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Barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families)

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Abstract

Thesis title

Barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families).

Background

Concern over patient safety has been a serious healthcare issue and an international priority facing healthcare organisations globally. The risk of harm and unsafe practice in healthcare organisations has received great attention from both healthcare providers and patients. Patient safety culture has been acknowledged as a crucial element of healthcare organisations as it prevents patient harm and maintains safe, high-quality healthcare. Therefore, investigating the patient safety culture in Saudi Arabia is central to understanding the factors that contribute to patient safety from a broad perspective (healthcare professionals and patients/families). Understanding the safety culture in healthcare organisations may enable a robust and successful implementation of safe practice during medical care. Moreover, patient participation in patient safety is growing internationally, and is regarded in many healthcare systems globally as beneficial in raising awareness of adverse events and monitoring, and detecting any mistakes that were made during patients' own care. It is evident that in the patient safety literature, patients act as vigilant monitors over safety issues including use of medication, falls prevention, and infection control at the hospital so that they can ensure their own safety. Therefore, it is worth exploring patient perspectives and experiences of safety culture along with healthcare professionals in Saudi Arabia, where patient perspectives and experiences are unknown.

Study aim:

- The aim of this thesis is to obtain an understanding of the status of patient safety culture in Saudi Arabia, and the barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families).

Study objectives:

- To identify the factors contributing to the patient safety culture in Saudi Arabia.

- To explore healthcare professionals' perceptions of the current patient safety culture in their workplace and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

- To explore the experiences and perceptions of patients and families towards patient safety culture and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

Study design and methods

This study adopted an explanatory sequential mixed method approach to provide a comprehensive and accurate picture of patient safety culture in Saudi Arabia from multiple perspectives. Phase I utilised systematic review to identify factors contributing to patient safety culture in Saudi Arabia. Phase II utilised a cross sectional survey design using the pre-validated Hospital Survey on Patient Safety Culture (HSOPSC) tool with multidisciplinary healthcare professionals (n=363: RR: 30%) in three hospital sites in one Saudi Arabian city. Phase III used a qualitative approach (case study design) which gathered data from healthcare professionals (n=35) through focus groups and patients/ families (n=12) through semi-structured interviews. Convenience sampling was used with the survey participants, and purposive sampling was used with qualitative methods; both descriptive statistical analysis and thematic analysis were used in this mixed methods approach.

Findings

The findings from the systematic review (Phase I) identified a variety of factors that contribute to a patient safety culture in the Saudi context, with both strengths and weaknesses being reported. The findings from the survey (Phase II) showed that patient safety culture in the three participating hospitals is weak as all the 12 dimensions of patient safety culture across the three hospitals failed to meet the HSOPSC tool for a strength criterion. The findings from the qualitative study (Phase III) revealed that both patients/family members and healthcare professionals had negative perceptions towards patient safety culture and highlighted many aspects that they believed contribute to patient safety culture. A broad range of factors were identified in Phase III that act as barriers and facilitators to patient safety culture, and

these are categorised under four themes: communication, work conditions, organisational factors, and patient empowerment and centeredness. The findings of the three studies undertaken in this thesis revealed that patient safety culture in Saudi Arabia is compromised by several factors, related to different dimensions of patient safety culture including staff issues, communication, blame culture, leadership, reporting systems, work conditions, organisational factors, and person-centred care. The findings reveal that patients/family members observe tasks and activities of safety issues and actively are willing to participate in safety initiatives. They also offer the richest source of information related to safety issues as many of them witness details of individuals, organisation, and systems failures that pose a threat to patient safety. In the current research, healthcare professionals and patients both perceived that patient/family participation in patient safety initiatives can lead to positive outcomes because patients/families are able to identify factors that trigger errors and threaten patient safety.

Conclusion

This study revealed that patient safety culture is significantly exposed to many aspects that could represent threats to patient safety. Excessive communication breakdown, heavy workload, blame culture, poor leadership, inappropriate working conditions, and deficits in the organisational environment remain the most described issues that hinder the implementation of a positive patient safety culture. Although the findings provide insight to the barriers and facilitators, it should be noted that the number of barriers outweigh the facilitators, indicating an obvious deficit in the status of patient safety culture in Saudi Arabia. Policy makers in the healthcare system should take these into consideration to reduce barriers and to facilitate improvements to patient safety and quality of healthcare. Moreover, consideration should be given to the factors that may help to support the implementation of a positive patient safety culture, especially establishing a blame-free culture, improving communications and leadership capacity, learning from errors and involving patient perspectives in safety initiatives. This thesis demonstrates the advantages of combining surveys with qualitative methods to study safety culture, which are useful in identifying the key factors that may hinder the implementation of a safety culture. This study concludes that understanding patient safety culture from healthcare professionals' and patient/families' perspectives can benefit individuals and organisations in maintaining the safe delivery of healthcare.

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Albalawi A, Kidd L, Cowey E. Factors contributing to the patient safety culture in Saudi Arabia: a systematic review. BMJ Open 2020;10: e037875. doi:10.1136/bmjopen-2020-037875

Poster presentation

Albalawi A, Kidd L, Cowey E. Factors contributing to the patient safety culture in Saudi Arabia: a systematic review. Poster presentation- International Forum on Quality and Safety in Healthcare - Glasgow 2019 on 27/03/2019 to 29/03/2019.

Competition

Albalawi, A. 2018. Three Minutes Thesis (3MT®) competition. Presentation of own research to College of Medical, Veterinary & Life Sciences (MVLS), University of Glasgow

Author's Declaration

I declare that, except where explicit reference is made to the contribution of others, this thesis is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institutions.

Printed name: Abdulmajeed Al Balawi

Signature: Date: 31st August 2022

Dedication

This thesis is lovingly dedicated to my mother soul, Salma, who is a never-ending source of love and pride to me. The thesis is also dedicated to my father, Mohameed Al Balawi, whose daily prayers, sacrifices, and enormous efforts made me who I am today.

Acknowledgements

List of Abbreviations

ACSNI	Advisory Committee for Safety in Nuclear Installations
AHRQ	Agency for Healthcare Research and Quality
CASP	Critical Appraisal Skills Programme
CBAHI	Central Board for Accreditation of Healthcare Institutions
CFIR	Consolidated Framework for Implementation Research
EBP	Evidence-Based Practice
GCC	Gulf Cooperation Council
GDPR	General Data Protection Regulations
HSC	Health and Safety Commission
HSOPSC	Hospital Survey on Patient Safety Culture
IoM	Institute of Medicine
JCI	Joint Commission International
KSA	Kingdom of Saudi Arabia
MaPSaF	Manchester Patient Safety Framework
MoH	Ministry of Health
NRLS	National Reporting and Learning System
OECD	Economic Co-operation and Development
OED	Oxford English Dictionary
RCT	Randomised Control Trial
SAQ	Safety Attitude Questionnaire
SCS	Safety Climate Scale
SD	Standard Deviation
USA	United States of America
WHO	World Health Organization
YCFF	Yorkshire Contributing Factor Framework

Chapter One: Introduction to the Study

1.1 Introduction

The aim of this chapter is to provide a general introduction to the study. It begins with a justification of the study subject by illustrating the importance of patient safety in healthcare systems globally. It shows the global patient safety challenges that pose many risks to patients while they are receiving medical care. It also presents the need to conduct this research, its aims and research questions, methodological approaches and thesis structure.

1.2 Why the focus upon patient safety?

1.2.1 Patient safety – a global concern

Concern over patient safety is a serious healthcare issue and an international priority facing healthcare organisations globally (Sammer et al., 2010, Vincent and Amalberti, 2015, Dekker, 2016). Therefore, the concept of patient safety itself is defined differently and using various related terms, which are discussed in detail in the literature review of Chapter Three. The risk of harm and unsafe practice in healthcare organisations has received great attention from both healthcare providers and patients (Vincent and Amalberti, 2015, Flott et al., 2019). This attention was acknowledged after the report "To Err is Human" estimated that between 44,000 and 98,000 people die each year in United States of America (USA) hospitals due to medical errors (Kohn et al., 2000). It is also recognised that there is an association between safety culture factors and safety outcomes (Kohn et al., 2000, DiCuccio, 2015, Najjar et al., 2015). Patient safety is attracting the attention of international healthcare systems due to the increasing clinical and economic burden of unsafe care (Flott et al., 2019). It is estimated that one in 20 patients are exposed to preventable harm in healthcare settings worldwide (Panagioti et al., 2019). The definition of preventable harm is that it occurs as a result of a modifiable cause, and its recurrence can be avoided through adaptation to a process or adherence to guidelines (Panagioti et al., 2019). Preventable patient harm can occur in many ways, including errors made by healthcare professionals, healthcare system failures, a

combination of errors made by individuals, errors caused by systems, and patient characteristics (Nabhan et al., 2012, Leitch et al., 2021).

According to the World Health Organization (WHO) (2018), the prevalence of harm to patients while in healthcare facilities is high, approximately 1:300 compared to airplane accidents, which are 1:1,000,000. Despite the increasing efforts that have been put into patient safety initiatives worldwide, patient harm represents the 14th leading cause of mortality and morbidity around the world (WHO, 2018). For example, the WHO (2018) highlighted the fact that 42.7 million adverse events are recorded annually worldwide among hospitalised patients; patient safety is therefore perceived as a serious issue. In addition, there are different elements associated with the complexity of increasing patterns of safety incidents, including the increased length of stays in hospital, vulnerability to healthcare-associated infections and increased medical service costs (WHO, 2018).

It is estimated that the direct medical cost of medication errors each year in the USA is US $17 billion, and worldwide, US $42 billion (WHO, 2018). Other cases of patient harm and errors related to hospital care, such as infections and pressure ulcers, account for US $6.5 billion of the annual costs in the USA (Schwendimann et al., 2018). In a retrospective analysis of 2,699 patient chart records in Canda, it was concluded that adverse events such as pressure ulcers, falls, medication errors, and hospital acquired infections resulted in longer hospital stays and higher treatment costs (Tchouaket et al., 2017). During 2011-2013, Morello et al. (2015) conducted a cohort study in Australia which revealed that the hospital costs of patients who had experienced falls were AUD $6,669 higher than those of patients who did not, and their hospitalisations lasted eight days longer, on average. Moreover, indirect impacts of medical errors on human life, such as losing a job or remaining disabled, were also acknowledge as an increased economic pressure on healthcare organisations and governmental budgets (Shreve et al., 2010).

Issues of patient safety, harm and unsafe care remain in both developed and developing countries and these bring challenges to healthcare systems across the globe (Wilson et al., 2012, Lunevicius and Haagsma, 2018). In the USA, a developed country, medical errors were reported to be one of the top three leading causes of mortality (Makary and Daniel, 2016). Preventable harm related to medication errors

is reported globally for around one in 30 patients in medical care and more than one-quarter of this harm is considered to be severe or life-threatening (Hodkinson et al., 2020). Adverse events related to medication errors have been identified in Australian healthcare; these are considered to be one of the most common types of incident after falls and they are estimated to affect between 2% and 3% of hospitalised patients (Roughead and Semple, 2009). Medication errors in Australian hospitals were also reported to be increasing by Roughead et al. (2016), who conducted a systematic review that included 17 studies in Australia from 2008 to 2013, and found that errors (excluding errors of timing) occurred in around 9% of medication administrations in Australian hospitals. In an earlier study, but which drew on data from Canadian hospitals, Baker et al. (2004) investigated the rate of adverse events among patients (n= 4164) from hospital admissions in four Canadian hospitals, and highlighted the fact that the incident rate was 7.5% of annual hospital admissions; the majority of these were classified as potentially preventable errors. In the United Kingdom (UK), the number of incidents reported from English NHS organisations to the National Reporting and Learning System (NRLS) (2020) from April 2019 to March 2020 was 2,246,622. The top four reported incident categories were related to: the implementation of care and ongoing monitoring/review; patient accidents; access, admission, transfer, discharge including missing patient; and medication issues (National Reporting and Learning System, 2020).

Medical errors or harmful incidents to patients were found to be a serious threat to patient safety as they may impact on patients' physical, psychological, emotional and social lives (Savage and Ford, 2008, Bari et al., 2016). It is argued that the patient might suffer considerable psychological trauma both as a consequence of the adverse events and through the handling of the incident (Vincent and Coulter, 2002). Similarly, it is argued that poor safety management and involvement in medical errors may influence healthcare providers in certain ways, including feelings of guilt, emotional distress and depression (West et al., 2006, Nydoo et al., 2020). West et al. (2006) conducted a longitudinal cohort study to determine the association of self-perceived medical errors with resident physicians' quality of life, burnout, depression, and empathy, which stated that physicians are the second victims of medical errors as they feel significant emotional distress and depression when they are involved in errors. Therefore, it is believed that medical errors lead to negative emotions among

medical staff, suggesting that adequate training programmes regarding patient safety are important to enhance positive responses and learning from errors (Bari et al., 2016, Nydoo et al., 2020).

In addition, the risk of harm and injuries in healthcare environments also applies to healthcare professionals, as they encounter various safety issues that might increase the risk of incidents and safety (Savage and Ford, 2008). For example, these include exposure to infectious disease, radiation, dealing with sharps objects and exposure to violence (Alhassan and Poku, 2018). Thomas et al. (2015) examined incidents reported by staff from up to 30 critical care units between 2009 and 2013 in the northwest of England and found that a significant number experienced harm against staff while at work. The study highlighted that over the five-year period and out of 19,945 incidents reported, 7% of these were linked to harm against staff (Thomas et al., 2015). With respect to the classification of these incidents, the majority of them were categorised under physical assault, sharps injury, contamination to blood-borne viruses and manual handling incidents (Thomas et al., 2015). Moreover, abuse and violence in the workplace are personal safety issues that affect healthcare workers (Vincent, 2006, Beus et al., 2016). Thus, in global terms, there is growing evidence of safety problems in healthcare settings; this requires the development of policies and guidelines that decrease the challenges to maintain patient safety and minimise the occurrence of safety incidents (Vincent, 2006, Vincent and Amalberti, 2015).

1.2.2 Patient safety culture in Saudi Arabia

The studies mentioned here focus on Westernised nations. Patient safety is also a major concern in developing countries, including Saudi Arabia, due to the serious and considerable danger to patients in hospitals (Elmontsri et al., 2018, Wilson et al., 2012). A systematic review conducted by Harrison et al. (2015) focussing on studies from Southeast Asia found four issues linked to deficits in patient safety: risk of patient infection; medication errors/use; the quality and provision of maternal and perinatal care; and the general quality of healthcare provision. Another systematic review of 14 studies described the status of the patient safety culture in Arab countries as suboptimal due to certain factors such as a blame culture, poor communication and professional relationships (Elmontsri et al., 2017).

In the Saudi Arabian healthcare system, the context for the research described in this thesis, an increasing number of complaints and claims against healthcare providers are referred to the Medico Legal Committee (MLC) due to mortality or morbidities (Samarkandi, 2006). The MLC are responsible for investigating claims of professional malpractice resulting in morbidity or mortality in Saudi Arabia (Al-Saeed, 2007). An investigation includes reviewing all patient medical records and interviewing the presumed accused medical staff members, in order to reach a verdict (Al-Saeed, 2007). For example, Ghaffar et al. (2015) conducted a literature review to assess the frequency of medical errors between 2007 and 2014, and found that in 2007, only 1,165 cases were referred to the MLC, compared to 2,413 cases in 2013. Interestingly, this figure is still increasing as in 2018 the number of medical malpractice cases referred to the MLC in Saudi Arabia was 9305; a report from General Authority for Statistics (2019) indicates that patient safety incidents are still on the increase in Saudi Arabia.

Al Wahabi et al. (2017) conducted an analysis of reports of sentinel events that were reported to the Ministry of Health (MoH) in Saudi Arabia from 2012 to 2015. The authors found that the total number of reported events was 433, 91% of which were classified as preventable events. This study also highlighted that the majority of these incidents were linked to lack of policy and procedure, and poor communication – 55% and 35%, respectively (Al Wahabi et al., 2017). Arabi et al. (2012) found that categories of incidents reported to King Abdulaziz Medical City (KAMC) in Riyadh, Saudi Arabia were linked to deficits in the safety culture, including inappropriate staff behaviours, poor communication, and insufficient supplies and equipment. Adverse medication events were found to be common in Saudi Arabia and regarded as potentially risking serious harm to patients. They were most common at the prescribing stage, followed by the dispensing and administering stages (Aljadhey et al., 2016).

1.2.3 Patient involvement in patient safety culture

Patient involvement in patient safety is internationally recognised as one of the most important factors for improving healthcare quality and safety (Longtin et al., 2010, Vaismoradi et al., 2015, O'Hara et al., 2018). Patients can actively contribute to safer care in a number of ways, including ensuring that medications are used safely,

participating in infection control efforts, reporting safety incidents, observing and checking the process of care, monitoring types of care, and to providing input during the development of safer procedures (Rainey et al., 2015, Severinsson and Holm, 2015, Hernan et al., 2015). Improving safety requires enabling and prioritising safety at all organisational levels, from frontline workers to management and patients (Tan et al., 2019). For example, studies on patient safety cultures in Saudi Arabian healthcare organisations focus mostly on the perspective of healthcare providers, using widely used survey tools in understanding the perception of healthcare providers towards patient safety culture (Elmontsri et al., 2017). However, in Saudi Arabia there is a lack of studies that examine patient opinions or perceptions of safety culture and key efforts to promote patient participation in safety in healthcare settings. Thus, it important to obtain an in-depth understanding of patients' views and perceptions of safety culture and associated factors that influence the promotion of a positive safety culture alongside with healthcare providers perspectives. As a result of this gap in the knowledge, the current study has been undertaken to examine the views of health professionals and patients concerning factors influencing the implementation of a patient safety culture.

Although there is data to demonstrate the current status of patient safety in the Saudi Arabian healthcare context, there is a lack of understanding as to the factors that influence patient safety culture in Saudi hospitals. Therefore, investigating this is central to understanding the factors that contribute to patient safety from a broad perspective. Developing a patient safety culture is a crucial step for improving patient safety. For this reason, it is important that hospitals assess their patient safety culture. Moreover, it is vital that the gaps in the current evidence are filled regarding patient safety issues in Saudi Arabia. Understanding the safety culture in healthcare organisations will enable a robust and successful implementation of safe practice during medical care.

1.3 Significance and potential impact of the study

A positive and robust patient safety culture has been acknowledged as a crucial element of healthcare organisations as it prevents patient harm and maintains safe, high-quality healthcare (Kohn et al., 2000, Sammer et al., 2010, Lee et al., 2019). An

integrative literature review was undertaken by Lee et al. (2019) to examine the relationships between safety culture, patient safety and quality of care outcomes which stated that it is necessary to create workplace environments that emphasise safety as the top priority, and this can be achieved by building a learning culture that fosters improvements in patient safety. A patient safety culture has been linked to different aspects of patient safety issues, including healthcare professionals' performance, the prevalence of adverse events, and mortality rates (Ulrich and Kear, 2014). A positive and strong patient safety culture has also been found to significantly reduce the number of adverse events in a healthcare organisation (DiCuccio, 2015, Lee et al., 2019). Camargo Jr et al. (2012) obtained surveys from 3,562 staff from 62 urban emergency departments across 20 US states which highlighted the importance of improving patient safety culture and increasing the commitment to report incidents. Thus, it is believed that a strong patient safety culture is associated with high safety performance in healthcare organisations (Braithwaite et al., 2017, O'Donovan et al., 2019).

With increasing concerns regarding the patient safety culture within healthcare settings in Saudi Arabia, it is essential that we have a clear assessment and understanding of the barriers to and facilitators of the implementation of positive patient safety (Al Wahabi et al., 2017). The findings from the current study provides a description of the current status of patient safety culture in Saudi Arabia healthcare context, and the perceptions of the patient safety culture from different perspectives. The current study also bridges the gaps in current evidence by identifying the barriers to and facilitators of the implementation of a positive patient safety culture in the Saudi healthcare context and the role of patient and health professional perspectives within this. Consequently, the findings of the current study will contribute to identifying barriers and facilitators to a strong patient safety culture, increasing awareness of patient safety culture goals, highlight the importance of involving patient and family members' perspectives of patient safety, and based on these, provide recommendations for improvement opportunities to enhance patient safety and quality of care. The current study has implications for both healthcare practices and research evidence contribution by providing valuable evidence regarding the factors contributing to, and influencing the implementation of, a positive patient safety culture from different perspectives (healthcare professionals and patients/families).The

findings emerging from the current study could be used directly by healthcare organisations to improve the conditions of clinical practice, by decision makers to promote improvement initiatives, and by accreditation authorities to update their regulations and standards.

1.4 Aim and objectives

1.4.1 Aim of the study

The main aim of the study is:

- To obtain an understanding of the status of patient safety culture in Saudi Arabia, as well as the barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families).

Objectives:

- To identify the factors contributing to the patient safety culture in Saudi Arabia.

- To explore healthcare professionals' perceptions of current patient safety culture in their workplace and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

- To explore the experiences and perceptions of patients and families towards patient safety culture and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

1.4.2 Research questions

The study has the following research questions:

- What are the factors contributing to a patient safety culture in Saudi Arabia from the perspective of healthcare professionals and patients?

- What are healthcare professionals' perceptions of the patient safety culture in Saudi Arabian hospitals?

- What are the barriers to and facilitators to implementing a positive patient safety culture in Saudi Arabian hospitals?

- What are patients' perspectives/experiences regarding the safety culture in Saudi Arabian hospitals?

1.5 Methodological approach

The current study adopted a mixed methods approach, incorporating a systematic review (Phase I), quantitative and qualitative approaches (Phases II and III). The current study focused on 2–3 case study sites in order to provide a comprehensive and accurate picture of the factors influencing patient safety culture in Saudi Arabia.

Firstly, a narrative systematic review of the available studies focusing on factors that influence patient safety culture in Saudi Arabia was conducted for Phase I. The objective of this was to explore the factors contributing to the patient safety culture in Saudi Arabia, from both the perspective of healthcare professionals and that of patient. This phase addressed the first research question.

Secondly, a descriptive cross-sectional survey design was adopted for Phase II of this study. The objective of this phase was to assess healthcare professionals' (physicians, nurses, pharmacists and allied healthcare) perceptions of the patient safety culture via a self-administrated questionnaire. This phase addressed the second research question.

Thirdly, a qualitative study was conducted, to seek the views, opinions and experiences of key stakeholders (healthcare professionals and patients/families) with regards to the safety culture in Saudi Arabian hospitals. This phase also identified the barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families). This phase addressed research questions 3 and 4. Figure 1.1 below shows an overview of the study phases.
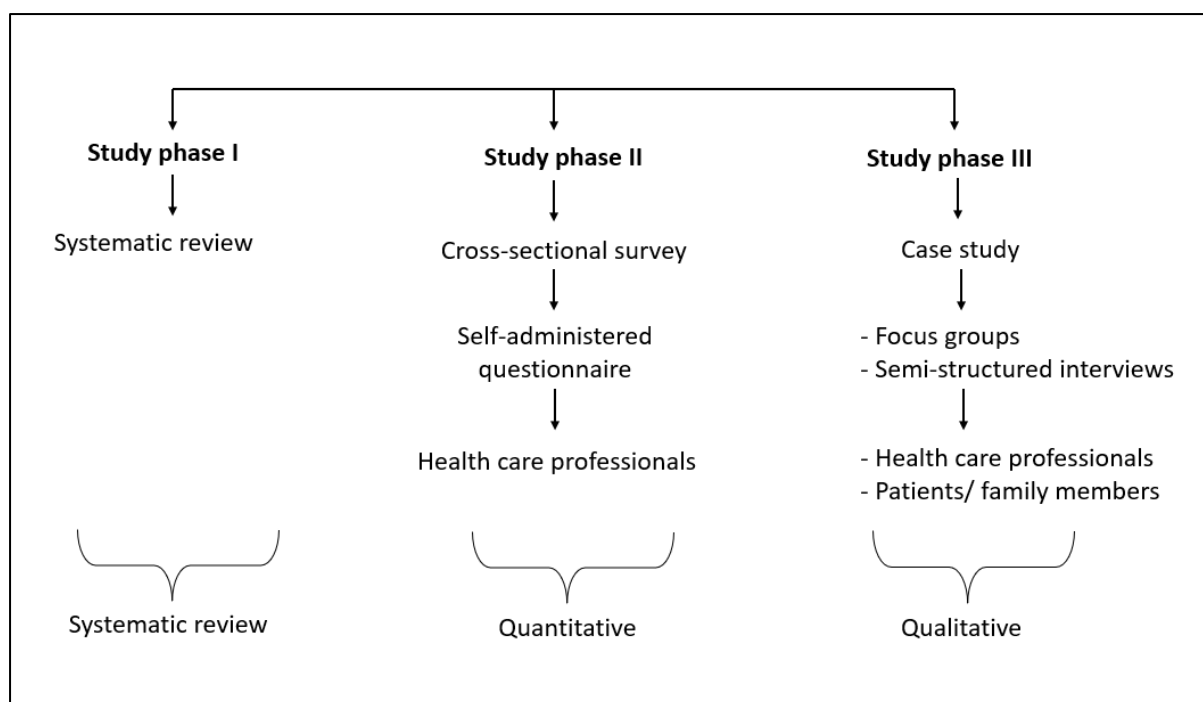
Figure 1.1 Overview of the study phases

1.6 Thesis structure

The thesis consists of ten chapters. Table 1.1displays the outline of the study and structure of the thesis. A short description of each chapter is presented below.

Table 1.1 Structure of the thesis

Chapter One	Introduction to the study
Chapter Two	Healthcare system in Saudi Arabia
Chapter Three	Literature review
Chapter Four	Research methodology
Chapter Five	Research methods
Chapter Six	Systematic review (Phase I)
Chapter Seven	Findings of Phase II (quantitative)
Chapter Eight	Findings of Phase III (qualitative)
Chapter Nine	Discussion
Chapter Ten	Conclusion and recommendations

Chapter One: The first chapter provides an introductory overview of the study and an overview of the purpose of the study, highlighting the importance of addressing issues of patient safety. It describes the aim, objectives and research questions of the study with the methodology and study phases.

Chapter Two: This chapter sets the context for the work undertaken in the thesis. Chapter two critically reviews the literature related to the healthcare system in Saudi Arabia and highlights the aspects that can compromise patient safety culture.

Chapter Three: This chapter reviews the literature regarding the concept of patient safety and safety culture in healthcare delivery. It explains the aspects of patient safety culture, dimensions and theory.

Chapter Four: This chapter explains the overall methodological approaches used to carry out this study. It describes the research paradigms that underpin the research and explains the rationale for choosing the mixed methods approach for the study design.

Chapter Five: This chapter explains the methods used to carry out this study. It describes the details of methods used for data collection and analysis for both study phases. It also presents the study rigour and ethical consideration applied during the research process.

Chapter Six: This chapter presents the findings from the systematic review of Phase I of this study, which identifies the factors contributing to the patient safety culture in Saudi Arabia.

Chapter Seven: Presents the findings of Phase II of this study (quantitative research), which used a self-administered questionnaire with healthcare professionals from three hospital sites. This study measured the perception of patient safety culture among healthcare professionals with the HSOPSC instrument, which determines the patient safety culture dimensions and whether they are strong or need improvement.

Chapter Eight: Presents the findings of Phase III of this study (qualitative research), which used two research methods: a focus group with healthcare professionals and semi- structured interviews with patients and family members. It identifies the barriers

and facilitators related to patient safety culture from the key stakeholders' points of view.

Chapter Nine: Presents the findings from all three studies and discusses the main findings with consideration of the literature in the field. It also links the findings to the theoretical framework of patient safety culture.

Chapter Ten: Presents the conclusion of the study and also highlights its main limitations as well. The recommendations and suggestions for future research are provided at the end of this chapter.

Chapter Two: Healthcare System in Saudi Arabia

2.1 Introduction

This chapter presents the overview of the Kingdom of Saudi Arabia (KSA), in relation to the geography, demographics, population and challenges facing the healthcare system. The healthcare system of Saudi Arabia is briefly discussed with a general overview on the main health providers characteristics and challenges facing healthcare system that may contributing to patient safety and quality of healthcare delivery. This chapter critically investigates current research related to patient safety cultures, in order to determine the gaps in the literature. Thereafter, justifications are given for conducting the current study in Saudi Arabia.

2.2 Healthcare system in Saudi Arabia

2.2.1 Overview of Saudi Arabia

Saudi Arabia is the largest country in the Gulf Cooperation Council (GCC) region and the second largest in the Arab world, with a total area of approximately 2,150,000 km^2. It is situated in the Arabian Peninsula and it shares its border with eight countries: the United Arab Emirates, Kuwait, Qatar, Bahrain, Oman, Iraq, Yemen and Jordan (see Figure 2.1). The country is divided into 13 regions and 134 governorates. Riyadh is the capital, and it is located in the centre of Saudi Arabia with a total population of 8,660,885 million. Arabic is the official language of the country; however, the English language is widely used, and it is considered a formal language in the healthcare system across the country. Saudi Arabia is regarded as a religious and spiritual place due to the fact that the two holy Muslim places, Makkah and Madinah, are located in the country, which is visited by millions of Muslims from around the world every year (Mufti, 2000).

Figure 2.1 Saudi Arabia map (Operation world map)

Saudi Arabia has the largest and fastest growing population in the GCC region (Sajjad and Qureshi, 2020). Its population was 34,218,169 million in 2019 compared to 27.1 million in 2010 (General Authority for Statistics, 2019). The growth rate is estimated to be 2.52% and the fertility rate is 2.27 births per woman. Youth and children represent more than two- thirds of the Saudi population at 67%; those aged 0–14 account for 30.3% and those aged 15–34 account for 36.7% (General Authority for Statistics, 2019). The growth of Saudi Arabia's population has led to estimations of future populations of 39.8 million by 2025 and 54.7 million by 2050 (Sajjad and Qureshi, 2020). The health of the Saudi population has greatly improved as life expectancy is currently 75.37 years whereas in the 1950s it was 40.45 years (Sajjad and Qureshi, 2020). The increasing growth of the population indicates the need to increase the capacity of health services and improve health outcomes.

2.2.2 Vision 2030

In 2016, Saudi Arabia launched Vision 2030, a public policy which aims to transform the country from its current status of an oil-dependent economy to one relying on multiple sources of income (Rahman and Al-Borie, 2020). Vision 2030 is regarded a transformation comprehensive strategy from the government to change the country into a modern and prosperous one (Thompson, 2017, Rahman and Al-Borie, 2020). The key factors that Vision 2030 focuses on to achieve its goals are the improvement of human capital, information and communications technology, education and employment (Rahman and Al-Borie, 2020). Vision 2030 has been widely introduced to the public in order to achieve successful implementation; it stresses the importance of accountability, transparency, communication and public engagement (Rahman and Al-Borie, 2020). The improvement of the healthcare system is one of the top priorities of Vision 2030 in order to meet the health needs of the population (Alharbi, 2018). The government agreed that investment in the private sector is required in order to improve the quality and efficiency of healthcare services and to maintain the sustainability of the pattern of healthcare delivery (Rahman and Al-Borie, 2020).

2.2.3 Historical development of Saudi healthcare system

Historically, traditional and spiritual medicine such as herbs, cauterisation and scripts from the holy Quran were commonly employed to treat sick and injured people in Saudi Arabia before the establishment of healthcare services (Alharthi et al., 1999). It is worth noting that incidences of epidemic diseases that spread through communities were high among local people and pilgrims in the early and mid-20th century due to limited health services (Alharthi et al., 1999). In the early 1920s the Saudi Arabian healthcare system was founded with the establishment of the first public health department in Makkah in order to provide free health services for local people and pilgrims (Almalki et al., 2011). It was the first substantial step in the Saudi healthcare system towards the delivery of curative healthcare services (Alharthi et al., 1999). Following this, the Ministry of Health (MoH) was established in the 1950s. The MoH oversees a structured healthcare system that provides medical care based in hospitals and primary healthcare centres (Alharthi et al., 1999, Almalki et al., 2011).

Since then, and due to the increase demand for health services and changes in the economic context of Saudi Arabia, improvements to and expansion of healthcare systems have been increasing (Almalki et al., 2011).

The current healthcare system in Saudi Arabia is based on three levels: primary health care (health centres); secondary healthcare (general hospitals); and tertiary healthcare (specialised hospitals). A variety of healthcare services are provided based on the severity of illness and the referral system (Almasabi, 2013). Three sectors provide healthcare services in Saudi Arabia across primary/secondary/tertiary care: the MoH, the private sector and another governmental sector including teaching hospitals, national guard health affairs and armed force medical service. Figure 2.2 shows all three healthcare providers and the numbers of hospitals and bed capacity for each. Each of these providers has different healthcare systems in terms of authority, funding, management, infrastructures, target population and workforce (Almalki et al., 2011). While there is diversity and complexity among these different healthcare providers, the MoH is responsible for managing, planning and formulating health policies and for observing all providers in order to achieve the healthcare objectives that have been set by the Saudi government (Almalki et al., 2011).
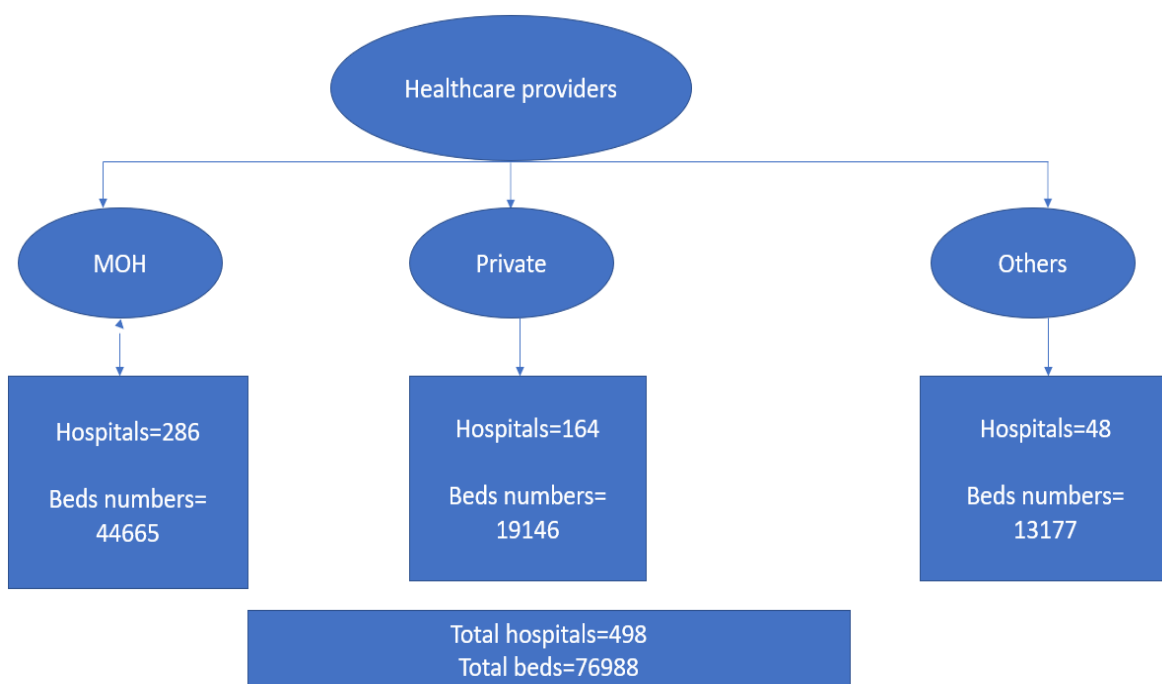
Figure 2.2 Healthcare providers in Saudi Arabia

The MoH is regarded as the main healthcare provider in Saudi Arabia with the highest number of facilities and bed capacity; it provides free healthcare services for all citizens (Sajjad and Qureshi, 2020). It is estimated that 60% of health services in Saudi Arabia are provided by the MoH (Almasabi, 2013). Saudi Arabia is divided to 13 health regions, and in each health region there is a General of Health Affairs under the control of the MoH, which supervises all health service providers in the region, including the MoH, private and other governmental health providers. The government of Saudi Arabia has given high priority to the development of healthcare services at all levels: primary, secondary and tertiary. As a result, the budget allocated to healthcare is rising; there has been an increase in healthcare expenditure and improvements initiatives in recent decades. The Saudi Arabia healthcare expenditure was approximately US$35.4 billion in 2014 and it was estimated to reach US$45 billion in 2020 (Rahman and Al-Borie, 2020). The health and social care sectors are allocated 14% of the total country's budget, which is the highest after the education sector. This reflects the high level of investment made by the government to improve the healthcare system (Sajjad and Qureshi, 2020). The government is planning to invest U$72 billion in the healthcare sector under Vision 2030, which increases the Saudi healthcare market by 12.3% (Sajjad and Qureshi, 2020, Rahman and Al-Borie, 2020).

2.2.4 Challenges of Saudi healthcare

Although the government of Saudi Arabia has given high priority to the development of healthcare services at all levels, healthcare systems still face enormous challenges with providing high-quality healthcare due to population growth, lifestyle changes, rises in chronic diseases, limited infrastructure, high expectations and the rising cost of health care (Rahman and Al-Borie, 2020). A literature review conducted by Almalki et al. (2011) reported a number of challenges in the Saudi healthcare system related to workforce, finance and expenditure, accessibility to health services, health insurance, the utilisation of electronic health (e-health) and the lack of a national system for health information. Workforce is one of the top issues in the Saudi Arabian healthcare system due to a shortage of national healthcare professionals (physicians, nurses, pharmacists) (Al-Hanawi et al., 2019). Foreign or expatriate healthcare professionals working in the Saudi Arabian healthcare sector constitute

two-thirds of the total workforce (Ministry Of Health, 2020). Relying on a high number of expatriates in the workforce is a major concern of health managers due to the high turnover, which limits the sustainability of health services (Falatah and Salem, 2018). Moreover, workforce diversity in the Saudi healthcare system and differences in culture and language lead to barriers between healthcare providers and patients including communication barriers (Almutairi, 2015). With the current shortage of Saudi healthcare professionals and the growth in both the population and number of elderly people, Saudi Arabia requires a 25% increase in the workforce in order to facilitate and manage the expected health obligation based on this growth (Al-Hanawi et al., 2019).

Although the healthcare system is planned around the fact that 70% of the population is under the age of 40, some health indicators reflect the fact that the country must work to overcome the challenges and potential demand of advanced medical care (Rahman and Al-Borie, 2020). For example, it was estimated that by 2020 the number of elderly would have increased from 1 million (4%) to 2.5 million (7%) of the total population (Sajjad and Qureshi, 2020). Also, there has been a notable sharp increase in chronic diseases including obesity, diabetes, hypertension and coronary heart diseases (Alotaibi et al., 2017, Rahman and Al-Borie, 2020, Al-Daghri et al., 2011). Saudi Arabia was ranked the highest out of 22 Arab countries in terms of the prevalence of type 2 diabetes (Meo et al., 2017). Also, the World Health Organisation (WHO) ranked Saudi Arabia as second in the Middle East and seventh in the world for the prevalence of diabetes and obesity (Ministry Of Health, 2020).

Another challenge for the healthcare system in Saudi Arabia is related to the high number, around five million, of pilgrims visiting Saudi Arabia annually. They receive free medical care, which increases the pressure and workload of the Saudi healthcare facilities (Almasabi, 2013, Rahman and Al-Borie, 2020). Vision 2030 targets an increase in the number of pilgrims visiting Saudi Arabia, up to 30 million by 2030. This means that there is an urgent need to build new hospitals, increase hospital bed capacity, and maintain human and financial resources (Al-Hanawi et al., 2019). Policy makers in Saudi Arabia must implement a comprehensive transformation plan in order to achieve the goals of Vision 2030 and enhance the quality and safety of healthcare services in Saudi Arabia (Albejaidi and Nair, 2019).

2.2.5 Accreditation status

Accreditation is certification by an external authorised body following a visit by assessors and surveyors in order to assess the structure and process of healthcare organisation performance (Braithwaite et al., 2006). The accreditation process is internationally recognised as a fundamental process in healthcare organisations to clarify the quality and safety of healthcare services (Greenfield and Braithwaite, 2008). Accreditation programmes provide a benchmark for organisational structure and management, as well as improving compliance to standards and policy and enhancing the public's confidence in the quality and safety of the healthcare services provided by accredited organisations (Alkhenizan and Shaw, 2011). In the Saudi Arabian healthcare context, in 2005, the Central Board for Accreditation of Healthcare Institutions (CBAHI) was developed by the Saudi Health Council to grant accreditation certificates to all governmental and private healthcare facilities (Central Board for Accredation of Healthcare Institutions. CBAHI, 2016). The role of CBAHI is to establish healthcare quality and patient safety standards and to evaluate all hospitals and primary healthcare centres for compliance with these standards. CBAHI accreditation is compulsory for all hospitals and primary healthcare facilities in Saudi Arabia, even though some hospitals prefer to be accredited by international agencies such as Joint Commission International (JCI) accreditation (AlKhenizan and Shaw, 2010).

In terms of safety standards, the CBAHI developed 20 national essential safety requirements (Appendix 1), which are compulsory in all hospitals if the accreditation certificate from CBAHI is to be granted (Central Board for Accredation of Healthcare Institutions. CBAHI, 2016). Therefore, every hospital should observe these 20 domains of safety requirements developed by CBAHI in order to maintain safety and minimise errors. However, the quality and safety standards of CBAHI have been criticised for not being patient centred and because patients and communities were not involved in the process of their development (AlKhenizan and Shaw, 2010). This aspect of lack of patient involvement in patient safety influenced the design of the current study, as reported in Chapter Four (section 4.7), which included the patient/family perspective in the design of the study to cover these gaps.

Although the CBAHI programme contributes significantly to the improvement of the quality and safety of healthcare services in Saudi Arabia as it believed to minimises conflicts in healthcare environments and improves communication and the utilisation of policy and guidelines, there is no evidence regarding its impact on the improvement of the safety culture (Almasabi and Thomas, 2017). It is argued that the sustainability of the CBAHI benefits is limited due to the structure of the assessment/evaluation of hospitals. These are carried out by CBAHI surveyors as a scheduled snapshot visit once every 3 years; there is no continuous monitoring (Almasabi and Thomas, 2017). Almasabi and Thomas (2017) conducted a mixed methods study using a survey, documentary analysis and semi-structured interviews to evaluate the impact of the CBAHI accreditation programme. They found that the participants' perceived improvements in quality and the safety culture required sustained improvements on a daily basis, rather than merely focusing on achieving the assessment cycle. The study also stated that there were communication barriers between hospitals and the public, which limited the community's participation in the improvements to healthcare services (Almasabi and Thomas, 2017). This issue is discussed further in relation to the interview findings with the patients/family members of the current study, reported in Chapter Eight.

Although the national CBAHI accreditation programme was developed in 2005 and is mandatory for all hospitals in Saudi Arabia, some hospitals still do not have this accreditation. According to the CBAHI statistics, out of 408 hospitals registered for an accreditation certificate, 160 hospitals have not yet been accredited. Achieving the accreditation appears to present a challenge for some healthcare organisations in Saudi Arabia due to healthcare professionals' perception of accreditation as being a long process that will be difficult due to limited resources and infrastructure (Al-Qahtani et al., 2012). It will be difficult to motivate staff to participate in the implementation of the accreditation goals unless accreditation is perceived as a benefit for clinical practice (Almasabi and Thomas, 2017). The status of and current evidence on patient safety culture in Saudi Arabia is addressed in the next chapter.

2.3 Chapter summary

This chapter describes the development and history of the healthcare system in Saudi Arabia, identifying a notable plan and a big investment from government to improve healthcare services. It described the challenges facing the healthcare system in Saudi Arabia, including the rise in chronic diseases, an ageing population, and issues related to workforce diversity, infrastructure, and resources. It highlighted the limited of accredited hospitals by the local accreditation programme (CBAHI), which may affect the safety and quality of healthcare services. The next chapter describes the status of patient safety culture in Saudi Arabia and critically reviews the literature on patient safety culture with its compromised factors.

Chapter Three: Literature Review

3.1 Introduction

This literature review chapter covers key aspects related to the concept of safety, including different definitions of safety, safety culture and patient safety culture. It also provides details of the historical development of patient safety culture and patient safety incidents. It explains the importance of patient safety in the delivery of healthcare services, and it provides an overview of the patient safety culture and the role played by individuals and organisations in the occurrence of errors. It also discusses aspects of the patient safety culture, including its dimensions and measurements, improvements strategies and worldwide initiatives. It critically investigates the importance of a positive patient safety culture in organisations and individuals' contribution to improving safety outcomes. It highlights the literature around patient involvement in patient safety initiatives, and due to the settings of the current study in Saudi Arabia, it describes the status of and current evidence relating to the patient safety culture in the country.

3.2 Search strategy

The literature searches were carried out throughout the PhD study and were iterative. Their purpose was not to address specific research as in the systematic review in Phase I, but rather to provide a narrative context for the work undertaken in this thesis. The first search was conducted in 2018 and the last iteration of the search conducted in 2021. The search strategy employed three electronic databases MEDLINE, CINAHL, Embase and, more generally, the Google Scholar website. The search was limited to sources written in the English language only including grey literature sources too (e.g., reports, guidelines etc.). Numerous key words and terms were used, as follows: safety, health and safety, safety culture, safety climate, culture, patient safety, history of patient safety, patient harm, human errors, patient safety culture, organisational culture, safety managements, patient safety culture assessment, patient safety culture dimensions, Saudi Arabia, Saudi healthcare system and Kingdom of Saudi Arabi (KSA), developed countries, developing countries. The search strategy and specific search terms changed slightly from start to finish with the

progression through the stages of the PhD, which evolved as knowledge of the area grew and findings came to light.

3.3 Concept of safety

The concept of safety is often related to being free from accidents and harm (Vincent and Amalberti, 2015). However, the term 'safety' has another meaning, which is having control over all hazards and conditions that cause physical, psychological and material harm, and which are used in different situations and environments (Dekker, 2016). In the Oxford English Dictionary (OED) (2011), the term 'safety' is defined as "the condition of being protected from or unlikely to cause danger, risks or injury". The concept of safety is associated with different levels in order to cover all of the phases of an accident, including prevention, control and mitigation (Dekker, 2016).

Safety is the focus of attention and plays a substantial role in many organisations, including industries, the chemical field and healthcare settings (Beus et al., 2016, Aven, 2014). From the technical perspective, safety is defined as the antonym of risk, which means that there is a strong relationship between risk and safety – reducing risks leads to higher levels of safety (Möller et al., 2006). Aven (2014) stated that risk is a situation or unwanted event that causes harm and put human of stake condition leads to uncertain outcomes. Therefore, Möller et al. (2006) stressed that understanding the severity of risk and probabilities, and highlighting undesirable events might limited potential harm rate and achieve a high standard of safety.

3.3.1 Safety I and Safety II

Healthcare has gradually changed over the past three decades, shifting from focusing on individual responsibility when it comes to safety, quality, and performance (Reason, 2000a) to developing a systems perspective when it comes to addressing problems of variation and adverse outcomes (Sujan et al., 2019). The traditional approach (referred to as Safety I) to improving safety has focused on counting incidents, understanding the cause of incidents, and developing strategies to prevent or minimise them (Hollnagel, 2018, Hollnagel et al., 2015). However, based on the so-called Safety II approach, safety management is intended to make sure that as much as possible goes right, so that daily tasks are met (Hollnagel, 2018). Therefore, in this case, safety is

measured by the number of things that go right, and is managed by what it achieves (successes, accomplishments) (Hollnagel et al., 2015). It is thus essential that the focus of safety management should shift from ensuring as few things go wrong as possible to ensuring as many things go right as possible (Hollnagel et al., 2015).

Globally, the Safety I approach focuses on understanding why patient safety events have occurred using standard techniques (e.g., root cause analysis, incident reporting, failure modes, and effects analysis (Hollnagel, 2019, Haavik, 2021). In contrast to the conventional Safety I approach that focuses on preventing harm through standards and rules, Safety II focuses on enhancing the human capability for working safely without following specific rules (Hollnagel, 2019, Haavik, 2021). The Safety I vs. Safety II debate revolves around a number of issues, including the definition of safety, the role of people in safety, as well as how businesses focus on safety (Cooper, 2022). For example, in Safety I, people are seen as problems that must be controlled, but in Safety II, they are seen as responsible contributors to a solution. Therefore, Safety II serves as progress rather than replacing Safety I, because Safety II does not create a new discipline or practice – it simply brings a different perspective to what happens and how it happens, and as a result, safety must be capable of adapting, tolerating change, being resilient, and recovering from failures (Cooper, 2022). The concept of Safety II involves a system's ability to respond to varied conditions. This assumes that everyday performance variability provides the adaptations that are necessary to respond to varying conditions, and therefore, is the reason why things work as they should (Braithwaite et al., 2015).

As a development of resilience engineering (RE), resilient healthcare (RHC) emerged around 2012; this approach views humans as a positive resource for dealing with disturbances and variable conditions in complex organisations (Ellis et al., 2019). This definition of resilience refers to a system's ability to respond safely to changing circumstances due to its flexibility, robustness, and adaptability (Woods, 2015). With the RHC approach that incorporates RE concepts into healthcare settings and uses a Safety II approach, there is a complementary perspective to be gained from learning from incidents and understanding how everyday clinical work is performed successfully (Iflaifel et al., 2020). RHC recognises that healthcare systems such as clinics, wards, hospitals, or even entire countries are complex adaptive systems that

constantly change, and this can lead to unexpected work situations. Thus, resilience means treating safety as a core value, planning and preparing for it in advance, anticipating, monitoring, learning, and responding accordingly (Sujan et al., 2019). Moreover, An RHC approach is not concerned with the coping and resilience capacities of individuals, but with the factors and methods that enable workers, teams, and organisations to adjust and cope successfully with different types of situations (Ellis et al., 2019). Therefore, it is important to recognise that safety problems are not caused by or linked directly to a lack of knowledge, training, or effort by healthcare professionals. They are usually the result of work that is complex, often involving technology; hence, policymakers and managers must monitor and control the resources, constraints, and multiple demands placed on them (Hollnagel et al., 2018).

3.4 Safety culture

The term 'safety culture' first appeared in the report of the Nuclear Agency by the Organisation for Economic Co-operation and Development (OECD) following the Chernobyl disaster in 1986 (Hohenemser, 1988). This report identified that aspects of organisational 'culture' including working environment conditions and administrative systems have a direct impact on the likelihood of accidents occurring. In addition, the report highlighted that deficits in the coordination and proper exchange of information among staff were considered to be the main causes of the accident, along with a lack of safety culture among staff in the work environment (Hohenemser, 1988).

The term 'culture' itself refers to a multi-layered concept that was originally derived from the anthropological context (Smircich, 1983). Culture is a collection of beliefs, practices and symbols that are learned and shared between groups of people; they vary according to the internal and external factors that shape views and ways of living (Brown et al., 2020). Culture is also seen as a set of structures and routines that are common in a group of people and which are considered to be acquired rather than innate, and their existence is due to the capacity of humans to learn any culture (Brown et al., 2020).The concept of culture has been linked increasingly with the study of organisations (Feng et al., 2008). According to Schein (2010), culture is a dynamic phenomenon that is reproduced and created by interactions and shaped by the behaviours and values of others. Moreover, in healthcare organisations, safety culture

refers to different forms and subsets of organisational culture with regard to the values and beliefs concerning health and safety within an organisation (Singer et al., 2009). Therefore, it is central to understand the safety culture within a healthcare organisation because it reflects the ability of individuals or organisations to deal with the risks and hazards that might occur (Singer et al., 2009).

Safety culture has been discussed widely in the literature and extensively defined in numerous ways (Wiegmann et al., 2004, Mearns et al., 1998). A safety culture is conceptualised by Cox and Cox (1991) as the attitudes, beliefs, perceptions, and values that employees share in relation to safety. Cooper (2000) defined a safety culture as a sub-facet of organisational culture that is thought to affect members' attitudes and behaviour in relation to an organisation's ongoing health and safety performance. The most common definition of safety culture that was stated by the Advisory Committee for Safety in Nuclear Installations (ACSNI), which has also been adopted by the UK Health and Safety Commission (HSC): "The safety culture of an organisation is 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 organisation's health and safety management" (HSC, 1993, p.23). All of these definitions are linked to shared safety values among the whole group or individual organisational members, thus contributing to everyone at every level of the organisation (Wiegmann et al., 2004). Safety culture is not just about individual behaviour, but involves the entire management team in order to improve safety (Antonsen, 2017).

3.5 Safety culture *vs* safety climate

Although the terms 'safety culture' and 'safety climate' are used in the literature as interchangeable terms, there is some debate and disagreement over the use of each term (Wiegmann et al., 2004). Both concepts share common aspects of definitions and they are characterised by the same purpose, which is describing problems in their social and behaviour context (Yule, 2003). Safety culture refers to shared values among groups of individuals or organisations, for all levels of organisations; these shared values influence their behaviour (Reason, 2000b). The safety culture is also considered to be complex phenomenon that reflects behavioural and institutional

issues such as organisational values, norms, assumptions and expectations. A safety culture can be reflected within an organisation', in which establishing safety standard and learning from mistakes and incidents are prioritised (Wiegmann et al., 2004).

On the other hand, the safety climate concept was defined by Zohar (1980) as particular perceptions that employees share about their work environment. Safety climate is regarded as a snapshot of the workforce's perception of the level of safety in their environment at a particular point in time (Wiegmann et al., 2004). Safety climate focuses on psychological characteristics and mood, whereas safety culture is concerned with the personality of individuals and intentions and behaviours (Wiegmann et al., 2004). It therefore refers to the degree to which individuals and groups are committed to personal responsibility for safety – that is, act to preserve, enhance, and communicate safety concerns (Wiegmann et al., 2004). The safety climate is also concerned with intangible issues including situational and environmental aspects at a specific time and it is highly subject to change (Wiegmann et al., 2004, Yule, 2003). Therefore, a safety climate assessment represents and describes the atmosphere of safety in organisations that are under investigation in general sense but without a focus on the specific details to barriers and facilitators (Halligan and Zecevic, 2011). However, both concepts, the safety culture and the safety climate, differ in their measurement tools, which include surveys, observations and interviews (Yule, 2003, Kalteh et al., 2021). Although there are some similarities and differences between both terms, improving the level of the safety climate and the safety culture has been found to effectively minimise the rate of incidents and to improve safety performance (Kalteh et al., 2021).

3.6 Organisational culture and human factors

3.6.1 What is organisational culture?

Organisational culture is a set of enduring attributes, such as values, assumptions and beliefs, that are unique to each individual organisation (Day, 2019, Westrum, 2004). The organisational culture provides insight into what is valued and what should be done within a business (Westrum, 2004). Another way to describe organisational culture includes observed behavioural regularities, group norms, espoused values, rules of the game, climate, embedded skills, habits of thinking,

shared meanings, and root metaphors (Schein, 2010). The most famous definition of organisational culture is "the way we do things around here" (Schein, 2010, p.11) which indicates that it is behaviour focused. It is important that an organisation's culture is based on shared perceptions of its daily practices (Weaver et al., 2013). Cultures can be classified into four broad categories, consisting of clan cultures, adhocracy cultures, hierarchy cultures, and market cultures. Clan culture is related to team culture, which emphasises the training and development of employees (Kim and Robert, 1999). These classifications are further linked to healthcare organisations (Gifford et al., 2002). Adhocracy culture refers to organisations that value their growth, assets, and external support. In terms of market culture, this refers to culture valuing productivity and efficiency, with a focus on planning and group settings. The last organisational culture, hierarchy culture, values stability and control which are enhanced by information management and communication (Gifford et al., 2002).

It has been believed that organisational culture affects patient safety in many ways, including how care is delivered, how staff communicate, and how a setting can be created that supports safe practice and minimises errors (Day, 2019). However, across a variety of healthcare settings there is a correlation between positive organisational culture and improved clinical outcomes, including reduced mortality rates (Mannion and Smith, 2018). The safety culture of an organisation is characterised by open and trusting communication, a shared understanding of the importance of safety, and confidence that preventive measures can work (Kaufman and McCaughan, 2013). Indeed, a positive safety culture is associated with both a higher level of employee safety compliance and better organisational performance in healthcare settings (Mannion and Smith, 2018). Moreover, aspiring to a positive safety culture could encourage professionals to report incidents and analyse them, which could be an effective tool for safety improvement (Mannion and Davies, 2018). Thus, having a clear understanding of organisational safety culture is helpful for establishing effective safety initiatives and interventions to improve patient safety culture. The organisational safety culture determines whether safety takes priority at all levels of the organisational hierarchy; if management is committed to organisational safety, and if it is provided with the necessary resources to achieve quality and safety (Kagan and Barnoy, 2013), then it is considered to be prioritised.

This influenced the current study design that aimed to examine patient safety culture in healthcare organisations in Saudi Arabia and to explore the factors that influence safety culture from different perspectives.

3.6.2 Human factors

The term 'human factors' refers to environmental, organisational, and job factors, as well as individual and human characteristics that impact behaviour at work in a way that may influence health and safety (Flin et al., 2009). The human factors aspect is usually viewed from three perspectives: the job, the individual, and the organisation, to which extent and how they affect people's health and safety behaviours (Flin et al., 2009). Patient safety incidents often occur when human factors and ergonomics are not taken into account in the design and implementation of technologies, processes, workflows, jobs, teams, and systems related to healthcare (Carayon et al., 2013). Therefore, understanding human error and identifying the mechanisms of human error involved in patient safety have been the main focus of human factors approaches in patient safety (Carayon et al., 2014). A significant number of studies indicate that organisational and human factors are perceived as causes of accidents and they have received considerable attention in the patient safety literature, rather than focusing on the failure itself (Reason, 2000b, Ternov and Akselsson, 2005, Lowe, 2006). The role of human factors and ergonomics in patient safety is crucial; hence, patient safety activities should reduce and mitigate medical errors, as well as enhance employees' motivation, job satisfaction, and acceptance of new technologies (Mao et al., 2015).

According to (Reason, 2000b), two different types of errors or accidents might occur in any organisation: individual errors and organisational errors. Thus, understanding the differences between these accidents is valuable in terms of reducing the probability of errors occurring and building management actions based on specific failures. Reason (2000b) identified two main approaches to investigating errors or accidents – personal and system approaches. The personal approach, which is mainly concerned with individual errors, shows that errors or unsafe acts arising from individuals are related to human behaviours, forgetfulness, lack of motivation, carelessness and moral weaknesses (Reason, 2000b). On the other hand, the system approach focuses on individuals' work and their ability to build defences that

prevent errors or reduce their effects. Indeed, the system approach looks at errors as consequences of problems rather than their causes (Reason, 2000b). Therefore, the unique feature of this approach is that it represents organisational factors as contributing to errors rather than focusing on individual factors (Reason, 2000b, Carayon et al., 2014). Moreover, the use of the systems approach is viewed as valuable because it addresses comprehensive targets that are able to develop different programmes to manage the workplace, teams, people and tasks (Carayon et al., 2014). On the other hand, users of the personal approach place the blame for errors on individuals. Therefore, managers focus on the individuals themselves in order to make them less fallible or wayward (Reason, 2000b).

3.6.3 Swiss cheese model

With the growing attention paid to medical errors and the complexity of capturing their risk factors, the Swiss cheese model was developed by James Reason. It has recently also become known as the Reason model (Reason, 1990, Reason, 2000b). This model is widely utilised as it provides justification for the mechanism of system failure that increases the chance of errors and accidents occurring. The Swiss cheese model represents slices of cheese as organisations or systems with different layers that provide defences or barriers to prevent accidents. However, there are gaps and holes in the slices of cheese that are probably caused by individuals' weaknesses, and which may increase the chances of hazards passing through all the defence layers Figure 3.1. Therefore, this model shows the role of individual and system failures in the trajectory of hazards and it identifies two major categories of failure that are responsible for destroying all of the defence layers and causing accidents (Reason, 2000b).
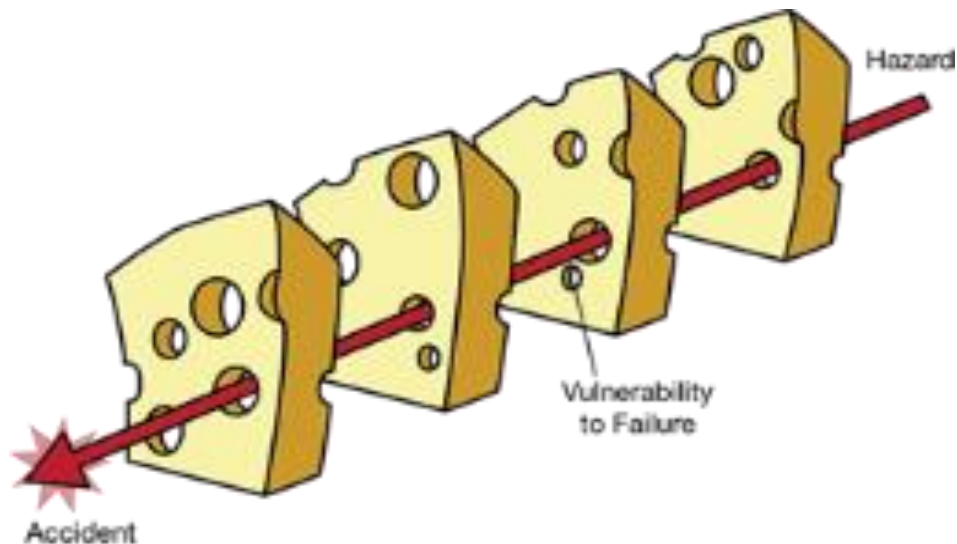
Figure 3.1 Swiss cheese model (adapted from Reason, 2000)

Firstly, there is active failure, which is defined as unsafe events or acts made by frontline individuals that are directly connected to accidents (Reason, 2000b). Hennessey (2010) stated that errors or accidents caused by active failure were usually found to be crucial and they directly contributed to safety outcomes. There are different types of forms associated with active failure, including slips, lapses, mistakes and non-adherence to policy, standards and procedures (Olivares et al., 2014, Reason, 2000b). According to (Reason, 2000b), all of the forms associated with active failure are classified under errors and violence resulting from a lack of skills, knowledge, concentration and commitment to regulations and roles.

On the other hand, there is latent failure, which is defined as the failure of organisations or poor decisions made by managers that contribute to a breakdown in systems, leading to active failure (Reason, 2000b, Bentley, 2009). Therefore, latent conditions can remain hidden in organisational systems for a long time until they are obvious due to the effects of active failures (Reason, 2000b). According to (Lowe, 2006), latent failures are "accidents waiting to happen" due to a combination of interrelated or interacting issues in the work environment, which generate the likelihood of errors. Vincent (2003) identified various latent elements that contribute to the likelihood of errors occurring, including safety culture, staffing issues, poor communication among staff, inadequate resources and a lack of effective communication between healthcare workers and patients. Therefore, one of the

management approaches for such latent conditions is the system approach, which is considered feasible as it treats situations proactively rather than reactively (Reason, 2000b). This approach focuses the effort of management on the weakness of the system itself, in order to prevent the errors from occurring rather than dealing with the errors that already exist. Consequently, in order to reduce errors or harm, strategies need to be implemented that address the condition of human environments rather than focusing only on the human condition or behaviours themselves (Reason, 2000b, Ternov and Akselsson, 2005).

3.7 Safety culture theory, models/frameworks

3.7.1 Safety culture models

With the recognition of the importance of understanding safety culture, a variety of models and frameworks have been developed in recent decades that outline the principles of safety culture and guide theory, research, and practice (Cooper, 2018). Cooper (2000) classifies safety culture under three domains: psychosocial, behavioural, and situational elements. Cooper (2000) describes safety culture as the subculture of an organisation's overall culture, which refers to an interactive relationship between people's psychological behaviours and situational factors (see Figure 3.2). Cooper's (2000) model is linked to the psychosocial factors of values, perception, and attitude, which can be measured via safety climate questionnaires; and the behavioural aspects that refer to patterns of behaviour, which can be assessed through checklists. In terms of situational factors linked to the organisation's system, these can be assessed through audits and inspections (Cooper, 2000). Cooper (2000) argues that safety culture is a complex phenomenon that requires attention to be paid to the ways people think and behave. Despite the broader meaning of safety culture that covers three domains, the focus in the patient safety literature is on people's perceptions and beliefs, so the situational and behavioural factors got less attention. The psychological, behavioural, and situational elements of this model reflect the accident causation relationships of the environment, culture, and organisation in creating a hazardous situation (Reason, 2000a). Thus, it is argued that psychological, situational, and behavioural factors all interact to cause accidents at all levels of an organisation (Cooper, 2000).
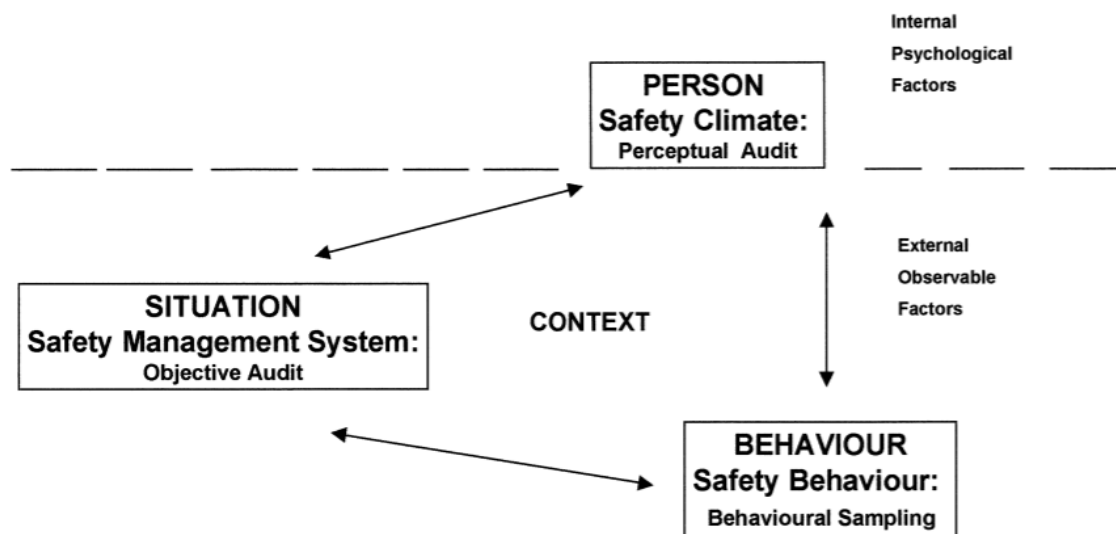
Figure 3.2 Cooper's reciprocal safety culture model (Cooper, 2000)

Another model, developed by Guldenmund (2000), classifies organisational culture into three levels including basis assumptions, espoused values, and artefacts (Figure 3.3). This model is based on Schein's (1992) three-layered cultural model, which assesses: (1) basic assumptions; (2) espoused beliefs and values; and (3) behaviours and artefacts (Schein, 1992). The Guldenmund (2000) model differentiates between safety culture and safety climate based on the relationship of both concepts with safety, risk management, and safety performance. Basic assumptions are concerned with the safety culture of whole organisations and is regarded as unconscious and unspecified (Guldenmund, 2000). In relation to espoused values and beliefs, this is considered explicit and conscious, and is concerned with people's attitudes; it reflects the function of groups and behaviours of people related to safety. Finally, in relation to artefacts, this is concerned with visible issues associated with safety aspects related to inspection, incidence, accidents, near misses, and different type of behaviour (Guldenmund, 2000). This model highlights that safety culture is a component of organisational culture that influences the attitude and behaviour of individuals, leading to increased or decreased risk episodes. All of the models discussed above are based on a similar concept that describes the safety culture and discusses the overall theory underpinning how safety culture should be considered. Therefore, based on the

models discussed above, Simler's sense of safety culture is about people's attitudes, values, and the structure of organisations that inform the understanding of safety culture within organisations. While the above models specify the concept of safety culture, the next section presents a number of frameworks to describe and represent all of the variables that lead to an understanding of patient safety culture. The following section discusses how the frameworks are about patient safety more specifically and their roles in assessing patient safety culture in healthcare organisations.

Basic assumptions
• The nature of reality and truth. Ultimate source of values and action.

Espoused values/attitudes
• Relatively explicit and conscious. Attitudes, policies, training manuals, procedures, formal statements, bulletins, accident and incident reports.

Artefacts
• Visible organisational structure and process regarding safety aspects including inspection, incidence, accidents, near misses, and different type of behaviour.

Figure 3.3 Three levels of organisational culture (Guldenmund, 2000)

3.7.2 Patient safety frameworks

To date, there is no evidence-based framework that summarises the factors contributing to patient safety culture from different perspectives (healthcare professionals and patients). According to Chodhry et al. (2007), the field of safety culture lacks integration between the models of general organisational culture, revealing a variety of safety-related elements that do not align with one specific framework of safety culture. In order to address the complex dynamic of safety culture development, Bisbey et al. (2021) conducted a narrative review that attempts to integrate current ideas about safety culture into an integrated framework that is consistent with the original concept of organisational culture. The Functional

Framework for Safer Culture (Bisbey et al., 2021) provides the fundamental enabling factors that allow employees, groups, and leadership to adopt a safer culture within an organisation. The review identified the enabling factors that allow safety cultures to develop over time through the creation of safety-appropriate norms, values, and assumptions at three levels: organisational, group, and individual (Table 3.1). A safer culture can be described as a collection of enabling factors, or building blocks, that play a vital role in shaping the culture.

In this framework (Bisbey et al., 2021), the enabling factors describe the conditions that foster employee learning and the development of a safety culture, and the enacting factors describe how it is put into action and influences safety outcomes. This framework is useful to those who are interested in designing safe, effective, and efficient work systems where safety culture can thrive, and specifically how safety culture may be adopted by healthcare professionals, expressed in healthcare systems, and permeated throughout an organisation. Therefore, by understanding and advancing theory about the complex, dynamic processes involved in safety culture development, this framework guides efforts to understand and develop safety culture in practice. Although this framework was not available at the outset of the current study, it is valuable for future work.

Table 3.1 Framework for understanding the development of safety culture (Bisbey et al., 2021)

Factor Levels	Factors enabling the development of safety culture
Organisation level	- Leader commitment and prioritisation of safety - Policies and resources for safety
Group level	- Cohesion (members' commitment to the group and its goals) - Psychological safety (an environment in which information can be shared freely, and employees feel comfortable reporting and discussing errors)
Individual level	- Safety related knowledge - Sense of control - Individual commitment to safety - Enacting behaviours - Communication and information exchange, teamwork and collaboration, incident reporting, and fair rewarding and punishing

Another framework is the Manchester Patient Safety Framework (MaPSaF), which was initially developed by Kirk et al. (2007), was specifically designed for primary healthcare organisations to assess and understand their safety culture. The MaPSaF is underpinned by Westrum's theory of how organisations process information, distinguishing three types: pathological, bureaucratic, and generative (Westrum, 2004). Pathological organisations are those in which management and staff do not care about safety and are only concerned with complying with regulations and not getting caught. A bureaucratic organisation is one that is comfortable with systems and numbers, has successfully implemented a risk management system, and is highly focused on statistics. Lastly, generative organisations place a high value on safety, which is ingrained in all employees throughout the organisation; the company is honest about failure and uses it to improve safety rather than assigning blame (Westrum, 2004, Parker et al., 2008).

It was later further developed by (Parker, 2009) to include support for adapting the primary care versions of the MaPSaF to acute, mental health, and ambulance settings, which classifies organisations' safety culture under five levels. These levels are pathological, reactive, bureaucratic, proactive, and generative, which cover 10 dimensions of patient safety culture Table 3.2. The pathological level is concerned with the effort that people or organisations apply to safety issues and risk management. The reactive level is concerned with the level at which patient safety is prioritised and the action taken when incidences occur. The bureaucratic level is concerned with availability of systems responsible for managing safety issues. The proactive level is concerned with attention paid to patient safety issues in healthcare organisations to limit patient safety issues before they occur. Finally, the generative level is concerned with managing patient safety as an integral part of the organisation (Parker, 2009).

Table 3.2 MaPSaF dimensions

MaPSaF Dimensions
• Commitment to overall continuous improvement
• Priority given to safety
• System errors and individual responsibility
• Recording incidents and best practice
• Evaluating incidents and best practice
• Learning and effecting change

- Communication regarding safety issues
- Personnel management and safety issues
- Staff education and training
- Teamwork

The five levels of this framework are valuable in examining the current state of patient safety culture in hospitals and describing how patient safety issues are prioritised and handled (Parker, 2009). The framework also helps determine the strengths and weaknesses of patient safety culture within organisations and among healthcare professionals, which is then able to guide and facilitate improvement strategies. Moreover, it helps to evaluate the effectiveness of patient safety programmes and interventions adopted by healthcare organisations (Parker, 2009). The MaPSaF provides a unique opportunity to reflect on the progress of the organisation's safety culture, recognising that incidents result from both system failures and individual mistakes (Parker et al., 2008). As a result, it corresponds to the idea of individual vs. organisational (active/latent) failure that causes errors (section 3.6.3). Therefore, it is considered useful for building a comprehensive picture of patient safety culture, as it determines the stage of organisations' safety culture and examines perceptions of patient safety culture dimensions (Parker, 2009, Marshall et al., 2017).

Another useful patient safety framework is the Yorkshire Contributory Factors Framework (YCFF). This framework is evidence based and it was developed from a systematic review of 95 papers that identified the factors contributing to patient safety incidents (rather than safety culture per se) (Lawton et al., 2012). The YCFF framework categorises the factors into different domains including active failures, situational factors, local working conditions, latent organisational and latent external factors (Figure 3.4). Thus, this framework is widely regarded as a detailed tool that enables the identification and classification of contributing factors into several main domains in a clear and understandable way (Hernan et al., 2015, Polisena et al., 2015).

This is important because it helps healthcare professionals, managers, and healthcare organisations to understand the factors contributing to patient safety incidence. Therefore, it can address the causes of underlying patient safety issues and can help organisations to create an improvement strategy based on the factors

identified (Khajavi et al., 2013). It is clear that there is a strong relationship between deficits in the patient safety culture and the number of patient safety incidents (DiCuccio, 2015, Braithwaite et al., 2017). By identifying factors that lead to patient safety incidents, organisations can proactively prevent rather than manage incidents reactively, since the possible causes have been identified beforehand(Najjar et al., 2015). Therefore, preventive measures can be implemented, and a patient safety culture is promoted. The fact that some of the key factors and domains of this framework are reflected within the models and frameworks described above suggests that it is useful in capturing the factors contributing to patient safety culture. All the frameworks reviewed above emphasise the importance of safety knowledge and skills, individual behaviour, education and training, and communication, teamwork, and leadership, which directly impact safety outcomes (e.g., injuries, errors). However, out of all the frameworks above, the YCFF was used in the systematic review (Phase I) in the current study to gather a wide range of contributing factors to patient safety culture as it captures patient safety incidents that might be reflective of the safety culture more generally. The justification for the selection of this framework is provided in the Phase I systematic review chapter (section 6.2.7).
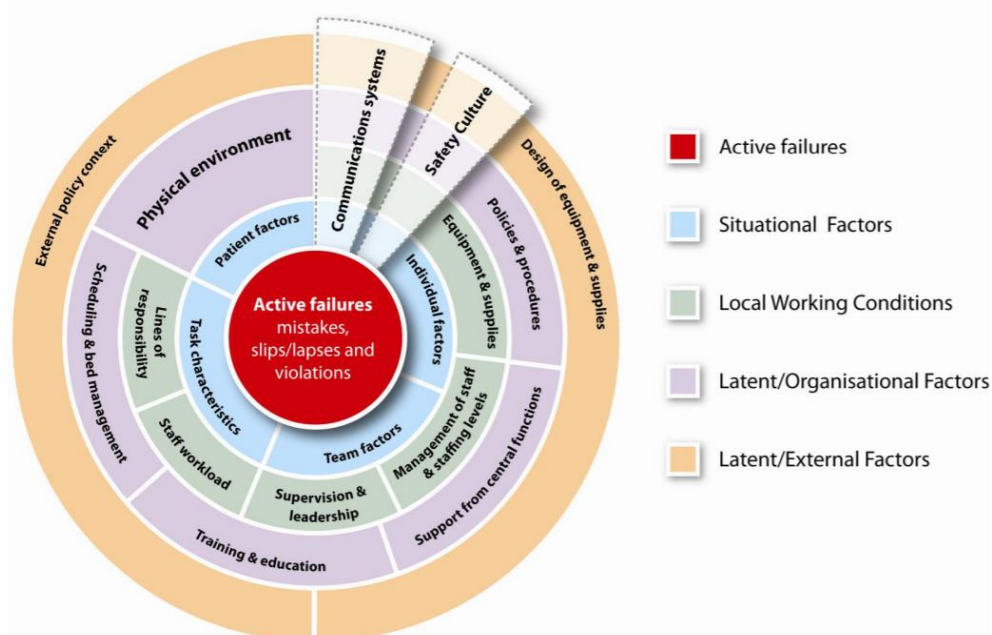
Figure 3.4 YCFF framework (Lawton et al., 2012)

3.8 Patient safety culture

The concept of patient safety was clearly defined by the Institute of Medicine (IOM) as "prevention of harm to patients" (p.7)(Erickson et al., 2003). An expansion of this basic definition was developed by the Agency for Healthcare Research and Quality (AHRQ) as "freedom from accidental or preventable injuries produced by medical care" (p.1) (AHRQ,2006). The issue of patient safety is linked to quality concerns as safety is an essential dimension of quality. It involves avoiding unsafe or poor-quality care and reducing or controlling the potential risks to a certain point that can limit or reduce their impact (Kazandjian et al., 2008). The World Health Organisation (WHO) stated that patient safety is the reduction of risk of unnecessary harm associated with health care to an acceptable minimum (WHO, 2011).

Patient safety culture is a phenomenon concerned with different dimensions of hospital safety and improving the quality and safety of healthcare services (Sammer et al., 2010). Patient safety culture is defined as a subset of an organisation's culture that specifically concerns values and beliefs related to patient safety (Halligan and Zecevic, 2011). Patient safety culture is viewed as a component of social learning, and of approaches of thinking and behaving that form a basic requirements for a high standard of patient safety (Mustard, 2002). Building safer healthcare is dependent on the patient safety culture of an organisation as this influences the behaviour of the organisation's members and facilitates commitment to raising and sustaining attention to patient safety (Mustard, 2002, Wiegmann et al., 2004, Kalteh et al., 2021). Wiegmann et al. (2004) conducted an integrative review of research on safety culture which identified five components that shape a positive safety culture: organisational commitment, management involvement, employee empowerment, reward systems and reporting systems. According to the WHO (2018), organisations with a positive patient safety culture are characterised by five fundamental subsets of culture that enhance the implementation of strong and effective safety management:

- A culture that supports all healthcare professionals in taking responsibility for safety inside healthcare organisations – for themselves, their co-workers, patients and visitors.

- A culture that prioritises and values safety as a top priority goal in the healthcare organisation.

- A culture that encourages and rewards the identification, communication and resolution of safety issues.

- A culture that enhances education and organisational learning from accidents.

- A culture that provides appropriate resources, structure and accountability in order to maintain an effective safety system.

The promotion of a patient safety culture is one of the core elements for improving patient safety and the quality of healthcare services. Different approaches and strategies linked to the promotion of a positive patient safety culture include leadership, teamwork and behaviour change (Weaver et al., 2013). Similarly, positive patient safety cultures were assessed by Sammer et al. (2010), who categorised patient safety cultures under the following seven domains.

- Leadership: Leaders recognise the healthcare environment is a high-risk environment and try to adjust vision/mission, staff competency and human resources.

- Teamwork: concerned with feelings of collegiality, collaboration and cooperation among staff. Relationships are open, safe, respectful and flexible.

- Evidence-based: concerned with patient care practices based on evidence. Provides standardisation in policy and guidelines to reduce variation in practices among staff and departments. Processes are designed to achieve high reliability.

- Communication: concerned with open communication based on structured language and channels that are understood by all healthcare professionals to exchange information and messages. Supports a 'speaking up' culture and responsibilities.

- Learning: The hospital supports learning from errors and previous mistakes. Learning opportunities are equal and fair for all healthcare professionals. Hospitals support the promotion of opportunities for improvement, seeking to improve individuals and the organisation's performance.

- Just: a culture that acknowledges errors as system failures rather than individual failures. Culture supports non-punitive responses to errors and reduces the blame culture.

- Patient-centred: patient care is centred around the patient and their family. Patients actively participate and contribute to the hospital's safety initiatives.

- Creating a positive culture of patient safety is central to healthcare improvements, which can be achieved through a variety of strategies that are centred on individuals. These can facilitate performance change and maintain a positive commitment to achieving high levels of patient safety and quality of healthcare.

The extent to which the data from the current study aligned with these domains is considered later in the discussion chapter (Chapter Nine).

3.9 Measuring patient safety culture

Patient safety culture has become a significant issue associated with improvement strategies, which are concerned with enhancing patient safety and minimising the risk of errors in healthcare organisations (Halligan and Zecevic, 2011, Morello et al., 2013). The measurement of the patient safety culture in healthcare organisations is a core element of improving the nature of patient safety there (Weaver et al., 2013, Morello et al., 2013). With regard to the assessment of patient safety culture, most measurement tools are based on a quantitative approach (e.g., surveys) and rarely utilise a qualitative approach (Wiegmann et al., 2004, Flin, 2007). An integrative review of the literature was conducted by Lee et al. (2019) to examine the relationships between safety culture, safety, and quality of care outcomes in hospital settings. A total of 17 studies were reviewed, in which safety culture was measured by various self-administered questionnaires including the HSOPSC, Safety Climate Scale (SCS), and Safety Attitude Questionnaire (SAQ)(Lee et al., 2019). However, Wiegmann et al. (2004) stressed that the process of assessing patient safety should consider important aspects including measurement methods, the level of analysis and implementation constraints. Combining methods of assessment of patient safety culture has also been acknowledged as providing unique potential benefits such as a comprehensive understanding of the safety culture (Wiegmann et al., 2004, Halligan and Zecevic, 2011).

In relation to qualitative methods, Halligan and Zecevic (2011) reported that although interviews, focus groups, and observations have been used, qualitative methodologies for assessing patient safety culture appear to be in their infancy. Despite this, a qualitative approach is regarded as beneficial as it provides a deep understanding of the phenomena of interest and allows the researcher to explore in-depth issues that

might only be shallowly explored using a quantitative approach (Listyowardojo et al., 2017, Ridelberg et al., 2014). For example, in the patient safety context, mixed methods studies using qualitative and quantitative approaches are considered to provide a more comprehensive and accurate picture of patient safety culture (Listyowardojo et al., 2017, Wami et al., 2016b). Listyowardojo et al. (2017) undertook a mixed methods study to assess safety culture at a public maternity hospital in China, using SAQ survey tool with 1482 respondents and interviews with 18 hospital staff. The findings revealed that in a mixed methods assessment of safety culture, interview findings are corroborated by the survey, providing a more comprehensive and accurate picture of the safety culture.

The tools used to carry out an assessment of safety culture vary in organisations; they can be used to measure the psychological, behavioural and situational aspects of safety culture (Cooper, 2000). Psychological aspects are concerned with people's beliefs, values, attitudes and perceptions towards safety and they can be measured by a questionnaire (Cooper, 2000). The behavioural aspects of safety culture can be examined via observations, documentation and discussions with target groups, whereas the situational aspects of a safety culture are reflected in the organisation's policies and procedures; these can be measured via audits of safety management systems and inspections (Cooper, 2000). Sorra and Nieva (2004b) stated that an evaluation of the patient safety culture is central to determining any safety issues that might influence safe clinical practice. The value of assessing patient safety culture in healthcare organisation has been reported as helping hospitals to identify the safety issues that require attention, and setting benchmarks and indicators of improvement strategies (Alswat et al., 2017, Morello et al., 2013).

Around the world, there are many tools for assessing safety culture; among the most widely used are the (SAQ), (SCS), and the (HSOPSC) (Singla et al., 2006, Colla et al., 2005, Lee et al., 2019). In terms of the HSOPSC, which was developed in the US by the AHRQ is recognised as an international survey as it is used in over 45 countries and has acceptable psychometric properties, which are specifically developed for healthcare settings to assess patient safety culture at the individual, unit, and organisational levels (Sorra and Nieva, 2004b). Moreover, this tool covers a wide range of patient safety culture dimensions compared to other tools. This survey

contains 12 dimensions of patient safety culture, and 42 items at three different levels: department/unit level, hospital level, and individual outcomes. These items were measured using a 5-point Likert scale, ranging from 1 = Strongly Disagree to 5 = Strongly Agree. The HSOPSC questionnaire is considered to be one of the most utilised instruments in the assessment of patient safety culture among healthcare professionals worldwide (Sorra and Dyer, 2010, Etchegaray and Thomas, 2012, Elmontsri et al., 2017). It has been translated into different languages in order to assess patient safety culture among healthcare workers across countries. It is a valid and reliable tool, and a justification for why this tool was chosen in the current study and a more detailed description of its psychometric properties are provided in Chapter Five (section 5.2.3).

The SAQ is a valid tool used around the world to identify the factors from a healthcare professionals' perspective that may lead to medical errors (Sexton et al., 2006). This tool contains 30 items under six main domains: safety climate, teamwork climate, stress recognition, perception of the management, working condition and job satisfaction (Sexton et al., 2006). In relation to SCS, this is also considered a valid tool and it is used widely to assess the safety climate in healthcare settings (Kho et al., 2005). This tool encompasses different items related to handling errors, safety concerns, leadership and overall safety recommendations (Kho et al., 2005). Both the SAQ and SCS are valid and reliable tools to measure patient safety culture, but the SAQ is more detailed and includes more items to determine patient safety culture compared to SCS.

Despite the differences in these tools, they share the similar purpose of assessing the perceptions and attitudes of healthcare professional towards patient safety culture. Therefore, all the tools address similar core dimensions of a patient safety culture, including communication, teamworking, leadership, organisational learning and the management of safety (Singla et al., 2006). Although no particular survey is recommended over another, Singla et al. (2006) conducted a systematic review to identify patient safety culture measurement tools, which highlighted the fact that the HSOPSC survey and the Safety Attitude Questionnaire (SAQ) are only 2 out of 13 surveys that provide a range of wider comparative data that may be useful for a comprehensive assessment of patient safety cultures. Therefore, the researcher

selected the HSOPSC tool in the current study, as stated in the section 5.2.2, because it is a useful instrument that contains extensive information for assessing patient safety culture at a hospital level as a whole or at a unit level within a hospital. Moreover, it has been validated in different countries worldwide (Sorra and Dyer, 2010). In addition, since it can be used as a baseline assessment tool to assess patient safety culture or any improvements made over time, and is widely used in different locations in the Saudi healthcare context, it supports the aim of the current research to explore healthcare professionals' perception of patient safety culture.

3.10 Patient involvement in safety initiatives

Patient involvement in safety initiatives is increasing globally and becoming a core priority of the WHO programmes that enable patients and their family to engage with the provision of safe healthcare (World Health Organization, 2013). Although patient safety and minimising errors is the main responsibility of healthcare providers and healthcare systems, it is believed that the involvement of patients is crucial when promoting empowerment and awareness of medical errors (Davis et al., 2011, Vaismoradi et al., 2015). Patients, family and carers have been found to play an active role in ensuring the safety of the care received and they have the ability to participate in safety initiatives to avoid harm (Hor et al., 2013, Hernan et al., 2015). A literature review undertaken by Entwistle et al. (2005) found that patients both have the ability and are willing to identify adverse events in their care that might not be captured or reported by healthcare professionals. Another study conducted by O'Hara et al. (2018) used a cluster randomised controlled trial, conducted in 33 hospital wards across three NHS trusts (five hospital sites) in the north of England, and included 2471 inpatients to explore experience of safety within hospital. The study concluded that patient participation in patient safety is valuable, as it contributes effectively to reporting any safety concerns that occur in healthcare organisations. There are different strategies that can be employed to support the active involvement of patients in safety management, including patient voice programmes, education, training on reporting adverse events, and involvement in decision making (Severinsson and Holm, 2015). For example, a systematic review of 28 studies undertaken by Davis et al. (2015) looking into the effectiveness of strategies to involve patients in safety issues, such as reminding staff to wash their hands, found that the encouragement of participation in

safety issues is the most effective strategy to increase patient attention, which can be achieved by reinforcement and recognition from healthcare professionals of the patients' role in patient safety. A quasi-experimental intervention study was undertaken by (Schwappach et al., 2013) to investigate the effect of a patient safety campaign on patient safety behaviours and adverse events. The study reported that safety advisory in terms of educational campaigns has the potential to decrease adverse events and unsafe situations because it provides awareness and perceived behavioural control without increasing safety concerns, and is a useful tool to share safety information with patients and healthcare workers (Schwappach et al., 2013). Strategies to support patient involvement in safety initiatives will be considered further in relation to the current study findings in the discussion chapter.

The effectiveness of the involvement of patients in safety initiatives was found to be particularly high when patients participated in improving their own safety (Davis et al., 2011). For example, patients can use a treatment diary, share information about adverse events and allergies, and self-manage conditions, for instance with self-kidney dialysis at home and parenteral feeding (Severinsson and Holm, 2015). A systematic review of 14 individual experimental and quasiexperimental studies plus one systematic review conducted by Hall et al. (2010) to determine the effectiveness of interventions designed to promote patient involvement in improving safety found that strengthening patient participation in evidence-based decision making can increase patient empowerment. Moreover, several safety problems occur at the point of patient care, at the bedside – for example, medication administration errors or improper hand washing – and have a relatively high likelihood of being noticed by patients (Schwappach, 2010).

In addition, recently, increasing attention has been paid to using patients' feedback and their experience to improve the safety and quality of healthcare (Longtin et al., 2010, Albutt et al., 2020). A mixed methods feasibility trial was undertaken by Hernan et al. (2020) in Australian primary care practices to investigate the feasibility of patient feedback on a safety intervention in primary care. The primary and secondary outcomes of the study were: including patient feedback of the factors contributing to safety, reporting safety incidences, and determining the safety culture in healthcare organisations. The study findings demonstrated that introducing an innovative patient

feedback intervention in primary care is feasible, and in this case, patients were contributing effectively to safety improvement strategies and activities (Hernan et al., 2020). Patient feedback and experiences provide important insights into safety issues in healthcare organisations. In the study by O'Hara et al. (2018) that used cluster randomised controlled trials, the most common issues raised by patients related to physical harm, emotional harm, medication issues, ward management, equipment failures, infection risks, staffing problems, dignity/respect, and food and nutrition (O'Hara et al., 2018). These issues are discussed in detail in the discussion chapter in terms of their relevance to the findings of the current study.

Initiatives to engage patients in improving safety have been adopted in some healthcare systems, including the NHS in UK, Australia and USA (Lawton et al., 2017). They allow patients to volunteer and to contribute to improvements in the safety of the healthcare system by completing a survey or participating in patient panels (Lawton et al., 2015). However, the involvement of patients in safety initiatives has been criticised for potentially increasing the responsibilities of patients, increasing anxiety and possibly influencing the level of trust between healthcare providers and patient (Bishop and Macdonald, 2017). Bishop and Macdonald (2017) undertook a qualitative study in Canada using focus groups with patients to describe patients' perception of their involvement in patient safety, and stressed the importance of encouraging patients to participate in patient safety initiatives. Despite the effectiveness of patient involvement in safety initiatives, some of the safety initiatives focus solely on healthcare professionals or systems change only, and there is a limited amount of research involving patients' perspectives of the evaluation of patient safety (Vaismoradi et al., 2015). The current study addressed these gaps in the evidence by involving patients and family members in addressing the barriers and facilitators towards patient safety culture, as discussed in section 1.3. Therefore, it is believed that safety initiatives that encourage the engagement of patients and their family, as the main consumers of healthcare services, would be beneficial to understand the barriers and concerns related to the safety of healthcare delivery (Severinsson and Holm, 2015).

3.11 Status of patient safety culture in Saudi Arabia

The previous sections have considered patient safety in countries across the world; in this section, it is important to assess patient safety culture in Saudi Arabia, since it helps to provide a clear picture of the situation of patient safety culture and identify any gaps in the research area. Several studies conducted in Saudi Arabia are concerned with the assessment of the patient safety culture (Alahmadi, 2010, Aboshaiqah and Baker, 2013, Hamadan et al., 2017, Walston et al., 2010, El-Jardali et al., 2014). Alahmadi (2010) conducted a longitudinal study in 13 general hospitals in Riyadh using questionnaires with 1224 healthcare professionals to evaluate the organisations' culture and how it supported patient safety. The study revealed that under-reporting of events, blame culture, communication and leadership are the areas that need most improvement. The findings of this study are likely to resonate with the experiences of many healthcare professionals in Saudi Arabia as it employed a large sample size and covered a broad geographical area (13 hospitals).

Hamadan et al. (2017) carried out a longitudinal survey in the isolation unit located in King Fahad medical city in Riyadh to assess the perceptions of patient safety culture among nurses (n=92). The study used the English version of the Hospital Survey on Patients Safety Culture (HSOPSC) (Sorra and Nieva, 2004a), and it is clear from their findings that the majority of participants graded the patient safety culture in their organisation as very good (53.8%). However, the generalisation of these findings may be limited due to the small sample size (92 participants) and the fact that the sample was taken from one department's isolation unit. In addition, the population of this study was limited to nurses, which limited the representativeness of the sample by omitting the perspective of different multidisciplinary teams (Polit and Beck, 2017). Therefore, multiple perspectives of the patient safety culture from a broader range of healthcare settings would provide more rigorous conclusions regarding perceptions of the safety culture (Dekker, 2016).

A cross-sectional study conducted by Walston et al. (2010) to investigate the climate of hospital patients' safety in Riyadh, Saudi Arabia, using a questionnaire containing 60 items related to personal characteristics and safety climate dimensions. The study involved a large sample size – 496 participants from four hospitals – and a wider population including physicians, nurses, pharmacists and technicians. The findings of

this research revealed that the safety climates of the hospitals were reported to be influenced by three factors: management support, reporting systems and resource adequacy (Walston et al., 2010). While this study focused on the perspectives of healthcare professionals, their findings did not provide evidence regarding patient perspectives about the safety climate. Moreover, this study showed that there is diversity in the safety climates among the participating hospitals. For example, MoH hospitals were found to be significantly higher in terms of their reported positive safety climate compared to others hospitals such as private and university hospitals (Walston et al., 2010).

In another cross-sectional descriptive study, (Aboshaiqah and Baker, 2013) aimed to identify factors contributing to patient safety culture from nurses' perspective and to explore their impact on the management of patient safety. The study used the HSOPSC survey tool that was used by a previous study (Alahmadi, 2010) and their participants (n=498) were registered nurses with a response rate of 83%. Numerous issues were identified that were believed to support the patient safety culture, including hospital management and organisational learning. In the hospital management context, patient safety was considered a top priority, and the hospital environment provided support for organisational learning skills (Alahmadi, 2010). However, communication, hospital handovers and a non-punitive response to errors were found to be the elements that mostly affected the patient safety culture (Aboshaiqah and Baker, 2013). A blame culture is one of the most substantial barriers to reporting errors, as it increases the fear of punishment and losing a job (Waring, 2005). The study of Aboshaiqah and Baker (2013) highlighted the fact that a diversity of culture and language among staff nurses seemed to be a strong issue that reduced the ability of nurses to speak freely regarding their patient safety concerns.

A descriptive cross-sectional design study by (Alquwez et al., 2018) involved 351 nurses working in three general hospitals in the central region of Saudi Arabia, using the HSOPSC tool to assess the status of patient safety culture in the selected hospitals, as perceived by nurses. The study reported that nurses perceived only two patient safety areas as strengths: teamwork within units and organisational learning – continuous improvement. On the other hand, six areas of patient safety were identified as weaknesses, namely, overall perception of patient safety, handoffs and transitions,

communication openness, staffing, frequency of events reported, and nonpunitive response to errors. Further, Alzahrani et al. (2018) conducted a cross-sectional study aiming to investigate the safety attitudes of doctors and nurses (n=503) employed in emergency departments of two MoH hospitals in Saudi Arabia using the SAQ questionnaire. The results of the study revealed that there is a negative attitude towards patient safety among nurses and doctors on every dimension of the SAQ, especially those related to hospital management and stress recognition (Alzahrani et al., 2018). Moreover, the study found that work environment and human resources were the most frequently reported safety concerns that affected the attitude of nurses and doctors towards patient safety.

A systematic review conducted by Elmontsri et al. (2017) explored the status of the patient safety culture in Arab countries including Saudi Arabia and provided comprehensive insight into the strengths and weaknesses of the patient safety culture. This review identified three elements that were considered strengths: organisational learning, teamwork and management support. On the other hand, a blame culture, staffing issues (insufficient staff and workload), and deficits in communication were particularly viewed as aspects that negatively influenced patient safety culture, and urgently required further improvements. Despite this review, (Elmontsri et al., 2017) described serious issues that might influence patients' safety culture in the Arab world and put patients at risks. However, their findings should be treated carefully due to some methodological aspects. Firstly, the review limited its inclusion criteria to quantitative studies that used a specific survey tool (HSOPSC) for assessing patient safety culture. Secondly, the review excluded studies based on patients' perspectives or involved patients and it focused on the healthcare perspective only, which may limit the factors that might potentially have been identified from the patients' view. This is addressed in the current study, where the perception of patient safety culture and related factors is explored from different stakeholders' perspectives (healthcare professionals and patients/family members), as outlined in (section 1.5).

The previous studies concerned with the patient safety culture in Saudi Arabia provide valuable insights into many of the aspects that seem to influence the safety and quality of healthcare services. However, most of these studies utilised a quantitative study design, using only a survey instrument to address patient safety culture dimensions

(Alahmadi, 2010, Aboshaiqah and Baker, 2013, Hamadan et al., 2017, Walston et al., 2010). A survey-only approach to measuring patient safety culture has been criticized for omitting details about contributing factors and underlying causes compromising its implementation and sustainability (Halligan and Zecevic, 2011, Marshall et al., 2017). It is evident that there is an absence of studies conducted in Saudi Arabia using a qualitative design or mixed methods approach to investigate the safety culture phenomena. This was an important gap that influenced the design of the current study (Chapter Four, section 4.3.2). Furthermore, there is a lack of robust evidence regarding the factors that promote safety culture in Saudi Arabia, as discussed in (section 1.2). Thus, identifying the factors contributing to the patient safety culture is essential, as it will improve our understanding of the strengths and weaknesses of patient safety management and inform improvement initiatives. Thereby, these gaps in the evidence regarding the factors that influence patient safety culture were covered in Phase I of the current study (Chapter Six).

Therefore, with an absence of studies conducted in Saudi Arabia that utilise a mixed methods design to investigate patient safety culture, the patient perspective of the safety culture remains unknown. To address current gaps in the evidence, the researcher conducted a sequential mixed methods study utilising different approaches including a systematic review and employing quantitative and qualitative approaches to enable the researcher to obtain a comprehensive understanding of the patient safety culture and underlying factors that shape this phenomenon in Saudi Arabia. The study was divided into three phases by their research methodology, in order to answer the research questions.

3.12 Chapter summary

This chapter reviewed the literature related to patient safety culture and highlighted the significant findings related to the aspects that influence patient safety culture, including the role of individuals and the system in the causation of errors. It is highlighted that patient safety issues are worldwide concerns, stressing the importance of assessing patient safety culture for the improvement of healthcare systems globally. The measurement tools and dimensions of patient safety culture were described, highlighting the importance of using a variety of methods to paint a

comprehensive picture of the safety culture in healthcare organisations. However, there is a limited qualitative understanding of the factors influencing patient safety culture, and relatively little patient involvement in patient safety initiatives. Therefore, this chapter discussed the importance of enabling patients and their families to become more involved in safety initiatives; this is regarded as a unique aspect that enhances patient safety via the shared understanding and responsibilities with healthcare professionals. While studies in the field of patient safety culture in the Saudi Arabian healthcare context focus on healthcare professionals, it is worth investigating patient safety culture from a wider perspective (healthcare professionals and patients/family members) using different methodological approaches. Thus, the next chapter presents a detailed justification of the research methodology that was adopted in the current study.

Chapter Four: Methodology

4.1 Introduction

This chapter explains the philosophical research underpinning this study. In addition, it provides a rationale for the chosen methodological approach and a detailed description of the mixed methods approaches. Specifically, this chapter covers the research design and explains the approach of the three phases (systematic review, quantitative study, and qualitative study) of this research to achieve the research aim and objectives stated below.

Study aim:

- The aim of this thesis is to obtain an understanding of the status of patient safety culture in Saudi Arabia, as well as the barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families).

Study objectives:

- To identify the factors contributing to the patient safety culture in Saudi Arabia.

- To explore healthcare professionals' perceptions of current patient safety culture in their workplace and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

- To explore the experiences and perceptions of patients and families towards patient safety culture and the impact of perceived barriers and facilitators on the implementation of a positive patient safety culture.

4.2 Research paradigm and philosophy

4.2.1 Research paradigms

Understanding the philosophical approaches to research is regarded as fundamental before conducting research to ensure that an appropriate philosophy underpins the research process and decision making in relation to the research process followed (Žukauskas et al., 2018). The researcher needs to have a clear vision of the

paradigms that provide philosophical, theoretical, instrumental, and methodological foundations (Saunders et al., 2009). In scientific research, a paradigm refers to a concept that encompasses theories and practices that shape and explain perception, beliefs, and awareness related to scientific research (Cohen et al., 2002). A scientific research paradigm is characterised by a rigorous procedure consisting of certain steps in order to create a link between the research questions and research aims with its methods (Cohen et al., 2002). According to Gliner et al. (2011), a scientific research paradigm consists of an approach to research, a way of accomplishing it, and a way of putting it into practice. Therefore, it is believed that it is important to obtain clarity of the paradigm so that the researcher can structure their inquiry, making explicit the philosophical assumptions that underpin their methodological choices (Weaver and Olson, 2006). The key to understanding paradigms is to understand how they bridge disciplines' requirements for knowledge with their methodologies to generate that knowledge (Al-Ababneh, 2020). According to Scotland (2012), paradigms are comprised of several components, which can be classified as: ontology, epistemology, methodology, and methods. It is vitally important for researchers to know the fundamental ontological and epistemological assumptions and to further understand how these assumptions determine the selection of appropriate methodologies and methods (Scotland, 2012).

Ontology refers to the nature of reality and is concerned with the study of the nature of phenomena as they exist (Žukauskas et al., 2018). Ontological assumptions refer to how we view the world; researchers need to take a stance on their understanding of how something really is and how it works (Alharahsheh and Pius, 2020). Ontology is important for research in science, as it helps researchers recognise the level of certainty they can have about the nature or existence of the objects they are studying (Weaver and Olson, 2006, Saunders et al., 2009). On the other hand, epistemology is concerned with the nature and form of knowledge (Moon and Blackman, 2014). Epistemological assumptions are defined as assumptions about how knowledge can be generated, acquired, maintained and communicated (Scotland, 2012). In this respect, epistemology is concerned with how a researcher aims to discover knowledge to reach reality, distinguish between right and wrong, and view the world around them (Moon and Blackman, 2014, Alharahsheh and Pius, 2020). Therefore, epistemological assumptions are considered important because they influence how

researchers frame their research and deal with such issues validity, scope, and methods of acquiring knowledge, how to produce or gain knowledge, and determining to what extent it is applicable (Saunders et al., 2009). The key issue with epistemology is how the process of gathering information is conducted (Alharahsheh and Pius, 2020).

In relation to the methodology, this refers to the general research strategy to accomplish the research, identifying the methods that will be used in line with the outlined research plan (Scotland, 2012). A methodology is a design process that guides the way research is conducted, not the instruments or methods that are used in the process (Moon and Blackman, 2014). Therefore, the methodological assumption does not specify any specific method to be followed, but rather emphasises the nature of the procedure followed to attain the goal of the research (Igwenagu, 2016). In contrast, methods are defined as those techniques and procedures used to collect and analyse data (Scotland, 2012).

4.2.2 Research philosophy

A scientific research philosophy is a system of thought that guides a researcher in gaining new, reliable knowledge of the research object (Žukauskas et al., 2018). However, each researcher is guided by their own approach to the research itself (Moon and Blackman, 2014). Therefore, different researchers may hold different assumptions about the nature of truth and knowledge, as well as about how it is acquired. Many authors have distinguished and discussed four major approaches to research philosophy: positivist, interpretivist, pragmatist, and realistic research philosophy (Saunders et al., 2009, Žukauskas et al., 2018, Creswell and Creswell, 2018). Positivist philosophy is objectivist, based on the beliefs that knowledge is gained through the scientific method based on the unprejudiced use of the senses, meaning it is accurate and true (Moon and Blackman, 2014). In positivism, scientists dissociate themselves from personal values and work independently based on objective analysis, most typically associated with quantitative methodologies (Crossan, 2003). The positivist view of the world provides assurance of unambiguous and accurate facts about the world and it is something posited, something that is given (Crossan, 2003). The principle of positivism is what is posited or given through

direct experience and what is observed when applying scientific methods (Al-Ababneh, 2020).

In contrast to the positivist research philosophy is the interpretivist philosophy, in which a researcher understand the social world based on principles of what the researcher interest are (Saunders et al., 2009). The interpretivist research philosophy, typically embodied in qualitative methodologies, proposes that the social world can be interpreted subjectively (Saunders et al., 2009). A fundamental principle of interpretivism is the idea that the researcher plays a specific role in observing society as it exists (Žukauskas et al., 2018, Crossan, 2003). In addition, the interpretivist paradigm assumes that reality is subjective and that individuals perceive reality differently (Al-Ababneh, 2020). Therefore, this type of approach would enable researchers to understand different factors including behavioural aspects based on participant experiences, which would contribute to the description of reality based on the assumptions and beliefs of the interpretivist researcher (Alharahsheh and Pius, 2020).

In relation to pragmatism, this approach declares that the choice of research philosophy is determined mainly by the research problem (Al-Ababneh, 2020). A pragmatist is not inherently driven by one perspective or another and uses a combination of philosophical approaches to address the research question. This way, researchers are free to select the methods, techniques, and procedures that meet their needs and scientific objectives (Creswell and Creswell, 2018, Saunders et al., 2009). A pragmatist philosophy lies somewhere between the positivist and interpretivist research philosophies, where researchers use both objective and subjective criteria to bring multiple explanations and interpretations for science (Creswell and Creswell, 2018). Hence, pragmatism provides the foundation for mixed methods studies, where the researcher uses both types of data because, when combined, both types of data provide the most insightful results (Creswell and Creswell, 2018). Another philosophy that relates to scientific enquiry is realism, which asserts that there is a world of reality separate and independent of thoughts and beliefs (Žukauskas et al., 2018). This research philosophy is based on the principles of positivism and interpretivism and assumes a scientific approach to knowledge development (Žukauskas et al., 2018). Two types of realism exist: direct realism and

critical realism. In direct realism, researchers are seeing the real world accurately, while critical realist researchers see the world as sensations rather than real things directly, requiring more critical analysis (Saunders et al., 2009).

Pragmatism was the philosophical assumption employed for this study, since it is a good fit for stances or positions driving knowledge claims in mixed methods studies (Creswell and Creswell, 2018, Biesta, 2010). By employing mixed methods research based on pragmatic philosophical assumptions, the researcher can then choose methods and assumptions that best address the concerns or problems they seek to solve (Morgan, 2007). Thus, in the current study, pragmatic assumptions are supported by using either quantitative approaches or qualitative approaches that facilitate exploration of patient safety culture based on both subjectivism and objectivism (Tashakkori and Teddlie, 2010, Morgan, 2007). In the quantitative phase of the current study, a positivist paradigm was employed in a deductive process based on theories and concepts about patient safety culture dimensions (Saunders et al., 2009, Moon and Blackman, 2014). This is considered valuable, because it enables researchers to focus on measuring the phenomena within systematic investigations. From there, data was collected to prove or disprove those theories and concepts (Tashakkori and Teddlie, 2010). As a consequence, natural and social science methods were used in this study, enabling analysis of perceptions among healthcare workers and explaining them through statistical techniques. The quantitative phase aimed to describe the patient safety culture in Saudi Arabia, however, in order to adequately explain and explore patient safety issues identified in the quantitative phase in further depth, an interpretive, qualitative approach was also necessary (Saunders et al., 2009). This was achieved using an inductive approach in which the researcher gathered data from healthcare professionals and patients through interviews and focus groups. A qualitative lens was important for providing a deeper understanding of meanings rather than only 'facts', and then developed concepts based on the analysis of the subsequent data (Moon and Blackman, 2014). From a patient safety perspective, a qualitative approach was important because it provides details regarding the viewpoints and beliefs of individuals regarding safety culture, as opposed to the predominant use of quantitative methods that do not provide as much rich data (Churruca et al., 2021).

4.3 Mixed methods research

In social science methodological literature, the mixed methods approach was first used by Campbell and Fiske (1959) in their article that formalised the practice of using multiple research methods (Johnson et al., 2007). Generally, the term 'mixed methods research' refers to research that integrates both qualitative and quantitative data in one study (Tashakkori and Teddlie, 2010, Wilkinson and Staley, 2019). A key aspect of the definition of mixed methods research is the mixing of the qualitative and quantitative components within the study (Halcomb and Hickman, 2015). Thereby, it is believed that when using mixed methods research, the qualitative and quantitative elements are integrated to produce a comprehensive understanding of the research problem which can occur at any stage of research, but is critical to its validity and rigour (McKim, 2017). A mixed methods research design is a research approach that is based on its own philosophical assumptions and methods of investigation in order to provide directions on gathering and analysing data from multiple sources (Maxwell, 2016). Mixed methods research is defined by Johnson et al. (2007) as follows:

''Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration'' (p.123)*.*

Another definition of mixed methods is provided by (Creswell and Creswell, 2018):

''Mixed methods involves combining or integration of qualitative and quantitative research and data in a research study'' (p.14)*.*

Many researchers have debated that combining two different research approaches, qualitative and quantitative within a single study, leads to mixed world views in defining knowledge and how we acquire it (Venkatesh et al., 2013). Mixed methods research has been described as the third methodological paradigm, with quantitative and qualitative methods being the first and second paradigms, respectively (Venkatesh et al., 2013). While proponents of mixed methods research have highlighted areas where combining methods could be more efficient than a single method design, there has been debate regarding whether or not combining methods based on radically different

paradigms is even effective (Doyle et al., 2009). Despite this, mixed methods have received considerable attention and have been regarded to be of particular value when researchers are seeking an overall understanding of a phenomenon where research is fragmented, inconclusive, or ambiguous (Venkatesh et al., 2013). Thus, there has been a movement towards promoting 'mixed methods' which combine qualitative and quantitative approaches, noting that many studies will use one method as the primary one, but all studies are enhanced by combining these methods as well.

According to Venkatesh et al. (2013), there are seven purposes and justifications for combining quantitative and qualitative data in a research study: complementarity, completeness, developmental, expansion, corroboration/ confirmation, compensation, and diversity (Table 4.1). In relation to complementarity, this concerns obtaining mutual viewpoints about similar experiences or associations (Venkatesh et al., 2013). The idea is that both types of research have value and are complementary in some respects, thus combining them will have added value to the study findings. As a result, both data sets are used in order to answer the same research question, giving researchers greater certainty and wider implications (Maxwell, 2016). Another benefit of mixed methods research is the expansion of the study, which concerns explanation or clarification of a prior method. This means that a mixed methods design is an approach that enables researchers to explore their field with sufficient depth and breadth (Dawadi et al., 2021).

Table 4.1 Purposes of mixed methods

Purpose	Description
Complementarity	Mixed methods are used to gain complementary views about the same phenomenon or relationship
Completeness	Mixed method designs are used to make sure a complete picture is obtained
Developmental	Questions for one strand emerge from the inferences of a previous one (sequential mixed methods), or one strand provides hypotheses to be tested in the next one
Expansion	Mixed method designs are used to explain or expand upon the understanding obtained in a previous strand of a study
Corroboration/ confirmation	Mixed method designs are used to assess the credibility of inferences obtained from one approach (strand)
Compensation	Mixed methods enable the compensation of the weakness of one approach by using the other

Diversity	Mixed methods are used with the hope of obtaining divergent views of the same phenomenon

In addition, research combining quantitative and qualitative analysis helps to bridge the epistemological gap between the two paradigms by providing a more encompassing approach to knowledge creation (Wilkinson and Staley, 2019). It is argued that using both methods together is likely to aid researchers in developing a more comprehensive and in-depth understanding of a research topic (Terrell, 2012). The mixed methods approach helps to compensate for one method's weaknesses by employing another (Dawadi et al., 2021). As such, a quantitative approach can provide strong results where a qualitative approach is weak, and vice versa. Moreover, the triangulation component of a mixed methods approach is another advantage. The combination of different types of data can provide insights into phenomena that the individual methods cannot, which results in more valid and more robust conclusions than a single method can provide (Doyle et al., 2009, Tashakkori and Teddlie, 2010). Thus, triangulating data leads to a well-validated conclusion as well as enhancing the credibility of inferences derived from a single approach (Venkatesh et al., 2013).

In a research study, this process of combining methods is called triangulation, which helps ensure that the biases resulting from the use of a single method or a single observer are overcome (Noble and Heale, 2019). Campbell and Fiske (1959) described triangulation as multiple operationalism, which implies that using more than one method as part of a validation process ensures that the explained variance reflects the underlying phenomena. Triangulation refers to the attempt to interrogate different ways of understanding a research problem from combining different perspectives (method triangulation) or from different findings (data triangulation) (Tashakkori and Teddlie, 2010).

In spite of the potential benefits of using mixed methods research, conducting mixed research studies can be challenging compared with a single approach (Tashakkori and Teddlie, 2010). Firstly, it might be more costly and time consuming to collect and analyse data (David et al., 2018). Research design, specifically budget and time estimations, can be a challenge for researchers. While quantitative and qualitative methods carrying different epistemological and philosophical frameworks, there are a

number of concerns regarding their integration, including whether the assumptions in each paradigm are granted equal value in the study and whether the data obtained through the two methodologies are viewed as incomparable (Doyle et al., 2009, Venkatesh et al., 2013). An essential task of the mixed methods approach is to choose and maintain a suitable design and data integration (Dawadi et al., 2021). The appropriateness of a design is highly dependent upon the study's purpose and the relative importance of the qualitative and quantitative strands, and whether both data sets are given equal weight or if one dominates the other (Venkatesh et al., 2013). In the current study, the mixed methods approach was chosen as the most appropriate design to investigate patient safety culture from different perspectives; the justification for the selection of this method is presented in section 4.3.2.

4.3.1 Types of mixed methods research

There are various types of mixed methods research design, regarded by scholars as efficient and practical since they offer the most opportunities for building researchers' understanding of a mixed methods research design as outlined in Table 4.2, below (Creswell and Creswell, 2018, Terrell, 2012, Wilkinson and Staley, 2019). First is the convergent parallel mixed methods design. A convergent design, a popular approach to mixing methods, follows pragmatism as a theoretical assumption (Creswell and Creswell, 2018, Yvonne Feilzer, 2010). It is based on the combination of qualitative and quantitative approaches to generate triangulated results (Arghode, 2012). The first step involves collecting two different types of data simultaneously, then analysing them independently using quantitative and qualitative methods of data analysis. An integrated approach to research helps researchers gain a more comprehensive picture than using purely quantitative or qualitative data alone (Terrell, 2012). Therefore, this approach combines two data sets to obtain a complete picture of an issue and to verify one set of findings with another (McKim, 2017).

Table 4.2 Types of mixed methods research

Types of mixed methods	Description
Convergent parallel mixed methods	The quantitative and qualitative data are collected simultaneously and analysed separately. Both results are compared to derive overall conclusion.

Exploratory sequential design	The qualitative data are collected and analysed first, followed by the quantitative data. Quantitative data help to confirm or validate the qualitative data.
Explanatory sequential design	The quantitative data are collected and analysed first, followed by the qualitative data. Qualitative data help to explain and contextualise the quantitative data.
Embedded designs	Data are collected quantitatively and qualitatively at the same time, but part of a larger quantitative or qualitative design. One type of data is secondary to the other.

Second is the exploratory sequential design. In an exploratory sequential design, researchers apply the constructivist principle as they explore an issue in-depth during the first phase, and turn to the post-positivist principle during phase two to identify and measure the variable and statistical trend (Creswell and Creswell, 2018). This approach first collects qualitative information to uncover a phenomenon, and then gathers quantitative information to confirm it (Wilkinson and Staley, 2019). Therefore, an analysis of qualitative data helps develop quantitative measures or instruments from the qualitative findings. Finally, the researcher tests the variable that they identified quantitatively and evaluates how the quantitative data extends and generalises the qualitative findings (Terrell, 2012). It is argued that the exploratory sequential design can be used when the researcher and research issue are more qualitatively oriented, which requires a substantial amount of time and the researcher wishes to test the product's transferability or generalisability to a larger sample of people (Creswell and Creswell, 2018).

Third is the explanatory sequential design. This design involves both quantitative and qualitative phases; the first phase collects and analyses the quantitative data, and the second phase collects and analyses the qualitative data, which it uses to explain the quantitative results (Creswell and Creswell, 2018). In this design, a quantitative finding is followed up and explained through qualitative data (Maxwell, 2016). The qualitative design helps explain certain quantitative results, and the findings from the quantitative phase inform the formulation of qualitative research questions. For example, it allows the researcher to formulate appropriate follow-up questions during a focus group interview or individual interview.

Fourthly, embedded designs are characterised by one dominant method, while the other data set plays a secondary or supporting role (Doyle et al., 2009). In this design, it is presumed that a single data set is not sufficient; different questions need to be answered and different types of data are required for each type of question (Doyle et al., 2009). A key component of the embedded design is a collection of both quantitative and qualitative data, although one of the data types has an additional role as part of the overall work (Creswell et al., 2003). Therefore, using this design is helpful when a researcher wishes to integrate a qualitative component into a quantitative design, as in an experimental or correlational design (Halcomb and Hickman, 2015).

The integration process refers to the mixing or integrating of quantitative and qualitative techniques during a particular stage of the research process (Tashakkori and Teddlie, 2010). In this regard, integration refers to the synthesis or mixing of the data that occurs at any point throughout the research process – during data collection, analysis or interpretation (Fetters et al., 2013). According to Zhang and Creswell (2013), there are three distinct mixing procedures within the mixed methods literature, namely integration, connection, and embedding. An integration approach consists of collecting two sets of data concurrently (qualitative and quantitative) and analysing each set separately, so here the integration occurs during the interpretation (Zhang and Creswell, 2013). In relation to connection, researchers can mix the two data sets in phases in mixed methods studies, such that one approach builds on the findings of another (Zhang and Creswell, 2013). In embedding, one of the data types is embedded within the other, frequently a small qualitative component nested within a larger quantitative study (Zhang and Creswell, 2013). Integrating qualitative and quantitative research approaches can be done at the level of design, methods, and interpretation and reporting of results (Fetters et al., 2013). In terms of integration at the design level, there are three basic types of design and four advanced mixed methods frameworks incorporating one of the basic types, including exploratory sequential, explanatory sequential, and convergent designs (Fetters et al., 2013). For integration at the methods level, data collection and analysis is achieved by connecting, building, merging, and embedding the data (Zhang and Creswell, 2013). Finally, in terms of integration at the interpretation and reporting level, qualitative and quantitative data is incorporated via three approaches: integrating by narrative,

integrating by data transformation, and integrating by joint displays (Fetters et al., 2013). The next section describes the rationale behind the selection of the mixed methods design utilised in the current study.

4.3.2 Justification for selecting a mixed methods study design

The current study adopted a mixed methods design due to the large number of studies, both internationally and in the Saudi context, explaining patient safety culture using quantitative research based on surveys alone (Elmontsri et al., 2017, Halligan and Zecevic, 2011). This leads to lower weight compared to qualitative research that offers more holistic detail of factors influencing patient safety culture (Titi et al., 2021). For this reason, the mixed methods approach was chosen for use in the current study because qualitative research complements quantitative research in the explanation of findings, and enables deeper insight (Tashakkori and Teddlie, 2010) into, in the case of the current study, safety culture. Quantitative methods can identify factors that are statistically associated with patient safety culture, but they may not explain why they are associated with it (Halligan and Zecevic, 2011). Several authors argue for the worthiness of combining qualitative and quantitative approaches in exploring a complex and sensitive topic such as patient safety, as discussed in section 3.11 (Listyowardojo et al., 2017, Wami et al., 2016a, Halligan and Zecevic, 2011). Mixing multiple research methods allows for a more substantial theoretical contribution and enables multiple research questions to be examined concurrently (Tashakkori and Teddlie, 2010). In the current mixed methods study, qualitative and quantitative methods complement each other to provide greater insight into a phenomenon than they can provide individually (Wilkinson and Staley, 2019).

Although there are many study designs in the mixed methods field, an explanatory sequential mixed methods design was selected for this study as it is the most suitable method of obtaining answers to the overall research questions (Creswell and Creswell, 2018). Sequential explanations can be used to explain quantitative outcomes through the collection and analysis of qualitative data (Maxwell, 2016). Further information about patient safety culture is provided through the qualitative component, identifying determinants and highlighting key issues and concerns. Therefore, using a sequential mixed methods design in the current study bridges the gaps in the evidence base related to the lack of studies in Saudi Arabia utilising

qualitative approach in addition to a quantitative approach when exploring the underlying factors that shape safety culture. In addition, with increasing attention on patient and family involvement in safety issues and its impact on safety culture (Albutt et al., 2020), as well as the growing knowledge gap on patient perspectives in Saudi Arabia, these gaps are being filled by the use of the qualitative approach as the most appropriate means of accessing patient and family views regarding safety culture.

In the current study, both quantitative and qualitative data were collected and analysed separately. Thereby, integration took place at the level of interpretation and reporting of the results. Consequently, the quantitative findings provided a solid foundation for building and designing the qualitative component. Interview questions for healthcare professionals' focus groups discussions were developed following analysis of the quantitative component. It was deemed important to explain the quantitative findings in greater depth to understand the perceptions of key stakeholders about patient safety culture (Halligan and Zecevic, 2011). As Creswell and Creswell (2018) argue, collecting quantitative and qualitative data allows researchers to combine and triangulate the results obtained from each form of data to obtain insights into the accuracy and validity of the other than would be possible with either type of data alone. Another benefit of mixed methods research reported by Creswell and Creswell (2018) is that one type of data can help to explain another, so that both data types can be built upon each other. Therefore, in the current study, quantitative and qualitative designs were used with multiple measures from various complementary sources of the same phenomenon (Greene, 2008). In the quantitative approach, a cross-sectional survey design was adopted using a validated and reliable self-administrated questionnaire to measure patient safety culture perception among healthcare professionals (addressing RQ2). The data was supplemented by a qualitative approach that adopted a case study design to provide in-depth understanding from multiple perspectives, experiences and processes that shape and influence the implementation of a positive patient safety culture (addressing RQs 3 and 4) (Creswell and Creswell, 2018).

The current study phases are discussed in detail in the following section. The justification for the overall design for each study phase is also presented, and the aligned to each phase methods are discussed in Chapter Five.

4.4 Systematic review approach (Phase I)

4.4.1 Rationale for adopting a systematic review approach

Conducting a systematic review is widely regarded as a gold standard approach that identifies, appraises and synthesises the best accessible evidence in order to guide clinical practice and inform the direction of further research enquiries (Boland et al., 2017). Although there are different types of literature review, the best-known type is a systematic review due to its use of a defined and transparent methodology that reduces the risk of bias (Grant and Booth, 2009).The evidence drawn from systematic reviews, therefore, is considered to be more reliable and transparent due to the fact that the methods are rigorous/using exhaustive searching to ensure no evidence is overlooked (Bettany-Saltikov, 2012, Boland et al., 2017). The process of a systematic review follows a research protocol that clearly states the research question and provides details of the review methods, which allows the reader to assess the validity and quality of the review findings.

In addition, the systematic review approach is considered robust and reliable as it provides methodological transparency and replicability of the process for future research (Grant and Booth, 2009). Thereby, systematic reviews' features outweigh those of other types of reviews such as general literature reviews where the criteria for the selection of papers are not always clearly stated (Boland et al., 2017). For example, the possibility of bias with a general review may increase as the researcher might select literature that supports their views and beliefs (Boland et al., 2017). However, the structured approach within a systematic review allows the researcher to assess the methodological quality of each study included, which demonstrates the quality and value of the review findings. Boland et al. (2017) stated that there are 10 steps to conducting a systematic review (Figure 4.1), which will provide structured scientific methods that minimise bias and enhance the rigour of the review.

1 • Planning the review
2 • Performing scoping search, identify review question
3 • Literature searching
4 • Screening title and abstract
5 • Obtaining papers
6 • Selecting full -text papers
7 • Data extraction
8 • Quality assessment
9 • Analysis and synthesis
10 • Writing up, editing and disseminating
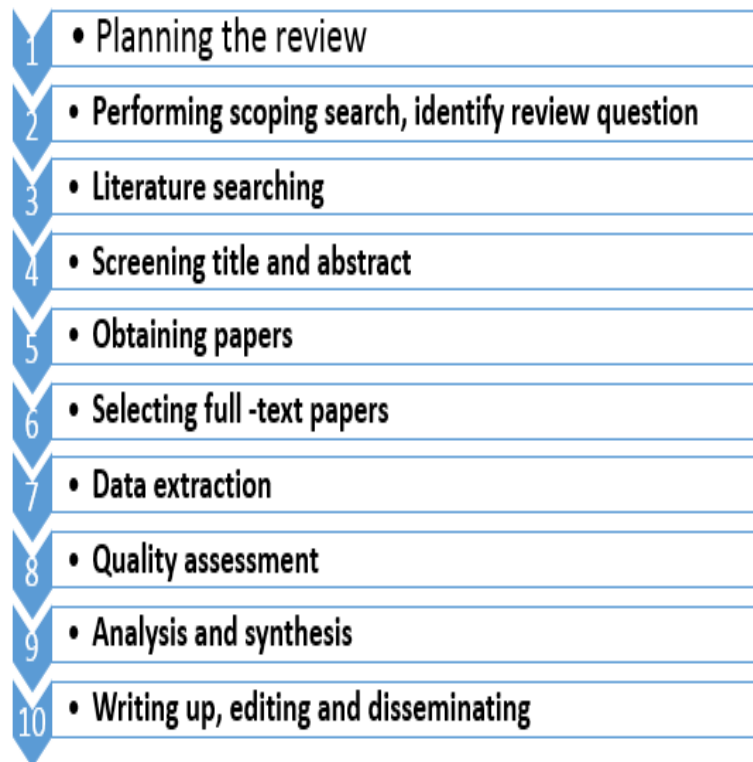
Figure 4.1 Steps of conducting a systematic review (Boland et al., 2017)

4.4.2 Systematic review level evidence for patient safety culture in Saudi Arabia

While there is increasing focus on the patient safety culture in Saudi Arabia (Al Wahabi et al., 2017), there have been no systematic reviews providing evidence about the factors contributing to the patient safety culture in Saudi Arabia specifically. The most recent systematic review relevant to the context of the review reported on in this chapter was conducted by Elmontsri et al. (2017); it provided evidence on the status of the patient safety culture across a number of Arab countries. Although Saudi Arabia was included, it was not a specific focus of the paper. Elmontsri et al.'s (2017) review concludes that the blame culture and communication are the most serious issues reported in health care organisations in Arab countries. However, their review limited the included studies to those using only the HSOPSC as a measurement tool for patient safety culture. This could potentially mean that other relevant information from different study designs undertaken with different instruments is missing. It is also recognised that the evidence drawn from the Elmontsri et al.'s (2017) review was based solely on healthcare professionals' perspectives. Thereby, as the

patient/family perspective was not included in this review; they might have a different perspective of safety culture.

Considering the importance of the different healthcare systems among Arab countries and their impact on patient safety culture (as discussed in section 1.3), it would be beneficial for further systematic review to focus on the Saudi Arabia region and its health context to identify the factors contributing to the patient safety culture from different perspectives. In addition to this, the current review adopted the YCFF, which facilitates an understanding of the relevant contributing factors (Lawton et al., 2012). The methods used to undertake the review, and its findings, are reported on in Chapter Six.

4.5 Quantitative approach (Phase II)

4.5.1 Study design

A descriptive cross-sectional survey design was adopted for Phase II of this study (Polit and Beck, 2017). The objective of this phase was to assess the perspectives of patient safety culture among healthcare professionals (physicians, nurses, pharmacists and allied healthcare) through a self-administered questionnaire in the Madinah region of Saudi Arabia. A cross-sectional survey design involves collecting data once at a certain point in time (Polit and Beck, 2017). This study design is regarded as being useful in descriptive or exploratory studies when the researcher is interested in participant perspectives of patient safety culture in different settings (Sorra and Dyer, 2010). Thus, in the current study, data was gathered from multiple people and departments, allowing comparison and aggregation. Moreover, studies using cross-sectional designs are considered cost-effective because the data can be collected within a short period of time, people's privacy is maintained because of anonymity, and the researcher can examine a number of variables at the same time (Levin, 2006). It facilitates use of the same structured set of data collection instruments in different settings, which helps to reduce the cost of the research in terms of resources and minimises selection bias during data collection (Sedgwick, 2014). However, cross-sectional study designs cannot assess patient safety culture over time, which is one of their main limitations. However, capturing change over

time was not part of the current study's research questions, so this limitation is not relevant (Levin, 2006).

4.6 Qualitative approach (Phase III)

4.6.1 Study design

Phase III used a qualitative, case study design. In qualitative research, understanding and insights are explored in a particular context, and the researcher seeks to uncover the meanings behind the findings (Merriam and Tisdell, 2016). The focus of qualitative research is on how people interpret and understand their experiences as a way of understanding social reality (Tuffour, 2017). Thereby, it is concerned with understanding social issues that impact human interaction and behaviour (Creswell and Creswell, 2018). Research with qualitative methods is exploratory, evolving and takes place in real contexts where individuals are interacted with and their contexts are reflected upon (Choy, 2014). Therefore, researchers play an important role in qualitative research, as they are considered the primary tools for collecting data (Merriam and Tisdell, 2016). Moreover, the researcher's knowledge and background are integral to the process of conducting qualitative research, as they add context to the interviewing, observing, and analysing activities (Denzin and Lincoln, 2011). Hence, transparency and methodological awareness are key elements in establishing and ensuring the trustworthiness of the qualitative research (Denzin and Lincoln, 2011).

4.6.1.1 Qualitative approaches

A qualitative study can take several approaches, including ethnography, grounded theory, case studies, and phenomenology (Saunders et al., 2009, Creswell and Creswell, 2018). All of these approaches share an overarching aim, which is to understand human experience from its various perspectives, but they differ in their approaches and focuses (Polit and Beck, 2017). These approaches will be briefly considered here, and a rationale presented for why they were considered unsuitable for the current study, before going on to discuss the qualitative case study design in further detail.

In phenomenological studies, human experiences are described from the point of view of the people involved, which is called 'lived experience' (Polit and Beck, 2017). The purpose of this type of research is to investigate the presence of a specific phenomenon and use the data collected and the personal experiences of participants to explain the phenomenon (Teherani et al., 2015). Usually, a phenomenological study design focuses on individual experiences, daily lives, and daily social interactions, with the main methods of collecting data for this research being interviews and observations (Teherani et al., 2015). Phenomenology is seen as a useful approach, as it allows a deeper understanding of poorly understood areas, such as complex interaction processes, feelings, and practices (Goulding, 2005). As a result, phenomenology's fundamental principles are based on acknowledging human experience as a valuable source of knowledge (Goulding, 2005). However, phenomenological research was considered to be less suitable for addressing the aims and research questions of the current study. This was because phenomenology delves into the experience of individuals from the first-person view (Van Manen, 2017), as opposed to the case study, which provides in depth and a focused investigation of an individual, groups, and institutions regarding patient safety culture.

In an ethnographic research design, observing and analysing humans and their behaviour in their natural environment is part of this scientific methodology (Polit and Beck, 2017). Using this design, researchers can describe human behaviours and their cultural and symbolic dimensions by observing behaviours directly and defining them accordingly (Merriam and Tisdell, 2016). It is believed that a major aim of ethnography is primarily to explain how cultures are constructed and reinforced by the subcultures and behaviours of their members (Goulding, 2005, Yin, 2016). In ethnography, a key characteristic is that it is labour intensive and requires extensive direct contact with group members as a means of looking for rounded, holistic explanations (Yin, 2016). In the current study, an ethnographic design was not appropriate, as the researcher wanted to use methods such as interviews and focus groups in order to obtain deeper explanations for the survey findings, rather than simply observing actions and behaviours. Moreover, in response to the evidence of the existence of a blame culture within the Saudi Arabian healthcare context (Elmontsri et al., 2017), there was the possibility of staff

chaining behaviour because of a Hawthorne effect (Haessler, 2014). Therefore, the researcher may have difficulty obtaining enough information to fully understand the patient safety culture.

In grounded theory, the concept refers to studies that collect data, analyse the data, and then develop a theory based on the data (Goulding, 2005). This design differs in that it emphasises the development of a theory based on data collected during the research (Merriam and Tisdell, 2016). The key to this design is the development of embedded categories, which can then be used to form meaningful theories that explain study-specific behaviours (Turhan, 2019). This design helps explain social situations or processes through data utilising different data collection methods, including participant observation, interviews, and literature reviews (Turhan, 2019). As the current study aimed to understand the perceptions of stakeholders regarding patient safety culture, rather than to generate a conceptual theory to explain individual behaviour, a grounded theory approach was considered to be less suitable for addressing the aim and research questions of the current study.

The following sections present more detail on the case study design approach, and explains why this was considered to be the most suitable method to address the aims and research questions of the current study.

4.6.1.2 Case study design in more detail

In a case study design, individuals or groups of individuals, programmes, or institutions are examined in detail to provide insights into the issue within the case selected (Yin, 2017). Therefore, in case study research, the focus is not on the individual and their stories as it is in narrative research, but on the contextual understanding of the case and the issue being understood through the selected case (Yin, 2017). The case study method allows researchers to explore and comprehend complex issues from a qualitative angle as they are able to see beyond the quantitative statistics and understand the underlying behavioural conditions (Gerring, 2004). Case studies are often filled with detailed qualitative accounts that are valuable in describing or exploring data in real-life situations, but also explain the complexity of real-life situations not visible through experimental or survey research (Merriam and Tisdell, 2016).

According to the purpose of the study and the design chosen by the researcher, a case study can be categorised as quantitative or qualitative research (Houghton et al., 2013). The strength of case studies is their method of integrating different perspectives of knowledge about a specific phenomenon in the context of a data analysis process, where both quantitative and qualitative data are considered (Yin, 2017). Therefore, a qualitative case study requires the researcher to be interested in the meaning of experiences to the subjects rather than generalising the findings (Houghton et al., 2013). A case study incorporates multiple methods of collecting data and multiple methods of analysis in order to gain a holistic understanding of a phenomenon (Gerring, 2004).

There are three different types of case study, namely exploratory, explanatory, and descriptive (Yin, 2017). In exploratory case studies, the purpose is to investigate any phenomenon in the data that is of interest to the researcher. When a phenomenon under study does not have clear outcomes, an exploratory case study is used to examine the phenomenon. An explanatory case study investigates a real event in order to reach an explanation of how/why it happened. A descriptive case study describes natural phenomena occurring or related to the data (Yin, 2017). Within these different approaches to case study, there are also different designs, including holistic single case, embedded single case, holistic multiple case, and embedded multiple case designs as outlined in Table 4.3 (Yin, 2017). In terms of comparison between holistic and embedded case studies, the fundamental difference is that the holistic approach has only one unit of analysis whereas the embedded study approach has multiple units.

Table 4.3 Type of case study designs

Case study designs	Description
Holistic single case	One unit of analysis with a single study
Holistic multiple case	One unit of analysis with multiple cases to understand the differences and the similarities between the cases
Embedded single case	More than one unit of analysis with a single case
Embedded multiple case	More than one unit of analysis with multiple cases

4.6.1.3 Justification for case study design

In the current study, Phase III adopted a case study design in order to further explore and explain the patient safety culture in particular settings (that was identified from the findings of Phase II). Since the context and environment may influence and shape the presence of barriers and facilitators to a positive patient safety culture, Phase III aimed to explore and compare the similarities and differences of the different case study sites involved (Yin, 2017). The case study sites chosen for this study are discussed further in Chapter Five (section 5.3). The case study design is considered appropriate for use in complex and sensitive topics whereby the researcher studies the phenomena within their real-life context; in the current study, the researcher wanted to discover the underlying contextual factors that influence patient safety culture that required the adoption of different methods (Halligan and Zecevic, 2011). The case study design was also able to provide in-depth understanding from multiple perspectives, experiences, and processes (Creswell and Creswell (2018); thus, adopting this research design was suitable to identify the factors that shape patient safety culture in the Saudi Arabian healthcare context (addressing RQs 3 and 4). Moreover, it facilitated in-depth understanding of the barriers and facilitators that impact the implementation of a positive safety culture and specifically, why/how they are perceived to affect safety in clinical practice in Saudi Arabian hospitals.

An embedded single case study design was therefore adopted, which enabled the researcher to access and examine different case sites utilising a variety of data collection methods (Yin, 2017). Focus group discussions were used to obtain insights from healthcare professionals, with the use of semi-structured interviews to obtain patient/family member perspectives (Yin, 2016). The focus group and interview methods used will be further addressed in Chapter Five (section 5.3).

4.7 Chapter summary

The research paradigms, philosophy, and the selection of philosophy for the study were described and justified in this chapter. The current study used a mixed methods approach to investigate patient safety culture in Saudi Arabia from multiple perspectives: healthcare professionals and patients/family members. The selection of

the mixed methods approach was based on the current gaps of evidence including the lack of studies in Saudi Arabia investigating patient safety culture in more depth using a qualitative approach or mixed methods. Moreover, to date, the patient/family member perspective and their experiences of safety culture in Saudi Arabia remain relatively unknown. With this in mind, the use of mixed methods in the current study was useful to provide a range of perspectives that can be applied to the complexity of patient safety culture and to identify any underlying issues that are difficult to determine using single methods or one perspective. The current study is divided into three phases incorporating a systematic review, quantitative approach, and qualitative approach; thus, an explanation was provided for the choice of study design and methodology in order to address the study goals and research questions. The next chapter provides a detailed description of the methods adopted in the study phases to answer the research questions and develop an in-depth understanding of patient safety culture.

Chapter Five: Methods

5.1 Introduction

In the previous chapter, the researcher presented the methodological underpinnings of this research. This chapter presents the methods used in Phase II and Phase III. The Phase I systematic review methods are described in Chapter Six. Research methods describe how the researcher collects data and analyses it, which indicates the manner in which data collection and analysis are conducted and executed (Scotland, 2012). Therefore, the procedure and the details of the selection of participants, sampling, research instrument, collection process, and analysis process are described in this chapter.

5.2 Phase II (quantitative approach)

5.2.1 Study setting

The research was conducted in three hospitals located in the Madinah health region in the west of Saudi Arabia. The three hospitals – namely King Fahad Hospital, the Maternity and Children's Hospital, and Ohud Hospital – are located in Madinah city and are the largest public hospitals functioning under the Ministry of Health (MoH) in the region. King Fahad Hospital is a tertiary government hospital with 500 beds, which provides general and specific care, and covers all multidisciplinary teams and specialities. The Maternity and Children's Hospital also has 500 beds, while Ohud Hospital has 300 beds. The selection of these three large hospitals is due to their proximity within one geographical area, and all having similar organisational structures and managerial levels that facilitate prediction of patient safety culture in the Madinah region. Moreover, using multiple hospital sites was likely to be useful in purposively sampling a broader range of perspectives than from one site alone, and achieving the sample size required for the current study (Polit and Beck, 2017).

5.2.2 Data collection tool

The current study used the English version of the HSOPSC survey, which was developed in the US by AHRQ – it is initially discussed in section 3.9 and attached

in the appendices (Appendix 2) (Sorra and Nieva, 2004b). The researcher decided to use the English version of HSOPSC in this study, because English is the predominant language in the healthcare settings of Saudi Arabia. Secondly, the workforce diversity among healthcare professionals in the Saudi Arabian healthcare context (Almutairi et al. (2013) means that the English version would be more suitable. Permission to use the HSOPSC for the current study was obtained from AHRQ, as attached in Appendix 3.

5.2.3 Validity and reliability of the HSOPSC tool

The HSOPSC was developed and designed in order to assess the culture of patient safety among healthcare providers in hospital settings (Sorra and Nieva, 2004b). The survey was piloted with 1437 participants in US hospitals, and the results revealed that it is valid and reliable with acceptable reliability coefficients ranging from 0.63 to 0.84 in all 12 dimensions, according to Cronbach's alpha, which requires coefficients to be greater than or equal to 0.60 (Sorra and Nieva, 2004b). Sorra and Dyer (2010) conducted a study to assess the psychometric properties of HSOPSC dimensions using 331 hospitals, 2,267 units, and 50,513 hospital staff respondents. The study found that all 12 dimensions and 42 items included in the survey had acceptable psychometric properties at the three levels of analysis: individuals, units, and hospitals based on the analysis results of intraclass correlations, design effects, multilevel confirmatory factor analyses, model fit indices, item factor loadings, internal consistency reliability analyses, and dimension intercorrelations. Therefore, the HSOPSC questionnaire has been validated in many countries, and widely tested in different languages and cultures (Chen and Li, 2010, Perneger et al., 2014, Najjar et al., 2013). The psychometric properties of the Arabic version of the HSOPSC questionnaire were tested by Najjar et al. (2013), who concluded that it is similar to the original version, with good validity and acceptable reliability. Moreover, the original/English version of the HSOPSC tool has been used in previous studies in Saudi Arabia (Al-Ahmadi, 2009, Alahmadi, 2010, Aboshaiqah and Baker, 2013). This indicates its appropriateness for use in the Saudi healthcare context. Therefore, as stated earlier, with the communication language being English in Saudi Arabian healthcare settings, this survey tool was used without translation into Arabic, and was distributed as a web-based survey after an initial pilot study.

5.2.4 Pre-test of the web-based questionnaire/process

Prior to commencement of the study, an online survey website run by 'Jisc' was used to design the survey and create a link for distribution, which was supported by the University of Glasgow**.** It was important to perform a pre-test of the questionnaire so that any faults in the design and administration of the survey could be detected and addressed (Maymone et al., 2018). The pre-test of the web survey was conducted two weeks before the main data collection period began in order to test the distribution process and data collection procedure (Maymone et al., 2018). This was to ensure access to the web-based questionnaire worked properly and to check its readability and the practicality of recruitment via the website (Polit and Beck, 2017). The pre- test was conducted in two stages. Firstly, the questionnaire was sent to a group of supervisors and researchers at the University of Glasgow to check the design of the web page and the readability and accessibility of the survey. Secondly, the researcher sent the questionnaire to a small group of 10–15 healthcare professionals in the three selected hospitals, as mentioned above. This process of distribution was carried out by the IT department of Madinah Health Affairs, using a sample frame from the list provided by the human resources department. The participants in the pilot study were excluded from the main study. This strategy of piloting the web-based questionnaire was to provide the researcher with the ability to reduce any errors related to access and technical issues, and confirm its readability (Maymone et al., 2018). Consequently, no concerns were raised during the pre-test of the web-based questionnaire process.

5.2.5 Study population

The target population in Phase II was healthcare professionals (e.g., physicians, nurses, pharmacists and allied healthcare professionals) of any grade/level of experience working in one of the three selected hospitals.

Inclusion criteria

- Participants must be registered as healthcare professionals (e.g., physicians, nurses, pharmacists and technicians).

- Participants must have at least one year's post qualification experience to ensure that they have completed the hospital orientation and competency programme.

- Participants must work at one of the three hospitals selected (King Fahad Hospital, Maternity and Children's Hospital, or Ohud Hospital).

- Participants must be able to understand verbal and written English sufficiently to complete the questionnaire/consent forms and understand the participant information sheet.

Exclusion criteria

- Those unable to provide written informed consent.

- Those who are working in the hospital(s) but do not have direct contact with treatment or care plans, such as gatekeepers, cleaners, drivers, porters and administration services.

- All healthcare students.

- Those not working in one of the three hospitals selected above.

- Those with less than one year's experience.

- Those with insufficient understanding of verbal and written English.

5.2.6 Sample size

In this phase of the study, a nonprobability sampling approach was used to obtain the target population and to represent the entire population of workers across the three hospitals selected for the study (Polit and Beck, 2017). A convenience sampling method was employed to select potential participants from each hospital (Polit and Beck, 2017). The sample frame was determined by the information provided by the IT department in Madinah Health Affairs, from the list provided by the human resources department (DiGaetano, 2013). The total number of healthcare professionals working in the three hospitals at the time of the study, who fit the eligibility criteria, was targeted in order to establish a sample frame (DiGaetano, 2013). The total number of healthcare professionals was estimated to be 3,000; therefore, to calculate the sample size for Phase II, the guidelines set out by Rolfe

(2006) were used to determine the minimum sample size. Thus, the following formula was used to determine the sample size:

Sample size = $\frac{N}{1+N(e)2}$ which allows ±5 % margin of error and 95% confidence interval level. N= Population size, e= margin of error (.05).

Sample size = $\frac{N}{1+N(e)2}$ = $\frac{3000}{1+7.5}$ = 353 participants.

5.2.7 Site set up and access

The researcher, prior to the commencement of the study, visited Madinah Health Affairs and the three proposed hospitals, and held meetings with the IT department, managers and nursing directors. The purpose of these meetings was to introduce the study, explore the infrastructure in place, obtain support from managers, and raise awareness of the study among healthcare professionals. The IT department in Madinah Health Affairs confirmed their ability to generate the sample frame and disseminate the web-based survey. The dissemination process utilised the proposed hospitals' databases, using the email addresses of healthcare professionals to send anonymous invitations with URL links to the survey. The researcher provided the IT department with the link, and they subsequently distributed this to the potential participants from the sample frame identified.

5.2.8 Recruitment

Following identification of the potentially eligible participants by the IT department in the Madinah Health Affairs office, the researcher provided the link for distribution. The questionnaire was sent to potential participants via an anonymous URL with an accompanying invitation letter (Appendix 4), participant information sheet (Appendix 5), and privacy notice (Appendix 6). Recruitment was conducted between July and mid-August 2019. The distribution process was conducted by the IT department of Madinah Health Affairs using the email addresses of healthcare professionals. On the first page of the questionnaire, participants were asked to tick a box to indicate that they gave their consent to participate in the survey (Appendix 7). The researcher had no access to individuals' email addresses.

The first email was sent to participants at the beginning of the data collection period (July 2019), and reminder emails were sent after two weeks following the commencement of data collection to increase the response rate as suitable method stated by (Millar and Dillman, 2011). Moreover, the researcher employed strategies to increase the response rate, such as distribution of posters in hospital departments and using education department facilities to raise awareness/attention regarding the study (VanGeest et al., 2007, DiGaetano, 2013).

5.2.9 Data analysis

The quantitative data was analysed using SPSS (version 25) with a significance level of p-value of ≤ 0.05 used to report the statistical significance of results. The AHRQ guideline for analysing the HSOPSC data was followed in order to describe and interpret participants' responses toward patient safety culture dimensions (Sorra and Nieva, 2004b). Descriptive analysis (frequencies and percentages) was obtained for background demographic information about respondents (work area/unit, staff position, work experience, working hours, and whether they have direct interaction with patients, etc.). Following this, the researcher combined the two lowest response categories (Strongly disagree/Disagree and Never/Rarely) and the two highest response categories (Strongly agree/Agree and Most of the time/Always) for all items in all sections. This is recommended by the AHRQ guidelines to make the results easier to view in the report (Sorra and Nieva, 2004b). The midpoints of the scales are reported as a separate category (Neither or Sometimes). The use of multiple choice has some advantages, but there are also disadvantages, including that respondents are more likely to select the 'safe' option at the centre of the scale rather than revealing their true opinions – a phenomenon known as the central tendency bias (Kostoulas, 2013). In order to avoid this, it is recommended that items are provided with a number of options that encourage them to express a positive or negative opinion (Batterton and Hale, 2017). Nevertheless, when interpreting the data, Likert items with many potential responses can sometimes be condensed into a few categories that have more meaning (Kostoulas, 2013). This supports the AHRQ recommendation to condense positive and negative responses together, an approach that the current study also used.

The total percentage of positive, negative, and neutral scores were calculated for each questionnaire item. Then, a composite of positive frequencies was calculated by grouping 42 questionnaire items into 12 patient safety culture dimensions, as guided by the AHRQ guidelines, after reversing negatively worded items. Each dimension contained 3–4 survey items which were used to calculate an overall percentage of the positive frequency of each dimension. An average of the percentage of positive responses for all survey items in every dimension was calculated by adding the total number of positive responses within a composite/dimension (numerator) and dividing this by the total number of responses to all items (denominator) in the same composite. The dimension that had at least 70% positive response was considered an area of strength, whereas those scoring less were considered areas of improvement, as described by AHRQ guidelines (Sorra and Nieva, 2004b).

In addition, the survey included two additional items that asked respondents to provide an overall patient safety grade from 'Excellent' to 'Failing', as well as the number of events reported over the past 12 months (from 0–21 or more), which presented their results separately. Cronbach's alpha was conducted to assess the reliability of the HSOPSC survey instrument. One-way analysis of variance (ANOVA) was used to compare the mean scores of dimensions across hospitals, and post hoc tests were conducted to identify the differences when the ANOVAs were significant. One-way ANOVA was used to compare perceptions of patient safety culture with the demographic characteristics of individuals, including profession groups, experience, work unit, and work hours followed by post hoc tests (Tukey's test) were conducted to identify the differences when the ANOVAs were significant in the categorical study variables.

In the last section of the survey, participants were given space for their comments therefore, all the written comments provided by the participants were coded and analysed using the manifest content analysis approach (Bengtsson (2016). The manifest content analysis describes what is visible and present on the surface of a text and staying close to that text (Kondracki et al., 2002). It is concerned with data that are easily observable without needing to determine intent or uncover a deeper meaning (Kondracki et al., 2002). Therefore, in this part of survey, the manifest

content analysis was conducted with four main stages as follows: the decontextualisation, the recontextualisation, the categorisation, and the compilation (Bengtsson, 2016).

Decontextualisation: The researcher familiarises themselves with the data and identifies the meaning unit through a coding process. Every identified meaning unit is tagged with a code that should be understood in context.

Recontextualisation: The researcher labels equivalent units with the codes and ensures that all aspects of the content have been addressed.

Categorisation: The researcher creates categories (brings the subject together) by grouping similar codes to a category.

Compilation: Involves writing up, ensuring to stay close to the original meanings and contexts and refer back to the original text.

5.3 Phase III (qualitative approach)

5.3.1 Study setting

The researcher included two of the hospitals who participated in Phase II, both located in the Madinah region of Saudi Arabia and the study was conducted from September to December 2019. Each hospital was considered a case study site. This design helped the researcher to explore the patient safety culture in each particular setting, and the similarities and differences of the different case studies involved (Yin, 2017). The selection of two hospitals in this phase out of the three hospitals involved in Phase II was due to the limited time available to the researcher as a PhD student. Moreover, the two hospitals were selected due to their ability and willingness to take part in the study; one of the hospitals participating in Phase II was not as cooperative with the researcher and did not agree to provide facilities to conduct focus group discussions and interviews. However, the two hospitals selected for the current study phase were still sufficient to meet the research objectives, as they were among the largest public hospitals in Madinah with multidisciplinary teams and specialties. Therefore, the researcher decided to focus on those two hospitals, using the case study approach, which allowed sufficient time for the researcher to investigate each

case comprehensively. This phase utilised two research methods: focus groups with healthcare professionals, and interviews with patients/family members based on appropriateness to the target populations and research questions (Creswell and Creswell, 2018).

5.3.2 Focus group discussions with healthcare professionals (addressing RQ3)

Focus groups (n=6) were undertaken to gain further insight into the barriers and facilitators regarding the implementation of a positive patient safety culture in Saudi Arabian hospitals from the perspectives of healthcare professionals, and to probe for further explanation of some of the Phase II findings. A focus group discussion is a facilitated discussion involving a group of people, used to explore a set of issues of interest (Liamputtong, 2011). It was also suitable to identify additional factors contributing to the safety culture that might not have appeared in the quantitative survey (Stewart and Shamdasani, 2014). This method is regarded as being feasible in this complex area of interest, which requires a more in-depth understanding of the participants' beliefs, views and experiences in the actual implementation of a patient safety culture in practice (Stewart and Shamdasani, 2014). The focus group design also allowed the researcher to observe the dynamics involved in the interactions between a group of participants, along with their different views and experiences, which reflect their natural environments (Stewart and Shamdasani, 2014). This provided important contextual information that assisted in the analysis and interpretation of the participants' narratives and accounts (Hammarberg et al., 2016).

5.3.2.1 Population

The target population for the focus group discussions was healthcare professionals (i.e., physicians, nurses, pharmacists, allied healthcare and hospital managers) working in the two hospitals selected in the Madinah region of Saudi Arabia during the period of this study. Participants from Phase II were eligible to take part, but new participants were also invited (i.e., participation in Phase II was not a prerequisite for participation in Phase III).

Inclusion criteria:

Participants must:

- Be registered as healthcare professionals (physicians, nurses, pharmacists and allied healthcare).

- Work at one of the selected hospitals.

- Be able to understand verbal and written English sufficiently to complete the consent forms/understand participant information sheet and share their experience during group discussion.

- Have at least one year post qualification experience, to ensure that hospital orientation and competency programme completed.

Exclusion criteria:

- Unable to provide written informed consent.

- No direct contact with treatment or care plans, such as gatekeepers, cleaners, drivers, porters and administrators.

- All healthcare students.

- Not working at either of the two selected hospitals.

- Less than one year of experience.

- Insufficient understanding of verbal and written English.

5.3.2.2 Recruitment and informed consent

The researcher asked the IT department in the Madinah Health Affairs office to send an email to all staff who were contacted during Phase II (survey), letting them know that Phase III was starting and if interested, to contact the researcher. An invitation letter (Appendix 8), participant information sheet (Appendix 9), and privacy notice (Appendix 6) were attached. The researcher also distributed posters about the study across hospital departments, with the researcher's contact details, invitation letters (Appendix 8) and participant information sheets (Appendix 9) to increase interest in the study. Interested participants were asked to contact the researcher directly by email or phone and they would be given the opportunity to ask any questions they may have. Those who contacted the researcher showing interest in

the study were asked permission to be contacted after 24 hours to ensure they were still interested in taking part. If they were, then the researcher established whether they met the study criteria and arranged to meet with them (at least 24 hours later). At this point, potential participants had an opportunity to ask further questions about the study and informed consent was obtained face to face (Appendix 10) from those still willing to take part. Each participant kept a copy of the signed informed consent (Appendix 10), and another copy was kept in the study file. Participants were given a unique identification number once they signed the consent form. Participants were reminded that they were free to say no, and that they could withdraw from the study at any time without any obligation and this would have no impact on their workplace.

5.3.2.3 Sampling and sample size

A purposive, non-probability sampling technique (Creswell and Creswell (2018) (to include a mix of different healthcare professional disciplines, levels of experience, and position/role within the organisation) was used in this approach to identify potential participants who met the eligibility criteria. Three focus group discussions were held at each site: one pilot focus group, one group with frontline staff, and a third group with heads of departments, supervisors and managers. The participants were placed into one of these groups based on their position, providing a comfortable environment for participants to express their opinions without any managerial considerations about power and hierarchy that may prevent staff from speaking freely (Stewart and Shamdasani, 2014). It was therefore critical that the study sample captured a wide range of perspectives on the topic of each group of healthcare workers based on their skills mix and who would have valuable knowledge to contribute to the study (Green and Thorogood, 2018). In total, six focus group discussions were held across the two sites, with every focus group having between five and eight participants (Stewart and Shamdasani, 2014). Thus, the total sample size was 35 participants; this number is justified in a qualitative approach as data saturation was reached (this occurs when no new themes are identified from the data) (Green and Thorogood, 2018). Although there is some debate regarding data saturation definitions and purposes (Saunders et al., 2018), some researchers do agree on a few general principles and concepts: no new data, no new themes, no new codes, and the ability to replicate the study (Guest et al.,

2006). Thereby, the aim of qualitative inquiry was not to acquire a specified number of participants, but instead to gather sufficient information to fully explain the phenomenon under study (O'reilly and Parker, 2012).

5.3.2.4 Topic guide

The topic guide (semi-structured questions) was developed based on the literature in the field of patient safety culture concepts and dimensions within hospitals (Sorra and Nieva, 2004a, Sammer et al., 2010). Additionally, the findings from the Phase II quantitative approach were used in the development of the topic guide, such as the dimensions scoring the lowest positive score for safety culture, in order to ensure it was more concise and in line with the aim of the project (Creswell and Creswell, 2018). Therefore, the structure of the topic guide was developed to be more flexible, with questions potentially subject to change to allow for the investigation of any new issues appearing in the group discussions (Stewart and Shamdasani, 2014). Moreover, the topic guide was discussed with the supervisory team at the University of Glasgow, as they are experts in the field to enhance its credibility (Yin, 2016, Stewart and Shamdasani, 2014). Appendix 11 presents the topic guide developed for the study.

5.3.2.5 Pilot study

Prior to commencing the main focus groups for data collection, the researcher conducted a pilot study. A pilot study is considered to be an essential step before conducting the main study, as it tests the feasibility of the research protocol, including instruments, recruitment strategies, and the identification of any issues that might arise (Creswell and Creswell, 2018). Therefore, the aim of this pilot study was to ensure the suitability of the topic guide, the practicality of conducting focus groups, to test the equipment and to test out the recruitment strategy (Green and Thorogood, 2018). The researcher conducted a small-scale focus group discussion involving 4-6 participants in each hospital, using the same recruitment strategies and topic guide as in the main study. Audio recordings and notes were taken during the discussion and then transcribed verbatim by the researcher, which help the researcher to ensure accuracy and enhance rigour (Green and Thorogood, 2018). None of the data obtained from the pilot study was intended to be included in the

main study; however, no major modifications of the topic guide following the pilot study were required, hence the data gained from the pilot study were included in the main study.

5.3.2.6 Conducting focus groups

Following recruitment, the participants were contacted to arrange a suitable date, time and place for conducting the focus groups (Stewart and Shamdasani, 2014). Three focus groups were held in each hospital (n=6 in total) with each lasting approximately 60 minutes. The focus groups were led by the researcher and supported by a note taker at each site who was responsible solely for taking notes and observing the recording device. Prior to the commencement of the focus groups, participants were reminded of the importance of confidentiality and were reminded not to reveal sensitive information or data about other participants or the discussions that took place (Stewart and Shamdasani, 2014).

At the beginning of each focus group discussion, the facilitator introduced themselves, welcomed participants, explained the aim of the group discussion, outlined the topic, reminding participants they were free to leave at any time and explained the rules of the focus group discussion (Stewart and Shamdasani, 2014). For example, respecting each other's opinion, not speaking over each other, giving each other time to speak, and keeping the discussion in the group confidential (Green and Thorogood, 2018). The focus group discussion was conducted in the English language for the same reason as in Phase II: English is the language of communication in hospitals among healthcare professionals. The discussion was audio-recorded, so participants were asked to avoid using names during the discussions, and were informed that their names, and any other names identified during the discussion, would be omitted from the transcript (Stewart and Shamdasani, 2014). Participants were asked questions regarding their perceptions of patient safety culture, including barriers to and facilitators of the implementation of positive safety culture in practice, using the topic guide (Appendix 11). At the end of the focus group discussions, the researcher thanked all participants and served refreshments to the participants.

5.3.3 Semi-structured interviews with patient/family (addressing RQ4)

Semi-structured interviews were undertaken with patients/family members discharged from the same two hospitals to explore their perceptions and experiences of patient safety culture. A semi-structured interview is an in-depth interview with an individual, used to gather detailed information using a flexible topic guide or open-ended questions (Jamshed, 2014). Interviewing is the most commonly used method of gathering qualitative information and can be one of three types: structured, semi-structured, or unstructured (Yin, 2016). Semi-structured interviews are viewed as useful since they guide the researcher to obtain specific information and direct the conversation towards the problem of interest (Yin, 2016). One strength of this method is that the researcher can be very flexible with questions and probe until no further information can be gathered (Merriam and Tisdell, 2016). As a result, the researcher is able to respond to what the interviewees say as well as follow up on any interesting topics raised by moving freely between topics and listening to the respondent to determine how the interview should flow (Merriam and Tisdell, 2016).

In the current study, the aim of this method was to explore patients' perceptions of safety culture, to investigate their experience, and to identify factors that contribute to the safety culture from their point of view. As previously discussed in Chapter Four (section 4.6), patient perspectives/opinions and experiences are valuable for improving the safety and quality of healthcare (Hernan et al., 2015, Vaismoradi et al., 2015). Thus, this study sought to understand patient safety culture from the patient/family themselves, rather than relying solely on healthcare providers. Patients/family members are in a position to provide a rich description of safety culture in Saudi hospitals and identify further factors contributing to safety culture that have not yet been discovered by healthcare professionals.

5.3.3.1 Population

The target population for the semi-structured interviews was patients/family members who had recently been discharged from one of the two hospitals selected for Phase III in the Madinah region of Saudi Arabia during the period of the study. The recruitment protocol was to identify and approach people while they were still

in hospital prior to discharge, but the interviews took place after people had been discharged.

Inclusion criteria:

Participants were included if they were:

- Aged ≥ 18 years;

- Admitted to hospital but were about to be discharged within 48 hours or were a family/carer of a patient about to be discharged;

- Physically well and medically stable;

- Able to participate in an interview;

- Able to give written informed consent; and

- Able to understand Arabic.

Exclusion criteria:

Participants were excluded if they were:

- Aged < 18 years;

- Medically unstable;

- Unable to communicate due to disability or illness; or

- Unable to provide written informed consent.

5.3.3.2 Recruitment and informed consent

The researcher explained the details of the study to the senior staff nurses in each department of the participating hospitals, including details about potential participants, inclusion and exclusion criteria, and the recruitment process, in order to identify participants who met the inclusion criteria. Following this, a senior nurse was requested to ask potential participants whether they would be interested in taking part in the research, and if so, they were provided with an invitation letter (Appendix 12), participant information sheet (Appendix 13) and privacy notice (Appendix 6). All of the documents (invitation letter, participants information sheet, privacy notice and consent form) provided to the participants with Arabic version.

They were asked to contact the researcher if they were interested in finding out more about the study or gave their permission for the nurse to pass on their contact details so that the researcher could make contact with them to offer further information. After this point, if they were interested, the researcher confirmed whether or not they met the study criteria and if so, arranged to go and meet with them at least 24 hours later. At this meeting, potential participants had the opportunity to ask any further questions about the study, and informed consent (Appendix 14) was obtained from those willing to take part in the study. Every participant kept a copy of the signed informed consent (Appendix 14) and another copy was kept in the study file. Participants were given a unique identification number once they provided consent to participate in the study. Following recruitment, participants were contacted to arrange a suitable date/time and place for the interview. The interview was arranged for one week following the patient's discharge from hospital to allow for the patient to reflect on their experience/knowledge, reduce hospital stress, and for participants to be interviewed in a comfortable environment, encouraging them to speak freely (Rubin and Rubin, 2011).

5.3.3.3 Sampling and sample size

The purposive sampling technique (to include participants with a range of age groups and genders) was used in this approach to identify potential participants fitting the eligibility criteria as outlined above (Creswell and Creswell, 2018). As previously described, sample sizes in a qualitative approach are generally smaller than in the quantitative approach (Creswell and Creswell, 2018). This is due to the nature of the naturalistic paradigm, where the researcher values deep understanding of the subject studied, rather than pursuing generalisations for the wider population (Yin, 2016). Therefore, the number of participants was dependent on data saturation, as discussed above in (section 5.3.2.2) (Creswell and Creswell, 2018). In total, 12 participants were interviewed in the current study, which included a range of people who met the sampling frame criteria and ensured that sufficient depth and breadth of information was obtained.

5.3.3.4 Topic guide

The interview guide (Appendix 15) was developed from the literature review and the findings from a systematic review conducted by the researcher in Phase I. Views were also sought from panel experts (supervisory team and experts in patient safety from the participating hospitals) (Sammer et al., 2010, Sutton et al., 2015, Vaismoradi et al., 2015, Hernan et al., 2015). The purpose of these interviews was to explore what patients/family members thought about the safety culture in hospitals, as well as to find out what health safety issues people might notice while in a healthcare setting, to ensure that people are safe when they are in hospital. The interview guide consisted of around ten questions and topics and aimed to assess respondents' perspectives on patient safety culture dimensions that can identify what is working well and what is not, and help to identify where patient safety needs to be improved. This interview guide was developed in English, then translated into Arabic prior to use to allow participants to speak freely and explain their views in their original language (Adams, 2015). The English version of the interview guide was discussed with the supervisory team to ensure that it was appropriate for the aim of the study and to enhance the validity (Adams, 2015).

5.3.3.5 Pilot study

Prior to commencing the main interviews with the participants for data collection, the researcher conducted a pilot study. A pilot study is considered a substantial step in testing the proposed study design, instruments, and recruitment strategy process, as discussed in section 5.3.2.4 (Creswell and Creswell, 2018). Thereby, following the translation of topic guide into Arabic, it was pilot tested on a small scale (two participants) using the same recruitment strategies as in the main study to enhance its validity and ensure that all questions could be clearly understood by the participants (Rubin and Rubin, 2011). Audio recordings and notes were taken during the interviews and then transcribed verbatim by the researcher, which helped the researcher to ensure accuracy and enhance rigour (Green and Thorogood, 2018). No major modifications of the topic guide following the pilot study were required, so the data obtained from the pilot study were included in the main study.

5.3.3.6 Conducting semi-structured interviews

At the beginning of each interview, the researcher introduced himself, welcomed the participants, explained the aim of the interview and outlined the topic, and re-checked consent with the participant and that they were happy to proceed. Each interview was one-to-one – participant and researcher – with each interview lasting 25-40 minutes. All interviews were conducted in Arabic. If the participant wished for a family member to stay with them during the interview, they were informed that anything said by the third party would not be included in the data and would appear as "(disruption)" in the transcript. To minimise bias during the interview, the researcher used various techniques such as presenting himself with a neutral introduction and explaining the research goals, speaking less than participants by not asking too many questions, and staying non-directive to allow participants to express their own ideas (Yin, 2016). Moreover, specific attention was paid to body language and facial expressions to avoid participants feeling that the researcher's responses guided their answer, thus affecting their perspectives (Yin, 2016). However, the researcher built rapport with participants, providing them with open, informal discussions and listening actively to their concerns and opinions in a relaxed informal setting. He also used probes and follow-up questions which allowed participants to expand on their opinions (Yin, 2016).

The researcher explored patient and family/carer perspectives, experiences, and opinions of patient safety culture in the hospital setting during their period of stay. The interviews were held in venues preferred by participants, either in the participant's home or in hospital (Rubin and Rubin, 2011). Each interview was audio-recorded, so participants were asked to avoid using names during the interview, and also informed that their names would not be used in the transcript to maintain confidentiality (Adams, 2015). At the end of the interview, the researcher thanked all participants and, if the interview was conducted in hospital, served refreshments.

5.3.4 Data analysis

The amount of data generated from the qualitative approach is generally large; therefore, the central aim of data analysis is to reduce the complexity of the data to

produce a meaningful data set that answers the research questions (Creswell and Creswell, 2018). According to Creswell and Creswell (2018), data analysis in the qualitative approach requires a series of steps, beginning with preparing the data, identifying the overall sense of the data as a whole, conducting the coding process, creating the themes, and presenting the description of the themes. This study employed an inductive approach in order to generate codes and guide thematic analysis to ensure that analysis was data driven (Burnard et al., 2008, Braun and Clarke, 2013). The inductive approach is widely used for analysing qualitative data, which is useful when the study's phenomenon is unknown or there is insufficient information about it to allow the findings to emerge from the frequent or significant themes that are inherent within the raw data (Burnard et al., 2008, Terry et al., 2017). All audiotape recordings from the interviews were listened to carefully, and then transcribed verbatim into a Word document by the researcher.

Thematic analysis was chosen because it is regarded by qualitative researchers as a useful way to generate insights that not only answer the research questions, but also illuminate previously unexplored aspects of the research, especially in the current study, where the patient /family perceptions of patient safety culture are unknown (Terry et al., 2017). It is acknowledged that in the qualitative phase, some findings of the systematic review and survey were used to develop a topic guide for interview questions to be further explained in the qualitative phase. However, through the inductive analysis of the raw data, themes are generated inductively, without trying to fit into an existing framework or the researcher's preconceived ideas. While thematic analysis and framework analysis are the most common methods used in qualitative data analysis (Gale et al., 2013), the researcher used thematic analysis which is a method acknowledged as enabling the structure of ideas, leading the researcher to identify important aspects of the data items that may useful to formulate themes. There are some similarities between thematic and framework analysis, including searching for, analysing, and reporting themes and patterns within data (Furber, 2010). The main difference between the two is that framework analysis uses a matrix output to allow researchers to analyse data according to participants and themes in a systematic manner (Ward et al., 2013). A framework analysis employs a structured approach to inductive and deductive thematic analysis by combining data description and abstraction to carry out cross-sectional analyses (Arifin et al., 2019).

However, the researcher used the thematic analysis approach due to its theoretical freedom and its ability to provide rich and detailed descriptions of complex datasets and identify interesting aspects that can lead to themes (Braun and Clarke, 2006).

Although thematic analysis is flexible, the flexibility can lead to inconsistency and a lack of coherence when developing themes from research data (Nowell et al., 2017). Critics of thematic analysis have argued that it fragments the original data and may cause misinterpretations since guidelines are not clear; thus, the conclusions are subjective and lack transparency (Smith and Firth, 2011). In spite of its disadvantages, it is often used by researchers who are unfamiliar with qualitative methods because it is easy to grasp and relatively quick to learn compared to framework analysis. The process of adapting framework analysis can be time-consuming, requiring the team's commitment and the experience of researchers (Nowell et al., 2017). Therefore, in the current study and from the reflection of the thematic analysis approach, the researcher synthesised the key features of a large dataset and constructed the themes based on the interpretation of what appeared in the transcripts, producing a clear and organised report. This helped the researcher examine the perspectives of healthcare professionals and patients/families, interpreting the findings of phases I and II and discovering new themes and insights surrounding patient safety culture in Saudi Arabia.

The six steps of thematic analysis outlined by (Braun and Clarke, 2006) were followed in the current study which is considered a robust and useful approach for qualitative data analysis. The steps are:

Familiarisation with the data: In the first step, the researcher familiarises themselves with the data by listening to the recorded data and taking notes of their observations to link it to the literature in order to identify any patterns. The records from the note taker are also considered sources of data (Stewart and Shamdasani (2014); therefore, the memo file records were also transcribed and included in the data analysis.

- Coding: This step creates an opportunity to generate clear, concise labels to describe the data in light of the broad research question for which the analysis is being conducted. Codes also give an analytical reading of the data, and the researcher codes every item of data by reading and re-reading the transcript

several times, ending this phase by reviewing all their codes and relevant data extracts.

- Searching for themes: A 'theme' refers to a coherent and meaningful pattern in the data relevant to the research question. In this phase, the researcher identifies patterns in the codes and makes it possible to combine them into possible themes.

- Reviewing themes: This phase is concerned with verifying that the themes apply both to the extracted data and to the entire dataset, thus ensuring the analysis remains as close to the participants' voice as possible and a coherent pattern is evident within the data.

- Defining and naming themes: this phase involves detailed analyses of each theme, including naming the themes and explaining how they relate to the full story.

- Writing up: this phase consists of writing up the findings by weaving the analytic narrative with data extracts to tell the reader a coherent story about the data and contextualising it within existing literature. All themes and subthemes for the current study were supported with relevant quotes from the interview transcripts.

These steps were followed in the analysis of the data generated from both the focus group discussions and semi-structured interviews. However, as the semi-structured interviews with patients/family members were conducted in Arabic, which sought to understand people in their natural setting, the researcher took into consideration the impact of the translation process on the trustworthiness of the research (Regmi et al., 2010). Translation is a process whereby data are collected in one language and turned into another; it has been criticised, though, as language is embedded within the sociocultural context (Regmi et al., 2010). Therefore, reaching equivalence between two languages may be difficult and risks losing some natural meaning (Regmi et al., 2010, Chen and Li, 2010).To address this, the researcher used the technique reported by Brislin (1970) and used by Chen and Boore (2010), which comprises the following steps:

- All audiotaped recordings were listened to carefully and then transcribed verbatim into a Word document in Arabic, the same language of the participants. Observation data from field notes, including non-verbal communication and impressions, were also transcribed which contributed to understanding the perception and responses of the participants. Thus, data

analysis was conducted in the original language (Arabic) of the participants and then only the concepts, categories, and themes that emerged were translated.

- After the concepts, categories and themes had emerged, two bilingual translators (researcher AA and a second researcher HA) translated the concepts, categories and themes into English. The final English version was created with agreement between both translators.

- Another bilingual person (AM) took the English version and back-translated the concepts, categories and themes from English into the original language (Arabic) for further accuracy and to ensure the meaning was not lost.

- To gain conceptual equivalence, a panel committee including translators and the researcher were involved to reach a final agreement on the translation.

Data analysis was conducted by the principal researcher under scrutiny from the academic supervisory team who reviewed and informed the coding framework and developing analysis.

5.4 Study trustworthiness

Measuring the quality of the research is essential to decreasing bias and ensuring the findings have enough integrity to be effective in improving practices and policy (Rolfe, 2006, Polit and Beck, 2017). Thereby, in order to achieve rigour in the research process and results, each element of the study methodology must be systematic, transparent, and accurate (Hadi and Closs, 2016). In general, research project evaluators adopt some trustworthiness criteria that have been explored in the literature as related to a particular research approach, such as qualitative, quantitative, or mixed methodologies (Anney, 2014). Each method of research employs different evaluation criteria to ensure rigour, which is because each approach focuses on different philosophical and methodological assumptions (Anney, 2014). There are four components of trustworthiness in qualitative research, as discussed by Lincoln and Guba (1985), namely credibility, dependability, transferability, and confirmability, which are considered to be the main trustworthiness principles to ensure the rigour of qualitative findings. The applications of these elements to the current study are discussed below.

5.4.1 Credibility

In qualitative research, credibility has to do with whether the findings and interpretation of the data are truthful and the extent to which other people believe them (Lincoln and Guba, 1985). It refers to the degree of alignment between respondents' views and the way the researcher represents them (Tobin and Begley, 2004). Therefore, credibility refers to whether or not there is confidence in how well the data and analysis process consider the intended focus (Anney, 2014). This is demonstrated through a number of strategies that are used in the development and implementation of the study. In the current study, credibility was established by adhering to methodological guidance within data collection and interpretation of findings, as discussed above, which provides detailed information of methods used along with justifications for their selection. In addition, to ensure the credibility of the generated data, participants who were knowledgeable about patient safety culture were recruited from different backgrounds, positions, and experiences. The findings of the current study were presented transparently using excerpts from the interview transcripts and presenting the reader with a clear flow from data collection to data analysis to ensure that the findings are believable (Tobin and Begley, 2004).

Another critical issue for achieving credibility is use of the methods of triangulation in this study, which is widely regarded as useful to ensure credibility and conformability in qualitative studies (Johnson et al., 2020). In the current study, the researcher used different data sources and data collection methods in order to reduce the bias associated with using a single source and method (Tobin and Begley, 2004). Triangulation methods were also used to describe the process of interpretations, assertions, themes, and study conclusions by using multiple sources of evidence. Consequently, the findings of the current study have greater credibility and confirmability.

Peer debriefing was used in the current study as a technique to enhance credibility as the researcher discussed the research methodology, data analysis, and interpretations on a continuous basis with the supervisory team, who are skilled qualitative researchers (Noble and Smith, 2015). This approach enhances credibility and trustworthiness because the researcher is able to confirm that the emerging themes are based on the data and are reasonable and conceivable to an

uninterested analyst (Hadi and Closs, 2016). Moreover, during the analysis of data, and to establish credibility, a reflexive journal was kept to keep track of the process of decision making and to capture initial impressions of the generated themes. In this way, the researcher's position within the study and personal beliefs are acknowledged and reduced, which in turn contributes to credibility by reducing researcher bias (Noble and Smith, 2015).

5.4.2 Dependability

Dependability in qualitative research refers to the stability of data over time and conditions (Lincoln and Guba, 1985). In other words, it indicates the possibility of repeating the findings if the same participants were utilised in a study of similar context (Graneheim and Lundman, 2004). According to Lincoln and Guba (1985), having an audit trail is essential to establishing dependability because readers will be able to see how the conclusions were drawn, including the decision making process of the researcher. Therefore, maintaining detailed records of key features in interactions and any changes in the emergent design of the study, as well as justifications of these decisions, is one way to increase dependability (Clissett, 2008). Accuracy and consistency of the study findings are central to maintaining dependability (Murphy and Yielder, 2010). Therefore, in the current study, the researcher ensured dependability by preserving all transcripts and notes used for collecting and analysing data, with a clear outline connecting the data interpretations.

5.4.3 Transferability

Transferability refers to the extent to which the findings can be transferred to other settings or groups of participants (Tobin and Begley, 2004). The key issue of establishing transferability is of providing a 'thick description' of the setting and the informants regarding research settings and the interview process (Tuckett, 2005). Therefore, it is essential to provide a clear and concise description of culture and context, participants, data collection, and process of analysis to promote transferability. Providing a rich and extensive set of details concerning methodology and context, thick descriptive data enhance research judgements and enable the researcher to compare the research context with other contexts (Anney, 2014). In the current study, a detailed description of the research participants, the

selection/recruitment criteria, study settings, data collection method, and analysis procedures was given to facilitate analysis and interpretation, and enhance transferability (Anney, 2014). Thus, the reader should be able to evaluate whether transferability was achieved and whether the findings can be applied to a wider population or in a different context (Johnson et al., 2020, Hadi and Closs, 2016).

5.4.4 Confirmability

Confirmability is the degree to which the findings of an investigation can be confirmed or corroborated by other researchers (Lincoln and Guba, 1985). It involves establishing that data and interpretations are derived clearly from the data and are not merely figments of the inquirer's imagination; this is achieved by clarifying the association between the results and the data collected (Tobin and Begley, 2004). There are different techniques that enhance confirmability in qualitative studies, including audit trials, reflective journals, and triangulation (Anney, 2014). To eliminate researcher bias and increase confidence in research findings, confirmability should be linked to participants' voices. The researcher ensured that both the participants' and researcher's voices were represented in the current study. An audit trail can enable this by providing visible evidence that the researcher did not simply find what they intended to find (Anney, 2014). Therefore, to ensure the confirmability in the current study, different methods were undertaken, including supervisors auditing the methodological approaches during each of the study phases. For example, in every study phase, the supervisors check and recheck the data and examine the data collection and analysis procedures in order to identify any potential biases or distortions. Additionally, the researcher kept a reflexive research diary throughout the data analysis process to document the coding, themes, and patterns that were acknowledged and concerned with the researcher's position within the study to eliminate researcher bias (Hadi and Closs, 2016). Finally, triangulation methods were used to obtain data from different sources and methods that enhanced the confirmability as well (Johnson et al., 2020).

5.5 Ethical consideration

5.5.1 Research ethics approval

The current study obtained two ethical approvals from the University of Glasgow, College of Medicine, Veterinary and Life Science research ethics committee under reference number 200180156 *(*see Appendix 16*)*. Another ethical approval was obtained from Madinah Health Affairs ethics committee in Saudi Arabia under reference number H-03-M-084 (see Appendix 17).

5.5.2 Informed consent

The researcher ensured that the participants were free to take part in the research without coercion and without being penalised for not taking part. The researcher ensured that the participants understood the study purpose/details, the voluntary nature of participation, and their right to withdraw from the study at any time without any obligation. Written informed consent was obtained from all the participants in this study. Prior to consent, the participants also had the opportunity to ask any questions related to their participation, including benefits, risks, and data protection and storage.

5.5.3 Confidentiality and anonymity

The issues of confidentiality and anonymity were maintained in this research; all information collected from the participants was kept strictly confidential to ensure that identification of the participants taking part in this study was not possible. The names of individuals and organisations participating in this research were replaced by ID codes known only by researcher, to be used in the study documentation. The participants had the nature of the data to be used in the study explained to them and they were informed about the secure steps the researcher adopted to protect and store their data. In the focus group discussion, anonymity amongst those who attended the same focus groups was not possible, therefore the researcher encouraged the participants to keep the discussion within the focus group confidential and to avoid discussing this information outside the group.

5.5.4 Beneficence and non-maleficence

The issue of beneficence and non-maleficence was also considered. The researcher avoided any harm or risk to the participants from taking part in this study. The people were recruited from similar grades/levels of experience, so this helped people feel comfortable discussing things in front of each other. For this reason, the participants had the freedom to talk without any concerns or effect on their job status. The researcher ensured that all participants understood verbal and written English sufficiently to complete the questionnaire/consent forms and understood the participant information sheet in order to give their opinions and perspectives clearly.

5.5.5 Participant withdrawal

All participants were informed they were free to withdraw from the study at any point, without being obliged to give notice or provide any explanation.

5.6 Data management, storage, and retention

Data were only accessible by the researcher and his supervisors. The Data Protection Act 2018 was followed throughout. All personal data obtained during the study were securely stored and processed in accordance with the General Data Protection Regulations (GDPR) (2018). No names of individuals or organisations participating in this study were used; these were replaced by ID codes known only by the researcher, and only these codes were used in study documentation. To protect the anonymity of the participants, their personal data were stored separately from the raw data. Personal information was retained until data collection was completed and no further focus groups/interviews were required. Following this, it was destroyed in accordance with the University of Glasgow regulations after two months from the study completion data collection. Consent forms were stored in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow where they will remain for ten years, as per the University of Glasgow policy.

All data in the questionnaire was anonymised and stored on a password-protected computer at the University of Glasgow, with access only by the researcher. All focus group discussions and semi-structured interviews were audio recorded and

transcribed verbatim for analysis. The audio recordings were destroyed as soon as they were transcribed, and then the transcriptions were stored on a password-protected computer with access only by the researcher. Audio files were not transferred via email or a memory stick. Transcripts and paper copies of study information were retained in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years, as per the University of Glasgow policy.

5.7 Chapter summary

This chapter detailed and justified all of the research methods used to complete the current study, with details of the study settings, population, inclusion criteria, data collection procedure, and ethical considerations. The methods undertaken in Phase I are discussed fully in the next chapter (Chapter Six). For the quantitative approach in Phase II, the current study used a self-administered questionnaire utilising the HSOPSC instrument. For the qualitative approach in Phase III, the current study used focus group discussions with healthcare professionals, and semi-structured interviews with patients/family members. To develop a comprehensive picture of the patient safety culture in Saudi Arabia, the current study used different methods of data collection and different sources of data, including input from healthcare professionals and patients/family members, which offered a greater insight into experiences of patient safety culture, recommendations for the implementation of a positive patient safety culture based on different perspectives, and helped to enhance the trustworthiness and transferability of the study findings. The findings from Phases II and III are discussed in Chapters Seven and Eight; however, the next chapter presents the Phase I systematic review with details of its methods, findings, and discussion.

Chapter Six: Phase I Systematic Review

6.1 Introduction

This chapter presents the methods used to undertake this phase, and the findings from a systematic review of the literature that aimed to identify the factors contributing to the patient safety culture in Saudi Arabia. The systematic review was undertaken to address the first research question of this project. The rationale of adopting the systematic review approach was discussed in Chapter Four (section 4.4.1). This chapter provides a detailed description of the methods undertaken while conducting this review including search strategy, inclusion and exclusion criteria, quality appraisal, data extraction and syntheses of findings. The chapter provides a summary of the results and a synthesis of the factors contributing to the patient safety culture in a clinical setting in Saudi Arabia. The synthesis of the findings is framed by the YCFF, which helps to facilitate the understanding of the relevant domains of the factors identified in the current review, as discussed in section 3.7 (Lawton et al., 2012).

A protocol for the current systematic review was developed and registered on PROSPERO, the international prospective register of systematic reviews under number CRD42018091152 and for full details of this protocol see link https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=91152.

6.1.1 Aim, objectives, and review question

The aim of this systematic review was to explore the factors contributing to the patient safety culture in Saudi Arabia. Specifically, the objectives were to:

- To identify the factors contributing to the patient safety culture in Saudi Arabia.

- To explore the perspective of patient safety culture among healthcare professionals and patients in Saudi Arabia.

Thus, the research question formulated to guide this systematic review was:

What are the factors contributing to a patient safety culture in Saudi Arabia from the perspective of healthcare professionals and patients?

6.2 Methods

6.2.1 Search strategy

An initial scoping literature search was conducted using electronic databases and Google Scholar, which provided an overview of the literature related to the topic and helped to refine the search strategy in preparation for the systematic review. Following this, a discussion was held with the supervisory team and a librarian at the University of Glasgow was consulted in March 2018 to confirm potential databases and the search strategy process. The systematic search was conducted in May 2018 using five electronic databases – MEDLINE, CINAHL, Embase, PsycINFO and the Cochrane database of systematic reviews – using Medical Subject Headings (MeSH) and keywords. In preparation for writing this thesis, the search was updated in July 2020. No further studies identified to include in the current review.

The key search terms were developed initially based on the previous review by Elmontsri et al. (2017). Through discussions with supervisors and the University librarian, synonyms and index terms were developed for the main search terms identified by Elmontsri et al (2017). The search strategy was originally developed and tested in one electronic database, i.e., Medline. From there, the search strategy was tailored to different databases depending upon what their MeSH headings were in each. Examples of how the search was undertaken in each database are provided in (Appendix 18). The MeSH terms used in this review included "safety", "patient safety", "healthcare safety", "safety management", "patient harm", "risk management", "organisation culture", "organisation climate" and "Saudi Arabia". In addition, the key words used in the search also included: patient safety, healthcare safety, safety culture, safety climate, safety practice, Organi?ation* culture, Saudi Arabia*, Kingdom of Saudi Arabia (KSA), Saudi Arabia (SA), as outlined in Appendix 18.

In order to expand the search process and make it more sensitive so that it retrieved the maximum number of relevant papers and abbreviations related to the terms used were identified and different spellings (British and American) were also considered. Boolean operators such as 'AND' and 'OR' were used to combine and limit the search process where relevant. Truncations symbols such as (*,?) were used to capture

different word endings and spelling variations (Bettany-Saltikov, 2012, Boland et al., 2017). Ongoing trials within a clinical trial registry (ClinicalTrials.gov) and ongoing reviews from the PROSPERO website were searched.

In addition, to maximise the search and decrease the possibility of omitting relevant literature, the search was supplemented by screening all the reference lists of the relevant papers that were identified in the database search and which met the inclusion criteria. The tables of content in the two relevant journals (British Medical Journal (BMJ) Safety and Quality, Journal of Patient Safety) were also searched to determine whether they contained relevant literature that met the inclusion criteria0). Moreover, to obtain additional unpublished material that might be relevant, the grey literature was searched, including doctoral theses on the EThOS website, and the ProQuest Dissertations and Theses database (https://search.proquest.com). Finally, the search was limited to studies published in the English language due to limited time and resources. No timeframe restriction was applied to this review while searching in the databases or during the manual search.

6.2.2 Inclusion and exclusion criteria

The current review considered all studies conducted across all healthcare sectors in Saudi Arabia that were concerned with the measurement or assessment of factors influencing or contributing to patient safety culture. The review sought studies from both the perspective of healthcare professionals (doctors, nurses, pharmacists, or allied healthcare) and, to address the gaps in current evidence and previous systematic reviews in this field (as discussed in section 4.4.2), from the perspective of patients. In order to be included in the review, the studies needed to meet the following eligibility criteria.

Inclusion criteria:

- Empirical studies that investigated patient safety, safety culture/climate and the effectiveness of intervention programmes for addressing patient safety in the healthcare sectors in Saudi Arabia.

- Study settings that included general hospitals, primary healthcare centres, tertiary hospitals, university hospitals, private hospitals, military and National Guard hospitals.

- Study participants who were healthcare professionals, including doctors, nurses, pharmacists, technicians and allied healthcare, or patients, carers and family members.

- All study designs addressed the phenomena of interest by a quantitative design (e.g., cohort study, cross-sectional, longitudinal survey, observational study), or by a qualitative design (e.g., phenomenology, ethnography, grounded theory, case study), or by mixed methods.

- Unpublished literature including reports from grey literature and student theses.

- Must be published in the English language.

Exclusion criteria:

- Studies not conducted in Saudi Arabia.

- Studies conducted in non-healthcare settings or industries.

- Participants not registered as healthcare professionals and were neither patients nor family members.

- Non-empirical descriptive studies (theoretical papers, views, essay, editorials, newspapers and magazine articles).

- Abstracts or posters only.

- Not written in the English language.

6.2.3 Screening of the papers

Reference management software (EndNote x7) was used to manage the database search results and remove duplicates from the search results. Following this, Covidence software was used to allow the search results to be screened for inclusion. This tool is a web-based systematic review program which enables reviewers to work together on systematic reviews in an organised and unbiased manner (Babineau, 2014). The process of screening was undertaken in two stages. Firstly, there was the initial screening of titles and abstracts against the inclusion criteria to identify potentially relevant papers that broadly addressed patient safety culture in Saudi Arabia. Secondly, relevant papers were obtained in a full-text screening to decide whether to include or exclude them based on the detailed inclusion and exclusion

criteria as described above. Two reviewers completed the screening process independently (AA, researcher, and LK, primary supervisor). Discrepancies were resolved by discussion and by a third reviewer (EC, second supervisor).

6.2.4 Data extraction

A standard data extraction form was developed and utilised to elicit and extract all information relevant to the aim and objectives of this study from the selected studies. The form consisted of the following details: study author, bibliographic citation, design/methods, setting and participants, sample size, aim of the study, and findings. Data were extracted independently by the researcher (AA) and checked by LK and EC to ensure the quality of the data extraction process and to eliminate bias.

6.2.5 Quality assessment of included studies

An evaluation of the methodological quality of individual studies in a systematic review is important to describe the quality of each study and ensure the overall quality, validity and trustworthiness of the evidence (Boland et al., 2017). The review reported on in this chapter used two suitable critical appraisal tools aligned to the different study designs of the included studies. The adopted version of the Newcastle-Ottawa Scale for cross- sectional studies was used for quantitative studies utilising a cross-sectional design (Wells et al., 2015). This tool been used in previous reviews and described as an appropriate tool for assessing quality in descriptive cross-sectional studies (Elmontsri et al., 2017, Modesti et al., 2016, Herzog et al., 2013). The tool contains seven different items as a checklist format including selection of sample, comparability of subjects and assessment of outcomes. The tool scores each item with a 0, 1, or 2, with a maximum total score of 10 for each paper based on the answers to the statements in the checklist. This provides a clear presentation of the quality of each study. A score of 9–10 determines a very good study, 7–8 is a good study, 5–6 is satisfactory, and 0–4 is unsatisfactory. The Critical Appraisal Skills Programme (CASP) was used for studies that were undertaken with a qualitative design (Critical Appraisal Skills Programme, 2016). This program is well known, and it has different critical appraisal tools for a variety of study designs, including qualitative studies. This appraisal tool for qualitative studies contains 10 questions concerned with the appropriateness of the research

methodology, methods, recruitment strategy and rigour of the data analysis. Each question is answered "yes" if 'clear, adequate information is described' and "no" if there is 'insufficient information described to answer the question'. Two reviewers performed this process of methodological quality assessment independently (AA, researcher, and LK, primary supervisor). Disagreements were resolved by discussion and a third reviewer (EC, second supervisor).

6.2.6 Analysis and synthesis

This review employed a descriptive narrative synthesis method (Popay et al., 2006), which systematically highlights and summarises the evidence from the main characteristics of each study. The variation in the populations and measurement tools of the studies shows their heterogeneity, which limited the possibility of meta-analysis in the current review (Boland et al., 2017). While narrative synthesis is criticised for lacking transparency, it remains an important technique for bringing together heterogeneous evidence that offers a way to explore and understand the underlying arguments and justifications of claims made in included studies (Campbell et al., 2019). The narrative synthesis approach helps to describe the similarities and differences between the studies included in terms of methodological quality, designs, methods, measurement outcomes and findings (Bettany-Saltikov, 2016). Evidence extracted from the included papers was synthesised into themes, and explored to see where the data aligned with the YCFF as well as the overall study objectives and the review question. These included identifying factors contributing to the patient safety culture and exploring the perspective of the patient safety culture among healthcare professionals and patients in Saudi Arabia. Two independent reviewers, (AA, researcher, and LK, primary supervisor) coded the contributory factors into different domains according to the YCFF (Lawton et al., 2012).

6.2.7 Background and justification of the selection of the YCFF framework

This framework is evidence based and it was developed from a systematic review of 95 papers that identified the factors contributing to patient safety incidents, as discussed previously in Chapter Three (section 3.7) (Lawton et al., 2012). It is important to note that the YCFF framework was not originally created as a method

of identifying the factors contributing to patient safety culture. The framework was developed to produce a framework of contributory factors that contribute to patient safety incidents. To explain further why the YCFF is, nonetheless, a valuable framework for understanding safety 'culture', adverse events and patient safety incidents in hospitals have been linked to the level of patient safety culture within healthcare organisations (Mardon et al., 2010, Najjar et al., 2015). The evidence showed that hospitals scoring higher on patient safety culture reported significantly fewer adverse events and patient safety incidents (Najjar et al. (2015), suggesting that these aspects are linked to developing a positive safety culture. To date, there is no evidence-based framework that summarises the factors contributing to patient safety culture from different perspectives (healthcare professionals and patients). However, because there is a strong relationship between deficits in the patient safety culture and the number of patient safety incidents (DiCuccio, 2015), the decision was made to adopt the YCFF in the current review as it was believed that it could help to capture a wide range of contributing factors to patient safety culture. This is consistent with previous approaches where the framework has been used as an analysis tool to proactively identify factors contributing to patient safety performance at both individual and organisational levels (Lawton et al., 2012).

In addition, although the domains of YCFF contributing factors are encompassed with some models in the patient safety field such Reason's model that categorises and classifies causation of errors, as discussed in section 3.6.2 (Reason, 2000), the YCFF provides a range of factors and a brief explanation of them, indicating their relevance to patient safety. However, the Reason (2000) model is based on non-healthcare settings, which might limit some of the factors contributing to errors/incidents that specifically exist in the healthcare setting. Therefore, the focus of the YCFF in the hospital setting would be more effective in addressing patient safety in a comprehensive way to determine the underlying causes of the reduction in patient safety culture that may lead to the increased prevalence of incidents.

6.3 Results

6.3.1 Results of search strategy

The electronic database search of this review identified 419 potentially relevant papers. After duplicates were removed, 384 papers were screened in terms of their title and abstract to determine their relevance to the eligibility criteria. In total, 363 papers were excluded during the first stage of screening (title and abstract) due to their irrelevance. In total, 21 papers were retrieved in full text for the second stage of screening. Seven papers were excluded in the full-text screening stage due to not complying with all of the inclusion and exclusion criteria. Thus, 14 papers fulfilled the inclusion criteria of this review; these were obtained and included in this systematic review as outlined in the PRISMA diagram (Figure 6.1). A total of four additional papers were retrieved from the manual search. No relevant grey literature was found.
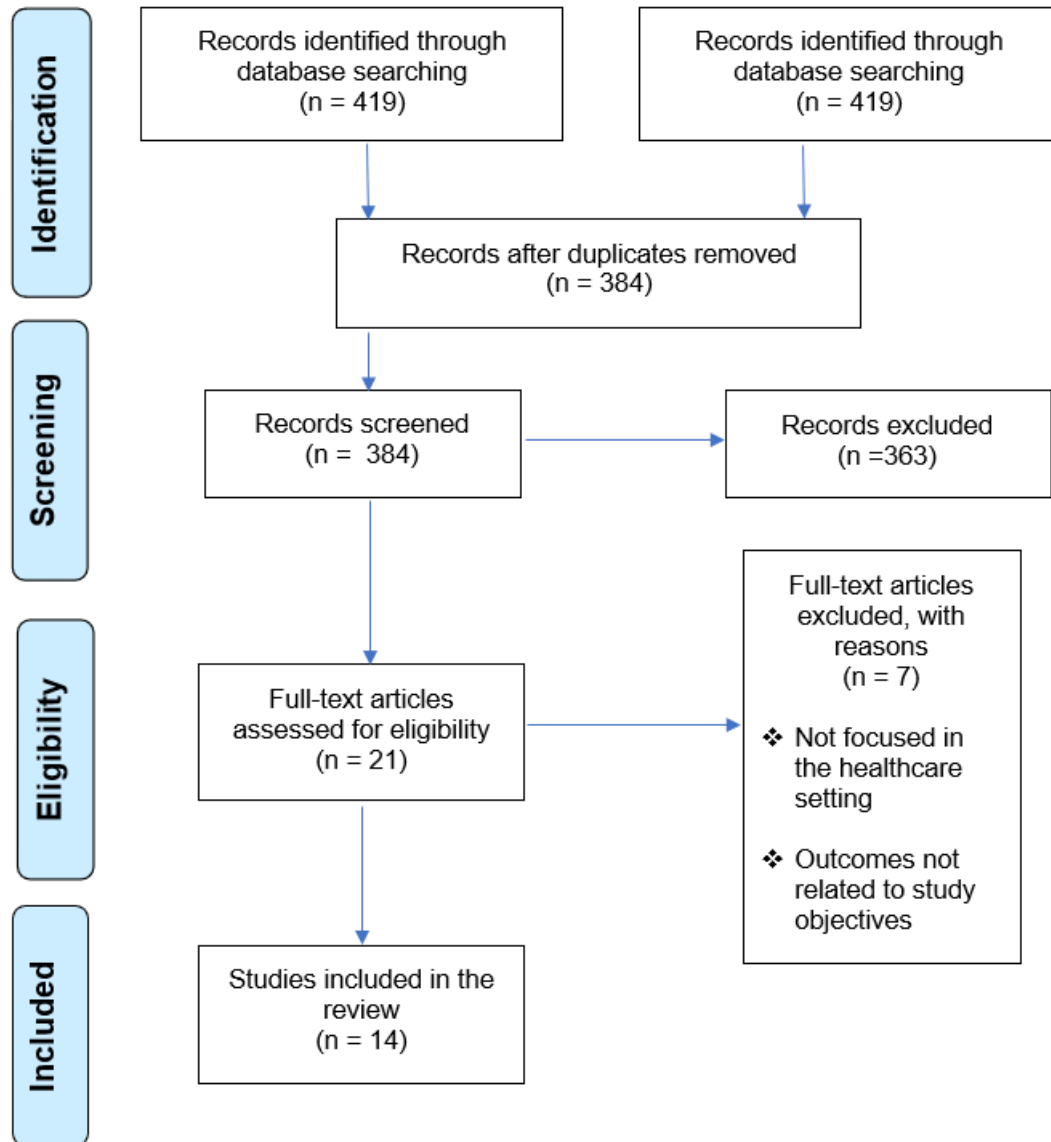
Figure 6.1 PRISMA flow diagram

6.3.2 General characteristics of the included studies

All of the 14 studies are similar in that they investigate patient safety in Saudi Arabia and identify the factors contributing to the patient safety culture from solely healthcare professionals' perspectives. Hence, the evidence drawn from this review is based on the perspective of healthcare professionals. There is a key gap in the perspectives of patients, family members and carers on patient safety culture in Saudi Arabia. This gap in the evidence is addressed in the current study, in Phase III in Chapter Eight (section 8.4). In total, 12 studies adopted a quantitative approach, all of which followed a cross-sectional survey design (Aboshaiqah and Baker, 2013, Al Malki et al., 2018, Al-Ahmadi, 2009, Alahmadi, 2010, Al-Awa et al., 2012, Alayed et al., 2014, Almutairi et al., 2013, Alswat et al., 2017, El-Jardali et al., 2014, Hamaideh, 2017, Taher et al., 2014, Walston et al., 2010). Two studies used a qualitative approach and employed focus group interviews as a qualitative method (Aljadhey et al., 2014, Alkorashy, 2013).

Although all of the cross-sectional studies employed a self-administrated questionnaire as the data collection instrument, they differed in terms of the types of questionnaires used. For example, seven studies (Alahmadi, 2010, Aboshaiqah and Baker, 2013, El-Jardali et al., 2014, Al-Awa et al., 2012, Alswat et al., 2017, Al-Ahmadi, 2009, Hamaideh, 2017) used the HSOPSC, which is considered to be a valid and reliable tool and is discussed in Chapter Three (section 3.7). Two studies (Alayed et al., 2014, Al Malki et al., 2018) used the Safety Attitude Questionnaire (SAQ), which is a valid tool used around the world to identify the factors from a healthcare professionals perspective that may lead to medical errors (discussed in Chapter Three, section 3.7) (Sexton et al., 2006). Two studies (Almutairi et al., 2013, Taher et al., 2014) used the Safety Climate Scale (SCS), which is also considered a valid tool and is used widely to assess the safety climate in healthcare settings (see Chapter Three, section 3.7) (Kho et al., 2005). In the study conducted by Walston et al. (2010), the authors developed their own questionnaire based on the literature related to safety climate; this contained 60 items on safety climate dimensions. However, as limited details were provided regarding the process of the development of this questionnaire and no copy of the questionnaire items/version were provided, the validity and reliability of the questionnaire items are an issue. Therefore, the

findings of this study should be treated with caution due to its poor methodological quality.

The two qualitative studies employed focus group interviews and focussed on exploring the factors and challenges facing patient safety culture (Aljadhey et al., 2014, Alkorashy, 2013). Of these, the study conducted by Alkorashy (2013) focused only on nurses' perceptions; however, in the other qualitative study, Aljadhey et al. (2014) focused on different healthcare professionals' perspectives regarding the challenges facing patient safety in Saudi Arabia. Patient perspectives were not included in either study.

The participants of the included studies vary, six studies involved only nurses working in hospital departments and eight studies involved different healthcare professionals including nurses, physicians, allied healthcare, pharmacists and managers. The sample size of the included studies ranges from 23 to 2592 participants and none of the studies were conducted in a primary healthcare setting; the majority were carried out in different hospital settings, such as Ministry of Health (public hospitals), teaching hospitals, private hospitals, military hospitals and psychiatric hospitals. Eight studies out of 14 included in this review were conducted in hospitals in Riyadh city, the capital of Saudi Arabia (section 2.2.1). From the remaining studies, two were conducted in the Jeddah region, one in the Dammam region and the location of the others is unknown. Thus, the generalisability of the findings might be limited due to the studies' settings, as they were based on only three health regions in Saudi Arabia, leaving 10 health regions unstudied. Moreover, none of the studies included in the current review were conducted in the Madinah health region where the researcher conducted Phase II and Phase III of the current study so, the findings potentially transferable to Madinah health region (Polit and Beck, 2017).

6.3.3 Quality of studies included

The validity of evidence drawn from any systematic review is dependent on the quality of the empirical studies included in that review. Thus, as described in section 6.4.5, two quality appraisal tools were used in this review to measure the quality of all of the included studies. The studies implementing a cross-sectional survey were assessed by the Newcastle–Ottawa Scale, which showed that the majority (all except

two) of the studies were of good quality. The other two (Aboshaiqah and Baker, 2013, Al-Awa et al., 2012) were rated as poor quality as they failed to provide a description of some methodological aspects such as sampling strategy, which makes it difficult to judge their populations and whether they were representative enough of the target population (Polit and Beck, 2017). This might increase the potential for selection bias or limit the representativeness of the sample (Polit and Beck, 2017).

Although sample size has a major impact on generalisability Polit and Beck (2017), some of the included studies do not provide justification for their sample size calculations and whether they were based on power calculations or not (Aboshaiqah and Baker, 2013, Al Malki et al., 2018, Al-Awa et al., 2012, Alayed et al., 2014, Alswat et al., 2017, El-Jardali et al., 2014, Walston et al., 2010). The response rates also vary across the studies; two studies had a response rate 47.4% (Alahmadi, 2010, Al-Ahmadi, 2009), three studies (Taher et al., 2014, Hamaideh, 2017, Alswat et al., 2017) had a response rate of 53%, 56% and 57% respectively, and the remaining studies had above 60% response rate which is considered sufficient (Nulty, 2008). Thus, the reliability and validity of evidence may be enhanced as the majority of the studies in this review achieved above 60% response rates (Polit and Beck, 2017).

The key strengths of the studies included are the clarity of the research questions, the objectives and the validated measurement tools of the outcomes, which describe the variables and the validity of the measurement methods used to address these variables (Bowling, 2014, Polit and Beck, 2017). However, the study conducted by Walston et al. (2010) used a non-validated questionnaire and the study failed to provide details regarding face and content validity, which affects the validity of the findings (Polit and Beck, 2017). Face and content validity are essential elements that are concerned with constructing and formulating the questionnaire items, measuring the extent to which they are related to the subject being studied and are clearly worded (Bowling, 2014). The process of statistical analysis was very well described and justified in the majority of studies except Al-Awa et al. (2012) who failed to provide details of the statistical analysis process. It is therefore difficult to determine whether they used sufficient statistical tests to analyse the data. Overall, the majority of studies were rated as 'good' based on the score of the critical appraisal findings outlined in (Table 6.1). There were some methodological issues related mainly to the

selection of the participants and representativeness of the target population, which makes it difficult to judge their populations and whether they were representative enough of the target population (Aboshaiqah and Baker, 2013, Al-Awa et al., 2012). This might increase the potential for selection bias or limit the representativeness of the sample (Polit and Beck, 2017).

Two studies (Alkorashy, 2013, Aljadhey et al., 2014) used a qualitative approach and they were assessed based on the CASP tool, as described in section 6.4.5. The study conducted by Aljadhey et al. (2014) was rated poor quality due to the fact that it was not conducted in an appropriate methodological way, and it failed to consider essential elements in the research methods to avoid any source of bias. No inclusion and exclusion criteria were described for this study and the recruitment strategy was not appropriate as it was based on the researcher's knowledge and their personal contacts with experts interested in patient safety and quality. This may have introduced a degree of bias within the sample and potential coercion in relation to the participants' involvement in the study. In addition, data collection was not facilitated in a practical way, as they conducted all the focus group interviews (9) in one day. This is a potential issue that may limit the study researcher's ability to gather enough information, observe group dynamics and take notes during discussions. Additionally, it may have limited the study researcher's ability to reflect on any new ideas or patterns that emerged during later focus groups, therefore any emerging discussions did not inform any changes to the interview guides of subsequent focus groups. It could also be criticised for not providing sufficient information to the ethical considerations that they obtained to maintain and manage the interview environment in order to provide privacy and confidentiality which influence the rigour of this study (Polit and Beck, 2017). The last study conducted by Alkorashy (2013) was rated as good quality as it provided a clear description of the methodological aspects. However, the relationship between the researcher and the participants was not clearly defined, affecting study credibility. The researcher did not provide any information about the way that he situated himself in the study and how his role influenced the data collection. Table 6.2 outlines the summary of the results of the qualitative studies.

Table 6.1 Results of the critical appraisal of the included studies (cross-sectional studies). Newcastle–Ottawa Scale adapted for cross-sectional studies

No	Study author/ year	Selection				Comparability	Outcome		Total out of 10
		Representativeness of the sample	Sample size	Non respondents	Ascertainment of exposure		Assessment	Statistical test	
1	Aboshaiqah and Baker, 2013	-	-	-	++	-	+	+	4
2	Al Malki et al., 2018	+	-	+	++	+	+	+	7
3	Al-Ahmadi, 2009	+	-	-	++	+	+	+	6
4	Alahmadi, 2010	+	-	-	++	-	+	+	5
5	Al-Awa et al., 2012	-	-	+	++	-	+	-	4
6	Alayed et al., 2014	+	-	+	+	+	+	+	6
7	Almutairi et al., 2013	+	-	+	+	+	+	+	7
8	Alswat et al., 2017	+	-	+	++	+	+	+	7
9	El-Jardali et al., 2014	+	+	+	++	+	+	+	7
10	Hamaideh, 2017	+	+	+	++	+	+	+	8
11	Taher et al., 2014	-	-	+	++	-	+	+	5
12	Walston et al., 2010	+	-	-	+	+	+	+	5

* - = (This means the study is marked 0)   + = (This means the study is marked 1)   ++= (This means the study is marked 2)

Table 6.2 Results of the critical appraisal of the included studies (qualitative studies) (CASP tool)

Statements	Aljadhey et al., 2014	Alkorashy, 2013
1- Was there a clear statement of the aims of the research?	☐	☐
2- Is a qualitative methodology appropriate?	☐	☐
3- Was the research design appropriate to address the aims of the research?	☐	☐
4- Was the recruitment strategy appropriate to the aims of the research?	X	☐
5- Was the data collected in a way that addressed the research issue?	X	☐
6- Has the relationship between researcher and participants been adequately considered?	X	X
7- Have ethical issues been taken into consideration?	X	☐
8- Was the data analysis sufficiently rigorous?	X	☐
9- Is there a clear statement of findings?	☐	☐
10- How valuable is the research?	☐	☐

6.3.4 Key findings

The following data were extracted and outlined in the table of evidence below (Table 6.3) and the findings synthesised into themes aligned with components of the YCFF (Table 6.4). A wide range of factors contributing to the patient safety culture in Saudi Arabia was identified. Many of the studies included in the current review classified and reported the factors that they identified as strengths or potential areas for improvement (weaknesses). Therefore, this study synthesising the data from the included studies and outlines the summary of the factors identified as strengths and weakness to the patient safety culture (Table 6.4).

Table 6.3 Table of evidence

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
Aboshaiqah and Baker, 2013	Cross-sectional descriptive study Method: Hospital survey on patient safety culture (HSOPSC).	N= 498	One tertiary care hospital in the capital Riyadh, Kingdom of Saudi Arabia. Participants are nurses.	• To identify the factors that nurses perceive as major contributors to a culture of patient safety. • To examine the effects of these perceptions on nurses' participation and engagement in the patient safety culture.	• Strength factors: Clear/ strong hospital management, support for patient safety and organisational learning. • Area of potential improvement: Hospital handoffs and transitions, communications, non-punitive response to error and supervisor/manager expectations and actions promoting patient safety. • Culture and language differences among nurses were found to inhibit effective communication.
Al-Ahmadi, 2010.	Cross-sectional survey Method: Hospital survey on patient safety culture (HSOPSC).	N= 1224	13 general hospitals in Riyadh city, Saudi Arabia. Participants are healthcare professionals including nurses, technicians,	To evaluate the extent to which organisation culture supports patient safety in Saudi hospitals and the extent to which safety is a strategic priority.	• Overall Patient Safety Grade was rated as excellent or very good by 60% of respondents, acceptable by 33% and failing or poor by 7%. • Strength factors: Organisational learning/ continuous improvement,

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
			managers and medical staff.		teamwork within units and communication about errors. • Area of potential improvement: Under-reporting of events, non-punitive response to error, staffing issues, teamwork across hospital units and lack of leadership capacity.
El-Jardali et al., 2014	Cross-sectional survey Method: Hospital survey on patient safety culture (HSOPSC).	N= 2572	One large hospital in Riyadh, Kingdom of Saudi Arabia. Participants are healthcare professionals including physicians, nurses, clinical and non-clinical staff, pharmacy and laboratory staff, dietary and radiology staff, supervisors, and hospital managers.	To explore the association between patient safety culture predictors and outcomes, taking into consideration respondent characteristics and facility size.	• Strength factors: Organisational learning/ continuous improvement and teamwork within units. • Areas of potential improvement: Non-punitive response to error, staffing and communication openness. • High work load • Rushed work
Al Ayed et al., 2014	Cross-sectional descriptive study Method: Safety Attitude	N=216	ICUs wards in six urban and teaching hospitals in Saudi Arabia.	To examine nurses' attitudes towards safety culture in six Saudi Arabian intensive care units (ICUs).	• High workload • Lack of good communication and collaboration systems • Low nurse management and leadership

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
	Questionnaire (SAQ).		Participants are nurses.		• Low ability to speak freely regarding safety concerns
Al Malki et al., 2018	Cross-sectional descriptive study Method: Safety Attitude Questionnaire (SAQ).	N= 144	ICUs wards in two teaching hospitals in Saudi Arabia. Participants are healthcare professionals (nurses, physicians and respiratory therapists).	To examine attitudes to patient safety in two intensive care units from the perspective of health care professionals in Saudi Arabia.	• Negative attitude towards patient safety • Poor safety management and working conditions • High workload and low staff ratio • Poor administration support • Lack of good communications and reporting of incidence • Lower ability to speak freely regarding safety concerns • Inadequate staff levels and competency skills

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
Al-Awa et al., 2012	Cross-sectional survey Method: Hospital survey on patient safety culture (HSOPSC).	N= 605	22 units in one hospital King Abdulaziz University Hospital (KAUH) Participants are nurses.	To evaluate the perception of the KAUH nursing staff about patient safety after the application of the Canadian accreditation process and the contributing factors that could explain any changes in the hospital's safety culture.	• Strength factors: Supervisor/manager expectations and actions promoting patient safety, organisational learning/continuous improvement, teamwork within units and hospital management support for patient safety. • Area of potential improvement: Non-punitive response to error, staffing issues and communication openness
Alswat et al., 2017	Cross-sectional survey Method: Hospital Survey on patient safety culture (HSOPSC).	N= 2592	One tertiary care teaching hospital in Riyadh, Saudi Arabia. Participants are healthcare workers (physicians, nurses, pharmacists, technicians, dietary, administrative staff).	• To re-assess patient safety culture in a multi-site Medical City in Riyadh, Saudi Arabia. • To explore the association between patient safety culture predictors and patient safety grade, perception of patient safety, frequency of events reported and number of events reported.	• Strength factors: Organisational learning/ continuous improvement, teamwork within units, hospital management support for patient Safety and feedback, communication about errors. • Areas of potential improvement: Non-punitive response to error, staffing and communication openness. • High workload

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
Almutairi et al., 2013	Cross-sectional survey Method: Safety Climate Survey (SCS).	N= 319	One medical city in the Riyadh region, Saudi Arabia that is an 800-bed teaching hospital and medical referral centre. Participants are nurses.	• To explore the safety climate perceptions of the multicultural nursing workforce in a Saudi tertiary hospital. • To investigate the association between diversity of the nursing workforce and their perception of clinical safety climate.	• Working environment clinically unsafe • Lack of effective communication • Dissatisfaction with leadership • National diversity, background of nurses influences perception of patient safety
Al-Ahmadi, 2009	Cross- sectional Survey Method: Hospital survey on patient safety culture (HSOPSC).	N= 1224	11 Hospitals in Riyadh, Saudi Arabia (9 public and 2 private). Participants are healthcare professionals and administrative staff (physicians, nurses, technicians and managers).	• To explore the perceptions of Riyadh hospitals' staff on patient safety and error reporting. • To identify factors that influence the levels of frequency of events reported.	• Factors influence reporting of events: • Feedback and communication about errors, staff positions, teamwork across units, non-punitive response to error, supervisor/managers' expectations and actions promoting patients safety, and type of hospital
Taher et al., 2014	Cross-sectional survey Method: Safety Climate Survey (SCS).	N= 509	Five dialysis units in 3 cities in Saudi Arabia (Riyadh, Jeddah and Dammam). Participants are healthcare	To assess the safety climate as perceived by nurses and physicians in the dialysis units in Saudi Arabia.	• Nurses had higher perception than physicians of positive safety climate in their organisations. • Leadership, reporting of incidence and

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
			professionals (physicians and nursing).		communications are the main factors reported to influence safety climate.
Hamaideh, 2017	Cross- sectional Survey Method: Hospital Survey on patient safety culture (HSOPSC).	N= 224	Three psychiatric hospitals in Saudi Arabia. Participants are nurses.	To assess the perception of mental health nurses about patients' safety culture and to detect the factors that may affect patients' safety culture at psychiatric hospitals.	• Strength factors: Organisational learning/ continuous improvement, supervisor/manager expectations and actions promoting patient safety and teamwork within units. • Area of potential improvement: Non-punitive response to error, staffing, communication openness, hospital handoffs and transition and frequency of events reported.
Walston et al., 2010	Cross- sectional Survey Method: Local survey developed based on patient safety climate dimensions.	N= 496	Four hospitals in Saudi Arabia from 4 category (Ministry of health, private, military and teaching facilities). Participants are healthcare professionals (physicians, nurses, pharmacists, technicians).	To study the factors that create a patient safety climate in Saudi Arabian hospitals, how they differ by ownership and their effect on the perceived overall climate of patient safety.	• Three factors significantly affect patient safety climate negatively: • Management support • Reporting systems • Resource adequacy

Bibliographic citation	Study design/ method	Sample size	Setting and participants	Aim(s) of study	Findings
Alkorashy, 2013	Qualitative study, using focus group interviews	N= 23	One hospital in Saudi Arabia affiliated to Ministry of health. Participants are nurses.	To explore nurses' perspectives regarding factors shaping patient safety management in Middle East hospitals.	Factors affecting and inhibit safety management: • Heavy workload • Patients' expectations of safety • Nursing leadership • Nurses' working hours • A safety culture • Dominant culture of blame
Aljadhey et al., 2014	Exploratory qualitative study, using focus group.	N= 65	Riyadh, Saudi Arabia Participants are healthcare professionals (physicians, nurses, pharmacists, technicians, hospital quality coordinators and community pharmacist).	• To explore the views and opinions of healthcare practitioners toward current issues about medication safety in hospitals and community settings in Saudi Arabia. • To identify challenges to improving it; and explore the future of medication safety practice.	Factors contributing to medication safety problems: • Limited use of technology • Communication gaps between healthcare institutions/ healthcare professionals and patients • Non-adherence to policies and procedures • Under-reporting of medication errors • Multilingualism and cultural diversity • Workload and inadequate numbers of staff

Table 6.4 below summarises all the factors contributing to the patient safety culture identified from the current systematic review, which in general act as strength factors and areas of potential improvement/weakness factors, as reported by the included studies. These factors were aligned with the following domains based on the YCFF as shown in the (Table 6.5). Interestingly, the weakness factors identified in this review appeared in most of the YCFF domains particularly *situational factors, local working conditions, latent organisational factors and general factors.* On the other hand, the strengths appeared only in three domains: situational factors, local working conditions and latent organisational factors.

The factors described in (Table 6.4) fall into five main categories of the YCFF, which is adopted in this study to understand and organise the domains relating to the factors identified. Table 6.5 shows the main domains of the factors identified from each study in this review and how they are related: situational factors, local working conditions, latent organisational factors, latent external factors and general factors based on the YCFF.

Table 6.4 Summary of the factors identified across all included studies (reported strengths and weakness of patient safety culture)

Area of potential improvement/weaknesses	Strengths
❖ **Situational factors** ➢ Team factors Lack of teamwork across hospital units, collaboration between departments and hospitals ➢ Individual staff factors Low experience, competency skills, rushed work, staff position ❖ **Local working conditions** ➢ Workload & staffing issues High workload, inadequate staff levels, low staff-to-patient ratio, working long hours, rushed work ➢ Leadership, supervision roles Lack of leadership capacity, low nurses' management and leadership, poor safety management and working conditions, poor administration support, blame culture ➢ Drugs, equipment and supplies Resources inadequate, reporting system required to be developed ❖ **Latent/Organisational factors** ➢ Support from other departments Lack of good collaborations system, logistic support, limited use of technology, managerial support. ➢ Staff training and education Insufficient provision of training and education resource, structure of learning from errors and dissemination of guidelines ❖ **General factors**	❖ **Situational factors** ➢ Team factors Good teamwork within units, feedback and communication about errors ❖ **Local working conditions** ➢ Leadership, supervision roles supervisor/manager expectations and actions promoting patient safety ❖ **Latent/organisational factors** ➢ Support from other departments Hospital management, support for patient safety and organisational learning ➢ Staff training and education Organisational learning/continuous improvement

- ➤ Safety culture

  Awareness of safety concerns, non-punitive response to error/blame culture, culture and language diversity, fear of punishment

- ➤ Communication – written and verbal

  Lack of good communication, openness, lack of reporting system, hospital handoffs and transitions, communications gaps between healthcare institutions/ professionals/ patients, under reporting of events

Table 6.5 Coding the factors based on YCFF (Lawton et al., 2012)

Author/year	Situational factors				Local working condition			Latent/Organisational factors					Latent/ external		General factors	
	Team factors	Individual staff factors	Task characteristics	Service user factors	Workload& staffing issues	Leadership, supervision roles	Drugs, equipment supplies	Physical environment	Support from other departments	Scheduling and bed management	Staff training and education	Local policies, protocols, procedure	Design of equipment, supplies& drugs	National polices	Safety culture Organisational values, beliefs	Communication – written and verbal
Aboshaiqah, 2013						🔴			🟢		🟢				🔴	🔴
AlMalki et al., 2018		🔴			🔴	🔴			🔴		🔴				🔴	🔴
Al-Ahmadi, 2009	🔴	🔴			🔴				🔴						🔴	🔴
Alahmadi, 2010	🟢				🔴	🔴			🔴		🟢					🔴
Al-Awa et al., 2012	🟢				🔴	🟢			🟢		🟢					🔴
Alayed et al., 2014	🔴				🔴	🔴			🔴						🔴	🔴

Almutairi et al., 2013						🔴									🔴	🔴
Alswat et al., 2017	🟢				🔴	🟢			🟢		🟢				🔴	🔴
El-Jardali et al., 2014	🟢	🔴			🔴	🔴					🟢				🔴	🔴
Hamaideh, 2017	🟢				🔴	🔴					🟢				🔴	🔴
Taher et al., 2014		🔴				🔴									🔴	🔴
Walston et al., 2010					🔴		🔴									🔴
Aljadhey et al., 2014		🔴			🔴	🔴	🔴					🔴			🔴	🔴
Alkorashy, 2013					🔴	🔴									🔴	

*Strength factors: 🟢   **Area of potential improvement/weakness factors:** 🔴

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The domains of the YCFF and how the findings align are discussed in the following section to highlight the strengths and weaknesses identified across the studies.

6.3.4.1 Situational factors

Situational factors are factors related to the characteristics of the people in the workplace setting itself. This refers to the variety of aspects that influence the workplace, including team factors, individual staff factors, patient factors/services user factors and task characteristic factors. Team factors are concerned with the interaction, cooperation and functioning of staff members within a group and hospital departments, and were identified as both weakness and strengths in this study. Teamwork within a unit was reported to be a strength factor as it was perceived by healthcare professionals as being a beneficial aspect that enhanced patient safety culture in some of the studies (Alahmadi, 2010, Al-Awa et al., 2012, Alswat et al., 2017, El-Jardali et al., 2014, Hamaideh, 2017). The team members within a unit reported that they effectively and efficiently coordinate their activities, facilitate clear and concise communication and provide each other with feedback regarding errors, which maximises team functioning. However, teamwork across hospital units and multidisciplinary teams was found to be an area that required potential improvement due to deficits in interprofessional teamwork across disciplines, which may compromise patient care in some studies (Al-Ahmadi, 2009, Alahmadi, 2010, Alayed et al., 2014). For example, Alayed et al. (2014) identified differences in the perceived quality of teamwork between healthcare professional groups. Specifically, nurses stated that there were higher levels of collaboration among the nursing team in the ICU than in other multidisciplinary teams.

In terms of individual staff characteristics, four studies (Al-Ahmadi, 2009, El-Jardali et al., 2014, Taher et al., 2014, Aljadhey et al., 2014) reported that staff had a negative attitude towards patient safety. This was especially the case with perceptions of hospital management and working conditions. For example, Al-Ahmadi (2009) and Taher et al. (2014) found that higher staff position and experience had a positive impact on the perception of patient safety and the reporting of events. The nurses reported that they had a higher perception and interest of patient safety issues in their organisations compared to physicians.

Rushed work, different languages and cultural diversity were also mentioned as factors that affect the staff's ability to discuss their concerns regarding patient safety issues due to inadequate time or language difficulties (Aljadhey et al., 2014, El-Jardali et al., 2014). In the study conducted by Aljadhey et al. (2014), the impact of multilingualism and cultural diversity was identified as influencing the occurrence of medication errors, especially when conveying verbal orders. This miscommunication related to language and culture barriers is believed to affect the quality and safety of healthcare delivery as it increases the risk of harm and safety issues.

The task characteristic factors and services users' factors set out in the YCFF are concerned with specific factors related to tasks or patients such as abnormal physiology and aggressive attitude, which make individuals vulnerable to errors. However, none of the data extracted were aligned with these elements of the framework.

6.3.4.2 Local working conditions

The term 'local working conditions' refers to the work environment conditions and whether or not they support patient safety and create a safe environment. They cover a broad range of issues including staffing issues and workload, leadership and equipment supplies. One of the most common factors influencing patient safety culture identified in this study is leadership and supervision role. These were highlighted by all of the included studies as weakness factors that required further improvements except one (Al-Awa et al., 2012). In particular, several characteristics were identified that affect critical leadership functions related to patient safety culture. These included, poor performance management, lack of clarity over responsibilities and a lack of leadership capacity to promote staff support or encouragement and provide feedback (Al-Ahmadi, 2009, Alahmadi, 2010, Al-Awa et al., 2012, Alayed et al., 2014, Walston et al., 2010, Alkorashy, 2013, Aljadhey et al., 2014). Moreover, the study by Walston et al. (2010) found that three factors were reported significantly affect the climate of patient safety: management support, reporting systems and resource adequacy. All of these factors relate to working conditions and therefore they are expected to be more

likely to create challenges to health care organisations' ability to improve and enhance patient safety culture.

In addition, studies by Alayed et al. (2014) and Almutairi et al. (2013) showed that nurses perceived nursing management as poor, the result of which can lead to dissatisfaction at work and a negative attitude towards patient safety. Similarly, Alkorashy (2013) highlighted that one of the reported barriers facing nursing was the poor leadership style, which created and sustained a dominant blame culture in their organisations. Regardless, effective management and support for patient safety culture were also reported as strength factors by (Al-Awa et al., 2012).

In relation to workload and staffing issues, heavy workload, staff shortages, insufficient skills and poor staff to patient ratio were reported as weakness factors hindering patient safety culture (Al-Ahmadi, 2009, Alahmadi, 2010, Al-Awa et al., 2012, Alayed et al., 2014, El-Jardali et al., 2014, Alswat et al., 2017, Hamaideh, 2017, Aljadhey et al., 2014, Alkorashy, 2013). Alayed et al. (2014) investigated nurses' attitude towards safety culture in the ICU and found that a shortage of staff numbers and staff/patient ratio were described by nurses as issues that needed improvement as they prevented nurses from spending adequate time with patients, which raised safety concerns. Work overload and an inadequate number of staff were believed to be common factors contributing to medication errors by the participants in the study conducted by Aljadhey et al. (2014). Moreover, two studies (Al Malki et al., 2018, El-Jardali et al., 2014) indicated that healthcare professionals are suffering from issues such as working long hours which could put them in crisis mode and influence inhibit optimum patient care.

In relation to drugs, equipment and supplies, adequacy of equipment and supplies were considered as barriers in working conditions that hindered optimal patient safety (Aljadhey et al., 2014, Walston et al., 2010). The limited use of technology, especially with regard to prescribing medications and relying on handwriting, was also identified by Aljadhey et al. (2014). The participants believed that this was an important issue with regard to safe patient care as it created difficulties with understanding the physicians' handwriting.

6.3.4.3 Latent/organisational factors

Latent organisational factors are concerned with factors related to the physical environment, support from central functions, scheduling and bed management, training and education, and local policies and procedures. However, the data extracted from the included papers in the review aligned only with three categories of latent organisational factors (Table 6.5). These categories included to support from central functions, training and education, and local policies and procedures, which were reported as both strength and weakness factors. In relation to organisational learning, continuous improvements were mentioned as strength factors in the majority of studies due to the ability of healthcare organisations to create an environment supportive of learning that improves knowledge and skills (Aboshaiqah and Baker, 2013, Alahmadi, 2010, Al-Awa et al., 2012, Alswat et al., 2017, Hamaideh, 2017, El-Jardali et al., 2014). However, only one study by Al Malki et al. (2018) showed that 47% of the participants indicated that education and training in their organisation was a weakness factor that needed further improvements. Thus, the participants of Al Malki et al. (2018) stressed that the establishment of a training and orientation programme was required to improve healthcare professionals' competency and practices related to patient safety issues, such as identifying patients correctly and complying with guidelines. Lack of knowledge and experience regarding medication errors were also reported as barriers by Aljadhey et al. (2014); these have wider implications for minimising drug errors.

In relation to support from central functions, poor administrative support and the suboptimal management of patient safety aspects were recognised and it was evident that they remained an issue hindering safe practice (Al Malki et al., 2018, Al-Ahmadi, 2009, Alahmadi, 2010, Alayed et al., 2014). For example, certain aspects of poor organisational structure were identified, including a lack of collaboration between departments, a lack of logistical support, limited use of technology, inappropriate prioritising of patient safety issues and insufficient patient safety standards and activities in place to promote a positive patient safety culture. These aspects were believed to be important variables related to deficits in the central network management system within an organisation, which may adversely affect patient safety culture. Another important factor highlighted by

Aljadhey et al. (2014) was non-adherence to policy and procedure, which was highlighted by the participants in some cases as being due to the lack of dissemination of guidelines in the workplace.

6.3.4.4 Latent external factors

Latent external factors are concerned with factors related to the design of the equipment, supplies and drugs, and national policies. However, no studies reported data aligning with these categories of the YCFF.

6.3.4.5 General factors

General factors are concerned with factors related to the communication systems and safety culture within organisations, which directly affect patient safety. These factors are considered further below.

Communications

Communications are related to the availability and effectiveness of the processes and systems within organisations for the exchange of information between staff, patient, groups, departments and services; they include both written and verbal communications. Although communication between healthcare providers, patients and services users is central to providing safe and effective healthcare, this review highlighted that poor communication was the most frequently reported weakness factor, besides the blame culture and leadership. The studies by Al Malki et al. (2018), Alayed et al. (2014) found that poor communication systems were identified by the participants as root causes of the errors and the development of malpractice in healthcare settings. Specifically, communication breakdowns were recognised in different areas including among hospitals departments, during patient handoffs, and between patient and healthcare professionals (Aljadhey et al., 2014, Al-Ahmadi, 2009). Another study by Aboshaiqah and Baker (2013) highlighted that communications openness among nurses was rated as poor, which raises concerns regarding safety and the ability to report errors.

In addition, a lack of availability and function of reporting systems was also identified as an issue that may limit the willingness to reporting incidents and learn from errors (Walston et al., 2010, Al-Ahmadi, 2009). Walston et al. (2010) found

that the lack of effective reporting systems to support and encourage staff members to report incidents is related to the barriers in the infrastructure of the healthcare organisation itself. Further, it is evident that there are no anonymous reporting systems in any healthcare organisations in Saudi Arabia, which negatively affects the patient safety culture due to limited incident-reporting approaches.

Safety culture

The safety culture is concerned with organisational values, beliefs, and practices surrounding the management of safety and learning from errors. It informs staff behaviours, attitude and awareness of creating a "just culture" that provides an environment that is supportive, free from blame and trusting in daily practice. The perception of safety culture and awareness is identified in the majority of the studies in this review as one of the weakness factors (Al Malki et al., 2018, Al-Ahmadi, 2009, Alayed et al., 2014, Alswat et al., 2017, El-Jardali et al., 2014, Taher et al., 2014, Aboshaiqah and Baker, 2013). Particularly, studies reported that safety culture varies among healthcare professionals and is influenced by staff position, experience, cultural background and language (Taher et al., 2014, Al Malki et al., 2018, Aboshaiqah and Baker, 2013).

In addition, a blame culture is one of the significant major barriers to a positive patient safety culture, as it limits the ability of people to speak freely about their concerns due to a fear of criticism or punishment. Interestingly, the blame culture/ punitive response to errors was reported in the majority of the studies in this review as a weakness factor that influenced the safety culture and the reporting of incidents. The study conducted by Alswat et al. (2017) found that 31% of the participants were concerned that their mistakes would be held against them and 29% were written up when they reported the incident. Fear of reported incidents as a reaction to the blame culture was also reported by Aboshaiqah and Baker (2013), who found that 25% (n=109) of nurses worry that their mistakes will be held against them. Similar findings came from another study by Alkorashy (2013), who conducted a focus group to investigate the factors shaping safety management from a nursing perspective. This study highlighted that 100% (n=23) of nurses identified a dominant blame culture in their organisations. Participants in

the study of Aljadhey et al. (2014) stated that the underlying reason for not reporting medication errors was fear of punishment from hospital administration and losing their job. Therefore, this is a serious issue and it may result in failing to report safety issues inside healthcare organisations in Saudi Arabia, which has a high impact on patient safety.

6.3.5 Summary of the findings

All studies investigated patient safety culture in Saudi Arabia and identified the factors contributing to the patient safety culture and their impact on healthcare delivery. Several factors contributing to patient safety culture were identified in this review, which aligns with the common factors of the YCFF. Interestingly, the most frequently reported factors that show a weakness/potential for improvement are related to workload and staffing issues, leadership supervision roles, the blame culture and communication. On the other hand, organisational learning/ continuous improvement, teamwork within units and support from hospitals management for patient safety were the most common factors identified as strengths. This suggests that the patient safety culture in Saudi Arabia is influenced by different factors, which consequently might affect patient safety and the quality of care.

6.4 Discussion

This systematic review sought to identify factors contributing to the patient safety culture in Saudi Arabia. Thus, 14 studies met the criteria for inclusion in the review. The factors identified in this review functioned as both strength factors and weakness factors/areas of potential improvement. In fact, the factors identified in this study can be considered strengths if reported by the participants as being strong aspects that support the patient safety culture. On the other hand, the factors that required improvement reflect the weakness and frailty of the aspects that reduce and hinder a positive patient safety culture. Interestingly, the number of factors perceived as requiring improvement outweighed the strength factors. This indicates that there are gaps and weaknesses in the patient safety culture in the Saudi Arabia healthcare system. The findings of this review illustrated that the factors influencing patient safety culture were related to different domains, in line with the YCFF (Lawton et al., 2012).

The YCFF holds numerous strengths for understanding the factors influencing patient safety culture and it could therefore play a part in the development of patient safety. The utility of the YCFF is quite detailed, representing the contributing factors under categorised domains centred around active failures and errors (Lawton et al., 2012). This helps to facilitate an understanding of the contributing factors' structure and to elicit their classifications and characteristics to inform hospital stakeholders and encourage them to develop acceptable patient safety standards and implement interventions designed to reduce the impact of these factors on the patient safety. Thus, the factors identified in this study were categorised according to the YCFF domains, including situational factors, local working condition, latent organisational factors and general factors. These domains of YCFF represent and address the range of conditions and aspects that reduce patient safety culture and make patients vulnerable to harm. However, although the YCFF provided valuable insights into factors contributing to patient safety culture, the data from this study was not aligned with all domains of the YCFF. In particular, no data extracted from the studies aligned with the latent external factors domain. This may be due to the fact that the categories of the latent external factors domain are similar to the items in the other domains in the framework (Table 6.5), which may have caused confusion when ranking the contributing factors. Thus, further validation of the YCFF framework to capture factors related to safety culture in general instead of safety incidents would strengthen and increase the robustness of the results.

The findings of this review show that leadership, a 'blame' culture, workload/staffing issues and communication are the overall aspects most frequently reported in the majority of studies across the domains of the YCFF as hindering a positive safety culture. These findings were consistent with the study conducted by Elmontsri et al. (2017), which found that the 'blame' culture and communication openness were serious issues identified as the negative factors facing healthcare systems in various Arab countries. Therefore, it could be argued that the existence of a blame culture is dominant in Arab countries' healthcare systems, including, as the current review has identified, within Saudi Arabia. This may be related to poor leadership and a lack of regulations supporting patient safety (Elmontsri et al., 2017). Thus, decision makers in Saudi Arabian healthcare systems should consider the importance of this punitive approach as it might limit reporting and learning from errors.

This punitive approach to errors is considered to be one of the common causes of under-reporting of incidents, due to fear of punishment (Waring, 2005, Hartnell et al., 2012, Pfeiffer et al., 2010). The evidence from this study shows that 25% (n=109) of nurses participating in the Aboshaiqah and Baker (2013) study and 100% (n=23) of nurses in Alkorashy (2013) expressed their concerns regarding their mistakes and errors being held against them. Consequently, this fear of punishment represents a significant worry among nurses about issues such as losing their job or position. Alkorashy (2013) highlighted another issue related to the dominant blame culture – the inability of healthcare providers to give their opinion, and concerns over safety issues that directly impact on human performance and attitude towards patient safety (Clarke et al., 2007).

Effective communication remains an integral part of patient safety culture due to the fact that it helps to facilitate and support the working of multidisciplinary teams (Leonard et al., 2004). The lack of adequate communication and collaboration between staff and patients is another factor identified in this study that may limit interaction and transform information between users. The deficit in communication potentially contributes to patient safety incidents (Halligan and Zecevic, 2011). This review highlighted that the quality of communication in general was reported as poor and was perceived to impact highly on the patient safety culture within an organisation. These deficiencies in communication were linked to different aspects, particularly poor communication among healthcare professionals, among hospitals departments and between healthcare providers and patients (Table 6.4). Aboshaiqah and Baker (2013) indicated that the different languages and cultures among nurses made the adoption of the optimal degree of communication difficult. This is probably explained by the workforce diversity in the Saudi Arabian healthcare system and the impact of the different languages and cultures on caregivers, which might influence the level of collaboration and effective communication between them (Almutairi, 2015). Therefore, this failure to communicate well may be related to poor leadership and leaders' ability to establish successful implementation strategies to support and establish effective communications channels (Connerley and Pedersen, 2005).

Poor communication may also be related to the infrastructure of the organisation's system. This is related to hospitals' capacity to provide effective systems /resources

for communication, training, technical support and feedback to improve quality of care (Dingley et al., 2008). Walston et al. (2010) reported that there is a lack of reporting systems in Saudi Arabia, which may affect voluntary reporting of incidents and the way that healthcare providers learn from previous errors. Therefore, it is clear that communication in healthcare organisations is less than the optimal level, which raises concerns over patient safety issues. This issue requires more attention and appropriate management from hospital administration.

Although this review identified that communication in general is one of the main factors contributing to the patient safety culture, this finding needs further exploration to identify how deficits in communications develop into barriers to a positive safety culture. It is important to understand the role of communication gaps in the reduction of patient safety culture and how they cause errors in the Saudi health context. Thus, more evidence is required to examine in greater depth the structure and mechanism of the communication system, in order to investigate the difficulties that affect patient safety, whether related to deficits in the organisation's systems or individual barriers. Moreover, further evidence is required to explore the availability of reporting systems in healthcare organisations and their practicality, to determine how they can support and encourage the implementation of a positive safety culture.

A high workload, rushed work, an inadequate number of staff and working for long hours were also identified in this review as factors requiring improvement that were believed by the participants to significantly influence patient safety culture (El-Jardali et al., 2014, Alayed et al., 2014, Al Malki et al., 2018, Alswat et al., 2017, Alkorashy, 2013, Aljadhey et al., 2014). This evidence is consistent with studies which highlighted that workload is a complex issue that directly affects patient safety, due to staff's limited ability to provide adequate patient supervision, and the influence it has on decision making (Al Ma'mari et al., 2020). High workload reduces attention/vigilance and increases distress from working under pressure (Holden et al., 2011, Aiken et al., 2002). Murphy and While (2012) found that high workload leads to fatigue among nurses, which is linked to physical and cognitive impairment, which in turn increases the risk of medication errors. Another study aiming to investigate the relationship between nursing daily workload and patient safety

incidents and mortality rate, reported that there was an increase in patient safety incidents of up to 30% with high daily workloads (Fagerström et al., 2018).

Furthermore, these findings are similar to the evidence from a cross-sectional study conducted by Rafferty et al. (2007), which examined the effect of patient-to-nurse ratios on patient outcomes, including mortality rate and quality of care. The results of this study showed that mortality rate is significantly associated with the patient-to-nurse ratios, with the highest ratio resulting in an increase in mortality rate of around 26% (Rafferty et al., 2007). An observational study in nine European countries found that one additional patient over and above a particular level was associated with an increased likelihood of an inpatient dying within 30 days of admission by 7% (Aiken et al., 2014). Workload and shortages of staff were also linked to poor patient satisfaction due to reduced level of communication between nurses and patients, which in turn limited holistic care (Aiken et al., 2002). In relation to the impact of workload on healthcare providers, evidence shows that it is associated with high burnout and job dissatisfaction among nurses working in different hospitals, thus impairing nursing performance (Carayon and Gürses, 2005). Therefore, high workload as a working condition seems to lead to sub-optimal patient care and contributes to the threat of reduced patient safety and quality of care. However, the evidence from the Saudi Arabian healthcare setting regarding the impaired relationship between patient safety culture and workload is limited. Consequently, more evidence from the Saudi healthcare setting is required to explore how workload influences patient safety culture. This is essential to understand the nature of workload types and how patient safety is affected by this factor. Also, to reflect the actual relationship between workload and the likelihood of errors.

Strength factors contributing to safety culture identified in this review are related to organisational learning/continuous improvement, teamwork within units and support from hospital management for patient safety. It is worth noting that the level of hospital support for patient safety culture and teamwork collaboration were generally reported across the included studies as both strength factors and areas that needed improvement. This variation in patient safety culture among healthcare professionals is related to differences in organisational policies, rules, strategies and general infrastructure that supports patient safety (Firth-Cozens, 2004). Another possible

reason for the variation in the teamwork within units, multidisciplinary teams and hospital departments may be the lack of a standardised system that facilitates staff interactions and engagement for patient safety (Firth-Cozens, 2004, Dingley et al., 2008). Therefore, decision makers in the healthcare system in Saudi Arabia should value the importance of consensus in patient safety standards and taxonomy as it can facilitate the successful implementation of high-level patient safety and quality of care.

Organisational learning/continuous improvement was the factor described by the participants as a strength, as it was reported that it actively enhances the improvement initiatives to maintain the patient safety culture. This acknowledgment of organisational learning may be due to the fact that educational departments are mandatory in Saudi hospitals, which ensures a continuity of learning. Indeed, organisational learning is fundamental in healthcare systems globally; this reflects on the organisation's ability to create, acquire and transform knowledge into clinical practice (Argote and Fahrenkopf, 2016). However, while health organisational learning is regarded as a strength in various ways, it could be argued that this does not reflect the current state of patient safety culture. This demonstrates the importance of creating a learning culture within healthcare organisations that contributes to enhancing the organisation's willingness to learn from errors. Therefore, adopting a learning culture is central to achieving a safe and high quality of healthcare (Edmondson, 2004, Morello et al., 2013).

In addition, there are key benefits to adopting a learning culture that effectively responds to errors and adverse events. For example, it increases the opportunities for individuals and organisations to use these failures as learning opportunities, it provides feedback following incident analysis and establishes the usefulness of improvement initiatives (Edmondson, 2004, Morello et al., 2013). Although the evidence from this review shows that learning environments in Saudi healthcare organisations foster some patient safety culture aspects, learning environments criticised because of its impact on organisational culture, which should support the creation of a safe healthcare environment (El-Jardali et al., 2014). Thus, learning systems and continuous improvements in Saudi healthcare organisations should motivate individuals to learn from previous mistakes and consider various

development approaches that address individuals' needs. Moreover, learning from patient experience and feedback is also another suitable tool that provides an in-depth understanding of patient safety threats. It is therefore suggested that such initiatives be implemented in practice (Ward and Armitage, 2012).

While there are efforts to explore patient safety culture in Saudi Arabia, a major finding of the current review is the apparent absence of patient and family members' perspectives on patient safety culture and the factors contributing to patient safety culture. Undoubtedly, patient and family participation in healthcare safety is central to the prevention of errors and to guide improvement strategies (Severinsson and Holm, 2015, Vaismoradi et al., 2015). Therefore, there is an increasing trend of engagement and involvement of patients in patient safety initiatives globally, which shows the ability of patients/families to reduce errors and to actively serve as a patient safety team (Severinsson and Holm, 2015). However, the successful implementation of patient involvement in patient safety depends on the health care organisation's culture, which should provide positive empowerment and encouragement to promote patient participation efforts (Vaismoradi et al., 2015). This encouragement and support are a key component of patient participation as it motivates patients to share responsibilities and values and facilitates an appropriate engagement process (Severinsson and Holm, 2015).

In the absence of evidence about patient views regarding the patient safety culture in Saudi Arabia, further empirical studies are required to obtain an in-depth understanding of patient perceptions, concerns and experiences related to safety in healthcare organisations. This is important in order to explore the nature of patient/family roles in patient safety activities and to identify potential safety concerns from the patients' perspective. Moreover, this is also fundamental to identifying factors related to the patient safety culture that are not captured by healthcare providers, but which can provide comprehensive information about the status of patient safety in healthcare environments (Hernan et al., 2015). Therefore, the key benefit from investigating patient perspectives regarding safety culture is that this information may reflect the infrastructure of patient safety initiatives, the status of patient involvement and the effectiveness of improvement strategies.

6.5 Strengths and limitations

The strength of this review is that it used YCFF to understand the factors contributing to patient safety culture. This framework provides useful classifications and details of contributing factor domains and hence a greater description of the factors that impact on patient safety culture. However, using other theoretical frameworks may identify more factors contributing to patient safety culture. Although an effort was made to identify literature relevant to the aim of this review by expanding the search strategy to a variety of study designs including quantitative, qualitative and mixed methods studies, the majority of the included studies were cross-sectional surveys that used different measuring tools; this may create self-reporting bias (Polit and Beck, 2017). Moreover, these cross-sectional studies failed to provide details of the complex nature of the factors contributing to patient safety culture. Only two studies used a qualitative approach, which can provide in-depth data about the status of the patient safety culture in some healthcare settings. However, due to the poor methodological quality of one of the qualitative studies Aljadhey et al. (2014) (Table 6.2), the findings should be treated with caution. Thus, due to the dearth of qualitative studies as well as the questionable quality of one of these studies, it is recommended that further qualitative studies be conducted to capture the factors that act as barriers and facilitators to the implementation of a positive patient safety culture.

In addition, this systematic review also excluded non-English publications, which may create publication bias and mean that some relevant papers were missed (Boland et al., 2017). Another limitation of this review is that, due to the lack of studies conducted in primary healthcare, the generalisability of these findings may be limited to hospital settings only. Interestingly, to date, no studies were included which have examined the patients' perspective of the patient safety culture. Thus, this review suggests that future research which aims to explore and evaluate patients' and families' views of safety culture in Saudi Arabia would be novel as it may provide evidence that contributes to the improvement of the patient safety culture in Saudi Arabia.

6.6 Chapter summary

This review identified a wide range of factors that contribute to patient safety culture in Saudi Arabia. These factors were categorised as strengths and weakness

factors/areas for potential improvement, in order to provide an understanding of the categories of factors affecting the patient safety culture. However, it is clear that the number of weakness factors outweigh the strength ones, which may compromise the implementation of a positive patient safety culture in healthcare organisations. Therefore, policy makers in the Saudi healthcare system should pay attention to the factors that may help to support the implementation of a positive patient safety culture, especially establishing a blame-free culture, improving communication and leadership capacity, learning from errors and involving patient perspectives in safety initiatives. Although the current review demonstrates that patient safety culture in Saudi Arabia has been the focus of recently published research, it is evident that there is a lack of patient/family perspectives regarding their safety and concerns in healthcare organisations. Therefore, it is recommended that further research be conducted to explore patients' perceptions and to provide comprehensive views of the factors contributing to patient safety culture. Moreover, although this review has highlighted the factors contributing to patient safety culture, there is a need for further research to understand how these acts as barriers and/or facilitators in the implementation of a positive patient safety culture in Saudi Arabia. Thereby, Chapters Seven and Eight present the findings from Phase II and III undertaken in the current thesis to address the gaps in the evidence identified in the current review.

Chapter Seven: Phase II Findings

7.1 Introduction

This chapter presents the quantitative findings from the cross-sectional survey that used the HSOPSC questionnaire in Phase II of the current study (Sorra and Nieva, 2004b). The aim of this phase was to explore the perception of patient safety culture among healthcare professionals from three hospitals in the Madinah region of Saudi Arabia. Specifically, the purpose was to provide a snapshot of current patient safety culture within the three hospitals in the Madinah region of Saudi Arabia, not only to offer an understanding of current issues (potential barriers and facilitators), but also to inform the next stage of the qualitative research.

The first section describes the questionnaire distribution, the response rate, and the demographic characteristics of the respondents, including their professions and work areas. After that, the chapter reports participants' perceptions of 12 dimensions of safety culture, identified through the HSOPSC, across three hospitals together, and then presents each hospital separately. The frequency of positive, negative, and neutral responses, the mean, and the standard deviation (SD) of the percentages of positive responses are presented for each dimension items and the composite of each dimension. Three hospitals are compared with respect to the percentages of positive responses (mean) for 12 dimensions. The relationship between safety culture dimensions and the demographic characteristics of participants is explored (professional group, experience, and number of working hours per week). The remaining two outcome variables – patient safety grade and the number of events reported in the previous 12 months – across the three hospitals are also presented, along with the reliability test of the questionnaire. The chapter concludes with a summary of the key findings.

7.2 Patient safety culture dimensions

As previously discussed (see section 5.2.2), the HSOPSC questionnaire consists of 42 items (24 positively worded items and 18 negatively worded items) which all measure 12 dimensions of patient safety culture. Table 7.1 shows all 12 patient safety culture dimensions and their items.

Table 7.1 HSOPSC domains and items

Domains	Number of items
1.Teamwork within units A1. People support one another in this unit. A3. When a lot of work needs to be done quickly, we work together as a team to get the work done. A4. In this unit, people treat each other with respect. A11. When one area in this unit gets really busy, others help out.	4
2. Supervisor/Manager Expectations & Actions Promoting Patient Safety B1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures. B2. My supervisor/manager seriously considers staff suggestions for improving patient safety. B3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts. R B4. My supervisor/manager overlooks patient safety problems that happen over and over. R	4
3. Organisational Learning—Continuous Improvement A6. We are actively doing things to improve patient safety. A9. Mistakes have led to positive changes here. A13. After we make changes to improve patient safety, we evaluate their effectiveness	3
4. Management Support for Patient Safety F1. Hospital management provides a work climate that promotes patient safety. F8. The actions of hospital management show that patient safety is a top priority. F9. Hospital management seems interested inpatient safety only after an adverse event happens. R	3
5. Overall Perceptions of Patient Safety	

A15. Patient safety is never sacrificed to get more work done. A18. Our procedures and systems are good at preventing errors from happening. A10.It is just by chance that more serious mistakes don't happen around here. R A17. We have patient safety problems in this unit. R	4
6. Feedback & Communication About Error C1. We are given feedback about changes put into place based on event reports. C3. We are informed about errors that happen in this unit. C5. In this unit, we discuss ways to prevent errors from happening again.	3
7. Communication Openness C2. Staff will freely speak up if they see something that may negatively affect patient care. C4. Staff feel free to question the decisions or actions of those with more authority. C6. Staff are afraid to ask questions when something does not seem right. R	3
8. Frequency of Events Reported D1. When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? D2. When a mistake is made, but has no potential to harm the patient, how often is this reported? D3. When a mistake is made that could harm the patient, but does not, how often is this reported?	3
9. Teamwork Across Units F4. There is good cooperation among hospital units that need to work together. F10. Hospital units work well together to provide the best care for patients. F2. Hospital units do not coordinate well with each other. R F6. It is often unpleasant to work with staff from other hospital units. R	4

10. Staffing A2. We have enough staff to handle the workload. A5. Staff in this unit work longer hours than is best for patient care. R A7. We use more agency/temporary staff than is best for patient care. R A14. We work in "crisis mode" trying to do too much, too quickly. R	4
11. Handoffs & Transitions F3. Things "fall between the cracks" when transferring patients from one unit to another. R F5. Important patient care information is often lost during shift changes. R F7. Problems often occur in the exchange of information across hospital units. R F11. Shift changes are problematic for patients in this hospital. R	4
12. Non-punitive Response to Errors A8. Staff feel like their mistakes are held against them. R A12. When an event is reported, it feels like the person is being written up, not the problem. R A16. Staff worry that mistakes they make are kept in their personnel file.	3
12	**42**
*R= Reverse code (negatively worded questions)	

7.3 Questionnaire distribution and response rate

The questionnaire was distributed between July and August 2019 using an online survey platform run by 'Jisc', which was used to design the survey and create a link for distribution. Jisc is a United Kingdom not-for-profit company that provides network and IT services and digital resources in support of higher education institutions. This platform is supported by the University of Glasgow. The sample consisted of 363 healthcare professionals recruited from three hospitals selected for this phase, as detailed in section 5.2.5.

The minimum sample size required to be representative for a whole population of this study was 351 participants, based on the sample size calculation discussed in the previous chapter (section 5.3.2.2). Of the 1200 questionnaires distributed over the three hospitals sites, 363 were returned completed, giving an overall response rate of 30%. This is considered low; the response rate for each hospital site is described in Table 7.2, below. Table 7.2 shows the number of participants in each hospital. The largest number of responses came from hospital A (n=215, 59.2%), followed by hospital B (n=127, 35%) and the lowest percentage of participants belonged to hospital C (n=21, 5.8%).

Table 7.2 Number of the participants per hospitals

Hospital name	Frequency	Percent	Response rate
Hospital A	215	59.2	54%
Hospital B	127	35.0	32%
Hospital C	21	5.8	14%
Total	363	100.0	100.0

7.4 Demographic characteristics of the participants

Table 7.3 below provides descriptive information about the numbers and percentages of healthcare professionals who participated in this study. Of the 363 participants, the majority of healthcare professionals who participated in the study were registered nurses (n=251, 69.1%). Physicians were the second most common participants (n=39, 10.7%), followed by physician assistant/nurse practitioners (n=20, 5.5%). Sixteen of the participants were pharmacists (4.4%) and 12 were technicians (3.3%)

from various departments (e.g., EKG, Lab, Radiology). There were seven dieticians (1.9%) and there was a similar number of respiratory therapists and physical, occupational, or speech therapists (n=4, 1.1%). Other participants (n=10, 2.8%) were of different backgrounds (supervisors of allied healthcare, midwife, head nurse, quality and patient safety officers, and nursing educators).

Table 7.3 Healthcare professionals' categories

Healthcare professional category	Frequency	Percentage
Registered Nurse	251	69.1%
Staff Physician	39	10.7%
Physician Assistant/Nurse Practitioner	20	5.5%
Pharmacist	16	4.4%
Dietician	7	1.9%
Respiratory Therapist	4	1.1%
Physical, Occupational, or Speech Therapist	4	1.1%
Technician (e.g., EKG, Lab, Radiology)	12	3.3%
Others	10	2.8%
(Supervisors, midwife, head nurse, quality and patient safety officers and nursing educators)		
Total	363	100%

Table 7.4, which reports the work areas of the respondents, shows that among the total respondents (n=363) the sample came from a wide range of hospital departments, but predominantly the largest proportion of the participants worked in the emergency department (n=100, 27.5%) and the lowest number of participants (n=1, 0.3%) was from psychiatry/mental health department. Fifty (13.8%) of the participants worked in many different hospital units, while 47 (12.9%) were from intensive care unit (ICU). Participants from medicine and surgery units were n=46 (12.7%), n=36 (9.9%) respectively. The rest of the participants with small percentages were from variety of the hospitals departments, as detailed in the (Table 7.4).

Table 7.4 Healthcare professionals and work areas

Healthcare professionals work areas	Frequency	Percentage
Many different hospital units/No specific unit	50	13.8%
Medicine	46	12.7%
Surgery	36	9.9%
Obstetrics	15	4.1%
Paediatrics	2	0.6%
Emergency department	100	27.5%
Intensive care unit (any type)	47	12.9%
Psychiatry/mental health	1	0.3%
Rehabilitation	2	0.6%
Pharmacy	14	3.9%
Laboratory	7	1.9%
Radiology	2	0.6%
Anaesthesiology	4	1.1%
Others	37	10.2%
Total	363	100%

Table 7.5 below describes the characteristics of the respondents in relation to many aspects (years of work in this hospital; years of work in current hospital work area/unit; years of work in current speciality or profession; hours of work per week; and direct contact with patients). It is noted that the participants were an experienced group of staff, since more than two thirds of the sample had worked in their hospital for six years or more. The largest proportion of the participants (n=267, 73.6%) had experience from one to ten years in their current speciality or profession. In relation to working hours, 262 participants (72.2%) reported that they worked 40 to 59 hours per week, indicating that this was the most common category of working hours per week among respondents. The majority of the respondents n=322 (89%) were in contact with patient directly which indicate that the sample are representative of the population who work in clinical areas which may reflect actual practice for patient safety.

Table 7.5 Characteristics of the respondents (n=363)

Items	Variables	Frequency/ percentages
Years of working in this hospital	1 to 5	134 (36.9%)
	6 to 10	129 (35.5%)
	11 to 15	66 (18.2%)
	16 to 20	22 (6.1%)
	21 or more	12 (3.3%)
Years of working in current hospital work area/unit	1 to 5	182 (50.1%)
	6 to 10	114 (31.4%)
	11 to 15	43 (11.8%)
	16 to 20	19 (5.2%)
	21 or more	5 (1.4%)
	1 to 5	148 (40.8%)
Years of working in your current speciality or profession	6 to 10	119 (32.8%)
	11 to 15	58 (16%)
	16 to 20	25 (6.9%)
	21 or more	13 (3.6%)
	Less than 20	19 (5.2%)
Working hours per week	20 to 39	33 (9.1%)
	40 to 59	262 (72.2%)
	60 to 79	33 (9.1%)
	80 to 99	8 (2.2%)
	100 or more	8 (2.2%)
Direct interaction or contact with patients		
	Yes	322 (88.7%)
	No	41 (11.3%)

7.5 Perception of patient safety culture

Based on the AHQR guidelines as mentioned earlier in section 5.2.9, the survey items were grouped according to their related safety culture dimensions identified by (Sorra and Dyer, 2010, Sorra and Nieva, 2004b). Then, the two lowest response categories (Strongly disagree/Disagree and Never/Rarely) and the two highest response categories (Strongly agree/Agree and Most of the time/Always) for all items in all of the sections were combined. The total percentage of positives, negatives and neutrals with mean score and standard deviation (SD) were calculated for each composite after reverse negatively worded items that described in the (Table 7.1) The percentages of the positive responses were calculated within the 12 patient

safety culture dimensions and their items which indicated the overall perception towards 12 patient safety culture dimensions.

Firstly, the percentages of the positive responses for each of the 12 patient safety culture dimensions were investigated among n= 363 respondents in the 3 hospitals sites. Secondly, the percentages of the positive responses for each of the 12 patient safety culture dimensions were reported separately for every site to measure any differences of positive rating of 12 patient safety culture dimensions between the sites. The dimensions of higher positives scores indicate more positive perception and attitudes towards patient safety culture. Table 7.6 shows the distribution of positive, neutral, negative responses and Mean & SD of %'s of positive responses of 363 study subjects grouped for all sites towards their perceptions on patient safety culture.

Table 7.6 Distribution of positive, negative, and neutral responses and Mean & SD of rate of positive responses of n=363 grouped for all sites

Domains & Items	Responses No. (%)			Mean of % Positive responses	SD of % Positive responses
	Negative	**Neutral**	**Positive**		
1.Teamwork within units A1. People support one another in this unit.	80(22)	38(10.5)	245(67.5)	63.57%	7.33%
A3. When a lot of work needs to be done quickly, we work together as a team to get the work done.	67(18.5)	51(14)	245(67.5)		
A4. In this unit, people treat each other with respect.	76(20.9)	45(12.4)	242(66.7)		
A11. When one area in this unit gets really busy, others help out.	100(27.5)	72(19.8)	191(52.6)		
2. Supervisor/Manager Expectations & Actions Promoting Patient Safety B1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.	84(23.1)	47(12.9)	232(63.9)	45.77%	18.55%
B2. My supervisor/manager seriously considers staff suggestions for improving patient safety.	98(27)	50(13.8)	215(59.2)		
B3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.	159(43.8)	82(22.6)	122(33.6)		

B4. My supervisor/manager overlooks patient safety problems that happen over and over.	199(54.8)	68(18.7)	96(26.4)		
3. Organisational Learning—Continuous Improvement A6. We are actively doing things to improve patient safety. A9. Mistakes have led to positive changes here. A13. After we make changes to improve patient safety, we evaluate their effectiveness	56(15.4) 88(24.2) 79(21.8)	31(8.5) 83(22.9) 48(13.2)	276(76) 192(52.9) 236(65)	64.63%	11.55%
4. Management Support for Patient Safety F1. Hospital management provides a work climate that promotes patient safety. F8. The actions of hospital management show that patient safety is a top priority. F9. Hospital management seems interested in patient safety only after an adverse event happens.	95(26.2) 56(15.4) 171(47.1)	80(22) 60(16.5) 74(20.4)	188(51.8) 247(68) 118(32.5)	50.77%	17.77%
5. Overall Perceptions of Patient Safety A15. Patient safety is never sacrificed to get more work done. A18. Our procedures and systems are good at preventing errors from happening. A10.It is just by chance more serious mistakes don't happen around here. A17. We have patient safety problems in this unit.	99(27.3) 85(23.4) 174(47.9) 163(44.9)	77(21.2) 72(19.8) 77(21.2) 69(19)	187(51.5) 206(56.7) 112(30.9) 131(36.1)	43.80%	12.27%
6. Feedback & Communication About Error C1. We are given feedback about changes put into place based on event reports. C3. We are informed about errors that happen in this unit. C5. In unit, we discuss ways to prevent errors from happening again	91(25.1) 69(19) 64(17.6)	129(35.5) 107(29.5) 89(24.5)	143(39.4) 187(51.5) 210(57.9)	49.60%	9.39%
7. Communication Openness C2. Staff will freely speak up if they see something that may negatively affect patient care.	89(24.5)	118(32.5)	156(43)	39.57%	3.79%

C4. Staff feel free to question the decisions or actions of those with more authority.	124(34.2)	93(25.6)	146(40.2)		
C6. Staff are afraid to ask questions when something does not seem right.	108(29.8)	126(34.7)	129(35.5)		
8. Frequency of Events Reported D1. When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	127(35)	102(28.1)	134(36.9)	41.23%	4.93%
D2. When a mistake is made, but has no potential to harm the patient, how often is this reported?	118(32.5)	99(27.3)	146(40.2)		
D3. When a mistake is made that could harm the patient, but does not, how often is this reported?	97(26.7)	97(26.7)	169(46.6)		
9. Teamwork Across Units F4. There is good cooperation among hospital units that need to work together.	105(28.9)	70(19.3)	188(51.8)	47.5%	10.1%
F10 Hospital units work well together to provide the best care for patients.	80(22)	66(18.2)	217(59.8)		
F2. Hospital units do not coordinate well with each other.	145(39.9)	71(19.6)	147(40.5)		
F6. It is often unpleasant to work with staff from other hospital units.	138(38)	87(24)	138(38)		
10. Staffing A2. We have enough staff to handle the workload.	226(62.3)	36(9.9)	101(27.8)	27.95%	8.90%
A5. Staff in this unit work longer hours than is best for patient care.	215(59.2)	55(15.2)	93(25.6)		
A7. We use more agency/temporary staff than is best for patient care.	147(40.5)	71(19.6)	145(39.9)		
A14. We work in "crisis mode" trying to do too much, too quickly	226(62.3)	70(19.3)	67(18.5)		
11. Handoffs & Transitions F3. Things "fall between the cracks" when transferring patients from one unit to another.	145(39.9)	91(25.1)	127(35)	37.27%	6.14%
F5. Important patient care information is often lost during shift changes.	137(37.7)	59(16.3)	167(46)		

F7. Problems often occur in the exchange of information across hospital units	155(42.7)	93(25.6)	115(31.7)		
F11. Shift changes are problematic for patients in this hospital.	132(36.4)	99(27.3)	132(36.4)		
12. Non-punitive Response to Errors A8. Staff feel like their mistakes are held against them. A12. When an event is reported, it feels like the person is being written up, not the problem. A16. Staff worry that mistakes they make are kept in their personnel file.	195(53.7) 194(53.4) 235(64.7)	75(20.7) 82(22.6) 58(16)	93(25.6) 87(24) 70(19.3)	22.9%	3.3%

The percentages of the positive responses of each of the 12 patient safety culture dimensions of 363 participants were shown in (Table 7.7) which illustrates those dimensions as strengths or those that need improvement. Dimension scores exceeding 70% positive rating were considered an area of strength, whereas those scoring less than 70% were considered areas for improvement, as described by the HSOPSC user guide and used in previous study (Alswat et al., 2017). Table 7.7 below shows percentages of the composite positive responses of each of the 12 patient safety culture dimensions across all study sites which ranged from 22.9% to 64.6%. The dimensions with the highest percentage of the positive scores were "Organisational learning–continuous improvement" (64.6%) followed by "teamwork within unit" (63.5%) and "Management Support for Patient Safety" (50.7%). Although, none of these three dimensions with the highest percentages reached the threshold of 70% positive score to be an area of strength. It suggests that most of the respondents agreed that they were actively doing things to improve patient safety culture, people support one another inside units and patient safety is a top priority of hospital management. All other composites scores of the dimensions were less than 50% as described in the (Table 7.7) which indicate that it is considered an area of potential improvement as well. Moreover, the two lowest percentages of the positive scores were "non-punitive response to error" (22.9%) followed by "Staffing" (27.9%). The "non-punitive response to error" findings suggests that there is a blame culture as respondents feel that their mistakes are held against them and kept in their

personal file. For the staffing dimension respondents indicated that there was high workload and staff work longer hours than what should be considered best for patient safety.

Interestingly, none of the 12 dimensions of the patient safety culture that were examined reached 70% to be considered an area of strength. Therefore, these results indicate that all participants across all study sites considered all the 12 dimensions of the patient safety culture as areas for potential improvement.

Table 7.7 The percentages of positive responses of n=363 study subjects towards their perceptions on patient safety culture

Patient safety culture domains	Number of items	Average % of positive responses
Teamwork within units	4	63.57%
Supervisor/Manager Expectations & Actions Promoting Patient Safety	4	45.77%
Organisational Learning-Continuous Improvement	3	64.63%
Management Support for Patient Safety	3	50.77%
Overall Perceptions of Patient Safety	4	43.80%
Feedback & Communication About Error	3	49.60%
Communication Openness	3	39.57%
Frequency of Events Reported	3	41.23%
Teamwork Across Units	4	47.5%
Staffing	4	27.95%
Handoffs & Transitions	4	37.27%
Non-punitive Response to Errors	3	22.9%

In the following sections, the results of the percentages of the composite positive responses to HSOPSC are presented for each hospital separately to measure the perception of patient safety culture among participants, and to examine whether there are any differences in patient safety culture between healthcare professionals in participating hospitals.

7.6 Comparisons of positive responses between three hospitals

The mean positive response for each of the 12 patient safety culture dimensions was evaluated separately for every hospital site to measure any differences between the sites (Figure 7.1). Figure 7.1 shows that all the dimensions required improvement, as none of the dimensions in any hospital site reached 70%.
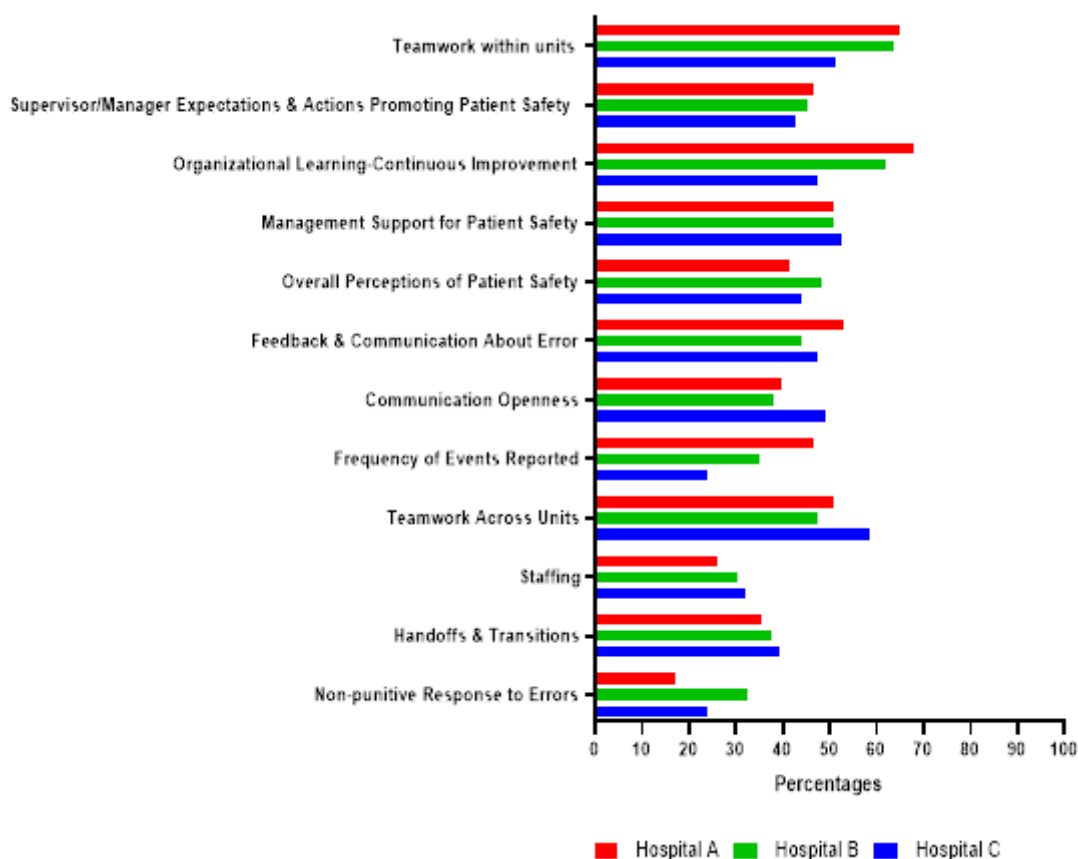
Figure 7.1 Comparison of mean positive responses in 12 domains among the three hospitals

Additionally, statistical analysis was performed to compare mean positive response scores across the three hospitals. One-way analysis of variance (ANOVA) was used to compare the mean scores of dimensions across hospitals, and post hoc tests were conducted to identify the differences when the ANOVAs were significant. Table 7.8 below provide the descriptive statistics of all domains.

Table 7.8 Descriptive statistics of all domains

Name of the domain	Mean	Standard deviation	Standard error	95% confidence interval for mean
Teamwork within units	63.57	37.95	1.99	59.65 to 67.48
Supervisor/Manager Expectations & Actions Promoting Patient Safety	45.80	24.68	1.29	43.25 to 48.35
Organizational Learning-Continuous Improvement	64.63	38.57	2.02	60.65 to 68.60
Management Support for Patient Safety	50.75	31.84	1.67	47.46 to 54.03
Overall Perceptions of Patient Safety	43.80	23.42	1.23	41.38 to 46.22
Feedback & Communication About Error	49.57	40.43	2.12	45.39 to 53.74
Communication Openness	39.55	34.55	1.81	35.98 to 43.18
Frequency of Events Reported	41.22	32.25	1.73	36.86 to 45.57
Teamwork Across Units	47.52	30.15	1.58	44.41 to 50.63
Staffing	27.96	24.15	1.26	25.47 to 30.45
Handoffs & Transitions	37.26	35.64	1.87	33.37 to 41.14
Non-punitive Response to Errors	22.94	32.57	1.71	19.58 to 26.30

The mean of positive responses for the 12 dimensions ranges from 67.9% to 17.2% in hospital A, from 63.6% to 35.5% in hospital B, and from 58.3% to 23.8.5% in hospital C (Table 7.9). The vast majority of the dimensions (n=9) scored < 50% of the positive percentages in hospitals B and C, which indicates that there is a lower perception of patient safety culture that needs improvement in both hospitals. All three hospitals shared similar lowest percentages for two dimensions, namely 'non-punitive response to error' and 'staffing'.

The findings show that nine out of 12 HSOPSC dimensions in the three hospitals had significant differences in their mean scores (p-value < 0.05). However, three

dimensions, namely 'supervisor/manager expectations & actions promoting patient safety', 'management support for patient safety' and 'handoffs & transitions' did not show any significant differences in their mean scores (Table 7.). The findings of the Tukey post hoc test are presented in the table and was used in the second stage of the ANOVA analysis to determine which hospital site was statistically higher than the other two mean values. The findings show that hospital A was higher in four dimensions: 'teamwork within units', 'organisational learning/continuous improvement', 'feedback & communication about errors' and 'frequency of events reported'. Hospital B was higher in only two dimensions: 'overall perceptions of patient safety' and 'non-punitive response to errors'. Hospital C was higher in four dimensions, as described in (Table 7.).

Table 7.9 Comparison of average rate of positive responses (mean) of 12 domains among the three hospitals

Domains	Average % of positive responses			$F_{(2,360)}$-value	p-value
	Hospital A (n= 215)	Hospital B (n= 127)	Hospital C (n= 21)		
Teamwork within units	64.8*	63.6	51.2	28.35	<0.0001
Supervisor/Manager Expectations & Actions Promoting Patient Safety	46.4	45.3	42.8	0.399	0.671
Organizational Learning-Continuous Improvement	67.9*	61.9	47.6	33.84	<0.0001
Management Support for Patient Safety	50.6	50.9	52.4	0.098	0.906
Overall Perceptions of Patient Safety	41.3	48.0*	44.0	10.389	<0.0001
Feedback & Communication About Error	53.0*	44.1	47.6	33.276	<0.0001
Communication Openness	39.7	37.8	49.2*	29.023	<0.0001
Frequency of Events Reported	46.7*	34.9	23.8	307.149	<0.0001
Teamwork Across Units	50.9	47.6	58.3*	10.321	<0.0001
Staffing	26.0	30.5	32.1*	11.336	<0.0001
Handoffs & Transitions	35.3	37.4	39.3*	5.978	0.003
Non-punitive Response to Errors	17.2	32.5*	23.8	408.96	<0.0001

*Statistically higher than the other two mean values by post hoc test (Tukey's test)

Overall, the findings suggest that the perceptions of patient safety culture among hospitals were vary, since there were significant differences between the means of the positive responses for most of the dimensions (9 out of 12) between hospitals. Although all dimensions across the three hospitals required improvements, 'non-punitive response to error' and 'staffing' showed the lowest mean of positive responses across the three hospitals, suggesting that all three hospitals shared similar factors that hinder positive patient safety culture that need further exploration in the next qualitative study (Phase III). The next section provides the perception of patient safety culture in regard to the characteristics of the participants.

7.7 Differences in perception of patient safety culture with respect to demographic characteristics

One-way ANOVA was used to compare perceptions of patient safety culture with the employment and profession characteristics of individuals, including profession groups, experience, work unit, and work hours.

7.7.1 Perception of patient safety culture and work unit/department

The one-way ANOVA result shows that there are statistically significant differences between work area and six patient safety culture dimensions, namely 'supervisor/manager expectations & actions promoting patient safety', 'management support for patient safety', 'feedback & communication about errors', 'frequency of events reported', 'staffing', and 'non-punitive response to errors'. The other dimensions were not significantly different regarding work unit (Table 7.). Further to this, the post-hoc test (Tukey's test) indicates that numbers of work areas differed significantly from others in respect to the mean of positive responses (grouped for all sites), which marked as (*) in (Table 7.10).There was no trend/no clinical area that clearly differed from the others in the mean of positive responses, but both medical and emergency units were statistically different in the mean of the positive responses in four out of six dimensions of patient safety culture (Table 7.10).

Table 7.10 Comparison of mean positive responses in 12 domains in relation to working unit/department

Domains	Working unit					$F_{(4,358)}$-value	p-value
	Medicine	Surgery	Emergency unit	ICU	Others		
Teamwork within units	70.6	61.1	59.0	67.0	63.9	0.901	0.463
Supervisor/Manager Expectations & Actions Promoting Patient Safety	40.8*	46.5	42.5	54.8*	46.6	2.576	0.037
Organizational Learning-Continuous Improvement	63.0	51.8	71.6	65.2	63.2	1.907	0.109
Management Support for Patient Safety	40.5*	37.9	53.3	56.7*	53.7	3.597	0.007
Overall Perceptions of Patient Safety	40.2	45.1	41.5	48.4	44.8	1.053	0.380
Feedback & Communication About Error	36.9*	44.4	57.6*	53.2	47.9	2.450	0.046
Communication Openness	33.3	37.9	37.6	46.1	41.2	0.973	0.422
Frequency of Events Reported	31.8	29.6*	52.3*	38.2	40.3	3.113	0.015
Teamwork Across Units	42.4	42.3	48.5	50.5	48.9	0.807	0.522
Staffing	24.4*	36.8*	22.5*	31.4	29.7	3.205	0.013
Handoffs & Transitions	33.7	44.4	36.0	40.4	36.4	0.558	0.694
Non-punitive Response to Errors	21.7	29.6*	15.0*	22.7	27.6*	2.615	0.015

*Statistically different with each other by post hoc test (Tukey's test)

7.7.2 Perception of patient safety culture and professional groups

The one-way ANOVA shows five dimensions were not significantly different regarding the health professional groups, and the rest of the dimensions were statistically significantly different, as described in (Table 7.). Further post-hoc tests (Tukey's test) were conducted to identify which healthcare worker groups were different from others, with the findings presented in (Table 7.). There is evidently a significant difference between nurses and other groups with regard to the mean of positive responses. For example, nurses express significantly more positive views on patient safety culture than other groups (Table 7.).

Table 7.11 Comparison of mean positive responses in 12 domains in relation to healthcare profession groups

Domains	Staff position in hospital			$F_{(2,360)}$-value	p-value
	Nurses	Physicians	Others		
Teamwork within units	64.2	62.1	61.3	0.157	0.855
Supervisor/Manager Expectations & Actions Promoting Patient Safety	46.8	41.0	44.3	1.033	0.357
Organizational Learning-Continuous Improvement	68.5*	49.5*	55.9	5.833	0.003
Management Support for Patient Safety	53.1*	36.7*	49.0	4.629	0.010
Overall Perceptions of Patient Safety	44.6*	34.6*	46.2	3.510	0.031
Feedback & Communication About Error	52.4*	27.3*	51.5*	6.829	0.001
Communication Openness	40.6	31.6	40.2	1.158	0.315
Frequency of Events Reported	44.1*	23.9*	38.9	4.060	0.018
Teamwork Across Units	49.5*	37.2*	44.8	3.153	0.044
Staffing	26.3*	28.2	36.3*	3.885	0.021
Handoffs & Transitions	37.6	32.0	39.1	0.453	0.636
Non-punitive Response to Errors	22.1	20.5	28.9	1.086	0.339

*Statistically different with each other by post hoc test (Tukey's test)

7.7.3 Perception of patient safety culture and years working in their hospital

The one-way ANOVA was used to explore the association of staff years' work experience in their hospital with the 12 dimensions of patient safety culture in the HSOPSC survey, and only one dimension, the frequency of events reported was found to be significant (P <0.021). The other dimensions were not significantly different regarding years of work experience (Table 7.). The findings revealed that the participants with more working experience in their hospital (11 years or more) had more positive perceptions towards the frequency of events reported. The post hoc test (Tukey's test) showed that there were statistically significant differences between healthcare workers with 11 to 15 years of experience and those with >=16 years compared with other groups of experiences that are not statistically different in the mean of positive responses.

Table 7.12 Comparison of mean positive responses in 12 domains in relation to work experience

Domains	How long worked in this hospital ? (in years)				$F_{(3,359)}$ - value	p-value
	1 to 5	6 to 10	11 to 15	>=16		
Teamwork within units	65.5	60.6	68.6	57.3	1.052	0.370
Supervisor/Manager Expectations & Actions Promoting Patient Safety	42.5	45.5	49.2	52.9	2.184	0.090
Organizational Learning-Continuous Improvement	66.6	63.8	68.2	52.9	1.376	0.250
Management Support for Patient Safety	52.4	47.2	56.5	46.0	1.627	0.183
Overall Perceptions of Patient Safety	45.1	41.7	46.6	41.2	0.959	0.412
Feedback & Communication About Error	52.2	45.7	57.5	38.2	2.359	0.071
Communication Openness	40.5	37.7	45.9	30/4	1.720	0.162
Frequency of Events Reported	38.3	41.6	54.0*	26.5*	3.701	0.021
Teamwork Across Units	49.6	45.3	47.3	47.8	0.441	0.724
Staffing	25.9	27.7	29.2	34.5	1.222	0.301
Handoffs & Transitions	38.0	37.6	31.4	44.1	0.925	0.429
Non-punitive Response to Errors	18.6	26.8	20.7	29.4	1.968	0.119

*Statistically different with each other by post hoc test (Tukey's test)

7.7.4 Perception of patient safety culture and working hours per week

Working hours were found to vary statistically significantly with three dimensions of patient safety culture; organisational learning–continuous improvement, staffing and non-punitive response to errors. Staff working 40–59 hours per week were had the highest mean of positive responses, which suggests that long working hours (<59) influence positive perceptions towards safety culture negatively. Post hoc analysis (Tukey's test) indicated that positive response to patient safety culture was most significantly associated with working hours between 40–59 followed by 20–39 for the dimensions reported significance differences in perception of patient safety culture with working hours (Table 7.).

Table 7.13 Comparison of mean positive responses in 12 domains in relation to working hours per week

Domains	Number of hours working per week					$F_{(4, 358)}$-value	p-value
	<20	20 to 39	40 to 59	60 to 79	>=80		
Teamwork within units	60.5	53.0	66.6	57.6	51.6	1.705	0.148
Supervisor/Manager Expectations & Actions Promoting Patient Safety	40.8	43.2	47.1	43.9	39.1	0.824	0.510
Organizational Learning-Continuous Improvement	56.1	51.5*	68.7*	52.5	60.5	2.827	0.025
Management Support for Patient Safety	49.1	37.3	53.5	45.4	45.8	2.335	0.055
Overall Perceptions of Patient Safety	48.7	37.1	44.6	43.9	37.5	1.258	0.286
Feedback & Communication About Error	47.3	35.3	51.9	42.4	58.3	1.710	0.147
Communication Openness	38.5	38.3	40.3	37.3	35.4	0.135	0.969
Frequency of Events Reported	43.8	36.3	43.6	30.3	31.2	1.117	0.348
Teamwork Across Units	47.4	47.7	47.4	50.7	42.2	0.220	0.927
Staffing	40.8*	37.1	24.5*	36.4	32.8	5.249	<0.0001
Handoffs & Transitions	39.5	50.7	36.2	37.9	21.9	1.810	0.126
Non-punitive Response to Errors	35.1*	31.3	19.2*	34.3	29.1	3.302	0.011

*Statistically different with each other by post hoc test (Tukey's test)

7.8 Patient safety grades

Figure 7.2, below, is a bar chart showing the frequency and proportion of the participants' ratings of overall safety in their organisations, which indicate the respondents' opinions towards the level of the patient safety at their hospitals. Over one third of the respondents (n=136, 37.5%) reported that they perceived patient safety to be at an acceptable level, whereas 125 (34.4 %) of the respondents reported patient safety at a very good level and 63 (17.4%) rated it as excellent. Finally, 32 (8.8%) and 7 (1.9%) of the respondents rated the patient safety levels in their hospitals as poor and failing, respectively. The findings revealed that most participants thought that patient safety was acceptable in their hospital, even though data shows so many domains fell below the cut-off of 70% to be strengths.
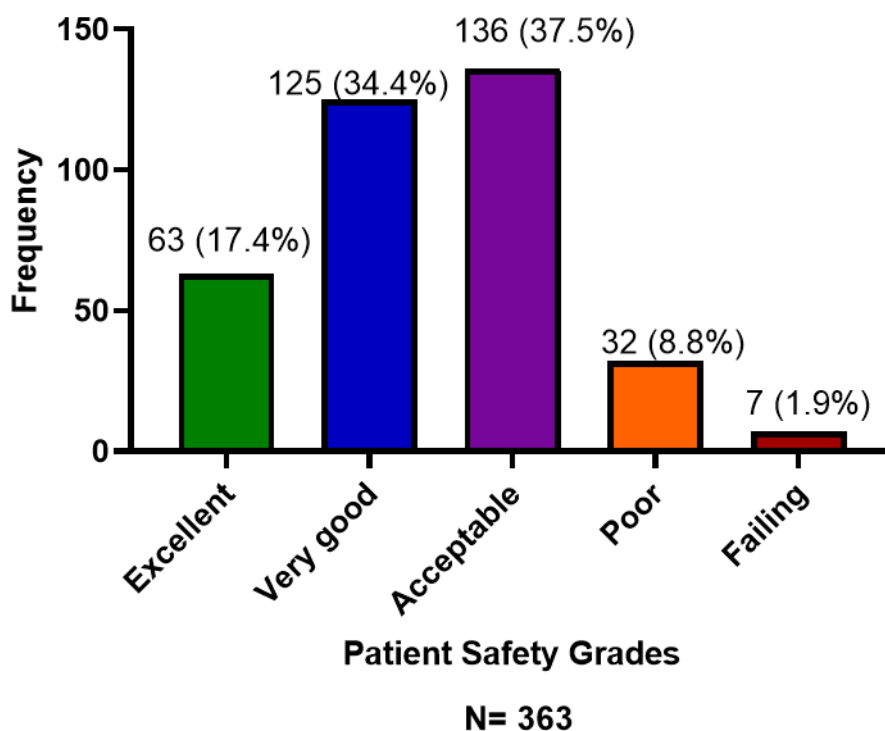
Figure 7.2 Patient safety grades

7.9 Number of events reported, in the past 12 months

As shown in the bar chart below Figure 7.3, nearly two thirds of respondents had reported at least one safety event in their hospital in the previous year and more than a quarter (28.4%) had reported between three and 10 events. Moreover, three to five events were reported by 73 participants (20.1%), and 30 (8.3%) reported six to 10 events in the last 12 months. Lastly, 11 to 20 events were reported by 13 respondents (3.6%), and 14 (3.9%) respondents reported 21 or more events in the last 12 months. However, this finding shows that reporting of events among staff was low, which may have increased the possibility of the existence of underreporting of errors.
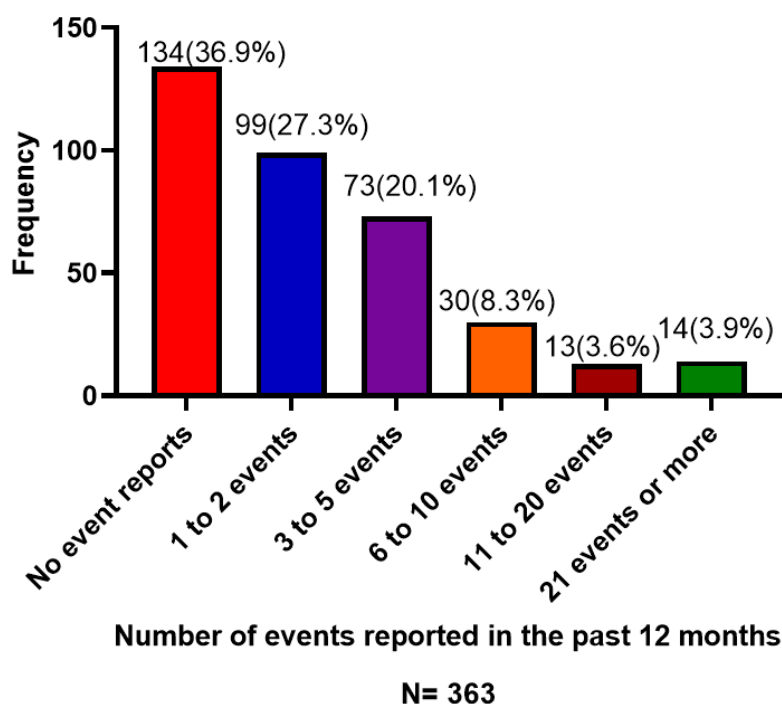
Figure 7.3 Number of events reported in the past 12 months

7.10 Coding of open-ended comments

All the written comments provided by the participants were coded and analysed using the manifest content analysis approach (Bengtsson (2016), as described in section 5.2.9). Table 7. provides a summary of the categories and quotes from the analysed text. From the 363 respondents to the survey, different comments were provided which mainly related to the four categories (staff issues, teamwork, characteristic of the survey, and others). Most of the comments raised concerned staffing issues, with respondents complaining about understaffing and excessive workload which put them under too much stress to maintain safe practice and effective patient safety. Teamwork was also mentioned by respondents, who argued that improved cooperation and teamwork among healthcare professionals would reduce errors and improve patient safety. Moreover, some comments related to the questionnaire itself: it was reported as either good or very long, as it contained a lot of questions. Finally, most of the comments were either not related to the topic or ambiguous, including thanks to the researcher and organisations.

Table 7.14 Categories and quotes based on analysis of open-ended responses

Categories	Quotes (respondents' comments)
Staff issue	"Nurse patient ratio need to be improved". "The number of nursing staff is not enough". "To provide a patient safety need to increase the number of staffs". "Enough staffing and improve the equipment for the patient safety use". "Lacking nursing staff affecting the patient safety". "Please provide enough staff for us if you want to achieve patient safety effectively". "Lack of staff, sometimes we need to do multi-tasking that we can't follow the indicated policies".
Teamwork	"Shortage of staff made a pressure on the nurses". "Doctors and nurses must work more as a team to prevent errors". "Staff aren't trying to collaborate the whole time".
Characteristics of survey	"Need to be more cooperative with each other". "Excellent survey". "A lot of questions". "Patient safety should be identified clearly at the beginning of the survey".
Others	"Thanks, Good luck, NA, No comments, Good, Nothing, I love my work".

7.11 Reliability test of the HSOPSC dimensions responses

To determine the reliability of the questionnaire, Cronbach's alpha test was performed for each of the 12 HSOPSC dimensions to assess for (internal consistency) to which items within each dimension relate to each other. Dimensions with Cronbach's alpha values α = ≥0.6 were considered as an acceptable reliability whereas, higher alpha indicates good reliability(Sorra and Dyer, 2010). The results of reliability test of the 12 domains are shown in the (Table 7.). Therefore, Cronbach's alpha for the 12 domains ranged from 0.43 to 0.88, with an overall Cronbach's alpha coefficient of α = 0.95. Thereby, nine domains achieved good reliability (0.70 or greater) and two domains had acceptable reliability; namely, 'Organisational learning-continuous improvement' (α = 0.69), 'Frequency of events reported' (α = 0.65). One domain had low reliability; namely, 'Feedback & communication about error' (α = 0.43) as detailed in (Table 7.).

Table 7.15 Reliability of HSOPSC domains

Name of the domain	Number of items	Cronbach's alpha (95% CI)
Teamwork within units	4	0.874(0.834,0.906)
Supervisor/Manager expectations & actions promoting patient safety	4	0.816(0.759,0.863)
Organisational learning-continuous improvement	3	0.881(0.840,0.913)
Management support for patient safety	3	0.696(0.591,0.777)
Overall perceptions of patient safety	4	0.744(0.663,0.810)
Feedback & communication about error	3	0.840(0.786,0.883)
Communication openness	3	0.437(0.243,0.587)
Frequency of events reported	3	0.868(0.822,0.903)
Teamwork across units	4	0.651(0.540,0.740)
Staffing	4	0.721(0.632,0.792)
Handoffs & Transitions	4	0.865(0.822,0.899)
Non-punitive response to errors	3	0.792(0.720,0.848)
All items in scale	42	0.955(0.943,0.965)

7.12 Chapter Summary

This chapter presented the findings of the Phase II survey using the HSOPSC which explored the perception of patient safety culture among healthcare professionals in three hospitals in the Madinah region. The study revealed that all 12 patient safety culture dimensions in the three hospitals studied under optimal level to be strength areas which suggested that they were areas with potential for an improvement. The majority of the HSOPSC dimensions scored below 50% of the positive percentages, highlighting deficiencies and weakness areas of the patient safety culture, and potentially indicating the presence of poor patient safety practice in the study areas. The two dimensions of patient safety culture reported in the three hospitals sites with the lowest mean positive responses were 'non punitive response to error' and 'staffing' which may be indicative of a blame culture and issues, such as high workload and insufficient staff. Therefore, the current study found that healthcare professionals have negative perceptions towards patient safety culture within their institution. Despite this, the patient safety grade was reported as being acceptable, which could be explored more in the Phase III qualitative study.

The Phase II findings indicate that all dimensions of patient safety culture measured by HSOPSC need to be improved. However, most of the dimensions still need further investigation in the next phase – for example, communication, staff issues, teamwork across units, frequency of reporting errors, and non-punitive responses to errors. The reason for this is because Phase II provides a snapshot of the current perceptions of safety culture without examining the underlying issues that hinder or enhance positive safety culture. These findings of the Phase II guided Phase III, so, with a qualitative approach in the next phase, further investigation helped to discover and understand the barriers and facilitators to the implementation of a patient safety culture. Phase II gave an overall breadth to our understanding of the factors influencing patient safety culture; however, to understand more about how these factors influence patient safety culture, more in-depth exploration using qualitative methods are needed, which is covered in Phase III.

Chapter Eight: Phase III Qualitative Findings

8.1 Introduction

This chapter presents the qualitative findings of Phase III of the mixed methods research study. The overall study aimed to identify the barriers to and facilitators of a patient safety culture in Saudi Arabia from different stakeholders' perspectives. Phase III was undertaken to supplement Phase II and to probe for further explanations, and aid contextual understanding, of the findings of the Phase II quantitative study. Phase III gives a clear picture of and comprehensive information about the influence of reported barriers to and facilitators on the implementation of a positive patient safety culture from healthcare professionals' and patients' perspectives, thus enabling a deep understanding of some of the factors and issues identified superficially in the quantitative Phase II. Phase III employed a qualitative methodology comprising two research methods based on their appropriateness for the target populations and research questions (Creswell and Creswell, 2018). The first method was focus groups with healthcare professionals (n=35) and the second was semi-structured interviews with patients/ families (n=12). Two hospital sites were selected for the qualitative phase of the study (as described in section 5.3.1). Thematic analysis was employed for the data analysis and this study adopted the six processes of Braun and Clark (2006) that are detailed in (section 5.3.4). The findings are organised under themes and subthemes, and illustrative quotes are used to provide a short description of the data that emerged from the interviews and focus groups.

8.2 Characteristics of the participants

8.2.1 Demographics of health professionals' participants

A total of 35 healthcare professionals, from across two hospital sites, participated in one of six focus group discussions between September 2019 and November 2019. The demographic details of each participant are presented in the following section (Table 8.1) with key identifiers for each individual within each group. The nursing profession represented half of the participants, with 18 nurses taking part.

In general, none of the participants had fewer than six years of experience and the majority had more than ten years of experience. Three focus groups were held at each hospital site, with healthcare professionals being allocated to one of these groups. An example of key identifier is presented in section 8.3. Table 8.1 shows the demographic details of healthcare professionals who participated in the focus group discussions from both hospital sites.

Table 8.1 Demographic details of healthcare professionals from focus groups

	Participants	Number (n)	Percentages (%)
Gender	Male	15	43
	Female	20	57
Nationality	Saudi	17	48.5
	Others*	18	51.5
Job position	Nurse	18	51.4
	Physician	9	25.7
	Allied healthcare providers*	8	22.8
Age group	20 - 29	4	11.4
	30 - 39	19	54.2
	> 40	12	34.2
Years of experiance	6-10	9	25.7
	11-15	13	37.1
	>16	13	37.1
Qualification	Diploma	4	11.4
	Bacheolar	15	42.8
	Master	7	20
	PhD	9	25.7
Level of position	Manager	16	45.7
	General staff	19	54.2
Hospital site	Hospital A	19	54.2
	Hospital B	16	45.7
Total		35	100

*Others (Sudanese, Egyptian, Indian, Filipino and American).

*Allied healthcare providers (Pharmacist, respiratory therapist, occupational health, risk manager and laboratory specialists).

8.2.2 Demographics of patient/family participants

Twelve patients and family members were interviewed (eight patients and four family members) between October and December 2019. Participants were from different nationalities, ages, education levels, and different cultural backgrounds, which would allow a holistic view of patient safety culture to be obtained. Full demographic details of the participants are presented in Table 8.2.

Table 8.2 Demographic details of participants from semi-structured interviews

	Participants	Number (n)	Percentages (%)
Gender	Male	8	66.6
	Female	4	33.3
Nationality	Saudi	7	58.3
	Others*	5	41.6
Age group	30-39	5	41.6
	40-49	5	41.6
	> 50	2	16.6
Level of education	Diploma	4	33.3
	Bacheolar	4	33.3
	Master	2	16.6
	PhD	2	16.6
Participants type	Patient	8	66.6
	Family member	4	33.3
Hospital site	Hospital A	7	58.3
	Hospital B	5	41.6
Total		12	100

*Others (Sudanese, Egyptian and Jordanian).

8.3 Presentation of the findings

This section presents the findings of the analysis of the participants' transcripts from the interviews with key stakeholders (focus groups and semi-structured interviews). Individuals in each focus group are identified by their participant number (S1, S2, etc.) followed by the focus group number (FGP1, FGP2, FGM1, FGM2) and then by the hospital site (A or B) e.g., (S4, FGM2A). The key identifiers in the semi-structured interviews with patients and family members are their participant numbers (P1, P2, etc.), followed by hospital site (A or B) and their category (patient or family member) e.g., (P10B, patient).

In recognition of the high degree of consistency and commonality in the findings across the two participating hospitals it was considered appropriate to present the data from both sites together in the following sections. The themes identified from both focus groups and interviews were presented in this chapter. When these perspectives are considered together, it facilitated understanding of the overlap and similarities between the different perspectives of healthcare professionals and patients/families towards patient safety culture. Examples from both focus groups and interviews are woven together here, rather than being presented separately as the focus groups followed by the interviews. Four themes were identified from the six focus groups and 12 interviews held with the healthcare professionals and patients/families, which contain both focus group and interview data, and these are presented in the following section.

8.4 Themes and subthemes from focus groups and interviews

The data from each case (interviews and focus groups) were initially coded to provide a number of categories which were then grouped thematically across all cases to ensure that the themes incorporated all the relevant data. The data are presented by theme, in a narrative approach that focuses on the story that the respondents gave, drawing on verbatim quotes from the actual transcripts to illustrate the points made. Illustrative quotes give a short description of the position of the respondents to aid interpretation of the theme. Four themes were identified across the focus group interviews with healthcare professionals and interviews with patients/families on both hospital sites. Table 8.3 shows the themes, subthemes, and codes that are presented

in detail in the following section and supported with quotes from the interview transcripts to gain an understanding of the perceptions, experiences and opinions of different stakeholders with regard to a patient safety culture. Each theme and subthemes are illustrated with quotes taken from focus groups and interviews which numbered according to participants perspective, staff (S), patient or family (P) and from both perspectives (B) in Table 8.3. Each of the themes identified will be discussed in the following section and supported with data extracted from the interview transcripts.

Table 8.3 Themes and subthemes identified from focus groups and interviews

Theme	Subthemes			
Communication	**Interpersonal Communication**		**Documentation**	**Reporting System**
	Staff–Staff: Poor communication system (S) Lack of coordination (B) Difficult to reach the person you need (S) Poor communication among multidisciplinary teams (S) Handover (B) *Staff–Patient:* Language barrier (B) Lack of interaction (B) Culture and language diversity (B) Lack of feedback/response (B) Lack of translators (B)		Absence of electronic documentation (S) Poor record keeping (B) Patient identification and verification (B) Inadequate hospital information systems collecting, storing and sharing patient safety data and information (S)	Unclear reporting system (S) Absence of electronic reporting system (B) Considered as flawed and exacerbates the blame culture (S) Under reporting of errors (S) Lengthy investigation periods (S) No feedback following incident (S) Delay in action following incident (S)
Theme	**Subthemes**			
Work Conditions	**Staff Factors**	**Management/Leadership**	**Professionalism**	**Cultural & Social Factors**
	Insufficient staff (B) Nurse-patient ratio (B) Workload (B)	Poor leadership equated with lack of action on safety issues (S)	Staff behaviour (P) Lack of respect/dignity (P) Carelessness (P)	Blame culture (S) Blame culture – puts people off reporting (S)

	Deficits in knowledge and awareness of patient safety (S) Lack of collaboration & teamwork (B) Staff turnover/changes (S) No clear job description (S) Inadequate staff orientation and qualifications (S) Skills mix and staff competency (S)	Lack of supervision and monitoring staff (S) Absence of feedback following reporting incidents (S) Lack of accountability and responsibility (B) Lack of staff value/ encouragement (S) Leaders act as a role model (S)	Lack of response (P) Lack of attention (P)	Culture of negativity (S) Cover-up to avoid blame (S) Workforce and cultural diversity (B)
Theme	**Subthemes**			
	Environmental Factors	**Hospital Facilities & Resources/Equipment**	**Policy & Guidelines**	**Education and Training**
Organisational Factors	No patient confidentiality, privacy (B) Interruptions, noise (B) Crowdedness (B) Inadequacy with hospital security (B) Poor physical environment (poor cleanliness, poor	Lack of medical equipment/ resources (B) Deficit in IT systems (S) Lack of moving handling devices (B) Lack of services/resources (computers, infrastructure) (B)	Prioritising patient safety policy exists (facilitators) (S) Lack of adherence to policies (S) Deficit of implementation and dissemination (S) Diversity of regulations and practice (S)	Focused programme of education/orientation for staff (B) Suggestion for Arabic class for staff who do not speak Arabic (B) Education – needed for all disciplines and levels of staff (B)

Theme	Subthemes		
	ventilation floor wet, light problems) (B) Poor hospital construction/ maintenance (S) Conflict of visiting time and number of visitors (S)	Lack of medications (B) Deficit in the electronic system for prescribing medication (S)		More awareness (B)
Patient Empowerment and Centredness	**Patient/Family Engagement**	**Person-centred Care**	**Patient/Family Needs**
	Limited patient involvement in patient safety initiatives (B) Lack of sharing decision making (B) Encourage patient to speak up (S) Positive role of patient/family towards their safety (B) Value of learning from patient experience and involvement(B)	Lack of person-centred care (P) Lack implementation of patient needs, preferences (food, sleep) (P) Limited emphasis on patient rights (B)	Encouraging patient/family participation in safety initiatives/awareness programmes (P) Community involvement in patient safety (P) Implementing focused programme for patient safety (P) Learning from patient experience (B)

S: Staff perspective; P: Patient or family perspective; B: Both staff and patient perspectives

8.4.1 Communication

Communication was considered across both groups (patients and healthcare professionals) to be a fundamental element that facilitated and maintained a positive safety culture in healthcare environments. The findings identified that strong and effective communication requires collaborative strategies aimed at improving communication processes and empowering healthcare professionals and patients to be proactive in communication and collaboration. This in turn was believed to enhance trust and improve safe practice. Deficits in communication were highlighted by the participants in three subthemes called interpersonal communication, documentation and reporting system.

8.4.1.1 Interpersonal communication

The term 'interpersonal communication' explains how healthcare team members and patients exchange information, and the interactions and relationships between them. Interpersonal communication appeared to influence team performance and patient safety negatively if not performed competently and efficiently. Taking into consideration the importance and complexity of interpersonal communication in healthcare environments due to the different elements involved, the issues and factors identified by the participants and related to interpersonal communication fit into two categories (staff-staff and staff-patient) as described further below.

<u>Staff–staff</u>

Participants across the six focus groups commented on elements of poor interpersonal communication between staff members. This was highlighted in many forms, including poor communication systems, a lack of coordination among staff in dealing with patients, difficulties reaching the people you needed to talk to, poor communication among multidisciplinary teams and poor communication at handover. Firstly, the communication systems inside healthcare organisations, intended to facilitate effective communication between multidisciplinary teams, were criticised as they were perceived as not useful for approaching colleagues and they did not facilitate discussion between different professional groups.

"Actually, we don't have a professional way to do a [sic] communication inside the hospital" (S4, FGM2A).

"Let's start with challenges or barriers of patient safety. Actually, first thing is communication. Lack of appropriate communication between the staff is the big challenge in our institution" (S4, FGM1A).

Different healthcare professionals agreed on the status of the communication system inside their organisations and they described how its weaknesses negatively impact patient safety and put patients at risk of errors and incidents. For example, one pharmacist stated that,

"I think the bad communication between the pharmacist and the prescriber because we have a weak system. We need to communicate with the physician to verify orders and other things" (S1,FGM2A).

This statement was supported by another participant (physician consultant) who stated that:

"Communication is our big problem, communication between staff to staff, nurse to doctor, doctor to doctor and the pharmacy to the physician to confirm the order and double check with his order" (S4, FGM2A).

Deficits in communication also led to a gap between professionals that could lead to medication errors, as stated by another participant:

"This is one of the gold standard of patient safety. What happen here, there is gap between the pharmacy and the nursing at the ward. I think some medication, they are giving to the patient without labelling. Specially the medication given in the syringe and it is not labelled. I think this is one of the weaknesses of the patient safety" (S6, FGM1B).

Deficits in communication also reported among hospitals as stated by healthcare professionals:

"Really the communication between hospitals is more difficult than the communication inside the hospitals itself" (S2, FGM2B).

"When we are doing consultation[referral] to other hospital so we can't communicate to the specialty we are needed, sometimes they don't responded (S6, FGM2B).

The participants also expressed their criticisms about the communication gap between multidisciplinary teams, particularly as it eliminated coordination and prevented teamwork. Some concerns were raised as follows:

> *"The coordination and the communication between the team is still poor"* *(S5, FGM1A).*

> *"Teamwork can help enhance patient safety. And we face this issue with team building due to lack of communication. If you don't have the communication, we don't have teamwork. So that's my point" (S6, FGM1A).*

The problem of a lack of coordination was also highlighted from the patient/family perspective as well. Patients or their families explained that they had raised concerns over patient safety inside the healthcare organisations. One family member stated that:

> *"There was lack of coordination between patient, patient companions, and the treating staff (doctors and nurses) in relation with the safety of patient" (P1A, family member).*

Both staff members and patients believed that handover was sometimes given inappropriately due to workforce diversity and that this was caused by language barriers between staff, which led to miscommunication. From the staff perspective, one nurse stated that she had difficulty reading and disseminating important information to her team during handovers due to the language barrier.

> *"When I am endorsing [handover] my case to another shift, I don't know this consent is for what. We have to ask one Saudi nurse just read this one and what is on and for what?" [Because consent was written in an Arabic language, the nurse didn't understand so, she struggled with handover process] (S1, FGP1A).*

From the patient perspective, the conflict in the handover between staff was also noted as one participant felt that mistakes made during handover led to the occurrence of errors.

> *"Sometimes you may undergo a treatment which is not genuinely for you as the treating staff may confuse you with somebody else. Also, patients happen to struggle with understanding some treating staff's language as they don't speak Arabic" (P3B, patient).*

Staff–patient

The participants emphasised the importance of the staff-patient relationship for creating the foundation for safe and high-quality healthcare delivery. The discussions among healthcare professionals revealed some staff-patient communication barriers that were related to many aspects of communication, including language barriers, culture and language diversity, a lack of interaction, a lack of feedback and a lack of translators. In relation to the diversity of culture and language, certain concerns were raised by the participants in this study related to communications barriers when the staff did not share the same language as the patient or did not understand the patient's cultural background. Some of the nurses recounted examples of difficult situations that they had faced when working in culturally diverse settings that required knowledge and experience in interpersonal cultural communication. Therefore, nurses considered that knowledge about other cultures and languages was important in order to communicate properly with patients and treat them fairly.

> *"Barriers in communication [is a safety issue] because for us as nurses we have transcultural differences. Let's say, from the nurses. Some of us came from other countries and we have a lot of difference in cultural" "When you go to one country, you need to learn about their culture, and you need to pass their exams like IELTS. So, here we don't have like that. So, we came here [Saudi Arabia] even we are newly hired, we don't know even how to speak even what is inside our heart" (S3, FGM1B).*

Language barriers specifically were also highlighted by the participants in all the focus groups as one of the main issues that prevent staff from understanding their patients' needs. This was thought to be one of the biggest challenges when communicating with culturally diverse patients. Most patients speak Arabic language, which is not true for the staff, especially nurses who have come from different countries. Thereby, many language problems occurred when the staff member was unfamiliar with Arabic or had insufficient knowledge about the language. The participants claimed that patients could feel worried about this if they were unable to discuss their condition effectively with staff. The language barriers mean that healthcare workers are unable to explain things to the patient or convey

important information, which in turn leads to misunderstandings over what is happening to them. Patients are unable to clarify matters such as medications with staff due to these communication barriers. The following examples are from healthcare professionals' perspectives.

"That's when language barrier comes in.. because we cannot really address the problem of the patient subjectively or objectively because we cannot understand what they saying" (S2, FGP2B).

"We are facing a language barrier, I can't make perfect aspect because there is a barrier of language. I don't know Philippine language he don't know Arabic. Can I communicate? Can I make him oriented about this medication? we have language barrier already between the patient and nursing staff from outside the country" (S6, FGM1B).

Language barriers between staff and patients were also mentioned during most of the interviews with patients/families, who considered that it hindered effective communication. Patients believed that a standardised language for patients and staff would play a critical role in determining a good level of safety and minimising errors. One patient stated that:

"Errors can be prevented if both patients and the treating staff speak a language that both of them understand. Unfortunately, most of the time, there is always lack of communication between patients and the treating staff as they don't understand each other's language" (P6A, patient).

The participants also expressed concern over the challenges that patients faced with explaining to staff their needs, health status and what they needed to feel safe. Patients and family members reported that communication with staff was poor, and they pointed out that they struggled to exchange information with staff, which limited their ability to receive safe and high-quality care.

"Communicating with the treating staff was really hard as some of them do not speak the native language of patients. Under these circumstances, patients cannot express their needs, pain, and other things related to their medical case to the treating staff" (P9A, family member).

"I couldn't communicate with the treating staff as English was always used by them. As a result, I couldn't get any information about my medical condition, nor could I tell them exactly about certain pain I was undergoing" (P10B, patient).

The lack of professional interpreters in healthcare was raised as an issue by the participants because this was perceived as directly affecting the communication between the healthcare professionals and the patients. Madinah city, where this study was conducted, is considered the second holiest city of Islam and it is visited annually by more than two million people from all over the world. Therefore, the participants in the current study were working in a culturally diverse area, which meant that interpreters were required to be available all hours at the hospitals. The participating healthcare professionals stated that a lack of translators in a multicultural country makes it challenging for staff to take patients' history and carry out assessments – this means that decisions may need to be made in the dark, which is a patient safety issue.

> "*All the nationalities come here. Most of the time, no translators*" (S2, FGP1A).

> "*If critical patients are coming, we have big difficulty with the translation, we are treating the patients blindly*" (S2, FGP1A).

Some nurses felt that the lack of interpreters increased the responsibility placed on them to ensure that patients received the correct information. They had many ways of doing this, such as searching for nurses who spoke the same language as the patient, even if they were from other departments. There was a suggestion that the lack of interpreters increased their workload and time constraints as they had to rely on taking time out of direct patient care to seek out nurses of the same nationalities as the patients. This could result in a low prioritisation of safety issues by members of staff.

> "*In some case there if a patient coming in with different nationality and he need something, we can call this manager or the one who can fluently speak the language that the patient is speaking*" (S2, FGP2B).

> "*There are translators list we have, but I did not see even one translator in the area. We have to search for the nurses those who are the same nationality of patient*" (S2, FGP1A).

The patients' and families' perspectives were similar to those of the staff as they identified the lack of an interpreter during their stay in hospital as one of the major obstacles to receiving appropriate healthcare. They believed that the presence of an interpreter in a healthcare organisation is important because it facilitates

interaction between patients/family and staff. It would also enable a shared understanding of the patient's assessment and instructions and it would bridge communication barriers. The participants also commented on the use of nurses as interpreters and they suggested the use of professional interpreters in order to transfer the information literally and objectively.

> *"I noticed several times doctors calling for certain nurses to come over and translate for them what the patients said. This, of course, affects the patient safety, as the nurse might not report to the doctors what the patient said accurately" (P5B, family Member).*

> *"I believe that the only way to prevent such errors is either the nurse should be an Arab, or there should be a translator there to translate for you" (P3B, patient).*

Both staff and patients agreed that the response to patients' needs/problems and feedback was limited. The patients explained that the lack of feedback given to them increased their anxiety about their condition, which compromised patient safety as the medical team and hospital management failed to meet their requirements.

> *"Doctors do not respond to patient's needs accordingly" (P2A, patient).*

> *"No up-to-date general feedback on the condition of patient from doctors……To me, patient safety should come in the first place. Hence, a regular check-up plays a big role in the patient safety" (P1A, family member).*

> *"Treating staff do not inform patients or keep them updated with their medical condition" (P9A, family member).*

> *"As I know, the only way to report patient concerns was the suggestion box. I once dropped a suggestion in it, but I never got feedback" (P2A, patient).*

8.4.1.2 Documentation

Good record keeping is essential and integral to clinical practice in order to facilitate the safety, quality and continuity of care. Both groups of participants (patients and healthcare professionals) reported poor quality documentation and record keeping, which was mainly due to the absence of an electronic documentation system that could effectively gather, store, and share patient information, including safety issues. Although there has been a global shift towards the use of electronic-based documentation systems in healthcare, the participants claimed that the

documentation system was still confusing because some people are still partially using paper-based documents, which does not meet current healthcare requirements in relation to patient safety. The participants found that there were inconsistencies between the use and accurate completion of electronic and paper-based documentation, which could significantly impinge on patient safety.

> *"We don't have still an electronic documentation [National reporting and learning system] where you can access the patients file in the system" (S3, FGM1B).*

> *"We don't have an electronic system. I don't know system for file document or electronic file… nothing is electronic, previous examination, previous procedure, history. Nothing in system" (S6, FGM1B).*

Patients were also anxious about the unavailability of an electronic file system that stored patient information; they believed that this put them at risk of having critical information missing from previous visits to the hospital and any investigations that they had had done. The participants indicated that they preferred a computer system as everything would be recorded and it could be accessed by any member of the multidisciplinary team when needed.

> *"Due to the lack of electronic files, some of the previous history, investigations of the diseases are not available, and this in turn affects following up the patients" (P6A, patient).*

Some patients discussed their experiences of how the lack of proper documentation in an electronic system had risked their safety due to the increased chance of errors or delays to patient care.

> *"Once, a nurse wanted to give me an injection which was not assigned to me [not documented in an electronic system], and she insisted on that until I convinced her she was mistaken" (6SA, patient).*

> *"In relation with medications, patients had to look for nurses, and remind them of giving these medications to them" (P2A, patient).*

In relation to patient identification and verification, the participants pointed out that the use of an electronic system for documentation was required because it would enhance patient safety and help to safeguard patients. For example, errors could occur, especially when ordering medication, as the nurses sometimes found it

difficult to understand the doctors' handwriting. Therefore, the healthcare professional participants stated that verifying patient details before carrying out any procedures, such as administering medication, required detailed electronic records to maintain the best decision making and to avoid issues with poor handwriting in order to support patient safety.

> *"The doctor should write a clear order for the medications. Why we are not writing in the system. As a doctor, actually, we do have a bad handwriting" (S3, FGM1A).*

Efficient handovers and teamwork were also compromised by the lack of accurate documentation, which negatively impacted patient safety. If one member of the team did not document patient information as accurately as others and this was placed in the patient's file, it would lead to conflicts, misunderstandings and gaps in the patient's history.

> *"If the doctor did not take a good story during the interview of the patient. When the nurse shift to other ward, the nurse will have a conflict in endorsement 'cause the nurse cannot extract information from the other nurse because is not the thorough assessment, thorough history was taken from the patient" (S1, FGP1A).*

8.4.1.3 Reporting system

The reporting system for patient safety issues was frequently mentioned in a negative way by the participants across all focus group discussions due to its complexity and lack of clarity. This led the staff to be less motivated to report incidents. The participants viewed the reporting system in their organisations as complicated and confusing. Frontline staff appeared to be unclear about the reporting process and the responsibilities of managers were not used efficiently to share information from the incident reports. There was a clear sense that most of the staff were not familiar with the reporting processes /channels and they pointed out the difficulties of reporting they experienced due to the absence of a standardised electronic reporting system.

> *"Staff are misguided how to report. What to use to report? To whom to report? There are different forms or methods that we are reporting. We have sometimes official form specifically what to report. If medication error we*

have separate sentinel, fall separate, but other than this, we are sending to our direct manager thru email. And feedback is very limited" (S2, FGP2B).

"We know it is not appropriate our situation and is not good. So, we need data, we just need a reporting system" (S3, FGM1A).

"The problem is there is a misunderstanding of reporting system process. We need to inform staff or aware them that reporting incidence is not a punishment. It's a line for improvement and is good and healthy to report any incidence" (S3, FGM1B).

In addition to the concerns stated by healthcare professionals through the focus group discussion, the lack of a reporting system was found to be an issue from the patients' perspective as well. Their main point was that such a system was important because it would facilitate access to authorities by patients and their families when needed. The participants talked about the necessity of providing reporting channels in hospital for patients and their families so that they could report any factors that caused harm to patients and report any complaints to the authorities.

"Ever since I entered the hospital, my sole concern was receiving the treatment. Although I had some suggestions and complaints, I couldn't find ways to report them due to the absence of suggestions and complaints box" (P10B, patient).

"In my opinion, there should be a channel of communication between patients and the responsible authorities regarding the patient safety and patients' complaints, i.e., emails" (P5B, family member).

Another participant said that the reporting process for patients/families was limited, so the only way they could make contact was by a phone call to the Ministry of Health.

"We weren't aware of the process we should follow in case we wanted to complain about something in relation with the patient safety, but now we are aware of the fact that there is a phone line we can use to contact the Ministry of Health in case of any complaints or fears regarding the safety of the patient" (P4B, family member).

The participants felt that the reporting system was a major concern for staff. They were mainly concerned about the process of incident reporting, which was criticised for being flawed and for exacerbating a blame culture. This led to under-reporting. Staff mentioned that reporting was used against staff, there was a delay in feedback

and action following an incident and that the investigation period was long. This negatively affected reporting behaviours.

> *"So, reporting itself makes you in trouble because it used against you" (S3, FGM1A).*

> *"The reporting is something scary… [staff are] afraid from the punishment, from blame, also that's the culture of negativity" (S2, FGM1B).*

> *"Because in Saudi Arabia, we underreport in every area. We don't have any data about anything because everyone afraid to do the report for OVR [Occurrence Variance Report] or about medication error or ADR [Adverse Drug Reaction] because they may affect my colleague or may affect me in future" (S4, FGM1A).*

Healthcare professionals participated agreed that reporting an incident was fraught with difficulty because they perceived it would be used 'against them'. They perceived that they could be attacked for reporting any issues and this discouraged them from reporting anything. Many of the participants described negative experiences after they had reported an incident; they felt anxious and disappointed about the visibility of the management of incident reporting in their hospitals. For example, the lengthy investigation period, which staff may not wish to/have the time to engage in was also mentioned by the participants as an issue associated with engaging with reporting incidents. This put pressure on healthcare providers and in turn was suggested to compromise patient safety because it stopped healthcare staff from reporting incidents. This meant that the opportunity was lost to learn from previous incidents and to prevent their re-occurrence in the future.

> *(Talking with emphasis or stress on words) "But the thing is they will keep calling you… in your mobile. They will ask you an explanation, you will go there and even they will tell you we will keep this one in your file? For what?" Nurse (S3, FGM1A).*

> *"This is the culture in our hospital. The OVR [Occurrence Variance Report] is against of you, not for improvement or the KPI [Key Performance Indicators]. That is why they are afraid even they used it before against the staff. If you do a mistake, you inform, I did mistake for anything. Later on, they will use it against of you. They will remove you from this area because of this mistake. What you made about it. And other staff if they say, if they see this problem, they will not write. They will blame me, they will kick me, they will resign me. Yeah, they will become panic" (S4, FGP1A).*

> *"Why fill out the report when you're going to be blamed for it" (S3, FGM1B).*

In addition, the healthcare professionals revealed an absence of/delay in providing feedback following the reporting of a safety incident. This demotivated the staff and made them feel that they were being ignored. The participants highlighted the importance of feedback following an incident as it is an opportunity to learn from errors and therefore highlight further improvements that can be made. It was underlined that there were no incentives for staff to report patient safety incidents, particularly as they are not viewed by the organisation as an opportunity for improvement but rather just a way of pointing the finger of blame. The lack of feedback following the reporting of an incident was a major concern for the participants as it left them unfamiliar with the results of the investigation and they did not receive feedback containing corrective actions.

"I did not receive any feedback. Did they work on my report? because if they work it, I should be aware and why still happening" (S2, FGP2B).

"After the reporting I don't know what happen for my reported. That's the reason make us not reported or others not reported. Also, some staff, they said no benefit for reporting, they are not doing anything" (S4, FGP2B).

"How many years I am writing this one. I am not receiving feedback from the patient safety regarding what happen to what I report. So, they might think this is no benefit of that" (S3, FGM1B).

8.4.2 Work conditions

This theme reflects the features of work environments and the conditions that expedite or interrupt the implementation of a positive patient safety culture in healthcare environments. The participants discussed and identified many factors, which were categorised into three subthemes: staff factors, management/ leadership and cultural and social factors.

8.4.2.1 Staff factors

There were many staff related factors highlighted from the discussions across the focus groups and interviews. Insufficient staff, the nurse–patient ratio, workload, deficits in knowledge about patient safety, the lack of collaboration/ teamwork, staff turnover, inadequate staff orientation, no clear job description and staff skills and

competency were common factors highlighted by the participants that negatively influenced patient safety either directly or indirectly. The shortage of staff was one of the major concerns and challenges as it increased the workload for the healthcare professionals, who reported that this limited their ability to provide safe and high-quality care. Inadequate staff numbers were seen as a serious issue due to the increased pressure and workload this appeared to put on staff, particularly nurses, who were particularly affected by low staff-patient ratios.

"I think one of the big issues is lack of employees, the lack of the staff" (S6, FGM1B).

"We have like 20 patients handled by two staff nurses. This is will affect patient safety" (S3, FGM2B).

"The short of staff makes our staff busy and no time, because she will be assigning in one room for five patients – There is no enough nurse to finish the work in the same time" (S5, FGP1A).

Patients and family members also believed that the shortage of staff was obvious to them too, and they acknowledged that the hospitals were understaffed. The patients noted that there was a low nurse-to-patient ratio, and that this led to a heavy workload and fatigue for nurses. The participants believed that more staff were required to provide high-quality treatment and to deliver the best care.

"The big issue was related to the shortage of nurses. There was only 1 nurse responsible for taking care of ten patients at the same time. The shortage of the treating staff has a bad impact on patient safety. They were always exhausted when serving and taking care of patients due to the overload of work" (P8A, patient).

"Another area which needs development is the number of the treating staff. I believe that the number of the treating staff should increase to contain the big number of patients. This way, patients can receive effective treatments" (5SB, family member).

Patients also highlighted that the staff shortage was evident in the time it took for nurses to respond to their patients. They criticised the delays, which resulted in increased patient stress and levels of dissatisfaction with the health care they received.

"I really have many fears. One important fear is the shortage of the treating staff. I happened to call for a nurse many times to come over, but she used

to take a lot of time to respond. This is, of course, due to the large number of patients comparing to the small number of nurses" (P6A, patient).

The workload was consistently described by patients/families interviewed as one of the major difficulties faced by staff when they were trying to complete a task properly. Patient care such as bed baths and changing the bedding was pointed out by some of the patients/families interviewed as one of the main issues that had an impact on nurses' workload and patient safety.

"As I mentioned before, the number of nurses should increase, so that they can deal with the large number of patients. For instance, one nurse can't handle ten patients effectively at a time" (P2A, patient).

"A few numbers of staff really affect patient safety. Sometimes companions had to clean the patient, bed, and change bed sheets instead of the hospital staff" (P1A, family member).

Another patient stated that due to the workload and the short amount of time that the nurses had to spend with the patients, the latter were at risk of medication errors.

"The large number of patients comparing to the small number of nurses made nurses distracted and less attentive. Once, a nurse wanted to give me an injection which it was not assigned to me, and she insisted on that until I convinced her she was mistaken" (P6A, patient).

Several of the healthcare professionals spoke about workload in their areas and they linked this to implications for patient safety. For example, a high or stressful workload was perceived to increase stress and put pressure on staff, which caused them to lose concentration. This subsequently increased the risk of errors. Staff workload also compromised patient safety because the low nurse–patient ratio meant that nurses were handling too many complex patients at any one time. Staff felt tired and that negatively affected their performance. The nurses' comments below highlight the possibility of making mistakes due to the impact of workload and long working hours, especially for critical patients.

"We cannot make the standardised proportion to patient safety [due to] nurse to patient ratio. Also, staff most of the time are tired. One staff they are handling three intubated patients at a time. What about the safety of the patient? And nurse to patient ratio, maybe the nurse will miss most of things of patient care due to workload of staff" (S2, FGP1A).

"Sometimes I have to work in two places or to do the work of my colleague so, workload will affect my performance so, better to change the system. Don't allow to work more than 8 hours or 7 hours like this. Some work for 16 hours for example, sure he cannot concentrate. any error or mistake due to performance" (S1, FGM2B)

"They are under stress they have so many needles stick injury because of this one [workload]. The staff nurses are exhausted and will make some mistake during the patient care. This mistake it will be like in medication or in cannulation that it will affect the patient life or the patient safety" (S4, FGP1B).

In addition to the impact of workload on staff well-being, stress, burn out and turnover were issues mentioned by the healthcare professionals. These affected the whole organisational system, which in order to be efficient required sustainable staff knowledge and awareness of the policies and procedures related to patient safety. The high staff turnover due to the workload was therefore a challenge for hospitals as it meant that they lost trained staff, thus increasing the burden of staff training and education. This situation made it more difficult for organisations to replace staff and they were always looking to recruit qualified staff.

"In every month there is a termination" (S1, FGP1A).

"A large issue with the staff termination that affecting really the patient safety. You get tired to educate the staff, improve him, empowering him with all the resources, education and skills to do a proper patient care. After one year he will leave and one of the department which is a critical department, emergency department, 35 % staff been replaced within one year" (S2, FGM2A).

The limited time that nurses had to communicate with patients was also mentioned as a consequence of the heavy workload. A respiratory therapist commented that large workloads were obvious in every department, which increased the possibility of patients not being seen or lacking the required care, due to time constraints.

"Workload, for us, 1:4 ratio. One staff with four patients but we are dealing with more patient sometimes. The workload it will effects on communication" (S4, FGM2B).

"[In] every department the workload is more than what they can handle and at time you see that a staff that assigned either he may not be able to see all his patients" (S5, FGM2A).

Staff members' lack of knowledge and awareness of a patient safety culture were perceived as an issue that limited their perceptions of, and implementation of actions contributing positively to, patient safety. The participating healthcare professionals stated that some members of staff were unfamiliar with the importance and value of implementing a patient safety culture. This revealed a gap between frontline staff and managers' goals. The value of the sustainability of a patient safety culture among healthcare professionals was criticised because its objective was viewed as being simply to gain accreditation.

> *"Sometimes some of the staff they will tell you, "we are doing that one just to get the accreditation not for the sake of patient safety itself" (S2, FGM2A).*

> *"Sometimes even our staff they didn't know what's the meaning of patient safety" (S4, FGP1A).*

Another issue identified by the participants that was linked to the lack of staff knowledge and awareness of patient safety was inadequate staff orientation and competences.

> *"I think there is some [thing] wrong within the unit orientation from the middle management because transferring of information. It might not reach them" (S3, FGM1B).*

> *"Sometime the doctor came they doesn't know the rule, they don't know how to fill the forms. They don't know how to enter order in the system for x-ray or for lab. This one lost time for nursing and they are taking it this responsibility for my nurse" (S5, FGM2B).*

Other concerns related to staffing issues also emerged from the focus group discussions, such as the lack of a clear job description, skills mix and staff competencies. The participants appeared to be stressed about the possible consequences if staff members did not have a clear sense of their roles and responsibilities, which led to some staff pushing other tasks onto other professionals.

> *"Clear job description. This is the most important. No clear job description [for staff]" (S4, FGM1A).*

> *"Our barrier to patient safety not only the overload for nurses. Also, from the multidisciplinary team they are not awareness of their role or job" (S5, FGM2B).*

In addition, due to the lack of an official job description that outlined their specific duties, some of the nurses in the study described how their role was expanded with tasks that were originally not part of their work. Consequently, nurses from across the two hospitals identified different tasks they did which were not initially part of their duties, including domestic duties.

"The big problem here in our hospital we are covering the PT [Physio Therapist] and RT [Respiratory Therapist] and really are overload, even sometimes we are work as a social worker, you are a nurse or the respiratory therapist or the social worker or the ward class, this is overload for the nurses, it will affect the patient safety" (S4, FGP1A).

"The nurse here in hospital will be responsible for everything. I am caring to clean the room more than clean patient. Because the administration people, they will come they will look into the floor. If they saw something not good in the floor, they will blame me" (S5, FGP1A).

Other healthcare professionals talked about the importance of having staff orientation and annual assessments to ensure that standards were maintained, and of employing staff suitably qualified to work in the various areas and who met the requirements of the job. They also highlighted the importance of recruiting suitably qualified staff for specific areas, which would help to address the teamwork angle and the feeling of staff being overworked and carrying other team members. Some participants expressed their concerns over the quality of professional qualifications amongst some healthcare professionals and they argued that sub-standard qualifications had a direct impact on patient safety, as illustrated in the following examples.

"Lacking the competencies and qualifications sometimes make it difficult to provide patient safety" (S5, FGM1A).

"The recruitment of nurses from oversees they are selecting nurses for critical areas and written in their contract as a critical care nurse. They came as critical care nurse when they came here in our hospital the sad fact, they don't know about anything and don't work at all in ICU [Intensive care units]" (S4, FGP1A).

"We should ensure number one that the staff are oriented with their job description" (S5, FGM2B).

8.4.2.2 Management/leadership

The issue of leadership was highlighted across both groups of participants (patients and healthcare professionals). Leadership was regarded as a vital element of building a safe and caring culture that focuses on an improvement strategy based on individual and organisational needs. Proper leadership from higher authorities was perceived by the participants as the gold standard. It was perceived that leaders should proactively address and prioritise safety in order to create an organisational context in which safe healthcare can be reliably delivered. In the participants' view, leadership/management roles differed; some saw them as facilitators and others were described as barriers. From the facilitator perspective, some participants stated that leaders in their organisations supported and motivated them to achieve a high standard of patient safety and they were considered to be role models.

> *"Leadership is concerned about patient safety and nursing safety" (S4, FGP1A).*

> *"We are trying to motivate them if there are some deficiencies that they will note, we are encouraging to them to report because this will improve the patient safety culture of the hospital" (S3, FGM2B).*

Another comment about crucial aspects related to leaders and a positive safety culture was related to the active role they play in making sure that policies/guidelines are followed and in providing feedback to encourage staff to participate in safety initiatives such as reporting incidents. An interesting point highlighted by one of the participants of the group that comprised the senior staff with leadership roles explains the strategies adopted by managers to implement a just culture that is the opposite of a blame culture.

> *"Good safety culture in this hospital, is due to following the standards, and supervision and feedback about the compliance of the staff. In my opinion, we should encourage self-reporting of OVR* [Occurrence Variance Report] *because now all the reporting against others" (S1, FGM2B).*

> *"We are creating just culture, we are not concerned about who is staff who did the mistake, we are concerned about how to improve the process" (S7, FGM2A).*

On the other hand, poor leadership equated with a lack of action over safety issues. This was also reported by the healthcare professionals' participants as a barrier to the implementation of a safety culture at work. The participants largely agreed that leaders dealt inappropriately with safety issues arising at work, especially those reported by frontline staff.

> *"We reported this problem to the person in-charge, he or she might not be able to take the action" (S5, FGM2A).*

> *"Some of the leaders in the department, they don't want to take the action to solve the problem. Just they are thinking I will just write, that is my part. Well in fact they have to initiate the improvement from the beginning at that time" (S2, FGM2A).*

Another problem shared in relation to deficits in leadership was related to a lack of supervision and monitoring of staff. There was concern over management support for staff members, because without it the staff did not have clear roles and responsibilities. Therefore, the healthcare professionals noted that the lack of supervision limited their ability to actively gain knowledge and experience from senior managers. This would reduce the gaps in knowledge and provide safer practice.

> *"New staff are not already supervised properly. Because I am a senior staff, I have so many workload" (S2, FGP2B).*

> *"Lack of close supervision either from the head of the department or from the region itself… there is no follow up or close monitoring of current situation and current patient care. When I came to my department, even to do or not to do. No one ask me "what are you doing?" There is lack of supervision" (S1, FGM2A).*

Staff values and encouragement by leaders were also raised as an issue that needed to be addressed in order to support staff and encourage them to engage effectively with patient safety issues. The participants recognised the importance of leadership in building and sharing patient safety culture goals in their organisation; if leadership engaged actively in this area, it could spread a shared understanding and ethos of patient safety in their areas.

> *"Need people who can explain patient safety to the hospital and share the patient safety culture to everybody and after that applied. If people don't understand patient safety. They will not apply it" (S3, FGM1A).*

"If the leadership never support you never encourage you to raise the issue, that will make you always blamed. They will always try to find someone did the mistake. And I think this kind of leadership never help the patient safety" (S6, FGM1A).

8.4.2.3 Professionalism

Several of the common issues that contributed to the implementation of a positive patient safety culture were identified from interviews with patients/families. They were mainly related to negative staff behaviour such as a lack of respect/dignity, carelessness, a lack of response and a lack of attention. The participants stated that patient safety in hospitals could be affected by staff behaviour and their attitude towards their professional role. The importance of staff employing a positive attitude when dealing with patients was stressed due to the significant impact that this could have on patients' feelings and their satisfaction with effective holistic care. Some of the patients agreed that it was important to see staff compassion, respectful behaviours and a concern for patient rights, which contributed to patients' feelings of safety and reduced distress in hospitals.

"Patients should be aware of their rights in the health institution. The staff at the hospital should enjoy good attitudes towards both patients and other colleagues. Furthermore, they should be disciplinary at work" (P2A, patient).

"The treating staff should show empathy and compassion to patients. Furthermore, they should show a great deal of patience even when overloaded" (P8A, patient).

"Good attitudes of the treating staff give patients a dose of hope and comfort. For instance, smiling at them help them feel relaxed and less anxious. This in turn will help them resist their illnesses" (P5B, family member)

Some patients felt that there was a lack of respect and dignity towards them while they were in hospital. They were upset by the attitudes of some of the staff members and they considered this to be a threat to their dignity. A lack of respect was the most commonly used term relating to the staff behaviour, as stated in the following example:

"I wasn't comfortable with the attitudes of some of the treating staff yet some of the treating staff were not nice enough when dealing with patients… they never gave patients enough time when speaking about their medical conditions" (P10B, patient)

Patient dignity was affected by the attitudes and behaviours of staff. Some patients explained that the staff did not treat them with dignity, since they referred to the patients by their bed number rather than by name. It could also potentially lead to safety issues for patients, as it may cause confusion between patient bed numbers, particularly in a room with five patients.

"They even refer to patients with their beds' numbers, rather than by their names, which makes it hard for patients to interact with the treating staff if they are not aware of their beds' numbers. As a patient, I felt lack of respect when they referred to me by my bed's number" (P9A, Family Member).

"Patients should be treated more positively and in a humane way" (P4B, family member).

The participants spoke of experiences where careless and irresponsible members of staff caused patient safety problems, as described in the following examples:

"Some of the bad nurses' attitudes caused patient discomfort. These bad attitudes are represented by showing carelessness and boredom during the working hours" (P5B, family member).

"Carelessness of the staff is very clear at the hospital. They sometimes don't give patients the mediations unless patients remind them of doing so" (P2A, patient).

"Some nurses didn't use to wear gloves during performing their work with patients" (P6A, patient).

Another participant stated that patient safety was compromised due to the lack of attention from healthcare professionals. One patient commented that the staff were not vigilant or not well acquainted with all the aspects of patient care.

"Low professionalism in performing the treating task for each patient separately. Only what they care about is give mediations without paying attention to any complications that may occur. The main concern of the treating staff is to treat the patient illness without paying attention to the complications that might take place, which in turn can result in another illness" (P1A, family member).

8.4.2.4 Cultural and social factors

Both staff and patients acknowledged that a safety culture plays a critical role in determining the level of patient safety and the willingness of healthcare professionals to establish and maintain a healthy environment that supports the ultimate goal of preventing patient harm. A culture of patient safety was seen by the majority of the healthcare participants not as a culture of improvement but one of blame. Staff are always concerned about how to safeguard themselves rather than looking on incidents as learning and an opportunity for improvement. Thereby, a blame culture was highlighted by the participants as a major cultural barrier to a positive patient safety culture. A blame culture was considered to be an obstacle to the detection and reporting of errors.

> *"We have here the blaming policy too much which affect the staff. That is why you cannot see too much incident especially staff nurses. They are afraid to report any incident happen in their shift. Why? Because they are afraid. Who will be blame? The nurse who reported the event" (S1, FGM1A).*

> *"I received an OVR [occurrence variance report] and you are investigated as [if] you killed someone. So, this thing [blame culture] will stop us from talking" (S3, FGM1A).*

> *"For punishment not for improvement they use it" (S4,FG P1A).*

Fear was identified as a common consequence of a blame culture among the healthcare professionals, especially nurses, who reported a high level of criticism and reprimands in their work areas. The problem of fear was highlighted and linked to many situations including the fear of punishment, losing jobs, salary deduction and influencing relationships with colleagues.

> *"We are afraid for the blame culture. We are afraid for the any punishment that might be receive" (S3, FGM1B).*

> *"Also, the fear actually regarding his reporting. Fear to lose his colleague. Fear that he will blame him later after this report … this is all culture. This make our staff not reporting unless you are pushing them to write regarding any incident in their department" (S4, FGM2A).*

Interestingly, the issue of punishment was confirmed by one of the leaders, who stated that salary deduction was widely used in their organisation as a way of

punishing healthcare professionals. This finding suggests that the organisational style, which appeared to favour a blame culture, may negatively affect the healthcare professionals and prevent them from feeling psychologically and safe about reporting patient safety incidents.

> *"I cover the general director for a long time, during that period, the amount of papers that I have signed for deduction of salaries because of such issues is enormous" (S7, FGM2A).*

Fear of a blame culture and the culture of negativity was also mentioned by another nurse who stated that nurses covered up things to avoid being blamed by the doctors in the form of a verbal reprimand.

> *"So, some of the staff they are fear, they feel that I don't need to inform the doctor because maybe the doctor will get angry for or shout to me, why you don't understand this order. So, we have that fear of negativity" (S3, FGM1B).*

> *"When I ask the staff to express out what they have. They are still afraid. I think they are afraid from blaming or anything like this" (S4, FGP2B).*

The issue of covering up incidents because of a blame culture was reinforced by another participant who emphasised the importance of speaking up to solve safety problems.

> *"There is a defensive secrecy. I think we should not hide any problem. We should face the challenge and tackle the problem" (S4, FGM2A).*

The participants also highlighted that the blame culture had the effect of making everyone prioritise their own protection, which limited teamwork among staff and could be a barrier to actual hand care due to the time constrains. For example, staff nurses felt that paperwork had to take priority sometimes as it helped to safeguard the nurses from blame when they properly documented everything related to patient safety.

> *"For us here, mostly, honestly everyone protect himself" (S3, FGP1A).*

> *"Nurses most of the time, they are busy with the documentation. If they did not document, they will be blamed tomorrow" (S2, FGP1A).*

The issue of cultural and workforce diversity overlapped and was acknowledged in two subthemes: communication (section 8.4.1) and cultural and social factors (section 8.4.2.4). The healthcare participants talked about the effect of workforce cultural diversity and the cultural composition of the staff, which may be linked to a deficit in teamwork, communication and the capacity of staff to adapt to environments. Some concerns were identified by the participants related to culture and language diversity between patients and staff; these were barriers to safe communication with patients. Therefore, staff suggested Arabic classes to improve staff members' ability to understand their patients and overcome cultural barriers.

> *"Most of the staff, they come from different countries, and facing new culture living in" (S3, FGP1A).*

> *"Because of this language barrier. So, I guess if they will make Arabic classes to the staff maybe that will be better" (S3, FGM1B).*

> *"Non-Saudi staff they have language barrier to deal with patient. My suggestion for new staff they should have some Arabic classes to deal with the patients" (S4, FGM2B).*

Workforce diversity was also mentioned by patients and their families which they believed negatively impacted the level of communication and limited the ability of patients to build effective relationships with staff. The participants highlighted that with the increasing workforce diversity in the healthcare environment, patients and their families will be less engaged in healthcare delivery and that consequently, the implementation of positive patient safety will be more challenging. Patients and family members suggested that by reducing the gaps in the workforce and cultural diversity, patients could be involved effectively in decision making, understand more about their care and enhance their safety.

> *"Having nurses of different nationalities and cultures (Indians, Filipinos, etc.) may create a barrier of communication for patients as many of those nurses cannot speak the native language of patients. Those nurses' cultures may collide with the patients' culture, and this in turn leads to discomfort and miscommunication" (P9A, Family Member).*

> *"I couldn't communicate with the treating staff as English was always used by them. As a result, I couldn't get any information about my medical condition, nor could I tell them exactly about certain pain I was undergoing" (P10B, patient).*

"When all the treating staff around you speak your language, patients feel relaxed and secured. On the contrary, when patients don't understand the language of the treating staff, they feel unsafe and anxious. Hence, change must take place soon, all treating staff, pharmacists, and other employees at the hospital should speak Arabic so that they can communicate with patients easily in every kind of aspects" (P3B, patient).

8.4.3 Organisational factors

Organisational factors were identified across both groups of participants (patients and health professionals) and refers to the process and structure within organisational system that shape, develop and maintain patient safety in healthcare organisations. Four sub-themes were identified: environmental factors, hospital facilities and resources/equipment, policy and guidelines, and education and training.

8.4.3.1 Environmental factors

In relation to environmental factors, the participants discussed and identified some factors that negatively influence patient safety culture and were considered a threat to patient safety in working areas. These concerns raised were related to a lack of patient confidentiality and privacy, interruptions/noise in areas, crowdedness, inadequate hospital security, a poor physical environment (poor cleanliness, poor ventilation, floor wet, light problems), poor hospital construction/maintenance and conflicts between visiting times and the number of visitors.

A lack of patient confidentiality and privacy were highlighted across both groups of participants as a crucial patient safety issue that limited holistic patient care and increased the risk of patient harm. The healthcare professionals revealed that there is a lack of patient privacy, which impacts on patient care and safety in many ways. For example, it was noted that due to the lack of privacy, people do not feel that they can ask questions or clarify information, which could lead to misunderstandings between staff and patients. This issue was identified particularly in the pharmacy as the participants stated that patient confidentially was broken due to the absence of a secure place or a rule allowing only one patient at a time at the pharmacy window. Patients therefore feel insecure when they are receiving instructions from the pharmacist because the front of the pharmacy is an open area; this makes patients confused due to the noise and lack of confidentiality.

"The environment could affect the patient safety specially like for example in out-patient pharmacy. You need the privacy for …sometimes, you couldn't reach this privacy and you will not provide the patient, or the patient will not prepare to hear this information about medications because this is related to his confidential information. So, you cannot give the full information" (S4, FGM1A).

Furthermore, it was identified that the same problem existed with other staff as they felt unable to explain things to the patient freely and confidentially due to the lack of patient privacy. This limited patients' access to a high standard of safe health care, and it could increase the number of medical errors. This was explained in the following statement that emphasises the importance of minimising breaches of patient confidentiality and privacy by making sure that staff and patients cannot be overhead by other patients or people. Therefore, in order for staff and patients to communicate effectively and confidentially, there is a need for an appropriate place that enhances confidentiality.

"There is no privacy for patient education some education needs very special structure. No place for this. No place for patient privacy some instructions said to the patient, all other patients hear these instructions" (S1, FGM1B).

"Privacy for patient education, because sometimes female very shy from receiving instructions from pharmacist and not concentrate" (S3, FGM1B).

"At least there should be a room where the staff should communicate with the patient and patient will communicate with the staff" (S5, FGM2A).

In addition to issues with patient privacy, disruption to nursing/medical care because of crowdedness was noted, especially from visitors who did not adhere to visiting times. Some nurses stated that crowdedness had become a major barrier to patients receiving timely proper care, which worsened the patient safety issue.

"I will talk also about environment. For example, in medical unit is very crowded. People are coming, no time for visiting. There is visiting hours, but they are allowing some people(visitors) to come and without specific time for the rounds. Instead of they can relax so, they will be disturbed" (S2, FGM1A).

"Instead of providing care to the patient. We cannot give because too much people surrounding with them. So, it will prevent us to give proper care to the patient". (S2, FGM1A).

Patients and their families additionally talked about crowdedness within the hospital environment that put them at risk. They reported that the hospital wards were not appropriately managed admission to the hospitals in the way that help to maintain patient safety. The participants recounted cases of five patients with their relatives in one room, which risked broken patient privacy and the transmission of infections.

> *"Another problem was the crowdedness. There were 5 patients in the room along with 5 companions. This resulted in lack of privacy"*
> *(P6A, patient).*

> *"Each room had 5 patients which is too many. This made me fearful of getting infected of infectious diseases" (P2A, patient).*

> *"There are many conditions that make patients anxious and uncomfortable at the hospital. Among these conditions are waiting too long in the crowded emergency unit, waiting long for the medical analysis, and feeling uncomfortable in the crowded rooms" (P4B, family member).*

Other concerns were raised by patients/families, such as the negative consequences of the noise caused by the overhead calling systems of hospitals, which increase patients' stress and lack of sleep.

> *"Patient safety does not only mean their physical safety; it includes also their psychological state. Frequent calling for doctors through the paging system caused disturbance to patients and patient companions" (P5B, family member).*

The participating healthcare professionals also recognised that patient safety may be compromised due to inadequate hospital security. It was highlighted that there is a weakness in the hospital security system that should limit access to patients by unauthorised people. It was clearly stated that the security system was not working well or protecting patients from harm as it was mentioned that anybody with a hospital staff uniform could access patients, without having to show any identification.

> *"We need to have a secured ward which is like electronically you cannot enter if you are not working there" (S3, FGM1B).*

> *"Anybody with lab coat he can access to the patient. Nobody he can prevent. There is no system can prevent this person to contact directly with the one patient" (S3, FGM2A).*

Another staff participant felt that security should always be in place to prevent child abduction, which is considered one of the threats to patient safety inside healthcare organisations.

> *"We need all the time the door must be secured, and the security should be present there because of child abduction and the time of visit. It is very long time, everybody is going and coming and at the time of visit the nurse is busy with the work so this is very dangerous time. We need to make it security is more" (S6, FGM2B).*

Other issues identified by the healthcare professionals related to poor physical environment, such as poor cleanliness, poor ventilation, wet floors and lighting problems. These problems were linked to potential hazards and physical risks to patients, which could lead to harm through slips and falls.

> *"Sometime the environment will affect the patient safety. That what I mean, Sometime the floor was not dry that lead patient falls. Sometime the lighting, the patient cannot see the environment clearly. Also, it will affect the staff during the work. It will harm for the patient" (S4, FGP2B).*

A similar concern was identified from the patient perspective.

> *"Cleanliness workers used to leave toilets wet after cleaning them, so their floors were always slippery. This in turn made patients subject to slipping in the toilet" (P6A, patient).*

From the patient/family perspective, poor cleanliness and ventilation were commonly described as critical issues in the physical environment that hindered patient safety. Participants were particularly concerned with the issues that dominated the hospital environment and put them at risk (e.g., scared of becoming infected).

> *"Lack of ventilation and lack of cleanliness are major problems. For instance, having 5 patients with 5 companions- not to mention visitors- in a room with an area of $20m^2$ can cause patients' discomfort. In relation to cleanliness, a room with such an area cannot meet the personal needs for some patients, not to mention the possibility for some patients to get infected with particular diseases" (P9A, family member).*

> *"During my stay at the hospital, I noticed that cleanliness was of a low level, including the floor and bed sheets. Of course, this may lead patients to get infected" (P10B, patient).*

Poor hospital construction and maintenance were also acknowledged as being one of the issues that reduced patient safety and increased the risk of patient harm. The participants raised concerns regarding the safety of patients and staff during hospital maintenance and it was reported that it was a challenge for staff to determine the risk of hazards as there were no warning signs.

> *"The hospital is undergoing construction, renovation ... mostly our patients and staff will be affected because we don't know if safety measures are really there" (S2, FGP2B).*

8.4.3.2 Hospital facilities and resources/equipment

Many factors identified across both groups of participants (patients and health professionals) as hindering a positive patient safety culture were related to hospital facilities and resources/equipment. These issues were highlighted in many areas of the hospital's facilities, and they included a lack of medical equipment/resources, deficits in the IT system, a lack of moving and handling devices, a lack of medications, deficits in the electronic system for prescribing medications and a bed crisis.

With regard to the lack of medical equipment and resources, this was reported widely by individuals as a big issue and the participants felt that the hospitals were not good at dealing with it. The unavailability of equipment was believed by the participants to have significantly influenced the delivery of healthcare and services. Staff nurses reported that they were limited in many essential resources in their work areas, such as sheets to cover patients' beds and infusion pumps.

> *"Actually, we face some critical equipment we are need it, it's not available in the department" (S2, FGM2A).*

> *"Resources we don't have syringe pump, infusion pump, bed sheets. Only in ED, I think there is … we are receiving patients on mattress. There are no bedsheets at all" (S2, FGP1A).*

Another perspective was gained from staff who stated that insufficient supplies of equipment gave rise to infection control hazards because the patients had to share equipment.

"So, due to lack of some equipment which is valuable for the patient. Then, what you do is you are using from another patient and you keep using for another patient until you may find that 1 or 2 patients have same bacteria" (S4, FGM2A).

A few participants from patient group expressed their concern regarding the shortage of medical equipment, due to its unavailability or the fact that it did not function. This was a barrier to the ability of the health organisations to provide safe and high-quality healthcare services.

"There are poor cleanliness and unavailability of medical equipment" (P5B, family member).

"The emergency unit is too small, crowded, and not equipped well. Patient safety requires great efforts. When patient find that all services are integrated and available along with a cooperative treating staff, they feel safe and secured" (P4B, family member).

Another problem that was identified was a lack of moving and handling devices, which were used to facilitate moving patients safely. It was noted that due to the absence of these devices, staff nurses were struggling to move patients on their own, which could put them at risk of harm such as back pain and injuries. The risk of patient harm such as falling was also recognised as a consequence of the unavailability of moving and handling devices. Therefore, the participants felt that both patient safety and staff safety were at risk.

"Staff especially female they are movement the patient without any assisting device. They will have back pain, or they will have injury because of this" (S4, FGP2B).

"Material not available … it will harm the patient, it will affect them, The patient will fall down or near to fall down. This is the effect of lack of material" (S4, FGP2B).

"I am the one trying to transfer the patient from one bed to another. Some nurses now they have back pain and disc prolapse effect of pushing the beds and moving patient alone {without moving handling devices" (S5, FGP1A).

Deficits in the IT system in relation to saving patient data, viewing patient history and system access overlapped and were acknowledged in two subthemes: documentation 0) and here under hospital facilities and resources (0). The healthcare professionals talked about the poor quality of the IT system and how this

influenced patient safety culture at different levels of the organisations due to limited support of electronic files, history and effective documentation. The IT systems were also criticised as they caused safety problems due to mistaken patient identity in record keeping.

> *"Patient information saving with another patient data. So, really it is very difficult. Many times, we face this problem. According to them, problem with the system" (S6, FGM2A).*

> *"We don't have system. I don't know system for file document or electronic file. nothing is electronic, previous examination, previous procedure, history. Nothing in system" (S6, FGM1B).*

Other concerns explored by the participants were related to the poor infrastructure and resources of the hospitals, which acted as a barrier to the implementation of a positive patient safety culture. The participants highlighted that because they lacked proper infrastructure such as computers, many tasks involved with healthcare delivery were affected. For example, one participating nurse stated that the unavailability of computers made it challenging for the nurses to do their documentation.

> *"There is lacking of the computers that sometimes you cannot write your nurses notes" (S1, FGP1A).*

An issue revealed by the patients and family members regarding the lack of services and infrastructure was the limited number of toilets and space in patients' rooms. The participants believed that patient safety was severely compromised due to being exposed to the risk of infection, as personal needs could not be maintained within such a poor hospital environment.

> *"Having one toilet in each room for five patients along with their companions was a big problem. I was always scared of getting infected by anyone through the toilet as some patients didn't have the minimum level of awareness about cleanliness" (P6A, patient).*

> *"There was only 1 toilet serving five patients in the same room" (P8A, patient).*

> *"Having five patients with five companions – not to mention visitors – in a room with an area of 20m² can cause patients discomfort. In relation to cleanliness, a room with such an area cannot meet the personal needs for*

some patients, not to mention the possibility for some patients to get infected with particular diseases" (P9A, family member).

Another patient safety issue identified by the healthcare participants was related to the availability of medications as some participants noted that there was a shortage of medications in hospitals, which increased the pressure on staff to treat patients effectively and safely. Two physician consultants stated that:

"We have some shortage in a critical medications and critical equipment to save the patient during a resuscitation" (S4, FGM2A).

"Also, we have a lack of medications like antibiotics sometimes" (S6, FGM1B).

The participants mentioned that bed management, which determined the flow of patients inside the hospital, was an issue. Some patients complained about the length of time waiting for a bed, an appointment or follow-up. Patients felt that the failure in bed management led to delays in obtaining medical care at the proper time, which compromised their safety and lengthened their hospitalisation period.

"I had to stay at the ED for a long time waiting for a vacant bed from 8am to 12am" (P2A, patient).

"The long period of medical review [follow up] is another problem. Sometimes I had to wait for eight months for a medical review" (P5B, family member).

Another opinion from a staff physician showed that the unavailability of beds was widespread and that it limited patients' ability to have the medical care required by their condition.

"We have lack of independent area in the ward. If you have patient, it doesn't meet the criteria for ICU admission, but you need close monitoring in the ward. We don't have a special room or the ward that contain the monitoring" (S6, FGM1B).

8.4.3.3 Policy and guidelines

Attention was paid to hospital policies and the guidelines system and their implementation in clinical practice. The participants raised some areas of concern related to the existence of policy and guidelines, and their implementation and dissemination to clinical departments. The participants agreed that guidelines exist (which is a positive facilitator) but the main issues were related to non-compliance with these policies and guidelines by healthcare professionals.

> *"We have a clear policy regarding patient safety but nobody or still somebody not following this policy" (S4, FGM2A).*

> *"We have a lot of guidelines. For the doctors, we have our guidelines to manage the patient in a correct way without any error" (S6, FGM2B).*

Adherence to policies was mentioned widely by the respondents in all of the group discussions, and these revealed that some staff do not comply with the policy. The lack of adherence to policies was believed to compromise quality of care and patient safety as it prevented the hospitals from achieving the highest standard.

> *"There are many standards the people worked for many years making this and implement and trying their best. Then some individuals they are not following" (S6, FGM2B).*

> *"There are clear rules, everything is established. Maybe implementation, we need to make it the people more compliance to implement this very nicely" (S6, FGM2B).*

The respondents linked this non-compliance with policy to the different understandings of the concept of patient safety held by staff. They believed that applying policies effectively would have a significant impact on preventing errors. They highlighted the need for a shared understanding of patient safety across the hospital/culture and saw this as a priority for hospital management in order to enhance adherence to policy.

> *"Most people don't follow policies and don't follow privileges because they don't think that will affect patient safety. Because they think they save the patient by practice, only by practice. Not by following the policies and the procedures" (S3, FGM1A).*

The implementation and dissemination of policies and guidelines were also considered to be key factors that would enable staff to sustain a positive patient

safety culture. Participants believed that implementation takes more than just writing a policy; it also requires education across the whole hospital to get staff on board and to make them aware of policies and how to implement them. Some of the healthcare professionals suggested that hospital management was responsible for conducting, updating and implementing policy in the hospital systems and they stressed proper implementation and dissemination strategies. A nursing manager said:

"To make policies and those policies need to be applied, but before you apply it there is an education part. I think we missed the gap in education. That can really affect our implementation. We cannot apply if don't understand if I don't explain to you what to do and how to do" (S6, FGM1A).

8.4.3.4 Education and training

Education and training were highlighted by the healthcare participants as an important key factor that helps staff to maintain a positive safety culture in the wards/hospitals. It was perceived that education would also help people to develop a shared understanding and sense of purpose/direction to promote patient safety. Staff felt that education and quality improvement go hand in hand and that therefore education should be aligned with solving and addressing patient safety issues so that people see actions being taken on the problems they report.

"Regarding how to improve patient safety. There are many forms of education. We can train the staff on how to do things or competency-based education whereby you have to find out when you have the problem, what happened and if he or she doesn't know it and you do the competency on him and find out where is the problem" (S5, FGM2A).

"Part of the continuous education should be based on what barriers on the reports. At a result of the report, we will find a solution what the issue. If they don't know for example how to store the medications in the area, part of the plan in the education in the next month everyone knows how to store the medications in the area" (S4, FGM1A).

Suggestions were mainly focused on a specific programme relating to patient safety. Several participants expressed their concern about the lack of focused programmes of education to address staff members' gaps in knowledge and skills. For example, one participant raised the issue of some healthcare staff working without proper orientation, which had a significant impact on patient safety.

"We need to have a focus programmes",, [education programmes covered safety issues]" (S5, FGM1A).

"It should be explained the new staff, should be orient them and explain them well about how to use the OVR, the OVR forms like sentinel and all this form orient them properly and the channel of whom to give" (S4, FGP2B).

In addition, a more tailored programme of education is needed that will specifically provide the required/missing skills among staff. Another participating nurse stated that it was necessary to offer an educational programme within hospitals for those nurses who did not speak Arabic, in order to improve their Arabic language skills. It was felt that this would enhance staff performance and provide safe care.

"I guess if they will make Arabic classes to the staff maybe that will be better" (S3, FGM1B).

Another participant said that education was needed for all disciplines and levels of staff, not just certain groups such as nurses, in order to promote a shared understanding and culture across the organisation. Also, this would help to develop and establish a shared sense of responsibility for patient safety rather than it just falling to nurses, who are easy targets to blame when something goes wrong.

"Continuous education giving only for the nurses. Doctors also, and all the healthcare practitioners or healthcare providers need continuous education" (S1, FGM1A).

8.4.4 Patient empowerment and centeredness

Both groups of participants (healthcare professionals and patients) discussed many issues surrounding patient empowerment and centeredness towards patient safety, the value of patient/family involvement in patient safety, and the current status of patient/family engagement with safety initiatives. Thereby, these issues were categorised into three subthemes: patient/family engagement, person-centred care, and patient needs.

8.4.4.1 Patient/family engagement

The level of patient/family engagement with safety issues seemed to vary, as some of the participants described wider engagement from patients and families as limited whilst others stated that the engagement of patients and families made a positive contribution to the safety culture. The participants highlighted some issues that demonstrated the lack of patient empowerment, which prevented them from being more active in patient safety improvements. For example, the participants said that there was limited patient involvement in patient safety and a lack of sharing decision making which all considered to be barriers to a positive patient safety culture. It was recognised that when patient/family involvement in patient safety was limited, it negatively influenced the ability of patients to understand their own health and wellbeing, making decisions about their health care, and becoming partners in health care. The participants suggested that the lack of patient involvement in patient safety was part of a wider cultural issue where patients and their families were not heavily involved in their care or decisions about their care.

"Patient themselves they don't have any role in their safety.. sometimes awareness of the patient about their safety to achieve complete safety of the patient, they don't know who's the doctor responsible for him" (S6, FGM2B).

In my institution and in the Saudi Arabia patient involvement in patient safety is very very weak… [including] sharing his opinion in his safety (S4, M1SA).

On the other hand, some facilitators to patient involvement were identified in the participating hospitals. For example, staff and hospital policies encouraging patients to speak up, emphasising the positive role of patients/families in their safety, learning from patients' experiences, and encouraging patients/families to participate in safety initiatives/awareness programmes.

"We have a very active process in our hospital regarding patients speaking up… covering a lot of policy in our hospital which involves our patients speaking up about their complains or concerns, meeting with people and discussing their concerns, and we can communicate with the patient about their experiences" (S2, FGM2B).

However, overall limited patient/family engagement with safety initiatives was reflected in patients' and families' accounts. They reported that there were limited processes and strategies that enabled them to take responsibility for their safety. Patients and families acknowledged that the failure of effective and successful patient involvement in safety initiatives was related to their limited power and a lack of encouragement from staff to be involved. Secondly, it was related to the deficit in patient knowledge and awareness about participation in safety issues, which influenced their contribution and responsibilities.

> *"I believe that involving a patient, patient companions, and family members in the medical treatment affects the patient safety at hospitals positively. However, unfortunately, they are not involved. If the treating staff educate them, even by giving a lecture, on sterilisation, hand hygiene, infectious diseases, they will play a big role in the patient safety" (P5B, family member).*

> *"We weren't involved in any initiative for improving patient safety. I only observed some medical awareness at the hospital on teeth and protection from viruses" (P4B, family member).*

Both groups of participants (healthcare professionals and patients) drew attention to the benefits of involving patients in patient safety and addressing safety issues; their involvement was considered to be a facilitator in their hospital organisation. Patients/families' involvement in safety issues was stated to have a significant positive role in observing care, noticing issues and reporting issues to staff in order to prevent harm to patients. One health professional participant, however, stated that patients are involved in patient safety only for specific issues such as fall prevention, but that this positively contributes to working with staff as a partnership.

> *"Patient involvement in patient safety is very weak Like for example for the fall prevention. We have to involve these relatives and the patient about the fall. We will teach them how to prevent patient from fall so the watcher itself can do the intervention if the nurses are not around so they can put the bed up or they can do something. Because we are giving them teaching in preventing from fall" (S2, FGM1A).*

Another participant, one of the nurses, highlighted that when patients lacked capacity, family members were involved as the second eye of the nurses, to safeguard patients from harm and to help meet the patients' needs, particularly after discharge from hospital.

"When the patient need assistance for the feeding or for the bathroom or … like this. We are teaching their families how to do it in the right way before they discharge if patient still in the unit an even with the discharge. How to deal with their patients" (S3, FGP2B).

It was perceived that patients and families also played an important role in maintaining patient safety and preventing harm to patients throughout their hospital stay, as another example was given from a nurse perspective. The nurse raised the value of patient/family engagement in safety issues, as this enabled the patients to recognise unsafe situations that could put their safety at risk.

"We have risk of child abduction or child risk of fall. If we teach the patient from the start during admission to take care of those two, so they will help us more. To save them from abduction or from the fall of risk if they know, they should they have their role to prevent this event to happen" (S6, FGM2B).

Patients themselves also believed and explained that they have substantial role in patient safety by working collaboratively with staff in recognising issues surrounding their care. Patients felt they have ability to promote patient safety if they involved in share decision making and exchanging information and knowledge with healthcare professionals.

"I think if the medical staff shared ideas concerning patient safety with patients and their families, this would improve the general safety in the health environment" (P2A, patient).

"I think the patient companion has his own viewpoint about the patient safety he can share with the treating staff… I wonder why the patient companion can't be involved in giving their own suggestions and thoughts about the patient safety when they are very close to the patient and very aware of his or her environment, needs and difficulties they face on daily basis" (P4B, family member).

Participants perceived that patients and family members have a role in patient safety through preventing errors, checking aspects of their medications, asking questions to clarify issues of confusion and reporting concerns to medical team.

"Patients can play a great role in preventing medical errors by learning from doctors the nature of their medications and times of taking them" (P6A, patient).

"I believe that the patient and patient companions can participate in the patient safety through drawing the attention of the treating staff to certain defects or the need for developing certain aspects within the medical environment regarding the right time and secured ways of receiving medications, communicating with the treating staff, and maintaining patients' dignity" (9SA, Family Member).

Patients and families can contribute to patient safety by making sure they are responsible for their own care, which includes reminding staff when medications are due, as described by a participating patient:

"Sometimes patients had to remind nurses of the medications they should have taken on certain times. In brief, if patients weren't concerned about how things go on at the hospital, they would lose a great deal of their rights" (P6A, patient).

Another way in which patients and family members contributed to patient safety was by sharing information with other patients about safety hazards and minimising the risk of infection.

"I think that patients can contribute to patient safety through reminding other patients of washing their hands, not disturbing other patients while they are asleep, and avoiding contact with other infected patients" (P8A, Patient).

"As far as I am concerned, eliminating patients from being part of the process of making decisions and policies relevant to patient safety is a big mistake. Those patients who stay long at a hospital must have a lot of experience to share with the hospital administration regarding patient safety" (P10B, patient).

Healthcare professionals also stressed the importance of patient/family involvement in patient safety and suggested that active participation reduces the risk of errors and encourages patients and families to be vigilant with regard to their care and needs.

"We [are] getting the family involved in patient safety issues and we are having a meeting with doctors and relatives of patients to discuss about patient safety issues and once we have the feedback out of the pilot study, it will be implemented to the whole hospital. I think it will add more to the patient safety culture inside the hospital" (S7, FGM2A).

"We need to have an engagement of the patient, which is very top essential on the patient safety is to know your patients. We need to put in the priority is the engagement of patient. So, the patient should tell us what they understood with regards to their current situation, what they might need

when they are after care after they got operated. What they need? what they should do?" (S3, FGM1B).

8.4.4.2 Person-centred care

Both groups of participants (healthcare professionals and patients) believed that promoting person-centred care is fundamental to supporting and establishing a patient safety culture. Therefore, involving patients in patient safety is part of a broader movement towards greater implementation in person-centred care. However, the following quotes show how staff are concerned about the lack of patient/family engagement in patient safety in their hospitals. It was noted that patients often did not even know what their diagnosis was or what their medication was for, let alone being invited to share their views on patient safety. This reflected the vulnerability of the patients in hospital and the failure to implement person-centred care approaches.

"I think the family are [left] out of the patient safety decision or patient safety sharing. I don't know if they are involved in any level. I believe sometimes the patient himself he doesn't know what's the diagnosis, he doesn't know what's his medications and what is that for" (S4, FGM1A).

"Patient-centred care is another issue. Patients never have someone speak up for them. We decide so many things but never ask the patient whether this is okay for them. So, I think this is another issue with [implementing] patient-centred care" (S2, FGP1A).

There was also an emphasis on the importance of putting the patient at the centre of care, which is more than just how clinicians treat patients. It is also about how health services and government allocate resources and develop policies that truly put the patient at the centre of care. Person-centred care, according to patients and families, is vital for enhancing safety levels within healthcare institutions, since it improves shared decision-making and self-management and maintains patient preferences. Nevertheless, some patient participants expressed concern that the failure to implement a patient-centred care model, particularly for food preferences, had an impact on patient safety.

"Types of foods offered at the hospital that do not take into account the medical condition of the patients. For instance, some patients have high cholesterol, others are diabetic" [not providing a choice of meals based on medical condition of patients] (P5B, family Member).

8.4.4.3 Patient needs

Patient family needs have emerged as a key subtheme of empowerment and centredness as participants have identified many ways of improving patient safety culture, such as encouraging patients to participate in safety initiatives, promoting awareness, implementing a focused programme for patient safety, involving the community in patient safety, and learning from patient experiences. Participants stressed the importance of patient engagement to prevent harm to patients in healthcare delivery, and said that it can improve both delivery and quality by creating an environment in which discussion can lead to safer outcomes.

> *"We need to put in the priority is the engagement of patient in safety. So, the patient should tell us what they understood with regards to their current situation. What they might need when they are after care after they got operated. What they need? what they should do? Maybe they are not oriented well so, the management itself" (S3, FGM1B).*

> *"Patients have a wide range of needs which may put the facility under pressure. However, approaching and listening to their suggestions can facilitate dealing with their needs and challenges" (P9A, Family Member).*

The participants suggested that community involvement in patient safety is needed to provide better access and provide more ways to enhance patient safety awareness, which in turn will increase participation in patient safety initiatives in the future.

> *"I believe that patient education should not be limited to patients at hospitals, instead, it should exceed the boundaries of hospitals and be within the whole society. This can be achieved by organising awareness campaigns for people in schools, governmental departments, malls, etc. By doing so, people would be aware of their rights as patients, and help them understand the way they should act when they enter hospitals". (P9A, Family Member).*

Another participant mentioned that specific training in patient safety and lessons learned from patient experiences would allow patient safety to be improved over time.

> *"If I had a chance to participate in improving patient safety, I would recommend delivering lectures and making videos for patient that contribute to patient safety improvements" (P6A, patient).*

8.5 Chapter summary

Throughout this chapter, the findings provided rich and comprehensive data on the main barriers and facilitators of establishing a positive patient safety culture in Saudi Arabia. In two participating hospitals, the qualitative findings highlighted perceptions about safety culture from two groups of participants (healthcare professionals and patients) who came from various backgrounds, cultures, job positions and departments. The barriers and facilitators identified belonged to four themes: communications, work conditions, organisational factors, and patient empowerment and centredness, as outlined in Figure 8.1. However, the current study shows that barriers to implementing a positive patient safety culture generally outnumbered facilitators. The study identified several barriers to patient safety culture implementation, including deficits in interpersonal communication, workload, insufficient staff, lack of resources, blame culture, non-adherence to policy, poor physical environments and limited patient involvement in safety initiatives. Key facilitators were prioritising patient safety in organisations, existence of policy and guidelines towards patient safety, positive role of leadership, and value of patient participation in patient safety initiatives. The study provided additional insight into communication, staff issues, blame culture, leadership, organisational factors, working conditions, and workload that were identified superficially in Phases I and II. The next chapter will discuss the findings from each study phase in relation to the wider context of current literature in the patient safety field.

Figure 8.1 Summary of themes and subthemes of patient safety culture

Chapter Nine: Discussion

9.1 Introduction

This chapter presents and discusses the key findings obtained from the three phases of this thesis in relation to the wider context of current literature in order to draw an overall picture of significant issues that impact upon patient safety culture in Saudi Arabia. It brings together the key findings from the three research studies that make up this PhD and integrates them to understand the current status of patient safety culture in Saudi Arabia and to develop an understanding of the barriers and facilitators of the implementation of a positive patient safety culture in Saudi Arabia. The study's limitations and strengths are also presented in this chapter. The practical implications of this study are discussed in relation to the healthcare environment in Saudi Arabia to improve patient safety outcomes.

9.2 Main research findings

This section is guided by the research aim, objectives, questions, and methodology utilised in the current study. The first objective was to identify factors contributing to the patient safety culture in Saudi Arabia, which was achieved during Phase I through a systematic review (Chapter Six:). The second objective was to assess healthcare professionals' perception of patient safety culture in Saudi Arabia, which was achieved during Phase II using a cross-sectional survey (Chapter Seven:). Thirdly, the study objective to explore barriers to and facilitators of the promotion of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families), as well as to explore how these reported barriers and facilitators influence and shape the implementation of a positive patient safety culture from the perspectives of these stakeholders. These last two aims were achieved during Phase III through a qualitative study using two research methods (focus groups and semi-structured interviews) (Chapter Eight). Integrating the findings from the three phases of this study allows a comprehensive picture to be drawn of the barriers and facilitators of patient safety culture in Saudi Arabia. The key issues emerging from the study findings are discussed in the following sections.

9.2.1 Factors contributing to a patient safety culture in Saudi Arabia from the perspective of healthcare professionals and patients

Phase I aimed to identify the factors contributing to patient safety culture in Saudi Arabia and addresses RQ1 through the use of the systematic review approach. The evidence drawn from this systematic review (Albalawi et al. (2020) highlighted that ineffective leadership, a blame culture, workload/inadequate staffing, and poor communication are major hindrances to a positive patient safety culture. Thus, the evidence from the current systematic review is consistent with similar findings from previous study that identify blame culture and poor communication as the most dominant issues among various Arab countries, including Saudi Arabia (Elmontsri et al., 2017). The findings of the current review indicate that patient safety in the Saudi context is at risk due to a range of factors that may limit safety outcomes (DiCuccio, 2015). For example, communication failure and blame culture may contribute to an increased number of errors and could limit the ability of healthcare professionals to learn from their mistakes (Edmondson, 2004, Morello et al., 2013). Therefore, it is imperative that organisational culture that encourages reporting errors, avoids blame, and improves communication is central to improving patient safety culture (Nygren et al., 2013).

Although the findings of the Phase I review (Albalawi et al., 2020) provide important baseline information regarding factors contributing to patient safety culture in Saudi Arabia, they offer a limited an understanding of the complex nature of these factors and their interplay with the context of the environment, organisation and people working there due to the methodological approach used for most of the included studies – namely the survey design. Despite the dearth of studies using qualitative approaches or mixed methods to assess patient safety culture worldwide (Pol et al., 2021), it is believed that adopting mixed methods to measure safety culture is useful in providing insight into the sources of safety culture variability (Pumar-Méndez et al., 2014). This statement is supported by another study (Granel et al., 2020) conducted in Spain using three different methodological approaches (survey, interviews, and observations) to measure perceptions of patient safety culture among nurses and to describe the strengths and weaknesses of the perceived safety culture. Granel et al. (2018) found that staff issues (pressure, workload, and insufficient staff), work conditions, and blame culture were the most influential issues for patient safety

culture. It was also highlighted that different methods are crucial in identifying and addressing critical patient safety culture concerns and issues that require more detailed explanations and require complex solutions to address (Granel et al., 2020). The systematic review undertaken as part of this thesis identified a distinct absence of patient/ family voice, which could contribute to understanding patient safety culture. In addressing this gap, the current study aimed to include the perspectives of patients and family members, as discussed in the following phases.

The findings of Phase I point to knowledge gaps that require more research and development to understand patient safety culture in a more comprehensive way and to determine the underlying causes of deficit in patient safety culture that need to be addressed. The conditions of patient safety in the Saudi healthcare context seem to have a great deal of room for improvement to address the issues beyond the current challenges of the country's patient safety culture. Therefore, the Phase I review highlighted that further research is also required to investigate the perceptions of healthcare professionals regarding patient safety culture that help to inform policy makers of the level of patient safety culture among this group. This was achieved through Phase II in this thesis, in which a quantitative study assessed the overall perception of patient safety culture in three selected Saudi hospitals. The findings of Phase II showed the need to obtain perspectives of patient safety culture from patients and their families, and to explore how the reported factors impact on patient safety. The data generated in Phase II were further investigated in Phase III, in which a qualitative study assessed patient safety culture from different stakeholders' perspectives (healthcare professionals/patients and families).

9.2.2 Healthcare professionals' and patients' perceptions of the patient safety culture in their organisations

Phase II aimed to explore healthcare professionals' perceptions of patient safety culture in Saudi Arabia, which addressed RQ2 through the use of a cross-sectional survey. Although the use of surveys was identified earlier as a potential issue in this evidence base (Halligan and Zecevic, 2011), it was adopted in this phase to provide an understanding of the experiences of people working in the hospitals that were selected. This provided relevant background context of the specific barriers and facilitators to patient safety culture that they faced so that these could be explored in

more depth in the qualitative phase. The findings from the survey show that patient safety culture in the three participating hospitals is weak and requires improvement. This result is comparable with other studies conducted in Saudi Arabia and is considered convergent in relation to the level of patient safety culture (Hamaideh, 2017, Alswat et al., 2017, Al-Awa et al., 2012). The similarities in the findings may be due to similarities in hospital infrastructure, national and local policies and guidance and staff attitude towards patient safety culture (Titi et al., 2021). These findings support the Phase I results (Albalawi et al. (2020) that show that blame culture and workload are the most reported factors contributing to patient safety culture in Saudi Arabia. Such findings are not unique to countries in the Middle East. For example, similar findings were identified in a mixed methods study in Spain (Granel et al. (2020) to assess nurses' perception of patient safety culture and found that blame culture is one of the most described factors that hinders patient safety culture and limits the opportunity to improve it. Therefore, it is crucial for healthcare organisations to regard reporting errors as a learning opportunity that can be used to discover and solve problems regarding safety concerns, not as personal failures that limit the frequency of reporting errors (Tigard, 2019). The positive scores for the patient safety culture domains were disappointing because none of the dimensions are considered strengths, but some dimensions (teamwork within units and organisational learning - continuous improvements) are considered to be higher, at 63.5% and 64.6%, respectively. This result indicates that learning culture and teamwork are present, but low, and respondents are positive about learning and working together as a team as well as improving patient safety culture. Conversely, the findings reveal deficiencies in patient safety culture dimensions, including nonpunitive responses to errors and staffing in this study area, indicating a low standard of patient safety culture. The variations in the patient safety culture dimensions may be due to inherent cultural differences or to the workforce diversity in the healthcare system (Almutairi, 2015). Consequently, it is important to consider the implications for of each domain on the wider culture to build a picture of organisations and understand how the health and safety culture can be improved. As a result, the organisational safety culture comprises shared working practices, the tendency to accept or tolerate risk, how they manage hazards, and how they handle near-misses and accidents.

Phase III aimed to explore the barriers to and facilitators of the implementation of a positive patient safety culture in Saudi Arabia from multiple perspectives (healthcare professionals and patients/families, and how the reported barriers and facilitators influence and shape the implementation of a positive patient safety culture), which addressed RQ3 and RQ4 through the use of focus groups and semi structured interviews. The study findings revealed that both patient/family members and healthcare professionals had negative perceptions towards patient safety culture and highlighted many aspects that they believed contribute to patient safety culture, as outlined in Chapter Eight.

The majority of the factors that emerged in Phase III were common to both groups, which reflected the evidence from a qualitative study involving four focus groups and eight semi structured interviews with 34 patients and carers from south-east Australia (Hernan et al., 2015). Hernan et al. (2015) reported that patients and family members have a similar sense of safety issues as healthcare professionals and are able to successfully comment on the elements that impact patient safety. The Phase III findings reveal that patients/family members observe tasks and activities of safety issues and actively are willing to participate in safety initiatives. They also offer the richest source of information related to safety incidents as many of them witness details of individuals, organisations, and system failures that threaten patient safety. This is consistent with the findings of a systematic review undertaken by Park and Giap (2020) that included 42 studies from around the world, which highlighted that patient and family engagement is increasingly emerging as a potential approach for improving patient safety. Therefore, the current study contributes to the advancement of current literature on the importance of the patient perspective in the safety of healthcare delivery.

The current approach to accessing and harnessing patient views about safety issues in the current study maximises and supports the utility of the insight generated towards understanding the concepts of patient safety culture and the factors affecting them using patient perspectives, as outlined by (Lee et al., 2020, Rainey et al., 2015). The current study supported the evidence from a systematic review by Chegini et al. (2021) that included 19 studies to explore patient engagement in patient safety and suggests that patient experiences and opinions need to be enhanced and utilised to

resolve the issues and complex situations related to the clinical environment and patient safety issues. The review by Chegini et al. (2021) emphasises the significance of healthcare professionals in empowering patient engagement in patient safety, and they need to be more patient-centred in their approaches to support patient engagement. In this respect, reflecting on the positive influence of the patient/family role in patient safety, patients should contribute directly to patient safety initiatives, prioritising patient involvement alongside healthcare professionals. In the next section, the findings were summarised from studies together to facilitate the understanding of the barriers to and facilitators of the implementation of a patient safety culture, which are discussed in detail.

9.3 Overall summary of the three studies

In general, the results of the three studies together reveal significant factors and issues behind patient safety culture in three participating hospitals from Saudi Arabia, which explain the perceptions of different stakeholders who described a negative safety culture within all three hospitals. The factors identified by the various stakeholders in the three studies are believed to influence patient safety culture, both negatively and positively, and have therefore been summarised as the barriers and facilitators of implementing a patient safety culture in Saudi Arabia (Table 9.1). To expand the knowledge of patient safety culture in Saudi Arabia, the main results related to the dimensions of patient safety culture were discussed after the integration of the results and compliance with the assumptions regarding mixed methods sequential explanatory research. The findings of the three studies contribute to a deeper understanding of the organisational, cultural, and contextual factors that impact safety culture implementation in Saudi Arabian healthcare. Therefore, the value of a mixed method approach such as that used in the current study goes beyond the quantitative assessment provided solely by the use of the HSOPSC, which demonstrated that Saudi Arabian patient safety culture needs to be strengthened. Healthcare professionals viewed patient safety cultures as weak in Saudi Arabia according to the HSOPSC dimensions, which is consistent with the literature that finds weak patient safety cultures to be widespread worldwide for most patient safety culture dimensions (Reis et al., 2018, Mello and Barbosa, 2017). However, in the qualitative stage (focus group discussion and semi-structured interviews with different stakeholders), it was

useful to clarify the results found during the previous stages and identify the factors that explain healthcare professionals' perceptions of the patient safety culture. The qualitative data also support the survey results and provide a more detailed picture of patient safety issues including work conditions, ineffective reporting systems, communication gaps, lack of human resources, and an existing culture of blame. In light of these challenges associated with patient safety culture implementation identified in the current study, it is possible to explain why patient safety culture was perceived as weak in previous studies (Elmontsri et al., 2017), and also helps to articulate the barriers and facilitators for implementing a positive patient safety culture in Saudi Arabia.

Table 9.1 Summary of the three studies of (barriers and facilitators) of implementing a patient safety culture

Phase number	Weaknesses (Barriers)	Strengths (Facilitators)
Phase I	Ineffective leadership Blame culture High workload/ inadequate staff Poor communication Lack of teamwork/collaboration across hospital units Lack of reporting systems Low staff experience, low staff competence Communication gaps between healthcare institutions/ professionals/patients Inadequate resources/ equipment	Collaborative teamwork within hospitals units Clear feedback and communication regarding errors Realistic manager expectations and supportive actions promoting patient safety Effective organisational learning/staff education and continuous improvement
Phase II	Teamwork within units Supervisor/manager expectations and actions promoting patient safety Organisational learning/continuous improvement Management support for patient safety Overall perceptions of patient safety Feedback and communication about error Communication openness Frequency of events reported Teamwork across units Staffing Handoffs and transitions Non-punitive response to errors	None fit with criteria to be strengths

Phase III	**Communication** ***Interpersonal communication*** Poor communication system, lack of coordination, handover, language barrier, lack of interaction, culture and language diversity, lack of feedback/response and lack of translators ***Documentation*** Absence of electronic documentation and poor record keeping ***Reporting system*** Unclarity of reporting system, no feedback following incident and delay in action following incident **Work conditions** ***Staff factors*** Insufficient staff, nurse–patient ratio, workload, knowledge and awareness gabs, lack of collaboration and teamwork, staff turnover/changes, no clear job description, inadequate staff orientation and qualifications, skills mix and staff competency ***Management/leadership*** Poor leadership, lack of supervision and monitoring staff, absence of feedback following reporting incidence, lack of accountability/responsibility and lack of staff value/encouragement ***Professionalism*** Staff behaviours, lack of respect/dignity, carelessness, lack of response and lack of attention ***Cultural and Social Factors*** Blame culture, culture of negativity, cover-up to avoid blame, workforce and cultural diversity	- Leadership (act as a role model) - Positive teamwork among staff - Priority given to patient safety by policy - Positive role of patient/family towards their safety, and safety culture - Learning from patient experience - Staff education and learning strategies

	Organisational factors *Environmental Factors* Confidentiality, privacy, interruptions, noise, crowdedness, hospital security, poor cleanliness, poor ventilation and visiting time *Hospital Facilities and Resources/Equipment* Lack of medical equipment/resources, deficit in the IT system, lack of moving handling devices, lack of services/resources, lack of medications, deficit in the electronic system for prescribing medications *Policy and Guidelines* Lack of adherence to policies, deficit of implementation and dissemination, diversity of regulations and practice *Education and Training* Limited focus programme of education/orientation for staff, need for Arabic classes for staff who do not speak Arabic, fairness of education – needed for all disciplines and levels of staff **Patient Empowerment and Centeredness** *Patient/Family engagement* Limited patient involvement in patient safety initiatives, lack of sharing decision making, limited encouragement of patient to speak up *Person-Centred Care* Lack of person-centred care, lack of implementation of patient needs and goals, preferences (food, sleep) and limited emphasis of patient rights	

The findings of the three studies undertaken in this thesis show that patient safety culture in Saudi Arabia is compromised by several factors, indicating that policy makers in the healthcare system should take these into consideration to reduce barriers and to facilitate improvements to patient safety and quality of healthcare. Although the findings provide insight to the barriers and facilitators, it should be noted that the number of barriers outweigh the facilitators, indicating an obvious deficit in the status of patient safety culture in Saudi Arabia. The majority of the barriers and facilitators identified in the research related to dimensions of patient safety culture already identified in the literature (Sammer et al. (2010), including staff issues, communication, leadership, reporting systems, work conditions, organisational factors, and person-centred care. It is clear that patient safety culture is significantly exposed to many aspects that could represent threats to patient safety. Excessive communication breakdown, heavy workload, blame culture, poor leadership, inappropriate working conditions, and deficits in the organisational environment remain the most commonly described issues that hinder the development of a positive patient safety culture. This confirms the complexity of the patient safety culture in Saudi Arabia that requires an improvement strategy to address and help strengthen it in the future.

Poor communication within and across departments and among multidisciplinary teams along with language barriers are the most frequently mentioned barriers to establishing patient safety culture identified in the current study. This finding is consistent with another recent mixed methods study in Saudi Arabia that captured the complexity of patient safety culture from different healthcare professionals especially poor communication between healthcare professionals (Titi et al., 2021). Similar findings were also reported in a systematic review of regional Arab countries, including Saudi Arabia, that share similar healthcare contexts, as it was noted that challenges with communication are among the most frequently described issues influencing patient safety culture (Elmontsri et al., 2017). The current study supports the findings of (Alshammari et al., 2019), who found that due to shortages of Saudi healthcare professionals, different expatriate healthcare professionals are recruited from other countries with differences in religion, culture, social values, and language, which are all believed to create barriers between healthcare providers and patients. A systematic review included 12 papers to identify the issues and challenges related

to the culture and language differences of the health workforce in Saudi Arabia conducted by Almutairi (2015) highlights that most communication barriers between patients and healthcare providers in Saudi Arabia are a result of cultural incompetence and language differences. The review also suggests some strategies to address patient–healthcare professional communication, including interpreters and proficiency language tests for those whose first language is not Arabic, in order to improve clinical practices and error rates (Almutairi, 2015). The effect of poor relationships between healthcare providers and patients due to communication barriers was described by the patients/family members who participated in the current study, as they feel it may increase the possibility of errors and limit the provision of holistic care. Lack of feedback regarding their health conditions and concerns was also noted, especially from the patient/family perspective, which may explain the poor communication and interaction between healthcare providers and patients.

Cultural diversity and workforce were identified by both groups (healthcare professionals and patients/family members) as barriers to positive patient safety culture due to their impact on optimal communication, teamwork, and differences in health beliefs and behaviours. It was also noted that workforce diversity leads to cultural and language barriers that prevent patients and their families from understanding healthcare professionals and an inability to engage in decision making in relation to their care. The current study findings support those of Almutairi et al. (2015) who undertook a case study in multicultural work environments in Saudi Arabia and reported that such environments are risky to patient safety due to conflicts in a range of areas, including differences in cultural norms, beliefs, behaviours, and language. With increasing workforce diversity in the Saudi Arabian healthcare system, language and cultural diversity are described as a complex barrier to the improvement of healthcare services including patient safety culture (Albejaidi and Nair, 2019, AlYami and Watson, 2014).

Fear of criticism and punishment was highlighted by healthcare professionals as common consequences of a blame culture facing healthcare professionals in their areas. It is noted that a perceived blame culture was an underpinning factor in the poor error-reporting rates identified in Phase I and Phase II. For example, in the

current study, the staff especially nurses stated that aspects such as cover-ups and underreporting exist because staff want to protect themselves from punishment. This finding is in line with other studies that reported barriers to the reporting of incidents due to fear of blame (Waring, 2005, Pfeiffer et al., 2010, Lee et al., 2018).

In the current study, participants referred to many aspects related to the availability of resources including human resources, insufficient staff numbers, nurse–patient ratio, workload, and turnover. Staff shortages, nurse–patient ratio, and workload were common factors mentioned in both groups of participants (healthcare professionals and patients) that were said to be highly stressful. Understaffing and poor patient–staff ratio was perceived by the participants as a significant cause of tension/pressure due to time constraints that limit the time staff can spend with patients, which in turn directly relates to quality and safety in healthcare. Inadequate numbers of staff were associated with high workload, fatigue and burnout, and turnover, which in turn were perceived as being associated with lower perceptions of patient safety culture (Al Ma'mari et al., 2020). Work overload and long working hours were linked to loss of vigilance and attention, which were regarded as common factors beyond individual factors that lead to errors (Reason, 2000a, Holden et al., 2011). Fagerström et al. (2018) report that nurses' workload negatively impacts on patient safety, as it is found that it increases the patient safety incidence up to 30% and the mortality rate up to 40%.

Patients and their family members participating in the current study mentioned that the patient/family role is crucial. They can work collaboratively with hospital teams to maintain patient safety by drawing the attention of the treating staff to their medication, reminding them of the right time to take it, dosage, reactions, and to clarify the accuracy of label medication with patient identification. These findings are supported by various literature that also views patients/family members as a key factor in the management of patient safety (Hor et al., 2013, Vaismoradi et al., 2015, Severinsson and Holm, 2015, O'Hara et al., 2018). Moreover, Ward and Armitage (2012) conducted a systematic review of 13 studies to examine the ability of patients to report safety issues; the review reported that patients are valuable sources of information on patient safety, demonstrating their ability to report safety concerns in hospitals. O'Hara et al. (2018) found that patients offer a unique perception of patient

safety in their organisations that enhance an understanding of patient safety incidence not captured by hospital reporting systems. Patients can act as a safeguard, recognising the risks associated with healthcare services and providing accurate information that can prevent both threats to patient safety and serious complications (Davis et al., 2007). Patients were also found participating actively in recognising and reporting clinical deterioration in their health condition during their stay in hospital, which further improved their safety by recognising risk and harm in the early stages before an incident occurred (Albutt et al., 2020).

It was very clear that some barriers and facilitators identified in the current study are common among both the healthcare professionals and patients/family members who participated in this study. This demonstrates consistency in the perception and beliefs of patient safety culture among both groups. Hence, patient perspective added value to this study due to their ability to identify and report safety issues and concerns from different views of healthcare professionals. It also contributes to provide a specific instance of the wider concept of patient safety culture and presents a variety of factors that hinder safety culture. This supports the evidence that patients/family members effectively play a role in maintaining and managing patient safety despite this being the sole responsibility of healthcare professionals (Park and Giap, 2020).

Adopting a mixed methods approach for the current study allowed it to reveal unique and rich information regarding patient safety culture in Saudi Arabia. The current study has provided detailed, qualitative perspectives of patient safety culture instead of relying on a survey tool alone – an approach that is criticised for being unable to provide a full picture of patient safety culture, the underlying causes of the reduction in safety culture, or to predict management opportunities (Pumar-Méndez et al., 2014). Interviews with key stakeholders (healthcare professionals and patient/family) expand our understanding of the survey's findings, that focus only on the perception of patient safety culture, and promote experience of both healthcare professionals and patient of safety related factors linked to obstacles successful safety culture implementation (Churruca et al., 2021). Hence, it is recommended that a mixed methods approach is adopted in this type of investigation in order to explore patient

safety culture to provide richer, stronger, and more accurate data (Pumar-Méndez et al., 2014, Churruca et al., 2021).

9.4 Study strengths and limitations

9.4.1 Strengths

One of the most important strengths of this study was that it involved different stakeholders' perspectives to study the complex topic of patient safety culture in Saudi Arabia for the first time. The combination of the perceptions of healthcare professionals (physicians, nurses, pharmacists, allied healthcare) from different levels and departments alongside patients and family members gave a unique perspective to the current study, providing an opportunity to explore the barriers and facilitators of patient safety culture from wider perspectives. The methodological strength of the current study was the qualitative approach adopted. The inclusion of patients/family members in this study is unique as it responds to calls from recently published research studies for more patient involvement in patient safety (O'Hara et al., 2018, Park and Giap, 2020). Thus, the current study enabled patients/family members to express their perceptions regarding safety culture in hospitals to highlight the contributory factors, and to discuss how this impacted on their health and wellbeing. The patients/family members participating in the current study were able to effectively recognise safety issues and concerns that threaten the overall safety culture and make suggestions to improve the safety culture in their healthcare organisations. Previously, patients and family members were never included in research or given the opportunity to identify issues that affected them directly, whereas this study provided a detailed and comprehensive understanding of how this participant group perceived patient safety culture alongside healthcare professionals' perspectives.

The sequential explanatory mixed methods approach was another methodological strength of the current study as it allowed the findings obtained from each phase to be explained and explored further in subsequent phases. The current study also demonstrates the importance of adopting a mixed methods approach in investigating patient safety culture, as integration of the findings from quantitative and qualitative components offered a comprehensive picture of the barriers and facilitators that

influence a patient safety culture. For example, it contributes to a shift in the design of studies, such as moving away from reliance on surveys. Thus, the findings from the current study contribute significantly towards the knowledge gaps of patient safety in the Saudi context, with a richer and deeper understanding yielded from different stakeholder perspectives.

9.4.2 Limitations

This study has some limitations which should be taken into consideration. A cross-sectional design was used in Phase II, where the data were collected at one specific point in time due to time and financial constraints; this ultimately limited the prediction of long term trends (Setia, 2016). Data were collected from three hospitals in one health region in Saudi Arabia, thereby generalisability of the findings to other geographical areas in Saudi Arabia may be limited. However, the researcher believes that the findings of this study are applicable to other regions of the country, especially for Ministry of Health (MoH) healthcare organisations that share similar healthcare systems and workforce cultural diversity. This means that while the MoH is the main provider of healthcare services in Saudi Arabia with about 60% of hospitals run by the MoH, the study findings would be of benefit to other healthcare settings to improve patient safety culture.

Despite the effort undertaken to increase the response rate for the survey in Phase II, it remained low, meaning that many healthcare professionals' opinions were missed. The response rate may be influenced by a range of factors. Firstly, the participating hospitals are the largest hospitals in the health region studied, and during the study period the staff were working extra hours according to changes in their patterns of duties to accommodate the preparation for pilgrims, which may reduce the time available for staff to engage with this study. Secondly, the use of web-based surveys is generally associated with lower response rates compared with paper-based ones (Daikeler et al., 2020). Finally, the lower response rate may be a reflection of organisational culture and staff engagement with improvements to patient safety culture strategies.

In the current study there is a difference in the proportion of respondents between the organisations and in each participant group, which could indicate a potential

systematic bias (Gerhard, 2008). As the researcher selected different healthcare professionals to participate in the study without specifying a specific number for each group, the selection bias may be increased, which is acknowledged as a limitation of the current study. The majority of the participants in the study were nurses – 251 of 363 – reducing the generalisability of the findings to a broader population. Even though systematic bias is independent of the size of the study population and statistical significance does not reflect the presence or absence of bias(Malone et al.,2014), the current study shows differences in the number of participants between the three organisations, which might influence the conclusions drawn (Malone et al., 2014).

Chapter Ten: Conclusion and Recommendations

10.1 Introduction

This chapter presents the conclusion and recommendations of the current research study which were generated from the main findings of the three phases of the thesis. A series of recommendations are made for various aspects that should be considered for improving Saudi Arabia's patient safety culture from the angles of policy, practice, and research.

10.2 Conclusion

The aim of this research was to explore barriers and facilitators to the promotion of a positive patient safety culture in Saudi Arabia from multiple perspectives. A mixed methods design was used to obtain an in-depth understanding of the complexity of patient safety culture from different perspectives (healthcare professionals and patients/families). The study was divided into three phases to offer insight into the actual factors affecting the ongoing process, activities, and potential barriers to adopting and implementing a positive patient safety culture in the Saudi healthcare context. Phase I systematic review identified factors contributing to patient safety culture in Saudi Arabia and found that communication, blame culture, reporting system, and workload are the most reported factors hindering a positive patient safety culture. This systematic review revealed that there had been a limited number of mixed methods studies (quantitative and qualitative) conducted on patient safety culture in Saudi Arabia, particularly focusing on the factors that influence implementation of safety culture in hospital settings. In addition, patients' and family members' perspectives toward safety culture were unknown. This exposed a gap in the understanding of safety culture in the Saudi healthcare context, thus highlighting the need for further exploration by undertaking a study to provide insight into patient safety culture, exploring the barriers of and facilitators to implementation of a positive safety culture among healthcare professionals and patients.

Following the systematic review, the Phase II study measured patient safety culture and provided an overview of the state of the patient safety culture among healthcare

professionals using a sample of 363 participants from three hospitals in Saudi Arabia. The Phase II study utilised a cross sectional survey design and used the HSOPSC tool, which is a validated self-administered questionnaire. The findings showed that the overall level of patient safety culture in the participating hospitals is low. None of the 12 dimensions of patient safety culture fit with the set criteria for strengths, as per the HSOPSC guidelines, meaning healthcare professionals had negative perceptions towards the patient safety culture within their institutions. By assessing patient safety culture, these healthcare organisations will become aware of the different aspects that require serious attention and this can inform improvement initiatives. Moreover, assessment makes it possible for hospitals and healthcare providers to identify the existing challenges and strengths of their organisational culture regarding patient safety and use this information to guide their improvement strategies and interventions.

In Phase III, qualitative approaches were used to obtain a detailed understanding of the perceived barriers and facilitators of the implementation of a positive patient safety culture in Saudi Arabia. This phase also aimed to explore patient/family members' perceptions of safety culture in the Saudi healthcare setting. It was found that the identified barriers and facilitators could be classified under four themes: communication, organisational factors, environmental issues, and patient centredness and empowerment as detailed in (section 8.4). Communication barriers related to a deficit in communication between staff and patients, language barriers, lack of reporting system, and hospital documentation, which were linked to the cultural and workforce diversity differences between patients and healthcare professionals.

In addition, the major barriers included blame culture, heavy workloads, high patient-staff ratios, insufficient staff, lack of resources, lack of collaboration and teamwork, professionalism, leadership/management, and patient/family involvement in safety initiatives. Frequent concerns about blame and punishment for medical errors were highlighted in this study. Therefore, a national reporting system and culture change are both necessary to make reporting safety concerns essential elements for a system that is easily accessible and provides patients and healthcare professionals with feedback and support.

Participants from all stakeholder groups (healthcare professionals and patients) felt strongly that assessment of patient safety culture is important for the delivery of high quality and safe medical care and is an essential part of understanding the organisation's culture to develop improvement strategies. Improvements could be made through more effective implementation of interventions that focus on weaknesses, including communication, leadership, blame culture, staff issues, and working conditions. Health policymakers and decisionmakers need to consider patient safety culture as a serious concern and try to correct the culture of blame and punishment; they should encourage organisations to continually improve patient safety culture-related processes and procedures that effectively facilitate implementation of safety culture. Health policymakers and decisionmakers in Saudi Arabia should work towards the creation of a just and proper culture in the workplace and encourage healthcare workers to report incidents and safety concerns. In this study, the results demonstrate the benefits of combining surveys with qualitative methods to investigate safety culture, an approach that helps obtain a comprehensive understanding of the underlying thoughts or opinions of individuals regarding safety culture. Thus, this approach facilitates the identification of a range of factors that could reduce overall positive culture within healthcare organisations with regard to safety and quality of healthcare.

10.3 Recommendations

Overall, the findings of this research show that the current state of patient safety culture in Saudi Arabia is challenged by various factors that create obstacles for healthcare professionals and organisations to maintain safety culture in their settings. Consequently, this thesis proposes a number of recommendations that could help improve safety culture within Saudi healthcare organisations. The following recommendations are based on the findings from this study and include suggestions from the participating healthcare professionals and patients/families. The recommendations were formulated with a specific emphasis on the perspectives of healthcare professionals, patients/families, and organisations for maintaining positive patient safety issues. Consideration is also given to the feasibility of implementation and the resources required to sustain a positive patient safety culture in healthcare

settings. The following recommendations have implications for practice, policy, and future research.

10.3.1 Recommendations for practice and organisations

The findings of this study show that creating work environments that enhance implementation of a positive patient safety culture require fundamental changes and strategies to promote and overcome the challenges faced by Saudi healthcare organisations. The implementation of such a culture, in practice, is a complex and challenging process as it requires individuals and healthcare organisations to change behaviours and create a culture of learning. The following recommendations can help those involved in the patient safety culture implementation process:

- Improve communication among healthcare professionals and patients. This is considered an important part of patient safety culture in order to reduce misunderstandings that cause errors and safety concerns. Improvements in communication can be achieved by developing effective communication channels that facilitate communication within healthcare organisations – transforming information, reducing language barriers, and supporting coordination and collaboration between teams, particularly during patient handovers, in order to reduce the possibility of medical errors in clinical practice. Establishing Arabic courses for non-Arabic speaking healthcare professionals will improve their language and enable them to speak with patients more easily and meet their needs effectively and safely.

- Create a blame-free, 'just' culture that encourages healthcare professionals to report incidents without any fear or concerns so that they feel empowered to learn from their mistakes. Managers and supervisors can help create a just culture by providing feedback about adverse incidents to their staff to ensure that the learning and improvement following an incident report takes place at the individual, team, and organisational level. The feedback can include ways to improve patient safety practices based on analyses of errors and incidents.

- Improve the physical work environment and promote patient safety as a top priority within healthcare organisations. Make appropriate workplace

adjustments including infrastructure and adequate equipment/supplies, and maintain building safety and security. Ensure that hospital facilities and medical equipment are maintained properly in order to ensure the availability of services for patients and to enable healthcare professionals to do their jobs efficiently. Patient confidentiality and privacy should be maintained, and healthcare professionals should always perform professionally when dealing with patients: respect their opinion, listen to their concerns, and assure that they provide safe healthcare for the patient.

- Improve staffing issues. This is regarded as one of the main negative issues dominating the Saudi Arabia healthcare system. This can be achieved by allocating sufficient staff, improving the recruitment process, and ensuring the nurse-patient ratio is low enough to allow healthcare professionals sufficient time for delivery of effective and safe care. Moreover, workload issues should be resolved as staff shortages increase workload, which limits the opportunity for individuals to engage in patient safety activities.

- A supportive working environment must be created that encourages and appreciates healthcare professionals so that they feel valued and appreciated. Leadership must prioritise patient safety, encourage healthcare professionals to participate in the implementation process of safety culture initiatives and decision making, and listen to healthcare professionals' concerns and suggestions for improving safety culture in their organisations. It is also recommended that staff achievements in patient safety practice be recognised to support healthcare professionals to adopt patient safety practices in their everyday roles and to reflect hospital management's commitment to patient safety initiatives.

- Improve and support patient involvement in patient safety initiatives by valuing patient participation and providing appropriate strategies to facilitate their full engagement in safety practices. Healthcare organisations should ensure they provide the resources and infrastructure necessary for patient participation and encourage collaboration among healthcare professionals to promote a safer healthcare system. Patient participation should be compatible with their health conditions, abilities, and task nature.

10.3.2 Recommendations for policy and management

Policymakers and managers should ensure that patient safety culture remains central to their policies and guidelines to support the implementation process, dissemination, and sustainability of a positive safety culture in the healthcare setting. Policymakers and management should:

- Establish clear policies and guidelines that define healthcare professionals' job description to enhance staff responsibility in maintaining patient safety, and monitor healthcare professionals' performance.

- Establish a system that regularly measures and evaluates patient safety culture in healthcare organisations that also supports feedback and learning to ensure healthcare professionals and organisations follow evidence-based clinical guidelines.

- Establish robust policies and guidelines that determine healthcare professionals' and patients' role in maintaining a patient safety culture in healthcare organisations that facilitates national improvement strategies among different healthcare service users.

- Create a national reporting system that facilitates reporting of incidents and safety issues from different groups (healthcare professionals and patients) with effective feedback to support a culture of learning from errors and previous mistakes.

- Establish continuous education and training programmes for all healthcare professionals to enhance knowledge and skills regarding patient safety standards and taxonomy. In addition, conduct orientation programmes for new staff to increase their level of knowledge and awareness of patient safety requirements and make them aware of what is expected of them. In order to improve the patient safety culture, organisations need to develop training programmes focusing on the concepts of patient safety culture to build awareness among healthcare professionals on the dimensions of patient safety. In addition, this process should be repeated on a regular basis so that improvements can be properly assessed and monitored.

10.3.3 Recommendations for future research

Taking into account the findings of this study, there are important areas of future research that need consideration. Future research could explore patient safety culture on a larger scale across the country, following the findings of this study to investigate the factors that influence patient safety culture, determining applicability to wider settings. To understand how factors influence patient safety culture over time, future research should carry out long-term evaluations using longitudinal study to detect developments or changes of factors over time. Moreover, future research should be extended to include other areas, such as primary care, out-patient departments, and hospitals not run by the MoH such as private hospitals, national guard and military hospitals, to compare the factors that impact on patient safety culture in such settings to identify whether context plays a role in influencing the main facilitators and barriers to safety culture.

Future research should aim to incorporate the patient/family perspective to identify the relationship between patient/family involvement in safety initiatives and patient safety outcomes. A qualitative approach would be helpful to better understand how patients themselves believe they can improve patient safety, in terms of their role and participation in safety initiatives. This would provide a more nuanced understanding of patients' role and perception of voidability. Moreover, more knowledge is needed on the effectiveness of various interventions that involve patient feedback or other patient involvement strategies to increase patient participation in safety initiatives alongside healthcare professionals. In addition, further research must be undertaken to test interventions with regards to the barriers identified in this study in order to facilitate improvement strategies.

10.3.4 Recommendations for implementation of patient safety culture

In this section, the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) is used as a theoretical framework to guide the understanding of the barriers and facilitators influencing the implementation of a patient safety culture in the Saudi Arabian healthcare context. CFIR is regarded as a conceptual framework developed to offer systematic assessment of multilevel

implementation contexts and to facilitate understanding of factors that might influence implementation of interventions and their effectiveness (Damschroder et al., 2009). A conceptual framework is a system of concepts, assumptions, expectations, beliefs, and theories that provide a comprehensive understanding of a phenomenon to be studied. It provides a layout of key factors, constructs and variables, with the relationships between them, that influence the phenomenon of interest (Jabareen, 2009). Conceptual frameworks enhance the efficiency of research and relevance of the findings to inform implementation practice due to their work as an interpretive approach to social reality (Jabareen, 2009). During the analysis, it seemed that many of the barriers and facilitators related to aspects evident in the wider implementation literature. Hence, for the purpose of the recommendation section, the findings were aligned to this framework to support an understanding of the barriers and facilitators to the implementation of a positive safety culture in the Saudi healthcare context. While this framework is used to help explain the study findings in relation to implementation, it was never intended to be used to guide data collection and analysis, therefore it is possible that there may not be data for all of the domains. It is recognised, however, that it would have been possible to use the framework to guide data collection and analysis. This could be a potential limitation of the current research, however, is one that could be addressed in future research now that a greater understanding of the barriers and facilitators to the implementation of a positive patient safety culture have been identified in the current study findings.

The CFIR is composed of five major domains and 39 constructs reflecting the evidence base of factors most likely to influence implementation of interventions, thereby, in the current study, the findings were mapped to the appropriate construct, as follows:

- Intervention characteristics, concerned with characteristics that might influence implementation including stakeholders' perceptions, evidence strength, and quality and complexity of interventions.

- Outer setting, which concerns the external context or environment that might influence implementation such as patient needs and resources, cosmopolitanism, and external policy and incentives.

- Inner setting, concerning the implementing organisation that might influence implementation of an intervention including networks and communication, culture, implementation climate, and leadership engagement.

- Characteristics of individuals, which concerns the individuals involved in the implementation including knowledge and beliefs about the intervention and other personal attributes.

- Process, which concerns the stages or tactics that might influence the implementation process including planning, engaging appropriate individuals, reflecting, and evaluating.

The study findings show that implementing a patient safety culture is a complex process that is influenced by a variety of interacting factors pertaining to the different domains of the CFIR framework as outlined in Table 10.1.

Table 10.1 Mapping the key findings of the three studies into CFIR domain and construct

CFIR Domain	CFIR Construct	Findings	
		Facilitators	Barriers
Intervention characteristics	- Intervention source	- Priority being given to patient safety	- Negative perceptions of patient safety culture
	- Complexity	- Value of patients/family members in patient safety	- Lack of confidentiality, privacy, interruptions, noise, overcrowding, and hospital security
Outer setting	- Patient needs and resources - Cosmopolitanism - External policy and incentives		- Lack of patient empowerment and centredness - Limited patient/family involvement in patient safety - Lack of shared decision making, encouragement of patients to speak up - Lack of coordination and collaboration - Lack of adherence to policies, deficit of implementation and dissemination, and diversity of regulations and practice
Inner setting	- Network and communications		- Lack of interpersonal communication, documentation and reporting system. - Lack of feedback following incidence, delay in action being taken following incidents
	- Culture		- Blame culture, culture of negativity, cover-ups to avoid blame, and workforce and cultural diversity

	- Implementation Climate		- Lack of focused training programmes to facilitate and improve knowledge, skills regarding patient safety issues
	- Readiness of implementation	- Leaders behave in a professional manner, prioritise patient safety, and actively act as role models	- Lack of supervision and monitoring of staff, absence of feedback following incidence reporting, lack of accountability/responsibility, and lack of staff value/encouragement
			- Shortages of medical supplies/resources, devices, equipment, medications, and technology.
			- Insufficiency of human resources, insufficient staff numbers, nurse–patient ratio, workload, and turnover
Characteristics of individuals	- Knowledge and beliefs of the implementation		- Insufficient knowledge, staff competencies and skills regarding patient safety
			- Limited staff orientation and qualification issues
	- Personal attributes		- Professionalism of healthcare professionals including lack of respect/dignity, carelessness, lack of response, and lack of attention
Process	- Planning	- Positive healthcare organisation's commitment to improving implementation strategies through patient safety planning	- Limited individual engagement and shared responsibility in the implementation process, especially for patients and their families
	- Engaging		

10.3.4.1 Intervention characteristics

The intervention characteristics domain concerns the key attributes of interventions that influence the success of implementation. The factors identified in the current study were related to two CFIR constructs of this domain, namely intervention source and complexity.

10.3.4.1.1 Intervention source

The intervention source construct is described as the perception of key stakeholders about whether the intervention is externally or internally developed. In the current study, negative perceptions were found regarding key stakeholders' perceptions of positive patient safety culture implementation due to limited evidence and quality of intervention. Negative perceptions of patient safety culture were identified among different individuals, groups, and areas, indicating that changing the negative perception of individuals over time can drive the successful implementation of interventions (Bennett, 2016). Therefore, it could be argued that understanding staff perceptions towards patient safety culture implementation will help reveal important details that can lead to more appropriate management input and action that align with individuals' needs.

10.3.4.1.2 Complexity

The complexity of the implementation process was perceived as being a challenge in the current study, which should be taken into consideration in relation to enhancing the implementation of a safety culture. It is clear that conditions including lack of confidentiality, privacy, interruptions, noise, overcrowding, and hospital security all play a part in hindering the process, and restructuring of the healthcare delivery team is required. Other factors identified by patients/family members that put patients at risk of harm such as falls were related to aspects such as leaving wet floors without appropriate cautionary signage, light problems in rooms, and activation of alarms. Acknowledging such complexity ultimately improves understanding of the important components of the barriers and facilitators of implementation.

10.3.4.2 Outer setting

This domain concerns the external context or environment that might influence implementation. In the current study with regards to the outer setting, barriers and facilitators to the implementation of a patient safety culture were identified concerning three constructs of the outer setting of the CFIR domain: patient needs and resources, cosmopolitanism, and external policy and incentives.

10.3.4.2.1 Patient needs and resources

The construct of patient needs and resources refers to how accurately an organisation knows and prioritises patient needs and the barriers and facilitators in meeting those needs. Lack of patient empowerment and centredness was identified as one of the main barriers to the implementation of positive patient safety culture, and concerns were raised about certain aspects that influence involvement and learning from different groups' experiences. The current study suggests that appropriate co-ordination between the provider and patient could help to facilitate implementation strategies that share responsibilities among staff and patients to ensure opportunities for engagement are not missed (Sutton et al., 2015).

10.3.4.2.2 Cosmopolitanism

The cosmopolitanism construct refers to the degree to which an organisation is networked with others. Healthcare professionals reported fewer connections to other organisations outside their own, limiting their ability to transfer patients safely between hospitals. Coordination and collaboration mechanisms and lack of collaborative teamwork were perceived as barriers to the implementation of a patient safety culture. These findings are in line with a literature review that reported that collaboration among multidisciplinary teams and hospitals is a challenge that requires motivation at various levels to provide optimal support and enhance team performance (Xiao et al., 2013).

10.3.4.2.3 External policy and incentives

The external policy and incentives construct concerns policy and regulation, external mandates, recommendations, and guidelines consisting of strategies for spreading interventions. Barriers identified concerns about policy and regulations in

practice highlighted gaps in adherence to policy and diversity of regulations among healthcare providers who do not have the expertise or resources to sustain a positive patient safety culture. This was also exacerbated by a deficit of implementation and dissemination of clinical guidelines in clinical practice to increase adherence and limited variations in practice. This finding reflects the need for counselling alongside proper dissemination of guidelines and policy to ensure effective implementation of patient safety strategies and adherence to policy (Fleming and Wentzell, 2008).

10.3.4.3 Inner setting

In relation to the Inner setting, factors identified are associated with CFIR construct, network and communications, culture, implementation climate and readiness of implementation. In the light of this, a number of issues emerged concerning failure of communication system, blame culture, leadership engagement and resources that facilitate implementation intervention.

10.3.4.3.1 Network and communications

Communication barriers were identified including interpersonal communication, documentation and reporting system. Both groups – patients and healthcare professionals – face difficulties and challenges in communication, which in turn leads to disturbances in the interaction and exchange of information with colleagues and patients.

Based on the findings from the current study, a national reporting system in Saudi Arabia could be established to facilitate reporting, anonymity, timely feedback, and action following incidents. Additionally, the establishment of a clear and effective reporting system may help to overcome lack of staff knowledge and awareness of reporting procedures, forms, and general information concerning the reporting system identified in the current study that may limit staff's willingness to participate effectively in reporting incidents in their areas (Lee et al., 2018).

10.3.4.3.2 Culture

Participants in both groups emphasised issues related to cultural and social factors, including blame culture, culture of negativity, cover-ups to avoid blame, and workforce and cultural diversity. Blame culture was regarded as a barrier that limited the implementation success in their organisations, which in turn stopped healthcare professionals from learning from their mistakes and led to failure of successful implementation of positive patient safety culture.

Therefore, organisational change is central to the inner setting by creating networks among healthcare professionals and patient to enhance trust in safety culture programmes and increase team members communications within healthcare system (Ballaro et al., 2020). However, the fundamental issue is the need for overcoming the blame culture by implementation of ' Just culture' that values the balance accountability between organisations system and individuals behaviours (Paradiso and Sweeney, 2019). Moreover, shifting from blame culture to just culture would be beneficial to the implementation process by creating a strong culture of safety where the staff are managed fairly when involved in medical errors (Edwards, 2018).

10.3.4.3.3 Implementation climate

This construct concerns the capacity for change, shared receptivity of those involved, and the level of support and expectation for those interventions within their organisation including learning climate. Several barriers were identified related to learning, including lack of focused training programmes for all levels of healthcare professionals in order to facilitate and improve knowledge, skills, and discussion of patient safety issues. Therefore, implementation climate should be considered by adopted strategies to help create clear organisational culture, having learning climate, engagement of key stakeholders and accountability of leadership (Farokhzadian et al., 2018).

10.3.4.3.4 Readiness of implementation

The readiness of implementation construct provides tangible and immediate indicators of an organisation's commitment to implementing an intervention, comprised of two sub-constructs: leadership engagement, and available resources.

Leadership engagement

Leadership and management were considered by both groups of participants to be crucial for supporting the implementation of a positive patient safety culture in healthcare organisations, and were found as barriers and facilitators. The participants reported barriers and a reduction in the effectiveness of leadership, mainly due to poor leadership style, lack of supervision and monitoring of staff, absence of feedback following incidence reporting, lack of accountability/responsibility, and lack of staff value/encouragement. Staff criticised the leaders in their areas for not adequately assisting them to resolve patient safety issues and being reluctant to increase staff motivation to address safety issues. Therefore, it could be argued that successful implementation of patient safety culture facilitated by role of leadership, policy establishment and shred understanding of the benefits from the implementation.

Available resources

A wide variety of barriers to the development of a positive patient safety culture were identified, with both groups linking these to hospitals facilities and resources/equipment. These issues were related to shortages of medical supplies, human resources, devices, equipment, medications, and technology. These challenges of inadequate facilities and equipment were believed to create a stressful working environment, as the ability of staff to provide appropriate medical care was limited and patients were put at risk. Therefore, the findings from the current study suggest that hospital managers should pay attention to allocating the necessary resources to overcome challenges that threaten implementation of a positive patient safety culture.

10.3.4.4 Individuals' characteristics

The individual characteristics domain refers to individuals' attitudes toward the value of interventions, as well as their familiarity with facts, truths, and principles related to interventions. So, with regards to individuals' characteristics, factors identified were related to two constructs: knowledge and beliefs of the implementation, and personal attributes.

10.3.4.4.1 Knowledge & beliefs of the implementation

Insufficient knowledge, staff competencies and skills regarding patient safety issues were the factors identified most commonly as barriers to the implementation process. The evidence drawn from the current study suggests that training and education programmes may be required to improve implementation by improving stakeholders' knowledge and awareness of implementation strategies. Moreover, effective implementation of patient safety culture should consider educational interventions that promote behaviours change of healthcare professionals and patient to address underlying resistance of implementations (Wilson et al., 2011).

10.3.4.4.2 Personal attributes

Personal attributes barriers identified were related to the professionalism of healthcare professionals. It is believed to be a foundation on which to address unprofessional behaviours that limit safe practice (DuPree et al., 2011). Patients/family members who participated in the current study reported a variety of professionalism issues related to staff behaviour, lack of respect/dignity, carelessness, lack of response, and lack of attention. Therefore, it is found that the unprofessional behaviour of healthcare professionals affects patient health and wellbeing; thus, the importance of including professionalism as a component of medical education is emphasised (Nagler et al., 2014).

10.3.4.5 Process

The process domain concerns implementation strategies including planning, engaging appropriate individuals, reflecting, and evaluating. In relation to this

domain, aspects identified related to the CFIR constructs were planning and engaging.

10.3.4.5.1 Planning

Planning refers to the degree to which an intervention strategy or method is planned in advance and the quality of those strategies or methods. Planning was viewed as crucial by participating healthcare professionals, especially those working at higher levels in the healthcare system. Planning activities for patient safety were seen by healthcare participants as facilitators and highlighted their healthcare organisation's commitment to improving implementation strategies through patient safety planning. Thus, the participants in the current study were aware of the importance and necessity of a patient safety culture to maintain safe and high quality healthcare delivery, drawing attention to the activities that can be engaged with to promote a safety culture in healthcare organisations.

10.3.4.5.2 Engaging

The importance of engaging appropriate individuals to facilitate implementation was highly acknowledged by both groups of participants. However, there was a clear limit to individuals' engagement and shared responsibility in the implementation process, especially for patients and their families. Thereby, findings from the current study indicate that failure to engage staff in developing and implementing a new intervention may limit adaptability and accessibility of their implementation in practice.

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Appendices

Appendix 1: National essential safety requirements

HR.5	لدى المستشفى آلية مناسبة لاعتماد الممارسين الصحيين المؤهلين لتقديم الرعاية الصحية للمرضى. The hospital has a process for proper credentialing of staff members licensed to provide patient care.
MS.7	أعضاء الطاقم الطبي يمتلكون جميعاً امتيازات سريرية محددة وسارية. Medical staff members have current delineated clinical privileges.
PC.25	لدى المستشفى سياسات وإجراءات واضحة تحكم عملية استخدام وتداول وإعطاء الدم ومشتقاته. Policies and procedures guide the handling, use, and administration of blood and blood products.
PC.26	المرضى المعرضون لخطر الجلطات الوريدية يتم التعرف عليهم ومعالجتهم Patients at risk for developing venous thromboembolism are identified and managed.
QM.17	لدى المستشفى آلية مناسبة لضمان التعرف الصحيح على المرضى. The hospital has a process to ensure correct identification of patients.
QM.18	لدى المستشفى آلية مناسبة لاتقاء الخطأ في هوية المريض أو الخطأ في مكان أو نوع الإجراء العلاجي أو الجراحي. The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.
AN.2	أطباء وفنيو التخدير يمتلكون المؤهلات المناسبة لممارسة التخدير. Anesthesia staff members have the appropriate qualifications.
AN.15	التخدير المتوسط والعميق وتسكين الألم يقدم حصراً من قبل الممارسين الصحيين المؤهلين لذلك. Qualified staff perform moderate and deep sedation/analgesia.

المتطلبات الوطنية الأساسية لسلامة المرضى.

National Essential Safety Requirements

IPC.4 لدى المستشفى لجنة متعددة التخصصات معينة للاشراف على برنامج مراقبة و منع العدوى.
There is a designated multidisciplinary committee that provides oversight of the infection prevention and control program.

IPC.15 يدعم تصميم المنشأة وتوفر الإمدادات ممارسات عزل المرضى عند الحاجة.
Facility design and available supplies support isolation practices.

MM.5 لدى المستشفى نظام لسلامة الأدوية الخطره (High Alert Medications).
The hospital has a system for the safety of high-alert medications.

MM.6 لدى المستشفى نظام للسلامة من الأدوية التي تبدو متشابهة الشكل والاسم.
The hospital has a system for the safety of look-alike and sound-alike (LASA) medications.

MM.41 لدى المستشفى آلية مناسبة للرصد والتعرف على والتبليغ عن الأخطاء الطبية الجسيمة بما في ذلك الأخطاء القريبة الحدوث والحالات الخطرة والسلوك المعرّض للمخاطر التي يحتمل أن تضر المريض.
The hospital has a process for monitoring, identifying, and reporting Significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.

LB.51 لدى بنك الدم آلية مناسبة لتجنب انتقال الامراض عن طريق نقل الدم أو الصفائح.
The blood bank develops a process to prevent disease transmission by blood/ platelet transfusion.

FMS.9 تضمن المستشفى أن كل شاغليها آمنين من أخطار الاشعاعات.
The hospital ensures that all its occupants are safe from radiation hazards.

FMS.32 تضمن المستشفى الصيانة السليمة لنظام الغازات الطبية .
The hospital ensures proper maintenance of the medical gas system.

FMS.21 لدى المستشفى نظام فعال للإنذار ضد الحريق.
The hospital has an effective fire alarm system.

FMS.22 لدى المستشفى نظام إخماد حريق فعال في المناطق المطلوبة.
The hospital has a fire suppression system available in the required area(s).

FMS.23 مخارج الطوارئ متوفرة وموزعة بشكل صحيح في أنحاء المستشفى.
There are fire exits that are properly located in the hospital.

FMS.24 مبنى المستشفى وشاغلوه في مأمن من الحريق والدخان.
The hospital and its occupants are safe from fire and smoke.

Appendix 2: Hospital Survey on Patient Safety Culture (HSOPSC)

Hospital Survey on Patient Safety

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank.

- *An **"event"** is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.*
- ***"Patient safety"** is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.*

SECTION A: Your Work Area/Unit

In this survey, think of your "unit" as the work area, department, or clinical area of the hospital where you spend *most* of your work time or provide *most* of your clinical services.

What is your primary work area or unit in this hospital? Select ONE answer.

a. Many different hospital units/No specific unit

b. Medicine (non-surgical)

c. Surgery

d. Obstetrics

e. Pediatrics

f. Emergency department

g. Intensive care unit (any type)

h. Psychiatry/mental health

i. Rehabilitation

j. Pharmacy

k. Laboratory

l. Radiology

m. Anesthesiology

n. Other, please specify:

Please indicate your agreement or disagreement with the following statements about your work area/unit.

Think about your hospital work area/unit…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Ag ▼
1. People support one another in this unit	☐1	☐2	☐3	☐
2. We have enough staff to handle the workload..........................	☐1	☐2	☐3	☐
3. When a lot of work needs to be done quickly, we work together as a team to get the work done	☐1	☐2	☐3	☐
4. In this unit, people treat each other with respect	☐1	☐2	☐3	☐
5. Staff in this unit work longer hours than is best for patient care	☐1	☐2	☐3	☐

SECTION A: Your Work Area/Unit (continued)

Think about your hospital work area/unit…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Ag ▼
6. We are actively doing things to improve patient safety	☐1	☐2	☐3	☐
7. We use more agency/temporary staff than is best for patient care	☐1	☐2	☐3	☐
8. Staff feel like their mistakes are held against them	☐1	☐2	☐3	☐
9. Mistakes have led to positive changes here	☐1	☐2	☐3	☐
10. It is just by chance that more serious mistakes don't happen around here	☐1	☐2	☐3	☐
11. When one area in this unit gets really busy, others help out	☐1	☐2	☐3	☐
12. When an event is reported, it feels like the person is being written up, not the problem	☐1	☐2	☐3	☐
13. After we make changes to improve patient safety, we evaluate their effectiveness	☐1	☐2	☐3	☐
14. We work in "crisis mode" trying to do too much, too quickly	☐1	☐2	☐3	☐
15. Patient safety is never sacrificed to get more work done	☐1	☐2	☐3	☐
16. Staff worry that mistakes they make are kept in their personnel file	☐1	☐2	☐3	☐
17. We have patient safety problems in this unit	☐1	☐2	☐3	☐
18. Our procedures and systems are good at preventing errors from happening	☐1	☐2	☐3	☐

SECTION B: Your Supervisor/Manager

Please indicate your agreement or disagreement with the following statements about your immediate

supervisor/manager or person to whom you directly report.

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Ag ▼
1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	□1	□2	□3	□
2. My supervisor/manager seriously considers staff suggestions for improving patient safety	□1	□2	□3	□
3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts..	□1	□2	□3	□
4. My supervisor/manager overlooks patient safety problems that happen over and over	□1	□2	□3	□

SECTION C: Communications

How often do the following things happen in your work area/unit?

Think about your hospital work area/unit…	Never ▼	Rarely ▼	Some-times ▼	Mo the ▼
1. We are given feedback about changes put into place based on event reports	□1	□2	□3	□
2. Staff will freely speak up if they see something that may negatively affect patient care	□1	□2	□3	□
3. We are informed about errors that happen in this unit	□1	□2	□3	□
4. Staff feel free to question the decisions or actions of those with more authority	□1	□2	□3	□
5. In this unit, we discuss ways to prevent errors from happening again ...	□1	□2	□3	□
6. Staff are afraid to ask questions when something does not seem right .	□1	□2	□3	□

SECTION D: Frequency of Events Reported

In your hospital work area/unit, when the following mistakes happen, *how often are they reported?*

	Never ▼	Rarely ▼	Some-times ▼	Mo the ▼
1. When a mistake is made, but is *caught and corrected before affecting the patient*, how often is this reported?..	□1	□2	□3	□
2. When a mistake is made, but has *no potential to harm the patient*, how often is this reported?	□1	□2	□3	□
3. When a mistake is made that *could harm the patient*, but does not, how often is this reported?..	□1	□2	□3	□

SECTION E: Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety.

□	□	□	□	□
A	**B**	**C**	**D**	**E**
Excellent	Very Good	Acceptable	Poor	Failing

SECTION F: Your Hospital

Please indicate your agreement or disagreement with the following statements about your hospital.

Think about your hospital…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
1. Hospital management provides a work climate that promotes patient safety	□1	□2	□3	□4	□5
2. Hospital units do not coordinate well with each other	□1	□2	□3	□4	□5
3. Things "fall between the cracks" when transferring patients from one unit to another .	□1	□2	□3	□4	□5
4. There is good cooperation among hospital units that need to work together	□1	□2	□3	□4	□5

SECTION F: Your Hospital (continued)

Think about your hospital…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
5. Important patient care information is often lost during shift changes	□1	□2	□3	□4	□5
6. It is often unpleasant to work with staff from other hospital units..	□1	□2	□3	□4	□5
7. Problems often occur in the exchange of information across hospital units....................	□1	□2	□3	□4	□5
8. The actions of hospital management show that patient safety is a top priority	□1	□2	□3	□4	□5
9. Hospital management seems interested in patient safety only after an adverse event happens	□1	□2	□3	□4	□5
10. Hospital units work well together to provide the best care for patients	□1	□2	□3	□4	□5
11. Shift changes are problematic for patients in this hospital	□1	□2	□3	□4	□5

SECTION G: Number of Events Reported

In the past 12 months, how many event reports have you filled out and submitted?

□ a. No event reports   □ d. 6 to 10 event reports

□ b. 1 to 2 event reports   □ e. 11 to 20 event reports

□ c. 3 to 5 event reports   □ f. 21 event reports or more

SECTION H: Background Information

This information will help in the analysis of the survey results.

1. How long have you worked in this hospital?

□ a. Less than 1 year   □ d. 11 to 15 years

☐ b. 1 to 5 years   ☐ e. 16 to 20 years

☐ c. 6 to 10 years   ☐ f. 21 years or more

2. How long have you worked in your current hospital <u>work area/unit</u>?

☐ a. Less than 1 year   ☐ d. 11 to 15 years

☐ b. 1 to 5 years   ☐ e. 16 to 20 years

☐ c. 6 to 10 years   ☐ f. 21 years or more

3. Typically, how many <u>hours per week</u> do you work in this hospital?

☐ a. Less than 20 hours per week   ☐ d. 60 to 79 hours per week

☐ b. 20 to 39 hours per week   ☐ e. 80 to 99 hours per week

☐ c. 40 to 59 hours per week   ☐ f. 100 hours per week or more

SECTION H: Background Information (continued)

4. What is your staff position in this hospital? Select ONE answer that best describes your staff position.

☐ a. Registered Nurse   ☐ j. Respiratory Therapist

☐ b. Physician Assistant/Nurse Practitioner   ☐ k. Physical, Occupational, or Speech Therapist

☐ c. LVN/LPN   ☐ l. Technician (e.g., EKG, Lab, Radiology)

☐ d. Patient Care Asst/Hospital Aide/Care Partner   ☐ m. Administration/Management

☐ e. Attending/Staff Physician   ☐ n. Other, please specify:

☐ f. Resident Physician/Physician in Training

☐ g. Pharmacist

☐ h. Dietician

☐ i. Unit Assistant/Clerk/Secretary

5. In your staff position, do you typically have direct interaction or contact with patients?

☐ a. YES, I typically have direct interaction or contact with patients.

☐ b. NO, I typically do NOT have direct interaction or contact with patients.

6. How long have you worked in your current specialty or profession?

☐ a. Less than 1 year   ☐ d. 11 to 15 years

☐ b. 1 to 5 years   ☐ e. 16 to 20 years

☐ c. 6 to 10 years   ☐ f. 21 years or more

SECTION I: Your Comments

Please feel free to write any comments about patient safety, error, or event reporting in your hospital.

<div style="border:1px solid black; height:480px;"></div>

THANK YOU FOR COMPLETING THIS SURVEY.

Appendix 3: Permission to use the HSOPSC for the current study

Dear Abdulmajeed Al Balawi,

Thank you for the information about your use of the Surveys on Patient Safety Culture™ (SOPS™). We in the Patient Safety Culture Surveys Support Group at Westat (SafetyCultureSurveys@westat.com) have been authorized to respond on behalf of the Agency for Healthcare Research and Quality (AHRQ) by Ms. Randie Siegel, Associate Director, Office of Communications and Knowledge Transfer, Publishing and Electronic Dissemination. Our group, as the Safety Culture Surveys support contractor, handles the majority of permissions for these tools and their related documents in English, notifies AHRQ of requests for permission to translate these documents, and maintains an electronic community for International users.

Based on the description you provided of your project, AHRQ grants you permission to use the Hospital Survey in English, for your research at the University of Glasgow in the United Kingdom. We understand that this research will be carried out at three hospitals in the Madinah region of Saudi Arabia. AHRQ requests that you note on the survey forms that the form is "reprinted/translated with permission from the Agency for Healthcare Research and Quality (an Agency of the United States Department of Health and Human Services); Rockville, Maryland USA." Additionally, all reports, professional publications, graduate theses, or Web site postings should properly credit AHRQ using the following citation:

Surveys on Patient Safety Culture™. Agency for Healthcare Research and Quality, Rockville, MD USA. https://www.ahrq.gov/sops/index.html

The AHRQ SOPS survey and related materials may be found on the AHRQ website at: https://www.ahrq.gov/sops/index.html. For technical questions, please contact us. We can also put you in touch with other non-U.S. users of the survey (go to https://www.ahrq.gov/sops/international/index.html for more

information).

If you have questions about permissions issues, please feel free to contact Ms. Siegel, Manager of Copyrights & Permissions, Office of Communications and Knowledge Transfer.

Sincerely,
Darby

****

AHRQ Surveys on Patient Safety Culture™ Technical Assistance Westat | 1700 Research Blvd | Rockville, MD 20850 phone: 1-888-324-9749 | fax: 1-888-852-8277 | email: SafetyCultureSurveys@westat.com

Appendix 4: Invitation letter (Phase II) Web-based survey

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of Project: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Name of Researcher(s): Abdulmajeed Albalawi

Dear colleagues,

I am Abdulmajeed Albalawi, a PhD candidate from Nursing & Healthcare school at University of Glasgow. I would like to invite you to participate in a study that I am conducting as a part of my doctoral project entitled, *Barriers and facilitators of patient safety culture in Saudi Arabia.* The purpose of the study is to explore the perceptions of patient safety culture and barriers and facilitators to the promotion of a positive patient safety culture in Saudi Arabia, from multiple perspectives (healthcare professionals and patients/families).

You will be provided with a participant information sheet explaining the study including information on confidentiality, anonymity and data protection process. Your participation in this research study is strictly voluntary. You have the right to say no or if you decide that you wish to take part, you can later withdraw from the study without giving a reason.

By agreeing to participate in the study, you will be asked to complete a web-based survey which will take around 10-15 minutes to complete. On the first page of the survey you will be asked to tick a box to indicate that you agree to consent to participate in the survey which will confirm agreement of your voluntary participation. Your views, opinions and responses to this survey are highly valuable and may help to contribute to the promotion of a positive patient safety culture in practice.

This study has been reviewed and gained ethical approval from both the University of Glasgow research ethics committee and Madinah health affairs ethics committee. If you have any questions regarding your participation please contact me:

Email: Phone:

Kind regards

Abdulmajeed Albalawi

PhD candidate at University of Glasgow

Appendix 5: Participant information sheet (Phase II): Web-based survey

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

1. **Study title.**

Barriers to and facilitators of patient safety culture in Saudi Arabia.

2. **Invitation**

You are being invited to take part in a research study that will be conducted by Abdulmajeed Albalawi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and the signed consent form to keep.

3. **What is the purpose of the study?**

Patient safety culture has become a crucial element within healthcare organisations in order to prevent patient harm and maintain safe, high-quality healthcare. Positive and strong patient safety culture have also been found to significantly reduce the number of adverse events in a healthcare organisation. Therefore, patient safety culture assessment is considered a valuable tool for evaluating healthcare organisation environments to which are vulnerable to adverse events. The aim of this study is to explore the perception of patient safety culture from multiple perspectives, including healthcare professionals and patients and their families.

4. **Why have I been invited to participate?**

You have been invited because you are a healthcare professional working at one of the selected hospitals namely (King Fahad Hospital, Maternity and Children's Hospital, and Ohud Hospital) during this study period.

5. **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form

before completing the self-administered questionnaire. You are free to say no and withdraw from the study at any time without any obligation or giving reasons.

6. What will happen to me if I take part?

If you decide to take part in the study, you will be asked to sign a consent form (by ticking a box) and complete an online questionnaire about your thoughts and experiences relating to patient safety culture. The questionnaire will take around 10-15 minutes to complete.

7. What do I have to do?

Please take time to decide if you wish to take part. If you do wish to take part, you will be asked to tick a box which will appear on the first page of the questionnaire to indicate that you agree to consent to participate in the survey. Then, you can complete the questionnaire which contains 12 questions/statements about patient safety culture. You will be asked to rate how much you agree or disagree with these questions/statements (1 = Strongly Disagree to 5 = Strongly Agree).

8. What are the possible disadvantages and risks of taking part?

There are no potential disadvantages or risks involved of taking part in this study. It will not be possible to identify anyone from the responses to the questionnaire so everything that you say will be kept anonymous and confidential.

9. What are the possible benefits of taking part?

Some people may derive no personal benefits from taking part. However, some participants may feel that in completing the questionnaire, their knowledge of patient safety culture and implementing this in their area has improved. The findings may benefit participants' healthcare organisations and accreditation authorities to build and sustain initiatives for promoting a positive patient safety culture.

10. Will my taking part in this study be kept confidential?

All data that we collect from you will be anonymous and confidential, no identifiable information is required as part of this study. No names of individuals or organisations participating in this study will be used; these will be replaced by ID codes known only by the researcher. All data in the questionnaire will be anonymous and will be stored on a password-protected computer at the University of Glasgow with access only by the researcher and his supervisors at the University of Glasgow. Finally,

upon completion of the study, the anonymous data in paper form will be saved on a storage device and stored in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years as University of Glasgow policy.

11. What will happen to my data?

All study data will be held in accordance with The General Data Protection Regulation (2018). The raw data will be stored in in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed, or your data will be securely destroyed in accordance with the relevant standard procedures. Names of organisation participated will be replaced by ID codes known only by the researcher which will be store separately from the raw data to protect anonymity of any organisations/participants participated in the study in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years per University of Glasgow policy. Your data will form part of the study results that will be published in expert journals, presentations, student dissertations/theses (if applicable) and on the internet for other researchers to use. No identifiable information will appear in any publications.

12. What will happen to the results of the research study?

The findings of this study will be published in scientific journals and appropriate conferences. A copy of the published findings will be available to you should you wish to receive this.

13. Who is organising and funding the research?

The research organised by Abdulmajeed Albalawi, PhD student at University of Glasgow. The funding of this project is based on the researcher's scholarship from the Royal Embassy of Saudi Arabia's Cultural Bureau in London.

14. Who has reviewed the study?

The research has been reviewed by Madinah Health Affairs Ethics Committee and the University of Glasgow, College of Medical & Veterinary and Life Sciences Ethics Committee for non-clinical research.

15. Contact for Further Information

For further information please contact: Abdulmajeed Albalawi

Email: Phone:

Appendix 6: Privacy notice

University | College of Medical,
of Glasgow | Veterinary & Life Sciences

Nursing & Health care School

Privacy Notice for project title: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Your Personal Data

The University of Glasgow will be what is known as the 'Data Controller' of your personal data processed in relation to the research project purposes: in-depth exploration of patient safety culture from different stakeholder perspectives, and identifying barriers to and facilitators of the implementation of positive patient safety culture, providing a framework for informing the future implementation of patient safety initiatives in Saudi Arabia. This privacy notice will explain how The University of Glasgow will process your personal data.

Why we need it

We are collecting your basic personal data such as name, contact details, address, your hospital name, and your professional background; if you are a doctor, nurse, allied healthcare, manager, patient, family member where relevant. We are collecting this information if you have already agreed to take part in this study, in order to arrange with you a place, time and date for the focus group discussion/interview. We will only collect data that we need in order to provide and oversee this service to you.

Legal basis for processing your data

- We must have a legal basis for processing all personal data. In this instance, the legal basis is: Public task/Official authority – as these data form part of the research project.

What we do with it and who we share it with

- All the personal data we obtain from you will be processed by staff at the University of Glasgow in the United Kingdom.

How long we keep it for

Your data will be retained by the university until data collection is completed and no further focus groups/interviews are required. After this time, your data will be securely deleted after two months from the study completion date (December 2020).

What are your rights?*

You can request access to the information we process about you at any time. If at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected or erased. You may also have the right to object to the processing of data and the right to data portability.
If you wish to exercise any of these rights, please contact dp@gla.ac.uk.
Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the University Data Protection Officer who will investigate the matter.

Our Data Protection Officer can be contacted at dataprotectionofficer@glasgow.ac.uk

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/

Appendix 7: Consent form (Phase II): Web-based survey

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of project: Barriers and facilitators of patient safety culture in Saudi Arabia.

Name of researcher(s): Abdulmajeed Albalawi

CONSENT FORM

Please initial box

I confirm that I have read and understood the Participant Information Sheet version 1 dated 05/05/2019.

I confirm that I have read and understood the Privacy Notice version 1 dated 05/05/2019.

I have had the opportunity to think about the information and ask questions, and understand the answers I have been given.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University archiving facilities in accordance with relevant Data Protection policies and regulations. Personal data will be destroyed two months after the study is completed.

I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers.

I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project.

I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study.

I agree to take part in the study.

Name of participant: Date: Signature:

Name of researcher: Date: Signature:

Appendix 8: Invitation letter (Phase III): Focus groups

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of Project: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Name of Researcher(s): Abdulmajeed Albalawi

Dear colleagues,

I am Abdulmajeed Albalawi, a PhD candidate from Nursing & healthcare school at University of Glasgow. I would like to invite you to participate in a focus group discussion (small group discussion) that I am conducting as a part of my doctoral project with entitled, *Barriers and facilitators of patient safety culture in Saudi Arabia.* The focus group discussion should last no longer than one hour, and each focus group will be 6-10 healthcare professionals (i.e., physicians, nurses, pharmacists and technicians).

The purpose of the study is to explore the perceptions of patient safety culture and barriers and facilitators to the promotion of a positive patient safety culture in Saudi Arabia, from multiple perspectives (healthcare professionals and patients/families). During this focus group discussion, you will have the opportunity to share your opinions, experiences and thoughts about patient safety culture with colleagues in a similar position or grade to you.

You will be provided with participants information sheet explained study details and researcher contact details to responded to if you wish to take part. Your participation in this research study is strictly voluntary and you have the right to withdrawal from study at any time without given reason. By agreeing to participate in the study, you will be asked to sign an informed consent. After the confirmation of your participation you will provided with a date, time and place of conducting focus group discussion. Your views, opinions and responses to this study are highly valuable and may help to contribute to the promotion of a positive patient safety culture in practice.

This study has been reviewed and gained ethical approval from both the University of Glasgow research ethics committee and Madinah health affairs ethics committee. If you have any questions regarding your participation, please contact me:

Email: Phone:

Kind regards

Abdulmajeed Albalawi PhD candidate at University of Glasgow

Appendix 9: Participant information sheet (Phase III): Focus groups

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

1. Study title

Barriers to and facilitators of patient safety culture in Saudi Arabia.

2. Invitation

You are being invited to take part in a research study that will be conducted by Abdulmajeed Albalawi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and the signed consent form to keep.

3. What is the purpose of the study?

Patient safety culture has become a crucial element within healthcare organisations in order to prevent patient harm and maintain safe, high-quality healthcare. Positive and strong patient safety culture have also been found to significantly reduce the number of adverse events in a healthcare organisation. Therefore, patient safety culture assessment is considered a valuable tool for evaluating healthcare organisation environments to which are vulnerable to adverse events. The aim of this study is to explore the perception of patient safety culture from multiple perspectives, including healthcare professionals and patients and their families.

4. Why have I been invited to participate?

You have been invited because you are a healthcare professional working at one of the selected hospitals namely (King Fahad Hospital, Maternity and Children's Hospital, and Ohud Hospital) during this study period.

5. Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent

form before commencing focus groups discussion. You are free to say no and withdraw from the study at any time without any obligation or giving reasons.

6. What will happen to me if I take part?

If you decide to take part in the study by respond to this information sheet the researcher will contact you to discuss the information on this sheet, answer any questions that may you have and you will be asked to sign a consent form. The consent form confirms that you have read and understood this information sheet and agreed to take part, a copy of information sheet and signed consent will provide to keep with you. Then, you will be provided with a convenient date/ time and place of focus groups discussion. You will be participating once in a focus groups discussion which last no longer than one hour, and each focus group will be 6-10 healthcare professionals (i.e., physicians, nurses, pharmacists and technicians). You will be placed in a group whose post is similar to your position/grade so, you can speak freely about your opinion. During discussion the group will be asked about their perception and experiences of patient safety culture. There are no correct or wrong answers, you have flexibility to talk about any parts you found useful. The interview will be audio recorded which help us to type up what you have said to allow the researcher to accurately capture your views. It will be done without identifying you, and if we use any quotes in publications, this will be done also without identifying you. Once the audio recording has been typed up and checked to make sure it is accurate, it will be destroyed.

7. What do I have to do?

You should take enough time before deciding to take part. If you do wish to take part, contact the researcher via the email/number below. The researcher will then respond to you to discuss this information sheet, answer any questions you have and supply a consent form for you to sign. Then, you will be provided with the details of when and where it is suggested the focus group will take place. If you do not wish to take part then you are not required to do anything and we will not contact you again.

8. What are the possible disadvantages and risks of taking part?

There are no potential disadvantages or risks involved of taking part of this study. However, we understand that the importance of your time and some conflicts with your timetable might happened due to taking part in the focus group. So, we try to

organise a time convenient to you and is likely to take place during day time between 9am – 4pm.

9. What are the possible benefits of taking part?

It is expected that there will be no direct benefits for the participants of taking part in this study. We hope you will find the experience of taking part in the focus group interesting and useful. However, some participants may feel that it is improving their knowledge of patient safety culture.

Also, the findings may benefit your healthcare organisations and accreditation authorities to build improved initiatives for patient safety culture.

10. Will my taking part in this study be kept confidential?

All information about your participation in this study will be kept confidential in accordance with the General Data Protection Regulation (2018). You will be given a unique ID codes known only by the researcher to be used in study documentation to protect you to be identifiable. No names of individuals or organisations participating in this study will be used; these will be replaced by ID codes known only by the researcher in the study documentations. Your focus groups discussion will be audio-recorded and transcribed verbatim, any identifiable information (names) will be replaced by ID codes in the transcripts. Transcripts (typed copies of your interview) will be kept electronically on a password protected computer at the University of Glasgow. No individual will be identifiable at any stage in the study, publication or presentation of the findings. Prior to the focus group starting and at the end of the focus group, participants will be reminded of the importance of maintaining confidentiality of the discussions and encouraged not to discuss these with others outside of the focus group. Your personal details will be stored in a separate locked cabinet from all the information we collect and will be securely destroyed two months following completion of the study in accordance with University of Glasgow policy.

11. What will happen to my data?
Data can only be accessed by the researcher and supervisors.

The Data Protection Act 2018 will be followed throughout. All personal data obtained during the study will be securely stored and processed in accordance with the General Data Protection Regulations (GDPR) (2018). No names of individuals or organisations participating in this study will be used; these will be replaced by ID codes known only by the researcher which will be used in study documentation. To

protect anonymity of participants personal data will be stored separately from raw data. Personal data will be retained until data collection completed and no further focus groups/ interviews required and then will be destroyed accordance with University of Glasgow regulations after two months from study completion date December (2020). Consent forms will be stored in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years per University of Glasgow policy.

All focus groups discussion will be audio-recorded and transcribed verbatim for analysis. The audio-recordings will be destroyed as soon as they are transcribed, and then transcriptions will be stored on a password-protected computer with access only by the researcher. Audio-files and transcriptions will not be transferred via email or a memory stick. Transcripts and paper copies of study information will be retained in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years as per University of Glasgow policy.

12. What will happen to the results of the research study?
The findings of this study will be form part of the study result that will be published in expert journals, presentations, student dissertations/theses and on the internet for other researchers to use (if applicable). Your name will not appear in any publication.

13. Who is organising and funding the research?
The research organised by Abdulmajeed Albalawi, PhD student at University of Glasgow. The funding of this project is based on the researcher's scholarship from the Royal Embassy of Saudi Arabia's Cultural Bureau in London.

14. Who has reviewed the study?
The research has been reviewed by Madinah health affairs ethics committee and the University of Glasgow, college of medical& veterinary and life science ethics committee for none clinal research.

15. Contact for Further Information

For further information please contact: Abdulmajeed Albalawi

Email: Phone:

"Thank you for reading this information sheet"

Appendix 10: Consent form (Phase III): Focus groups

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of project: Barriers and facilitators of patient safety culture in Saudi Arabia.

Name of researcher(s): Abdulmajeed Albalawi

CONSENT FORM

	Please initial box
I confirm that I have read and understood the Participant Information Sheet version 1 dated 05/05/2019.	☐
I confirm that I have read and understood the Privacy Notice version 1 dated 05/05/2019.	☐
I have had the opportunity to think about the information and ask questions, and understand the answers I have been given.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University archiving facilities in accordance with relevant Data Protection policies and regulations. Personal data will be destroyed two months after the study is completed.	☐
I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers.	☐
I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project.	☐
I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study.	☐
I agree to take part in the study.	☐

Name of participant: Date: Signature:

Name of researcher: Date: Signature:

Appendix 11: Topic guide (Phase III): Focus groups

![University of Glasgow logo | College of Medical, Veterinary & Life Sciences]

Nursing & Health care School

Title of project: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Name of researcher(s): Abdulmajeed Albalawi

❖ **Introduction 5- 10 minutes**

Welcome participants/ introduce myself and notetaker:

Good mooring/ afternoon. My name is………… and this is my colleague………………...

Thank you for coming today to participate int this focus group discussion.

The purpose of the focus group discussion

We are here today to talk about your perceptions, opinions and experiences of patient safety culture in your healthcare organisation. The purpose is to get your perceptions of patient safety culture, in order to explore the barriers to and facilitators of the promotion of a positive patient safety culture in your organisation. Your opinion of the patient safety culture in your organisation is valuable to us as it will help us to identify the things that can help to support a good patient safety culture and the things or challenges that might make this difficult or stop it happening. There are no right or wrong answers, you have the right to say what you really think and how you really feel.

Instructions regarding the focus group/ procedure

Some rules of the focus group will be explained to the participants, including:

1- *Respect each other's opinion/ no wrong or correct answers*

2- *One person speaking at a time/ give colleagues time to speak*

3- *Keep discussion in this room confidential /do not take it outside this room*

Explain the procedure:

My role is to lead this focus group discussion by discussing some issues related to patient safety culture and I will organise the conversation between the members involved. My colleague …… will be taking notes during the discussion to make sure we don't miss anything you have said. The discussion will be audio recorded so if you feel you want to stop the recording, just let me know.

- ❖ **Focus group discussion will cover the following topics/areas: Initial questions.**
- Perception/understanding of patient safety culture in the workplace (e.g., what do you think about patient safety in your unit/hospital? How important is patient safety in your unit/hospital/day to day work?)
- Perception of areas of weakness/strengths regarding patient safety culture in the workplace (e.g., what helps create a good safety culture? What stops this or hinders this?).
- Leadership (e.g., what kind of leadership do you have, what happens when something goes wrong?)
- Work environment/ teamwork/staffing issues/workload (e.g., How well would you say that teams work together to address patient safety issues? what helps with this or stops this from happening?)
- Communications verbal/written (e.g., how well do professionals/teams communicate with each other about patient safety issues/concerns? What helps support good communication or stops this?)
- Reporting systems/feedback of errors (e.g., how easy is it to report any concerns or errors? Do you have any personal concerns about reporting errors in your hospital?)
- Status of patient involvement in patient safety initiatives (e.g., what kind/level of involvement do patients and their families have in patient safety issues? Is this largely reporting anything? What happens after they report something? How is this followed up? Are they encouraged to speak up about things that are concerning them?

- ❖ **Closure 2 minutes**

Thank you very much for coming today and sharing with us your opinions and experiences. Your time is very much appreciated, and your comments have been very helpful.

Appendix 12: Invitation letter (Phase III): Semi-structured interview

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of Project: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Name of Researcher(s): Abdulmajeed Albalawi

Dear participants,

I am Abdulmajeed Albalawi, a PhD candidate from Nursing & Healthcare School at University of Glasgow. I would like to invite you to participate in an interview that I am conducting as a part of my doctoral project with entitled, Barriers and facilitators of patient safety culture in Saudi Arabia. The Interview should last around one hour, and each interview will be at convenient place suitable to you (home or hospital avenue).

The purpose of this study is to explore what patients/ family and hospital staff think about the safety of health care in hospitals. Also, to find out what health safety issues/ problems people might notice to making sure that people are safe when they are in hospitals. During this interview, you will have the opportunity to share your opinions, experiences and thoughts about patient safety during your stay in hospital. You will be provided with participants information sheet explained study details and researcher contact details to responded to if you wish to take part. Your participation in this research study is strictly voluntary and you have the right to withdrawal from study at any time without given reason. By agreeing to participate in the study, you will be asked to sign an informed consent. After the confirmation of your participation you will provided with a date, time and place of conducting an interview where suitable to you after one week from hospital discharge.

Your views, opinions and experiences can help to tell us about what's working well and what's not working well and help to identify where we need to make improvements in patient safety.

This study has been reviewed and gained ethical approval from both the University of Glasgow research ethics committee and Madinah health affairs ethics committee.

If you have any questions regarding your participation please contact me:

Email: Phone:

Kind regards

Abdulmajeed Albalawi

PhD candidate at University of Glasgow

Appendix 13: Participant information sheet (Phase III): Semi-structured interview

Nursing & Health care School

1. **Study title.**

Barriers to and facilitators of patient safety culture in Saudi Arabia.

2. **Invitation**

You are being invited to take part in a research study that will be conducted by Abdulmajeed Albalawi, PhD candidate at the college of Medicine, Dentistry and Nursing at the University of Glasgow. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you decide to take part in this study, you will be given a copy of this participant information Sheet and the signed consent form to keep.

3. **What is the purpose of the study?**

Making sure that people are safe when they are in hospital is a really important issue for countries across the World. It is important that we find out about what people working in hospitals and people, like yourselves, who are in/have been in hospital, think about patient safety so that we can make sure that we have measures in place to maintain safety.

4. **Why have I been invited to participate?**

You have been invited because we would like to speak to people who have recently been in hospital or had a family member in hospital to tell us about their experiences and thoughts on patient safety in hospitals. Your views can help to tell us about what's working well and what's not working well and help to identify where we need to make improvements in patient safety.

5. **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form before commencing interviews. If you decide to take part, you are still free to withdraw from the study at any time and without giving a reason.

6. What will happen to me if I take part?

If you decide to take part in the study, you will be invited to take part in an interview with the researcher. The interview will be arranged for a suitable time and date of your choosing. The interview can take place either at your home or in a room in the hospital. The interview will focus on your recent experiences of being in hospital but ask you to think mainly about any safety issues that you noticed. You will also be asked to sign a consent form indicating that you are willing to take part and we will ask for some information regarding your contact details and demographic variables (age, gender, patient/ family members/ carer). This information will only be used to describe the group of people who take part in the study. It will not be possible to identify you.

7. What do I have to do?

You should take enough time before deciding to take part. If you do wish to take part, there is a contact email/number for the researcher to reply to below. The researcher will then be responded to you to discuss this information sheet, answer any questions you have and seeks a consent form for you to sign. Then, if you do decide to take part, the researcher will ask you to sign a consent form (which you will be given a copy of to keep too). We will then arrange a convenient time, date and place to meet with you to hold the interview. You will be participating once in an interview which last no longer than one hour, and each interview will be one-to-one, participant and researcher. However, if you wish for a family member to stay with you during the interview, you will be informed that anything said by the third party will not be included in the data and will appear as "(disruption)" in the transcript. During the interview you will be asked about your perception and experiences of patient safety. There are no right or wrong answers. The interview will be audio recorded which help us to transcribe (type up what you have said to allow the researcher to accurately capture your perception and experiences. Once the audio recording has been typed up and checked to make sure it is accurate, it will be destroyed. It will not be possible to identify you.

8. What are the possible disadvantages and risks of taking part?

There are no anticipated disadvantages or risks involved of taking part in this study. it's not expected that you will be upset by the nature of the interviews but if at any

time you feel uncomfortable or wish not to discuss anything, then you can let us know and we can discuss whether you wish to stop the interview or keep going.

9. What are the possible benefits of taking part?

although there may be no direct benefits for you in this study, we hope that the views and thoughts that you tell us can help to ensure that patient safety is maintained in hospitals in the future.

10. Will my taking part in this study be kept confidential?

All information about your participation in this study will be kept confidential in accordance with the General Data Protection Regulation (2018). You will be given a unique ID codes known only by the researcher to be used in study documentation to protect you to be identifiable. No names of individuals or organisations participating in this study will be used; these will be replaced by ID codes known only by the researcher in the study documentations. Your interview will be audio-recorded and transcribed verbatim, any identifiable information (names) will be replaced by ID codes in the transcripts. Transcripts (typed copies of your interview) will be kept electronically on a password protected computer at the University of Glasgow. No individual participant will be identifiable at any stage in the study, publication or presentation of the findings. Your personal details are stored in a separate locked cabinet from all the information we collect until two months after the study ends, and then will be destroyed securely in accordance with University of Glasgow policy.

11. What will happen to my data?

Data can only be accessed by the researcher and supervisors.
The Data Protection Act 2018 will be followed throughout. All personal data obtained during the study will be securely stored and processed in accordance with the General Data Protection Regulations (GDPR) (2018). No names of individuals or organisations participating in this study will be used; these will be replaced by ID codes known only by the researcher which will be used in study documentation. To protect anonymity of participants personal data will be stored separately from raw data. Personal data will be retained until data collection completed and no further focus groups/ interviews required and then will be destroyed accordance with University of Glasgow regulations after two months from study completion date

December (2020). Consent forms will be stored in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years per University of Glasgow policy.

All interviews will be audio-recorded and transcribed verbatim for analysis. The audio-recordings will be destroyed as soon as they are transcribed, and then transcriptions will be stored on a password-protected computer with access only by the researcher. Audio-files and transcriptions will not be transferred via email or a memory stick. Transcripts and paper copies of study information will be retained in a locked cabinet in a locked room in the Nursing & Health Care School at the University of Glasgow for ten years as per University of Glasgow policy.

12. What will happen to the results of the research study?

The findings of this study will form part of the study result that will be published in expert journals, presentations, student dissertations/theses and on the internet for other researchers to use (if applicable). Your name will not appear in any publication.

13. Who is organising and funding the research?

The research organised by Abdulmajeed Albalawi, PhD student at University of Glasgow. The funding of this project is based on the researcher's scholarship from the Royal Embassy of Saudi Arabia's Cultural Bureau in London.

14. Who has reviewed the study?

The research has been reviewed by Madinah health affairs ethics committee and the University of Glasgow, college of medical& veterinary and life science ethics committee for none clinal research.

15. Contact for Further Information

For further information please contact: Abdulmajeed Albalawi

Email: Phone:

"Thank you for reading this information sheet"

Appendix 14: Consent form (Phase III): Semi-structured interview

University of Glasgow | College of Medical, Veterinary & Life Sciences
Nursing & Health care School

Title of project: Barriers and facilitators of patient safety culture in Saudi Arabia.

Name of researcher(s): Abdulmajeed Albalawi

CONSENT FORM

	Please initial box
I confirm that I have read and understood the Participant Information Sheet version 1 dated 05/05/2019.	☐
I confirm that I have read and understood the Privacy Notice version 1 dated 05/05/2019.	☐
I have had the opportunity to think about the information and ask questions, and understand the answers I have been given.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University archiving facilities in accordance with relevant Data Protection policies and regulations. Personal data will be destroyed two months after the study is completed.	☐
I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers.	☐
I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project.	☐
I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study.	☐
I agree to take part in the study.	☐

Name of participant: Date: Signature:

Name of researcher: Date: Signature:

Appendix 15: Interview guide (Phase III): Semi-structured interview

University of Glasgow | College of Medical, Veterinary & Life Sciences

Nursing & Health care School

Title of project: Barriers to and facilitators of patient safety culture in Saudi Arabia.

Name of researcher(s): Abdulmajeed Albalawi

❖ **Introduction 5 minutes**

Welcome participant/ introduce myself:

Good mooring/ afternoon. My name is…………

Thank you for coming today to participate in this interview.

The purpose of this interview

We are here today to talk about your perceptions, opinions and experiences of patient safety during your stay in hospital. The purpose of this study is to explore what patients/ family and hospital staff think about the safety of health care in hospitals. Also, to find out what health safety issues/ problems people might notice to making sure that people are safe when they are in hospitals. During this interview, you will have the opportunity to share your opinions, experiences and thoughts about patient safety during your stay in hospital. There are no right or wrong answers, you have the right to say what you really think and how you really feel.

❖ **Semi–structured interview will cover the following topics/areas:**

- Perception of patient safety in hospital (e.g., what does patient safety mean to you, what do you think about patient safety, can you think of any concerns or issues you noticed when you were in hospital?)

- Experience/opinion of the level of healthcare received (safe, harm and adverse events) (e.g., please tell us what happened with your concerns or experience in as you can?)

- Communications with health care providers (any difficulties, language barriers, concerns) (e.g., how well did staff keep you informed of things? how well do you think the doctors and nurses talked to each other about

what was happening? How much did they ask about what you thought of things?)

- Identify factors contributing to patient safety from patient/family perspective (e.g., what kinds of things happened to make sure you were kept safe and well? What did the staff do?)

- Status of patient/family involvement and engagement of patient safety initiatives (e.g. how did staff involve you or your family in discussions or decisions when you were in hospital? How involved were you in decision making during your time in hospital?)

❖ **Closure 2 minutes**

Thank you very much for coming today and sharing with us your opinion and experience. Your time is very much appreciated, and your comments have been very helpful.

Appendix 16: Ethical approval from University of Glasgow

Dear Dr Lisa Kidd

MVLS College Ethics Committee
Project Title: *Barriers and facilitators influence and shape the implementation of a positive patient safety culture from multi perspective (healthcare professionals and patients) in Saudi Arabia*
200180156

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study.
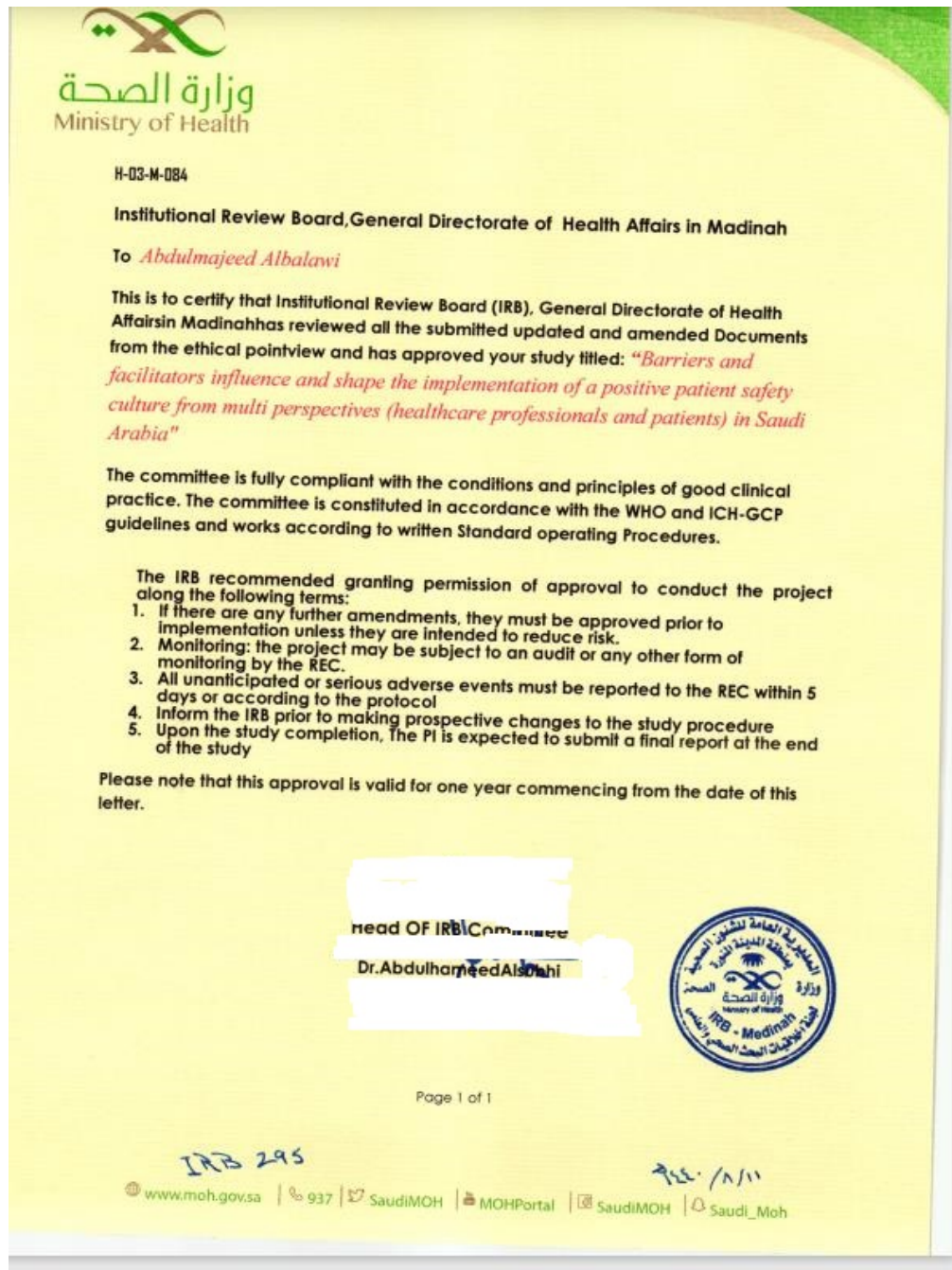
We are happy therefore to approve the project, subject to the following conditions.

- Project end date as stipulated in original application.

- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)

- The research should be carried out only on the sites, and/or groups defined in the application.

- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.

- For projects requiring the use of an online questionnaire, the University has an Online Surveys account for research. To request access, see the University's application procedure   at https://www.gla.ac.uk/research/strategy/ourpolicies/useofonlinesurveystoolforresearch/ .

- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Terry Quinn

Appendix 17: Ethical approval from Saudi Arabia

Appendix 18: Search strategy results

1 safety/ or patient safety/ or safety management/ or patient harm/	69508
2 (patient safety or healthcare safety or safety culture or safety climate or safety practice).tw.	20354
3 organizational culture/ or risk management/	32470
4 organi?ation* culture.tw.	1564
5 Saudi Arabia/	10885
6 (Saudi Arabia* or KSA or SA).tw.	32371
7 1 or 2	79816
8 3 or 4	33056
9 5 or 6	35697
10 7 and 8 and 9	14

07/06/2018

1	patient safety/ or patient harm/ or patient risk/	98498	Advanced
2	(patient safety or healthcare safety or safety culture or safety climate or safety practice).tw.	34617	Advanced
3	1 or 2	112717	Advanced
4	organization/ or organizational climate/	111144	Advanced
5	organi?ation* culture.tw.	1921	Advanced
6	4 or 5	112066	Advanced
7	Saudi Arabia/	14950	Advanced
8	(Saudi Arabia* or KSA or SA).tw.	53532	Advanced
9	7 or 8	56892	Advanced
10	3 and 6 and 9	9	Advanced

#1	MeSH descriptor: [Patient Safety] explode all trees	(m)	548
#2	MeSH descriptor: [Patient Harm] this term only	(m)	3
#3	Safety or patient safety or healthcare safety or patient harm or safety management:ti,ab		166274
#4	#1 or #2 or #3		166274
#5	MeSH descriptor: [Safety Management] explode all trees	(m)	239
#6	patient safety culture:ti,ab		478
#7	safety culture or safety climate or safety practice:ti,ab		7672
#8	healthcare organi?ation* culture:ti,ab		55
#9	#5 or #6 or #7 or #8		7894
#10	MeSH descriptor: [Saudi Arabia] this term only	(m)	158
#11	Saudi Arabia*:ti,ab		478
#12	KSA or SA:ti,ab		3507