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**A MIXED METHODS INVESTIGATION OF  
BEHAVIOURAL DETERMINANTS RELATING  
TO MEDICATION ERROR REPORTING BY  
HEALTH PROFESSIONALS IN THE UNITED  
ARAB EMIRATES**

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**MPharm, PgCert**

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## **ABSTRACT**

Improving the effectiveness and efficiency of medication error reporting is key to enhancing patient safety. The aim of this research was to explore medication error reporting in the United Arab Emirates (UAE), examining the attitudes, beliefs, behaviors and experiences of health professionals.

The first phase was a Joanna Briggs Institute registered systematic review of the beliefs, attitudes and experiences of health professionals relating to medication error reporting. Findings indicated the need for original research employing a mixed methods approach to quantify and generate in-depth information, grounded in theories of behaviour change.

In the second phase, a cross-sectional survey of health professionals in the UAE was conducted to determine the behavioural determinants and facilitators and barriers of medication error reporting. Principal component analysis of responses from 294 health professionals identified six components: knowledge and skills related; feedback and support related; action and impact related; motivation related; effort related; and emotions. Responses were neutral for the motivation and effort related components, but negative for the emotions component. Comparison of component scores identified that, nurses, females, those with greater experience and being older were more likely to be positive in their responses ( $p < 0.05$ ). In terms of emotions, the component with the lowest scores, older respondents with greater experience gave more positive responses ( $p < 0.05$ ).

In the final phase, face-to-face semi-structured interviews with 29 health professionals explored in-depth the behavioural determinants of medication errors reporting in the UAE.

The theoretical domains framework was employed in constructing the interview schedule and interpreting the findings. 'Goals' and 'intentions' were determinants which acted as facilitators while 'beliefs of the consequences', 'emotions', 'social influences and environmental context' were barriers.

This doctoral research has generated original findings which can support the development of interventions, based on behaviour change techniques, to enhance medication error reporting. These changes could impact at the levels of the organisation, health professional and patient.

**Keywords:** medication errors; systematic review; cross-sectional survey; interviews; theoretical domains framework; barriers; facilitators; the United Arab Emirates.

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## **Dedication**

I dedicate this thesis in memory of my mother (1961- 2007). Throughout my life, her voice has always whispered, 'you can do it'. She made so many sacrifices and emphasised the importance of education, shaping me into the person I now am. She would have been so proud in my completing a PhD.

## EXTERNAL OUTPUT

The doctoral research has resulted in the following outputs to date.

### Published peer reviewed papers

1. Alqubaisi M, Stewart D, Tonna A, Strath A. Health professionals' beliefs, attitudes and experiences of medication error reporting: a systematic review protocol. *The JBI Database of Systematic Reviews and Implementation Reports*. 2014; 12(10):109-120.
2. Alqubaisi M, Tonna A, Strath A, Stewart D. Behavioural determinants relating to health professional reporting of medication errors: a qualitative study using the Theoretical Domains Framework. *European Journal of Clinical Pharmacology* 2016; ;72:887-895.
3. Alqubaisi M, Tonna D, Strath A, Stewart D. Quantifying behavioural determinants relating to health professional reporting of medication errors: a cross-sectional survey using the Theoretical Domains Framework. *European Journal of Clinical Pharmacology* 2016; 72: 1401–1411.

The following paper is in development:

- A systematic review of health professionals' beliefs, attitudes and experiences of medication error reporting

### Peer reviewed conference abstracts

1. Alqubaisi M, Strath A, Tonna A, Stewart D. Health professionals' beliefs, attitudes and experiences of medication error reporting: a systematic review. (Poster presentation at Patient Safety & Quality Congress, Middle East, March 2014. Awarded second prize).
2. Alqubaisi M, Strath A, Tonna A, Stewart D. Health professionals' beliefs, attitudes and experiences of medication error reporting: a systematic review protocol (Oral presentation at the European Society of Clinical Pharmacy symposium, Copenhagen, Denmark, October 2014).



3. Alqubaisi M, Strath A, Tonna A, Stewart D. Exploring the attitudes, beliefs, behaviours and experiences of health care professionals in the United Arab Emirates on medication error reporting. (Poster presentation at the European Society of Clinical Pharmacy Conference, Lisbon, Portugal, October 2015).
4. Alqubaisi M, Strath A, Tonna A, Stewart D. Exploring the attitudes, beliefs, behaviours and experiences of health care professionals in the United Arab Emirates on medication error reporting (Poster presentation at BMJ International Forum on Quality & Safety in Healthcare in Gothenburg, Sweden April 2016).

## ABBREVIATIONS

BCTs	Behaviour change techniques
CINAHL	Cumulative Index of Nursing and Allied Health Literature
DARE	Database of Abstracts of Reviews of Effectiveness
HCPs	Health care professionals
HAAD	Health Authority Abu Dhabi
IOM	Institute of Medicine
IPA	International Pharmaceutical Abstracts
IQR	Interquartile range
JB	Joanna Briggs Institute
MASTARI	Meta-Analysis of Statistics Assessment and Review Instrument
MEDLINE	Medical Literature Analysis and Retrieval System Online
MHRA	Medicines and Healthcare Products Regulatory Agency
MOH	Ministry of Health
MRC	Medical Research Council
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
NRLS	National Reporting and Learning System
NPSA	National Patient Safety Agency
PCA	principal component analysis
PRISMA	Transparent Reporting of Systematic and Meta-Analyses
QARI	Quality assessment of five qualitative studies Abu Dhabi
RCUK	Research Councils United Kingdom
SEHA	Health Services Company
SEMP	Scottish Centre for Evidence-based Multi-Professional Practice
SPSS	Statistical Package for the Social Sciences
TDF	Theoretical Domains Framework
UAE	United Arab Emirates
UK	United Kingdom
US	United States
WHO	World Health Organization

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## **CHAPTER 1: GENERAL INTRODUCTION**

This chapter commences with an overview of the global emphasis on patient safety in all healthcare settings, followed by description of Reason's model of error causation. The term 'medication error' and associated terms are defined along with coverage of key systematic reviews. Attention is then paid to medication error reporting, with the overall aim of the doctoral research and the aims of the research phases stated.

### **1.1 PATIENT SAFETY**

#### **1.1.1 To Err is Human**

The United States (US) Institute of Medicine (IOM) in 1999 published the seminal report, 'To Err Is Human: Building a Safer Health System' which aimed to increase awareness of medical errors (errors in healthcare).<sup>1</sup> This report stimulated deeper examination of patient safety research and associated practices and has now been cited over 15,000 times in the academic literature. At the time of publication, it was described as 'groundbreaking', suggesting that 2-4% of all deaths in the US were attributed to medical errors.<sup>2</sup> The main content was based on the analysis of multiple studies which had been conducted by a variety of organisations, concluding that 44,000-98,000 people died each year as a result of preventable medical errors. The authors called for comprehensive, coordinated efforts by health care providers, governments, consumers and others to promote patient safety and set a minimum goal of 50 percent reduction in errors over the next five years. It was noted that preventing death and injury from medical errors would require dramatic, system wide changes and moving the focus from medical errors to patient safety.

The report recommended a four-tiered strategic approach to achieve a better safety record:

1. Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
2. Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organisations and practitioners to develop and participate in voluntary reporting systems.
3. Raising performance standards and expectations for improvements in safety through the actions of oversight organisations, professional groups, and group purchasers of health care.
4. Implementing safety systems in health care organisations to ensure safe practices at the delivery level.

It has been stated that the report impacted greatly the management of healthcare globally in that it 'brought the issues of medical error and patient safety to the forefront of national [and international] concern', attracting the attention of healthcare providers.<sup>3</sup>

### **1.1.2 Models of error causation**

While there are many different models and theories of error causation, the two which are described mostly within healthcare are 'the Swiss Cheese Model' and 'Human Error Theory'. Orlandella and Reason (1990) proposed the 'Swiss Cheese Model of system failure and accident causation, which has gained widespread acceptance in many fields including healthcare.<sup>4</sup> The principle behind this model is based on layered security as shown in Figure 1.1. This illustrates that, while many layers of defence lie between 'hazards' and 'losses' (accidents or errors), there are flaws in each layer that, if aligned, can allow the losses to occur.

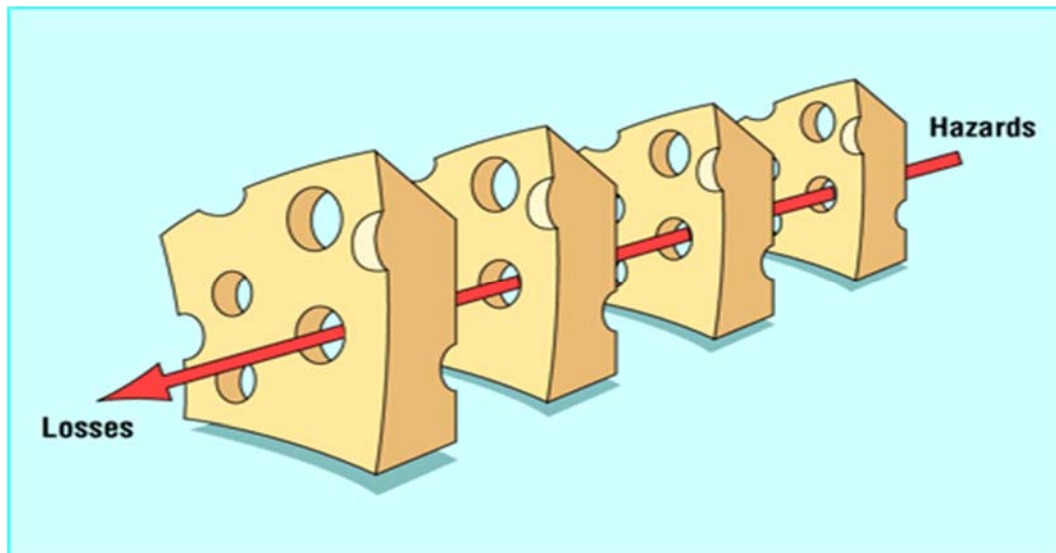


Figure 1.1: The 'Swiss Cheese Model' of how defences, barriers, and safeguards may be penetrated by an accident trajectory (adapted from Reason, 2000)<sup>5</sup>

Human error theory originated from the work of Reason (1990) in a range of industries including aviation and engineering.<sup>4</sup> Reason's human error theory has been applied widely to healthcare, considering institutional and strategic issues, influencing factors, unsafe acts and failed defences. The classification of errors based on a psychological approach is shown in Figure 1.2, highlighting four broad types of errors.



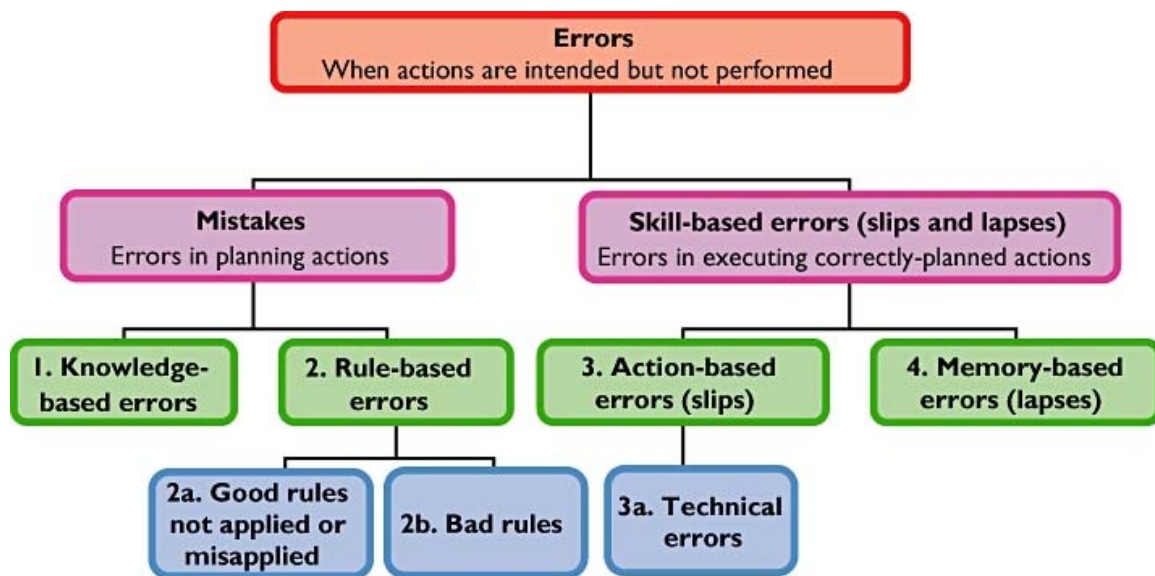


Figure 1.2: The classification of errors based on a psychological approach (adapted from Aronson et al, 2009)<sup>6</sup>

There are two broad categories of errors, which are mistakes and skill-based errors.

Mistakes are classified as:

- (i) knowledge-based errors, due to deficient knowledge (general, specific, professional)
- (ii) rule-based errors, the misapplication of a good rule or the failure to apply a good rule; and the application of a bad rule.

Failures of skill are classified as:

- (iii) action-based errors, 'slips', the performance of an action that was not what was intended
- (iv) memory-based errors, 'lapses', when something is forgotten.

## **1.2 MEDICATION ERRORS**

### **1.2.1 Definitions**

While 'To err is human' used the term 'medical errors', 'medication errors' is the term which is applied specifically to medication. The most widely used and accepted definition of the term 'medication error' is that of the United States (US) National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP). A medication error is defined as, 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the health care professional, patient or consumer'.<sup>7</sup>

The United Kingdom (UK) National Patient Safety Agency (NPSA) proposes a similar definition of 'any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicines advice, regardless of whether any harm occurred or was possible'.<sup>8</sup>

In a philosophical discussion on the construction of the term, Ferner and Aronson (2006) suggest a definition of 'failures in the treatment process that lead to, or have the potential to lead to harm to the patient'.<sup>9</sup> All definitions emphasise harm and prevention.

There is some overlap and often confusion between the terms 'medication error' and 'adverse drug reaction'. The United Kingdom (UK), Medicines and Healthcare products Regulatory Agency (MHRA) defines an 'adverse drug reaction' as 'a harmful and unintended reaction that occurs at a dose normally used for the prophylaxis, diagnosis or treatment of disease or the modification of physiological functions'.<sup>10</sup>

Those adverse drug reactions which are deemed preventable are also considered to be medication errors.<sup>11</sup>

Whatever the definition of 'medication error', it is clear that these greatly affect patient care. According to a report published by the US Institute of Medicine in 2006, medication errors accounted for 1.5 million injuries annually at a cost of up to \$1.35 billion in the form of lost productivity, wages, and additional medical expenses.<sup>12</sup> Data from the UK, collated and reported by the National Patient Safety Agency for the period from October 2010 to September 2011, illustrated that medication errors were the second most common cause of patient safety issues (following patient accidents) during hospital stay, contributing to 11% of all incidents, affecting 134,684 patients.<sup>8</sup>

The medication use process involves three key steps of prescribing, dispensing and administration of medication. These are generally considered to be the three classifications of medication errors and any errors arising during these processes are considered as medication errors, even if these are intercepted and corrected prior to reaching the patient (i.e. near misses).<sup>13</sup>

Prescribing errors are the most commonly occurring of all medication errors. Dean et al (2000) developed a comprehensive definition of the term 'prescribing error' using a consensus based approach.<sup>14</sup> The term 'prescribing error' is defined as, 'the result of a prescribing decision or prescription writing process that results in an unintentional but significant reduction in the probability of the treatment given being timely and effective or an increased risk of harm compared with generally accepted practice'. This definition encompasses the two distinct processes of decision-making and prescription writing.

The definition of a 'dispensing error' was proposed by Beso et al (2005) as, 'one or more deviations from an interpretable written prescription or medication order, including written modifications to the prescription made by a pharmacist following contact with the prescriber'.<sup>15</sup>

Keers et al (2013) proposed a definition of 'a medication administration error' as, 'a deviation from the prescriber's medication order as written on the patient's chart, manufacturers' instructions or relevant institutional policies'.<sup>16</sup>

### **1.2.2 Related systematic reviews**

This section provides an overview of published systematic reviews related to medication errors, as highlighted in Table 1.1. Emphasis is placed on the limitations of the primary studies reviewed. Key limitations of the literature in this area are: the lack of consistent terminology and definitions of 'medication', 'prescribing', and 'administration' errors; and often poorly defined outcome measures. Furthermore, Alsulami et al (2013) noted that there was a paucity of high quality research which originated from the Middle East and none of the systematic reviews covered medication error reporting,<sup>17</sup> which is the focus of this doctoral research.

Table 1.1 Summary of systematic reviews relating to aspects of medication errors

Authors, year of publication	Stated review aim	Search terms	Databases	Literature inclusion dates	Stated key limitations of literature
<b>Maisoon et al, 2006</b> <sup>18</sup>	To systematically locate and review studies that have investigated the incidence of medication errors (MEs) in pediatric inpatients and identify common errors	medication error(s), administration error(s), prescribing error(s), dispensing error(s), drug error(s), drug mistake(s), drug mishap(s), medication mistake(s), medication mishap(s), administration mistake(s), dispensing mistake(s), prescribing mistake(s), wrong drug(s), wrong dose(s), incorrect drug, incorrect dose, incorrect route of administration, and drug death, combined with the following key words: pediatric(s), paediatric(s), child, infant(s), adolescent(s), neonates(s), and neonatal.	Medline, Embase, Pharmline, International Pharmaceutical Abstracts, CINAHL, British Nursing Index	Varied depending on database, generally 1951-2006	1. Literature was hindered by variation in definitions employed by different researchers, varying research methods and setting. 2. Lack of theory-based research. 3. The initial concern about MEs in pediatrics was validated but the actual size of the problem remained unknown.
<b>Miller et al, 2007</b> <sup>19</sup>	To synthesise peer reviewed knowledge on medication errors in paediatrics	paediatric and medication errors, preventable adverse event	PubMed, Embase, CINAHL	2000 - 2005	1. The definition of medication error was non-uniform across the studies. 2. Dispensing and administration errors were most poorly evaluated. 3. Unique recommendations for strategies to reduce medication errors were identified; none were based on evidence.
<b>Ross et al, 2009</b> <sup>20</sup>	In order to inform the design of an educational intervention, a systematic review of the literature on prescribing errors made by junior doctors was undertaken.	prescribing adj4 error\$.tw, prescription adj4 error\$.tw, prescription or prescribing adj4 mistake\$.tw, drug adj1 error\$.tw, medication adj error\$.tw, adverse adj2 drug\$ adj2 event\$.tw, adverse adj2 drug\$ adj2 reaction\$, .tw, medication adj2 adverse adj2 event\$.tw, exp Prescriptions, Drug, exp Medication Errors, Patient Care, exp Physicians, exp Medical Staff, exp Hospitals, exp Primary Health Care, junior.tw, doctor\$.tw, medical staff.tw.	Medline, Embase, Science and Social Sciences Citation Index, CINAHL, Health Management Information Consortium, PsychINFO, ISI Proceedings, The Proceedings of the British Pharmacological Society, Cochrane Library, National Research Register, Current Controlled Trials	1990-2007	1. Considerable variation was seen in design, methods, error definitions and error rates reported.

<b>Lewis et al, 2009</b> <sup>21</sup>	To review the prevalence, incidence and nature of prescribing errors in hospital inpatients	error(s), medication error(s), near miss(es), preventable adverse event(s), prescription(s), prescribe, medication order(s), incident report(s), incidence, rate(s), prevalence, epidemiology, inpatient(s), hospital(s), hospitalization	Medline, Embase, CINAHL, International Pharmaceutical Abstracts	1985 - 2007	1. The reported rates of prescribing errors varied greatly due to variations in the definition of a prescribing error, the methods used to collect error data and the setting of the study. 2. Lack of standardization between severity scales prevented any comparison of error severity across studies.
<b>Alsulami et al, 2013</b> <sup>17</sup>	To review studies of the incidence and types of medication errors in Middle Eastern countries and to identify the main contributory factors involved.	Medication error(s), prescribing error(s), dispensing error(s), administration error(s), documentation error(s), transcribing error(s), medication mistake(s), drug mistake(s), prescribing mistake(s), dispensing mistake(s), administration mistake(s), transcribing mistake (s), wrong medication, wrong drug(s), wrong dose(s), wrong route of administration, wrong calculation(s), physician(s), pharmacist(s) and nurse(s)	Embase, Medline, Pubmed, the British Nursing Index, CINAHL	1980-2011	1. Most studies were of poor quality 2. There was a lack of standardisation of terms, methods and outcome measures.
<b>Keers et al, 2013</b> <sup>16</sup>	To systematically review and appraise empirical evidence relating to the causes of medication administration errors in hospital settings.	error(s), medication error(s), incident report(s), near miss(es), drug error(s), treatment error(s), medication safety, drug safety, preventable adverse event(s), adverse event(s), medical error(s), clinical incident(s), adverse drug event(s), adverse health care event(s), health care error(s), medication incident(s), cause(s), factor(s), reason(s), aetiology, etiology, causality, causalities, predictor(s), association(s) and drug/ medication/ medicine administration(s), dose/drug/medicine/medication preparation(s), drug/ medication/ medicine delivery, omission(s), drug utilisation, commission(s), drug/ medication/medicine supply, drug/medication/medicine handling	Medline, Embase, International Pharmaceutical Abstracts, ASSIA, PsycINFO, British Nursing Index, CINAHL, Health Management Information Consortium, Social Science Citations Index	1985-2013	1. Few studies sought to determine the causes of intravenous administration errors 2. Limited use of established error causation frameworks to analyse data and a focus on issues other than the causes of administration errors among studies.

<b>Metsala et al, 2014</b> <sup>22</sup>	To identify the types of medication errors which happen in elderly acute care.	pharmacy or drugs, medical error or deviation, elderly, nursing or acute care or intensive care	CINAHL, Medline, Cochrane, JBI Connect+ databases and Finnish healthcare databases Medic and Ohtanen	2001 -2011	1. Overall poor quality of studies included in the review
<b>Karthikeyan et al, 2015</b> <sup>23</sup>	To review studies of the incidence and types of medication errors and to identify the main contributory factors involved.	medication error(s), prescribing error(s), dispensing error(s), administration error(s), documentation error(s), transcribing error(s), medication mistake(s), drug mistake(s), prescribing mistake(s), dispensing mistake(s), administration mistake(s), transcribing mistake(s), wrong medication(s), wrong drug(s), wrong dose(s), wrong route of administration(s), wrong calculation(s), physician(s), pharmacist(s) and nurse(s)	Embase, Pubmed, EBSCO, Scopus, the British Nursing Index, CINAHL	Not stated	1. Limited number of studies 2. Lack of consistency in terminology of the studies included in the review
<b>Salmasi et al, 2015</b> <sup>24</sup>	To systematically identify and review research conducted on medication errors in Southeast Asian countries in order to identify common types of errors and estimate its prevalence in this region.	medication error(s), prescribing error(s), dispensing error(s), administration error(s), documentation error(s), transcribing error(s), medication mistake(s), drug mistake(s), prescribing mistake(s), dispensing mistake(s), administration mistake(s), transcribing mistake (s), wrong medication, wrong drug (s), wrong dose (s), wrong route of administration, wrong medication history taking, wrong calculation(s), physician(s), pharmacist(s) and nurse(s)	Embase, Medline, Pubmed, ProQuest Central and the CINAHL	Not stated	1. Lack of studies on errors in Southeast Asian countries
<b>Aldhwaihi et al 2016</b> <sup>25</sup>	To review published studies exploring the incidence and types of dispensing errors in hospital pharmacies and factors contributing to these errors.	Dispensing, Drug(s), Medication, Medicine(s), Error(s), Incident(s), Near miss(es), Mistake(s), Hospital, Secondary care, Inpatient, Outpatient, Pharmacy, Pharmacist, and Dispensary.	PubMed, Scopus, Ovid, and Web of Science	2000-2015	1. Limited number of studies 2. Lack of consistency in terminology

### 1.3 MEDICATION ERROR REPORTING

Effective and efficient medication error reporting systems and processes are key to promoting patient safety. Two key organisations within this field are the NCCMERP and the National Patient Safety Agency (NPSA) in the UK. Both the NCCMERP and the NPSA place much focus on medication error reporting. In 1995, the US Pharmacopeial Convention spearheaded the formation of the NCCMERP, the key role of NCCMERP is to lead 25 US national healthcare organisations collaborating and cooperating to address the interdisciplinary causes of errors and to promote the safe use of medication.<sup>26</sup>

The goals of NCCMERP are:

- i. Stimulating the 'development and use of reporting and evaluation systems by individual health care organizations'
- ii. Stimulating 'reporting to a national system for review, analysis, and development of recommendations to reduce and ultimately prevent medication errors'
- iii. Examining and evaluating the causes of medication errors
- iv. Increasing awareness of medication errors and methods of prevention throughout the health care system.
- v. Recommending strategies for system modifications, practice standards and guidelines, and changes in packaging and labeling.

The strategies stated for achieving these goals in relation to medication error reporting are to:

- i. Heighten awareness of reporting systems available to or within health care organizations
- ii. Stimulate and encourage reporting and sharing of medication errors both nationally and locally
- iii. Develop standardization of classification systems for the collection of medication error reports so that databases will reflect reports and categorization systems
- iv. Encourage systems and provide targeted feedback so that appropriate prevention strategies can be developed and implemented in facilities.



In the UK, the NPSA was established in 2001 to develop the National Reporting and Learning System (NRLS), to collect information on reported patient safety incidents aiming to reduce risks to patients receiving NHS care and improve safety. The NPSA describes 'tools and guidance to help organizations improve their reporting levels'.<sup>10</sup> These include:

- i. ensuring quality reports
- ii. engaging frontline staff and management
- iii. reporting regularly
- iv. reporting serious incidents quickly
- v. making reporting matter by reviewing the steps they can take to increase reporting and ensuring consistency

Adopting these tools and guidance into practice should increase reporting system efficiency with subsequent impact on the incidence, prevalence, nature and severity of medication errors thus improving patient safety and care.

## **1.4 HEALTHCARE IN THE UNITED ARAB EMIRATES**

### **1.4.1 Background**

This doctoral primary research was conducted in the United Arab Emirates (UAE), which comprises seven emirates: Abu Dhabi, Dubai, Fujairah, al-Qaywayn, al-Khaimah, Ajman and Sharjah (see Figure 1.3). The UAE neighbours Oman to the South East and North, and Saudi Arabia to the West and South. The UAE has one of the most well developed and wide ranging healthcare systems within the Asian region, aiming to meet the health needs of the society.<sup>27</sup> Hospital provision is a combination of private enterprises and government funded hospitals. According to the World Health Organisation (WHO), the government financial support for healthcare for the period 1999-2006 amounted to \$43 billion.<sup>28</sup> About 2.9% of the UAE's gross domestic product is spent on the healthcare, in line with WHO standards and recently free healthcare has been made available for all citizens.<sup>27</sup>

There are five government healthcare regulators: the Ministry of Health; Ministry of Finance; Federal Health Insurance Authority; Dubai Health Authority (DHA); and the Health Authority Abu Dhabi (HAAD). As of 2016, the population in the UAE was estimated at 9,266,971, of which Emirati nationals represented 19%, with the remainder being expatriates, predominantly from south and southeast Asia (around 60% of the UAE population), and western Europe (around 10%). (National Bureau of Statistics 2014) While Arabic is the official language, English is spoken widely, particularly within professional settings. There are currently 104 hospitals throughout the seven Emirates and the World Health Organization (WHO) reports that there are currently 19.3 physicians and 40.9 nurses and midwives per 10,000 persons.<sup>27</sup>



Figure 1.3 Map of the United Arab Emirates

#### **1.4.2 Medication error reporting in the UAE**

The policy of medication error reporting in UAE (Abu Dhabi) was established in May 2009 by the health authority of Abu Dhabi (HAAD) (Appendix 1.1). The purpose of the policy is to provide guidance for the health care professionals to take responsibility in medication error detection, reporting, evaluation, and prevention. The NCCMERP definition of 'medication error' has been adopted and all health professionals are mandated to report all medication errors, including those which have 'been detected and corrected through intervention by another health care professional or patient, before actual medication administration'.

## **1.5 MEDICAL RESEARCH COUNCIL FRAMEWORK**

Any intervention which are developed and implemented with the aim of enhancing medication error reporting is a 'complex intervention'. These are defined by the UK Medical Research Council (MRC) framework as 'interventions with several interacting components'.<sup>29</sup> The dimensions of complexity can be multiple, such as the:

- number of and interactions between components within the experimental and control interventions
- number and difficulty of behaviours required by those delivering or receiving the intervention
- number of groups or organizational levels targeted by the intervention
- number and variability of outcomes
- degree of flexibility or tailoring of the intervention permitted.

The MRC states that the process from development through to implementation of a complex intervention may take a wide range of different forms and emphasises the need for a good theoretical understanding of how an intervention could bring about change. The key elements of the development and evaluation process are illustrated in Figure 2.2.

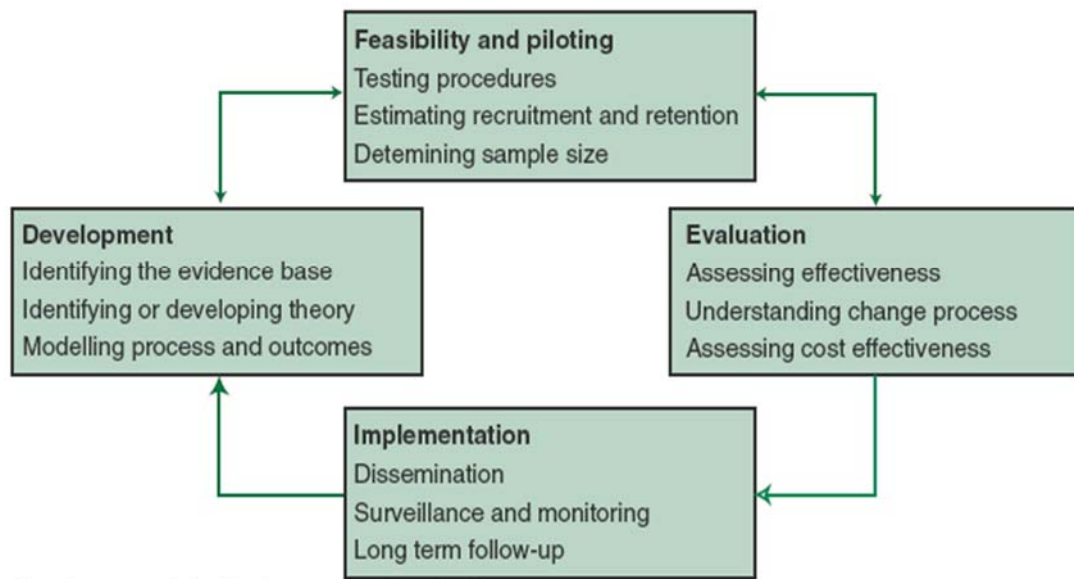


Figure 2.2: Elements of the development and evaluation process (adapted from Medical Research Council, 2008)<sup>29</sup>

This doctoral research focuses on the initial stages of the development of a complex intervention:

- Identifying the Evidence Base
- Identifying/Developing Appropriate Theory
- Modelling Process and Outcomes

## 1.6 STUDY AIMS

The overall aim of this research was to explore health professional reporting of medication errors in Abu Dhabi, the UAE, as a preliminary step to the development of interventions to improve and optimise the effectiveness and efficiency of medication error reporting thus impacting patient safety.

The research was conducted in three phases, each with aims as described below.

**Phase 1:** To critically appraise, synthesize and present the available evidence on health professionals' beliefs, attitudes and experiences of medication error reporting.

More specifically, the review sought to answer the following questions in relation to health professionals (i.e. doctors, nurses and pharmacists):

- What are their beliefs and attitudes towards medication error reporting?
- What are their experiences of medication error reporting? (e.g. nature of feedback obtained, any subsequent changes in their practice, ease of use of the reporting system, any improvements required to optimize medication error reporting).
- What are the reasons given or factors which are associated with under-reporting of medication errors? (e.g. lack of awareness or understanding of the reporting system, fear of possible consequences of reporting, and forgetting to report).

**Phase 2:** To quantify the behavioural determinants of health professional reporting of medication errors in Abu Dhabi, the UAE.

The detailed research questions were:

- Which behavioural determinants impact error reporting,? Which of these are facilitators or barriers to error reporting?
- Are there significant differences in behavioural determinants between demographic variables?

**Phase 3:** To provide more depth to and explain the quantitative findings. In particular, this phase aimed to describe and understand the behavioural determinants of health professional reporting of medication errors in the Abu Dhabi, the UAE.

The detailed research questions were:

- How do specific behavioural determinants impact error reporting?
- Why do specific behavioural determinants impact error reporting?
- Are there any differences between health professions?
- How could error reporting be improved and optimised?

## CHAPTER 2: METHODOLOGY

This chapter introduces research paradigms, methodologies and methods with justification for those selected for this doctoral research. Aspects of robustness in quantitative research and rigour in qualitative research are introduced, with emphasis on data validity, reliability, trustworthiness and bias.

### 2.1 RESEARCH PHILOSOPHY

There are four philosophical assumptions that impact the direction of all research:

1. **Ontology**, which relates to the nature of reality and its characteristics. Researchers embrace the idea of multiple realities and report on these multiple realities by exploring multiple forms of evidence from different individuals' perspectives and experiences;
2. **Epistemology**, how researchers know what they know. Researchers try to get as close as possible to participants being studied. Subjective evidence is assembled based on individual views;
3. **Axiology**, the role of values in research. Researchers make their values known in the study and actively report their values and biases; and
4. **Methodology**, the theoretical framework of the methods used in the research processes.<sup>30</sup>

#### 2.1.1 Philosophical paradigms

Fossey et al refer to a 'paradigm' as, 'a system of ideas, or world view, used by a community of researchers to generate knowledge'.<sup>31</sup> Bowling (2009) and Cresswell (2013) state that a paradigm is the 'process of scientific practice based on people's philosophies and assumption about the world and the nature of knowledge'.<sup>30,32</sup>



To ensure the most appropriate research design, the paradigm should be congruent with researcher beliefs in terms of the nature of reality.<sup>33</sup>

Research paradigms are traditionally classified into four philosophically distinct categories of positivism, constructivism, transformative and pragmatic. Each relates to accepted scientific frameworks, as illustrated in Table 2.1.

Table 2.1: Features of research paradigms (adapted from Guba and Lincoln 1990, Onwuegbuzie 2004, Bowling 2009, and Creswell 2013)<sup>32,34-37</sup>

	<b>Positivism</b>	<b>Constructivism</b>	<b>Transformative</b>	<b>Pragmatic</b>
<b>Ontology</b>	Naive realism. Researcher may not be able to understand it or get to it because of lack of absolutes	Relativism: local and specific constructed and co-constructed realities	Participation between researcher and communities/ individuals being studied. Often a subjective-objective reality emerges	Reality is what is useful, is practical, and 'works'
<b>Epistemology</b>	Reality can only be approximated. Interaction with research subjects is kept to a minimum. Validity comes from peers, not participants	Reality is co-constructed between the researcher and the researched and shaped by individual experiences	Co-created findings with multiple ways of knowing	Reality is known through using many tools of research that reflect both deductive (objective) evidence and inductive subjective) evidence
<b>Axiology</b>	Researchers' biases need to be controlled and not expressed in a study	Individual values are honoured, and are negotiated among individuals	Values need to be interrogated	Values are discussed because of the way that knowledge reflects both the researchers' and the participants' views
<b>Methodology</b>	Experiments/surveys Verification of hypotheses; chiefly quantitative methods	Researcher is a 'passionate Participant' within the world being investigated	Use of collaborative processes of research. Questioning of methods, highlighting issues and concerns	Research process involves both quantitative and qualitative approaches to data collection and analysis

This doctoral research was conducted in three specific phases aligned to the research aims. The field work of primary data collection and generation in phases two and three employed paradigms of positivism in phase two (cross sectional survey) and constructivism (phenomenological interviews) in phase three. The characteristics of these are given in Table 2.2.

Table 2.2: Summary of the distinct research paradigms employed in this research

Characteristic	Positivist	Constructivist
<b>Research approach</b>	Quantitative (deductive)	Qualitative (inductive)
<b>Research methodology</b>	Cross-sectional survey	Phenomenology
<b>Research instrument/tools</b>	Online questionnaire	In-depth semi-structured, face to face interviews
<b>Study sample</b>	Entire population studied. Detailed inclusion and exclusion criteria	Purposive sample
<b>Data analysis</b>	Descriptive and inferential analysis. Content analysis	Descriptive and framework approach

## 2.2 EVIDENCE SYNTHESIS THROUGH SYSTEMATIC REVIEW

The first phase of this research was a systematic review of the literature. This was conducted for several reasons: to identify and characterise gaps in the literature; to explore methodological strengths and weaknesses; and to inform later stages of the research. Furthermore, conducting systematic reviews is highlighted within the first stage of the MRC complex interventions framework described in Chapter 1.

The most commonly cited definition of evidence based practice is that of Sackett, ‘the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.’<sup>38</sup>

There is an accepted hierarchy of research evidence, with well-designed systematic reviews and meta-analyses of randomised controlled trials at the top of the pyramid as shown in Figure 2.1.



Figure 2.1: Hierarchy of evidence (adopted from Markman and Callanan 1984, Greenhalgh 1997)<sup>39,40</sup>

A systematic review is defined as a 'well-planned review to answer specific research questions using a systematic and explicit methodology to identify, select, and critically evaluate results of the studies included in the literature review'. Systematic review differs from more traditional (narrative) literature reviews in several ways, as described in Table 2.3.

Table 2.3 Comparison of narrative and systematic reviews (adapted from Cook et al, 1997)<sup>41</sup>

<b>Feature</b>	<b>Narrative review</b>	<b>Systematic review</b>
<b>Question</b>	Broad Scope, overview	Focussed, specific
<b>Search</b>	Not usually specified	Comprehensive and explicit
<b>Appraisal</b>	Variable	Robust and rigorous; checklist driven
<b>Synthesis</b>	Narrative only	Meta-analysis, meta-synthesis, narrative; answers question
<b>Inferences</b>	Sometimes evidence-based	Always evidence-based

Greenhalgh stated that systematic reviews have specific advantages as a result of using explicit methods. These include: limiting bias; generating reliable and accurate conclusions; delivering required information to healthcare providers, researchers, and policymakers; and generating new hypotheses about subgroups of the study population.<sup>40</sup>

Key characteristics of a systematic review are:

- a clearly defined question;
- an explicit, reproducible method with clear inclusion and exclusion criteria for studies;
- a systematic search that attempts to identify all studies that would meet the eligibility criteria;
- an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and
- a systematic presentation, and synthesis, of the characteristics and findings of the included studies, which includes the search methodology (adapted from Cochrane handbook)<sup>42</sup>

### **2.2.1 Systematic review organisations**

There are several public and private sector organisations, including the Cochrane Collaboration, Campbell Collaboration and the Joanna Bridge Institute (JBI), which have been established with the specific aim of supporting systematic reviews.

The Cochrane Collaboration produces systematic reviews of healthcare interventions based largely on quantitative evidence (although there are moves to extend to qualitative evidence) while the Campbell Collaboration produces systematic reviews on the effects of social interventions based on quantitative evidence. JBI, however, has a more pluralistic view of evidence on quantitative and qualitative evidence,<sup>43</sup> hence the systematic review in this doctoral research was registered with JBI.

JBI was founded in 1996 and is an international not-for-profit, research and development arm of the school of the translational science based within the Faculty of Health Sciences at the University of Adelaide in South Australia. JBI specialises in evidence-based healthcare, producing systematic reviews of healthcare practices with an interest in improving healthcare internationally.<sup>44</sup>

JBI collaborates with more than 70 entities across the world including affiliates such as the Scottish Centre for Evidence-based Multi-professional Practice,<sup>45</sup> based at Robert Gordon University. The SEMP's activities include training in conducting systematic reviews, promoting and supporting the synthesis, transfer, and use of evidence through identifying feasible, appropriate, meaningful, and effective healthcare practice to assist in the improvement of healthcare globally.<sup>45</sup> The doctoral student (principal investigator) undertook JBI training prior to conducting this review; the principal supervisor is also an accredited trainer with the JBI.

## **2.3 QUANTITATIVE VERSUS QUALITATIVE METHODOLOGIES**

Research methodologies are categorised as quantitative or qualitative (or mixed); key characteristics are provided in Table 2.4. Quantitative and qualitative research methodologies differ generally in their aim, research questions, objectives, data collection and generation instruments they use, and the forms of data they produce.<sup>46</sup>

Quantitative research has been described as, 'explaining phenomena by collecting numerical data that are analysed using mathematically based methods' and the data are usually collected to test a hypothesis, resulting in accepting or rejecting the null hypothesis of no difference<sup>35</sup> In contrast, qualitative research refers to inductive, holistic, subjective and process-oriented approaches to understand, interpret, describe and phenomena or to develop. It is a systematic, subjective approach used to describe life experiences and give them meaning.<sup>47,48</sup>

Phase two of this research employed a quantitative approach to quantify aspects of medication error reporting while a qualitative approach was employed in phase 3 to explore and describe the phenomenon of medication error reporting in greater depth.

Table 2.4: Comparison of qualitative and quantitative methodologies (adapted from Johnson and Onwuegbuzie 2004, Bowling 2009, Creswell 2013)<sup>32,35</sup>

Characteristic	Qualitative	Quantitative
<b>Research aim</b>	Focuses on providing a complete, detailed and rich description of the research topic	To quantify, classify, count, construct and test statistical models in an attempt to explain what is observed
<b>Design</b>	May be planned or emerge as the study unfolds	All aspects of the study are designed carefully before data are collected
<b>Sample</b>	Tend to be small sample sizes	Tend to be large sample sizes
<b>Data gathering, collection</b>	The researcher is the data-gathering instrument	The researcher uses tools (e.g. questionnaires, equipment) to collect data
<b>Form of data</b>	Data are in the form of words (interviews), pictures (videos) or objects (artifacts)	Data are in the form of numbers and statistics
<b>Data</b>	Qualitative data are more richer, time consuming, and should not be generalized	Quantitative data are more efficient, able to test hypotheses, but may miss contextual data

## 2.4 QUANTITATIVE METHODOLOGIES

The two main quantitative methodologies are those described as experimental and cross-sectional surveys. An experimental research design (correlational, causal) assumes that the cases being studied can be manipulated by the researcher in order to measure a change or a difference<sup>49</sup> These methodologies are described in Table 2.5.



Table 2.5: Quantitative research methodologies

Common quantitative methodologies	Description
<b>Survey</b>	Explores and describes phenomena in real-life situations to determine meanings and frequencies of the phenomenon under investigation, and describe and categorise information related to the phenomenon (Burns and Grove, 2011)
<b>Experimental (correlational)</b>	Explores relationships between variables to determine the degree of relationship between the two variables without introducing an intervention (Walker, 2005; Burns and Grove, 2011)
<b>Experimental (causal)</b>	The researcher manipulates an independent variable and observes the outcome on a dependent variable whilst keeping other unrelated variables constant (Walker, 2005)

Given the research aim of the phase two, the quantitative phase, a survey methodology was more appropriate. Creswell (2003) describes a survey design as one which 'provides a quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population'.<sup>34</sup> Survey design is used to make inferences about certain characteristics, and to make claims about the study population. Surveys are commonly used in research, largely due to the ease of use, structured format, easily coded and quantifiable data, and the ability to statistically compare cases. However, there are disadvantages due to many inherent biases (see later).

### 2.4.1 Survey data collection tools

The questionnaire is the most commonly used tool in survey research, with the two main formats being paper based and online. While the popularity of the online approach is increasing, there are several advantages and disadvantages to consider, as highlighted in Table 2.5.

The online approach was selected for phase two for reasons of lower cost, ease of distribution and data entry.

Table 2.6: Advantages and Disadvantages of e-mail Survey Methods  
(adapted from Wright, 2005)<sup>50</sup>

<b>Advantages</b>	<b>Disadvantages</b>
The cost of data collection is low	Possibility of problems of cooperation
Participants can access and save the responses in real time	The researcher may not probe the respondents for further information
The method is convenient for respondents due to self-administration	Possibility of failing to reach the response target

### 2.4.2 Sampling and data analysis in quantitative research

Garson (2012) describes sampling as the process of selection of a particular group of participants for a study, noting that collecting data from a target population does not necessitate researching all members of that population.<sup>51</sup> Probability sampling techniques are most commonly employed in quantitative research and are described in greater detail in Table 2.6. However, as described in Chapter 4, the entire population of health professionals was researched, without sampling.

Table 2.7: Probability Sampling (adapted from Morgan, 2008)<sup>52</sup>

<b>Probability Sampling</b>	<b>Procedure</b>	<b>Common Usage</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Simple random</b>	Selected from population according to chance. Each member has same probability of being selected.	Large, easily accessible populations.	High chance of being representative. Not much information about population required.	Can be inefficient, expensive.
<b>Systematic</b>	Similar to simple random sampling, but participants are chosen at specific intervals	Large, homogenous populations.	High chance of being representative.	Underlying patterns or non-random variations in the population can cause a sampling bias.
<b>Stratified</b>	Population is divided into homogenous subgroups, based on prior knowledge of the population, before randomly sampling from each subgroup.	Large, well-known populations.	More representative of population than simple random sampling, data can be more manageable, can control for regional differences in population size.	Requires accurate knowledge of subgroups and sizes.
<b>Cluster</b>	Similar to stratified sampling, but a sample of subgroups is first taken, and then samples within each selected subgroup are taken. Data is grouped according to subgroups, or 'clusters'.	Very large populations with known subgroups.	Often cheaper and more efficient than other techniques.	High chance of sampling error, a systematic bias in a particular cluster can influence the impression of the larger population.

## 2.5 QUALITATIVE METHODOLOGIES

Qualitative methodologies are viewed generally as ‘naturalistic’ or ethnographic, aiming to explore and explain the lived experience. Table 2.7 provides a comparison of the five methodologies most commonly employed in the qualitative, namely narrative, phenomenology, grounded theory, ethnography and case study methodologies.<sup>30</sup>

Table 2.8: Description of the five common qualitative methodologies (adapted from Czarniawska, 2004, Petty et al, 2012, Teddlie and Tashakkori, 2009 and Baxter and Jack, 2008)<sup>53-56</sup>

Methodology	Description
Narrative	Relates to spoken or written text of a single event or a series of events which are chronologically connected
Phenomenology	Provides an in-depth understanding of the distinctive lived experience of individuals by exploring the meaning of a phenomenon
Grounded theory	Attempts to develop a theory constructed from the data of participants with an experience of the phenomena under investigation, to explain these phenomena
Ethnography	Describes and interprets human cultures using methods such as participant-observation or interviews with the aim of getting an indepth understanding of a particular culture
Case study	Explores a case (or multiple cases) through in-depth data collection involving multiple sources of information rich in context

A qualitative, phenomenological approach was employed in phase three of this study. This was considered most appropriate to allow generation of in-depth, rich data to describe and understand participants’ experiences and behaviours of the phenomenon of medication error reporting.

### 2.5.1 Qualitative methods

Van Maanen (1983) defines qualitative methods as an array of interpretive techniques which seek to describe, decode, translate and otherwise come to terms with the meaning, not the frequency of certain more or less naturally occurring phenomena in the social world.<sup>57</sup> The three most common qualitative methods are the use of participant observation, focus group discussions and in-depth interviews.<sup>32,34</sup>

Given that medication error reporting could be a highly sensitive topic, one-to-one interviews were selected as the method.

The most common types of interview are structured, semi-structured and unstructured, as summarised in Table 2.8. A semi-structured approach was selected for phase three.

Table 2.9: Features of structured, semi-structured and unstructured interviews (adopted from Bowling, 2009)<sup>32</sup>

<b>Structured</b>	<b>Semi-structured</b>	<b>Unstructured</b>
Set of questions asked in a standard way across all participants	Specific topic areas and a general set of questions but the interview flows like a conversation and topics are covered as they come up	Topic area to be explored but what gets covered is left up to the participant. An opening question might introduce the topic
Fixed questions with fixed order	Open questions, order can vary	Non-directive in-depth interview
Control lies with researcher	Control lies with both researcher and participant	Control lies with participant
Data will be probably coded in advance	Data will be probably coded and analysed after each interview (iterative development)	Data will probably be coded and analysed after interview (iterative development)
Data generation tool: questionnaire	Data generation tool: interview schedule	Data generation tool: interview guide

### **2.5.2 Sampling and data analysis in qualitative research**

Qualitative research uses non-probability sampling as it does not aim to produce a statistically representative sample or draw statistical inference. Purposive sampling is one of the most common sampling strategies; it groups participants according to preselected criteria relevant to a particular research question.

Purposive sample sizes are often determined on the basis of theoretical saturation (the point in data collection when new data no longer brings additional insights to the research questions).<sup>58</sup> In this sense then generalizability is not sought by the researcher and the focus is less on sample size and more on sample adequacy.<sup>59</sup> Bowen argues that adequacy of sampling relates to the demonstration that saturation has been reached, which means that depth as well as breadth of information is achieved.

Francis et al (2010) described an approach to qualitative sample size determination as follows:<sup>60</sup>

- i. initial analysis sample - researchers should specify in advance the sample size at which the first round of analysis will be complete;
- ii. stopping criterion - researchers should specify in advance how many more interviews will be conducted, without new themes emerging, before the research team can conclude that the data saturation has been achieved (usually taken as three consecutive interviews);
- iii. independent coders - the initial analysis sample should be reviewed independently; and
- iv. the data saturation methods and findings should be reported so that the readers can evaluate the evidence.

Qualitative data analysis is a recursive process, where the researcher needs to move back and forth, as needed, to interpret and reinterpret the data throughout.<sup>55</sup> The Framework Approach is one of the broad families of analysis methods often termed thematic analysis or qualitative content analysis. It was developed by researchers, Ritchie and Spencer in 1980s and is used increasingly in healthcare research where the objectives and research questions are defined clearly in advance.<sup>61</sup>

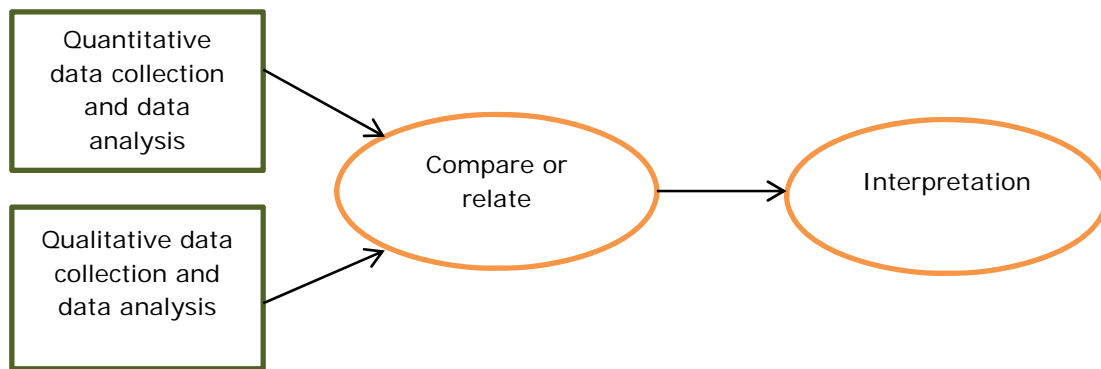
It is most commonly used for the thematic analysis of semi-structured interview transcripts and consists of steps of: familiarization; identifying a thematic framework; indexing; charting; and mapping and interpretation.<sup>62</sup>

## **2.6 MIXED METHODOLOGIES AND MIXED METHODS**

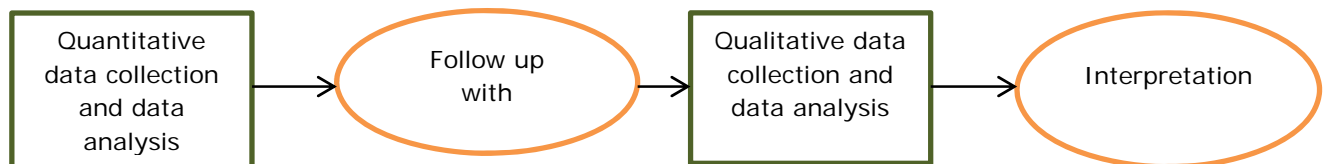
Many researchers such as Creswell (2003),<sup>63</sup> Thomas (2003),<sup>64</sup> and Krathwohl (1993)<sup>65</sup> have viewed quantitative and qualitative methodologies and methods as complementary and can be combined within one study.

A mixed method study has been defined as focusing on 'collecting, analyzing, and mixing both quantitative and qualitative data in a single study or series of studies'. The use of quantitative and qualitative approaches, in combination, provides a better understanding than either approach alone. There are four basic mixed methods designs, the convergent parallel design, explanatory sequential design, exploratory sequential design and the embedded design Creswell and Plano Clark (2011),<sup>66</sup> as illustrated in Figure 2.2

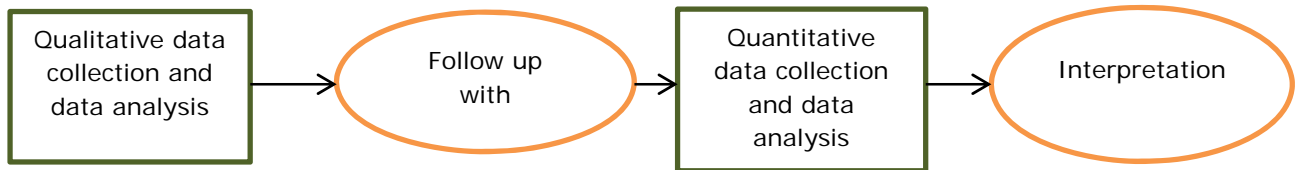
**(a) The convergent parallel design**



**(b) The explanatory sequential design**



**(c) The exploratory sequential design**



**(d) The embedded design**

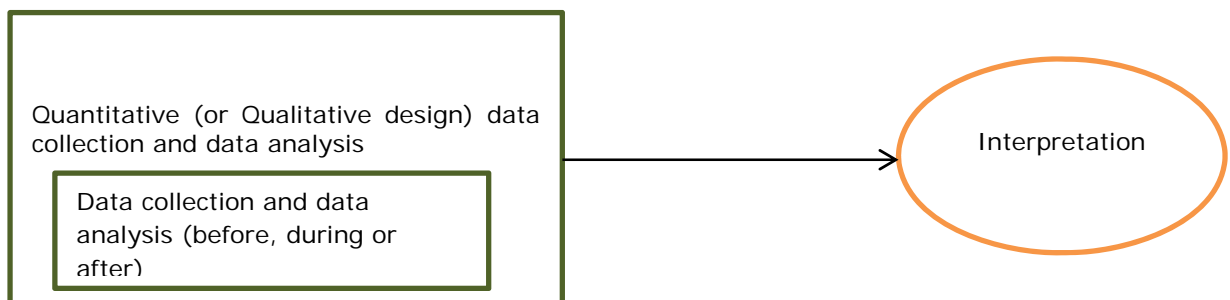


Figure 2.2: Mixed methods designs



Overall, this study employed a mixed methods sequential explanatory design, of survey (phase two) followed by in-depth, face-to-face interviews (phase three) with a purposively selected sample. The quantitative approach allowed collection of statistical data around facilitators and barriers to medication error reporting while the qualitative approach provided further explanation and rich data.

## **2.7 THE USE OF THEORY IN RESEARCH**

Theories are formulated to explain, predict, and understand phenomena and, in many cases, to challenge and extend existing knowledge. The theoretical framework introduces and describes the theory that explains why the research problem under study exists.<sup>67</sup> Theories can connect pieces of research data to generate findings which fit into a larger framework of other studies. The MRC complex interventions highlight the need to consider theory as part of intervention design.<sup>29</sup>

### **2.7.1 The Theoretical Domains Framework**

The Theoretical Domains Framework (TDF) was developed by a group of psychological theorists, health service researchers and health psychologists.<sup>68</sup> It is derived from 33 theories of behaviour change and comprises of 14 domains and 84 constructs that allows synthesis of a multitude of coherent behavior change theories into a single framework. TDF allows assessment and explanation of behavioral problems and associated barriers and enablers, and inform the design of appropriately targeted interventions.<sup>69</sup> TDF was applied throughout phases two and three. The TDF domains and their descriptors are outlined in Table 2.9.

Table 2.10: The Theoretical Domain Framework (adapted from Cane, O'Connor and Michie 2012)<sup>69</sup>

<b>Domain</b>	<b>Examples</b>
Knowledge	An awareness of the existence of something
Skills	An ability or proficiency acquired through practice
Social/Professional Role and Identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
Beliefs about Capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
Optimism	The confidence that things will happen for the best or that desired goals will be attained
Beliefs about Consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way
Goals	Mental representations of outcomes or end states that an individual wants to achieve
Memory, Attention and Decision Processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
Environmental Context and Resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours
Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event
Behavioural Regulation	Anything aimed at managing or changing objectively observed or measured actions

## **2.8 ROBUSTNESS AND RIGOUR**

### **2.8.1 Robustness in quantitative research**

The traditional criteria to achieve the goal of robustness in quantitative research are internal validity, external validity and reliability.

Validity is referred to as, 'the accuracy and truth of the data being produced in terms of the concepts being investigated'.<sup>70</sup> The internal validity is concerned with the confidence placed in the processes and data collected, and external validity (generalizability) of the findings.<sup>71</sup> While there are a number of different approaches to determining validity (e.g. face, content, construct, criterion, concurrent, predictive etc.)<sup>32,72-74</sup> those employed in this study were face and content. Face validity considers the extent to which the tool (questionnaire) covers the concept it purports to measure in terms of transparency or relevance. Content validity considers the extent to which the tool represents all facets of a given construct.<sup>75</sup>

Reliability is referred to as, the extent to which results are consistent over time.<sup>76</sup> While there are several approaches to determining reliability of the tool (e.g. test-retest validity), these could not be applied due to the online nature of the method of data collection. Internal consistency was determined (see later).

### **2.8.2 Rigour in qualitative research**

Guba 1981, proposed four criteria that need to be considered by qualitative researchers in pursuit of a trustworthy study,<sup>77</sup> as described in Table 2.11.

Table 2.11: Components of trustworthiness (Adapted from Guba 1981, Hasson and Keeney, 2011; Farrelly, 2013)<sup>36,70,71,77</sup>

Trustworthiness	Description
<b>Credibility</b>	Ensuring that findings are an accurate reflection of a wider reality by: employing well-established methodologies and methods; providing detailed description of the phenomenon under investigation; encouraging participant honesty through direct instructions, developing rapport, and giving opportunities for withdrawing from the study; and meeting with team members frequently for debriefing sessions and peer review
<b>Dependability</b>	Similar to reliability, described as the extent to which similar findings if the study were repeated with the same methods etc.
<b>Transferability</b>	Similar to external validity (generalisability) and is described as the extent to which the findings can be applied to other contexts and settings. Achieved by providing detailed information so that readers can judge the applicability of the study to their own setting etc.
<b>Confirmability</b>	Relates to the basis of the findings, and the extent to which they have arisen from data gathered rather than the biases and preconceived notions of the researcher, team etc.

### 2.8.3 Bias as a threat to validity, reliability and trustworthiness

Research bias arises when 'systematic error is introduced into sampling or testing by selecting or encouraging one outcome or answer over others'.<sup>78</sup> Quantitative, qualitative and mixed methods studies have particular methodological issues and constraints hence there is potential for bias. There are different forms of bias; the most common categories of bias are described in Table 2.12.

Table 2.12: Forms of bias (Adapted from Bowling 2009)<sup>78</sup>

Type of bias or error	Description
<b>Acquiescence response set</b>	Participants will more frequently endorse a statement than disagree, <i>'yes-saying'</i>
<b>Design bias</b>	Faulty methods, sampling and analysis
<b>Evaluation apprehension</b>	Participant anxiety may lead to giving responses which they think are expected
<b>Interviewer bias</b>	The interviewer may subconsciously, or consciously, bias by appearing to hold certain values or by asking leading questions
<b>Non-response bias</b>	Non-response reduces effective sample size. Differences between responders and non-responders reduces generalisability
<b>Recall (memory) bias</b>	Selective memories in recalling events
<b>Reporting bias</b>	Failure of the participant to reveal full information
<b>Sampling bias</b>	Non-representative selection of participants

Measures taken to minimize bias were considered and described throughout chapter 4 and 5.

## 2.9 SUMMARY

In summary, this chapter has presented many underlying methodological concepts which are applied in all phases of the research. The specific research methods are described in detail in Chapters 3, 4 and 5.

Figure 2.3 gives a schematic summary of the research paradigms, methodologies and methods employed for each phase of the research.

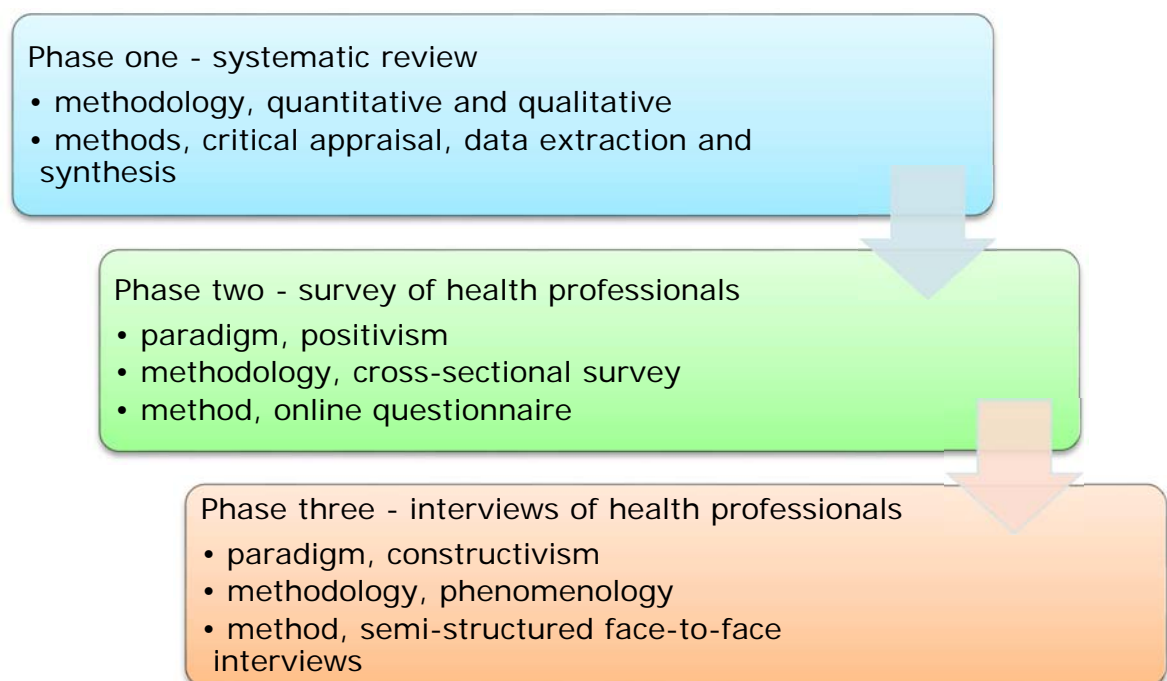


Figure 2.3: Methodological phases of current research

## **CHAPTER 3: A SYSTEMATIC REVIEW OF HEALTH PROFESSIONALS' BELIEFS, ATTITUDES AND EXPERIENCES OF MEDICATION ERROR REPORTING**

### **3.1 INTRODUCTION**

This chapter provides the aim, method, results and discussion of a Joanna Briggs Institute (JBI) registered systematic review of health professionals' beliefs, attitudes and experiences in relation to the medication error reporting.

As illustrated in Chapter 1, a number of systematic and narrative reviews have been published which focus on the incidence, nature and causes of medication errors (including classifications of prescribing, administration and dispensing errors). There is, however, a lack of any review which focuses on any aspect of medication error reporting by health professionals.

A preliminary search of the JBI Database of Systematic Reviews and Implementation Reports, the Cochrane Library and the Centre for Reviews and Dissemination revealed that there was neither a systematic review published nor underway on this topic. This indicates a major gap in the literature in terms of the beliefs, attitudes and experiences of health professionals in relation to medication error reporting. In order that error reporting systems operate efficiently and optimize their positive contribution to medication errors and thus patient safety, it is vital that all health professionals understand the reporting processes. This includes key components such as appropriate errors reporting and feedback at the individual practitioner and organizational level to allow reflection on and implementation of changes to practice to further improve patient safety.

This systematic review focused on these aspects and synthesized the available literature on issues of beliefs, attitudes and experiences, with specific attention to issues around under-reporting of medication errors by health professionals. At this stage, any studies, which focus on patient reporting of medication errors, were excluded.

### **3.1.1 Review aim and questions**

The aim of this review was to critically appraise, synthesize and present the available evidence on health professionals' beliefs, attitudes and experiences of medication error reporting.

More specifically, the review sought to answer the following questions in relation to health professionals (i.e. doctors, nurses and pharmacists):

- What are their beliefs and attitudes towards medication error reporting?
- What are their experiences of medication error reporting? (e.g. nature of feedback obtained, any subsequent changes in their practice, ease of use of the reporting system, any improvements required to optimize medication error reporting).
- What are the reasons given or factors which are associated with under-reporting of medication errors? (e.g. lack of awareness or understanding of the reporting system, fear of possible consequences of reporting, and forgetting to report).

## **3.2 METHODS**

A review protocol was developed according to best practice.<sup>79</sup> Following peer review within RGU, subsequent modification and further peer review within JBI, the protocol was registered with the JBI Database of Systematic Reviews and Implementation Reports and published.<sup>80</sup>



### **3.2.1 Inclusion criteria**

#### **Types of participants**

This review only considered studies that included health professionals, specifically doctors, nurses and pharmacists, as these are the health professionals involved in the patient medication journey and in the processes of prescribing of medicines (doctors, nurses and pharmacists all have prescribing rights in certain countries, e.g. the UK), administering medicines (all are involved) and dispensing medicines (all may be involved to some extent in different countries).

#### **Phenomena of interest**

While there was no intervention (as would be the case in reviews of effectiveness or cost-effectiveness), the qualitative component of this review considered studies that investigated the phenomenon of medication error reporting from a number of different health professional perspectives (i.e. doctors, nurses, pharmacists). The quantitative component considered studies (most likely survey-based) which measured attitudes and beliefs using tools such as Likert-type scales.

#### **Types of outcomes**

This review only considered studies which reported beliefs, attitudes and experiences of health professionals (doctors, nurses, pharmacists) in relation to medication error reporting.

## **Types of studies**

This review considered any research design (quantitative, qualitative and mixed). Quantitative studies were included with outcomes around attitudes and beliefs, while qualitative with outcomes around attitudes, beliefs and experiences. Quantitative studies focused on observational (e.g. cross-sectional surveys to measure attitudes and beliefs using Likert type scales) and qualitative included ethnography, phenomenology and grounded theory studies most likely using either interview (e.g. structured, semi-structured, unstructured) and focus group approaches for data generation. No studies were excluded on the basis of the design or approach to data generation.

### **3.2.2 Search strategy**

The search strategy aimed to find published studies. A three-step search strategy was utilized in this review as follows:

1. An initial scoping search of MEDLINE and CINAHL was undertaken, using search terms of ['belief\*' or 'attitude\*' or 'experience\*'] and 'medication error reporting';
2. To ensure that all relevant papers were captured, the keywords, main title and abstract words/phrases were identified. Searches of all databases were undertaken. The search string was:

- a. 'medication error\*' or 'prescribing error\*' or 'transcribing error\*' or 'dispensing error\*' or 'administration error\*'

and

- b. 'report\*'

and

- c. 'health professional\*' or 'healthcare professional\*' or 'doctor\*' or 'general practitioner\*' or 'physician\*' or 'consultant\*' or 'nurse\*' or 'pharmacist\*'

and

- d. 'belief\*' or 'view\*' or 'experience\*' or 'opinion\*' or 'attitude\*';

- 3. The search string was applied with results and exceptions recorded. The reference lists of all identified papers were reviewed for additional studies. Studies were identified from the bibliographic databases described in Table 3.1.

Table 3.1 Scope of selected bibliographic databases

Searched databases	Scope
Medline	Medical Literature Analysis and Retrieval System Online, or MEDLARS Online is a bibliographic database of life sciences and biomedical information. It includes bibliographic information for articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care. it contains over 14 million records. <sup>81</sup>
Cumulative Index of Nursing and Allied Health Literature	CINAHL is the largest and most in-depth nursing research database. The CINAHL Plus with Full Text database provides full text for 734 journals, and indexing for 5,000 journals from the fields of nursing and allied health. <sup>82</sup>
International Pharmaceutical Abstracts	IPA is an online database produced in conjunction with the American Society of Health-System Pharmacists. It provides a comprehensive collection of information on drug use and development from 1971 to the current day. <sup>83</sup>
Embase	Embase is a biomedical and pharmacological database of published literature designed to support information managers and pharmacovigilance in complying with the regulatory requirements of a licensed drug. <sup>84</sup>
Scopus	Scopus is a bibliographic database containing abstracts and citations for academic journal articles. It covers nearly 22,000 titles from over 5,000 publishers, of which 20,000 are peer-reviewed journals in the scientific, technical, medical, and social sciences (including arts and humanities). <sup>85</sup>
Psycharticles	A robust database offering complete access to the full text of more than 80 landmark journals in behavioural science and related fields spanning education, nursing, business and neuroscience <sup>85,86</sup>
Cochrane Database of Systematic Reviews	Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care. <sup>87</sup>
JB1 Database of Systematic Reviews	The JBI Database of Systematic Reviews and Implementation Reports is a peer-reviewed, online journal that publishes systematic review protocols and systematic reviews of healthcare research following the JBI methodology. <sup>88</sup>
Database of Abstracts of Reviews of Effectiveness (DARE)	DARE, is focused primarily on systematic reviews that evaluate the effects of health care interventions and the delivery and organization of health services. <sup>89</sup>

All studies identified during the database search were assessed for relevance to the review aim and questions by two independent reviewers (principle researcher and principal supervisor). The full article was retrieved for all those that appeared to meet the inclusion criteria. A search of Google Scholar (online search engine) was undertaken to ensure that all relevant studies have been identified. Only studies published as peer reviewed papers were included; abstracts, conference proceedings and letters etc. were excluded. The search included peer reviewed studies published in English between 1992 and 2013 (i.e. a 20-year timeframe as the scoping search identified a body of literature published within that time period).

### **3.2.3 Assessment of methodological quality**

All studies identified during the database search were assessed for relevance to the review protocol based on information via the title, abstract and full study review by two independent reviewers.<sup>80</sup>

Quantitative papers selected for review were assessed by the two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the JBI Meta- Analysis of Statistics Assessment and Review Instrument (JBI-MASARI) (Appendix 3.1).

Qualitative papers selected for retrieval were assessed by the two independent reviewers for methodological credibility prior to inclusion in the review using standardized critical appraisal instruments from the JBI Qualitative Assessment and Review Instrument (JBI-QARI) (Appendix 3.2).

#### **3.2.4 Data collection**

Quantitative and qualitative data were extracted independently by the two reviewers from papers included in the review using standardized data extraction tools. The data extracted included specific details about the populations, study methods and outcomes of significance to the aim and specific review questions.

#### **3.2.5 Data synthesis**

It was considered that pooling of data derived from quantitative studies was likely to be inappropriate due to an observational study design; hence the findings were presented in narrative form including tables and figures to aid in data presentation where appropriate.

Qualitative research findings were, where possible, pooled using JBI-QARI. This involved the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings (Level 1 findings) rated according to their quality, and categorizing these findings on the basis of similarity in meaning (Level 2 findings). These categories were then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesized findings. Where textual pooling was not possible, the findings were presented in narrative form.

### 3.3 RESULTS

#### 3.3.1 Hits

Table 3.2 shows the number of 'hits' generated through applying the search string.

Table 3.2 Number of hits generated from applying the search string

1	medication error*	21,107
2	prescribing error*	1,402
3	transcribing error*	51
4	dispensing error*	899
5	administration error*	1,996
6 (types of medication errors)	1 or 2 or 3 or 4 or 5	14,704
7	health professional*	77,243
8	healthcare professional*	14,471
9	doctor*	109,064
10	general practitioner*	37,129
11	physician*	426,933
12	consultant*	30,933
13	nurse*	463,528
14	pharmacist*	58,247
15 (health professionals)	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	990,181
16 (reporting)	report*	2,092,366
17 (experiences etc.)	experience* or opinion* or view* or belief* or attitude*	1,190,547
18 (review questions)	6 and 15 and 16 and 17	724

### **3.3.2 Description of studies**

The Transparent Reporting of Systematic and Meta-Analyses (PRISMA) flowchart is given in Figure 3.1. Database searching yielded 724 titles, 100 of which were duplicates. Title, abstract and full paper screening resulted in 13 papers for critical appraisal. The 13 papers reported 13 studies; eight of these were quantitative in design (survey methodology) and five qualitative (methodology not stated but methods of focus groups (n=3) and semi-structured interviews (n=2)).



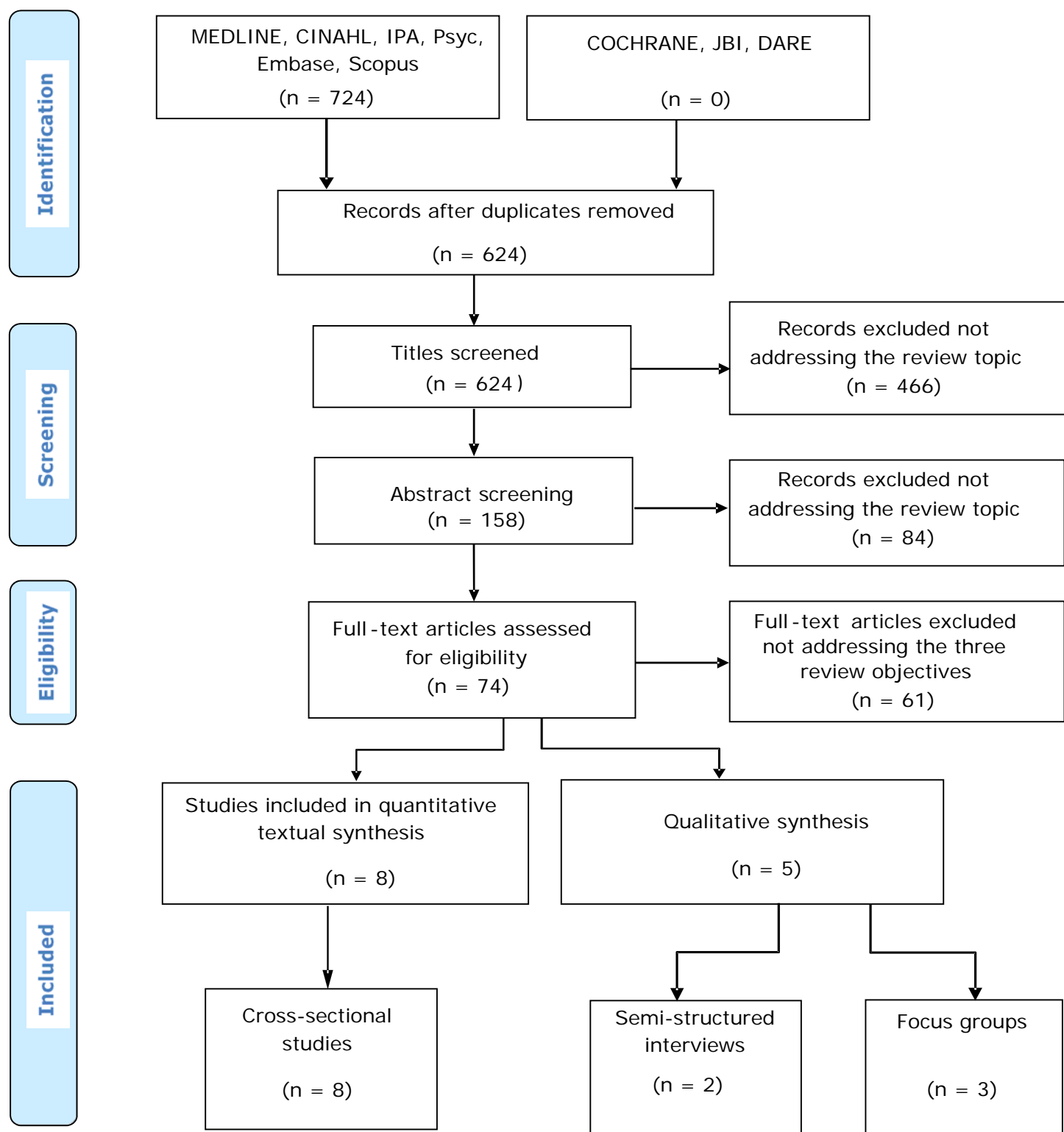


Figure 3.1 PRISMA flowchart for the search and study selection process

### **3.3.3 Methodological quality**

The methodological quality of the 13 studies, based on application of JBI MASTARI and JBI-QARI by the two independent reviewers, is reported in Tables 3.3 and 3.4.

The quantitative studies were generally robust with respect to all of the stated criteria. Limitations included the absence of clearly defined inclusion and exclusion criteria and any strategies to deal with confounders<sup>90</sup> Notably, the outcomes were measured using objective criteria with consideration of data validity. All quantitative studies were considered appropriate to include in the stages of data extraction and synthesis.

The key limitations of all five qualitative studies surrounded the absence of description of study philosophy (e.g. constructivism) and methodology (most presumed to be phenomenology since none included any aim around the generation of new theory as would be the case for grounded theory methodology or appeared to employ case study methodology). All studies were considered to be sufficiently rigorous to be included in data extraction and synthesis.

### **3.3.4 Data extraction**

Data extraction of these 13 studies is given in Tables 3.5 and 3.6 for the quantitative and qualitative studies respectively.

Table 3.3: JBI-MASTARI quality assessment of eight quantitative studies

<b>Criteria/ Author, Year</b>	<b>Wakefield et al (1999)<sup>91</sup></b>	<b>Stratton et al (2004)<sup>92</sup></b>	<b>Wild et al (2005)<sup>93</sup></b>	<b>Evans et al (2006)<sup>94</sup></b>	<b>Patrician et al (2009)<sup>95</sup></b>	<b>Sarvadikar et al (2010)<sup>96</sup></b>	<b>Chiang et al (2010)<sup>97</sup></b>	<b>Bahadori et al (2013)<sup>90</sup></b>
Was study based on a random or pseudo-random sample?	U	U	U	Y	Y	Y	Y	Y
Were the criteria for inclusion in the sample clearly defined?	Y	Y	Y	Y	Y	Y	Y	N
Were confounding factors identified and strategies to deal with them stated?	Y	Y	Y	Y	Y	Y	Y	N
Were outcomes assessed using objective criteria?	Y	Y	Y	Y	Y	Y	Y	Y
Was follow up carried out over a sufficient time period?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Were the outcomes of participants who withdrew described and included in the analysis?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Were outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y	Y	Y
Was appropriate statistical analysis used?	Y	Y	Y	Y	Y	Y	Y	Y

Y, yes; N, no; U, unclear; N/A, not applicable (cross-sectional design hence no follow-up)

Table 3.4: JBI-QARI quality assessment of five qualitative studies

<b>Criteria/ Author, Year</b>	<b>McArdle et al (2003)<sup>98</sup></b>	<b>Kingston et al (2004)<sup>99</sup></b>	<b>Sanghera et al (2007)<sup>100</sup></b>	<b>Hartnell et al (2013)<sup>101</sup></b>	<b>Williams et al (2013)<sup>102</sup></b>
There is congruity between the stated philosophical perspective and the research methodology	U	U	U	U	U
There is congruity between the research methodology and the research question or objectives	U	U	U	U	U
There is congruity between the research methodology and the methods used to collect data	U	U	U	U	U
There is congruity between the research methodology and the representation and analysis of the data	U	U	U	U	U
There is congruity between the research methodology and the interpretation of the results	U	U	U	U	U
There is a statement locating the researcher culturally and theoretically	N	N	Y	N	N
The influence of the researcher on the research, and vice versa, is addressed	U	U	U	U	U
Participants, and their voices, are adequately represented	Y	Y	Y	Y	Y
The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body	Y	Y	Y	Y	Y
Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data	Y	Y	Y	Y	Y

Y, yes; N, no; U, unclear

Table 3.5 Data extraction of quantitative studies

Authors, year	Specified aim/objective	Setting (country, institution)	Design	Participants	Key findings	Conclusion
Wakefield et al 1996	To analyse and assess nurses' perceptions of why medication administration errors may go unreported	United States (Iowa) Acute care hospitals	Cross-sectional survey	Nurses in 24 hospitals  No sample size stated; responses from 1384	Factor analysis revealed four factors explaining why may not report errors: fear; disagreement over whether an error occurred; administrative responses to errors; and effort required to report errors	Potential changes to systems and management responses could improve current practice  Changes need to take into account influences of organisational, professional and work group culture
Stratton et al 2004	To obtain nurses' reasons why medication administration errors are not reported	United States (Colorado)  Hospitals	Cross-sectional survey	No sample size stated; responses from 284 nurses	The fear of adverse consequences was the primary reason for not reporting errors	There is a need to explore both individual and systemic safeguards to focus on the reported causes and underreporting of errors

Wild & Bradley 2005	To suggest differing needs for training and other interventions to enhance error reporting	United States (Connecticut)  Community hospital	Cross-sectional survey	No sample size stated; responses from 24 residents and 36 nurses	<p>Fewer residents than nurses knew of and had used the reporting system</p> <p>Residents were less likely than nurses to report being comfortable discussing errors with supervisors and to rate the hospital administration as non-supportive of error reporting</p>	<p>Error reporting systems may give a biased picture of errors</p> <p>Hospitals may need to initiate other interventions to improve reporting</p>
Evans et al 2006	To assess awareness and the use of the current incident reporting system and to identify factors inhibiting reporting of incidents in hospitals	Australia (south)  Principal referral hospitals, major referral hospital, rural base hospitals	Cross-sectional survey	<p>263 doctors and 799 nurses in 6 hospitals</p> <p>773 responses, 72.8%</p>	<p>Most were aware of the reporting system</p> <p>More likely to report incidents which were habitually reported, often witnessed and associated with immediate outcomes</p> <p>Most frequently reported barrier to reporting was lack of feedback</p>	To improve incident reporting clarification is needed of which to report, the process should be simplified and feedback given

Patrician & Brosch 2009	To assess nurses' perceptions of the reasons for not reporting errors and the extent of underreporting	Assume United States, although not stated explicitly  One hospital	Cross-sectional survey	268 nurses in one hospital  43 responses, 16%	The top 5 reasons for not reporting were: perceptions that the administration focused on the individual and not the system; blame attributed; fear of adverse consequences; peer will consider the reporter incompetent; and error not important enough	A positive organisational culture, or perception thereof, prevents truthful reporting
Sarvadikar et al 2010	To investigate attitudes of health professionals in reporting medication errors	United Kingdom (Aberdeen)  Tertiary referral hospital	Cross-sectional survey	98 health professionals (doctors, nurses and pharmacists) surveyed  56 responses, 57%	Doctors were unlikely to report less serious errors  Nurses and pharmacists were likely to report less serious as well as serious errors despite fears of disciplinary action  All were more likely to report an error as clinical scenarios had worsening patient outcomes	There are differing attitudes to reporting errors hence different approaches are required to encourage reporting

Chiang et al 2010	To examine the factors that influence the failure to report medication adverse events by nurses	Taiwan (southern) Tertiary hospitals	Cross-sectional survey	1000 nurses in 5 hospitals  872 responses, 87.2%	The strongest predictors of not reporting were the experience of making errors, differences in attitude of reporting self and co-workers and perceived error rate	Educating nurses about the goals of reporting and using reporting data to enhance patient safety culture is recommended
Bahadori et al 2013	To study the factors influencing not reporting medication error, from nurses' viewpoints	Iran (Miandoab) University hospital	Cross-sectional survey	100 nurses in one hospital  83 responses, 83%	The most important reasons for not reporting were related to managerial factors, factors related to the process of reporting and fear of the consequences of reporting	Establishing a mechanism to improve quality rather than focus solely on finding the culprits and blaming them can result in improving patient safety



Table 3.6 Data extraction of qualitative studies

Authors, year	Specified aim/objective	Setting (country, institution)	Design	Participants	Key findings (level 1 themes)	Conclusion
McArdle et al 2003	To investigate doctors' attitudes and beliefs about medication error reporting	Assume United Kingdom, although not stated explicitly  One hospital	Semi-structured interviews	15 doctors of varying grades	Key themes were the importance of reporting, the use of the reporting process, fear of disciplinary action, loss of peer respect and lack of feedback	Errors should be a learning experience but only if relevant and timely feedback is given
Kingston et al 2004	To examine attitudes of medical and nursing staff towards reporting incidents (adverse events and near-misses), and to identify measures to facilitate incident reporting	Australia (Adelaide)  Metropolitan public hospitals	Focus groups	14 medical and 19 nursing staff in 5 focus groups conducted in 3 hospitals	Key themes were lack of knowledge, time constraints and complexity of the process, lack of feedback, culture of blame, and no value	Strategies to improve incident reporting must address cultural issues
Sanghera et al 2007	To explore the attitudes and beliefs relating to the reporting of medication errors	United Kingdom  Hospital intensive care unit	Semi-structured interviews	13 health professionals (doctors and nurses) who had committed a medication error	Key themes were not being aware an error had occurred, process of reporting, no benefit, motivational and cultural factors	Greater feedback on errors seems essential to improve current practice and increase reporting