

Improving Patient Safety in Libya: The Way Forward

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ABSTRACT

Background: Patient safety has become a major public health issue. The increasing number of adverse events in healthcare has led many countries around the world to establish new organisations, regulations and policies to tackle the issue of patient safety and provide high quality care, including in Libya. There is very limited research about the issue of patient safety in developing countries and in particular Libya. The level of patient harm in developing countries is very high. There is also a lack of systematic approach towards improving patient safety.

Aim: This study aimed to develop a patient safety improvement framework for healthcare settings in Libya using a pragmatic approach based on lessons from UK and subject matter expertise.

Methodology: The data used to develop the conceptual framework was collected using a triangulation design method which involved literature review, documentary analysis, focus groups and a Delphi study. The framework was validated through a mixed-methods approach using questionnaires and surveys.

Results: The results showed that patient safety requires a systems approach that would start with regulations and policies, education and training, information technology, leadership and management as well as patient involvement and continuous monitoring. In Libya, the priorities were mainly linked to introducing a regulatory framework to enhance the quality of care. The results are also supported by Libyan healthcare professionals, who affirmed the need for medical education reform to raise awareness about patient safety among healthcare professionals.

Conclusions: The results from this study indicate that patient safety can be improved through the application of conceptual frameworks that are Libyan-oriented. This study developed a framework which will result in delivering a high quality of care to patient if established.

DEDICATION

***This thesis is dedicated to my parents
“Abdulssalam and Jamelah”***

DECLARATION OF ORIGINALITY

I declare that this thesis has been composed solely by myself and it has not been submitted previously for a degree at any University. The work presented in this thesis is entirely my own except where states otherwise by reference or acknowledgement. I hereby declare that I have received support and guidance from my supervisors; Dr. Ricky (Reetoo) Banarsee and Prof. Azeem Majeed to carry out the research presented in this thesis.

Name: Mustafa Elmontsri

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LIST OF ABBREVIATIONS

NRLS	National Reporting and Learning System
PSI	Patient Safety Indicators
OECD	Organization for Economic Co-operation and Development
MoH	Ministry of Health (Libya)
UN	United Nations
WHO	World Health Organization
IOM	Institute of Medicine
DOH	Department of Health
AHRQ	Agency for Healthcare Research and Quality
NPSA	National Patient Safety Agency.
CQC	Care Quality Commission
IHI	Institute for Healthcare Improvement
NHS	National Health Services
UK	United Kingdom
USA	United States of America

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CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter offers an overview of the research and the problem being investigated. I will start by providing an overview of the research background as well as discussing the justifications for selecting this area of research. I will also provide an overview of the Health System in Libya and present the aims, objectives and research questions for this study. I will discuss my motivations for carrying out this research as well as the challenges faced during this journey. A brief outline of the research methodology adopted for this research is also discussed. This is followed by an overview of the thesis structure.

1.1. Context of the research

It would be unfair to think that health professionals irrespective of their specialty intend to harm patients while they are being cared for because health professionals are trained and educated to be proficient; and aim to be error-free in their practice. However, mistakes and accidents occur in healthcare as healthcare workers are not immune from the human tendency to make errors. Similarly, system failures such as lack of monitoring, accountability and continuous improvement culture could contribute to the occurrence of medical errors. For this reason, medical errors should not go unseen and should be recognised to help understand the root causes of such errors (Reason, 2000). In this project, the focus is on the problem of patient safety in developing countries and in particular, Libya. Developed nations have realised the need to improve the quality and safety of healthcare to ensure that patients are protected from harm. As argued by Vincent (2013), it is vital not to isolate safety from

broader concerns about cost and quality in healthcare. In other words, policy makers should not focus on the number of patients being treated in hospitals but rather on the quality of care being delivered to them. It is crucial that safety takes precedence when safety and productivity conflict (Vincent, 2010). Providing healthcare to large numbers of people is the main objective of healthcare services but this should be done safely.

Assessing the quality of healthcare services has been based for a long time on the results of healthcare services being delivered to patients. Babylonians used to pay for medical services in accordance with the results (they received) and, similarly, doctors who caused negative outcomes on patients had parts of their bodies mutilated in the Middle Ages (Shoyer et al., 1995). The results of healthcare are measured as noted above by the number of adverse events that could harm patients (Thomas and Panchagnula, 2008). However, such adverse events can also offer the opportunity for healthcare providers to enhance their services and create a safer healthcare system. Adverse events that have the potential to harm patients along with near misses which are also classed as potential adverse events provide greater opportunity for policy makers to investigate such incidents to identify the system failure that led to such occurrences. However, I discovered in my early literature search that error reporting in health systems is one of the biggest challenges that face healthcare providers due to the existence of a blame culture (Waring, 2005; Khatri et al., 2009; Cooper et al., 2017). Thus, it is crucial to understand that healthcare delivery is a complex process which requires continuous improvement efforts to learn from mistakes and near misses. Several studies, governmental and independent reports have reported the negative results of healthcare. Among those reports is the one published by the Institute of Medicine (IOM) in 1999 which estimated that 44,000 to 98,000 deaths in the United States were caused by medical errors (Kohn et al., 1999). Such statistics raised the alarm about the need to focus on the problem of patient safety in many developed nations around the world.

Patient safety is defined as the *“freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimise the likelihood of errors and maximises the likelihood of intercepting them when they occur”* (Kohn et al., 2000, p.211). This definition entails that patients should not be harmed

and if errors occur, there should exist a system which learns from such errors to ensure that they do not occur again. It is also important to note that patient safety should be considered as an ongoing improvement journey within healthcare systems. As Florence Nightingale did when she witnessed patients die unnecessarily, she learnt how to minimise risk and harm because of her own experience and she devoted her life to improve patient safety (Woodward, 2011). She once stated that:

“It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm”

Therefore, patient safety has been always an issue in the provision of care to patients, but more attention has been given to this issue following the publications of several studies and reports as noted above which highlighted the size of the problem. The World Health Organization (WHO) identified patient safety as a significant problem within healthcare which led to the establishment of the World Alliance for Patient Safety in 2004 that aimed to promote patient safety in healthcare and facilitate improvements across a global level. The World Alliance for Patient Safety aimed to foster collaboration, share experiences and develop integrated approaches to patient safety (WHO, 2009). The alliance stressed on the need for integrated healthcare services due to the complexity of healthcare delivery. Care is delivered to patients in fast-moving environments that involve a vast array of individuals and technology. It also requires quick decisions and judgements to be made by healthcare professionals which means that things could go wrong, and that unintentional harm would be caused to patients. In addition to this, healthcare delivery differs from one country to another which promoted WHO to establish a World Alliance for Patient Safety to develop international standardisation of terminology and define common methods for measurement and reporting of adverse events. Having said this, international efforts may not be successful if they fail to take into account the local contextual factors, organisational culture and commitment from policy makers and top management towards enhancing the quality and safety of care.

The field of patient safety has progressed rapidly over the past two decades due to increased pressure from stakeholders and healthcare providers to enhance the quality and safety of their services (Vincent and Amalberti, 2016). Due to the long-term impacts of poor care, it has become critical for governments to introduce legislations

and laws to regulate healthcare providers so that patients are provided with efficient and safe care. Despite this, patient safety remains a major public health problem across many developed nations including the United Kingdom (UK) (Vincent et al., 2001; Francis, 2013) and the United States (Kohn et al., 1999; Berwick and Leape, 1999; Makary and Daniel, 2016). This shows that patient safety is evolving along with the changes in the care delivery process. In other words, it is crucial for healthcare providers to continually audit and review their performance in regard to patient safety. Several patient safety indicators have been developed for areas such as hospital-acquired infections, blood safety, surgery, obstetrics, and intensive care by leading organisations such as the AHRQ and the Organization for Economic Co-operation and Development (OECD). The purpose of patient safety indicators (PSI's) is to identify potential adverse events in healthcare so that lessons can be learnt to avoid such events in the future. A systematic review carried out by Dr Foster Unit at Imperial College London into patient safety indicators found that such PSI's are widely used in the US and that similar efforts in Europe have started to develop a PSI set which incorporates both AHRQ PSIs and OECD indicators (Tsang et al., 2008). Despite these movements in regard to patient safety, such field remains under researched in developing countries and in particular, Libya. I will discuss the rationale for this study and the motivations behind selecting this research topic in section 1.3.

1.2.1 Definitions of patient safety

This section will present some common definitions of patient safety which have been obtained from different sources. One of the early definitions of patient safety was presented above was introduced by the IOM report in 1999. Since then, several scholars and agencies have developed other definitions of the term. For example, Vincent (2006, p. 14) defined patient safety as the:

“Avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare”.

Vincent (2006, p. 14)

The Agency for Healthcare Research and Quality (AHRQ) in the United States is one of the organisations that promote patient safety research and improvements in

healthcare has developed a glossary for patient safety terms. The definition of the patient safety term according to the AHRQ is the:

“Freedom from accidental or preventable injuries produced by medical care”

(AHRQ, 2008).

As part of the World Alliance for Patient Safety mentioned above, the WHO produced an international classification for patient safety (ICPS) to facilitate aggregation of data across countries and different disciplines as pointed out by Sherman et al (2009). The international classification for patient safety aimed at identifying and defining the common terms associated with patient safety and quality of care that was developed through a two-stage web-based Delphi survey which involved patient safety experts from various fields (e.g. health informatics, infection control, safety and quality control, health policy and reporting systems). The final ICPS covered 48 key concepts (Runciman et al., 2009). Patient safety is defined according to the ICPS as:

“The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”

(Runciman et al., 2009, p.19).

1.2. Rationale of the study

There has been a massive shift in the need for focusing on improving quality and safety of healthcare in the last twenty years not just in secondary care but also in all aspects and stages of care (Kirk et al., 2007; Gaal et al., 2010; Makary et al., 2006; Donaldson et al., 2017). The knowledge about safety science in healthcare has been one of the most important transformations in the last twenty years (Morath and Turnbull, 2005). Safety science focused on understanding the root causes of medical accidents and how patients should be protected from unintentional harm caused by poor care. WHO (2012) reported that estimates of the size of the problem in developing and transitional countries are scarce but undoubtedly millions of patients suffer from disabling injuries and unnecessary death due to unsafe healthcare. Makary and Daniel (2016) that medical error is the third leading cause of death in the USA. A retrospective review of 1014 medical and nursing records in two London hospitals in England conducted by Vincent et al (2001) reported that 10.8% of patients have suffered some kind of

adverse event while receiving treatment in these hospitals. According to that study, 50% of these adverse events were preventable. Another study by Sari et al (2007) was carried out in one English NHS hospital, which reviewed 1006 admissions, indicated that 11% of those admissions had experienced at least one safety incident. Williams et al (2008) investigated the rate of adverse events in a one acute hospital in Scotland found that 8% of the 450 patient records reviewed witnessed a patient safety incident. In England, a recent public inquiry into the serious failings at the Mid Staffordshire NHS Foundation Trust stressed the need for focusing on developing a positive patient safety culture across the organisation to ensure that incidents are reported and investigated (Francis, 2013). Furthermore, the inquiry found that the leadership failed to give sufficient explicit priority to the protection of patients and failed to observe patient safety and quality standards.

Such studies, inquiries and investigations which showed the high prevalence of adverse events as well as the associated human and physical costs to poor care led many Western countries to introduce and create patient safety organisations as well as develop new policies, regulations and interventions to improve patient safety. Several influential reports were published by the Department of Health (DoH) (2000, 2001) in England to acknowledge the problem of patient safety and that healthcare providers have a legal and moral responsibility to tackle the issue of patient safety. In the USA, the National Patient Safety Foundation (NPSF) which is a non-profit independent organisation was established to raise awareness about the issue of patient safety and develop pathways for applying new interventions that aim to improve the quality and safety of healthcare. In 2003, the Canadian Patient Safety Institute was also established as a non-profit independent corporation to build a safer and efficient healthcare system. The National Patient Safety Agency (NPSA) for England and Wales was established in 2001 with the purpose to monitor patient safety incidents including prescribing and medication error reporting. Similar organisations were established in Australia and other European countries. The WHO had also taken a step towards raising awareness about patient safety as discussed above by establishing the World Alliance for Patient Safety in 2004.

The issue of patient safety and adverse events in developing countries is very under researched. A retrospective study by Wilson et al (2012) reviewed medical records of 15,548 hospital admissions in eight countries (Yemen, Egypt, Sudan, Jordan, Kenya, South Africa, Tunisia and Morocco). The study reported that one or more adverse events were shown in 8.2% of all the records that were obtained from the participating hospitals. The study indicated that over 80% of these adverse events could have been avoided or prevented. Lack of adequate training and supervision, failure to follow appropriate protocols or policies as well as lack of awareness about patient safety were among the causes of such events. Several studies in Arab countries were carried out to explore the status of patient safety culture among healthcare workers reported that non-punitive response to error is seen as a serious issue which needs to be improved. Healthcare professionals in the Arab countries tend to think that a 'culture of blame' still exists that prevents them from reporting incidents (Elmontsri et al., 2017).

Rages (2014) carried out a doctorate research study to examine the perception of patient safety culture amongst health care workers in Libyan Hospitals in which 346 health care workers who were working as doctors, nurses, technicians, pharmacists and managers were surveyed. The study concluded that the state of patient safety culture in Libyan hospitals was very weak and it was noted that there was a lack of an effective patient safety system to deal with patient issues. The study identified several factors influencing upon patient safety in Libya such as the poor quality of training and education, shortage of staff and the political landscape.

My own experience working for the Ministry of Health in Libya, as well as working for the Care Quality Commission in London with UK qualifications (BSc (Hons) in Occupational Safety and Health and MSc in Risk Management) have shaped my thinking about improving human lives through empirical research. In the UK, there are many regulatory movements, stakeholders' pressure, media scrutiny and wider public awareness about improving the quality of care provided to patients. In Libya and in many other developing countries especially in Africa, patients are not fully aware of their rights nor have any role in the process of care. There is huge gap between health systems in Western countries and those in developing countries such as Libya which

is now operating with very limited resources and weak paper documentation system. Therefore, there is a need to move towards a more structural and process-oriented approach to improving patient safety in such countries. A safe and secure environment is pre-condition to provide a robust health system either in Libya, Afghanistan or Somalia. The current conflict in Libya affects the provision of health services and public health in a direct and indirect manner. Therefore, it would more feasible for countries that go through transitional stages to develop an evidence-based national health policy as part of post-conflict reconstruction efforts. Thus, it is critical to understand and explore the factors that influence upon the successful implementation of patient safety interventions in such environments to enable the development of evidence-based frameworks that will result in long-term positive impact.

There is no doubt that negative impacts resulting from armed conflicts lead to deaths, injuries, destruction of properties and infrastructure as well as long-term public health problems. Such problems arise due to the reduced access to food, poor hygiene, poor health services and lack of clean water (Murray et al., 2002). Population displacement, heightened risk of disease transmission and breakdown of health and social services are also caused by armed conflicts (Leaning et al., 2013). Libya has gone through a destructive war in 2011 followed by another civil war in 2014 which prevented me from travelling to Libya to carry out field visits and surveys. My initial research proposal was about assessing the status of patient safety culture among healthcare workers in Libya where I intended to use a validated questionnaire survey developed by the Agency for Healthcare Quality and Research to benchmark the data from Libya with other countries in the region as well as western countries. However, the war that erupted in Libya in 2014 meant that I can no longer travel there as the UK's issued a travel ban to Libya due to security reasons. This has affected the progress of my research. The focus of this thesis was shifted towards developing a framework for patient safety improvement in Libya using a different data collection approach.

To date it appears that little attention to patient safety research has been given by researchers in developing countries due to the limited resources, access difficulties to study settings as well as lack of regional or international support to enhance the quality of health services in such countries. It was evident in the literature the lack of research

on patient safety in Libya and that patient safety culture remains to be weak (Rages, 2014). It is proven by many health systems that long-term positive impacts can be achieved through having an integrated approach to patient safety as a core pillar for improving the quality of health care. Along with Donabedian's (1980) quality of care dimensions; structure, process and outcomes, patient safety should be incorporated at the three phases to ensure patients are protected from harm. The policy level, hospital level and healthcare professionals' level. Hence, lessons that can be learnt from other developed nations and from exiting systems can help healthcare organisations in developing countries to avoid prospective hazards and deliver safer care to patients at all times; this is another motivation for this study.

As highlighted earlier, there is very limited research on the issue of patient safety in developing countries and in particular in Libya. In fact, there is not any previous work that carried out specifically to measure the rate of adverse events or level of harm to patients in Libya nor any studies that aimed to develop tools for enhancing patient safety. Taking this into account, it would not also be feasible to expect western models, approaches and interventions to work for other health systems in developing countries without understanding the organisational and contextual factors as well as understanding the socio-cultural factors that may influence the adoption of such interventions. Therefore, it is important to develop a comprehensive framework for patient safety improvement while taking such variables into account. This study aims to investigate the success factors that would enable developing countries to establish patient safety systems so that they can provide reliable and efficient care to patients. Such systems will also help in regaining the lost trust between healthcare professionals and patients in such countries.

1.3. Libya's health system

Libya is located in North Africa with a total land area of 1.8 million square kilometres. It is the fourth largest country in Africa and has borders with six countries (Egypt, Sudan, Chad, Niger, Algeria and Tunisia). It is bordered by the Mediterranean Sea from the north with over 1900 kilometres of coastline.

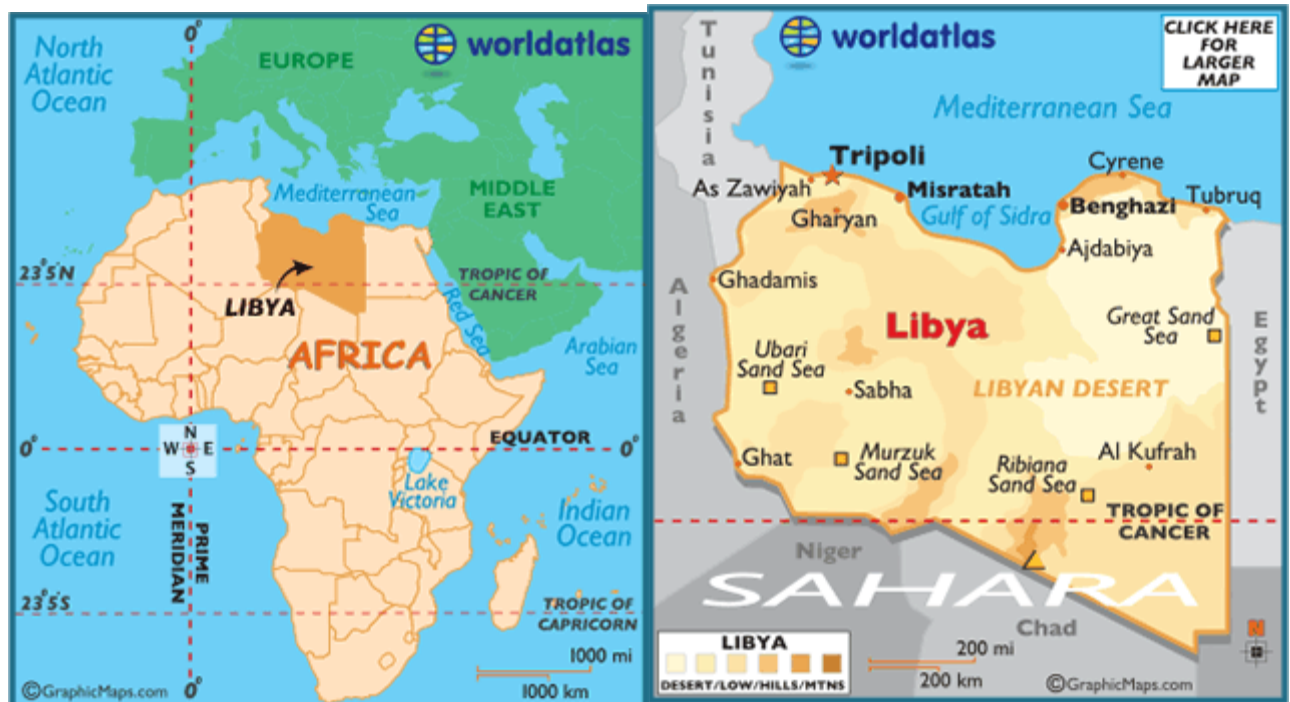


Figure 1.1: Map of Libya (free from: <http://www.worldatlas.com>)

In 2015, the total estimated population is 6.5 million. 85% of Libya's population is urban with 42% of Libya's population aged under 24 years. Life expectancy at birth for males is 74.7 years and 87.3 years for females. The provision of healthcare services and education in Libya is free of charge to all residents. Libya has witnessed improvements following the discovery of oil in 1950s which helped the country to improve life expectancy, maternal mortality and childhood immunisation for all births. However, there is more concern about the rise of non-communicable diseases in the past 10 years. The main health service provider is the public health sector which is directly funded by the Libyan government. The government spends 3.3% of GDP on health services which is as mentioned earlier provided free of charge to all citizens including preventive, curative and rehabilitation services. A series of primary health care units, centres, polyclinics, general hospitals and rehabilitation centres in urban and rural areas along with tertiary care specialised hospitals are used to deliver healthcare services to people (The Health Information Centre of Libya, 2012). In late 2011, according to a report released by the MOH Libya had 96 hospitals with 20,689 beds,

25 specialised units with 5,970 beds, 1,355 primary health centres, 37 polyclinics and 17 quarantine units.

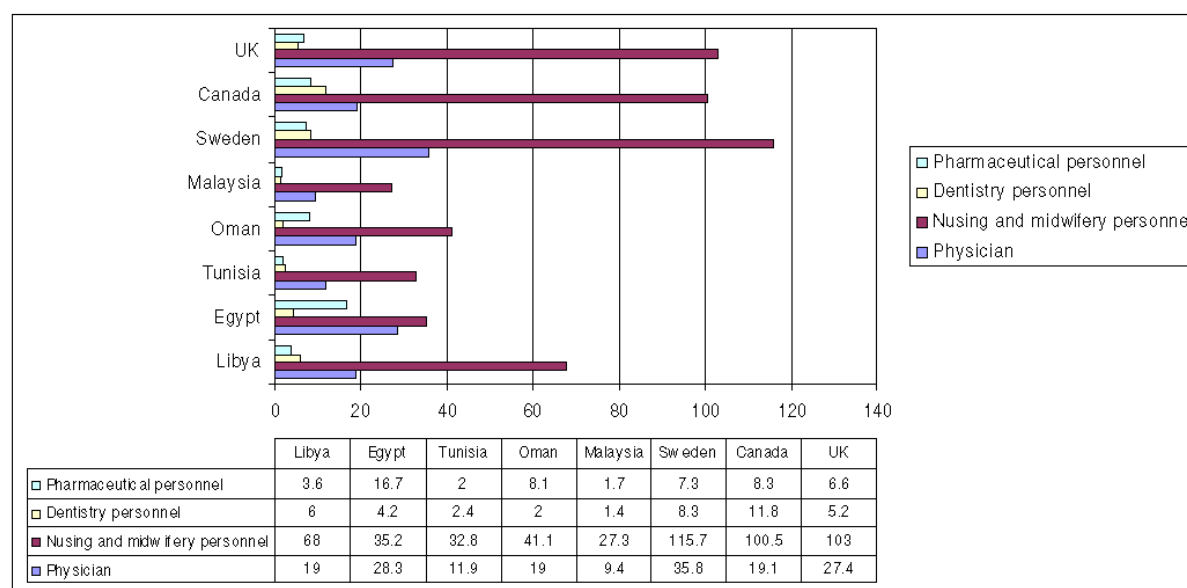


Figure 1.2: Human resources per 10,000 population, international comparison

The total number of doctors in Libya is around 10,000 in which 16% of them are foreign while the rest are Libyans. Trained health personnel care for around 90% of pregnant women and that trained personnel attended 99% of all deliveries. Table 1.1 shows the number of hospital beds per 10,000 population in Libya compared with other countries around the world.

Table 1.1: Health infrastructure in Libya, international comparison (WHO, 2011)

Country	Hospital beds per 10,000 population	Radiotherapy units per 1,000,000 population
Libya	37	0.9
Egypt	17	0.7
Tunisia	21	1.1
Oman	19	0.7
Malaysia	18	1.7
Sweden	28	8.3
Canada	34	7.7
UK	34	5.4

The WHO in collaboration with the Libyan Ministry of Health (MoH) conducted an assessment of the Health System in Libya in 2012 and found that several challenges face the current health system which include the following (The Health Information Centre of Libya, 2012):

- Lack of evidence and lack of high quality of care and productivity
- Chronic need for maternal and antenatal care services.
- Dire need for mental health and psychological support services (as of February 2012, only 14 psychiatrists serving the entire population).
- Prevalence of HIV drug-injecting users (87% in Capital).
- Road traffic accidents (RTA) are one of the most significant public health issues in Libya
- Lack of leadership and ambiguous MoH policy

The provision of health services in Libya is delivered through three different levels:

- The first level of healthcare in Libya is the provision of preventative and curative services through primary care units and primary care centres that are distributed over the country. There are also polyclinics that are staffed by physicians, laboratories as well as pharmacies which provide services to patients. Care for children, minor surgery, general medical care for the adult and elderly, family planning, obstetric care, antenatal care, school health services, preventive services, health promotion services as well as dispensing of pharmaceutical prescriptions are among the services provided by the primary care units and centres. However, in reality, such primary care units lack the necessary equipment or expertise to provide basic health services such as in the UK where general practitioners can relieve some workload from secondary hospitals. There is also lack of the use of information technology and electronic medical records in Libya which affects the coordination of care between primary and secondary care providers.
- The second level of care in Libya is provided through a number of general and specialist hospitals. These hospitals are supposed to be working through a referral system in coordination with the primary care units and centres. However, due to the lack of referral system and the absence of electronic records or systems, general and specialised hospitals are faced with excessive burden and pressure. The health system in Libya is organised in a hierarchical

way in which the MoH manages and controls all of the healthcare providers through local health secretariats. Patients are referred to a tertiary level hospital if the treatment cannot be provided at the primary or secondary care providers (Abudejaja and Singh, 2000). These hospitals suffer from major operational shortcomings due to corruption, delays to building maintenance, bureaucratic procedures and delays in supply (El-Taguri et al., 2008; Mohapatra and Al-Shekteria, 2009).

- The third level of care is provided through tertiary care hospitals which are present in cities. There is also huge growth of private health sector in Libya due to the lack of trust between patients and public hospitals (Osborne, 2010).

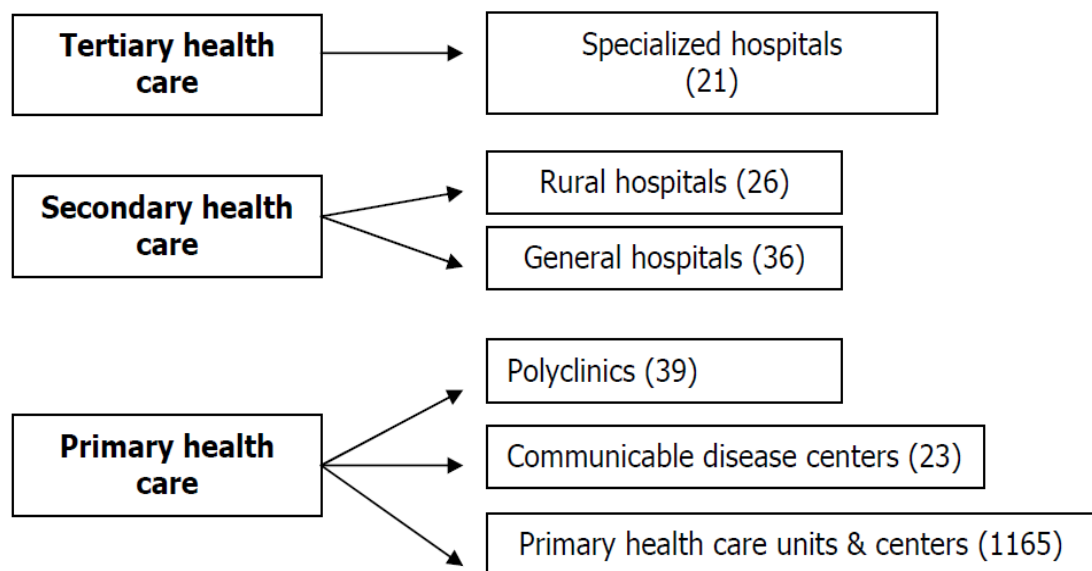


Figure 1.3: Distribution of healthcare providers in Libya

1.5 Aim, objectives and research questions

Aims	Objectives	Research Question	Methods
Aim 1 To review the progress in patient safety in the past 15 years and to identify concepts to improve patient safety, their barriers as well as their critical success factors.	1.1 To critically review the history and progress of patient safety research over the past 15 years.	Q1: What are the critical components that are associated with good patient safety?	• Descriptive Research Design • Systematic Review • Literature Review
	1.2 To explore the incidence and prevalence of patient safety problems in various health-care settings around the world	Q2: What are the incidence and prevalence of patient safety problems in various health-care settings?	
	1.3 To explore the status of patient safety culture and identify the main problems, barriers and challenges particularly in relation to patient safety in the Arab countries.	Q3: What are the common issues, problems, barriers and challenges in relation to patient safety in Arab countries?	
Aim 2 To develop a patient safety improvement framework that is oriented to the Libyan context and capable	2.1 To examine the current existing patient safety models that are applied in the Western Context	Q1: Within developed health care systems, what factors have been found to lead to better practices of patient safety?	• A Two-Round Modified Delphi Technique
	2.2 To seek expert advice in order to identify the key factors that are the most important in the improvement of patient safety.		

of improving patient safety in the Libyan healthcare system.	2.3 To explore the Libyan healthcare professionals' perceptions of patient safety practices in the UK.	Q2: What are the contextual barriers or facilitators to maximising patient safety in the healthcare settings?	• A Qualitative Approach (Focus Groups)
	2.4 To use the identified factors/elements to develop a framework capable of improving patient safety in the Libyan healthcare system		
Aim 3 To validate the developed framework and determine its fitness and appropriateness as a tool to improve patient safety, in Libya.	1.4 To assess Libyan healthcare professionals' perceptions of the developed framework and its applicability in the Libyan system	Q1: What is the perception of the health system users in Libya in relation to the critical components associated with patient safety improvement in Libya?	Mixed Method Approach • Cross-sectional survey questionnaire for patients, nurses and doctors • Semi-structured Interviews with Libyan health policy makers
	1.5 To assess Libyan patients' perspective on the applicability of the framework.		
	1.6 To make recommendations for the enhancement of patient safety in the Libyan health care systems.		

1.6 Overview of the methodology

A Triangulation Design which is one of the most common mixed-method approaches used in research is adopted for this research as shown in Figure 1.1. Chapter three provides a detailed discussion on the methodological approach.

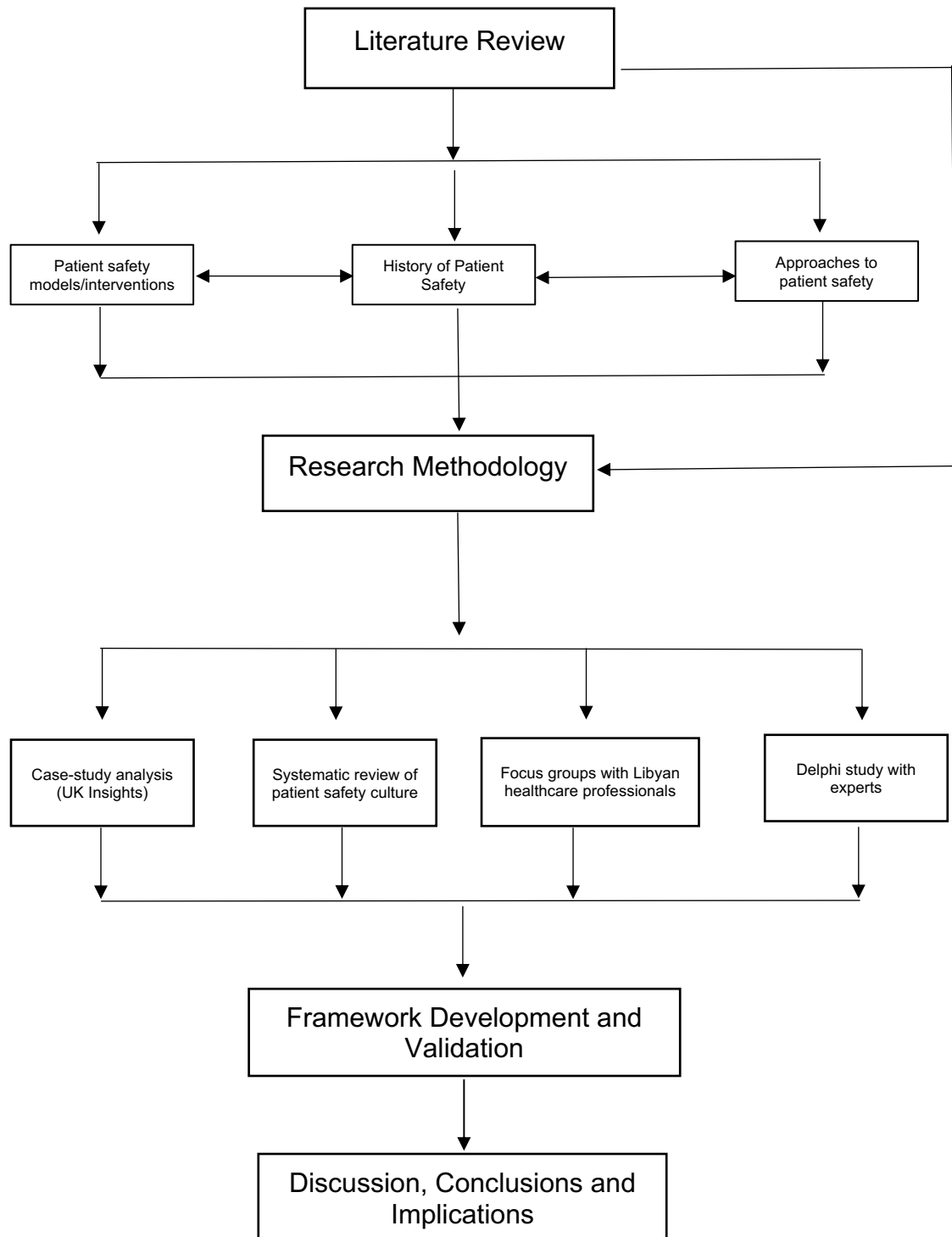


Figure 1.4: Overview of the Research Methodology

1.7 Study Significance

Patient safety has gained much attention around the world and that WHO is engaged in many activities that aim to enhance patient safety. However, this area remains under researched in many developing countries including Libya. Libya has gone through different phases which affected upon the governance process of public institutions and sectors. Libyan receive free universal healthcare and education, but the quality of such services remains to be poor (Al-Lagilli et al., 2011). Adding to this, the recent crisis which erupted in 2011 following the toppling of the Gaddafi regime has worsened the services provided to patients. Patient safety improvement cannot be ensured without an integrated approach that is supported by the political system in the country. There is an urgent need to reform the current health system in Libya to allow for improvements and developments that will lead to better services (El-Oakley et al., 2013). The current health system in Libya does not meet the needs of patient, which also resulted in a deteriorating level of trust between patients and healthcare providers. Thus, a holistic approach is urgently needed to enhance the quality of care in Libya. Therefore, this study would be of high significance as it would contribute to existing knowledge about the need to improve and enhance patient safety to avoid medical harm and also to help policy makers and healthcare practitioners to understand the factors, variables and dimensions of patient safety that need to be taken into account.

This study would also encourage the execution of more research in Libya in regard to patient safety to help understand the challenges that face healthcare providers in developing patient safety interventions. There is not a formal performance measurement programme in Libya which also contributes to the poor design and delivery of healthcare services. El-Taguri et al (2008) asserted that hospitals in Libya are managed by a crisis approach rather than through strategic approach. There is also absence of national statistics on the rate of adverse events along with the absence of any formal patient safety strategies that could provide benchmarking data. This study would enable the systematic enhancement of the quality of healthcare services in Libya through combining different core pillars. Therefore, understanding the success factors for patient safety system implementation would help in devising a well-defined framework for patient safety improvement in Libya. This study also

collected several types of data using different sources and methods which also enhances the feasibility and validity of the developed framework. As reported by many studies, there is a need to measure healthcare performance and to use patient safety indicators to ensure that lessons are learnt. The study would be of high significance to academic, policy makers and healthcare practitioners.

1.8 Structure of the thesis

The thesis consists of 7 chapters. I will briefly outline the contents of each chapter to provide the readers with an overall understanding of the content and flow of the thesis.

Chapter 1. Introduction – in this chapter, I discuss the rational of the study as well as provide the reader with an overview of the Libyan health system. The chapter presents the aims, objectives as well as an overview of the study significance and how the thesis is structured.

Chapter 2. Literature Review – I critically reviewed the relevant literature to highlight the existing discussions and views about the importance of patient safety and how healthcare organisations need to focus on developing an integrated approach to improving patient safety. The literature review focuses on the current challenges that face healthcare organisations when it comes to improving patient safety as well as the role of patient safety education, governance, information technology, leadership and management along with the creation of patient safety culture to promote reporting and learning from previous incidents.

Chapter 3. Research Methodology – I discuss the research methodology adopted for data collection, analysis and reporting of the data related to this research. This chapter discusses the data triangulation method that was adopted for this thesis.

Chapter 4. Results & Analysis – This chapter is divided into four parts to present the results of the empirical studies that were carried out as part of this thesis. The chapter presents the findings of the case study analysis that was carried out to identify the lessons which can be learnt from the UK experience in improving patient safety in Libya. It also presents the findings of the systematic review that focused on patient safety culture in Arab countries following by a discussion then presents the findings of two focus groups that were carried out with Libyan healthcare professionals to identify the challenges, barriers and ways for improving patient safety in Libya. The chapters

also presents the findings of a two-round Delphi study that was carried out with international experts to identify priority areas for patient safety improvement in Libya.

Chapter 5. Patient Safety Improvement Framework – I present the framework that was developed in this thesis to improve patient safety in Libya. The chapter discusses the different components of the framework supported by the existing literature. I also present the findings of the framework validation with policy makers, healthcare professionals including nurses and doctors in Libya that was carried out to examine the suitability and usefulness as well as the applicability of the framework in Libya.

Chapter 6. Discussion – this chapter presents a general discussion on the findings of the thesis along with personal reflection on the applicability and importance of the developed framework in enhancing patient safety in Libya and other developing countries. The conclusions are presented in this chapter.

Chapter 7. Recommendations & Implications– I present the contribution to knowledge, study implications, study limitations, recommendations and some ideas for future research.

1.9 Chapter summary

The purpose of this chapter was to provide an overview of the overall thesis. For this reason, this chapter started by discussing the context of the research and providing a critical background about the importance of patient safety especially for developing countries due to the lack of well-established research in this field. The chapter then discussed the rational and the motivations behind this study. The practical and academic needs to carry out such a research study were also discussed to contribute and to add new knowledge to existing literature and provide actionable recommendations that would lead to long-term improvements in patient safety. The chapter then presented the aims, objectives and the research questions. The significance of the study as well as the thesis structure were included in this chapter. The following chapter presents the literature review.

CHAPTER 2

LITERATURE REVIEW

2.1. Introduction

This chapter presents a critical evaluation of the existing literature associated with patient safety, risk and health and safety management systems. I discuss the historical development of patient safety in healthcare, the factors that hinder or support patient safety improvement as well as discussing the role of risk management in enhancing the quality and safety within the healthcare sector. Moreover, this literature review discusses the systems approach to patient safety along with how governments around the world have realized the need to support patient safety initiatives. The aim of this thesis is to develop a framework for enhancing patient safety within a developing country context. In order to do so, it was necessary to explore previous literature on patient safety.

2.2 Aims of the literature review

The literature review method adopted for this thesis is discussed in section 2.2.2 which has focused on the general literature associated with patient safety improvement. It should be noted that healthcare is a complex and vast system and the focus of this thesis is on the macro-aspects of healthcare quality improvement by focusing on patient safety in particular. A descriptive approach was used to explore the existing literature and the theoretical evidence which informed patient safety in order to gain insights about the challenges that face organisations when it comes to improving patient safety. It could be argued that it would not be possible to cover all published literature regarding patient harm, quality of care and patient safety as part of this thesis due to the large volume of published material in these areas. However, including all studies would not serve the overall purpose of this thesis. Therefore, my review of

literature focused on the themes set out in Figure 2.1 to cover three inter-related themes:

- The problem of patient safety as defined in theory and practice
- Systems approach to patient safety
- The impact of organisational management theories on patient safety improvement

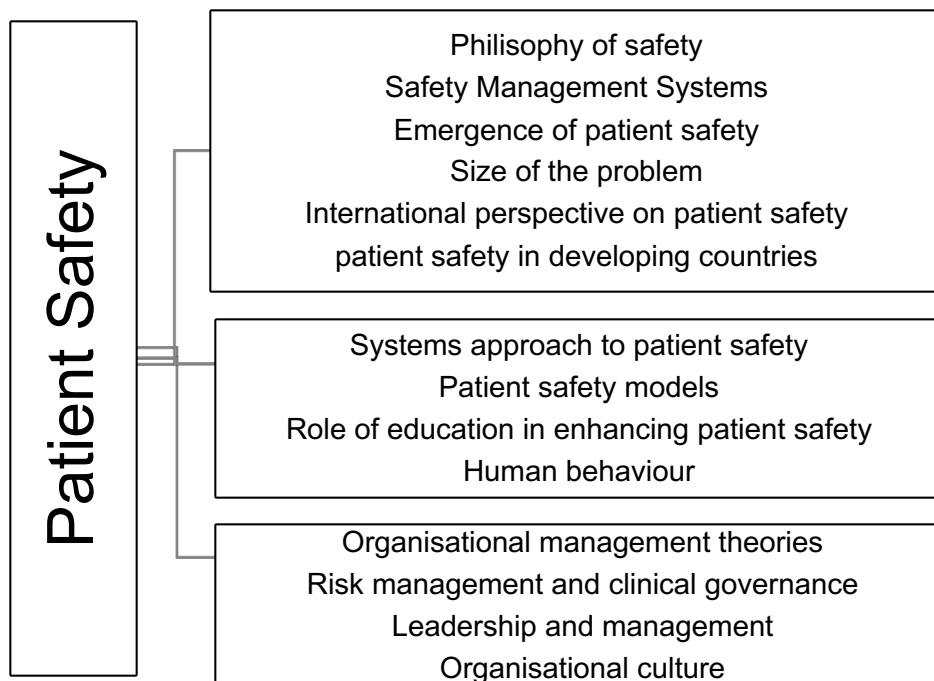


Figure 2.1: Literature review plan

2.2.1 Objectives of the literature review

By reviewing the existing and past research, the objectives of this literature are:

- Provide an overview of the philosophy of safety and safety management systems
- Define and understand the historical development of patient safety within the healthcare sector
- Critically discuss the factors that hinder the successful integration of patient safety interventions within healthcare systems
- Identify themes and patterns that would help in achieving the overall aim of this thesis through examination and evaluation of existing theory and practice related to patient safety

2.2.2 Method

The first search for this literature review was performed between September 2013 and April 2014. Another search was carried out following the change of my research path as a result of the developments in Libya in early 2015 to capture further evidence that would help in shaping my research. This literature review is also updated annually to include any significant studies that can add value to this thesis. A range of sources were used in this literature review including electronic databases such as Medline, PubMed, Science Direct, Embase, Cochrane Library and Google Scholar. Other searchers were carried out to identify paper and electronic documents in Imperial Library, public domain as well as from governmental websites such as the Department of Health, World Health Organization and the Agency for Healthcare Research and Quality. A list of the journals that were identified is included in Appendix D. Other sources were also looked at which included:

- Textbooks and book chapters
- Reference lists of published papers
- Published dissertations
- Technical reports and working papers
- Conference proceedings
- Advice from patient safety experts

The following key research terms and phrases shown in Table 2.1 as part of this literature review:

Table 2.1: Research terms used in the literature review

- | |
|--|
| <ul style="list-style-type: none">• <i>Patient safety, patient safety improvement, history of patient safety</i>• <i>Patient harm, adverse events, risk management, risk assessment</i>• <i>Health and Safety, Safety Management Systems, Health and Safety Executive</i>• <i>Error in healthcare, incident reporting</i>• <i>Human factors and patient safety, systems theory, human error</i>• <i>Patient safety culture, organisational culture, blame culture</i>• <i>Leadership and patient safety, teamwork, communication</i>• <i>Patient involvement, patient safety regulations, information technology in healthcare</i>• <i>Safety policies, developing countries, Libya health system</i>• <i>Clinical governance, monitoring and measurement of safety</i> |
|--|

2.3 Philosophy of Health and Safety

'Health' is defined by the WHO constitution (WHO, 1984) as '*a state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity*'. Seedhouse (1986) criticised this definition by describing it as 'hopelessly idealistic'. The importance of mental and social factors for health were recognised in the WHO definition of 'health' which was then used by Downie et al (1992) when they defined health promotion as "*the balanced enhancement of physical, mental and social facets of positive health, coupled with prevention of physical, mental and social ill health*" (pp. 25-26).

Health is viewed as a foundation for achievement and not an end in itself which should be based on everyone's right for self-determination and the innate need for autonomy (Seedhouse, 1986). Ball and Ball-King (2014) pointed out that Seedhouse's conclusion on discussing the philosophy of health is that 'good life promotion' is an illegitimate extension of health care. Four building-blocks form a continuum of life that includes; the basic needs for daily living, access to information on matters that affect one's health/life; education and awareness on how to use the information to improve the standards of living and also having a feeling of responsibility towards the community in which an individual is living in. hence, the concept of health and the freedom of illness requires the meeting of individual and group needs so that services and treatments can be person-centered. Seedhouse (1986, p. 158) reported that '*a state of health often exists for a person who has no evidence of disease, a disease-free state is not critical for health to occur*'.

Seedhouse's view on health supports the holistic nature of health in which one approach is not always right to tackle the 'health' issues. Figure 2.2 shows the state of health of an individual or a group as proposed by Seedhouse (2008) where it is affected by internal and external factors. Working with people to understand their needs is important for effective health promotion as argued by Seedhouse (1997) in which he stated that health promotion is about working with people '*to identify with or for each individual or group those foundational components which are lacking, or those which are most in need of renovation - and then work on those aspects of the problem*

so defined, in a way most appropriate to the skills of that worker."(Seedhouse 1997, pp.138-139).

On the other hand, organisations can express the value of safety through policies, practices and procedures as noted by Sinclair et al (2010). Cooper (2001) argued that the idea of 'safety is a value' can be linked to the "fundamental philosophy that all injuries are preventable and that the goal of zero injuries can be achieved". The importance associated with safety within an organisation is the definition provided by Newman et al (2012) the concept of safety values. Newman et al asserted that safety information exchange between employees and managers is the prediction of safety values. This would mean that safety is perceived to be an important issue which requires attention, communication and support from all stakeholders. This leads to the discussion around how safety can be maintained, monitored and improved. There are also other variables that affect upon the transfer of safety messages and information as noted by Colley and Neal (2012). This could be linked to communication, management and leadership styles adopted by managers and supervisors. They argued that managers may only focus on the safety elements that concern their personal safety schema such as organisational safety priorities and corporate value and will be less likely to pay attention to the issues that related to employees' day-to-day struggles. Hence, having a safety management system could provide organisations with the opportunity to create an environment where the importance of safety is well-shared across all levels. Ball and Ball-King (2014) pointed out that the 'health' component in health and safety is 'largely about ill-health from exposure to hazards and not about health gains – physical, psychological and emotional – of public life'.

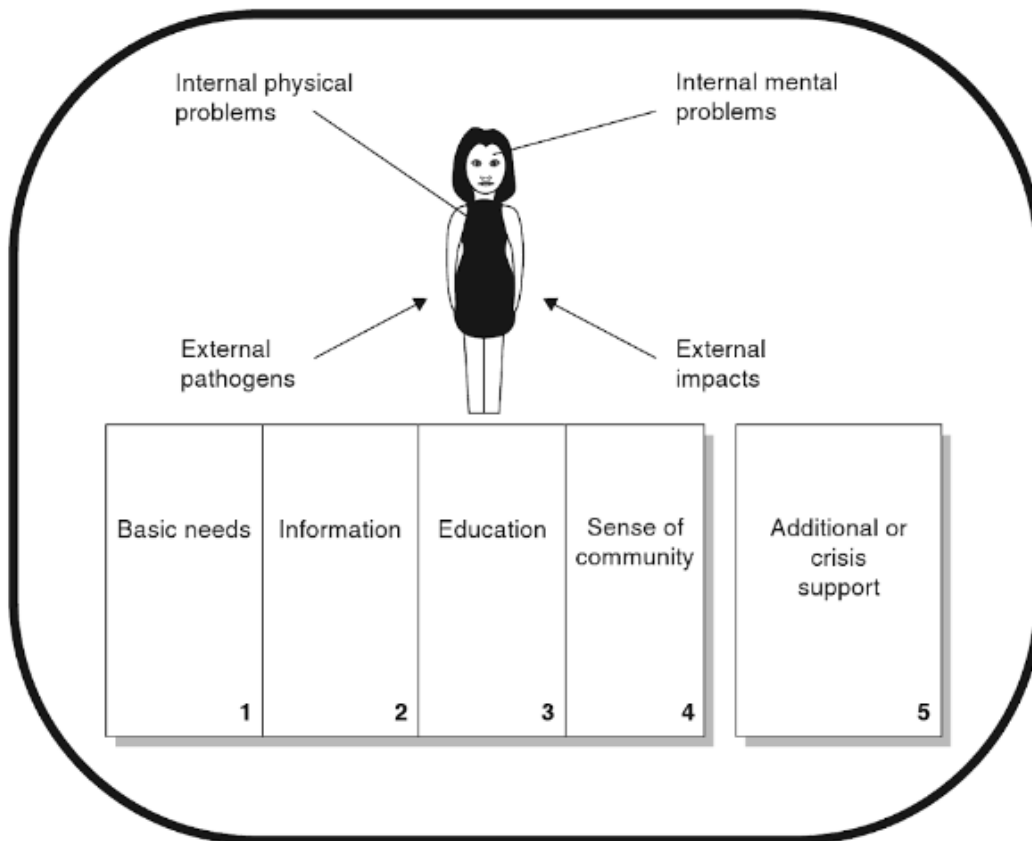


Figure 2.2: The state of health of an individual or a group (Seedhouse, 2008)

2.4 Safety Management Systems

One example of a system safety method is Safety Management System (SMS) which is defined as an ‘organised approach to managing safety, to include the necessary organisational structure, accountabilities, policies, and procedures’ (ICAO, 2009). According to the International Labour Organisation guide on occupational health and safety (ILO, 2001), an SMS should contain the following elements; policy, organising, planning and implementation, evaluation and action for improvement. The ILO advises that strong leadership and commitment to safety management activities should be showed by employers to enhance the culture of safety within organisations. Velazquez and Bier (2015) indicated that policy, risk management, safety assurance and safety promotion are the main four pillars of an SMS. Lie et al (2015) also stressed the importance of planning for occupational safety and health that should be an integral part of any organisation’s planning functions. The literature indicates that despite the implementation of safety systems, accidents still occur which could be linked to the high level of formalisation and rigidity within safety management systems that makes

them less likely to respond to changing situations. The Health and Safety Executive in England identified that policy existence, organising, planning and implementing, measuring performance and reviewing performance are the starting points for a successful health and safety management system (HSE, 2008).

Poor safety management has been linked to many modern disasters in many sectors (aviation, manufacturing and healthcare) (Robson, 2002). In the same way, good safety management has also been linked with financial benefits through the reduction of cost associated with delays, lost-time accident and closures etc. The implementation of an SMS should be done based on the individual needs and circumstances of an organisation so that its benefits can be accomplished (OECD, 1999). It could also be argued that having a safety management system shows that organisations are moving towards a more pragmatic and proactive approach to risk management and control (Johnson, 1999) and hence, that will lead to an improvement to the well-being of people. This has led many countries to introduce health and safety laws and regulations to enable organisations develop new safety management strategies to protect the well-being of people and resources. The Health and Safety at Work Act 1974 in the UK is an example of this. Several other regulations were introduced such as the Management of Health and Safety at Work Regulations, the Control of Substances Hazardous to Health Regulations and other specific regulations for certain industries such as the construction, oil and gas and agriculture.

It could also be argued that the availability of national and international safety standards could provide opportunities for organisations to develop effective safety management systems depending on their own needs and situations (Ahonen et al., 2002). Ball and Ball-King (2013) highlighted a key issue when it comes to implementing laws and regulations. For example, they noted that the Health and Safety at Work Act 1974 in England requires those responsible for some hazard to reduce the risks until as low as reasonably practicable. They also indicated that the requirements under the Civil Law requires duty holders to provide 'reasonably safe' premises. Hence, this could create some confusion and unclarity around the extent to which 'reasonably practical' and 'reasonably safe' is reasonable!. This suggests that the interpretation of laws and regulations requires clear and specific codes of practice

to help organisations and employers to provide a safe and healthy workplace. Robson et al (2007) carried out a comprehensive systematic literature review to examine the correlation between the implementation of safety management systems and its impact on employees' health, safety and well-being. They reported that there was a decrease in injury rates following the implementation of some form of safety management system (18%). Others such as Koh (1995) highlighted that increases in productivity and reduction in absenteeism as a result of accidents could be achieved through the implementation of safety management systems. Nielsen (2000) argued that there are not clear boundaries between safety management systems, activities and procedures.

The HSE's HSG65 is a health and safety guide that was issued by the Health and Safety Executive, which was previously based on the concept of policy, organising, planning, measuring performance, auditing and review to a new model of managing health and safety in its revised version in 2013 (HSE, 2013) which is based on the PDCA model (Plan, Do, Check, Act). According to the new HSG65 guide, moving towards the PDCA model helps organisations to achieve a sense of balance when it comes to systems and behavioural aspects of management. The guide also shows that health and safety should not be considered as a stand-alone system but rather a part of an overall organisational strategy that seeks to continuously improve its performance in all aspects of management. Moreover, the HSE's guide indicates that the keys to effectively manage health and safety in any industry, size or nature of organisation is having a strong commitment from the leadership and management across all levels in the organisation, having trained and skilled workforce as well as an environment where people feel involved and trusted. It could be argued that such factors are also crucial in managing the patient safety risk within healthcare organisations through the creation of an environment where staff feel confident to report incidents and engage in discussions around safety matters.

Power (2004) pointed out that there is a need for 'intelligent' risk management that is not control obsessed and enables organisations to challenge the effects of the internal control system processes. Power indicated increasing public participation in risk management processes is important to challenge the older politics of risk which was solely based on expert judgement. Similarly, it was highlighted by Gallagher et al

(2001) that safety management systems can lead to failures in improving the overall safety if they fail to meet the needs of an organisation through adaptation and customisation of the system. For example, they noted that failures could also result due to lack of engagement, consultation and involvement of key players. This suggests that communication, information sharing, and employees' engagement and involvement are crucial for developing an effective management system. Traditionally, investigations and inquiries into investigations and mishaps always accepted the fact that human error as an adequate explanation for the causation of incidents. It was reported by Wright et al (1991) and Cooper et al (1984) that consistent finding of inquiries across a range of professions and industries linked human error to tragedies. Accident causation theories are discussed later in this chapter but there is a complex sequence of events which leads to the occurrence of an accident.

It could be noted that employers are legally required to put in place arrangements for the control of health and safety risks by ensuring that a policy is written and shared as well as having a systematic process for the assessment of risk and its management. Staff consultation and involvement are critical for the successful implementation of safety management systems as that will help in customising such systems to the local organisational needs.

2.5 Healthcare quality and safety

“Health is a state of complete physical, mental and social well-being and not merely as the absence of disease or infirmity”

(WHO, 1947, p. 1-2).

Health care systems are designed to improve the status of health and well-being of people. The provision of care should be done in a professional manner where patients are protected from harm. Healthcare professionals irrespective of their specialties are trained to maximise health and minimising pain, thus, it would not be fair to accuse healthcare workers of causing harm to patients. However, accidents will always happen. The Institute of Medicine (IOM, 2001) report titled *“Crossing the Quality Chasm: A New Health System for the 21st Century”* outlined a practical framework for

enhancing the quality and safety of healthcare. They proposed six dimensions of quality in healthcare as shown in Figure 2.3.



Figure 2.3: Dimensions of healthcare quality (adapted from IOM, 2001).

A core dimension is safety which suggests that quality and safety are interrelated. In order to provide high quality care, it is crucial that patients are treated safely. Thus, healthcare organisations need to ensure that problems and errors are handled in a systematic manner to prevent medical errors (Reason, 2000). Vincent (2013) affirmed that safety takes precedence over cost and productivity when it comes to healthcare as errors could lead to devastating outcomes. The intended results of the healthcare system are usually addressed by the concept of quality whereas safety is concerned with how the system is functioning and how patients should be protected from harm through adopting a proactive approach to accident prevention (Vincent, 2013). The focus of this thesis is on the safety dimension as it would not be very practical or achievable to focus on the six dimensions. It could also be argued that if safety is improved, then the other dimensions will improve accordingly. This is because of the fact that safety will aim to raise the standards of care through involving patients and their families in the process of care which will result in a patient-centered care. I also argue that understanding the process of safety improvement will yield in effective and

equitable care through the utilisation of resources and ensuring that patients receive the right care at the right time by the right people.

2.6 Emergence of patient safety

“To improve patient safety, we have many good ideas and concepts, some solid evidence and many promising avenues to explore, but we are never the less still at the beginning.”

(Vincent, 2006:236)

Vincent realised that patient safety evolves with time and that policy makers need to adopt a flexible approach towards patient safety which is based on continuous learning and improvement. Vincent (2010) stressed the fact that the practice of medicine will always be associated with inherent risks. The Hippocratic Oath contains the promise “to abstain from doing harm” and the words for “kill” and “cure” were similar in the Ancient Greeks. Over the past three decades, there has been much rigorous academic research and investigation of the healthcare-associated risks. However, throughout the history of medicine and nursing, patient harm recognised for example in the nineteenth century, Florence Nightingale observed the high infection levels in hospitals which was one of the biggest problems in healthcare at that time. During the 1960s, systematic studies about the hospital-associated harm started to emerge which was mainly triggered by insurance and litigation practices. In recent decades, high profile events emerged which further increased awareness about the issue of patient safety in healthcare. The landmark report which was mentioned in the introduction by the Institute of Medicine “To Err is Human” (IOM, 1999) along with the UK’s DOH report “An Organisation with a Memory” (Donaldson, 2002) in addition to other inquiries such as the Bristol Heart Inquiry resulted in better attention towards patient safety. This was evident because of the level of harm that was caused to patients due to system and organisational failures. Therefore, it is crucial to understand how such harm occurs so that our ability to reduce it improves.

Errors associated with healthcare and their effects are prevented and mitigated through patient safety interventions. There is wider evidence that substantial public health harm is caused due to poor patient safety in both developed and developing

nations. In the past, research in patient safety has been only associated with developed nations. However, there is a shift of focus to developing countries in recent years due to the global awareness of the need to enhance patient safety standards to all patients (Elmontsri et al., 2017, Wilson et al., 2012, Syed et al., 2008). There is an increasing trend in the global policy towards ensuring that access to care should be universal but should also be effective and of sufficient quality (Frenk and De Ferranti, 2012; WHO, 2017). Due to the increasing complexities of healthcare delivery, patient safety remains a persistent challenge in practice (Dixon-Woods, 2010). Studies in developed countries provided valuable insights about issues of patient harm due to poor care but there is more need for knowledge about the epidemic of unsafe care particularly in developing countries (WHO, 2011). Studies have shown that improving systems rather than targeting individuals results in reduction in the number of medical errors (Kohn et al., 2002, Nolan, 2000, Carayon et al., 2006). This indicates that healthcare organisations should focus on the problem of patient safety so that they can provide patients with high levels of care.

2.7 How big is the problem of patient safety?

Undoubtedly, healthcare is a hazardous business as it evolves around complex systems, advanced technology, sick patients and fallible professionals. Healthcare is classed as a 'safety-critical industry' as errors or design failures can lead to the loss of life (Illingworth, 2015; Institute of Medicine, 2001). Medical errors and deficiencies in the quality of care do not represent necessarily a lack of resources or failure of professional compassion (Institute of Medicine, 2001) but such deficiencies and errors occur due to gaps in the whole system and the inability of organisations to change (Berwick, 1989). Hence, health systems need to align all different functions and activities to deliver safe and high quality care. No health system is free of the occurrence of medical errors and harm to patients as studies over the world shown that harm caused by health care affects all health systems (Vincent and Amalberti, 2016). It is estimated that around a one in 10 patients admitted to hospital in the UK and other countries have a chance of being harmed. In Africa and the East Mediterranean, it is estimated that up to 18% of inpatient admissions were associated with adverse events. The study reported that around 3% of hospital admissions are associated with death or permanent disability (Wilson et al., 2012).

The cost of unsafe health system is not only human, but the financial cost is also significant. In 1999, the cost of medical error was estimated to be around \$29 billion per year in the United States (Kohn et al., 1999). The NHS Litigation Authority in the UK paid out more than £1.1 billion in litigation claims which is expected to rise to £1.4 in the coming years (NHS Litigation Authority, 2015). There is a need to create a culture of systems not just a culture of safety when it comes to improving patient safety (Mauro, 2016). In England, the Care Quality Commission (CQC) plays a major role in creating a positive change in patient safety. The CQC identifies health quality and patient safety failings and laps in different health and social care providers through regular unannounced inspections. According to the CQC (2017), safety remains among its greatest concerns. The CQC reported that 11% of NHS acute non-specialist trusts are rated as inadequate for safety. Moreover, more than half of trusts are required to improve how they respond to people needs how they organise their services. In its recent report, the CQC indicated that 60% of trusts requires improvement and 7% were rated as inadequate (CQC, 2017). As discussed in later sections of this review, patient safety research has been mainly carried out in developed nations and the level of patient harm in developing countries is very limited due to the absence of studies.

2.8 International Perspective on Patient Safety

As noted above, the problem of patient safety is an international one as reports from several countries highlighted the level of patient harm caused by poor systems and that further actions are needed to enhance the quality and safety of healthcare. It was evident that patient safety is becoming an international priority, for example, the World Health Organization established the Global Alliance for Patient Safety in 2004 in collaboration with the Pan American Health Organization, the UK' department of health and the US' department of health and social services as well as collaborating with other regional agencies. It is hoped that such an alliance would help in raising awareness among policy makers and healthcare workers about the issue of patient safety. It also aims to facilitate the use of error reporting and results so that lessons can be learnt across a global level. Some of the efforts taken by the US and the EU in regard to improving patient safety will be discussed. It was not possible to include all

efforts taken by other countries due to the limitations of this literature review. However, I can confirm that several countries especially in the Western world has established agencies and introduced legislations and national policies to promote patient safety.

2.7.1 United States

In the US, “To Err is Human” report raised the alarm and proposed that systemic failures cause or risk harm to patients rather than the actions of individuals. It was also affirmed in the report that a shift from a blame culture (section 2.17 discuss this further) is needed to enable healthcare organisations improve and learn from their past mistakes. Similarly, there was a shift towards the role of leadership and management in enhancing the process of patient safety within healthcare organisations (Leape and Berwick, 2005). The Patient Safety and Quality Improvement Act was passed by the US Congress in 2005 as part of the political leadership support towards enhancing the level of safety. This Act facilitated the process of creating patient safety organisations across the US to improve patient safety through the collection and analysis of data on patient events. Several other organisations such as the Agency for Healthcare Research and Quality, National Patient Safety Foundation and the Institute of Healthcare Improvement were also engaged in the process of improving patient safety across the US and at a global level.

2.7.2 European Union

Similarly, at the European level, the issue of patient safety came also into sight and was further stressed following the Luxembourg Conference in 2005 “Patient Safety – Making it Happen” which was supported and funded by the European Commission. The Luxembourg Declaration was announced following this conference which contained a list of practical recommendations to national authorities and healthcare providers across EU countries (EU Luxembourg Declaration, 2005). A European Forum was established based on these recommendations to focus on the member countries activities associated with patient safety improvement and to promote information sharing and organisational learning. The European Commission also supported that establishment of the Safety Improvement for Patients in Europe (SIMPATIE) that aimed to bring together the national efforts and follow on the Luxembourg Declaration. Several EU countries also participated in the WHO Global Alliance for Patient Safety (WHO, 2005). In 2012, the EU Network for Patient Safety

and Quality of Care (PaSQ) was launched by the European Commission and EU member states to help countries develop and implement specific policies on patient safety (European Commission, 2012). Therefore, it could be argued that countries and the political leadership have realised the need to improve patient safety in developed nations, but more efforts are needed in developing countries.

2.7.3 UK efforts to improve patient safety

A detailed case study analysis is presented in chapter 4 of this thesis which focused on the UK's journey over the past 14 years in relation to patient safety improvement. The case study analysis highlighted some of the bottlenecks, challenges and initiatives that were introduced by the UK government as well as other non-governmental institutions to enhance patient safety. It should be noted here that the UK's problem in relation to patient safety started when 30 to 35 children under one died after open-heart surgery in the Bristol Unit in the 1990s. Public inquiry into these incidents found that unsafe arrangements to care for very sick children were practiced which then emphasised upon the importance of clinical governance within National Health Service (NHS) organisations. As discussed in Chapter 4, the problem of patient safety was then highlighted by other reports which led to the introduction of legislations, regulatory agencies and professional bodies to help improve the standards of care. For example, as shown in Figure 2.4, following the establishment of the National Patient Safety Agency in 2002, healthcare organisations were required to report all types of incidents and adverse events to allow the process of learning from such incidents to the National Reporting and Learning System which is still in operation until now. It can be seen that reporting of incidents has been increasing gradually over the years.

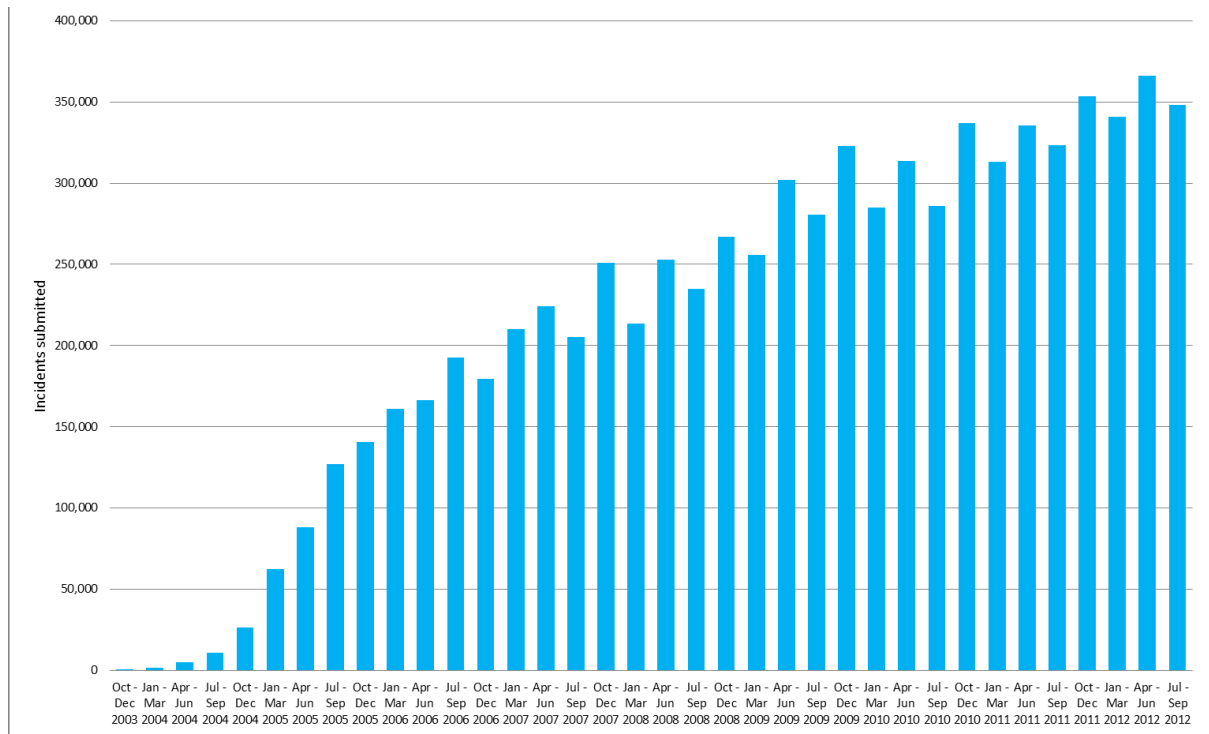


Figure 2.4: Number of patient safety incidents reported in England from October 2003 to September 2012 (NRLS Issue, September 2013)

2.9 Patient safety in developing countries

Over the past decades, policy makers around the globe have taken actions to improve safety in healthcare. In the UK, USA and Canada, several regulations and regulatory agencies were established to monitor and assess the quality and safety of care. Healthcare providers are urged to set clear safety goals and performance indicators as part of an ongoing process of improvement. However, there is a rising concern about the level of harm among patients in developing countries due to the lack of accountability. An example to this, the level of healthcare-associated infection affects hundreds of millions of people around the world and is considered one of the major global issues to patient safety in developing countries (Pittet et al., 2008). The World Health Organization created the World Alliance for Patient Safety in 2004. The Alliance's first global challenge was the prevention of healthcare-associated infection, 'Clean Care is Safer Care', was launched in 2005 in which 72 ministries of health signed a pledge of their support to implement actions that reduce healthcare-associated infection, 30 of these were developing countries (WHO, 2009).

Patient safety in developing countries is affected by material context, staffing issues and inter-professional working relationships (Aveling et al., 2015). In other words, shortage of financial resources, shortage of medical expertise and lack of advanced information technology affects upon the process of healthcare delivery in such countries. Shifting the blame culture in healthcare setting is also critical to improving overall patient safety in developing countries (Elmontsri et al., 2017). Efforts to tackle patient harm in developing countries must be scaled up and 'knowledge must be translated into practice' to make healthcare safer (WHO, 2011). In a systematic review that aimed to explore the current knowledge of patient safety and quality of care in developing countries in Southeast Asia found that four inter-related safety and quality concerns were evident which include the risk of patient infection, medications errors/use, the quality and provision of maternal and perinatal care and the quality of healthcare provision overall (Harrison et al., 2015).

Developing countries lack the required resources which could result in lack of commitment to healthcare by policy makers. Adequate supplies to control and perfection infections are not readily available and the compliance with hand hygiene, blood safety or proper waste disposal is very poor (WHO, 2000). There is also lack of quality control in disinfection and sterilisation as well as poor coordination of care especially to seriously ill-people. It is also recognised by the WHO that patient safety improvement in developing countries require different strategies due the limited capacity and infrastructure of these countries. Such strategies would need to be developed based on the available resources and expertise while taking into account the lack of regulations and accountability within such health systems.

2.10 Systems approach to patient safety

Patient safety requires a systematic approach which takes into account several factors in order to ensure that resources are utilised in the best manner and that healthcare workers are protected from harm. In the literature, different frameworks that focus on improving the interaction between humans, equipment and the working environment were found. Such frameworks focus on understanding the organisational factors that influence patient safety. For the purpose of this thesis, I will review some of these models which are of high relevance to the overall aim of this study. It was noted that

within these frameworks, more emphasis is being put on organisational factors that influence on patient safety. One of these models was developed by Reason (1990; 1997) known as the “Swiss Cheese Model” (Figure 2.5) which uses the slices of cheese to represent a series of barriers that are designed to prevent accidents. The idea is that such slices/barriers have holes in them and that if the holes in each barrier/slice line up with each other, an accident is highly likely to occur.

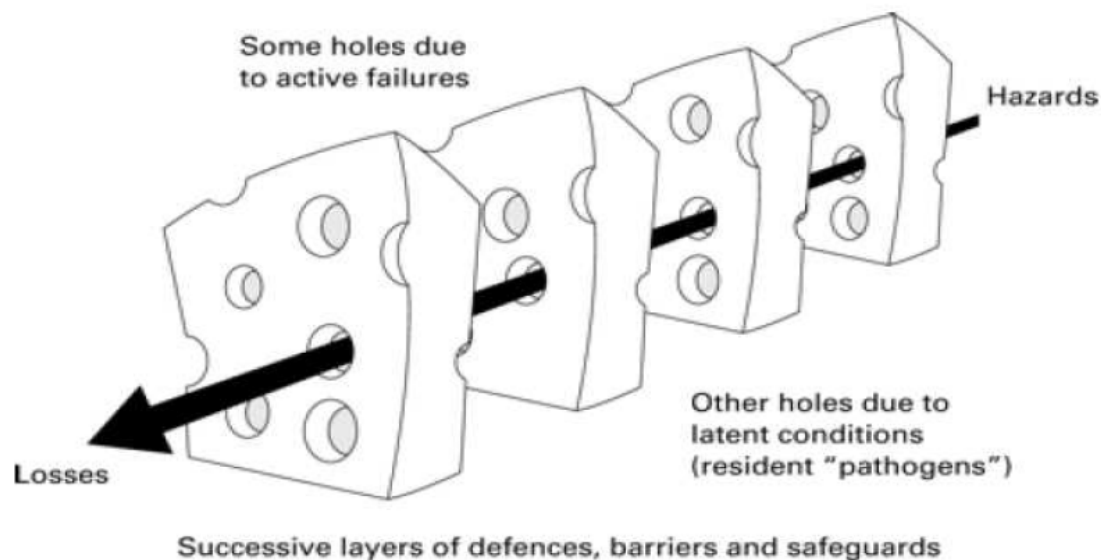


Figure 2.5: Swish Cheese Model (Source: Reason, 1997)

This model is widely adopted in the healthcare safety literature (Mooney, 2010; Reason, 2000; Morath and Turnbull, 2005) to highlight the need for integrating the process of care so that holes are not lined up to result in failures in the system. However, it could be argued that the complexity of healthcare ‘system’ may result in the creation of ‘holes’ where there is not sufficient level of performance measurement, auditing and monitoring. This model was described by Wachter (2008) as the widely accepted model for ‘system safety’. I will give an example of where failures could take place in a ward. If a nurse forgets to write down the time and dose given to a patient and then she/he hands over to another nurse who is expected to continue with giving medications to the patient. Nurses should be trained on how to involve patients in the process of care and if the patient is not asked, then there is a risk of giving the patient an extra does which he/she does not need or there is a risk of not giving the patient the required medication on time. Such failures could arise due to the absence of defence barriers such as well-defined hand-over protocols etc. Another critical point

to this model is that it mainly focuses on the direction of causality or linear model of accident occurrence as highlighted by Hollnagel (2004) and Dekker (2011). In other words, it could be assumed that the model focuses mainly on the parts and not on the whole system. Thus, as highlighted by Reason et al (2006) and Dekker (2011) that the Swiss Cheese model may not be applied in all situations due to the dynamic nature of accident causation especially in healthcare.

Another important framework which helps in understanding the complexity of healthcare delivery was proposed by Vincent et al (1998) which provided a link between difficult working conditions and the likelihood of making an error. According to Vincent et al (1998), seven types of factors impact upon the patient treatment which are as the following:

- Institutional context
- Organisation and management
- Work environment
- Team
- Individual
- Task factors
- Patient characteristics

Surely that each of these factors has many sub-factors that will influence upon the direction and quality of work being delivered. Thus, Vincent et al (1996) argued that there should be dynamic interactions between all these factors to ensure consistency and continuity of services. Vincent et al framework can be used as a starting point to understand the need for having a holistic and integrated approach towards patient safety improvement. The sub-factors for each dimension the framework are highlighted in table 2.2.

Table 2.2: Factors that influence upon clinical practice (source: Vincent et al., 1998)

Institutional context	Economic and regulatory context National Health Service Executive Clinical negligence scheme for trusts
Organisational and management factors	Financial resources and constraints Organisational structure Policy standards and goals Safety culture and priorities

Work environment	Staffing levels and skills mix Workload and shift patterns Design, availability, and maintenance of equipment Administrative and managerial support
Team factors	Verbal communication Written communication Supervision and seeking help Team structure
Individual (staff) factors	Knowledge and skills Motivation Physical and mental health
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient characteristics	Condition (complexity and seriousness) Language and communication Personality and social factors

Another important framework for quality assurance in healthcare comprises the categories of 'structure', 'process' and 'outcome' (Donabedian, 1966; 2003). The term 'system design' is used by Donabedian to mean 'structure' which includes the process of recruiting staff, building hospitals, legal protection of participants, drug testing and finance. According to Donabedian (2003), healthcare quality can be improved by focusing on what enhances the patient outcomes. In other words, by focusing and strengthening the system design along with the processes and procedures for providing care. This enables healthcare organisations to measure patient outcomes as well as evaluate the effectiveness and utilisation of resources. It could be argued that Donabedian and Vincent frameworks are more concerned with the organisational aspects of safety while the interactions between these aspects is not much explored by such models.

Finally, another framework was proposed by Carayon et al (2006) based on a systems engineering approach. They argued that when designing the work system, it is crucial to take into account the well-being of patients, employees as well as the organisational outcomes (Carayon et al., 2006). According to this framework shown in Figure 2. 5,

five components which include; person, tasks, tools and technologies; physical environment and organisational conditions are vital when designing systems and it is important to understand how such factors interact and influence each other. They pointed that patient safety improvement requires a systems approach, but such model does not take into account the cultural and organisational elements of different health systems. For example, it was argued by Boaden and Walshe (2006) that frameworks and models which focus on organisational aspects tend not to take into account the ‘culture and structures’ which are critical to the healthcare sector. As noted in Figure 2.6, this model is based on Donabedian’s framework for quality in healthcare but put much emphasis on the need for understanding the relationships between the different factors. Again, this framework does not provide a holistic approach to patient safety improvement as it focuses mainly on the internal factors. It does however highlight the importance of having the required resources in place, training and education for the healthcare workers as well as the importance of teamwork and communication to ensure patients receive high quality care.

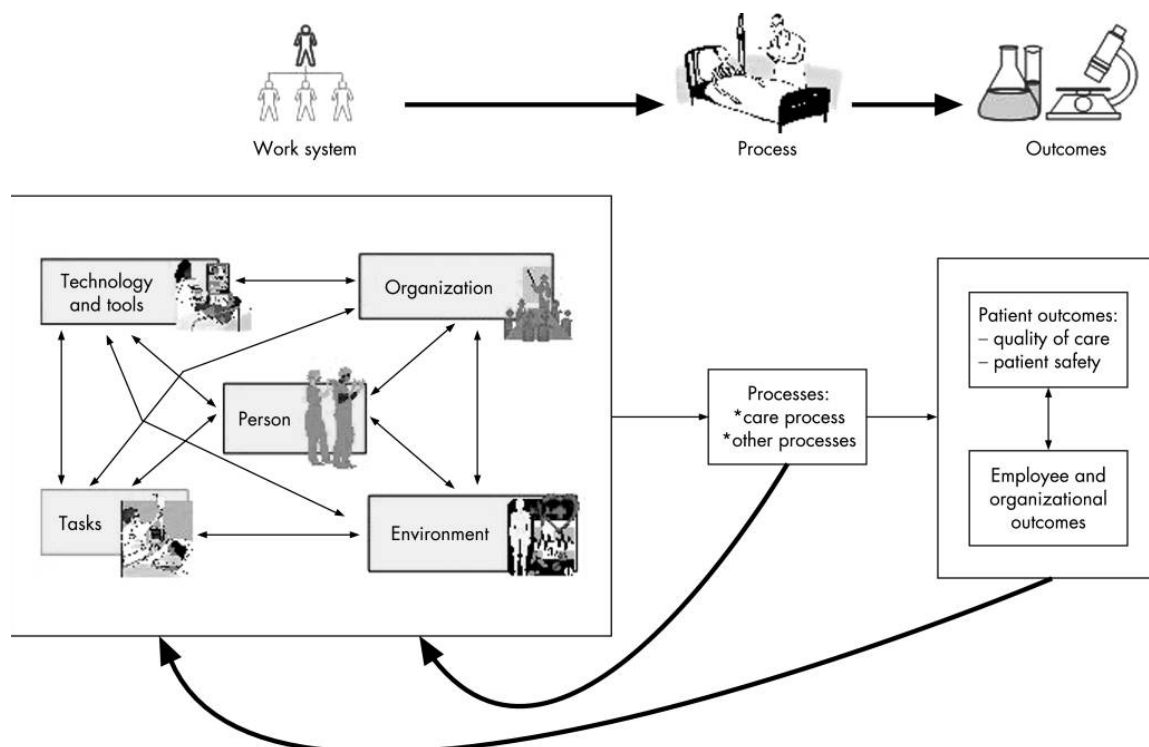


Figure 2.6: SEIPS model (Carayon et al., 2006)

While reviewing the existing frameworks and models associated with patient safety, it could be argued that:

- There is a wide acknowledgement of the influence of the organisation or system on patient safety

- System and organisation tend to be used interchangeably when designing frameworks associated with patient safety
- It was noted that those frameworks which focus on the system aspects tend to include more factors
- There is more evidence needed to explore the dynamic interrelationship of the different system parts/functions
- All of the studies and frameworks are focused on healthcare systems in developing countries
- None of the systems highlighted the role and importance of political leadership in enhancing patient safety

As highlighted by Gilbert et al (2007) and Dekker (2011) that existing frameworks does not take into account the complex socio-technical and cultural issues. Healthcare organisations operate within a dynamic complex socio-technical system as reported by several studies (Plsek and Wilson, 2001; Braithwaite et al., 2009; Plsek and Greenhalgh, 2001). Therefore, it is vital to focus on the wider systemic factors that influence upon patient safety especially in developing countries. Hence, this thesis would aim to fill in the gap in the existing literature about the need to develop a holistic framework which takes into account the role of different factors.

The following sections would focus on discussing the dimensions and factors which enhance the creation of a safe system within the healthcare. This is based on the critical evaluation of the existing literature in regard to organisational management theories and how certain organisational arrangements can lead to improvements in patient safety.

2.11 Risk management

As noted in some of the frameworks above that organisations need to focus on developing certain processes and procedures in place to enhance the organisational performance and avoid medical harm. One of the widely used aspects of management in organisations is risk management which is concerned with identify the different types of risks that could hinder the organisational performance. Risk management focuses on the gathering of information, evidence and expertise to prevent loss of life, reputation or money. As noted by Rasmussen (1997) that attaining overall

organisational success requires the management of business and organisational risks. Moreover, the practice of risk management enables organisations to identify the threats that might influence upon its ability to meet its long-term objectives. As noted by Ball and Ball-King (2011), there is no universally accepted definition of the term 'risk management' or 'risk assessment' but they highlighted that risk management is about 'what to do' with the identified risks. Hence, it should be made clear that risk management is about the overall process of identifying, analysing, managing and monitoring the risks.

It was pointed out by Stock and Sharman (2002) that risk management approaches focus on a proactive approach to the management of risk in today's era due to the learning opportunities gained from previous experiences. Thus, in order for healthcare organisations to function as per the desired outcomes, it is crucial that risk management is practiced within these organisations to enable them to identify the sources of threat so that control measures are put in place to control such risks/threats.

2.12 Risk management in healthcare

It could be argued that within healthcare organisations especially in the UK, the practice of risk management started during the 1990 with the rise of health and safety enforcement projects. The practice of risk management was mainly to ensure that organisations adhere to the requirements of the Health and Safety at Work Act 1994 along with the Management of Health and Safety at Work Regulations 1999. In the UK, the Health and Safety Executive is the statutory organisation with a role to monitor specific functions relating to health and safety in practices in all sectors. This means that healthcare organisations are among others are required by health and safety laws to ensure that users are protected from any types of risks including patients. It was pointed out by Cohen (1999) that risk management in healthcare could be described as the process of minimising or preventing harm through identification, analysis, treatment and evaluation. Similarly, the WHO (2009) described risk management as "*activities, which identify, analyse and reduce risk*". It could be argued that healthcare organisations can achieve their desired outcomes through integrating risk management in the corporate governance arrangements. This will help them adopting a more proactive approach to accident prevention. It also encourages the involvement

of different stakeholders in the process of risk assessment as well as promoting the process of open communication.

Healthcare organisations could be subject to different types of risks which can be either; financial, clinical, economic, political, reputational or environmental. Thus, having a proactive approach to managing risks would enable healthcare organisations to identify such threats and develop control measures in place to avoid such risks. As noted by Carthey et al (2001), risk management within healthcare organisations would help in building improved organisational resilience and flexibility to face uncertainty. It was pointed out by Ball et al (2008) that standards may be used as a way to set reference points for performance. Standards would help set reference points about acceptable levels of risk especially in situations where the process of decision-making is difficult. This can be applied to the healthcare sector as organisations can follow certain standards to ensure that patients are protected from harm.

2.13 Clinical governance

As discussed above, it is crucial for healthcare providers to take certain arrangements in place to enhance their organisational performance. One of the concepts that is believed to make healthcare is safe and effective is known as clinical governance which was launched in the UK in 1997 as part of the NHS reforms (Department of Health, 1997). Clinical governance is described by Scally and Donaldson (1998) as:

“A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”.

(Scally and Donaldson, 1998, p. 61)

It can be understood from this definition that healthcare organisations are urged to develop continuous improvement strategies and initiatives to enable them achieve excellence in clinical care. This could be linked to quality improvement efforts being undertaken by organisations to enhance their quality of services. Clinical governance focuses on the need to carry out audits and performance measurement to identify gaps and weaknesses in the system. It also emphasises upon the need to enhance patient

safety through continuous monitoring and measurement of patient data. More importantly, clinical governance promotes patient focus and public involvement activities which are very critical to the process of care. According to NPSA (2004), healthcare organisations are urged to be open about patient safety through the investigation and analysis of safety incidents to allow for improvement. A system of accountability is also enhanced by clinical governance practices which also encourages the creating of learning organisations. Thus, it could be argued that such management practices would allow healthcare organisations to continuously monitor and measure their performance so that improvements are made. Thus, a holistic approach to patient safety should also focus on the need to integrate risk management and clinical governance as part of the organisational structure.

2.14 Organisational culture

The previous sections focused on the need for organisations to focus on developing effective processes and systems in place that support patient safety. However, it is also important to consider the influence of culture on organisations. As noted by Schein (2004) that culture is a term which is difficult to define and that the issue of organisational culture is that we cannot see it, measure it or touch it but it is formed as a result of the behaviours and interactions of individuals within these organisations (Schein, 2004; 1990). According to Schein (1985), culture is described as:

“A pattern of shared basic assumptions that a group learns as it solves its problems of external adaptation and internal integration, that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think and feel in relation to those problems.”

(Schein, 1985, p. 17)

In the literature, it was evident that organisational culture, communication systems, patient involvement, leadership styles and human resources management practices influence the successful implementation of patient safety interventions (Firth-Cozens and Mowbra, 2001; Wakefield et al., 2001; Nieva and Sorra, 2003; Pronovost et al., 2003). Therefore, organisational culture should be considered as critical factor when it comes to improving patient safety within healthcare organisations. Schein (1992) asserted that culture is transmitted through behaviours, attitudes, values and beliefs

among groups which will set their mind to a certain way of thinking. This means that their actions will also be influenced by their beliefs and values. Flin et al (2004) stressed the need to balance cost reductions and budget cuts with quality and patient safety standards. Zohar (2000) asserted that if managers will be rewarded for their cost reductions that could influence upon patient safety and the culture of safety within organisations. Moreover, organisational changes would also affect upon the development of positive safety culture as highlighted by Parker et al (2006). Fleming and Wentzell (2008) pointed out that a change in leadership could result in the introduction of new systems and processes that could affect safety. This could suggest cultural variables should be taken into account when developing patient safety systems so that resistance to change and other barriers are prevented. Singer et al (2009) reported that the organisation's climate of safety is highly influenced by the aspects of organisational culture. This could mean that if the leadership is not committed towards safety that will create a negative attitude towards safety from the rest of workforce which is dangerous for healthcare organisations.

2.15 Safety culture

Safety culture is very central to this thesis because cultural variables influence upon the adoption of administrative systems. Moreover, developing countries suffer from high levels of corruption, bureaucratic arrangements and lack of transparency which could all affect upon patient safety improvement efforts. It was affirmed by many studies that a positive safety culture would enable staff to discuss patient safety and harm more openly so that lessons can be learnt to improve services (Frankel et al., 2003; Cox and Flin, 1998). In the past, it was highlighted by Deilkas and Hofoss (2010) that traditional approach to patient safety was mainly associated with establishing mortality committees, reorganisation health service providing systems as well as scrutinising accidents. However, recent developments in the academic literature as well as policy guidance from leading organisations such as the WHO, IHI, National Patient Safety Foundation and the Health Foundation in the England and the Care Quality Commission all encourage the need for creating a positive safety culture as an effective and sustainable strategy for safety improvement (Azimi et al., 2012).

Similarly, it was argued by Bonner et al (2009) that the rate of adverse events and medical errors is associated with healthcare workers' attitudes towards safety. Establishing a culture of safety would enable healthcare organisations to identify wrong practices and encourage open discussions of safety issues (Alizadeh, 2005). As noted by the DOH (2000), a positive safety culture would enable organisations to learn from past mistakes. Pizzi et al (2005) asserted that commitment towards patient safety can be enhanced through a positive safety culture among healthcare workers. A positive safety culture as highlighted by Pizzi et al (2005) has the following features:

- Recognition of a high risk environment,
- A blame free reporting system,
- Collaborative work environment, and
- C commitment of resources to change unsafe situations.

Sammer et al (2010) carried out a systematic review into what forms a positive safety culture have identified seven sub-cultures of patient safety which are:

- leadership
- teamwork
- evidence-based
- communication
- learning
- just, and
- patient-centred

it was also evident in the literature that a positive management approach to safety culture would guide the behaviours of the health workforce and establish a sense of responsibility towards safety. Neiva and Sorra (2003) asserted that the top management should place patient safety high on the agenda to influence upon the behaviours of their healthcare workers. Therefore, it could be assumed that safety culture can be created in the workplace through understanding how human behaviours and attitudes are shaped as discussed in the following section.

2.16 Human factors and patient safety

Safety culture as noted above is the shared values among healthcare workers in the workplace. These shared values will influence upon the individual's behaviours and attitudes towards safety. In the field of patient safety, it was evident in the literature

that more focus needs to be shifted towards human factors engineering (HFE) which is defined as the *“discipline concerned with the design of tools, machines, and systems that take into account human capabilities, limitations, and characteristics”* (Gosbee, 2002, p. 352). In other words, it is important for healthcare organisations to ensure that human factors and behaviours are taken into consideration when developing systems and policies. Human factors has become critical as it evaluates how people, equipment and the environment interact with each other. Such interaction influences upon the overall process of healthcare delivery (Carayon, 2016). Safety culture is influenced by the behaviours and leadership styles as discussed above. This means that existing systems should be evaluated to identify any weaknesses that could lead to adverse events.

Human factors engineering also takes into account the internal and external factors which could affect upon human performance (Nacioglu, 2016). The risk of occurrence of unsafe events could be increased due to the influence of several circumstance on human performance. For example, it was noted that mental and physiological states such as boredom, hunger, stress, fatigue and dehydration play significant role in the occurrence of unsafe events. On the other hand, the process of decision making can be directly influenced by attention, reasoning, perception, judgement and memory. This also leads to the importance of developing a teamwork culture within healthcare environments to enable team member's support each other in times of difficulties (Weller et al., 2014). The WHO Curriculum for patient safety stressed the importance on human factors in healthcare organisations. It helps to understand relationships between humans-humans, humans-medical equipment and humans-environment (WHO, 2008). This suggests that people are more likely to do the right things in the right environment. Hence, such important dimension is crucial when improving patient safety in developing countries. This leads to the level of training, support and feedback healthcare workers receive to enhance their skills and adjust to the working environment. It could be concluded that human performance is highly influenced by the availability of right tools, equipment and managerial as well as leadership support. Such issues are very critical to health systems in developing countries.

2.17 Education and training

Many developed nations have integrated patient safety and quality into the medical and nursing curriculum to raise awareness and improve the skills and competencies of the health workforce. This also helps in changing the human behaviours and perceptions towards patient safety as noted above. The WHO has developed the Patient Safety Curriculum Guide for Medical Schools that is designed to be implemented in any medical school irrespective of geography or culture. Many medical schools around the world have integrated the curriculum into their teaching and learning materials (Walton et al., 2011). Thus, it is highly urgent for medical and nursing educational establishments in developing countries to implement such guide to help raise awareness about patient safety improvement among the workforce. Training and development programmes should be available for clinical and support staff through their careers. Improving patient safety requires the changing of culture of healthcare organisations and professionals through training and engagement (Patey et al., 2007). Medical and nursing colleges along with professional agencies and bodies have realised that ongoing training and licence validation is crucial for ensuring that healthcare workers are competent. The issue of medical licensing and certification in developing countries should also be brought to attention as such practices influence upon patient safety. General Medical Council in the UK has also introduced several modules on patient safety to enhance knowledge, expertise and skills of practitioners.

It was argued by Ferlie and Shortell (2001) that educational interventions should be assessed in terms of their effectiveness. They argue that efforts to improve patient safety through education of individuals have succeeded in only marginal ways. This could be because of the fact that patient safety relies heavily on teamwork and interaction. Thus, education and training should focus on developing communication and teamwork skills. This will be discussed further in later sections of this literature review. For example, maternity team training was found effective in its contribution to preventing errors, thus improving patient safety in acute obstetric emergencies as reported by Merién et al (2010). All levels and types of formal, informal and continuing medical education programmes should be included when designing and implementing training in patient safety as highlighted by Elkin and Gorman (2002). This could be because of the fact that the process of care evolves with technology and changes in

the nature of disease. Thus, healthcare workers need to update their skills, knowledge and competencies on an ongoing basis. On-the-job-training is also seen as an important tool as noted by Manning et al (2003). They argued that staff nurses should provide coaching to the more junior nursing staff as that will help in rectifying practices that could affect patient safety. Simulation-based education and training has become very common in medical colleges to enhance patient safety (Ziv et al., 2000; Kyrkjebø et al., 2006; Aggarwal et al., 2010). Therefore, this is another important dimension that should be taken into consideration when thinking of improving patient safety in developing countries. Such countries may suffer from poor education infrastructure as well as lack of resources which affects the process of medical and nursing education.

2.18 Leadership for patient safety

Moving from the role of education to enhancing patient safety within healthcare organisations, it is important to discuss that medical and health professionals need supportive leadership so that they can use their skills and competencies that they learnt. In the literature, it was evident that leadership plays a vital role in patient safety. It is because leaders influence upon the shaping and creation of the organisational culture as noted above. Leaders' attitudes towards safety would affect upon the perception of other healthcare workers (Yang et al., 2009). It is very common among hospitals in today's era that boards and senior executives discuss patient safety on a regular basis as well as highlight its importance to other workers (Jha and Epstein, 2010). Moreover, it was pointed out by Ebright et al (2002) that a new approach to patient safety should involve senior nurses in a leadership role. This helps in understanding patients' needs and meet their expectations. As discussed above, the process of decision making with healthcare environment is complex and critical to the safety of patients. Thus, leaders would need to focus on creating a just and open culture where all workers have the ability to share their views, concerns and opinions that would help in improving the services. Another important strategy which has proven to be effective is known as 'leadership walkrounds' (Frankel et al., 2003). Leadership walkrounds would involve a group of senior executives and clinicians conducting regular visits to different units and wards within healthcare settings. This would help in talking directly to nurses and patients to identify any weaknesses in the system and highlight any adverse events or near misses.

It was also pointed out by Manser (2009) that leaders need to encourage teamwork to enhance patient safety. Manser asserted that leaders need to alter their leadership styles depending on the situation. In other words, leaders need to value contributions from staff as well as encourage participation in decision-making. Künzle et al (2010) highlighted the importance of leaders in promoting team performance and safety. They argued that leaders within healthcare organisations need to have clear and unambiguous behaviours that can be adapted based on situational demands. This again highlights that without effective leadership within healthcare organisations that are committed towards enhancing the quality of services, patient safety efforts would be hindered. This was noted by Bennis and Townsend (1995) who stated that:

“Leaders are interested in direction, vision, goals, objectives, intention, purpose, and effectiveness - the right things. Managers are interested in efficiency, the how-to, the day-to-day, the short run of doing things right.”

(Bennis and Townsend, 1995: 6)

It was demonstrated by inquiries into the Mid Staffordshire Trust and in Bristol Infirmary that the failure of the leadership team to function as an effective team leads to failures in large systems to improve safety. This also affirmed by Donaldson (2001) who argued that the changes required within healthcare organisations will not be made without the commitment of organisational leaders. This suggests that leaders have a responsibility as well as the authority to promote patient safety within healthcare environments. Leader should also act as mentors to other healthcare workers so that they can overcome the daily challenges (Mohr et al., 2002). Therefore, leadership for patient safety is critical as it affects upon the organisational culture, safety culture, teamwork and communication as well as creating a culture of trust among healthcare workers. Leaders play an important role in promoting teamwork as discussed in the next section.

2.19 Teamwork and communication

Another important dimension in the field of patient safety is the need to improve team-working and communication across healthcare organisations. This was evident also in many inquiries such as the Bristol Royal Infirmary inquiry (Department of Health, 2001) which reported that flawed communication, poor structural organisational, inadequate

resources, ineffective leadership and team-working were linked to poor paediatric cardiac surgery that caused high mortality rates within the organisation. Teamwork enables healthcare workers to support each other to ensure that patients receive the required level of care. A study by Schenkel (2000) aimed at promoting patient safety in hospital emergency departments reported that teamwork and communication between pharmacists and emergency physicians are among the system-level efforts in error prevention. As discussed above, leadership commitment towards improving patient safety requires open and flexible communication among all healthcare workers. It will also help in creating a culture of trust as well be discussed in the following section. It was affirmed by Turnball (2001) that teamwork is highly critical for the success of healthcare systems. Turnball indicated that care providers (physicians, nurses, pharmacists and leaders) as well as consumers (patients and their families) should all be included in creating teamwork culture within organisations. Patients can be empowered through involving them in the process of care as well as preventing errors and mitigating the effects of errors if they happen through teamwork. As discussed in chapter 1, the process of care is very complex when compared with other industries. Thus, teamwork as noted by Bender (2000) is crucial for the prevention of errors in healthcare environments. In addition to this, Bender asserted that poor communication between healthcare providers and patients would lead to errors. This shows that healthcare providers need to develop the skills of the workforce so that they can work in coordination to provide high quality care.

Other studies reported that poor communication and handover of patients leaving hospitals could have harmful safety implications and the rise of adverse events (Kripalani et al., 2007; Forester et al, 2003). In other words, speeding up discharges without coordinating with other departments and healthcare workers could result in negative impacts. However, it should also be noted that healthcare team learn their skills and competencies through different ways which affects upon their communication and teamwork skills. It could be argued that medical students, allied health professionals, doctors, nurses, ancillary staff and pharmacists learn in linear fashion (individualistic approach) which might not be practical in day-to-day routine. It was also noted that several medical schools and universities have recognised the need to train professionals together so that they can improve their communication and

teamwork skills (Marshall and Gordon, 2010; Hall and Weaver, 2001; Lerner et al., 2009; Walton et al., 2011). It was also evident that training helps healthcare workers to develop such skills as reported by Jones et al (2008) which found that team training is useful for individual members to improve their ability to cope with stressful situations and share personal experience of unsafe practice in mental health services. Catchpole et al (2008) affirmed that team training also improves patient safety within theatre teams and helps in developing operating room skills. Team training was also beneficial in labour and delivery within maternity services (Mann et al., 2006) and during medical education (Thompson et al., 2008). This shows that urgent need for healthcare organisations to assess the effectiveness of their teamwork and communication and how it affects upon the overall process of care.

2.20 Trust and blame

“Blaming and punishing for the inevitable errors that will be made by well-intentioned people working in health care drives the problem of iatrogenic harm underground and alienates those who are best placed to prevent such problems from recurring”

(Runciman et al., 2003, p. 978)

When making errors in media, customer service, academic or purchasing, an apology or some form of compensation may be used to rectify the error. However, in healthcare, the situation is different as such errors and mistakes could lead to devastating situations in which money or apology cannot put right. Patients, their families, doctors and nurses involved would all be affected by this impact. It is human nature that those involved would blame themselves if a patient is harmed. This is called as the ‘second victim’ situation as highlighted by Wu et al (2009). The problem of blame culture in healthcare organisations hinders efforts to improve patient safety. It was affirmed by the Francis inquiry (Francis, 2013) that the problem of blame culture still exists in healthcare organisations in England. The report quoted the following:

“To place too much emphasis on individual blame is to risk perpetuating the illusion that removal of particular individuals is all that is necessary. That is certainly not the

case here. To focus, therefore, on blame will perpetuate the cycle of defensiveness, concealment, lessons not being identified and further harm”

(Francis, 2013, p. 35).

This affirms that blaming will not lead to system improvements on the long-term. It is crucial that mistakes in healthcare organisations are reported, discussed and investigated so that the root causes are identified. It would be difficult for healthcare professionals to report any incidents if they believe that they will be blamed for such failures. It was affirmed by Parker et al (2006) that a major factor which prevents disclosure to patient safety is blame. Several scholars highlighted the need for healthcare organisations to move away from blame culture as it discourages disclosure and reporting (Woodward et al., 2009; Lawton and Parker, 2002; Cooper et al., 2017). Such culture would also encourage healthcare workers not to report or admit mistakes and harmful systems would be created as a result (Sorensen et al., 2008). A culture of blame cannot only be shifted if healthcare workers develop a culture of trust among them. A culture of trust is vital not only among patients and doctors but among managers, practitioners, policy makers and the general public. Several scholars investigated the value and nature of trust in healthcare (Smith, 2005; Rowe and Calman, 2006; Pilgrim et al., 2010). A culture of trust is found to be positively correlated with high quality care. Senior staff can create a culture of trust as argued by Bark et al (1997) through talking openly about past mistakes and encourage their colleagues to report such incidents to help create a learning organisation. Leaders have a major role to play in creating a culture of trust by encouraging disclosure of the unsafe systems to enable improvement and learning (Mohr et al., 2002). Therefore, it could be argued that policy makers in healthcare need to focus on the issue of building a culture of trust and eliminating the culture of blame to help create learning organisations that would improve based on previous performance.

2.21 Gap in literature

It was highlighted in the literature that patient safety requires a more integrated approach based on the involvement of key stakeholders such as policy makers, healthcare professionals, patients and their families. However, it was also noted that patient safety is influenced by many factors such as the lack of leadership support and

management commitment towards incorporating safety practices as well as the difficulties that face organisations to shift the blame culture that exists which hinders the reporting of incidents and adverse events. Moreover, most of the reviewed studies were mainly associated with health systems in developed countries where only few studies were carried out to trigger the alarm about the size of the problem in developing countries. It could be argued that the barriers that hinder developing countries from adopting patient safety systems and interventions even through proposed by the WHO are not addressed in the literature.

Furthermore, the literature suggested that there is a research opportunity to focus on the factors that influence patient safety in healthcare settings in developing countries and how such countries can adopt a more integrated approach to improve the quality of care. The WHO has introduced some initiatives such as raising awareness about the negative effects of infection control in developing countries (Pittet et al., 2008) but effectiveness and performance measurement of such initiatives remains to be limited. Moreover, it was argued by Carpenter et al (2010: p. 48) that *“patient safety research in developing and emerging countries has been infrequent and limited in scope”*. Alhawsawi and Barach (2017) asserted that strong regulatory bodies are highly needed in developing countries to enforce higher quality standards for healthcare providers and healthcare professionals. There is a need for further research to identify the challenges and priority areas for patient safety improvement in developing countries. This will help in contributing to existing knowledge as well as identify pragmatic themes for enhancing the quality of care.

2.22 Chapter summary

The purpose of this chapter was to critically review the past research related to patient safety. The review highlighted that the field of patient safety has evolved over the past three decades and that several countries as well as international organisations have realised the importance of enhancing patient safety to provide patients with reliable and efficient care. The review also indicated that most of the existing research on patient safety has been carried out in developed countries as they have the resources required to introduce new interventions and initiatives. Considerable efforts were made to enhance patient safety across many developed nations such as the US and UK, but

little has been done to highlight the size of the problem in developing countries. There still remains a knowledge gap on how to strengthen health systems in developing countries to enhance the quality and safety of healthcare. More importantly, it is important to reflect on the fact that patient safety has become a major public health problem as set out by the WHO and further efforts are needed to support developing countries strengthen their health systems. This requires the provision of evidence-based models and frameworks that would help such nations to incorporate patient safety into their health policy planning. The following chapter presents the research methodology.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the research methodology that was adopted for this thesis. I present a description and justification of the research design that was selected for this thesis. I also discuss the different data collection tools that were used. The selection of this methodology was largely supported by previous literature.

3.2 Philosophical approach

Several Philosophical approaches exist in literature. Research philosophies are linked to the development of knowledge and the nature of that knowledge. Collis and Hussey (2003) pointed out that researchers can determine the style of tools that used for data collection based on the assumptions of research philosophies. In other words, the selection of tools would depend on the nature knowledge being acquired. I will not go into detail about the different types of philosophical approaches, but I will discuss the selected philosophy which underpinned the research methodology adopted for this thesis. The overall aim of the thesis is to achieve improvement through the development of knowledge. Therefore, pragmatism philosophy was selected as it encourages to focus on the usefulness of knowledge. As described by Peirce (1992), pragmatism is a “theory of truth” that seeks the reality of human thoughts. Peirce defines pragmatism as:

“Consider what effects that might conceivably have practical bearings, we conceive the object of our conception to have. Then, our conception of these effects is the whole of our conception of the object”

(Peirce, 1992: 132).

Patton (2002) and Cherryholmes (1992) described pragmatists as those who look for what worked best and seek to provide solutions to problems. Thus, my aim of this thesis is to identify ways for improvement based on what works best. Pragmatists tend to conduct dynamic and innovative research which is adaptable to changes in the environment and responds to how the study evolves (Cheeryholmes, 1992). Moreover, it was highlighted by Rorty (1999) that the pragmatist approach enables researchers to change the question from “Does this knowledge accurately reflect the underlying reality?” to asking, “Does this knowledge serve our purposes?” This was also affirmed by Tashakkori and Teddlie (2003) who argued that methodological pragmatism focuses on what works as the truth regarding the research questions under investigation. Hence, this philosophical approach was selected to guide my research methodology.

3.3 Methodological approach

The methodological approach adopted for data collection and to achieve the objectives of the study will be discussed in this section. All study phases are interrelated, and it was important to select the right approach for collecting data. Before I discuss the different tools used for data collection, it is important to briefly describe the differences between the most common research approaches known as the; qualitative, quantitative and mixed method approaches. This will help in clarifying the research design adopted for this study. A research design as highlighted by Creswell (2013) provides an outline of the tools used for collecting, analysing and discussing the data in relation to the research questions or objectives. Bryman and Bell (2007) pointed out that there are five main types of design. It is important that these designs are not confused with the methods of data collection as maintained by Bryman and Bell (2007). These types are:

- Experimental

- Cross-sectional
- Longitudinal
- Comparative
- Case study

3.3.1 Qualitative methods

Qualitative research methods allow researchers to collect non-numerical outcomes of data which is widely used in business studies, education, social sciences and health care science (Hussey and Hussey, 1997). Qualitative research aims to collect textual data using an inductive approach to develop concepts and themes. Data collection is done by the researchers as they act as the key instruments by observing behaviours, reading and evaluating documents or interviewing people. What is good about qualitative research is its connection with the phenomena being explored as it often takes place in natural settings (Ghuri et al., 1995). There are several data collection techniques that are used in qualitative research as pointed out by Creswell (2013) which include; action research, case study research, ethnography, interviewing, observations and analysis of archival documents. The reasons for selecting this approach for this thesis are further discussed and justified in section 4.8.

3.3.2 Quantitative methods

The opposite of the qualitative approach is known as quantitative methods which is associated with numbers that are analysed using statistical procedures. This is because the science problem is composed of variables that can be measured using numbers (Creswell, 2013). According to Creswell, quantitative research is usually adopted to test a hypothesis by assessing relationships between variables. Statistical procedures are used to analyse quantitative in which researchers use an objective position as the procedures used for analysing quantitative data are often described in detail which can be replicated by others. Hence, a quantitative approach would be more convenient if researchers are seeking to quantify relationships between different variables of interest. In my initial research proposal, it was planned that a quantitative approach would be adopted as the initial research aimed to understand relationships between different variables associated with patient safety culture such as the relationship between leadership support and the level of reporting incidents. The use

of quantitative approach usually tends to rely on large scale sampling that allow researchers to examine group means and variances. As noted by Denzin and Lincoln (2000) that quantitative methods stress upon the measurement and analysis of correlation or casual relationships between variables. Therefore, this approach was not adopted for this thesis as this thesis is not seeking to examine correlational relationships nor seek to test a hypothesis.

3.3.3 Mixed methods

Mixed method approach enables researchers to combine both quantitative and qualitative approaches for data collection. In other words, as pointed out by Jick (1979), these approaches would complement each other through utilising the strengths of each approach and minimising biases. Johnson and Onwuegbuzie (2007) asserted that there is no agreed definition of mixed methods. I have used Creswell and Plano-Clark (2007) to define mixed methods as they define it as:

“As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of qualitative and quantitative approaches in many phases of the research process. As a method, it focuses on collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone”

(Creswell and Plano-Clark, 2007)

It would be more effective if there were some data available on the rate of adverse events in Libyan health system as that will allow me to use such data to measure the level of harm compared with other health systems and also find relationships between different variables. However, due to the lack of such data, a mixed method using both quantitative and qualitative approaches will not be suitable for this study. However, Creswell noted that mixed method approach can be adopted using a Triangulation design where researchers can use different qualitative methods for collecting different types of data from different sources which was adopted for this research.

3.4 Case study design

The approach adopted for this thesis is based on a case study design. The reason is that this research is aiming to improve patient safety in Libya based on understanding the contextual and organisational factors that prevent the Libyan health system from incorporating patient safety into the existing structure. Moreover, I am trying to investigate the problem through its real life context by communicating with Libyans and experts who are familiar with the Libyan geo-political position. Moreover, I have also collected data based on the analysis of the UK system in relation to patient safety as reported in Chapter 4. This is how Yin (2003) defined a case study design:

“An empirical inquiry that investigates a contemporary phenomenon within its real life context, especially when the boundaries between phenomenon and context are not clearly evident”

(Yin, 2003; p. 63)

To be able to understand the dynamics associated with patient safety, data was collected using participants and direct observations as well as a pragmatic approach. Case study design as evidenced in the literature is very valuable for health science and services research as it helps in evaluating programmes and developing interventions. Yin (2003) asserted that case study design should be considered when researchers are aiming to answer the question of ‘how’ and ‘why’ as well as when researchers cannot manipulate or influence upon the behaviours of those recruited in the study. The case study design should also be adopted when researchers want to cover the contextual conditions because of their relevance to the phenomenon being investigated. As explained further in section 4.8, the case study design is very convenient for this thesis as it allowed me to focus on the contextual factors.

3.5 Methods used for data collection in this thesis

The data collection methods that were used in this thesis will be discussed here in further details. Chapter 4 will compile the results of all phases of the study. Creswell et al (2003) noted that all research designs have limitations, it was ensured that different methods were used for data collection so that a holistic framework for patient safety improvement in Libya is developed.

3.5.1 Literature review

As Hart (1998) pointed out that a literature review aims to survey the available academic literature to identify gaps in knowledge on a given subject. Hart asserted that literature reviews enable researchers to suggest fruitful avenues for research. The literature review also helps researchers to attain a high standard of scholarly rigour in their thesis through demonstrating originality and enables researchers to make a new contribution to an area of knowledge when the gaps are identified through the literature survey (Hart, 1998). Therefore, it could be argued that this study is built on the basis of the literature review. As highlighted by Phillips and Pugh (2002) that demonstrating originality in research will depend on the extent to which researchers carried out a solid and systematic understanding of a subject area. In research, a literature review is a fundamental methodological ingredient. The overall purpose of a literature review is to form the basis of the goal of this thesis through brining the reader with up-to-date synthesis of relevant literature. It was argued by Carnwell and Daly (2001) that a good literature review should have a clear search and selection strategy as well as being based on many sources. Colling (2003) stressed the importance of referencing which should be accurate throughout the literature review. Therefore, a literature review was conducted which was presented in Chapter 2 along with the search strategy. This review highlighted the gap in the literature as well as the justifications for this study.

3.5.2 Document analysis

Document analysis is a qualitative tool that is used to elicit meaning, gain understanding and develop empirical knowledge (Corbin and Strauss, 2008). Documents can vary in type, length, publisher and authors which contain text and images as well as analysis case studies. The overall purpose of the document analysis method is to review and evaluate existing evidence to identify patterns and themes. This method was adopted for the case study analysis of the UK's journey in regards to patient safety. The document analysis was an efficient tool to identify the critical events in the UK's journey over the past 15 years. Altheide et al (2008) pointed out that document analysis allows researchers to search for contexts, patterns, processes and underlying meanings. They also argue that document analysis will expand as *"recording technologies improve ad become more accessible, including print and electronic media, audiotapes, visuals, Internet materials..."* (Altheide et al., 2008, p.

129). This method was also used as part of this thesis to enable develop patterns and themes that useful for the development of the framework for patient safety improvement in Libya.

3.5.3 Systematic review

A systematic review was also used as a method for data collection. Systematic reviews are not as traditional or narrative reviews as they use more rigours and well-defined approach to review the literature (Cronin et al., 2008). They pointed out that systematic reviews help to answer well-focused questions using a well-planned method. The characteristics of systematic reviews were highlighted by Parahoo (2006) who indicated that they should contain specific questions and specific time frames. Inclusion and exclusion criteria of the studies found should also be clearly outlined so that bias is avoided. Hence, it was decided to use a systematic review to capture the current status of patient safety culture in Arab countries that share some cultural and organisational structures in health systems with Libya. The systematic review was carried successfully and was also published in the British Medical Journal (BMJ Open). The systematic review also highlighted the current problems associated with patient safety in Arab countries which further provided evidence to help develop the framework. Chapter 4 presents the findings of the systematic review along with detailed discussion of the methodology adopted for the systematic review.

3.5.4 Focus groups

Focus group is also a qualitative method used by researchers to collect textual data. It is described by Hussey and Hussey (1997) as an interview with a group of participants to discuss a specific subject in order to identify patterns and themes. Focus group is defined as:

“A group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research”.

Powell and Single (1996, p 499)

Focus groups were mainly used in market research and are dated back to the 1920s as market researchers were interested in gathering information about product

preferences (Basch, 1987). Focus groups have become a useful tool in healthcare research to identify ways for improving health services as well as the effectiveness of certain interventions on human behaviours (Rudolph and Hill 1994). It was pointed out by Hussey and Hussey (1997) that focus groups are used to congregate data related to the opinions, experiences, feelings, reactions, beliefs and attitudes of a group of people. Patton (1990) described the application of focus groups in different types of research. He pointed out that focus groups can have different types of purposes such as:

- Action research – to solve problems (specific in nature)
- Applied research – to identify and explore programme effectiveness
- Formative evaluation – to define areas for improvement
- Basic research – to add new knowledge or test a fundamental theory

Focus groups were employed as a method in this thesis to gain deeper insights about the existing problems that face the Libyan healthcare system in improving patient safety. Due to access issues in Libya, the focus groups were conducted with Libyan healthcare professionals in the UK who have studied and worked in Libya but have left the country in the past years. Two focus groups were carried out. The focus groups were conducted in alignment with the guidelines set by Hussey and Hussey (2007) as well as Saunders et al (2003) as discussed in more details in Chapter 4.

3.5.5 Delphi study

The Delphi technique has been widely used in health services and policy research as it supports decision-making and gives a way of structuring a large mass of information and expertise so that informed judgement, forecasting and decision-making can be achieved (Rowe and Wright, 2012). It can be used to discuss both numerical and non-quantifiable nature of problems. It is believed that the Delphi technique has the capacity to deal with ambiguity and multi-dimensionality based on its ability to draw on the informed judgement of a group of experts systematically which made it one of the highly reliable tools to support decision-making in the fields of medicine, sociology and policy making (Ziglio, 1996; Falzarano and Zipp, 2012; Landeta, 2006). A key strength of the Delphi technique is the fact that it does not force consensus but helps in identifying where agreement exists among international experts (Thomson et al., 2009;

Verstappen et al., 2015; Elwyn et al., 2006). Some of the many advantages of the Delphi technique are: ability to conduct a study in geographically dispersed locations as it is the case of this protocol, time and cost effectiveness as well as allows the discussion of complex and broad problems. I explain further in the following chapter the use of Delphi technique in patient safety research. The rounds as well as the questionnaires that were used to identify the priorities are also discussed in Chapter 4.

3.5.6 Structured interviews

Structured interviews are also a qualitative method used for gathering opinions, views, perceptions and comments from individuals regarding a specific subject. It was pointed out by Fontana and Frey (2000) that interviews can have many advantages including the ability of the interviewer to control the context of the study and guiding the interview process. It also helps researchers to clarify any areas of ambiguity to the participants to enhance clarity about the problem being studied. Structured interviews were used as discussed in Chapter 5 to validate the developed framework with Libyan system users. The selection of this approach was very cost effective and was adopted using electronic communication with policy makers and health professionals in Libya. This allowed for an opportunity for those participants to share their views and insights about the framework which was shared with them prior to the interviews. Further details about the interview procedures as well as the participants are discussed in Chapter 5.

3.5.7 Questionnaire survey

A short questionnaire survey was also used as part of the framework validation process as outlined in Chapter 5. The use of a questionnaire survey is a flexible and cost effective method which allows researchers to collect data from a large sample (Creswell, 2013). Questionnaires can be either open-ended or closed-ended type. This refers to the type of questions being asked to participants. I have used a Likert-scale questionnaire type to allow the participants to rate different dimensions of the framework. The questionnaire was developed based on existing literature on framework evaluations in different sectors. The participants were given the opportunity to provide any comments in regards to the practicability of the framework.

3.6 Data triangulation

This thesis is mainly driven by qualitative research. It was decided to adopt the concept of data triangulation which means that a phenomenon can be examined and investigated from more than one source of data. According to Denzin (1978), there are four basic types of triangulation which are; data sources, methods, investigators and theories. Denzin believes that triangulation opens the way for researchers to gain richer and deeper insights about a research problem. Hence, it was decided to use this approach to enhance the validity of my research. It could be argued that analysing this research problem using multiple perspectives allowed me to enhance the originality as well as the validity of this study.

3.7 Data analysis

Content analysis and thematic analysis method were used for analysing the qualitative data. As highlighted in Chapter 4, qualitative data analysis is about detection, defining, categorising, exploring and mapping ideas and concepts. It was pointed out by Ritchie and Spencer (2002) that researchers to focus on establishing themes and concepts through understanding the internal structure of text. As noted above, different methods for data collection but were mainly associated with qualitative data except the findings of the questionnaire survey which was used for validating the framework in Chapter 5. Therefore, I have adopted the principles of thematic analysis and content analysis to find association and develop new concepts.

3.8 Justification of selected design

The philosophical approach adopted for this study has influenced upon the selection of tools for data collection. I also agree with the argument made by Flynn et al (1990) that the right paradigm is the one that incorporate multiple, complementary methodologies to triangulate findings. Hence, I adopted the data triangulation approach so that the weaknesses of any of the adopted tools are avoided. In addition to this, I have a personal interest in having practical application of this research. This has influenced the selection of the case study design so that I can engage with practitioners, experts and healthcare professionals to develop a pragmatic framework. I have adopted this approach to enable me gain insights and comments on the developed framework from the system users. This makes the framework more Libyan-

oriented and fits with the current needs of developing countries. It was also asserted by Pettigrew et al (1992) that the use of case study design is widely adopted in healthcare research as it helps in identifying causes of poor performance through investigating the problem in its natural settings. I wanted this research to as practicable as possible to help healthcare systems in developing countries improve the standards of care they deliver to patients. The selection of this design also enabled me to investigate patient safety issues in context by combining organisational, human, policy and practical factors that influence upon patient safety improvement. In addition to this, by interacting with Libyan healthcare professionals who are either in the UK or in Libya as well as involving experts in patient safety who have developed rich experience over the past years in studying patient safety, this adds more validity and reliability to the study findings. The qualitative approach enabled me to gain deeper insights and meanings which were very helpful in developing the framework.

3.9 Ethical considerations

It was important to comply with the Imperial College London research ethics. As noted in Chapter 1, access to study settings was hindered due to civil war that erupted in Libya in 2014. This has influenced the design of the study as it would have been very risk for myself to carry out field visits in Libya during 2014 and 2015. To ensure that this study takes into account Blaxter's et al' (1996) view in which they stated that research should be conducted ethically, systematically, legally, scientifically, anonymously, confidentially, and professionally. It was vital to comply with the ethics guidelines in the college even though this study was not carried within NHS hospitals and it did not involve patients or their medical records. However, the study involved healthcare professionals and experts in which it was important that they are informed about their rights while participating in the study. It was ensured that all participants either in the focus groups, Delphi study or in the framework validation stage that participants are informed about the nature of study and their ability to withdraw from the study at any stage. They were also assured that their confidentiality is respected and their responses will remain anonymous. The participants were also informed that their participation is voluntary and that they will not receive any incentives by participating in this study. The study did not engage the participants in any hazardous or risky activities which could have impacted upon their health or well-being.

3.10 Chapter Summary

The aim of this chapter was to discuss the research design adopted for this thesis. I firstly discussed the philosophical approach which underpinned my selection of the study design as well as discussing the differences between different methodological approaches. The choice of the case study design and the different tools that were used for collecting the data were also justified in this chapter. The chapter also highlighted how the data collected was analysed and presented in each chapter. The following chapter presents the results of the different study phases.

CHAPTER 4

RESULTS & ANALYSIS

4.1 Introduction

This chapter will be divided into four main parts. The chapter will present the results of four different studies which will then be followed by Chapter 5 that presents the patient safety improvement framework. I will start by presenting the findings of the case study analysis of the UK's journey in patient safety, the findings of the systematic review followed by the findings of the focus groups study with Libyan healthcare professionals. The final part will present the findings of the modified Delphi study. Each study will be introduced by presenting an introduction and the overall purpose of the study. The chapter will also discuss the methods adopted for each study followed by the results and a general discussion on the findings of each study. I will then present a general commentary on the overall findings and how these studies contributed to the development of the framework.

The four phases of the study are inter-linked and were used to understand the contextual, organisational and conceptual factors that hinder the improvement of patient safety so that an integrated framework is developed. The UK Case Study analysis provides a good insight about the UK's journey into patient safety whereas the systematic review study provided data on the current perception safety culture in Arab countries. The focus groups study helped in gaining deeper insights from Libyan healthcare professionals and the modified Delphi study was used to gain expert advice on the priorities for patient safety improvement in Libya.

4.2 Part One - Case Study Analysis: Insights from UK System

4.2.1 Method

Publications focusing on UK patient safety were searched in academic databases and content analysed. In order to carry out a detailed analysis of the UK's journey in regard to patient safety. The selection of the UK based on the fact that it is one of the countries that has given political support to the issue of patient safety. The UK has also one of the best health systems in the world. The findings of this work has been published as an article in the International Journal of Health Care Quality Assurance which has the copyrights for this publication but licensed the author to use and reproduce the work (Elmontsri et al., 2018). Hence, a case study design was adopted for this chapter. A case study is defined by Bromley as:

“systematic inquiry into an event or a set of related events which aims to describe and explain the phenomenon of interest”

(Bromley, 1990, p. 302).

According to Flyvbjerg (2011) and Merriam (2009), a case study is classified as exploratory and explanatory in nature which aims to understand the issue in real life settings and recommended to answer *how* and *why* research questions. Thus, it could be argued that a case study analysis would contribute to the achievement of the overall aim of this thesis. Furthermore, my own experience while working in the UK, it was noted that the health and medical professions are highly regulated and that healthcare providers need to comply with multiple types of regulations, rules and standards. I have always questioned the effectiveness of the existing regulatory framework in the UK, but this could be done in a separate PhD. Moreover, the methodology adopted for this thesis is based on the triangulation methodology and mainly by triangulating data sources. As noted by Eisner, that data triangulation enables researchers to provide *“confidence of evidence that breeds credibility”* (Eisner, 1999, p. 110). Data triangulation also helps researchers to corroborate findings by reducing the potential of biases which could exist in a single study. As explained in chapter 3, the research methodology adopted for this thesis was based on collecting different types of evidence to help develop a pragmatic framework which will help in improving patient safety in developing countries and Libya in particular. Patton (1990) pointed out that

triangulation can help researchers to guard against accusation that study findings are mainly of a single source or a single method.

4.2.1.1 Document analysis

Therefore, document analysis was chosen as it is described in the literature as a systematic procedure for evaluating and reviewing documents. These documents can either be electronic (computer-based) or printed (Bowen, 2009). Document analysis is a qualitative tool that is used to elicit meaning, gain understanding and develop empirical knowledge (Corbin and Strauss, 2008). Documents can vary in type, length, publisher and authors which contain text and images as well as analysis case studies. Therefore, it could be argued that document analysis would give me the opportunity to identify the challenges as well as the tools for improvement that were adopted by the UK over the past years to enhance patient safety. These documents contain information which has been compiled by group of professionals and experts. In addition, many university professors and senior academics have taken part in developing policy and governmental reports based on their sound judgement and expertise. Thus, such documents are rich with information that will help understand the current status of patient safety in the UK so that lessons can be learnt to improve patient safety in Libya. Another advantage associated with document analysis is accessibility. As highlighted by Deacon et al (1999) that revolution in information technology has made it possible to access documentations. Thus, it is a cost-effective method taking the limited resources I had while completing my PhD.

4.2.1.2 Reliability

Researchers need to pay attention to the issue of reliability and validity of methods adopted when carrying out research so that their findings are protected from biases. Document analysis is one of the qualitative methods that is widely used in health and social research to identify patterns over the years. However, it is important to comply with Scott' (1990) and Deacon et al (1999) criteria for reliability when it comes to using documents for research. These are outlined in table 4.1. The documents used for this case study analysis have been evaluated against these criteria to ensure that they add value to the overall research process.

Table 4.1: Reliability criteria for using documents

Criterion	Description
Authenticity	The origin of the document is not questionable
Credibility	Documents are accurate and free from error
Representativeness	Represents the case study being investigated
Meaning	How relevant is the information and is it easy to interpret?

4.2.1.3 Analysis approach

The process of document analysis goes through different stages. It starts with skimming to have an idea of the type of document followed by reading which involves the process of thorough examination and then interpretation of data. Hence, elements of thematic analysis and content analysis were combined. However, the focus was more on thematic analysis as it helps to generate well-defined themes that will be easier to interpret and understand by readers. Thematic analysis allows researchers to recognise patterns within data. It involves careful reading, re-reading and review of data so that coding and category construction is carried out. This will help in uncovering themes pertinent to a specific issue. A chronological account of events was built supported by other academic research to identify patterns and themes.

4.2.1.4 List of some documents analysed

Table 4.2 presents some of the high profile documents that were analysed. A full list of the documents and peer-reviewed articles that were used as part of this analysis is included with the references list at the back of this thesis.

Table 4.2: List of some documents analysed

Title	Publisher	Year
<i>'Patient Safety 2030'</i>	NIHR Imperial Patient Safety Translational Research Centre	2016
<i>'The UK: your partner for global healthcare solutions. Improving the quality and safety of patient care'</i>	UK Trade and Investment	2016

<i>'A Safer Place for Patients: learning to improve patient safety'</i>	National Audit Office	2005
<i>'Learning Report: Safer Patients Initiative, Lessons from the First Major Improvement Programme Addressing Patient Safety in the UK'</i>	The Health Foundation	2011
<i>'Patient safety in health care professional educational curricula: Examining the learning experience'</i>	Patient Safety Education Study Group	2009
<i>'Safety First: One Year On: Outlining progress on the recommendations of Safety First'</i>	National Patient Safety Agency	2007
<i>'A decade of improving patient safety'</i>	National Institute for Health Research	2016
<i>'NHSLA Risk Management Standards 2013-14'</i>	NHS Litigation Authority	2012
<i>'Learning from Bristol: report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995'</i>	Department of Health	2001
<i>'Continuous improvement of patient safety'</i>	The Health Foundation	2015
<i>'National NHS Staff Survey 2007'</i>	Healthcare Commission (now CQC)	2008
<i>'Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry'</i>	The Stationery Office	2013
<i>'Improving Safety Through Education and Training'</i>	Education and Training Commission for Patient Safety	2016
<i>'Guide to the Healthcare System in England'</i>	Department of Health	2013
<i>'Helping the NHS put patients at the heart of care: the patient and public'</i>	Department of Health	2009

<i>engagement support programme 2009-10'</i>		
<i>'Safety First'</i>	Department of Health	2006
<i>'Building a safer NHS for patients: implementing an organisation with a memory'</i>	Department of Health	2001
<i>'An organisation with a memory'</i>	Department of Health	2000
<i>'State of Health Care and Adult Social Care in England 2014/15'</i>	Care Quality Commission	2015

4.2.2 General overview

The publication of studies on healthcare safety epidemiology in the United States (Brennan et al., 1991) and from Australia (Wilson et al., 1995) has shifted the focus on safer healthcare. In Western health services, studying safety failures suggests that about one in ten people who enter hospital care experience some form of adverse event and one in 300 patients suffers serious consequences (Baker et al., 2004, Zegers et al., 2009, Hogan et al., 2012). A study by Landrigan et al (Landrigan et al., 2010) suggested an even higher rate of 25 harmed per 100 admissions. Landrigan's study (Landrigan et al., 2010) affirmed that this rate failed to change over time in their study population. A global patient safety movement was triggered by the publication of the Institute of Medicine's landmark report "To Err is Human: Building a Safer Health System" (Kohn et al., 2000). However, despite the progress made into the field of patient safety, harm to patients is still considered to be a reality in the provision of health services worldwide (Landrigan et al., 2010, Leistikow et al., 2011, Wachter, 2010).

The core of patient safety is to prevent errors that are associated with healthcare as well as mitigating the effects of these errors (Vincent, 2010). In 2004 the World Health Organization (WHO) launched the World Alliance for Patient Safety to foster international collaboration and facilitate improvements worldwide in the field of patient safety (Donaldson and Fletcher, 2006). However, healthcare systems across the globe continue to experience avoidable patient harm. In England, 3.6% of deaths in acute hospitals are attributed to avoidable problems in care (Hogan et al., 2015). Even worse

trends are present in the United States as a recent study by Makary et al (Makary and Daniel, 2016) estimated that medical error is the third leading cause of death in the US. There are also other economic implications associated with poor care quality and adverse events. The Continuous Improvement Report, published by the United Kingdom's Health Foundation, affirmed that unsafe care is expensive, unreliable systems are unproductive and costs can be reduced by providing safer care (Illingworth, 2015). Unnecessarily high use of resources and litigation costs lead to economic implications (Marshall and Øvretveit, 2011). For example, the cost of excess hospital days in the UK which is attributed to patient injuries alone amounts to over £1 billion (Vincent et al., 2001).

4.2.3 UK response to patient safety issues

A wide range of events and influences have contributed to the emergence of patient safety initiatives in the United Kingdom (UK). In the 1970s and 1980s, there was a growth of audit and other quality activities, as well as an increase in litigation costs. High-profile cases such as the Bristol paediatric cardiac surgery inquiry (Kennedy, 2001), the Shipman Inquiry (DoH, 2007) as well as learning from other industries that focused on safety, human error in healthcare (Reason, 2000) and findings of a major review studies on adverse events (Brennan et al., 1991, Wilson et al., 1995) shifted the focus towards patient safety in the UK. In 2000, the UK's Chief Medical Officer (CMO) and Department of Health (DoH) published "an organisation with a memory" report (DoH, 2000). This was the government's first report that set the scene for patient safety improvement in the NHS. The report indicated that 400 people in the UK die or are seriously injured from events related to medical devices each year. Another 10,000 people have experienced adverse reactions to drugs and hospital-acquired infections that cost the NHS over £1 billion per year. The NHS was described as having an old-fashioned approach to learning lessons from mistakes. More importantly, the report focused on the need to shift the organisational culture which inhibited reporting. Additionally, there was an absence of a national, cohesive system that can help in sharing lessons learnt when things do go wrong (DoH, 2000). "Building a Safer NHS for Patients" is another report published by the DoH in 2001 in response to the CMO's report and detailed specific plans and timetable for promoting patient safety. Building local capacity, promoting a reporting culture and sustaining change through education,

learning and performance assessment at both local and national levels were specific key areas targeted for action (DoH, 2001). For example, aiming to reduce the number of serious errors in the use of prescribed medicines by 40% by 2005. Key changes required to improve patient safety was to establish the National Patient Safety Agency (NPSA) in 2001. Their aim was to encourage reporting and learning from patient safety incidents and near misses.

Another stakeholder in patient safety management in the UK is the National Audit Office (NAO). They published the “A Safer Place for Patients” (Terry et al., 2005) report. In it the NAO examined NHS’ performance with regards to promoting a patient safety culture and encouraging reporting and learning from incidents. The report concluded that a more open and fair culture has been created at a local level and there has been progress with improvements in reporting. The report also concluded that there were delays in establishing an effective national reporting system and lessons were not shared by all organisations. Moreover, the first major patient safety improvement programme was known as The Safer Patients Initiative (SPI) which was a large-scale intervention developed by the Institute for Healthcare Improvement (IHI) (The Health Foundation, 2011). The first phase was launched in 2004 to test ways of improving patient safety across organisational levels. The Health Foundation reported that the PSI has increased awareness of avoidable harm and helped in raising the profile of patient safety within NHS hospitals. Numerous patient safety campaigns and collaborations were launched across UK universities, the NHS and beyond as the profile of patient safety increased (Slater et al., 2012, Burston et al., 2011). However, patient safety issues remain to be an ongoing problem for the NHS as reported by several UK inquiries such as the inquiry into the care provided by Mid Staffordshire NHS Trust (Francis, 2013) which reported that the hospital has “*a culture focused on doing the system’s business – not that of the patients*”. Among the issues identified were poor staffing levels, difficulties in reporting and inefficient monitoring. It is also reported that over 13 patients were killed or harmed every day in the NHS. There were 622,000 patient safety incidents recorded in general hospitals (acute, non-specialist, NHS trusts) in the six months from October 2014 to March 2015 in England and Wales (NIHR, 2016). 23,000 of these incidents caused moderate or severe harm.

4.2.4 Patient safety governance and regulation

Patient safety in the NHS is heavily regulated. There are a number of regulatory bodies which set standards and monitor organisations to ensure that their operations are in compliance with those standards. These regulatory bodies also enforce consequences on organisations that do not meet the standards. The Care Quality Commission (CQC), the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Agency and Monitor (now part of NHS Improvement) as well as the National Clinical Assessment Service (NCAS now part of the NHS Litigation Authority) are among the major arm's-length bodies of the DoH which have a regulatory role (DoH, 2013). In addition to monitoring organisations, other government bodies are also responsible for regulating healthcare professionals in specialised areas of medicine to ensure they comply with the standards set. The Professionals Standards Authority for Health and Social Care (PSA) oversees statutory bodies that regulate health professionals. Different healthcare professions such as dentists, opticians and midwives are regulated by separate bodies under the PSA. There are nine separate regulatory bodies being overseen by the PSA. These regulatory bodies conduct audits, monitor performance and report to the Parliament on serious issues. Organisations that hold voluntary registers for health and social care occupations are also accredited against a set of standards set by the PSA. Fitness to Practice Schemes are also introduced by these professional regulatory bodies to emphasise upon the individual responsibility of clinicians toward patient safety (Terry et al., 2005).

The CQC has the responsibility of registering, monitoring, inspecting and regulating both NHS and private healthcare services in England to ensure these organisations meet the fundamental standards of quality and safety. The CQC has the power to issue improvement notices as well as limit a provider's activities if services fall below minimum standards. The CQC also issues fines and cautions as well as prosecuting when patients have been harmed or put at risk. The CQC works to ensure that patients are provided with safe, effective and high quality care either in hospitals, care homes, dental and general practices and other care services. Monitor, which was established in 2004 has also regulatory powers and works with CQC and NHS England to ensure that patients receive high quality care. As of April 2016, Monitor has become part of

NHS Improvement which is the responsible body for overseeing NHS trusts. Following the high-profile inquiry into the Mid Staffordshire NHS Foundation Trust, the final results which were published in 2013 (Francis, 2013) concluded that the health care system requires more effective regulation and a culture of care. This has again shifted the focus of patient safety and quality improvement on the top of the government's agenda. In response, the CQC has developed new five quality domains; safety, effectiveness, caring, responsiveness and well-led in which it started to rate health care providers against these domains. The governance and regulation of patient safety NHS in the UK is flexible and responsive to any lessons learnt from incident investigations and public inquiries. The NHS Improvement was established in April 2016 to bring together Monitor, NHS Trust Development Authority, Patient Safety, the National Reporting and Learning System, the Advancing Change Team and the Intensive Support Teams. It is believed that NHS Improvement's priority is to offer support to providers and local health systems so that they can improve.

4.2.5 Improving patient safety through education and training

Education plays a major role in developing safe, high quality, health and nursing care (Francis, 2013, Slater et al., 2012, Mansour, 2012, Wong et al., 2010, Pearson et al., 2009). Health Education England (HEE) reported that patient safety education and training for undergraduates and apprentices alone is not sufficient to ensure improvements in patient safety (Education and Training Commission for Patient Safety, 2016). HEE recognises the importance of accompanying patient safety education and training with a learning culture within provider organisations, and a supportive system that enables healthcare workers to provide effective and safe care to patients. More importantly, healthcare professionals in the NHS are provided with opportunities for learning and development throughout their careers. For example, following the Berwick review into patient safety (Berwick, 2013), the National Quality Board's (NQB) Human Factors in Healthcare committed to including human factors principles and practices in core education and training in the NHS in England (NHS England, 2016).

Patient safety education in England is promoted and encouraged by many agencies including professional regulators. The General Medical Council (GMC) and Nursing and Midwifery Council (NMC) work in collaboration with undergraduate and

postgraduate education providers and HEE to ensure that medical and nursing students are conversant with patient safety and quality improvement. A recent report by the DoH titled “Culture Change in the NHS” (DoH, 2015) described medical students as the “eyes and ears of the service today and the safety leaders of the future”. Furthermore, HEE established the Commission on Education and Training for Patient Safety which aims to provide recommendations to HEE to ensure awareness all healthcare staff on patient safety. Several bodies in England have recommended the integration of patient safety education and training in the medical curriculum as well as part of the staff’s development programmes. The NPSA developed training for nurses and midwives based on lessons learnt from other industries. DoH’s Safety First publication in 2006 recommended that the NHS Institute for Innovation and Improvement should work in collaboration with medical Royal Colleges and education providers to ensure that advances are incorporated in education and training to support patient safety.

The ‘Safety First’ (DoH, 2006) report also emphasised the importance of developing a patient safety curriculum. In this regard, there are 15 Royal Colleges in the UK responsible for setting and monitoring postgraduate medical training to ensure that all doctors are trained to practice at the highest possible standard (UK Trade and Investment, 2016). The GMC also has a statutory responsibility to set, maintain and promote standards of undergraduate and postgraduate medical education in the UK including aspects of patient safety. The WHO (WHO, 2009) published a patient safety curriculum guide for medical schools which has been adopted by many educational providers in the UK to enhance the level of their patient safety education and training. Simulation-based training is being used as one of the strategies to reduce errors and improve patient safety (Salas et al., 2005). For example, the National Institute for Health Research Patient Safety Translational Research Centre at Imperial College London hosts one of the busiest programmes in patient safety as it offers a two-year Master’s degree in Patient Safety, training workshops and an annual symposium since 2007. Moreover, 100 students have also been awarded the MSc for Quality and Safety (NIHR, 2016).

4.2.6 Patient involvement in patient safety

The DoH's report "Building a Safer NHS for Patients" (DoH, 2001) emphasised that patients need to be given a clear role in helping to promote and achieve patient safety goals. Patient and public involvement in safety was also promoted by the NPSA since its inception. Several campaigns and numerous leaflets that aimed to encourage and empower the "active" patient were introduced in the NHS over the past decade along with strict guidelines for healthcare staff on how to engage, communicate and involve patients or families following error or harm (NPSA, 2007; 2006; 2009). There is a widespread belief that patients can help to improve the safety of healthcare once they are involved (Hibbard et al., 2005, Davis et al., 2011). The NHS Constitution, which establishes the principles and values of the NHS in England, makes it clear that patients must be told about any safety incident related to their care. Patients are also provided with information and the maximum support they need during any treatments. The NHS Constitution clearly sets out patient's rights to an open and transparent relationship with healthcare providers (DoH, 2009a). Patient and public involvement in the UK is one of the important pillars of healthcare policy as it is seen as a tool to improve the quality of services and also enhance accountability for public spending. The DoH (DoH, 2009b) views patient and public involvement as an opportunity for patients to drive the design and delivery of high-quality services. Patients in the UK are given the opportunity to participate in the decision-making process as well as having the opportunity to evaluate the services and lodge complaints towards healthcare providers which will consequently lead to an improvement in the healthcare system (Longtin et al., 2010). Patients are also invited to present their experiences of healthcare to board-level executives and within education to evaluate their levels of satisfaction and their perspective on the clinical outcomes of treatment (Langer et al., 2016, Jha et al., 2014).

4.2.7 Patient safety measurement and monitoring

One of the strategies adopted by the NHS in the UK is learning from incidents. Incident reporting is a method used for improving safety in industries such as aviation and has also been established in healthcare (Forman and Goodman, 1990, Barach and Small, 2000). NHS organisations are required by regulatory agencies in the UK to report incidents (Rooksby et al., 2007) and hospital incident reporting is a component of

individual hospital risk governance processes (Benn et al., 2009). In 2003, the National Reporting and Learning System (NRLS) was established by the NPSA which requires all hospitals to report to any incidents. Currently, it receives over 1 million reports per year in England (Hutchinson et al., 2009). These reported incidents are analysed and used for learning purposes to help NHS organisations avoid such incidents in the future. Furthermore, risk management standards for hospitals have been defined by the NHS Litigation Authority which requires hospitals to have a documented process for internal and external reporting of all incidents and near misses (NHS Litigation Authority, 2012). Thus, hospitals are required to report all types of incidences that occur within their premises to ensure future lessons are learnt. Incident reporting schemes should be developed in accordance with the needs of their host organisation to ensure their effectiveness as they have technical and social components (Balka et al., 2007) which is the case in the British system as these reporting systems are adapted to the local needs.

There are also other data which is used by the NHS to measure and monitor the patient safety performance that have links to incident reporting such as the annual NHS Staff Survey which includes some questions on safety culture and incident reporting (Healthcare Commission, 2008). A rating is also awarded by the NHS Litigation Authority following a risk management assessment that is conducted within each hospital (NHS Litigation Authority, 2012). Traditionally, routine NHS information systems were mainly developed for management and administrative purposes and not to help with measuring health status or the outcomes of health care as argued by (Majeed et al., 1994). There are different interventions used in the NHS to monitor patient safety such as the safety walk-arounds which are used as a visible indicator of senior management commitment to safety that helps in establishing a good safety culture (O'Dea and Flin, 2001). Risk registers are commonly used across healthcare settings in the English NHS divisional, department and trust levels which are mandated by external regulators such as the NHS Litigation Authority. These local risk registers are updated on a regular basis at divisional and departmental levels in which all identified risks are graded using a standard risk matrix. Those risks with the highest scores are included in the trust's overall risk register (McIlwain, 2006).

As part of the monitoring process, the Francis report (Francis, 2013) made 209 recommendations that aim to change the culture of corporate self-interest and cost control that was associated with the failings at Mid Staffordshire Foundation Trust. A number of changes have occurred in the NHS following the publication of Francis report which included the creation of Patient Safety Collaboratives that work in conjunction with Academic Health Science Networks to support organisations and individuals to build safety improvement skills. A national campaign “Sign Up to Safety” was also launched in 2014 that aims to reduce avoidable harm by 50% and save over 6,000 lives (Woodward and Director, 2015). CQC’s 2014/2015 State of Care report rated 13% of hospitals as “inadequate” in terms of patient safety and a further 61% as “requiring improvement” (Care Quality Commission, 2015). A number of reasons were cited in the report behind this poor performance on patient safety that include; failure to investigate and learn from patient safety incidents, issues with staffing levels and training and support. Another intervention that is used by the NHS to monitor performance of patient safety is known as the NHS Safety Thermometer which was developed to create a tool that allow NHS trusts to improve their patient safety using a simple measuring tool. For example, the Safety Thermometer included data from surveys of 6.6 million people, across 1,156 organisations in the 2015. Never Events are also captured as part of the NHS Improvement programme. In April 2016, there were 28 Serious Incidents reported which could highlight that there exist weaknesses in how organisations manage fundamental safety processes in the NHS (NHS Improvement, 2016).

Hence, patient safety in the UK has become embedded in the dictionary of healthcare professionals, policymakers, patients and the media. Some of the root causes of error have been untangled which led to the implementation of specific interventions that have proven to be efficient in reducing patient harm over the past decade. More importantly, research and intervention have become integral elements in policy prioritisation. It could be argued that healthcare professionals in the UK hold patient safety at the heart of what they do as a result of the efforts discussed above that led to improving outcomes for patients.

4.2.8 Lessons learnt for patient safety improvement in Libya

Libya's health system has suffered long periods of poor funding, neglect and lack of development and modernisation programmes (El Oakley et al., 2013). Libya's health services are provided free to all people and it has an average of 37 hospital beds per 10,000 people which makes it the among highest number per person in Africa (WHO, 2010). The quality of healthcare in Libya deteriorated following the civil war in 2011 (Daw et al., 2015). The widespread distrust of quality of care in Libya further triggered a multimillion dollar medical tourism industry in neighbouring countries (Saleh et al., 2014).

Libya has a golden opportunity to strengthen its health system and improve quality of care but that depends on the country's ability to refrain, manage and resolve the consequences of its ongoing conflict. A radical reform to the health system is required to ensure that health professionals offer high-quality, accessible primary and secondary care that meets the needs of Libya in the 21st century (Majeed, 2013). The back-bone for advancing the medical field and improving the quality of healthcare services is scientific medical and health research (Rahman and Fukui, 2003). However, in developing countries such as Libya, there is very limited published medical research (Bakoush et al., 2007, Benamer et al., 2009). Thus, studies that estimate the level of harm in the Libyan health system are not available nor are there any published studies that measure the users' satisfaction of the health system. Thus, there are a number of lessons which can be learned from the British experience in patient safety. Firstly, patient safety should evolve based on the changes in the health system. Continuous learning and a culture of continuous monitoring and evaluation is key to ensure that patients receive high quality care at all times. The UK's journey of patient safety has been through continuous development. The cumulative knowledge about patient safety as well as public inquiries have also shifted the government's focus towards patient safety.

Hence, I would argue that the single most important milestone for Libya's health system is to introduce regulation and standards. Governance and regulation helped institutionalise patient safety as a priority in the UK. Regulations that establish minimum standards for patient safety hold health care providers accountable and

enable enforcement actions. The development of these regulation should be based on analysing the current needs and should be goal-oriented. Undoubtedly, health care is organised and financed in many different ways across countries but there exists a number of common interrelated challenges which must be addressed by strategies that aim to improve the safety of patient care. The critical step that should be taken by policy makers in Libya is to create an environment that is receptive to change at all levels of the Libyan health system. Key players and front-line staff should be involved in the process of improving patient safety including doctors, nurses, managers, administrators, policy makers and allied health professionals as well as patients and their families. As outlined above, landmark reports from respected health institutions in many countries have helped in shifting the focus towards the value of patient safety and reduce harm to patients. A call for strong patient safety leadership at all levels of the health system accompanied this shift (Leape, 2004, Leape and Berwick, 2000).

Secondly, regulations and standards alone are not enough as seen in the UK's context. Change requires robust and effective measurement. Setting priorities for actions requires understanding and learning from the nature and scale of harm to patients that results from current systems of care (Small and Barach, 2002). Research studies that involved retrospective review of patient health care records have helped many countries generate knowledge about the level of patient harm (Baker et al., 2004, Brennan et al., 1991, Wilson et al., 1995, Vincent et al., 2001). Large reporting systems such as the NRLS used in England provided opportunities for lessons to be learnt. It is vital that policy makers in Libya ensure that such reporting systems are not merely used for counting the frequency of patient safety incidents but rather focus on the need of analysing these incidents to understand and identify the factors which contribute to the occurrence of such accidents. This will also help in developing preventative strategies that aim to reduce future risks to patient as part of the risk management governance process. There also other measurement approaches which should be adopted such as patient and staff surveys to measure satisfaction. Complaints analysis and direct observation should also be considered as part of the measurement and monitoring of healthcare services.

Thirdly, it is also important to include patients and their families in the process of improving quality of healthcare and patient safety. Health professionals in Libya need to be encouraged and policies should be put in place to ensure that patients are involved in the process of care. The wider system will benefit from such policies that encourage patient participation as their concerns are vital to improving the quality of services. Currently, patient involvement is left to the individual hospitals as there is no nationally stipulated policy. It could be argued that patients will be more empowered to voice their concerns about any issues that could lead to harm or diminish their experience. Most of all, patients must be treated with respect and dignity and should be viewed as valued collaborators in the healthcare system. However, this cannot be achieved without strict regulations, policies and procedures that encourage patient involvement. Patients in the UK have been empowered to help in shaping and supporting policy development as well as being active participants as patient safety advocates and also to raising public awareness about patient safety issues. A constitution similar to the NHS constitution could help in providing a path for patient's awareness about their roles, rights and responsibilities

Fourthly, medical education in developed countries has been transformed over the last 40 years as a result of the changes in the medical environment. Medical education has shifted from the traditional apprenticeship model of learning (Dall'Alba and Sandberg, 1996, Jain et al., 2015, McClurg et al., 2015). Libyan medical educational strategies and assessment methods require urgent updating to cope with the changes in the delivery of care to patient (Sagher, 2006, Richardson et al., 2009, Benamer and Bakoush, 2009). The medical education curriculum in Libya has not been modernised in recent decades (Richardson et al., 2009) and urgent policy decisions are needed especially in the provision of funding and updating the curriculum as well as promoting medical and health research. Many developed countries have realised the importance of patient safety education and training including the UK. Hence, for Libya, patient safety education and training should be a core element of the national strategy to improving patient safety in the country. These training and educational programmes should be designed based on best-practice so that they can be impactful. Three main dimensions should be considered when developing education and training programs on patient safety; content, delivery method and feedback. Medical and nursing schools

in Libya should benefit from the WHO Patient Safety Curriculum that is being adapted by many medical and nursing schools around the globe including in the UK. Lessons from the HEE should be learnt as well as from the professional and regulatory agencies in the UK such as the GMC which promotes patient safety education in the undergraduate and postgraduate education. There are also no clear plans that clearly specifies the process of human resources management within the health sector in Libya. The lack of accreditation systems and professional agencies as well as lack of link between continuous medical education programs and career development in the country (WHO, 2010). This will have ongoing significant impact on health care delivery and patient safety in particular.

Finally, one of the key priorities that was identified in the WHO strategy for the development of the health system in Libya was “*developing a long-term national vision for health development and reforming and updating the health system*” (WHO, 2010). This is because there is very limited data and information available about the health system’s performance in Libya (Chan et al., 2012). Technology data and information are critical for the improvement of patient safety (Bates and Gawande, 2003). As the case of the UK’s system, there are different regulatory bodies that regulate organisations, health professionals and specialist areas of medicine. There are also other regulatory agencies that regulate medications, medical equipment and supplies to ensure they all conform to the set standards. Electronic Medical Records are not yet introduced to the Libya health system as well as using online prescribing methods to ensure patients are provided with the right medication. Patient safety in Libya should be considered as an integral element of the country’s health system future development to ensure that patients’ trust in the health system is restored.

To ensure that patient safety management systems are efficient, patient safety should not be viewed as a leadership and management issue but rather as a matter that is dependent on systemic factors. Thus, doctors and patients’ involvement is crucial for the success of patient safety initiatives. In other words, a system approach must be taken in redesigning the healthcare system for safer care delivery (Akins and Cole, 2005). Medical errors causes are rooted in the policy and organisational level of healthcare. As outlined in Francis report (Francis, 2013), there is high levels of

interconnections and interdependence between healthcare professionals who function under resource and performance pressures and lapses might occur. There also budget constraints which might influence patient safety and care quality. Health systems worldwide are facing financial constraints as a result of the global economic downturn (Tingle, 2016). This fact was also emphasised in Francis' report as there were shortages in staffing levels. The approach that is adopted in response to constrained budgets is trying to do "more with less" which will have an impact on patient safety if not carefully planned (Yu A, 2016). Patient-care is also becoming increasingly complex due to advances in medicine and technology which increases the risk of errors being made. There is also a trend towards the personalisation of medicine which will make the process of care more complex. In addition to the need of creating a free-blame culture where individuals are encouraged to report errors to help in analysing and improving systems.

The UK and Libya are very different in many aspects including the level of parliamentary roles and funding allocated to healthcare sector. However, it could be argued that the Libyan healthcare system can benefit from the rich past patient safety experience in the UK. Given the centralised structure of the healthcare system in Libya, implementing some of the strategies for improving patient safety can be relatively easier. It is worth mentioning also that Libya was able to modernise its health infrastructure in the past which facilitate implementing changes.

4.3 Results Part Two—Systematic review

4.3.1 Introduction

For decades, human errors in complex systems have been a topic of debate due to their consequences. For example, system failures in the aviation industry cause great publicity and are addressed very quickly because of the impact they make as they involve a large number of people and resources. In the healthcare sector, accidents can be deadly but they do not attract as much attention as they affect fewer people at a time. Errors in healthcare settings began being drawn to public attention in the 1990s (Wong et al., 2004). "To Err is Human" has triggered debate on the important issue of patient safety and a commitment to deliver high-quality, safe healthcare has become

a policy goal of governments around the world over the past 15 years (Kohn et al., 2000). However, patients are continuing to suffer avoidable harm and substandard care (Dixon-Woods et al., 2013). According to the Institute of Medicine, safety is defined as “the freedom of accidental injury”. On the other hand, the World Health Organization (WHO) defines patient safety as the “reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”. Safety culture has now become a significant concept for healthcare organisations that are determined to improve patient safety. It is very important that the dynamics of this construct “safety culture” are understood to produce positive change. Hence, it is vital that the underlying cultural factors present within an organisation should be known so that the safety culture can be transformed (Nieva and Sorra, 2003). Several studies have investigated this areas both at organisational and individual levels in relation to safety culture with different measurements, techniques and modes so that the contributing factors are understood. Thus, managers and leaders are encouraged to establish and sustain safety culture, as it is fundamental to total systems safety (Gandhi et al., 2016).

Patient safety is based on continuous learning as there is a great need to report and learn from errors, accidents, near misses and adverse events so that such events can be avoided in the future. The traditional approach to patient safety which is based on establishing mortality committees and scrutinising accidents (Deilkås and Hofoss, 2010) can no longer be efficient as the healthcare system is becoming more complex (Nolan, 2000). Major health organisations such as the WHO, National Patient Safety Foundation (NPSF), the Joint Commission International (JCI) and the Institute for Health Care Improvement (IHI) are encouraging healthcare organisations to develop a culture of safety as an effective strategy for sustainable safety improvement (Azimi et al., 2012). A growing body of evidence indicates that the rate of medical errors and adverse events are associated with the attitudes of healthcare professionals towards safety (Bonner et al., 2009). In this regard, patient safety culture, which is considered as a component of the organisational culture includes the shared beliefs, attitudes, values, norms and behavioural characteristics of employees (Fleming and Wentzell, 2008) which will consequently influence upon the staff member attitudes and behaviours in regards to their organisation’s ongoing patient safety performance. Frameworks, surveys and assessment tools have been developed over the past

decade to help organisations measure and understand what type of culture exists in the organisation and to identify areas of strength and gaps so that factors that might improve or hinder improvement efforts can be identified (Nieva and Sorra, 2003, Colla et al., 2005, Morello et al., 2013).

4.3.1.1 Patient safety in the Arab countries

Both the developed and developing world are aiming to improve patient safety (Donaldson and Philip, 2004). Developing countries have been encouraged by the joint global initiative of the WHO and the World Alliance for Patient Safety (WAPS) to launch a concerted effort which will help in the assessment of the magnitude of the problem. One of the studies that has evaluated patient safety in Arab countries has used the Patient Safety Friendly Hospital Initiative (PSFHI) standards. The PSFHI is one of the WHO initiatives that helps in supporting institutions in countries to launch a comprehensive patient safety program which was launched by the Eastern Mediterranean Regional Office of the WHO in 2007 to help improve the level of patient safety in the region (Siddiqi et al., 2012). Ministries of health of seven countries in the Middle East have been assessed using the PSFHI which included Egypt, Jordan, Morocco, Pakistan, Sudan, Tunisia and Yemen. One hospital in each country was assessed against the PSFHI standards. The study found that none of the participating hospitals achieved a baseline score of 50% across the PSFHI standards. It was also found that commitment of the leadership and management is one of the key areas that is wanting in all institutions. Leadership is significant in patient safety as it recognises safe care as a system-related problem (Clarke et al., 2007). Furthermore, it was found that patients in these countries are not being involved nor do they have a “voice” in matters related to the care they receive. Another study which was carried out by the WHO (WHO, 2003) found that no accreditation programs are being adopted in the Eastern Mediterranean region. This has encouraged few countries in the region to develop and implement accreditation programs to healthcare institutions (El-Jardali, 2006). More importantly, it was reported that accreditation programs have helped in improving the perception on the quality of patient care and patient safety in Saudi hospitals (Al Awa et al., 2011). Furthermore, a study was performed in hospitals from Egypt, Jordan, Kenya, Morocco, South Africa, Sudan, Tunisia and Yemen to assess the frequency and nature of adverse events to patients in these countries. The study

found that of the 15,548 records that were reviewed, 8.2% showed at least one adverse event. A range of 2.5% to 18.4% per country was found and 83% of these adverse events were judged to be preventable. The study also found that 30% of these events were associated with the death of the patient (Wilson et al., 2012). In Palestine, it was reported that one in seven patients suffers harm in Palestinian hospitals (Najjar et al., 2013). These statistics suggest that patient safety is a major concern for the health policy agenda in Arab countries and it is vital that the causes of harm to patients are identified and understood to develop strategies for improvement.

4.3.1.2 The Hospital Survey on Patient Safety Culture (HSPSC)

One of the widely used and validated tools for measuring patient safety culture is the Hospital Survey on Patient Safety Culture (HSPSC) which was developed by the Agency for Healthcare Research and Quality (AHRQ) in the United States (Sorra and Nieva, 2004). This instrument contains 12 dimensions as shown in Appendix E where each dimension consists of 3 to 4 survey items, totalling 42 survey items. The survey uses a 5-point Likert response scale of agreement “Strongly disagree to strongly agree” or frequency “Never to Always”. The survey has been widely used in many countries worldwide, some of these are highlighted in Appendix E. The aim of this systematic review is to identify the overall status of patient safety culture in the Arab countries. The review also aims to explore the weaknesses, strengths and future opportunities for patient safety improvement in the Arab region.

4.3.1.3 Objectives

- To explore the status of patient safety culture in Arab countries based on the findings of the Hospital Survey on Patient Safety Culture
- To determine how widely is the Hospital Survey on Patient Safety Culture (HSOPSC) used in Arab countries
- To determine the differences of the understanding of patient safety culture among Arab healthcare staff and compare the strengths and weaknesses
- To identify the key issues, problems, barriers and challenges particularly in relation to patient safety in the Arab countries
- To generate themes that can be helpful for developing a holistic framework for improving patient safety in Libya based on the findings of the systematic review.

4.3.2 Methodology

4.3.2.1 Search strategy

Electronic search of Medline, EMBASE, CINAHL, ProQuest and PsychINFO, Google Scholar and PubMed databases, with manual searches of bibliographies of included articles and key journals. English and Arabic language studies published between January 2005 and December 2015 that used the Hospital Survey on Patient Safety Culture in a healthcare setting in any Arab country. Table 4.3 summaries the keywords that were used to execute the search.

Table 4.3. Summary of the search terms

Field	Database
Arab countries	Mesh terms: Arab, Arab countries, Arab world. All fields: Algeria or Bahrain or Egypt or Iraq or Jordan or Kuwait or Lebanon or Libya or Mauritania or Morocco or Oman or Palestine or Qatar or Saudi Arabia or Sudan or Syria or Tunisia or United Arab Emirates (UAE) or Yemen, or Arabic, or middle east.
Safety	Safety or patient safety or patient culture or hospital safety or healthcare safety or safety climate
Healthcare Setting and participants	Hospital or nursing or healthcare worker or teaching hospital or primary healthcare, or clinic or government hospital or private hospital
Assessment terms	Perception or assess* or measure*
Survey instrument	Hospital survey on patient safety culture

4.3.2.2 Inclusion and exclusion criteria

Titles and abstracts were examined independently by two reviewers and were selected or excluded based on the following criteria:

- Selection criteria: studies were included if they met the following criteria: 1) were concerned any of the Arab countries mentioned in table 1, 2) used the HSOPSC as an instrument for assessing patient safety culture, 3) were published in English or Arabic language, and 4) were conducted in primary care, secondary or tertiary care settings.

- Exclusion criteria: studies were excluded based on the following criteria: 1) studies that use tools other than the AHQR's Hospital Survey on Patient Safety Culture, 2) studies that are conducted in residential care facilities, 3) studies that involve patients, 4) studies that are conducted in non-Arab countries, and 5) studies that have less than 50 participants. The flow chart in Figure 4.1 illustrates the selection process.

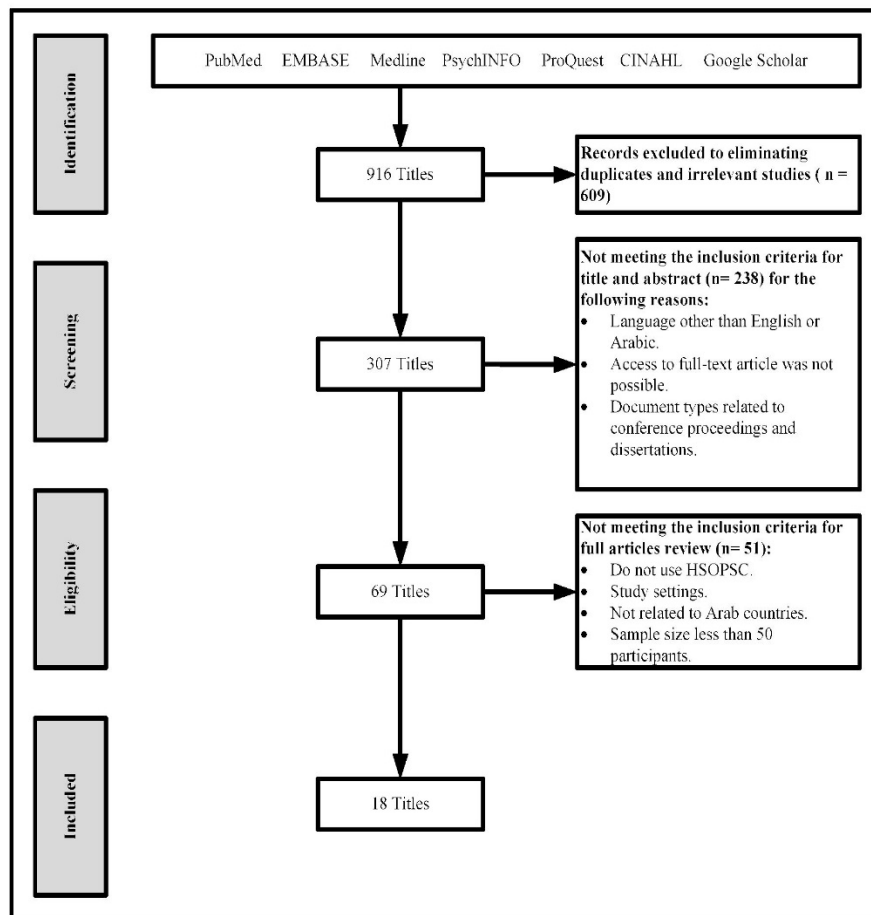


Figure 4.1: Selection process workflow

The data was extracted based on study setting, type and number of participants, composite scores for individual HSOPSC categories, and origin of the study. The quality of included studies in the review were assessed through an adapted version of the New castle-Ottawa scale (Wells et al., 2000).

4.3.3 Results

18 papers met the inclusion criteria. The country with the most studies was Saudi Arabia (6 studies), while the rest were distributed as follows: Egypt (4 studies), Jordan (3 studies), Oman (2 studies), Kuwait (1 study), Lebanon (1 study), Palestine (1 study).

Of the 18 papers, 16 were conducted among hospital staff, while 2 were performed in a primary care setting. Collectively, the studies include a total of 17,541 participants. Most selected studies had a response rate above 60% except Ahmed et al (2011), AbuAlRub et al (2014), El-Jardali (2010) and Alahmadi (2010) which had a response rate of 59.2%, 57%, 55.5% and 47.7% respectively. Only two studies used both electronic and paper format to collect data whereas the rest of the studies used paper format only.

4.3.3.1 Type of participants

There was a wide variation in the type of participants in our reviewed studies. The majority of the studies have included multiple healthcare professionals. Out of these studies, seven have included non-clinical staff (e.g. administrative, managerial staff). Seven studies have only surveyed nurses.

4.3.3.2 Strengths and area of potential improvement

Participants in the studies differed significantly in their positive response to different items in the survey. Surprisingly, there was a recurring theme among studies regarding perceptions of patient safety culture. Participants perceived non-punitive response to error to be the least practised in their organisation (Table 4.4). This composite is defined as the extent to which staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file. On the other hand, organisation learning and continuous improvement were positively rated along with teamwork within units in most of the studies. Table 4.4 summaries the key strengths and areas of potential improvement based on each country; only three areas of strength and three areas that require improvements have been added in the table as these have received the highest and lowest ranking respectively.

As noted in Table 4.5, the dimensions that were rated as strengths included organisational learning/continuous improvement, teamwork within units and hospital management support for patient safety. On the other hand, non-punitive response to error, staffing and communication openness were seen as areas that require further improvement in the perception of the participants in these studies. As seen in table 4.5, almost most of the studies reported that non-punitive response to error is the least positively ranked area irrespective of the type of the participants or the study sittings. The lowest mean score of the non-punitive response to error dimension was scored in Saudi Arabia (Al Awa et al., 2011), Palestine (Hamdan and Saleem, 2013) and Egypt

(Aboul-Fotouh et al., 2012) (16%, 17% and 19.5% respectively). Studies that were conducted in primary care settings (Ghobashi et al., 2014) (Mohamed et al., 2015) did not show any variation in terms of positive scores on the organisational learning and continuous improvement dimension when compared with the studies carried out in hospital settings as well as on the dimension of teamwork within units.

Table 4.4: Percent of positive score in each dimension

First author, year	country	Safety culture dimensions (percentage of positive score) *											
		1	2	3	4	5	6	7	8	9	10	11	12
Aboul-Fotouh, 2012	Egypt	34.6	39.7	33.4	24.6	27.2	19.5	78.2	33.9	49.3	46.4	38	58.1
AbuAlRub, 2014	Jordan	60.3	75	64.3	33.5	70.3	26.2	84.8	60.6	32.9	56.5	57.3	83.8
El- Jardali, 2010	Lebanon	57.3	68.1	68.2	49.7	78.4	24.3	78.3	72.5	36.8	66.4	56.0	82.3
Alahmadi, 2010	Saudi Arabia	60	77	63	61	74	22	87	59	27	70	50	84
El-Jardali, 2014	Saudi Arabia	42.9	63.3	59.4	51.5	70.4	26.8	79.6	65.3	35.1	60.6	61.6	78.5
Al-Ahmadi, 2009	Saudi Arabia	44.2	63.3	56.2	47.6	65.4	21.1	75.9	51.4	31.2	64	56.3	69.9
Al Awa, 2012	Saudi Arabia	36	58	57	47	61	16	74	45	15	51	51	68
Ammouri, 2014	Oman	49.7	68.7	58.8	57.7	25.2	21.4	81.1	50.7	27	60	66.1	83.4
Hamdan, 2013	Palestine	36	46	35	48	37	17	62	43	38	56	44	71
Abdelhai et al 2012	Egypt	38	63	43.5	57	57.3	29.9	50	71.1	40	35.5	41.1	51.7
Ahmed et al 2011	Egypt	37.9	35.4	33.7	52.1	56.3	52.9	57.1	56.5	42.9	59.6	61.8	59.6

Saleh et al 2015	Jordan	46.1	46	37	44.3	44.5	30.7	49.2	43.3	30.4	43.3	43.8	49.8
Khater et al 2014	Jordan	49	59.5	69.1	41.7	53.5	21	68.1	60	34.5	57.9	41.7	78.8
Ghobashi et al 2014	Kuwait	45	62	32	47	67	24	75	61	41	53	63	82
Aboshaiqah, 2013	Saudi Arabia	36	67	61	22	90	49	82	52	54	49	55	70
Aljabri, 2012	Saudi Arabia	51	71	57	51	73	22	79	57	31	67	60	77
Al-Mandhari et al 2014	Oman	54	62	65	44	67	25	84	53	30	60	64	83
Mohamed et al 2015	Egypt	66.7	66.7	60	75	80	66.7	73.3	60	60	75	70	80

* 1. Communication openness. 2. Feedback and communication about error. 3. Frequency of events reported. 4. Handoffs and transitions. 5. Management support for patient safety. 6. Non-punitive response to error. 7. Organizational learning—continuous improvement. 8. Overall perceptions of patient safety. 9. Staffing. 10. Supervisor/manager expectations and actions promoting safety. 11. Teamwork across units. 12. Teamwork within units.

Table 4.5 Summary of the reviewed studies

No	First author and year	Country	Setting	Number of participants	Participant type	Strength	Area of potential improvement
1	(Aboul-Fotouh et al., 2012)	Egypt	1 teaching hospital	510	Health professionals	- Organisational learning/continuous improvement - Teamwork within unit - Staffing	- Non-punitive response to error - Handoffs and transition - Hospital management
2	(AbuAlRub et al., 2014)	Jordan	1 hospital	57	Nurses	- Organisational learning/continuous improvement - Teamwork within unit - Feedback and communication about errors.	- Non-punitive response to error - Staffing - Handoffs and transition
3	(El-Jardali et al., 2010)	Lebanon	68 hospitals	6807	Clinical and non-clinical staff	- Teamwork within unit - Hospital management support for patient safety - Organisational learning/continuous improvement	- Non-punitive response to error - Staffing - Hospital handoffs and transitions
4	(Alahmadi, 2010)	Saudi Arabia	13 hospitals	223	Health professionals	- Organisational learning/continuous improvement - Teamwork within unit - Feedback and communication about errors.	- Non-punitive response to error - Staffing - Teamwork across hospital units.

5	(El-Jardali et al., 2014)	Saudi Arabia	1 hospital	2572	Clinical and non – clinical staff	• Organisational learning/ continuous improvement • Teamwork within unit • Hospital management support for patient safety	• Non-punitive response to error • Staffing • Communication openness
6	(Al-Ahmadi, 2008)	Saudi Arabia	9 public hospitals and 2 private	1224	Clinical and non-clinical staff	• Organisational learning/ continuous improvement • Teamwork across hospital units. • Supervisor/ manager expectations and action	• Handoffs and transition • Communication openness • Non-punitive response to error
7	(Al Awa et al., 2011)	Saudi Arabia	1 hospital	605	Nurses	• Organisational learning/ continuous improvement • Teamwork within unit • Hospital management support for patient safety	• Non-punitive response to error • Staffing • Communication openness
8	(Ammouri et al., 2015)	Oman	4 hospitals	414	Nurses	• Teamwork within unit • Organisational learning/ continuous improvement • Feedback and communication about errors.	• Non-punitive response to error • Hospital management support for patient safety • Staffing

9	(Hamdan and Saleem, 2013)	Palestine	11 hospitals	1460	Clinical and non-clinical staff	• Teamwork within unit • Organisational learning/ continuous improvement • Supervisor/ manager expectations and action promoting safety	• Non-punitive response to error • Frequency of events reported • Communication openness
10	(Abdelhai et al., 2012)	Egypt	Teaching hospitals	400	Health professionals	• Feedback and communication about error • Hospital management support for patient safety • Hospital handoffs and transitions	• Non-punitive response to error • Supervisor/ manager expectations and action promoting safety • Staffing
11	(Ahmed et al., 2011)	Egypt	2 university hospitals	128	Nurses	• Teamwork across hospital units • Supervisor/manager expectation and actions promoting safety • Teamwork within units	• Frequency of reported events • Feedback and communication about error • Communication openness
12	(Saleh et al., 2015)	Jordan	2 public hospitals, 2 private hospitals and 1 teaching hospital	242	Nurses	• Teamwork within units • Organisational learning/ continuous improvement • Communication openness	• Staffing • Non-punitive response to error • Supervisor/manager expectations and actions

13	(Khater et al., 2015)	Jordan	15 public hospitals, 4 privates hospitals and 2 teaching hospitals	658	Nurses	• Teamwork within units • Organisational learning/continuous improvement • Frequency of events reported	• Non-punitive response to error • Staffing • Handoffs and transitions
14	(Ghobashi et al., 2014)	Kuwait	4 primary care centres	369	Clinical and non-clinical	• Teamwork within units • Organisational Learning / continuous improvement • Management support for patient safety	• Non-punitive response to error • Frequency of events reported • Staffing
15	(Aboshaiqah and Baker, 2013)	Saudi Arabia	1 hospital	498	Nurses	• Hospital management support for patient safety • Organisational learning/continuous improvement	• Hospital handoffs and transitions • Communication openness • Non-punitive response to error
16	(Aljabri, 2012)	Saudi Arabia	2 hospitals	726	Health professionals	• Organisational learning/continuous improvement • Teamwork within units • Hospital management support for patient safety	• Non-punitive response to error • Staffing • Hospital handoffs and transitions

17	(Al-Mandhari et al., 2014)	Oman	5 hospitals	398	Clinical and non-clinical	• Organisational learning/ continuous improvement • Teamwork within units • Management support for patient safety	• Non-punitive response to error • Staffing • Handoffs and transitions
18	(Mohamed et al., 2015)	Egypt	28 primary health centres	250	Clinical and non-clinical	• Teamwork within units • Management support for patient safety • Supervisor expectations and actions promoting safety	• Staffing • frequency of events reported • non-punitive response to errors

4.3.4 Discussion

This review has focused on the status of patient safety culture in Arab countries to identify the areas of strengths and the areas of concerns. Since the publication of the Institute of Medicine (IOM) report “To err is human” (Kohn et al., 2000), patient safety culture has become a core element in improving patient safety. It was suggested in the IOM’s report that any efforts which aim to improve patient safety culture should move away from a “blame culture” and focus on removing “error provoking” aspects of care delivery systems (Kohn et al., 2000). The review showed that healthcare organisations in the Arab world are moving towards the need to assess and evaluate the patient safety culture of healthcare professionals to ensure that improvement strategies are being developed on evidence-based practices. It could also be argued that policymakers and practitioners in developing countries are becoming more aware of the risk of unsafe healthcare (Carpenter et al., 2010, Wilson et al., 2012). The review showed that the HSPSC is not widely used in the Arab world as the HSOPC was only used in Saudi Arabia, Egypt, Jordan, Oman, Lebanon, Kuwait and Palestine. None of the reviewed studies were conducted in Arab countries that are located in North Africa. Interestingly, both the English and Arabic versions of the HSPSC questionnaire were used in the selected studies. Eight studies have used the Arabic version but only one study reported that the psychometric properties of Arabic version were validated (El-Jardali et al., 2010).

It was clear that healthcare staff in the Arab world are concerned about having a supportive organisational structure that encourages error reporting. There is growing evidence that suggests that the rate of medical errors and adverse events is associated with the attitudes and perceptions of professionals towards safety (Bonner et al., 2009, Flin et al., 2003). Moreover, a study by Najjar et al (2015) which looked at the relationship between patient safety culture and adverse event rates in Palestinian hospitals found that departments with positive patient safety culture had lower rates of adverse events. In this regard, many developed countries have realised the importance of improving personnel safety behaviours to achieve high safety and reliability in addition to exploiting modern technology and advanced managerial systems (Miller et al., 2009). Non-punitive response to error has been negatively rated by all participants in all countries which suggests that a culture of medical dominance

exists in the organisational structures of the Arab health systems. This medical dominance will also influence upon the inter-professional relationships between the healthcare staff as argued by Adamson et al (1995). The success or failure of team-based work systems implementation has been linked to effective leadership which is a key variable for the functioning of teams (Avolio et al., 1996, Day et al., 2004). To ensure safe and efficient work medical teams, interactive human factors such as communication, supervision or team structure were considered vital to achieve that (Donchin et al., 1995, Kosnik, 2002). On the other hand, lack of coordinated care or team work failure and breakdowns in communication will result in an unfavourable outcome for the patient (Flin et al., 2003). There is a need to encourage team members through positive behaviour and feedback by leaders (Cole and Crichton, 2006). Ensuring accountability with avoiding blame and negativity needs to be balanced by leaders.

4.3.4.1 System changes to improve patient safety

Patients have a right to be protected by healthcare providers (Spath, 2012). Systems that minimise the likelihood of errors while maximising the likelihood of intercepting these errors need to be established (Carayon et al., 2006). An efficient operating mechanism that is dependent on the collaboration of the sub-parts to achieve an outcome is what describes the system-approach to patient safety (Pronovost et al., 2015). Provider organisations across different care settings, policy-makers, regulators, educational institutions and patients are the sub-parts of the patient safety system (Pronovost et al., 2015). The rate of errors in complex systems such as those that deliver health care is influenced by many factors. A nested hierarchy of factors that determine the safety of a healthcare system have been suggested by Vincent et al (Vincent et al., 1998). The system factors related to work environment, institutional context, organization and management, individual team members, tasks and patients (Vincent et al., 1998). This could imply that improving work conditions would involve improvements to interface design, to the physical environment, to the ergonomics of equipment or the reduction of distractions and interruptions which influence the propensity to error (Nolan, 2000). A basic requirement of a safe system is using protocols, checklists and other reminders for patient and clinician interactions (Nolan, 2000). The use of these aids would benefit making informed decisions and creating a

culture of safety through complying with rules and procedures. A widely known and well-established systems-based model in patient safety research is known as ‘Swiss Cheese Model’ of safety (Reason, 2000) in which it proposed that hazards within complex systems are prevented by a series of barriers. Thus, a systems-based approach to patient safety in Arab countries is highly needed.

4.3.4.2 Patient safety reporting systems

The review indicated that healthcare staff in the Arab world are not being encouraged to report incidents which can be investigated so that lessons can be learnt. This is could be because such reporting systems are not being implemented by healthcare organisations in the region due to the lack of the required regulations to manage and promote patient safety as the case in developed countries including the United States (Liang et al., 2007). Hence, as argued by Leape (1994), adverse event reporting systems will not be efficient within a punitive culture. Thus, there is a need for a fundamental culture change to ensure that all innovations which are introduced to improve patient safety can achieve their potential. More importantly, healthcare staff should have the opportunity to learn from such reporting systems by ensuring that there is a policy for effective feedback as that will help organisations learn from failures in the delivery of care (Benn et al., 2009). In other words, policy makers should work in collaboration with healthcare providers to ensure that reporting systems are being implemented and that staff are encouraged and supported to report any incidents which might have an impact on the patient’s health. Leape (2002) affirmed that patient safety reporting systems helps healthcare organisations to improve patient safety which is very significant to Arab countries as reported by this review. This is to ensure that when incidents occur in the workplace, organisations need to understand what happened and why so that the probability of recurrence is reduced and to figure out if the existing interventions are effective or not (Vincent, 2003).

4.3.4.3 “Just” culture

A prerequisite to achieving lasting improvement is the need to embed the goal of providing safe care in the culture of the organisation (Waring, 2005). Culture transformation is a complex endeavour as it evolves in response to past events, local conditions, the mood of the workforce and the character of the leadership (Reason,

1998). On the other hand, safety culture reflects the “ability of individuals or organisations to deal with risks and hazards so as to avoid damage or losses and yet still achieve their goals” (Reason, 2000). Thus, organisations need to ensure that a positive patient safety culture is in place which encourages honest disclosure of information and that a sincere interest in rectifying the problems is demonstrated (Waring, 2005). It could also be assumed that healthcare organisations in the Arab world should move away from the culture of blame to a “just” culture which encourages the acknowledgement of error so that learning from errors can be achieved. In other words, employees need to feel that they will not be punished or concealed for acknowledging errors. This could imply that positive safety culture will help in encouraging honesty and fostering learning by balancing the individual and organisational accountability to achieve better quality care.

4.3.4.4 Education and regulation

Milligan (2007) pointed out that a more fundamental change is required within healthcare curricula in order to improve patient safety. This suggests that countries in the Arab world should focus on the need of providing training and education programs to healthcare professionals and students on the importance of a systems approach in creating a patient safety culture. The review indicated that organisational learning and continuous improvement has been ranked as one of the areas of strength in the Arab countries. However, there needs to be a holistic approach to patient safety management by ensuring that all relevant elements such as resources, training, education and policies are in place to create a sustainable culture of safety in the workplace. In the United States as a result of the IOM’s report, the US Congress passed the Patient Safety and Quality Improvement Act in 2005 which aims at improving quality and safety through the collection and analysis of data on patient events. This shows that patient safety has to be improved by the involvement of all relevant stakeholders including policy makers, healthcare providers and patients as well as their families.

4.3.4.5 Communication and staffing

The review indicated that staff in the healthcare sector in the Arab world perceived teamwork within units to be acceptable when compared with other dimensions of the

survey. Teamwork efforts cannot be successful without open communication within the care team. Thus, it is important that training programs on teamwork and communication are provided to all staff so that different disciplines in medicine are connected to improve team performance. It was revealed by Pronovost et al (2003) that the Accreditation Council on Graduate Medical Education in the US endorsed the inclusion of “interpersonal and communication skills” in their core competencies in 1999. This shows that establishing interdisciplinary team training can help improving patient safety as it will help in reducing the misunderstandings among individuals and teams which might impact upon the patient’s care. Therefore, policy makers in the Arab countries should ensure that staff have the ability to speak up when there are concerns in the workplace as well as being able to consult and seeking help whenever it is needed to ensure high quality care is provided to all patients at all times. It was also found that levels of staffing is a common issue that is shared by many Arab countries. Insufficient staffing is likely to cause stress as staff will be forced to work under pressure and for long hours. It is well-evidenced that when nurses work more than 12 hours at one time, the risk of making an error increases significantly (Rogers et al., 2004).

4.3.4.6 Limitations

Due to the lack of relevant research literature in Arabic, this systematic review was restricted to English-language publications only that have been peer-reviewed. This could have limited other studies that have used the HSPSC. The reported studies were conducted in different healthcare settings (e.g. secondary and primary care) which might influence the perception of patient safety culture among healthcare workers. .In terms of the limitations of the review, responses to patients’ safety culture items are likely to be dependent on the organisation where the questionnaire has been conducted. Intrinsic organisational culture elements such as management support, level of funding, and size of the organisation can limit the generalisability of some of the reviewed studies. Another limitation is the fact that not all Arab countries have used the HSPSC which could also limit the generalisability of the reviewed studies. Moreover, the comparison between the reviewed studies may be difficult because of the variation in the type of participants (e.g. nurses, doctors and administrators). Nurses may have different perception of patient safety culture as they are in

continuous contact with patients. It could be argued that mixed-method studies can help in enhancing the understanding of patient safety culture in the healthcare sector in Arab countries. The use of qualitative approaches such as semi-structured interviews and focus groups with healthcare professionals, patients, policy makers and familiar can further identify the root causes of poor safety culture that exist in some healthcare settings. Qualitative findings can support quantitative findings and provide more insightful explanations about the challenges that face health systems in Arab countries.

4.3.4.7 Conclusion

Patient safety remains a global problem that affects both developed and developing countries. Healthcare organisations should focus on the need of assessing safety culture as that will provide basic understanding of the safety related perceptions of their staff. Safety culture assessment tools can help healthcare organisations in identifying the areas for improvement. It is also very important that policy makers in the Arab countries establish a just culture in the workplace where employees should be encouraged to report any adverse events, errors, incidents or near misses so that lessons can be learnt. More importantly, safety culture should be measured on a regular basis to evaluate the effectiveness of patient safety programs and interventions. Healthcare leaders, researchers and legislators in the Arab countries need to realise that patient safety is a serious public health concern which costs lives. This review has identified that non-punitive response to error is seen as a serious issue which needs to be improved as healthcare professionals in the Arab countries tend to think that a “culture of blame” still exists that prevents them from reporting incidents. Thus, policy makers need to ensure that legislations and regulations are introduced to encourage healthcare organisations to implement patient safety reporting systems which will help identify risks to patients and help healthcare organisations learn from their mistakes.

4.4 Results Part Three – Focus Groups

4.4.1 Introduction

The section of this chapter discusses the focus groups study that was carried as part of this research. The objective of the focus group is to gain insights about the problems associated with patient safety in the Libyan healthcare settings by directly interacting with Libyan healthcare professionals. As I noted above, due to access problems, these focus groups were carried out with Libyan healthcare professionals who are practicing in the UK but whom have good knowledge and understanding to the Libyan health system as they had to meet certain inclusion criteria as discussed in the methodology section.

It is well-evidenced in the literature that healthcare professionals have a major role to play in improving patient safety. This is because of the fact that their knowledge, attitudes and skills regarding patient safety would influence upon their practices. In some developing countries as discussed in the literature review, the quality of medical and nursing education needs to be enhanced in accordance with the changes in healthcare. Moreover, there is a need to establish professional and accreditation bodies to ensure that those healthcare workers are provided with the required training as well as renew their medical or professional licensees. Healthcare professionals who have inadequate level of safety knowledge will also have negative attitudes towards reporting of safety incidents as argued by McMullan et al (2010) and LaPointe et al, (2003). It was also highlighted by Sutker (2008) that physicians have a significant role in patient safety as they interact with patients, nurses, managers and families. Sutker argued that teamwork and communication are crucial when it comes to physicians' role in patient safety. Therefore, it could be argued that Libyan healthcare professionals would provide great insights about the issue of patient safety in Libya. This is because of the fact that they had to integrate with the UK's health system and comply with the working practices and protocols within the UK along with their participation and involvement in patient meetings, training and development courses. Moreover, such healthcare professionals will be able to compare their current practices with the difficulties they face in Libya and will provide rich information about the challenges and problems associated with healthcare quality and safety.

Maintaining patient safety within healthcare settings as noted in the literature is a very challenging tasks for managers and healthcare professionals as the healthcare delivery is very complex and require high levels of communication and teamwork. Moreover, as noted by Frieese and Aiken (2008) that patient safety improvements requires a range of actions in environmental safety, management, performance improvement and risk management activities such as equipment safety, infection control and safe use of medicines. As noted in the previous systematic review presented in Part 1 that healthcare professionals in the Arab countries have a low tendency to report incidents due to the existence of blame culture. Hor et al (2013) asserted that healthcare policy makers are urged to create a model that aims to suspend the culture of blame so that healthcare individuals are encouraged to report incidents and do not feel afraid from reporting errors. Furthermore, clinicians also have a role to play in encouraging patients to contribute to the safety system as found by Hor et al (2013). Therefore, Libyan healthcare professionals practicing in the UK will be able to reflect upon their own experiences so that more understanding of the problem of patient safety in Libya is achieved. Douma (2015) asserted that healthcare organisations should focus on building an infrastructure at organisational level which supports change. Thus, it would be interesting to find out how Libyan healthcare professionals view the organisational arrangements and system structure in Libyan in promoting change, teamwork, communication and patient involvement.

Therefore, the main objectives of these focus groups are:

- To explore the perceptions of Libyan healthcare professionals regarding patient safety practices in Libya
- To identify the barriers and enablers of patient safety in Libyan healthcare settings
- To identify the areas for improvement based on the participants' experiences of the Libyan health system compared to their practices in the UK
- To explore through discussion and interaction the Libyan healthcare professionals' views regarding medical and nursing education in Libya
- To critically evaluate the findings and provide develop a framework for improving patient safety in Libya using the focus groups' findings along with findings of the other studies.

4.4.2 Methodology

Focus groups are qualitative research methods that are used to investigate social and health research. They enable researchers to explore intermediate variables and themes to explain certain situation or phenomenon. Focus groups are defined by Kitzinger (1995) as *“a form of group interview that capitalises on communication between research participants in order to generate detail”*. Focus groups have been found to be very effective in identifying the needs and attitudes of research participants (Kitzinger, 1995). In other words, they enable researchers to interact directly with research participants to discuss and explore different ideas and thoughts. The reason this method was selected is because I wanted to gather Libyan healthcare professionals in an open debate and discussion about the problems associated with patient safety in Libya. It allowed me to overcome access problems to participants and was a cost-effective method to gather a group of professionals to discuss this issue.

Focus groups do also have disadvantage as any other research method. One of these disadvantages is the large number of ideas or views that could be generated in these discussions which could lead to biases in data analysis. Another problem with focus groups is the ability to move away from the subject of discussion to discuss other irrelevant matters. In order to overcome such disadvantages, Hussey and Hussey's (2007) guide in managing focus groups research was followed by having a pre-defined list of topics and questions to guide the focus groups. It was also ensured that each group does not involve more than 8 professionals to allow the participation of all members of the group as well as enable them to answer the questions in more details. Moreover, the timing of each focus group was limited to 1 hour so that the participants do not feel bored or lose interest in participating. It was highlighted by Gillis and Jackson (2002) that focus group discussions are more dynamic and active which result in achieving cumulative understanding of the identified problem. Gillham (2000) also indicated that focus group discussions allow participants to comment and build on emerging issues. It was decided to use focus groups so that I do not restrict the views being sought such as when using a questionnaire survey or one-to-one interviews. Burns and Grove (2001) pointed out that focus group discussions is very appropriate for exploratory research.

Larger sample size would surely generate larger data but will limit the participation of each participant in the discussions. Moreover, focus groups with large sample size will be very difficult to manage and control as noted by Barbour and Kitzinger (1999). Thus, as noted above, 8 participants were involved in each focus group that was carried out. In total, two focus groups with 16 Libyan healthcare professionals were conducted. This sample size allowed for dynamic interaction among the participants and also enable me to manage and control the discussion so that we focus on the main questions. I should also stress on the fact that the purpose of these focus groups is not generalise findings or investigate patient safety culture behaviours but mainly to gain in-depth insights about barriers and challenges associated with patient safety improvement in Libya based on the participants' experiences. The inclusion criteria that were used to recruit the participants in the focus groups are:

- Being a Libyan healthcare professional working in the UK
- Must have worked in Libyan health system
- Must have graduated and trained in Libya
- Agreeing to participate in the focus groups

The focus group discussions were conducted in Arabic and English language as all the participants were speaking both languages. The discussions were recorded using a recorder so that all data is captured for the analysis. The participants gave consent for the recording of the discussions as they were assured that the recorded would be destroyed following the completion of the research.

Purposive sampling technique was used to recruit the participants in the focus groups. As noted by Bloomberg and Volpe (2008), purposive sampling allows the recruitment of information-rich participants to gain understanding of the subject under study. Therefore, purposive sampling technique allowed me to use personal contacts to recruit participants. Snowballing method was used in which healthcare professionals were used to invite their colleagues and friends to participant who meet the inclusion criteria. It was highlighted by Green and Thorogood (2009) that snowball sampling is very effective when the sample is representative of marginalised individuals. It is also used to recruit 'hidden populations'. Table 5.4 presents the key topics questions that were used to guide the focus groups. Each focus group covered to phases as shown

in Table 4.6. Each phase focused on a specific dimension which were included based on the findings of the literature review and the findings of the systematic review. The participants were then asked to reflect upon each of these dimensions using one or two questions for each dimension. This allowed for the participants to have a focused but dynamic and interactive session to share their insights and experiences. It also allowed me to control and manage the discussion so that deeper insights are gained.

Table 4.6: Focus groups discussion guide and questions

Phase 1	<i>Leadership and management support</i>	Do you think there is support and commitment from the leadership and management in Libya regarding patient safety? Why not?
	<i>Culture of safety</i>	How do you rate the culture of safety in Libyan healthcare settings, what are main problems?
	<i>Incident reporting</i>	How is accident and incident learning in Libya? How about electronic medical records?
	<i>Patient involvement</i>	Do you value patient involvement? What are the obstacles to patient involvement in Libya?
Phase 2	<i>Professional accreditation</i>	Is professional licensing and certification in Libya fit for purpose? What are the gaps?
	<i>Medical and nursing education</i>	What are the changes you believe are needed in the medical and nursing education in Libya?
	<i>Continuous professional development</i>	Can we discuss CPD practices in Libya? What are your thoughts about CPD?

4.4.3 Results

The analysis findings of the two focus groups that were carried out Libyan healthcare professionals practising in the UK will be presented in this section. The characteristics of the participants are included in Appendix F. Wong (2008) asserted that analysing

focus group data is similar to analysing any other qualitative research data. According to Dey (1993), qualitative data analysis should lead to well-defined themes that are based on the views of the participants. Similarly, Basit (2003) identified two levels of qualitative data analysis. The first level is descriptive account of the data where the researcher reads the notes without making any assumptions. The second level is interpretative in which the research creates and separates themes based on the analysis of the available data. The process of content analysis for analysing the data generated from the focus groups was adopted. I did not focus on the number of words but I developed a particular strategy so that was helpful to generate themes based on the analysis of each dimension as recommended by Braun and Clarke (2006).

The analysis approach also adopted the mechanisms explained by Braun and Clarke (2006). They indicated that thematic analysis *“provides core skills that will be useful for conducting many other kinds of analysis”* (Braun and Clarke, 2006). They provided six-phase guide which was followed that starts with 1) becoming familiar with the data, 2) generate initial codes, 3) search for themes, 4) review themes, 5) define themes, and 6) write-up. These themes were then examined again to identify if recurrent elements were present. The main themes that were generated following the focus groups data analysis are presented in the next sections. These themes were very helpful in developing the framework presented in Chapter 5.

Phase one analysis

▪ *Theme 1: lack of leadership commitment towards patient safety*

Not surprising for me but it was evident that the participants in the interviews were concerned about the management and leadership commitment patient safety. The discussions were mainly associated with policy planning and strategic management in which the participants believe that healthcare managers in Libya are not engaged in such practices. They highlighted that most of the hospitals and primary care units in Libya are managed using a top-down hierarchy in which resources, staff allocations and budgets are being distributed by the Ministry of Health through its regional secretariats and offices across the country. Within this themes, the participants raised issues such as; goal-setting, strategic planning, workers' involvement in meetings, performance measurement. The participants also felt that leadership and management styles differ in Libya to those applied in western countries. They raised

the issue of cultural differences and how lack of accountability, transparency and performance measurement is affecting upon the overall management practices. They also complained about the lack of open-door policy within healthcare settings in Libya which prevents doctors, nurses and other workers to share their concerns. Most of the reasons associated with the lack of commitment was linked to culture, lack of law and accountability measures.

▪ ***Theme 2: Poor awareness of safety***

The second theme which was emerged from the analysis is linked to the lack of positive safety culture within Libyan healthcare settings. The main problems were mainly associated with lack of training and continuous development. They also emphasised upon the role of the Ministry of Health in monitoring healthcare providers and that collaboration is needed between different governmental agencies. It was alarming when the participants raised concerns about recruitment of foreign nurses and doctors without strict interviews or checks. Among the categories that were generated in this theme include; lack of regular training, education from early years about safety, support from top management, lack of regulations and laws as well as absence of accreditation programmes. Some participants indicated that previous attempts were made to gain accreditation from quality assurance agencies but due to lack of commitment from the top management as well as the absence of expertise such attempts failed. It is important to note that patient safety culture dimensions as found in the literature were linked to leadership, teamwork, open communication as well as patient-centred (Sammer et al., 2010). However, based on the analysis of the data, it was evident that more work is needed to promote positive patient safety culture among healthcare workers through showing commitment, provision of training and continuous learning opportunities. The participants also noted that they are rarely involved in any discussions or meetings about patient harm or inviting patients to discuss aspects of poor care. This shows that there is definitely a need to promote improvement in patient safety culture using an integrated approach.

▪ ***Theme 3: fear and blame***

It was mentioned by the participants that their experience in the UK is totally different when it comes to reporting of incidents. They asserted that reporting here is for

knowing what went wrong but in Libya it is for shaming and blaming. There was a sense of fear noticed during the discussions as healthcare workers raised their concerns about reputation and public image. The participants indicated that there is no process of learning from previous accidents but normally hospitals cover up the facts to avoid problems with authorities. The participants also noted that patients are not fully familiar of their rights despite the existence of an old code of practice for Libyan healthcare workers which requires them to do their jobs safely. However, as there is a lack of accountability as noted by the participants, there is a culture of fear and blame which prevents all workers from reporting accidents. This again shows that these are system and organisational failures which led to the creation of such environments. All healthcare workers should be encouraged to report incidents so that lessons can be learnt but as was raised by the participants that fear is preventing healthcare workers from reporting incidents. Moreover, it was highlighted by the participants that if you report any mistake you might be shamed by other people which affect upon your reputation. This is very critical to patient safety as all patients should receive high quality care free from harm and they should be informed about any risks that could affect upon their well-being.

▪ ***Theme 4: lack of trust and awareness***

Interestingly, the problem of commitment from top management was almost mentioned in every discussion along with the lack of clear governance structures. The participants raised their concerns about the absence of regulatory frameworks that organise health services in the scope of continuous improvement and learning. They differentiated between patient involvement and patient awareness. The participants highlighted that due to the absence of organisational arrangements and policies which encourage patient involvement in making decision making, it is up to the individual doctors to engage and inform patients about the choices. They asserted that doctors tend to use their morale attributes and manners to discuss issues with patients and their families but there is no formal policy or structure which encourages doctors to engage patients in the care process. They believe that foreign nursing teams is also a problem due to the cultural and language barriers which prevent patients from asking questions.

The participants were also concerned about the level of trust among Libyan doctors/nurses and patients. They noted that due to the bad reputation that healthcare providers in Libya have over the past decades which result from poor planning, lack of skilled workforce as well as absence of any performance measurement or quality improvement. The patients have been influenced by many organisational factors and thus they lost their trust in the health system. The participants indicated that some physicians in Libya made huge good reputations because of their relationships with patients. This shows that it is crucial for policy makers in Libya to consider the need for reforming the current healthcare practices to encourage patient and family involvement. This will also help in identifying any problems in advance so that patient harm is prevented. The participants were concerned about the lack of organisational policies or systems in which patients are provided with support and guidance. This again indicates the lack of a vision and strategy in relation to patient safety improvement which should be supported by the top leadership and management.

Phase two analysis

▪ Theme 1: absence of clear guidelines

The participants highlighted the issue of poor licensing system in Libya which has been affected by the number of foreign doctors and nurses being employed in Libya. They asserted that following graduation from the University, doctors for example receive one-year of training and then they can practice medicine either in private or public sector. There are not royal colleges as those available in the UK as highlighted by the participants but voluntary societies and committees that are formed by different specialists to ensure that those practice in any field are accredited by these societies. There is also failures in the professional accreditation process such as that clearly provided by the General Medical Council in the UK. They also indicated that there is no clear guidelines about renewing licenses after years of non-practice. There is not well-defined Libyan code of conduct for physicians or nurses as highlighted by the participants which increases the risk of lack of accountability. They also indicated that lack of professional accreditation is threatening patient safety in Libya as many nurses and doctors practice in public and private sector without being examined or assessed in regards to their qualifications or experiences. The issue of corruption and lack of

transparency was also highlighted by the participants which affects upon the recruitment process.

▪ ***Theme 2: teamwork and inter-professional collaboration***

It was nearly almost all of the participants who indicated that education and training are crucial for patient safety improvement in Libya. They noted that the current curriculum being taught in Libyan medical and nursing colleges requires change and that more up-to-date learning material is needed to ensure that graduates understand the complexities and emerging issues in medicine. The participants also raised their worried about the lack of the provision of training to healthcare workers especially on issues related to patient safety. They indicated that in the UK some consultants and nurses work as improvement leads to enable continuous improvement. They also asserted that there is always an opportunity to receive training or attend a national conference to keep up to date with changes in the field. The main changes which the participants highlighted include the following:

- Introduction of simulation-based learning tools
- Hands-on training and student involvement in discussions
- Workshops and team-based problem solving techniques
- Teamwork and communication seminars
- Patient safety training and awareness
- Introduction of technology
- Access to medical journals

The participants asserted that there is a need for medical and nursing students to receive access to online articles to enable them review recent published research in their chosen fields. They raised their concerns about the lack of educational reforms about the past years which affected upon the graduates' skills and competencies.

▪ ***Theme 3: contextual and organisational factors barriers to CPD***

This discussion about CPD was very rich in information due to the fact that medical science and technologies advance everyday but current practices in developing countries remain the same. They pointed out that during their practice in the UK, several technologies and standards were introduced which required them to attend training sessions. However, in Libya, they maintained that lack of commitment from

Huma Resources and top leadership is influencing CPD practices. They also indicated that even if course were offered, there will be insufficient places on these courses which will cause problems among staff. They also indicated that sometimes they cannot travel to conferences or events because there is shortage of staff in their units/hospitals. They believe that the top management is not concerned about CPD especially with the absence of professional colleges and accreditation bodies that require healthcare professionals to obtain certain credits to be promoted.

In summary, it was clearly evident that Libyan healthcare professionals who participated in the focus groups were very concerned about the standards of patient safety in Libya. They raised their concerns about the lack of accountability and regulatory frameworks as well as the absence of efficient quality improvement systems in place which allows organisations to learn from previous failures. Interestingly, the participants indicated that their experiences did not influence upon their integration with the UK health system as there are clear protocols and guidelines which they follow in doing their day-to-day job. They also emphasised upon the level of teamwork across their units and that information sharing is very practical which helps in reducing patient harm.

4.4.4 Discussion

The focus group study showed that Libyan healthcare professionals are very concerned about patient safety in Libya due to the lack and absence of regulatory frameworks and commitment from the top management. It was highlighted by Bagnasco et al (2011) that healthcare professionals are required to improve the quality of their clinical practices so that they can provide high quality and efficient care to patients. Baid and Hargreaves (2015) argued that ensuring high quality of care and patient safety is strongly connected to an individual health care professional's knowledge. Thus, it is crucial for policy makers and managers within the healthcare sector to understand the important role of continuous professional development as well as training among healthcare workers irrespective of their fields. A study by Ahmed et al (2013) which investigated the link between training and patient safety among healthcare workers found that senior doctors' knowledge about patient safety following training courses in root cause analysis, patient safety theory and small-group facilitation was improved. It should also be noted that training courses cannot be used

solely for enhancing patient safety culture among healthcare workers but continuous professional development as well as involvement in strategic planning and meetings will help raise more awareness about the issue of patient safety.

The results of the focus group study indicated that there are significant contextual, organisational and environmental factors which influence upon patient safety improvement in Libya. They noted that more efforts are needed by policy makers to shift the focus among healthcare workers as well as managers towards patient safety. This starts by ensuring that awareness is established through showing commitment, provision of training and educational interventions as well as introducing legislations and laws that encourage healthcare providers to engage in quality improvement practices. Libyan healthcare professionals were very concerned about the lack of clear policies and guidelines about professional certification as well as lack of patient involvement in the process of care. Therefore, the findings of this qualitative study will be very useful for identifying the main components of the patient safety improvement framework that is presented in Chapter 5.

4.5 Results Part Four – Modified Delphi Study

4.5.1 Introduction

The aim of this Delphi study is to identify key priority areas for patient safety improvement in developing countries and countries in transition. The study aims to achieve consensus on the most important areas to improve patient safety in developing countries while using Libya as a case-study. The study objectives include the following:

- Identify the most important areas in regards to improving patient safety in developing countries
- To seek expert advice to identify the key factors that are the most important in the improvement of patient safety.
- To identify the barriers that hinder the implementation of patient safety systems
- To develop a patient safety improvement framework that is oriented to the Libyan context and capable of improving patient safety in the Libyan healthcare system.

Libya is chosen as a case study as the country is undergoing a transitional stage. Libya provides universal health coverage free of charge. The health system in Libya is mainly funded by the state. Health services are delivered through primary health care centres, polyclinics, rehabilitation centres and general hospitals in urban and rural areas.

4.5.2 Methodology

A modified Delphi approach is adopted for this phase of the study to identify the key priority areas for patient safety improvement in Libya. This modified Delphi adopts a structured questionnaire for round 1 and a small sample size (Hsu et al., 2007). The Delphi technique has been widely used in health services and policy research as it supports decision-making and gives a way of structuring a large mass of information and expertise so that informed judgement, forecasting and decision-making can be achieved (Rowe et al, 2011). It can be used to discuss both numerical and non-quantifiable nature of problems. It is believed that the Delphi technique has the capacity to deal with ambiguity and multi-dimensionality based on its ability to draw on the informed judgement of a group of experts systematically which made it one of the highly reliable tools to support decision-making in the fields of medicine, sociology and policy making (Ziglio, 1996; Falzarano and Zipp, 2013; Landeta, 2006). A key strength of the Delphi technique is the fact that it does not force consensus but helps in identifying where agreement exists among international experts (Thomson et al., 2009). Some of the many advantages of the Delphi technique are: ability to conduct a study in geographically dispersed locations as it is the case of this protocol, time and cost effectiveness as well as allows the discussion of complex and broad problems.

4.5.2.1 Use of Delphi method in patient safety research

The Delphi method was used to identify the barriers to Implementation of patient safety systems in healthcare institutions with 23 experts in healthcare quality and healthcare systems approach in which 18 U.S states were represented (Akins and Cole, 2005). The Delphi method was also used to determine developmental progression of quality and safety competencies in nursing education with 18 subject matter experts (Barton et al., 2009). It was also used by the WHO World Alliance of Patient Safety to develop an International Classification for Patient Safety in which 253 experts responded to the first round of the Delphi method (Thomson et al, 2009). The Delphi method was also

used to identify and assess for face and content validity of a group of safety indicators with a panel of 30 experts representing all specialities working in labour and delivery units (Haller et al., 2010). It was also used by researchers in the U.S to identify priority patient safety outcome measures for use in monitoring and evaluating progress in improving patient safety with 47 national clinical and research experts (Farley et al., 2008). The Delphi method was used to identify the causes of patient safety incidents and devise solutions for patient safety in primary care in which 20 physicians and patient safety experts were recruited (Verstappen et al., 2015). A three-round Delphi study was also carried out with a panel of 20 national experts in Canada to develop a set of Canadian consensus-based indicators for the safe use of medication for both in-patient and outpatient settings (Nigam et al., 2008).

4.5.2.2 Delphi process

The initial Delphi protocol outlined a three-rounds of the Delphi process to take place. However, due to time constraints as well as the constructive feedback received from the participant experts, it was decided a two-round process would be sufficient for this study. Therefore, two rounds of the Delphi took place as shown in Figure 4.2; each round was distributed by email. The Delphi method process was as the following:

- **Pre-Delphi process:** An email Invitation was sent to the panel of international experts requesting their voluntary participation in the Delphi study. The experts came from different geographical areas including those from North Africa and the Middle East, WHO and from the United Kingdom and the United States. The experts are selected based on their familiarity with health systems in developing countries as well as their wealth of publications in the field of patient safety. Those who agreed to participate were sent a questionnaire along with a consent form and participant information sheet providing more details about the purpose of the Delphi study.
- **Round 1:** All panel members were asked to rank a number of elements based on the pre-prepared identified domains and topics using a 5-point Likert scale. As part of round one, the panel members were asked to identify five barriers to implementation of patient safety systems in healthcare institutions in developing countries. The communication process was managed by email where the participants completed and returned the questionnaires for analysis.

- **Round 2:** Each panel member received feedback of a list of themed topics with supporting statements. Panel members were asked to rate the importance of each topic using a 5-point Likert scale. They were also asked to rank the barriers based on the reported common barriers that were provided by the participants in Round 1. The communication in this round was also done via email in which the participants were sent reminder emails.

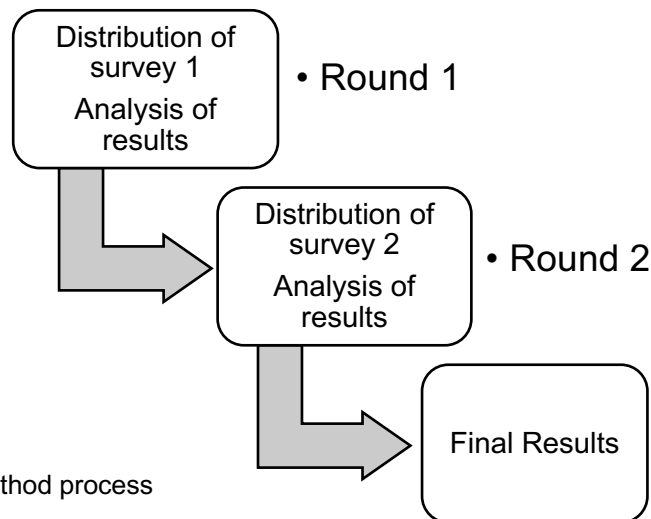


Figure 4.2: Delphi method process

4.5.2.3 Questionnaire survey used in the Delphi process

The first-round survey questions can be found in Appendix C which contained several themes and critical process for patient safety improvement mainly directed to developing countries. The items in the questionnaire were identified based on the findings of the different phases of this thesis highlighted above as well as guidelines provided by the World Health Organization in regard to patient safety research priorities in developing countries. As this was a modified Delphi study, it was important to keep the questionnaire as short as possible for easy management and completion by the participants who already have busy schedules. Therefore, the list of items were shared with leading scholars in patient safety who made constructive and positive comments on the list of items.

The participants in the Delphi rounds were asked to rate the themes and elements under each domain. When ranking the elements, they were reminded that these elements are aimed at improving patient safety in Libya which is witnessing major challenges at the moment as a consequence of the war. In other words, to what extent do they believe that each element is of a high importance at this stage to help

healthcare institutions in Libya provide a relatively safer care to patients? They were asked to rank the items based on a 5-Likert Scale as the following:

- “5” represents “very important”
- “4” represents “important”
- “3” represents “no opinion”
- “2” represents “not very important”
- “1” represents “unimportant”

There were also asked to give an overall rank of the importance of each domain within the questionnaire. The domains were as the following:

1. Regulation and governance
2. Leadership and management
3. Information technology
4. Education and training
5. Measurement, analysis and monitoring
6. Patient and public involvement
7. Infrastructure and working environment

4.5.3 Results

4.5.3.1 Key priority areas

The data was analysed using descriptive statistics so that those highly ranked were included in the second round of the Delphi process. Following the distribution of Round One questionnaire, each domain and element ranking that was done by the respective Delphi expert were checked. The average mean for each element was calculated and those that were ranked as “very important and “important” were considered significant for the inclusion in the second round. As shown in table 4.7, the main themes and elements that were rated “very important” are included for the second round. Spreadsheets were utilised to enter the responses for each element of priority. The average mean for each element is shown in Table 4.7 below. 100% of the variables had a ranking over 3 and above.

In regard to the qualitative data that was received from the Delphi experts regarding the barriers to patient safety systems implementation, similar items were grouped together by ensuring that those similar barriers are grouped using the original wording

received from the experts. The barriers were then used in the Round Two so that they can be ranked in terms of importance on a 4-Likert Scale. It should be noted that the Delphi experts are the final judges on the importance of the different items used in both surveys as highlighted by Hasson et al (2000) that researchers should not add new items during the analysis of Delphi experts' responses.

As this is a modified Delphi study, a number of 12 experts were targeted of this study who had significant experience in the field of patient safety as well as having good understanding of health systems in developing countries. For ethical matters, the identities of those experts will not be revealed. Following Round One, 10 participants returned the completed questionnaires. However, in Round Two, only six experts returned the questionnaires.

- ***First round priority themes and items***

Based on the ranking of the overall themes (seven themes), as shown in Figure 4.3, the most important theme was leadership and management followed by regulation and governance. The experts have pointed out that leadership and management commitment are critical to the improvement of patient safety. This was also evident in the findings of the literature review as well as the focus groups study. This indicates that policy makers and healthcare managers, executives and leaders need to develop new leadership and management styles so that they can promote patient safety in healthcare settings.

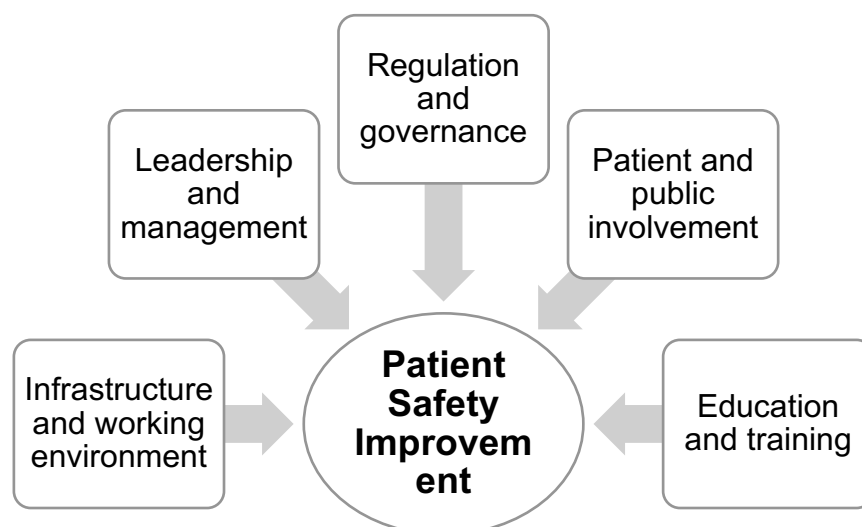


Figure 4.3: Round One Priority themes for patient safety improvement in Libya

Table 4.7: Round One priority elements

Domain	Item	Mean
1. REGULATION AND GOVERNANCE	1.2 Establishing an independent patient safety agency in Libya to regulate healthcare providers	4.2
	1.3 Introducing evidence-based Patient Safety Indicators for all healthcare institutions	3.9
Domain	Item	
2. LEADERSHIP AND MANAGEMENT	2.1 Senior leaders communicate the priority of patient safety to all stakeholders.	4.5
	2.3 Leaders and managers should incorporate patient safety accreditation and legal requirements as integral parts of its performance improvement.	4.2
	2.4 Leaders and managers should develop plans and support systems for proactive collecting and analysis of patient safety information for future improvement	3.7
Domain	Item	
3. INFORMATION TECHNOLOGY	3.3 Providing opportunities for patient to access their medical records	4.4
	3.4 Providing training for all healthcare staff in using IT	4.0
Domain	Item	
4. EDUCATION AND TRAINING	4.1 Ensuring that there is a staff professional development programme with patient safety as a cutting theme	4.6
	4.2 Embedding patient safety in all levels of education and training for healthcare professionals (i.e. undergraduate and postgraduate training, continuous improvement	4.0
	4.3 Ensuring that training curricula are high-quality, locally and clinically relevant, and delivered effectively.	3.7
Domain	Item	
5. MEASUREMENT, ANALYSIS AND MONITORING	5.1 Introducing Incident Reporting System for all healthcare institutions	4.4
	5.2 Ensuring that data collected from reporting systems are used for future learning to improve service delivery	3.8
Domain	Item	

6. PATIENT AND PUBLIC INVOLVEMENT	6.1 Implementing a patient satisfaction questionnaire.	4.6
	6.3 Ensuring that written policies on patient's rights are available, disseminated, or made visible to patients and their families	4.1
	6.4 Ensuring that patients are encouraged to speak up and act upon the patient's voice	3.6
Domain	Item	
7. INFRASTRUCTURE AND WORKING ENVIRONMENT	7.2 Ensuring that a system to reduce risk of health care-associated infections is implemented	4.3
	7.3 Developing a safe waste management system according to international standards	3.9
	7.4 Developing and enforcing Infection control policies (hand washing, injection waste, blood transfer etc...)	3.5

From the initial analysis of the findings, it was noted that the experts were mainly concerned about the role of leadership and management as well as the role of education and training. Interestingly, the infrastructure and working environment domain was also seen as critical component of improving patient safety. On the other hand, the participants were not very keen on introducing electronic medical records to patients as that requires significant investments and resources which might not be a priority at this stage. Furthermore, it was noted that the participants highlighted the need for measuring patient satisfaction as well as ensuring that patients are encouraged to speak up. Round One showed that five main domains are of high priority to the Libyan health system as shown in Figure 4.3.

▪ ***Second round priority themes***

The updated Delphi Questionnaire was then revised as per the feedback received from Round One and was circulated to the same participants who responded in the First Round. It was vital to see what the experts believe are the most priority themes and items for the Libyan health system so that a national policy for patient safety improvement can be introduced. This also shows that developing countries face further challenges as discussed in the literature in regard to patient safety

improvement when compared with developed nations. For example, in the UK, Electronic Medical Records have been in use for long time whereas in Libya such simple requirement has not been introduced yet. Furthermore, patient safety also requires political support by establishing an independent agency responsible for monitoring and accrediting or registering healthcare providers based on a set of standards or performance indicators.

As noted above, in Round Two, six completed questionnaires were returned. The modified Delphi method as shown in the literature can recruit a sample of 5 to 10 people to ensure that it provides valuable insights. For this reason, I have made sure that the selected experts represent those with extensive experience in the field as well as have familiarity with the contextual and geo-political factors that hinder health systems in Libya and other developing countries. As it can be seen in Figure 4.4, the most priority themes for patient safety improvement in Libya were ranked as the following:

1. Leadership and management
2. Regulation and governance
3. Infrastructure and working environment
4. Education and training

This again shows that leadership is a top priority as that can create quick fixes in the system by developing new leadership styles and policies which will promote better patient services. Moreover, regulation and governance were also ranked the second as there needs to be a local regulation to raise the importance of patient safety which is then followed by infrastructure and working environment.

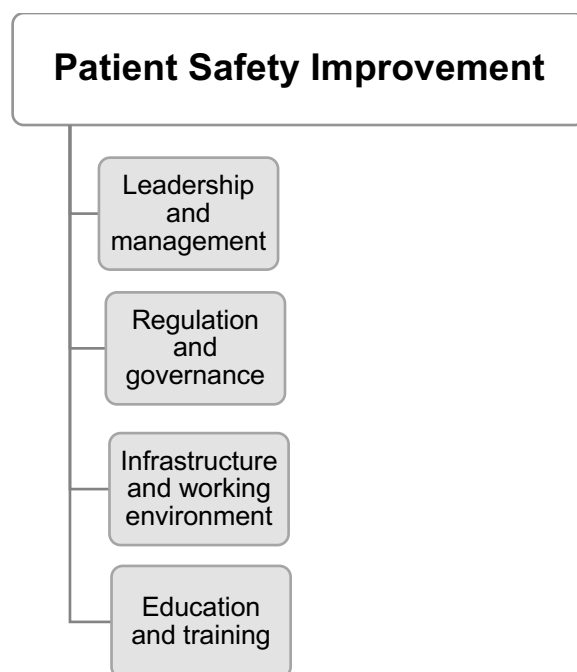


Figure 4.4: Round Two Priority themes for patient safety improvement in Libya

The participants were also asked to rank the elements in the second round by focusing mainly on the most significant and highly important priority for patient safety improvement in Libya. Table 4.8 presents the main elements under each domain.

Table 4.8: Round Two priority elements

Domain	Item	Mean
1. REGULATION AND GOVERNANCE	Establishing an independent patient safety agency in Libya to regulate healthcare providers	4.5
Domain	Item	
2. LEADERSHIP AND MANAGEMENT	Senior leaders communicate the priority of patient safety to all stakeholders.	4.4
	Leaders and managers should develop plans and support systems for proactive collecting and analysis of patient safety information for future improvement	4.0
Domain	Item	
3. INFORMATION TECHNOLOGY	Providing training for all healthcare staff in using IT	4.5
Domain	Item	
4. EDUCATION AND TRAINING	Embedding patient safety in all levels of education and training for healthcare	4.6

	professionals (i.e. undergraduate and postgraduate training, continuous improvement	
	Ensuring that there is a staff professional development programme with patient safety as a cutting theme	4.1
Domain	Item	
5. MEASUREMENT, ANALYSIS AND MOINTORING	Introducing Incident Reporting System for all healthcare institutions	4.3
Domain	Item	
6. PATIENT AND PUBLIC INVOLVEMENT	Implementing a patient satisfaction questionnaire.	4.4
	Ensuring that written policies on patient's rights are available, disseminated, or made visible to patients and their families	3.9
Domain	Item	
7. INFRASTRUCTURE AND WORKING ENVIRONMENT	Developing and enforcing Infection control policies (hand washing, injection waste, blood transfer etc...)	4.3
	Developing a safe waste management system according to international standards	4.1

4.5.3.2 Barriers to implementation of patient safety systems

Round One Delphi questionnaire asked the participants to list a number of five barriers which they believe hinder the implantation of patient safety systems in developing countries. This question was added so that the experts can then rank these identified barriers in Round Two. The responses to this question are very important to further understand the barriers and challenges that hinder patient safety systems implementation in developing countries based on expert advice. It was decided to add the question in an open-ended style so that the participants can add the barriers they believe are significant.

The first-round questionnaire compiled a number of barriers. However, not all participants provided five barriers as some of them added two or three. As shown in Table 4.9, there were 19 barriers identified by the participants in the first round. These 19 barriers were grouped based on similarity as some of the experts have shared the

same barriers which brought the total number of barriers to 19. Those presented in Table 4.9 are not arranged based on priority or importance, but they were grouped in a list so that they can be sent around with Round Two questionnaire. Following the completion of Round One, these barriers were included in the Round Two questionnaire and the participants were asked to rank them using 4-Likert Scale based on importance as the following:

- RANK 4 “Very Important Barrier”
- RANK 3 “Important Barrier”
- RANK 2 “Not Very Important Barrier”
- RANK 1 “Unimportant Barrier”

Table 4.9: Barriers to safety system implementation in developing countries (Round One)

1.	Absence of political leadership support and commitment
2.	Lack of awareness among patients and the public
3.	Resistance to change to new initiatives
4.	Lack of information and readily available resources
5.	Poor infrastructure
6.	Lack of resources and inadequate staffing
7.	Culture of blame
8.	Inadequate expertise and skilled workforce in patient safety
9.	Lack of leadership understanding and commitment
10.	Lack of regulatory framework
11.	Lack of awareness of patient safety
12.	Lack of transparency
13.	Corruption and bureaucracy
14.	Cost of patient safety technology
15.	Little oversight and monitoring of health systems
16.	Absence of inspections and monitoring
17.	Belief that safety is only relevant to richer countries
18.	Complexity of patient safety interventions
19.	Absence of involvement of all stakeholders in the healthcare process

As it can be seen in the table above, the barriers were varied and have covered almost most of the points that were found in this thesis. It can be seen that patient safety can be hindered by many barriers which should be taken into account by policy makers and strategic planners. This list of barriers as noted above was included in Round Two in which the Delphi experts were asked to rank these barriers in terms of importance based on a 4-Likert Scale. Following the analysis of the responses in Round Two, and as shown in Table 4.10, the Delphi experts have ranked 7 out of the 19 barriers as the most important. Among these barriers is the lack of regulatory framework, lack of leadership understanding and commitment and lack of information and readily available resources. This again shows that patient safety improvement requires an integrated approach in which different organisational and contextual factors are taken into account.

Table 4.10: Barriers to safety system implementation in developing countries (Round Two)

1.	Lack of leadership understanding and commitment
2.	Lack of information and readily available resources
3.	Little oversight and monitoring of health systems
4.	Belief that safety is only relevant to richer countries
5.	Absence of political leadership support and commitment
6.	Lack of awareness among patients and the public
7.	Lack of regulatory framework
8.	Lack of resources and inadequate staffing
9.	Inadequate expertise and skilled workforce in patient safety

4.5.4 Discussion

For patient safety to be truly global, and as highlighted by the Institute of Medicine, low and middle-income countries need to be included in the patient safety community (Zhu et al., 2014). Thus, it could be argued that over the coming 15 years, harm reductions are likely to come from these countries. More importantly, there is a need to ensure that those tools which have been developed in high-income countries can also be developed in low income countries. Countries in transition such as Libya can also be fertile for innovation in the healthcare sector. There is also a need for the

healthcare system in developing countries to have the right capabilities to produce changes in the delivery and design of services so that the quality and value of healthcare in the 21st century can be improved. Satisfaction, biological and functional parameters should be used to measure the outcomes as part of the re-design efforts of healthcare systems (Batalden and Splaine, 2002). The capacity of the healthcare system should be built for improvement by successful healthcare leaders of the 21st century in developing countries.

Policy makers and all stakeholders in healthcare organisations in developing countries should focus on the need of aligning all organisational strategies for improvement (professional development, financing, operations and education) and should perform patient assessment, data gathering, process assessment and outcome measurement to achieve organisational improvement (Brandrud et al., 2011). In other words, the professional environment, staff, patient and family as well as the leadership and management should all be engaged in all phases of the improvement work. For example, the management and leadership of healthcare organisations can play a significant role in improving patient safety through the establishment of caring relationship with clinical staff, building patient safety infrastructure and promotion of organisational culture change in support the quality and patient safety improvement efforts (Bradley et al., 2003; Künzle et al., 2010). The absence of legal frameworks regarding patient safety improvement along with limited resources and expertise in the field could also influence upon the capabilities of health systems in developing countries. Due to the limited resources, investment in information technology systems in developing countries may not be possible and that will impact upon the overall improvement of care delivered to patients.

Global research on patient safety should shift the focus on investigating the issues that face low-income countries and countries in transition in improving their patient safety performance (Bates et al., 2008). Research collaboration across countries and international organisations would be very beneficial for countries that have poor infrastructure for conducting empirical research studies. The findings of research could also be disseminated on a global and regional scale to help low-income countries translate these findings into policy recommendations. Patient safety requires a

systems approach as it is highly dependent on systemic factors. Redesigning the healthcare system for safer care delivery requires a systems approach in which individual and organisational factors are taken into account (Waterson, 2009). Healthcare institutions would be vulnerable to mistakes in patient safety if a narrow focus on one isolated process without taking into consideration the systematic nature of medical errors is adopted (McNutt et al., 2002). Hence, this modified Delphi study will help in establishing a point of reference for policy makers in developing countries on the vital elements and components that are required when developing a national strategy for patient safety improvement. This research would also help in bridging the gaps between developed and developing nations and to encourage collaborative research projects between institutions and researchers so that sustainable solutions and improvements can be made.

4.6 General commentary

All healthcare professionals and stakeholders in the process of healthcare delivery should have personal responsibility to patient safety. A positive culture of patient safety is highly needed in developing countries to ensure that discovering and reporting errors is being rewarded not punished. This modified Delphi study helped in identifying the key priorities for the improvement of patient safety in developing countries using Libya as a case-study and will also help shifting the focus of policy makers in these countries on the key important elements that are needed when developing a national strategy for patient safety improvement. The study also identified some of the barriers that hinder the implementation of patient safety systems so that comprehensive and efficient national patient safety policies and strategies are developed.

The findings of the systematic review, the focus groups study as well as the Delphi study indicate that patient safety improvement in developing countries is very challenging and require an integrated approach. The findings presented in Chapter 4 also showed that the UK has gone through different stages and phases for improving patient safety and the journey is still ongoing. Moreover, the findings of the literature review highlighted the urgent need for policy makers to develop a systems approach to patient safety by taking into account the role of leadership and management, education and training, information technology as well as the need for patient and

family involvement. It was realised during this research process that achieving perfection in patient safety is impossible due to the complexity of healthcare delivery along with the complexities associated with managing human resources. It was also realised that there is a long way to go for patient safety improvement in developing countries and that more research is needed to understand the complexities associated with patient safety improvement. This study has focused on one of the countries that face challenges in regard to strengthening its health system. The study also aimed to understand the variables and factors that influence upon patient safety improvement.

Based on the findings of the above chapters, the next chapter presents a holistic framework for patient safety improvement that was developed based on the insights from the UK's experience, critical evaluation of the existing literature as well as based on the findings of the empirical studies presented in Chapter 4. I will introduce the Patient Safety Improvement Framework in the next chapter and discuss the different framework components. I will also discuss the validation process which was adopted to test the appropriateness and usefulness of the framework in the Libyan context. The findings of this thesis as well as a critical evaluation of the framework are discussed in Chapter 6.

4.7 Chapter summary

The purpose of this chapter was to present the findings of the empirical studies that were carried out as part of this research. The chapter presented the findings of the UK case study analysis, systematic review, focus groups and the modified Delphi study. A general commentary on the findings was also discussed in this chapter. The chapter provided insights about the main themes, components and dimensions that are significant to the development of the patient safety improvement framework in Libya. The following chapter presents the Patient Safety Improvement Framework that was developed based on the findings of this study. The following chapter also discusses the validation of the framework with Libyan healthcare workers and policy makers.

CHAPTER 5

PATIENT SAFETY IMPROVEMENT FRAMEWORK

5.1. Introduction

This chapter presents the Patient Safety Improvement Framework which was developed as part of this research study. The process that was used to develop the framework as well as the main components of the framework are discussed in this chapter. The study found that patient safety improvement requires an integrated and holistic approach to ensure that sustainable improvements can be maintained. Patient safety improvement requires integration of functions, involvement of stakeholders, robust decision making and continuous learning as well as creating a positive safety culture. I will also discuss how the framework was validated with Libyan system users and present some expected benefits of the developed framework.

5.2 Definitions of ‘framework’

It is important before discussing the developed framework is to describe what it is actually meant by the term ‘framework’. In the literature, the term is used to describe ‘theoretical’ or ‘conceptual’ frameworks. It is also used to describe operational and simulation models. A framework is defined by Popper (1994) cited in Sayed (2012) as a *“set of basic fundamental principles, which can help to promote discussions and actions”* (Sayed, 2012, p. 10). I also go with Struebing and Klaus (1997) pointed out that frameworks are used to help organisations identify pathways for development. The term framework is defined in the English Oxford Dictionary as *“A basic structure underlying a system, concept, or text”*. Yusof (2000) stated that flowcharts, diagrams, pictorial or graphical representations can be used to portray frameworks. The term is used in the literature to describe networks, maps, operational models and theoretical principles. It is also used to provide guidelines for implementation and adoption.

According to Aalbrektse et al (1991), a framework can be used to communicate and illustrate a new vision to the organisation or provide valuable insights about the organisation's weaknesses and strengths. It also helps organisations to identify causal relationship between the different elements contained in the framework. The term 'conceptual framework' is widely used in the literature. Conceptual framework is defined by Jabareen (2009) as:

"A network, or "a plane," of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena".

(Jabareen, 2009, p.51)

Conceptual framework is also defined as:

"A visual or written product, one that "explains, either graphically or in narrative form, the main things to be studied—the key factors, concepts, or variables—and the presumed relationships among them"

(Miles and Huberman, 1994, p. 18).

Thus, taking these definitions into account, a framework for this study is defined as a set of interrelated components, elements, concepts and variables that are needed to improve patient safety in developing countries. A diagram is used to provide an illustration representation of the framework in this thesis.

5.3 Overview of framework development process

This framework was developed based on multiple methods for data collection. The collection of different types of data enabled me to identify the most important and critical areas for patient safety improvement. A data triangulation approach was used to ensure that bias is minimised. The development process of this framework is discussed in this section based on the methods presented in Chapter 3. Existing literature was used to guide the design of this thesis. In other words, this framework was informed by critical evaluation of existing literature to lay the foundations for the framework. However, it was noted that the field of patient safety remains to be under-researched in developing countries. Therefore, it was necessary to carry out some

empirical studies to enable the collection of primary data. This enabled me to develop robust understanding of the different barriers, issues and challenges associated with patient safety improvement. Thus, developing a well-synthesised framework will help guide the process of patient safety improvement in developing countries. This will also enable policy makers to better understand the variables associated with implementing patient safety systems.

I have also discovered that patient safety requires a systems approach in which awareness and commitment are crucial for the successful implementation of patient safety interventions. Reviewing the exiting literature along was not helpful in identifying the main problems associated with patient safety in developing countries. Thus, qualitative approaches such as documentary analysis, focus groups and Delphi study were used to generate further evidence that can help in identifying the different dimensions and themes for patient safety improvement. The diagram in Figure 5.1 shows the systematic approach that was used to develop the model. The main lessons of each phase which contributed to the development of this framework are also highlighted following Figure 5.1

The framework as shown in Figure 5.2 represents the major components and a further discussion of these components is presented in section 5.6. These components are interrelated as patient safety requires a systems approach in which communication and cooperation are crucial to the success of the overall improvement process. The rationale behind this design of the framework is based on the fact that patient safety requires commitment from the top political leadership as well as the management of healthcare organisations. It also should be driven and facilitated by continuous commitment and the provision of the required resources. Moreover, as noted in the study findings presented in the chapters above, patient safety is highly influenced by cultural and organisational factors. Healthcare delivery is a complex process which requires continuous measurement and analysis of data so that areas for development can be identified. McFadden et al (2015) found that leadership behaviours and styles is linked to employees' perception of a strong safety climate. This means that leaders would need to value their significant role in patient safety improvement so that sustainable changes can be made.

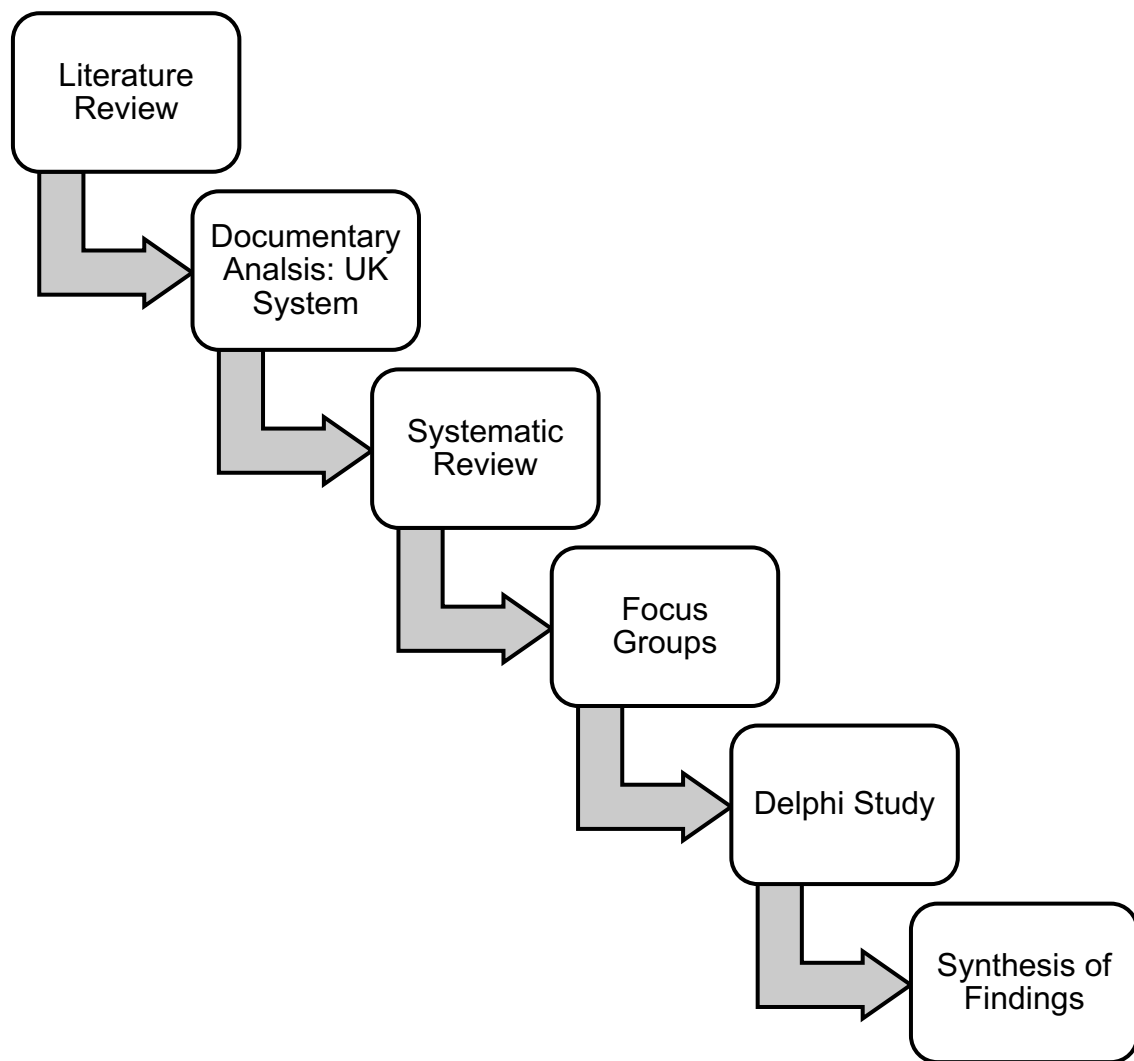


Figure 5.1: Framework development process

➤ **Literature Review**

The literature review phase was one of the important phases in developing this framework as it captured the existing debates about patient safety improvement. It also helped in understanding the different dimensions that influence upon patient safety. This stage involved a detailed and critical examination of the published work that was obtained from different sources as presented in Chapter 2. The review of literature also helped in the process of designing the study and understanding the current theoretical debate about patient safety improvement.

➤ **Documentary Analysis**

In order to focus more on the key critical elements associated with patient safety improvement. It was important to use case study analysis approach to focus on the

lessons that can be learnt from the UK in order to enhance patient safety in Libya. This phase which is presented in Chapter 4 provided a critical evaluation of the UK's journey in regard to patient safety improvement over the past 15 years. It also provided better insights about the obstacles, challenges as well as the important success factors that should be taken into account.

➤ **Systematic Review**

The systematic review was carried out to capture the problems associated with patient safety in Arab countries as that will further highlight the main areas of concern in regard to patient safety improvement. It helped understand the organisational factors as well as the barriers. The systematic review highlighted the challenges that face Arab health systems when it comes to improving patient safety. The findings can be linked to Libya's health system as such countries have many things in common.

➤ **Focus Group**

The aim of the focus groups was to listen to Libyan healthcare professionals and discuss the main areas that require improvement as well as highlight the challenges associated with patient safety in Libya. The focus groups were very helpful tools to further capture the main areas of concern as well as discuss possible solutions. The findings of the focus groups were significant to the development of this framework.

➤ **Delphi Study**

Using expert advice was also critical. A modified Delphi study was carried out with international experts in the field of patient safety so that priority areas for patient safety improvement in Libya can be identified. The findings of the Delphi study were in alignment with the findings of the focus group as well as the relevant literature. It also shed the light on the importance of raising awareness as well as enhancing leadership and management commitment.

➤ **Synthesis of Findings**

Based on the outcomes of the above phases, the findings and results of the study were synthesised to develop a well-integrated framework that will help in improving patient safety in Libya and in other developing countries. The synthesis of the findings helped in developing the framework presented in Figure 5.2. The framework provides an integrated approach to patient safety improvement in Libya.

5.4 Overall aim of the developed framework

My aim of developing this framework for patient safety improvement is to provide a well-evidenced and systematic approach that can be used by governmental organisations and policy makers in Libya and other developing countries to manage patient safety within healthcare settings. It is also intended to add to the existing literature a new improvement framework for patient safety which can be tested, examined and used for a point of reference for further research in the field. It could be argued that that informed decisions can be made by policy makers in developing countries in regard to patient safety improvement by following or adopting this framework. This is because of the fact that this framework was developed based on synthesising different academic and empirical evidence. It is also hoped that this framework will contribute to integrating the concept of patient safety thinking within healthcare providers in developing countries so that sustainable improvements can be made.

5.5 The main framework

The illustration representation of the framework is shown in Figure 5.2. This framework highlights the main components associated with patient safety improvement especially in developing countries. It is also assumed that this framework captures the critical elements that reflects the current needs of health systems in Libya and other developing countries. A discussion of the main components is presented in section 6.6 which shows that interlinked functions of each component. It should be taken into account that this framework is based on the existing situation and was developed based on analysis of different types of data. The applicability of this framework and its usefulness could change with any developments in the field of patient safety in developing countries. The benefits of this framework are discussed in section 5.8. To ensure that this framework is appropriate and suitable for the Libyan system, it was validated with a number of healthcare professionals in Libya to examine its appropriateness. The validation process and the findings are presented in section 6.7.

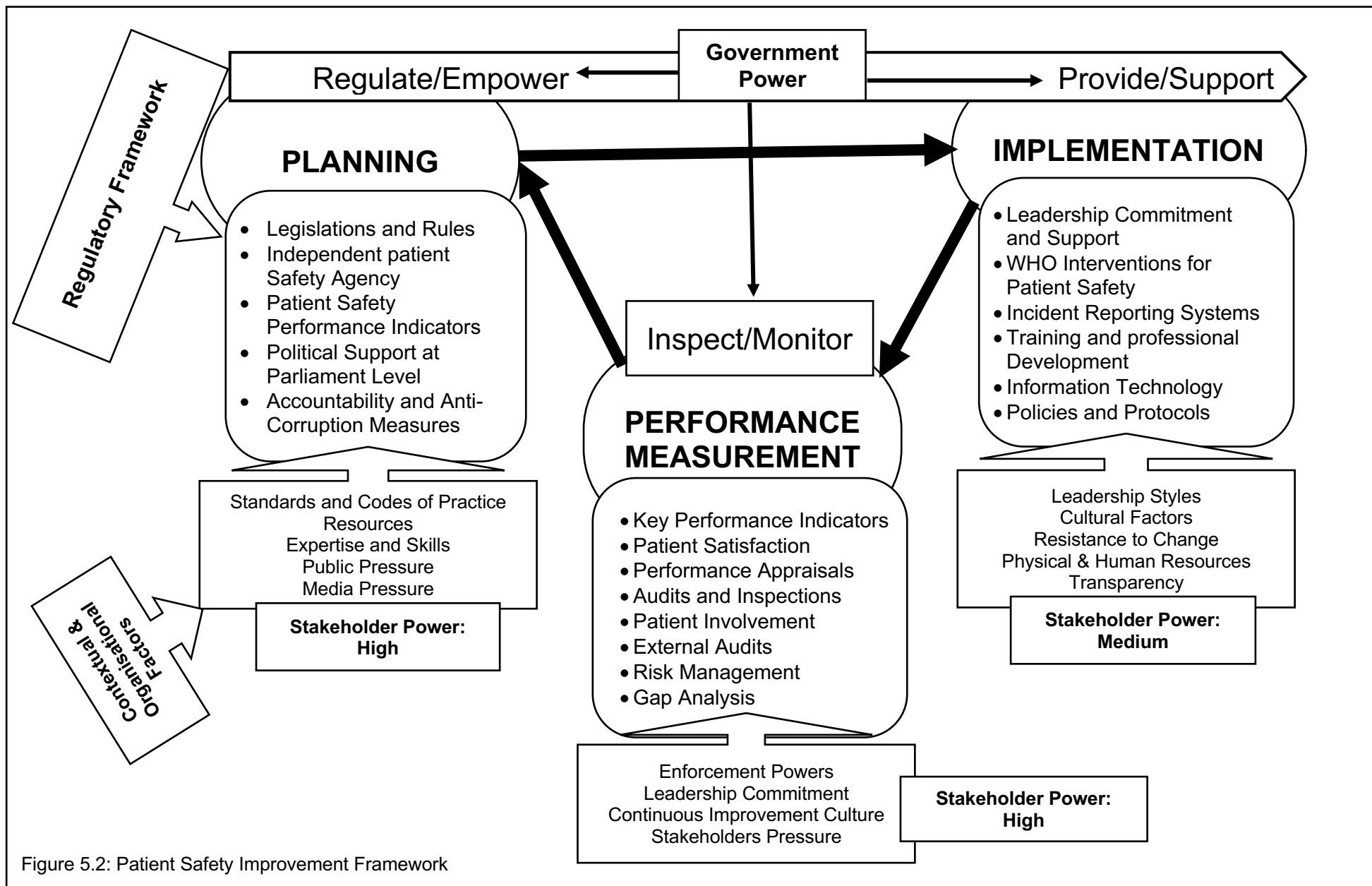


Figure 5.2: Patient Safety Improvement Framework

5.6 Framework components

The interrelated approach to patient safety improvement has been highlighted in the diagram above shown in Figure 5.2. The framework has taken into account all the variables which hinder upon successful implementation of patient safety systems in developing countries. Table 5.1 discusses the descriptions of the main terms/components used in the framework which will then be followed a discussion on each element of the developed framework.

Table 5.1: Definitions of the main framework components

- **Planning:** planning is crucial for developing clear policies and protocols that aim to promote patient safety. Planning as noted in the framework is associated with the role of the Ministry of Health, the Parliament and politicians as well as healthcare managers and leaders. Planning needs to be supported by national regulations and laws, standards, codes of practice as well as performance indicators.
- **Implementation:** this refers to the need for ensuring that all policies, plans and protocols are being implemented at the organisational level. This stage follows the planning stage as the core foundations need to be identified in the planning stage. There are many practical tools which can be adopted to enhance patient safety that include the WHO interventions as well as guidelines provided by leading organisations around the world. Implementation also refers to the need for establishing a reporting system at the Ministry level where healthcare organisations can report incidents. It also refers to the provision of the required resources, information technology as well as expertise to ensure that patient safety policies are being implemented.
- **Performance Measurement:** this refers to the need for measuring performance against set of key indicators. It also reflects the role of the regulatory agencies in inspecting and monitoring healthcare providers to ensure that they comply with the relevant standards and guidelines. It also shows that need for the results to be feed backed into the planning stage for further improvements.

- Arrows: the arrows show the interrelationship between the different phases and that each phase need to feed into the other so that a holistic approach can be adopted.
- State Power: this refers to the role of the national government in providing the required regulations (Regulate/Empower), as well as provide and support healthcare organisations along with its role of monitoring and inspecting healthcare providers. The State Power is crucial for the successful implementation of the framework
- Stakeholder Power: this refers to the role other stakeholders have in the process of improving patient safety in developing countries. It shows that in the planning stage, the stakeholders can have high power as well as in the performance measurement stage. This helps in raising awareness about patient safety as well as reminding the authorities that they will be held accountable for their actions.
- Regulatory Framework: this refers to the need for introducing legislations, independent regulatory agencies as well as laws at the national level
- Contextual and Organisational Factors: this refers to the different set of factors that influence upon the different phases. Each phase (planning, implementation and performance measurement) requires ensuring that such factors are taken into account.

I will now discuss the different components under each element of the framework. It should be noted that these are just brief descriptions as there has been already research carried out into each aspect of the framework to show the importance of education and training, leadership commitment as well as communication.

➤ ***Components of the Planning Dimension:***

- Legislations and Rules

It was evidenced in the study that regulations and laws are critical to guiding improvements in patient safety. Therefore, it is important that regulations that encourage improvement in the quality and safety of healthcare are introduced in Libya and in other developing countries to achieve sustainable benefits. The regulations will also set out the clear requirements and performance indicators which will be useful for

healthcare organisations. It will also highlight the need for ensuring that patients treated fairly and equally.

- Independent patient Safety Agency

As shown in many countries, there is a need to ensure an independent agency is established to promote, support and monitor healthcare organisations in regard to patient safety improvement. The role of the agency should also include helping organisations to raise awareness about patient safety, provision of training and development, encourage incident reporting as well as public guidance documents and evidence-based interventions that will help in improving patient safety standards.

- Patient Safety Performance Indicators

There are widely available performance indicators used for patient safety which need to be adopted in Libyan healthcare settings as well as in other countries to ensure that patient receive high quality care. Therefore, it is crucial that performance indicators are identified in the planning stage to help healthcare providers achieve basic standards in quality. They will also help in raising awareness among healthcare workers and patients.

- Political Support at Parliament Level

Without the political support and leadership commitment from the top, it will not be possible to achieve sustainable improvements in patient safety in developing countries. The introduction of regulations, laws and establishment of patient safety agencies require support from the political leadership so that all the resources needed are provided. The political support is also needed to fight corruption and introduce transparent management practices in healthcare organisations.

- Accountability and Anti-Corruption Measures

The government has a role to play in fighting corruption as well as stakeholders also have a role. It is crucial for healthcare providers in developing countries to engage in transparent practices and should also realise that their actions and decisions could put them at risk of being questioned. These measures will help ensure that all patients receive the same level of care irrespective of their background or geographical location. It will also ensure that healthcare workers practice against a well-defined code of practice.

➤ ***Components of the Implementation Dimension:***

- **Leadership Commitment and Support**

Leadership and management commitment are crucial for the successful implementation of safety interventions and systems. This was evident in the literature as well as in the findings of this study. Therefore, it is vital that the top leadership shows high levels of commitment towards improving patient safety. The implementation of laws and regulations as well as protocols will not be done without this commitment from the top leadership.

- **WHO Interventions for Patient Safety**

Developing countries and Libya can all benefit from the current work done by the WHO to enhance patient safety. There are several tools, initiatives, programmes and standards that were introduced by the WHO to promote patient safety. These can be adopted by local healthcare providers to establish systems that can prevent patient harm and enhance the quality of care.

- **Incident Reporting Systems**

This refers to the need for healthcare providers to develop incident reporting systems so that they can capture all the accidents and adverse events which take place for future learning. In order to improve safety, it is important to measure it. Without such systems, healthcare organisations will not be able to learn from past failures and mistakes.

- **Training and professional Development**

Another important element is the need to encourage all healthcare workers to attend training in health and safety as well as motivate them to embark on professional development activities. This will help in enhancing their skills and competencies as well as lead to better patient outcome. The role of education and training has been evident in the literature in regard to patient safety improvement.

- **Information Technology**

Healthcare organisations also need to adopt new technologies and medical equipment to ensure patients receive the best quality of care. Fighting corruption will allow healthcare organisations to invest in new technology that can be used to coordinate the care process and also enhance the level of patient safety.

- **Policies and Protocols**

The preparation of policies and protocols is crucial for enhancing the quality and safety of care. In other words, it is vital that all units/departments have clear policies and protocols for the treatment of cases. These policies will also highlight the need for healthcare workers to comply with basic health and safety rules. The policies will help in coordinating the care process as well as enhance the quality of care as healthcare workers will not risk-taking short-cuts which might put patients at risk.

➤ ***Components of the Performance Measurement Dimension:***

- **Key Performance Indicators**

As noted above, in measuring performance, organisations need to do this against a set of key performance indicators. These can be provided in the planning stage and should be measured by regulatory bodies to rank healthcare providers based on their performance. This will encourage other healthcare providers to engage in such activities.

- **Patient Satisfaction**

Patient outcomes can be measured through patient satisfaction surveys. This will help healthcare organisations to understand the different issues and problems that might hinder the provision of high-quality care. Moreover, patient satisfaction will help in identifying weaknesses and strengths that will lead to better performance.

- **Performance Appraisals**

All healthcare workers should also be assessed in regard to achieving their objectives. This can be done through Human Resources and line managers. Performance appraisals are found to be good tools to identify areas for development and also reflect upon previous performance.

- **Audits and Inspections**

Clinical and organisational audits are crucial for identifying any variations in the services. They will also highlight the areas for improvement. Audits will need to be carried out in collaboration with different teams and departments as well as involving patients and their families. Regular inspections should be carried out by regulatory agencies to ensure that healthcare providers comply with the standards.

- **Patient Involvement**

Patient involvement is highly needed in Libya and in other developing countries to ensure that patients understand the process of care as well as share their concerns

and insights. Patient involvement helps in reducing patient harm as those patients will be aware of the risks associated with the process of care. It also helps in raising awareness about self-care and adherence to medications.

- External Audits

External audits can be carried out by external bodies and agencies to identify the areas that require improvement within hospitals. WHO and other organisations can help such countries in identifying the areas that require development. This also helps in raising the standards of care based on international experiences.

- Risk Management

Risk management should not just be adopted in the performance measurement stage but also in the planning stage to help identify any possible risks that could hinder the performance. Risk management also helps in developing control measures based on lessons learnt from previous incidents. Therefore, risk management should be seen as an ongoing process that will feed into the planning and implantation stage.

- Gap Analysis

Healthcare organisations should use systematic tools to identify areas for development and improvement. It is very important for healthcare organisations to carry out gap analysis by involving all stakeholders.

5.7 Framework validation

5.7.1 Method

In order to ensure that this developed framework is relevant to the Libyan context, it was important to validate its theoretical application with Libyan healthcare professionals. According to Jabareen (2009), validating a theoretical framework can be done through seeking validation among outsiders to the researcher. In other words, it is important that frameworks are shared with other people to ensure its appropriateness and usefulness. Validation also helps to understand the applicability of the developed framework as noted by Rykiel (1996). This framework is directed to policy makers and healthcare professionals in developing countries and particularly in Libya. Thus, it was decided to examine the appropriateness of the framework of Libyan system users. It should also be noted that the practicality and effectiveness of the framework with require actual implementation which is outside the remit of this research. Moreover, the nature of the developed framework entails that several

actions and decisions need to be taken which require time. Seeking external advice on the developed framework was done through adopting a mixed-method approach as explained briefly in Chapter 3. Interviews and a short questionnaire survey with a number of healthcare workers as well as policy makers were used to enable the participants to share their insights about the framework and its usefulness for the Libyan context.

Due to access problem as discussed earlier in this thesis and time constraints, the validation process was done using online communication channels. This enabled the participants to have time to reflect upon the validity of the framework. Personal contacts were used to communicate with senior managers and policy makers as well as convenience sampling method to communicate with healthcare professionals. In regard to the interviews, and as pointed out by Yin (1994) and Guest et al (2006) that when researchers feel that saturation is achieved, no more interviews are needed. This was taken into account when planning the validation stage. The interviews were carried out using Skype Video with five senior managers and policy makers who gave their feedback and insights about the framework. It was also ensured that the same list of questions is asked to each participant so that bias is avoided.

The framework was sent to the participants in advance so that they can have their own time to reflect upon its contents. Each interview lasted for about 30 to 35 minutes which focused mainly on the applicability and appropriateness of the developed framework for the Libyan health system. It was important to understand the perception of the system users in regard to the suitability of the framework as highlighted by Law et al (1991). Balci and Sargent (1982) asserted that validation helps to strengthen the practicability of models. It was also important to ensure that the framework is validated in the context of the research frame by interacting with system users as suggested by Rao et al (1998). Schlesinger et al (1979) cited in Refsgaard and Henriksen (2004) indicated that validation helps to identify if the models or frameworks that were developed are of reasonable precision and reliability to be used for its overall purposes.

This Patient Safety Improvement Framework was mainly developed for the Libyan health system based on expert advice as well as synthesis of recent literature. Therefore, it would be more feasible to check the usefulness of this framework for the Libyan context by interacting with Libyan healthcare professionals and policy makers. Those participants will have better insight about the current problems that face the Libyan health system. Table 5.2 shows the characteristics of the participants in the validation phase.

Table 5.2: Participants in the validation phase

Interviewee Code	Position	Experience	Duration of Interview, Location
LY020	Hospital Manager	19	30 minutes, Skype
LY021	MoH – Operations	28	37 minutes, Skype
LY022	Regional Secretariat Supervisor	25	29 minutes, Skype
LY023	Senior Consultant	17	35 minutes, Skype
LY24	Lecturer/Faculty of Medicine	13	32 minutes, Skype

It is not the attention of this validation phase is to assume that the framework is scientifically or statistically tested to yield in better results but to explore if the framework meets the system users' expectations in terms of having a holistic approach to improvement patient safety. It was argued by Shannon (1998) that all frameworks require enhancement and modifications for them to be absolute correct. The interviews findings will be discussed along with the short survey questionnaire findings.

A short questionnaire survey was also developed based on existing literature regarding framework validation which aimed at exploring whether the content, context and applicability of the framework is feasible. The questionnaire survey was also used to guide the interviews as it provided specific questions about the applicability of the framework. As shown in table 5.3, the short questionnaire survey included six questions and also allowed the participants to add any comments and suggestions for improvement. The questionnaire survey targeted managers and healthcare workers in

the Libyan health system. Convenience sampling technique through personal contacts was used to recruit the participants. The purpose of the questionnaire is not to statistically analyse any correlational variables but to only explore the views of the participants regarding the framework. The short questionnaire was based on previous studies and PhD dissertations that assessed the applicability of theoretical and conceptual models or frameworks in which all advise that it should be short, focused and straightforward. A 5-Likert scale was used in the short questionnaire survey to explore the participants' agreement or disagreement with the questions being asked. The same tool was used to guide the interviews, but further discussions were present during the interviews as the participants had more time to discuss the framework with me.

The purpose of the interviews and the questionnaire survey is to test whether the framework is fit for purpose. In other words, does it provide a systematic approach to improving patient safety in Libya? Does the framework cover the main themes and variables that healthcare workers are familiar with? As shown in Table 5.3, these questions were very specific as the participants had the chance to review the framework in advance. This made it easier for them to reflect upon their views and opinions regarding the framework.

Table 5.3: Framework validation questions

Q1: Do you agree or disagree with the contents of this Patient Safety Improvement Framework? (5 Strongly Agree, 1 Strongly Disagree)
Q2: Do you agree or disagree with the fact that this framework is Libyan-context oriented?
Q3: Do you agree or disagree with the completeness of the framework?
Q4: Do you agree or disagree with the clarity of the framework?
Q5: Do you agree or disagree with the usefulness of the framework of the Libyan health system?
Q6: Do you agree or disagree with the universality and applicability of the framework in the Libyan context?
Do you have any comments/suggestions for improving the framework?

5.7.2 Validation results

As noted above, the validation process was carried out with Libyan healthcare professionals to explore the appropriateness and usefulness of the developed framework. Five interviews were carried out as shown in table 5.2 above, in addition to 23 questionnaire surveys were returned. It was noted that the participants in the interviews were very supportive to the idea and subject of the research. They also indicated that such research is crucial for developing countries to enhance the standards of better care. Interestingly, the participants highlighted the issue of stability and security when it comes to enhancing the process of care. This was highlighted due to the current armed conflict in Libya which has affected upon health services.

It was clearly noted that the participants were in agreement of almost all of the elements in the questionnaire survey. However, two interviewees raised their concerns about the applicability and universality of the developed framework as it is mainly focused on the health issues in Libya. This was discussed in great detail and it was highlighted that the framework covers the most important problem when it comes to strengthening health systems which is the role of leadership and in particular the political leadership. The participants highlighted that the framework would provide a good starting point for developing a national strategy for patient safety improvement in Libya. Among the themes which were generated based on the notes that were taken during the interviews include:

- Raising public voice and pressure on policy makers
- The role of media, schools and universities in raising awareness about patient safety
- Resistance to change in Arab culture
- Fear from litigation

It was highlighted that a whole system reform is highly needed for the Libyan health system to ensure that it meets the expectations of the users. Moreover, the participants indicated that regulations also play a role in enhancing the quality and safety of healthcare. It was evident in the discussions with the interviewees that without committed and supportive leadership, all projects and interventions of

improvement will fail. The findings of the returned questionnaires indicated that most of the participants agreed with the fitness and usefulness of the development framework as shown in Figures 5.3, 5.4 and 5.5.

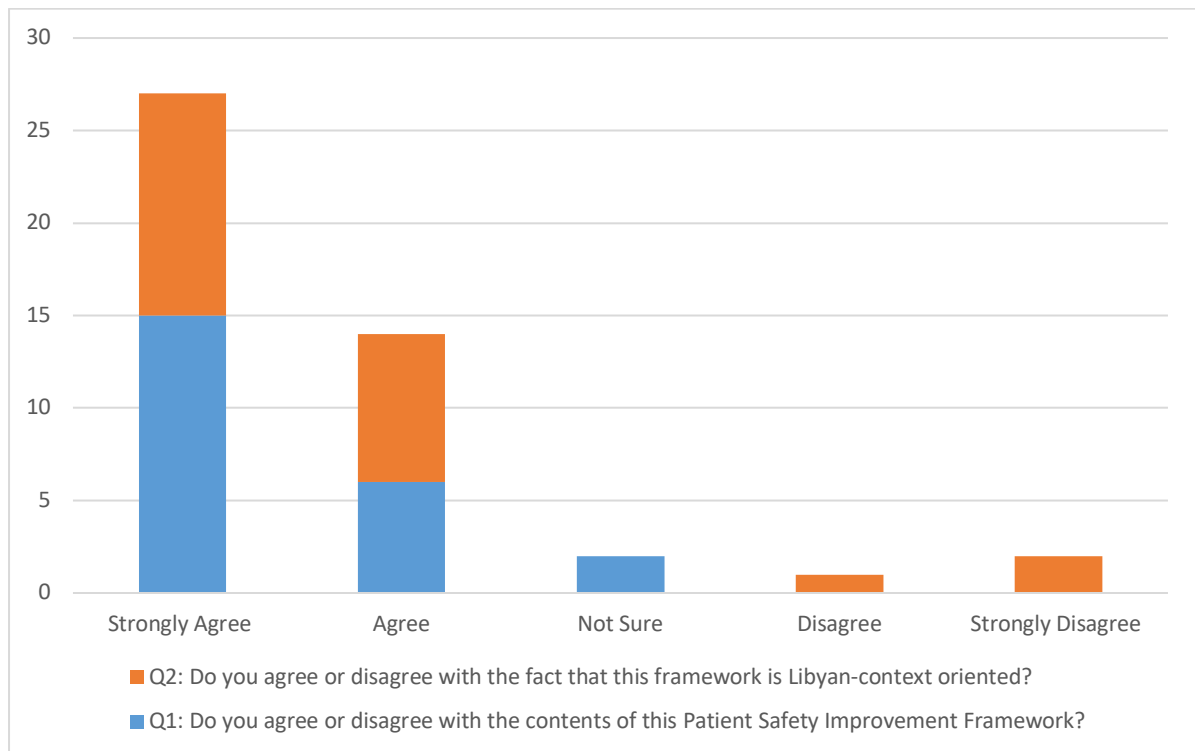


Figure 5.3: Contents and context of the framework

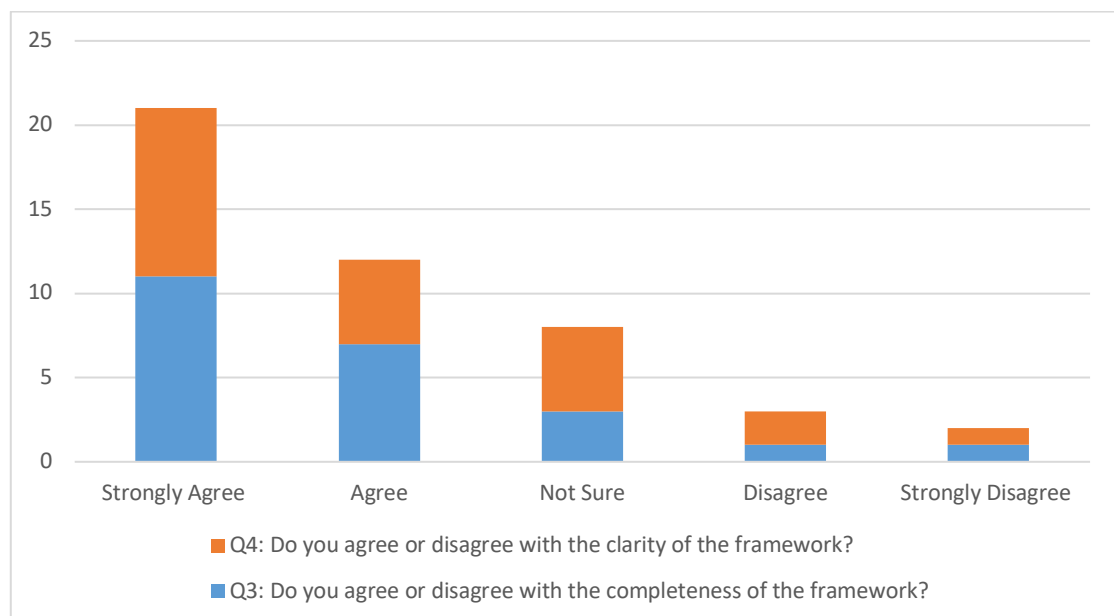


Figure 5.4: Clarity and completeness of the framework

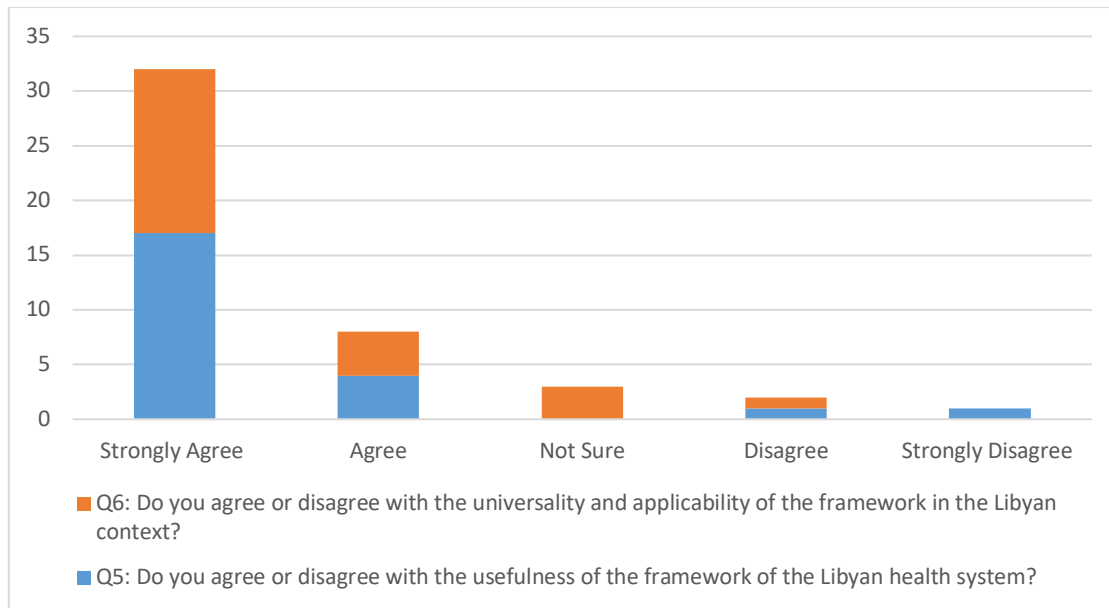


Figure 5.5: Universality and usefulness of the framework

Therefore, it could be argued that this developed framework has been rated to be appropriate and useful for the Libyan context based on the validation findings. Moreover, the framework was highly accepted by all participants in which only constructive and positive comments were returned as part of the questionnaire survey. However, it was clearly evident among the participants in the validation stage that without strong leadership that has a clear vision for improving patient safety in Libya, the journey will take very long. Hence, it could be argued that the findings of this thesis would help in contributing to the existing literature as well as inform policy makers and legislators that patient safety requires a systems approach. I will discuss some of the benefits of the developed framework in the next section.

5.8 Benefits of the framework

The expected benefits of this framework are discussed in this section. Firstly, it should be taken into account that patient safety research remains to be very limited in developing countries that further evidence and empirical studies are needed to capture the rate of patient harm and how poor performance is affecting upon the public health in these countries. However, taking the findings of this study into account along with the available research on patient safety, it could be argued that this framework can be used as a point of reference to guide change projects and programmes in many

developing countries at the national level. Patient safety should be considered as a core aspect of healthcare delivery within developing countries. The focus should be on the number of patients being treated in hospitals but on the patient outcomes. Therefore, this framework showed the importance of commitment from different stakeholders in Libya and in other developing countries in improving the standards of care delivered to patients. The framework also proposes that healthcare managers should aim to create a culture of safety within healthcare settings to enable the organisations learn from previous incidents and mistakes. More importantly, patient safety improvement should be considered an ongoing activity to enable the creation of patient safety culture among healthcare workers, patients and their families. As shown in the framework, different stakeholders need to be engaged in the process of patient safety improvement to achieve better results and improve patient outcomes. Thus, it could be argued that the framework can generate the following benefits:

- Enhancing patient satisfaction: the framework will enable healthcare organisations in Libya to regain the lost trust between patients and healthcare providers. In other words, the framework will aim to improve the standards of care, interaction with patients as well as involvement of patients and their families in the process of care. This will lead to better system performance and will influence upon patient satisfaction.
- Cost reduction: the framework can also help in utilising resources in the future so that healthcare organisations can minimise the costs associated with poor care such as litigation, insurance claims and lawsuits. The framework will also enable organisations to adopt some operational measures for waste management and reduces absenteeism as employees will be working in healthy and safe environments. This will reduce the levels of stress and the number of lost-days as a result of absenteeism.
- Reputation and public image: the framework will also lead to significant changes in the corporate image and reputation of healthcare organisations. These organisations will be viewed as learning organisations that focus on patients' involvement and carry out investigations in incidents to learn new ways for improvement.
- Better employee commitment and satisfaction: the framework can also influence upon the levels of commitment among employees which will be easy

for these organisations to retain them. In other words, those employees who feel that their views and opinions are being taken into account in the planning and decision-making process will be more likely to retain and feel empowered.

- Compliance with regulations and standards: the framework will also be beneficial in creating a systematic approach to comply with any local regulations or standards associated with the health and safety at work, well-being of staff and care standards.
- Foundations for future improvements: the framework will also guide the organisations to adopt other tools and systems to enhance operation performance in other business areas. It will help in improving governance structures as well as operational performance in the long-run.

5.9 Chapter summary

I have presented the Patient Safety Improvement Framework in this chapter. I also discussed the process for developing the framework and the overall aim of such a framework. The chapter also discussed the different framework components and elements. I also outlined some of the expected benefits of this framework and presented the process of validating the framework with system users in Libya. The following chapter presents a general discussion on the overall thesis findings as well as reflection on the practicability and limitations of the developed framework.

CHAPTER 6

DISCUSSION

6.1 Discussion

In improving patient safety, the problem is not about not knowing what to do but rather on how to prioritise the goals and make use of the resources available. There are widely available tools, techniques, interventions and best practices that have been developed over the past few decades which have led to improvements in the process of healthcare delivery (Berwick et al., 2006). Continuous learning, mindfulness and accountability are critical for improving patient safety (Weick and Sutcliff). There is also an increasing need to put more emphasis on safety over productivity and on teamwork, simplification and increased standardisation along with the creation of a learning organisation as part of the efforts being undertaken to improve patient safety. However, it should be noted that health systems operate in an environment that is influenced by political, cultural, social and institutional factors which should be considered when improving patient safety (Peabody et al., 2006). Thus, a political support and commitment is critical for improving patient safety in developing countries. Hospitals can be high risk areas if left without proper resources. Therefore, a comprehensive, effective national programme for patient safety improvement is needed at the top level. Such a programme should set out the national regulations, guidelines, policies, strategies and specific rules.

A regulatory body at the national or regional level is essential in developing countries, which is empowered by regulations and laws with strong enforcement activities and associated standards of performance. In the UK, the National Reporting and Learning System (NRLS) is one of the systems used to identify problems rapidly and share solutions across the entire system. The Care Quality Commission is another independent body that monitor the social and health care services in the UK with the

aim to enhance the quality of services through monitoring, inspection and evaluation. In Canada, the Canadian Patient Safety Institute (CPSI) promotes leading practices and raises awareness about patient safety through coordination with stakeholders, patients and the general public. It should also be noted that the creation of a system where there is continual learning from past events is crucial in the process of improving patient safety in developing countries. Thus, a regulatory framework is needed to ensure that organisations can learn from their past events to mitigate future risks.

Many developed nations have integrated patient safety and quality into the medical and nursing curriculum to raise awareness and improve the skills and competencies of the health workforce. The WHO has developed the *Patient Safety Curriculum Guide for Medical Schools* that is designed to be implemented in any medical school irrespective of geography or culture. Many medical schools around the world have integrated the curriculum into their teaching and learning materials (Walton et al., 2011). Thus, it is highly urgent for medical and nursing educational establishments in developing countries to implement such guide to help raise awareness about patient safety improvement among the workforce. Training and development programmes should be available for clinical and support staff through their careers. Improving patient safety requires the changing of culture of healthcare organisations and professionals through training and engagement (Patey et al., 2007).

In addition to regulations, education and training, there is a need for strong patient safety leadership that encourage meaningful and sustained change towards improving the quality and safety of care. Collective leadership by all individuals within the health system is required to eliminate harm to patients. Leaders also play a significant role in promoting team performance which lead to better safety performance (Künzle et al., 2010). There is also a need for political and health system leadership to ensure that the reliable regulatory and governance frameworks are established to improve patient safety. In addition to the political leadership, organisational leadership is also crucial in directing teams towards achieving the values and goals of a health service organisation. Evidence indicates that there is a positive correlation between positive organisational performance and clinical leadership (Tsai et al., 2015).

Research resources for addressing patient safety problems remain disproportionately low in developing countries when compared with developed nations. Support for research and development remains weak in developing countries (WHO, 2011). Thus, it is crucial for developing countries to support research activities associated with improving patient safety practices across healthcare organisations. Collaboration among medical schools and healthcare organisations is highly encouraged in developing countries to identify the root causes and develop effective programmes for patient safety improvement. Research will enable policy makers to understand the burden of unsafe care and how to tackle patient safety problems in these countries. Research also enables organisations to gather data and information so that system measurement can be achieved based on the concept of 'what cannot be measured cannot be improved'. Data and information is identified as among the important pillars of patient safety improving in this century (Yu et al., 2016).

Patient and staff involvement is another important factor that should be considered by healthcare providers in developing countries. Patients can help healthcare providers improve their practices, services and decision-making processes through reflecting upon their experiences (Vincent, 2010). Thus, policies and strategies should be developed to encourage patient and family involvement in the process of care so that lessons can be learned. In addition to this, patients can act as sources of information when it comes to developing policies and strategies for care.

As noted above, education and training as critical for enhancing the competencies and skills of healthcare workers so that they can remain up-to-date with developments in their fields. It has become widely accepted that health workforce should be trained on patient safety so that they can deliver safe healthcare (Alper et al., 2006; Ziv et al., 2000; Cronenwett et al., 2007; Sandars et al., 2007; Lee et al., 2016; McCarthy et al., 2016). However, as argued by Aiken et al (2014) education in patient still remains superficial. This raises questions about the type of training is being provided to health professionals in Libya in regard to patient safety. While carrying out the literature review, I have come across some universities and colleges in the western countries that use patients as teachers to raise awareness about patient safety. Moreover, several professional organisations as showed in Chapter 4 especially in the UK have

introduced compulsory training in regard to patient as part of the overall reforms in medical and nursing education. The medical and nursing education in Libya needs to be reformed so that it can produce health workers with sufficient skills and understanding in patient safety.

Several studies have shown that patient safety education and training is crucial in raising awareness about patient safety as well as creating positive safety culture in healthcare settings. For example, Walton et al (2006) developed an educational framework for patient safety education and training in Australia which aims to describe the competencies and skills that healthcare workers need to enable them to provide safe and reliable care. However, a systematic review by Nie et al (2011) into Patient safety education for undergraduate medical students concluded that *“There are only a few relevant published studies on the inclusion of patient safety education into the undergraduate curriculum in medical schools”*. The authors also argued that *“patient safety continues to provide major challenges for integration into existing medical education curricula”* (Nie et al., 2011, p. 8). Brock et al (2013) pointed out that inter-professional education in team communication can be useful in improving patient safety. Communication is one of the important factors that influence upon patient safety and care coordination. Therefore, it is highly urgent for policy makers in Libya to consider adopting the WHO Patient Safety Curriculum Guide so that awareness is enhanced among medical and nursing students to achieve sustainable improvement in patient safety.

Another important dimension in patient safety improvement is the role of continuous monitoring and auditing in healthcare. This dimension was included because without learning from previous mistakes, health systems will never develop. However, health systems in developing countries and in Libya in particular are not being held accountable by independent bodies for their poor performance. In the UK, several organisations have a regulatory role to ensure that healthcare providers either funded publicly or privately are providing acceptable standards of care. The CQC carries out inspections to hospitals and primary care centres in the UK to ensure that they comply with the quality and safety standards as set out in the regulations. Areas for improvement are identified and ratings are calculated which are published in the public

domain. This raises the levels of commitment towards patient safety among executives and leaders. It was asserted by Vincent et al (2014) that *“first, it is necessary to abandon the search for a single measure of safety”*. They argued that many dimensions of safety exist in most organisations and too many factors influence safety which should be taken into consideration to develop a systems approach to safety. This can be done through regular audits to identify any problems.

It was pointed out by Greene et al (2012) that healthcare organisations need to seek out information about safety incidents to harness the learning to influence future functioning. They argue that safe organisations do not only rely on single metrics or incidents to develop safety strategies, but they analyse safety information across the organisation so that long-term organisational improvements are made. Therefore, investments in technology are needed in health systems to enable organisations collect and measure data on patient safety. Previous incidents will enable healthcare organisations to develop more effective strategies for accident prevention. Similarly, clinical audits will enable healthcare professionals to identify any weaknesses in protocols or treatments. Flottorp et al (2010) pointed out that audit and feedback is vital tool in enhancing the quality and safety of healthcare as healthcare professionals will develop new skills and competencies through learning from past performance. Therefore, it is crucial as it was showed in the framework that continuous monitoring and auditing of healthcare setting is required to ensure that areas for improvement are identified. It also helps in raising awareness about the importance of patient safety among healthcare workers. Such process would also involve patients and their families so that a more holistic approach to patient safety is adopted. In addition to this, there is a need to establishing independent regulatory bodies to inspect hospitals against standards and performance indicators.

This developed framework is mainly directed towards healthcare settings in Libya and other developing countries. The implementation process of the framework should be done with a national reform of the health system which Libya is in need of following the recent armed conflicts. Other countries that share cultural and contextual factors with Libya can also benefit from implementing this framework. Therefore, the most important points that should be taken into account when implementing the framework

in Libya are discussed in this section. These points provide specific guidance to policy makers and practitioners in Libya in relation to the implementation of the proposed patient safety improvement framework.

- Improving patient safety in Libya should start by introducing a robust governance and regulatory framework. This will need to be introduced by the State of Libya to guide improvements in healthcare. Most countries have realised the need to introduce legislations to manage and monitor healthcare services. This means that the State should regulate healthcare providers including the public sector. Law will lead to organisational changes and will promote executives and leaders to start thinking about patient safety. Healthcare organisations will have to start with basic steps as noted in the framework to improve patient safety within their healthcare settings. Patient safety will also be critical and essential element of board meetings and discussions.
- Leaders and managers across Libya would need to be reminded for their roles and responsibilities towards patients. This will enhance their levels of commitment as well as remind them that they will be held accountable for their decisions and actions. The top management would then carry out assessment and examination of the current weaknesses, needs and resources need to enhance patient safety. This will help in identifying the skills and expertise needed as well as the physical resources. Healthcare providers will then have their goals, strategies and objectives clarified for long-term improvement. This requires commitment from the top management and leadership. Head nurses, departmental heads, healthcare professionals as well as patient representatives should be included in the assessment stage.
- An integral element of the framework is the provision of expertise and consultants in healthcare quality improvement. This can be done through working with regional organisations and also consultancy companies so that local expertise can be developed. Provision of training and development opportunities to all healthcare workers on patient safety, human factors, risk assessment, infection control, blood safety and safety culture is crucial. This will help in raising awareness about patient safety improvement as well as

encourage healthcare workers to share their concerns, views and problems in the current services.

- Integration of technology is crucial in medical care and healthcare services delivery. Thus, healthcare organisations would need to ensure that all healthcare workers are provided with all the needed technologies, tools and equipment to enable them to provide high quality and safe care.
- Basic health and safety requirements will also need to be met such as the providing safe working environments that are free from hazards, waste management, and fire safety and so on.
- Patient satisfaction must be measured through using qualitative and quantitative tools as that will help identify areas for improvement.
- Reporting of incidents will require a web-based system which should be developed by taking into account the available resources and accessibility issues such as the availability of Internet and other physical equipment.

6.2 Conclusions

Patient safety improvements in developing countries and particularly in Libya requires a support and commitment from the political leadership. Patient safety in developing countries should not only focus on counting adverse incidents and events but rather adopting a proactive method for continuously seeking out problems in the care process to ensure that patient receive high quality care at all times. I have also found that patient safety in the UK has gone through ups and downs over the 15 years in which many lessons can be learnt from this experience. There is no question that patient safety is a sensitive and important issue in the process of healthcare delivery. This was evident in this thesis through the empirical studies that were conducted as well as the documentary analysis. Patient safety requires a holistic approach that enables healthcare professionals to carry out their practices safely. This means that organisational, environmental, management, leadership and cultural factors influence upon patient safety improvement. More importantly, it was found that having political support and leadership commitment to patient safety is crucial as that influences others organisational and operational dimensions. This commitment and support has to translate into decisions, provision of resources, regulation, accountability,

establishment of transparent policies and fighting corruption within health systems in developing countries.

I also found that patient safety evolves with time due to the changes in the process of care. The delivery of healthcare has become more complex due to advancements in technology as well as the complexity of diseases which require integrated approaches to care. Coordination and communication are crucial factors for providing high quality care to patients. This research concluded that communication and information sharing are critical variables that should be incorporated within patient safety improvement protocols and strategies. This study has used multiple types of data and sources to develop and validate a holistic framework for patient safety improvement in Libya. It was proved that patient safety requires a systems approach which is in alignment of the findings of the literature reviews. However, I contributed to the knowledge by emphasising upon the need to integrate cultural and political factors when improving patient safety in developing countries. This was clearly raised by all study participants. Furthermore, when validating the framework as discussed in the previous chapter, there was consistency among all the participants that a regulatory framework is highly needed in Libya to lead a strategic approach for patient safety improvement.

Multiple complex factors which influence upon patient safety improvement especially in developing countries were found. A positive culture of safety is a must for changing behaviours, perceptions and attitudes towards safety in developing countries. The creation of a positive safety culture as found by this thesis requires a committed and supportive leadership which puts safety on top of the agenda. The Libyan health system has deteriorated further following the recent war in 2011 which had significant implications on public health and patient safety. Resource utilisation is also crucial for enhancing patient safety in Libya. A 'just' culture is also needed to allow healthcare professionals share their concerns and views about methods for improving services with policy makers and managers. A blame culture exists in the Arab health systems as reported by the systematic review that was carried out in this research. This type of culture would hinder any attempts to improve overall system performance. Thus, change initiatives are required by the top management to encourage employees to report any incidents and issues so that improvements can be adopted to enhance the

quality of care. I found that a top-down approach to patient safety improvement in Libya is urgently needed which must be supported by the involvement of all stakeholders including healthcare workers, patients and their families as well as non-governmental organisations.

The study also presented a framework which was developed based on an extensive literature review and systematic review of patient safety dimensions along with sound academic underpinning. The framework was also developed based on the insights from the British journey over the past 15 years. Expert advice was also used to develop the framework. Thus, this framework was created to contribute new knowledge about patient safety improvement. As discussed in Chapter 5, the framework reflects the in-depth thinking and the practical aspects associated with patient safety improvement. The framework was also validated through system users in Libya so that it can be used as a reliable tool for improving patient safety. It is clearly that patient safety is not at the top of agenda of policy makers in Libya nor in other developing countries due to the lack of national policies and systems that aim to enhance the quality of care.

Finally, the proposed framework has considered the internal and external factors which influence upon patient safety improvement. It also clarifies the role of all stakeholders' involvement in the process of improvement by focusing on the role of government, non-government sector, the general public, international organisations as well as media in taking a proactive and supportive role in improving patient safety in developing countries. This framework can be utilised in other developing countries that share the same contextual factors with Libya.

CHAPTER 7

RECOMMENDATIONS & IMPLICATIONS

7.1 Recommendations

Recommendations are crucial elements of research studies and investigation findings as noted by Bryman (2008). Therefore, I share the following recommendations for policy makers and healthcare workers in developing countries as well as recommendations directed to international organisations to help improve the standards of care in less developed nations.

- There is a need to introduce new regulations and accreditation systems to encourage hospitals to adopt national and international standards for enhancing the quality of care.
- It is recommended that healthcare workers are provided with training to raise their understanding of the contextual and organisational factors that influence upon patient safety and that they have a role in raising awareness about patient rights and also being positive towards adopting change in their workplaces.
- It is highly recommended for healthcare providers in Libya to use external expertise to re-design the health system structure where it allows for the introduction of information technology to manage patient records and files. This requires again political leadership and the provision of the required resources.
- There is a need to collaborate with the WHO to organise Staff capacity development and training.
- An independent body should be established to monitor healthcare organisations such as the CQC in the UK to ensure that these organisations are working in accordance with the available standards. This helps in ensuring that patients are protected using proactive policies.

- The introduction of new procedures and policies that promote transparency, accountability and anti-corruption are needed.

7.2 Contribution to knowledge

This research adds significant value to the literature by providing a simplified, well-evidenced and synthesised method to improve patient safety in developing countries. It could be argued that this study would enable improvements in patient safety both in practice and policy. Furthermore, the study makes different types of contributions and implications as discussed in this section for academics, practitioners and policy makers. The contributions of this study will enable us to understand patient safety in more depth. I will discuss the contributions of this study in alignment with Remenyi and Williams (1998) views regarding contributions to the body of knowledge. Remenyi and Williams argued that contribution to the body of knowledge can include one or more of the following:

- New ways of applying existing theories or science
- Extending our ability to understand phenomena
- Providing unifying explanations for events and circumstances
- Rejecting invalid theories

Moreover, Hart (1998) pointed out that originality in research can be explained by the fact that the research; has not been done before, new in style and form, without imitation or copy and authentic. Thus, it was found that there is a clear gap following the extensive literature review that was carried out about patient safety improvement. The focus of this study was mainly linked to patient safety in developing countries which remains to be under researched. The literature review also highlighted that there is an absence of an integrated and holistic approach to patient safety improvement in Libya and in developing countries in general. There was not a formal process that can be adopting to develop and enhance patient safety within health systems in developing countries. Thus, this study was designed so that a well-evidence framework for patient safety improvement in Libya can be developed by taking into account the existing evidence available as well as using new pragmatic methods for collecting data to develop the framework. Different regulatory and policy functions need to be integrated along with other organisational, leadership and individual factors that need to change to enable creating a positive safety culture within health systems. More importantly,

this study found that patient safety needs to be put at top of the agenda in national governance policies. Therefore, my contributions can be summarised into the following points:

- ✓ The subject of this research study is the first study that has been carried in Libya to develop an integrated framework for patient safety improvement based on expert advice and evidence elsewhere. Previous work by Rages (2014) indicated that there is a need for an integrated policy for patient safety in Libya. Thus, this developed framework can be used by researchers, policy makers and practitioners as a point of reference and a guide to improve patient safety practices within healthcare settings. This will further contribute to the current debate about the value and importance of improving patient safety.
- ✓ The study also adopted a data triangulation methodology which has not been adopted in previous studies to develop a well-integrated framework for patient safety in Libya and other developing countries.
- ✓ This research also provides guidance on the need to integrate different organisational factors to enhance patient safety. It emphasised upon the role of leadership and proposed that political leadership is critical to patient safety improvement in developing countries. This is important because the study analysed different patient safety initiatives that were introduced in the UK and found that without a national policy and regulations, it would be very difficult for developing countries to improve patient safety.
- ✓ My research also presents a pragmatic framework for patient safety improvement that is validated through systems users to identify its usefulness and appropriateness for the Libyan health system. This is also a contribution to knowledge as most existing theoretical and conceptual frameworks have not been evaluated in terms of their suitability.
- ✓ The study would also add significant contribution to policy making at international level where organisations such as WHO would benefit from the findings of this study.
- ✓ The research also highlighted the most important priority areas for patient safety improvement in Libya based on expert advice.

This study adds new knowledge to literature and existing debate about patient safety in general as well as patient safety in developing countries and Libya in particular.

Therefore, the study would be of high significance to academics and researchers interested in understanding the difficulties, challenges and barriers to hinder patient safety improvement in developing countries. The study also provides new knowledge about patient safety in Libya. This will help in strengthening existing literature as well as generating more knowledge about patient safety. I was also able to publish several publications as a result of this thesis in peer-reviewed journals which will add new knowledge and generate more knowledge. It will also encourage and enhance the use of different data collection methods in the future such as focus groups, Delphi and document analysis to strengthen the reliability and validity of findings. The study also adds to the current systems and models a new framework for patient safety improvement which could be tested in the future.

The study has focused on the macro aspects associated with healthcare improvement. Thus, this study would have policy implications by providing policy makers, legislators and international organisations with an integrated approach to patient safety improvement. This could lead to important policy changes in Libya that could include the introduction of new regulatory agencies and laws. Protocols, codes of practise, guidance documents and standards could also be developed which can be linked to the policy implications of this study.

7.3 Study limitations

It was important to enhance the validity and reliability of this research, but it is acknowledged in research that studies are not always free of flaws. First-time researchers are always faced with difficulties and hardships due to their limited experience in carrying out lengthy studies. Another issue is the availability of resources and access to needed data. This PhD was carried by myself being supported by wonderful supervisors. Access to study settings, funding, methodological and implementation issues are among the limitations which I would like to highlight in this section. These issues are briefly discussed as follows:

- It should be noted that the application of management theory into practice can be challenging and requires assessment of the local needs. Management is about alignment of the resources to meet organisational goals and objectives. Hence, the application of the theoretical framework would be faced with

limitations in all different activities of management such as planning, organising, staffing, directing and controlling. The application of this framework should be considered as per the teaching of the system theory. A system is composed of regularly interdependent or interacting groups of activities, sub-systems and boundaries that need to be considered as they form the whole system.

Access to study settings: I faced problems to access study settings in Libya in my first and second year of the PhD due to the problems there. This meant that I had to change the scope of my research after around 13 months. The access also limited my ability to implement the framework in Libya as I discuss later.

- Due to resources limitations, I was not able to conduct a full Delphi study with experts from around the world in the field of patient safety. I therefore adopted a modified Delphi study. The study would have benefited from a full Delphi study, but I found that several studies has used a modified Delphi when resources are limited.
- I adopted focus groups method to interview Libyan healthcare professionals who residing in the UK. It could be argued that such healthcare professionals would not have up to date information and knowledge about the Libyan health system. We have thought about this when designing the study and we used inclusion criteria as I discussed in chapter 3 to ensure that such participants have good understanding of the Libyan health system and that they must have worked in Libya and graduated from Libya. Therefore, the study would have been better enhanced if such healthcare professionals were working in Libya but due to access problems this was not possible.
- Time constraints, as I noted above, I had to change the scope of my project due to access problems which meant that I had to work while also thinking about time constraints as this study had to be completed in four years.
- The study would have benefited if quantitative methods were used to analyse the rate of patient harm in Libya, but such data was not available. It would have been more beneficial to relate to such data to explain the need for enhancing patient safety in Libya.
- Finally, the generalisability of the findings could also be challenged due to the fact that this study was not only carried out in Libya which could have different settings to other developing countries. Another important issue is the cultural

differences between developing countries as Libya would be surely different to Vietnam in terms of national and organisational culture. Hence, the generalisability of this study may be limited to countries that share the same resources, culture and organisational structures.

7.4 Future research

This study could open the scope for future research into the field of patient safety in Libya and in developing countries. Based on the challenges, findings and results of my study. I thought of sharing some of research ideas that can be explored in the future. These are some of these ideas:

- Examination of the rate of adverse events and patient harm in healthcare settings in developing countries using qualitative and quantitative methods.
- To investigate and assess patient safety culture among healthcare workers in the private health sector and compare that with public hospitals.
- To examine the role of leadership and management styles in improving patient safety culture and how leadership behaviours influence upon healthcare workers' commitment towards patient safety.
- To explore the extent to which public hospitals in Libya follow WHO patient safety protocols and interventions as well as if such hospitals are being accredited by any other international agencies.
- To explore the role of education and training in medical schools in Libya in establishing and enhancing awareness about patient safety within the healthcare sector.

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APPENDICES

Appendix A – List of Publications and Events Attended

- **Elmontsri, Mustafa.**, Almashrafi, Ahmed., Banarsee, Ricky. and Majeed, Azeem., 2017. Status of patient safety culture in Arab countries: a systematic review. *BMJ Open*, 7(2), p.e013487.
- **Elmontsri, Mustafa.**, Banarsee, Ricky. and Majeed, Azeem., 2017. Key priority areas for patient safety improvement strategy in Libya: a protocol for a modified Delphi study. *BMJ Open*, 7(6), p. e014770.
- **Elmontsri, Mustafa**, Almashrafi Ahmed, Dubois Elizabeth, Banarsee, Ricky. and Majeed, Azeem. 2018. Improving Patient Safety in Libya: Insights from the British Health System, *International Journal of Health Care Quality Assurance*, 31(3), 237-248.
- **Elmontsri, Mustafa.**, Banarsee, Ricky. and Majeed, Azeem., 2017. Improving patient safety in developing countries - moving towards an integrated approach. *JRSM open*, 9(11), 2054270418786112

Elmontsri, Mustafa

From: SRA Headquarters <SRA_Headquarters=sra.org@mail95.suw15.mcsv.net> on behalf of SRA Headquarters <SRA_Headquarters@sra.org>
Sent: 26 July 2017 11:53
To: Elmontsri, Mustafa
Subject: SRA Annual Meeting - Poster Presentation Acceptance



Subject: SRA 2017 Annual Meeting Abstract Acceptance

"Risk Analysis and Patient Safety: A tool for Improvement" has been accepted for the 2017 Meeting in Arlington, VA, on

10-14 December, as a **Poster Presentation**, on Monday, December 11, 6 - 8 pm in a dedicated poster session/reception. The online program will be available by August 15. You will be able to view it by going to

<http://sra.org/events/sra-2017-annual-meeting>

Please note that all persons attending the Annual Meeting (or any part thereof) are **required** to pay the appropriate registration fee as indicated on the registration form. Most importantly, **ALL PRESENTERS MUST REGISTER FOR THE MEETING BY 11 OCTOBER TO ENSURE INCLUSION OF THEIR ABSTRACT IN THE FINAL PROGRAM.** (Registration will open at the end of August at www.SRA.org.) If for any reason you need to cancel your presentation, as a courtesy to the Society and the other meeting participants, please contact the Annual Meeting Committee chair (Terje Aven, terje.aven@uis.no) AND Jennifer Rosenberg of the SRA Secretariat



Certificate of Attendance

I certify that

Mustafa Elmontsri

attended the

International Forum on Quality and Safety in Healthcare 2017

held at ExCel, London

Wednesday 26th April 2017 ☐

Thursday 27th April 2017 ☐

Friday 28th April 2017 ☐

This event has been approved by the Federation of the Royal Colleges of Physicians of the United Kingdom
for 21 category 1 (external) CPD credit(s).
Code: 109885

Dr Ashley McKimm
Head of Innovation and Improvement
on behalf of BMJ and Institute for Healthcare Improvement

This is to certify that

Mustafa Elmontsri

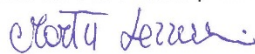
attended a focus group organised by
Universities UK International on

PhD Outward Mobility

on 1st December 2016

Date: 01/12/16

Facilitators: Marta Lezzerini, International Partnerships Officer



Catriona Hanks, Policy Researcher – Outward Mobility

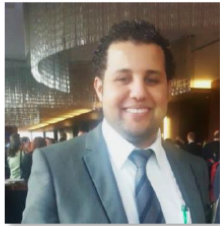


PCPH Noticeboard



PhD Student Win

Congratulations to PCPH PhD student Mustafa Elmonstri. His poster, Risk Perception in Libya: An Overview, was selected as one of the 2013 Student and International



Award Winners at the Society of Risk Analysis Annual Meeting. He received a \$600 prize for his winning poster.

New General Practice Society

Imperial College School of Medicine now has a General Practice Society.



An enthusiastic group of students have created a society to spread the joy of Primary Care and ensure more Imperial students consider General Practice as a career. Operating under the name ICGPS (or 'GPsoc') it aims to host internal events as well as inform members of relevant external events. Further information about the group can be found on the [Facebook page](#).

If you have any suggestions for events, or would like to advertise



PCPH Summer Seminar Series

The Summer PCPH Seminar Series will be organised by Dr Michael Soljak. Please [contact](#) him if you have suggestions for speakers.

SharePoint

ICT are offering SharePoint user training. Requirements are being collated and courses will be run for those interested. Please [register your requirements](#). Note all future courses will be for SharePoint 2013. [SharePoint Help](#).

Website Redesign

The Imperial website redesign is well underway. You can find out

Appendix B – Ethical Approval for Modified Delphi Study



Imperial College Research Ethics Committee
Imperial College London
Room 221
Medical School Building
St Marys Campus
London
W2 1PG
Tel: +44 (0)207 594 9484

researchethicscommittee@imperial.ac.uk

Dr Reetoo Banarsee
Imperial College London
Department of Primary Care and Public Health
Charing Cross Campus
London
W6 8RP

22/02/17

Dear Dr Banarsee,

Study Title: Development and validation of a patient safety improvement model for Libyan healthcare settings.

ICREC reference: 16IC3598.

The above study was approved by your Head of Department on 14/09/16 and by the Joint Research Compliance Office on 22/02/17.

Under the Imperial College Research Ethics Committee process, a study that has been reviewed by the Joint Research Compliance Office and Head of Division/Department (or Principal), where no significant ethical issues have been identified in the protocol or ethics application, can be approved without requiring it to go to full committee.

Documents

The documents reviewed were:

- ICREC Application form
- Protocol (v3 14/02/17)
- Email invitation (v3 14/02/17)
- Participant info sheet (v3 14/02/17)
- Consent form (v3 14/02/17)
- Delphi questionnaire (v3 14/02/17)

Yours sincerely,

A handwritten signature in black ink, appearing to read "G. Roper".

Gary Roper,
Head of Regulatory Compliance,
Imperial College London

Appendix C – Delphi Questionnaire Round One

**Imperial College
London**

Mustafa Elmontsri
PhD Student
Department of Primary Care and Public
Health
Imperial College London

Room 309, Reynolds Building
St Dunstan's Road
London W6 8RP
Tel: +44 (0)7716048560

m.elmontsri10@imperial.ac.uk
www.imperial.ac.uk/medicine/people/m.elmontsri10

Project Title: Development and Validation of a Patient Safety Improvement Model for Libyan Healthcare Setting

Email Invitation

Dear Expert,

My name is Mustafa Elmontsri, I am a PhD student at Imperial College London. I am currently undertaking a study that aims to identify the key areas for patient safety improvement in developing countries and in particular to Libya. I am under the supervision of Dr. Ricky Banarsee and Professor Azeem Majeed from the Department of Primary Care and Public Health at the School of Public Health, Imperial College London.

We are very interested in your views as an expert in the field concerning the key areas and elements that should be included as a part of a national strategy to improve patient safety in developing countries and countries in transition. Patient safety is well-researched, governed and investigated in developed nations which is not the case in developing countries such as Libya.

Your views will be gathered on three separate occasions as part of a modified Delphi study. The participant information sheet and questionnaire will be circulated by email and completion should take no more than 10 minutes and can be done in one "sitting" or across several, to fit in with a busy schedule. The questionnaire is administered through Survey-Monkey software.

The data from the questions will be summarised prior to reporting, so individuals will not be identifiable. This will maintain confidentiality of your responses and participation.

I would be highly honoured and grateful for your participation in the study. If you would like to participate in this study, please confirm to me by replying to this email.

Should you have any questions, please don't hesitate to contact me.

Yours sincerely
Mustafa Elmontsri
PhD Student
Department of Primary Care and Public Health
Imperial College London
m.elmontsri10@imperial.ac.uk

Title of Project: Development and Validation of a Patient Safety Improvement Model for Libyan Healthcare Settings

Delphi Questionnaire for Round One

Key priority areas for patient safety improvement in developing countries (Libya as case study): a modified Delphi study

Instructions

The following table presents suggested items, areas to address, critical processes and for patient safety improvement in healthcare institutions in developing countries as identified in current literature on patient safety in healthcare and by national patient safety organisations such as the World Health Organization.

When ranking the elements, please remember that these elements are aimed at improving patient safety in Libya which is witnessing a major challenges at the moment as a consequence of the war. In other words, to what extent do you believe that each element is of a high importance at this stage to help healthcare institutions in Libya provide a relatively safer care to patients?

Please place a rank in each respective "Rank" column for each element under each domain. Rank each element from 1 to 5, in the context of its importance to improving patient safety in developing countries, where;

- "5" represents "very important"
- "4" represents "important"
- "3" represents "no opinion"
- "2" represents "not very important"
- "1" represents "unimportant"

Please also give an overall rank of importance to each domain from 1 to 5.

Thank you for your time and effort for filling in this questionnaire

Domain	Element	Rank current importance	Overall Domain importance rank
1. REGULATION AND GOVERNANCE	1.1 Introducing patient safety law at parliament level		
	1.2 Establishing an independent patient safety agency in Libya to regulate healthcare providers		
	1.3 Introducing evidence-based Patient Safety Indicators for all healthcare institutions		
	1.4 Setting standards for the government bodies that regular healthcare providers, professions and specialist areas of medicine		
Other (please state)			
Domain	Item	Rank current importance	Overall Domain importance rank
2. LEADERSHIP AND MANAGEMENT	2.1 Senior leaders communicate the priority of patient safety to all stakeholders.		
	2.2 Ensuring that procedures are developed and approved by the governing body when required		
	2.3 Leaders and managers should incorporate patient safety accreditation and legal requirements as integral parts of its performance improvement.		
	2.4 Leaders and managers should develop plans and support systems for proactive collecting and analysis of patient safety information for future improvement		
Other (please state)			
Domain	Item	Rank current importance	Overall Domain importance rank
3. INFORMATION TECHNOLOGY	3.1 Introducing Electronic Medical Records for managing patient's information		
	3.2 Using technology for the prescribing of medications		
	3.3 Providing opportunities for patient to access their medical records		
	3.4 Providing training for all healthcare staff in using IT		
Other (please state)			
Domain	Item	Rank current importance	Overall Domain importance rank
4. EDUCATION AND TRAINING	4.1 Ensuring that there is a staff professional development programme with patient safety as a cutting theme		

		4.2 Embedding patient safety in all levels of education and training for healthcare professionals (i.e. undergraduate and postgraduate training, continuous improvement)		
		4.3 Ensuring that training curricula are high-quality, locally and clinically relevant, and delivered effectively.		
		4.4 Developing mechanisms for periodic gathering of information on healthcare providers' opinions and expectations in regard to factors		
Other (please state)				
Domain	Item		Rank current importance	Overall Domain importance rank
5. MEASUREMENT, ANALYSIS AND MONITORING	5.1 Introducing Incident Reporting System for all healthcare institutions			
	5.2 Ensuring that data collected from reporting systems are used for future learning to improve service delivery			
	5.3 Measuring patient safety culture among healthcare staff at all levels			
	5.4 Ensuring that Clinical performance measures as developed by national, regional or professional institutions (as applicable) are implemented in the everyday clinical practice			
Other (please state)				
Domain	Item		Rank current importance	Overall Domain importance rank
6. PATIENT AND PUBLIC INVOLVEMENT	6.1 Implementing a patient satisfaction questionnaire.			
	6.2 Providing training in patient satisfaction and interpersonal communication for staff			
	6.3 Ensuring that written policies on patient's rights are available, disseminated, or made visible to patients and their families			
	6.4 Ensuring that patients are encouraged to speak up and act upon the patient's voice			
Other (please state)				
Domain	Item		Rank current importance	Overall Domain importance rank

7. INFRASTRUCTURE AND WORKING ENVIRONMENT	7.1 Staff and patients are protected from health and safety hazards (noise, display screen equipment, manual handling etc...)		
	7.2 Ensuring that a system to reduce risk of health care-associated infections is implemented		
	7.3 Developing a safe waste management system according to international standards		
	7.4 Developing and enforcing Infection control policies (hand washing, injection waste, blood transfer etc...)		
Other (please state)			

Please list the top five barriers to implementation of patient safety systems in healthcare organisations in developing countries:

1.
2.
3.
4.
5.

Appendix E – Systematic Review Appendices

HSPSC dimensions
Unit-level aspect of safety culture
Supervisor/Manager Expectations & Actions Promoting Safety (4 items)
Organisational Learning - Continuous Improvement (3 items)
Teamwork Within Units (4 items)
Communication Openness (3 items)
Feedback and Communication About Error (3 items)
Non-punitive Response to Error (3 items)
Staffing (4 items)
Hospital-level aspects of safety culture
Hospital Management Support for Patient Safety (3 items)
Teamwork Across Hospital Units (4 items)
Hospital Handoffs and Transitions (4 items)
Outcome variables
Overall Perceptions of Safety (4 items)
Frequency of Event Reporting (3 items)

Some of the countries that have applied the HSPSC		
Author	Country	Sample Size
Sorra & Nieva (2004)	USA	1437 (21 hospitals)
Olsen (2008)	Norway	1919 clinical/non clinical staff (1 hospital)
Pfeiffer & Manser (2010)	Switzerland	2989 clinical/non clinical staff (1 hospital)
Smits et al. (2008)	Netherlands	583 clinical/non clinical staff (8 hospitals)
Hellings et al. (2007)	Belgium	2813 clinical/non clinical staff (5 hospitals)
Bagnasco et al. (2010)	Italy	724 clinical/non clinical
Waterson et al. (2009)	England	1437 clinical/non clinical staff (3 hospitals)
Sarac (2011)	Scotland	1969 clinical staff (7 acute hospitals)
Najjar et al. (2013)	Palestine	2022 clinical/non-clinical (13 hospitals)
Bodur & Filiz2 (2010)	Turkey	309 clinical/non-clinical (3 hospitals)
Robida (2013)	Slovenia	976 clinical/non-clinical (3 hospitals)
Hedsköld et al (2013)	Sweden	84,215 clinical/non-clinical (national-wide survey)
Nie et al. (2013)	China	1160 physicians and nurses (32 hospitals)
El-jardali et al. (2010)	Lebanon	6807 clinical/non-clinical (68 hospitals)
Alahmadi (2010)	Saudi Arabia	223 clinical/non-clinical (13 hospitals)

Appendix F – Participants characteristics in the focus groups

Participant Code	Gender	Years Of Experience	Speciality
LY01	Male	18	A&E
LY02	Male	22	Dermatology
LY03	Male	15	Paediatrics
LY04	Male	17	ENT
LY05	Male	20	General surgery
LY06	Male	18	Surgery
LY07	Male	9	Paediatrics
LY08	Female	15	Gynaecology
LY09	Female	12	Gynaecology
LY010	Male	19	ENT
LY011	Male	13	General medicine
LY012	Male	20	A&E
LY013	Male	11	GP
LY014	Male	8	Paediatrics
LY015	Male	24	Dermatology
LY016	Male	21	Public Health