hospitals (Hospital A and Hospital B) in a city in China were selected for this study. There are many similarities between the two hospitals. Both of them are classified and accredited as secondary public hospitals (district hospitals). They located in suburban area of the city, and both hospitals are perceived as the leading hospitals in their districts (District A and District B).

Hospital A is located to the north-east of the city about 42 kilometres away from the central business district (CBD). It was established in 1947. This hospital is under the management of local district Bureau of Health. The number of Huko residents (permanent residents) of district A is 0.87 million in 2012. Hospital A has 550 beds. There are 32 clinical departments (no psychiatric department). The total number of separations in 2008 was 26,267.

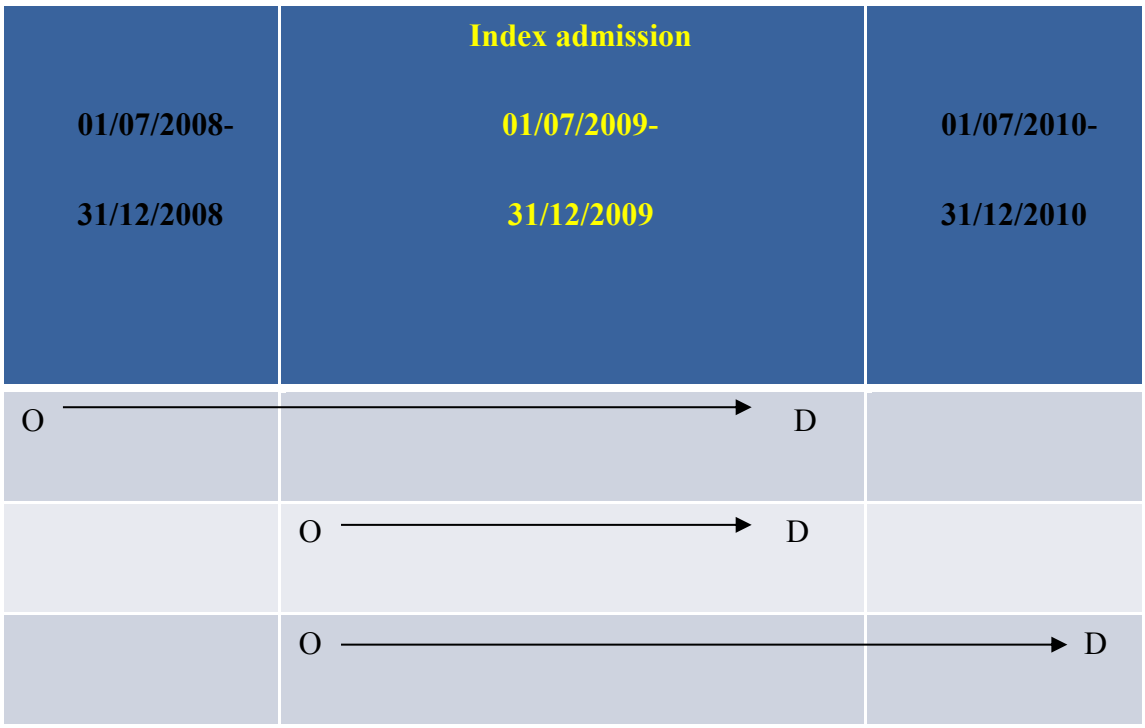
Hospital B is located to the north of the city about 46 kilometres away from the CBD. It was established in 1957. This hospital is under the management of the local district Bureau of Health. The number of Huko residents (permanent residents) of district B is 1.66 million in 2012. Hospital B has 503 beds. There are 17 clinical departments (no psychiatric department). The total number of separations in 2008 was 13,984.

4.3 Time frame

The **index admission** was the admissions sampled from 1 July 2009 to 31 December 2009. An AE which occurred and was detected during index admission was included. If an AE occurred 12 months before index admission and was detected during index admission, this case is

included only if the AE was in some way responsible for the index admission. In addition, an AE is included in this study if it occurred during index admission but was detected in the 12 months after discharge from index admission (Figure 4.1).

Figure 4.1 Research time frame



(O: AEs occurred, D: AEs detected)

Adapted from: Wilson, Runciman et al. (1995)

4.4 Sample selection

The inclusion criteria for this study were as follows: patients over 18 years old who admitted for a minimum of 24 hours (or died in hospital within 24 hours after admission) in Hospital A and Hospital B from 1 July 2009 to 31 December 2009.

4.4.1 Sample size

During the period 1 July 2009 to 31 December 2009 (index admission), the target population (excluded patients admitted in pediatric department) accounted 18,564, which included 12,369 from Hospital A and 6,295 from Hospital B.

Based on previous research and consideration of the quality of medical records in China, for this study, it was estimated that the prevalence of AEs would be 5% (95% CI of ±1%). No difference was expected between the two hospitals. After statistical calculation of sample size, 1,662 medical records were required to achieve the results stated before.

Since it was expected that some selected medical records would be either unavailable or unusable, based on the experience of previous studies (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004; Mendes, Martins et al. 2009), over-sampling was considered necessary. The size of the over-sample in the literature is variable. Canadian and Swedish research oversampled by 10% (Baker, Norton et al. 2004; Soop, Fryksmark et al. 2009), while the figure was 1% in Dutch research (Zegers, De Bruijne et al. 2007). An Australian study did not oversample, but about 3% of the selected sample was eliminated from screening for various reasons (Wilson, Runciman et al. 1995). Developing counties normally oversample by 20% (Mendes, Martins et al. 2009; Wilson, Michel et al. 2012). Following a consideration of the information contained in medical records in China and discussion with hospital staff from a records-keeping office, 10% over-sampling was perceived as a reasonable number for this study. Therefore, another 166 records were required (1,662*10%). Overall, a total of 1,828 medical records were required for this study.

4.4.2 Sampling process

In order to maintain each selected medical record had equal probability of selection, a systematic sampling method was conducted by the research-in-charge from each hospital from patients' information systems at each hospital. Patients' information was sorted in an order of discharge data and time, and equal-probability method was processed. The sampling interval was 10, which was calculated based on the formula below:

Sampling interval = target population (18,564) /sample size (1,828)

= 10.2

At the beginning of the sampling process, all the medical records from the paediatric department were excluded. The first medical record was randomly picked by the research-in-charge in each hospital. After that, every 10^{th} medical record was selected. If the selected record satisfied the inclusion criteria, this record was counted as one sample. In addition, this medical record would be given a unique research number, which would appear in the review forms later. If not, the next available record which satisfied the criteria was counted. The sampling process continued till the last medical record in the patients' information system.

In total 1,897 medical records were selected in the two participating hospitals, and the numbers of selected records from each hospital were in proportion to the admission numbers. One thousand two hundred and seventy-three cases were selected from Hospital A (67.1%), and the other 624 medical records were from Hospital B (32.9%). An identifier was kept by the research-in-charge from each hospital, which contained the matching information between the research numbers to medical records numbers.

4.5 **Review process**

In this study, the data were mainly collected from the review of paper-based medical records. Hospital A launched electronic medical records (EMRs) in early 2009. It was still in transition between paper-based medical records to EMR during from July 1 2009 to December 31 2009. However, most of the data were still collected from paper-based medical records, as the EMRs contained only a small proportion of information at that time. Hospital B introduced EMRs in 2010, and therefore, all reviewed materials from this hospital were paper-based.

Before the review process started, all the selected medical records were de-identified by the staff from medical administrative department for confidentiality and bias control. All

information could potential identify the patients were all covered up, such as patient's name, medical records numbers, responsible doctors' names and signatures, responsible nurses' name and signatures.

The review process and review forms were designed based on the Harvard Medical Practice Study (Brennan, Leape et al. 1991) and other similar studies (Wilson, Runciman et al. 1995; Davis, Lay-Yee et al. 2002; Baker, Norton et al. 2004; Zegers, de Bruijne et al. 2009). Two stages were involved: screening by nurses and reviewing by doctors, which was same as other similar studies. In general, "injury or complication" would be detected during the screening process by nurses, and doctors would make judgments on whether the "injury or complication" resulted in disability, death, or prolonged hospital, and caused by health care management.

4.5.1 Screening process

In the screening stage (Figure 4.2), each medical record was screened by a nurse according to seventeen explicit screening criteria, as illustrated in Box 4.1. Nurses read all information contained in a medical record, such as the abstract of medical record, admission note, progress note, consent form for operation, consent form for anesthesia, consent form for blood transfusion, consent form for particular examination/treatment, critical condition notice, medical advices, reports of examinations, chart of vital signs, documents about imaging, pathological reports, etc.

Through the screening process, if none of the criteria was satisfied in a record, this record was marked as negative and no further investigation was conducted. If one or more criteria were found in a record, this record was considered as a potential AE case. And the screening nurse forwarded this record to the researcher-in-charge in their own hospital for further review (Brennan, Leape et al. 1991; Wilson, Runciman et al. 1995; Baker, Norton et al. 2004). At the same time, a Review Form 1 (RF1) was completed by nurses and attached to each record screened, whether it was positive or negative (Wilson, Runciman et al. 1995) (See Appendix D

and Appendix E).

The quality control was arranged for screening process. Firstly, information which could help research team to identify any screening positive cases was sought. For example, the infection control office of each hospital provided a list of nosocomial infections from 1 July 2009 to 31 December 2009 for all admitted patients. The research-in-charge carefully matched the medical record numbers between the nosocomial infection case and the selected medical records, in order to identify any possible screening positive records. Secondly, the author of this thesis read through all completed RF1 to identify any mistakes. For example, one screening criteria was satisfied, however, it was incorrectly marked as screening negative case. The screening status for that particular medical record would be changed to screening positive and forwarded for doctors' review.

4.5.2 Review process

In the second stage, the review stage (Figure 4.3), a pair of doctors independently reviewed each screened positive record (potential AE cases) forwarded from the nurses. The doctors read RF1 first and then conducted an exhaustive analysis of each medical record on their own to confirm whether it was a case with AE(s) or not. After the review process, a Review Form 2 (RF2) for each record was completed by each doctor (see Appendix F and Appendix G).

However, several similar studies in recent years only used one physician to review each record (Sari, Sheldon et al. 2007; Mendes, Martins et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012), because the agreements between reviewers did not indicate improvement with two doctors review each record (Zegers, de Bruijne et al. 2010). However, Forster, Taljaard et al. (2012) argued that given the accuracy of reviewers, multiple reviewers should be involved for review each medical record. Therefore, this study followed the traditional way on review process with two doctors for each record, which was same as some previous studies (Brennan, Leape et al. 1991; Wilson, Runciman et al. 1995; Davis, Lay-Yee et

al. 2002; Baker, Norton et al. 2004; Zegers, De Bruijne et al. 2007; Soop, Fryksmark et al. 2009).

For bias control purpose, there were three principles for the arrangements of review doctors and reviewed medical records. The first principle for the arrangements of pairs of doctors was based on doctors' specialist. Medical records from surgical patients were reviewed by a pair of surgeons. Internists reviewed records selected from medicine departments. Secondly, the arrangements for the pairs of doctors were not fixed for reliability purpose (Zegers, de Bruijne et al. 2010). In other words, doctor A and B could review the record X as a pair, and for review of record Y, doctor A would be a pair with doctor C. In addition, a doctor reviewer would not review his/her patients' medical records.

During the review process, three important questions were answered by the reviewers (doctors). First, doctors were asked to judge if any unintended injuries or complications were present, and if the injuries resulted in disability, death or prolongation of hospital stay. If either of the two elements was not satisfied, the record was marked as negative and the review process was ceased. If both of the elements were satisfied, the review process continued.

Second, the reviewers were asked to consider if the injury or complication was caused by healthcare management. The reviewers needed to give a confidence score for causation using a 1-6 scale. For comparison purposes, this study used two standards (2 and greater and 4 and greater) as thresholds for causation judgment. Score 2 means: slight-to-modest evidence for management causation, and score 4 means: management causation more likely than not, more than 50-50 but close call. Using 2 and greater is the same as that used Australian and New Zealand studies (Wilson, Runciman et al. 1995; Davis, Lay-Yee et al. 2002), while researchers in other countries use 4 as the benchmark (Brennan, Leape et al. 1991; Baker, Norton et al. 2004; Zegers, de Bruijne et al. 2009). If the causation score was less than 2, the particular event was not considered an AE. If more than one AE was identified in a record, each of the AE were

identified and documented.

Third, the doctors were asked to judge the degree of preventability by using another 1-6 scale based on their experience, and the results fell into categories of “no preventability” (score 1: virtually no evidence for preventability), “low preventability” (score 2: slight-to-modest evidence for preventability and score 3: preventability not likely, less than 50-50 but close call) and “high preventability” (score 4: preventability more likely than not, more than 50-50 but close call, score 5: strong evidence for preventability, and score 6: virtually certain evidence for preventability) (Wilson, Runciman et al. 1995). During the review process, if the reviewers had questions, they were encouraged to seek advice from the expert panel. Please see session 3.8 for more details for expert panel.

If there were disagreements about the presence of an adverse event, a causation score or a preventability score between the two doctors, the cases were discussed by the two reviewers (Wilson, Runciman et al. 1995). If consensus could not be achieved, a third reviewer made the final decision (Zegers, De Bruijne et al. 2007).

The quality control was arranged for review process as well. Firstly, after the review process, the research-in-charge from each hospital would carefully match the patients’ information on RF1 and RF2 with the original medical records. Secondly, the author of this thesis read through all completed RF2 to identify any possible mistakes. For example, two review doctors had disagreement on the causation score of an AE, but the disagreement was overlooked by the research-in-charge. In this situation, the discussion between the two doctors involved in that particular AE case would be arranged for consensus.

Figure 4.2 Screening process

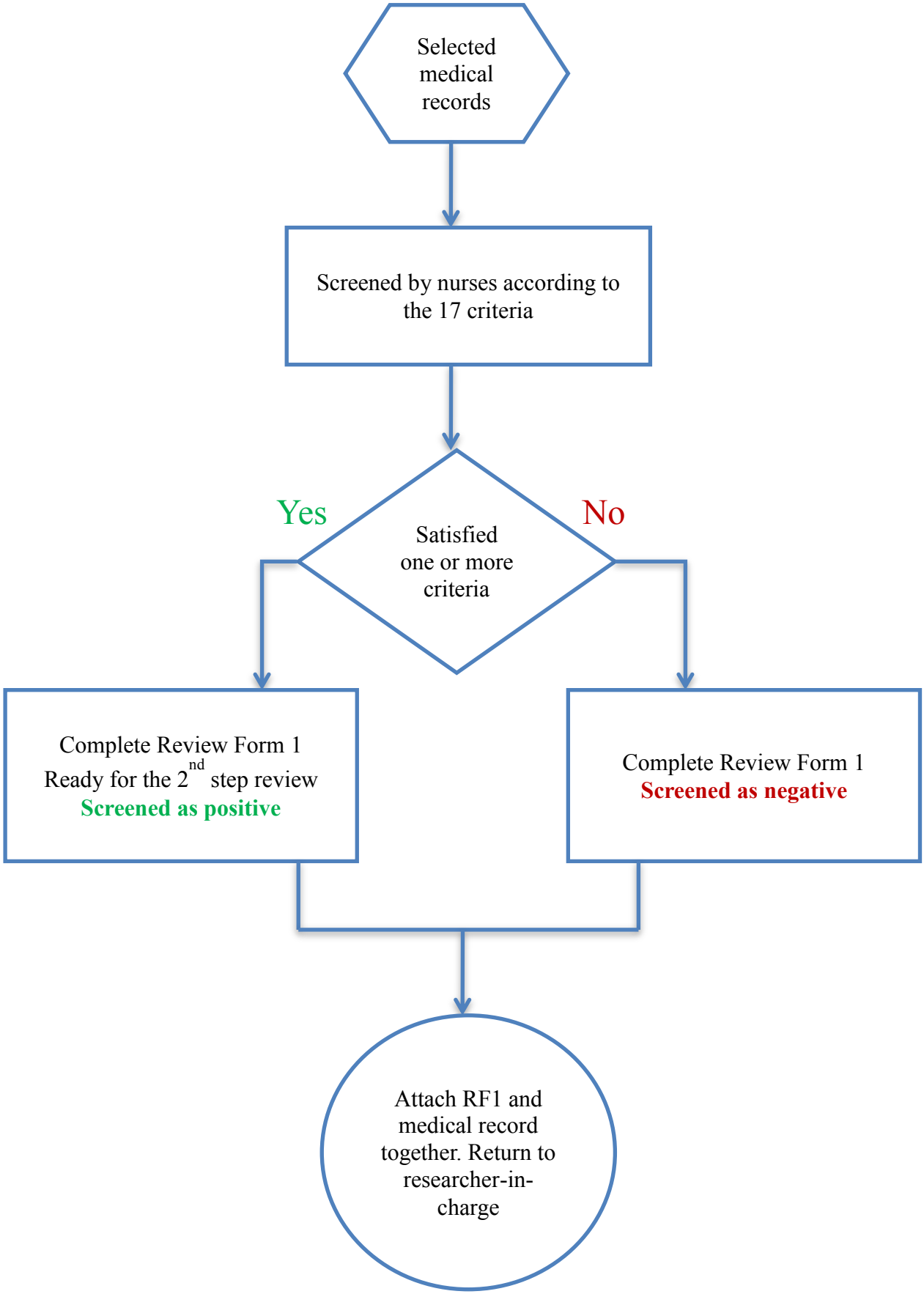
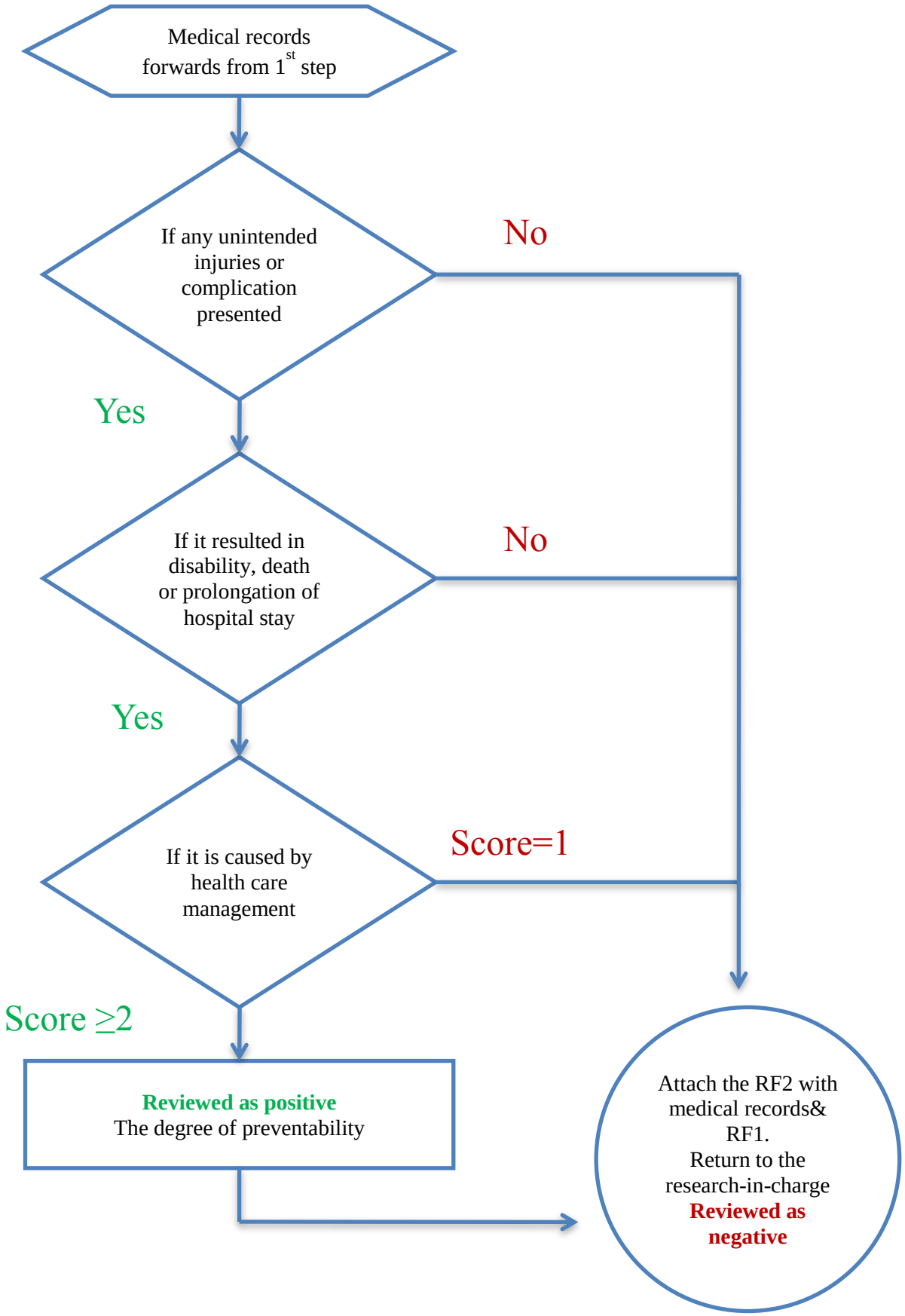


Figure 4.3 Review process



Box 4.1 Screening criteria before and after modifications

Original 18 screening criteria	***17 screening criteria of this study***
Unplanned admission before index admission	
Unplanned readmission after discharge from index admission	Unplanned readmission after discharge from index admission in 7 days
	Unplanned readmission after discharge from index admission in 28 days
Hospital-incurred patient injury	Hospital-incurred patient injury
Adverse drug reaction	Adverse drug reaction
Unplanned transfer from general care to intensive care	Unplanned transfer from general care to intensive care or transfer from one unit to another unit
Unplanned transfer to another acute care hospital	Unplanned transfer to another acute care hospital
Unplanned return to the operating theatre	Unplanned return to the operating theatre
Unplanned removal, injury or repair of organ during surgery	Unplanned removal, injury or repair of organ during surgery
Other patient complications (AMI, CVA, PE, etc)	Other patient complications (AMI, CVA, PE, etc)
Development of neurological deficit not present on admission	Development of neurological deficit not present on admission
Unexpected death	Death case
Inappropriate discharge to home	
Cardiac/respiratory arrest, low Apgar score	Cardiac/respiratory arrest, low Apgar score
Injury related to abortion or delivery	Injury related to abortion or delivery
Hospital-acquired infection/sepsis	Hospital-acquired infection/sepsis
Dissatisfaction with care documented in the medical record	Dissatisfaction with care documented in the medical record
Documentation or correspondence indicating litigation	Documentation or correspondence indicating litigation
Any other undesirable outcomes not covered above	Any other undesirable outcomes not covered above
Source: Wilson, Runciman et al. (1995)	

4.6 **Review forms**

For comparison purpose, the screening tool used in this study was originally extracted from previous similar studies in Australia and Canada (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004). Translations were carried out by three bilingual linguistics students, two bilingual health science professionals and one Australian qualified translator. Research instruments (RF1 and RF2) were also translated from English to Chinese by the author of this thesis, a bilingual senior researcher on hospital quality control and one Australian qualified translator.

A meeting was held between the research team from Monash University, Chinese experts in hospital management and hospital managers from the two participating hospitals. During the meeting, the six versions of translation for screening criteria were listed in a table with anonymous of translators and the most suitable translation for each criterion was selected. To make the screening criteria more suitable to the Chinese context, the original 18 criteria were modified to 17 criteria (Box 4.1) in the meeting, with agreement of all attendants. The interpretation of each criterion was well defined as well (see Appendix H). In addition, RF2 was slightly amended during the meeting.

4.7 Recruitment and training

The screening process was designed to be conducted by nurses, and the second-stage reviewers were experienced doctors. All the participating nurses and doctors were recruited from their own hospitals; therefore, all the reviews in this study were internal reviews. The data collectors were selected by each hospital to ensure their good character. All participating nurses had at least 5 years clinical working experience by the commencement of this study. The screening nurses in Hospital A were selected from clinical departments except pediatric department, while in Hospital B, all nurses involved in screening were recruited from the records-keeping office. The participating doctors for reviewing process were recruited from clinical departments except pediatric with at least 10 years clinical working experience. Participating nurses and doctors were not paid extra for their workload due to this study, but their participations could be converted to credits for continuing education.

An additional expert panel was formed to provide medical advice to reviewers, especially the second-stage reviewers, when necessary (Wilson, Runciman et al. 1995; Zegers, De Bruijne et al. 2007), because it was possible that a doctor from the general medicine department would be asked to review a medical record from the neurological department. The members of expert panel included the directors of each clinical departments (except pediatric), the director of quality control department and the chief medical officer from each hospital.

One-day intensive training was provided at each hospital by the same researcher(s) to ensure reliability (Thomas, Studdert et al. 2000). The trainees included participating nurses, doctors and members of expert panel. The training session provided information about definition of AEs, examples of AEs non-AEs, PAEs and non-PAEs, distinguishing between AEs and other concepts, such as the difference between medical incidents and AEs, instructions on completing review forms and information about the overall organisation of the project.

4.8 Pilot study

A pilot study was conducted in Hospital A with a small scope (20 medical records) to test the review forms and research organization. The 20 patients were randomly selected from the electronic patient information system, and were admitted to hospital from 1 January 2008 to 1 February 2008. All trained nurses and doctors from Hospital A participated the pilot study. After the pilot study, nurses and doctors provided feedback on the review forms, and the approximate time required for each record. The research team and hospital managers estimated the time required for data collection and the workload for the participating nurses and doctors. Neither RF1 nor RF2 were revised after the pilot study. Additional training meeting was arranged with nurses to answer any questions and resolve any uncertainty about the criteria they encountered during the pilot study. Among the 20 medical records, 3 were screened as positive and forwarded to doctors for review, with the result of one AE being identified by the doctors. Therefore, it was expected that 15% of selected medical records would be screened as positive and the prevalence of AEs would be around 5% for this study.

4.9 Confidentiality

In this study, the most crucial and sensitive problem was maintaining the anonymity of the hospitals, the healthcare providers and the patients. The two hospitals were not allowed to be named, and are addressed as Hospital A and Hospital B. In addition, the data about prevalence, preventability and consequences of AEs from the two hospitals were combined and no comparison was allowed between the hospitals. Each participant (nurses, doctors, research-in-charge, hospital managers, etc.) signed a confidentiality agreement to maintain secrecy and anonymity. Any contact with patients about this study was totally prohibited.

Patients' names were not identified. Each selected medical record was given a unique research number by the research-in-charge, which appeared on RF1 and RF2. One copy of the medical

record number and research number identifiers was kept by the researcher-in-charge of each hospital. He/she only had the identifiers for his/her own hospital. After data collection and analysis, the identifiers were destroyed.

4.10 **Reliability**

According to the previous research, inter-rater reliability can be assured by measuring the kappa statistic. Generally speaking, the inter-rater reliability in the first stage review process was better than in the second stage. The reliability for the screening process ranged from moderate agreement to substantial agreement (0.4-0.8) (Brennan, Leape et al. 1991; Wilson, Runciman et al. 1995; Davis, Lay-Yee et al. 2002; Baker, Norton et al. 2004; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Wilson, Michel et al. 2012).

For the present research, inter-rater reliability was only measured in the screening stages. In total, 42 screened positive cases and 41 screened negative cases were randomly selected by the author of this thesis by conducting a systematic sampling method. These records were screened by other nurses for reliability testing. Two doctors were asked to review each medical record independently, which could be considered as a form of reliability test to some extent. Therefore, no further inter-rater reliability test was arranged for review process.

4.11 **Analysis strategy**

The data analyses were performed by using Statistical Product and Service Solutions (SPSS) 20 software. And an alpha coefficient of 0.05 was set an indicating statistical significance. Descriptive statistics was performed to analysis sample' characteristics, including demographic factors, disease distribution and quality of information.

In the section to analysis the screening process result, descriptive statistics, chi-square, t-test and logistic regression were used. In the univariate analysis, chi-square was used to explore the relationship between each single variable (age group, gender, type of payment, type of

admission and departments) and the screening status. T-test was performed to investigate the relationship between length of stay (LOS) with screening status. Descriptive statistics (frequency, mean and standard deviation) were performed to examine LOS, disease distribution and selected criteria for screening positive. In addition, a logistic regression was conducted to evaluate the impact of a number of factors on the likelihood that a medical record would be screened as positive. Finally, the inter-rater reliability between nurses on screening status was measured by the Kappa coefficient.

In the section to analysis the review process result, descriptive statistics, chi-square, t-test and logistic regression were used. In the univariate analysis, chi-square was used to explore the relationship between each single variable (age group, gender, type of payment, type of admission and departments) and the AEs detection. T-test was performed to investigate the relationship between LOS with the appearance of AEs. Descriptive statistics (frequency and mean) was performed to examine disease distribution, selected criteria for review positive, consequence of AEs, average additional length of stay, classifications of AEs and preventability of AEs. In addition, a logistic regression was conducted to evaluate the impact of a number of factors on the likelihood that an AE would be detected in a medical record. Finally, another logistic regression was applied to assess the impact of each screening criterion on the likelihood of identifying AEs.

4.12 **Ethical approval**

Permission of the two participating hospitals was granted in March 2010, and ethical approval was obtained in December 2010 from Monash University (see Appendix I). The patients whose records were selected had been discharged or were deceased at the time of data collection and there was no contact with patients. Therefore, consent was not sought from patients.

CHAPTER FIVE: RESULTS

The medical record audit study reported in this thesis applied RMMR design to investigate the prevalence of AEs and characteristics of AEs in two Chinese hospitals. The results are presented in four major sections. At the beginning of this chapter, characteristics of sample were stated in the form of descriptive statistics. General results of the medical records audit study was represented in the second section, which provided the key information and results of the entire study process. In the third part of this chapter, results generated from screening process were analysed. Univariate analysis for screening positive cases was represented, followed by a logistic regression to investigate the impact on patients' characteristics on the likelihood to be screened as positive in the screening process. The reliability of the screening process was included as well. In the fourth section of this chapter, features of review positive cases (AEs cases) are analysed at the beginning by using univariate analysis, followed by the discussion about characteristics of AEs. Finally, two logistic regression tests were represented to explore the impact of patients' socio-demographic factors and selected particular screening criteria on the likelihood to be later reviewed as positive cases (AEs cases).

5.1 Characteristics of patients

The data collection started in February 2011 at the two hospitals. There were 1,897 medical records selected for this study, of which 50 were eliminated for various reasons:

- discharged patient with less than 24 hours hospital stay 1,
- patient's name on electronic record not matching the paper record 2,
- incorrect patient number 12,
- unavailable/missing medical records 17, and
- H1N1 cases without medical records 18.

Therefore, in total, 1847 medical records were eligible for screening by nurses, which included 1,234 records from Hospital A (66.8%), and the other 613 from Hospital B (33.2%).

In the 1,847 medical records, the proportions of patients' gender were roughly equal. There were 893 male patients (48.3%) and 954 female patients (51.7%). The age of patients ranged from 18 to 97 years old with an average of 52.1 years. Lengths of stay (LOS) for patients were between 1 and 111 days. On average, patients stayed in hospital for 10.5 days (mean). About two thirds of the patients (60.4%) were admitted to the hospitals as "emergency and urgent" patients. Another one third of the patients (38.7%) were elective admission patients. Only small proportion of patients were transferred from another hospital or readmitted, 0.5% and 0.3% respectively. Patients who had the New Rural Cooperative Medical Scheme (NCMS), catastrophic disease insurance or private health insurance were categorised as "other insurance type" with a proportion of 35.8%. Another 31% of patients were out-of-pocket patients, and they were not covered by any type of insurance, or their health insurance could not cover their inpatient hospital service. Twenty-three percent of patients were covered by the BMI. In addition, a small number of patients (8.1%) were covered by GHI.

Over half of the patients (57.3%) was admitted in surgical wards (including obstetric patients), and 40.7% of the medical records were from non-surgical (medical) departments. Emergency and ICU had 21 cases and 16 cases in this study, respectively. According to the International Classification of Diseases-10th Revision (ICD-10), in the 1,847 selected medical records, the most common principal disease diagnosis was the circulatory system, which accounted for about a quarter (23.3%) of the disease distribution in this study (Table 5.1). The other disease categories included injury, poisoning and certain other consequences of external causes; disease of the digestive system; pregnancy, childbirth and the puerperium; factors influencing health status and contact with the health service; disease of the respiratory system; neoplasms; diseases of the genitourinary system; diseases of the nervous system; and diseases of the musculoskeletal system and connective tissue. These ten categories made up over 92% of principal diagnoses in the sample (Table 5.1). It should be noted that, although the samples were systematically selected from the patient record system of each hospital, the "percentage of

sample" does not necessarily reflect morbidity of the disease in the residential population. The percentages here only illustrate the proportions of hospital admissions.

Table 5.1 Principal diagnosis of sampled medical records in two hospitals (N=1,847)

ICD-10 category ranked	Number of Sample	%of sample
IX Diseases of the circulatory system	430	23.3
XIX Injury, poisoning and certain other consequences of external causes	286	15.5
XI Disease of the digestive system	229	12.4
XV Pregnancy, childbirth and the puerperium	229	12.4
XXI Factors influencing health status and contact with health services	129	7.0
X Diseases of the respiratory system	123	6.7
II Neoplasms	102	5.5
XIV Diseases of the genitourinary system	100	5.4
VI Diseases of the nervous system	45	2.4
XIII Disease of the ear and mastoid process	40	2.2
IV Endocrine, nutritional and metabolic disorders	38	2.1
VII Diseases of the eye and adnexa	35	1.9
XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	21	1.1
I Certain infectious and parasitic diseases	11	0.6
III Diseases of blood and blood-forming organs and certain disorders involving the immune mechanism	11	0.6
V Mental and behavioural disorders	4	0.2
VIII Disease of the ear and mastoid process	4	0.2
XII Diseases of the skin and subcutaneous tissue	4	0.2
Unknown	4	0.2
XVII Congenital malformations, deformations and chromosomal	2	0.1
Total	1,847	100.0%

The quality of each medical record was measured using a scale from 1 to 5, and scored by the screening nurse. The more information which was provided, the higher the score assigned. Score 1 represented no information was available, while 5 indicated all information was available. In total, 97.4% of the medical records provided most information or all information to nurses for screening (score = 4 or 5). Only 37 records (2%) had half information available (score = 3) and 7 records had less information available (score = 2) (Table 5.2).

Table 5.2 The information score of sampled medical records in two hospitals (N=1,847)

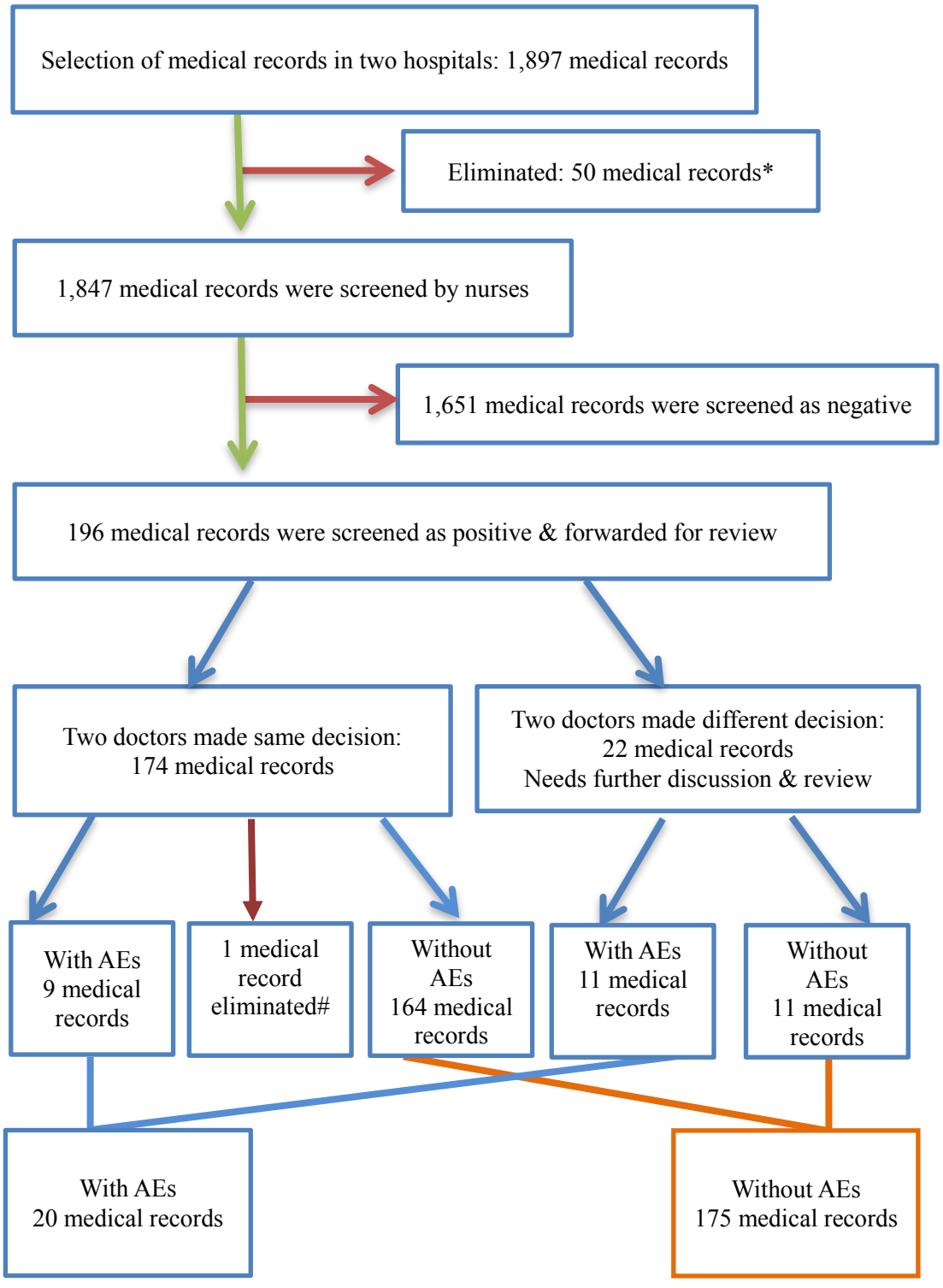
Score	Description	Frequency	Proportion %
1	No information is available	0	0
2	Less information is available	7	0.4
3	About half information is available	37	2.0
4	Most information is available	951	51.5
5	All information is available	852	46.1
Total		1847	100.0

5.2 General results

In screening process, each medical record was screened by a trained nurse according to the 17 screening criteria. At the beginning, 186 out of 1,847 medical records were screened as positive. Then, the infection control office of each hospital provided a list of nosocomial infections during from 1 July 2009 to 31 December 2009 for all admitted patients. After carefully matching the medical record numbers, another 6 records with nosocomial infections were identified as positive records, which were previously screened as negative cases. The author of this thesis, NC, also reviewed all the negative review forms. She then discovered 4 medical records were death cases but were incorrectly marked as negative cases. Therefore, 196 (10.6%, 9.3%-12.1%, 95% CI) medical records in total were judged as screened positive cases, which were forwarded to doctors for further review (Figure 5.1).

In review process, a pair of doctors reviewed each medical record individually. One medical record was eliminated because the information on RF1 did not match the medical record. Doctors achieved agreement on 174 records, which included 9 records with AEs, while they disagreed about the other 22 medical records on three main questions (appearance of AE, causation score, and preventability). A meeting was arranged for the doctors to discuss their disagreement. After the discussion, disagreement was reconciled by 21 pairs of doctors. Only 1 medical record was reviewed by the third doctor to make the final decision due to unresolved disagreement. Among those 22 medical records, there were 11 medical records with AEs. Therefore, in total, 20 medical records with AEs were detected in this study (Figure 5.1). The prevalence of AEs was **1.14% (0.69%-1.68%, 95% CI)** with a causation score rating of at least 2. When the causation score of 4 was applied as the threshold, the prevalence of AEs reduced to **0.7% (0.36%-1.15%, 95% CI).**

Figure 5.1 Flow diagram of study process



*The reasons for elimination (50):
Stay in hospital less than 24 hours: 1;
Patient's name on electronic record does not match the paper record: 2;
H1N1 cases without medical records: 18;
Incorrect number on medical records: 12;
Unavailable/missing medical records: 17.

#The reason of elimination (1):
The information on RF1 did not match the medical record:1.

5.3 Analysis of screening process

In order to gain insight into the results of the screening process, this section has three main parts. In the first part, univariate analysis was performed for age, gender, type of payment, LOS, type of admission, disease, department and selected criteria on screening. In second part, a logistic regression was conducted to investigate the impact on patients' characteristics on the likelihood to be screened as positive in the screening process. At the end of this part, the reliability of the screening process is reported.

5.3.1 Features of screening positive cases

In this section, the variables of age, gender, type of payment, LOS, type of admission, disease distribution and admitted departments of patients who had screened as positive and positive screening criteria are analysed individually in order to explore the relationship between each single variable and the screening status.

5.3.1.1 Age

The average age of the sample was 52.1 years. The average age for the 196 screening positive records was 58.1, while the average age for the remaining 1,651 screening negative records was 51.4 years. Based on an analysis of the 196 screening positive medical records, the positive cases increased along with patients' age. The age groups 55-64 and 65-74 had the highest rate of screening positive cases, with more than two fifths of the total positive cases. The rate of AE screening positive cases was lower in the age group 85 plus (Table 5.3).

The age distributions of screening positive cases and sampled cases did not exactly match. Patients younger than 55 years old had lower screening positive rate than the sample, while patients 55 years old and over had higher screening positive rate than the sample age proportions. Therefore, admission rates and screening positive rates were lower in patient age

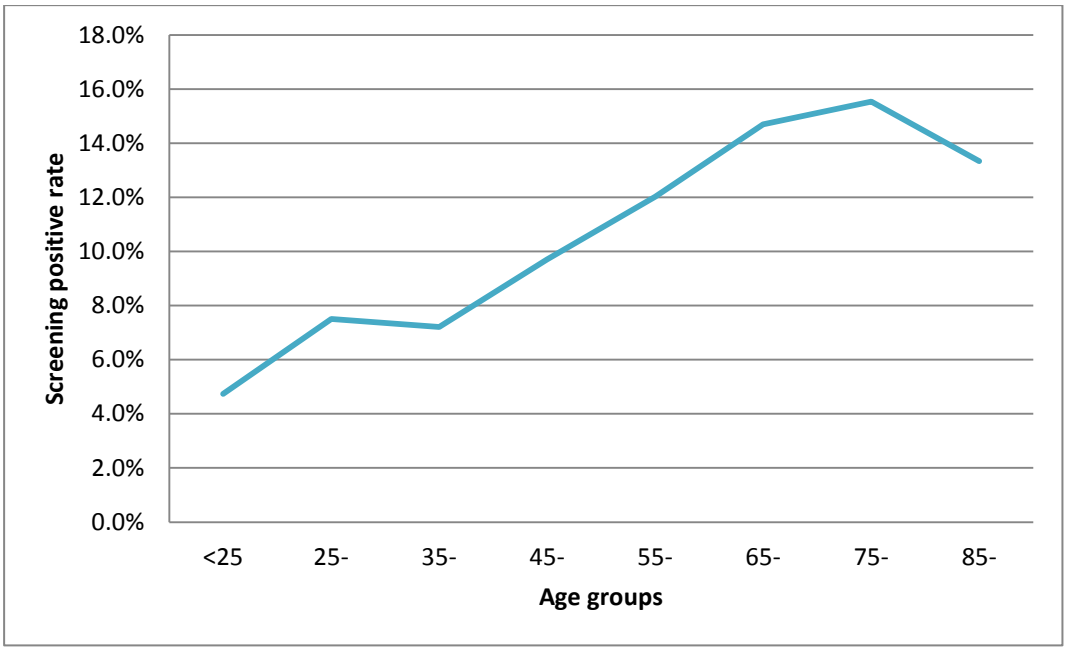
under 55, and the rates were higher in patients aged 55 and over.

Table 5.3 AE screening positive cases and age-specific AE screening positive rate (N=1,847)

Age group (years)	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
<25	169	9.1	8	4.1	4.7
25-	253	13.7	19	9.7	7.5
35-	236	12.8	17	8.7	7.2
45-	309	16.7	30	15.3	9.7
55-	316	17.1	38	19.4	12.0
65-	313	16.9	46	23.5	14.7
75-	206	11.2	32	16.3	15.5
85-	45	2.4	6	3.1	13.3
Total	1847	100.0	196	100.0	10.6

In general, the screening positive rate increased along with increased age (Table 5.3 and Figure 5.2). To investigate the effect of the age-specific factor on screening positive rate, the age group 85 plus was combined with the 75-84 age group for statistical calculation. The chi-square test was performed with the Pearson chi-square value = 23.474, $p<0.01$. The conclusion is that the **AE screening positive difference between different age groups is statistically significant**. AE screening positive rate increases along with patients' age.

Figure 5.2 Age-specific AE screening positive rate (N=1,847)

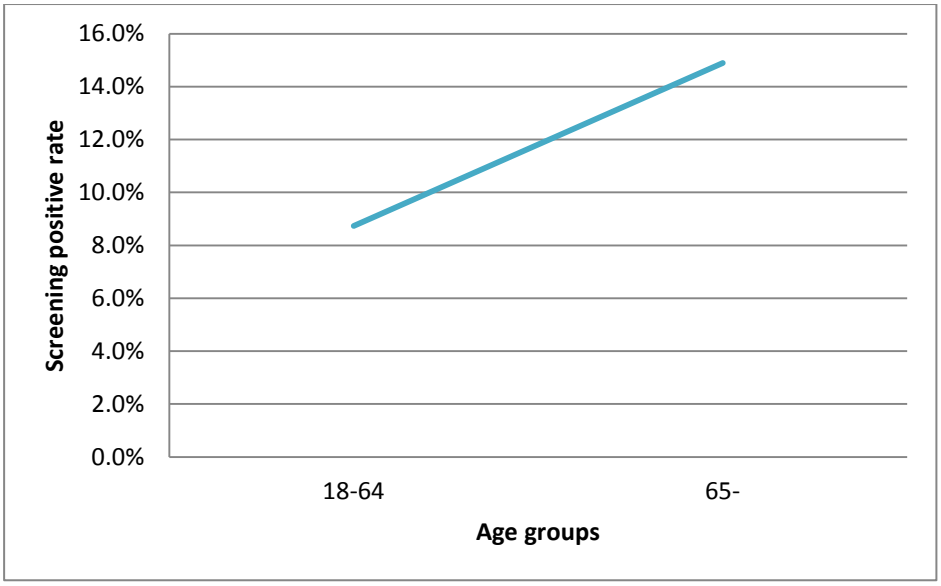


For easy comparison purposes, patient ages were re-grouped as 18-64 and 65 plus using 65 years old as a cut-off point (Table 5.4 and Figure 5.3). The chi-square test was applied and the Pearson chi-square value = 15.050, $p<0.001$. The conclusion is that the **screening positive rate of AE differences between the two age groups is statistically significant**. The AE screening positive rate is higher in older patients (65 years and over).

Table 5.4 AE screening positive cases and age-specific AE screening positive rate (regrouped) (N=1,847)

Age group (year)	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
18-64	1283	69.5%	112	57.1%	8.7%
65-	564	30.5%	84	42.9%	14.9%
total	1847	100.0%	196	100.0%	10.6%

Figure 5.3 Age-specific AE screening positive rate (regrouped) (N=1,847)



5.3.1.2 Gender

It appeared that female patients and male patients had similar risk to be screened positive (Table 5.5). The screening positive rate of male patients was 10.8%, while the rate for female patients was 10.5%. The chi-square test was processed, and the Pearson chi-square = 0.12, p = 0.911. These statistics indicate that **the difference of screening positive rate between male patients and female patients has no statistical significance**.

Table 5.5 AE screening positive cases and gender-specific AE screening positive rate (N=1,847)

Gender	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
Male	893	48.3	96	49.0	10.8
Female	954	51.7	100	51.0	10.5
Total	1847	100.0	196	100.0	10.6

5.3.1.3 Type of payment

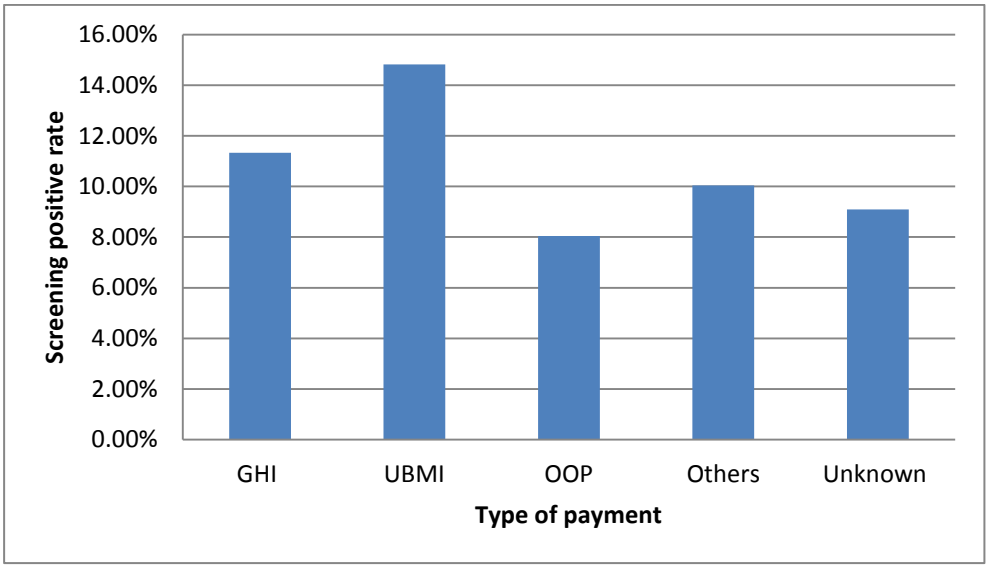
Patients with BMI cover had a higher screening positive rate (14.8%) than patients with GHI (11.3%) and Others (10.0%) including RCMS, catastrophic disease arrangements and private health insurance. The other 30% were recognised as out-of-pocket patients (OOPs) and they had the lowest screening positive rate (8.0%) (Table 5.6 and Figure 5.4).

Statistical tests were run to examine the significance of the four different types of payment. The Pearson chi-square =12.209, p<0.01. The **AE screening positive rate between government health insurance, BMI, out-of-pocket patients, and other schemes are statistically significant.** Patients with BMI are more likely to be screened positive, followed by GHI, Others and OOPs.

Table 5.6 AE screening positive cases and type of payment-specific AE screening positive rate (N=1,847)

Payment	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
GHI	150	8.1	17	8.7	11.3
BMI	425	23.0	63	32.1	14.8
OOP	572	31.0	46	23.5	8.0
Others	667	36.1	67	34.2	10.0
Unknown	33	1.8	3	1.5	9.1
Total	1847	100.0	196	100.0	10.6

Figure 5.4 Type of payment-specific AE screening positive rate (N=1,847)



To investigate further, patients were regrouped into two groups: insured and uninsured (Table 5.7). A statistical test was performed to examine the significance of screening positive rate for patients with insurance and patients without insurance, and the Pearson chi-square = 5.536, $p<0.05$. **The AE screening positive rate for patients with insurance is higher than that for patients without insurance and the difference is statistically significant.**

Table 5.7 AE screening positive cases and type of payment-specific AE screening positive rate (regrouped) (N=1847)

Payment	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
Insured	1242	67.2	147	75.0	11.8
Uninsured	572	31.0	46	23.5	8.0
Unknown	33	1.8	3	1.5	9.1
Total	1847	100.0	196	100.0	10.6

5.3.1.4 Length of stay

The average length-of-stay (ALOS) of screening negative cases was 10.0 days (9.64-10.42, 95% CI), while it was 4.0 days longer for patients screening positive (Table 5.8). An independent-sample *t*-test was conducted to compare the ALOS of the screening positive group and screening negative group. **There is a significant difference in ALOS in those two groups (*t*-test: *t*=4.379, *p*<0.001)**, which suggests that the screened positive cases had longer ALOSs than the screened negative cases.

Table 5.8 Average length of stay of AE screening positive and negative cases

	# case	ALOS (day)	95% CI (day)	Median (day)	SD	Minimum (day)	Maximum (day)
Screening negative	1,651	10.0	9.6-10.4	8.0	8.05	1	111
Screening positive	196	14.0	12.3-15.7	11.0	12.4	1	74
Total	1,847	10.5	10.1-10.9	8.0	8.7	1	111

In positive cases, ALOS for male patients was about 2 days longer than for female patients (15.0 days vs. 13.1 days) (Table 5.9). T-test was performed, and the results were *t*=1.054, *p*=0.293. In terms of ALOS, there is no difference between male patients and female patients. In addition, the ALOS of patients under 65 years old was 13.9 days, while the ALOS was 14.2 days for those aged 65 years and above (Table 5.9). A *t*-test was conducted to explore the impact of age on ALOS. Again, there was no statistically significant difference in ALOS for the two age groups, *t*=-0.168, *p*=0.867. Thirdly, the *t*-test was repeated to investigate the difference of ALOS of patients with different insurance status. Again, there was no statistical difference in ALOS between patients insured and uninsured, *t*=-0.314, *p*=0.754.

In summary, **patients with longer hospital stays are more at risk of being screened as positive in the screening process. However, in screening positive records there was no difference of ALOS on the basis of patient's gender, age or insurance status.**

Table 5.9 Average length of stay of AE screening positive and negative cases by gender, age group and type of payment

		ALOS in screening negative cases (days)	ALOS in screening positive cases (days)
Gender	Female	9.5	13.1
	Male	10.6	15.0
Age group	Under 65 years old	9.7	13.9
	65 and above years old	11.0	14.2
Type of payment	Insured	10.6	14.2
	Uninsured	9.0	13.5

5.3.1.5 Type of admission

In this study, majority of patients were admitted as either emergency and urgent cases (60.4%) or elective cases (38.8%). Only a few patients were transferred from other hospitals or readmitted, 0.5% and 0.3%, respectively. For statistical purposes, those transferred and readmissions were regrouped to the emergency and urgent and elective types (Table 5.10).

A statistical test was conducted to examine the significance between emergency and urgent admission and elective admission, and the results of the Pearson chi-square = 0.10, p = 0.92. **Therefore, the screening positive rate between emergency & urgent admission and elective admission is not statistically significant.**

Table 5.10 AE screening positive cases and type of admission-specific AE screening positive rate (regrouped) (N=1,847)

Type of admission	# Sample	Proportion of sample %	# Screening positive	Proportion of positive %	Screening positive rate %
Emergency & urgent	1120	60.6	120	61.2	10.7
Elective	727	39.4	76	38.8	10.5
Total	1847	100.0	196	100.0	10.6

5.3.1.6 Principal diagnosis

The ICD 10 codes of sample cases were collected from patient records. The categories of principal diagnoses were classified based on the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) Version for 2010 (WHO 2010) (see Appendix J). The major categories of diseases of screening positive cases are listed in Table 5.11. Of the 196 screening positive cases, the ten most common primary (principal) diagnoses are ranked in Table 5.12. The ten categories comprise 93.5% of the screening positive cases.

Table 5.11 AE screening positive cases and ICD-10 disease category-specific AE screening positive rate (N=1,847)

ICD-10 category	# Sample	Proportion of sample (%)	# Screening positive	Proportion of screening positive (%)	Screening positive rate (%)
I	11	0.6	5	2.6	45.5
II	102	5.5	25	12.8	24.5
III	11	0.6	2	1.0	18.2
IV	38	2.1	4	2.0	10.5
V	4	0.2	0	0	0
VI	45	2.4	3	1.5	6.7
VII	35	1.9	1	0.5	2.9
VIII	4	0.2	0	0	0
IX	430	23.3	62	31.6	14.4
X	123	6.7	12	6.1	9.8
XI	229	12.4	15	7.7	6.6
XII	4	0.2	0	0	0
XIII	40	2.2	4	2.0	10.0
XIV	100	5.4	11	5.6	11.0
XV	229	12.4	16	8.2	7.0
XVII	2	0.1	0	0	0
XVIII	21	1.1	3	1.5	14.3
XIX	286	15.5	19	9.7	6.6
XXI	129	7.0	14	7.1	10.9
unknown	4	0.2	0	0	0
total	1,847	100.0	196	100.0	10.6

The information in Table 5.12 suggests the following: patients admitted with circulatory system diseases, neoplasms, injury, poisoning and certain other consequences of external causes, and pregnancy, childbirth and the puerperium, as well as digestive diseases comprise most AE screening positive cases.

Table 5.12 Top 10 ICD-10 disease category-specific AE screening positive cases (ranked) (N=183)

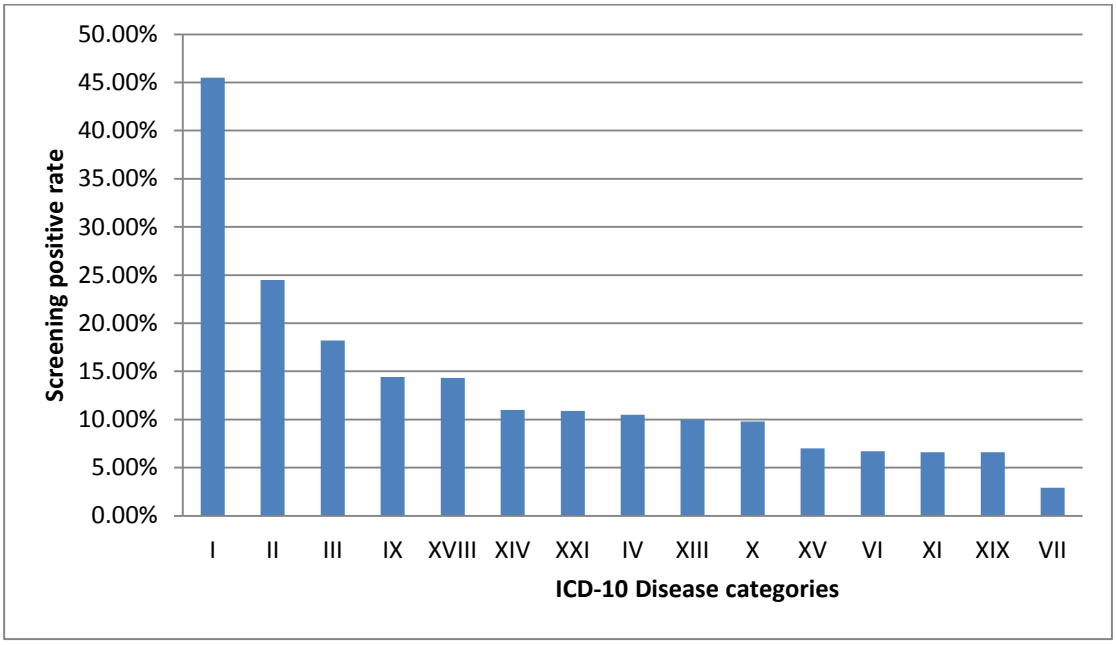
ICD-10 category	Category	#Screening positive	Proportion of screening positive (%)
IX	Diseases of the circulatory system	62	31.6
II	Neoplasms	25	12.8
XIX	Injury, poisoning and certain other consequences of external causes	19	9.7
XV	Pregnancy, childbirth and the puerperium	16	8.2
XI	Disease of the digestive system	15	7.7
XXI	Factors influencing health status and contact with health service	14	7.1
X	Diseases of the respiratory system	12	6.1
XIV	Diseases of the genitourinary system	11	5.6
I	Certain infectious and parasitic diseases	5	2.6
IV	Endocrine, nutritional and metabolic disorders	4	2.0
Total		183	93.5

However, the composition of AE screening positive case in the hospitals does not necessarily reflect the risk of occurrence of AE among different diseases, because the numbers of patients for each disease category varied. For instance, circulatory system disease had the highest screening positive proportion; however, this might due to being highest number of patients admitted to the hospitals. Therefore, the screening positive rate needed to be calculated, and the results are illustrated in Table 5.13 and Figure 5.5.

Table 5.13 ICD-10 disease category-specified AE screening positive rate (ranked) (N=196)

ICD 10 Category		Screening positive rate (%)
I	Certain infectious and parasitic diseases	45.5
II	Neoplasms	24.5
III	Diseases of blood and blood-forming organs and certain disorders involving the immune mechanism	18.2
IX	Diseases of the circulatory system	14.4
XVIII	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	14.3
XIV	Diseases of the genitourinary system	11.0
XXI	Factors influencing health status and contact with health services	10.9
IV	Endocrine, nutritional and metabolic disorders	10.5
XIII	Diseases of the musculoskeletal system and connective tissue	10.0
X	Diseases of the respiratory system	9.8
XV	Pregnancy, childbirth and the puerperium	7.0
VI	Diseases of the nervous system	6.7
XI	Disease of the digestive system	6.6
XIX	Injury, poisoning and certain other consequences of external causes	6.6
VII	Diseases of the eye and adnexa	2.9

Figure 5.5 ICD-10 disease category-specific AE screening positive rate (ranked) (N=196)



Patients admitted for infectious and parasitic diseases had the highest chance to be screened as positive, 45.5%, followed by patients with neoplasms, 24.5%. Patients of the two categories comprised 6.1% of sample cases; nevertheless, they accounted for 15.4% of AE screening positive cases. Patients who were diagnosed with blood and blood-forming organ diseases and immune system disorders were also at high risk of being screened positive (18.2%). In addition, 14.4% of patients admitted for circulatory system disease were screened as positive.

5.3.1.7 Clinical departments

The 1,847 patient records were selected from 47 clinical departments in the two hospitals. The names of departments were merged in each hospital and between hospitals. For example, there were three orthopedics departments in Hospital A and two in Hospital B (Table 5.14), which are merged together as one department in Table 5.15.

In Hospital A, Gynecology & Obstetrics (G&O) were separate departments, while it was combined as one department in Hospital B. Hence, G&O was combined together during data analysis. Hospital A had several departments, which hospital B did not have, such as hematology and rheumatology. Those kinds of departments are listed as separate ones in Table 5.15. After consolidation, the number of departments was reduced to 21.

For clear understanding, the 21 departments were re-grouped into four categories: surgical departments, medical (non-surgical) departments, G&O, and others (Table 5.15). Medical records selected from surgical and medical departments composed over 80% of the sample. Another 16.5% of the sample was selected from G&O. Emergency and ICU, and general wards accounted for only a small proportion of the sample (1.9%).

Half of the screening positive records were from medical departments, which contributed to the biggest proportion (Table 5.15). The other screening positive cases consisted of 32.7% from

surgical departments, 11.7% from G&O, and 4.6% from others.

However, the composition of screening positive case does not necessarily reflect the risk of being screened as positive across wards, because of the different proportions of bed allocations and admissions in the two hospitals. Therefore, the screening positive rate needed to be evaluated.

In regard to the screening positive rate, from a category perspective, the "Others" category (including emergency, ICU and general ward) had the lowest rate in both proportion of sample and proportion of screening positive, while it had the highest screening positive rate (24.3%). In contrast, 13.6% of the records from medical departments were screened as positive, although they had more records in the screening positive pool than other categories. The screening positive rate was 7.6% in G&O, which was the lowest category across the five (Figure 5.6). On the other hand, from an individual clinical department perspective, the top five clinical departments ranked by screening positive rate were: ICU (41.7%), general ward (25.0%), hematology (21.6%), oncology (21.1%) and neuro-surgery (17.2%).

In order to assess the significance of the categories of departments and screening positive rate, a chi-square test was performed, and the result of the Pearson chi-square = 21.715, p <0.001. Hence, the **AE screening positive rates between surgical departments, medical departments, G&O and others are statistically significant.** Medical records from emergency, ICU and general wards had the highest risk to be screened as positive, followed by medical departments and surgical departments, while G&O had the lowest risk.

Table 5.14 AE screening positive cases and clinical department-specific AE screening positive rate (N=1,847)

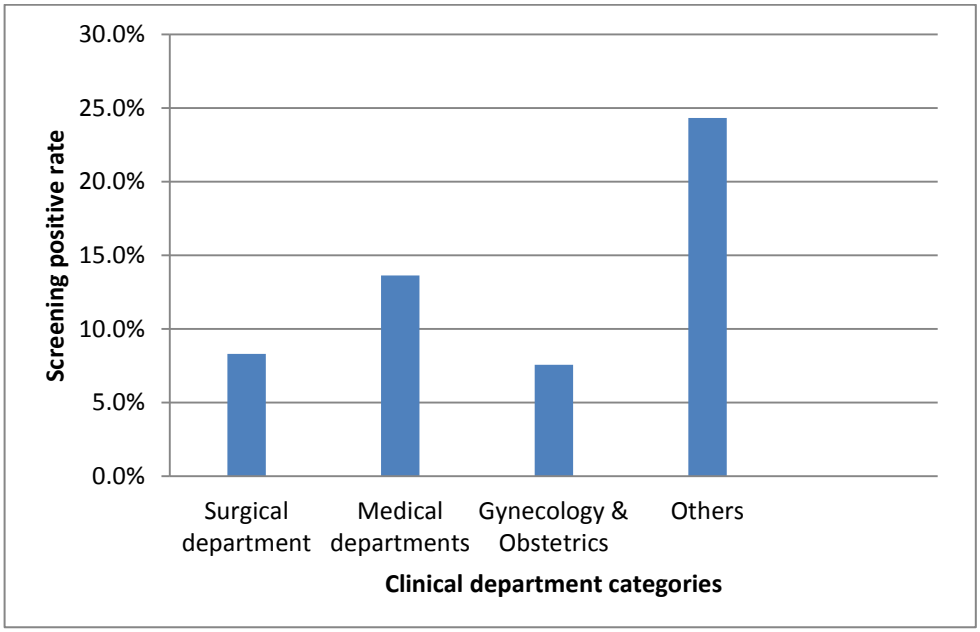
Hospital	Name of ward	# of sample	proportion of sample (%)	screening positive N=196	proportion of screening positive (%)	screening positive rate (%)
Hospital A	Cardiac medicine 1	63	3.4	14	7.1	22.2
	Cardiac medicine 2	44	2.4	5	2.6	11.4
	Respiratory	47	2.5	11	5.6	23.4
	Hematology	97	5.3	21	10.7	21.6
	General surgery 1	69	3.7	6	3.1	8.7
	General surgery 2	70	3.8	6	3.1	8.6
	General surgery 3	36	1.9	0	0.0	0.0
	Orthopedics 1	60	3.2	6	3.1	10.0
	Orthopedics 2	59	3.2	4	2.0	6.8
	Orthopedics 3	38	2.1	0	0.0	0.0
	Urology	38	2.1	3	1.5	7.9
	Prenatal	66	3.6	1	0.5	1.5
	Postnatal	90	4.9	11	5.6	12.2
	Delivery suite	1	0.1	0	0.0	0.0
	Neuro-medicine 1	49	2.7	1	0.5	2.0
	Neuro-medicine 2	52	2.8	2	1.0	3.8
	Neuro-medicine ICU 1	17	0.9	3	1.5	17.6
	Neuro-medine ICU 2	20	1.1	6	3.1	30.0
	Ophthalmology	35	1.9	2	1.0	5.7
	Stomatology	11	0.6	0	0.0	0.0
	E.N.T.	24	1.3	0	0.0	0.0
	Neuro-surgery	31	1.7	8	4.1	25.8
	ICU	8	0.4	2	1.0	25.0
	Emergency	21	1.1	3	1.5	14.3
	Cardiac surgery	17	0.9	0	0.0	0.0
	Gastroenterology	44	2.4	3	1.5	6.8
	Thoracic surgery	21	1.1	2	1.0	9.5
	Rheumatology	15	0.8	2	1.0	13.3
	Gynecology	53	2.9	2	1.0	3.8
	Endocrinology	34	1.8	3	1.5	8.8
	General ward	4	0.2	1	0.5	25.0
Hospital B	Endocrinology	27	1.5	3	1.5	11.1
	Cardiac medicine 1	53	2.9	10	5.1	18.9
	Cardiac medicine 2	60	3.2	4	2.0	6.7
	Respiratory	53	2.9	4	2.0	7.5
	Urology	30	1.6	6	3.1	20.0
	Neuro-surgery	33	1.8	3	1.5	9.1
	Neuro-medicine	59	3.2	8	4.1	13.6
	General surgery	47	2.5	6	3.1	12.8

Hospital	Name of ward	# of sample	proportion of sample (%)	screening positive N=196	proportion of screening positive (%)	screening positive rate (%)
Hospital B	Orthopedics 1	45	2.4	0	0.0	0.0
	Orthopedics 2	56	3.0	4	2.0	7.1
	Oncology	38	2.1	8	4.1	21.1
	Gynecology and Obstetrics	94	5.1	9	4.6	9.6
	Ophthalmology	5	0.3	0	0.0	0.0
	E.N.T.	6	0.3	0	0.0	0.0
	Stomatology	3	0.2	0	0.0	0.0
	ICU	4	0.2	3	1.5	75.0
	Total	1,847	100.0	196	100.0	10.6

Table 5.15 AE screening positive cases and clinical department category-specific AE screening positive rate (regrouped) (N=1,847)

Category	Name of ward	Sample N=1,847	Proportion of sample	Screening positive N=196	Proportion of screening positive (%)	Screening positive rate(%)
Surgical	Orthopedics	258	14.0	14	7.1	5.4
	General surgery	222	12.0	18	9.2	8.1
	Urology	68	3.7	9	4.6	13.2
	Neuro-surgery	64	3.5	11	5.6	17.2
	Oncology	38	2.1	8	4.1	21.1
	Thoracic surgery	21	1.1	2	1.0	9.5
	Cardiac surgery	17	0.9	0	0.0	0.0
	Ophthalmology	40	2.2	2	1.0	5.0
	E.N.T.	30	1.6	0	0.0	0.0
	Stomatology	14	0.8	0	0.0	0.0
	Subtotal	**772**	**41.8**	**64**	**32.7**	**8.3**
Medical	Cardiac medicine	220	11.9	33	16.8	15.0
	Neuro-medicine	197	10.7	20	10.2	10.2
	Respiratory	100	5.4	15	7.7	15.0
	Hematology	97	5.3	21	10.7	21.6
	Endocrinology	61	3.3	6	3.1	9.8
	Gastroenterology	44	2.4	3	1.5	6.8
	Rheumatology	15	0.8	2	1.0	13.3
	Subtotal	**734**	**39.7**	**100**	**51.0**	**13.6**
G&O	Gynecology & Obstetrics	304	16.5	23	11.7	7.6
	Subtotal	**304**	**16.5**	**23**	**11.7**	**7.6**
Others	Emergency	21	1.1	3	1.5	14.3
	ICU	12	0.6	5	2.6	41.7
	General ward	4	0.3	1	0.5	25.0
	Subtotal	**37**	**2.0**	**9**	**4.6**	**24.3**
Total		1,847	100.0	196	100.0	10.6

Figure 5.6 Clinical department category-specific AE screening positive rate (N=196)



5.3.1.8 Satisfied criteria

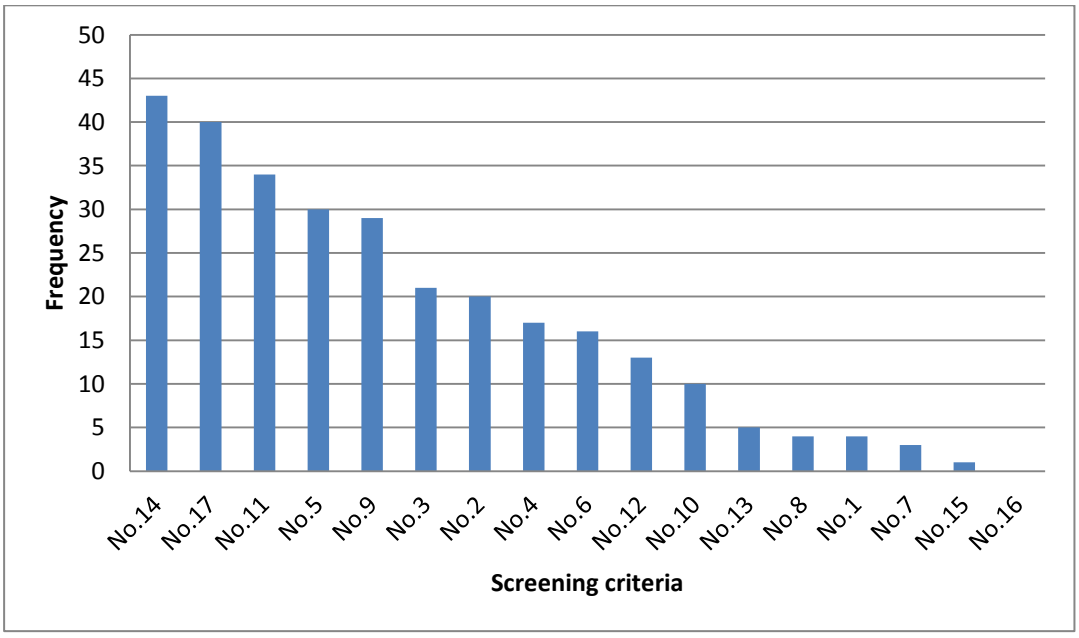
To be screened as a positive case, the medical record needed to satisfy at least one of the 17 screening criteria in the screening process. It was also possible that a case satisfied more than one criterion in the screening process. Therefore, the data provided in this section is by both frequency of selection of each criterion and number of medical records.

In total, the 17 criteria were selected 290 times in the 196 screening positive cases. The most frequently selected criterion was "No. 14 Hospital-acquired infection/sepsis" (43 times), followed by "No. 17 Any other undesirable outcomes not covered above" (40 times) and "No. 11 Unexpected death" (34 times) (Table 5.16 and Figure 5.7). On the other hand, some criteria had less chance to be selected in the screening process, such as "No. 1 Unplanned readmission in 7 days after discharge from index admission" (4 times). "No. 7 Unplanned return to the operating theatre" (3 times) and "No.15 Dissatisfaction with care documented in the medical record" (1 time). "No. 16 Documentation or correspondence indicating litigation" was not selected at all in this study.

Table 5.16 Number of satisfied AE screening criteria in AE screening positive cases (N=196)

	Criteria for screening positive	Frequency #	Proportion of positive %
1	Unplanned readmission in 7 days after discharge from index admission	4	1.4
2	Unplanned readmission in 28 days after discharge from index admission	20	6.9
3	Hospital-incurred patient injury	21	7.2
4	Adverse drug reaction	17	5.9
5	Unplanned transfer from general care to intensive care or transfer from one ward to another	30	10.3
6	Unplanned transfer to another acute care hospital	16	5.5
7	Unplanned return to the operating theatre	3	1.0
8	Unplanned removal, injury or repair of organ during surgery	4	1.4
9	Other patient complications (AMI, CVA, EE, etc.)	29	10.0
10	Development of neurological deficit not present on admission	10	3.4
11	Unexpected death	34	11.7
12	Cardiac/respiratory arrest, low Apgar score	13	4.5
13	Injury related to abortion or delivery	5	1.7
14	Hospital-acquired infection/sepsis	43	14.8
15	Dissatisfaction with care documented in the medical record	1	0.3
16	Documentation or correspondence indicating litigation	0	0.0
17	Any other undesirable outcomes not covered above	40	13.8
	Total	290	100.0

Figure 5.7 Frequency of satisfied AE screening criteria in AE screening positive cases (ranked) (N=196)



In 196 screening positive cases, 71.9% of cases (141 records) were found satisfied only one criterion. The proportion of screening positive cases with two, three, four, five and six criteria were 15.3%, 7.7%, 3.6%, 1.0% and 0.5% (Table 5.17).

Table 5.17 AE screening positive cases with number of satisfied AE screening criteria (N=196)

Number of positive criteria	Number of positive case	Proportion (%)
1	141	71.9
2	30	15.3
3	15	7.7
4	7	3.6
5	2	1.0
6	1	0.5
Total	196	100.0

Table 5.18 illustrates the frequency of selection of each criterion in single selected cases and multiple selected cases. In single selected cases (N=141), the most frequently selected criteria were “No. 14 Hospital –acquired infection/sepsis” (24 cases), followed by “No. 17 Any other undesirable outcomes not covered above” (20 cases), “No. 11 Unexpected death” and “No. 2 Unplanned readmission in 28 days after discharge from index admission” (17 cases).

Fifty-five screening positive records had more than one screening criteria were found satisfied, and were named as multiple selected cases. The most common co-positive criteria were “No. 9 Other patient complications (AMI, CVA, EE, etc)” (23 cases), followed by “No. 17 Any other undesirable outcomes not covered above” (20 cases) and “No. 14 Hospital–acquired infection/sepsis” (19 cases).

.

Table 5.18 AE screening criterion-specific AE screening positive cases (N=196)

	Number of positive criteria	Number of positive case	Criteria																	AE case	Review positive rate
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17		
Single selected	1	141	2	17	11	8	16	13	0	3	6	3	17	0	1	24	0	0	20	12	8.51%
Multiple selected	2	30	0	2	2	7	5	1	0	0	9	4	6	4	3	8	1	0	8	4	
	3	15	1	0	2	0	3	2	1	0	7	1	7	6	0	4	0	0	11	0	
	4	7	1	1	5	2	3	0	1	1	4	1	2	1	1	4	0	0	1	3	
	5	2	0	0	0	0	2	0	0	0	2	1	2	1	0	2	0	0	0	0	14.55%
	6	1	0	0	1	0	1	0	1	0	1	0	0	1	0	1	0	0	0	1	
	Subtotal	55	2	3	10	9	14	3	3	1	23	7	17	13	4	19	1	0	20	8	
Total	Total	196	4	20	21	17	30	16	3	4	29	10	34	13	5	43	1	0	40	20	10.20%

5.3.2 The factors associated with screening positive

To evaluate the impact of a number of factors on the likelihood that a medical record would be screened as positive in the screening process, direct logistic regression was conducted. Six independent variables were included in this model (age, gender, LOS, types of admissions, insurance status and categories of departments) (Table 5.19). **Age** (p<0.01), **LOS** (p<0.001), **patients from medical departments** (p<0.01) and **patients from emergency, ICU or general wards** (p<0.05) were statistically significant contributors to the model. Gender, types of admissions and insurance status did not have significant differences (Table 5.20).

Table 5.19 Variables coding for logistic regression analysis in AE screening process

Variables	Coding			
	0	1	2	3
Age	18-64	65 and over	-	-
Gender	Male	Female	-	-
Types of admission	Elective	Emergency and urgent	-	-
Insurance status	Uninsured	Insured	-	-
Categories of departments	Surgical departments	Medical departments	G&O department	Others
LOS	Continuous variable			

Table 5.20 Logistic regression results of factors associated with AE screening positive cases

Variables	B	S.E.	Wald	df	Sig.	Exp(B)
Age	.452	.171	6.958	1	.008	1.571
Gender	.045	.167	.072	1	.789	1.046
LOS	.039	.007	30.629	1	.000	1.040
Types of admissions	.004	.160	.001	1	.982	1.004
Insurance status	.219	.186	1.389	1	.239	1.245
Categories of departments			15.889	3	.001	
Medical departments	.537	.183	8.661	1	.003	1.711
G&O	.362	.294	1.521	1	.217	1.437
Others (emergency, ICU, general ward)	1.396	.420	11.065	1	.001	4.040
Constant	-3.266	.261	156.276	1	.000	.038

Compared with patients aged between 18-64 years old, patients who were 65 years and older were more likely to be screened as positive cases with OR=1.57. In addition, LOS also had a significant contribution to the model with OR=1.04, which illustrates that patients with longer stays in hospital face more risk. Furthermore, patients from medical departments and others departments (emergency, ICU and general ward) were more likely to be screened as positive compared with patients from the surgical wards (OR=1.71 and OR=4.04, respectively).

The strongest predictor of screening a medical record as positive was if the patient was admitted in the emergency, ICU or general wards. Compared with records from surgical departments, records selected from emergency, ICU and general wards were four times more likely to be screened as positive. In addition, patients from medical departments were also more likely to be screened as positive. Another predictor was patient's age. The risk for older patients to be screened as positive increased by 50%. Last but not least, LOS was an important predictor in this model, with an odds ratio of 1.04, which indicates that each extra day patients stayed in hospital increases by 4% the risk of being screened positive.

5.3.3 Reliability in screening process

An assessment of reliability in the screening process was conducted. In total, 83 medical records were randomly selected from the two hospitals with 41 records screened as negative and 42 records as positive, initially. Those medical records were screened again by another nurse, who was randomly picked up by the research-in-charge of each hospital. The Kappa value was measured. The interpretation of the Kappa coefficient was based on the work of Landis and Koch (1977): 0 = poor, 0.01 to 0.20 = slight, 0.21 to 0.40 = fair, 0.41 to 0.60 = moderate, 0.61 to 0.80 = substantial, and 0.81 to 1.00 = almost perfect.

In general, 41 medical records were screened as negative the first time, and 4 of them were judged as positive by another nurse. When 42 screened positive records were screened again, only 73.8% (31 records) were considered positive records (Table 5.21). Based on these data, the reported Kappa value was 0.64, with a significance of $p < .0005$, which represents substantial agreement between nurses.

Table 5.21 Inter-rater reliability result of AE screening process

		Second AE screening		
		Negative	Positive	**Total**
First AE screening	Negative	37	4	41
	Positive	11	31	42
Total		48	35	83

5.4 Analysis of review process

Twenty medical records were identified with 22 AEs by doctors. Eighteen records (90%) had only one AE and the other 2 records each contained 2 AEs. Therefore, the prevalence of reviewed positive rate (AEs) was **1.14% (0.69%-1.68%, 95% CI)**.

The total patients with AEs reduced to 12, if a causation score of at least 4 as threshold was applied. In these 12 medical records, only 12 events were identified. In other words, only one AE was found in each medical record. Consequently, the prevalence of AEs reduced to **0.7% (0.36%-1.15%, 95% CI).**

In this section, features of AEs cases are analysed first by using univariate analysis, which is similar to the previous analysis for the screening results. Secondly, characteristics of AEs are discussed on the basis of their nature, type, consequence, and preventability. Finally, the impact of factors on the likelihood of occurrence of AEs is investigated. In addition, the relationship between selected particular screening criteria and later confirmation as an AE case is investigated.

5.4.1 Features of review positive cases

In this section, the variables of age, gender, type of payment, LOS, type of admission, disease distribution and admitted departments of patients who had AEs are analysed individually in order to explore the relationship between each single variable and the occurrence of AEs. The socio-demographic and other factors of the 20 patients with AEs are listed below (Table 5.22). All the 20 patients were discharged from hospitals, and there was no death case. The general description of each AE would be summarised later in preventability section.

Table 5.22 List of socio-demographics and other factors of patients with AEs

No.	age	gender	Insurance	Department	ICD code	Length of stay	Admission type	Information score
1	50	M	Other	General surgery	K82.0	20	Emergency	4
2	64	M	Other	General surgery	C24.1	43	Elective	5
3	60	F	OOP	General surgery	D13.5	8	Elective	4
4	73	M	OOP	General surgery	C18.7	23	Transfer	4
5	33	F	BMI	Urology	N20.1	13	Elective	5
6	58	M	BMI	Urology	N41.9	16	Elective	5
7	56	M	OOP	Urology	N13.1	11	Emergency	4
8	80	M	BMI	Orthopaedics	S72.1	34	Emergency	4
9	57	F	OOP	Orthopaedics	S82.1	48	Emergency	4
10	74	F	Other	Orthopaedics	S72.1	12	Emergency	4
11	56	M	Other	Neuro-surgery	S06.9	37	Emergency	4
12	79	M	Other	Neuro-surgery	I61.4	55	Emergency	5
13	32	M	OOP	Neuro-surgery	S06.4	50	Transfer	4
14	25	F	BMI	G&O	O42.9	11	Elective	4
15	65	F	Other	Neuro-medicine	G45.0	22	Emergency	4
16	47	F	Unknown	Neuro-medicine	I63.9	25	Elective	4
17	70	M	GHI	Neuro-medicien	I63.9	7	Elective	5
18	63	M	GHI	Cardiac medicine	I21.0	11	Emergency	4
19	52	F	GHI	Respiratory	J45.9	16	Emergency	4
20	56	M	Other	Hematology	Z51.1	18	Elective	4

5.4.1.1 Age

The range of age of patients who had AEs (review positive) was 25 to 80 years, with an average 57.5 years (Table 5.23). Almost 40% of AE cases happened in the 55-64 age group, and no AE case was identified for patients under 25 years old, between 35-44 years old and over 85 years old (Table 5.24). In order to investigate the effect of age on AE occurrence, those patients with AEs were regrouped into two age groups: under 65, and 65 and over. Fourteen

patients fell in the under 65 years old age group, and the other 6 patients were 65 years old and over. A chi-square test indicated no significant association between age and AE status (Pearson chi-square = .000, p =1.000). Therefore, increase in age does not increase the risk of patients suffering AEs.

Table 5.23 The comparison of average age, by AE screening result and AE review result

	Sample	Screening negative	Screening positive	Review negative	Review positive
Average age (years)	52.1	51.4	58.1	52.1	57.5

Table 5.24 AE review positive cases by age-specific (N=20)

Age group (years)	# Sample	Proportion of sample (%)	# Screening positive	Proportion of positive (%)	Screening positive rate (%)	AE case	Proportion of AE (%)
<25	169	9.1	8	4.1	4.7	0	0
25-	253	13.7	19	9.7	7.5	3	15.0
35-	236	12.8	17	8.7	7.2	0	0
45-	309	16.7	30	15.3	9.7	3	15.0
55-	316	17.1	38	19.4	12.0	8	40.0
65-	313	16.9	46	23.5	14.7	4	20.0
75-	206	11.2	32	16.3	15.5	2	10.0
85-	45	2.4	6	3.1	13.3	0	0
Total	1,847	100.0	196	100.0	10.6	20	100.0

5.4.1.2 Gender

Among the 20 patients with AEs, there were 12 male patients and 8 female patients. A chi-square test indicated no significant association between gender and AE occurrence (Pearson chi-square = 0.678, p = 0.41).

5.4.1.3 Type of payment

Seven patients had some kind of insurance in the "others" category. Five patients were OOP patients. Four patients were covered by the BMI and three patients by the GHI. In addition, one medical record did not specify the type of insurance. For statistical purposes, the type of payment was re-grouped into patients with insurance (BMI, GHI and Others) and patients without insurance (OOPs). A chi-square test for type of payment found no significant association between AE appearance and having insurance coverage or not (Pearson chi-square = 0.003, $p = 0.96$).

5.4.1.4 Length of stay

The LOS for patients suffering AEs ranged from 7 days to 55 days (Table 5.25 and Table 5.26), and they had about 14 days longer stays (average 24 days) in hospital than those without AEs (average 10.3 days). An independent t-test was performed, t = 4.043, $p < 0.01$. The results indicate that **patients with AEs have statistically significantly longer stays in hospital than patients without AEs.** In other words, patients who have longer hospital stays are more likely to have AEs.

Table 5.25 The comparison of average length of stay between patients with AEs and without AEs (N=1,847)

Patients	# case	ALOS (day)	95% CI (day)	Median (day)	SD	Minimum (day)	Maximum (day)
With AEs	20	24.0	16.9-31.1	19.0	15.124	7	55
Others	1,827	10.3	9.9-10.7	8.0	8.487	1	111
Total	1,847	10.5	10.1-10.9	8.0	8.695	1	111

Table 5.26 The comparison of average length of stay, by AE screening result and AE review result

Study process	Process results	N	Length of stay (day)
Sample total		1,847	9.7
Screening process	Screening negative	1,651	10.0
	Screening positive	196	14.0
Review process	Review negative	176	12.9
	Review positive	20	24.0

5.4.1.5 Type of admission

Ten patients were admitted as emergency or urgent cases, and eight were elective patients. The other two patients were transferred from other hospitals. No AEs were found in the patients who were readmitted to hospital. In order to determine the difference between different types of admission associated with AE status, the 20 patients with AEs were regrouped into emergency and urgent admission (11 cases) and elective admission (9 cases). A chi-square test indicated no significant association between type of admission and AE status (Pearson chi-square = 0.083, $p = 0.773$).

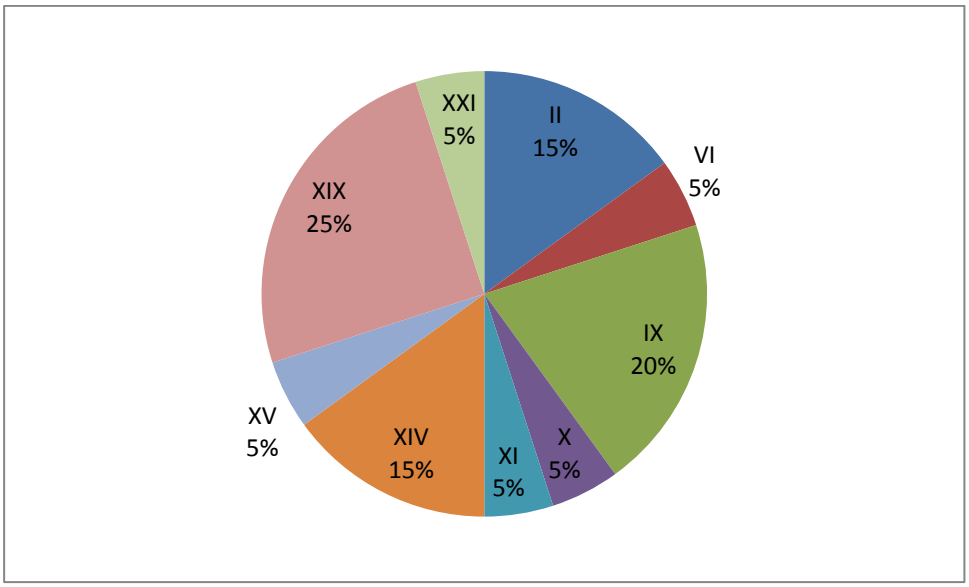
5.4.1.6 Principal diagnosis and clinical departments

The 20 AE cases included 9 categories of disease. Three quarters of AEs were from injury, poisoning and certain other consequences of external causes (25%), circulatory system diseases (20%), neoplasms (15%) and genito-urinary system diseases (15%) (Table 5.27 and Figure 5.8).

Table 5.27 AE review positive cases by disease category-specified (N=20)

ICD-10 category	# of sample	AE cases	Proportion of AEs (%)	Review positive rate (%)
II	102	3	15.0	2.9
VI	45	1	5.0	2.2
IX	430	4	20.0	0.9
X	123	1	5.0	0.8
XI	229	1	5.0	0.4
XIV	100	3	15.0	3.0
XV	229	1	5.0	0.4
XIX	286	5	25.0	1.7
XXI	129	1	5.0	0.8
Total	1,847	20	100.0	1.2

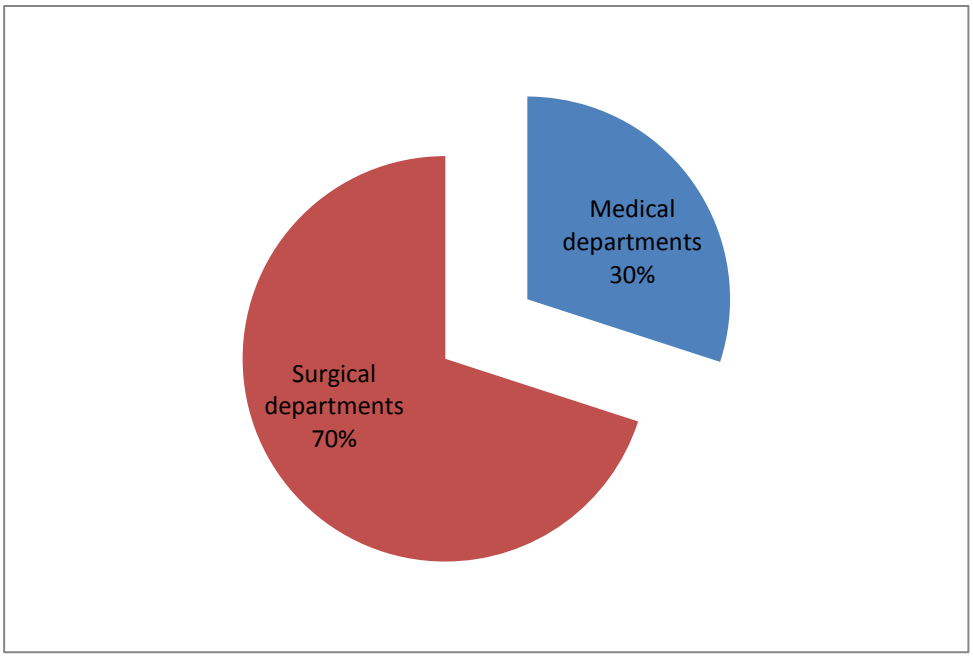
Figure 5.8 AE review positive cases by disease category-specified (N=20)



Among 20 patients with AEs, most were from surgical departments (13 cases), which included five patients from general surgery, three from urology, three from orthopaedics, and three from neurosurgery. Six cases were identified in medical departments. Neurology had three AEs. In cardiology, respiratory and haematology, one AE case was found in each department. In addition, one case was identified from O&G. For the purposes of statistical analysis, the case from O&G was merged into the category of surgical departments. After re-grouping, there were 14 cases from surgical departments and six from medical departments (Figure 5.9). A chi-

square test indicated no significant association between type of admission department and AE status (Pearson chi-square = 0.832, $p = 0.362$).

Figure 5.9 AE review positive cases by clinical department category-specified (N=20)



5.4.1.7 Satisfied criteria

In the 20 records with AEs, 17 screening criteria were selected 38 times in the screening process. The most common reasons to be screened as positive were "hospital-acquired infection/sepsis" (26.3%), followed by "unplanned transfer from general care to intensive care or transfer from one ward to another" (15.8%) and "other patient complication" (15.8%) (Table 5.28).

Twelve records had only one criterion selected in the screening process, and the other eight records had two or more criteria. To evaluate the association between single or multiple criterion/criteria selected and AE status, a chi-square test was performed, which suggested that in terms of AE status there was no significant difference between single-criterion cases and multiple-criteria cases (Pearson chi-square = 1.573, $p = 0.321$) .

Table 5.28 AE review positive cases with satisfied screening criteria in AE screening process (N=20)

	Criteria	# Positive	% Positive
1	Unplanned readmission in 7 days after discharge from index admission	0	0
2	Unplanned readmission in 28 days after discharge from index admission	1	2.6
3	Hospital-incurred patient injury	5	13.2
4	Adverse drug reaction	3	7.9
5	Unplanned transfer from general care to intensive care or transfer from one ward to another	6	15.8
6	Unplanned transfer to another acute care hospital	0	0
7	Unplanned return to the operating theatre	2	5.3
8	Unplanned removal, injury or repair of organ during surgery	2	5.3
9	Other patient complications (AMI, CVA, EE, etc.)	6	15.8
10	Development of neurological deficit not present on admission	0	0
11	Unexpected death	0	0
12	Cardiac/respiratory arrest, low Apgar score	1	2.6
13	Injury related to abortion or delivery	0	0
14	Hospital-acquired infection/sepsis	10	26.3
15	Dissatisfaction with care documented in the medical record	0	0
16	Documentation or correspondence indicating litigation	0	0
17	Any other undesirable outcomes not covered above	2	5.3
	Total	38	100.0

5.4.2 Characteristics of AEs

This section describes the characteristics of cases that reviewed positive (AEs), and the nature, consequence and classifications of AEs are discussed separately. It is necessary to point out that the judgements about consequence and preventability of AEs for the two medical records which contained more than one AE are based on the overall impact on patients and preventability, rather than based on each individual event.

5.4.2.1 The nature of AEs

AEs may be caused by either human error and/or system error. In this study, 14 out of 20 AE cases were considered due to human error by the doctor reviewers. Only one AE was recognised as deriving from a system error. The most common place for AEs to happen was in patients' wards (18 cases), one case happened at the patient's home, while another case occurred in the operating theatre. All AEs occurred and were detected during index admission, with the exception of one event which occurred before but was detected during index admission.

5.4.2.2 The consequences of AEs

In 18 out of 20 patients with AEs (90%), the hospital stay was prolonged by between 1 to 20 days. In total, 113 extra hospital days resulted from AEs. On average, the additional stay in hospital was 5.7 days (113 days/20 patients) per patient. Forty per cent of patients suffered temporary disability resulted from AEs. Surprisingly, no permanent disability or death caused by AEs was recommended by doctors.

If a causation score of 4 and greater was applied, over 90% of patients with AEs had prolonged hospital stays. The total additional stay in hospital was 51 days, an average of 4.25 days per patient (51 days/12 patients). Furthermore, one third of AEs (4 out of 12) resulted in temporary disability to patients.

5.4.2.3 The classification of AEs

The classification for each AE may be single or multiple. All 22 AEs identified in this study were classified into 7 classifications (Table 5.29). The surgical classification includes all AEs resulting from or related to surgery or surgical procedures. Different types of drugs or fluids are covered by drug-related, including oral tablets, intravenous therapy, and chemotherapy. Clinical management includes a wide range from nursing care to patient monitoring.

Diagnostic-related AEs includes wrong, missed or lacking diagnosis. Medical AEs relate to therapy, in particular non-invasive procedures. System-related AEs include AEs that cannot be classified in any other individual categories, such as communication errors and ward management. It is necessary to point out that eight AEs (36%) related to nosocomial infection were classified as both clinical management and system-related at the same time due to the nature of complicated causes for nosocomial infection. Therefore, about half of AEs were related to clinical management (35.5%) and the system (32.3%). Only three AEs were classified as surgical or diagnostic, respectively.

Table 5.29 The classification of AE review positive cases

Classification	# of AEs	Proportion %
(1) Surgical	3	9.7
(2) Drug	3	9.7
(3) Clinical management	11	35.5
(4) Diagnostic	2	6.5
(5) Medical	1	3.2
(6) System-related	10	32.3
(7) Anaesthesia-related	1	3.2
Total	31	100.0

5.4.2.4 The preventability of AEs

In this study, all the 22 AEs were judged as preventable AEs (PAEs) by doctors. Three were in the low preventability category (score from 2 to 3), while the other 17 AEs were highly preventable (score from 4 to 6) (Table 5.30). The prevalence of preventable AEs is **1.14% (0.69%-1.68%, 95% CI)**. In addition, the prevalence of highly preventable AEs in this study is **0.97% (0.56%-1.48%, 95% CI)**.

Table 5.30 List of preventability score and description of patients with preventable AEs (N=20)

	No.	Prevent-ability Score	AE description
Low preventability	1	2	Patient took out urine catheter by himself, which caused urethral injury (1st AE). Patient had cardiopulmonary insufficiency in ICU (2nd AE).
	2	2	Patient discharged from hospital against medical advice after the Extracorporeal shock wave lithotripsy for ureteral calculus. This patient returned to hospital for ureteroscopic lithotripsy and ploypectomy later.
	3	3	The patient was shivering for 30 minutes when the nurse flashed the venous catheter during chemotherapy. It was suspected that some bacteria or other pathogen were involved.
Highly preventability	4	4	Patient was prescribed to Aspirin and had gastric discomfort with a sudden drop of blood pressure (69/49 mmHg) after coronary angiogram.
	5	4	Patients had tibial and fibular fracture. After surgery, the patient had pulmonary infection due to long time rest in bed.
	6	4	Patient was admitted because of left hip fracture and developed pressure sore during hospital stay.
	7	4	Patient had upper respiratory tract infection after resection of right kidney.
	8	4	Patient had upper respiratory tract infection after Caesarean Section.
	9	4	Patient was admitted because of dizziness. During the hospital stay, patient had hospital-acquired infection-urinary tract infection.
	10	4	Patient had pulmonary infection caused by trachea cannula.
	11	4	Patient had electrolyte disturbance (1st AE) and urinary infection (2nd AE), caused by nasal feeding and indwelling urinary catheter.
	12	4	Patient was prolonged hospital stay due to missed and lack of diagnosis.
	13	4	Patient had urinary tract infection, which could be due to improperly clean after craniotomy.
	14	4	Patient had allergic symptoms (nausea and vomiting) during intravenous infusion, and was transferred to ICU for further treatment and monitor.
	15	5	Patient had 1000ml drainage after cholecystectomy caused by insufficient hemostasis, and returned to theatre for second operation.
	16	5	Patient had bleeding after surgery caused by insufficient hemostasis, and was transferred to ICU.
	17	5	After surgery, patient developed dyspnoea suddenly and coughed denture out when nurse slapped the patient's back. Because patient was not informed to remove denture before General Anaesthesia.
	18	5	Patient had nosocomial infection-upper respiratory tract infection.
	19	5	Patient had hospital acquired upper respiratory tract infection after surgery.
	20	6	The patient went back home during hospitalisation and developed upper respiratory tract infection after that.

5.4.3 The factors associated with review positive

5.4.3.1 Patients' characteristics and odds ratios for association with AEs

Direct logistic regression was performed to assess the impact of a number of factors on the likelihood that an AE would occur to a patient. The model contained 7 independent variables (age, gender, LOS, type of admission, insurance status, categories of departments, and death case) (Table 5.31). As shown in the table below (Table 5.32), only one of the independent variables, LOS, made a unique statistically significant contribution to the model, with an odds ratio of 1.06. This illustrates that longer stays in hospital increase the risk of AEs. In other words, patients staying in hospital for each extra day have 6% increased risk of suffering AEs. At the same time, LOS was the strongest predictor in judging if a medical record contained AEs.

Although older patients and insured patients are more likely to suffer AEs compared with young patients and uninsured patients, the differences are not obvious enough to be considered as predictors for this model. The odds ratio for patients from medical departments (0.68) was less than 1, indicating that medical record selected from medical departments were less likely to detect AEs than those from surgical departments, controlling for other factors in the model. In other words, the risk of surgical patients suffering AEs is 1.5 times than medical patients.

Table 5.31 Variables coding for logistic regression analysis in AE review process

Variables	Coding	
	0	1
Age	18-64	65 and over
Gender	Male	Female
Insurance status	Uninsured	Insured
Types of admission	Elective	Emergency and urgent
Death case	No	Yes
Categories of departments	Surgical departments (including G & O)	Medical departments
LOS	Continuous variable	

Table 5.32 Logistic regression results of factors associated with AE review positive cases

Variables	B	S.E.	Wald	df	Sig.	Exp(B)
Age	.134	.531	.064	1	.800	1.144
Gender	-.346	.479	.524	1	.469	.707
Insurance status	.216	.529	.167	1	.682	1.242
LOS	**.054**	**.012**	**21.741**	**1**	**.000**	**1.055**
Type of admission	-.162	.473	.117	1	.732	.850
Death case	-17.386	6701.643	.000	1	.998	.000
Categories of departments	-.389	.539	.522	1	.470	.678
Constant	-5.034	.667	56.944	1	.000	.007

5.4.3.2 Screening criteria and odds ratios for association with AEs

Direct logistic regression was performed to assess the impact of each screening criterion on the likelihood of identifying AEs (Table 5.33). It was noticeable that a few criteria had great standard errors (such as criterion 6, 10, 11, 12, 13, and 15), which could result from the low proportion of AE cases (around 1% of the sample).

Table 5.33 Logistic regression results of screening criteria associated with AE review positive cases

	B	S.E.	Wald	df	Sig.	Exp(B)
Criterion 1	-16.837	16379.743	.000	1	.999	.000
Criterion 2	1.164	1.537	.573	1	.449	3.201
Criterion 3	4.973	1.071	21.573	1	**.000**	**144.483**
Criterion 4	1.655	1.027	2.594	1	.107	5.231
Criterion 5	4.936	.946	27.211	1	**.000**	**139.182**
Criterion 6	-15.779	8683.310	.000	1	.999	.000
Criterion 7	-3.310	13.677	.059	1	.809	.037
Criterion 8	6.143	1.414	18.881	1	**.000**	**465.465**
Criterion 9	1.825	.958	3.624	1	.057	6.200
Criterion 10	-21.269	8394.418	.000	1	.998	.000
Criterion 11	-31.701	5842.821	.000	1	.996	.000
Criterion 12	9.851	4074.879	.000	1	.998	18973.851
Criterion 13	-24.221	13460.273	.000	1	.999	.000
Criterion 14	5.239	.858	37.249	1	**.000**	**188.440**
Criterion 15	-13.667	40192.970	.000	1	1.000	.000
Criterion 17	-.703	1.197	.345	1	.557	.495
Constant	-6.832	.713	91.903	1	.000	.001

Four criteria had a unique statistically significant contribution to the model, p <0.001 (Criterion numbers 3, 5, 8 and 14). Criterion 8 “Unplanned removal, injury or repair of organ during surgery” was a strong predictor with the odds ratio of 465.47, followed by criterion 14 “Injury

related to abortion or delivery" (OR = 188.44), Criterion 3 "Hospital-inquired patient injury" (OR = 144.48) and Criterion 5 "Unplanned transfer from general care to intensive care" (OR = 139.18).

Several predictors of this model were identified through logistic regression. The strongest one was Criterion 12 "Cardiac/respiratory arrest, low Apgar score" (OR=18974). When a record was screened positive due to or partly due to this criterion, the risk of this record being judged as an AE case increased dramatically. Other predictors included Criterion numbers 8, 14, 3, and 5, which have been analysed before. In addition, Criterion 9 "Other patient complications", Criterion 4 "Adverse drug reaction", and Criterion 2 "Unplanned readmission in 28 days" all had odds ratios of more than 1. However, compared with other predictors, they had a less strong effect on this model.

5.5 Summary

This chapter represented results from two principal outcomes measures: screening process and review process. The major findings in relations to each process were generated through two parts. In the first part, univariate analysis was performed for age, gender, type of payment, LOS, type of admission, disease, department and selected criteria. In addition, considering confounding, a logistic regression was conducted to investigate the impact on patients' characteristics on the likelihood to be screened / reviewed as positive. And more analysis about characteristics of AEs was conducted in review process session.

In the screening process, 10.6% medical records were screened as positive by nurses. There were risk factors found associated with screening positive by univariate analysis. The risk factors included:

- Older patients (age ≥65).
- Patients entitled with some kind of health insurances.
- Longer hospital stays (suspicious if more than 14 days, highly suspicious if more than 24 days).
- Patients admitted for the reasons of "certain infectious and parasitic diseases", "neoplasms" and "diseases of blood and blood-forming organs and certain disorders involving the immune mechanism".
- Patients admitted to "others" departments (including emergency, ICU and general ward) and "medical" departments (including cardiac medicine, neuro-medicine, respiratory, hematology, endocrinology, gastroenterology and rheumatology).

The logistic regression suggested that older patients, longer hospital stay, patients from medical departments and patients from emergency, ICU or general wards were statistically significant to associate with to be screened as positive.

In the review process, 22 AEs were identified by doctors in 20 medical records. And the prevalence of AEs was 1.14% (0.69%-1.68%, 95% CI). There was only one risk factor, longer hospital stays, were identified associated with occurrence of AEs via univariate analysis. Eighteen out of the 20 patients who had AEs during their hospital stays were prolonged hospital stay with an average of 5.7 days. Forty percent of patients suffered temporary disability due to AEs. In regards to preventability, all AEs were considered preventable and 85% of them were highly preventable. In order to investigate the impact of a number of factors on the likelihood that an AE would occur to a patient, a direct logistic regression was performed. There was only one factor, LOS, made an only statistically significant contribution to the model. In another logistic regression, 4 screening criteria illustrated the statistically significant contribution on the likelihood of identifying AEs. These three criteria were:

- Unplanned removal, injury or repair of organ during surgery
- Injury related to abortion or delivery
- Hospital-inquired patient injury
- Unplanned transfer from general care to intensive care.

CHAPTER SIX: DISCUSSION

This thesis aims to investigate the AEs in Chinese hospitals from a hospital-wide level. A systematic review to literature in the past 7 years has been conducted. And there was no such study has been identified in China. In order to determine the prevalence, preventability and consequence of AEs in Chinese hospitals, a two-step medical record audit study was carried out, which also provides the basis for an international comparison. This chapter begins with a report of the principal findings of this thesis, followed by an international comparison about the prevalence, and characteristics of AEs. A discussion of factors influencing reviewers' clinical decision-making processes and the quality of medical records in China will contribute to a better interpretation and understanding of the results.

6.1 Principal findings

The systematic review in this thesis included 7 studies; four developed countries and three developing countries. The reported prevalence of AEs varied from 6.1% to 12.3%. In addition, studies conducted in developing countries reported a lower prevalence of AEs than studies in developed countries, and a higher proportion of AEs was considered preventable occurred in developing countries than in developed countries. Furthermore, a serious research gap was identified by the systematic review that there are no studies to investigate the AEs from a hospital-wide perspective in China.

This medical record audit study was conducted to find out the prevalence, consequence, and preventability of AEs in Chinese hospitals. In total, 1,847 medical records were screened by trained nurses according to 17 explicit screening criteria. 10.6% of them (196 records) were screened as positive, and contained potential AEs which required further review by doctors. The risk factors "red flags" for patients having potential AEs (screened as positive) included:

- Older patients (age ≥65).
- Patients who are insured.

- Longer hospital stays (suspicious if more than 14 days, highly suspicious if more than 24 days).
- Patients admitted for the reasons of "certain infectious and parasitic diseases", "neoplasms" and "diseases of blood and blood-forming organs and certain disorders involving the immune mechanism".
- Patients admitted to departments of cardiac medicine, neuro-medicine, respiratory, hematology, endocrinology, gastroenterology, rheumatology emergency, ICU and general ward.

In the review process, doctors reviewed 195 screening positive medical records, and 22 AEs were judged by doctors in 20 medical records. Therefore, the prevalence of AEs was **1.14% (0.69%-1.68%, 95% CI)** when a causation score of 2 (slight-to-modest evidence for management causation) and greater was applied. When a causation score of 4 (management causation more likely than not, more than 50 -50 but close call) and greater was used as the threshold, the prevalence of AEs reduced to **0.7% (0.36%-1.15%, 95% CI).**

All the identified AEs were considered preventable, and 18 AEs were considered highly preventable in 17 medical records. The prevalence of highly preventable AEs was 0.97% (0.56%-1.48%, 95% CI). Most of the AEs prolonged patients' hospital stays. On average, each patient with AE(s) had a prolonged hospital stay by 5.7 days. 40% of AEs caused temporary disabilities to patients. Unexpectedly, the reviewers did not identify any severe consequence caused by AEs, such as permanent disability or death.

The predictor for patients suffering AEs during hospital stay was

- Longer stay in hospital (suspicious if more than 24 days).

Several triggers were identified as associated with AE occurrence, and these were also considered risk factors, and should cause alarm in the clinical environment:

- Unplanned readmission in 28 days after discharge from index admission
- Hospital-incurred patient injury
- Adverse drug reaction
- Unplanned transfer from general care to intensive care or transfer from one ward to another
- Unplanned removal, injury or repair of organ during surgery
- Other patient complications (AMI, CVA, EE, etc.)
- Cardiac/respiratory arrest, low Apgar score
- Hospital-acquired infection/sepsis.

To extrapolate study results to the level of the two hospitals involved, the volume of admission of the two hospitals except paediatrics in 2009 (37,262) and the prevalence of AEs (1.14%) were taken into account. Overall, the total estimated number of AEs per year in the two hospitals was 424 events (37,262 x 1.14%). The number of patients who developed a temporary disability caused by AEs was 170 (424 x 40%) annually. In addition, 2,416.8 extra days (424 x 5.7 days) were required for patients to stay in hospital.

The cost of prolonged hospital stay due to AEs was also estimated. According to Hao and Ma (2011), ALOS in Chinese secondary hospital was 9.5 days with an average expense of 9508.27 CNY in 2010. Hence, the total expense of extra stay in the 2 hospitals caused by AEs could reach almost 2.5 million CNY per year, which is equivalent to 440,000 AUD.

Expense of prolonged stay caused by AE =

(Average expense per admission 9,508.27 Yuan/average length of stay 9.5 days) x

Total additional hospital stay due to AEs 2,416.8 days

= **2,418,904 Yuan**

6.2 International comparison

In order to understand and interpret the results of this thesis, it is necessary to compare the findings from this study with that in other countries. Seven studies with large-scale samples investigated the prevalence of AEs were discussed in Chapter 2 (Sari, Sheldon et al. 2007; Aranaz-Andrés, Aibar-Remón et al. 2008; Mendes, Martins et al. 2009; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). In addition, four studies from Thailand, Tunis, Jordan and Palestine were taken into account for further understanding of AEs in developing countries (Asavaroengchai, Sriratanaban et al. 2009; Hayajneh, AbuAlRub et al. 2010; Letaief, El Mhamdi et al. 2010; Najjar, Hamdan et al. 2013).

6.2.1 The prevalence of AEs and screening positive rates

Compared with previous literature, this study found a very low prevalence of AEs. In respect of study design, the Tunisian study (Letaief, El Mhamdi et al. 2010) adopted a traditional two-stage RMRR as this study. Although only 11.7% of medical records were screened as positive, around 85% of screened positive records were confirmed as AE cases. Therefore, the prevalence of AEs was 10.0% (Letaief, El Mhamdi et al. 2010). However, the Thai study and Palestinian study applied global trigger tools (GTT) to investigate AEs (Asavaroengchai, Sriratanaban et al. 2009; Najjar, Hamdan et al. 2013). According to the previous research, studies utilized GTT normally reported higher prevalence of AEs (Landrigan, Parry et al. 2010; Classen, Resar et al. 2011; Good, Saldaña et al. 2011). It was therefore not surprising that Thai study and Palestinian study reported higher prevalence (24% and 14%, respectively) compared with other studies which adopted RMRR. In addition, the Jordanian study interviewed nurses to gain a perceived 28% of frequency of AEs (Hayajneh, AbuAlRub et al. 2010).

The previous studies had indicated age of patients, length of stay in hospital and admitting in

surgical departments were all the predictors for patients to suffer AEs during their hospitalisations (Wilson, Runciman et al. 1995; Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). However, the only "red flag" was found in this study was longer hospital stay, especially longer than 24 days.

In terms of the screening process, in general, studies adopted RMRR in developed countries reported the screening positive rate is to be around 50%, such as Australia, Canada and the Netherlands (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004; Zegers, de Bruijne et al. 2009). While the literature review indicated that developing countries normally have lower screening positive rate, and in consequence may result to lower review positive rate (prevalence of AEs). It was expected that the proportion of screening positive records would be around 15% and the prevalence about 5% in the two hospitals in China. However, only 10.6% records were screened as positive in this study, and the prevalence of AEs in the two Chinese hospitals was only 0.7% (with a causation score of 4 as threshold, the same as other similar studies), which is the lowest of all studies.

Different from the previous similar studies, this study also explored the "red flags" for patients to be screened as positive, which included: older patients (age ≥65); patients who are insured; longer hospital stays (suspicious if more than 14 days, highly suspicious if more than 24 days); patients admitted for the reasons of "certain infectious and parasitic diseases", "neoplasms" and "diseases of blood and blood-forming organs and certain disorders involving the immune mechanism"; and patients admitted to departments of cardiac medicine, neuro-medicine, respiratory, hematology, endocrinology, gastroenterology, rheumatology emergency, ICU and general ward.

Surprisingly, there was no statistically significant association between type of admission (emergency VS. elective) and the AEs screening positive status, which could result from the

patients' emergency status and disease distributions in emergency departments in Chinese hospitals. The emergency department is supposed to provide medical service to patients with emergency situations only. However, emergency departments in Chinese hospitals provide medical service for both emergency patients and non-emergency patients. And 50% of patients received medical service in emergency departments were in fact non-emergency patients, and the most common reasons for them to come to emergency departments were colds, gastro and sore throat (Li and Gao 2006). In addition, about one thirds of patients who were admitted in the emergency wards were chronic diseases patients (Kang and J 2004; Li and Gao 2006). Therefore, not all patients admitted as emergency patients were actually in emergency situations, which could be a possible reason to explain this finding.

In regard to the screening criteria, developing countries normally adopt existing criteria lists from previous studies in developed countries with little modification. However, it is not clear if the existing criteria are suitable in different contexts. The reliability of this study in the screening test showed substantial agreement (0.64), which is similar to previously published results (0.53-0.70) (Mendes, Martins et al. 2009; Wilson, Michel et al. 2012).

6.2.2 The consequences and preventability of adverse events

In contrast with previous literature, this study found out the consequence caused by AEs was less severe and more proportion of AEs was preventable. Different from previous results in developing countries that AEs tend to have severe consequences (refer to Chapter 2 for details), this study found no permanent disability or death resulting from AEs. In addition, Chinese doctors suggested that all of the AEs found were preventable to some extent, and 87% were highly preventable (score rating of at least 4: preventability more likely than not, more than 50-50 but close call). In other studies, an AE would be classified as a PAE if the preventability score was 4 or above (Brennan, Leape et al. 1991; Baker, Norton et al. 2004; Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Letaief,

El Mhamdi et al. 2010). For comparison, only highly preventable AEs in this study are listed in Table 6.1 as PAEs. This may indicate that reviewers had confusing concepts of AEs (Wilson, Michel et al. 2012). Other factors may have influenced reviewers' decision-making processes, which will be discussed in detail in the following sections of this chapter.

6.2.3 The classifications of adverse events

It is difficult to compare classifications of AEs between studies, because different frameworks of classifications are applied in different studies. Each study selects the best framework of classification to fully represent their results. Generally, there is no description of how to classify AEs to each classification, which may have resulted in the same AEs being classified to different classifications in other studies even though the same framework was applied.

In the present study, the framework of classifications of AEs was adopted from Canadian studies (Baker, Norton et al. 2004). More AEs were classified as clinical management (11 AEs, 35.5%) and system-related (10AEs, 32.3%) than in other studies (Baker, Norton et al. 2004; Mendes, Martins et al. 2009). Eight out of 22 AEs were hospital-acquired infections. Because the Canadian classifications of AEs do not have nosocomial infection as an individual classification, these 8 AEs were classified as both clinical management and system-related at the same time in this study. The remaining three AEs classified to clinical management were insufficient patient monitoring (2 AEs) and pressure ulcers (1 AE). If the framework of classification from the UK project (Sari, Sheldon et al. 2007) was applied to this study, nosocomial infection and pressure ulcers would be listed as individual types, and the classifications of AEs for the present study would be very different.

In contrast, surgical-related AEs normally take the biggest proportion among all AEs in previous literature (Sari, Sheldon et al. 2007; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009; Letaief, El Mhamdi et al. 2010), but only three AEs (9.7%) were considered as this

type in this thesis. It may associate with structure of hospital inpatient service, such as different proportion of surgical and non-surgical admissions. For example, there were only one third of selected medical records from surgical departments in the Dutch study, but more than half of AEs were considered as surgical-related. While in the present medical record audit study, majority of records (57.3%) were selected from surgical departments. But there were only few AEs were surgical-related. Again, this does not necessarily mean there are fewer surgical-related AEs in China than in other countries. It may be simply due to different standards of classifications.

In conclusion, this study had the lowest screening positive rate and prevalence of AEs reported to date in both developed and developing countries. The inter-rater agreement between screening nurses was similar to previous studies (0.64 in this study, 0.50-0.73 in previous studies). No severe consequence due to AEs was identified, such as permanent disability or death, and most AE cases led to prolongation of hospital stay. This result may suggest the patients were not very sick and/or the quality of health care is better compared with the other countries. On the other hand, it may also indicate under-reporting in the screening and reviewing processes of this study, which is more conceivable and almost certainly explains the low screening positive rate and low prevalence. Therefore, the estimations of the total number, consequence and cost of AEs in the two Chinese hospitals could be under-estimated as well. The reasons contributed to the under-estimated results are discussed as followed.

Table 6.1 The comparison of major research findings between the present study and the previous studies in developing countries

Study	Sample size	Screen positive rate %	Screen positive/ Review positive %	Prevalence of AEs %	PAEs %	Temporary disability %	Permanent disability %	Death %
Mendes, Martins et al. (2009)	1,103	41.0	18.6	7.6	66.7	-	-	-
Letaief, El Mhamdi et al. (2010)	620	11.7	84.9	10.0	60.0	-	-	21
Aranaz-Andres, Aibar-Remon et al. (2011)	11,379	33.9	30.9	10.5	59.0	-	-	5.8
Wilson, Michel et al. (2012)	15,548	21.6	38.1	6.1	83.0	16	14	30
This study	1,847	10.6	6.1	0.7	85.0	33	0	0

6.3 Impact factors to the study results

In this medical record audit study, both the screening positive rate (10.6%) and review positive rate (1.14%) were much lower than previous reported rates by other studies. Although this study applied the most widely accepted methodology to investigate AEs, the results are highly likely to be under-estimated and do not fully reflect the actual situation. There are a few crucial factors may have impact on the underestimations, which can be understood from two important viewpoints. First, the quality of results in AE studies heavily relies on data collectors' decisions and performance. However, there are many different factors which influence the clinical decision-making (CDM) of nurses and doctors, sometimes positively way, while sometimes negatively. Second, the quality of medical records in China probably has impact on the results to some extent.

6.3.1 Factors influencing nurses' and doctors' clinical decision-making

The reviewers involved in the present AEs study could have a profound impact on the result. It is not the problem in China only, actually it has been highlighted by previous studies (Aranaz-Andrés, Aibar-Remón et al. 2008; Soop, Fryksmark et al. 2009; Wilson, Michel et al. 2012). Their knowledge of, perceptions of, and attitude towards AEs could potentially influence their decisions and judgements. Therefore, in this section, factors influencing nurses' and doctors' clinical decision-making (CDM) processes will be discussed.

6.3.1.1 Factors influencing nurses' CDM in screening process

The CDM for nurses in screening processes may be influenced by the nature of the explicit decision assistance. In addition, nursing education and their professional character may also have positive impact on their judgements.

6.3.1.1.1 Explicit decision aids

The 17 screening criteria listed in the RF1 were decision aids to nurses, which assisted nurses to make more reliable CDMs in the screening process. Decision aids provide a vital role on CDM. Goldberg (1970) claimed that 'models of the men are generally more valid than the men themselves'. Having a decision aid could increase the accurate of clinical decisions. Another study conducted by de Dombal (1988) also supports this opinion. In de Dombal's study, he found that clinical doctors with more experience could make more correct diagnoses. For example, senior clinicians could have 82% correct diagnosis of acute abdominal pain, while doctors with less experience could only make 71% correct decisions. However, with computer-aided systems, even junior doctors could make 91% correct diagnoses, even more accurate than experienced surgeons.

Using explicit criteria to review is like cooking guided by a cookbook. The 17 criteria were provided to the nurses before they start reviewing medical records. Nurses, under instruction of the criteria, paid specific attention to certain parts of the medical records. They considered each medical record is "guilty until proven to be innocent". For example, when nurses read the Criterion number 8 in RF1, 'Unplanned removal, injury or repair of organ during surgery', they will focus on the operation records, preoperative discussion record and consent form. If none of these factors is found, this particular medical record will be regarded as "innocent".

To some degree, using explicit criteria may result in "missing the forest for the trees" (Weingart, Davis et al. 2002). The problems identified through explicit review may only be limited to the listed specified criteria. Reviewers do not contribute personal opinions other than following the criteria, especially when dealing with complicated problems. Therefore, some kinds of elements could be missed if these elements are not identified by the explicit criteria (Lilford, Edwards et al. 2007). However, for utilisation as a screening tool, explicit criteria have advantages.

Explicit criteria are straightforward and strict (Brook, McGlynn et al. 1996). Decisions made based on explicit criteria are objective, consistent and reliable (Donabedian 1981). The inter-rater reliability is generally better for explicit reviews than implicit reviews (Lilford, Edwards et al. 2007). They are easy to apply, even for inexpert people (Donabedian 2003). A study conducted by Weingart, Davis et al. (2002) showed that nurses identified 45.7% of quality problems by using explicit criteria. In contrast, doctors did implicit reviews and found 2.1% of quality problems. Another study also indicated the significant difference between explicit review (63%) and implicit review (2%) in healthcare quality (Brook, McGlynn et al. 1996).

Therefore, a valid screening tool is necessary in the study of AEs to reflect the true situation and capture potential AEs. The screening tool used in this study was originally extracted from previous similar studies in Australia and Canada (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004). However, the 17 screening criteria in this study were not fully localised to the Chinese context, even after modifications, which may have had a direct influence on the results.

The most commonly identified five screening criteria in five studies are compared below (Table 6.2). “Unplanned admission before index admission” and “readmission after discharge from index admission” were the two leading reasons for medical records screened as positive in other studies, not only in developed countries but also in developing countries (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004; Mendes, Martins et al. 2009; Letaief, El Mhamdi et al. 2010). Around 40% of screening positive records were selected by these two criteria in an Australian study (Wilson, Runciman et al. 1995). The proportion of these two criteria was lower in Brazil (Mendes, Martins et al. 2009), but they still identified 20% of records as screening positive cases. However, “unplanned admission before index admission” was removed from screening criteria list in the present study based on discussion with experts, because it did not fully fit the Chinese context. Although there were two criteria related to

readmission in the Chinese study, they only accounted for around 8% of screening positive reasons.

The low rate of readmission criteria in the study may have reduced the number of records for the detection of AEs. In addition, the low rate also may reflect that this criterion does not fit the Chinese healthcare context very well. Patients' readmission data could be identified only if patients were admitted to the same hospital as the previous admission. If a patient was readmitted to a different hospital, this patient would be treated as a new patient for the hospital, because inpatient information is not shared between hospitals in China.

To take another criterion as an example, among 1,847 screened medical records, only one record documented patient dissatisfaction with care (Criterion 15), and none of the medical records had documentation or correspondence indicating litigation (Criterion 16 in this study). This does not mean that patients were highly satisfied with their healthcare, or that there is a low litigation rate in China compared with other countries. It could be caused by the regulation of Chinese medical records. In China, there is no requirement to write down patients' dissatisfaction or litigation issues in medical records. In 2010, the Ministry of Health **(**2010**)** issued a new edition of guidelines for medical record writing, but the new guideline does not have the requirement to document dissatisfaction and litigation in medical records. In addition, doctors and nurses are reluctant to record patients' dissatisfaction due to the culture of punishment (Shu, Tao et al. 2013).

Table 6.2 The comparison of the top 5 most commonly identified screening criteria in AE screening process between the present study and other studies

Rank	Australian study (Wilson, Runciman et al. 1995)	Canadian study (Baker, Norton et al. 2004)	Brazilian study (Mendes, Martins et al. 2009)	Tunisian study (Letaief, El Mhamdi et al. 2010)	Present study
1	Unplanned admission before index admission	Unplanned admission before index admission	Unplanned admission in 12 months after discharge from index admission	Unplanned admission before index admission	Hospital –acquired infection/sepsis
2	Unplanned readmission after discharge from index admission	Unplanned readmission after discharge from index admission	Any unwanted events not mentioned above	Hospital acquired infection/sepsis	Any other undesirable outcomes not covered above
3	Any other undesirable outcomes not covered above	Other patient complications	Unplanned admission during 12 months before index admission	Hospital incurred patient injury	Unexpected death
4	Other patient complications	Any other undesirable outcomes not covered above	Unexpected complications	Unexpected death	Unplanned transfer from general care to ICU or from one ward to another
5	Hospital-acquired infection/sepsis	Adverse drug reaction	Death	Unplanned transfer to ICU	Other patient complications

6.3.1.1.2 Educational and professional character of nurses

Nurses used to be considered as doctors' assistants and helpers. However, with social changes, especially increased education for nurses, nursing has been considered an autonomous profession with unique knowledge and interventions for patients (Lacey and Cox 2009). It is more collegial than the previously hierarchical relationship with other healthcare professionals including doctors (Stein, Watts et al. 1990).

Nurses believe clinical work is a collective task with interdisciplinary cooperation (Degeling, Kennedy et al. 2001). Their training emphasises communication, cooperation and holistic nursing approaches from the beginning (Krogstad, Hofoss et al. 2004). In addition, they consistently use a team-based approach to deliver, evaluate and improve health care, and advocate team-based management in hospitals (Degeling, Kennedy et al. 2001).

Among all the health care professionals, nurses have most direct and constant contact with patients. They collect first-hand patient data and create a holistic picture of patients' situations and treatments (Lacey and Cox 2009). Compared with doctors, nurses normally have more general perceptions about patient care rather than only focusing on the clinical aspects. They consistently observe and evaluate patients during their daily work. Doctors mainly working under the cure model, while nurses tend to work more under the care model, and provide more care to patients (Degeling, Kennedy et al. 2001). Compared with doctors, nurses believe that they are more likely to be aware and recognise the occurrence of AEs (Shu, Tao et al. 2013).

Nurses are more willing to accept existing problems and have more perceptions from a system level. When considering variation during health care, nurses tend to stress the system level such as resources, while doctors normally deny it (Degeling, Kennedy et al. 2001). In addition, nurses also tend to accept that there are problems existing in the clinical environment and are more willing to improve it (Hindle, Haraga et al. 2008). Nursing staff strongly disagree that there is no necessary to report an AE, if no harms to patients. At the same time, they expect to

get feedback and interventions about how to prevent the occurrence of a similar AE in the future (Shu, Tao et al. 2013). Therefore, nurses have more open and accepting attitudes to AEs. This attitude potentially influences their CDM during the screening process.

Nurses understand the necessity and importance to report AEs and they do it more habitually. A research study in Australia indicated that nurses submitted 88% of incident reports, while only 2% of reports were initiated by doctors (Kingston, Evans et al. 2004). A Chinese study found nurses are more familiar with reporting system than doctors in hospitals (Shu, Tao et al. 2013). Nurses feel embarrassed about making mistakes but believe it is still necessary to report them. Rather than considering loyalty to colleagues, the intention for nurses to disclose mistakes is mainly for self-protection (Kingston, Evans et al. 2004).

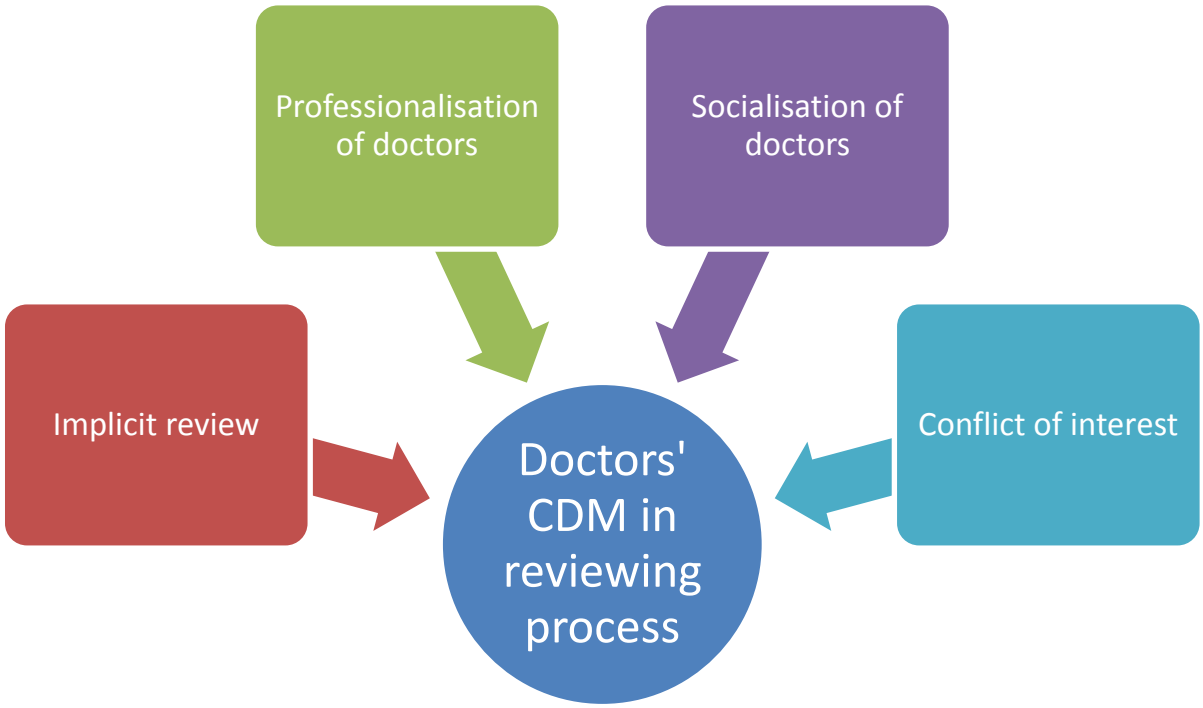
In regards to patient safety, different groups of healthcare professionals have different perceptions about it. Nurses normally have a better understanding and perception of patient safety compared with other healthcare professionals. They are also more aware of the need to take action to improve patient safety and become involved in patient safety programs (Hindle, Haraga et al. 2008). In the past three decades, developed countries have made significant contributions to the investigation of the association between nursing and quality of health care, and there is a direct relationship between nursing care and quality of health care (Needleman, Buerhaus et al. 2002; Kane, Shamliyan et al. 2007). A Chinese study conducted in 2012 also indicated that increasing nursing care has a positive effect on increasing hospital quality and patient safety (Zhu, You et al. 2012).

6.3.1.2 Factors influencing doctors' CDM in the review process

Compared with international studies, this study had the lowest review positive rate. Only 10% of screened positive records were judged as AE cases, which is also the lowest rate across similar studies (Sari, Sheldon et al. 2007; Aranaz-Andrés, Aibar-Remón et al. 2008; de Vries, Ramrattan et al. 2008; Mendes, Martins et al. 2009; Soop, Fryksmark et al. 2009; Zegers, de

Bruijne et al. 2009; Letaief, El Mhamdi et al. 2010; Aranaz-Andres, Aibar-Remon et al. 2011; Wilson, Michel et al. 2012). During the review process, doctors' CDM may have been influenced by four major factors, resulting in underestimation in this study: implicit review process, professionalisation of doctors, socialisation, and conflict of interest (Figure 6.1). These factors influencing doctors may be general to any doctors who participate in similar AE studies.

Figure 6.1 Factors influencing CDM for doctors in review process



6.3.1.2.1 Implicit review for doctors

In the implicit review process, doctors made decisions about the occurrence of AEs based on their own judgments and integrity. Different from explicit standards and criteria, implicit review is subjective, although the definition of AEs and pre-data collection training had provided. The decisions will be made depending on each reviewer's opinion, professional knowledge and clinical experience.

Since the nature of medicine and hospital care is complex, more professional considerations need to be taken into account during medical record review. However, those professional considerations are hard to represent explicitly. Therefore, people argue that implicit review is probably a suitable way to investigate quality (Hayward and Hofer 2001) and is able to capture more multi-level problems (Weingart, Davis et al. 2002).

However, doctors using the implicit review method found fewer quality problems in reality (Brook, McGlynn et al. 1996; Weingart, Davis et al. 2002). They focus on the full picture of clinical care and may often "miss the trees for the forest" (Weingart, Davis et al. 2002). Four reasons may result in under-estimated results of AEs if implicit medical record review is applied.

First, reviewers do not have unified standards and criteria. When doctors review medical records, the standards and criteria they use are in their minds, and those standards and criteria are not specified unless they reveal them (Donabedian 1981). Each reviewer uses his/her own standards and criteria based on their perceptions and understandings of AEs, which are potentially different to other reviewers', to make decisions (Lilford, Edwards et al. 2007). AE is a relatively new concept in China. In the Chinese healthcare system, healthcare professionals are more familiar with the concepts of medical dispute, medical incident, medical error and medical accident (more details in Chapter 3), which could include AEs in some cases, but not always. The confused and incorrect understanding of the concept may aggravate the variation of standards and criteria by each doctor.

Second, implicit review always produces disagreements between doctors because of different standards and criteria they perceived. The inter-rater reliability between physicians varies from good to poor according to different studies in other countries (Caplan, Posner et al. 1991; Rubin, Rogers et al. 1992; Localio, Weaver et al. 1996; Murff, Forster et al. 2003). Judgments concerning preventability have relatively lower agreement than judgments about the presence

of AEs (Murff, Forster et al. 2003). Therefore, it is important to take the tendency of disagreement into account when the implicit review method is utilised (Localio, Weaver et al. 1996).

In addition, judgments made by doctors may be influenced by knowing patients' outcomes first, and an unfavoured outcome may introduce bias. According to Caplan, Posner et al. (1991), 30% of decisions could be influenced by changing patients' outcome from permanent disability to temporary disability and vice versa. Reviewers normally review more harshly medical records ending with permanent disability or death to patients.

Finally, doctors are reluctant to make judgments about other colleagues' work. Doctors normally refuse to "second-guess" other peoples' jobs (Hayward and Hofer 2001). At the same time, they may have negative attitudes towards other peers reviewing their clinical cases (see Section "Socialisation of doctors" below for further discussion). Doctors may assume every medical record contains no AEs before they find enough evidence to support their own standards. Different to "guilty until proven to be innocent" by using explicit review, implicit review believes "innocent until proven to be guilty".

6.3.1.2.2 Professionalisation of doctors

Doctors normally pay less attention to patient safety issues compared with professional knowledge (Durani, Dias et al. 2013), and they are also reluctant and afraid to admit mistakes. The education experience for doctors is different from that for nurses. Throughout medical school training, doctors are trained to take responsibility and a leadership role (Hall 2005). The training concentrates on taking actions and improving patients' outcomes and saving patients' lives (Hall 2005). They treat themselves as warriors against disease and death. In addition, doctors consider themselves as omnipotent and build up self-confidence (Krogstad, Hofoss et al. 2004). The expectations of perfections make it difficult for them to acknowledge and disclose mistakes or AEs (Robbennolt 2009). Normally, medical students study in a highly

competitive environment independently (Hall 2005). When they work in hospitals, doctors perceive clinical work mainly as an individual task rather than a collective cooperation, a view which is shaped during their professional training (Degeling, Kennedy et al. 2001). Unfortunately, patient safety is not a priority for medical training due to laggard education in medical training. Learning about patient safety is not considered as important as learning about more techniques and skills (Durani, Dias et al. 2013).

Doctors in China do not integrate patient safety into their professional culture effectively. They do not have sufficient perceptions and knowledge about patient safety (Ha, Zhou et al. 2009). In China, undergraduate training for medical students only focuses on basic medical knowledge, theories, skills and manipulations (Zhang, Li et al. 2012). There is a lack of training for patient safety and the identification and management of AEs and "near-misses" (Zhang, Duan et al. 2010). In July 2012, the "WHO Patient Safety Curriculum Guide for Medical School – Chinese edition" was published and it provides a great resource for medical/nursing schools. It advocates having patient safety training from students through to the whole career. However, it will be a long process from "knowing what to do" to "knowing how to do" and finally to "doing it" (Zhang, Li et al. 2012). It is assumed that culture change is possible but it will take a long time with little progress.

In fact, the safety culture in China is desperately deprived. Hospital managers and health care professionals are lack of clear understanding of safety culture (Cao 2007). Instead, most hospitals in China still have a punitive culture as dominant. Doctors are afraid to reveal or report other colleagues' AEs and at the same time afraid to be revealed by other people (Li and Liu 2009; Wang and Zhang 2009).

In the clinical environment, doctors mainly focus on diagnosis and treatment (Stein 1967). These are still considered the dominant tasks for hospitals and patient care in many countries (Krogstad, Hofoss et al. 2004), including Chinese hospitals. Doctors believe they are doing the

most important work in the hospital, and therefore, they are situated at the top of the hierarchy in a clinical environment (Hindle, Haraga et al. 2008). Nurses are supposed to work under the instruction of doctors and concentrate on accomplishing tasks assigned by doctors (Hughes 2008). Therefore, doctors also need to take responsibility for nurses' work (Hindle, Haraga et al. 2008). Consequently, doctors need to be more accountable than nurses when something wrong happens to patients (Stein 1967), especially AEs related to medical-treatment, such as adverse drug events. In addition, because of doctors' underlying omnipotent belief, self-confidence and accountability to patients built up through their training, they are extremely afraid to acknowledge mistakes or errors (Stein 1967).

6.3.1.2.3 Socialisation of doctors

Doctors are reluctant to be reviewed or to reveal peers' mistakes or AEs because of their professional culture. In the Chinese healthcare system, the patient-centered care model has been advocated for several decades, but most hospitals still work on the doctor-centered model. Patients stay in hospital for a brief time, and doctors' decision-making process is mainly based on patients' physical outcomes (Baumann, Deber et al. 1998), such as decreased blood pressure. In addition, due to highly specialised nature of medicine, it is relatively easy for doctors to only focus on patients' specific medical problems rather than having a holistic view (Relman 2007).

In the cure model, doctors are the principal care providers, which lays the foundation of their superior position in the hospital's hierarchical structure (Baumann, Deber et al. 1998). Doctors believe they have the absolute right to make decisions about patients' treatment plans (Leipzig, Hyer et al. 2002) and expect unequal power.

This hierarchical power structure also reinforces the autonomy of doctors. Doctors rank autonomy as the most important issue in their clinical work (Degeling, Kennedy et al. 2001). They enjoy the autonomy and do not like other people to challenge it (Hindle, Haraga et al.

2008). They continuously reject or have negative feelings about measuring, evaluating and comparing their clinical work performance with others (Degeling, Kennedy et al. 2001), because doctors consider it as a violation of their autonomy. As a last resort, doctors assume only their peers could make judgements about their performance because of self-regulation (Baumann, Deber et al. 1998). In addition, they prefer internal review to external review, because they perceive internal review would be less challenging, less objective and less formalised than external review (Curnock, Bowie et al. 2012). Doctors expect internal reviewers to consider more socialisation factors rather than being critical in reviewing.

Indeed, the results of internal review may be largely influenced by socialisation factors. Reviewers may develop friendships with some of their colleagues in private, and reviewers may also dislike someone in their private life by instinct. Reviewers may feel reluctant and uncomfortable to review and judge their colleagues' work, even though the reviewers were anonymous during the review process in the present study.

In this study, all the doctors were recruited from their own hospital. Therefore, socialisation factors were unavoidably involved during the CDM process for the identification of AEs and potentially influenced the results of the reviewing process. In addition, in China, doctors are employees of hospitals. They work for the hospital and obtain their salary from the hospital. However, in Australia, doctors only have a cooperative relationship with hospitals, rather than an employment relationship. To some extent, reviewers in this study may have considered that the performance of colleagues and the hospital represented their own job, which may have caused biased perceptions during the study.

Even when reviewing the same medical record, nurses and doctors often draw different conclusions. When reviewing medical records for quality issues, doctors who made decisions always considered factors other than fault (Weingart, Davis et al. 2002). Doctors have tolerance for mistakes. They generally accept that some mistakes will happen as a part of daily clinical

work (Durani, Dias et al. 2013). Compared with nurses, doctors always found fewer quality problems during medical record review (Weingart, Davis et al. 2002; Kingston, Evans et al. 2004), because, subconsciously, they may think making mistakes or quality problems is usual care (Weingart, Davis et al. 2002).

When AEs happen, doctors may keep AEs "in-house" rather than exposing them due to their professional culture (Kingston, Evans et al. 2004). Considering the uncertain nature of medicine, doctors keep loyal to their colleagues as self-protection. To disclose a peer's mistakes is considered unsupportive and unethical, and makes doctors feel embarrassed. At the same time, doctors are concerned about litigation caused by revealing mistakes (Kingston, Evans et al. 2004). Furthermore, the medical hierarchy structure also inhibits junior doctors from speaking up (Durani, Dias et al. 2013) and revealing patient safety issues.

6.3.1.2.4 Conflict of interest as an influence in doctors' CDM

An ideal review process is independent and objective, but if there is any conflict of interest involved, it is almost certain that reviewers will defend their own interests by human instinct. To identify and reveal AEs threatens doctors' financial interest and more importantly safety interest, in particular in the current Chinese context. Therefore, this may be another consideration contributing to the underestimation of the reviewing process in the present study.

First, doctors have a personal incentive to conceal AEs. The salary for doctors in China is modest, even by Chinese standards. The government pays only around 50% of doctors' income (Yip and Hsiao 2008). The other half of their income comes from commissions for medical services and drug prescriptions (Hu, Tang et al. 2008). Therefore, the salary and bonus for doctors is closely tied to the hospital's profit. Given the marketisation of hospitals in China, to detect and report AEs may have a negative influence on the hospital's profit, which could influence the doctors' own incomes. The conflict of interest is quite obvious here. In regard to the present study, all the reviewers were recruited from their own hospital. If the results were

exposed, both the hospitals and doctors would suffer financial loss.

In addition, doctors may also worry that AE disclosure could potentially cause medical disputes, which has been stated as the significant barrier for doctors to reveal AEs (Gallagher, Waterman et al. 2003; Robbennolt 2009). Although mediation and lawsuits can be used to solve disputes in China, compromise settlement agreements have become mainstream. A study conducted in Shanghai in 2008 (He and Sun 2012) found that 90% of medical disputes were settled by compromise settlement agreements. Both hospitals and patients prefer this method to deal with disputes for the sake of their own interest (He and Sun 2012). On average, in each tertiary hospital in China, 100 cases of medical disputes required monetary compensation (He and Sun 2012). The compensation paid to patients could range between 100,000 Yuan to over 1 million Yuan (Wang and Wang 2007), which is equivalents to 17,000 to over 170,000 Australian Dollar. In addition, due to the nature of the punitive culture and disciplinary purposes, hospitals normally have internal liability investigation systems. Doctors with responsibility in medical disputes will receive punishment, both financial and administrative (Pei 2004). Doctors need to pay some part of compensation in proportion to their responsibility in disputes. In China, since there is no medical indemnity insurance for doctors, any compensation needs to be paid from their own savings. The potential financial lost has been identified as the first reason for doctors not report AEs in a Chinese study (Shu, Tao et al. 2013). At the same time, doctors involved with medical disputes would normally have less opportunity to be promoted professionally in the following years, especially for disputes with extensive public attention. And doctors do worry about this, and rank it as one of the top 3 reasons to not reported AEs (Shu, Tao et al. 2013).

When a medical dispute is involved, the situation becomes complicated. Doctors have the considerations of income, personal reputation and future promotion opportunity. More importantly, personal safety will become the biggest concern, especially in the current Chinese

context. In China, many medical disputes result in medical disturbances in order to obtain more compensation, and sometimes lead to violence to healthcare professionals. Research conducted by the Chinese Medical Doctors' Association (2007) indicated that over 97% of hospitals had the experience of hospital violations, with an average of 15 cases each year in each hospital, and about seven health professionals being injured during hospital violations in each hospital.

In developed countries, the hospital emergency codes system is normally available for staff safety. According to the Australian emergency codes, hospital staff could call for a “code black” if they feel threated or face violence in any Australian hospitals (Department of human service 2005). Once a “code black” was set off, a series of integrated response would happen, including ward staff, ward managers, security, hospital managers and police (Australian Capital Territory Health Information 2013). In addition, people who assault hospital staff get more severe punishment in Australia (Hill 2012).

Unfortunately, there is insufficient such emergency response mechanism for staff safety in Chinese hospitals. Furthermore, there is no law, regulations or governance specific to hospital violations in China to date. The punishments to people who assault hospital staff violently sometimes even less (Xinhua Net 2013). Given the tension of the current doctor-patient relationship in China, doctors would not put their own safety at risk to acknowledge AEs.

Hospitals are supposed to be the place to provide health services to patients, however, they have become battlegrounds between doctors and patients. Doctors perceive the tension between doctors and patients more intensively than patients and this tension has influenced doctors in many ways (Xie, Qiu et al. 2009; Le, Wei et al. 2011). Therefore, doctors have strong personal incentives to deny the occurrence of AEs and conceal them. Given the current doctor-patient tension in China, they have every reason to suspect revealing AEs could be a huge risk to their personal safety. When personal safety is under threat, doctors would not consider quality improvement and pursue safety for their patients, which are higher- level needs than their own

safety.

6.3.1.3 Summary

In conclusion, many factors may influence nurses' and doctors' CDM in the screening and reviewing process, which may have had a direct impact on the underestimation of results (Table 6.3). Nurses generally have open attitudes towards AEs, and have explicit criteria to aid their CDM. Although the validity and reliability of the screening tool is questionable, nurses made more objective, unbiased decisions about screening results with less conflict of interest. On the other hand, doctors' decisions on the identification and preventability of AEs were highly dependent on doctors' subjective judgements. There are many other factors which may influence their CDM, from the character of their education to potential conflict of interest. All those factors may have impacted on the underestimation of the results in the reviewing process. Therefore the screening results in this study may be more reliable and creditable, and have more important meanings than the reviewing result.

Table 6.3 The comparison of factors influencing CDM for nurses and doctors

Factors	Nurses	Doctors
Educational character	Emphasis on communication, cooperation and holistic approach	Emphasis on improving patients' medical outcomes Build up self-confidence and feeling of omnipotence
Professional character	Most direct contact with patients First-hand patient data Team-based approach Care of patients	At the top of hierarchy Focus on diagnosis and treatment Enjoy and defend autonomy Take full responsibility Cure of patients
Perception to clinical work	Collective task	Individual adventure
Perception to quality problems	Accept Report habitually Feel embarrassed for making mistakes	Denial/reject Deal with it "in house" Keep loyalty to colleagues and not reveal other people's problems Have tolerance for mistakes
Perception to patient safety	Better understanding Active to take action	Lack of understanding Reluctant to take action
Objective decision aids	Yes Explicit criteria (17 screening criteria)	No Implicit criteria (personal experience, knowledge, attitude and perceptions)

6.3.2 Quality of medical records

The quality of medical record is a widely-accepted and determinant disadvantage of any retrospective medical review studies which investigate AEs (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004). When RMRR design was introduced, this drawback had been acknowledged (Hiatt, Barnes et al. 1989). In this study, the low rate of screening positive and review positive cases could be influenced by the quality of information contained in the selected medical records.

The quality of medical records largely depends on individual physician's work (Diamond, Rask et al. 2001), and has a major impact on study results. The majority of medical records are written by doctors in China. Nurses only make a few parts of the records, such as patient's vital signs (Ministry of Health 2010). Common doubts about medical records include completeness, truthfulness and ability to interpret (Donabedian 2003).

Under-reporting is a common issue in patients' medical records all over the world, and same as in China (Chu, Wang et al. 2001; Liu, Ren et al. 2007; Chen, Chen et al. 2011; Li 2013; Luo, Shen et al. 2013). A medical record is a summary of the patient's daily situation rather than a description of everything, so some AEs may not be recorded (Walshe 2000). The more detailed the medical records, the more AEs could be found (Wilson, Runciman et al. 1995; Baker, Norton et al. 2004). Weissman, Schneider et al. (2008) found numbers of AEs reported by patients were not documented in the medical records at all. Therefore, those AEs could not be identified by record-based review. Delayed medical service and diagnosis were also found to be under-reported in patients' medical records (Diamond, Rask et al. 2001). More discussion about the information defects of medical records in China had been described in section 3.2.5.

In China, the phenomenon of "make up" to medical records does exist in hospitals, and some crucial information about patient safety and AEs might be changed or deleted during the "make up". The first reason for doctors and nurses to amend records is to avoid lawsuits or take the responsibilities to patients' negative outcomes. Second, they always amend medical records especially before the assessment of quality of medical records, which has been conducting for more than 20 years in China. According to Di (2002), revisions and "making up" of information in medical records was common in their hospital. Therefore, the truthfulness and accuracy of the information contained in medical records is doubted. However, the data to illustrate the proportion of "make up" medical records in China is lack. Doctors and nurses "make up" medical records in order to conceal errors or problems, and consequently are reluctant to acknowledge it as human nature. Therefore, the medical records selected in this study might had been "made up" and revised before the data collection, and some valuable information about AEs might had been removed.

Another significant disadvantage of conducting record-based reviews in China is the limited accessibility to patients' information. As it discussed in background chapter, each hospital is still an isolated information silo for inpatients' medical records in China. Reviewers did not have access to patients' medical records in other hospitals, and the inability to access comprehensive information could influence the study results. For example, this study was designed to include AEs which occurred in index admission but were discovered after. As expected, no AE was found in this situation. If patients did have AE during the index admission period but went to another hospital to obtain medical service for the AE, there was no way for the reviewers to access that information and detect AEs (Hiatt, Barnes et al. 1989). Nurses could not make correct judgments if patients were readmitted to another hospital after discharge from index admission, and this particular medical record would most probably not be considered as an AE case in this study. Hence, the quality of medical records had a profound impact on the results of this study in both the screening and reviewing processes.

6.4 Limitations

Generally there are two weaknesses associated with all studies which adopt the RMRR method: underestimation of AEs and overestimation of PAEs. Medical records have the problems of availability, completeness, veracity, and difficulty of interpretation (Donabedian 2003), which are related to the under-estimated result of AEs. Another general weakness is hindsight bias. Reviewers' decision-making about the causation and preventability of AEs may be influenced by knowing the outcomes and severity first (Zegers, de Bruijne et al. 2009). The proportion of PAEs is normally overestimated, because of lack of consideration of the severity of cases and the complexity of the situation at the time AEs occur (McDonald, Weiner et al. 2000; Sari, Sheldon et al. 2007).

Beyond these general weaknesses, this study has another three limitations. First, only two secondary-level hospitals participated in this study, and both were from urban areas in the same city. This limits the generalisability of the results to other level hospitals or to rural areas in China. Second, the sensitivity of this study to AE identification was not tested. The screening tool was adopted from previous studies with some modifications, and there was no further testing for false negative cases in this study. Therefore, the sensitivity and adaptability of the screening tool to the Chinese context are unknown. Thirdly, the result of the reviewing process was based on doctors' implicit evaluation. The additional length of stay and preventability were determined by reviewers' experience and knowledge rather than objective scale.

6.5 Implications for policy and practice

The results and lessons learnt from this study could be valuable implications for further studies, because avoiding or strengthening some of the lessons could make the study process more smooth and ensure better quality results. Firstly, establish governance in patient safety could help to conquer many barriers from an administrative perspective during studies of AEs and potentially achieve culture change. In addition, the screening results in this thesis have been considered more important and may serve as guides to clinical work and further study in China. Therefore, the importance of nurses in improved patient safety and the reduction of AEs cannot be over-emphasised. Thirdly, as discussed previously, the quality of medical records is a crucial and determinant factor in any study based on medical records audit and should be further improved, since it directly influences the quality of study results. Furthermore, the safety of healthcare professionals should be well protected first in order to achieve the patient safety goal.

6.5.1 Establish governance for patient safety

The governance for patient safety should be established. By doing this, a culture change from punitive culture to safe culture is undergoing unobtrusively and imperceptibly. On the other hand, an organisation with established safety culture could be relatively easier to establish the integrated governance system. The senior level officers from national level or hospital managers from organisational level should take the responsibility for patient safety rather than punish or blame individual healthcare professionals, who are at the "sharp-end" of AEs. At the same time, workforce are aware the responsibilities and accountabilities to patient safety (Australian commission on safety and quality in healthcare 2011).

Leadership as a precondition of AEs study could not be over-stressed. The successful implementation of the study of AEs greatly relies upon the wisdom and foresight of hospital leaders, especially in the countries with under-developed AEs knowledge, such as China. The hospital managers' attitudes to and perceptions of AEs laid the foundations for the conduct of the present study. When hospital managers decide to carry out a study of AEs, they need to go through several stages before they make the decision (Figure 6.2). Each of the stages could become a barrier to obstruct patient safety programs. For instance, Akins and Cole (2005) reported the top seven barriers from the leadership and system level to the implementation of patient safety programs, such as the study of AEs. Lack of understanding and involvement with AEs study by senior leadership, not setting it as a top priority, and being unwilling to change all could have negative impacts on the implementation of an AE study.

Figure 6.2 The decision-making process of hospital managers on implication of AEs study

Apart from the factors discussed above, a researcher-in-charge with administrative power is required for a successful AE study. This person will coordinate inter-departmental relationships and communication. Since a range of departments need to cooperate together during data collection, communication between different clinical departments is critical. The researcher-in-charge is ideally from a senior level of leadership with administrative rights to allocate resources and workloads to relevant departments. In addition, different departments could complete the task more efficiently if they are assigned by a senior leader; especially in the hospitals maintain a top-down management style.

A regular AE monitoring surveillance is supposed to be established from either national or hospital level (Australian commission on safety and quality in healthcare 2011). The time interval for monitoring AEs could be every month in every hospital, and the number of selected medical records each time does not need to be a big number, such as 10 records. Nevertheless, it is extremely important to keep this monitoring continuous. In particular, monitoring and management of AEs could be strengthened in specific clinical departments and/or specific groups of patients with high risk to occur AEs. Therefore after several years, systematic data about AEs could be gained through this continued monitoring scheme. Continuous monitoring of AEs is necessary to observe and evaluate the effect of patient safety programs. In addition, by analysing the continuous data, any trend change in AEs would be easily identified, which could provide valuable information for strategic goals and priority-setting at national or organisational levels (Landrigan, Parry et al. 2010).

6.5.2 Give nurses a legitimate voice in AE reduction and patient safety

One of the most important lessons learnt from this study was to give nursing staff a legitimate voice to be more actively and frequently involved in AEs reduction and other patient safety programs. It is true that to achieve the quality goal successfully in healthcare, it is essential to have collective cooperation between doctors, nurses and other healthcare professionals. No

single group of professionals could achieve the goal by themselves (Lacey and Cox 2009). However, nurses play a direct and profound role and should be encouraged to actively involved in preventing and/or reducing AEs, quality assurance and patient safety improvement.

During the process of patient care, nurses are at the "sharp end" (Hughes 2008). They are the last defence against some AEs, such as adverse drug events caused by wrong medication (Choo, Hutchinson et al. 2010; Durani, Dias et al. 2013). Furthermore, the prevention of some types of AEs is mainly based on nursing interventions, such as pressure ulcers, falls, and intravenous cannulation-associated pulmonary air embolisms (Considine and Botti 2004). Therefore, the voice from nurses could not be ignored, and they should be involved in policy-making or protocol-drafting about AEs control and patient safety improvements. Ideally, more nurses should be included in senior level of leadership from both national and organisational level. Since nurses are the people who are most likely to encounter and interpret AEs, their involvements on priority and strategic plan setting is necessary.

In addition, patient safety could be improved if more training provided to nurses. According to Durani, Dias et al. (2013), providing simple or basic training about AEs to nurses could have augmented effects on preventing and reducing AEs. Therefore, more training about patient safety and evidence-based interventions should be arranged and provided for nursing staff. And more resource should be allocated to nurses to design and lead clinical initiatives to address patient safety issues based on their daily practice (Friesen, Farquhar et al. 2005).

A crucial role for nurses in preventing and/or reducing AEs is to recognise the risk factors for AEs, identify, interpret and take action on signs of AEs (Considine and Botti 2004). The results of this study could guide daily clinical activities of nurses, which suggest the following factors could be "red flags" for patients to suffer AEs in Chinese hospitals:

-Patients aged 65 years old and over

-Covered by health insurance

-Stay in hospital for 14 days (highly suspicious if longer than 24 days)

-Admitted to non-surgical departments

-With principal diagnoses of infectious diseases, neoplasms or blood and immune system diseases.

Overall, the goal of patient safety cannot be achieved by any individual category of healthcare professionals. It requires effective interdisciplinary cooperation. However, compared with other categories of healthcare professionals, nurses play a profound role in AE reduction and patient safety, and as front-line staff, nurses can make a sustainable change. Therefore, the important role of nurses on patients safety should be emphasised, and hospital managers should encourage nurses to be actively involved in patient safety program.

6.5.3 Improve the quality of medical records

When the RMRR was firstly designed to measure AEs in 1980s, the quality of medical records had been stated as the most significant and determinant factor to detect AEs (Hiatt, Barnes et al. 1989). As a crucial impact factor, it has been discussed in almost any single study to investigate the prevalence of AEs. As Baker, Norton et al. (2013) pointed out AEs study could be feasible and applicable in developing countries if good quality of documentation available. In other words, poor quality of medical records is considered as one of the main barrier to conduct AEs study in developing countries. However, generally the quality of medical records in developing countries has significant difference compared with developed countries (Michel 2003). This thesis has discussed the importance of quality of medical records impact to AEs study in developing countries (refer to section 2.4.3) and in China (refer to section 3.2.5 and section 6.3.2), which has reflected the necessity to improve quality of medical records.

The quality of medical records could be improved by different ways to provide more valuable, complete and true information. And most of interventions for improvements require the support

from system level and infrastructure development. First, a rigid regulation about documentation should be issued, with the requirements to record all AEs-related information. In particular, AEs-related information should be included in the abstracts of medical records, which are required to be uploaded and reported to MOH compulsorily. Second, continuous quality control about medical records should be strengthened. Traditionally, the quality control about medical records is targeted to finalised records only, which is called as terminal medical records in Chinese hospitals. However, a real-time assessment to the medical records which are currently in-use would achieve more benefits and better quality (Li 2013). The real-time monitoring could pay more attention to the records selected from surgical departments or ICU, because higher prevalence of AEs has been reported by previous literature (Aranaz-Andrés, Aibar-Remón et al. 2008; Zegers, de Bruijne et al. 2009). Third, the electronic medical records (EMRs) should be promoted and eventually an EMR sharing system could be set up. Huge efforts are required from central governments level, such as policy-making, funding and infrastructure-developing to achieve this goal. Healthcare professionals are unable to change the information recorded in an EMR unless authority is granted, which could help to maintain the authenticity of information from some way. Also, the real-time monitoring to the quality of medical records could be easier conducted with less human resource and time consumption if EMR applied. In addition, a shared EMR system could collect more comprehensive and integrated information about patients, and more problems are supposed to be identified. For example, readmission for DRG could be detected even though in different hospitals. Fourth, more training to doctors and nurse would be valuable and necessary. The training program could include assessment criteria to medical records and interpretation to regulations about documentation. And this training should be included in the orientation program for new staff (Li 2013; Luo, Shen et al. 2013).

6.5.4 Protect healthcare professionals' safety

Healthcare professionals must feel safe from both financial and physical levels, before they could focus on improving patient safety and reporting AEs. In order to protect the financial interest of doctors and nurses, the introduction of medical indemnity is necessary. Some AEs may result to providing financial compensation to patients, healthcare professionals, especially doctors, do not need to pay the money from their own saving if this insurance system established. In addition, an emergency warning mechanism should be set up to protect staff personal safety, such as emergency hospital codes system and violent reporting system. In order to promote the introduction of those systems, the accreditation for hospitals could set it as one of the requirements on measuring the governance. Furthermore, a law or regulation should be launched for the safety and aggressive behaviours management in healthcare industry which requires the cooperation between ministry of health and police force.

6.6 Implications for research and potential research directions

The implications for research and further research directions could also be drawn from this thesis. As it discussed before, nurses have profound role in patient safety improvement from policy-making and practice level. The significant role in research level also needs to be highlighted. In addition, the recruitment and training need to be strengthened for better quality and less biased results. Finally, a couple of further research directions could be generated based on this thesis in order to have more clear understanding towards AEs in China.

6.6.1 Give nurses opportunities to engage in AEs research

The importance role of nurse in AEs reduction and patient safety improvements from practice level has been discussed before. From the research level, the importance of nurses could not be over-emphasised as well (Needleman and Hassmiller 2009). For example, some guideline or

handbook about patient safety and AEs control was produced based on a large amount of effort from nursing staff (Agency for healthcare research and quality 2008). The situation in China is similar. Although there is a lack of AE research in China, the available research about hospital quality and patient safety improvement has been mainly conducted by nurses (Jiang and Li 2004; Ha, Zhou et al. 2009; Li and Liu 2009; Li and Shi 2011; Liu, Zhang et al. 2011). Therefore, efforts from nurse on patient safety research should be promoted. More research funding could be provided to nurses, including financial support and workload support. In the future research, it could be considered to not separate different disciplines to different panels for screening and review of the medical records. And nurses should be given more opportunities to engage in AEs research as member of the research team, rather than subordinate roles, and having a patheway to higher degree qualifications for nurses.

6.6.2 Strengthen recruitment and training in AEs study

To minimise bias, nurses and doctors for screening and reviewing should be recruited from external resources, such as other hospitals or medical organisations (Aranaz-Andres, Aibar-Remon et al. 2009). However, this approach could not apply in the present study because the "external process" was not supported by hospital managers and staff in China.

Even though external reviewers are not available, it would still have been possible to improve reliability and reduce bias if more comprehensive and detailed training could have been provided. Nurses and doctors are key resources for the study of AEs, particularly in the process of screening and reviewing. The quality of data they collect determines the quality of the overall results (Sari, Sheldon et al. 2007; Soop, Fryksmark et al. 2009; Zegers, de Bruijne et al. 2009). Even though in developed countries, healthcare professionals have more knowledge about AEs, the importance of training is still highlighted and emphasised (Baker, Norton et al. 2013). In fact, AE is a totally new concept in China, and many nurses and doctors may have heard of this concept first during the training sessions.

Therefore, more training should be arranged before data collection. The training contents could include definitions of AEs, theories of AEs, measuring methods, and the significance of the study of AEs for patient safety. The most important thing to emphasise during the training would be that a high prevalence of AEs does not mean poor quality and unsafe healthcare. Training sessions should be more focused on difference between AEs and medical accidents. A clear explanation should be given if an event could be called as AE if there were no errors or mistakes.

In addition, training about AEs should be part of the continuing professional development for doctors and nurses (Michel, Quenon et al. 2007). In the training session, doctors and nurses can directly communicate with experts on hospital quality improvement. It is also an engaging process, and doctors and nurses will be actively involved in patient safety programs if they have in-depth understandings of the field.

6.6.3 Potential research directions

This study is a pioneering work in China. The feasibility and difficulty of the use of the retrospective medical record review (RMRR) method to conduct the study of AEs has been shown by this work. In addition, the limitations and experience gained from this study have been discussed in detail. Other organisations or people could use this study as an example, and carry out similar AE studies in other settings. Other countries with similarities to China could also benefit from this study. If further studies could avoid or improve the issues found in this work, the quality of the results could be better, such as providing more training and using localised screening tools.

Given the new and under-researched nature of AEs in China, this study could be used as a base study, and there are a number of directions which further research could take. First of all, screening tools could be localised in order to have better cultural adaptability. For the purpose of international comparison, this study adopted an existing screening tool from previous studies

in developed countries. However, the low rate of screening criteria reflected the importance of localisation.

Second, further research could explore other methods of measuring AEs. Retrospective medical records review (RMRR) has acknowledged disadvantages, such as underestimation, hindsight bias, and dependency on quality of medical records. Further studies could explore other methods for the detection of AEs. By using the same population as this study, different results could reflect the impact of different methods for the detection of AEs. The methods which could be further explored include prospective medical record review, direct observation, reporting systems and global trigger tools.

In addition, a screening tool for AE identification could be established if more detailed data were available. A screening tool for AEs could be similar to a screening tool for suicide. If patients are satisfied with some factors (x), then the result (y) would be expected. Based on the results of this thesis, it is not possible to make a screening tool yet. However, if more data could be provided, it would be possible to set up the tool to include factors such as comorbidity, invasive procedure etc., and it could be easily implemented in clinical environments.

Furthermore, more research could be conducted in CDM in AE studies. This study creatively interpreted the results from a CDM perspective, but few CDM research studies concentrate on AE detection and occurrence. Further understanding of the CDM of doctors and nurses could help to reduce and prevent AEs.

6.7 **Conclusion**

This thesis aimed to investigate the AEs in Chinese hospital from the hospital-wide level. The reported prevalence of AEs was found vary from 3.2% to 16.6% over the past 2 decades. The systematic review found studies conducted in developing countries revealed lower prevalence

of AEs than studies in developed countries. But a higher proportion of AEs was considered preventable in developing countries than in developed countries. In addition, there is no study was identified through the systematic review to investigate the AEs from a hospital-wide perspective in China. All the available studies were only focused on specific service in hospital or specific AEs. Clearly, a serious research gap was identified in China.

A medical record audit study was conducted to investigate the prevalence of AEs in two Chinese hospitals. The characteristics of AEs were examined in detail. As a pioneering study, it has filled a research gap which has been identified in the systematic review, and enabled comparison with other countries. The screening positive rate was 10.6% (9.3%-12.1%, 95% CI) and the review positive rate (prevalence of AEs) was 1.14% (0.69%-1.68%, 95% CI). All of the AEs were considered preventable, and 85% were highly preventable. No severe consequence was found to be caused by AEs, such as permanent disability or death.

The result yielded from this medical record audit study had radically difference from previous studies in developed and developing countries. Both the screening positive rate and the review positive rate are the lowest rate so far in similar studies about AEs across the world. Rather than reflecting the true problems, the results are almost certain to be under-estimated due to combination of different factors, such as factors influenced nurses' and doctors' CDM and quality of medical records in China.

Despite the under-estimated results, this thesis has achieved a remarkable contribution. Firstly, the systematic reviewed conducted in this thesis analysed and summarised key information about AEs' studies in the past 7 years, which could be helpful to insight AEs from a global level. Secondly, this thesis could be the start of evidence-based studies about AEs in China and a drive to further patient safety programs. Thirdly, apart from analysing factors influencing the results from a methodological perspective, this thesis has blazed a new trail to analyse factors from a CDM perspective.

In addition, this thesis may have implications for policy, practice, and further research. From the policy and practice level, the governance for patient safety should be established, such as switching to safety culture, strengthening leadership and establishing regular monitor on AEs. Nursing staff plays a profound role on AEs reduction and patient safety improvement. In addition, the quality of medical records could be improved through different ways. The safety of healthcare professionals could be protected by launch of medical indemnity insurance and policy or law for the prevention and management of aggressive behaviour in healthcare. From the research level, numbers of implications could be drawn from this thesis as well. For example, the results of screening had more important meaning in the Chinese setting; therefore, nurses should be encouraged actively involved in future studies about AEs and patient safety. More and upgraded training is required in future medical record audit study. Other methods of AEs' detections could be explored and make comparisons, such as direct observation and global trigger tool.

As a groundbreaking study, this thesis is as an important step forward in achieving safer healthcare in China. However, the results about AEs in Chinese hospitals of this thesis must be interpreted with causation, because it was highly likely to be under-estimated. If the policymakers and hospital managers use this data to benchmark without any consideration, an erroneous conclusion will be generated, that the prevalence of AEs is lower in China. This will consequently result to lowered quality improvement effort on AEs and cause more patient injuries (AEs) happen but hidden in the future.

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APPENDICES

Appendix A The reported classifications of AEs in included studies in chronological order, sub-divided into developed countries and developing countries

		Developed countries				*Developing countries*			
Study / Classification		Sari, Sheldon et al. (2007)	Aranaz-Andrés, Aibar-Remón et al. (2008)	Soop, Fryksmark et al. (2009)	Zegers, de Bruijne et al. (2009)	Mendes, Martins et al. (2009)	Aranaz-Andres, Aibar-Remon et al. (2011)	Wilson, Michel et al. (2012)	Median
Drug related		14.0%	37.4%	30.1%	15.3%	5.6%	8.2%	5.0%*	14.0% (5.6%-30.1%)
Diagnostic related		5.1%	2.8%	11.3%	6.3%	10.2%	6.1%	19.1%	6.3% (5.1%-11.3%)
Procedure related		44.9%	25.0%	63.6%	71.2%	65.8%	28.5%	24.4%*	44.9% (25.0%-65.8%)
	Surgical procedure	36.8%	-	49.4%	54.2%	35.2%	-	18.4%	36.8% (26.8%-51.8%)
	Medical procedure	8.1%	-	14.2%	17.0%	30.6%	-	6.0%*	14.2% (7.05%-23.8%)
Others	Therapeutic error	-	-	-	-	-	-	34.2%	-
	Nosocomial infection	14.0%	25.3%	-	-	-	37.1%	-	25.3% (14.0%-37.1%)
	Obstetric related	-	-	-	-	8.3%	-	9.0%*	8.65% (8.3%-9.0%)
	Neonatal related	-	-	-	-	-	-	8.0%*	-

	Developed countries			*Developing countries*				
	Sari, Sheldon et al. (2007)	Aranaz-Andrés, Aibar-Remón et al. (2008)	Soop, Fryksmark et al. (2009)	Zegers, de Bruijne et al. (2009)	Mendes, Martins et al. (2009)	Aranaz-Andres, Aibar-Remon et al. (2011)	Wilson, Michel et al. (2012)	Median
Fracture	-	-	-	-	1.9%	-	1.5%	1.7% (1.5%-1.9%)
Falls	2.2%	-	-	-	-	-	0.5%*	1.4% (0.5%-2.2%)
Anaesthesia related	-	-	-	-	0.9%	-	0.5%*	0.7% (0.5%-0.9%)
Clinical management	7.4%	-	-	3.7%	-	13.4%	-	7.4% (3.7%-13.4%)
Pressure ulcer	8.8%	-	-	-	-	-	-	-
Care related		7.6%	-	-	-	-	-	-
System events	-	-	-	-	6.5%	-	-	-
Discharge	-	-	-	1.4%	-	-	-	-
Others	3.7%	1.8%	-	-	0.9%	-	-	1.8% (0.9%-3.7%)

Appendix B The template of an abstract of a medical record

医疗机构_____（组织机构代码：_____）

医疗付费方式：☐ **住 院 病 案 首 页**

健康卡号： 第 次住院 病案号：

姓名 _____ **性别** ☐ 1.男 2.女 **出生日期**_____年____月____日 **年龄**_____**国籍**

（年龄不足 1 周岁的） **年龄**_____月 **新生儿出生体重**_____克 **新生儿入院体重** 克

出生地_____省（区、市）_____市____县 **籍贯**_____省（区、市）____市 **民族**

身份证号_____**职业**_____ **婚姻** ☐ 1.未婚 2.已婚 3.丧偶 4.离婚 9.其他

现住址_____省（区、市）____市____县_____ **电话**_____ **邮编**

户口地址 _____省（区、市）____市____县_____ **邮编**

工作单位及地址_____ **单位电话**_____ **邮编**

联系人姓名_____ **关系**_____ **地址**_____ **电话**

入院途径 ☐ 1.急诊 2.门诊 3.其他医疗机构转入 9.其他

入院时间_____年____月____日____时 **入院科别**_____**病房**_____ **转科科别**

出院时间_____年____月____日____时 **出院科别**_____**病房**_____ **实际住院**_____**天**

门（急）诊诊断_____**疾病编码**

出院诊断	疾病编码	入院病情	出院诊断	疾病编码	入院病情
主要诊断：			**其他诊断：**		
其他诊断：					

入院病情：1.有，2.临床未确定，3.情况不明，4.无			

损伤、中毒的外部原因_____**疾病编码**

病理诊断：_____**疾病编码**

_____**病理号**

药物过敏 □1.无 2.有，过敏药物：_____ **死亡患者尸检** □ 1.是 2.否

血型 □ 1.A 2.B 3.O 4.AB 5.不详 6.未查 **Rh** □ 1.阴 2.阳 3.不详 4.未查

科主任 _____ **主任（副主任）医师** _____ **主治医师** _____ **住院医师**

责任护士 _____ **进修医师** _____ **实习医师** _____ **编码员**

病案质量 □ 1.甲 2.乙 3.丙 **质控医师**_____ **质控护士**_____

期_____年_____月_____日

手术及操作编码	手术及操作日期	手术级别	手术及操作名称	手术及操作医师			切口愈合等级	麻醉方式	麻醉医师
				术者	Ⅰ助	Ⅱ助			
							/		
							/		
							/		
							/		
							/		
							/		
							/		
							/		

离院方式 □ 1.医嘱离院 2.医嘱转院，拟接收医疗机构名称：

3.医嘱转社区卫生服务机构/乡镇卫生院，拟接收医疗机构名称：_____4.非医嘱离院 5.死亡 9.其他

是否有出院 31 天内再住院计划 □ 1.无 2.有，目的：

颅脑损伤患者昏迷时间： 入院前____天____小时____分钟 入院后____天____小时____分钟

住院费用（元）：总费用_____（自付金额：_____）

1.综合医疗服务类：（1）一般医疗服务费：_____（2）一般治疗操作费：_____（3）护理费：

（4）其他费用：

2.诊断类：（5）病理诊断费：_____（6）实验室诊断费：_____（7）影像学诊断费：

（8）临床诊断项目费：

3.治疗类：（9）非手术治疗项目费：_____（临床物理治疗费：_____）

（10）手术治疗费：_____（麻醉费：_____手术费：_____）

4.康复类：（11）康复费：

5.中医类：（12）中医治疗费：

6.西药类：（13）西药费：_____（抗菌药物费用：_____）

7.中药类：（14）中成药费：_____（15）中草药费：

8.血液和血液制品类：（16）血费：_____（17）白蛋白类制品费：_____（18）球蛋白类制品费：

（19）凝血因子类制品费：_____（20）细胞因子类制品费：

9.耗材类：（21）检查用一次性医用材料费：_____（22）治疗用一次性医用材料费：

（23）手术用一次性医用材料费：

10.其他类：（24）其他费：

说明：（一）医疗付费方式　1.城镇职工基本医疗保险　2.城镇居民基本医疗保险 3.新型农村合作医疗 4.贫困救助　5.商业医疗保险　6.全公费　7.全自费　8.其他社会保险　9.其他

（二）凡可由医院信息系统提供住院费用清单的，住院病案首页中可不填写“住院费用”。

Source: Ministry of Health (2011)

Appendix C China Healthcare Quality Indicators System (CHQIS)

Category	1st level indicator	2nd level indicator
Inpatient death-related	1.1 Inpatient mortality rate	2.1 Neonatal mortality rate
		2.2 Neonatal mortality rate according to category of birth weight
		2.3 Neonatal mortality rate according to category of birth weight- directly admitted
		2.4 Neonatal mortality rate according to the categories of birth weight- transferred admitted
	1.2 Operative mortality rate	2.5 Operative mortality rate for diagnosis-related group (DRG)
		2.6 Operative mortality rate for key surgeries
		2.7 Perioperative mortality rate
		2.8 Perioperative mortality rate for key surgeries
		2.9 Operative mortality rate for diagnosis-related group (DRG) with high death risk
		2.10 Operative mortality rate for diagnosis-related group (DRG) with low death risk
		2.11 Operative mortality rate for patients returned to operating theatre
		2.12 Operative mortality rate for patients returned to operating theatre in 24 hours, 48 hours and 72 hours
	1.3 DRG mortality rate	2.13 DRG mortality rate with high death risk
		2.14 DRG mortality rate with low death risk
	1.4 Mortality rate for key diseases	
	1.5 Rate of failed resuscitation	2.15 Rate of failed resuscitation for DRG
		2.16 Rate of failed resuscitation for surgeries
		2.17 Rate of failed resuscitation for key surgeries
		2.18 Rate of failed resuscitation for key diseases
Unplanned return-related	1.6 Rate of unplanned return to operating theatre	2.19 Rate of unplanned return to operating theatre in 24 hours, 48 hours and 72 hours
	1.7 Rate of unplanned return to ICU	2.20 Rate of unplanned return to ICU in 24 hours, 48 hours and 72 hours
Adverse events-related	1.8 Incidence of AEs	2.21 Incidence of AEs in surgical patients
		2.22 Incidence of AEs in DRG
		2.23 Incidence of AEs in key diseases
		2.24 Incidence of AEs in key surgeries
	1.9 Incidence of nosocomial infection	2.25 Incidence of pulmonary infection related to respiratory machines in ICU
		2.26 Incidence of blood infection related to central venous catheter (CVC) in ICU
		2.27 Incidence of urinary tract infection related to urethral catheter in ICU
		2.28 Incidence of blood infection rate related to peripherally-inserted central venous catheter (PICC)
	1.10 Rate of wound infection	2.29 Incidence of wound infection according to national nosocomial infection surveillance (NNIS)
		2.30 Incidence of wound infection in key surgeries
		2.31 Incidence of wound infection in key surgeries according to NNIS

Category	1st level indicator	2nd level indicator
		2.32 Incidence of wound infection for each surgeon according to NNIS
	1.11 Incidence of pressure ulcers	2.33 Incidence of pressure ulcers according to degree of severity of pressure ulcers

Source: Zhao, Liang et al. (2009)

Appendix D Review Form 1 (RF1)

Research number:____		
Age:____	Gender:____ (M/F)	Health insurance type:____ (1. Government insurance scheme 2. Basic medical insurance 3. Out of pocket 4. Others)
Ward:____	ICD (International Classification Diseases) of the index admission: _____	
Length of stay:___ (days)	Admission status: _____ (1. Emergent and Urgent 2. Elective 3. Transfer 4. Readmission)	
Summary of admission features:_____ _____		
Please assign a score for Quality of this medical record (from 1 to 5):____ 1. No information is available 2. Less information is available 3. About half information is available 4. Most information is available 5. All information is available		
Please tick the criteria you can find. 1. Unplanned readmission after discharge from index admission in 7 days 2. Unplanned readmission after discharge from index admission in 28 days 3. Hospital-incurred patient injury 4. Adverse drug reaction 5. Unplanned transfer from general care to intensive care or transfer from one unit to another unit 6. Unplanned transfer to another acute care hospital 7. Unplanned return to the operating theatre 8. Unplanned removal, injury or repair of organ during surgery 9. Other patient complications (AMI, CVA, PE, etc) 10. Development of neurological deficit not present on admission 11. Death case 12. Cardiac/respiratory arrest, low Apgar score 13. Injury related to abortion or delivery 14. Hospital-acquired infection/sepsis 15. Dissatisfaction with care documented in the medical record 16. Documentation or correspondence indicating litigation 17. Any other undesirable outcomes not covered above		
Status: Positive/Negative		

Reviewer number:

Please attach this form with medical record together, if the record needs to forward.

Appendix E Review Form 1 (RF1) -- Chinese version

<table>
<tr><td colspan="3">**研究编码**:_____</td></tr>
<tr><td>**年龄**:__（岁）</td><td>**性别**:____ （1 男/2 女）</td><td>**医疗保险类型**:____ （1. 公费医疗 2. 基本医保 3. 自费 4. 其他）</td></tr>
<tr><td colspan="2">**病房**:_____</td><td>**本次入院原因的 ICD 编码**: _____</td></tr>
<tr><td colspan="2">**住院天数**:___（天）</td><td>**入院方式**: _____ （1.急诊入院 2. 择期入院 3. 转院 4. 再入院）</td></tr>
<tr><td colspan="3">**住院摘要**: _____</td></tr>
<tr><td colspan="3">**请对这份病历的信息质量评分** （从 1 到 5，填写一个数字）:____
6. 不能得到任何信息
7. 能得到很少信息
8. 能得到一半信息
9. 能得到大部分信息
10. 能得到所有信息</td></tr>
<tr><td colspan="3">**这份病历是否存在下列某些情况（请在前面的格子内划√，可以多选）**
1. □ 在本次入院出院后，患者于 7 天内非计划再入院
2. □ 在本次入院出院后，患者于 28 天内非计划再入院
3. □ 患者在院内发生的损伤
4. □ 药物不良反应
5. □ 非计划地把患者从一般病房转到重症监护室和/或从一个科室转到另一个科室
6. □ 非计划地把患者转院
7. □ 非计划地重返手术室
8. □ 手术期间非计划地切除、损伤或修补组织和/或器官
9. □ 患者的其他并发症（急性心肌梗死、脑血管意外、肺栓塞，等）
10. □ 入院时不存在，但住院过程中发生的神经功能缺损
11. □ 死亡病历
12. □ 心脏骤停/呼吸骤停，阿氏评分低于 7 分
13. □ 与流产或分娩有关的损伤
14. □ 医院内感染
15. □ 病历中记载的患者对服务的不满
16. □ 证明患者提出诉讼的文件信件
17. □ 其它，以及不能确定的可疑的不良后果</td></tr>
<tr><td colspan="3">**状态（请在相应的格子内划√）**：
1 □ 可能存在负性事件（初筛阳性） 2 □ 不存在负性事件（初筛阴性）</td></tr>
</table>

初筛护士编号：_____

请将此表和病历放在一起

Appendix F Review Form 2 (RF2)

Research number:_____

1 Presence or absence of AE

1.1 **Any unintended injuries or complication presented** Yes/No

1.2 **The injury/injuries result in**: Temporary disability Yes/No

Permanent disability Yes/No

Death Yes/No

Prolongation of hospital stay Yes/No

Status: **presence/absence of AE(s)**

(If either or the two elements is not satisfied, the review process will stop. If both elements are satisfied, please continue the review process)

2 Causation

Answer the following questions before assign a score for causation

2.1 **Is there a note in the medical record indicating that they healthcare management caused the injury?** Yes/No

2.2 Does the timing of events suggest that the injury was related to treatment?

Yes/No

2.3 Is lack of diagnosis or delayed diagnosis is a recognised cause of this injury?

Yes/No

Please assign a score for the causation according to the causation confidence scale: ____

1= virtually no evidence for management causation

2=slight-to-modest evidence for management causation

3=management causation not likely, less than 50-50 but close call

4=management causation more likely than not, more than 50-50 but close call

5=moderate/strong evidence for management causation and

6=virtually certain evidence for management causation

(If the score is 1, the review process will stop. if the score is or greater than 2, the review process will continue.)

3 Impact and nature of AE

3.1 Where the AE happen? ____

(1.Operation theater 2.Treatment room 3. Ward 4. Lift/corridor 5. Others, please clarify)

3.2 ICD of the AE(s)? _____

3.3 What kind of disability arising from the AE? _____

(1.temporary disability 2.permanent disability 3.death)

3.4 How many extra bed-days attributed to the AE? ____ (days)

4 Preventability

4.1 Please answer the following questions before you assign a score

4.1.1 **If there are any human errors or violations?** Yes/No

4.1.2 **If the AE is caused by a system error?** Yes/No

If yes, please clarify what kind of error(s)? _____

4.2 Please assign a score now: ____

No Preventability

1=virtually no evidence for preventability

Low preventability

2=slight-to-modest evidence for preventability

3=preventability not likely, less than 50-50 but close call

High preventability

4=preventability more likely than not, more than 50-50 but close call

5=strong evidence for preventability

6=virtually certain evidence for preventability

4.3 Please provide your opinions about how to prevent this kind of AE and discuss the failure reasons as well.

_____

_____

Reviewer number:

Please attach this form with RF1 and medical record together

Appendix G Review Form 2 (RF2) -- Chinese version

研究编码_____

1. 判断负性事件的结果

1.1. **是否存在不应该出现的损伤或并发症**……..　　是 / 否

1.2. **这些损伤或并发症造成了**:　住院时间延长…….　　是 / 否

暂时的功能损失…….　　是 / 否

永久的功能损失…….　　是 / 否

死亡……..　是 / 否

状态:　1 □ 属于负性事件　　2 □ 不属于负性事件

如 1.1 和 1.2 任何一项不存在，结束该病历评价。如 1.1 和 1.2 都存在，继续下面的评价工作。

2. 负性事件原因分析

病历里是否有证据提示：

2.1. **患者损伤是卫生服务管理的原因造成的?** ……是/否

2.2. **负性事件与治疗服务不当有关?** ……..是/否

2.3. **负性事件与诊断不足或诊断延迟有关?** …….是/否

您认为证据的充分程度: ____ (选择 1-6 之间的某个数)

1= 很显然，没有证据表明患者损伤是卫生服务管理的原因造成的

2= 有轻度或中度的证据表明患者的损伤是卫生服务管理的原因造成的

3= 不太可能是卫生服务管理的原因，有不到一半的可能性

4= 可能是卫生服务管理的原因，可能性超过一半

5= 有中等或很强的证据表明患者的损伤是卫生服务管理的原因造成的

6= 很显然，有肯定的证据表明患者的损伤是卫生服务管理的原因造成的

如果评分是 1，就结束这个评价。如果评分等于或大于 2，请继续下面的评价工作

3. 负性事件的性质和影响

3.1. 这个负性事件是在什么地方发生的? ____

(1. 手术室 2. 治疗室 3. 病房 4. 电梯/走廊 5. 其他地点，请说明_____)

3.2. 负性事件的损伤部位 _____ **(ICD 编码)** _____, _____

负性事件的发生原因 _____ **(ICD 编码)** _____, _____

3.3. 这个负性事件给患者造成什么样的损伤? _____

(1. 暂时的功能损失 2. 永久的功能损失 3. 死亡 4. 没有损伤或死亡)

3.4. 这个负性事件让患者延长了多长时间住院日? ____ (天)

4. 负性事件的可预防性

4.1. 请先回答下面的问题

4.1.1. **这个负性事件是否涉及到人为错误或沟通问题?** 是/否

4.1.2. **这个负性事件是否由医院的某个系统的漏洞/失灵造成的?** 是/否

如果是，请具体说明_____

4.2. 请给出可预防性的评分：____ （选择 1-6 之间的某个数）

不可预防

1= 很显然，没有可预防的证据

可预防性很低

2= 有轻度或中度的可预防性证据

3= 不太可能有可预防性，有不到一半的可能性

可预防性很高

4= 有可预防的可能性，可能性超过一半

5= 有很强的可预防性证据

6= 很显然，有肯定的证据表明是可以预防的

4.3. 请写出你的观点，怎样预防这类负性事件，并讨论失败的原因.

_____

_____

_____

_____

复审医生编号：_____

请将此评价表与病历和 RF1 放在一起

Appendix H Interpretation of each screening criterion

Criterion	Interpretation
1. Unplanned readmission after discharge from index admission in 7 days	Unplanned readmission after discharge from index admission in 7 days for diagnosis-related group (DRG).
2. Unplanned readmission after discharge from index admission in 28 days	Unplanned readmission after discharge from index admission in 28 days for DRG.
3. Hospital-incurred patient injury	Any injury incurred in hospital, including wards, car park, canteen etc.
4. Adverse drug reaction	Any unexpected adverse drug reaction, not including reactions related to chemotherapeutics.
5. Unplanned transfer from general care to intensive care or transfer from one unit to another unit	Judgement based on the record of preoperative conference, physical examination at admission and diagnosis at admission.
6. Unplanned transfer to another acute care hospital	Patients with tuberculosis who were transferred to infectious diseases hospitals were not included.
7. Unplanned return to the operating theatre	Unplanned return to the operating theatre for DRG.
8. Unplanned removal, injury or repair of organ during surgery	Judgement based on the record of preoperative conference rather than consent forms signed by patients.
9. Other patient complications (AMI, CVA, PE, etc)	No specific requirements
10. Development of neurological deficit not present on admission	Judgement about neurological deficit not present on admission made based on the record of physical examination at admission.
11. Death case	All death cases were included. For obstetric patients, deaths of either mothers or neonates were included.
12. Cardiac/respiratory arrest, low Apgar score	Judgement made based on the record of resuscitations. Apgar score ≤ 7 considered as low.
13. Injury related to abortion or delivery	First degree perineal laceration and/or episiotomy not considered injuries during vaginal delivery.
14. Hospital-acquired infection/sepsis	No specific requirements
15. Dissatisfaction with care documented in the medical record	No specific requirements
16. Documentation or correspondence indicating litigation	No specific requirements
17. Any other undesirable outcomes not covered above	No specific requirements

Appendix I Ethical approval

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**14 December 2010**
Project Number:	**CF10/2209 - 2010001252**
Project Title:	**The study of adverse events in Chinese Hospitals**
Chief Investigator:	**Prof Shane Thomas**
Approved:	**From: 14 December 2010 to 14 December 2015**

Terms of approval

1. MUHREC has issued a Waiver of Consent for this research under the Statutory Guidelines on Research issued for the purposes of HPP1.1(e)(iii) abd 2.2(g)(iii) – *Health Records Act 2001 (Vic)*.
2. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
3. Approval is only valid whilst you hold a position at Monash University.
4. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
5. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
6. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
7. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
8. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
9. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
10. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
11. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
12. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

Cc: Dr Hui Yang; Ms Na Chen

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
[redacted]
ABN 12 377 614 012 CRICOS Provider #00008C

Appendix J Disease categories according to ICD-10

ICD-10 Category	Code range
I Certain infectious and parasitic diseases	A00 – B99
II Neoplasms	C00 – D48
III Diseases of blood and blood-forming organs and certain disorders involving the immune mechanism	D50 – D89
IV Endocrine, nutritional and metabolic disorders	E00 – E90
V Mental and behavioural disorders	F00 – F99
VI Diseases of the nervous system	G00 – G99
VII Diseases of the eye and adnexa	H00 – H59
VIII Disease of the ear and mastoid process	H60 – H95
IX Diseases of the circulatory system	I00 – I99
X Diseases of the respiratory system	J00 – J99
XI Disease of the digestive system	K00 – K93
XII Diseases of the skin and subcutaneous tissue	L00 – L99
XIII Diseases of the musculoskeletal system and connective tissue	M00 – M99
XIV Diseases of the genitourinary system	N00 – N99
XV Pregnancy, childbirth and the puerperium	O00 – O99
XVI Certain conditions originating in the preinatal period	P00 – P96
XVII Congenital malformations, deformations and chromosomal abnormalities	Q00 – Q99
XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	R00 – R99
XIX Injury, poisoning and certain other consequences of external causes	S00 – T98
XX External causes of morbidity and mortality	V01 – Y98
XXI Factors influencing health status and contact with health services	Z00 – Z99
XXII Coders for special purposes	U00 – U89

Source: WHO (2010)