Exploring medication error causality and reporting in the Middle East.

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EXPLORING MEDICATION ERROR CAUSALITY AND REPORTING IN THE MIDDLE EAST

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Exploring Medication Error Causality and Reporting in the Middle East

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"If you don't go after what you want, you'll never have it. If you don't ask, the answer is always no. If you don't step forward, you're always in the same place."

– **Nora Roberts**

Abstract

'Medication Without Harm, WHO Global Patient Safety Challenge', published by the World Health Organization in 2017 calls for action to reduce patient harm which occurs as a result of unsafe medication practices and medication errors. Medication error related research conducted within the Middle East has been noted to be of poor quality. The aim of this research was to investigate issues relating to medication error causality and suboptimal reporting of medication errors, with the intention of contributing to the development of theory informed interventions.

The first phase was a PROSPERO registered systematic review which aimed to critically appraise, synthesise and present the available evidence around the incidence/prevalence, nature and causes of medication errors amongst hospitalised patients in Middle Eastern countries. Findings indicated the lack of robust and rigorous research generally, and specifically in Qatar. There was a clear need to theory informed primary research.

The second phase collated data recorded in medication error reports submitted within Hamad Medical Corporation (HMC), Qatar. The estimated incidence of medication errors in HMC, as derived from medication error reports was 0.44 per 1,000 medication orders which is lower than previous studies published in the region and elsewhere. According to Reason's Accident Causality Model, the vast majority were considered as active failures (slips, lapses, mistakes and violations). One further key finding was the lack of details recorded in the reports hence limiting any synthesis and conclusions. Notably, behaviour change theories could not be applied, hence specific targeted research was warranted.

The third phase comprised qualitative focus groups with samples of health professionals in HMC to explore the perspectives of health professionals on issues of medication error causes and contributory factors, and error

reporting. Theoretical Domains Framework (TDF) determinants suggested as being potentially associated with these errors were: social/professional role and identity; emotions; and environmental context and resources. There was a lack of recognition of nurses' roles and frequent policy non-adherence. Stress was perceived to be a major contributor to errors, as was excessive workload and lack of staff at key times. Discussions on issues of medication error reporting identified a number of facilitators and barriers. The TDF domain of emotions featured heavily, with several key themes emerging as barriers to reporting: fear and worry; and likely investigation follow reporting; impact on evaluation and appraisal processes.

This doctoral research has generated original findings which can be used as part of intervention development aiming to improve medication safety and optimise medication error reporting system. Future work should now focus on the feasibility/piloting phase of the Medical Research Council guidelines on complex interventions.

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Appendix 3: Published paper	Publication: Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical domains framework: A mixed-methods approach.
Appendix 4: Published protocol	Publication: Incidence, nature and causes of medication errors in hospitalised patients in Middle Eastern countries: a systematic review protocol. PROSPERO 2015
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Peer-reviewed output

Published peer-reviewed papers
Thomas B, Paudyal V, MacLure K, Pallivalapila A, McLay J, El Kassem W, Al Hail M, Stewart D. Medication errors in hospitals in the Middle East: a systematic review of prevalence, nature, severity and contributory factors. European Journal of Clinical Pharmacology 2019;75:1269-1282. (Appendix) https://link.springer.com/article/10.1007/s00228-019-02689-y
Stewart D, **Thomas B,** MacLure K, Pallivalapila A, El Kassem W, Awaisu A, McLay JS, Wilbur K, Wilby K, Ryan C, Dijkstra A. Perspectives of healthcare professionals in Qatar on causes of medication errors: A mixed methods study of safety culture. PloS ONE 2018;13(9):e0204801. (Appendix) https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0204801
Stewart D, **Thomas B**, MacLure K, Wilbur K, Wilby K, Pallivalapila A, Dijkstra A, Ryan C, El Kassem W, Awaisu A, McLay JS. Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical domains framework: A mixed-methods approach. PloS ONE 2018;13(10):e0204987. (Appendix) https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0204987
Thomas B, Pallivalapila A, Al Hail M, El Kassem W, Al Saad D, Singh R, Stewart DC, Paudyal V, MacLure K, McLay JS. Incidence, nature and causes of medication errors in hospitalised patients in Middle Eastern countries: a systematic review protocol. PROSPERO 2015 CRD42015019693. (Appendix) https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=19693

Peer-reviewed conference abstracts
Thomas B, MacLure K, Wilbur K, Wilby K, Pallivalapila A, Dijkstra A, Ryan C, El Kassem W, Awaisu A, McLay JS , Stewart D. Incidence, nature and causes of Medication errors reported at the Hamad Medical Corporation. Accepted for presentation at the American Society of Health System Pharmacist, Los Angeles, December 2019 Link: https://midyear.ashp.org/-/media/midyear-conference/docs/2019/MCM19-Professional-Poster-Listing-by-PA-Last-Name.ashx?la=en&hash=F72958046FFEA2AB185ED18F69579B35A45F990F
Thomas B, MacLure K, Wilbur K, Wilby K, Pallivalapila A, Dijkstra A, Ryan C, El Kassem W, Awaisu A, McLay JS , Stewart D. Key stakeholders, perspectives on medication safety practices and error reporting in Qatar–an exploratory sequential mixed-method study presented at the 24th Congress of the EAHP - Hospital Pharmacy 5PSQ-096, (2019): A246-A246. DOI: http://dx.doi.org/10.1136/ejhpharm-2019-eahpconf.529 Link: https://ejhp.bmj.com/content/26/Suppl_1/A246.1.abstract
Thomas B, MacLure K, Wilbur K, Wilby K, Pallivalapila A, Dijkstra A, Ryan C, El Kassem W, Awaisu A, McLay JS , Stewart D. A qualitative study of the experiences and behaviors of health professionals around medication error causality and reporting at Hamad Medical Corporation, Qatar. Presented at the American Society of Health System Pharmacist, Orlando, 2017 Link: https://www.ashp.org/-/media/assets/meetings-events/docs/MCM17-Professional-Poster-Listing.ashx
Thomas B, Rouf PA, Al Hail M, El Kassem W, Singh R, Paudyal V, Maclure K, McLay J, Stewart D. Incidence, nature and causes of medication errors in hospitalised patients in Middle Eastern countries: A systematic review. Qatar Medical Journal. 2017 Jun 19;2017(3):1.

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Stewart D, Maclure K, Al Hail M, Singh R, Pallivalapila A, El Kassem W, **Thomas B**, Wilbur K, Wilby K, Awaisu A, Ryan C. Exploring Medication Error Causality and Reporting: A Cross Sectional Survey of Hamad Medical Corporation Health Professionals. In Qatar Foundation Annual Research Conference Proceedings Volume 2016 Issue 1 2016 Mar 21 (Vol. 2016, No. 1, p. HBPP2094). Hamad bin Khalifa University Press.

DOI: https://doi.org/10.5339/qfarc.2016.HBPP2094

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https://www.qscience.com/content/papers/10.5339/qfarc.2016.HBPP2094

Abbreviations

Abbreviations	
AHRQ	Agency for Healthcare Research and Quality
AKH	Al- Khor Hospital
ASHP	American Society of Health-System Pharmacists
AWK	Al-Wakra Hospital
BCT	Behavior change theories
CDSR	The Cochrane Database of Systematic Reviews
CINAHL	Cumulative Index of Nursing and Cumulative Allied Health Literature
CQMD	Corporate quality management department
CQPSC	Corporate quality and patient safety committee
EHR	Electronic Health Record
EQUATOR	Enhancing the QUAlity and Transparency Of health Research
GCC	Gulf Cooperation Council
GDP	Gross Domestic Product
HCP	Healthcare professional
HGH	Hamad General Hospital
HH	Heart Hospital
HMC	Hamad Medical Corporation
IHI	Institute for Healthcare Improvement
IMSN	International Medication Safety Network
IOM	Institute of Medicine

IQR	Interquartile range
IRS	Incident reporting system
JCI	Joint Commission International
MHRA	Medicines and Healthcare Products Regulatory Agency
MoPH	Ministry of Public Health
MSQC	Medication Safety and Quality Center
NAM	National Academy of Medicine
NCCCR	National Center for Cancer Care and Research
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
NHS	National Health Strategy
NICU	Neonatal intensive care unit
NPRP	National Priority Research Program
NPSF	National Patient Safety Foundation
P&T	Pharmacy and Therapeutic Committee
PHCCs	Primary health care centers
PI	Principal Investigator
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
PROSPERO	International Prospective Register of Systematic Reviews
QNRF	Qatar National Research Fund
QNV	Qatar National Vision
QP	Qatar Petroleum
QPS	Quality and Patient safety
RCT	Randomised controlled trials

RGU	Robert Gordon University
RH	Rumailah Hospital
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
TDF	Theoretical Domains Framework
UAE	United Arab Emirates
UK	United Kingdom
UK - MRC	United Kingdom Medical Research Council
USA/US	United States of America
WH	Women's Hospital
WHO	World Health Organization
WWRC	Women's Wellness and Research Center

Chapter 1 : Introduction

This chapter provides a description of the structure and key definitions within the field of patient safety culture and medication errors. There is a narrative review of the published, peer-reviewed literature on medication errors in terms of causality, incidence, severity and reporting. There is emphasis on patient safety, safety culture, medication errors and error reporting in the global context and within the State of Qatar, which was the setting for the primary research. The overall aim of the doctoral research is stated, along with the aims and research questions of each of the research phases.

1.1 Thesis structure

This thesis is presented in six chapters. As described above, **Chapter one** provides the background and context to the doctoral research.

Chapter two describes the methodological and theoretical framework underpinning various research phases of this study. This chapter gives justification for the philosophical and methodological stances adopted throughout. There is consideration of the selection of key methods and emphasis on the theoretical frameworks employed.

Chapter three is a systematic review which aimed to critically appraise, synthesise and present the available evidence on the incidence/prevalence, nature and causes of medication errors amongst hospitalised patients in Middle Eastern countries. The review adopted a theory driven approach based on Reason's Accident Causation Model, and a narrative approach to data synthesis. The need for the primary doctoral research is highlighted in this chapter, hence providing evidence of the original contribution to knowledge described in later chapters.

Chapter four presents the quantitative phase of the study, giving the research aim, methodology, methods, results and discussion. This phase

comprises a theory-informed analysis of medication errors reported in HMC as part of routine practice.

Qualitative research conducted in Qatar is presented in **Chapter five**, describing the research aim, methodology, methods, results and discussion. Given the lack of qualitative studies identified from the systematic review presented in Chapter 3, phenomenologically driven focus groups were conducted with groups of health professionals based at Hamad Medical Corporation (HMC), Qatar. The qualitative research was grounded in theories of behaviour and behavioural change to provide in-depth understanding and generate rich data.

Chapter six is the final discussion chapter which collates and considers the findings from all three research phases. Academic, societal and economic impact is described along with key areas of further research. Recommendations are stated to advance patient safety in Qatar and beyond.

Figure 1-1 Summary of the structure of the thesis

1.2 Patient Safety

With the publication of 'To Err Is Human' by the 'Institute of Medicine' (IOM) (now known as the National Academy of Medicine (NAM)) in 1999, the scale of harm associated with medical care in the United States of America (US) was quantified. The report generated great concern among healthcare organisations, key stakeholders, leaders and patients across the world. It estimated that each year preventable harm due to medical negligence accounted for almost 98,000 lives in USA hospitals alone. This led to greater focus on patient safety practices and research globally. (1)

The report called for comprehensive, coordinated efforts by governments, healthcare providers, consumers and others to promote patient safety, setting a minimum goal of 50% reduction in errors by 2004. Promoting patient safety in healthcare settings remains a global challenge, with an estimated one in ten patients being harmed whilst receiving care. (2,3) Medication errors and their consequences have major economic consequences with associated global costs of US$ 42 billion annually. (2,4)

In an effort to raise awareness of key concepts and strategies in patient safety, the World Health Organization (WHO) published 'Medication Without Harm, WHO Global Patient Safety Challenge' in March 2017. (2,3) The challenge calls for action to reduce patient harm which occurs as a result of unsafe medication practices and medication errors. (2,3) The goal is to 'gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years', specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems. The challenge has drawn international attention and commitment to develop interventions to improve all stages of the medication use processes including prescribing, dispensing, administering, and monitoring. (5) Accumulation of evidence confirms that healthcare professionals often prescribe, dispense and administer medication in ways and circumstances that may increase the risk of patient harm. (6-13) The WHO report places emphasis on the need to focus attention on organisational safety culture. (3,5,14)

1.3 Safety culture

While the terms 'organisational safety culture' and 'safety culture' have appeared in the health-related literature for many years, there has been a lack of clear definitions and understanding, with the two terms used interchangeably. In 1993, the 'Study Group on Human Factors' in the US defined organisational safety culture as, 'the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management'. (15)

Much later in 2015, the National Patient Safety Foundation (NPSF) of the US Institute for Healthcare Improvement (IHI) defined safety culture as, 'one in which health care professionals and leaders are held accountable for unprofessional conduct yet not punished for human mistakes; errors are identified and mitigated before they harm patients; and strong feedback loops enable frontline staff to learn from previous errors and alter care processes to prevent recurrences'. (16)

The Agency for Healthcare Research and Quality (AHRQ) in the US further defined patient safety culture as 'an extent to which beliefs, values, and norms shared by staff throughout the organization support and promote patient safety'. (17) A positive (or indeed negative) safety culture influences the behaviours, perceptions, attitudes and commitment of healthcare professionals towards improving patient safety.

The IOM identifies three core elements of a positive safety culture as, (17)

1. A belief that despite the high risk involved in healthcare processes, they can still be designed to prevent errors.
2. Organisations' commitment to detect and learn from errors.
3. Building a 'just' environment where disciplinary actions are taken only when an individual intentionally increases risk to patients or peers.

It is clear from all of these definitions and descriptions that a positive safety culture encompasses aspects of the shared beliefs, values and norms of healthcare staff and that these need to be rewarded, supported, expected and accepted.

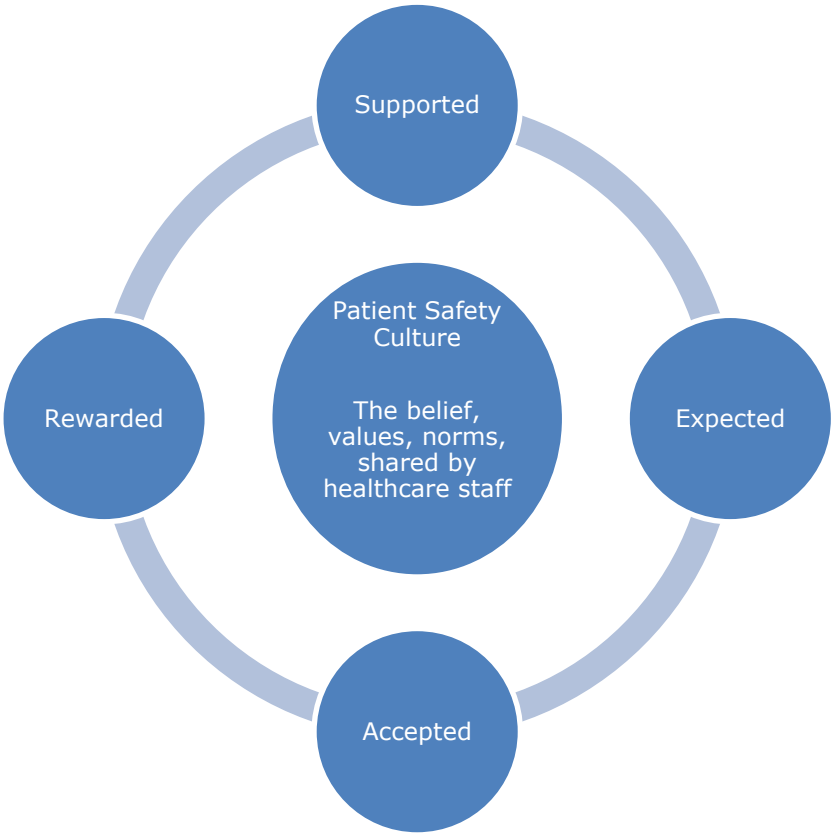


Figure 1-2 Schematic representing key components of safety culture

Several US based patient safety organisations lead developments in promoting a positive safety culture. These, and their aims, are described in Table 1.1.

Table 1-1 Key international organisations promoting safety culture

Organisation	Mission/ Aim
National Academy of Medicine (US) (18)	To improve health for all by advancing science, accelerating health equity, and providing independent, authoritative, and trusted advice nationally and globally
Joint Commission International (US) (3)	To improve patient safety and quality of health care in the international community by offering education, publications, advisory services, and international accreditation and certification
Institute for Healthcare Improvement (US) (4)	To improve health and health care worldwide
National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) (US) (19)	To maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting and promotion of medication error prevention strategies

Promoting a positive safety culture within healthcare organisations is anticipated to contribute significantly to the improvement of patient safety practices across the continuum of care through several factors such as leadership support, teamwork, evidence-based practice, good communication, just culture, learning and patient centred care. It is important that organisations adopt a 'just culture' (fairly balancing and understanding a system failure while observing a professional accountability) as opposed to a 'blame culture' (blame is centred towards an individual). (20)

This doctoral research focused on aspects of medication errors within the context of safety culture. Given the numerous terms contained within reports and publications, the following section defines key related terms and highlights those that are adopted throughout this thesis.

1.4 Medication error definitions and categories

There are many different definitions of the term 'medication error', as described in Table 1.2.

Table 1-2 Key definitions of 'medication error'

	Source	Definition(s)
Medication Errors	NCCMERP (19)	"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."
	AHRQ (21)	"A medication error is an error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication."
	NAM (22)	"Medication errors are events that may cause harm if inappropriate medication is used."
	UKMHRA (23)	"Any patient safety incidents where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines."
	Bates et al (24)	"Any error occurring in the medication use process."
	Ferner and Aronson (25)	"A failure in the treatment process that leads to, or has the potential to lead to, harm to the patient."

The most widely used definition is that of NCCMERP, 'any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer'. This definition has also been adopted by the WHO and IHI. This is also the definition which has been adopted by Hamad Medical Corporation (HMC), Qatar, the setting for the primary research.

As described in the NCCMERP definition, medication errors can occur at any stage of medication use processes. The focus of most of the published research on medication errors is illustrated in Figure 1.3.

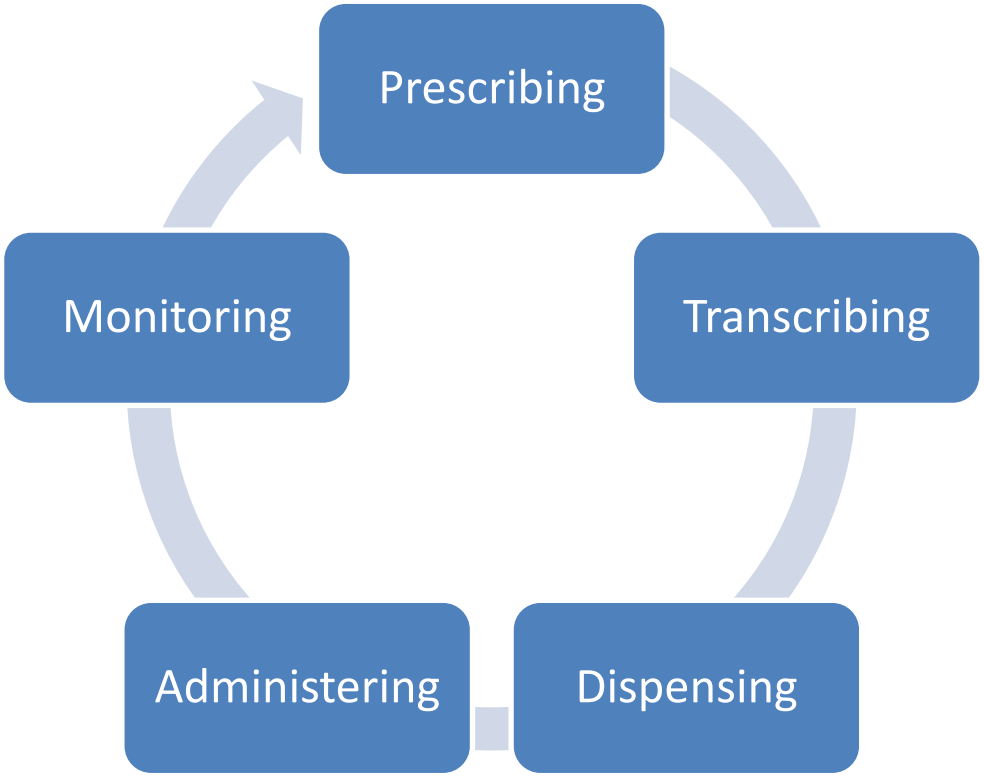


Figure 1-3 Stages of most focus of medication error research

While there are also many different definitions of categories of errors associated with each of these stages, the most commonly cited are given in Table 1.3.

Table 1-3: Key definitions of errors at different stages of the medication use process

Term	Definition
Prescribing error (10)	occurs 'as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or increase in the risk of harm when compared with generally accepted practice'
Transcribing error	'any deviation during the transfer of information from an order sheet to documentation forms or medication administration records'
Administration error (26)	"any deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies"
Dispensing error (11)	"to all errors occurring during the process of dispensing medication as included in the identified research papers, which are detected within the pharmacy (prevented dispensing incidents) and after the medication has left the pharmacy (un prevented dispensing incidents)"
Monitoring error(27)	when 'a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice'

1.5 Medication error reporting

While accepting that some medication errors are inevitable due to the many factors including nature of the processes, the dynamic environment of healthcare and the human component, it is essential that there are effective and efficient reporting processes and systems to facilitate rapid learning and changes in practice preventing further errors. This is important within the framework of safety culture.

Both the IOM and NCCMERP have strategic aims that highlight the value of effective and efficient medication error reporting systems and practices in reducing error prevalence and severity. (19,28) Two key goals of NCCMERP are to: stimulate the development and use of medication error reporting systems by healthcare organisations; and to stimulate the review and analysis of error reports leading to the development of recommendations to reduce, and ultimately prevent, errors. (19) The strategies stated for achieving these goals in relation to medication error reporting are to:

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

There is, however, evidence of widespread and significant under-reporting of medication errors by healthcare professionals. (20)

1.6 Narrative literature review

Given the large number of publications within the medication errors literature, this section presents the key findings of systematic reviews in the field of medication errors (and their subcategories) across the world, ending with a description of those originating from the Middle East.

Previous systematic reviews have highlighted the heterogeneity of studies in terms of error definitions, methods of measurement and outcome measures, (6,12,29-31) hence a narrative approach to data synthesis was selected a-priori.

The following method was used to search and review the literature.

The search was conducted using Cumulative Index of Nursing and Cumulative Allied Health Literature (CINAHL), Medline, PubMed and Science Direct. Search terms were (medication errors OR prescribing errors OR dispensing errors OR administration errors OR transcribing errors) AND (systematic reviews or meta-analysis). The period of the search was from 2008-2018, as the study team anticipated that, because an overwhelming majority of systematic reviews were published in the last 10 years that captured sufficient data on medication errors from all previous studies. The reference lists of all identified papers were also reviewed to identify additional studies. The data extraction tool was developed to extract the following: authors, year of publication, aim/objective, inclusion dates, and key findings in terms of incidence reported and the stated recommendations and limitations.

All systematic reviews that quantified incidence or prevalence of medication errors and/or provided information regarding causes or contributory factors associated with medication errors were included.

Systematic reviews published on specific mediations or solely on non-hospitalised patients (ambulatory care, outpatients, emergency etc.) were excluded from the review.

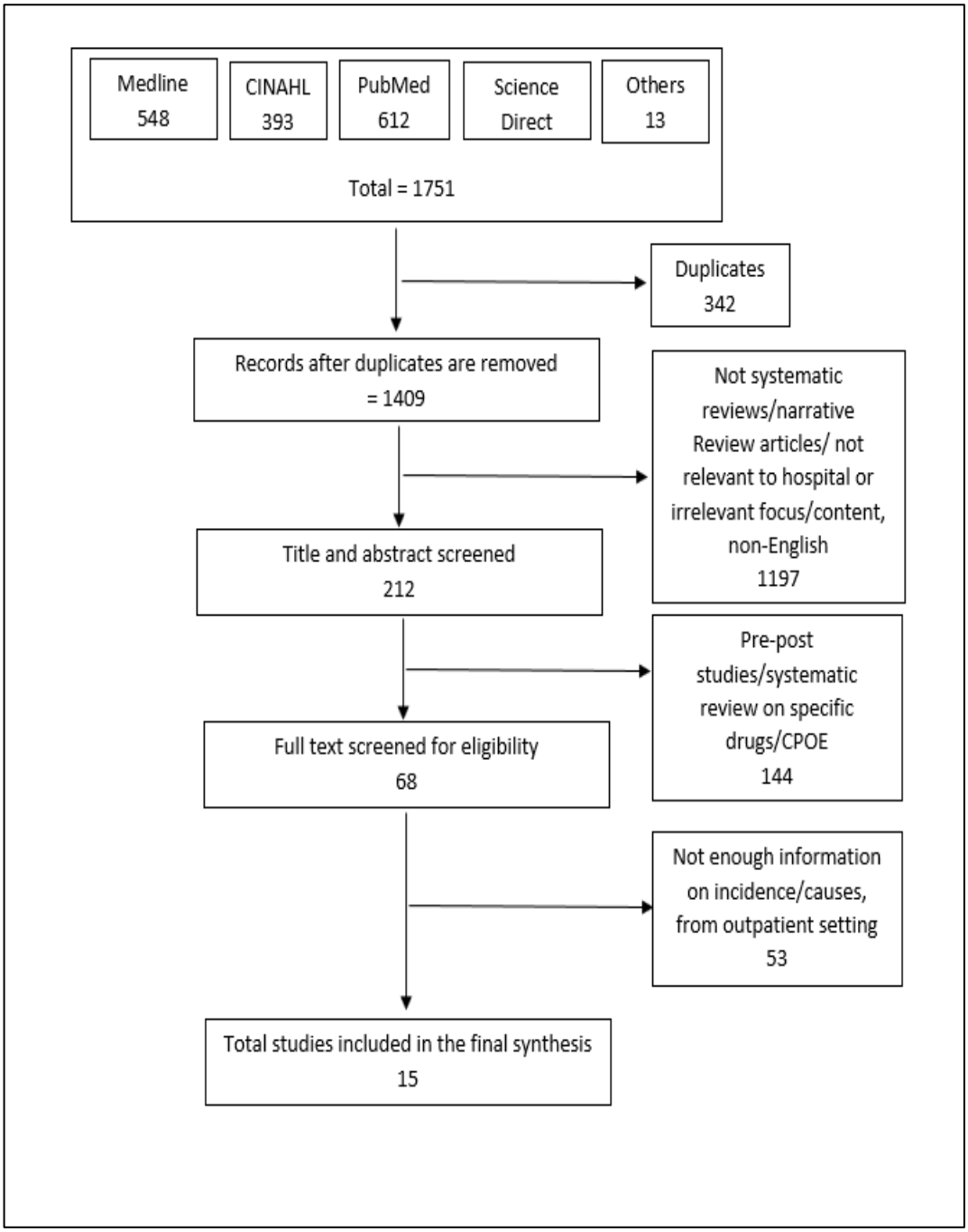


Figure 1-4 Summary of the structure of the thesis

Table 1-4: Data extraction of evidences from systematic reviews of medication errors

Evidence from systematic reviews of medication errors				
Author(s), publication year	**Stated review aim/objective**	**Literature inclusion dates**	**Key findings and reported incidence/prevalence/rate/ frequency/percentage**	**Stated key limitations and recommendations**
Alanazi, M. A. et al., 2016 (29)	To systematically investigate the literature regarding the prevalence and incidence of prescribing errors in high-risk medicines in inpatient settings.	1985 to May 2015	**Key findings** • 9 studies were included • Majority of the studies originated from western countries • Medication orders as denominator was most frequently used among the studies **Prevalence**: 0.24 to 89.6 per 100 orders	• Language limitations. • Small number of studies and low sample size makes it difficult to generalise. • There was heterogeneity in prescribing error definitions, and the use of and error severity scales.
Alshehri, G. H et al., 2017	To provide an up to-date and critical appraisal of the epidemiology and nature of medication errors and adverse drug events in this setting.	January 1999 to October 2016	**Key findings** • 20 studies were included • Medication errors were frequently associated with psychotropic and antipsychotic medications **Rate**: 10.6 to 17.5 per 1000 patient-days	• Studies identified heterogeneity in the denominator used, the population involved, and the outcome definition. Studies differed in data presentations and classification of drugs

Alsulami, Z., 2013 (30)	To identify and review studies of the incidence and types of medication errors in Middle Eastern countries and identify the main contributing factors.	Inception to October 2011	**Key findings** • 45 studies were included from 10/15 middle eastern countries • Majority of the studies were on prescribing errors followed by administration errors. • Poor knowledge of medicines was identified as a major contributory factor for errors • Majority of studies did not assess the severity of medication errors **Rate:** Prescribing error – 7.1 – 90.1% Administration error – 9.4 - 80%	• Might have missed some important studies as only studies in English language were included. • High data heterogeneity and different types of data reporting, interpretation, and classification systems were used.
Feinstein, M., et al., 2018	To determine the rate of medication error paediatric anaesthesia.	January 2004 to December 2018	**Key findings** • 22 studies were included • High heterogeneity among the articles included **Rate**: 0.08% (95% CI 0.05 -0.10%)	• Significant heterogeneity in definition among studies caused inconsistencies in measured outcome. • Majority of studies took place in academic hospitals which limits generalisability to private hospitals • Future studies should adhere to NCCMERP definitions to avoid inconsistencies
Gates PJ, 2018(32)	To review the incidence and severity of preventable adverse drug events (pADEs) resulting	January 2000 to December 2017	**Key findings** • 22 studies were included • Severity reported were mostly minor	• Heterogeneity among studies did not allow pooling of data and meta-analysis. • A strict inclusion criterion limited the number of studies

	from medication errors in paediatric inpatient settings.		**Incidence**: 0-17 pADEs per 1000 patient days or 1.3% of medication errors (of any type)	
J Alsaidan, 2018 (33)	To identify, summarise, review and evaluate published studies on medication errors, drug related problems and adverse drug events in the Gulf Cooperation Council countries.	1 January 1990 to 31 August 2016	**Key findings** • 54 studies were included • No qualitative studies • Prescribing errors were reported highest. **Incidence**: 8.5–16.9/100 admissions	• No quality threshold was in place for inclusion of studies. • Heterogeneity in definitions used did not allow pooling of data and meta-analysis. • Severity of harm caused due to medication errors was not assessed.
Keers, R. N., 2013 (12)	To systematically review and appraise empirical evidence relating to the causes of medication administration errors (MAEs) in hospital settings.	1985 to May 2013	**Key findings** • 54 studies were included • Causes of medication errors were categorised into Reason's model of accident causation. • Slips and lapses were the most commonly reported unsafe acts, followed by knowledge-based mistakes and deliberate violations. • Error Provoking conditions associated were poor documentation, heavy workload, and distractions etc., • Latent factors like cultural issues managerial issues were less well explored.	• Causes were described superficially, mostly related to quantitative surveys and observational studies. Limited used of qualitative studies or causation framework theories. • Only papers published in English language were selected, some relevant studies may have been missed. • More studies with theoretical pathways are needed to explore the multiple system factors linked to errors with emphasis on interventions designed to minimise medication administration errors.

Lewis, P. J 2009 (6)	To systematically review the prevalence, incidence and nature of prescribing errors in hospital inpatients.	1985 to October 2007	**Key findings** • 64 studies were included • Majority of the studies were from the university affiliated hospitals in UK and USA. • Most of the studies were carried out on adults. Data collectors were mostly pharmacists. **Error Rates -** 2–514 per 1000 items prescribed and 4.2–82% of patient charts	• Poor classification of errors among the studies. • Lack of standardization between severity scales made it impossible to compare results directly. • The lack of standardization between different studies, especially around definitions and data-collection methods, was a barrier to understanding the extent of prescribing errors
Matin, B. K, et al., 2018	To estimate the 1-year period prevalence of medication errors and the reporting rate to nurse managers among nurses working in hospitals in Iran.	January 2000 to May 2017	**Key findings** • 13 studies were included • High heterogeneity among the articles included **Period prevalence**: 53% (with a range of 17–88%)	• Results may not be generalizable to other countries.
Mekonnen, A. B 2018 (34)	To systematically investigate the literature on the extent of medication errors and adverse drug events, and the factors contributing to medication errors in African hospitals.	From inception to 31 August, 2017	**Key findings** • 51 studies were included • Prescribing errors were reported highest. • contributory factors reported were individual factors, and heavy workload **Percentage**: 8.4% ADE at hospital admissions	• No thematic analysis for causes of medication errors • Limiting the search to English language

Metsälä, E et al., 2013 (35)	Systematically reviewed studies to find out what kind of medication errors happen in elderly acute care.	2001 to 2011	**Key findings** • 20 studies were included • Most common causes of errors were nursing competency, prescription and patient related factors, organisational factors and culture	• Search was limited to studies published in English and Finnish only
Miller, M. R 2007 (36)	To synthesise peer reviewed knowledge on children's medication errors and on recommendations to improve paediatric medication safety by a systematic literature review	1 January 2000 to 30 April 2005	**Key findings** • 31 studies were included • Majority of the studies were from the university affiliated hospitals in UK and USA. • Most of the studies were carried out on adults. **Error Rates -** prescribing 3-37%, dispensing 5-58%, administering 72-75%, and documentation 17-21	• Differing definitions of numerator and denominator • Lack of consistent definition of medication errors • Poor methodology • Short data collection period • Poor generalisability of the data • Future research should use standardised definition, methodology and data collection.
Ross, S., 2008 (13)	A systematic review of the current published evidence to answer the research question 'how many prescribing errors are committed by junior doctors' was undertaken.	1990 to 2007	**Key findings** • 24 studies were included • Majority of the studies were from the hospitals in UK and USA and Canada. **Error Rates -** 2–514 per 1000 items prescribed and 4.2–82% of patient charts	• Considerable variation was observed in design, methods, error definitions and error rates reported. • Future research should be well constructed and generalizable using standard definitions and methods.

Salmasi, S et al., 2015 (37)	To systematically identify and review research done on medication errors in Southeast Asian countries in order to identify common types of medication errors and estimate its prevalence in this region.	From inception to December 2014	**Key findings** • 17 studies were included • Majority of the studies focussed on administration errors and prescribing errors • Staff shortages, heavy workload distraction, and misinterpretation of the prescription/medication chart were the main causes that lead to medication errors. • Only 41% of the studies were labelled as good quality. **Rate**: medication administration errors: 15.2 to 88.6% Prescribing errors: 7 - 35.4%	• No data related to incidence and nature of medication errors among half of the south east Asian countries. • Difficult to generalise the data as there is paucity of data from economically developed southeast Asian countries. • There was heterogeneity in approach to data collection. • Southeast Asian countries and suggests that a collective and standardized effort is needed to improve the reporting and documentation of ME with the aim of minimising the occurrence of such errors.
Tully, M. P., 2009 (7)	To identify all informative published evidence concerning the causes of and factors associated with prescribing errors in specialist and non-specialist hospitals, collate it, analyse it qualitatively and synthesize conclusions from it.	1985 to July 2008	**Key findings** • 16 studies were included • Majority of the studies were from the university affiliated hospitals in UK and USA. • Causes were grouped according to Reasons Model of Accident Causation. Active failures occurred mostly due to lack of knowledge with the medication or the patient. Error provoking conditions occurred mainly due to	• High data heterogeneity and different types of data reporting, interpretation, and classification systems were used. • Studies that used observational methods might be subjected to Hawthorne effect; studies with interviews might have had social desirability bias. • Further studies using in-depth qualitative interviews should be conducted in order to investigate the actual cause and

			lack of experience, heavy workload, fatigue, poor communication etc. Latent failure included reluctance to question senior administrators, inadequate training provisions etc. • Prescribing errors were multifactorial, and the most common types reported	multifactorial nature of error causation.

It is clear from these systematic reviews that medication errors (of all categories) are still highly prevalent and that there are a number of complex and inter-related causative factors. Notably, there have been no systematic reviews specifically on aspects of medication error reporting. Two of the systematic reviews described medication error studies conducted in the Middle East. (30) In 2013, Alsulami et al. published a systematic review of studies up to and including 2011 on the incidence and types of medication errors and main contributory factors in Middle Eastern countries. While noting that error rates were difficult to compare due to being expressed differently, prescribing errors ranged from 7.1% of prescriptions in a teaching hospital to 90.5% of prescriptions in a primary healthcare centre. Poor knowledge of medicines was identified as a contributory factor for errors by doctors and nurses. One limitation of this review was the lack of any theories of error causation in the synthesis stage. Furthermore, the review highlighted that published papers from Middle Eastern countries were relatively few and generally of poor quality. A later systematic review was published in 2018 summarising the incidence and nature of medication errors, drug related problem and adverse drug events reported among Gulf Cooperation Council (GCC) countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates). Almost all errors (91%) were related to prescribing issues in primary care facilities. The most common types of errors were dosing errors, error of omission and reconciliation errors.

1.7 Qatar

This section provides an overview of healthcare system in Qatar to provide context for the primary research.

Figure 1-5: Qatar

1.7.1 Demographics

Qatar is a sovereign Arab emirate occupying 11,571 km^2 of land in the Gulf of Persia and shares borders with Saudi Arabia to the west and United Arab Emirates to the south. (38) Qatar is one of the wealthiest and affluent countries in the world with Gross Domestic Product (GDP) per capita exceeding US $101,500. The economy largely depends on natural-gas and oil reserves. Data collated from Qatar's Ministry of Development Planning and Statistics reveals that of the 2.6 million inhabitants, only about 12% are native Qataris with the remainder being expatriates from neighbouring countries, notably India (20%), Nepal (13%), Philippines (10%), Pakistan (7%) and Sri Lanka (5%). Qatar is one of the fastest growing populations in the world and has an average life expectancy of 78.5 years (38-41).

1.7.2 Healthcare Delivery in Qatar

The first hospital in Qatar was opened in 1945, followed by the first state funded hospital (Rumailah Hospital) in 1957 with 157 beds. Hamad Medical Corporation (HMC), a non-profit health care provider, was established by decree from the Emir of Qatar in 1979 to provide medical facilities and treatment to the people of Qatar (42,43).

While the country predominantly relies on expatriate healthcare professionals to work in modern healthcare facilities, the government has invested in human resource development by encouraging, educating and training Qatari nationals and providing scholarship opportunities for pursuing careers in the healthcare sector (39,43). The quality of healthcare in Qatar is generally of a high standard and compares favourably to the standards of western countries. Over the last few years, the government has invested heavily in developing an 'ultra-modern healthcare sector'. A report from Alpen Capital (a financial advisory group) has noted that, in 2016, the healthcare spending growth in Qatar was highest in the Gulf region (44).

1.7.3 Qatar's National Health Strategy 2018-2022

The Qatar National Vision (QNV) 2030, published in 2008, is a long-term national strategy that guides economic, social, human and environmental reforms in the state of Qatar. 'Human Development' is one of the four pillars of the Qatar National Vision, which is strategically driven to guide Qatar's ambition to develop a healthy population through a National Health Strategy. The strategy outlines the commitment to building an integrated healthcare system to develop a world-class healthcare system and provide world-class treatment modalities and improve patient safety. The first strategy was launched in 2011 followed by an updated strategy in 2018. This is designed to meet the healthcare needs of current and future generations, to deliver comprehensive patient centred care through patient empowerment, teamwork, leadership and intelligence and thus embed a culture of patient safety and quality (45,46). There are,

however, several key healthcare related challenges as illustrated in Figure 1.5.

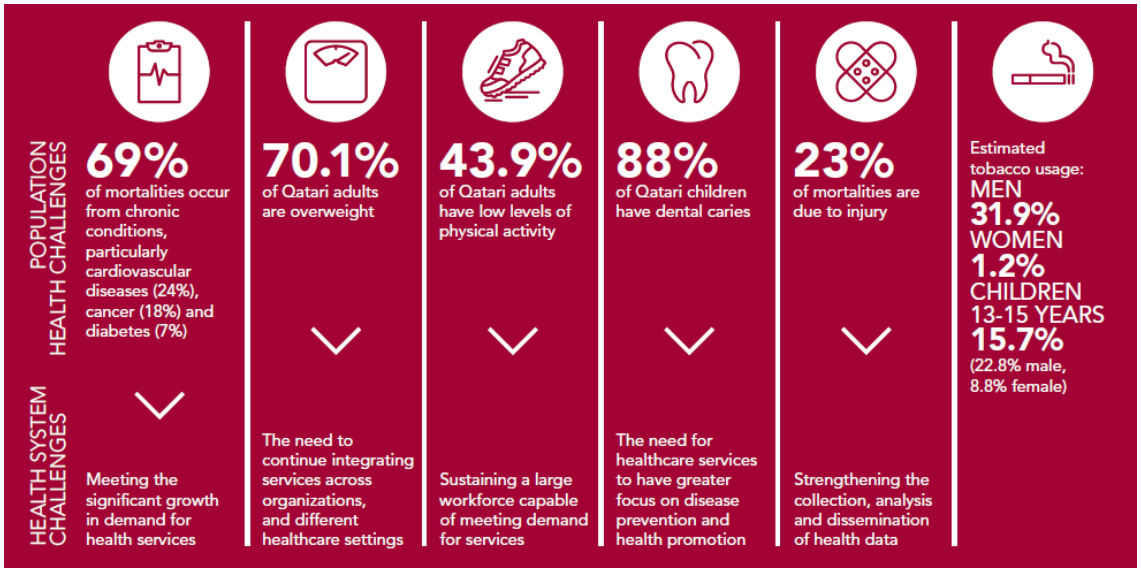


Figure 1-6: Challenges to the healthcare system

1.7.4 Structure of Healthcare Services under Ministry of Public Health

Unlike, other high-income countries where people are the main source of healthcare funding, in Qatar, healthcare costs are predominantly financed by government revenues, providing free treatment to the nationals and heavily subsidized treatments to all residents. The Ministry of Public Health (MoPH) is Qatar's highest health authority, which is responsible to plan and advise national healthcare priorities, to regulate and monitor healthcare systems and provide services to meet the national healthcare needs. The MoPH has a vision to create a healthcare system that will provide the most effective and advanced healthcare to its people and to be a model for the world to follow. Under the regulation of MoPH, the healthcare system in Qatar is primarily divided into private and public healthcare sectors. Healthcare services are currently structured as:

Primary health care centres: providing basic curative care and preventive healthcare through 23 primary healthcare facilities situated at different locations.

Specialized and teaching hospitals: HMC is one of the main providers of secondary and tertiary care healthcare. HMC manages twelve hospitals, nine of which are specialty hospitals and the remainder community hospitals. HMC also provides national ambulance services and residential care services.

Private hospitals and clinics: Six main private hospitals (Al Ahli Hospital, Al Emadi Hospital, Doha Clinic Hospital, American Hospital, Turkish Hospital, Aster Hospital) with inpatient facilities and several private day care clinics are also operated under the regulations of MoPH.

Some of the non-medical government ministries also provide medical care to their staff, such as Ministry of Interior, Qatar Armed Forces and Amiri Guard, Qatar Petroleum (QP) etc. The healthcare system is summarised in Figure 1.6

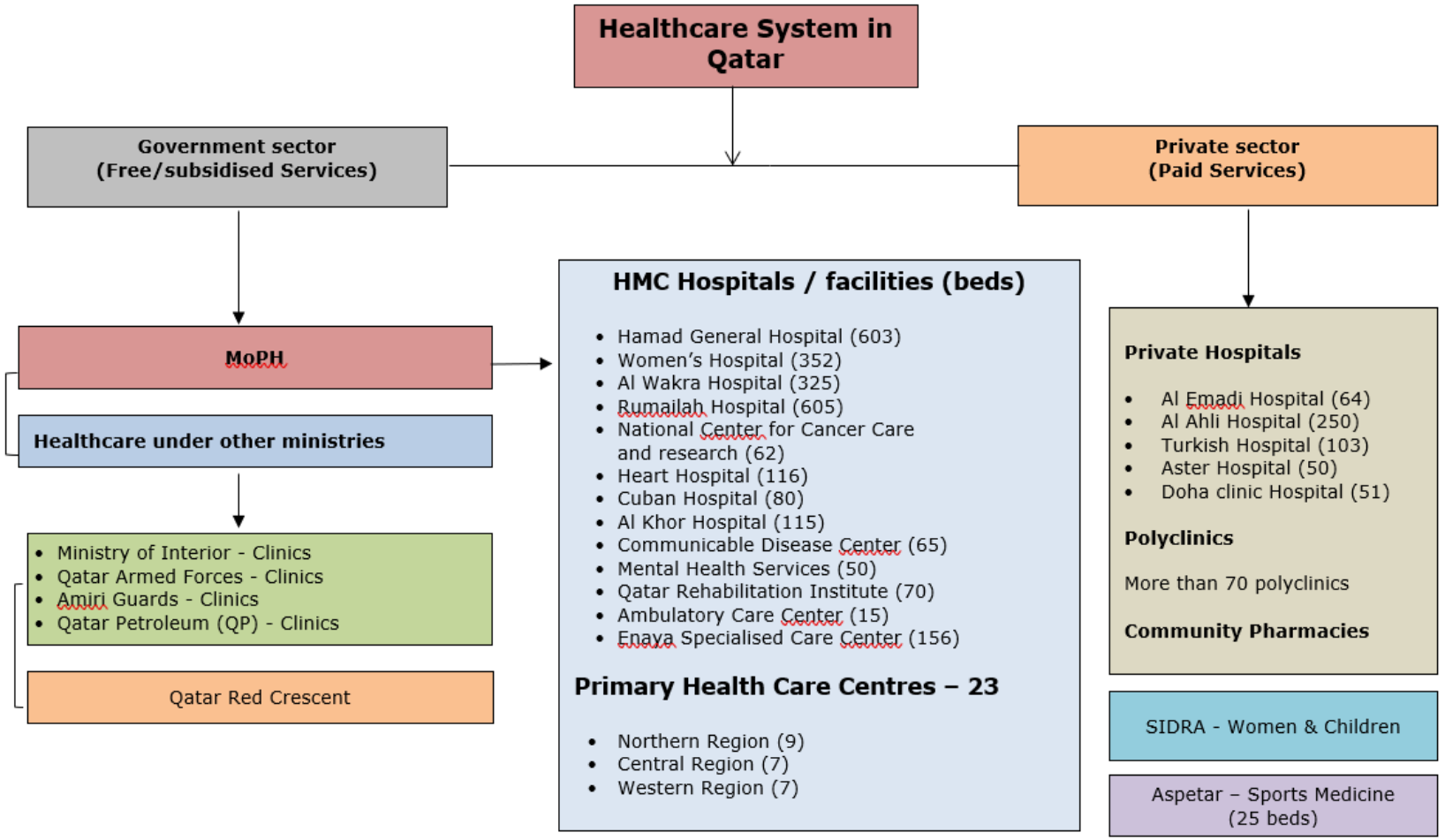


Figure 1-7: Structure of the healthcare system in Qatar

1.8 Medication error reporting and monitoring at Hamad Medical Corporation (HMC)

By international standards, HMC is the only healthcare organisation outside the US to have all hospitals accredited by the Joint Commission International (47,48).

The Medication Safety and Quality Center (MSQC) was established in 2016 to monitor medication safety practices within HMC. The centre is committed to prevent medication related harm and develop interventions to improve medication safety practices and further strengthen the pharmacovigilance practice at HMC. MSQC has developed a methodical system for reporting, monitoring, analysing, disseminating the incidents reported across HMC. The centre is a full member of the International Medication Safety Network (IMSN), an international organisation committed to preventing medication-related harm and contribute to safer healthcare (49).

Medication error reporting within HMC is policy driven (CL 7045: Managing and Reporting Medication Errors and Near Misses) (Appendix 1.1) and has recently migrated from a paper-based reporting to an electronic system (Cerner/RL6). HMC mandates all errors to be reported to the supervisory team immediately and should be reported to the incident monitoring system within 24hrs. The policy also states that the incident reports will be handled in a confidential manner and the documentation will be accessible to authorised personals only. All healthcare professionals are eligible to report the incidents. The completed reports are reviewed for appropriateness by the facility medication safety officers and then forwarded to the corporate MSQC. The MSQC then collates and reviews the completed reports and analyses them for quantity, quality, causality, seriousness and conducts root causes analysis for the significant preventable harm (Figure 1.7)

The centre summarises the reports and submit their reports and recommendations on a monthly basis to the pharmacy executive office. The pharmacy executive director informs the risk management, hospital quality and patient safety committee, and to the MoPH for further actions.

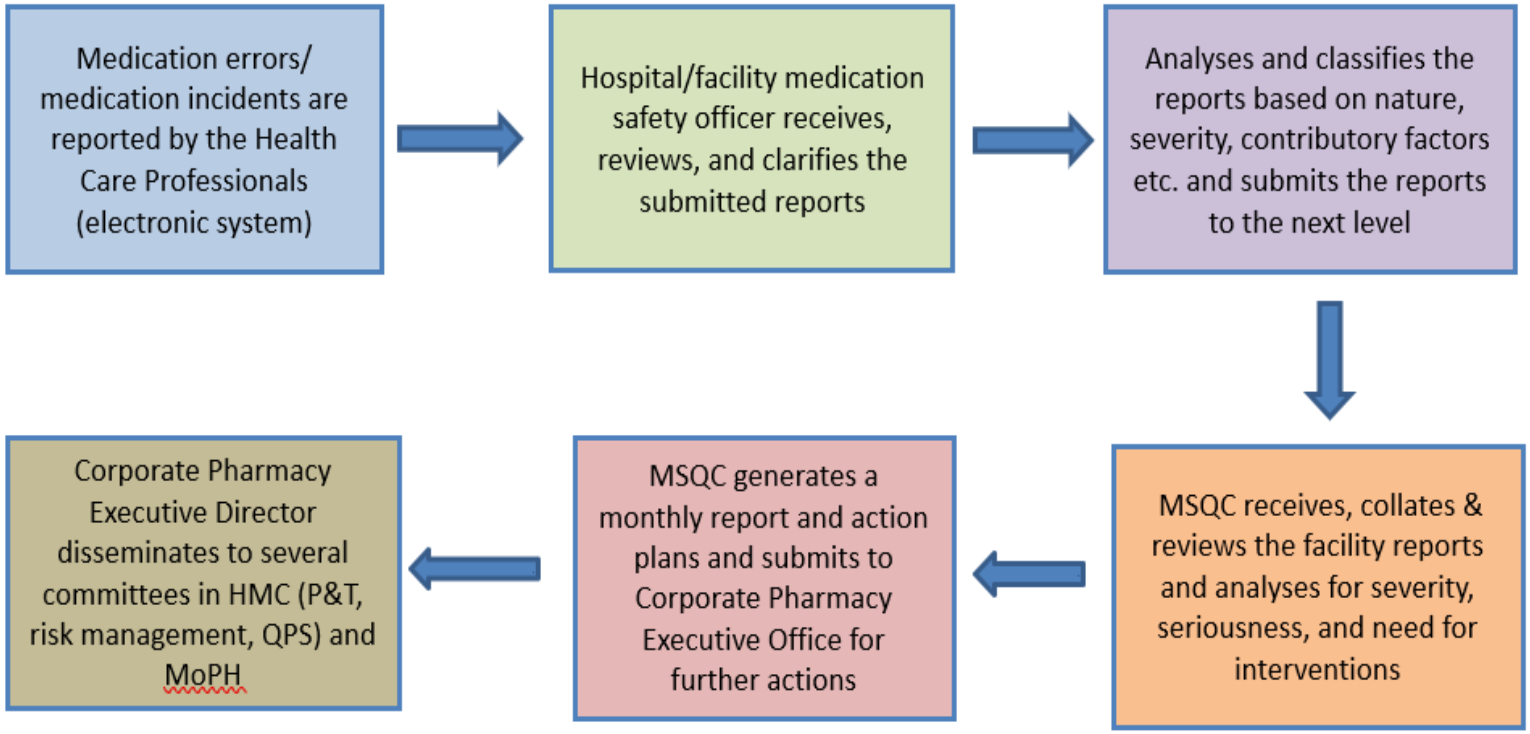


Figure 1-8: Process flow of medication error reporting, monitoring and dissemination at HMC

MSQC, Medication Safety & Quality Centre; P&T, Pharmacy and Therapeutic Committee; QPS, Quality and Patient safety; MoPH, Ministry of Public Health

1.9 Rationale for the doctoral research on medication errors

The recent WHO report highlights that medication errors continue to be a global issue with significant impact on patient care and patient safety. Of the two systematic reviews on aspects of medication errors specifically conducted within the Middle East, only few studies originated from Qatar. There is therefore a need for further research, particularly primary research using qualitative methodologies, since there were no such studies from Qatar captured within the systematic reviews. It was anticipated that the research would provide an in-depth understanding of medication errors and related causes thus potentially contribute to developing interventions aimed at reducing medication errors while also improving error reporting.

The overall aim of the doctoral research was to investigate issues relating to medication error causality and suboptimal reporting of medication errors, with the intention of contributing to the development of theory informed interventions.

Phase 1

The aim of this phase was to critically appraise, synthesise and present the available evidence on the incidence/prevalence, nature and causes of medication errors amongst hospitalised patients in Middle Eastern countries.

The key review questions were:

- What is the incidence/prevalence/rate/frequency of medication errors amongst hospitalised patients?
- What is the nature (e.g. classification, severity) of these errors?
- What are the causes or contributory factors (e.g. workload, lack of knowledge, poor communication) leading to these errors?

Phase 2

The aim of this phase was to collate data recorded in medication error reports.

The specific objectives were to:

1. Estimate the incidence of medication errors derived from submitted error reports
2. Describe the nature and severity of medication errors from submitted error reports
3. Explore the causative factors documented on medication error reports

Phase 3

The aim of this phase was to explore the perspectives of health professionals on issues of medication error causes and contributory factors, and error reporting.

The specific objectives were to explore:

1. Experiences of medication errors according to Reason's Accident Causation Model
2. Potential behavioural determinant of medication errors
3. Potential behavioural determinants of reporting of medication errors

1.10 Summary and conclusion

This introductory chapter provides and overview of the thesis and sets the stage for subsequent chapters. Prior to the research it was important to know about Qatar, its healthcare sector, current medication safety practices, background, what has been already published and what needs to be addressed more around this topic.

Chapter 2 : Research methodologies and theories

This chapter provides a brief overview of research philosophy and research paradigms in general, and application throughout this doctoral research. There is consideration and justification of the methodological approaches, with emphasis on research methods and issues of outcome measures, sampling and sample size. The need to embed theory throughout the research and the selection of the theoretical frameworks are also described.

2.1 Research philosophy

Derived from Greek for 'love of wisdom', philosophy is described as the 'development of logical reasoning that incorporates contemporary ideas with previously established methods of thought through structural phases'. (50) Creswell (51,52) describes four philosophical concepts to be considered at the outset of any research study.

1. **Ontology**, the nature of reality and its characteristics, classified on the basis of objectivity and subjectivity. Researchers embrace the idea of multiple realities and report on these multiple realities by exploring multiple forms of evidence from 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, concerned with judgement and ethics. Researchers make their values known in the study and actively report their values and biases.
4. **Methodology**, the theoretical framework of the methods used in the research processes. (52)

2.2 Philosophical paradigms

The term ‘paradigm’ can be described essentially as, ‘a collection of beliefs and concepts’. (52,53) Bowling(54) and Cresswell (52) take this further, stating that a paradigm is the ‘process of scientific practice based on people’s philosophies and assumption about the world and the nature of knowledge’. While research paradigms can be described in an array of complex categories, these can be simplified into three distinct categories which each related to accepted scientific frameworks. These are,

- Positivism, which advocates a single reality which can be measured hence, aligns to quantitative methods.
- Constructivism or interpretivism where there is no single reality or truth hence needs to be interpreted, aligning more to qualitative methods.
- Pragmatism where reality is constantly renegotiated, debated, interpreted. The best method to use is the one that solves the problem.

The links between philosophical concepts and paradigms is illustrated in Table 2.1.

Table 2-1: Features of research paradigms (adapted from Guba and Lincoln 1994, Onwuegbuzie 2004 , Bowling 2009, and Creswell 2013).

	Positivism	Constructivism	Pragmatic
Ontology	Researcher may not be able to understand reality it or get to reality because of lack of absolutes	Reality is thought to be local and specific constructed	Reality is what is useful, is practical, and 'works'
Epistemology	What we know can only be approximated. Interaction with research subjects is kept to a minimum	What is known is constructed between the researcher and the participants and shaped by individual experiences	What is known is discovered through using many tools of research
Axiology	Researchers' biases are not expressed	Individual values are honoured, and are negotiated among individuals	Values are discussed because of the way that knowledge reflects both the researchers' and the participants' views
Methodology	Experiments/surveys Verification of hypotheses; chiefly quantitative methods	Researcher is a 'passionate participant'; chiefly qualitative methods	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 (error analysis) in phase two aligned to positivism and phase three data generation (focus groups) to constructivism. These are described in further detail in Table 2.2 The methodological approach in this doctoral research is best described as 'multimodal', combining different methodologies appropriate to specific research outcomes. This is in contrast to a 'multimethod' approach which combined methodologies relating to the same or similar, linked research objectives. (52,53)

Table 2-2: Summary of the distinct research paradigms employed in this research

Characteristic	Positivist	Constructivist
Research approach	Quantitative (deductive)	Qualitative (inductive)
Research methodology	Cross-sectional	Phenomenology
Research method	Analysis of medication error reports	Focus groups
Study sample	Entire population studied and then sampled for further analysis	Purposive sample
Data analysis	Descriptive analysis	Descriptive and framework approach

2.3 Evidence synthesis through systematic review

The first phase of this research was a systematic review of the published literature on aspects of medication error studies conducted in the Middle East. This was conducted for several reasons:

- to identify key gaps in the literature
- to explore methodological strengths and weaknesses of the specific studies
- to inform later stages of the research.

Systematic reviews and metal-analyses of the data from randomised controlled trials (RCTs) at the top of the evidence-based medicine pyramid, as shown in Figure 2.1. While the systematic review described in Chapter 3 was conducted and reported according to best practice, this was a review of quantitative, observational studies and qualitative studies and not RCTs. The evidence generated from such a review would therefore sit further down the evidence hierarchy.

Figure 2-1: Hierarchy of evidence (adopted from Markman and Callanan 1984(56), Greenhalgh 1997(57))

A systematic review is defined as a 'a review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyze data from the studies that are included in the review'(58). Systematic review differs from narrative literature reviews, as described in Table 2.3.

Table 2-3: Comparison of narrative and systematic reviews (adapted from Cook et al, 1997).

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

Greenhalgh stated that systematic reviews will:

- limit bias
- generate valid and reliable conclusions
- deliver required information to healthcare providers, researchers, and policymakers
- generate new hypotheses about subgroups of the study population. (59)

Key characteristics of a systematic review are:

- a clearly defined review question
- an explicit, reproducible method with clear study inclusion and exclusion criteria
- a systematic search that attempts to identify all studies meeting the eligibility criteria
- an assessment of the validity of the findings of the included studies
- a systematic presentation, and synthesis, of the characteristics and findings of the included studies (58)

2.4 Quantitative versus qualitative methodologies

Research methodologies are categorised as quantitative or qualitative (or mixed); key characteristics of how these are described within healthcare related research are provided in Table 2.4. Essentially, quantitative research involves collecting numerical data that are analysed using mathematically based methods. In contrast, qualitative research generates in-depth and rich textual or audio-visual data allowing understanding, interpreting and describing phenomena. Quantitative and qualitative approaches are being increasingly used in healthcare related research to allow both a numerical analysis and in-depth description.

Table 2-4: Comparison of qualitative and quantitative methodologies (adapted from Bowling, Creswell)

Characteristic	Quantitative	Qualitative
Research aim	To quantify, classify, count, correlate, construct and test statistical models	Provides a detailed and rich description
Design	All aspects of the study are designed carefully before data are collected	May be planned in advance or emerge and adapt as the study unfolds
Sample	Tend to be large sample sizes	Tend to be small sample sizes
Data gathering, collection	The researcher uses tools (e.g. questionnaires, equipment) to collect data	The researcher is the data-gathering instrument
Form of data	Data are in the form of numbers and statistics	Data are in the form of words (interviews), pictures (videos) or objects (artifacts)
Data	Quantitative data are able to test hypotheses, but may miss contextual data	Qualitative data are richer but should not be generalized

Phase two of this research employed a quantitative approach to analyse data routinely collected through medication error report and phase three a qualitative approach to explore and describe aspects of medication errors and their reporting.

2.5 Quantitative methodologies

While there are many subcategories of quantitative methodologies, these can be described more generally as being either experimental or cross-sectional. Experimental methodologies (correlational, causal) assume that the cases being studied can be manipulated in order to measure a change or a difference. (60) These methodologies are described in Table 2.5.

Table 2-5: Quantitative research methodologies

Common quantitative methodologies	Description
Cross-sectional (e.g. surveys)	Describes real-life situations to determine meanings (e.g. frequencies, mean, standard deviation) of phenomena, and describe and categorise information
Experimental (correlational) (e.g. cohort studies, case-control studies)	Explores relationships between variables to determine the degree of relationship without manipulating an intervention (Walker, 2005; Burns and Grove, 2011)
Experimental (causal) (e.g. randomised controlled trials)	Manipulates an independent variable and observes the outcome on a dependent variable whilst attempting to keep other unrelated variables constant

A quantitative, cross-sectional survey methodology was selected for phase two. Surveys allow the researcher to make certain inferences about the study population. In phase two, a data collection from was developed to extract data routinely reported on medication error forms.

2.6 Qualitative methodologies

As noted earlier, qualitative methodologies set out to gather and report non-numerical data. While there are many different methodological approaches, the five most frequently reported are described in Table 2.6.

Table 2-6: Description of the five common qualitative methodologies

Methodology	Description
Narrative	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 lived experience of individuals by exploring the meaning of a 'phenomenon'
Grounded theory	Sets out to develop a theory constructed from the data of participants with an experience of the phenomenon
Ethnography	Describes and interprets human cultures with the aim of getting an in-depth understanding of a particular culture
Case study	Explores a case (or multiple cases) through in-depth data generation involving multiple sources of information

In phase three, the intention was to report the lived experiences of health professionals around the phenomena of medication errors and their reporting. A phenomenological methodology was particularly appropriate for this phase of the research as it focuses on the meaning and values of the lived experiences of the research participants. Phenomenological research methods are also anticipated to generate in-depth discussions between the participants and thus generate rich contextual data providing more real-life resonance in terms of issues identified in the earlier phases of the doctoral thesis.

Qualitative methods

The three most common qualitative methods are participant observation, focus group discussions and in-depth interviews (Bowling 2009, Creswell 2013). Strengths and weaknesses of each are summarised in Table 2.7. In this phase, providing the opportunity for discussion between participants was considered useful hence focus groups were selected.

Table 2-7: Features of participant observation, focus group discussions and in-depth interviews

Method	Strengths	Weaknesses
Participant observation	• Allows the researcher to directly see what participants actually do • The researcher can determine what does not occur • The researcher may observe events and happenings that escape the awareness of the participants • May provide information on things participants would be unwilling to talk about	• Sampling of settings and participants may be problematic • Some settings and content cannot be observed • Collection of unimportant material may be moderately high • Reactive effects may occur when participants know they are being observed • May place researcher at risk
Focus groups	• Useful for exploring ideas and concepts • Provides an opportunity for participants to discuss issues amongst each other • Researcher can assess how participants react to each other • Allows researcher probing	• May be difficult to find a focus group moderator with good skills • Reactive effects may occur if participants feel they are being watched or studied • Recruitment may be difficult in certain groups • Participants may be influenced by each other
In-depth interviews	• Allows probing and posing of follow-up questions by the researcher • Closed-ended interviews can provide exact information needed by researcher • Useful for exploration as well as confirmation	• Can be expensive and time consuming • Researcher effects may occur (e.g., untrained interviewers may distort data because of personal biases and poor interviewing skills) • Participants may not recall important information and may lack self-awareness

Focus group discussions were considered the most appropriate as the discussion amongst the participants would provide an interdisciplinary perspective of the experiences of the healthcare team or across a range of interdisciplinary individuals at different roles/grades. While individual interviews would provide depth of understanding of individuals' life experiences, there would be no opportunity for exchange of information between the participants (52,53)

2.7 The use of theory in research

There is a trend of the increasing use of theory within healthcare research generally and pharmacy practice research specifically. Theory is defined as '…an explanation of a phenomenon arrived through examination and contemplation of the relevant facts; a statement of one or more laws or principles which are generally held as describing an essential property of something'. (62) Theories can help to explain, predict, and understand phenomena and, in many cases, to challenge and extend existing knowledge. Theories can also connect pieces of research data to generate findings which fit into a larger body of other studies.

Two 'theories' were used in this research: Reason's Accident Causation(63,64) as described in Chapter 1 and the Theoretical Domains Framework (TDF)(65-67), which is an integrative framework developed from other theories hence is not a theory in itself. Reason's Accident causation model was applied in phases two and three and TDF in phase three.

2.7.1 The Theoretical Domains Framework

Evidence suggests that behavioural change interventions using a theoretical basis are far more effective than those developed using a more pragmatic approach. Whereas many other theories focus on individual factors (such as a belief, motivation etc.), the Theoretical Domains Framework (TDF) is an integrative framework developed from a synthesis of psychological theories aimed to propose interventions aimed at behaviour change. The TDF was developed by a group of psychological theorists, health service researchers and health psychologists. It is derived from 33 theories of behaviour change, comprising 14 domains and 84 constructs that allows synthesis of a multitude of coherent behavior change theories into a single, integrative framework. TDF allows assessment and explanation of behaviour and associated barriers and enablers and inform the design of appropriately targeted interventions. (65-67)

In the current research TDF was applied to characterise the determinants of a range of behaviours and to identify the barriers and facilitators that influenced the medication error reporting and causality at HMC.

The TDF domains and their descriptors are given in Table 2.8.

Table 2-8: The Theoretical Domain Framework (adapted from Atkin et al)

Domain	Examples
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

2.7.2 James Reason's Accident Causation Model

The historical person-centred approach to error used in healthcare and other industries is based on the philosophy that errors occur due to human weakness. (68-70) This approach was widely criticised for being blame oriented, wherein an individual is deemed completely responsible for errors and not providing attention to system-related issues. In 1990, James Reason introduced the 'accident causation model', a system centred model focusing on the principle that errors occur due to flaws in the much larger system and that humans are just a small part. (64) Prior to its use in the healthcare, this model was initially used in nuclear industry, aviation industry etc. (69)

Several studies have previously adapted the accident causation model to understand medication errors and medication non-adherence. (70-74) According to this model, a system is compared to a knife that has a sharp end (active failures) and a blunt end (latent failures). Active failures mostly occur due to frontline workers, they are unsafe acts that are conducted by people who are in direct contact with the patients or the system itself. Active failures are subcategorised as slips, lapses, mistakes and violations. While 'slips' and 'lapses' occur when a right plan is executed incorrectly, 'mistakes' and 'violations' happen when an incorrect plan is formulated and then followed. Active failures do not occur in isolation, but instead are believed to have a casual history and occur due to error provoking conditions that lie deep rooted within the system (latent failures). Error provoking conditions such as lack of knowledge among the staff, busy working environment etc. are anticipated to occur due to latent failures such as poor organisational policies or lack of budget for training and development. Latent failures are considered as inevitable and they lie dormant within the system, these mostly occur due to wrong strategic decisions, incorrect planning at top level management. Understanding such errors are important as they lead to proactive management and prevent errors and thus promote patient safety. (64,69,70)

Table 2-9: James Reason's Accident Causation model, with descriptions of types of failures

Reasons Accident Causation model with illustrations	
Slips	When a step of the plan is performed wrongly, e.g. choosing a wrong medication from the shelf during dispensing
Lapse	When a step of a plan is missed or omitted, e.g. omitting prescribing a medication following reconciliation
Mistakes	Occurs due to misapplication of rules or lack of knowledge, e.g. prescribing a wrong dose or medication due to lack of knowledge
Violations	Occurs when a person intentionally chooses not to follow the rule or policy (may not be with a purpose to cause harm, but to save time or achieve something more easily), e.g. prescribing an unauthorised medication to save time; not following the hospital policy/guideline while prescribing, dispensing or administering a medication
Error provoking conditions	Active failures result from the error provoking conditions such as patient factors, individual, team, environment etc.
Latent failures	Error provoking conditions are hidden within the organisational and surrounding culture, e.g. lack of budget to hire staff and provide training, lack of transparency among the healthcare professionals and patients, lack of resources to manage drug information questions etc.

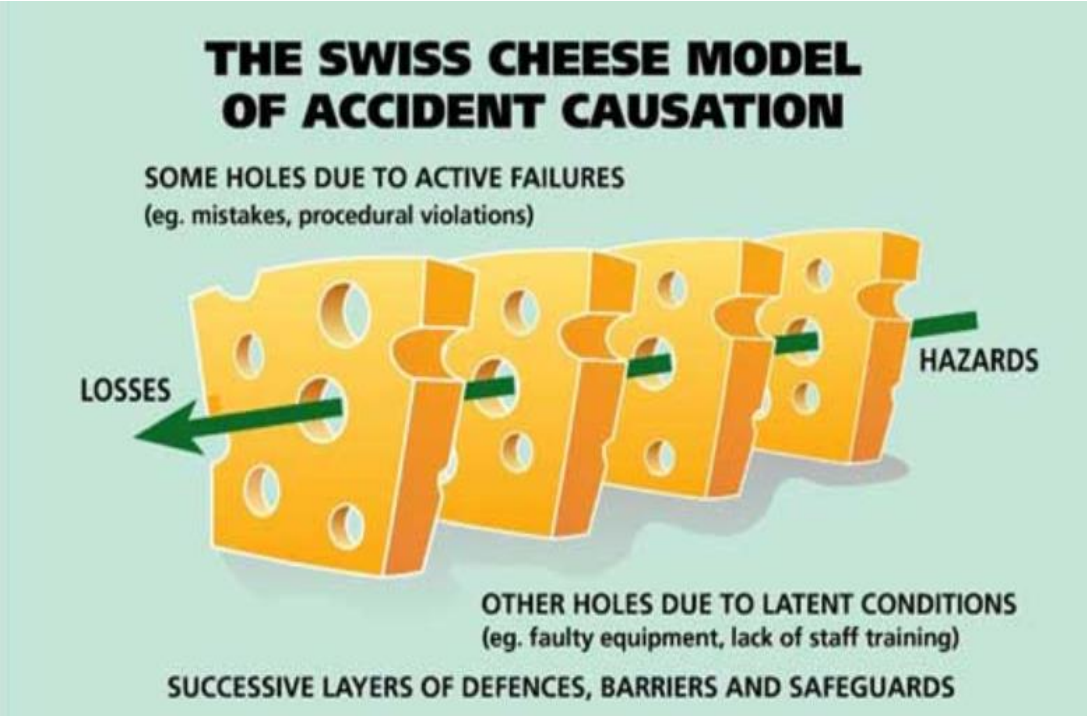


Figure 2-2 James Reason's Swiss Cheese Model illustrating the consequences of failures aligning.

2.8 Robustness and rigour

2.8.1 Robustness in quantitative research

The criteria adopted to promote robustness in quantitative research are internal validity, external validity and reliability.

Validity is considered to be, 'the accuracy and truth of the data being produced in terms of the concepts being investigated' (61). Internal validity relates to the research processes and the data collected, while external validity (also termed generalisability) relates to the extrapolation of research findings and conclusions from a study sample population at large within or beyond the study setting (61). While there are a number of categories of

internal validity, those employed in this study were face and content. Face validity considers the extent to which a data collection tool covers the concepts it aims to measure in terms of transparency or relevance and content validity the extent to which the tool represents all facets of a given construct (61). Reliability is referred to as, the extent to which results are consistent over time.

2.8.2 Rigour in qualitative research

The concepts of validity and reliability are quantitative, measurable and not applicable to qualitative studies. While there are many approaches to considering rigour in qualitative research Shenton's is a comprehensive approach that incorporates Guba's pursuit of a trustworthiness in a study.

Shenton (153) describes four criteria to consider in relation to qualitative research trustworthiness, as described in Table 2.10.

Table 2-10: Components of trustworthiness [Adapted from Shenton et.al (2004)]

Trustworthiness	Description
Credibility	Similar to validity by ensuring that findings are an accurate reflection 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
Dependability	Similar to reliability, described as the extent to which similar findings would be obtained had the study been repeated exactly
Transferability	Similar to external validity, described as the extent to which findings can be applied to other contexts and settings. Promoted by providing detailed information to allow readers to judge the applicability of findings to their own context.
Confirmability	Relates to the extent to which findings have emerged from the data gathered rather than the biases and preconceived notions of the researchers

In qualitative research, threats could also include reactivity and bias from the researcher as well as from the participant. To overcome this, a qualitative researcher must include a variety of strategies (such as reflexivity, prolonged engagement, triangulation, peer debriefing etc) to ensure that the findings represent the meaning as described by the participants. Reflexivity is one of the key factors to enhance the rigour and trustworthiness of qualitative research, allowing understanding of the ways in which the researcher's beliefs, experience and identity intersect with that of the participant. Reflexivity is defined as an 'active acknowledgement by the researcher that her/his own actions and decisions will inevitably impact upon the meaning and context of the experience under investigation'. (153)
Several key factors pertaining to reflexivity were considered in the doctoral research, such as the doctoral researchers influence on the participants' responses, study design (prospective reflexivity), professional history,

collegial relationships, selection of research design, approach to interviews and data collection etc.)

Further approaches to promoting validity, reliability and trustworthiness are described throughout this thesis.

2.9 Summary

This chapter has presented the underlying methodological concepts which are applied in all phases of the research. Figure 2.3 describes the methodological approaches applied throughout this research. The specific research methods are described in detail in Chapters 3, 4 and 5.

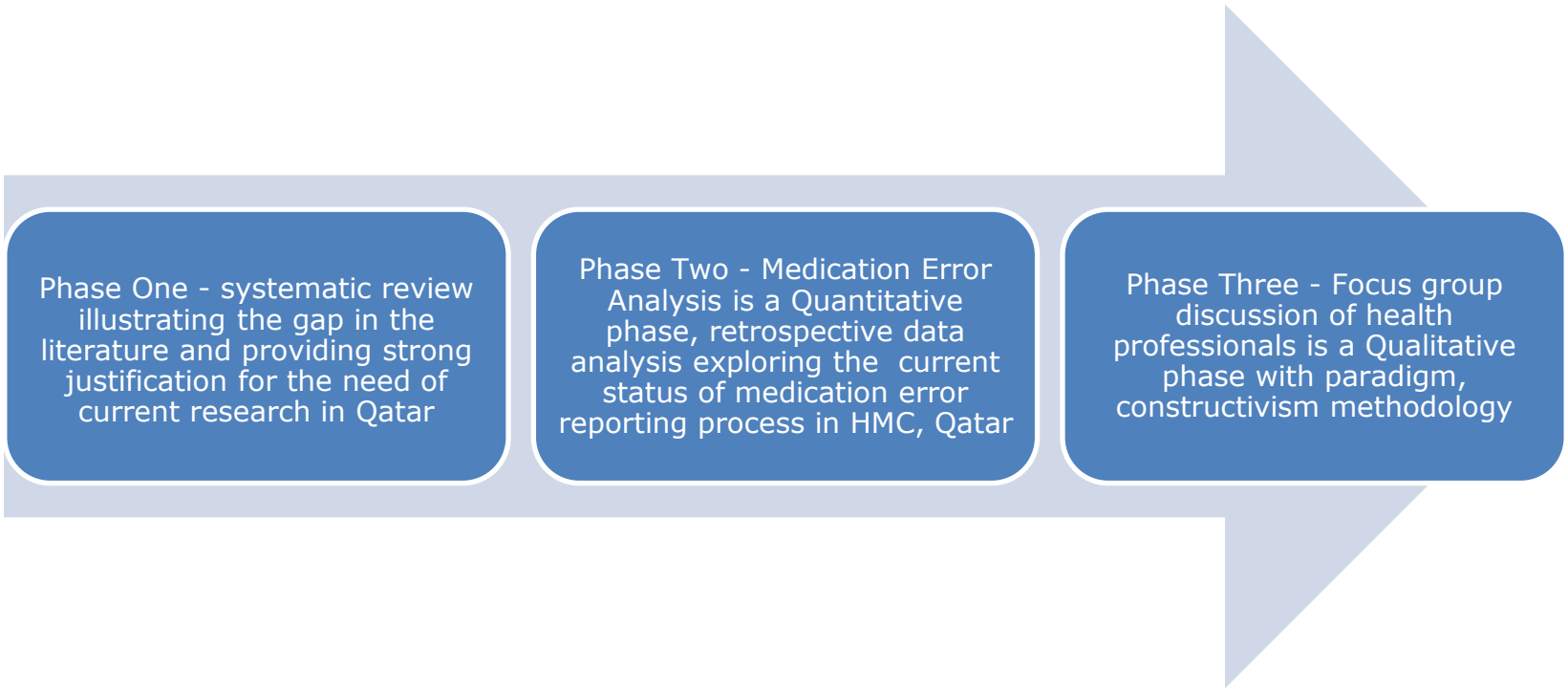


Figure 2-3: Methodological phases of current research

Chapter 3 : A systematic review of incidence/prevalence, nature and causes of medication errors among hospitalised patients in Middle Eastern countries

3.1. Introduction

This chapter provides the introduction, aim, method and discussion of a PROSPERO (International Prospective Register of Systematic Reviews) registered systematic review of incidence/prevalence, nature and causes of medication errors among hospitalised patients in Middle Eastern countries. As described in Chapter One, in 2013 Alsulami *et al* (30) published a systematic review including all studies published up to and including 2011 on the incidence/prevalence and contributory factors of medication errors in Middle Eastern countries. The review highlighted that published papers from Middle Eastern countries were relatively few and generally of poor quality. Since publication of that review, many more studies have been published hence it was timely to update the review prior to the collection and generation of primary research in Qatar.

The systematic review conducted within this doctoral research also extended that of Alsulami *et al*. by applying a theory-based approach, centred on Reason's Accident Causation Model (64), to the stage of data synthesis. Furthermore, this review highlighted gaps in the literature, thus providing a basis for the doctoral primary research.

3.2. Review aim and questions

This review aimed to critically appraise, synthesise and present the available evidence on the incidence/prevalence, nature and causes of medication errors amongst hospitalised patients in Middle Eastern countries.

The key review questions were:

- What is the incidence/prevalence/rate/frequency of medication errors amongst hospitalised patients?
- What is the nature (e.g. classification, severity) of these errors?
- What are the causes or contributory factors (e.g. workload, lack of knowledge, poor communication) leading to these errors?

3.3. Methods

A systematic review protocol was developed according to best practice, mapped to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines on developing systematic review protocols. (75) Following peer review within the doctoral supervisory team, the protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO). (76) The review aimed to capture both quantitative and qualitative studies. Studies on incidence and nature of errors will have employed quantitative designs while studies of causes or contributory factors may have employed quantitative, qualitative or mixed methods designs.

3.3.1 Inclusion criteria

Population

The review considered original primary research involving health professionals (specifically doctors, nurses or pharmacists) that reported the incidence/prevalence/rate/frequency, nature, severity, factors or causes of medication errors amongst hospitalised patients in any of the 16 Middle Eastern countries. Studies of hospital practitioners (or other key stakeholders such as risk managers) were also included.

Types of interventions, comparators

There were no interventions or comparators as would be the case in reviews of effectiveness or cost-effectiveness.

Outcome(s)

Quantitative outcomes were related to each of the review questions as follows: incidence/prevalence/rate/frequency of medication errors, the nature (e.g. classification, severity, patient outcomes) of errors; and causes and contributory factors leading to errors. Qualitative outcomes were around the causes and contributory factors.

3.3.2 Exclusion criteria

Studies of adverse drug reactions which were not classified as medication errors were excluded, as were review articles, letters, opinion papers, editorials and conference abstracts (due to lack of sufficient study details to allow critical appraisal and data extraction), Studies which employed a pre-, post-intervention design were also excluded due to the difficulty in quantifying incidence as part of data extraction and synthesis.

3.3.3 Study design

All study designs were included:

1. Quantitative designs - randomised controlled trials which may have captured data on incidence, nature and causes, non-randomised comparative studies, observational studies, cohort studies and before and after studies, surveys.
2. Qualitative designs - narrative, phenomenology, grounded theory, ethnography, case studies, action research.
3. Mixed methods design.

Language

Due to the difficulty in translation from other languages to English, only papers in English were included.

Capture dates

All papers published from 2000 until the end of March 2018 were included in the review.

3.3.4 Search terms

Search terms were:

- medic* OR prescrib* OR dispens* OR administ*

  AND

- Error* OR incident* OR mistake*

  AND

- Middle East OR Saudi Arabia OR Qatar OR United Arab Emirates OR Kuwait OR Bahrain OR Oman OR Palestine OR Israel OR Iran OR Iraq OR Syria OR Lebanon OR Egypt OR Jordan OR Turkey OR Yemen

Search terms were generated from a number of sources: the previous systematic reviews published around medication errors described in Chapter 1; the title and keywords from key papers in the field; and from Google Scholar scoping search and from the references of published literatures. These search strings were also used to search Medical Subject Headings (MeSH®).

3.3.5 Databases

To ensure adequate performances in search, the review included MEDLINE (including Epub ahead of print), PubMed, Embase, CINAHL (for nursing and allied health sciences), Science Direct and Google Scholar were used. The narrative review reported in Chapter one identified that almost all of the systematic reviews in the medication errors field had used at least three of these databases.

Table 3.1 describes the different databases included in the review.

Table 3-1: Description of all databases searched

Database	Description	Year started	Scope
Medline	Medical Literature Analysis and Retrieval System Online (a subset of PubMed), or MEDLARS Online is a bibliographic database of life sciences and biomedical information. It includes bibliographic information of articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care.	1964	Contains over 26 million records from more than 5,600 selected journals in 40 plus languages.
PubMed	PubMed is an online version of Index Medicus produced by the US National Library of Medicine. It covers back to 1966 and selectively to 1809.	1996	Has more than 27 million references including Medline.
Science Direct	Science Direct is operated by Elsevier. It covers articles from 1823 that include information on topics from Physical Sciences and Engineering Life Sciences Health Sciences Social Sciences and Humanities.	1997	Has more than 12 million references from 3,500 academic journals and 34,000 e-books.
Embase	A biomedical and pharmacological database that covers literature related to Pharmacology and Pharmaceutical Science; Pharmacoeconomics; Toxicology; Evidence-Based Medicine; Environmental Health Research and Policy Management.	1947	Covers 32 million records over 8,500 journals.
CINAHL	The Cumulative Index to Nursing and Allied Health Literature (CINAHL) is one of the most comprehensive databases used by nursing and allied healthcare professionals. It covers articles from 1981 on topics over 50 nursing specialties, speech and language pathology, nutrition, general health and medicine and more.	1961	Covers more than 5.8 million records from 5,500 journals.
CDSR	The Cochrane Database of Systematic Reviews (CDSR) is leading resource for systematic reviews and protocols in healthcare. It covers systematic reviews related to primary research in human health care and health policy.	2005	Contains over 10000 records.
Google Scholar and reference lists of all included studies were searched for potentially relevant studies			

3.3.6 Screening and selection

Independent, duplicate screening of titles, abstracts and full papers in relation to the review aim (detailed description of the search is given PRISMA flowchart describing systematic review), questions and inclusion criteria was independently performed by two reviewers. Disagreements were resolved by consensus and referred to a third reviewer whenever required.

3.4. Assessment of methodological quality

Papers were assessed for methodological quality and bias by two independent reviewers prior to inclusion in the review. Disagreements were resolved by consensus and referred to a third reviewer whenever required. The STROBE checklist (STrengthening the Reporting of OBservational studies in Epidemiology) was adapted and adopted as a quality assessment tool. STROBE is a reporting tool developed in 2004 by an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies. (77) While STROBE was developed for quantitative studies, it was also used in this review (with further minor adaptations) for any qualitative studies. The specific criteria were:

- Is there a clear statement of research aim?
- Is the research setting described?
- Is the term 'medication error' defined?
- Are categories of medication errors stated?
- Are medication error categories defined?
- Is the denominator defined (for studies reporting incidence etc.)
- Are data collection methods clearly described?
- If the sampling method described and appropriate?
- Is there consideration of reliability and validity?
- Are issues of generalisability considered?
- Are study limitations discussed?

This tool was selected for the systematic review based on the level of details described in the methods and results section. This tool is also endorsed by over 100 high quality journals and the International Committee of Medical Journal Editors. Given that a small number of qualitative studies were identified, the STROBE tool was adapted for these studies to include reference to research trustworthiness rather than the aspect of validity and reliability. This also provided for consistency of presentation of quality assessment findings between the quantitative and qualitative studies.

3.5. Data extraction

A data extraction tool was developed to extract the following: authors; country of publication/study; year of publication; study population; setting; recruitment; incidence; nature of errors; causes of errors. Data extraction was also performed by two independent reviewers, as per quality assessment.

3.6. Data synthesis

Synthesis is a key part of systematic reviews and refers to collating, combining and summarising the findings of individual studies. Pooling of data derived from quantitative studies was inappropriate due to the observational study designs and major differences in approaches to measurement of study outcomes hence the findings were presented in narrative form using the approach described by Popay et al. (78) While it had been intended that qualitative research would be pooled using a meta-synthesis approach, only two qualitative studies were identified.

The results were presented in tables and data was transformed and expressed in numerical values, in percentages, median and interquartile ranges wherever necessary. Data related to causes were expressed using a theoretical framework model using Reason's Accident Causation model. (64,70)

3.7. Results

3.7.2 Literature search

Database searching and review of reference lists yielded 452 articles, 110 of which were duplicates and excluded. Review of titles and abstracts excluded a further 129 papers, with reviewing the full papers excluding 79. Fifty papers were included in the quality assessment stage. The PRIMSA flowchart is given in Figure 3.1. Of the fifty studies, 48 were of a quantitative design and two were qualitative in nature.

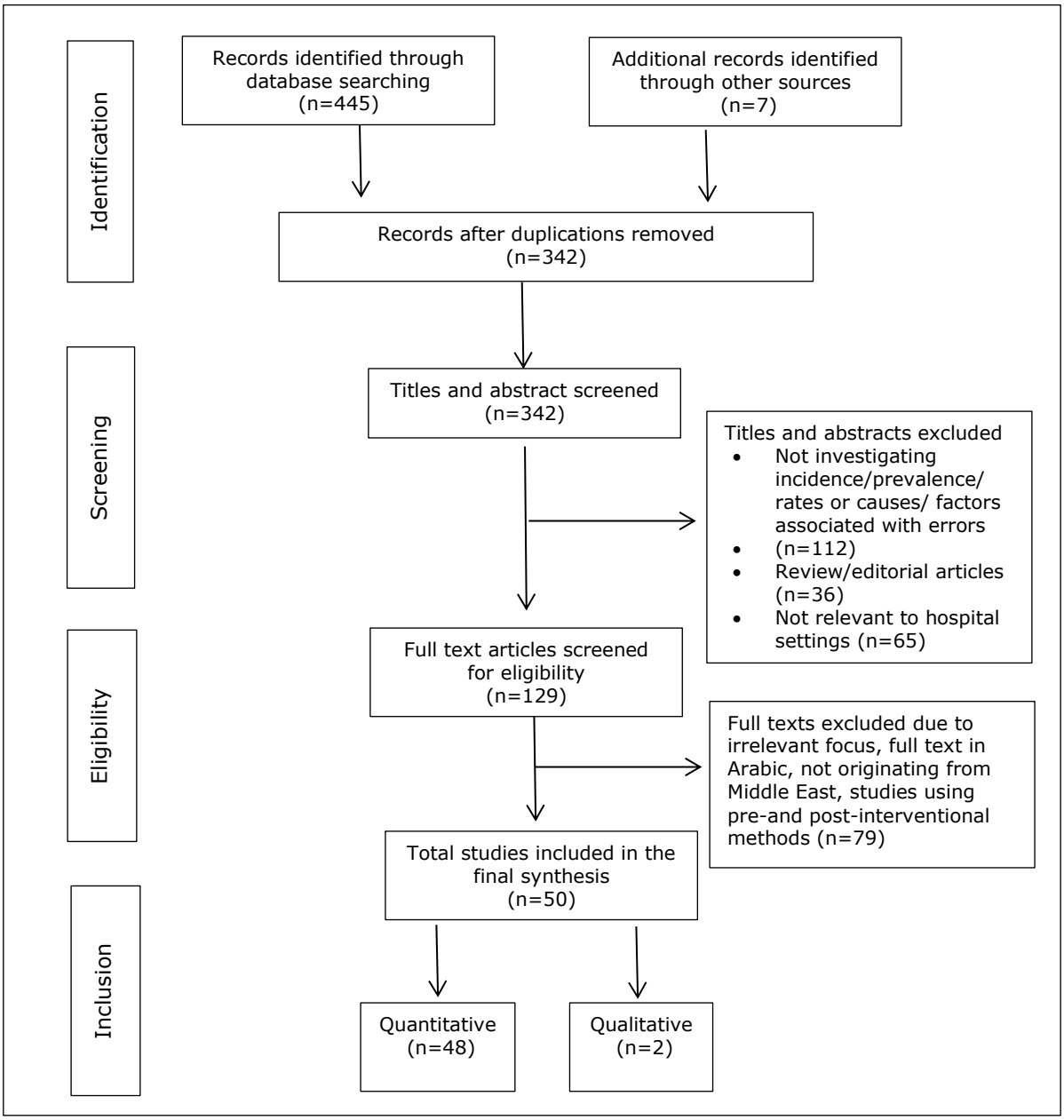


Figure 3-1: PRISMA flowchart describing systematic review search and study selection

3.7.3 Quality assessment

Of the 50 studies, none met all 11 STROBE-related quality assessment criteria. Thirteen studies (26%) met eight or more criteria, 21 (42%) between five and seven criteria, and the remaining 16 (32%) meeting four or less. Key limitations centred on lack of justification for the method of sampling and sample size, and not adequately considering issues of data validity and reliability (quantitative studies) and trustworthiness (qualitative studies). Quality assessment is given in Table 3.2.

Table 3-2: Quality assessment of studies included in the review

Author(s), year, country	Is there a clear statement of research aim?	Is the research setting described?	Is the term medication error defined?	Are categories of medication errors stated?	Are medication error categories defined?	Denominator defined?	Are data collection method clearly described?	If the sampling method described and appropriate?	Is there consideration of reliability and validity?	Are issues of generalizability considered?	Are study limitations discussed?
Al-Jeraisy,*et al* 2011, SA (79)	Y	Y	P	N	N	Y	Y	P	N	Y	Y
Abbasinazari et *al*, 2013, Iran (80)	Y	P	N	Y	P	Y	Y	N	N	N	N
Abbasinazari et *al*, 2013, Iran (81)	Y	Y	Y	P	P	Y	P	N	N	P	P
Abdar *et al*, 2014, Iran (82)	Y	Y	Y	P	P	NA	Y	Y	Y	P	Y
Al Ramahi et *al*, 2017, Palestine (83)	Y	Y	Y	N	N	Y	Y	Y	NA	Y	Y
Alakahli *et al* *et al*, 2014, Yemen (84)	Y	Y	N	P	N	Y	Y	P	N	Y	Y
Al-Dhawailie et *al*, 2010, SA (85)	Y	Y	Y	N	N	Y	Y	P	N	Y	Y
Al-Hajje et *al*, 2012, Lebanon (86)	Y	Y	Y	P	P	Y	P	P	N	P	Y
Aljadhey et *al*, 2013, SA (87)	Y	P	Y	P	P	Y	Y	P	P	Y	Y
Ali S et *al*, 2017, SA (88)	Y	Y	Y	Y	Y	N	Y	N	NA	Y	Y
Alshaikh et *al*, 2013 SA (89)	Y	Y	Y	P	P	Y	Y	P	Y	Y	Y
Al-Shara et *al*, 2011, Jordan (90)	Y	Y	Y	P	N	NA	Y	Y	N	N	Y
Arabi et *al*, 2012, SA	P	P	Y	P	P	P	Y	P	N	N	Y
Al Tehewy et *al*, 2016, Egypt (91)	Y	Y	Y	Y	N	Y	Y	N	N	Y	Y
Bagheri-Nesami et *al*, 2015, Iran (92)	Y	Y	Y	P	P	Y	Y	P	P	P	Y
Cheragi *et al*, 2013, Iran (93)	Y	Y	N	N	N	NA	N	N	N	Y	Y
Dabaghzadeh *et al*, 2013, Iran (94)	N	Y	Y	Y	P	P	P	P	P	N	Y
Dibbi *et al*, 2006, SA (95)	P	P	N	N	N	P	P	N	N	P	P

Author(s), year, country	Is there a clear statement of research aim?	Is the research setting described?	Is the term medication error defined?	Are categories of medication errors stated?	Are medication error categories defined?	Denominator defined?	Are data collection method clearly described?	If the sampling method described and appropriate?	Is there consideration of reliability and validity?	Are issues of generalizability considered?	Are study limitations discussed?
Ehsani *et al*, 2013. Iran (96)	Y	Y	Y	P	P	NA	Y	N	N	N	P
El-Shazly *et al*, 2017, Egypt (97)	Y	Y	Y	N	P	P	P	P	N	P	P
Fahimi *et al*, 2009, Iran (98)	Y	Y	Y	Y	Y	Y	Y	P	P	P	Y
Fahimi *et al*, 2008, Iran (99)	P	P	P	P	P	P	P	N	N	P	P
Fahimi *et al*, 2015, Iran (100)	Y	Y	Y	Y	P	P	P	N	P	P	P
*Farzi *et al*, 2017, Iran (101)	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y
Fathi *et al*, 2017 Iran (102)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
Gharekhani *et al*, 2014, Iran (103)	P	P	Y	P	P	Y	P	N	N	Y	P
Gorgich *et al*, 2016, Iran (104)	Y	Y	Y	N	Y	NA	P	P	N	P	P
Güneş *et al*, 2014, Turkey (105)	Y	Y	Y	P	P	NA	P	P	N	Y	P
Hamishehkar *et al*, 2014, Iran (106)	Y	Y	Y	N	N	P	P	P	P	P	P
Hammoudi *et al*, 2017, SA (107)	Y	Y	N	N	N	N	N	Y	N	N	Y
Hammour *et al*, 2016, Jordan (108)	Y	Y	Y	Y	Y	N	Y	N	NA	Y	Y
Kandil *et al*, 2012, Egypt (109)	Y	p	Y	Y	P	Y	P	P	N	N	N
Khammarnia *et al*, 2015, Iran (110)	Y	Y	N	N	N	N	Y	N	P	N	Y
Lustig *et al*, 2000, Israel (111)	Y	Y	N	P	P	Y	P	N	N	N	P
Ali MA *et al*, 2017, Egypt (112)	Y	Y	N	Y	N	N	Y	N	NA	Y	Y
Mrayyan *et al*, 2012, Jordan (113)	Y	Y	Y	Y	P	NA	Y	N	N	Y	Y
Mrayyan *et al*, 2007, Jordan (114)	Y	Y	Y	N	P	NA	Y	Y	Y	Y	Y
Pawluk *et al*, 2017, Qatar (115)	Y	Y	Y	P	P	N	P	P	N	P	Y

Author(s), year, country	Is there a clear statement of research aim?	Is the research setting described?	Is the term medication error defined?	Are categories of medication errors stated?	Are medication error categories defined?	Denominator defined?	Are data collection method clearly described?	If the sampling method described and appropriate?	Is there consideration of reliability and validity?	Are issues of generalizability considered?	Are study limitations discussed?
*Pazokian *et al*, 2014, Iran (116)	Y	Y	N	N	N	NA	Y	Y	Y	Y	Y
Sadat-Ali *et al*, 2010, SA (117)	Y	Y	Y	Y	Y	Y	Y	N	NA	Y	N
Saravi *et al*, 2015, Iran (118)	Y	Y	N	P	P	Y	Y	N	N	N	N
Shahrokhi *et al*, 2014, Iran (119)	Y	Y	Y	N	N	NA	Y	P	P	Y	P
Shehata *et al*, 2015, Egypt (120)	Y	Y	Y	Y	Y	N	Y	Y	Y	P	Y
Shohani *et al*, 2018, Iran (121)	Y	Y	N	N	N	N	Y	P	Y	N	Y
Suleiman *et al*, 2017, Jordan (122)	Y	Y	Y	Y	Y	Y	Y	N	NA	Y	Y
Toruner *et al*, 2012, Turkey (123)	Y	Y	Y	N	N	N	Y	N	N	Y	P
Vazin *et al*, 2012, Iran (124)	Y	Y	N	P	P	Y	P	P	Y	Y	P
Vessal *et al*, 2010, Iran (125)	Y	Y	Y	N	Y	P	Y	N	Y	P	Y
Youssif *et al*, 2013, SA (126)	Y	Y	Y	NA	NA	NA	Y	N	N	N	N
Zeraatchi *et al*, 2013, Iran (127)	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y

Y – Yes , N – No , NA – Not Available, P – Partially available SA – Saudi Arabia

* indicates - qualitative studies

3.7.4 Data extraction and synthesis

The first paper included in the review was published in 2000 (111), with most (80%, n=40) being published subsequently to the review of Alsulami *et al*. Figure 3.2 illustrates the increase in numbers of publications on medication errors in recent years.

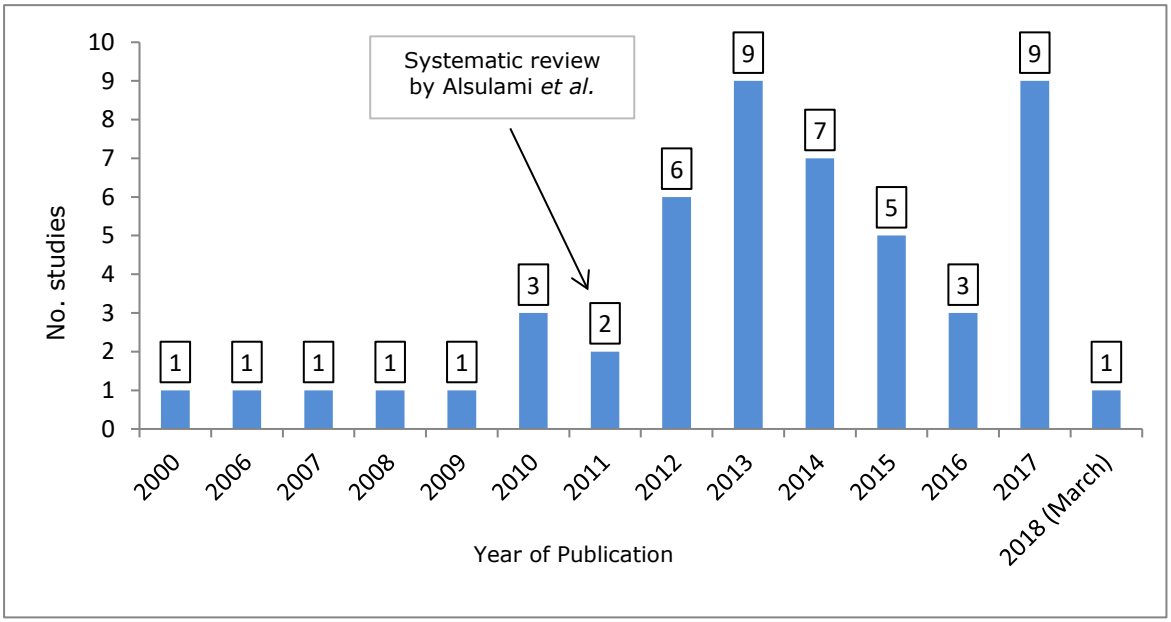


Figure 3-2 Medication error research, publications per year 2000-March 2018

3.7.5 Country of origin

Almost half of the studies were conducted in Iran (23, 46%), with the next being Saudi Arabia (10, 20%). Five studies (10%) were conducted in each of Egypt and Jordan, with two (4%) from Turkey and one each (2%) from Israel(111), Qatar, Yemen, Palestine (83) and Lebanon. There were no publications with data from more than one country.

3.7.6 Setting

Almost three quarters of the studies (33, 66%) were conducted in university-affiliated or academic hospitals (institutions that combine services of a hospital with education and research of health professional students), with just one fifth (10, 20%) tertiary care, non-teaching

hospitals, and less (3, 6%) in general hospitals. Three studies (3, 6%) did not state the type of hospital in which the study took place and one study used a national online database with data reported from different hospitals. Within each hospital, a range of specific patient groups were targeted, mostly adults, and the most common type of wards chosen were intensive care units.

3.7.7 Study aims

In more than half of the studies (26, 52%) the primary research aim was to determine the incidence/prevalence/frequency/rate of medication errors (or a sub-category of medication errors). Fewer focused on the causes of medication errors (16, 32%). Eight studies (16%) reported data relating to incidence/prevalence/frequency/rate and causes of medication errors.

3.7.8 Definition of Medication Errors or subcategories

The definition of medication errors (or sub-categories of medication errors) was inconsistent. Of 50 studies, 17 different definitions were used that differed markedly in wording and content. The most widely used definition was that of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) (128) in the United States (20, 40%). Ten studies (20%) adopted non-standardised definitions from previous studies or provided their own definition. Three studies (3, 7%) used the definition of medication errors as per Aronson *et al* (25). Two studies (5%) on prescribing errors used the definition of the American Society of Health-System Pharmacists (ASHP) (129). One study each used definitions provided by Dean *et al*, Bates *et al* (130) and Institute of Medicine (22). Twelve studies (24%) did not provide a clear definition of either medication errors or the sub-category being reported.

Table 3-3: Definitions of medication errors or subcategories of medication errors

Source	Error Classification	Definition
Non-standardized definitions from previous studies or provided their own definition	Prescribing errors	"A prescription error was defined as an incorrect or inappropriate drug selection (based on indications, contraindications and other factors), dose, route, rate of administration, or frequency. A prescription error also included illegible handwriting, an incomplete order (missing the dose, route, or frequency), incompatibility, incorrect instructions for using the drug product, and the use of non-standard nomenclature or abbreviations that requires further interpretation" (79).
		"A medication error is defined as any error in the medication uses process, whether there are adverse consequences".
		"…therefore, medication error is defined as any type of error in the prescription, transcription, dispensing and administration process which could bring about serious consequences"(90).
		"…any medication administered or prepared in a way that deviates from the prescription chart, the manufacturer's instructions and hospital policy which can be prevented and may cause injury to the patient" (96).
		"…any preventable event at each stage of pharmacotherapy process, such as prescription, transcription, distributing medication, and administration" (101).
		"Medication prescribing errors are defined as discrepancies between intended medication order and the prescription. There have been many reports concerning drug errors published in the medical literature including drug usage, prescribing practices and poor system design in medical practice which can result in occurrence of adverse drug events" (111).
		"Medication errors are broadly defined as errors in prescribing, dispensing or administration of a drug, irrespective of whether such errors lead to adverse consequences or not" (117).
		"A disorder in the treatment process, which is followed by a potential or actual risk of hazard for patient".
		"Disregarding the status of forming a damage, or risk, any avoidable incidence to occur during the process from medication request to patient monitoring" (123).
		"Mistakes associated with drugs and intravenous solutions that are made during the prescription, transcription, dispensing, and administration phases of drug preparation and distribution" (126).

NCCMERP(19,128)	Medication errors	"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"
	Medication Administration Errors	"A deviation from a prescriber's valid prescription or the hospital's policy in relation to drug administration, including failure to correctly document the administration of a medication (91).
Dean B (130)	Prescribing errors	"A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescribing writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice" (86,130).
Aronson et.al (25)	Medication errors	"A medication error is 'a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient" (94,103,127).
Bates et. Al (131)	Medication errors	"Errors occurring at any stage in the ordering or delivering processes of medications" (108).
Institute of Medicine (22)	Medication errors	"Medication errors are events that may cause harm if inappropriate medication is used".
ASHP(129)	Prescribing errors	"Prescribing error was defined as incorrect drug selection, dose, dosage form, frequency, route, or instructions. Incorrect drug selection was based on indication, contraindication, known allergies, existing drug therapy, and other factors".

From this point forward, data extraction and synthesis are presented together in relation to the specific review questions.

3.7.9 Review question 1 - Incidence/prevalence/ of medication errors

Of 32 studies quantifying medication errors, the most common methods of data collection were via review of medication charts or records (prescribing, dispensing and administration) (n=11, 31%) or by analysis of data from an error or incident monitoring system (n=9, 28%). Only one study employed multiple approaches to data collection. Data collection periods ranged from 20 days to two years. Data extraction of the 32 studies is provided in Supplementary Table 2.

Inconsistencies in definitions of 'medication error', 'prescribing error' etc., together with the vast range of approaches to data collection and presentation of findings, limited pooling of data hence a narrative approach to data synthesis was employed. Almost half of the studies (n=32, 47%) quantified 'medication errors' in general, with fewer solely reporting 'administration errors' (n=7, 22%) or 'prescribing errors' (n=6, 18%) and one (3%) reporting only transcribing errors. Three studies reported data with combinations of classifications of medication errors. The specific terms used in the studies to report medications errors varied and eight different denominators were used, the most frequent being 'total number of medication orders' or 'number of prescriptions' (n=13, 40%) followed by 'number of patients admitted' (n=6, 19%), 'total number of opportunities for errors' (n=4, 12%). One study (3%) each used, 'total number of preparations', 'total number of medications dispensed', 'total number of cases/records', 'total number of patient days' and 'total number of reports'. Four studies (13%) did not specify the denominator.

Given this marked heterogeneity, it was not possible to make valid comparisons of the outcome measure of prevalence. Even in studies which used the same outcome measure, the error definitions and methods of

measurement varied considerably. The following results should therefore be interpreted with caution.

Of the 13 studies reporting medication errors per 'total number of medication orders'/ 'number of prescriptions', the median across all studies was 10% (IQR 2-35%). The rates varied from 0.18 to 56 per 100 medication orders'/ 'number of prescriptions'. Of the six studies reporting 'number of patients admitted' the median was 28% (IQR 1-35%), varying from 0.15 to 40 errors per 100 patient admissions. Data extraction is given in Table 3.4.

Table 3-4: Data extraction of the 32 studies reporting medication error incidence/prevalence/frequency/rate

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
Al-Jeraisy, 2011, SA	**Hospital type -** tertiary care **Units/wards –** pediatric wards **No. beds -** 280	**Methodology –** retrospective **Data collection** - chart review **Duration -** 5 weeks	Prescribing errors	**Method –**no. of medication errors/ total medication orders **Terminology -** incidence **Incidence** - 56/100 medication orders
Abbasinazari, 2013, Iran	**Hospital type** – academic **Units/wards:** gastroenterology and endocrinology **No. beds -** NS	**Methodology -** prospective **Data collection** - chart review **Duration -** 2 months	Medication errors	**Method -** no.medication errors/ total no. patients admitted **Terminology -** frequency **Frequency -** 27%
Abbasinazari, 2013, Iran	**Hospital type** - aacademic **Units/wards** - orthopedic, gastroenterology wards **No. beds -** 620	**Methodology -** prospective **Data collection -** chart review **Duration -** 20 days	Medication administration errors	**Method -** medication errors/ total no. preparations and administrations **Terminology -** frequency **Frequency -** 20.6 %
Al Ramahi, 2017 Palestine	**Hospital type** – 3 government hospitals **Units/wards** – pediatric **No. beds -** NS	**Methodology –** prospective observational **Data collection –** EHR **Duration -** 1 month	Prescribing errors	**Method –** number wrong doses/total number of patients **Terminology -** Percentage **Percentage -** 40%
Alakahli, 2014, Yemen	**Hospital type** - 3 tertiary care hospitals **Units/wards** – intensive care **No. beds -** NS	**Methodology -** prospective **Data collection -** observational **Duration -** 4 months	Medication errors/ Prescribing and administration errors	**Method –** NS **Terminology -** Frequency **Frequency –** Prescribing errors -87.5% Administration errors – 12.41%

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
Al-Dhawailie, 2011, SA	**Hospital type** - academic **Units/wards** – Medical wards **No. beds -** 1200	**Methodology -** prospective **Data collection -** chart review **Duration -** 1 months	Prescribing errors	**Method –** no. pharmacist interventions/ total no. written medication orders **Terminology -** Frequency **Frequency -** 7.1%
Al-Hajje, 2008, Lebanon	**Hospital type -**7 hospitals **Units/wards** - medicine, intensive care, cardiology , pediatrics **No. beds -** NS	**Methodology -** prospective **Data collection -** chart review **Duration** - 1 months	Prescribing errors	**Method –** no. prescribing errors/ total no. of medication orders **Terminology –** percentage **Percentage –** 39.3 %
Al Jadhey, 2013, SA	**Hospital type** - academic **Units/wards** – general **No. beds -** 900	**Methodology -** prospective cohort study **Data collection –** IRS **Duration -** 4 months	Medication errors	**Method –** no. prescribing errors/ 1000 patient-days **Terminology -** Incidence **Incidence -** 23.2 /1000 patient days
Ali S, 2017 SA	**Hospital type** – tertiary care **Units/wards –** hospital wide **No. beds –** NS	**Methodology –** retrospective **Data collection –** IRS **Duration –** 1 year	Medication errors	**Method –** no of ME reported/ total number of prescriptions ordered **Terminology –** incidence **Incidence –** ME - 1.5/100 prescriptions
Alshaikh, 2013, SA	**Hospital type** - academic **Units/wards -** NS **No. beds -** 1000	**Methodology -** prospective **Data collection –** IRS **Duration -** 1 year	Medication errors	**Method –** no. medication errors/ total no. prescriptions **Terminology -** rate **Rate -**0.4%
Arabi, 2012, SA	**Hospital type** – academic **Units/wards –** hospital wide **No. beds -** 900	**Methodology –** retrospective **Data collection –** IRS **Duration -** 1 year	Medication errors	**Method –** no. incident reports / 1,000 patient days **Terminology –** incidence **Incident** – 5.8/1000 patient days

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
al Tehewy, 2016, Egypt	**Hospital type** - academic **Units/wards** – medical wards **No. beds** - 199	**Methodology –** prospective **Data collection -** observational **Duration -** 1 months	Medication administration errors	**Method –** total errors/ 100 opportunities of error (observation) *100 **Terminology -** rate **Rate –** 2.7/ observation
Dabaghzadeh, 2012, Iran	**Hospital type** - academic **Units/wards –** emergency department **No. beds -** 24	**Methodology –** prospective **Data collection -** chart review **Duration -** 1 month	Medication administration errors	**Method -** NS **Terminology –** incidence **Incidence –** 50.5%
Dibbi, 2006, SA	**Hospital type** – general **Units/wards** - intensive care **No. beds -** NS	**Methodology -** retrospective **Data collection -** chart review **Duration -** 2 years	Medication errors	**Method –** no. of records with ME/ total no. patient records **Terminology -** incidence **Incidence –** 26.3 %
El-Shazly, 2017, Egypt	**Hospital type** - academic **Units/wards –** NICU **No. beds -** NS	**Methodology -** prospective and retrospective **Data collection -** observation **Duration -** 6 months	Medication errors	**Method –** No. medication errors/ total no. written medication orders **Terminology -** percentage **Percentage -** 10.55%
Fahimi, 2009, Iran	**Hospital type** – academic **Units/wards** –hospital wide **No. beds -** NS	**Methodology –** prospective **Data collection -** observation **duration -** 5 months	Transcribing error	**Method –** no. medication errors/ total no. opportunity for errors **Terminology -** incidence **Incidence -** 51.8%
Fahimi, 2008, Iran	**Hospital type** - academic **Units/wards** – intensive care **No. beds -** 446	**Methodology -** prospective **Data collection -** observation **Duration -** 3 months	Medication administration errors	**Method –** no. prescribing errors/ total no. written medication orders **Terminology -** frequency **Frequency -** 9.4%

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
Fahimi, 2015, Iran	**Hospital type** - tertiary care **Units/wards –** respiratory wards **No. beds -** NS	**Methodology –** prospective **Data collection -** observation **Duration -** 1 year	Medication administration errors	**Method –** no. ME/100 admitted patients **Terminology -** rate **Rate -** 35.3 %
Gharekhani, 2014, Iran	**Hospital type** - academic **Units -** nephrology **No. beds -** 23	**Methodology -** prospective, **Data collection -** pharmacist interventions **Duration -** 18 months	Medication errors	**Method –** no. medication errors/ total no. medication orders **Terminology –** percentage/incident rate **Percentage -** 86.2% **Incidence –** 3.5 patient or 0.18/order
Hamishehkar, 2014, Iran	**Hospital type** - general **Units/wards –** infectious diseases **No. beds -** 25 beds	**Methodology –** prospective **Data collection –** chart review	Medication errors	**Method –** no. of ME/no of admission **Terminology –** mean **Mean -** 0.633
Hammour KA, 2016 Iran	**Hospital type** – academic hospital **Units/wards** – hospital wide study **No. beds –** 570 beds	**Methodology –** retrospective **Data collection** – IRS **Duration –** 14 months	Administration errors/dispensing errors/prescribing errors	**Method –** NS **Terminology -** percentage **Percentage –** Administration errors - 75.5% Dispensing errors – 12.8% Prescribing errors – 10.5
Kandil, 2012, Egypt	**Hospital type** - academic **Units/wards** – emergency **No. beds -** NS	**Methodology -** prospective **Data collection -** observation **Duration -** 9 months	Medication administration errors	**Method –** no. prescribing errors/ total no. written medication orders **Terminology -** percentage **percentage -** 4.18%

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
Khammarnia, 2015	**Hospital type** – general hospital **Units/wards** –ICU **No. beds -**14	**Methodology –** retrospective **Data collection -** chart review **Duration -** 3 months	Medication administration errors	**Method –** no. of ME/ total medication orders **Terminology –** Rate **Rate –** 17.3%
Lustig, 2000, Israel	**Hospital type** - academic **Units/wards** - intensive care **No. beds -** 400	**Methodology -** prospective **Data collection –** structured form **Duration-** 6 months	Prescribing errors	**Method –** no. prescribing errors/ 1,000 prescriptions **Terminology -** rate **Rate -** 11.2/1000 prescriptions.
MAS Ali, 2017 Egypt	**Hospital type** – academic hospital **Units/wards –** coronary care unit **No. beds -** 16	**Methodology –** prospective observational **Data collection –** chart review **Duration -** 12 months	Medication errors/prescribing errors/monitoring errors	**Method –** total prescription item reviewed /number of ME **Terminology -** incidence **Incidence –** prescribing errors – 9.03%, monitoring errors – 0.41%
Pawluk, 2017, Qatar	**Hospital type** – tertiary care **Units/wards –** neonatal intensive care **No. beds -** 80	**Methodology -** retrospective **Data collection –** IRS **Duration -** 16 months	Medication errors	**Method -** NS **Terminology –** total number of ME **Total Number -** 201
Sadat-Ali, 2010, SA	**Hospital type** – tertiary care **Units/wards -** NS **No. beds -** 470	**Methodology -** retrospective **Data collection –** IRS **Duration -** 2 years	Medication errors	**Method –** no. medication errors / 1000 admissions **Terminology –** Incidence **Incidence -** 1.58/1000 admissions
Saravi, BM, 2015, Iran	**Hospital type** – academic hospital **Units/wards -** NS **No. beds -** NS	**Methodology -** retrospective **Data collection -** IRS **Duration -** 1 year	Medication errors	**Method -** no. medication errors/ total no. admissions **Terminology –** percentage **Percentage -** 28%

Author	Setting	Method	Error type reported	Determination of error incidence/ prevalence/ frequency/ rate
Sulaiman 2017, Jordan	**Hospital type** – academic hospital **Units/wards –** internal medicine **No. beds - 54**	**Methodology –** prospective observational **Data collection -** direct observation and chart review **Duration –** 6 month	Medication errors	**Method –**no of ME/ total opportunities of errors * 100 **Terminology –** rate **Rate –** 12.6% ie. 2.6/patient
Vazin, 2012, Iran	**Hospital type** - academic **Units/wards** – intensive care **No. beds -** 11	**Methodology -** prospective **Data collection -** observation **Duration -** 38 shifts	Medication errors	**Method –** no. medication errors/ total no. opportunities for error **Terminology –** percentage **Percentage -** 7.6%
Vessal, 2010, Iran	**Hospital type** – academic **Units/wards -** nephrology **No. beds -** 15	**Methodology –** retrospective **Data collection -** chart review **Duration -** 4 months	Prescribing errors	**Method** - rate of prescription errors/ 100 medication orders **Terminology - r**ate **Rate -** 10.5 /100 medication order
Zeraatchi, 2013, Iran	**Hospital type** - academic **Units/wards** – emergency department **No. beds -** 46	**Methodology - prospective** **Data collection -** chart review **Duration -** 1 year	Medication errors	**Method –** ME/ total number of patients and/or medication orders **Terminology –** percentage/rate **Percentage -** 22% **Rate –** 0.41/patient and 0.18/ medication order

NS – Not Specified /No details available, NICU - neonatal intensive care unit, SA – Saudi Arabia, IRS – Incident reporting system, EHR – Electronic Health Record

3.7.10 Review question 2 – nature of medication errors

Almost all studies (31/32, 97%) provided data regarding the nature of the errors. For prescribing errors, the most commonly reported included errors of omission, wrong drug, wrong dose, wrong route, incomplete order, wrong duration, drug-drug interaction and wrong patient. Studies reporting administration errors were largely related to wrong administration time, wrong administration route and wrong infusion rate. Fourteen studies (43%) reported the specific medications most commonly associated with errors. Most frequently reported therapeutic groups included anti-infectives for systemic use, drugs used for alimentary tract and metabolism and cardiovascular drugs.

Thirteen studies (40%) reported error severity, with eight categorising according to the NCCMERP Index (132). These studies, however, provided very little methodological detail on the application of the index, specifically assessment of inter-rater reliability. In five studies, the most common category was B (near miss), with C (error occurred and reached the patient but with no harm) in two studies and E (error occurred and may have contributed to or resulted in temporary harm and required intervention) in one study.

3.7.11 Review question 3 – causes/contributory factors of medication errors

Twenty-four studies (48%) from six Middle-Eastern countries reported causes or contributory factors leading to medication errors. Approaches to data collection were largely based on questionnaires (15/24, 63%), data from incident reporting systems (n=4, 17%), direct observation of practice (n=2, 8%), semi-structured interviews (n=2, 8%) and retrieval of information from patient medical records (n=1, 4%). A total of 3919 health professionals were involved in these 24 different studies. Notably, none of these 24 studies used any theory (e.g. behavioural, organisational) in the processes of data collection or analysis. As described in the methods section, findings from these 24 studies were categorised according to Reason's Accident Causation model (64), (Table 3.5) and synthesis of the categories is provided in Table 3.6. Contributory factors most commonly reported were: active failures, largely slips, lapses and mistakes; error provoking conditions, particularly those relating to lack of knowledge and insufficient staffing levels; and latent conditions, most commonly heavy workload. Error provoking conditions such as lack of experience, poor documentation and look alike drugs, or latent conditions of issues relating to a blame culture were rarely reported.

Table 3-5: Classification of causes as per Reason's model of accident causation

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Abdar, 2014, Iran	Cross-sectional survey	**Setting –** 4 academic hospitals **Participants –** nurses **No. of Participants -** 238	**Error producing conditions** • insufficient staff • nurse fatigue • illegible handwriting • nurse workload	**Latent failures** • supervisory issues • not considering nurses' views	
Alshaikh M (2013) Saudi Arabia	Retrospective analysis from incident reporting system	**Setting –** academic hospital **Participants –** NA **No. of ME reported –** 949 **Duration –** 1 year	**Error Producing Conditions** • lack of knowledge • illegible handwriting	**Latent Failures** • performance deficit	
Al-Shara M. (2011) Jordan	Cross-sectional survey	**Setting -** NS **Participants –** Nurses **No. of Participants -** 126	**Active Failures** • **Slips** - sound alike • **Mistake** - prescribing wrong dosage • **Violation** - using abbreviations	**Error Producing Conditions** • heavy workload • unfamiliarity of nurses' with patients' medical conditions • unfamiliarity with the use of medications	
Ali S, (2017) Saudi Arabia	Retrospective analysis from incident reporting system	**Setting –** tertiary care hospital **Participants –** NA **No. of Participants -** NA	**Active Failures** • **Slips** - look alike sound alike medications	**Error Producing Conditions** • miscommunication of drug orders	**Latent Failures** • Lack of educational activities

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Al Tehewy M (2016) Egypt	Prospective observational study	**Setting -** academic hospital **Participants -** nurses **No. of Participants -** 28	**<u>Error Producing Conditions</u>** • heavy workload • patient condition (illiteracy, elderly)	**<u>Latent Failures</u>** • poor staffing • lack of policy and procedures • low commitment of hospital administration towards patient safety	
Bagheri-Nesami M (2015) Iran	Cross-sectional survey	**Setting –** 12 academic hospitals **Participants –** Nurses **No. of Participants -** 190	**<u>Active Failures</u>** • **Slips** - selecting wrong medication • **Lapse** - failed to put correct labels on medications • **Mistake -** delivered incorrect medication doses	**<u>Error Producing Conditions</u>** • physicians' medication orders illegible • many patients receiving similar medications • limited knowledge of medications	**<u>Latent Failures</u>** • poor communication • Limited access to medication information. • Medication experts not available.
Cheragi M (2013) Iran	Cross-sectional survey	**Setting -** academic **Participants –** nurses **No. of Participants -** 237	**<u>Active Failures</u>** • **Slips** - wrong patient, • **Lapse** - failure to give medication • **Mistake -** prescribing wrong dosage and infusion rate • **Violation -** using acronyms of medication names	**<u>Error Producing Conditions</u>** • large variety of drugs in the medication cabinet • sound alike medications • too busy and tired from excessive work (nurses)	**<u>Latent Failures</u>** • lack of training • lack of staffing

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Dibbi HM (2006) Saudi Arabia	Retrospective chart review	**Setting –** general hospital **Participants –** NA **No. of Participants -** 2627	**Active Failures** • **Slips –** choosing wrong medication (look alike and sound alike)	**Error Producing Conditions** • lack of knowledge • performance deficit	
Ehsani SR (2013) Iran	Cross-sectional survey	**Setting –** academic hospital **Participants –** nurses **No. of Participants -** 94	**Active Failures** • **Slips** - choosing wrong medication (look alike and sound alike) • **Violation -** using abbreviated names	**Error Producing Conditions** • fatigue from hard work • illegibility • insufficient pharmacological knowledge	**Latent Failures** • high patient -to- nurse ratio • insufficient education/training
Farzi S 2017 Iran	Semi structured individual interview	**Setting -** academic hospitals **Participants –** Physicians, Nurses and clinical pharmacists **No. of Participants -** 19	**Active Failures** • **Slips** -Look alike sound alike • **Mistake –** incomplete medication orders	**Error Producing Conditions** • lack of knowledge of healthcare team • lack of professional communication • lack of medication reconciliation • interruption/talking while medication administration • lack of pharmaceutical knowledge	**Latent Failures** • lack of monitoring or supervisory mechanisms • weak professional collaboration between healthcare team • lack of management decisions • lack of adequate staffing

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Fathi (2017) Iran	Cross-sectional survey	**Setting –** 7 academic hospitals **Participants –** Nurses **No. of Participants -** 500	**Active Failures** • **Slips** -Look alike sound alike • **Mistake –** wrong labelling	**Error Producing Conditions** • inappropriate behavior of patients • fatigue from hard work • phone call orders • high number of patients • noisy environment	**Latent Failures** • lack of monitoring or supervisory mechanisms • shortage of nursing staff • lack of drug information resources
Gorgich (2016) Iran	Cross-sectional survey	**Setting -** academic hospitals **Participants –** Nurses **No. of Participants -** 327	**Active Failures** • **Violation -** unreadable orders	**Error Producing Conditions** • fatigue due to high workload • large number of critically ill patients • poor physical environment (light, temperature) • poor communication between team members	**Latent Failures** • low ratio of nurses to patients • failure in emphasizing the importance of recording and reporting the medication errors • blame culture

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation	
Güneş Ü,Y (2014) Turkey	Cross-sectional survey	**Setting -** 2 government hospitals **Participants –** nurses **No. of Participants** 243	**Active Failures** • **Lapse** - physicians not writing drug route • **Mistake -** prescribing interacting drugs • **Violation -** physicians not writing the order or not in time	**Error Producing Conditions** • interruption by telephone, etc. while preparing medication • poor mathematical skills for drug dose calculation
Hammoudi (2017)	Cross-sectional survey	**Setting –** tertiary care hospital **Participants –** Nurses **No. of Participants -** 367	**Error Producing Conditions** • illegibility of patients records • wrong medication preparation by pharmacists	**Latent Failures** low staffing
Mrayyan (2012) Jordan	Cross-sectional survey	**Setting –** academic hospitals **Participants –** Nurses **No. of Participants -** 212	**Active Failures** • **Mistake -** inaccurate rate of total parenteral nutrition	**Error Producing Conditions** • poor quality or damaged medication labels • fear of disciplinary actions
Mrayyan (2007) Jordan	Cross-sectional survey	**Setting –** 11government and 11 private hospitals **Participants –** nurses **No. of Participants –** 799	**Active Failures** • **Slips** - nurses confused by different types and functions of infusion devices • **Lapse** - nurse fails to check the patient name with medication administration record	**Error Producing Conditions** • nurses distracted by other patients, coworkers or events on unit

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Pawluk S (2017) Qatar	Retrospective analysis from incident reporting system	**Setting –** tertiary care hospital **Participants –** NA **No. of Participants -** 201	**Active Failures** • **Lapse** – missing documentation • **Mistake -** error in calculation • **Violation -** improper use of hospital protocol		
Pazokian M (2014) Iran	Semi structured individual interview	**Setting –** academic hospital **Participants –** nurses **No. of Participants -** 20	**Active Failures** • **Mistake -** prescribing wrong medications	**Error Producing Conditions** • poo documentation • poor knowledge	**Latent Failures** • lack of attention of managers to staff physical and psychological issues leading to decrease in nurses' motivation • Risk management strategies insufficient
Shahrokhi A (2013) Iran	Cross-sectional survey	**Setting –** academic hospitals **Participants –** nurses **No. of Participants -** 150	**Active Failures** • **Mistake -** incorrect transcription	**Error Producing Conditions** • excessive workload • inadequate pharmacological knowledge • shortage of time	**Latent Failures** • Low nurse to patient ratio • inadequate number of staff in each working shift • Similar drug packing

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Shehata ZHA (2015) Egypt	Retrospective analysis from incident reporting system	**Setting –** government and private hospitals **Participants –** NA **No. of Participants – 1200 reports**	**Active Failures** • **Lapse** - lack of documentation	**Error Producing Conditions** • lack of knowledge and experience • excessive workload and distractions • incomplete prescribing instructions • illegible handwriting	**Latent Failures** • lack of drug information resources
Shohani M 2018 Iran	Cross-sectional survey	**Setting –** academic hospital **Participants –** Nurses **No. of Participants -** 120	**Error Producing Conditions** • lack of awareness of drug • fatigue and workload • lack of patient information • noisy working environment • heavy work load		**Latent Failures** • lack of motivation among nurses • lack of drug protocol • lack of training
Toruner EK 2012 Turkey	Cross-sectional survey	**Setting –** 4 tertiary care hospitals **Participants –** Nurses **No. of Participants -** 124	**Active Failures** • **Mistake -** reading the prescription in wrong way	**Error Producing Conditions** • long working hours • high patient – nurse ratio • lack of patient information	**Latent Failures** • unavailability of medications in appropriate forms • poor work environment

Author	Methodology	Setting, participants and Number	Classification of causes as per Reason's model of accident causation		
Vazin A (2012) Saudi Arabia	Prospective Observational study	**Setting –** academic hospitals **Participants – patients** **No. of Participants - 38**	**<u>Active Failures</u>** • **Slips** - memory lapses • **Lapse** - faulty dose checking (missing) • **Mistake -** preparation error • **Violation -** violating hospital rules	**<u>Error Producing Conditions</u>** • lack of drug knowledge • lack of interaction with other services • lack of patient information	**<u>Latent Failures</u>** • poor drug stocking and delivery
Youssif (2013) Saudi Arabia	Cross-sectional survey	**Setting –** government hospital **Participants –** nurses **No. of Participants -** 253	**<u>Active Failures</u>** • **Lapse** – dispensing wrong drug • **Mistake -** wrong packaging • **Violation -** poor adherence to protocol	**<u>Error Producing Conditions</u>** • illegible prescription • poor communication	**<u>Latent Failures</u>** • pharmacists not available 24hrs

Table 3-6: Human errors at different levels in an organisational hierarchy, classified based on the Reasons Accident Causation Model

Reference	Active Failure				Error Provoking Conditions									Latent Conditions					
	Slips	Lapse	Mistake	Violation	Lack of knowledge	Low staff	Patient conditions	Poor communication	Lack of experience	Distractions	Look alike drugs	Poor Documentation	Illegible orders	Heavy workload	Lack of training	Organization factors	Blame culture	Supervisory issues	Poor Organizational policies	Lack of information
Abdar *et al*, (82)						✓							✓	✓		✓		✓		
Alakahli *et al* (84)					✓								✓							
Al-Shara *et al*,	✓	✓		✓	✓				✓					✓						
Ali S *et al*,	✓							✓							✓					
Al Tehewy *et al*, (91)						✓	✓							✓				✓	✓	
Bagheri-Nesami et al, (20)	✓	✓	✓		✓							✓	✓					✓		✓
Cheragi *et al*, (93)	✓	✓	✓	✓		✓				✓	✓				✓					
Dibbi *et al*, (95)	✓				✓															
Ehsani *et al*, (96)	✓				✓	✓							✓	✓	✓					

*Farzi *et al*, (101)	✓		✓		✓	✓		✓		✓						✓		✓		
Fathi *et al*, (102)	✓		✓			✓		✓		✓								✓		✓
Gorgich *et al*,				✓		✓	✓	✓						✓			✓	✓	✓	
Güneş *et al*,		✓	✓	✓	✓					✓										
Hammoudi *et al*, (107)						✓							✓							
Mrayyan *et al*, (113)			✓														✓			
Mrayyan *et al*,	✓	✓								✓										
Pawluk *et al*		✓	✓	✓																
*Pazokian *et al*,			✓		✓			✓										✓	✓	
Shahrokhi *et al*,			✓		✓	✓					✓			✓						
Shehata *et al*,		✓			✓								✓	✓						✓
Shohani *et al*, (121)					✓	✓	✓			✓				✓	✓					✓
Toruner *et al*, (123)			✓		✓	✓				✓				✓		✓				
Vazin *et al*,	✓	✓	✓	✓	✓	✓										✓				
Youssif *et al*, (126)		✓	✓	✓		✓		✓					✓						✓	

3.8. Discussion

3.8.1 Statement of key findings

Heterogeneity in medication error definitions and scope, differences in methods of data collection and units of analysis of the studies included in this review limited data pooling. This heterogeneity limited data pooling conducted as part of the synthesis stage. Most frequently reported was the percentage of medication errors per total number of medication orders with a median across all studies of 10% (IQR 2-35%). Prescribing errors were the most common type of errors reported, with dose-related errors being most prevalent. Contributory factors associated with medication errors were multifactorial. Synthesis of findings according to Reason's Accident Causation (64) model identified that active failures (slips, lapses and mistakes) were most commonly reported followed by error provoking conditions (e.g. lack of knowledge, insufficient staffing), with latent failures (e.g. heavy workload) least reported. There was only one study from Qatar which reported medication errors occurring in a specialised setting (neonatal intensive care unit - NICU) and was limited to analysis of error reports submitted by pharmacists, with no focus on error causation.

3.8.2 Strength and weakness

There are several strengths to this review. The protocol was developed according to the standards of PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (75), registered in the PROSPERO database (76) and the systematic review reported according to PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) criteria (75). The synthesis adopted a theory driven approach based on Reason's Accident Causation Model (64), which could subsequently facilitate the development of interventions. There are, however, several weaknesses hence the review findings should be interpreted with caution.

Restricting the search to the English language and excluding those written in regional languages of Arabic or Persian may have limited retrieval of potentially relevant studies. It is, however, worth noting that English is the preferred language of most professional organisations in the Middle East.

3.8.3 Interpretation of key findings

Although there has been an increase in the number of medication errors studies originating from Middle East over the last few years, two thirds were from Iran and Saudi Arabia with none from eight countries. While the reasons for the lack of studies in other countries are unknown, this does have implications for the generalisability and transferability of review findings and conclusions. Furthermore, there was a lack of studies employing a qualitative approach to explore contributory factors of errors.

The majority of studies had key limitations in study design and lacked transparency in reporting key study details. Authors should be encouraged to adopt standardised reporting checklists available from the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network (133). This international network aims to 'improve the reliability and value of published health research literature by promoting transparent and accurate reporting.' An example is the STROBE checklist (Strengthening the Reporting of Observational Studies in Epidemiology) for reporting observational studies (77).

As noted in previous systematic reviews (6,7,12,26,29,30,34,36,37,134-136), many studies either did not define terms such as 'medication errors', 'prescribing errors' etc., or used non-standardised definitions. The most common terminologies used in this regard varied from error, failure, near miss, rule violation, deviation, preventable ADE and potential ADE etc. It is evident from these studies that the multiplicity of definitions or terminology used has led to variation in prevalence of medication errors, while making it difficult to quantify the medication error occurrence rates. There was also variation in the methods used and the duration of data collection. To further

advance this field of research, the adoption of standardised definitions and methodologies should be encouraged. This would enable analytical approaches such as meta-analyses and provide more robust and generalisable findings to inform practice.

Few studies reported the severity of errors, often providing little methodological detail. In a systematic review of tools used in error severity estimation, Garfield et al. highlighted that of the 40 tools assessed; only two were deemed to have acceptable validity and reliability (122).

Despite these issues around standardisation, it is evident from this systematic review that medication errors remain prevalent in hospitals in the Middle East. For those reporting medication errors, the median 'total number of medication orders'/ 'number of prescriptions' across all studies was 10% (IQR 2-35% and range of 0.18-56%). While differences in methodology, settings and patient populations limits comparisons to other systematic reviews, these figures are similar to those reported by Alsulami et al. in a systematic review of Middle Eastern studies up to 2011 (30). The prevalence of medication errors in the Middle East would appear to remain largely unchanged and at a similar level to those reported from around the world (6,7,12,26,29,30,34,36,37,134-136).

None of the 24 studies in this review and only two previous systematic reviews analysed causative factors according to Reason's theory. In a review of prescribing errors in hospitalised patients, Tully et al. reported that the active failure most frequently cited was a mistake due to inadequate knowledge of the drug or the patient. There were issues of lack of training or experience, fatigue, stress, high workload and inadequate communication between healthcare professionals [9]. In a systematic review of medication administration error studies, Keers et al. reported that slips and lapses were the most common unsafe acts (26). Our synthesis of study findings according to Reason's Theory are similar in those active failures of slips, lapses and mistakes were most common. Error provoking conditions included lack of

knowledge and insufficient staff. It is possible that other contributory factors may have been identified if the primary studies had used Reason's Theory in data collection and analysis. Using a theoretical framework in primary research would ensure that all possible explanations underlying medication errors are identified [84]. Given the accumulation of evidence from this and other systematic reviews a standardised, theory informed approach should be adopted. This is fundamental to the key stated WHO objective of assessing and scoping the nature of avoidable medication-related harm (2).

Policy makers, leaders, practitioners and other relevant stakeholders must continue working towards minimising the key identified contributory factors where possible.

3.9. Conclusion

While there has been a clear increase in the number of publications from selected Middle Eastern countries, there is need to improve the quality and reporting of studies. A standardised approach to quantifying medication errors prevalence, severity, outcomes and contributory factors is warranted.

3.10. Implications for further research

The systematic review identifies the lack of qualitative studies grounded in theories of behaviour and behaviour change originating from the middle-east to provide an in-depth understanding of specific issues that contributes to medication errors, such as social/professional role and identity, emotions, and environmental context and resources etc. The review further highlights paucity of quantitative data from Qatar around medication errors, guiding the doctoral thesis to further phases.

Chapter 4 : An analysis of medication error reports in Hamad Medical Corporation

4.1 Introduction

This chapter presents an overview of the medication error reporting system and process operating within HMC. This is followed by the introduction, aim, method, results and discussion of research utilising standard medication error reports as a source of data collection.

The systematic review presented in the previous chapter highlighted the lack of any consistency in medication error studies set in hospitals of the Middle East in terms of methods, methods of data collection and outcome measures. While nine studies described medication error data routinely collected via error or incident reports, none of these has been conducted in Qatar. Furthermore, these studies primarily reported error prevalence and did not present data relating to contributory factors.

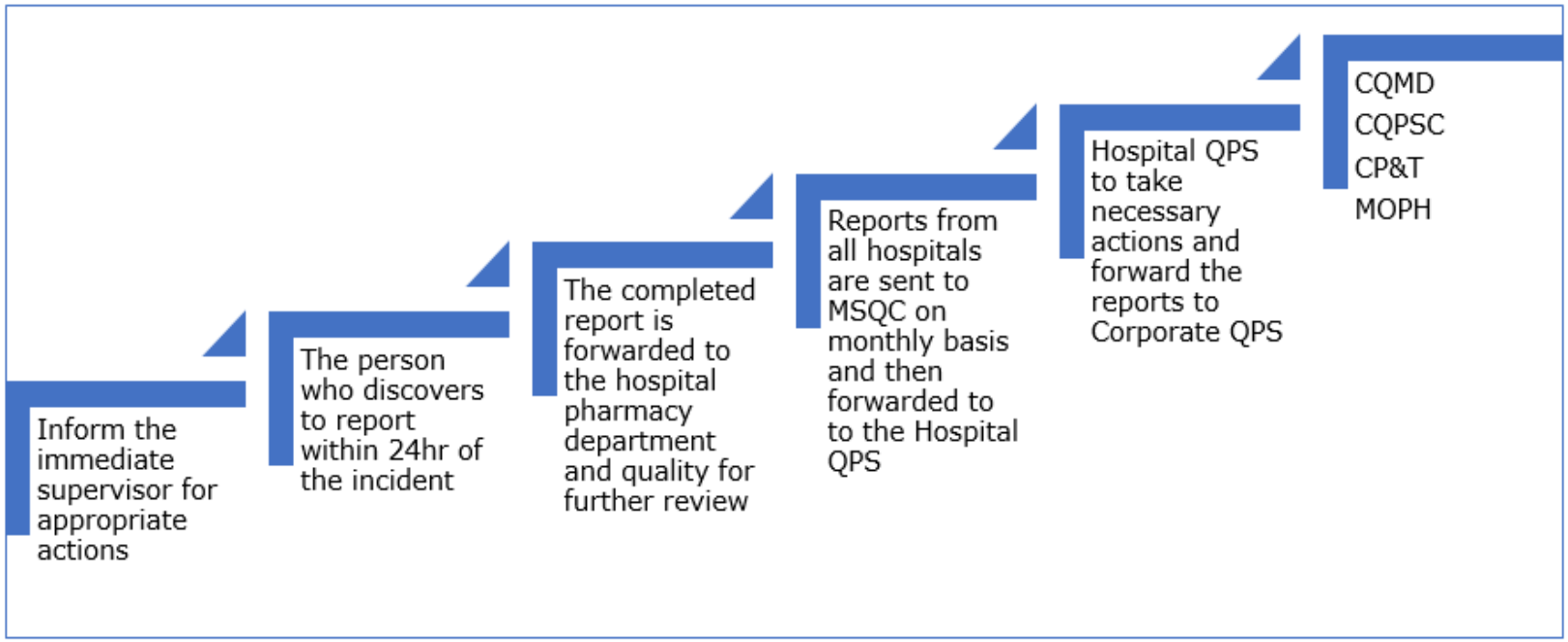
Prior to conducing further primary research on the causes and reporting of medication errors in Qatar, there was a need to study the actual reports.

As noted earlier, the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines a medication error as, *"any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional (HCP), patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"*.(137)

This definition has been adopted by Hamad Medical Corporation (HMC) in the policy on error reporting, 'Managing and Reporting Medication Errors and Near Misses' (CL-7045) (see Appendix 1.1). Within the policy, all medication errors and near misses must be reported immediately. A near miss is defined as, *"an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. An example of a near miss would be prescribing, transcribing, or administering medication to the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance."*

4.2 Medication error reporting in HMC

Medication Error reporting in HMC is policy driven and has recently migrated from paper-based reporting to an electronic reporting using RL Solutions (RL6) (20). To better understand the nature and scope of medication-related harm, improve the current medication safety practices, and further strengthen the pharmacovigilance activities, the pharmacy leadership at HMC established a corporate clinical unit, the Medication Safety & Quality Centre (MSQC). MSQC is responsible for collecting and collating data on safe medication use practices and to report to key stakeholders and policy makers. The medication error reporting process is described in Figure 4.1.



MSQC – Medication Safety and Quality Center, QPS - Quality and Patient Safety, CQMD - Corporate Quality Management Department, CQPSC - Corporate Quality and Patient Safety Committee, CP&T - Corporate Pharmacy and Therapeutic Committee, MOPH – Ministry of Public Health

Figure 4-1: Process flow of medication error reporting and analysis at HMC

The medication error policy mandates that the supervisor is informed immediately of all errors and near misses (e.g. wrong route, frequency, unclear/wrong order, wrong time administration, omission, wrong dispensing) so that appropriate corrective action can be taken if required. Furthermore, the individual identifying the error should, within 24 hours, submit a report via the electronic reporting system (RL6). If the error reaches the patient the physician, the error and progress should be documented in the patient's clinical progress notes. The completed incident report should also be forwarded to the hospital pharmacy department for further review and feedback. The reports are also sent to the medication safety and quality center for in-depth review and analysis. The Quality and Patient Safety department within each facility is responsible for taking appropriate action regarding serious incidents and forwarding the report to the Corporate Quality Management Department. This department is responsible for consolidating each facility's quarterly and annual reports, including action taken, and for sharing the data with the Corporate Quality and Patient Safety Committee, the Corporate Pharmacy and Therapeutic Committee and the Ministry of Public Health.

4.3 The reporting system (RL 6)

RL6 is a web-based online reporting system adapted by HMC for voluntarily reporting of medication errors (and other non-medication related incidents) by healthcare professionals in a standard format. This system has been in place since 2009 and was modified in 2015 to improve medication error reporting. Medication errors are classified into four levels and nine severity categories ranging from potential for error (category A) to actual error that may have contributed to or resulted in a patient's death (category I), as recommended by NCCMERP (ref).

This medication error form was designed to capture all medication related incidents and was divided into six main sections

4.3.1.1 The medication error reporting form (electronic)

General Event Information

This section includes general information about the event, including whether or not this was a medication related incident, the location of the person affected, any injury caused and whether the event was due to any malfunctioning of the equipment

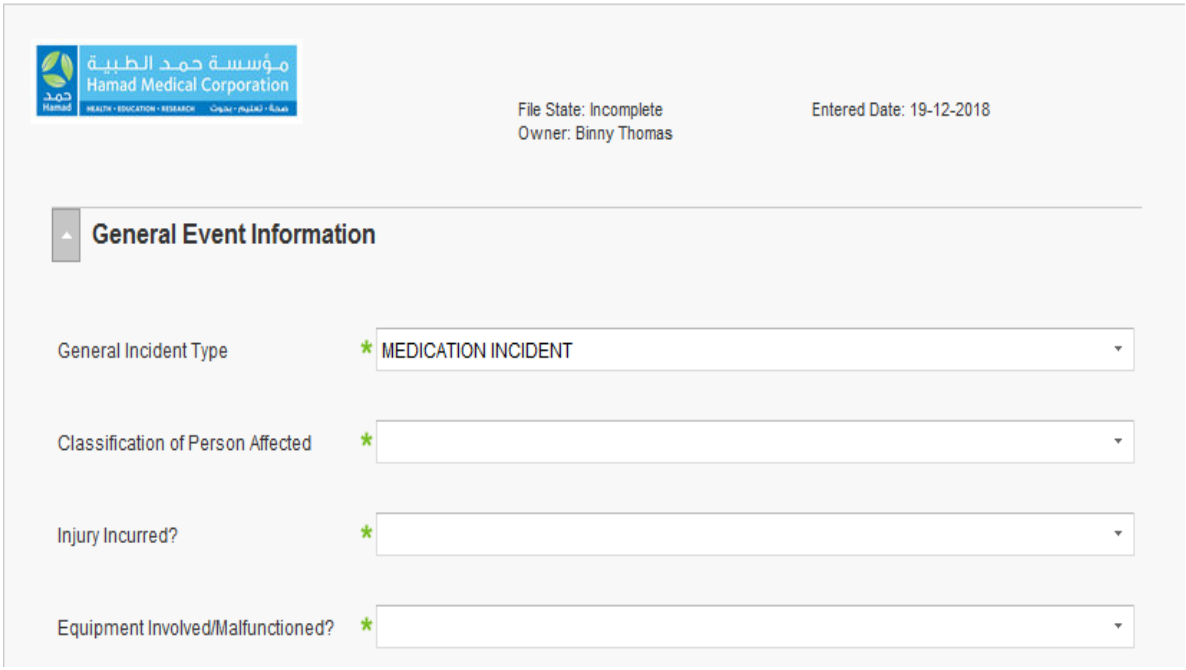


Figure 4-2: Screenshots of HMCs medication error electronic reporting form (general Information about the error)

Person Affected

This section gathers the demographic details of the person affected, including name, marital status, age, contact details etc.

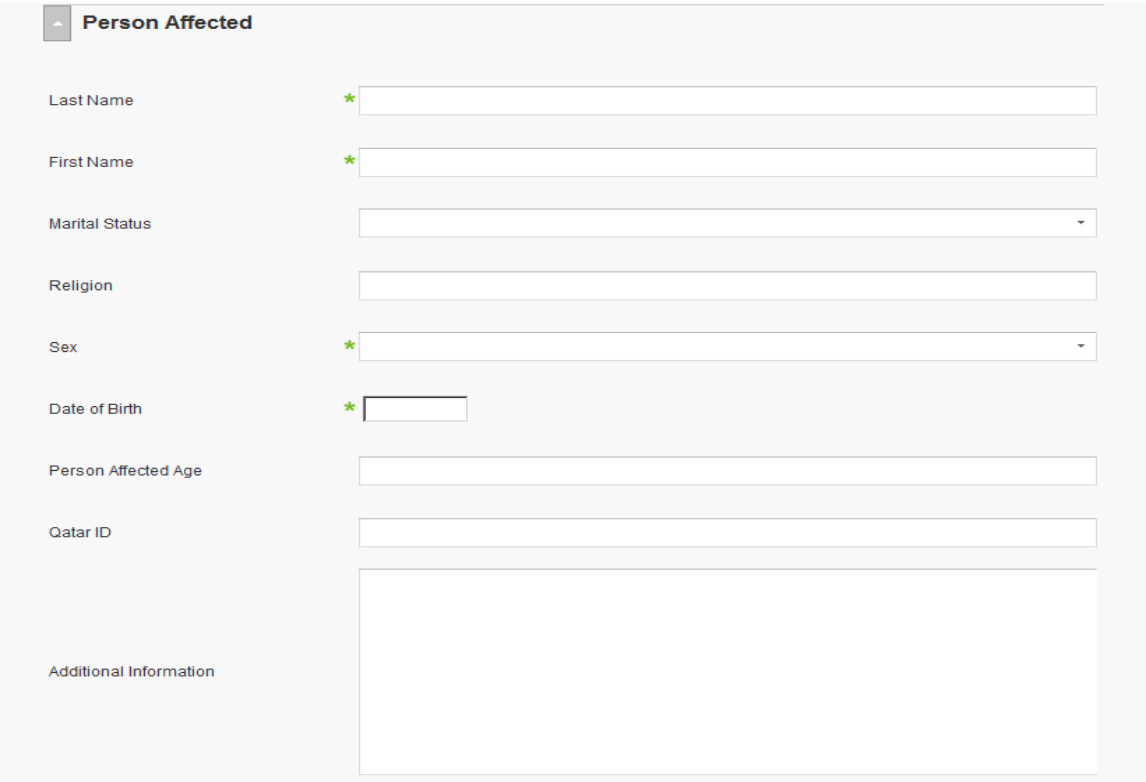
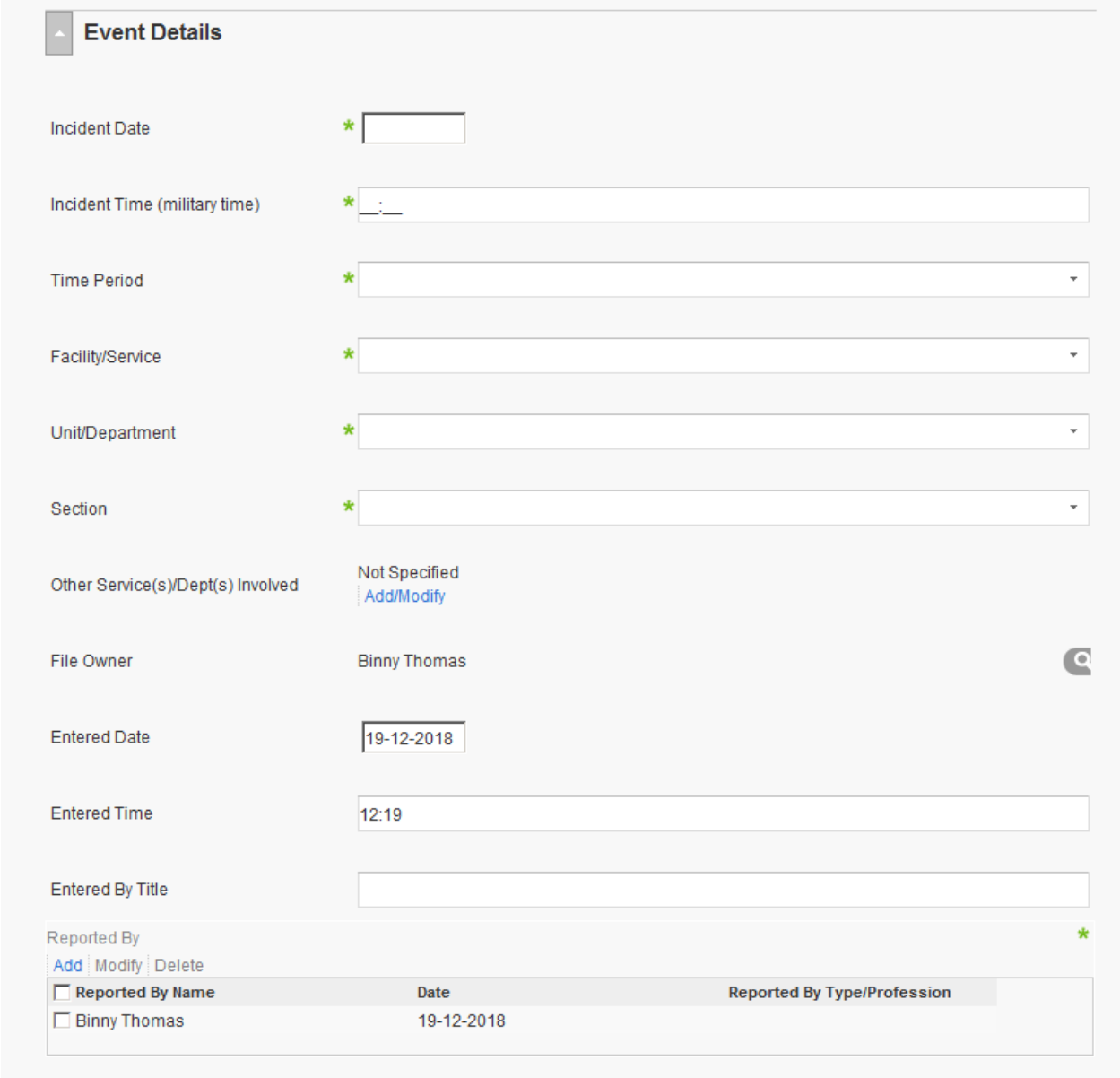


Figure 4-3: Screenshot of HMC medication error electronic reporting form

Event Details/specific event details

This section gathers details of the date and time of the incident, the hospital/facility involved, and the person who identified and reported the incident. The section also gathers a description of the type of medication error that has occurred (e.g. prescribing, dispensing etc.) causes/contributory factors, details of the immediate action taken to mitigate



the harm, severity of error, and a description of the error.

Figure 4-3: Screenshot of HMC medication error electronic reporting form

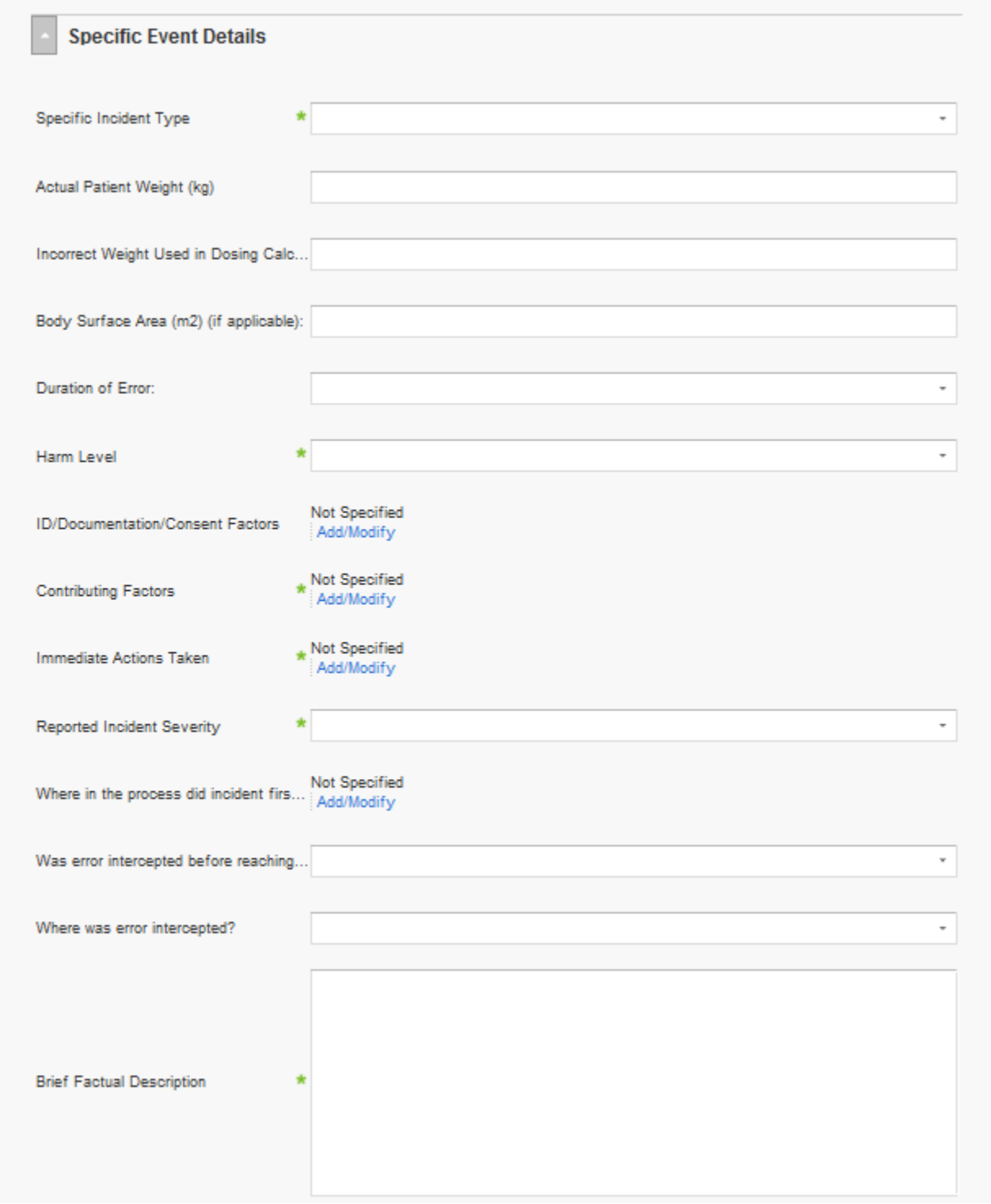


Figure 4-4: Screenshot of HMC medication error electronic reporting form

Healthcare Professional Involved

This section gathers details of the those involved in the error and those reporting the error.

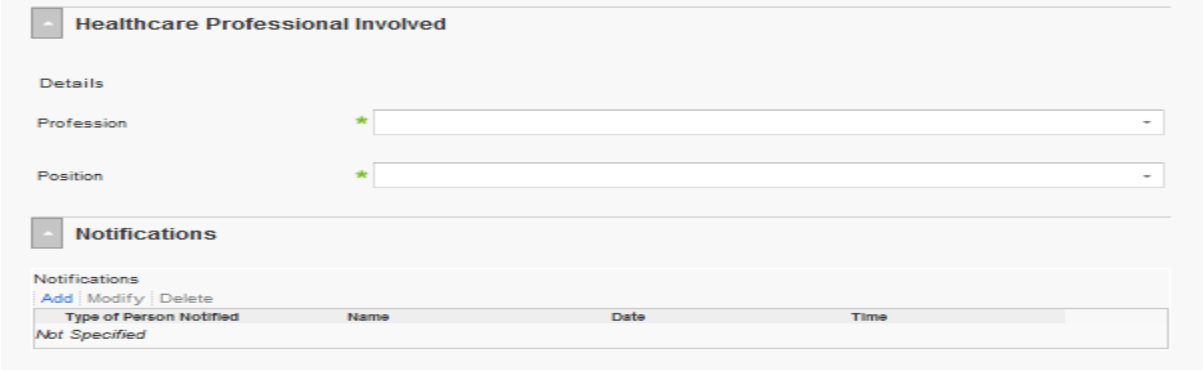


Figure 4-5: Screenshots of HMCs medication error electronic reporting form

Physician Comment

This section is completed, recording the action taken and subsequent progress.

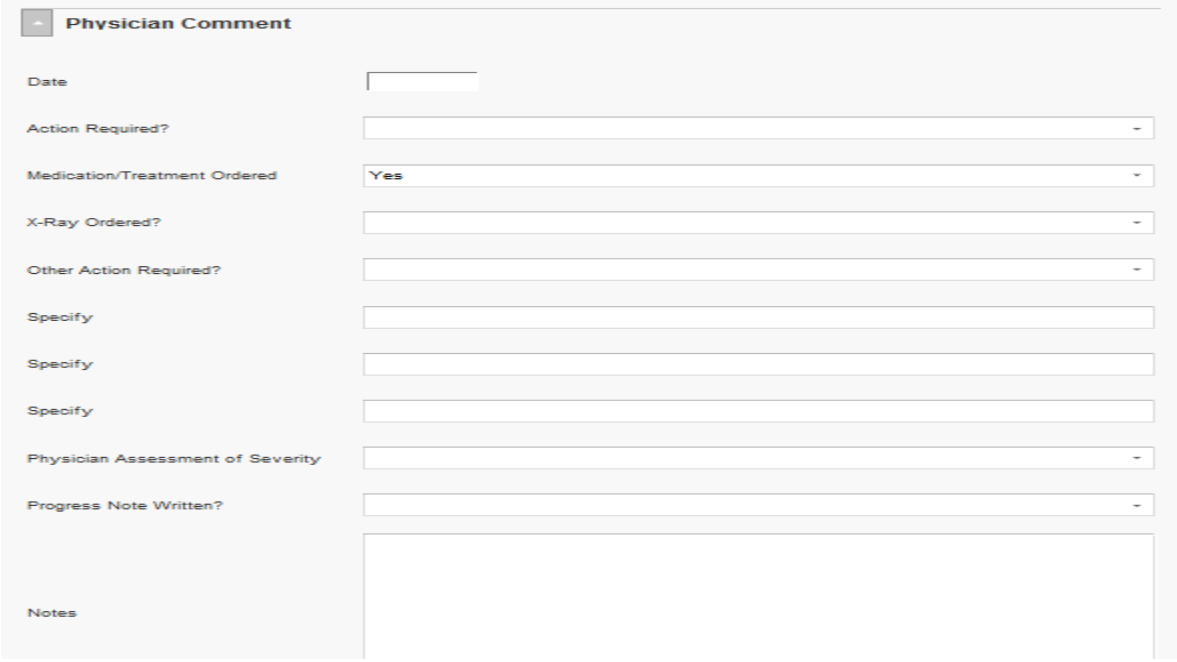


Figure 4-6: Screenshot of HMC medication error electronic reporting form

4.4 Aim and objectives

The aim of this phase of the doctoral research was to collate data recorded in medication error reports.

The specific objectives were to

1. Estimate the incidence of medication errors derived from submitted error reports
2. Describe the nature and severity of medication errors from submitted error reports
3. Explore the causative factors documented on medication error reports

4.5 Methods

4.5.1 Design

This was a retrospective review of all medication errors submitted to the HMC incident reporting system.

4.5.2 Data collection

All medication error reports submitted by a health professional during the period of January 2015 to December 2017 (i.e. 36 months) were included in the study. All reports were extracted from the RL6 database electronically and exported to Statistical Package for the Social Sciences version 20.0 add-on for Microsoft Office Excel. Multiple reports of the same event were counted as one (each report was identified using a unique number, hence were easily retrieved); if the same error was reported by multiple health professionals, only the first report was included. Given that the study also sought to report data completeness, there was no further data cleaning.

4.5.3 Analysis

The incidence of medication errors was calculated using the formula.

$$\textit{Incidence (i)} = \frac{\text{Total number of medication errors reported}}{\text{Total number of medications ordered}}$$

The incidence was expressed as per 1,000 medications ordered. The total number of medications ordered over the study period was generated by Cerner (an electronic prescribing system used by HMC). In Cerner, one 'order' represents each item prescribed to an individual patient, irrespective of route, duration etc.

The severity of medication errors was categorized using NCCMERP classification system, in which, severity of error varied from no error (circumstances or events that have the capacity to cause error), error no

harm, error harm and error death. The free text was the reporter stated severity, no modifications to these were done during the analysis as that might introduce bias. The nature and severity of the medication errors were analysed using descriptive statistics, using the classification assigned by the reporter.

The free text data on contributory factors of medication errors recorded by the reporter were independently analysed by two reviewers experienced in assessment of medication error reports (the doctoral student plus one other). Instances of non-consensus were referred to two further experienced assessors for final judgement.

Each reviewer applied Reason's Accident Causation Model (see previous chapters) as a framework for categorizing potential contributory factors as

- Active failures, e.g. forgetting to administer a medication at a scheduled time
- Error provoking conditions, e.g. a medication was ordered by an unauthorized physician and administered to the patient
- Latent failures, e.g. lack of knowledge or time, busy working environment, lack of training

While the research team had considered applying a behavioural change theoretical framework (Theoretical Domain Framework (TDF)) to characterize the behavioural determinants, this was not undertaken due to the lack of detailed information contained within the reports.

4.6 Results

4.6.1 Incidence of medication errors

A total of 18,390 incidents were reported over 36 months, as described in Figure 4.x. Of these 2,130 were excluded as duplicates and a further 2,720 excluded as not deemed errors by the study reviewers. Examples included medication out of stock and adverse drug reactions which could not have been prevented. The total number of individual medication error reported was therefore 13,540 giving a mean monthly reporting rate of 376 errors. Of the 13,540 reports, 6,237 had to be excluded as had incomplete information (e.g. facility, incident type) and a further 2,200 with no or almost no free text description of the error. Only 5,103 reports (37.7%) had sufficient information to be included in the remaining stages of analysis.

Over the 36 months, there was a total of 30,650,000 medication orders giving an incidence of (13,540/30,650,000) x 1,000 = 0.44 per 1,000 medication orders.

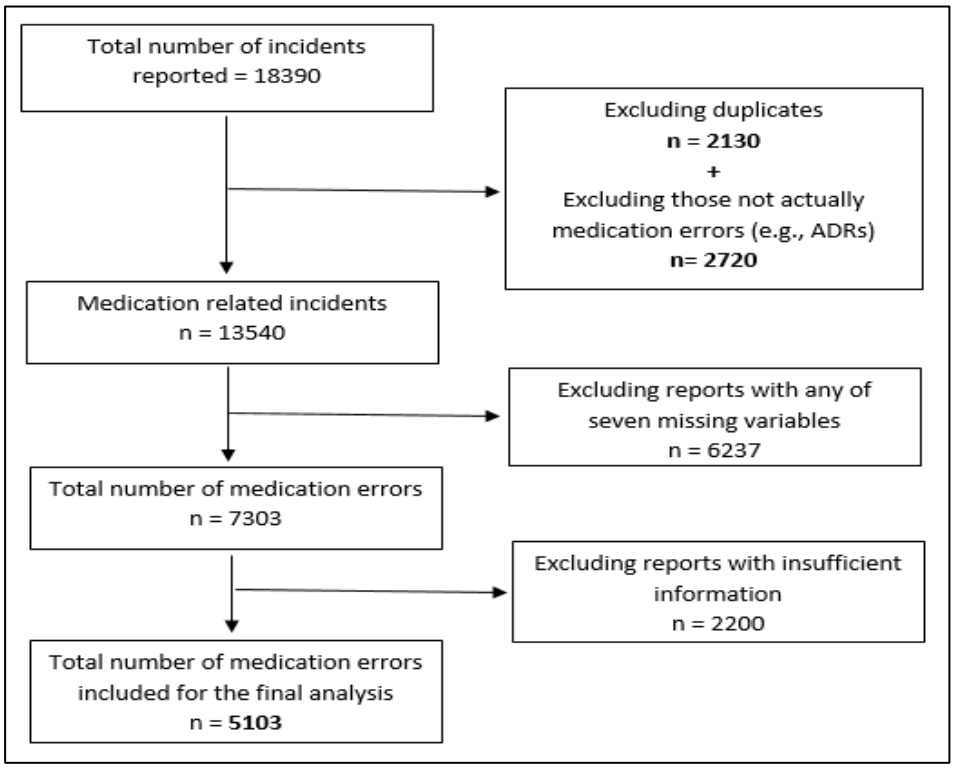
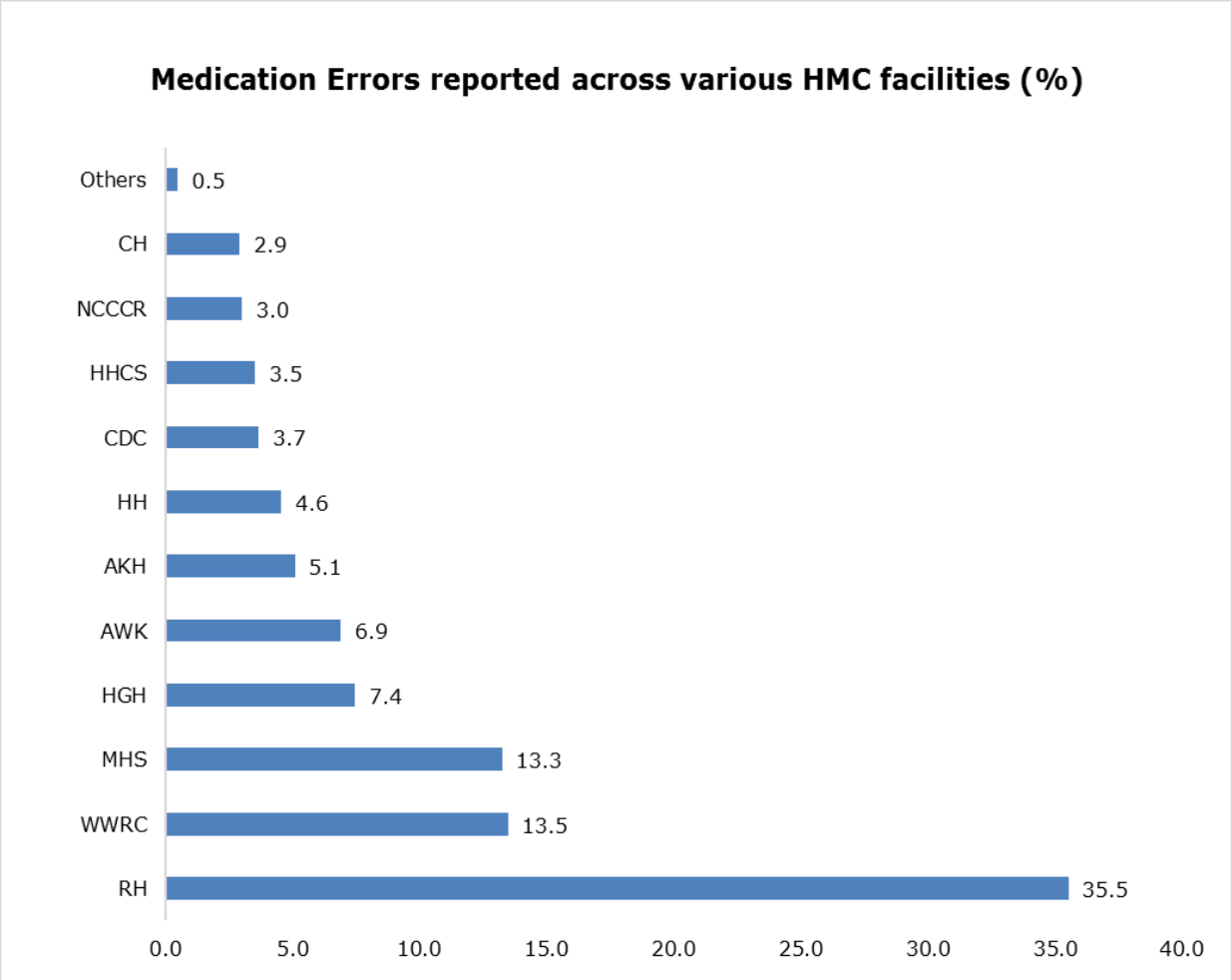


Figure 4-7: Medication incident and error reports included and excluded in the study

4.6.1.1 Medication errors reported across different HMC facilities

Almost three quarters of the reports originated from general hospital (medical and surgical hospitals) (61.5%, n=3183), with the remainder from speciality hospitals such as heart, cancer and mental health (Figure 4.8). Almost all the reports (94.1%, n=4800) were for adults. The majority (91.5%, n=4667) were submitted by pharmacists followed by nurses (7.6%, n=388) with very few (0.2%, n=11) by doctors.



ME – Medication Errors, RH - Rumailah Hospital, WWRC - Women's Wellness and Research Center, MHS - Mental Health Service, HGH - Hamad General Hospital, AWK - Al Wakra Hospital, AKH - Al Khor Hospital, HH – Heart Hospital, CDC – Communicable Disease Center, HHCS – Home Health Care services, NCCCR - National Center for Cancer Care and Research, CH –Cuban Hospital, Others include, Ambulatory Care Center, Qatar Rehabilitation center, Fahad Bin Jassim Kidney center & Ambulance services

Figure 4-8: Medication errors reported across different HMC hospitals (%)

4.6.1.2 Types of medication errors

Figure 4.9 illustrates that the majority of reports (87.9%, n=4485) were for prescribing errors, followed by administration errors (6.3%, n=322).

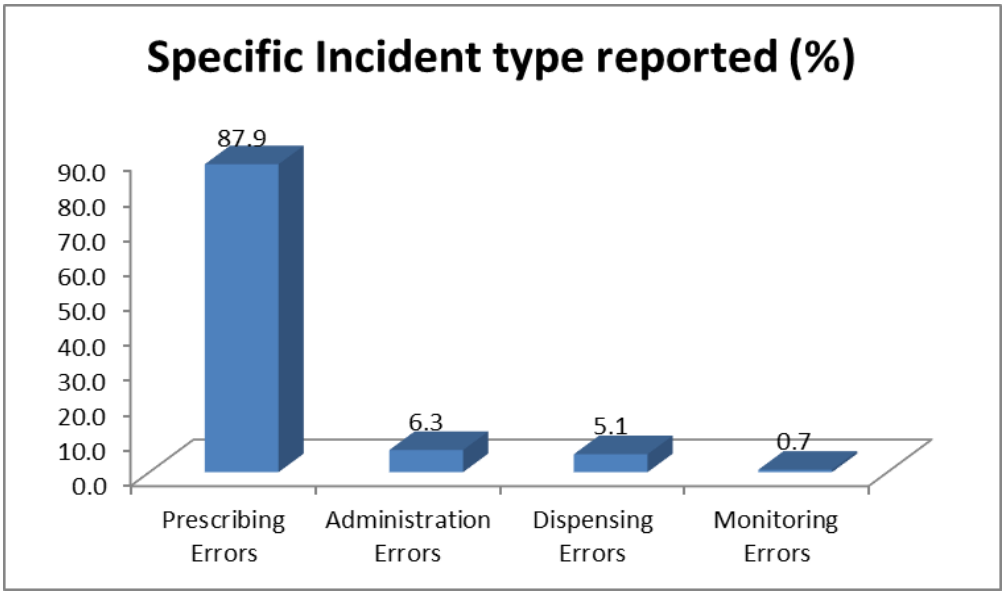


Figure 4-9: illustrates types of medication errors reported

Figure 4.10 illustrates the subcategories of prescribing errors, the most common being wrong dose (36%, n=1619), wrong frequency (14.6%, n=658) and duplication (ordering two or more medications with the same pharmacologic actions) (11.3%, n=510).

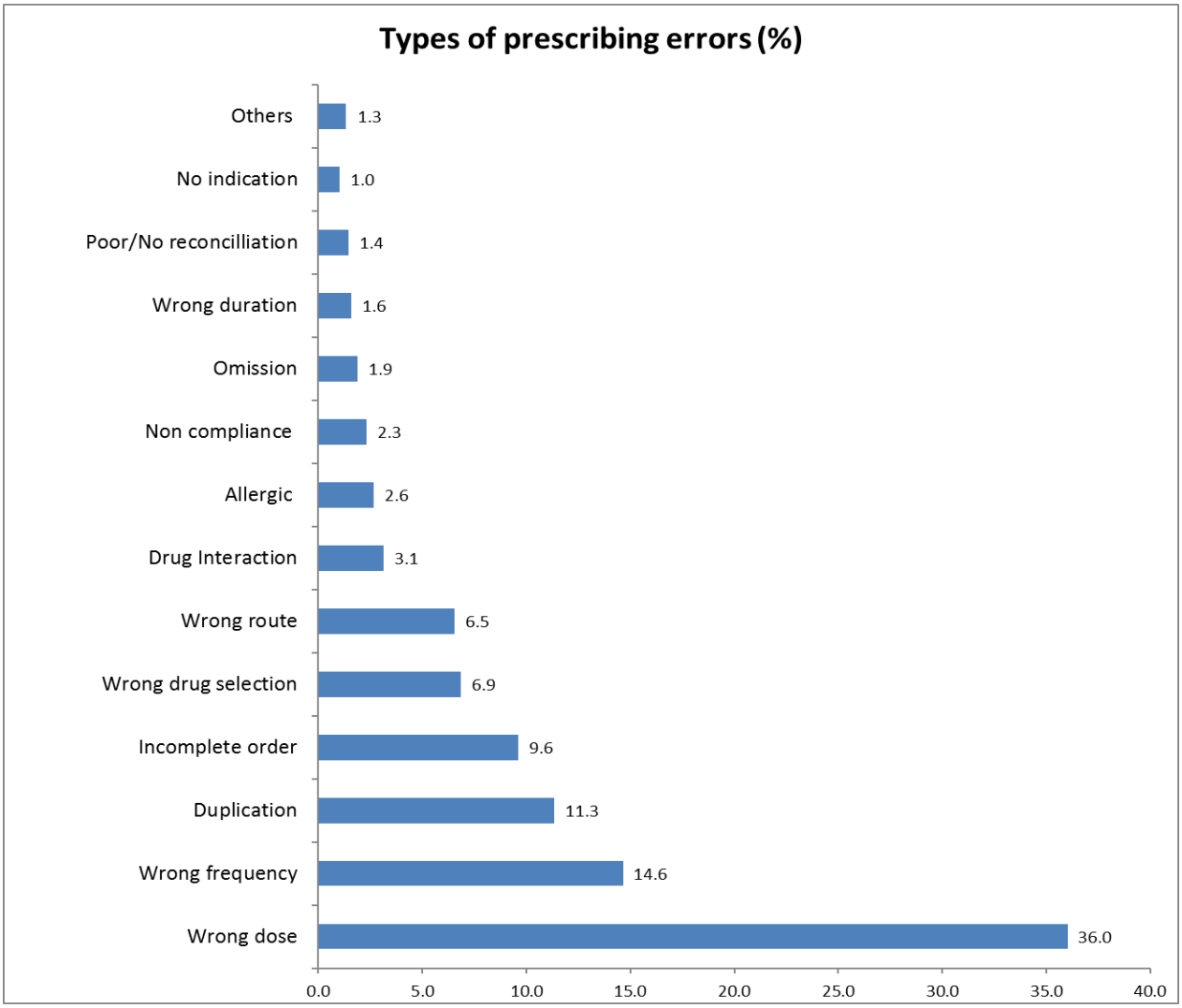


Figure 4-10: different types of prescribing errors reported

Of 322 medication administration errors, 18% (n=58) were non-compliance to the physicians' orders or prescriptions (e.g. monitoring errors, such as missing to monitor the response of an antihypertensive or anticoagulants prior to medication administration, wrong storage, discontinuing the medication etc,.) followed by administration of the incorrect medication (14.3%, n=46) or administering medication at the incorrect time (13%, n=42) (Figure 4.11).

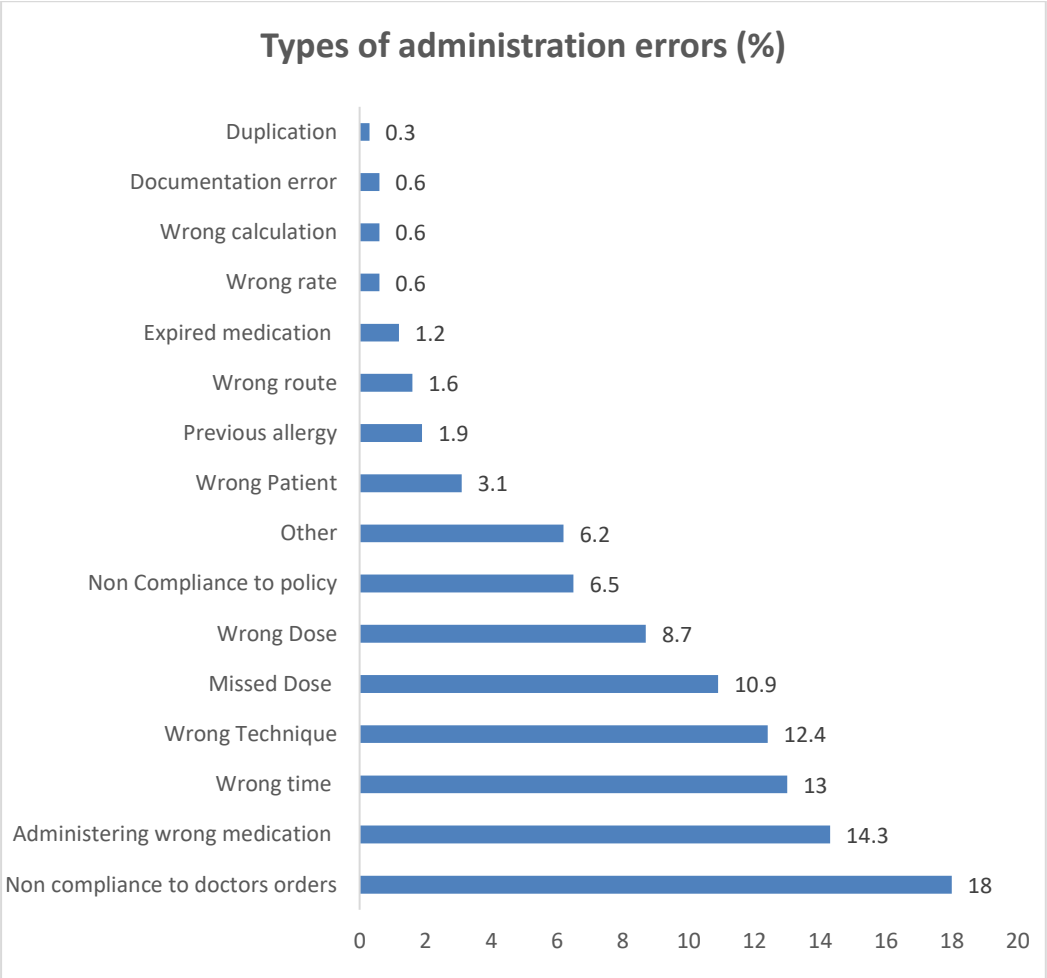


Figure 4-11: different types of medication administration errors reported

Dispensing and monitoring errors were less frequently reported, the most common dispensing error being wrong medication (24.5%, n=64), followed by delayed dispensing (19.9%, n=52) (Figure 4.12).

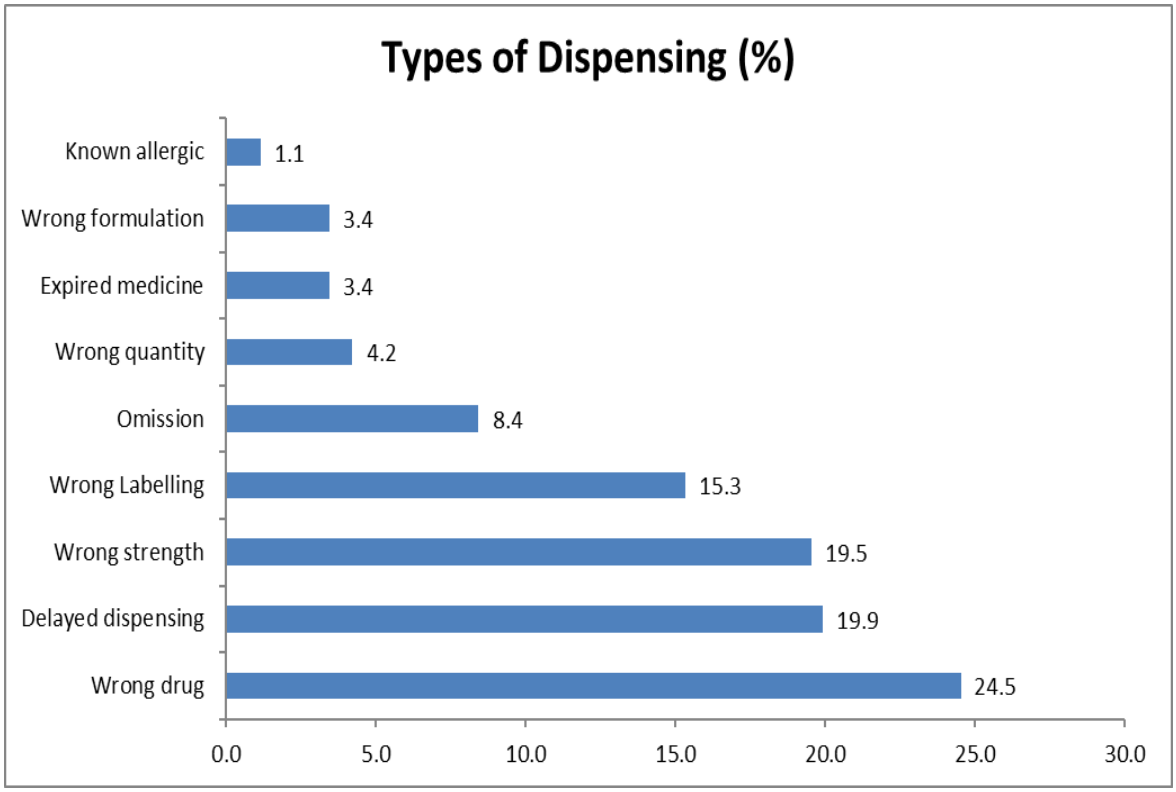


Figure 4-12: different types of dispensing errors reported

4.6.1.3 Medication categories

Classifying medications involved according to the Anatomical Therapeutic Chemical (ATC) classifications gave the most common as anti-infectives for systemic use (22%, n=1123) followed by medications used to treat neurological disorders (17.2%, n=876).

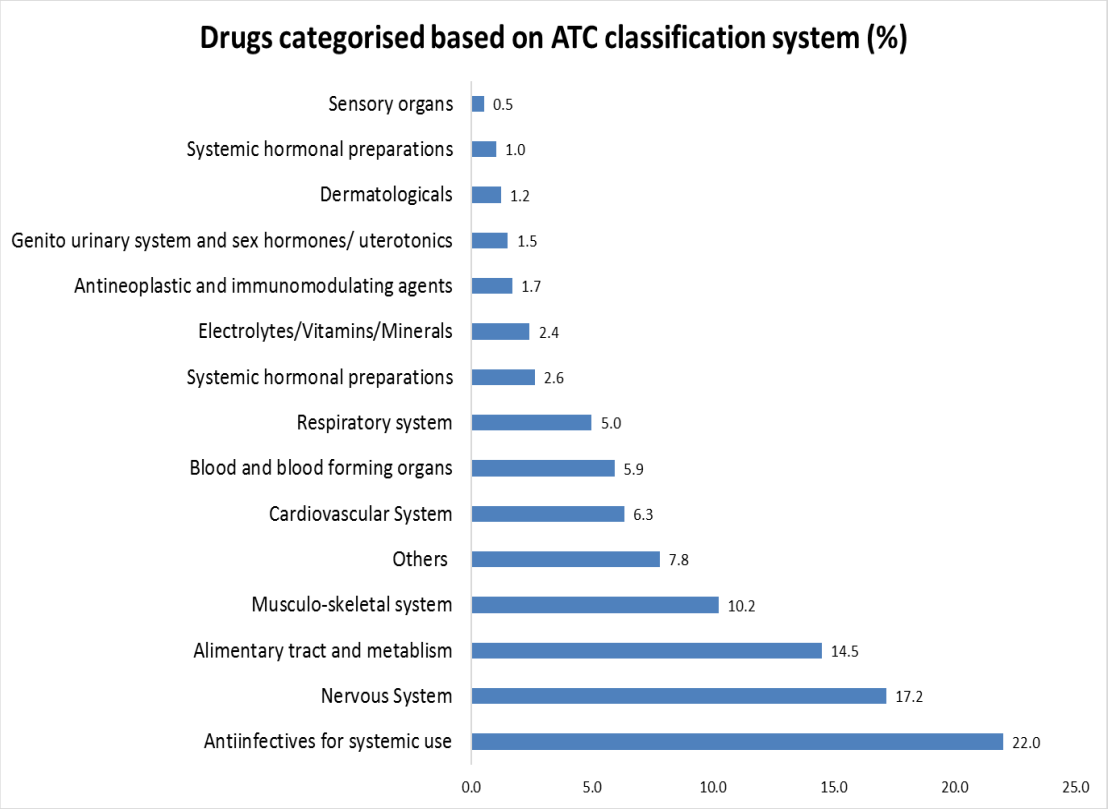


Figure 4-13: Medication categorised based on the Anatomical Therapeutic Chemical (ATC) Classification System

4.6.1.4 Severity of errors as reported

According to the reporter, most reports (77.3%, n=3943) were either Category A (circumstances or events that have the capacity to cause error) or B (an error occurred but the error did not reach the patient) (2.43%, n=124) followed by Category C (14.32%, n=731) (an error occurred that reached the patient but did not cause patient harm), Category D (5.90%, n=301) (an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm). Three (0.06%) errors were Category E (wherein an error occurred and may have contributed to or resulted in temporary harm to the patient and required intervention). Only one error (0.02%) contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization (Category F).

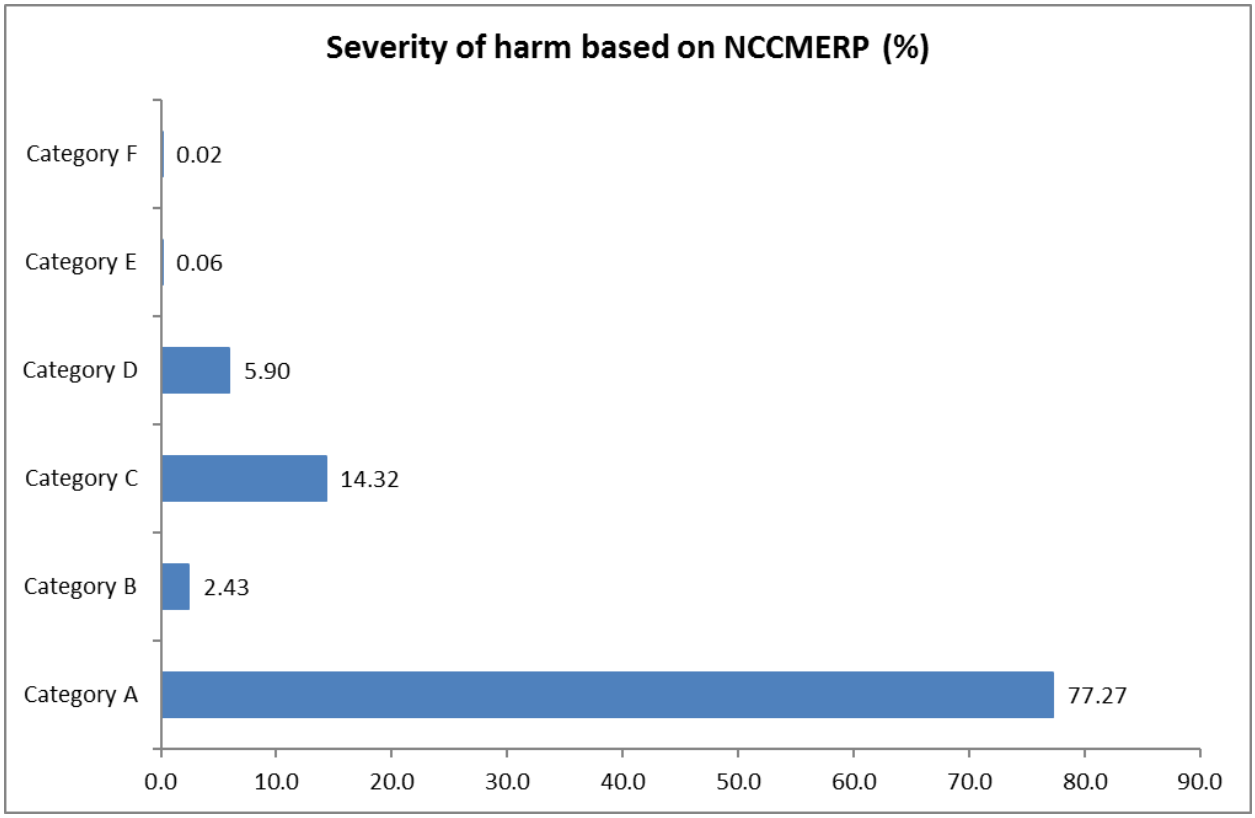


Figure 4-14 severity of harm based on NCCMERP severity index

4.6.2 Contributory factors potentially leading to error

As described in the methods, the 5,104 error reports were analysed according Reason's Accident Causality Model. Almost all (91.5%, n=4671) were classified as active failures (90%). These comprised mistakes (60.5%, n=), slips (15.1%, n=777), lapses (11.6%, n=595) and violations (4.2%, n=217). Around one tenth (8.5%, n=430) were classified as error provoking conditions (Figure 4.14). Further details and sub-classifications are given in Table 4.x. Note that, in many instances, the detailed sub-classification could not be given due to incomplete information.

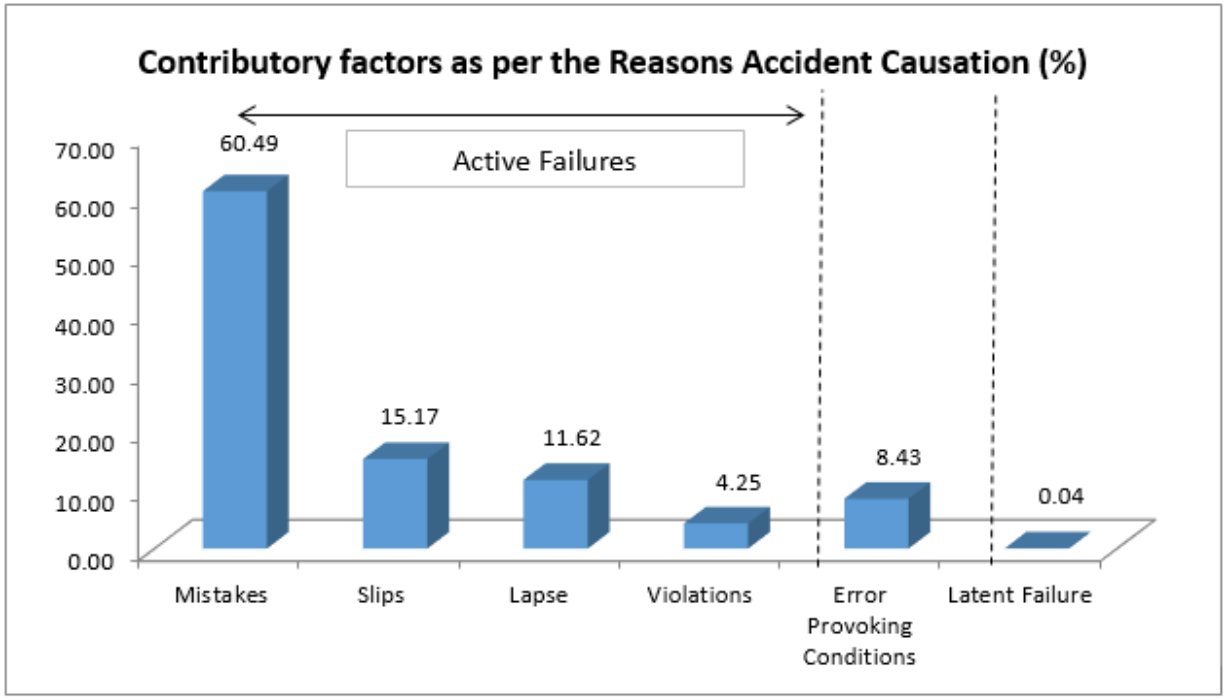


Figure 4-15: Contributory factors as per the Reasons Accident Causation

Contributory factors based on Reasons Accident Causation Theory	n (%)
Active Failures	
(Slips)	**n=777**
Incomplete Order	286 (36.9)
Selecting a wrong medication	279 (35.6)
Selecting a wrong dose	43 (5.5)
Wrong labeling	24 (3.1)
Look alike sound alike medications	24 (3.1)
Others	62 (8.0)
Not enough information for classification	83 (10.7)
(Lapse)	**n=595**
Missing information (route/age/dose/weight etc.)	395 (66.9)
Omission	146 (23.8)
Failure to collect the medication from pharmacy	12 (2)
Others	6 (1.2)
Not enough information for classification	36 (6.10)
(Mistakes)	**n=3089**
Skill based mistakes	675 (21.9)
Knowledge based mistakes	124 (4.0)
Technology based mistakes	62 (2.0)
Others	62 (2.0)
Not enough information for classification	2160 (69.9)
(Violations)	**n=217**
Noncompliance (policy/procedure/orders)	203 (94)
Ordering contraindicated medications	7 (3.2)
Patient or caregiver	2 (1)
Others	3 (1.3)
Not enough information for classification	2 (1)
Error provoking conditions	**n=424**
Lack of knowledge	148 (34.6)
Reconciliation	76 (17.9)
Technology based errors (Cerner issues)	29 (6.8)
Communication problems	9 (2.1)
Environment factors	9 (2.1)
Others	110 25.8)
Not enough information for classification	43 (10.1)
Latent factors	**n=2**
Organizational factors	<1

4.7 Discussion

4.7.1 Statement of key findings

The estimated incidence of medication errors in HMC, as derived from medication error reports was 0.44 per 1,000 medication orders. Almost all reports were submitted by pharmacists for prescribing errors which were largely wrong dose or wrong frequency errors relating to anti-infectives or neurological medications. Most errors were considered by the reporter to be minor in nature. According to Reason's Accident Causality Model (64,69), the vast majority were considered as active failures (slips, lapses, mistakes and violations).

4.7.2 Strengths and weaknesses

There are several strengths to this research. The systematic review presented in Chapter 3 provides evidence that this research is novel within Qatar and that the consideration of a theoretical framework of accident causation is novel within the Middle East. All medication error reports over a three-year period were included in the study, with no further sampling or exclusion, hence reducing bias. Much of the data presented was extracted from the electronic reports with no manipulation reducing the likelihood of error.

There are, however, a number of study weaknesses which should be considered during interpretation. The study findings are largely dependent on the validity and reliability of the data recorded in the error reports by the individual reporter. These are therefore potentially subjected to reporter bias by either under-reporting or selective reporting. While the determination of the potential causative factors was undertaken independently by experienced practitioners are researchers, this was still rather subjective. Furthermore, as the study was conducted within HMC, the findings may not be generalisable within Qatar, the Middle East or beyond. While the lack of completeness of the medication error reports could be considered a limitation of this study, this is an important finding

which will inform the development of the medication error reporting process within HMC.

4.7.3 Interpretation

Both NCCMERP and HMC have strategic aims that highlight the value of effective and efficient medication error reporting systems and practices in reducing error prevalence and severity.(138) The findings from this phase of the doctoral research provide evidence of the need that the reporting system and processes at HMC are not optimal. Of the reports extracted, around one fifth were either duplicate reports or reports for incidents not classified as medication errors. Furthermore, of the remaining reports, just over one third had sufficient details to be included in the study. Submission of incomplete reports (e.g. standardised variables or the narrative of the actual report) is a waste of time and effort on behalf of the reporter and also those involved in reviewing the reports. Furthermore, these reports can then not be used for the purpose of reflecting on healthcare practices hence will not contribute to improved patient safety. Several studies in other settings have also highlighted the issue of incomplete reports. (139-142)

The medication error incidence estimated from this study was 0.44 per 1,000 medication orders. The systematic review presented in Chapter 3 reported nine studies based on medication error reports. Of these nine studies, there was a lack of inconsistency in presentation of results. Studies used terms of 'errors per 1,000 admissions', 'errors per 100 prescriptions', 'errors per 1,000 patient days', 'percentage' etc. The results of this doctoral phase cannot be compared with similar studies of hospital settings in the Middle East. As stated in Chapter 3, there is a need to agree defined method and reporting standards for all such studies to facilitate data pooling, comparison and learning from best practice. Such developments would align to the aspirations of the WHO, 'Medication Without Harm' and also provide a standardised benchmark for determining the impact of any interventions.

There are other complications to the interpretation of incidence data which are likely to compromise its validity. To be valid, all medication errors have to be identified and reported promptly. There is accumulated evidence of widespread and significant under-reporting of medication errors by healthcare professionals.(113,114,143-148) The incidence data derived from this study can only be considered an estimate of the true incidence of medication errors in HMC.

It is notable that almost all medication error reports were submitted by pharmacists. While the nature and practise of clinical pharmacy involves review of prescribing, and thus the identification of errors, the number of pharmacists in HMC is very small compared to nurses and doctors. It would therefore appear that there is under-reporting by nurses and doctors specifically. In their practise, pharmacists are likely to identify (and therefore report) medication errors but are likely to be less aware of administration errors unless they are alerted to these by others or observe administration errors.

While most errors were categorised as no harm, the severity rating was undertaken solely by the reporter hence may have been subjected to biases including reporting and social desirability. Rating this severity of medication errors is not straightforward hence the validity of these findings may be questionable. A systematic review of the tools used to assess prescribing error severity in studies reporting hospital prescribing error rates highlighted that 57% of 107 studies included in the review had an assessment of severity. While 40 different tools were identified, only two were considered to have acceptable reliability and validity. (9)While it may be useful for the reporter in HMC to consider the severity and consequences of the error, the potential validity issue should be borne in mind. Given the limited information in many reports, it would be difficult for others to rate severity on this limited information.

One strength of this review was the application of Reason's Accident Causality Model (64,69) in analysing the narrative description of the reports. While the findings will be dependent on the richness of the narrative (and in many instances this was incomplete and reports

excluded), this does provide some indication of causality. Almost all errors were considered to be active failures (slips, lapses, mistakes and violations). According to this theory, contributory factors are:

1. Active failures which are unsafe acts committed by people who are in direct contact with the patient or system. They take a variety of forms including slips and lapses (errors in task execution), mistakes (errors in planning), and procedural violations (rule breaking).
2. Error producing conditions which can have adverse effects of error provoking conditions within the local workplace (e.g. time pressure, understaffing, inadequate equipment, fatigue, and inexperience).
3. Latent failures which arise from decisions made by policy makers, leaders and top-level management.

While none of the studies included in the systematic review of Chapter 3 included this theory, the findings of the studies were synthesised accordingly, with results similar to this phase of the doctoral research. Active failures of slips, lapses and mistakes were most common. Error provoking conditions included lack of knowledge and insufficient staff. (149) Similar findings have been reported in systematic reviews of studies not restricted to the Middle East. In a review of prescribing errors in hospitalised patients, Tully et al. reported that the active failures were most frequently cited (7), as did Keers et al. in a systematic review of medication administration error studies.(26)

This accumulation of evidence around active failures will be useful in considering any potential interventions aiming to reduce these factors. One limitation is that this theory does not describe the full range of behavioural determinants potentially leading to errors occurring. As described in Chapter 2, TDF is an integrative theoretical framework of behavioural determinants which can then be mapped to behaviour change techniques allowing the development of targeted interventions. While it has initially been suggested that a content analysis approach, based on TDF, could be used in the analysis of the error narratives, this was precluded by the depth and richness recorded by the reporter.

4.7.4 Implications for further research

This phase of the doctoral research, based on analysis of medication error reports, has highlighted issues in the reporting of medication errors together with the lack of information around the errors themselves and any potential behavioural determinants. These issues are the focus of the final phase of primary data collection reported in Chapter 5.

Chapter 5 : Qualitative interviews with health professionals at HMC (Focus Group Discussions)

5.1 Introduction

One key finding of the systematic review was a lack of qualitative research in the Middle East which focused on aspects of medication error causes and contributory factors. Furthermore, there is a notable lack of any qualitative research on the facilitators and barriers to medication error reporting.

5.2 Aim and objectives

The aim of this phase of the doctoral research was to explore the perspectives of health professionals on issues of medication error causes and contributory factors, and error reporting.
The specific objectives were to explore

- Experiences of medication errors according to Reason's Accident Causation Model
- Potential behavioural determinant of medication errors
- Potential behavioural determinants of reporting of medication errors

Note that the research in this phase was conducted as part of a study funded by Qatar National Research Fund, 'Exploring medication error causality and reporting in Hamad Medical Corporation: a study of the attitudes, beliefs and experiences of health professionals and other key stakeholders' (NPRP 7 - 388 - 3 – 095) (principal investigator Professor Derek Stewart).

5.3 Methods

Design

A qualitative, interpretative phenomenological methodology of focus groups was employed. As described in chapter 2, phenomenological studies provide in-depth exploration of experiences through the descriptions provided by those involved (Willis, 2007). (150) The phenomena in question were the occurrence of medication errors and their subsequent reporting (or not).

Focus groups providing multidisciplinary perspective were chosen above single discipline groups and were considered more appropriate than other forms of data generation such as one-to-one interviews for the main reason of the potential for discussion amongst wide range of health care participants thus providing the multidisciplinary team perspective.

Setting

The setting was Hamad Medical Corporation (HMC), Qatar. The focus group discussions were conducted at the conference hall in the Women's Hospital (was not a part of the pharmacy department).

Inclusion and exclusion criteria

As part of the funded study, all health professionals working in HMC were invited to participate in a cross-sectional survey (not part of the doctoral research). Respondents of the survey who expressed interest in participating in the focus groups (more than 350) were sampled purposively to represent a range of professions, hospitals and number of years of experience. Each sampled individual was contacted by email offering dates, times and location of each focus group.

Data generation

A pilot focus group was conducted to provide the doctoral research with real life experience in conducting a focus group, to allow consideration of the logistical issues, including timing, and to obtain feedback on the detail of the topic guide. The pilot data were not included within the final study dataset. The focus group topic guide (Apendix 5.1) was developed with

reference to Reason's Accident Causation Model (69) and TDF (65,151,152), and reviewed for credibility by the supervisory team and other members of the QNRF study. Initial discussions were based around views and experiences of error causation, contributory factors and reporting. The focus group topic guide is given in Appendix. It was planned that each focus group should have no more than ten participants and should be multidisciplinary, where possible. Focus groups were moderated by two experienced qualitative researchers (the doctoral student plus one other, with informed consent obtained from each participant at the outset. The moderator's main role was to facilitate the group discussion and to keep it focused around the themes without leading it. The moderator also ensured equal contribution of the healthcare professionals in the discussion. The co-ordination of activities 'on the day' of the focus group required more than a person, for several other tasks such as managing a room, materials, refreshments, managing all respondents' queries before the focus group, their arrivals and departures, specific needs of the individuals etc. Discussions were audio-recorded (with permission), transcribed verbatim and checked for transcribing reliability. Transcribing was shared between the two qualitative researchers who moderated the focus group discussion. All the recordings were reviewed by the doctoral student to check the accuracy and random samples were audited by the supervisory team to ensure the accuracy and completeness of the data. Not all, however, appropriate and significant nonverbal behaviors were captured and documented. Furthermore, clear audit trail was maintained which documented details of data gathering to promote dependability. Audit trails are qualitative strategies using in-depth approaches to establish the confirmability, which reassures that the findings are based on participants responses instead of researchers own perceptions and bias) (153) Sampling and recruitment continued to the point of data saturation (i.e. the point at which it appeared that no new themes were emerging from data analysis). (154) Focus groups were conducted between mid-May 2016 and mid-June 2016.

Analysis

Data analysis followed the Framework Approach, using Reason's Accident Causation Model and TDF domains deductively for to generate a coding framework (155), as follows

1. data familiarization, repeatedly listening to the audio-recordings and reading transcripts to promote data immersion
2. generating initial codes, using Reasons/TDF domains as headings, carried out independently by the doctoral student and one other member of the research team
3. identification of themes within each of Reasons/TDF domains, as for code generation
4. reviewing themes, which involved discussion between members of the research team
5. defining, naming and mapping themes.
6. producing the report, a narrative data analysis. Quotes were selected which best represented each of the themes, labeling each by profession to protect anonymity.

Promoting quality in research: trustworthiness

Steps were taken to enhance rigour and hence the trustworthiness of the findings. According to Lincoln and Guba, trustworthiness refers to the "truth value" of the study's findings or how accurately the investigator interpreted the participant's experiences.(55) As described in Chapter 2, rigour in qualitative research is established through credibility, transferability, dependability and confirmability. The following steps were taken to promote trustworthiness:

1. the doctoral student trained in qualitative interviewing and data analysis promoting credibility
2. the doctoral student's position and stance (as a pharmacist and medication safety officer in Qatar) was articulated and well-known to the supervisory team, and attempts made to promote both reflexivity and dependability

3. the research setting and participants were described to promote consideration of transferability
4. a clearly described sampling strategy was adopted to enhance credibility and dependability
5. all analysis was undertaken independently by two researchers to promote credibility and dependability
6. there was constant reflection and reflexivity to promote credibility and dependability

5.4 Ethics

The study received ethical approval from Hamad Medical Corporation, Medical Research Center Qatar, Qatar University Institutional Review Board and Robert Gordon University Research Ethics Sub-Committee (Appendix 5.3).

5.5 Results

5.5.1 Demographics of participants

The participants of the nine focus groups are given in Table 5.1. The duration of the focus groups was between 45 minutes to 1 hour. A total of 54 participants from different disciplines participated, with just under half (n=26, 48.1%) being nurses, followed by 18 (33.3%) pharmacists and 10 (18.5%) doctors. While almost all HMC hospitals were represented, the highest number of participants were from the Women's Hospital (n=19, 35.2%; where the focus groups were conducted), with no participants from the Cuban Hospital (provides a range of services to those residing in the western districts of Qatar). Most of the participants were highly experienced with only 11 (20.4%) having less than five years of experience

Table 5-1: Demographics of focus group participants

Code	Profession	Participants	Department	Years of practice
FG1	Mixed	N1	WH	11-15
		N2	WH	11-15
		P1	WH	6-10
		P2	WH	21-25
		D1	NICU	6-10
		D2	WH	6-10
FG2	Mixed	N1	HGH	11-15
		N2	WH	16-20
		P1	WH	11-15
		P2	AWK	11-15
		P3	HGH	11-15
		D1	HGH	6-10
		D2	HGH	16-20
FG3	Nurses	N1	RH	06-10
		N2	WH	11-15
		N3	HGH	06-10
		N4	HGH	11-15
		N5	HH	11-15
		N6	Quality	< 5
		N7	WH	< 5
		N8	HGH	Not Given
		N9	HGH	6-10
		N10	WH	Not Given
		N11	Quality	< 5
FG4	Mixed	P1	NICU	6-10
		D1	HGH	6-10
		D2	WH	6-10
		P2	RH	< 5
FG5	Pharmacists	P1	RH	< 5
		P2	AKH	6-10
		P3	AKH	< 5
		P4	WH	21-25
FG6	Mixed	N1	HGH	6-10
		D1	HGH	< 5
		D2	NICU	6-10
		P1	NICU	6-10
		P2	WH	6-10
FG7	Mixed	N1	WH	6-10
		N2	AWK	11-15
		P1	WH	11-15
		D1	WH	< 5
		N3	NCCCR	6-10
		D2	HGH	6-10
		N4	NCCCR	< 5
FG8	Nurses	N1	RH	6-10
		N2	HGH	6-10
		N3	HH	6-10
		N4	WH	< 5
		N5	HGH	16-20
		N6	HGH	6-10
FG9	Pharmacists	P1	WH	6-10
		P2	HGH	11-15
		P3	WH	16-20
		P4	WH	< 5

AKH Alkhor Hospital, **AWK** Alwakra Hospital, **HGH** Hamad General Hospital, **HH** Heart Hospital, **NCCCR** National Center for Cancer Care and Research, **RH** Rumailah Hospital, **WH** Women's Hospital; **P** Pharmacist, **D** Doctor, **N** Nurse

5.5.2 Causes of errors discussed (Reason's Accident Causation Model)

During the focus groups, there was wide-ranging discussion amongst the participants of their experiences across the spectrum of medication errors of prescribing, administration and dispensing errors.

These are presented in Table 5.2, with illustrative examples from all professions and levels of seniority, in terms of the Reason Model of Accident Causation, (63,64) of active and latent failures.

Table 5-2: Examples of active and latent failures discussed by focus group participants

		Illustrative examples
Active failures (errors, violations)	Knowledge-based errors	'Because we… we [pharmacists] do not know the doses actually, the accurate doses. For adult patients, we would know the doses, but for paediatrics we may not know.' (FG8P3) 'There are some specialties… if we're dealing with general hospital, medicine department has good orientation regarding own medication, but if you go to ortho [orthopaedics] or surgery, really their knowledge about medication is very low.' (FG5P3) 'Actually, I think we have a problem now with the new staff or the new doctors who don't know about our formulary.' (FG7P4) '…I don't think that education is done properly because nowadays when you go to the ward, X1, X2, X3 [names of the wards] the person… the nurse who's coming with me for the rounds doesn't know anything about the patient, and she'll call somebody, some other sister to ask each time that I ask her…' (FG1D2)
	Skills-based errors	'Most of the incidents happen, you know, the doctors get confused between dopamine and dobutamine in our unit. So, they are thinking about dopamine but they are prescribing dobutamine.' (FG4P2) 'The pharmacist got confused between giving amitriptyline and amlodipine, look alike, sound alike medication.' (FG7P1)
	Rule-based errors	'There are actually unapproved abbreviations used.' (FG2N2) 'Medication reconciliation is not being performed by all doctors. In fact right now, we are worried that medication reconciliation is not being done most of the time.' (FG8SP2)

		'…not following the policy because there is already a policy that we should not use unapproved medicines.' (FG2N1)
Latent failures	Organisational factors	'Yeah, shortage of staff, as he mentioned, it is one of the reasons [for errors occurring]. And this is why the medication errors are also increasing, so it's not always related to the knowledge of the resident. And if the resident is overloaded because he has to document for all the patients…' (FG2N1) 'Actually I see frequently this type of medication error…the antibiotic guideline is not clear...it should be simpler.' (FG7P1) Even I'm noting that during the rounds, with order decisions, the nurses are not informed. Sometimes they [the doctors] are discussing, sometimes in Arabic language The nurse, she cannot understand their plan and the decision.' (FG3N) There are two problems here, a load on the physician that can leads to many mistakes and a load on the pharmacist because he needs to dispense medication for this patient and at the same time answer the questions of physicians, nurses…' (FG5P4)
	Supervision issues	'One more thing what I noticed here, if any error is happening in our unit, it is not communicated with others. If you are communicating with others, a second person will not make that error. …if I inform the supervisor or someone, he will keep that matter between two or three persons.' (FG9P4) 'You see, the main thing is the administrative people need to sit together with the physicians and the nurses who are on the floor, to listen to them, and make amendments, changes. They have to ask us, the people who are on the floor, 'what is the problem, why these things are happening?' (FG1D2)
	Process design	'If I'm ordering a double medication then Cerner [electronic health record system] does alert me. But also many times Cerner alerts me for things that I don't care, this is routine. We do it all the time and it, I mean, it alerts me and what I do is override, override and give it. Suppose there is something which really needs to be seen then I will miss it.' (FG6D2) 'This is again another problem we have in Cerner [electronic health record system]. We built the system and we think that it is correct and it is perfect. It is not perfect. It will not stop you at any time from doing something wrong.' (FG7P1) 'So you are working in the pharmacy, I'm working in another unit, he is working in the transplant unit, she is working in the nursing office. We are all working together but we are not seeing each other. The system [Cerner] is connecting us together. So if there is a trouble with the system, a problem with the system, so mistakes happen.' (FG6D1)

5.5.3 Behavioural determinants associated with errors (Theoretical Domain Framework)

The following section describes the themes identified during analysis of the focus group transcripts in relation to causes of errors. These are mapped to the behavioural determinant domains of Theoretical Domain Framework (TDF). (65,151,152)

Domain 1, Knowledge (an awareness of the existence of something)

1. Lack of medication related knowledge

There was a recurring theme from all participants that lack of medication knowledge led to errors occurring. This was discussed mainly in relation to nurses and doctors,

> *'So coming to the nursing knowledge regarding the dose. I will never believe they have that much knowledge about the doses…'*
>
> (FG1D1)

> *'I do agree with that.'*
>
> (FG1D2)

> *'There is no physician will have full knowledge, full knowledge about all the medication.'*
>
> (FG5P4)

> *'Physicians are not medication-oriented. I cannot expect the physician to know everything about medication.'*
>
> (FG5P1)

Several noted that with that additional knowledge, errors could be avoided,

> *'If we have a good knowledge about the side effects or how, you know, the proper dosage for levetiracetam administration, this* [error] *could have been avoided*.'
>
> (FG6N1)

A few voiced the opposite view that lack of knowledge was not an issue given that their training and continuing professional development was sufficient,

> *'I don't think it's a knowledge gap because no nurse graduates from nursing school without having a basic knowledge about the medication and as our colleagues said that all the nurses have the competencies updated and reviewed.'*
>
> (FG2N1)

> *'from NICU* [neonatal intensive care unit] *wise they are giving proper education and training regarding the pharmacology as well as the calculations and everything.'*
>
> (FG4P1)

2. Knowledge is limited to a particular speciality/area

There were several settings or circumstances in which lack of medication knowledge was considered more likely to be an issue. There was much discussion regarding the influence of the speciality and that those working within the area of general medicine were likely to possess a more rounded knowledge as opposed to those in specialist areas, who had less knowledge of medication outwith their speciality,

> 'I*f we're dealing with the general hospital, medicine department they have good orientation regarding medication, but if you go to ortho* [orthopaedics] *or surgery, really their knowledge about medication is very low.'*
>
> (FG5P3)

> *'Some specialties have only limited knowledge of their medication. Let's say endocrinologist, you know the diabetic patient may take a lot of medication, between 10 to 12 medications. The endocrinologist knows the oral antidiabetic and let's say insulin.*
>
> (FG5P4)

3. Lack of knowledge attributed to staff induction

The lack of emphasis on medication related issues at induction for new staff was highlighted as a particular issue,

> *'We are bringing new staff and this* [training related to medication use] *is not incorporated in the curriculum of the training or the orientation of the staff.'*
>
> (FG2P2)

> *'Proper induction, you know, they should have proper induction regarding the medication, the medications that are used, how you do the checking and things like that. Nothing is done.'*
>
> (FG1D2)

4. Need for education and training to reduce medication errors

Many, across all professionals and grades of seniority, discussed the need for awareness raising and education and training to reduce the occurrence of medication errors,

> *'I guess just by, you know, like sister mentioned, you know, awareness. Creating awareness, okay. Such and such incident happened. These are the circumstances, the background, the contributing factors.*
>
> (FG7D1)

> *'Educational sessions for the physician will have great impact on decreasing medication error.'*
>
> (FG5P3)

> *'There is too much error in this area, they can provide another or a new continuous education for this field. It's very important and this can prevent such error.'*
>
> (FG7N1)

Domain 2, Skills (an ability or proficiency acquired through practice)

1. Suboptimal medication related skills

Suboptimal skills were considered to lead to medication errors. There was discussion around doctors' prescribing skills,

> *'The doctors are ignorant in writing the prescriptions. They are all…mostly all making errors.'*
>
> (FG3N)

There were also concerns over nurses' abilities relating to pharmaceutical calculations leading to medication errors,

> *'We need to think about the administration. I have seen plenty of times the paper on which they have written the calculation and it's wrong, actually most of the time.'*
>
> (FG4P1)

> *'And of course, there is an administration error also because as a nurse, she should also think about how ten tablets at a time will be given to this patient.'*
>
> (FG2N2)

Poor medication dispensing related skills of pharmacists were also identified as causes of medication errors,

> *'I feel it is negligence from the pharmacist, the person who has dispensed…there is definite negligence.'*
>
> (FG1D2)

Domain 3, Beliefs about capabilities (acceptance of the truth, reality, or validity about outcomes of behaviour in a given situation)

1. Lack of medication related competence

During the focus group discussions, doctors and pharmacists particularly were of the view that nurses were not competent to check the prescribed doses prior to administering medication,

'But you think it's… it's… it's valid to let the nurses check the dose before administering? No, I don't think it's possible. For me, I feel it's impossible for them to check the correct dose.'

(FG1D1)

'It's [checking the dose] *something beyond their* [nurses']*, I mean, capability.'*

(FG1P1)

There was, however, discussion that while nurses may not be competent to check the doses of all medication, they should be sufficiently competent around unusual doses, particularly those within their areas of practice,

'So you know, I cannot say that they [nurses] *are 100% competent enough but more than 70% or 80% I can say. We don't expect the nurse to know all the wrong doses, but she knows the unusual dose.'*

(FG4P1)

2. Overconfidence leading to medication errors

Doctors and pharmacists also discussed that, at times, they were over-familiar with medication, which resulted in them becoming overconfident and leading to medication errors occurring,

'Overconfidence with some particular medicines like I have been with this medicine for many years and I know by heart'

(FG1P2)

Domain 4, Social/professional role and identity (a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)

1. Doctors relying on pharmacists to correct errors

During discussion, it emerged that there were instances where doctors would rely on pharmacists to correct their prescribing errors and this led to complacency around prescribing,

'Yes. Most of the physician make a medication error and wait the pharmacist to correct it.'

(FG5P4)

2. Doctors reluctant to alter other doctors' prescribing

During one focus group, there was concern that doctors were unwilling to alter prescriptions written by other doctors, particularly for doctors from other specialities. The doctors considered this to be the responsibility of the original prescriber, even if a prescribing error had been made and initial prescriber was unavailable,

'This will happen when you're in the Ob-Gyn [obstetrics and gynaecology] *setup. If one physician came from Hamad from other… from cardiac or other site, if they write any prescription, if you call the Ob-Gyn doctor here, the on duty doctor, she will never agree to change because she will say it's an order from the consultant from cardiology or neurology.'*

(FG7P4)

3. Lack of recognition of the role of nurses

Some of the nurses described that they were often omitted from discussions around patient care and decision making, even when present on ward rounds or meetings. There were instances where discussions took place in a different language,

'Even I'm noting that during the rounds, order team decisions, the nurses are not informed. Sometimes they [the doctors] *are discussing in Arabic language. The nurse, she cannot understand their plan and what is the decision. Their decisions are… they're neglecting the nurses. They are not telling that the next plan for this patient.'*

(FG3N)

4. Policy non-adherence

Health professionals not adhering to various policies was considered a cause of medication errors,

'Not following the policy because there is already a policy we should not use unapproved decimal point. There is already a policy and with the physician supposed to be followed, so they are not following that policy

(FG2P1, N1)

'Not abiding the… complying with the policies'

(FG2D2)

'There are seven or eight points that the pharmacist should check. If the pharmacist, for example, dispensed the wrong medication it means that he didn't follow the policy.'

(FG5P4)

Domain 5, Goals (mental representations of outcomes or end states that an individual wants to achieve)

1. Promoting patient safety

It was apparent that focus group participants shared a common goal of promoting patient safety and reducing harm through the prevention medication errors. They were, however, realistic that not all errors could be prevented,

'But you know, serious errors are part of the package, you know. As we save lives, we are not ensuring… I mean, we should expect that we cannot have zero even serious errors because we are human beings'.

(FG5P1)

Domain 6, Emotions (a complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)

1. Stress leading to medication errors

Stress and high-pressure situations were described in all focus groups as influences on medication errors. While workload was a common factor leading to stress, patients themselves could also put undue pressure and hence cause stress in health professionals,

> *'According to the situation of the nurse, the nurse is having heavy load of work and she may have stress. Maybe some other stress, maybe… she cannot concentrate properly.'*
>
> (FG1N1)

> *'And I think that probably the stresses of the work* [leads to errors]*.'*
>
> (FG1D2)

> *'And parents are too tense than they are… even the parents they are too much angry. Yeah, they will scold the staff then like that time they will get pressure.'*
>
> (FG7N3)

Domain 7, 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)

Much of the discussion centred on aspects of environmental context and resources as key influences precipitating medication errors. These were discussed by almost all participants in all focus groups. There were several key themes within this domain.

1. Workload issues leading to medication errors

Workload issues were discussed by doctors, nurses and pharmacists. Doctors believed one of the reasons for errors to happen was the heavy workload that they had.

> *'Too many patients. Labour ward is full, you know, too many patients for the residents to see, doctors to see, you know.'*
>
> (FG1D2)

> *'Yeah, I'm working in emergency. So what I feel is it's too much… sometime it is too busy and doctors are giving too much orders…they cannot be able to cope with the situation.'*
>
> (FG1N1)

One pharmacist noted that the excessive workload for the doctor lead to errors occurring and that this workload also put pressure on other health professionals which could compound errors,

> *'There is two problems here, a load on the physician that can lead to many mistakes and a load on the pharmacist because he needs to dispense medication for this patient and at the same time answer the questions of physician, nurses, you know.'*
>
> (FG5P4)

One of the nurse also explained that the main cause of errors committed by junior medical staff was workload rather than lack of knowledge,

> *'And this is why the medication errors are also increasing, so it's not always related to the knowledge of the resident. And if the resident is overloaded because he has to document for all the patients and see all the patients and he is receiving calls from other units as well'*
>
> (FG3N)

2. Lack of staff at key times

Closely related to workload issues was a critical lack of staff at key times such as weekends and evening shifts, which could compromise patient safety,

> *'On the whole days of the week, there is complete staff, complete number of physicians. In weekend, well, only one physician, only one physician is going for the whole work.'*
>
> (FG4D2)

> *'Especially the areas like emergency, what I feel is that it is due to too much rush of patient and less staff. Less staff. They will be get… too much tense by the patients and they just want to do the things for faster than the… so it will make so much errors. Workload itself is the main cause because they are not getting time.'*
>
> (FG2N1)

3. System related issues

Discussion also centred on key issues related to the systems in operation in various wards and departments. There was particular concern over the implementation of Cerner (electronic health record system for hospitals, health care providers, clinics) from doctors, nurses and pharmacists,

> *'The electronic system is not robust, and I mean, the hardware is not good enough. You might land up in this, and if a clinician has to do so many cases, he also has to write the notes.'*
>
> (FG2D1)

> *'Yeah and this is what we are after Cerner. We are facing a lot and the most common potential errors we are facing after Cerner. We have now to concentrate on the mistakes or medication errors happening by the prescribing system.'*
>
> (FG5P2)

'Now, with the Cerner process, it has become more complicated.'

(FG2N1)

One senior doctor commented that following implementation of Cerner, fewer checks were being performed compared to the previous paper-based system,

'Before it was like, when you have the hard copy of medication profile, someone is checking, she has to check and countersign it. Now in the system, it is not there as far as I know. In the system, it's not there.'

(FG1D2)

Table 5-3: A summary of TDF domains and themes relating to causes of medication errors

Domain	Theme
Knowledge	1. Lack of medication related knowledge 2. Knowledge is limited to a particular speciality/area 3. Lack of knowledge attributed to staff induction 4. Need for education and training to reduce medication errors
Skills	1. Suboptimal medication related skills
Beliefs about Capabilities	1. Lack of medication related competence 2. Overconfidence leading to medication errors
Social/Professional Role and Identity	1. Doctors relying on pharmacists to correct errors 2. Doctors reluctant to alter other doctors' prescribing 3. Lack of recognition of the role of nurses 4. Policy non-adherence
Goals	1. Promoting patient safety
Emotions	1. Stress leading to medication errors

The following TDF domains were did not feature during focus groups discussions as determinants of medication errors,

1. **Optimism**, the confidence that things will happen for the best or that desired goals will be attained.
2. **Beliefs about Consequences**, acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.
3. **Reinforcement**, increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.
4. **Intentions**, a conscious decision to perform a behaviour or a resolve to act in a certain way.
5. **Memory, Attention and Decision Processes**, the ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.
6. **Social Influences**, those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.
7. **Behavioural Regulation**, anything aimed at managing or changing objectively observed or measured actions.

5.5.4 C. Behavioural determinants associated with reporting medication errors

The following section describes the themes identified during analysis of the focus group transcripts in relation to the reporting (or not reporting) of medication errors. These are mapped to the behavioural determinant domains of Theoretical Domain Framework (TDF).

Domain 1, Goals (mental representations of outcomes or end states that an individual wants to achieve)

Focus Group participants across all health professions, and at all levels of seniority, believed that the reporting of medication errors was of great important and essential to preventing future errors hence enhancing patient safety.

1. Prevention of future medication errors

Doctors, nurses and pharmacists all considered that reporting errors was a positive step in preventing future errors, but were also aware that this could not be achieved simply by completing and submitting the report,

> *'You should work on the prevention stage along with reporting because if you are only reporting, it will be like okay, I'm just sitting catching* [medication errors]*.'*
>
> (FG5P1)

> *'So if we want to change this and we want to learn… because we report medication errors to learn from them, how to avoid these errors in the future…'*
>
> (FG3N3)

> *'…when I see my reporting at the end, I reach a conclusion that this led to change in preventing errors in the future.'*
>
> (FG2D1)

> *'If we report, we'll be aware about this problem and then will try to prevent it in the future.'*
>
> (FG7P1)

2. Promoting patient safety

Promoting patient safety was a clear goal of medication error reporting,

> *'Yes, of course* [to report medication errors] *for patient safety. 'Yeah, we must, we have to focus on harm of the patient. Patient first.'*

(FG7N4)

One pharmacist and nurse in focus group 2 discussed that if a medication error was not reported, the same error could recur with worse consequences for the patient,

> *'We learn from our mistakes. If the errors are not reported, they will keep happening, and if it keeps happening, it may lead to a mortality the next time. So reporting an error is a must just for patient safety.'*

(FG2P3 & N1)

Domain 2, Knowledge (an awareness of the existence of something)

There were four key themes in relation to the TDF domain of knowledge: lack of knowledge in general concerning error reporting; lack of knowledge of error reporting policies; uncertainty of processes; and the expressed need for further education and training.

1. Lack of knowledge in general concerning medication error reporting

Senior staff noted that medication error reporting was not included in the induction and orientation programme for new staff hence there was a particular issues for newly recruited staff who they considered to be unaware of medication error reporting,

> *'Yeah, but the new staff, they don't know, they don't know about it* [medication error reporting]*, and every two to three months, we are bringing new staff and this is not incorporated in the curriculum of the training or the orientation of the staff.'*

(FG2P2)

2. Lack of knowledge of medication error reporting policy

During focus groups, there were discussions of the lack of knowledge of HMC medication reporting policies and this appeared to be a particular issue for the doctors,

> *'I think the doctors maybe didn't have orientation about this. They don't know about the policies* [medication error reporting] *of the HMC.'*
>
> (FG2P1)

3. Knowledge of medication error reporting processes

While the pharmacists appeared to be aware of how to report a medication error,

> *'We know how to report a medication error…'*
>
> (FG6P1)

doctors and nurses were less aware, with some admitting that they had no knowledge whatsoever,

> *'So the first thing I will tell you very honestly, I don't know how to. I don't know whom to speak to or how to actually report a medication error.'*
>
> (FG6D2)

One doctor had never reported a medication error,

> *'I'm not aware of it exactly* [medication error reporting]*. I know I've never reported a medication error. Maybe… maybe years ago when it was on paper. I don't recall to be honest.'*
>
> (FG7D1)

This was also the case for one nurse, stating,

> *'No. Because if anything happens in our department, we are usually informing our charge nurse. No, we don't do directly'*
>
> (FG7N2)

4. Expressed need for education and training

Many focus group participants, particularly those more senior, highlighted the need for education and training as a key step towards improving medication error reporting within HMC,

'Education of staff, encouraging the staff and reassuring the staff.'

(FG4D1)

'So, educating the staff, you know, getting that change of attitude'

(FG4P1)

One pharmacist suggested that education and training in reporting should be coupled with stressing that a blame free culture existed within HMC,

'If we make it like increase awareness about reporting and a free blame.'

(FG6P2)

Several others suggested the need for regular education and training, particularly for those who had not reported during a fixed time period,

You probably need timely orientations and it should be part of their [nurses] *orientation when they come to the hospital, right? And if you don't report for 2 years, like I have, maybe I got an orientation two years ago maybe, but I have never reported it, so I will forget it maybe, right?*

(FG6D2)

Domain 3, Skills (an ability or proficiency acquired through practice)

1. Possible lack of ability to recognise and report medication errors

During one focus group of nurses, several participants with between six and ten years of experience discussed that they had never had to submit a medication error report as they had never witnessed an error. Given that all errors, irrespective of severity should be reported according to HMC policy, this may suggest a lack of ability to recognise medication errors,

> *'In case, but it's* [a medication error] *never happened, so never. No, no, never happened that's why'.*
>
> (FG8N1)

> *'I'm here for the past six years. Six years, I have never heard anyone have a medication error also.'*
>
> (FG8N3)

During the same focus group, one nurse described submitting a medication error report but it was apparent that this had been submitted using the incorrect form,

> '*Using the direct adverse effect form* [the incorrect form].'
>
> (FG8N2)

There was also some discussion over a lack of consistency in what was considered to be a medication error,

> *'As I had told before, one medication error in my mind is not the same as a medication error in his mind.'*
>
> (FG6P1)

Domain 4, Social/professional role and identity (a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)

1. Professional obligation to report medication errors

While most of the participants considered it part of their professional duty to report medication errors,

> *'Yeah, we need to report this medication error. If you are… if you are setting aside all this blame-free culture and also, you know, everyone should come forward to report this error'*
>
> (FG6P1)

some participants expressed the opposite view. As the following doctor described, there were individuals within HMC who were working for the salary only,

> *'why should they report also when they don't feel like reporting, feel like acting on it and feel like improving the system? … you know, everybody almost I'll tell you 60… 70 to 80% of people I'm working with or I'm come across, they are just working because they need to work.*
>
> (FG1D1)

2. Perceived lack of reporting from doctors

There was a general acceptance that doctors were much less likely to report medication errors compared to pharmacists and nurses,

> *'Based on my experience for monitoring and analysing medication errors since two years ago, what is very noticeable is that high reporting, it is coming from the pharmacist, and there is also a percentage coming from the nurses especially for the administrating error but I never had for doctors.'*
>
> (FG2P1)

'Until now, I never received any medication error report from any physicians unless one ADR [adverse drug reaction] *report.'*

(FG2P2)

Domain 5, Intentions (a conscious decision to perform a behaviour or a resolve to act in a certain way)

1. Selectively reporting errors depending on severity

There was much discussion that health professionals were much more likely to report those medication errors considered less serious or those which did not result in harm to the patient,

'One thing I will definitely say. If it is a serious error or something, I don't think it is going to be reported. If there is no harm or something, they're not going to report it.'

(FG9P4)

The same pharmacist continued,

'…if you check the number of reports… if you analyze all the reporting that all the reports will be near misses. That is, there is no more… not much big errors.'

(FG9P4)

Several nurses, however, gave the opposite view that they were more likely to report medication errors which had caused harm to the patient rather than those 'near misses' which had not reached the patient,

I*f this is going to harm the patient, okay in such cases, definitely you will report but if it's something like… like a near miss, it never gets reported because we never give it to the patient.'*

(FG6N1)

2. Reporting for the wrong reason

During one focus group of pharmacists there was concern that, on occasion, a health professional would submit a report for an error committed by a colleague as a way of retaliation for that colleague submitting a report for an error committed by the first health professional,

> *'Yeah, he's suffering and he is now collecting any mistake for his colleague. He's not concentrating. Now, he is just collecting the mistakes for the other people who report.'*
>
> (FG5P2)

Domain 6, Beliefs about consequences (acceptance of the truth, reality, or validity about outcomes of behaviour in a given situation)

1. Reporting leading to improved practice

One positive consequence of reporting, discussed during all focus groups was the potential to improve professional practice which could prevent similar errors from occurring in the future,

> *'Yeah, it is essential and good* [reporting medication errors]*. You can prevent…you will learn from it. You will learn from it. And we can alleviate the fear of the staff.'*
>
> (FG8P1)

One pharmacist described how submitting a medication error report could be a positive action with impact throughout HMC,

> *'That's why I'm telling you report because you want to learn and others learn from your experience. See instead of having it as a negative point of view, they have converted it as learning and then positive. See if I report next time, people would learn not only me, but all throughout the corporation, across the corporation would know that having this experience, they can learn.*
>
> *(FG8P2)*

This was also described by a nurse,

'Well personally, yes because it would help in the future. Because it would help a lot of nurses to avoid the same error.'

(FG6N)

Despite these positive views, there was much discussion in all focus groups on the perceived negative consequence of submitting medication error reports.

2. Further investigation

One negative consequence of submitting a medication error report was that there was likely to be further investigation into the error which was a barrier to submitting further reports,

'We bring us here to this committee to discuss the medication errors like imagine someone who has done an error and then he reports, and then he's been called by two to three committees to investigate the errors. What he will go back?'

(FG2P2)

'And another thing, if you are going to report an error, you will not stop there here. You will be asked to write a letter, you will be asked to for a meeting, it doesn't stop from there. Again, next time they will ask you give me feedback on this. Give me explanation on this. So that is the… the… those are the things that compromises when you are reporting an error.' (FG3N)

3. Impacting staff appraisal

Closely linked the investigations acting as barriers to reporting, there was concern that reporting medication errors was likely to affect any evaluation of their performance resulting in less likelihood of reporting medication errors,

'Does affect the evaluation. Do you think that if she does an error and she does administer a wrong medication, do you think she will report it?'

(F
G3N1)

It will affect [*my performance appraisal]… the issue really…they decrease the evaluation. So even if you tell me hundred times that 'no you're going to be safe', I will think… I will take time before reporting. That's what I'm saying.*

(FG4P2)

4. Impacting working relationships

There was also much concern that submitting a medication error report for an error committed by a colleague would damage working relationships. This was expressed by all health professionals at all levels of seniority,

'And she said yeah I will report it, but she never reported that because we know that it will end up with the… with blame. It's not because I want to protect my colleague. It's because I don't agree that we should be blamed because this is the system that is provided to us to work in.'

(FG3N)

'I will not [report]*, I mean, why would I? Because, you know, I'm thinking about what happened to my friend. Isn't it? So even if you tell me a hundred times that' no you're going to be safe', I will think… never.'*

(FG4D2)

'If anyone is coming to improve you, I will like him. But if anyone is coming to report against me, I will be the enemy of him.'

(FG9P1)

5. Lack of confidentiality

Many focus group participants perceived that submitted medication error reports were not handled in a confidential manner and that there was potential for the details of the report to be shared with others leading to a lack of trust,

> *'No confidentiality. If you did something, everybody would know about it, but then the people who get to have the authority to report, they have to be trusted people. They have to have the confidentiality agreement that they will not spread the name.'*
>
> (FG5P1)

> *'…and there is no confidentiality. That is most important, it's gossiping. Everyone knows. Those who are not related also know that.'*
>
> (FG4D1&D2)

6. Lack of feedback

Despite almost all focus group participants identifying the goal of reporting of improved patient safety, the lack of feedback obtained when submitting a medication error report was a deterrent to further reporting,

> *'But still I didn't… never heard of any person coming back to us saying that this is the action. And this system* [reporting system]*, I never heard of any outcome. No, not even improvement… we are investing our time for nothing.'*
>
> (FG4D1)

> *'So no feedback, no appreciation, so do you need to take the stress? You work, do your assigned work, go home healthy and peaceful.'*
>
> (FG1D2)

'As you said, like you know some, some staff are reporting but they are not getting a feedback. I mean there is no point in reporting.'

(FG8N4)

Domain 7, 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)

1. Fear and worry

During all focus groups, the issue of reporting medication errors being associated with fear and worry emerged as a key barrier to reporting. For some, it appeared that this fear was real with reporting leading to punishment,

'You know people… when people think some error has happened, for me they should report openly but they don't… it won't happen in Hamad Hospital because they are… they are fearful actually. People are really… really… punished.'

(FG1P1 & FG1D1)

'Maybe people are afraid. They are afraid if they will be punished or someone or something… They're afraid.'

(FG2N2)

'And I think it's… if you report it, there's a lot of learning, but in the thing in… I think the thing in Qatar is that people are afraid of reporting because they're afraid.'

(FG4P2 & D2)

Domain 7, Reinforcement (increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)

1. Encouragement to report

Several focus group participants, particularly those in more senior positions, suggested different approached ways to enhance medication error reporting.

One pharmacist described a reward for the most active reporter within the department,

> *'I remember when we have a previous Director of Clinical Pharmacy service. She used to do every month the pharmacist who reporting the highest percentage of errors, and then they give him a certificate or a gift.'*
>
> (FG2P2)

One nurse described positive feedback,

> *'Yeah, if you will ask me I do encourage reporting of cases. I will always tell them this is an incident. It doesn't cause you any harm. This is a notification. This is not a punishment to anybody.'*
>
> (FG3N1)

Similarly, one pharmacist described feedback and encouragement report which was seen as a clear indication of a positive safety culture,

> *'I don't think so because every hospital is different than the others, but I'm talking about the Women's Hospital. The main reason for high reporting percentage from the pharmacist is the encouraging from the pharmacy administrations of reporting, and the safety culture.'*
>
> (FG2P1)

Domain 8, 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)

There were several themes relating to the working environment and the available resources.

1. No fair blame culture

One key theme which deterred reporting was the perception that the participants were not working in a no blame or fair blame culture. This was discussed by all professions in all focus groups,

> *'I remember when it started, it was like a blame-free* [culture] *and there was no name of persons involved…. Now, it has become mandatory to mention the name* [or the individual committing the error]*.'*
>
> (FG1P1)

> *'It is not a blame-free environment…they* [management] *are telling us 'blame free' but it is not at all. We will not report at any cost.'*
>
> (FG7N3)

> *'Actually, what I'm thinking about this whole subject is it's under reported and that's 100% true. And why, because I think from my perspective this is a punitive environment that we are living in.'*
>
> (FG6D1)

2. Time consuming to report

There was also discussion that completing and submitting a medication error report was time consuming and that health professionals were already working under pressure,

> *'Second thing, they have less time, you know. Maybe they will think they have seen one mistake. Suppose it is a prescribing error, they* [health professionals] *will call the doctor and get it*

corrected rather than reporting it so that they will save their time.'

(FG2N1)

'I think it's more of a headache. If you report and then you're being called for many meetings. We already have no time…'

(FG2D2)

Several participants considered the reporting process to also be tedious,

'System of reporting is very tedious. It is very long…For example, I'm verifying 200 prescription and in the 200 prescription, I have 50 medication errors. I will not be able to report.'

(FG4P2)

Table 5.4 is a summary of all themes, liked to TDF domains. Each theme is identified as either a facilitator or barrier of medication error reporting.

Table 5-4: A summary of TDF domains and themes relating to reporting of medication errors, identifying each as a barrier or facilitator

Domain	Theme	Facilitator	Barrier
Goals	1. Prevention of future medication errors	√	
	2. Promoting patient safety	√	
Knowledge	1. Lack of knowledge in general concerning medication error reporting		√
	2. Lack of knowledge of medication error reporting policy		√
	3. Knowledge of medication error reporting processes	√	√
	4. Expressed need for education and training	√	
Skills	1. Possible lack of ability to recognise and report medication errors		√
Social/professional role and identity	1. Professional obligation to report medication errors	√	√
	2. Perceived lack of reporting from doctors		√
Intentions	1. Selectively reporting errors depending on severity		√
	2. Reporting for the wrong reason		√
Beliefs about consequences	1. Reporting leading to improved practice	√	
	2. Further investigation		√
	3. Impacting staff appraisal		√
	4. Impacting working relationships		√
	5. Lack of confidentiality		√
	6. Lack of feedback		√

Emotion	1. Fear and worry		√
Reinforcement	1. Encouragement to report	√	
Environmental context and resources	1. No fair blame culture 2. Time consuming		√ √

The following TDF domains were did not feature during focus groups discussions as determinants of medication error reporting,

1. **Optimism**, the confidence that things will happen for the best or that desired goals will be attained.
2. **Beliefs about capabilities**, acceptance of the truth, reality, or validity about outcomes of behaviour in a given situation
3. **Intentions**, a conscious decision to perform a behaviour or a resolve to act in a certain way.
4. **Memory, attention and decision Processes**, the ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.
5. **Social influences**, those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.
6. **Behavioural regulation**, anything aimed at managing or changing objectively observed or measured actions

5.6 Discussion

5.6.1 Statement of key findings

This study highlighted experiences of medication errors across all of the sub-types of Reason's Accident Causation Model. During focus group discussions, specific TDF determinants suggested as being potentially associated with these errors were: social/professional role and identity; emotions; and environmental context and resources. Thematic analysis identified issues of doctors relying on pharmacists to correct their errors and being reluctant to alter the prescribing of fellow doctors. There was a lack of recognition of nurses' roles and frequent policy non-adherence. Stress was perceived to be a major contributor to errors, as was excessive workload and lack of staff at key times.

Discussions on issues of medication error reporting identified a number of facilitators and barriers. The TDF domain of emotions featured heavily, with several key themes emerging as barriers to reporting: fear and worry; likely investigation follow reporting; impact on evaluation and appraisal processes; that reporting an error committed by a colleague would damage professional relationships; and that reports were not always handled in a confidential manner.

5.6.2 Strengths and weaknesses

This study has several strengths, including the many steps taken to promote research trustworthiness, as described previously. However, the main limitation is that the qualitative findings may not be transferable to other healthcare professionals, settings and countries.

5.6.3 Interpretation

This study aligns to the WHO 'Global Patient Safety Challenge' calling for action to reduce severe, avoidable medication-related harm by 50% in the next five years. (2,3) The use of behavioural theory within the focus groups in this study identified key determinants which could facilitate intervention development. TDF has been incorporated within intervention

developments for smoking cessation, physical activity, hand hygiene, acute low back pain and schizophrenia. (156) To date only one other published study has applied TDF to explore potential causes of medication errors, focusing on prescribing errors in a sample of junior doctors in Scotland.(157) There are some similarities with the findings of this study, most notably within the domains of knowledge and skills, particularly the general lack of medication-related knowledge. While pharmacists can provide support, and indeed doctors were found to rely on pharmacists to correct errors, there are issues around staff complement and workload, particularly at key times.

TDF domains of social/ professional role and identify, emotions and environmental context and resources are related to organisational safety culture, as defined by 'Study Group on Human Factors'.(158) Concerns were expressed around nurses perceiving that their professional role was not recognised leading to poor communication compromising patient safety. There were instances of doctors relying on pharmacists to correct their prescribing errors and, at times, would not alter the prescribing of others, even when errors could potentially lead to patient harm. Themes of environmental context and resources also emerged in the discussions around workload as a leading cause of errors, with lack of staff at key pressure times of evening and weekends. Furthermore, the electronic prescribing and records system was considered to have introduced potential for error. While such systems have been shown to enhance patient safety, others have also highlighted the risky human factors and user-centred design issues that have been encountered. (159)

Stress was the main theme which emerged in the TDF emotions domain as a determinant of error, arising due to workload, work pressures and the influence of patients

These TDF determinants which were highlighted as potential contributors to medication errors can be used during the development of behaviour change interventions, defined as 'coordinated sets of activities designed to change specified behaviour patterns'. These are often complex, consisting of interacting components known as 'behaviour change techniques'

(BCTs), 'observable and replicable components designed to change behaviour'.(66) Michie et al. developed a cross-disciplinary taxonomy of evidence based BCTs (160), mapped to specific TDF domains. Whilst knowledge and skills can be impacted through education and training (160,161), altering aspects of social/ professional role and identity and environmental context and resources are more complex. Indeed, the work of Michie et al. (160,161) did not identify any evidence-based BCTs which mapped reliably to social/professional role and identity. Those for environmental context and resources relating mainly to restructuring the physical environment and providing prompts and cues for safer practice, which in this case would focus on the electronic medication systems. (160,161) Given this lack of specific, identified BCTs to support behaviour change together with the likely difficulties in changing the behaviour of individuals, it may be that action and support are required at the level of the organization (i.e. HMC level). This could include review of policies to encompass structures (e.g. resource allocation and distribution) and processes (e.g. those promote patient safety culture and minimise harm). These organizational actions could then lead to, and support, changing behaviours of teams and individuals. Qualitative research focusing on understanding the perspectives of key strategic decision-makers in relation to promoting all aspects of medication safety is warranted.

Effective and efficient medication error reporting systems impact patient care through early identification of issues informing safer systems of practice.(2,5) (1,5) HMC requires all errors, irrespective of severity, and near misses to be reported (24), hence the finding that less than one third of respondents had submitted any error reports in the last 12 months is likely evidence of significant under-reporting. This situation is not unique to Qatar or indeed the Middle East (7, 11-13), with the consequence that key opportunities to act on reports and improve medication practices are being missed.

Development of effective interventions to improve reporting is based upon the identification of facilitators and barriers and consideration of theories of behaviour change (16). While other quantitative and qualitative studies have identified barriers of reporting (6-15), there has been a lack of

attention paid to theoretical underpinning. On exploring error reporting behaviour in the focus groups, several facilitators emerged, related to the goals of reporting (promoting safety and preventing future errors), knowledge of processes and reinforcement around encouragement to support. Most discussion in the focus groups centred on the barriers relating to emotions. Fear and worry emerged as a key theme that deterred reporting, with some citing others being 'punished' following reporting. There were narratives around intense follow-up investigations that appeared to focus on the individuals involved rather than the system. There was concern that reporting errors could impact future appraisals and career progression as well as negatively affecting professional reputation and relationships.

In a study of one-to-one interviews with healthcare professionals in the UAE, Alqubaisi et al [21], identified several recurring themes of fear and impacting career progression and relationships, increasing the likely transferability of the findings. Given that these studies were conducted in the Middle East, it may be that these issues are related to the culture, although issues around emotions have also been identified in the US, Australia and the UK (7-9, 11-15). Furthermore, many healthcare professionals working in Qatar and the UAE are expatriate.

Relevant BCTs for those determinants identified during analysis of the qualitative data are given in Table 5.5.

Table 5-5: Mapping of relevant BCTs for optimising medication error reporting and description of BCTs (adapted from 34, 35)

Relevant behaviour change techniques (BCTs) for domains of beliefs of consequences and emotions	**Description of application of these BCTs to medication error reporting interventions**
Beliefs of consequences	
1. Emotional consequences	Prompt assessment of feelings after reporting a medication error
2. Anticipated regret	Induce or raise awareness of expectations of future regret about not reporting a medication error
3. Social and environmental consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of reporting a medication error
4. Comparative imaging of future outcomes	Prompt or advise the imagining and comparing of future outcomes of reporting v not reporting a medication error
5. Vicarious consequences	Prompt observation of the consequences for others when report a medication error
Emotions	
1. Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate reporting a medication error (includes 'stress management')
2. Emotional consequences	Prompt assessment of feelings after reporting a medication error
3. Social support (emotional)	Advise on, arrange or provide emotional social support (e.g. from colleagues, 'buddies' or staff) for reporting a medication error

Interventions based upon these determinants of behaviour are much more complex to develop and implement effectively compared determinants of knowledge and skills that can be effected by education and training (34, 35). Interventions should be co-developed with representatives of those who will deliver and receive the intervention. Although behaviour change focuses on the individual, commitment will be required at all levels of the organisation from policy makers, leaders and managers to all healthcare professionals and support workers. This is key within any organisation which operates a positive safety culture, defined as being 'founded on

mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measure' (36). It is noteworthy that one qualitative theme identified was the perception of a lack of a fair blame culture within the organisation hence the commitment at all levels of the organisation needs to be very obvious to all.

5.7 Conclusion

In terms of medication error causality, specific TDF determinants highlighted issues of social/professional role and identity, emotions, and environmental context and resources. Further attention on these issues at strategic and policy levels is required. Qualitative findings highlighted particular concerns around fear and worry; likely investigation follow reporting; impact on evaluation and appraisal processes; that reporting an error committed by a colleague would damage professional relationships; and that reports were not always handled in a confidential manner. These results can be used to develop theoretically informed interventions with the aims of improving the effectiveness and efficiency of the medication reporting systems impacting patient safety.

Chapter 6 : Discussion and Conclusion

6.1 Aims and key findings

The overall aim of this research was to explore medication error causality and reporting in Qatar. The research was conducted in three phases, each with aims and key findings as described below. The methodological approach in this doctoral research is best described as 'multimodal', combining different methodologies appropriate to specific research outcomes. (52,53)

Phase 1 aimed to aimed to critically appraise, synthesise and present the available evidence on the incidence/prevalence, nature and causes of medication errors amongst hospitalised patients in Middle Eastern countries. This PROSPERO registered systematic review identified 50 papers meeting all search criteria. Thirty-two studies quantified errors; definitions of 'medication error' were inconsistent as were approaches to data collection, severity assessment, outcome measures and analysis. Of 13 studies reporting medication errors per 'total number of medication orders'/ 'number of prescriptions', the median across all studies was 10% (IQR 2-35). Twenty-four studies reported contributory factors leading to errors. Synthesis according to Reason's model identified the most common being: active failures, largely slips, lapses and mistakes; error provoking conditions, particularly lack of knowledge and insufficient staffing levels; and latent conditions, commonly heavy workload. The review also identified a lack of primary research originating from Qatar.

Phase 2 aimed to collate data recorded in medication error reports this allowing estimation of incidence of medication errors, their nature and severity, and causative factors. All medication error reports submitted by a health professional during a three-month period of January 2015 were extracted for quantitative and free-text data. The estimated incidence of medication errors in HMC was 0.44 per 1,000 medication orders. Almost all reports were submitted by pharmacists for prescribing errors which

were largely wrong dose or wrong frequency errors relating to anti-infectives or neurological medications. Most errors were considered by the reporter to be minor in nature. According to Reason's Accident Causality Model, the vast majority were considered as active failures (slips, lapses, mistakes and violations). One further finding was the lack of detail recorded which compromised the extent of analysis, and notably a behavioural change theoretical framework could not be applied.

Phase 3 aimed to explore the perspectives of health professionals on issues of medication error causes and contributory factors, and error reporting. This was a qualitative, interpretative phenomenological methodology of 54 health professionals across nine focus groups. Reason's Accident Causation Model and TDF were used in the development of the topic guide and in analysis. Findings highlighted experiences of errors across all of the sub-types of Reason's Accident Causation Model. During focus group discussions, specific TDF determinants suggested as being potentially associated with these errors were: social/professional role and identity; emotions; and environmental context and resources. Discussions on issues of medication error reporting identified several facilitators and barriers. The TDF domain of emotions featured heavily, with several key themes emerging as barriers to reporting, most notably fear and worry, likely investigation follow reporting and impact on evaluation and appraisal processes.

The findings of all three phases are relevant to the concepts of 'organisational safety culture' and 'safety culture', with the focus on individual values, perceptions, and behaviours.

6.2 Originality of the research

This doctoral research has generated original findings which extend the knowledge base around medication error causality and reporting, with potential to impact professional practice, and patient care and safety.

The phase one systematic review protocol was registered with and published by PROSPERO, and the systematic review itself published in the European Journal of Clinical Pharmacology. The approach to data

synthesis by applying Reason's Model of Accident Causation was also original. Phases two and three were conducted in Qatar, generating original data in this setting. The systematic review itself added to the limited published studies investigating causality according to Reason's model. Phase three also adds to the very limited evidence base of applying a behavioural change theoretical framework to explore medication error casuality and reporting. The findings contributed to two papers published in PLOS ONE.

Strengths and weaknesses of the research have been highlighted throughout the preceding chapters. One key strength is the multimodal approach to the research comprising systematic review, quantitative research and qualitative research providing comprehensive coverage of the research field under investigation. Unlike mixed method this is not restricted to combining qualitative and quantitative methods to study a single problem, perhaps open to a range of best possible methodological combinations. (51,52)

6.3 Implications of research

6.3.1 Standardising terminology

Several systematic reviews have highlighted the issues of inconsistencies in methodological approaches in studies of medication errors, and also in the specific outcomes and reporting of those outcomes.(6,29,30,37) These inconsistencies have major implications for systematic review and meta-analyses, greatly limiting the potential for data pooling thus reducing the available levels of evidence. The systematic review presented in Chapter 3 provides adds weight to the argument for standardisation. There were many inconsistencies in terms of

- Definition of 'medication error' and subcategories of error
- Approaches to data collection and duration of data collection
- Reporting of errors and denominators used

In addition, the data presented in Chapter 4 collating data from medication error reports in HMC highlighted the poor completion of the error documentation. Even when the documentation variables were all completed, the specific detail of the errors were often lacking. These issues greatly reduce the usefulness of any report in achieving the goal of reporting articulated by NCCMERP, to 'stimulate the review and analysis of error reports leading to the development of recommendations to reduce, and ultimately prevent, errors'. (19)
Standardisation of research approaches, outcomes measures and reporting would also contribute to achieving the aspirations of 'Medication Without Harm, WHO Global Patient Safety Challenge'. As described in Chapter 1, this report calls for action to reduce patient harm which occurs as a result of medication errors. (2) Having valid and reliable data will provide a baseline from which to measure any improvement and standardisation will also facilitate from generalizing and transferring developments from other settings. Standardisation should also be relatively straightforward using technology-based solutions and training.

6.3.2 Intervention development

While accepting the study limitations discussed in Chapters 3-5, the findings of this study will contribute to the development of interventions to improve stages of the medication use processes. The findings can be used to facilitate the development of interventions to improve the processes of prescribing, dispensing, administering, and monitoring. The findings from this study will also lead to review and amendment of HMC's medication error reporting policy and practice.

Interventions developed and implemented with the aim of reducing medication errors and enhancing medication error reporting would be classified as 'complex' interventions. Such interventions are defined by the UK Medical Research Council (MRC) framework as 'interventions with several interacting components'. (67) Dimensions of complexity can be multiple, including 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 organisational levels targeted by the intervention
- ✓ number and variability of outcomes
- ✓ degree of flexibility or tailoring of the intervention permitted.

According to the MRC framework, there are four cyclical stages, as outlined in Figure 6.1.

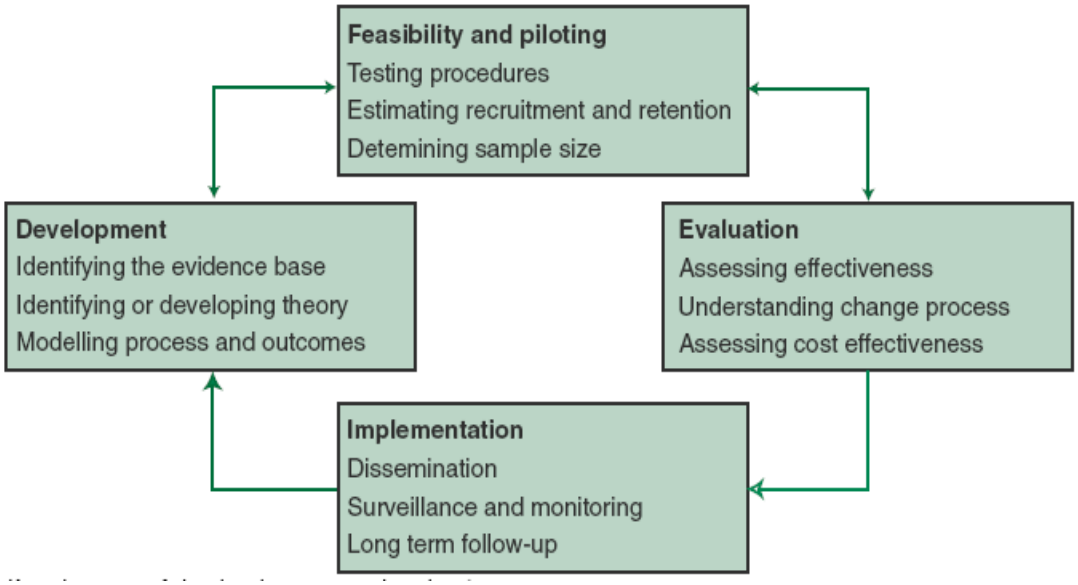


Figure 6-1 : The MRC framework relating to complex interventions

This doctoral research aligns to the development stage as follows

- the narrative review presented in Chapter 1 and the systematic review presented in Chapter 3 contribute to identifying the evidence base

- the study of medication error reports presented in Chapter 4 identified the need for further research
- error theory and behavioural change theory were considered throughout the research
- aspects of error causation were identified in Chapters 4 and 5
- the use of TDF as a theoretical behavioural change framework allowed identification of the key determinants of behaviour (i.e. error causation and suboptimal error reporting) to serve as targets for modelling the intervention
- the consideration of BCTs in Chapter 5 could form the basis of the specific interventions.

Application of Reason's Error Causation Model in Chapters 4 and 5 identified that most were 'active failures', with a minority 'latent failures' or 'error producing conditions'.(63,64) This is highly relevant to intervention development given that these latter two categories occur as a result of factors such as time pressure, understaffing, inadequate equipment and decisions made by policy makers, leaders and top-level management. Such factors are outwith the control of the individual health professional thus cannot be modified by BCTs.

The application of TDF in Chapter 5 relating to error causation identified issues of knowledge and skills around medication. As discussed, while these can be supported through education, training and support by clinical pharmacists, there are capacity and resource implications. The other TDF domains identified, namely social/ professional role and identify, emotions and environmental context and resources are related to organisational safety culture, as defined by 'Study Group on Human Factors'.(158) Mapping BCTs to these domains is not straightforward, as altering aspects of social/ professional role and identity and environmental context and resources are more complex. Notably, there are no evidence-based BCTs mapped to social/professional role and identity. (160,161) As discussed, intervention may be required at the organisational strategic level to

review policies, structures (including resource allocation and distribution) and processes.

In terms of medication error reporting, the key determinants of suboptimal reporting were beliefs of consequences and emotions. These are related to each other with worry being most likely related to the potential consequence of reprimand, affecting reputation and career progression. BCTs mapped to these domains could provide the basis for a complex intervention, which could then be tested through the feasibility/piloting and evaluation stages of MRC prior to implementation at scale.

As noted earlier, commitment is also required from policy makers, leaders and managers, particularly within a framework of positive safety culture, defined as being 'founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measure'.

6.4 Further research

Further research should focus on these further MRC stages, using the intervention constructed in the development stage, as follows

Study 1 – feasibility

Aim – to explore health professionals' perspectives of planned complex interventions which aim to reduce medication error causation and optimise medication error reporting.

Methodology and method - A qualitative methodology will provide rich data with a focus group method of purposively selected health professionals. Those include should represent different professions, clinical specialties and levels of seniority, including leaders and policy makers.

Outcome measures – perspectives of the feasibility, applicability, likely effectiveness and cost-effectiveness of the interventions. Findings will be used to modify the interventions.

Study 2 – piloting

The interventions will be piloted in selected, high medication-risk clinical areas.

Aim – to test the likely effectiveness of the intervention on a small scale and explore the experiences of those involved

Methodology and method – a quantitative before and after methodology. It should be noted that this is a pilot study hence is not powered for any specific outcome measures. The intention is to test the interventions in the clinical, real world settings. There will also be a qualitative phase of focus groups of purposively sampled health professionals who have experienced the intervention.

Outcome measures – the outcome measures for the quantitative phase will determined around the specific interventions, centring on the structures and processes related to the intervention. If baseline data is not routinely recorded as part of clinical practice, there may need to be a baseline period of data collection. Likely data to be collected relating to medication error reporting will be the number of reports, the completeness of the report and the level of detail recorded. The qualitative phase will focus on the real-life experiences of those involved in the intervention (i.e. the health professionals).

If both feasibility and piloting indicate that the interventions are appropriate, then these will proceed to the stages of evaluation, with fully powered sample sizes and qualitative components prior to large sale implementation. If not successful then the intervention will be modified accordingly.

6.5 Impact of research

Research Councils UK (RCUK) defines research impact as 'the demonstrable contribution that excellent research makes to society and the economy'. This research has potential to impact at several different levels, as described below.

6.5.1 Academic impact

Conducting this research has impacted the doctoral student, the members of the supervisory and advisory teams and the university. Presentation of the findings at national and international conferences and publication in peer-reviewed journals has added to the knowledge and evidence base around theoretically informed medication error causality and reporting research. While it is accepted that not all (or many) health professionals, policy makers or patients will attend conferences or read academic papers, efforts have been made to present the research throughout HMC to raise awareness at all levels.

6.5.2 The healthcare organisation

Chapter 1 While the research presented in the earlier chapters has focused on the MRC development phase, the specific findings will encourage the healthcare organisation to reflect and review policies, structures and processes as they relate to safe and effective medication use and medication error reporting. Patient care and safety and professional practice will be improved leading to the attainment of key organisational goals and those articulated by the WHO. Furthermore, the overall safety culture of the organisation will be enhanced.

6.5.3 Health professionals

Similar to the organisation, the research will impact health professionals through raising awareness, stimulating reflection and review of practice and through the implementation of any interventions. It is important that these interventions are delivered in such a manner that health professionals feel 'safe' in reporting errors and that these are considered within a framework of a 'just and fair' culture. This is particularly relevant given the behavioural determinants of beliefs of consequences and emotions which impacted suboptimal medication error reporting.

6.5.4 Patients

The most important impact should be in terms of enhanced patient care and patient safety. There is potential for this the findings of this doctoral

research to translate to practice with real and measurable benefits for patients.

6.6 Conclusion

This doctoral research has generated original findings in relation to issues of medication error causality and medication error. The research has resulted in several peer-reviewed publications. The conclusions are as follows

- the medication error research within the Middle East (and beyond) requires standardization and improved reporting in peer-reviewed publications
- medication errors remain highly prevalent, with issues of active failures being highly relevant
- there is a need to improve the quality of medication error reporting to enhance their usefulness and potential to impact professional practice and patient care
- there is a need to enhance the engagement of all health professionals in medication error reporting
- for error causality, specific attention should be paid to determinants of social/professional role and identity; emotions; and environmental context and resources
- key barriers to medication error reporting were related to determinants of beliefs of consequences and emotions.

These original findings can be used in the development of interventions with potential to impact organisational safety culture, professional practice and patient care. These findings align to the aspirations of the WHO.

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Appendices

Appendix 1: Journal Publication 1

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PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Medication errors in hospitals in the Middle East: a systematic review of prevalence, nature, severity and contributory factors

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Abstract

Purpose The aim was to critically appraise, synthesise and present the evidence of medication errors amongst hospitalised patients in Middle Eastern countries, specifically prevalence, nature, severity and contributory factors.

Methods CINAHL, Embase, Medline, Pubmed and Science Direct were searched for studies published in English from 2000 to March 2018, with no exclusions. Study selection, quality assessment (using adapted STROBE checklists) and data extraction were conducted independently by two reviewers. A narrative approach to data synthesis was adopted; data related to error causation were synthesised according to Reason's Accident Causation model.

Results Searching yielded 452 articles, which were reduced to 50 following removal of duplicates and screening of titles, abstracts and full-papers. Studies were largely from Iran, Saudi Arabia, Egypt and Jordan. Thirty-two studies quantified errors; definitions of 'medication error' were inconsistent as were approaches to data collection, severity assessment, outcome measures and analysis. Of 13 studies reporting medication errors per 'total number of medication orders'/ 'number of prescriptions', the median across all studies was 10% (IQR 2–35). Twenty-four studies reported contributory factors leading to errors. Synthesis according to Reason's model identified the most common being active failures, largely slips (10 studies); lapses (9) and mistakes (12); error-provoking conditions, particularly lack of knowledge (13) and insufficient staffing levels (13) and latent conditions, commonly heavy workload (9).

Conclusion There is a need to improve the quality and reporting of studies from Middle Eastern countries. A standardised approach to quantifying medication errors' prevalence, severity, outcomes and contributory factors is warranted.

Keywords Medication errors · Prescribing errors · Error causation · Systematic review · Middle East

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Introduction

In 1999, the 'Institute of Medicine' (now the National Academy of Medicine) published the seminal report 'To Err Is Human: Building a Safer Health System' quantifying the scale of harm associated with medical care in the United States (US) [1]. The authors called for coordinated efforts by governments, healthcare providers and consumers and others to promote patient safety, setting a minimum goal of 50% reduction in medical errors by 2004. Despite global advances in healthcare practices, an estimated one in ten patients is still harmed while receiving care [2]. In March 2017, the World Health Organization (WHO) published 'Medication Without Harm, WHO Global Patient Safety Challenge' [3, 4]. It called for action to reduce patient harm which occurs as a result of unsafe medication practices and medication errors. The aim is to 'gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next 5 years,

specifically by addressing harm resulting from medication errors or unsafe practices due to weaknesses in healthcare systems'. One key objective is to 'assess the scope and nature of avoidable harm and strengthen the monitoring systems to detect and track this harm' [3, 4].

A number of published systematic reviews have attempted to quantify medication errors at various stages of the medication use processes of prescribing, transcribing, verifying, administration, dispensing and monitoring [5–21]. These have largely focused on secondary care inpatients, with most reporting errors committed in targeted groups of patients including paediatrics, acute care, older people, mental health and perioperative care. Many of these reviews also reported data on contributory factors leading to errors [6, 9–11, 14, 17, 21]. One key limitation highlighted in many of these reviews is the lack of a standardised approach to defining and measuring errors, limiting the validity of any pooling of data from different studies and different systematic reviews. Furthermore, the very different healthcare structures and processes across the world may limit the generalisability of findings to other contexts. Given the first objective of the WHO challenge, there may be merit in conducting systematic reviews capturing studies from specific contexts to provide the most meaningful data which can be used to inform future strategies and interventions.

Given the differing healthcare systems, ethnicity, culture and work practices of the Middle East, there may be merit in conducting systematic reviews of studies within that geographical area (i.e. Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates and Yemen). In 2013, Alsulami et al. published a systematic review of studies up to and including 2011 on the incidence and types of medication errors in Middle Eastern countries and main contributory factors [10]. While noting that error rates were difficult to compare between studies due to being expressed differently, prescribing errors ranged from 7.1% of prescriptions in a teaching hospital to 90.5% of prescriptions in a primary healthcare centre. Poor knowledge of medicines was identified as a contributory factor for errors by doctors and nurses.

One limitation of this review was the lack of any theories of error causation in the synthesis stage. Incorporation of theory in primary studies or systematic reviews will yield findings which provide more comprehensive coverage of the key influential factors. The most commonly used and cited theoretical framework in this field is Reason's Accident Causation model. This model groups error causes as follows:

1. Active failures which are unsafe acts committed by people who are in direct contact with the patient or system. They take a variety of forms including slips and lapses (errors in task execution), mistakes (errors in planning) and procedural violations (rule breaking).
2. Error-producing conditions which can have adverse effects of error-provoking conditions within the local workplace (e.g. time pressure, understaffing, inadequate equipment, fatigue and inexperience).
3. Latent failures which arise from decisions made by policy makers, leaders and top-level management [22].

Furthermore, the review highlighted that published papers from Middle Eastern countries were relatively few and generally of poor quality. Given the advances in healthcare in recent years, an updated systematic review incorporating error theory is warranted.

The aim of this systematic review was to critically appraise, synthesise and present the available evidence of medication errors amongst hospitalised patients in Middle Eastern countries, specifically prevalence, nature, severity and contributory factors.

Methods

The systematic review protocol was developed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines [23] and registered with the International Prospective Register of Systematic Reviews (PROSPERO, CRD42015019693) [24].

Inclusion and exclusion criteria

Primary research studies of any design conducted in hospital settings in the Middle East (as defined in the introduction) which quantified medication errors (i.e. prescribing, administration or dispensing errors) published as full papers in English from 2000 to the end of March 2018 were included in the review. Studies which reported error nature, severity or associated causative factors were also included. Studies of adverse drug events which were not classified as errors were excluded, as were review articles, letters, opinion papers, editorials and conference abstracts.

Search strategy

The search was conducted in Cumulative Index of Nursing and Cumulative Allied Health Literature (CINAHL), Embase, Medline, Pubmed and Science Direct. Search terms (title, abstract, text, keyword) were (medic* OR prescrib* OR dispens* OR administ*) AND (error* OR incident* OR mistake*) AND (Middle East OR Bahrain OR Egypt OR Iran OR Iraq OR Israel OR Jordan OR Kuwait OR Lebanon OR Oman OR Palestine OR Qatar OR Saudi Arabia OR Syria OR Turkey OR United Arab Emirates OR Yemen). The reference lists of all identified papers were reviewed to identify additional studies.

Screening

Screening of titles (BT, DS), abstracts (BT, DS) and full papers (BT, DS) was independently performed by two reviewers, with disagreements resolved by consensus and referred to a third reviewer (KM) whenever required.

Assessment of methodological quality

Papers were independently assessed for methodological quality by two reviewers (BT and one of DS, VP, AP, JM, WEK, MAH) with disagreements resolved by consensus and referred to a third reviewer whenever required. The STROBE checklist (STrengthening the Reporting of OBservational studies in Epidemiology) was adapted as a quality assessment tool [25]. For all study designs, STROBE criteria retained were those relating to bias with addition of criteria specific to medication errors (e.g. error definitions). For qualitative studies, credibility and dependability replaced validity and reliability, and transferability replaced generalisability.

Data extraction

A bespoke data extraction tool was developed and piloted to extract the following: authors, country of publication/study, year of publication, study population, setting, recruitment, error quantification, nature of errors, error severity and contributory factors. Data extraction was also performed by two independent reviewers, as per quality assessment.

Data synthesis

Previous systematic reviews have highlighted the heterogeneity of studies in terms of error definitions, methods of measurement and outcome measures [5–21]; hence, a narrative approach to data synthesis was selected a-priori. Data related to error causation were synthesised using Reason's Accident Causation model as a theoretical framework in terms of active failures, error-producing conditions and latent failures [22].

Results

Study screening

Database searching and review of reference lists yielded 452 articles, 110 of which were duplicates and excluded. Review of titles and abstracts excluded 213 papers with full-paper review excluding a further 79. Fifty papers were included in the quality assessment stage. The PRIMSA flowchart is given in Fig. 1. Of the fifty studies, 48 were of a quantitative, cross-sectional design and two were qualitative in nature.

Quality assessment

Of the 50 studies, none met all 11 STROBE-related quality assessment criteria. Thirteen studies (26%) met eight or more criteria, 21 (42%) between five and seven criteria and the remaining 16 (32%) meeting four or less. Key limitations centred on lack of justification for the method of sampling and sample size, and not adequately considering issues of data validity and reliability (quantitative studies) and trustworthiness (qualitative studies). Supplementary Table 1 gives the findings of the quality assessment processes.

Characteristics of included studies

Almost half of the studies were conducted in Iran ($n = 23$, 46%), followed by Saudi Arabia ($n = 10$, 20%), Egypt and Jordan ($n = 5$ each, 10%), Turkey ($n = 2$, 4%) and one each (2%) from Israel, Qatar, Yemen, Palestine and Lebanon. None of the studies reported data from more than one country. Two thirds ($n = 33$, 66%) were conducted in university-affiliated or academic hospitals, one fifth ($n = 10$, 20%) tertiary care non-teaching hospitals and only three (6%) in general hospitals. Three studies (6%) did not state the type of hospital and one (2%) reported an analysis of a national online database. Within each hospital, a range of specific patient groups was targeted, mostly adults, and the most common types of wards chosen were intensive care units.

The definition of medication errors (or sub-categories of medication errors) was inconsistent. In the 50 studies, 17 different definitions were given, differing in wording and content. The most widely used was that of the US National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) [26]. Ten studies (20%) adopted non-standardised definitions from previous studies or provided their own definition. Three studies (6%) used the definition of medication errors as per Aronson et al. [27]. Two studies (4%) on prescribing errors used the definition of the American Society of Health-System Pharmacists [28]. One study each used definitions provided by Dean et al. [29] and the Institute of Medicine [30]. Twelve studies (24%) did not provide any definition of either medication errors or the sub-category being reported.

Quantifying medication errors

Of the 32 studies quantifying medication errors, the most common methods of data collection were via review of medication charts or records (prescribing, dispensing and administration) ($n = 11$, 31%) or by analysis of data from an error or incident monitoring system ($n = 9$, 28%). Only one study employed multiple approaches to data collection. Data collection periods ranged from 20 days to 2 years. Data extraction of the 32 studies is provided in Supplementary Table 2.

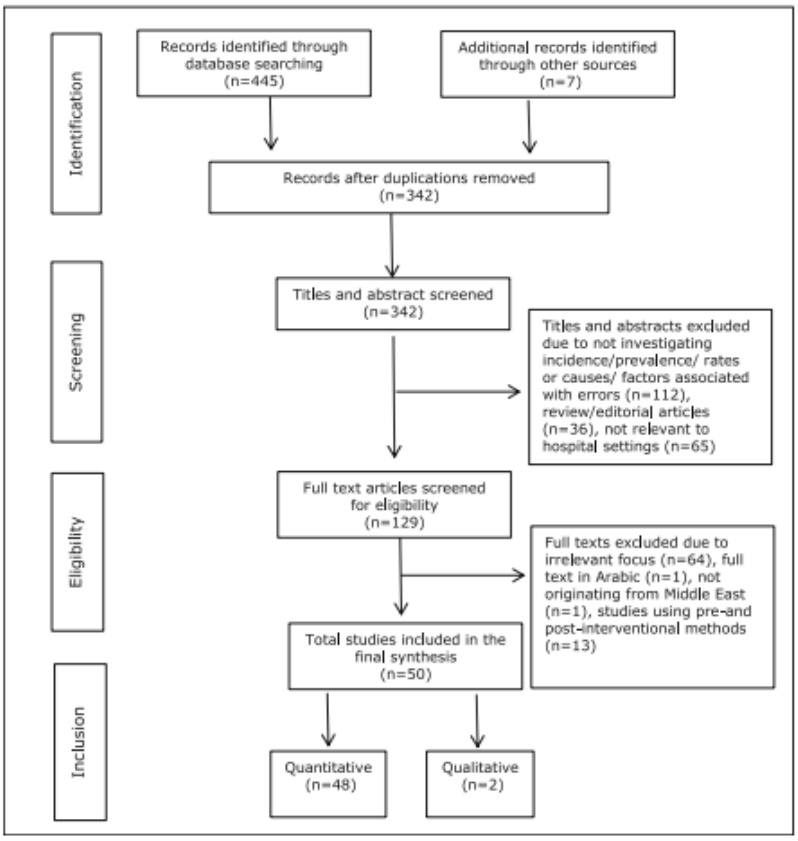

Fig. 1 PRISMA flowchart describing systematic review search and study selection

Inconsistencies in definitions of 'medication error', 'prescribing error' etc., together with the vast range of approaches to data collection and presentation of findings, limited pooling of data hence a narrative approach to data synthesis was employed. Almost half of the studies ($n = 32$, 47%) quantified 'medication errors' in general, with fewer solely reporting 'administration errors' ($n = 7$, 22%) or 'prescribing errors' ($n = 6$, 18%) and one (3%) reporting only transcribing errors. Three studies reported data with combinations of classifications of medication errors.

The specific terms used in the studies to report medications errors varied and eight different denominators were used, the most frequent being 'total number of medication orders' or 'number of prescriptions' ($n = 13$, 40%), followed by 'number of patients admitted' ($n = 6$, 19%) and 'total number of opportunities for errors' ($n = 4$, 12%). One study (3%) each used 'total number of preparations', 'total number of medications dispensed', 'total number of cases/records', 'total number of patient days' and 'total number of reports'. Four studies (13%) did not specify the denominator.

Given this marked heterogeneity, it was not possible to make valid comparisons of the outcome measure of prevalence. Even in studies which used the same outcome measure, the error definitions and methods of measurement varied considerably. The following results should therefore be interpreted with caution.

Of the 13 studies reporting medication errors per 'total number of medication orders'/'number of prescriptions', the median across all studies was 10% (IQR 2–35%). The rates varied from 0.18 to 56 per 100 medication orders'/'number of prescriptions'. Of the six studies reporting 'number of patients admitted', the median was 28% (IQR 1–35%), varying from 0.15 to 40 errors per 100 patient admissions.

Nature and severity of medication errors

Almost all studies (31/32, 97%) provided data regarding the nature of the errors. For prescribing errors, the most commonly reported included errors of omission, wrong drug, wrong dose, wrong route, incomplete order, wrong duration, drug-

drug interaction and wrong patient. Studies reporting administration errors were largely related to wrong administration time, wrong administration route and wrong infusion rate.

Fourteen studies (43%) reported the specific medications most commonly associated with errors. Most frequently reported therapeutic groups included anti-infectives for systemic use, drugs used for alimentary tract and metabolism and cardiovascular drugs.

Thirteen studies (40%) reported error severity, with eight categorising according to the NCCMERP Index [26]. These studies, however, provided very little methodological detail on the application of the index, specifically assessment of inter-rater reliability. In five studies, the most common category was B (near miss), with C (error occurred and reached the patient but with no harm) in two studies and E (error occurred and may have contributed to or resulted in temporary harm and required intervention) in one study.

Contributory factors

Twenty-four studies (48%) from six Middle-Eastern countries reported causes or contributory factors leading to medication errors. Approaches to data collection were largely based on questionnaires (15/24, 63%), data from incident reporting systems ($n = 4$, 17%), direct observation of practice ($n = 2$, 8%), semi-structured interviews ($n = 2$, 8%) and retrieval of information from patient medical records ($n = 1$, 4%). A total of 3919 health professionals were involved in these 24 different studies. Notably, none of these 24 studies used any theory (e.g. behavioural, organisational) in the processes of data collection or analysis. As described in the methods section, findings from these 24 studies were categorised according to Reason's Accident Causation model [22] (Table 1), and synthesis of the categories is provided in Table 2. Contributory factors most commonly reported were active failures, largely slips, lapses and mistakes; error-provoking conditions, particularly those relating to lack of knowledge and insufficient staffing levels and latent conditions, most commonly heavy workload. Error-provoking conditions such as lack of experience, poor documentation and look-alike drugs, or latent conditions of issues relating to a blame culture were rarely reported.

Discussion

Statement of key findings

Heterogeneity in medication error definitions and scope, differences in methods of data collection and units of analysis of the studies included in this review limited data pooling. Most frequently reported was the percentage of medication errors per total number of medication orders with a median across all studies of 10% (IQR 2–35%). Prescribing errors were the most common type of errors reported, with dose-related errors being most prevalent. Contributory factors associated with medication errors were multifactorial. Synthesis of findings according to Reason's Accident Causation model identified that active failures (slips, lapses and mistakes) were most commonly reported followed by error-provoking conditions (e.g. lack of knowledge, insufficient staffing), with latent failures (e.g. heavy workload) least reported.

Strengths and weaknesses

There are several strengths to this review. The protocol was developed according to the standards of PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols [23], registered in the PROSPERO database [24], and the systematic review reported according to PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) criteria [55]. The synthesis adopted a theory-driven approach based on Reason's Accident Causation Model [22], which could subsequently facilitate the development of interventions. There are, however, several weaknesses; hence, the review findings should be interpreted with caution. Restricting the search to the English language and excluding those written in regional languages of Arabic or Persian may have limited retrieval of potentially relevant studies. It is, however, worth noting that English is the preferred language of most professional organisations in the Middle East.

Interpretation of key findings

Although there has been an increase in the number of medication errors studies originating from Middle East over the last few years, two thirds were from Iran and Saudi Arabia with none from eight countries. While the reasons for the lack of studies in other countries are unknown, this does have implications for the generalisability and transferability of review findings and conclusions. Furthermore, there was a lack of studies employing a qualitative approach to explore contributory factors of errors.

The majority of studies had key limitations in study design and lacked transparency in reporting key study details. Authors should be encouraged to adopt standardised reporting checklists available from the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network [56]. This international network aims to 'improve the reliability and value of published health research literature by promoting transparent and accurate reporting.' An example is the STROBE checklist (Strengthening the Reporting of Observational Studies in Epidemiology) for reporting observational studies [25].

Table 1 Classification of medication error contributory factors

Author(s), year, country	Methodology	Setting, participants, number	Classification of contributory factors as per Reason's Accident Causation model [22]	
Abdar et al. 2014, Iran [31]	Cross-sectional survey	Setting—4 academic hospitals Participants—nurses No. of participants—238	Error-producing conditions • Insufficient staff • Nurse fatigue • Illegible handwriting • Nurse workload	Latent failures • Supervisory issues • Not considering nurses' views
Ali et al. 2017, Saudi Arabia [32]	Retrospective analysis from incident reporting system	Setting—tertiary care hospital Participants—not relevant No. of participants—not relevant	Active failures • Slips—look-alike sound-alike medications	Error-producing conditions • Miscommunication of drug orders Latent failures • Lack of educational activities
Alshaikh et al. 2013, Saudi Arabia [33]	Retrospective analysis from incident reporting system	Setting—academic hospital Participants—not relevant No. of errors reported—949 Duration—1 year	Error-producing conditions • Lack of knowledge • Illegible handwriting	Latent failures • Performance deficit
Al-Shara et al. 2011, Jordan [34]	Cross-sectional survey	Setting - NS Participants—nurses No. of participants—126	Active failures • Slips—sound alike • Mistake—prescribing wrong dosage • Violation—using abbreviations	Error-producing conditions • Heavy workload • Unfamiliarity of nurses with patients' medical conditions • Unfamiliarity with the use of medications
Al-Youssif et al. 2013, Saudi Arabia [35]	Cross-sectional survey	Setting—government hospital Participants—nurses No. of participants—253	Active failures • Lapse—dispensing wrong drug • Mistake—wrong packaging • Violation—poor adherence to protocol	Error-producing conditions • Illegible prescription • Poor communication Latent failures • Pharmacists not available 24 h
Al-Tehewy, et al. 2016, Egypt [36]	Prospective observational study	Setting—academic hospital Participants—nurses No. of participants—28	Error-producing conditions • Heavy workload • Patient condition (illiteracy, elderly)	Latent failures • Poor staffing • Lack of policy and procedures • Low commitment of hospital administration towards patient safety
Bagheri-Nesami et al. 2015, Iran [37]	Cross-sectional survey	Setting—12 academic hospitals Participants—nurses No. of participants—190	Active failures • Slips—selecting wrong medication • Lapse—failed to put correct labels on medications • Mistake—delivered incorrect medication doses	Error-producing conditions • Physicians' medication orders illegible • Many patients receiving similar medications • Limited knowledge of medications Latent Failures • poor communication • Limited access to medication information. • Medication experts not available.
Cheragi et al. 2013, Iran [38]	Cross-sectional survey	Setting—academic Participants—nurses No. of participants—237	Active failures • Slips—wrong patient, • Lapse—failure to give medication	Error-producing conditions • Large variety of drugs in the medication cabinet• Sound alike medications• Too busy and tired from excessive work (nurses) Latent Failures • lack of training • lack of staffing

Table 1 (continued)

Author(s), year, country	Methodology	Setting, participants, number	Classification of contributory factors as per Reason's Accident Causation model [22]		
			• Mistake—prescribing wrong dosage and infusion rate • Violation—using acronyms of medication names		
Dibbi, et al. 2006, Saudi Arabia [39]	Retrospective chart review	Setting—general hospital Participants—not relevant No. of participants - 2627	Active failures • Slips—choosing wrong medication (look alike and sound alike)		Error-producing conditions • Lack of knowledge • Performance deficit
Ehsani et al. 2013, Iran [40]	Cross-sectional survey	Setting—academic hospital Participants—nurses No. of participants—94	Active failures • Slips—choosing wrong medication (look alike and sound alike) • Violation—using abbreviated names	Error-producing conditions • Fatigue from hard work• Illegibility • Insufficient pharmacological knowledge	Latent failures • High patient -to- nurse ratio • Insufficient education/training
Farzi et al. 2017, Iran [41]	Semi-structured individual interviews	Setting—academic hospitals Participants—physicians, nurses and clinical pharmacists No. of participants—19	Active failures • Slips—look alike, sound alike • Mistake—incomplete medication orders	Error-producing conditions • Lack of knowledge of healthcare team • Lack of professional communication • Lack of medication reconciliation • Interruption/talking while medication administration • Lack of pharmaceutical knowledge	Latent failures • Lack of monitoring or supervisory mechanisms Weak professional collaboration between healthcare team • Lack of management decisions • Lack of adequate staffing
Fathi et al. 2017, Iran [42]	Cross-sectional survey	Setting—7 academic hospitals Participants—nurses No. of participants—500	Active Failures • Slips—look alike, sound alike • Mistake—wrong labelling	Error-producing conditions • Inappropriate behavior of patients • Fatigue from hard work • Phone call orders • High number of patients • Noisy environment	Latent failures • Lack of monitoring or supervisory mechanisms Shortage of nursing staff • Lack of drug information resources
Gorgich et al. 2016, Iran 55]	Cross-sectional survey	Setting—academic hospitals Participants—nurses No. of participants—327	Active failures • Violation—unreadable orders	Error-producing conditions • Fatigue due to high workload • Large number of critically ill patients • Poor physical environment (light, temperature) • Poor communication between team members	Latent failures • Low ratio of nurses to patients • Failure in emphasising the importance of recording and reporting the medication errors • Blame culture
Güneş et al. 2014, Turkey [43]	Cross-sectional survey	Setting—2 government hospitals Participants—nurses No. of participants—243	Active failures • Lapse—physicians not writing drug route • Mistake—prescribing interacting drugs • Violation—physicians not writing the order or not in time		Error-producing conditions • Interruption by telephone etc. while preparing medication • Poor mathematical skills for drug dose calculatio
Hammoudi et al. 2017, Saudi Arabia [44]	Cross-sectional survey	Setting—tertiary care hospital Participants—nurses No. of participants—367	Error-producing conditions • Illegibility of patients' records • Wrong medication preparation by pharmacists		Latent failures Low staffing
Mrayyan et al. 2007, Jordan [45]	Cross-sectional survey	Setting—11 government and 11 private hospitals Participants—nurses No. of participants—799	Active failures • Slips—nurses confused by different types and functions of infusion devices • Lapse—nurse fails to check the patient name with medication administration record		Error-producing conditions • Nurses distracted by other patients, co-workers events on unit
	Cross-sectional survey		Active failures		Error-producing conditions

Table 1 (continued)

Author(s), year, country	Methodology	Setting, participants, number	Classification of contributory factors as per Reason's Accident Causation model [22]	
Mrayyan et al. 2012, Jordan [46]		Setting—academic hospitals Participants—nurses No. of participants—212	• Mistake—inaccurate rate of total parenteral nutrition	• Poor quality or damaged medication labels • Fear of disciplinary actions
Pawluk et al. 2017, Qatar [35]	Retrospective analysis from incident reporting system	Setting—tertiary care hospital Participants—not relevant No. of participants—201	Active failures• Lapse—missing documentation • Mistake—error in calculation • Violation—improper use of hospital protocol	
Pazokian et al. 2014, Iran [47]	Semi-structured individual interviews	Setting—academic hospital Participants—nurses No. of participants—20	Active failures • Mistake—prescribing wrong medications	Error-producing conditions • Poo documentation • Poor knowledge	Latent failures • Lack of attention of managers to staff physical and psychological issues leading to decrease in nurses' motivation • Risk management strategies insufficient
Shahrokhi et al. 2013, Iran [48]	Cross-sectional survey	Setting—academic hospitals Participants—nurses No. of participants—150	Active failures • Mistake—incorrect transcription	Error-producing conditions • Excessive workload• Inadequate pharmacological knowledge • Shortage of time	Latent failures • Low nurse to patient ratio • Inadequate number of staff in each working shift • Similar drug packing
Shehata et al. 2015, Egypt [49]	Retrospective analysis from incident reporting system	Setting—government and private hospitals Participants—not relevant No. of participants—1200 reports	Active failures • Lapse—lack of documentation	Error-producing conditions • Lack of knowledge and experience • Excessive workload and distractions • Incomplete prescribing instructions • Illegible handwriting	Latent failures • Lack of drug information resources
Shohani et al. 2018, Iran [50]	Cross-sectional survey	Setting—academic hospital Participants—nurses No. of participants—120	Error-producing conditions • Lack of awareness of drug • Fatigue and workload • Lack of patient information • Noisy working environment • Heavy work load	Latent failures • Lack of motivation amongst nurses • Lack of drug protocol • Lack of training	
Toruner et al. 2012, Turkey [51]	Cross-sectional survey	Setting—4 tertiary care hospitals Participants—nurses No. of participants—124	Active failures • Mistake—reading the prescription in wrong way	Error-producing conditions • Long working hours• High patient–nurse ratio • Lack of patient information	Latent failures • Unavailability of medications in appropriate forms • Poor work environment
Vazin et al. 2012, Saudi Arabia [52]	Prospective observational study	Setting—academic hospitals Participants—patients No. of participants—38	Active failures • Slips—memory lapses • Lapse—faulty dose checking (missing) • Mistake—preparation error • Violation—violating hospital rules	Error-producing conditions • Lack of drug knowledge • Lack of interaction with other services • Lack of patient information	Latent failures • Poor drug stocking and delivery

Table 2 Synthesis of causative factors

Author(s), year, country	Active failure				Error-provoking conditions						
	Slip	Lapse	Mistake	Violation	Lack of knowledge	Insufficient staff	Patient condition(s)	Poor communication	Lack of experience	Distractions	Look alike drugs
Abdar et al. 2014, Iran [31]						✓					
Ali et al. 2017, Saudi Arabia [32]	✓							✓			
Alshaikh et al. 2013, Saudi Arabia [33]					✓						
Al-Shara et al. 2011, Jordan [34]	✓	✓		✓	✓				✓		
Al-Tehewy, et al. 2016, Egypt [36]						✓	✓				
Al-Youssif et al. 2013, Saudi Arabia [53]		✓	✓	✓		✓		✓			
Bagheri-Nesami et al. 2015, Iran [37]	✓	✓	✓		✓						
Cheragi et al. 2013, Iran [38]	✓	✓	✓	✓		✓				✓	✓
Dibbi, et al. 2006, Saudi Arabia [39]	✓				✓						
Ehsani et al. 2013, Iran [40]	✓				✓	✓					
Farzi et al. 2017, Iran [41]	✓		✓		✓	✓		✓		✓	
Fathi et al. 2017, Iran [42]	✓		✓			✓		✓		✓	
Gorgich et al. 2016, Iran [54]				✓		✓	✓	✓			
Güneş et al. 2014, Turkey [43]		✓	✓	✓	✓					✓	
Hammoudi et al. 2017, Saudi Arabia [44]						✓					
Mrayyan et al. 2007, Jordan [45]	✓	✓								✓	
Mrayyan et al. 2012, Jordan [46]			✓								
Pawluk et al. 2017, Qatar [35]		✓	✓	✓							
Pazokian et al. 2014, Iran [47]			✓		✓			✓			
Shahrokhi et al. 2013, Iran [48]			✓		✓	✓					✓
Shehata et al. 2015, Egypt [49]		✓			✓						
Shohani et al. 2018, Iran [50]					✓	✓	✓			✓	
Toruner et al. 2012, Turkey [51]			✓		✓	✓				✓	
Vazin et al. 2012, Saudi Arabia [52]	✓	✓	✓	✓	✓	✓					
Total number of studies	10	9	12	7	13	13	3	6	1	7	2

Author(s), year, country	Error-provoking conditions		Latent conditions						
	Poor Documentation	Illegible orders	Heavy workload	Lack of training	Organisation factors	Blame culture	Supervisory issues	Organisational policy issues	Information resource issues
Abdar et al. 2014, Iran [31]		✓	✓		✓		✓		
Ali et al. 2017, Saudi Arabia [32]				✓					
Alshaikh et al. 2013, Saudi Arabia [33]		✓							

Table 2 (continued)

Al-Shara et al. 2011, Jordan [34]			✓						
Al-Tehewy, et al. 2016, Egypt [36]			✓				✓	✓	
Al-Youssif et al. 2013, Saudi Arabia [53]		✓						✓	
Bagheri-Nesami et al. 2015, Iran [37]	✓	✓					✓		✓
Cheragi et al. 2013, Iran [38]				✓					
Dibbi, et al. 2006, Saudi Arabia [39]									
Ehsani et al. 2013, Iran [40]		✓	✓	✓					
Farzi et al. 2017, Iran [41]					✓		✓		
Fathi et al. 2017, Iran [42]							✓		✓
Gorgich et al. 2016, Iran [54]			✓			✓	✓	✓	
Güneş et al. 2014, Turkey [43]									
Hammoudi et al. 2017, Saudi Arabia [44]		✓							
Mrayyan et al. 2007, Jordan [45]									
Mrayyan et al. 2012, Jordan [46]						✓			
Pawluk et al. 2017, Qatar [35]									
Pazokian et al. 2014, Iran [47]							✓	✓	
Shahrokhi et al. 2013, Iran [48]			✓						
Shehata et al. 2015, Egypt [49]		✓	✓						✓
Shohani et al. 2018, Iran [50]			✓	✓					✓
Toruner et al. 2012, Turkey [51]			✓		✓				
Vazin et al. 2012, Saudi Arabia [52]					✓				
Total number of studies	1	7	9	4	4	2	7	4	4

A tick indicates that the specific causitive factor was reported

As noted in previous systematic reviews [5–21], many studies either did not define terms such as 'medication errors', 'prescribing errors' etc. or used non-standardised definitions. There was also variation in the methods used and the duration of data collection. To further advance this field of research, the adoption of standardised definitions and methodologies should be encouraged. This would enable analytical approaches such as meta-analyses and provide more robust and generalisable findings to inform practice.

Few studies reported the severity of errors, often providing little methodological detail. In a systematic review of tools used in error severity estimation, Garfield et al. highlighted that of the 40 tools assessed, only two were deemed to have acceptable validity and reliability [57].

Despite these issues around standardisation, it is evident from this systematic review that medication errors remain prevalent in hospitals in the Middle East. For those reporting medication errors, the median 'total number of medication orders'/ 'number of prescriptions' across all studies was 10% (IQR 2–35% and range of 0.18–56%). While differences in methodology, settings and patient populations limit comparisons to other systematic reviews; these figures are similar to those reported by Alsulami et al. in a systematic review of Middle Eastern studies up to 2011 [10]. The prevalence of medication errors in the Middle East would appear to remain largely unchanged and at a similar level to those reported from around the world [5–21].

None of the 24 studies in this review and only two previous systematic reviews analysed causative factors according to Reason's theory. In a review of prescribing errors in hospitalised patients, Tully et al. reported that the active failure most frequently cited was a mistake due to inadequate knowledge of the drug or the patient. There were issues of lack of training or experience, fatigue, stress, high workload and inadequate communication between healthcare professionals [9]. In a systematic review of medication administration error studies, Keers et al. reported that slips and lapses were the most common unsafe acts [11]. Our synthesis of study findings according to Reason's Theory is similar in that active failures of slips, lapses and mistakes were most common. Error-provoking conditions included lack of knowledge and insufficient staff. It is possible that other contributory factors may have been identified if the primary studies had used Reason's Theory in data collection and analysis. Using a theoretical framework in primary research would ensure that all possible explanations underlying medication errors are identified [58]. Given the accumulation of evidence from this and other systematic reviews, a standardised, theory-informed approach should be adopted. This is fundamental to the key stated WHO objective of assessing and scoping the nature of avoidable medication-related harm [3, 4].

Policy makers, leaders, practitioners and other relevant stakeholders must continue working towards minimising the key-identified contributory factors where possible.

Further research

There is a need for consensus-based research to define and standardise medication error definitions, approaches to data collection and outcome measures. Furthermore, theoretically informed qualitative research which allows in-depth exploration of contributory factors leading to medication errors is warranted. The findings from studies such as these would facilitate the development, testing, evaluation and monitoring of interventions aiming to reduce avoidable medication-related harm. There is evidence that consideration of theory allows comprehensive identification of the key issues to be targeted as part of intervention development leading to more effective and sustainable interventions compared to more pragmatic approaches [58].

Conclusion

While there has been a clear increase in the number of publications from selected Middle Eastern countries, there is need to improve the quality and reporting of studies. A standardised approach to quantifying medication errors' prevalence, severity, outcomes and contributory factors is warranted.

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Moza Al Hail: data collection, analysis, reviewing and approving final manuscript.

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Appendix 2: Journal Publication 2

PLOS ONE

RESEARCH ARTICLE

Perspectives of healthcare professionals in Qatar on causes of medication errors: A mixed methods study of safety culture

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Data Availability Statement: All quantitative data derived from the cross-sectional survey are given in the paper. For the focus group discussions, data are qualitative in nature and cannot be made publicly available due to ethical as they contain potentially identifiable information. Researchers who meet the criteria for access to confidential data may contact the Robert Gordon University Research Ethics Sub-Committee, Research-Integrity@rgu.ac.uk.

Abstract

Background

There is a lack of robust, rigorous mixed methods studies of patient safety culture generally and notably those which incorporate behavioural theories of change. The study aimed to quantify and explain key aspects of patient safety culture which were of most concern to healthcare professionals in Qatar.

Methods

A sequential explanatory mixed methods design of a cross-sectional survey followed by focus groups in Hamad Medical Corporation, Qatar. All doctors, nurses and pharmacists were invited to complete the Hospital Survey on Patient Safety Culture (HSOPS). Respondents expressing interest in focus group participation were sampled purposively, and discussions based on survey findings using the Theoretical Domains Framework (TDF) to explain behavioural determinants.

Results

One thousand, six hundred and four questionnaires were received (67.9% nurses, 13.3% doctors, 12.9% pharmacists). HSOPS composites with the lowest levels of positive responses were non-punitive response to errors (24.0% positive) and staffing (36.2%). Specific TDF determinants potentially associated with these composites were social/professional role and identity, emotions, and environmental context and resources. Thematic analysis identified issues of doctors relying on pharmacists to correct their errors and being reluctant to alter the prescribing of fellow doctors. There was a lack of recognition of nurses' roles and frequent policy non-adherence. Stress, workload and lack of staff at key times were perceived to be major contributors to errors.

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Conclusions

This study has quantified areas of concern relating to patient safety culture in Qatar and suggested important behavioural determinants. Rather than focusing on changing behaviour at the individual practitioner level, action may be required at the organisational strategic level to review policies, structures (including resource allocation and distribution) and processes which aim to promote patient safety culture.

Introduction

Promoting patient safety in healthcare settings is a global challenge, with an estimated one in ten patients being harmed whilst receiving care [1]. In an effort to raise awareness of key concepts and strategies in patient safety, the World Health Organization (WHO) published 'Medication Without Harm, WHO Global Patient Safety Challenge' in March 2017 [2,3]. The challenge calls for action to reduce patient harm which occurs as a result of unsafe medication practices and medication errors [2,3]. The goal is to 'gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years, specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems'. Accumulation of evidence confirms that healthcare professionals often prescribe, dispense and administer medication in ways and circumstances that may increase the risk of patient harm [4–8].

Whilst it is noted that the magnitude and nature of medication harm may differ between countries, globally the cost associated with medication errors has been estimated at US$ 42 billion annually [2,3]. The most commonly cited and accepted definition of the term 'medication error' is that of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) in the United States (US), 'any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer' [9]. Most research literature focuses on errors relating to prescribing, administration and dispensing, with evidence that causation is often complex and multifactorial. Systematic reviews have focused on causes of medication errors in different patient populations and settings [10–13]. Common to all systematic reviews is the relatively poor research methodologies reported in most of the primary literature, a lack of behavioural theory and organisational culture in study design. Furthermore, very few studies employed a mixed methods approach to allow quantification and in-depth description and explanation of contributory factors.

Behavioural theories may be used to provide explanation hence providing a robust and rigorous foundation for development of behaviour change interventions. The United Kingdom (UK) Medical Research Council (MRC) framework, 'Developing and implementing complex interventions' highlights the importance of considering theory, noting that interventions grounded in theory are more likely to be effective than those developed empirically or pragmatically' [14]. The Theoretical Domains Framework (TDF) is being used increasingly within health-related research to provide insight into influences on behaviour. TDF derives from 33 psychological theories and 128 theoretical constructs organised into 14 domains of behavioural determinants, as described in Table 1 [15].

It is apparent that there is also a need to focus attention on organisational safety culture. The 'Study Group on Human Factors' defines organisational safety culture as, 'the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour

Table 1. Description of TDF domains (adapted from Cain et al. [15]).

TDF Domains	Description
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 or measured actions	Anything aimed at managing or changing objectively observed

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that determine the commitment to, and the style and proficiency of, an organization's health and safety management [16].' While two systematic reviews have explored interventions to promote safety culture in hospitals in general and acute hospitals specifically, medication safety was not a feature of any primary research [17,18].

In an attempt to promote and standardise the measurement of organisational safety culture, the US Agency for Healthcare Research and Quality (AHRQ) and Medical Errors Workgroup of the Quality Interagency Coordination Task Force (QuIC) sponsored the development of the Hospital Survey on Patient Safety Culture (HSOPS) [19]. Items are clustered within 12 composites as presented in Table 2.

Research on medication errors within the Middle East has historically been reported to be of poor quality [20]. Recently, Elmontsri et al. conducted a systematic review to explore the status of patient safety culture in Arab countries based on the findings of the HSOPS [21]. Data from 18 studies across seven countries (excluding Qatar) were included, identifying that composites relating to non-punitive response to error to be infrequently practised in their organisation, that staffing levels were often inadequate and that communication needed to be more open. The authors concluded that further research is warranted to provide explanation of these findings and to identify potential interventions to enhance culture and patient safety.

The aim of the present study was to quantify and explain key aspects of patient safety culture which were of most concern to health professionals in Qatar.

Table 2. HSOPS composites and definitions [19].

Composite	Definition: The extent to which. . .
Communication openness	staff freely speak up if they see something that may negatively affect a patient and feel free to question those with more authority
Feedback and communication about error	staff are informed about errors that happen, are given feedback about changes implemented, and discuss ways to prevent errors
Frequency of events reported	mistakes of the following types are reported: mistakes caught and corrected before affecting the patient; mistakes with no potential to harm the patient; and mistakes that could harm the patient but do not
Handoffs and transitions	important patient care information is transferred across hospital units and during shift changes
Management support for patient safety	hospital management provides a work climate that promotes patient safety and shows that patient safety top priority
Non-punitive response to error	staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file
Organisational learning—continuous improvement	mistakes have led to positive changes and changes evaluated for effectiveness
Overall perceptions of patient safety	procedures and systems are good at preventing errors and there is a lack of patient safety problems
Staffing	there are enough staff to handle the workload and work hours are appropriate to provide the best care for patients
Supervisor/manager expectations and actions promoting patient safety	supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems
Teamwork across units	hospital units cooperate and coordinate with one another to provide the best care for patients
Teamwork within units	staff support each other, treat each other with respect, and work together as a team

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Methods

Study design

A sequential explanatory mixed methods design was employed, with a cross-sectional survey followed by focus groups in samples of questionnaire respondents to provide further depth and explanation of survey findings [22,23].

Setting

The research was conducted within Hamad Medical Corporation (HMC), the main provider of secondary and tertiary healthcare in Qatar.

Cross-sectional survey

The first phase of the research was a cross-sectional survey.

Questionnaire development

The questionnaire was adapted from AHRQ HSOPS with items presented as 5-point Likert type scales; personal and practice demographic items were added. The common language of care delivery at HMC is English thus translation into other languages (e.g. Arabic) was not required. The questionnaire was piloted in a convenience sample of 100 healthcare professionals. Test-retest reliability was assessed in pilot respondents by requesting that the questionnaire be completed on a second occasion within an interval of two weeks. A high level of test-retest

for transcribing reliability. A clear audit trail was maintained which documented details of data gathering to promote dependability [25]. Sampling and recruitment continued to the point of data saturation, when no new themes emerged from data analysis [26]. Focus groups were conducted between mid-May 2016 and mid-June 2016.

Data analysis

Data analysis followed the Framework Approach, using TDF domains deductively for to generate a coding framework [27]. Two researchers independently read each focus group transcript repeatedly to ensure familiarity, then coded text to one or more TDF domains. Any disagreements were resolved by discussion which involved a third researcher if needed.

Ethics

The study received ethical approval from Hamad Medical Corporation, Medical Research Center Qatar, Qatar University Institutional Review Board and Robert Gordon University Research Ethics Sub-Committee. Return of the questionnaire was taken as an indication of informed consent; written informed consent was obtained from all focus group participants.

Results

Cross-sectional survey

Respondents' demographics and professional characteristics. One thousand, six hundred and four completed questionnaires were received, with most (67.9%) from nurses followed by doctors (13.3%) and pharmacists (12.9%). Around three quarters (70.9%) were female, <40 years (76.0%) and almost half (48.1%) with more than 10 years of experience as healthcare professionals. Respondents had varying involvement with medicines-related processes as follows: prescribing medicines (15.1%); administering (61.1%); preparation and dispensing (25.9%); and monitoring (42.0%) (Table 3).

Patient safety culture items. Positive responses to the HSOPS composites and items are given in Table 4. Composites with the lowest levels of mean positive responses were: non-punitive response to errors (24.0%); staffing (36.2%); communication openness (50.5%); handoffs and transitions (53.1%); and supervisor/manager expectations and actions promoting patient safety (56.5%). Composites with the highest levels of positive responses were: organisational learning–continuous improvement (85.5%); team working within unit (82.1%); and management support for patient safety (75.4%). For the two composites with mean positive responses of <50%, Chi-square was used to determine the associations between percentage positive responses and demographics/professional characteristics.

Non-punitive response to errors—all individual items contributing to this HSOPS composite attracted a low level of positive response, this was particularly the case for items relating to staff concerns over errors being kept in their personnel files (26.2%), and the perception that errors counted against them (14.6%). There were highly statistically significant associations with mean composite agreement and gender (females most positive, X^2 (1, N = 1547) = 8.23, $p<0.005$), age (older most positive, X^2 (4, N = 1555) = 11.62, $p<0.05$) and experience as a healthcare professional (the most experienced being most positive, X^2 (5, N = 1536) = 18.42, $p<0.005$).

Staffing–while all responses attracted a low level of positive response, this was particularly the case for work pressures and speed of work (23.5%). There were highly statistically significant associations with mean composite agreement and healthcare professions (doctors most positive and pharmacists least, X^2 (2, N = 1494) = 42.06, $p<0.001$), age (youngest least and

Table 3. Respondents' demographic and professional characteristics (N = 1604).

Characteristic	Percentage	Frequency, n
Current role in the hospital		
Clinical nurse educator	0.7	12
Clinical pharmacist	2.8	45
Consultant physician	5.4	86
Head/Charge/Specialist nurse	17.1	275
Nurse	50.0	802
Pharmacist	8.9	143
Pharmacy Director/Supervisor/Specialist	1.2	19
Resident Physician	3.5	56
Specialist Physician	4.5	72
Other	5.0	80
Missing	0.9	14
Age (years)		
≤29	24.2	392
30–39	41.8	670
40–49	21.5	345
50–59	9.5	153
≥60	1.6	25
Missing	1.7	19
Gender		
Male	27.6	442
Female	70.9	1137
Missing	1.6	25
Country of receiving entry-to-practice degree		
India	42.7	685
Philippines	17.6	283
Egypt	9.3	149
Qatar	9.2	148
Jordan	4.8	77
Other	14.5	231
Missing	1.9	31
Experience as healthcare professional in hospital (years)		
<1	1.6	25
1–5	19.1	306
6–10	29.4	471
11–15	21.4	343
16–20	12.0	193
>20	14.7	235
Missing	1.9	31
Experience as healthcare professional in Qatar (years)		
<1	8.5	136
1–5	40.3	647
6–10	21.8	350
11–15	16.5	264
16–20	5.1	82
>20	6.7	108
Missing	1.1	17

(*Continued*)

Table 3. (Continued)

Characteristic	Percentage	Frequency, n
Hours worked in a typical week		
<20	1.3	21
20–39	10.6	170
40–59	82.7	1326
≥60	3.0	48
Missing	2.4	39
In your role you typically have direct interaction or contact with patients		
Yes	85.6	1373
No	9.0	145
Missing	5.4	86
Your primary roles in the medicines process are (multiple options could be chosen)		
Prescribing	15.1	243
Administering	61.1	980
Preparation and Dispensing	25.9	415
Monitoring	42.0	673
Missing	3.1	49

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oldest most positive, X^2 (4, N = 1564) = 28.89, p<0.001) and experience as a health professional (positive responses increasing with experience, X^2 (1, N = 1550) = 42.06, p<0.001).

For those ten composites with higher mean agreement, several items had less than half responding positively. There were issues around: supervisors/ managers overlooking recurring patient safety problems (31.9% positive); that it was due to chance that serious errors did not occur (36.0%); problems occurring when exchanging information across hospital units (42.9%); staff being able to ask questions if things did not seem right (44.0%); that at particular pressure points supervisors/ managers wanted staff to work faster, even if this required shortcuts to be taken (46.1%); and staff feeling able to question those in positions of authority (46.6%).

More detailed data on the responses to individual items within each composite are given in S1 File.

Focus groups

Demographics of participants. Two hundred and ninety-five survey respondents (18.4%) expressed interest in participating in focus groups. Nine focus groups were conducted (duration 45–60 minutes), at which point data saturation was deemed to have been achieved. Fifty-four individuals from different disciplines participated, with just under half (n = 26, 48.1%) being nurses, followed by 18 (33.3%) pharmacists and 10 (18.5%) doctors. Most were highly experienced with only 11 (20.4%) having <5 years of experience. During the focus groups, there was wide-ranging discussion across the spectrum of medication errors of prescribing, administration and dispensing.

Behavioural determinants associated with errors. Themes and subthemes relating to safety culture identified during focus group discussions are mapped to TDF behavioural determinants, with illustrative quotes provided for each.

A. Social/professional role and identity (a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)

Table 4. Positive responses to HSOPS items and composites (N = 1604).

Statements	% positive response (100% representing the highest positive response to each statement)
Non-punitive response to errors, overall positive response = 24.0%**	
*Staff feel like errors count against them	26.2 (disagreed)
*When an error is reported, it feels like the person is being reported, not the problem	31.1 (disagreed)
*Staff worry that errors they make are kept in their personnel file	14.6 (disagreed)
Staffing, overall positive response = 36.2%	
We have enough staff to handle the workload	54.7 (agreed)
*We use more locum staff than is best for patient care	30.5 (disagreed)
*We work under pressure trying to do too much, too quickly	23.5 (disagreed)
Communication openness, overall positive response = 50.5%	
Staff will speak up freely if they see something that may negatively affect patient care	60.9 (agreed)
Staff feel free to question the decisions or actions of those with more authority	46.6 (agreed)
*In this unit, staff are afraid to ask questions when something does not seem right	44.0 (disagreed)
Handoffs and transitions, overall positive response = 53.1%	
*Things get missed when transferring patients from one unit to another	53.7 (disagreed)
*Important patient care information is often lost during shift changes	60.8 (disagreed)
*Problems often occur in the exchange of information across hospital units	42.9 (disagreed)
*Shift changes are problematic for patients in this hospital	55.1 (disagreed)
Supervisor/manager expectations and actions promoting patient safety, overall positive response = 56.5%	
My supervisor/ manager says a good word when he/she sees a job done according to established patient safety procedures	73.0 (agreed)
My supervisor/ manger seriously considers staff suggestions for improving patient safety	74.9 (agreed)
*Whenever pressure builds up, my supervisor/ manager wants us to work faster, even if it means taking shortcuts	46.1 (disagreed)
*My supervisor/ manager overlooks patient safety problems that happen again and again	31.9 (disagreed)
Frequency of events reported, overall positive response = 58.1%	
When an error is made, but is noticed and corrected before affecting the patient, how often is this reported?	53.5 (agreed)
When an error is made, but has no potential to harm the patient, how often is this reported?	56.9 (agreed)
When an error is made that could potentially harm the patient but does not, how often is this reported?	63.8 (agreed)
Overall perceptions of patient safety, overall positive response = 59.1%	
Patient safety is never sacrificed to get more work done	70.6 (agreed)
Our procedures and systems are good at preventing errors from happening	78.7 (agreed)
*It is just by chance that more serious mistakes don't happen around here	36.0 (disagreed)
*We have patient safety problems in this unit	51.3 (disagreed)
Feedback and communication about error, overall positive response = 61.9%	
We are given feedback about changes put into place based on error reports	55.8 (agreed)

(*Continued*)

Table 4. (Continued)

Statements	% positive response (100% representing the highest positive response to each statement)
We are informed about medication errors in this unit	62.0 (agreed)
In this unit, we discuss ways to prevent medication errors from happening again	68.0 (agreed)
Teamwork across units, overall positive response = 67.7%	
There is good cooperation among hospital units that need to work together	72.9 (agreed)
Hospital units work well together to provide the best care for patients	82.8 (agreed)
*Hospital units do not coordinate well with each other	57.5 (disagreed)
*It is often unpleasant to work with staff from other hospital units	57.5 (disagreed)
Management support for patient safety, overall positive response = 75.4%	
Hospital management provides a work environment that promotes patient safety	87.0 (agreed)
The actions of hospital management show that patient safety is a top priority	84.2 (agreed)
Hospital management seems interested in patient safety only after an error happens	54.9 (agreed)
Teamwork within units, overall positive response = 82.1%	
People support one another in this unit	81.1 (agreed)
When a lot of work needs to be done quickly, we work as a team to get the work done	83.4 (agreed)
In this unit, people treat each other with respect	81.9 (agreed)
Organisational learning—continuous improvement, Overall positive response = 85.8%	
We are actively doing things to improve patient safety	90.2 (agreed)
After we make changes to improve patient safety, we evaluate their effectiveness	81.3 (agreed)

*Reverse scored negatively worded statement

** Calculated from the mean items within each composite

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1. Doctors reliance on pharmacists to correct errors. During discussion, it emerged that there were instances where doctors would rely on pharmacists to correct their prescribing errors and this led to complacency around prescribing,

'Yes. Most of the physicians make a medication error and wait for the pharmacist to correct it.' (Focus Group [FG] 5 Pharmacist 4)

2. Doctors reluctance to alter other doctors' prescribing. During one focus group, there was concern that doctors were unwilling to alter prescriptions written by other doctors, particularly for doctors from other specialities. The doctors considered this to be the responsibility of the original prescriber, even if a prescribing error had been made and initial prescriber was unavailable,

'This will happen when you're in the Ob-Gyn [obstetrics and gynaecology] *setup. If one physician came from Hamad from other. . . from cardiac or other site, if they write any prescription, if you call the Ob-Gyn doctor here, the on duty doctor, she will never agree to change because*

she will say it's an order from the consultant from cardiology or neurology.' (FG7 Pharmacist 4)

3. Lack of recognition of the role of nurses. Some of the nurses described that they were often omitted from discussions around patient care and decision making, even when present on ward rounds or meetings. There were instances where discussions took place in a different language,

'Even I'm noting that during the rounds, team decisions, the nurses are not informed. Sometimes they [the doctors] *are discussing in Arabic. The nurse, she cannot understand their plan and what is the decision.'* (FG3 Nurse 1)

4. Policy non-adherence. Health professionals not adhering to various policies was considered a cause of medication errors,

'Not abiding the. . . complying with the policies' (FG2 Doctor 2)

'There are seven or eight points that the pharmacist should check. If the pharmacist, for example, dispensed the wrong medication it means that he didn't follow the policy.' (FG5 Pharmacist 4)

B. Emotions (a complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)

1. Stress leading to medication errors. Stress and high pressure situations were described in all focus groups as influences on medication errors. While workload was a common factor leading to stress, patients themselves could also put undue pressure and hence stress of health professionals,

'And I think that probably the stresses of the work [lead to errors].*'* (FG1 Doctor 2)

'And parents are too tense than they are. . . even the parents they are too much angry. Yeah, they will scold the staff then like that time they will get pressure.' (FG7 Nurse 3)

C. 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)

Much of the discussion centred on aspects of environmental context and resources as key influences leading to medication errors. These were discussed by all participants in all focus groups. There were several key themes within this domain.

1. Workload issues leading to medication errors. Workload issues were discussed by doctors, nurses and pharmacists. Doctors believed one of the reasons for errors to happen was the heavy workload that they had.

'Too many patients. Labour ward is full, you know, too many patients for the residents to see.' (FG1 Doctor 2)

'Yeah, I'm working in emergency. So what I feel is it's too much. . . sometime it is too busy and doctors are giving too much orders. . .they cannot to cope with the situation.' (FG1 Nurse 1)

One pharmacist noted that the excessive workload for the doctor can lead to errors occurring and that this workload also put pressure on other health professionals which could compound errors.

'There are two problems here, a load on the physician that can lead to many mistakes and a load on the pharmacist because he needs to dispense medication for this patient and at the same time answer the questions of physician, nurses.' (FG5 Pharmacist 4)

One of the nurses also explained that the main cause of errors committed by junior medical staff was workload rather than lack of knowledge.

'And this is why the medication errors are also increasing, so it's not always related to the knowledge of the resident. And if the resident is overloaded because he has to document for all the patients and see all the patients and he is receiving calls from other units as well' (FG3 Nurse 3)

2. Lack of staff at key times. Closely related to workload issues was a critical lack of staff at key times such as weekends and evening which could compromise patient safety.

'On the whole days of the week, there is complete staff, complete number of physicians. In weekend, well, only one physician is doing the whole work.' (FG4 Doctor 2)

'Especially the areas like emergency, less staff. They will be get. . . too tense by the patients and they just want to do the things for faster. so it will make errors. (FG2 Nurse 1)

3. System-related issues. Discussion also centred on key issues related to the systems in operation in various wards and departments. There was particular concern over the implementation of Cerner (electronic health record system for hospitals, health care providers, clinics) from doctors, nurses and pharmacists.

'The electronic system is not robust, and I mean, the hardware is not good enough.' (FG2 Doctor 1)

'We have now to concentrate on the mistakes or medication errors happening by the prescribing system.' (FG5 Pharmacist 2)

One senior doctor commented that following implementation of Cerner, fewer checks were being performed compared to the previous paper-based system.

'Before it was like, when you have the hard copy of medication profile, someone is checking and countersigning. Now in the system, it [checking] *is not there as far as I know.'* (FG1 Doctor 2)

Themes and subthemes for those behavioural determinants less related to safety culture are summarised in Table 5.

Discussion

Key findings

Our study of the causes of medication errors in Qatar highlighted that the key composites of patient safety culture which merit attention are: non-punitive response to errors; staffing;

Table 5. A summary of TDF domains and themes (less related to culture) relating to causes of medication errors.

TDF Domain	Subtheme	Illustrative quotes
Knowledge	1. Lack of medication related knowledge	'So coming to the nursing knowledge regarding the dose. I will never believe they have that much knowledge about the doses. . .' (FG1 Doctor 1)
	2. Knowledge is limited to a particular speciality/area	'If we're dealing with the general hospital, medicine department they have good orientation regarding medication, but if you go to ortho [orthopaedics] or surgery, really their knowledge about medication is very low.' (FG5 Pharmacist 3)
	3. Lack of knowledge attributed to staff induction	'Proper induction, you know, they should have proper induction regarding the medication, the medications that are used, how you do the checking and things like that. Nothing is done.' (FG1 Doctor 2)
	4. Need for continuing professional development to reduce medication errors	'There is too much error in this area, they can provide another or a new continuous education for this field. It's very important and this can prevent such error.' (FG7 Nurse 1)
Skills	1. Suboptimal medication related skills	'We need to think about the administration. I have seen plenty of times the paper on which they [nurses] have written the calculation and it's wrong, actually most of the time.' (FG4 Pharmacist 1)
Beliefs about Capabilities	1. Lack of medication related competence	'But you think it's. . . it's. . . it's valid to let the nurses check the dose before administering? No, I don't think it's possible. For me, I feel it's impossible for them to check the correct dose.' (FG1 Doctor 1)
	2. Overconfidence leading to medication errors	'Overconfidence with some particular medicines like I have been with this medicine for many years and I know by heart' (FG1 Pharmacist 2)
Goals	1. Promoting patient safety	'But you know, serious errors are part of the package, you know. As we save lives, we are not ensuring. . . I mean, we should expect that we cannot have zero even serious errors because we are human beings'. (FG5 Pharmacist 1)

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communication openness; handoffs and transitions; and supervisor/manager expectations and actions promoting patient safety. During focus group discussions, specific TDF determinants suggested as being potentially associated with these composites were: social/professional role and identity; emotions; and environmental context and resources. Thematic analysis identified issues of doctors relying on pharmacists to correct their errors and being reluctant to alter the prescribing of fellow doctors. There was a lack of recognition of nurses' roles and frequent policy non-adherence. Stress was perceived to be a major contributor to errors, as was excessive workload and lack of staff at key times.

Strengths and weaknesses

The mixed methods design is a key study strength providing quantification of results followed by in-depth explanation. Further strengths are the use of the validated HSOPS tool and embedding psychological behaviour change theory (TDF) within qualitative data generation and analysis [15,19]. There are, however, several limitations hence findings should be interpreted with caution. Self-reported questionnaire responses could not be validated and may have been impacted by response and social desirability biases [22]. While responses were received from healthcare professionals in all HMC hospitals, these may have been skewed towards females and nurses hence there are potential issues of lack of generalisability within Qatar and beyond. Similarly, qualitative findings may not be transferable to other healthcare professionals, settings and countries.

Interpretation

This mixed methods study has contributed to the expressed need for robustness and rigour in patient safety research within the Middle East [20]. Furthermore, it aligns to the WHO 'Global Patient Safety Challenge' calling for action to reduce severe, avoidable medication-related harm by 50% in the next five years [2,3]. Whilst the HSOPS questionnaire has been used

within the Middle East [21], this is the first study to publish Qatari data. There are, however, similarities between the Qatari data and those reported by Elmontsri et al. [21], with the lowest agreement scores (and hence of most concern) relating to the composites of non-punitive response to errors; staffing; communication openness; handoffs and transitions; and supervisor/ manager expectations and actions promoting patient safety. Within the two composites of lowest scores (non-punitive response to errors and staffing) there were issues with staff perceiving that errors counted against them and that details of errors committed were kept in their personnel files. This appeared to be an issue for male, younger and less experienced healthcare professionals. Staffing was the other key composite with very low agreement scores, particularly in relation to work pressures and speed of work, with similar statistically significant associations as for the non-punitive response to errors. There may be some merit in initially prioritising any intervention towards these specific groupings.

One limitation of the published studies using the HSOPS is the lack of qualitative research to provide in-depth explanation of the results [21]. The use of behavioural theory within the focus groups in this study identified key determinants which could facilitate intervention development. TDF has been incorporated within intervention developments for smoking cessation, physical activity, hand hygiene, acute low back pain and schizophrenia [28]. To date only one other published study has applied TDF to explore potential causes of medication errors, focusing on prescribing errors in a sample of junior doctors in Scotland [29]. There are some similarities with the findings of this study, most notably within the domains of knowledge and skills, particularly the general lack of medication-related knowledge. While pharmacists can provide support, and indeed doctors were found to rely on pharmacists to correct errors, the HSOPS data and the focus groups identified issues around staff complement and workload, particularly at key times.

TDF domains of social/ professional role and identify, emotions and environmental context and resources are related to organisational safety culture, as defined by 'Study Group on Human Factors' [16]. Concerns were expressed around nurses perceiving that their professional role was not recognised leading to poor communication compromising patient safety. This is also reflected in the HSOPS score of ~ 50% agreement for communication openness. There were instances of doctors relying on pharmacists to correct their prescribing errors and, at times, would not alter the prescribing of others, even when errors could potentially lead to patient harm. Themes of environmental context and resources also emerged in the discussions around workload as a leading cause of errors, with lack of staff at key pressure times of evening and weekends. Furthermore, the electronic prescribing and records system was considered to have introduced potential for error. While such systems have been shown to enhance patient safety, others have also highlighted the risky human factors and user-centred design issues that have been encountered [13].

Stress was the main theme which emerged in the TDF emotions domain as a determinant of error, arising due to workload, work pressures and the influence of patients. Issues of workload were also identified in the HSOPS data around staff numbers to handle the workload, working under pressure to do too much, too quickly.

These TDF l determinants which were highlighted as potential contributors to medication errors can be used during the development of behaviour change interventions, defined as 'coordinated sets of activities designed to change specified behaviour patterns'. These are often complex, consisting of interacting components known as 'behaviour change techniques' (BCTs), 'observable and replicable components designed to change behaviour' [30]. Michie et al. developed a cross-disciplinary taxonomy of evidence based BCTs [31], mapped to specific TDF domains [32]. Whilst knowledge and skills can be impacted through education and training [31,32], altering aspects of social/ professional role and identity and environmental context

and resources are more complex. Indeed, the work of Michie et al. [31,32] did not identify any evidence-based BCTs which mapped reliably to social/professional role and identity. Those for environmental context and resources relating mainly to restructuring the physical environment and providing prompts and cues for safer practice, which in this case would focus on the electronic medication systems [31,32]. Rather than focusing on changing behaviour at the individual practitioner level, action may be required at the organisational strategic level to review policies, structures (including resource allocation and distribution) and processes which aim to promote patient safety culture and minimise harm. Qualitative research focusing on understanding the perspectives of key strategic decision-makers in relation to promoting all aspects of medication safety is warranted.

Conclusion

This mixed methods study has provided further confirmation of key areas of concern relating to patient safety culture in Qatar. Non-punitive response to errors and staffing had the lowest levels of agreement, followed by communication openness, handoffs and transitions, and supervisor/manager expectations and actions. The qualitative component provided further detail of specific TDF determinants highlighting issues of social/professional role and identity, emotions, and environmental context and resources. Further attention on these issues at strategic and policy levels is required.

Supporting information

S1 File. Responses to each of the HSOPS composites.
(DOCX)

S2 File. Study questionnaire.
(DOCX)

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Appendix 3: Journal Publication 3

PLOS ONE

RESEARCH ARTICLE

Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical domains framework: A mixed-methods approach

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Data Availability Statement: All quantitative data derived from the cross-sectional survey are given in the paper. For the focus group discussions, data are qualitative in nature and cannot be made publicly available due to ethical concerns as they contain potentially identifiable information. This stipulation was made by the Robert Gordon University Research Ethics Sub-Committee. Researchers who meet the criteria for access to confidential data may contact the Robert Gordon

Abstract

Background

There is a need for theory informed interventions to optimise medication reporting. This study aimed to quantify and explain behavioural determinants relating to error reporting of healthcare professionals in Qatar as a basis of developing interventions to optimise the effectiveness and efficiency of error reporting.

Methods

A sequential explanatory mixed methods design comprising a cross-sectional survey followed by focus groups in Hamad Medical Corporation, Qatar. All doctors, nurses and pharmacists were invited to complete a questionnaire that included items of behavioural determinants derived from the Theoretical Domains Framework (TDF), an integrative framework of 33 theories of behaviour change. Principal component analysis (PCA) was used to identify components, with total component scores computed. Differences in total scores among demographic groupings were tested using Mann-Whitney U test (2 groups) or Kruskal-Wallis (>2 groups). Respondents expressing interest in focus group participation were sampled purposively, and discussions based on survey findings using the TDF to provide further insight to survey findings. Ethical approval was received from Hamad Medical Corporation, Robert Gordon University, and Qatar University.

Results

One thousand, six hundred and four questionnaires were received (67.9% nurses, 13.3% doctors, 12.9% pharmacists). Questionnaire items clustered into six components of:

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knowledge and skills related to error reporting; feedback and support; action and impact; motivation; effort; and emotions. There were statistically significant higher scores in relation to age (older more positive, $p<0.001$), experience as a healthcare professional (more experienced most positive apart from those with the highest level of experience, $p<0.001$), and profession (pharmacists most positive, $p<0.05$). Fifty-four healthcare professionals from different disciplines participated in the focus groups. Themes mapped to nine of fourteen TDF domains. In terms of emotions, the themes that emerged as barriers to error reporting were: fear and worry on submitting a report; that submitting was likely to lead to further investigation that could impact performance evaluation and career progression; concerns over the impact on working relationships; and the potential lack of confidentiality.

Conclusions

This study has quantified and explained key facilitators and barriers of medication error reporting. Barriers appeared to be largely centred on issues relating to emotions and related beliefs of consequences. Quantitative results demonstrated that while these were issues for all healthcare professionals, those younger and less experienced were most concerned. Qualitative findings highlighted particular concerns relating to these emotional aspects. These results can be used to develop theoretically informed interventions with the aims of improving the effectiveness and efficiency of the medication reporting systems impacting patient safety.

Introduction

In 1999, the United States (US) Institute of Medicine (IOM) published its seminal report, 'To Err Is Human: Building a Safer Health System' [1], that led to greater focus on patient safety practices and research globally. The report called for comprehensive, coordinated efforts by governments, healthcare providers, consumers and others to promote patient safety, setting a minimum goal of 50% reduction in errors by 2004 [1]. While many advances have been made in healthcare practices, an estimated one in ten patients is still being harmed whilst receiving care [2]. In March 2017, the World Health Organization (WHO) published 'Medication Without Harm, WHO Global Patient Safety Challenge', to 'drive a process of change to reduce patient harm generated by unsafe medication practices' [3, 4]. Medication errors, defined by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) in the US as, 'any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer' [5], are highly prevalent, with associated global costs of US$ 42 billion annually [3, 4]. Interestingly, the goal of the WHO challenge in 2017 is remarkably similar to that of the IOM in 1999, to 'gain worldwide commitment and action to reduce severe, avoidable medication-related harm by 50% in the next five years, specifically by addressing harm resulting from errors or unsafe practices due to weaknesses in health systems' [3, 4].

Both the IOM and NCCMERP have strategic aims that highlight the value of effective and efficient medication error reporting systems and practices in reducing error prevalence and severity [1, 5]. Two key goals of NCCMERP are to: stimulate the development and use of medication error reporting systems by healthcare organisations; and to stimulate the review and analysis of error reports leading to the development of recommendations to reduce, and

ultimately prevent, errors [5]. There is, however, evidence of widespread and significant under-reporting of medication errors by healthcare professionals [5].

A number of studies have quantified and characterised influences on reporting and potential reasons for under-reporting. Of the surveys published in the literature, most have been conducted in the US, Australia, and the United Kingdom (UK), with findings of barriers towards reporting including: fear of adverse consequences following reporting [6–8, 9, 10]; disagreement over error identification [7–9]; managerial factors [6, 10] lack of knowledge and awareness [11, 12]; lack of feedback [11]; and insufficient training [12]. Whilst there is a dearth of qualitative studies investigating error reporting, there are suggestions that barriers include: time constraints and burden of reporting; selective reporting depending on error severity; anxiety associated with reporting; lack of feedback following reporting; and cultural norms [13–15].

One key limitation of these studies is the lack of consideration of behavioural theories, rendering results to be of less value in development of interventions. The UK Medical Research Council (MRC) framework, 'Developing and implementing complex interventions' describes four phases of: intervention development, feasibility/pilot testing, implementation and evaluation [16]. Attention should be paid to theory as part of the development (intervention building) phase. Developers of medication error reporting intervention strategies need to be aware of relevant theories that are likely to result in more effective interventions than empirical approach.

Furthermore, there is a paucity of evidence on the impact of interventions to optimise healthcare professional reporting of medication errors. Evans et al. reported the evaluation of a complex intervention comprising intense education, a range of reporting options, changes in report management and enhanced feedback [17]. A lack of consideration of behavioural theories as part of the intervention development might have contributed to the considerable variation in results of improvement in reporting rates in only certain hospitals. There is therefore a need for research that explains the influences on medication error reporting behaviours in terms of psychological theories.

The Theoretical Domains Framework (TDF) is being used increasingly in healthcare-related research. TDF was developed through expert panel consensus and validation and aims to simplify and integrate the very many behaviour change theories into one framework [18]. The framework derives from 33 psychological theories and 128 theoretical constructs which are organised into 14 overarching domains of behavioural determinants. TDF has been incorporated within intervention developments in the fields of smoking cessation, physical activity, hand hygiene, acute low back pain and schizophrenia [19].

Alqubaisi et al. used TDF in two separate quantitative and qualitative studies of medication error reporting by healthcare professionals in the United Arab Emirates (UAE) [20, 21]. The quantitative study (n = 294) highlighted that the TDF domain of 'emotional related issues' appeared to be the dominant barrier to reporting, being common to all health professions [20]. In the qualitative study, key themes that appeared to impact error reporting were: the beliefs of the consequences of reporting; emotions; and issues related to the environmental context. The authors highlighted that these findings may not be generalizable or transferable outwith the study setting and population. There remains a need for further theory informed research on error reporting to confirm these findings. Furthermore, mixed methods research, that will allow quantification of facilitators and barriers to medication error reporting followed by in-depth exploration of any key issues identified, will allow specific targeting of interventions.

The aim of this study was to quantify and explain the behavioural determinants in terms of facilitators and barriers to reporting of medication errors by healthcare professionals in Qatar.

Methods

Design

This was a sequential explanatory mixed methods design comprising a quantitative cross-sectional survey followed by qualitative focus groups to gain deeper insight into the survey findings [22, 23].

Setting

The research was conducted within Hamad Medical Corporation (HMC), the primary provider of secondary and tertiary healthcare in Qatar. At the time of the study, there were eight specialist hospitals employing around 4,000 doctors, 9,000 nurses and 600 pharmacists. HMC policy on medication error reporting has adopted the NCCMERP definition of medication error, with healthcare professionals mandated to report all medication errors and near misses [24]. The reporting system is fully electronic, with all reports being reviewed by the HMC Quality Management Department. Quarterly and annual reports on medication errors and near misses, including action taken are shared with HMC Quality and Patient Safety Committee, and HMC Pharmacy and Therapeutic Committee.

Cross-sectional survey

The first phase of the research was a cross-sectional survey.

Questionnaire development. A draft questionnaire was developed based on published literature on medication error reporting behaviour and associated influences [6–17]. Items on behavioural determinants of error reporting were derived from TDF in the form of the Determinants of Implementation Behavior Questionnaire [25]. This was used in the development of individual questionnaire items, measured using 5-point Likert scales (strongly agree to strongly disagree). In addition, items relating to frequency of submitting medication error reports as well as personal and practice characteristics were included. The draft questionnaire was reviewed for face and content validity by a panel of 10 experts in medication error reporting practice and research in the UK and Qatar.

This was followed by 'think aloud testing' with a convenience sample of 20 healthcare professionals in Qatar. This involved each healthcare professional working through the questionnaire individually in the presence of a member of the research team and expressing what they thought in response to each item [26]. Findings resulted in removing several items and rewording others.

The questionnaire was then piloted with a sample of 100 healthcare professionals based in one hospital in Qatar. Test-retest reliability was assessed in all pilot respondents by requesting that the questionnaire be completed again within a two-week interval. A high level of test-retest reliability was achieved with $p<0.001$ for all Likert statements (Cohen's weighted kappa).

The findings of all questionnaire pre-testing were incorporated into the final version of the questionnaire which was formatted in Snap Surveys 10 Professional (software for web and email questionnaire design, publication, data entry and analysis). As the common language of care delivery at HMC is English, translation into other languages (e.g. Arabic) was not warranted. A participant information leaflet was developed to provide information on the aim of the study, rationale for inclusion as a participant, potential benefits of participation, estimated time to complete the questionnaire, confidentiality and anonymity. At the end of the questionnaire, respondents were invited to participate in focus group discussions to discuss responses in more detail. Those interested were requested to contact the researchers separately,

providing their email address, profession, base hospital, and length of experience as a healthcare professional.

Recruitment. All doctors, nurses and pharmacists working within HMC were eligible to participate, with no exclusions. Three hundred and sixty responses were required to give a margin of error of 5% with 95% confidence intervals [27]. Online participation was encouraged via HMC web alerts and promotional posters. In addition, paper-based questionnaires were distributed to all doctors, nurses and pharmacists. Data were collected from mid-January 2016 to mid-April 2016.

Data analysis. The survey instrument generated anonymised emails of online submissions that were imported into Snap Surveys before direct export to SPSS version 21.0. Data from paper-based questionnaire were entered manually.

Descriptive statistics were used to describe respondents' demographics and their responses to other survey item. Five-point Likert scale items relating to TDF behavioural determinants were subjected to principal components analysis (PCA). This is a statistical technique used to reduce a large number of items or variables to a smaller, more manageable number of components [28]. Data suitability for PCA was tested via: determination of the correlation matrix for co-efficient ($\geq$0.3); the Kaiser-Meyer-Olkin measure of sampling adequacy ($\geq$0.6); and Bartlett's test of sphericity ($\leq$0.05). The number of components was determined via Eigenvalues $>$1 and inspection of the scree plot. Oblique (Promax) rotation was used to aid the interpretation of the components given that there was reason to assume that selected attitudinal items could be correlated; missing data were excluded pairwise [29]. Where items cross loaded onto more than one component, the item was captured within the component of highest loading. Internal consistencies of the resulting component(s) were tested using Cronbach's alpha, aiming for $>$0.60 as desirable for psychometric scales [30]. Total component scores were obtained by assigning scores of 1 (strongly disagree) to 5 (strongly agree) to each of the Likert statement responses (hence treating the ordinal data as interval), with negatively worded items being reverse scored, and generating a summed score for each component.

Differences in total scores among health professions, gender, age and years of experience as a healthcare professional in relation to component scores were tested using Mann-Whitney *U* test (2 groups) or Kruskal-Wallis ($>$2 groups). P-values $\leq$0.05 were considered statistically significant.

Focus groups

To clarify, explore and explain issues identified in the survey phase, a qualitative approach was employed.

Sampling and recruitment. Questionnaire respondents who expressed interest in participating in the focus groups were sampled purposively providing a wide range of professions, hospitals and experiences. They were contacted via email and given the option of participating in single or mixed professional focus groups.

Topic guide development. The focus group topic guide was developed following analysis of questionnaire findings, with the intention of providing further description and explanation of key TDF behavioural determinants influencing medication error reporting. Case scenarios were also developed to encourage discussion of facilitators and barriers to reporting. The topic guide was reviewed for credibility by the same panel involved in reviewing the questionnaire.

Data generation. Focus groups were moderated by two researchers trained in qualitative research methods generally and the conduct of focus groups specifically. The focus groups were held in central locations within HMC, with signed, informed consent obtained from each participant at the outset. When discussing their experiences of medication error reporting,

participants were requested to not name any healthcare professionals or patients. Discussions centred on key behavioural determinants that could promote or hinder error reporting (as identified from the analysis of the survey data) and any steps that could be taken to enhance reporting. Discussions were audio-recorded (with permission) and transcribed in full, using a naturalistic approach in which every utterance is transcribed in as much detail as possible. A clear audit trail was maintained with documented details of data gathering to promote dependability [31]. Sampling and recruitment continued to the point of data saturation, at which no new themes were generated from the data analysis [32]. Focus groups were conducted between mid-May to mid-June 2016.

Data analysis. Data analysis followed the Framework Approach, a method widely used in applied or policy relevant qualitative research in which the objectives of the investigation are typically set in advance and shaped by the study objectives. The five steps of the approach were: familiarisation; identifying a thematic framework deductively, using TDF domains for coding; indexing; charting; and mapping and interpretation [33]. Two researchers coded each focus group independently, with consensus reached by discussion among the research team.

Ethics approval. The study was approved by the ethics committees of Hamad Medical Corporation, Robert Gordon University, and Qatar University.

Results

Cross-sectional survey

Respondents' demographics and professional characteristics. One thousand, six hundred and four questionnaires were received, with most (67.9%) from nurses followed by doctors (13.3%) and pharmacists (12.9%), giving an approximate response rate of 11.8% (doctors 7.7%, nurses 12.7%, pharmacists 55.8%). Around three quarters (70.9%) were female, <40 years (76.0%) and almost half (48.1%) with more than 10 years' experience as healthcare professionals. Respondents had involvement with medicines-related processes as follows: prescribing medicines (15.1%); administering (61.1%); preparation and dispensing (25.9%); and monitoring (42.0%) (Table 1).

Medication error reporting behaviour. Two-thirds of the respondents (66.8%) stated that they had not reported any medication errors in the preceding 12 months (Table 2).

Behavioural determinants of medication error reporting. PCA identified eleven components with eigenvalue > 1.0, explaining 68.1% of the variance. As many of the components had only a very small number of items loading, only six components with most items loading were retained (eigenvalues > 1.7), explaining 56.8% of the variance. All six components were found to be internally reliable (Cronbach's alpha ≥0.7). Responses to items within these six components are given in Tables 3–8. While most components comprised positive responses, the responses to emotions were negative hence inferential analysis was conducted to identify any significant differences among subgroups.

Component 1, knowledge and skills related to medication error reporting. (Minimum possible scale value = 12 (least positive), maximum = 60 (most positive), midscale = 36)

With a median value of 52 and interquartile ratio (IQR) of 48–58, respondents generally gave highly positive responses, particularly around awareness of the definition of medication error (97.1% agreement) and awareness of the differences between errors and adverse drug reactions (96.2%) (Table 3). The lowest level of agreement was for having the necessary experience to report medication errors (78.2%).

Component 2, feedback and support related to medication error reporting. (Minimum possible = 11 (least positive), maximum possible = 55 (most positive), midscale = 33)

Table 1. Respondents' demographic and professional characteristics (N = 1604).

Characteristic	Percentage	Frequency, n
Current role in the hospital		
Clinical nurse educator	0.7	12
Clinical pharmacist	2.8	45
Consultant physician	5.4	86
Head/Charge/Specialist nurse	17.1	275
Nurse	50.0	802
Pharmacist	8.9	143
Pharmacy Director/Supervisor/Specialist	1.2	19
Resident Physician	3.5	56
Specialist Physician	4.5	72
Other	5.0	80
Missing	0.9	14
Age (years)		
<30	24.2	392
30–39	41.8	670
40–49	21.5	345
50–59	9.5	153
≥60	1.6	25
Missing	1.7	19
Gender		
Male	27.6	442
Female	70.9	1137
Missing	1.6	25
Country of receiving entry-to-practice degree		
India	42.7	685
Philippines	17.6	283
Egypt	9.3	149
Qatar	9.2	148
Jordan	4.8	77
Other	14.5	231
Missing	1.9	31
Experience as healthcare professional in hospital (years)		
<1	1.6	25
1–5	19.1	306
6–10	29.4	471
11–15	21.4	343
16–20	12.0	193
>20	14.7	235
Missing	1.9	31
In your role do you typically have direct interaction or contact with patients?		
Yes	85.6	1373
No	9.0	145
Missing	5.4	86
Your primary roles in the medicines process are (multiple options could be chosen)		
Prescribing	15.1	243
Administering	61.1	980
Preparation and Dispensing	25.9	415

(*Continued*)

Table 1. (Continued)

Characteristic	Percentage	Frequency, n
Monitoring	42.0	673
Missing	3.1	49

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With a median value of 41 and IQR of 35–44, respondents generally gave positive responses (Table 4). The most positive responses were in relation to receiving feedback from the medication error reporting organisation (71.2% agreement) and that the feedback would be appropriate to the severity of the error (69.3%) while the lowest level of agreement was around the perception that there was a 'no blame' culture in the organisation (49.1%)

Component 3, action and impact following medication error reporting. (Minimum possible = 8 (least positive), maximum possible = 40 (most positive), midscale = 24)

With a median value of 32 and IQR of 30–36 (Table 5), respondents generally gave positive responses. The most positive responses were around the belief that each medication error report submitted could make a significant contribution to patient safety (94.5% agreement) and the least positive for the belief that each medication error report submitted would be appreciated by peers (61.6% agreement).

Component 4, motivation related to medication error reporting. (Minimum possible = 4 (least positive), maximum possible = 20 (most positive), midscale point = 12)

Respondents generally gave more neutral responses than for the previous three components (median value of 14 and IQR of 12–16, Table 6). While around two thirds of respondents (67.5%) disagreed that reporting medication errors was low priority compared to other professional duties, around one third (34.7%) agreed that reporting medication errors was something that they seldom forgot.

Component 5, effort related to medication error reporting. (Minimum possible = 9 (least positive), maximum possible = 45 (most positive), midscale = 27)

With a median value of 34 and IQR of 31–37, respondents generally gave positive responses (Table 7). The majority of respondents (83.7%) agreed that they were confident that they would report medication errors even if others they worked with did not. The lowest level of agreement (48.8%) was for the statement that reporting medication errors took very little effort.

Component 6, emotions related to medication error reporting. (Minimum possible = 9 (least positive), maximum possible = 45 (most positive), midscale = 27)

Respondents generally gave the most negative responses for this component (median value of 26 and IQR of 21–30.75, Table 8). These responses were consistent across all items. Almost two thirds of respondents agreed that they were concerned about the potential consequences

Table 2. Number of medication error reports respondents' recalled submitting in the preceding 12 months (N = 1604).

Number of reports	Percentage (n)
No event reports	66.8 (1072)
1 to 2 event reports	11.7 (187)
3 to 5 event reports	4.7 (76)
6 to 10 event reports	2.1 (33)
11 to 20 event reports	2.2 (36)
21 or more event reports	4.9 (79)
Missing	7.5 (121)

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Table 3. Component 1, knowledge and skills related to medication error reporting (Cronbach's alpha 0.938).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
I am aware of the definition of a medication error	62.7 (1005)	34.4 (552)	0.6 (9)	0.4 (7)	1.1 (18)	0.8 (13)
I am confident in my ability to recognise all medication errors	47.3 (759)	44.3 (710)	3.7 (60)	2.3 (37)	1.1 (17)	1.3 (21)
I am aware of the difference between a medication error and an adverse drug reaction	65.8 (1056)	30.4 (488)	1.5 (24)	0.6 (9)	0.9 (15)	0.7 (12)
I am aware of the policy relating to medication error reporting in Hamad Medical Corporation (HMC) hospitals	46.0 (738)	42.6 (683)	5.2 (84)	3.4 (55)	1.7 (28)	1.0 (16)
I find the policy straightforward to apply	37.6 (603)	47.4 (760)	11.0 (177)	1.7 (28)	1.1 (17)	1.2 (19)
I am aware of what is expected of me in relation to medication error reporting	36.3 (583)	53.4 (856)	5.1 (82)	2.8 (45)	1.1 (17)	1.3 (21)
I am aware of my responsibility for medication error reporting	40.2 (645)	50.9 (817)	4.6 (74)	1.8 (29)	0.9 (14)	1.6 (25)
I am aware of which medication errors should be reported	38.3 (614)	49.2 (789)	5.7 (92)	3.7 (60)	1.7 (27)	1.4 (22)
I know how to submit a medication error report	41.7 (669)	42.0 (674)	7.7 (123)	5.4 (87)	1.7 (27)	1.5 (24)
I have the ability to report medication errors	39.0 (625)	50.9 (817)	4.7 (76)	2.5 (40)	0.8 (13)	2.1 (33)
I have the necessary experience to report medication errors	32.4 (520)	45.8 (735)	11.3 (182)	7.0 (112)	1.6 (25)	1.9 (30)
I intend to report all medication errors	43.9 (704)	44.3 (711)	7.1 (114)	2.4 (39)	0.8 (13)	1.4 (23)

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of having to include the name of the professional on a medication error report (62.0%) and being concerned about patient confidentiality by having to include the patient name on a medication error report (59.8%). Just under half agreed that they were concerned about potential impact on their careers following submission of a medication error report (49.2%) and any potential reprimand or blame following submission of a medication error report (46.9%). There were statistically significant higher scores in relation to age (older more positive, $p<0.001$ Kruskall-Wallis), experience as a healthcare professional (more experienced most positive apart from those with the highest level of experience, $p<0.001$ Kruskall-Wallis), and profession (pharmacists most positive, $p<0.05$ Kruskall-Wallis).

Focus groups

Demographics of participants. Two hundred and ninety-five survey respondents (18.4%) expressed interest in participating in focus groups. Nine focus groups were conducted (duration 45–60 minutes), at which point it was considered that data saturation of themes was achieved. Fifty-four healthcare professionals from different disciplines participated, with just under half (n = 26, 48.1%) being nurses, followed by 18 (33.3%) pharmacists and 10 (18.5%) doctors. Most were highly experienced with only 11 (20.4%) having less than 5 years of experience.

Behavioural determinants associated with reporting medication errors. Table 9 gives the key themes that emerged during the focus group discussions. These are mapped to TDF behavioural determinants, identifying each as a facilitator or barrier to medication error reporting. Illustrative quotes are provided for each. Given that the emotions related

Table 4. Component 2, feedback and support related to medication error reporting (Cronbach's alpha 0.919).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
I receive sufficient encouragement and support from my multidisciplinary team to report medication errors	14.3 (229)	46.8 (751)	23.0 (369)	11.4 (183)	2.6 (42)	1.9 (30)
I receive sufficient encouragement and support from my peers to report medication errors	12.3 (198)	45.2 (725)	22.4 (360)	13.6 (218)	4.4 (71)	2.0 (32)
I receive sufficient encouragement and support from my seniors to report medication errors	16.0 (257)	51.5 (826)	19.5 (312)	8.4 (134)	2.7 (43)	2.0 (32)
I receive sufficient encouragement and support from my organisation to report medication errors	15.8 (253)	50.5 (810)	18.1 (291)	10.5 (169)	3.6 (58)	1.4 (23)
When I submit a medication error report, I am confident that I will receive feedback from the medication error reporting organisation	17.6 (282)	53.6 (859)	14.6 (234)	9.0 (144)	2.8 (45)	2.5 (40)
When I submit a medication error report I am confident that I will receive constructive feedback from the medication error reporting organisation	15.0 (240)	49.9 (801)	19.1 (307)	10.2 (163)	3.3 (53)	2.5 (40)
When I submit a medication error report I am confident that I will receive feedback from the medication error reporting organisation which is appropriate to the severity of the error	16.3 (262)	53.0 (850)	18.1 (290)	7.0 (113)	2.7 (43)	2.9 (46)
When I submit a medication error report I am confident that I will receive feedback from the medication error reporting organisation that focuses on the system and not the individual	15.0 (241)	49.6 (795)	18.5 (296)	10.5 (169)	3.6 (57)	2.9 (46)
I get professional reassurance from each medication error report that I submit	16.8 (270)	40.0 (641)	27.2 (437)	9.7 (155)	3.2 (51)	3.1 (50)
I feel that there is a 'no blame' culture in my organisation in relation to medication errors	12.0 (192)	37.1 (595)	22.2 (356)	18.8 (302)	8.4 (134)	1.6 (25)
I feel that there is a positive safety culture in my organisation in relation to medication errors	17.1 (275)	50.4 (809)	17.1 (274)	10.0 (161)	3.8 (61)	1.5 (24)

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component generated the most negative scores in the cross-sectional survey, the related sub-themes are described in greater detail. (Note, FG–focus group number; D–doctor number; N–nurse number; P–pharmacist number).

During all focus groups, the issue of reporting medication errors being associated with fear and worry emerged as a key barrier to reporting. For some, it appeared that this fear was real with reporting leading to punishment,

Table 5. Component 3, action and impact following medication error reporting (Cronbach's alpha 0.856).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
I prioritise reporting those medication errors which I consider to be more serious	29.9 (479)	44.8 (719)	9.9 (158)	10.0 (161)	2.4 (39)	3.0 (48)
I believe that each medication error report I submit will be appreciated by my multidisciplinary team	24.8 (398)	44.6 (715)	19.7 (316)	7.1 (114)	2.3 (37)	1.5 (24)
I believe that each medication error report I submit will be appreciated by my peers	21.8 (350)	39.8 (638)	23.8 (381)	10.5 (168)	2.7 (44)	1.4 (23)
I believe that each medication error report I submit will be appreciated by my seniors	23.8 (381)	45.9 (737)	18.5 (296)	7.4 (118)	2.9 (46)	1.6 (26)
I believe that each medication error report I submit can make a significant contribution to my professional practice	48.4 (777)	43.0 (690)	4.7 (76)	1.6 (26)	0.7 (12)	1.4 (23)
I believe that each medication error report I submit can make a significant contribution to the professional practice of others	46.0 (738)	45.4 (728)	4.7 (76)	1.7 (27)	0.9 (14)	1.3 (21)
I believe that each medication error report I submit can make a significant contribution to patient safety	54.6 (876)	39.9 (640)	3.1 (49)	0.5 (8)	0.9 (14)	1.1 (17)
I believe that each medication error report I submit can make a significant contribution to my organisation	47.0 (754)	44.4 (712)	4.4 (71)	1.6 (26)	0.8 (13)	1.7 (28)

https://doi.org/10.1371/journal.pone.0204987.t005

Table 6. Component 4, motivation related to medication error reporting (Cronbach's alpha 0.7).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
*For me, reporting medication errors is low priority compared to other professional duties	3.9 (63)	14.1 (226)	12.5 (200)	48.8 (782)	18.7 (300)	2.1 (33)
*I am too busy to report medication errors	4.8 (77)	14.2 (228)	15.7 (252)	43.6 (699)	19.3 (309)	2.4 (39)
*I need to be constantly reminded by others to submit a medication error report	3.9 (62)	16.5 (265)	13.4 (215)	47.2 (757)	16.7 (268)	2.3 (37)
Reporting medication errors is something I seldom forget	7.5 (121)	27.2 (437)	14.8 (237)	37.8 (606)	11.0 (176)	1.7 (27)

*, reverse scored

https://doi.org/10.1371/journal.pone.0204987.t006

'You know people. . . when people think some error has happened, for me they should report openly but they don't. . . it won't happen in [name of hospital] because they are. . . they are fearful actually. People are really. . . really. . . punished.' (FG1P1 & FG1D1)

'Maybe people are afraid. They are afraid if they will be punished or someone or something. . . They're afraid.' (FG2N2)

'And I think it's. . . if you report it, there's a lot of learning, but in the thing in. . . I think the thing in Qatar is that people are afraid of reporting because they're afraid.' (FG4P2 & FG4D2)

One negative consequence of submitting a medication error report was that there was likely to be further investigation into the error which was a barrier to submitting further reports,

'And another thing, if you are going to report an error, you will not stop there here. You will be asked to write a letter, you will be asked to for a meeting, it doesn't stop from there. Again,

Table 7. Component 5, effort related to medication error reporting (Cronbach's alpha 0.809).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
I am likely to report medication errors even if my peers do not	16.8 (269)	60.5 (971)	14.8 (237)	4.5 (72)	1.0 (16)	2.4 (39)
I am likely to report medication errors even if my seniors do not	16.0 (257)	59.0 (947)	15.1 (242)	6.1 (98)	1.0 (16)	2.7 (44)
I am confident that I will report medication errors even if others I work with do not	31.9 (512)	51.4 (824)	10.8 (173)	2.4 (38)	1.2 (20)	2.3 (37)
I believe it is my professional duty to report medication errors which others have made, irrespective of background	34.8 (558)	48.9 (784)	8.9 (143)	4.5 (72)	1.2 (20)	1.7 (27)
For me, reporting medication errors takes very little time	7.8 (125)	41.0 (657)	28.0 (449)	18.5 (296)	2.2 (36)	2.6 (41)
For me, reporting medication errors takes very little effort	7.8 (125)	41.6 (667)	23.5 (377)	21.3 (342)	2.9 (46)	2.9 (47)
I report medication errors even if there is very little time available to do so	30.9 (495)	52.1 (836)	9.7 (155)	4.3 (69)	1.5 (24)	1.6 (25)
Reporting medication errors is compatible with my daily practice	12.0 (192)	50.7 (814)	18.3 (293)	13.2 (212)	3.6 (58)	2.2 (35)
For me, submitting a medication error report is a normal part of my day	24.1 (387)	32.2 (516)	15.7 (252)	17.1 (274)	9.2 (147)	1.7 (28)

https://doi.org/10.1371/journal.pone.0204987.t007

Table 8. Component 6, emotions related to medication error reporting (Cronbach's alpha 0.843).

Statements	Strongly Agree % (n)	Agree % (n)	Unsure % (n)	Disagree % (n)	Strongly Disagree % (n)	Missing % (n)
*It is sometimes difficult for me to accept that I have made a medication error	9.0 (145)	31.5 (506)	13.8 (221)	32.9 (527)	11.0 (177)	1.7 (28)
*I feel uncomfortable about submitting a medication error report for an error I have made	6.9 (111)	28.7 (461)	16.0 (257)	35.8 (574)	10.0 (161)	2.5 (40)
*Others I work with will think less of me if I submit a report for a medication error I have made	6.1 (98)	25.1 (402)	23.6 (379)	34.2 (549)	7.7 (124)	3.2 (52)
*I am concerned about any potential reprimand or blame following submission of a medication error report	9.4 (150)	37.5 (602)	20.4 (328)	24.7 (396)	5.4 (86)	2.6 (42)
*I am concerned about the potential impact on my career following submission of a medication error report	10.2 (163)	39.0 (626)	18.8 (302)	23.2 (372)	5.9 (95)	2.9 (46)
*I feel uncomfortable about submitting a medication error report for an error others have made	8.2 (132)	32.1 (515)	19.1 (307)	30.8 (494)	7.7 (124)	2.0 (32)
*I am concerned about the potential consequences of having to include the name of the professional on a medication error report	13.7 (220)	48.3 (774)	14.4 (231)	17.6 (282)	3.4 (54)	2.7 (43)
*Others I work with will think less of me if I submit a report for a medication error they have made	8.3 (133)	31.2 (501)	24.1 (387)	27.0 (433)	6.3 (101)	3.1 (49)
*I am concerned about patient confidentiality by having to include the patient name on a medication error report	15.2 (244)	44.6 (716)	12.0 (193)	21.3 (342)	4.6 (74)	2.2 (35)

*, reverse scored.

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next time they will ask you give me feedback on this. Give me explanation on this. So that is the. . . the. . . those are the things that compromises when you are reporting an error.' (FG3N)

There was concern that reporting medication errors was likely to affect any evaluation of their performance resulting in less likelihood of reporting medication errors,

'Does affect the evaluation. Do you think that if she does an error and she does administer a wrong medication, do you think she will report it?' (FG3N1)

'It will affect [my performance appraisal]. . . the issue really. . .they decrease the evaluation. So even if you tell me hundred times that 'no you're going to be safe', I will think. . . I will take time before reporting. That's what I'm saying.' (FG4P2)

There was also much concern that submitting a medication error report for an error committed by a colleague would damage working relationships. This was expressed by all healthcare professionals at all levels of seniority,

'And she said yeah I will report it, but she never reported that because we know that it will end up with the. . . with blame. It's not because I want to protect my colleague. It's because I don't agree that we should be blamed because this is the system that is provided to us to work in.' (FG3N)

'I will not, I mean, why would I? Because, you know, I'm thinking about what happened to my friend. Isn't it? So even if you tell me a hundred times that' no you're going to be safe', I will think. . . never.' (FG4D2)

'If anyone is coming to improve you, I will like him. But if anyone is coming to report against me, I will be the enemy of him.' (FG9P1)

Table 9. A summary of TDF domains and themes relating to reporting of medication errors, identifying each as a barrier or facilitator.

Domain	Theme	Facilitator	Barrier	Illustrative quotes
Goals	1. Prevention of future medication errors	√		*'If we report, we'll be aware about this problem and then will try to prevent it in the future.'* (FG7P1)
	2. Promoting patient safety	√		*'Yes, of course [to report medication errors] for patient safety. 'Yeah, we must, we have to focus on harm of the patient. Patient first.'* (FG7N4)
Knowledge	1. Lack of knowledge in general concerning medication error reporting		√	*'Yeah, but the new staff, they don't know, they don't know about it [medication error reporting], and every two to three months, we are bringing new staff and this is not incorporated in the curriculum of the training or the orientation of the staff.'* (FG2P2)
	2. Lack of knowledge of medication error reporting policy		√	*'I think the doctors maybe didn't have orientation about this. They don't know about the policies [medication error reporting] of the HMC.'* (FG2P1)
	3. Knowledge of medication error reporting processes	√	√	Facilitator—*'We know how to report a medication error. . .'* (FG6P1) Barrier—*'So the first thing I will tell you very honestly, I don't know how to. I don't know whom to speak to or how to actually report a medication error.'* (FG6D2)
	4. Expressed need for educational and training	√		*'Education of staff, encouraging the staff and reassuring the staff.'* (FG4D1)
Skills	1. Possible lack of ability to recognise and report medication errors		√	*'As I had told before, one medication error in my mind is not the same as a medication error in his mind.'* (FG6P1)
Social/professional role and identity	1. Professional obligation to report medication errors	√	√	Facilitator—*'Yeah, we need to report this medication error. If you are. . . if you are setting aside all this blame-free culture and also, you know, everyone should come forward to report this error'* (FG6P1) Barrier—*'Why should they report also when they don't feel like reporting, feel like acting on it and feel like improving the system?'* (FG1D1)
	2. Perceived lack of reporting from doctors		√	*'Based on my experience for monitoring and analysing medication errors since two years ago, what is very noticeable is that high reporting, it is coming from the pharmacist, and there is also a percentage coming from the nurses especially for the administrating error but I never had for doctors.'* (FG2P1)
Intentions	1. Selectively reporting errors depending on severity		√	*'If this is going to harm the patient, okay in such cases, definitely you will report but if it's something like. . . like a near miss, it never gets reported because we never give it to the patient.'* (FG6N1)
	2. Reporting for the wrong reason		√	*'Yeah, he's suffering and he is now collecting any mistake for his colleague. He's not concentrating. Now, he is just collecting the mistakes for the other people who report.'* (FG5P2)
Beliefs about consequences	1. Reporting leading to improved practice	√		*'Well personally, yes because it would help in the future. Because it would help a lot of nurses to avoid the same error.'* (FG6N)
	2. Further investigation		√	*'We bring us here to this committee to discuss the medication errors like imagine someone who has done an error and then he reports, and then he's been called by two to three committees to investigate the errors. What he will go back?'* (FG2P2)
	3. Impacting staff appraisal		√	*'Does affect the evaluation. Do you think that if she does an error and she does administer a wrong medication, do you think she will report it?'* (FG3N1)
	4. Impacting working relationships		√	*'I will not [report], I mean, why would I? Because, you know, I'm thinking about what happened to my friend. Isn't it? So even if you tell me a hundred times that' no you're going to be safe', I will think. . . never.'* (FG4D2)
	5. Lack of confidentiality		√	*'. . .and there is no confidentiality. That is most important, it's gossiping. Everyone knows. Those who are not related also know that.'* (FG4D1&D2)
	6. Lack of feedback		√	*'So no feedback, no appreciation, so do you need to take the stress? You work, do your assigned work, go home healthy and peaceful.'* (FG1D2)
Emotion	1. Fear and worry		√	*'I think the thing in Qatar is that people are afraid of reporting because they're afraid.'* (FG4P2 & D2)
Reinforcement	1. Encouragement to report	√		*'Yeah, if you will ask me I do encourage reporting of cases. I will always tell them this is an incident. It doesn't cause you any harm. This is a notification. This is not a punishment to anybody.'* (FG3N1)

(*Continued*)

Table 9. (Continued)

Domain	Theme	Facilitator	Barrier	Illustrative quotes
Environmental context and resources	1. No fair blame culture		√	*'Actually, what I'm thinking about this whole subject is it's under reported and that's 100% true. And why, because I think from my perspective this is a punitive environment that we are living in.'* (FG6D1)
	2. Time consuming		√	*'I think it's more of a headache. If you report and then you're being called for many meetings. We already have no time. . .'* (FG2D2)

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Many focus group participants perceived that submitted medication error reports were not handled in a confidential manner and that there was potential for the details of the report to be shared with others leading to a lack of trust,

'No confidentiality. If you did something, everybody would know about it, but then the people who get to have the authority to report, they have to be trusted people. They have to have the confidentiality agreement that they will not spread the name.' (FG5P1)

'. . .and there is no confidentiality. That is most important, it's gossiping. Everyone knows. Those who are not related also know that.' (FG4D1 & FG4D2)

The following TDF domains did not feature during focus groups discussions as determinants of medication error reporting: optimism; beliefs about capabilities; memory, attention and decision processes; social influences; and behavioural regulation.

Discussion

Statement of key findings

This mixed methods study allowed quantification of issues relating to medication error reporting followed by in-depth exploration of key issues. The cross-sectional survey stage identified that over two thirds of respondents stated that they had not submitted any medication error reports in the preceding 12 months. In PCA, questionnaire items clustered into six components of: knowledge and skills; feedback and support; action and impact; motivation; effort; and emotions. Responses were most negative for the emotions component, with concerns over potential reprimand or blame, impact on reputation and career. Most concern was expressed by younger and less experienced healthcare professionals. On exploring these emotions related issues during qualitative focus groups, several key themes emerged as barriers to reporting: fear and worry; likely investigation follow reporting; impact on evaluation and appraisal processes; that reporting an error committed by a colleague would damage professional relationships; and that reports were not always handled in a confidential manner.

Strengths and weaknesses

The mixed methods design is a key strength of this study. As defined by Creswell and Clark, this focuses on 'collecting, analysing and mixing both quantitative and qualitative data in a single study. . .Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone' [22]. While there are many studies on error reporting behaviours, there is a lack of mixed methods approaches. The use of TDF as a theoretical lens is a further strength, allowing identification of determinants of medication error reporting grounded in accepted psychological behavioural theories [18]. The appropriateness of data suitability for PCA was confirmed through: the ratio of the number of responses to the number of questionnaire items (>5:1);

correlation matrix for co-efficients (≥0.3); Kaiser-Meyer-Olkin measure of sampling adequacy (≥0.6); and Bartlett's test of sphericity (≤0.05) [28, 29].

There are, however, several limitations to the study hence the results and findings should be interpreted cautiously. While an accurate denominator and hence response rate could not be calculated (e.g. those healthcare professionals in management or administration positions may have no roles in medication processes), even when these individuals are excluded, it is likely that the response rate was low, other than for pharmacists. This low response rate may have been due, in part, to the very sensitive nature of medication error reporting. There may also have been issues of other biases, notably social desirability bias, particularly in relation of knowledge based items [22]. Determining component scores involved treating the ordinal Likert scale data as interval and then undertaking analysis using non-parametric approaches. This assumes that the numerical distances between, for example, strongly agree-agree and strongly disagree-disagree are equivalent. While this may be a limitation, it is an approach commonly used in social sciences to allow determination of scale data (median, IQR). Furthermore, as in all self-reported surveys, it was not possible to validate the data. As the study was conducted in secondary care within Qatar, the findings may lack generalisability and transferability to other settings and countries. However, there are similarities in some key findings with other studies in the Middle East and beyond hence it is likely that the issues identified will resonate widely.

Interpretation of findings

Effective and efficient medication error reporting systems impact patient care through early identification of issues informing safer systems of practice [1, 5]. HMC requires all errors, irrespective of severity, and near misses to be reported [24], hence the finding that less than one third of respondents had submitted any error reports in the last 12 months is likely evidence of significant under-reporting. This situation is not unique to Qatar or indeed the Middle East [7, 11–13], with the consequence that key opportunities to act on reports and improve medication practices are being missed.

Development of effective interventions to improve reporting is based upon the identification of facilitators and barriers and consideration of theories of behaviour change [16]. As noted earlier, one key strength of this study is the incorporation of behavioural theory into the stages of data collection and generation, and analysis. While other quantitative and qualitative studies have identified barriers of reporting [6–15], there has been a lack of attention paid to theoretical underpinning. PCA identified six components, of which the responses to four were positive, one neutral and one negative. In general, respondents perceived that they were knowledgeable and skilled to enable error identification and reporting. Similarly, they viewed that they were provided encouragement and support from the organisation, seniors and peers to report, that their reports would be appreciated at these levels, and that reporting took little time and effort. The component relating to motivation gave more neutral scores, with issues around the priority of error reporting compared to other tasks and being too busy. The scores for the emotions component were much more negative in relation to feelings of discomfort on reporting errors committed by themselves or others, potential reprimand and blame, impact on reputation and career. The finding that younger and less experienced healthcare professionals had statistically significantly lower scores thus being more negative in relation to emotions may provide some evidence for prioritising and targeting these groups to receive intervention. Alqubaisi et al also reported PCA analysis of determinants of error reporting in the United Arab Emirates (UAE), identifying similar issues around emotions [20], which may add to the generalisability of the findings within the Middle East.

On exploring error reporting behaviour in the focus groups, several facilitators emerged, related to the goals of reporting (promoting safety and preventing future errors), knowledge of processes and reinforcement around encouragement to support. The triangulation of data from the quantitative and qualitative elements confirms that knowledge of processes, skills and goals are not key targets for intervention. Most discussion in the focus groups centred on the barriers relating to emotions identified from analysis of questionnaire responses. Fear and worry emerged as a key theme that deterred reporting, with some citing others being 'punished' following reporting. There were narratives around intense follow-up investigations that appeared to focus on the individuals involved rather than the system. There was concern that reporting errors could impact future appraisals and career progression as well as negatively affecting professional reputation and relationships.

While several other qualitative studies have identified anxiety being a barrier to reporting [13–15], the mixed methods approach has allowed the specific issues of anxiety to be quantified and explained. Furthermore, the use of TDF enabled mapping off barriers to specific behavioural domains, in this case emotions and related beliefs of consequences. In a study of one-to-one interviews with healthcare professionals in the UAE, Alqubaisi et al [21], identified several recurring themes of fear and impacting career progression and relationships, increasing the likely transferability of the findings. Given that these studies were conducted in the Middle East, it may be that these issues are related to the culture, although issues around emotions have also been identified in the US, Australia and the UK [7–9, 11–15]. Furthermore, many healthcare professionals working in Qatar and the UAE are expatriate.

The findings reported in this study align to the 'development' phase of the MRC complex interventions framework. The use of TDF aids the development of behaviour change interventions that are likely to be more effective than those developed without reference to theory [16]. Behaviour change interventions are 'coordinated sets of activities designed to change specified behaviour patterns'. These are complex and consist of interacting components known as 'behaviour change techniques' (BCTs) which are 'observable and replicable components designed to change behaviour' [34]. Evidence based BCTs have been mapped to specific TDF domains to facilitate intervention development [34, 35]. Relevant BCTs for those determinants identified during analysis of the quantitative and qualitative data are given in Table 10.

Interventions based upon these determinants of behaviour are much more complex to develop and implement effectively compared determinants of knowledge and skills that can be effected by education and training [34, 35]. Interventions should be co-developed with representatives of those who will deliver and receive the intervention. Although behaviour change focuses on the individual, commitment will be required at all levels of the organisation from policy makers, leaders and managers to all healthcare professionals and support workers. This is key within any organisation which operates a positive safety culture, defined as being 'founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measure' [36]. It is noteworthy that one qualitative theme identified was the perception of a lack of a fair blame culture within the organisation hence the commitment at all levels of the organisation needs to be very obvious to all.

Further work

Further research is warranted to focus on the development of the intervention aiming to optimise medication error reporting. Intervention development should be followed by the steps of feasibility and pilot testing, implementation and evaluation in accordance with the MRC framework. The ultimate outcome measures should focus on patient safety, harm and staff beliefs and experiences.

Table 10. Mapping of relevant BCTs for optimising medication error reporting and description of BCTs (adapted from [34, 35]).

Relevant behaviour change techniques (BCTs) for domains of beliefs of consequences and emotions	Description of application of these BCTs to medication error reporting interventions
Beliefs of consequences	
1. Emotional consequences	Prompt assessment of feelings after reporting a medication error
2. Anticipated regret	Induce or raise awareness of expectations of future regret about not reporting a medication error
3. Social and environmental consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of reporting a medication error
4. Comparative imaging of future outcomes	Prompt or advise the imagining and comparing of future outcomes of reporting v not reporting a medication error
5. Vicarious consequences	Prompt observation of the consequences for others when report a medication error
Emotions	
1. Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate reporting a medication error (includes 'stress management')
2. Emotional consequences	Prompt assessment of feelings after reporting a medication error
3. Social support (emotional)	Advise on, arrange or provide emotional social support (e.g. from colleagues, 'buddies' or staff) for reporting a medication error

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Conclusion

This study has quantified and explained the key barriers to medication error reporting which appear to be largely centred on issues relating to emotions and related beliefs of consequences. Quantitative results demonstrated that while these were issues for all healthcare professionals, those younger and less experienced were most concerned. Qualitative findings highlighted particular concerns around: fear and worry; likely investigation follow reporting; impact on evaluation and appraisal processes; that reporting an error committed by a colleague would damage professional relationships; and that reports were not always handled in a confidential manner. These results can be used to develop theoretically informed interventions with the aims of improving the effectiveness and efficiency of the medication reporting systems impacting patient safety.

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Appendix 4: Medication error policy at HMC

مؤسسة حمد الطبية
Hamad Medical Corporation

POLICY/PROCEDURE

TITLE:	**MANAGING AND REPORTING MEDICATION ERRORS AND NEAR MISSES**	ORIGINAL DATE: **February 2006**
IDENTIFICATION NUMBER:	**CL 7045**	LAST REVISION DATE: **May 2017**
HOSPITAL(S)	**ALL HMC HOSPITALS / ENTITIES**	NEXT REVIEW DATE: **May 2020**
		Sheet No. 1 of 3

1.0 POLICY STATEMENT/PURPOSE:

1.1 This policy is formulated for Hamad Medical Corporation (HMC) health care providers on the management and reporting of medication errors and near misses. The reporting process is a part of the quality and patient safety program when using medication for patients.

2.0 DEFINITIONS:

2.1 **Medication Error** – 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. Such an event may be related to professional practice, health care products, procedures and systems including: prescribing; order communication; product labeling; packaging; dispensing; compounding; nomenclature, administration, education, monitoring and use.

2.2 **Near Miss (Close Call)** – An event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. An example of a near miss would be prescribing, transcribing, or administering medication to the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance.

3.0 PROCEDURE/PROCESS:

3.1 The immediate supervisor shall be informed immediately of a medication error or near miss to take appropriate action to ensure patient safety:

3.1.1 In case of wrong medication (name, route, dose, frequency, etc.) administered to the patient, the attending physician shall be informed immediately, and the Nurse shall document it in the Nurses Progress Notes. If the error reached the patient, the attending physician should be informed immediately and the actions taken should be documented in the Nurses progress notes.

3.2 The person, who discovers the medication error and near miss, should complete and submit an incident report within 24 hours through Electronic Incident Reporting System (EIRS).

3.3 The completed incident report shall be forwarded by the Quality Department to concerned department for investigation and action.

3.4 Medication error resulting in an adverse event shall be documented in the Physician's Progress Notes.

3.5 A quarterly report shall be submitted by the Pharmacy to the Hospital QPS.

3.6 The Hospital QPS shall review the consolidated report and take further action if required.

3.7 The Hospital QPS Committee shall send the quarterly report to the Corporate QPS Committee.

3.8 The Corporate Quality Management Department is responsible to consolidate each facility's quarterly and annual reports including action taken and shares the data with the Corporate Quality and Patient Safety Committee, and the Corporate Pharmacy and Therapeutic Committee.

3.9 The medication errors and near misses reported information should be used to improve medication use process by considering them as one of the Quality Improvement and Patient Safety (QPS) indicators.

4.0 DOCUMENTATION: Not Applicable.

5.0 REFERENCES:

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5.2 Joint Commission International Accreditation Standards for Hospitals, 6th Edition. Medication Management and Use Chapter, Standards: MMU .7.1

6.0 ATTACHMENTS: Not Applicable.

Appendix 5: Focus Group Topic Guide

Case Vignette1

Hyperkalemia can cause altered cardiac electrical conduction resulting in death. We describe a case of a 23-year old pregnant patient who presented with severe epigastric pain and vomiting. She was severely pre- eclamptic and received initial treatment with intravenous labetalol and decision was taken to deliver. She quickly became hyperkalaemic (serum potassium level 6.4 mmol/L) and labetalol was discontinued, and intravenous hydralazine commenced. Post-surgery, her potassium levels were normal but due to rapidly rising blood pressure labetalol was recommenced, resulting in elevated potassium levels. Labetolol was discontinued, hydralazine prescribed, and potassium levels normalised. The adverse reaction was classified as 'probably' due to labetolol using the Naranjo Adverse Drug Reaction scale. Conclusion: This is the first reported case of labetolol induced hyperkalaemia in pregnancy, with life threatening consequences and hence all health professionals should be alert to this potential effect.

Case Vignette 2

We report a case of 22-year-old primigravida presented to Women's Hospital – Hamad Medical Corporation emergency with severe epigastric pain, nausea, and vomiting. On admission, she was dehydrated with remarkably worsening symptoms. Laboratory findings revealed significantly elevated liver enzymes with unknown etiology. Her past medical history showed an admission for nausea and vomiting 3 weeks previously and she was discharged on antiemetics, and esomeprazole for the first time. Due to the predominantly elevated liver enzymes, the clinical pharmacist discussed the possibility of esomeprazole-induced adverse effects and suggested to suspend esomeprazole based on the evidence from literature review. The liver enzymes showed a substantial improvement within days after the discontinuation of the drug; however, a rechallenge was not done since it could have adversely affected the mother or the fetus. Using the Naranjo Adverse Drug Reaction Probability scales, the adverse reaction due to esomeprazole was classified as "probably".

Case Vignette 3

Unintentional administration of insulin instead of influenza vaccine

In 2016, researchers published the results of an investigation where a cluster of 5 adult patients unintentionally received insulin instead of the influenza vaccine. The mix-up occurred at a public-school clinic in Missouri and was discovered following an investigation from the Saint Louis County Department of Public Health. Officials learned that a school nurse inadvertently administered Humalog U-100 insulin instead of the influenza vaccine. Acute hypoglycemia was reported in all 5 patients who received the insulin with varying degrees of symptoms.

After the first 2 patients complained of sweating and light headedness, the nurse reported the incidents to the supervising nurse, but did not stop administering vaccines. Two later patients would require hospitalization for their symptoms, one of which was documented to have a blood glucose level of 23 mg/dL. The investigation revealed that the influenza vaccine vial was kept in the nurse's office refrigerator along with a 10 mL vial of Humaog U-100 insulin; they were found to not be stored in separate, labeled containers or bins. The manufacturer of the influenza vaccine conducted its own analysis but found no deviations or manufacturing incidents that would suggest a quality control problem.

Questions and discussion

- What do you think actually happened?
- Do you think this could have been prevented?
- What kind of error is it? And why?
- Why do you think this has happened?
- What are the potential contributing factors?
- Have you seen such errors in your setting?
- If yes, do you think this should be reported? Why?
- Do you think reporting of medication errors is useful?
- What happens if we don't report such errors?
- What happens if you report? Are there any consequences to such reporting?
- Do you know anything about blame-free culture? Just culture?
- Do you know how to report a medication error in your facility?
- Have you ever reported any such errors?
- If yes, what was the feedback you have received after you report?
- What are the key barriers to reporting medication errors?
- What is that prompts you or guides you to report errors?
- Do you think you are appreciated for reporting such errors?