PATIENT SAFETY INCIDENT REPORTING AND LEARNING SYSTEM IN LIBYAN HEALTHCARE: AN EXPLORATORY STUDY

Thesis submitted for the degree of

Doctor of Philosophy

By HAMZA ATIA JABER

Cardiff University

School of Healthcare Sciences

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DEDICATION

I dedicate this work to Almighty Allah, whose guidance and blessings have made this achievement possible. To my mother, Fatima; my wife, Marwah; and my newborn son, Mohamed, for being integral parts of my entire PhD journey.

To patients, their loved ones and the public, as well as health care professionals, researchers and academics worldwide.

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ABSTRACT

Background

The Patient Safety Incidents Reporting and Learning System (PSI-RLS) is widely discussed in international literature but remains under-researched in developing countries like Libya and other resource-constrained settings. There is a notable lack of policies related to PSI-RLS in these contexts and limited evidence of their effectiveness in healthcare sectors. This study aims to comprehensively explore the concept of PSI-RLS in the Libyan healthcare sector, focusing specifically on understanding the experiences and perceptions of key healthcare policy stakeholders at the national level.

Study Design

A qualitative-exploratory approach was adopted for this study. Data were collected through policy analysis and semi-structured interviews with key stakeholders at the macro level, along with notetaking as a third source of data. Walt and Gilson's (1994) policy analysis framework was utilised for the policy analysis. Purposive sampling was employed to select stakeholders and participants, ensuring maximum variation and national representation. The semi-structured interviews were analysed using Braun and Clarke's (2006) six-step thematic analysis framework.

Findings

The analysis of the data generated three key themes: perceptions and attitudes toward patient safety, perceptions and attitudes toward patient safety incidents reporting and learning system and organisation of the healthcare sector. The medical liability statute in Libya influences both patient safety and the reporting of patient safety incidents. The findings of this study indicated a predominant focus on the legal aspects of patient safety, which overshadowed ethical considerations. There exists a national reporting process that allows patients or their families to report medical harm. Healthcare providers are not involved in reporting patient safety incidents at the national level, and medical liabilities are perceived as a barrier to such reporting within the Libyan healthcare sector. Notably, there was no evidence in Libyan healthcare policies that explicitly prevents healthcare providers from reporting patient safety incidents. Nevertheless, the lack of clarity and the

absence of a code of conduct in the current healthcare policies have fostered apprehension regarding the medical liabilities associated with medical harm. The concept of learning from patient safety incidents is non-existent in the context of the Libyan healthcare sector. This study underscores the critical role of policy and socio-cultural interventions in promoting a nationally recognised framework for reporting and learning from patient safety incidents within Libya's healthcare sector**.**

Conclusion

The study has contributed to new knowledge and understanding about the experiences related to patient safety and PSI-RLS within the Libyan healthcare sector. The medical liability statute in Libya influences the reporting process of patient safety incidents and shapes the attitudes of healthcare providers in this context. Libyan social culture emerged as an overarching theme that informed the three themes generated from the analysis. The findings of this study have valuable implications for patient safety, healthcare providers, and the entire healthcare sector in Libya.

LIST OF ABBREVIATIONS

PSI-RLS	Patient Safety Incidents Reporting and Learning System
PSI	Patient Safety Incident
RLS	Reporting and Learning System
WHO	World Health Organisation
MOH	Ministry of Health
MOJ	Ministry of Justice
ICU	Intensive Care Unit
NRLS	National Reporting and Learning System
NHS	National Health Services
PICU	Paediatric Intensive Care Unit
COVID-19	Coronavirus Disease 2019
IOM	Institute of Medicine
UHC	Universal Health Coverage
ADR	Adverse Drug Reaction
GPC	General People's Congress
GPE	General People's Committee
COM	Council of Ministers
HOR	House of Representatives
NIDS	National Information and Documentation System
MC	Medical Council
MIA	Medical Insurance Authority
IDC	Information and Documentation Centre
ICPS	International Classification for Patient Safety
OHSAS	Occupational Health and Safety Assessment Series

NPSA	National Patient Safety Agency
NASHP	National Academy for State Health Policy
GMC	General Medical Council
HCPC	Health and Care Professional Council
NMC	Nursing and Midwifery Council
ICPS	International Classification for Patient Safety

GLOSSARY

Term	Definition of Term
Healthcare Organisation	"An entity that provides, coordinates, and/or insures health and medical services for people" (WHO 2009).
Healthcare Provider	"A licensed person or organisation that provides healthcare services" (National Cancer Institute 2023).
Healthcare Sector	Organised public and private health services (including health promotion, disease prevention, diagnostic, treatment and care services), the policies and activities of health departments and ministries, health-related non-government organisations and community groups, and professional associations.
Medical	Relating to the science of medicine, or to the treatment of illness and injuries. Relating to services and professions of medical work that require qualified healthcare providers.
Medical Complications	Medical harm arising from medical interventions that adhere to recognised scientific principles.
Paramedical	Relating to services and professions that supplement and support medical work but do not require a fully qualified physician (such as nursing, radiography, emergency first aid, physical therapy, and dietetics).
Policy	A course or principle of action adopted by stakeholders on the issues to be addressed and on the approaches or strategies to deal with them.
Stakeholder	An individual or organisation that has an interest in the decisions made regarding the healthcare services.
System	"An interacting combination, at any level of complexity, of people, materials, tools, machines, software, facilities, and procedures designed to work together for a common purpose" (WHO 2020).
System Complexity	"A process with multiple steps and/or decision points" (WHO 2009).
System Improvement	"The result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and improvement of safety and quality" (WHO 2009).

1 CHAPTER ONE – Introduction and Background

1.0 Introduction

This chapter provides an overview of the research and the topic being explored. It begins with a discussion of the research background, focusing on safety and patient safety in healthcare. The concept of patient safety incident reporting and learning systems is then discussed. Additionally, an overview of Libya's country profile and healthcare sector is provided. The significance of the study and its contribution to new knowledge are briefly outlined. Finally, an overview of the thesis structure is presented.

1.1 Overview

Patient Safety Incident Reporting and Learning Systems (PSI-RLSs) that capture and provide structured learning are key to improving patient safety and preventing the occurrence of harm (World Health Organisation 2020). Establishing patient safety reporting systems is an important step in enhancing patient safety. Using such systems enables healthcare organisations to collect, analyse and share vital information regarding patient safety (Sheikhtaheri 2014). Knowledge about how to improve patient safety in healthcare has become the focus of a large body of research, primarily due to the potential of such knowledge to improve patient safety outcomes and reduce costly hospital incidents (Steyrer et al. 2013).

Patient safety is considered a major public health and human rights issue (Poorolajal et al. 2015). According to Elmontsri et al. (2017), patient safety is a global public health issue that impacts countries at all levels of development and is a fundamental requirement in healthcare delivery. While several studies have estimated the extent of patient safety problem in high-income countries, such estimates are scarce in low-income, developing and transitional countries.

1.2 Philosophy of Health and Safety

Health is defined in the Constitution of the World Health Organisation (WHO) (1948) 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”. However, 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, pp. 25-26) 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". Health is regarded by WHO as a fundamental human right (WHO 2021).

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-centred (Seedhouse 2008). Seedhouse’s view on health supports the holistic nature of health in which one approach is not always right to tackle the health issues.

Seedhouse (1986, p. 158) claims 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”. The WHO (2009) defines disease as “a physiological or psychological dysfunction”. 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. Working with people to understand their needs is important for effective health promotion as argued by Seedhouse (2004) 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 2004, pp.138-139).

On the other hand, organisations can demonstrate the value of safety by implementing policies, practices, and procedures, as noted by Sinclair et al. (2010). In addition, Cooper (2001) believed that the concept of "safety is a value" can be connected to the fundamental philosophy that all injuries are preventable and that the goal of zero injuries can be achieved. 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 heath gains – physical, psychological and emotional – of public life”.

1.3 **Safety in Healthcare**

"If you feel safer in a hospital than on an airplane—think again! Paradoxically, people are more frightened of air travel than they are of healthcare," said Sir Liam Donaldson, Chair of the World Health Organisation World Alliance for Patient Safety, during a conference on patient safety in London in November 2005. He explained that the risk of being killed in an air crash is one in ten million, compared to the risk of dying during a stay in a hospital in the Western world, which is one in 300 (Harth 2007).

Healthcare sectors worldwide continue to face significant human suffering and economic costs due to adverse events. Despite ongoing efforts, achieving improved safety remains a challenge (Liberati et al. 2018). Healthcare is increasingly exhorted to learn from industries like aviation and nuclear energy, which have successfully achieved high reliability while operating in hazardous environments (Liberati et al. 2018). Consequently, various tools and procedures from these sectors are now being applied in healthcare settings, including a variety of techniques for identifying hazards and risks. One notable example is the adaptation of root cause analysis for safety incidents, which has become widely utilised in healthcare (Liberati et al. 2018).

In recent years, healthcare has borrowed ideas from industries that have strong safety records, including teamwork and error reporting from aviation, and process improvement techniques from manufacturing (Sutcliffe et al. 2017). Additionally, the authors noted that healthcare's latest patient safety push is to encourage hospitals to become high reliability organisations.

Healthcare is a hazardous sector as it evolves around system complexity, advanced technology, sick people and fallible professionals. Moreover, healthcare is classed as a 'safety-critical industry' as errors or systems failure can lead to the loss of life (Illingworth 2015; Institute of Medicine 2001). According to the WHO (2009), healthcare is defined as "services received by individuals or communities to promote, maintain, monitor or restore health".

Healthcare is not as safe as it should be, since the publication of the seminal report *To Err is Human*, it is estimated that about 12% of patients still experience some form of harm associated with healthcare, around half of which is preventable (Papanicolas and Figueroa

2019). No healthcare sector is free of the occurrence of medical errors to patients, as studies worldwide have shown that harm caused by healthcare affects all healthcare sectors (Vincent et al. 2016).

Kennedy (2001) stated that approximately 5% of the 8.5 million patients admitted to hospitals in England and Wales each year suffer from medical harm that could potentially be prevented with standard care practices. While the exact number of fatalities resulting from these incidents is unknown, it is estimated that up to 25,000 deaths may occur annually.

Indeed, poor safety culture was found to be a causal factor of medical harm in Bristol Hospital and the National Health Services (NHS). Kennedy (2001) claimed that between 30 and 35 children undergoing heart surgery at Bristol Royal Infirmary died between 1991 and 1995 who would probably have survived if treated elsewhere. The story of the paediatric cardiac surgical service in Bristol is not an account of bad people. Nor is it an account of people who did not care, nor of people who wilfully harmed patients (Kennedy 2001). However, the circumstances of Bristol, and the NHS, at the time, led to the system for providing paediatric cardiac surgery (PCS) being flawed. All of these flaws, taken together, led to around one-third of all the children who underwent open-heart surgery receiving less than adequate care (Kennedy 2001).

Ensuring safety in healthcare is crucial to achieving Universal Health Coverage (UHC) and the best healthcare delivery worldwide, as it is one of the key aspects of healthcare quality (WHO 2019; WHO 2021). Over the past decade, significant efforts have been made to enhance safety in the healthcare sector, leading to widespread recognition and awareness of medical harm. Many countries have made substantial progress in assessing the scale and nature of this harm (Elmontsri et al. 2017). Additionally, they stated that several studies have examined the extent to which patients are harmed while receiving medical care. For example, the nature and scale of surgical adverse events, adverse drug reaction, infection and medication prescriptions have been catalogued. Skelly et al. (2023) defined the Adverse Event as “a harmful and negative outcome that happens when a patient has been provided with medical care”. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdome defines an Adverse Drug Reaction (ADR) as “a harmful and unintended reaction that occurs at a dose normally used for the prophylaxis, diagnosis or

treatment of disease or the modification of physiological functions" (Al Qubaisi et al. 2014). Errors in healthcare can have severe, even fatal consequences. Hence, patient safety has been extensively discussed and researched (Gartmeier et al. 2017). According to WHO (2009), a patient is "a person who is a recipient of healthcare". Safety is defined as "the freedom from hazard" whereas the hazard is "anything that can cause harm". Additionally, harm is defined as "a death, disease, injury, suffering and/or disability experienced by a person" (WHO 2009).

1.4 Patient Safety

Patient safety is a serious global public health issue that impacts patients in all healthcare settings, whether in developed or developing countries (Gao et al. 2019). The revelation that medical care itself can sometimes cause harm, including fatal and persistent harm, has caused significant concern (Leroy 2011). Since the publication of the Institute of Medicine (IOM) report "To err is human" (Kohn et al. 2000; Donaldson et al. 2000), patient safety culture has become a core element in improving patient safety. A patient safety culture is nonpunitive and emphasises accountability, excellence, honesty, integrity and mutual respect (Sherwood et al. 2012).

It is estimated that approximately 42.7 million patients worldwide endure disabling injuries or death annually due to unsafe medical practices and medical errors. The global cost associated with these unsafe medical practices and medical errors has been estimated at US$42 billion per year, which amounts to almost 1% of global expenditure on health (Gao et al. 2019). The modern patient safety movement began in the late 1990s and has gained momentum in recent years. Major reports from the United States and the United Kingdom, titled "To Err Is Human: Building a Safer Health System" and "An Organisation with a Memory," respectively, brought attention to the scale of the problem, the similarities with other high-risk industries, and the weakness of health sectors in provoking human error. The IOM has identified adverse events resulting from system failures in healthcare institutions as a leading cause of injury and death in the United States. These events contribute to over 44,000 deaths in U.S. hospitals annually and cost between $17 billion and $29 billion (Mekhjian et al. 2004). The United Kingdom's Department of Health indicated that adverse events occur in approximately 10% of all hospital admissions annually (Harth 2007).

“First, do no harm” is the most fundamental principle of any healthcare sector. The paramount goal of healthcare is to prevent harm to individuals (WHO 2023). Nevertheless, there exists compelling evidence of an immense burden of avoidable patient harm worldwide, spanning across both developed and developing healthcare sectors. This issue carries profound human, moral, ethical, and financial implications (WHO 2023).

The 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 2004). The report "To Err Is Human: Building a Safer Health System" garnered widespread public attention to medical errors and was an impetus in making patient safety a national priority (Flink et al. 2005). President Bill Clinton ordered the development of the Quality Interagency Coordination Task Force (QuIC) to recommend strategies for enhancing patient safety and healthcare quality. The QuIC report in 2004 outlined numerous strategies, including the implementation of mandatory reporting systems in all 50 states (Flink et al. 2005).

Jeffcott et al. (2009) argue that understanding and applying human factors in healthcare presents significant opportunities for enhancing patient safety. A key concept in human factors is “resilience”, which explores how individuals, teams and organisations monitor, adapt and respond to failures in high-risk situations. While resilience is a relatively new concept in healthcare, it is well-established in other high-risk industries. In addition, the authors suggest that resilience can benefit patient safety efforts because it represents a change in emphasis from a traditional, reactive focus on errors to seeing humans as a defence against failure.

Brittain and Carrington (2021) claim that organisational-level factors such as communication, environment, human factors, interdisciplinary collaboration, leadership, and culture influence patient safety. They note that the overall characteristics of healthcare organisations are poorly studied and evaluated yet impact every intervention within hospital systems. Additionally, in 2020, the Institute for Healthcare Improvement (IHI) and the Agency for Healthcare Research and Quality introduced the National Action Plan to

Advance Patient Safety. This framework identifies four key pillars essential for fostering a safer healthcare environment (AHRQ 2024):

1. Culture, Leadership and Governance
2. Patient and Family Engagement
3. Learning Systems
4. Workforce Safety

Healthcare staff may stay silent about concerns or safety events if an organization or a team has a culture of blame and retribution. Psychologically safe cultures focus more on learning and how system failures lead to safety events rather than on individual actions (AHRQ 2024). However, a culture focused on system failures does not preclude individual accountability where appropriate. The concept of just culture seeks to balance this systems-based approach to safety events with appropriate individual accountability if the events are negligent or repeated regularly (AHRQ 2024).

1.4.1 Patient Safety and Socio-cultural Perspective

Policymakers recognise that there are many barriers to effective safety management. One of the most significant issues is the reluctance of staff to participate in incident reporting (Rowley and Waring 2011). This reluctance is typically attributed to a 'blame culture' within healthcare sector, which discourages staff from being open and honest about their mistakes for fear of reprimand or disciplinary action (Rowley and Waring 2011). This focus on individual blame reflects a 'person-centered' perspective on safety that fails to consider underlying factors, highlighting the need to promote a 'just culture'. Such a culture encourages openness without the fear of being blamed (Rowley and Waring 2011).

In addition, the creation of a 'safety culture' is considered essential for successful safety management (Rowley and Waring 2011). This culture encompasses shared attitudes, beliefs, and practices related to safety, including mindfulness of potential dangers, openness, trust and information sharing. It also involves a reflective approach to safety improvement and effective leadership that prioritizes safety goals (Rowley and Waring 2011). This type of culture is commonly found in other high-risk, high-reliability organisations and is often suggested as a solution for enhancing patient safety management (Rowley and Waring 2011).

While the relationship between culture, safety and quality is complex, understanding which components of culture influence specific aspects of performance presents a significant challenge in healthcare organizations (Mannion and Davies 2018).

Healthcare organisational culture (from here, just culture) is "a metaphor for some of the softer, less visible, aspects of health service organisations and how these become manifest in patterns of care. The study of organisational practices derives from social anthropologists' approaches to the study of indigenous people: both seek to unravel the dynamics of unfamiliar tribes" (Mannion and Davies 2018).

There are two distinct perspectives on culture. The first perspective is optimistic about the potential for purposeful cultural management, viewing culture as something an organisation has—an attribute that can be assessed and manipulated to enhance care (Mannion and Davies 2018). In contrast, the second perspective focuses on gaining insights into organizational dynamics, without emphasizing whether they can be manipulated . This view considers organizational culture as integral to the organization itself—an account of local dynamics that cannot be easily separated from the present organizational environment (Mannion and Davies 2018). These two perspectives take us down different routes of assessing and managing local healthcare cultures. The first emphasises the use of metrics to assess the prevalent organisational culture around a performance domain, such as patient safety. In addition, the first emphasising quantitative measurement to identify targets for change and to track progress (a summative approach) (Mannion and Davies 2018). The second view seeks to explore local cultural dynamics, often working through dialogue and perhaps using images and narratives rather than measurement instruments. The second uses qualitative insights more discursively to prompt reflection, learning, and shared actions (a more formative strategy) (Mannion and Davies 2018). Narrative practices about performance can have important effects on local cultures and this has implications for clinician leaders, managers, and policymakers in how they talk about and manage performance and improvement (Mannion and Davies 2018).

1.4.2 Definitions of Patient Safety

Some common definitions of patient safety have been obtained from different sources. One of the early definitions of patient safety presented above was introduced by the Institute of

Medicine 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"*

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. In addition, the AHRQ has developed a glossary for patient safety terms and defined the patient safety term as: *"Freedom from accidental or preventable injuries produced by medical care"*

The WHO refers the patient safety as *"the prevention and mitigation of harm to patients"*. In addition, The WHO refers the patient safety within the broader health context *as "a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur".*

Patient safety was defined by the Institute of Medicine (IOM) *as "the prevention of harm to patients".*

1.5 Concept of Patient Safety Incidents Reporting and Learning System

One in 25 patient safety incidents will result in severe harm, including a shortening of life expectancy, permanent injury, major loss of function or death (Carson-Stevens and Donaldson 2017). Reporting and learning systems (RLSs) are designed to obtain information about patient safety incidents which can then be translated into individual and organisational learning in order to improve patient safety in the healthcare sector (Stavropoulou et al. 2015). The WHO (2020) stated that RLSs which capture and provide structured learning, are key to improving patient safety and preventing the occurrence of harm. Mahajan (2010) stated that an incident reporting system which would improve patient safety would allow front-end clinicians to have easy access for reporting an incident in a non-punitive manner, and that it will lead to enhanced learning regarding the causation of the incident and systemic changes which will prevent it from recurring. Incident reporting systems are intended to provide an

integrated view of the safety issues emerging across an organisation or healthcare sector as well as a structure within which those issues can be collaboratively investigated and addressed (Macrae 2016).

In addition, Liang and Ren (2004) asserted that patient safety incidents are not caused by bad doctors, bad nurses or bad administrators callously cutting corners. Instead, they stem from the underlying structure of the healthcare sector and its hidden flaws. However, fear of blame, legal penalties, the perception that incident reporting does not improve patient safety, and lack of knowledge about incident reporting systems are common barriers to reporting systems, as reported in the literature by healthcare professionals (Health Quality Ontario 2017). Furthermore, Wolf and Hughes (2008) stated that a lack of an incident reporting system or forms, a lack of information on how to report incidents, and a lack of feedback to the reporter are considered to be barriers to reporting patient safety incidents. In some countries, reporting patient safety incidents is mandatory. For instance, in the United States, incident reporting in New York State emerged statutorily in 1986 as part of the malpractice prevention program (Flink et al. 2005). This program was created by the legislature to document preventable events caused by human or mechanical errors that result in harm to patients. The statute requires hospitals to gather and report information on negative health outcomes and incidents (Flink et al. 2005).

Reporting patient safety incidents and learning from experience are the key steps to maintain and improve patient safety. Encouraging reporting and learning will also necessitate some cultural change (Gao et al. 2019).

1.5.1 Concept of Patient Safety Incident

Patient safety incidents are “any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare” (NHS 2022). The WHO (2009) state that a patient safety incident is "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient". The use of the word “unnecessary” in this definition recognises that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare (WHO 2009). Certain forms of harm such as an incision for a laparotomy are necessary harm and thus are not considered an incident. In addition, incidents arise from either unintended or intended acts (WHO 2009). According to Carson-

Stevens and Donaldson (2017), a patient safety incident is defined as “any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare”. Patient safety incidents in high-income countries receive huge attention from the public and the government in which public enquires are ordered to identify the root causes (Elmontsri et al. 2017).

Additionally, unsafe healthcare has variously been described as a ‘medical error’, an ‘adverse event’, or a ‘serious untoward incident’. Internationally, the favoured term is now patient safety incident (Carson-Stevens and Donaldson 2017).

Errors are, by definition, unintentional, whereas violations are usually intentional, though rarely malicious, and may become routine and automatic in certain contexts (WHO 2009). Moreover, an error is defined as “a deviation in a process of care that may or may not cause harm to patients” (WHO 2009). Karande et al. (2021) defined medical error "as an unintentional act (either of “omission” or “commission”) or one that does not achieve its intended outcome, the failure of a planned action to be finished as intended (an “error of execution”), using an incorrect plan to achieve a goal (an “errors of planning”), or a deviation from the method of care which could or might not cause harm to the patient. Liang and Ren (2004, p. 522) defined the error "as a mistake, an inadvertent occurrence, or an unintended event in a healthcare delivery which may, or may not, result in patient injury".

The WHO (2009) defined a medical error as "an adverse event or near miss that is preventable with the current state of medical knowledge", whereas an adverse event is defined as "an incident which results in harm to a patient" and a near-miss is “an incident that did not cause harm”. Leroy (2011) argues that medical errors in hospitals contribute significantly to morbidity and mortality. Preventable medical errors alone result in up to 98,000 annual deaths in the United States, equivalent to the daily toll of a fatal jumbo jet crash (Leroy 2011).

Sheikhtaheri (2014) stated that more than 20 definitions of near misses was reviewed, and all of them concluded that there is a general consensus that this concept should indicate a type of incident that has the potential to cause harm but ultimately does not. However, there are significant controversies in the details. Some definitions emphasise that a near miss is

an incident that did not reach the patient at all because it was intercepted beforehand. On the other hand, others highlight that a near miss may reach the patient but does not cause harm. Consequently, some researchers focus on the interception of an error, while others concentrate on the prevention of harm. These controversies can create confusion about whether a specific incident should be reported Sheikhtaheri (2014).

A study suggests distinguishing between two factors—"reaching the patient" and "patient harm"—and defining two separate concepts: "near miss" and "no harm incident." While this framework is appropriate, it fails to consider the reason for interception or harm prevention, such as chance or intervention. This factor should be considered, as it can provide different insights into the incidents (Sheikhtaheri 2014).

Nevertheless, in the context of the International Classification for Patient Safety (ICPS), regardless of the nature of the incident either unintended or intended acts, a patient safety incident is referred to as "an incident" (WHO 2009). The ICPS is a conceptual framework for an international classification which aims to provide a reasonable understanding of the world of patient safety and patient safety concepts to which existing regional and national classifications can relate (WHO 2009).

According to the internationally recognised standard for Occupational Health and Safety Assessment Series (OHSAS) 18001, the definition of an incident is "referred to as a work-related event(s) in which an injury or ill health (regardless of severity) or fatality occurred, or could have occurred". An accident gives rise to injury, ill-health or fatality whereas, a near-miss does not give rise to injury, ill-health or fatality. Thus, an incident can be either an accident or a near-miss (OHSAS 18001 2007). In addition, an incident is also defined by the WHO as "something that happened to the patient, a clinical outcome probably with harmful or potential harmful effects" (WHO 2009). An accident is defined by the WHO as "an event that involves damage to a defined system that disrupts the ongoing or future output of the system". An adverse event is a type of patient safety incidents that led to harm.

The concept of errors generally encompasses two main occurrences: harm and near misses. This is clearly seen in the definition of medication error, as medication errors are among the most common medical errors that result in illness and death worldwide (Bayazidi et al. 2012).

For instance, the United States National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines a "medication error" as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the health care professional, patient or consumer” (Al Qubaisi et al. 2014). Similarly, the United Kingdom National Patient Safety Agency (NPSA) defines it as "any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicines advice, regardless of whether any harm occurred or was possible” (Al Qubaisi et al. 2014). In a philosophical discussion of the term, Ferner and Aronson suggest a definition of "failures in the treatment process that lead to or have the potential to lead to harm to the patient” (Al Qubaisi et al. 2014). All these definitions emphasise harm and near-misses as crucial components.

1.5.2 Concept of Reporting and Learning Systems

In 2001, policymakers in the United Kingdom established the National Patient Safety Agency (NPSA). This agency subsequently launched the National Reporting and Learning System (NRLS), the first national patient safety reporting system. The NRLS is designed to collect information on safety incidents to enable analysis and generate learning to improve the state of care (Imperial College London 2024). "To close the safety gaps in my hospital, first I need to know where they are. Reporting systems serve as a map to show us where the gaps are and guide us in how to close them" (Healthcare Excellence Canada 2024). While reporting will always be important, its role in enhancing safety has been overemphasised. Reporting systems can provide warnings, highlight significant problems, and offer insights into causes. They serve an important function in raising awareness and generating a culture of safety (Vincent 2007). A study conducted by Panesar et al. (2013) found that the largest proportion of surgical patient safety incidents reported to the NRLS in England and Wales was from the trauma and orthopaedics’ specialty, 48,095/163,595 (29.4%). Of those, 14,482/48,095 (30.1%) resulted in iatrogenic harm to the patient and 71/48,095 (0.15%) resulted in death.

All reporting and learning systems, whether large or small scale, must create first a positive culture in which reports are encouraged and valued, and staff are praised for participating.

Generally, RLSs seek to capture and assemble information in three main domains: description (what happened), explanation (why it happened) and remedial measures (the actions that were taken as a result).

Reporting plays a central role in improving safety. Reporting systems fulfil one or more of five main functions:

1- public accountability

2- response to the patients and families involved

3- communications alert route

4- barometer of risk within healthcare

5- foundation for learning and improvement.

However, some of these functions may not be compatible with each other. For instance, using reporting systems primarily for accountability purposes can hinder their effectiveness in promoting improvement and learning. It may also create a sense of fear and apprehension among the staff, leading to a reduced willingness to report patient safety incidents.

Public accountability is "the obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public organisation or agency (or its designee) that has responsibility for oversight and is answerable to the general public".

There is no perfect reporting system, successful patient safety incident reporting systems are based on two fundamental principles.

- They make risks visible.
- They prevent harm.

According to the OHSAS 18001 standard, the risk is “a combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s)”. In addition, the hazard is defined by OHSAS 18001 standard as “source, situation, or act with a potential for harm in terms of human injury or ill health, or a combination of these.

The WHO has defined risk as “the probability that an incident will occur”, and the hazard as “a circumstance, agent or action with the potential of causing harm” (WHO 2011). For example, infection is a risk, and viruses are a hazard.

Reporting is considered crucial for enhancing the safety of healthcare for two reasons. Firstly, other high-risk industries have long relied on routine reporting and thorough investigation of incidents as a core element of their safety programs. Secondly, common-sense reasoning within healthcare has been that we must learn from the things that go wrong, and investigating patient safety incidents is the most effective way of learning. It is increasingly recognised that errors should be conceived as opportunities for organisational learning and improving patient safety in the long run (Gartmeier et al. 2017).

As a result of the IOM report, several actions occurred to bring medical error reporting systems into the forefront of public policy. In addition, the report also highlighted the importance of creating mandatory adverse event reporting systems as a mechanism to learn from these events and prevent similar events in the future (Flink et al. 2005). The National Academy for State Health Policy (NASHP) analysed legal and policy issues of State mandatory reporting systems, concluding that mandatory and voluntary systems can work together to help reduce death and serious injury in the healthcare sector (Flink et al. 2005). Incident reporting system deepens the understanding of the frequency of adverse events and near misses (Labib et al. 2019).

The healthcare sector can be analysed at three different levels: Micro, Meso, and Macro. Each level focuses on different aspects and scales of healthcare delivery and management (Smith et al. 2019; Lalani et al. 2023).

The micro level pertains to the individual level of healthcare, including day-to-day practices and interactions between healthcare providers and patients. Key aspects at this level include:

- Patient care: Direct interactions and treatment provided by healthcare professionals.
- Clinical practices: Implementation of medical procedures and protocols.
- Patient experience: Quality of care and patient satisfaction.

The meso level focuses on the organisational and community level, including the management and coordination of healthcare services within specific organizations or communities. Key aspects at this level include:

- Healthcare organisations: Hospitals, clinics, and other healthcare facilities.
- Community health services: Programs and initiatives aimed at improving health outcomes within a community.
- Support systems: Attitudes and support from managers, colleagues and patients.

The macro level involves the national and international level, encompassing broader systemic factors that influence healthcare delivery on a large scale. Key aspects at this level include:

- Policy and regulation: Legal and regulatory frameworks governing healthcare.
- Societal factors: Demographic, historical, and cultural influences on health services.
- Economic factors: Funding, resource allocation and economic policies affecting the healthcare sector.

The three levels help understand and address the complexities of healthcare sectors by providing a structured approach to analyse and improve healthcare delivery and outcomes (Smith et al. 2019; Lalani et al. 2023).

1.6 Libya's Country Profile and Healthcare Sector

Libya is an Arab country located on the north coast of Africa, to the south of the Mediterranean Sea (See Figure 1-1). It is the 17th largest country in the world and the fourth largest country in Africa, with a total area of 1,759,540 km2 (El-Mehdawi 1998; Atkinson 1996) and a coastline of approximately 1,900 km along the southern Mediterranean Sea. Libya is bordered by Egypt and Sudan to the east and southeast, Chad and Niger to the south and southwest, and Algeria and Tunisia to the west and northwest. The country is divided into three historic regions: Tripolitania in the west, Cyrenaica in the east, and Fezzan in the south (Oyeniyi 2019).

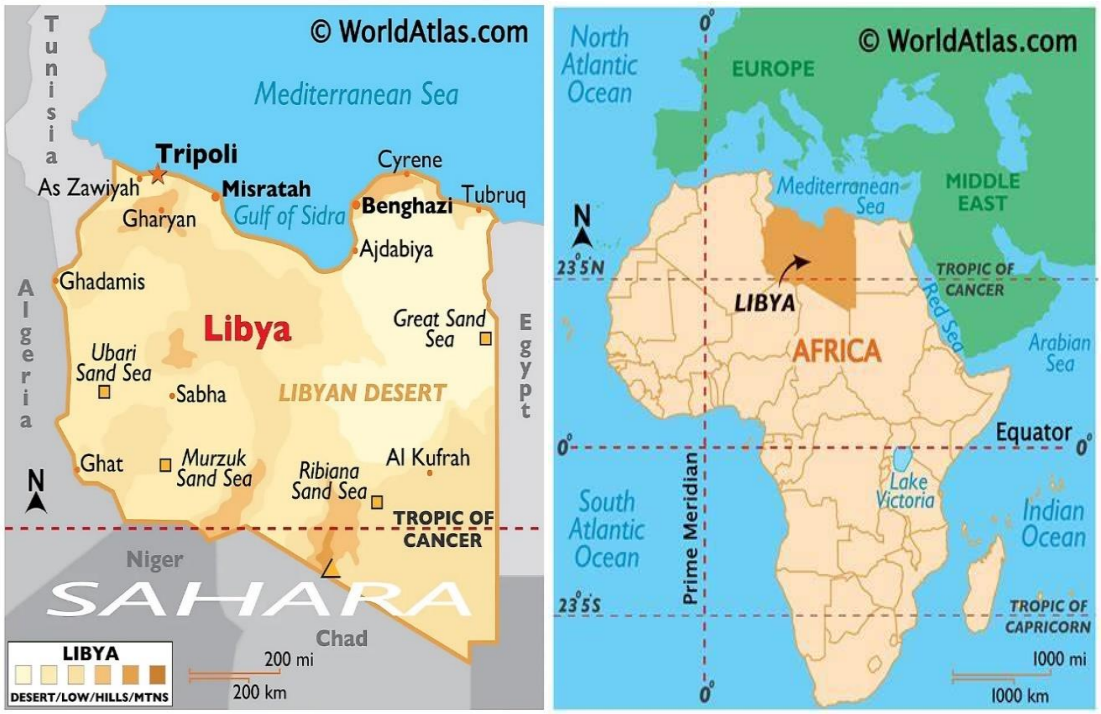

Figure 1-1 Map of Libya (https://www.worldatlas.com/maps/libya)

The population of Libya has increased by 32.6% over the past 25 years, reaching 6.3 million in 2015. More than 75% of the population resides in urban areas, and the life expectancy at birth was 75 years in 2012 (WHO 2015). Libya provides universal health coverage free of charge to its citizens. The healthcare is mainly state-funded and services are delivered through a comprehensive network of primary healthcare centres, polyclinics, rehabilitation centres, and general hospitals, located in both urban and rural areas (Elmontsri et al. 2017).

At the central level, the Libyan Ministry of Health (MOH) coordinates, supervises, and evaluates the implementation of national health programs, healthcare services and community health activities. The MOH also takes on the role of initiating, coordinating, and consolidating national health policies, strategies, programs, and activities, as well as overseeing their assessment process (Abudejaja and Singh 2000). The national health policy aims to achieve a comprehensive and uniform distribution of healthcare services among the population (Abudejaja and Singh 2000). Libya provides free health services to all its citizens and an average of 37 hospital beds per 10,000 people. This figure places it

among the highest in Africa in terms of hospital bed availability per capita (WHO 2011). However, the aftermath of the 2011 civil war led to a significant decline in the quality of healthcare in Libya (Daw et al. 2015). In Libya, there is a perception that the quality of public health care has deteriorated, leading to a lack of trust in the public healthcare sector among many citizens (Osborne 2010). Those who can afford it are choosing to pay for private healthcare instead of using the public system (Osborne 2010). Despite the fact that free medical care is available to all Libyans through the public healthcare sector, more and more Libyan citizens are opting for private medical care in search of better service (Osborne 2010).

The WHO in collaboration with the MOH conducted an assessment of the health sector in Libya in 2012 identified several challenges facing the current health sector, including the following (Information and Documentation Centre 2012):

- There is a lack of evidence, as well as a deficiency in high-quality care and productivity.
- Chronic need for maternal and antenatal care services.
- There is an urgent need for mental health and psychological support services; as of February 2012, there were only 14 psychiatrists available to serve the entire population.
- The prevalence of HIV among drug-injecting users is 87% in the capital.
- Road traffic accidents (RTAs) are among the most significant public health issues in Libya.
- There is a lack of leadership and ambiguity in the MOH's policies.

Libya’s healthcare sector has long been plagued by inadequate funding, neglect, and a lack of development and modernisation initiatives (El Oakley et al. 2013). There is evidence that the Libyan healthcare sector is currently facing numerous challenges, including the increasingly common practices of personally paying for treatment in the private sector and/or travelling for treatment abroad (El-Fallah 2014). The widespread distrust of quality of care in Libya further triggered a multimillion-dollar medical tourism industry in neighbouring countries (Saleh et al. 2014). On July 23-27, 2018, the Libyan MOH in

collaboration with the WHO country office decided to enhance various aspects of the Libyan healthcare sector (WHO 2018).

1.7 Significance of the Study

This study will introduce a novel viewpoint on Libyan healthcare, providing a baseline understanding of knowledge on stakeholders' experiences with PSI-RLS in Libya. The insights gained will enhance PSI-RLS experiences and consequently, patient safety. By collaborating with key stakeholders and policymakers in the Libyan healthcare sector, the findings will guide future practices and inform policy-making decisions. This will ensure that the study's impact extends beyond theoretical understanding, fostering improvements in the Libyan healthcare sector.

The study aims to contribute to addressing the gap in knowledge on PSI-RLS in the Libyan healthcare sector. Existing literature on PSI-RLS experiences cannot be presumed to be completely or readily conveyable to other settings such as Libyan healthcare. Therefore, this study will highlight the differences and similarities in PSI-RLS experiences in Libyan healthcare context and those documented internationally. It also anticipates addressing the knowledge gap in PSI-RLS behaviours of healthcare providers both in Libya and globally. In addition, this comprehensive study will also pave the way for future research in Libya and other resource-constrained settings, with the goal of exploring PSI-RLS behaviours in the healthcare sector.

Finally, the hope is that reporting patient safety incidents becomes part of the culture, practices and policy framework of the Libyan healthcare sector. This research will enhance patient safety within Libya's healthcare sector by proposing policy recommendations and practical measures for the establishment a unified framework of PSI-RLS. This study is therefore crucial to explore the experiences of Libyan stakeholders regarding the PSI-RLS, to bolster patient safety in Libya.

1.8 Contribution to New Knowledge

According to the research aim and objectives, and in view of the study findings (chapters four, five, six and seven), the researcher argues that the study has theoretically and practically produced new knowledge. The recommendations developed can be implemented by the

MOH and the related stakeholders in Libya to hopefully address the issue of implementing and operating the PSI-RLS in the Libyan healthcare sector. The details of these contributions are discussed in chapters eight and nine.

1.9 Structure of the Thesis

The thesis is structured into Nine chapters. Each chapter has been outlined to give readers a clear and concise understanding of the content and the logical progression of the thesis. Below is a brief overview of what each chapter covers:

CHAPTER ONE – Introduction and Background

This chapter sets the stage by introducing the research topic. I discussed the significance of the study and provide an overview of the Libyan health sector. This chapter also outlines the contribution to knowledge in accordance with the aim of the study. Furthermore, it highlights the structure of the thesis and provides a brief description of each chapter.

CHAPTER TWO – Literature Review

A thorough review of the existing literature related to the research topic is presented in this chapter. I critically reviewed the relevant literature to highlight current discussions and perspectives on the importance of PSI-RLSs in the global healthcare sector. Furthermore, I identified the theoretical viewpoints within the literature and pinpointed gaps that need to be addressed to enhance the current understanding of the topic.

CHAPTER THREE – Methodology and Methods

This chapter provides a rich description of the research design and methodology. It begins by outlining the research questions, aim, and objectives. It also provides a rationale for the chosen methodology. The chapter also delves into the research paradigm and philosophical standpoint, explaining the sampling process, data collection methods, data analysis, ethical considerations, and research trustworthiness.

CHAPTER FOUR – Policy Analysis

This chapter primarily explores and reviews the context of Libyan healthcare policy. It provides a background on Libya's healthcare policies and the methods for analysing these

policies. It presents a theoretical perspective on patient safety and the concept of PSI-RLS in Libya, highlighting the process by which patients report medical harm. Additionally, it identifies the relevant stakeholders involved in reviewing medical harm at the macro level.

CHAPTER FIVE – Findings: Theme One

This chapter presents a general discussion of the thesis findings, including the first main theme that emerged from the data. It categorised the findings in the context of the research aim and objectives, highlighting significant patterns and trends. The emerging data from this theme were presented under three subthemes. Additionally, it provides details about the stakeholders involved in the PSI-RLS in Libyan healthcare.

CHAPTER SIX – Findings: Theme Two

This chapter presents the second main theme that emerged from the data. Similar to Chapter Five, this chapter also presented the emerging data under two subthemes.

CHAPTER SEVEN – Findings: Theme Three

The third and last theme is presented in this chapter. There were two subthemes categorised under the third theme.

CHAPTER EIGHT – Discussion

This chapter presents a comprehensive discussion of the main findings, comparing them with existing literature. It explores the implications of the results from both theoretical and practical perspectives and offers concluding thoughts. Additionally, this chapter explores the meaning of the emerged data through a philosophical lens, specifically from a structuralist perspective.

CHAPTER NINE – Conclusion

This chapter concludes the thesis by providing an overview of the study and highlighting the main findings. It also emphasises the contributions to knowledge and the implications for policy and practice. The researcher concludes this chapter with recommendations for the Libyan healthcare sector, a discussion of the limitations encountered, and suggestions for future research.

1.10 **Chapter Summary**

In this first chapter, the researcher provided an overview of the study. The chapter started by discussing the context of the research and offering a critical background on the importance of safety and patient safety in healthcare. It also introduced the concept of patient safety incident reporting and learning systems. The significance of the study is highlighted, explaining how it can contribute new knowledge to existing literature and offer actionable recommendations for long-term improvements in patient safety within the Libyan healthcare sector. The next chapter will delve deeper into the literature review, exploring the concept of PSI-RLSs on a global scale. This exploration is essential for setting the scene and guiding the reader in understanding the context within which this study was conducted.

2 CHAPTER TWO – Literature Review

2.0 Introduction

This chapter explores and reviews the relevant available evidence, aiming to identify gaps in the literature and the lack of understanding regarding the experiences of PSI-RLSs in the healthcare sector. It examines literature related to the experiences of PSI-RLSs, emphasising the importance of understanding these systems and the factors that influence them. The chapter aims to understand the theoretical perspectives and policies governing the act of reporting and learning from patient safety incidents, drawing on existing literature from around the world. To achieve this, a comprehensive search was conducted to gather evidence on the reporting and learning from patient safety incidents among healthcare providers globally, with a particular focus on the Libyan healthcare context or similar environments. In addition, this literature review aims to describe and explore all existing evidence on PSI-RLSs in healthcare worldwide. Consequently, it provides an overview of the studies conducted on PSI-RLSs to date, which helps to shape the research broadly while narrowing the focus to healthcare contexts akin to Libya. Furthermore, the literature review will assist in identifying appropriate methods to explore the experiences of PSI-RLSs within the Libyan healthcare context.

2.1 What is a Literature Review?

Fink (2019) neatly defines a literature review as a "systematic, explicit, and reproducible method for identifying, evaluating, and synthesising the existing body of completed and recorded work produced by researchers, scholars, and practitioners". Cowell (2012) underlined the significance of literature reviews as a means to evaluate the current state of scientific knowledge. Broome (2000) recommended reviewing the literature as a strategy to assist in the development of concepts. Graduate students in nursing and other sciences often learn about synthesizing literature through various guides throughout their academic studies (Cowell 2012).

2.2 Purpose of Undertaking a Literature Review

The purpose of conducting a healthcare literature review is to provide a summary of information on a specific topic or question (Smith and Noble 2016). It also helps to make recommendations that are beneficial to healthcare professionals and institutions in making decisions and policies about particular interventions or care issues (Smith and Noble 2016). In addition, Noble and Smith (2018) indicated that conducting a literature review is increasingly vital for health professionals in light of the vast amount of literature available. They also added that a literature review helps to identify knowledge gaps that can guide future studies and research priorities. Moreover, Cowell (2012) asserted that reviewing literature offers a chance for researchers to find knowledge gaps; and hence making it easier to link a study to previous studies, to illustrate how theoretically significant a study may be and to blend the developed theory with existing ones. Nevertheless, it has been argued that this usually creates a deficiency in cross-disciplinary comparisons (Crilly et al. 2010).

Bearfield & Eller (2007) suggested that a well-written review may provide the reader with a comprehensive understanding of the significance and scope of the research topic. McNabb (2017) emphasises the importance of conducting a literature review to focus a research study by narrowing its scope and addressing speculative questions to enhance conceptual clarity. However, Becker (1993) and Heath & Cowley (2004) argued that when reviewing literature, a researcher is likely to miss social or cultural facts or pertinent details, by concentrating fully on the matters that appear related with reference to the existing literature and hence leading to bias (Heath 2006). Furthermore, Heath (2006) argued that one pitfall in reviewing literature is its tendency to stifle innovation as some researchers may impose their own preconceived knowledge and documented frameworks on the inquiry. This situation can lead to existing hypotheses negatively influencing the data collection process (Becker 1993).

Reviews illustrate the fundamental propositions backing the research questions and enable early researchers to demonstrate their knowledgeability and familiarity with the intellectual traditions surrounding their proposed research work and to assure reviewers (Paré et al. 2015). Furthermore, the authors argued that the literature review not only offers the researcher a chance to find gaps in the existing literature but also and presents a logic for

the impact of the proposed study on the documented literature, while helping the researcher to clarify research questions and incorporate them into directing hypothesis that offer likely guidance for the researcher (Paré et al. 2015).

Hart (2018) emphasised the importance of a literature review in academic research. He suggested that it serves as a tool to explore and identify the existing academic literature in a specific field, thereby revealing any knowledge gaps. These gaps, once identified, can guide researchers towards new and promising directions for their studies. Furthermore, Hart argued that a well-conducted literature review not only enhances the scholarly integrity of a thesis by showcasing its originality but also paves the way for researchers to make novel contributions to their field of study. Thus, the literature review plays a crucial role in advancing academic knowledge (Hart 2018).

There are various types of reviews such as narrative reviews, scoping reviews, and systematic reviews with reporting strategies such as meta-analysis and meta-synthesis (Thomas et al. 2023). Review authors should consider the scope of the literature review when selecting a type and method (Thomas et al. 2023). As stated above, there are numerous styles of reviewing literature in qualitative studies, some of which will now be further discussed in light of the decision to undertake a scoping review for the current study.

Narrative reviews generally attempt to summarise prior knowledge without generalising the reviewed literature (Green et al. 2006), while systematic reviews use structured procedures in collecting secondary data, evaluating and critiquing research papers, and summarising qualitative or quantitative results to satisfy eligibility requirements and a well-formulated research question (Borenstein et al. 2021; Higgins & Green 2008). A scoping review aims to draw the existing literature on a specific subject or topic to point out significant theories, research gaps, and implications for policy and practice (Arksey & O'Malley 2005).

Furthermore, critical reviews are aimed at critically evaluating and analysing (interpretively) prior literature on a specific research area to bring out strengths, shortcomings, arguments and other concerns with reference to theories, postulations and results. Realist reviews seek to inform, amplify and broaden traditional systematic reviews by the inclusion of information from qualitative and quantitative research work of

composite interventions utilised in various settings to guide policy. Descriptive reviews anticipate identifying explicable patterns and literature gaps with reference to prior postulations or theories.

2.3 Literature Review Method

A scoping review was most suitable for this study because, unlike the other types of review that answer relatively definite set of questions, scoping reviews may be utilised to not only outline the main ideas buttressing a study topic, but also to refine accepted definitions, as well as margins surrounding concepts of a research area (Arksey & O'Malley 2005). Unlike descriptive and narrative reviews, the main idea of scoping a field is to be as extensive as possible (Arksey & O'Malley 2005). Scoping review aims to generate a synopsis of the existing literature without necessarily always providing a summary solution to a distinct research problem (Arksey & O'Malley 2005). Indeed, conducting a systematic review involves reviewing a large number of studies, but only a small percentage of these studies will be included in the final review. This means that findings and evidence from studies not included in the final report may remain unpublished (Arksey & O'Malley 2005). In contrast, a scoping review seeks to present an overview of all material reviewed, making it important to include a large body of material in scoping studies (Arksey & O'Malley 2005).

Furthermore, when a researcher is uncertain about which specific questions can be addressed and answered, a scoping review can assist in identifying the most promising lines of inquiry (Tricco et al. 2016). Scoping reviews are suitable for finding gaps in a specific literature, explaining definitions, and exploring characteristics of a concept (Munn et al. 2018). They are also beneficial for exploring developing new insights when there is an uncertainty of what other more precise questions could possibly be suitably answered (Anderson et al. 2008). The scoping review approach is typically valuable when what is known about a topic of interest is yet to be extensively reviewed or is diversified and complex (Peters et al. 2015). The goal of scoping literature reviews is answering exploratory research questions through a comprehensive search and integration of literature (Colquhoun et al. 2014). Scoping reviews may also be utilised in the development of "policy maps" through the detection and charting of findings from policy files to inform practice in a given context (Anderson et al. 2008). This review sought to identify voids in

the PSI-RLS literature, provide an overview of the topic, and define key concepts and terminology. Consequently, a scoping review was more suitable for this research.

2.3.1 Background and Significance

To Err Is Human report considered as the landmark for patient safety. In that context, patient safety stands out as a priority strategy in the healthcare sector and widely discussed all over the world. Many studies have shown that health care is often hazardous rather than beneficial to patients (De Korne et al. 2010). Due to the promising value of the PSI-RLSs in patient safety research and quality improvement, the researcher envisions that there will be a widespread implementation of such systems in healthcare. Thus, searching on this side of patient safety can add knowledge and bring improvements to patient safety. In this study, a scoping review design was chosen to map the evidence regarding PSI-RLSs which is considered as a part to improve patient safety.

2.3.2 Aim of the Scoping Review

This review aims to explore existing literature associated with the patient safety incidents reporting and learning systems in the healthcare sector and what are gaps exist in the available literature.

2.4 **Scoping Review Method**

To map and present the relevant evidence on the concept of the PSI-RLS, a scoping literature review method was used. A scoping review, as defined by Arksey & O'Malley (2005), aims to map the existing evidence base or literature in a specific area. Colquhoun et al. (2014) stated that this type of review is designed to answer exploratory research questions by systematically searching the literature. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was introduced to ensure the rigour, replicability and generalisability of findings of scoping reviews (Tricco et al. 2018). Adherence to the PRISMA checklist and the six-stage framework of Arksey and O'Malley (2005) was maintained to enhance the quality of this review. Table 2-1 below outlines the six-stage framework of Arksey and O'Malley.

Table 2-1 Scoping Review Stages

Stages	**Description**
1. Identifying the study question	What is the existing evidence regarding patient safety incident reporting and learning systems in healthcare sector and what gaps exist in the available literature?
2. Identifying relevant studies	Searching within MEDLINE, EMBASE, CINAHL, Web of Science and Global Health; pre-specified keywords; English language.
3. Study selection	Step 1: Title screening. Step 2: Title and abstract screening. Step 3: A full-text review.
4. Charting data	Step 1: Designing data extraction form. Step 2: Data collection. Step 3: Charting data. Step 4: Coding the themes
5. Collating, summarizing and reporting results	Step 1: Discussing Data. Step 2: Announcing the results.
6. Consultation	Involvement of reviewers

2.4.1 Framework Stage 1. Identifying the Research Question

This study aimed to explore the experiences of Libyan stakeholders in PSI-RLS. Therefore, this literature review aims to explore the relevant literature for reporting and learning from patient safety incidents within the healthcare sector globally and in Libya. Initially, the review sought to answer the question "What is the existing evidence regarding patient safety incidents reporting and learning systems in Libyan healthcare sector and what gaps exist in the available literature?". However, there was a need to extend this to cover PSI-RLSs among other healthcare sectors within the Eastern Mediterranean Region (EMRO), as an earlier literature scope showed no Libyan literature on the topic. There was a further

broadening of the scope to cover PSI-RLSs in other areas outside the EMRO region due to low number of studies in the EMRO healthcare literature. Because of the scarcity of research work and in line with the principles of conducting a scoping review, all worldwide research work on PSI-RLSs was included in the review regardless of the quality of the research.

The EMRO region was chosen because Libya is part of it and shares a similar culture. According to the WHO (2014), the EMRO region has a common historical background, cultural compatibility and geographic continuity. Additionally, the EMRO demonstrates a high degree of diversity in the macroeconomic and developmental profiles of its countries, which invariably impacts the performance of healthcare sectors and the overall health status of the population (WHO 2014).

The study question was set to cover the worldwide literature about the concept of PSI-RLSs in the healthcare sector. However, the focus will be on studies from the EMRO region due to its cultural and historical similarities with Libya.

The research question is elaborated based on the PCC strategy (P - Population; C - Concept; C - Context). The definition is P: Healthcare providers; C – patient safety incidents reporting and learning systems; C – healthcare sectors.

2.4.2 Framework Stage 2. Identifying Relevant Studies

The search for relevant studies was carried out on five selected databases (MEDLINE, EMBASE, CINAHL, Web of Science, and Global Health) regarding the PSI-RLSs in the healthcare sector all around the world, and grey literature was excluded from this review. Furthermore, pre-specified keywords and search terms were used for searching in the selected databases, as shown in Table 2.2 below.

Table 2-2 Keywords and Search Terms for Database Searches

Summary of the keywords/ Search terms	
Sets	**Keyword/ search terms**
#1 Patient Safety Incidents	"Patient Safety" **OR** "Safety Climate" **OR** "Safe Care" **OR** "Clinical Safety"
AND	
#2 Reporting and Learning System.	"Reporting Errors" **OR** "Reporting system" **OR** "Reporting and Learning System"
AND	
#3 Healthcare setting and participants	Hospital* **OR** Clinic* **OR** "Healthcare sites" **OR** "Medical centre" **OR** "Medical sites"

The search was conducted in each database using the keywords and terms as shown in Table 2.2 above. Boolean operators were used during this search. The keywords or terms were combined using the Boolean OR and the Boolean AND across the five databases. The literature search yielded a total of 2294 papers related to PSI-RLSs in the global healthcare sector. Table 2.3 below presents the total number of papers found in the five selected databases.

Table 2-3 Total Number of Papers in Each Database

Databases	**Sets #1 AND #2 AND #3**
MEDLINE	526
EMBASE	893
CINAHL	332

Web of Science	515
Global Health	28
Total:	**2294**

A total of 175 papers published in languages other than English were removed. Additionally, 973 duplicate papers were excluded from the remaining papers on PSI-RLSs in the global healthcare sector. This left a final count of 1,146 papers related to PSI-RLSs in the healthcare sector worldwide, which advanced to stage three of this review.

2.4.3 Framework Stage 3. Selecting Studies

From a practical point of view, a limiting criterion was adopted regarding the coverage of the review in terms of language. By considering the time and budget constraints, a decision has been made to include only studies published in the English language. Non-English publications were excluded because of the cost and time involved in translating these publications. It is worth pointing out that some relevant papers could have been missed; however, these criteria were adopted to keep this review at a realistic and manageable level regarding the available time for conducting this review. The following are the inclusion and exclusion criteria of the scoping review.

Inclusion Criteria:

- English-language full-text publications.
- All studies that discuss PSI-RLS.
- Any study discussing PSI-RLS in the healthcare sector.

Exclusion Criteria:

- Non-English studies.
- Not set in the healthcare sector.
- Studies that involved medical education institutions.
- Studies that involved medical institution students as participants.

Step one of stage three involved title screening (see Table 2.1 above). Based on the titles, 980 papers from around the world were rejected as they did not meet the inclusion and exclusion criteria related to PSI-RLSs in the healthcare sector. Step two of stage three was the title and abstract screening. During this step, 49 papers were removed because they did not discuss PSI-RLSs in the healthcare sector. The left papers were passed to the last step of stage three which is a full-text review.

A total of 117 papers on PSI-RLSs in the healthcare sector worldwide were selected for review. A table was created to display the main characteristics of these papers, including title, first author/year of publication, country, and study background. The table also included decisions of "yes," "no," or "maybe," and was reviewed by two reviewers. The process of sifting and selecting studies began with the titles and abstracts of all papers being independently reviewed by the researcher and supervisors. Based on relevance to the study's objectives and inclusion/exclusion criteria, papers were categorised as "yes," "no," or "maybe". Papers in the "maybe" category or those resulting in disagreement between the reviewers were re-evaluated by the researcher using the eligibility criteria as a guide to make the final decision. Following a final review of the 117 studies, 46 papers were removed, and 71 papers that underwent a full-text review were included in this scoping review. The full texts of all "yes" selected papers were obtained and read in order to confirm whether they properly related to the research questions (Roncarolo et al. 2017). This decision was based on Badger et al.'s (2000) assertion that it cannot be assumed that abstracts are representative of the entire article or that they show the entire scope of the article. Therefore, following Arksey & O'Malley's (2005) scoping review methodology, the final studies selected were based on their ability to answer the review questions rather than solely on the study's quality. The literature search in the selected databases was conducted twice. The first search took place in 2020, and the final count of included papers was confirmed on March 24, 2020. The second search was carried out after conducting interviews in 2022 and yielded studies conducted outside the Libyan healthcare context. These studies had no impact on the theoretical view of the Libyan healthcare context. As a result, the final count of included papers from the first search was confirmed.

2.4.4 Framework Stage 4. Charting the data

This step aims to synthesize and interpret the studies' content, sorting key themes and issues and adopting a narrative synthesis approach that can be useful for appraising contributions qualitatively. Therefore, the included studies were classified into thematic categories according to their context, objectives and the focus of the study as well as the key findings. Then a table was formatted to show the characterisation of publications. Hence the following were collated on a chart according to the details below:

- Title of studies
- The surname name (s) of the first author (s)
- Publication year
- Country of origin
- Type of Study/ Methodology
- Area of study /key findings

Peters et al. (2015) argue that charting the results of a literature search is considered best practice, as it enhances transparency in the review process. The included studies are listed in a table in descending order by date of publication (see Appendix 1). Additionally, Figure 2-1 below presents a PRISMA flowchart summarising the process of the scoping review.

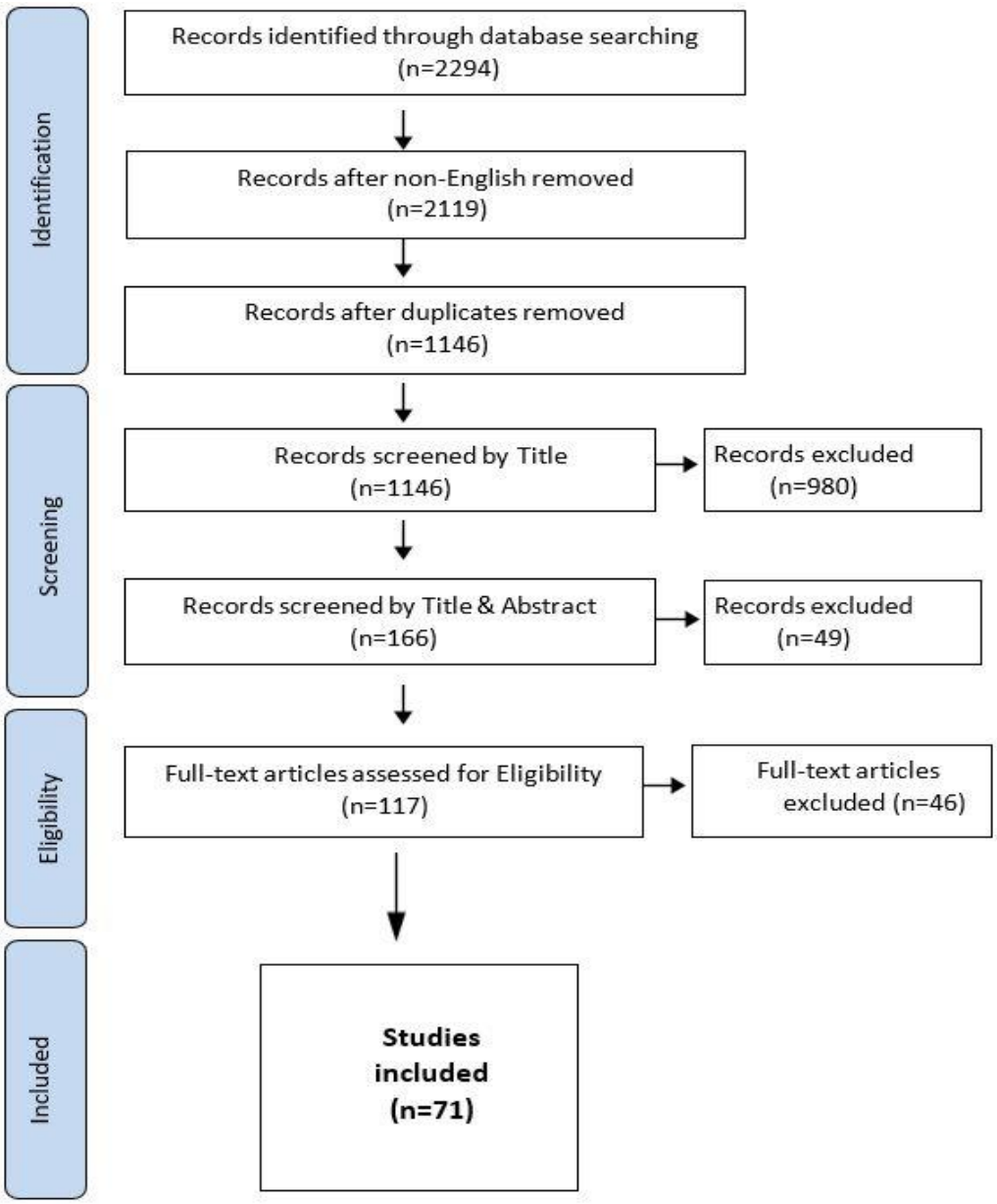

Figure 2-1 PRISMA Flowchart Summarising the Process of the Scoping Review

2.4.5 Framework Stage 5. Collating, Summarising and Reporting the Results

In a scoping review, after concluding on the final selection of documents, it is essential to proceed to analysing and summarising the findings. According to Armstrong et al. (2011), scoping review studies need thematic construction or analytic framework to present a narrative account of existing literature. Levac et al. (2010) recommend the use of qualitative thematic analysis or descriptive statistics based on the nature of the collated data. This review used a basic thematic framework to analyse the results. Common themes were

grouped together, and similarities between them were evaluated. Unlike a systematic review, the scoping study does not aim to assess the quality of evidence or present a view regarding the 'weight' of evidence. Therefore, a scoping review cannot determine if particular studies provide robust or generalisable findings (Arksey & O'Malley 2005; Munn et al. 2018). The results of the included studies have been summarised and discussed in the discussion section.

2.4.6 Framework Stage 6: Consultation

As recommended by Levac et al. (2010), the supervisory team examined the performance of the review to determine the accuracy of the results. The following section illustrates the results of the scoping review.

2.5 Scoping Review Results

Based on the inclusion and exclusion criteria in this review, 71 studies were identified. Out of these, no studies were conducted in Libya, 16 studies were conducted in the United States, 15 studies were conducted in the United Kingdom, and 14 studies were conducted in the EMRO region. The remaining 26 studies were conducted in various other countries or regions. The PSI-RLSs had significant international attention, and various methods were used to explore and examine these systems in the healthcare sectors. The patterns of included studies were summarised. Regarding the study designs of the included research papers, 43 studies employed a quantitative approach, while 17 studies used a qualitative approach. A mixed methods design was used in five papers, and there were six systematic reviews. The majority of studies have been conducted at the micro level, with fewer studies at the meso level. In contrast, macro-level studies have received less attention from researchers. Many studies failed to define patient safety incidents, errors, and complications. Additionally, there was significant variation in how these terms were used and defined across different studies.

The studies included in the review focused on two main themes (see Figure 2-2 below). The first theme is "Factors affecting the PSI-RLSs" with two subthemes and the second theme is "Characteristics of Patient Safety Incident Reporting and Learning Systems". Additionally, the reviewed papers indicate that the implementation and operation of PSI-RLS are influenced by contextual factors unique to each country. Therefore, the included

studies under each theme are narratively presented according to their region as classified by the WHO. There are six regions which are the EMRO region, South-East Asia Region (SEARO), European Region (EURO), Region of the Americas (AMRO), Western Pacific Region (WPRO) and African Region (AFRO).

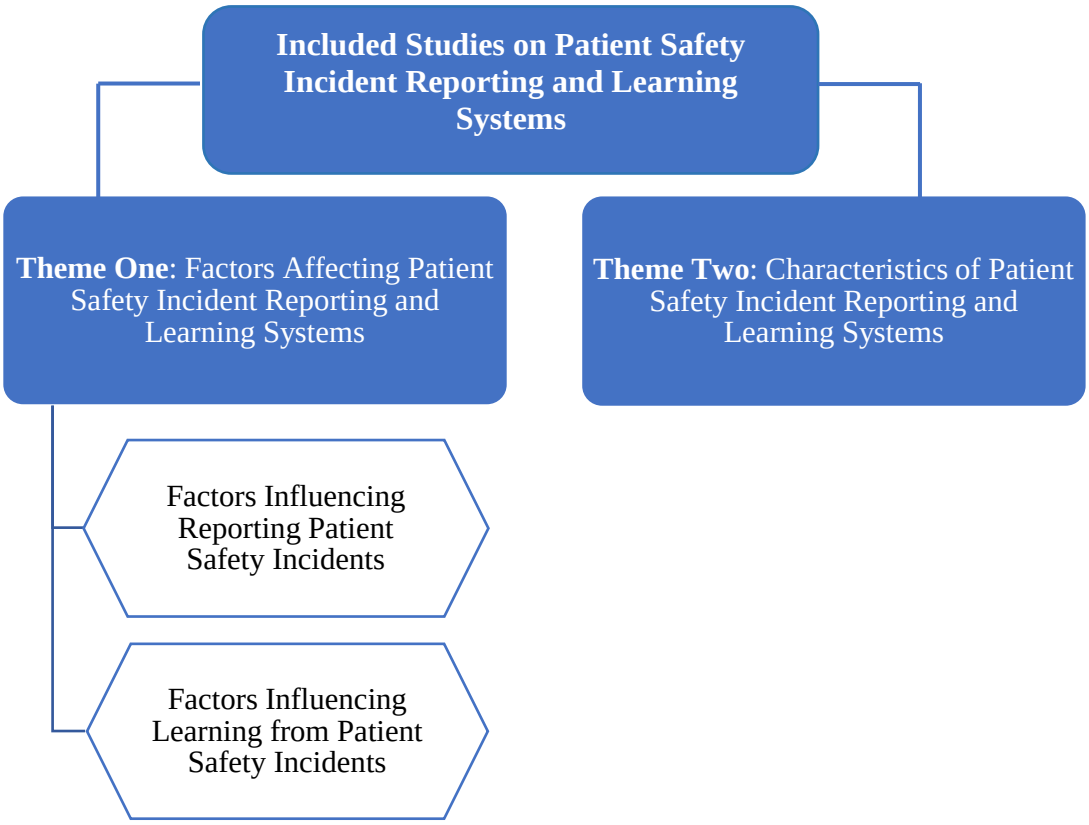

Figure 2-2 Summary of Themes and Subthemes from Scoping Review Studies

2.5.1 Theme One: Factors Affecting Patient Safety Incident Reporting and Learning Systems

There was a predominance of studies on theme one, with 39 out of the 71 included studies from around the world examining the factors influencing the reporting and learning from patient safety incidents. This theme focuses on understanding the perceptions, attitudes, and experiences of professionals regarding PSI-RLSs and is categorised into two subthemes. The first subtheme, "factors influencing reporting patient safety incidents," covers 33 studies, while the second subtheme, "factors influencing learning from patient safety incidents," includes 6 studies. The first subtheme will be presented first.

2.5.1.1 Factors Influencing Reporting Patient Safety Incidents

There were 33 studies in this subtheme that focused on identifying factors that can either hinder or facilitate reporting patient safety incidents. Medication error reporting systems have been extensively studied, with 17 out of the 33 studies focusing on this topic, including a systematic review by Vrbnjak et al. (2016) and a systematic review protocol by Al Qubaisi et al. (2014). . The remaining 16 out of 33 studies examined medical errors or incidents systems in healthcare sectors worldwide. The main areas of research were related to human factors such as the beliefs, attitudes, and experiences of health professionals in reporting medication errors. Carayon (2006) stated that human factors play a critical role in evaluating the interaction between people, systems, and the environment, which in turn influences healthcare delivery processes. Arabi et al. (2016) argue that the focus in healthcare has often been on developing incident reporting systems and monitoring the reporting rate. As a result, only a few organisations have focused on structuring a comprehensive review and on an investigation process designed to improve learning from incidents (Arabi et al. 2016). In addition, factors that influencing reporting patient safety incidents are influenced by the context of each healthcare sector. Hewitt et al. (2017) argue that increased attention to group norms and local contexts would enhance patient safety initiatives, such as incident reporting systems. However, some studies have highlighted the fear of punishments and legal ramifications as barriers to reporting patient safety incidents. The following are the barriers and enablers of reporting patient safety incidents by regions and based on the contextual factors of each healthcare sector.

In the EMRO region, 11 studies were conducted, with six in Iran, and one each in Egypt, Saudi Arabia, Jordan, Kuwait and Lebanon. Healthcare staff believe that near misses are not considered reportable incidents (AbuAlRub et al. 2015; Bayazidi et al. 2012). Fear of legal prosecution was a barrier for reporting patient safety incidents (Mahdaviazad et al. 2020; Jahromi et al. 2014; Labib et al. 2019). In addition, some countries are lack of such a system. The main reasons mentioned for underreporting were lack of an effective medical error reporting system, lack of personal attention to the importance of medical errors and lack of peer supporting a person who has committed an error (Poorolajal et al. 2015; Labib et al. 2019). For example, Labib et al. (2019) conducted in-depth interviews with 16 healthcare personnel in the Paediatric Intensive Care Unit (PICU) of a hospital in Egypt.

They found that there was no established Incident Reporting System (IRS) in the PICU, and most personnel never reported any event unless it was a sentinel event. The authors also argue that the study has prominent strengths. This is the first study to evaluate the effect of an intervention to create a voluntary anonymous IRS in PICUs in a teaching hospital in Cairo. In addition, they suggested that barriers related to the healthcare professional-organisational context need to be addressed. One of the most important factors to help enhance incident and error reporting is to overcome the fear of punishment among the personnel.

In Lebanon, Akel et al. (2019) stated that medication safety reporting by pharmacists is lacking due to the absence of an official reporting system. However, the Order of Pharmacists of Lebanon has since implemented such a system. To ensure its success, the project will need to be consolidated by raising awareness and changing perceptions among the general population and some health professionals to overcome the problem of underreporting.

A study in Saudi Arabia by Abuelsoud (2018) provided a strategy that can facilitate catching and correcting medication errors. The study aimed to outline the role of the medication safety officer in reporting medication errors across various medical specialities. To report any medication errors, the medication safety officer utilised a medication error report form based on the form from the MOH in Saudi Arabia. The study concluded that medication safety officers play a crucial role in detecting medication errors in different specialities. The recommendations provided by the medication safety officers were successful in rectifying and preventing many medication errors.

Alsaleh et al. (2017) In a cross-sectional study, a paper-based 25-item questionnaire was used to survey physicians working in seven government hospitals and twelve private hospitals across Kuwait. The study aimed to identify the perceived barriers in both sectors to establishing an adverse drug reaction (ADR) reporting system. Some of these barriers included a lack of training and education, communication gaps between private and government sectors, and the absence of a governing legislation and reporting system by the MOH. The study also revealed that the majority of physicians unanimously agreed on the necessity of reporting ADRs, viewing it as a professional obligation that would enhance

the quality of healthcare. However, most physicians were unaware of the existence of an ADR reporting system and did not know where to report ADRs in Kuwait. Despite their positive attitude, a significant number of physicians in the study never reported ADRs.

The results of a cross-sectional study by Mahdaviazad et al. (2020) conducted on healthcare professionals in the largest referral orthopaedic centre in southern Iran found that underreporting patient safety incidents was common, especially among physicians. Both physicians and nurses had poor knowledge about reporting patient safety incidents. The most significant perceived barriers were fear of blame, punishment and legal ramifications.

A study conducted in Iran by Jahromi et al. (2014) aimed to determine several factors associated with not reporting medical errors from the medical team's point of view. Data was collected using a questionnaire that included prevalent factors for not reporting and recording professional errors. Four hundred questionnaires were distributed, and three hundred were gathered. Reasons for not reporting professional errors were related to four factors: managers, errors, medical teams, and patients. Factors related to managers and errors were the most significant reasons for not reporting professional errors. Among the factors related to managers, the highest scores were given to their focus on wrongdoers rather than the results of errors, discrimination toward wrongdoers, and improper reactions. Regarding the factors related to errors, the severity and importance of medical errors, types of errors such as procedural errors, poor performance, delayed care, and the medical team not having a clear definition of errors had the highest scores. Among the factors related to medical teams, fear of legal prosecution, concerns over inadequacy, fear of losing one's position, and worry about significant errors from colleagues were the most important reasons for not reporting medical errors. Among the factors related to patients, uncertainty about errors, the patient's critical condition, and the prognostication of death were the most important reasons for not reporting and recording professional errors.

In 2015, AbuAlRub et al. conducted a study in Jordan to explore the awareness of the incident reporting system, incident reporting practices, and barriers to reporting incidents among Jordanian staff nurses and physicians. The study revealed that nurses were more informed about the incident reporting system compared to physicians. It was also found that physicians were less inclined to report incidents on 50% or more of occasions. The

major three barriers to reporting incidents were believing that there was no point in reporting near misses, lack of feedback and fear of disciplinary actions.

Bayazidi et al. (2012) conducted a quantitative and descriptive study in Iran. The study included 733 nurses working in Urmia teaching hospitals, and data were collected using a questionnaire. The study found that the rate of reporting medication errors among nurses was far less than the medication errors they had made. Most nurses made minor medication errors without harming patients rather than major errors resulting in patient harm. The nurses whose medication errors had not harmed the patients had reported less than a quarter of their errors. However, participants with major medication errors causing patient harm had reported less than half of their errors. Nurses perceived the most important barriers to medication error reporting as blaming individuals instead of the system, fear of consequences of reporting and fear of being blamed or punished for reporting errors that caused harm. They also identified no need to report if no harm to the patient and the belief that medication errors were unimportant. Additionally, the time-consuming nature of completing error reports was mentioned as a barrier. The study participants also highlighted the factors that facilitate reporting medication errors. These factors include having an anonymous reporting system, harm to the patient or patient vulnerability, perceived benefits of reporting, good professional relationships with nurse managers and physicians and eliminating the fearful atmosphere in the organisation to ensure a safe working environment.

Another study conducted in Iran by Nazmieh et al. (2018) aimed to determine the effect of senior managers' compliance in reporting nurses' treatment errors in the paediatric ward of Shahid Sadoughi Hospital in Iran. This interventional study included all nurses working in paediatric wards. The intervention was defined as various safety management drivers and the encouragement of staff to report errors without any fears or concerns from senior managers. The error reports were recorded and compared before and after the intervention. A voluntary, non-anonymous, and non-confidential reporting form was used to report incidents. This form comprised three parts: the first part gathered information about the patient's profile (family name, ward, hospitalisation date, age, and date of the error); the second part was allocated to the personnel information (shift, position, and error-induced

damage); and the third part pertained to the error type, causes of the error occurrence, and description of the error. Data analysis indicated a significant increase in error reporting following the intervention. In addition, the authors added that the most important step in reducing errors is to eliminate the obstacles to reporting errors by creating a situation in which each nursing staff member can honestly report their errors. Therefore, regarding the significant difference before and after the intervention, it is recommended that senior managers consider reporting medical errors as their priority.

In the EURO region, there were three studies conducted in the United Kingdom regarding professionals' beliefs, attitudes, and experiences of medication error reporting: a qualitative study by Williams (2013), a quantitative study by Williams (2015), and a systematic review protocol by Al Qubaisi (2014). The aim of the study, conducted by Williams et al. (2013), was to understand the attitudes of hospital pharmacists towards reporting medication errors. The study involved conducting focus groups with a total of 17 hospital pharmacists. The results indicated that while the hospital pharmacists recognised the importance of reporting medication incidents, they found the decision to report to be a barrier and a complex process, often depending on the severity of patient harm. Most hospital pharmacists expressed concerns about the implications of reporting medication errors on their working relationships with doctors and nurses. The reporting forms were considered to be too burdensome and time-consuming to fill out, plus there was a lack of positive feedback or system changes following an error. In addition, another two studies were conducted in the United Kingdom at hospitals, using surveys to assess staff awareness, knowledge, and attitudes towards incident reporting (Nicholas et al. 2015; Kreckler et al. 2009). Kreckler et al. (2009) surveyed 55 doctors and 82 nurses about incident reporting in a surgical setting. Nurses were more familiar with the local reporting system and more likely to have recently filed a report than doctors. Staff were most likely to report incidents when harm occurred. Doctors were less likely to report surgical complications compared to other incidents. Fear was a less significant barrier to reporting than other reasons.

In the AMRO region, there were Five studies from the United States and One study from Canada. Hewitt et al. (2017) conducted a qualitative case study in Canada, involving confidential in-depth interviews with physicians and nurses. The study objectives were to

investigate frames of physicians and nurses who report into a voluntary incident reporting system as well as to understand enablers and inhibitors of self-reporting and peer reporting. The study identified the enabling and inhibiting frames of self-reporting and peer reporting. The researchers found that frontline healthcare practitioners use three main frames to enable self-reporting: professional accountability, trust in the system and learning from errors. Additionally, three main frames were identified that promote peer reporting: severity of incident or repeated errors by a healthcare professional, learning from errors and anonymity. On the other hand, the study revealed that fear of blame, incompetence and career progression are three main barriers to self-reporting among frontline healthcare practitioners. Besides, the three main frames that inhibit peer reporting, include the fear of being labelled a tattletale, locus of responsibility, and professional boundaries. The study concluded that reporting behaviours are underpinned by frames that are derived from individual and sociocultural experiences of frontline workers. It is also recommended that healthcare sectors and hospitals consider the various factors that enable or inhibit self-reporting and peer reporting among different professional groups when aiming to improve the quality of information derived from incident reporting systems.

In a study in the United States by Jeffe et al. (2004) employed a focus group methodology to gain insights into workers' perspectives on key concepts and issues related to medical error reporting in hospitals. Nine focus groups—comprising four groups of 49 staff nurses, two groups of 10 nurse managers, and three groups of 30 physicians—were conducted across 20 academic and community hospitals from May to June 2002. A qualitative analysis of the focus group transcripts revealed the participants' perspectives. While participants understood the necessity of reporting errors associated with serious adverse events, there was considerable uncertainty regarding the reporting of less serious errors or near misses. Determining what should be reported emerged as a significant challenge for both physicians and nurses. Notably, nurses demonstrated a greater understanding than physicians regarding the reporting process. All groups identified barriers to reporting, including fear of reprisals, lack of confidentiality, insufficient time, inadequate reporting systems, and the absence of feedback following an error report. Some physicians expressed scepticism about the benefits of reporting errors. Fear of repercussions, whether disciplinary or legal, was cited as a barrier to reporting in all focus groups. The nurse

managers and staff nurses cited “fear of repercussions from the doctor” and “getting in trouble or being reprimanded”. Nurses also pointed out that filing an incident report could automatically be included in their personnel file and might be referenced during performance evaluations. Physicians shared concerns that reporting errors could tarnish their own or a colleague's professional record. The study concluded with several recommendations for enhancing the reporting process, including the implementation of anonymous, straightforward, and expedited reporting procedures, as well as the provision of critical feedback regarding reported errors. Another study in the United States by Mekhjian et al. (2004), mentioned several barriers that hinder reporting, such as the lack of anonymity, time requirements, fear of lawsuits, and the perception that the organisation does not effectively utilise the reports. It was noted that fear of malpractice claims is especially prominent among physicians. In addition, the focus on the design of voluntary and anonymous reports.

Two studies from the AFRO region found that setting up PSI-RLS is influenced by contextual factors such as lack of facilities and far form legal consequences. The study number titled “Barriers to the success of an electronic pharmacovigilance reporting system in Kenya: an evaluation three years post implementation” issued in (2018) by Agoro, stated that there was a decline in the rate of reporting the events in Kenya due to unavailable and unreliable internet in hospitals, when the reporting system shifted from paper form to online form. The results of the study declared that the reason for the failure of many e-health interventions in developing countries is the fact that many are based on research performed in different contexts, usually in the developed world, where the sociocultural and organisational influences are different.

Mauti and Githae (2019) conducted a cross-sectional, descriptive study using quantitative methods in two hospitals in Uganda. The study aimed to identify the factors influencing error reporting among physicians and nurses in Uganda. The findings revealed that almost half of the participants believed that reporting a medical error is a medical obligation. Surprisingly, neither of the hospitals had a medical error reporting system in place. More than two-thirds of the participants stated that they would not report medical errors. The majority of the participants believed that the law does not protect the practice of medical

error reporting. The study proposed that not punishing health workers who report medical errors and providing training on error reporting are crucial steps to enhance medical error reporting among nurses and physicians in Uganda.

There were five studies conducted in the SEARO region, with three in India and two in Indonesia. The three Indian studies are related to the reporting of medication errors, while the two Indonesian studies are related to incident reporting systems. Additionally, there are no studies in the WPRO region regarding the factors influencing the reporting and learning from patient safety incidents. After examining research papers on the factors associated with reporting patient safety incidents, the second subtheme will delve into the factors that influence learning from patient safety incidents, as illustrated below.

2.5.1.2 Factors Influencing Learning from Patient Safety Incidents

This subtheme consists of 6 of the 39 studies included under theme one. Studies classified under this subtheme highlight factors that can hinder or facilitate feedback and/or learning from patient safety incidents. Feedback is crucial in a reporting system and is widely recognised in the literature as an integral part of learning from patient safety incidents. Williams et al. (2020) mentioned that while many studies have recognised the lack of feedback as a perceived barrier to reporting safety incidents, few have outlined successful strategies to overcome this barrier. Sharing information is emphasised as a means to promote transparency and a sense of responsibility towards redesigned processes and patient safety initiatives within healthcare (Arabi et al., 2016). No studies from the EMRO, AFRO, SEARO, and WPRO regions were conducted to focus on factors affecting feedback and learning from patient safety incidents.

In the EURO region, three studies were conducted in the United Kingdom about the feedback and learning from patient safety incidents (Allen et al. 2018; Wallace et al. 2009; D'lima et al. 2016) and a systematic review by Serou et al. (2018).

A study conducted by Wallace et al. (2009) in the NHS trusts in England and Wales in 2006 discusses the practical implications and findings from a multi-method study of feedback from patient safety incident reporting systems. The study introduces a framework encompassing five general modes of feedback for safety incident reporting systems. These

feedback modes include both action and information outputs aimed at improving patient safety:

- Mode A feedback: immediate feedback to the reporter or others in the affected service.

- Mode B feedback: rapid response actions within local work systems to address immediate and serious threats to safety.

- Mode C feedback: providing risk awareness information to all frontline personnel.

- Mode D feedback: informing staff of actions taken, including information to reporters and the wider reporting community.

- Mode E feedback: involving systems improvement actions, such as developing and implementing specific action plans for improvements to work systems.

Additionally, the study highlights 15 system requirements essential for effective safety feedback. The five modes of feedback and the 15 system requirements are recommended for helping the NHS develop more effective feedback from incident reporting systems.

D'lima et al. (2016) conducted another study in the United Kingdom on learning from patient safety incidents. They argue that sharing data from incident reporting systems does not always result in improvements in systems and professional practice. This study aimed to investigate the perceptions and experiences of healthcare professionals using organisational-level feedback from incident reporting systems. A survey was circulated to registered users of the National Reporting and Learning System (NRLS), and 17 interviews with international safety science experts were also conducted. The interviews revealed various perceptions and experiences of effective feedback from incident reporting. Overall, eight concepts for effective feedback emerged from the qualitative dataset. These included visible sponsorship from executive staff, maintaining anonymity while promoting learning, rewarding reporters, supporting resource prioritisation for improvement, involving frontline staff in the safety improvement process, tailoring information for specific audience(s), providing information at various points in the alerting and response process, and facilitating ongoing communication with relevant stakeholders. The researchers

concluded that the current organisational-level feedback from incident reporting systems generally meets benchmarking needs and allows healthcare providers to monitor data quality. However, this is more likely to influence safety culture rather than effectively support improvements in systems and professional practice.

Two studies conducted in the AMRO, specifically in the United States. The two studies were conducted at the micro level about factors that help to learn from patient safety incidents (Okafor et al. 2016; Williams et al. 2020). Williams et al. (2020) claim that the absence of a closed-loop feedback system for frontline staff is seen as a major factor leading to underreporting of safety incidents. To address this, the feedback-to-reporter program was established with the goal of increasing the rate at which feedback is provided on safety reports to those who request it. The program covers five modes of feedback: (1) bouncing back information to the reporter, (2) rapid response for immediate threats or serious issues, (3) raising risk awareness among all frontline personnel, (4) informing staff of actions taken and (5) improving work systems safety. The authors claimed a successful increase in feedback to reporter rates from 2013 to 2018. However, it was noted that a multidimensional approach is necessary to further enhance the feedback rates, which includes regular alerts to managers, increased accountability, leadership, project management support, and positive reinforcement through recognition programs.

2.5.2 Theme Two: Characteristics of Patient Safety Incident Reporting and Learning Systems

Theme Two comprises 32 studies, with 13 conducted in the EURO region, 11 in the AMRO region (9 in the United States and 2 in Canada), 5 in the WPRO region and 3 in the EMRO region. The theme focuses on the characteristics of the PSI-RLSs, including their structure, design features, construction, anonymity, data consistency, and whether the reporting of patient safety incidents is voluntary or mandatory. Most studies in theme two concentrate on system design rather than the participation of healthcare staff and their perceptions and experiences of the PSI-RLS.

Studies under this theme were conducted in several countries, including the United States, the United Kingdom, Austria, Germany, Japan, Taiwan, and China. Some studies aimed to describe the experience of implementing an incident reporting and learning system for patient safety, with a focus on their design such as (Schubert et al. 2018; Gao et al. 2019;

Beattie et al. 2018; Chalasani et al. 2018; Cao and Ball 2017; Reed et al. 2014; Kantelhardt et al. 2011).

Many studies in the reviewed literature were interventions that addressed the characteristics of the PSI-RLSs. For example, Gong et al. (2017) stated that large amounts of low-quality data generated by poorly designed systems significantly hampered the system's effectiveness. Therefore, developing an effective PSI-RLS requires multidisciplinary knowledge such as medicine, human factors, and cognitive sciences. However, the issue of mandatory versus voluntary reporting was noted as it has been a subject of much debate in theme two. Flink et al. (2005) pointed out that the issue of whether adverse events and medical errors should be reported mandatorily or voluntarily is a matter of discussion in Congress and the medical community in the United States. Both the House and the Senate have bills to establish a national voluntary reporting system. Many argue that a voluntary system is the best approach for encouraging reporting in a nonpunitive environment (Flink et al. 2005).

There were three studies from the EMRO region under the second theme. Two studies were from Egypt and one was from Saudi Arabia. They described the characteristics of their PSI-RLS and identified some facilities that can enhance feedback and learning from patient safety incidents (ELMeneza and AbuShady 2020; Shehata et al. 2016; Arabi et al. 2016). ELMeneza and AbuShady (2020) describe the establishment of the Egyptian Neonatal Safety Training Network (ENSTN) as the first database to collect incidents in Neonatal Intensive Care Units (NICU) in Egypt. The system is voluntary, confidential, anonymous, nonpunitive, and independent. It also provides expert analysis, timely feedback, systems-oriented, responsive and alerts regarding recurrent errors reported to the database. Anonymity was ensured by not collecting any information about the individual reporting the error, the patient, or the people involved in the event. This anonymity overcomes the reporting barrier of fear of being stigmatized or punished by superiors. The report answers what, why, and how errors happened, as well as if actions were implemented to minimize the impact of the events. Reported incidents between November 2014 and June 2018 were analysed. After validation and verification of the reported incidents, the total was 2,724 incidents. The study concluded that the ENSTN incident reporting system has succeeded

in demonstrating the most common types and causes of medical errors in NICUs and underlying contributing factors. These findings warrant multidisciplinary collaborative training. Systemic and personal approaches are needed to improve patient safety in NICUs.

According to Shehata et al. (2016), this study is the first pioneer study that describes the medication error problem on the national level in Egypt. This study analyses reports from the Egyptian medication error reporting system. The national medication reporting system in Egypt is called the National Office for Handling and Reduction of Medication Errors (NO HARMe). The characteristics of the NO HARMe system are voluntary and nonpunitive. Reports to the system are used only for learning, not for punishing individuals or organisations. Another important feature of NO HARMe is the optional anonymity and confidentiality it offers. The user can either identify himself or report to the system anonymously. In all cases, the reporter's personal information is kept confidential, in any reports or publications. A non-random sample of 50 junior clinical pharmacists from seven different hospitals was selected, and the pharmacists were trained on the process of reporting of any medication errors that arose during their work, including near misses. All the reports received by the system were automatically gathered into a spreadsheet. Reports from June to December 2014 were analysed. Data were quantitatively analysed and results were expressed as frequencies and percentages. During the 6-month study period, 1200 reports were validated and included in this analysis. There were 42 identifiable reporters, all of whom were pharmacists working in governmental and university hospitals, and only 25 reports were submitted anonymously. The top reported medication errors types were incorrect dose, incorrect frequency, incorrect drug and drug interactions.

A study conducted in Saudi Arabia by Arabi et al. (2016) focused on the learning and feedback stage in the PSI-RLS. The authors highlight that the absence of feedback has been identified as a significant obstacle to incident reporting among doctors and nurses. The purpose of this study was to present a model for implementing a comprehensive management system for incident reports in the intensive care unit (ICU). To achieve this, a committee comprising of physicians and other healthcare professionals was established to review, analyse, and address the department's incident reports. The involvement of a diverse team of healthcare professionals, led by physicians, led to a significant

enhancement of the incident reporting system's effectiveness. The study suggests four crucial elements for establishing a successful incident report management system: 1) having the support of leadership, 2) engaging physicians, 3) adopting a multidisciplinary approach, and 4) utilising various feedback and communication channels.

In the EURO region, a study in the United Kingdom by Howell et al. (2017) conducted semi-structured interviews and a Delphi survey with experts in patient safety incident reporting systems. Forty recommendations emerged from the Delphi procedure on the role and use of the patient safety reporting system. The study discussed the difference between voluntary and mandatory data capture. Some experts recommended that never events or serious events should be mandatory reported, while staff shortages and risk assessments should be captured by a voluntary reporting system. There was also a discussion about maximizing learning and improving accountability. All experts involved in the study recommended that hospitals should have an executive board member responsible for patient safety and that hospitals should be accountable for investigating their own reports. However, there was a lack of consensus regarding who should provide feedback to reporters. Ten recommendations were made by the expert panel to improve patient safety incident data capture and maximize the potential for learning from reported patient safety incidents. These recommendations included the importance of standardising and linking datasets, as well as the importance of ensuring the anonymity of the reporter. It was agreed that the greatest value of reporting was obtaining solutions to errors from frontline staff. Another study in the United Kingdom by Mahajan (2010) stated that a lack of systematic analysis of reports and feedback directly to clinicians are major barriers to clinical engagement in reporting incidents. In this review, a robust systematic methodology for analysing incidents is proposed. This methodology is based on the human factors model and the learning paradigm, which emphasises a significant shift from the traditional judicial approach to understanding how 'latent errors' may play a role in a chain of events that can lead to an 'active error'. It is extremely important to provide feedback directly to clinicians to keep them engaged, and this feedback should target different levels of analysis. The author suggests a framework proposed by Vincent and colleagues for analysing critical incidents. He argues that comprehensive analysis of incidents must pay attention to psychological and human factors in the nature, mechanisms, and causes of the error. In this

regard, national reporting systems should work alongside local risk management structures for comprehensive analyses and cross-learning from the incidents. Therefore, it becomes logical that a standardised framework is used at all levels for analysis of the incidents

In addition, there were four studies from Germany, two of these studies were conducted at the micro level. A quantitative study conducted by Welker et al. (2015) evaluated the process of the critical incident reporting system in anaesthesiology. Additionally, a qualitative study by Kantelhardt et al. (2011) described the one-year experience of implementing a critical incident reporting system in a neurosurgical department. The third study, a quantitative study by Manser et al. (2017), aimed to compare incident reporting systems between German and Swiss hospitals. Finally, a study by Harth (2007) reviewed the factors that contribute to understanding a critical incident reporting system. A study conducted in Spain by Ramírez et al. (2018) aimed to assess which implemented improvement actions, following the analysis of reported incidents, were effective in reducing near-misses or adverse events. They stated that the characteristics and conditions of the incident reporting system in hospitals are voluntary, anonymous, non-punitive, and confidential. The incident reporting system aims to promote improvements within the organisation, independent of external authority, while analysing the time to respond and providing feedback to the reporting individual.

In the AMRO region, some studies discuss and focus on the design of the voluntary reporting systems (Gong 2010; Gong 2011; Okafor et al. 2015). In a study conducted in the United States, Okafor et al. (2015) described the design and implementation of a web-based system for voluntary incident reporting. The aim was to enhance physicians to report medical errors in an emergency department. The findings of the study indicated that the frequency of error reporting can be notably increased by implementing a voluntary, non-punitive, user-friendly and web-based reporting system. In addition, Gong (2010) stated that voluntary incident reports are valuable for studying adverse events and near misses. Human factors such as usability and ease of use play a crucial role in the acceptance of voluntary reporting systems. However, underreporting and low-quality reports in local organisations make it difficult to identify trends and patterns at the local, regional and national levels.

In a study by Flink et al. (2005), the development and evolution of New York State Department of Health's (NYSDOH) first mandatory adverse event reporting system is discussed. The study identifies critical elements necessary for the success of the mandatory reporting system. These include making the system legally required with protection from discovery, involving all stakeholders in the system's design and implementation, establishing clear and objective reporting criteria, providing ongoing training and educational support for system users and having a stakeholder advisory group for assessment and recommendations. Other important elements include a secure web-based system, ensuring adequate resources for operation and maintenance, providing feedback to users regarding their performance, and the ability to analyse data at both facility and statewide levels and disseminate lessons learned for the system's success.

Lubomski et al. (2004) stated that the healthcare community must consolidate reporting systems and consider how to share data from a single system that is useful to multiple stakeholders. It also highlighted that having multiple reporting systems within a single hospital or health sector would not be practical. They added, to encourage participation, reporting systems should be easy to use, anonymous, confidential, non-punitive and offer timely feedback to users. The study suggested focusing on four key areas to maximize the success of incident reporting systems: integrating with existing reporting structures, encouraging staff to report incidents, properly coding and analysing event reports and using incident data to enhance patient safety.

The WPRO region covered five studies. There were two studies from Jaban, (Kanda 2011; Seto et al. 2009), the study by Kanda (2011) outlines a double-stage reporting system implemented in Japan. This reporting stage of the system is divided into two stages: the first stage involves brief information about incidents, while the second stage provides more detailed accounts of the incidents. The system aims to achieve prompt notification through the first stage and detailed reporting through the second stage. An online report input system has been established to ensure ease of input and prompt information sharing. The study found that the first report stage was successful in identifying important incidents. Some incidents took more than two weeks to be reported in the second stage, which might have gone unreported without the initial brief reports to confirm their occurrence.

Additionally, the study concluded that voluntary incident reporting by healthcare professionals is essential for preventing incidents and improving the quality of healthcare.

Another study conducted in Taiwan by Lee et al. (2016) aimed to address some certain characteristics of a successful incident reporting system. These characteristics include being non-punitive, confidential, independent, with expert analysis, timely, system-oriented, and responsive. The study also discussed the establishment of the patient safety reporting system in Taiwan in 2006. The aim was to enhance patient safety, create a safe medical culture, and facilitate experience sharing and common learning among hospitals. The system aimed to be anonymous, voluntary, confidential, unaccountable, and common. The study emphasised the importance of paying close attention to the confidentiality of case data in the system to avoid disputes and enhance reporting intention when establishing an incident reporting system in a hospital.

Two studies from China, Gao et al. (2019) conducted a quantitative study to describe the characteristics of the national patient safety incidents reporting system, while Cao and Ball (2017) used a qualitative approach to describe a hospital nursing adverse events reporting system.

2.6 **Discussion**

First of all, there is no standard definition of patient safety incidents across the studies included in this review. Many studies did not provide a clear definition of patient safety incidents, errors, and complications. Additionally, there was significant variation in the usage and definitions of these terms across different studies. This inconsistency is supported by a systematic review of the literature on incident and error reporting systems in intensive care conducted by Brunsveld-Reinders et al. (2016). In some studies, the definition of patient safety incidents lacked clarity. For instance, Arabi et al. (2016) conducted a study in Saudi Arabia and defined an incident report as "a report of an undesired event that might affect a patient, employee, a family member, visitor, or equipment or property, and such an incident was not consistent with standard operations or care. These events might cause actual injury, or might have potential to cause injury, loss of function or death" (Arabi et al. 2016, p. 211). This study considered the impact of incidents on both human and non-human entities, such as equipment or property, and

included incidents affecting both patients and employees in the reporting system. Furthermore, it is important to note that the definition of an incident was not limited to patient safety incidents and the definition also was not clearly delineated between harmful and non-harmful events. However, the results of the study classified the reported incidents in a table according to the level of harm, categorising them as harmful or non-harmful events (Arabi et al. 2016, p. 215). In another study, Kreckler et al. (2009) indicated that an incident is more likely to be reported if it results in harm. In addition, they added that surgical complications are generally not perceived as reportable incidents, but they are discussed in mortality and morbidity meetings within the general surgical department of the hospital. In contrast, a study conducted by Ramírez et al. (2018) clearly defined patient safety incidents as ‘an event during an episode of patient care that had the potential to (near miss) or actually caused injury or harm (adverse events) to the patient.

For the purpose of this thesis, patient safety incidents are categorised as either medical harm or near-miss. According to the definitions of medical error, error, incidents, and patient safety incidents outlined in section 1.5.1 of the introduction chapter, these terms will be used interchangeably to indicate harm or near-miss, which are the two types of events related to patient safety. Therefore, the term "Patient Safety Incidents" will be used to encompass both medical harm and near-miss occurrences. Patient safety incidents can either result in harm to patients or be near-misses that could potentially harm patients. In the context of this thesis, both harm and near-miss events align with the context of the ICPS and the definition of an incident in OHSAS 18001, which focuses on harm and near-miss incidents that impact or could impact the human body, excluding considerations of impacts on assets and property.

In the first theme of the scoping review, it was highlighted that the reporting of patient safety incidents depends on factors of each healthcare sector. The context of the healthcare sector plays a significant role in determining how PSI-RLS is implemented. Williams and Osborn (2006) confirmed that each reporting system needs to be developed and designed by considering the risk management history, information technology environment, financial incentives and other incentives applied to institutions and individuals. Additionally, the formal decision-making framework of the country or state in which the

system is developed should be taken into account. Realistic funding, the availability of necessary skills and a clearly defined purpose are essential for the successful development of such a reporting system. It is important not to underestimate the challenges associated with obtaining these prerequisites. For instance, the implementation of the NRLS in the United Kingdom took 2 years longer than initially anticipated (Williams and Osborn 2006).

Research on PSI-RLS primarily focuses on its practical application. Many studies are largely concerned with how PSI-RLS can be implemented in real-world healthcare settings, emphasising tangible outcomes and benefits. However, despite this practical focus, there is a noticeable neglect of theoretical understanding. Many studies are not paying enough attention to the underlying principles or policies that govern the implementation of PSI-RLS in their context.

Theme two focuses on the characteristics of PSI-RLSs. A significant issue is whether reporting should be mandatory or voluntary, a topic heavily debated in theme two. This decision is crucial when implementing PSI-RLSs in different healthcare contexts. Some studies advocate for voluntary reporting of patient safety incidents. For instance, Mekhjian et al. (2004) emphasised the universal importance of an effective, voluntary, and anonymous reporting system. Conversely, Flink et al. (2005) discussed the development of New York State Department of Health's first mandatory adverse event reporting system. Additionally, another key study highlighted that the healthcare community should consolidate reporting systems and share data from a single system useful to multiple stakeholders. It also noted that having multiple reporting systems within a single hospital or healthcare sector is impractical (Lubomski et al. 2004).

There is a notable lack of feedback to reporters, as highlighted in a study conducted by Wallace et al. (2009) within the NHS. The study's findings indicate that feedback to reporters is not a crucial component of the current reporting and learning systems. Consequently, the study recommends that feedback processes should be integrated into the PSI-RLS's design.

It is worth noting that this review has several limitations. First, the keywords and terms used for searching the literature may be subject to criticism. However, the researcher made every effort to minimize bias. The research topic was divided into three sets (set 1, set 2

and set 3) to ensure that all aspects related to patient safety, reporting and learning, and the healthcare sector were captured appropriately. Subsequently, the three sets were collected and subjected to a title screening step. Second, many identified studies were from countries with a western culture, and very few studies from the EMRO region were included. Therefore, the findings of this review may not be widely applicable across all cultures. Third, the focus of the review was specifically on PSI-RLS experiences in healthcare organisations, so the findings may not apply to the experiences of other stakeholders. In addition, some studies are of poor quality requiring the researcher to summarize the main points as comprehensively as possible.

Nonetheless, the findings of this review offer a good understanding of the practice of PSI-RLS and the experiences of healthcare providers worldwide. It also highlights the importance of exploring the experiences of healthcare stakeholders regarding the concept of PSI-RLS in countries that have not been explored yet. Additionally, the array of research designs and methods used in the reviewed studies have informed my choice of an appropriate research design and methods for my study. Finally, due to the heterogeneous nature of research designs, study populations, and methods, the findings of the studies reviewed were presented in a narrative manner, which is considered suitable for a scoping review.

2.6.1 Literature Review and Theoretical Viewpoint

Wood and Ross-Kerr (2010) stated that when knowledge about a topic and the population exists, a conceptual framework must be provided for proposed studies. These studies are not exploratory but aim to identify relationships among specific, predetermined variables to answer questions about these variables. The current study cannot adopt a conceptual framework because there is no existing knowledge about the Libyan population regarding the concept of PSI-RLS.

However, Wood and Ross-Kerr (2010) also stated that sometimes there is no prior research on the selected topic, studies can be conducted based on concepts that have been studied in other populations (Wood and Ross-Kerr 2010). The current study cannot adopt a conceptual framework based on the concepts of other populations because the current scoping review shows a lack of common variables that affect PSI-RLSs also no studies

identify the correlation between the two variables, reporting and learning. Because reporting patient safety incidents can lead to various consequences, including social issues among healthcare staff, as noted by Jeffe et al. (2004). They noted that staff might hesitate to report incidents caused by others. Nurses were concerned about shielding their colleagues from disciplinary action, while physicians worried that reporting incidents could tarnish their own or a colleague's personal record (Jeffe et al. 2004). Consequently, reporting incidents does not always lead to learning and might create social issues among staff. No study has investigated the relationship between reporting and learning in the PSI-RLSs. For instance, does an increase in reporting patient safety incidents lead to greater learning from these incidents, or do the two variables (reporting and learning) influence each other? This question remains unexplored.

Furthermore, Wood and Ross-Kerr (2010) claim that when there is a great deal of knowledge and theory about the topic, the proposed studies always have theoretical frameworks to explain what the researcher expects to find. They added that in these studies, the researcher always knows the relationship among the variables in advance and can predict its direction. The prediction can be supported by a theoretical framework that explains why the variables affect one another. It is evident that many papers discuss the assumptions regarding the importance of PSI-RLS in the healthcare sector. However, there are no unified hypotheses or theories across different contexts regarding PSI-RLS or whether that reporting leads to learning. No study has provided a theory demonstrating that PSI-RLS can be applied to all contexts. Wood and Ross-Kerr (2010) argue that in the absence of a framework based on existing literature, it is customary to develop a rationale for the study. This rationale supports the need for exploratory research on the topic and discusses the potential usefulness of the findings. The rationale for the current study is based on the overall results of the scoping review, which concluded that there are no studies conducted in Libya and no common barriers or enablers for implementing PSI-RLSs; each context has unique characteristics that influence its implementation. Additionally, nearly two-thirds of the studies were conducted in developed western countries, which have social cultures different from Libya. Elmontsri et al. (2018) assert that it is important to recognise that the healthcare sectors operate within an environment influenced by social, cultural, institutional and political factors. These elements must be taken into account when striving

to enhance patient safety. Consequently, this research will not adopt a theoretical framework or hypotheses regarding the PSI-RLSs in the healthcare sector.

2.6.2 Literature Review Gaps

The current scoping review show gaps that can be potentially bridged by carrying out studies in areas that have witnessed a lack of knowledge. However, Wood and Ross-Kerr (2010) argue that the priority of carrying out new studies and filling out gaps in the literature depends on how much knowledge is available on a topic. Furthermore, they added that all research falls into one of three major levels; each level is based on the amount of knowledge or theory about the topic under study. At the first level, little to no literature is available on either the topic or the population. At the second level, there is knowledge about the topic and the population. At the third level, there is a great deal of knowledge and theory about the topic. Each level of knowledge limits the type of study that can be done. To the researcher's knowledge, no studies have been found in the literature exploring the concept of PSI-RLS or approaches to reporting patient safety incidents in the Libyan healthcare sector. Therefore, my study is positioned at the first level according to Wood and Ross-Kerr (2010). The most important characteristic of the first level studies is that they are based on topics that either have not been studied before or have not been studied in that particular population (Wood and Ross-Kerr 2010).

Few studies have examined the PSI-RLS at the national level. Thus, my research will focus on a unified and single national system that benefits multiple stakeholders. This suggests a gap that is hoped to be addressed in my study. The studies also demonstrate that although PSI-RLS has garnered international recognition, healthcare research on the topic seems to be highly focused on practical application, almost neglecting the need for a theoretical understanding of the policies related to the PSI-RLS. In developing countries, a lack of policies, procedures and a culture of safety have massive implications for healthcare delivery and health sectors. These factors are rank high among priority areas for improving patient safety (WHO 2010). In addition, there is a clear absence of policy review regarding the involvement of other stakeholders in the PSI-RLS to understand their experiences and perceptions for reporting and learning from patient safety incidents at their context. This suggested a gap that my study sought to address.

The characteristics of the reporting system in terms of mandatory or voluntary reporting will also be explored. This will provide new insights into the reporting process in Libyan healthcare. Furthermore, the studies provide evidence that it is not possible to accurately explore the subject of PSI-RLS in a population without considering the social-cultural background of the population being studied. This suggests that the international practice of reporting and learning from patient safety incidents and culture may vary greatly from cultural and societal beliefs in other nations like Libya. For instance, two studies from the EMRO region indicated that near misses are not perceived as incidents requiring reporting. My study sought to explore the experiences of Libyan stakeholders regarding the concept of PSI-RLS at national level. There was therefore the need to consider all the work that has been done on the topic internationally in relation to Libyan's social and cultural context and healthcare sector.

2.7 Conclusion

To summarize, the topic of PSI-RLS has attracted international attention. This scoping review includes 71 studies, which are organised around two main themes, with the first theme further divided into two subthemes. While healthcare researchers outside Libya are making great efforts to address challenges related to PSI-RLSs in the healthcare sectors, none of the 71 studies reviewed have explored this topic within Libyan healthcare context. A few studies conducted in contexts similar to Libyan healthcare, specifically within the EMRO region. Hence, it is evident that the concept of PSI-RLS remains unexplored in the Libyan healthcare sector.

Many studies have failed to define patient safety incidents consistently, with varying definitions used for incidents, errors, and complications. This overlap and confusion in terminology have made it difficult to extract a single, clear definition for patient safety incidents. Very few studies have explored PSI-RLSs at the national level. While many studies have focused on reporting patient safety incidents, less attention has been given to feedback and learning from these incidents. This suggests that the primary issue of PSI-RLSs lies of in the reporting of patient safety incidents, rather than in the learning from them.

Overall, there are no common barriers or enablers for PSI-RLSs; each healthcare context has unique characteristics that influence its implementation. Additionally, nearly two-thirds of the studies were conducted in developed Western countries, which have social cultures different from Libya. Therefore, this study does not adopt a theoretical framework or hypotheses for the PSI-RLSs in the healthcare sector.

2.8 Chapter Summary

In this chapter, the relevant literature has been reviewed. The literature about the all over experience of PSI-RLSs was explored. A scoping review was deemed most suitable for this research, among the various methods for conducting literature reviews. This scoping review adhered to the framework established by Arksey and O'Malley (2005), which consists of six stages. Inclusion and exclusion criteria were considered in this scoping review. The selected studies were categorised into two main themes, with the first theme further divided into two subthemes. The findings of the scoping review indicated that the concept of PSI-RLS remains unexplored within the Libyan healthcare sector. Additionally, the theoretical perspectives derived from the literature review were identified, along with the gaps that can be addressed in the existing literature.

3 CHAPTER THREE – Methodology and Methods

3.0 Introduction

Research methodology can be described as the process outlining the way in which the research is to be conducted (Green and Thorogood 2018). The goal of this chapter is to describe the reasons and processes through which the study was conducted. This will feature a discussion about the research aim and objective, which includes ontological and epistemological assumptions associated with this study.

3.1 Research Questions, Aim, and Objectives

When it comes to conducting research, designing the right questions is critical. A well-crafted research question can lead to valuable insights and meaningful conclusions. Therefore, putting time and effort into crafting effective research questions should be a top priority for any researcher (Wood and Ross-Kerr 2010). “A researchable question is one that yields facts to help solve a problem, produce new knowledge, add to theory, and/or improve nursing practice” (Wood and Ross-Kerr 2010, p. 5).

3.1.1 Designing the Research Questions

Although there are no hard-and-fast rules for asking research questions, there are guidelines that researcher can follow that will simplify the process. The way research questions are worded can have a profound effect on the research process that follows. There are two basic components to every question: the stem and the topic (Wood and Ross-Kerr 2010). For example, What nurses wear uniforms? is a simple question that has one stem and one topic, in which case the stem is "What" and the topic is "nurses wear uniforms". Furthermore, Wood and Ross-Kerr (2010) suggest that the design of research questions can be based on the level of knowledge or theory about the topic being studied. They argue that research questions can be classified into three levels. First, the level I questions have one variable in one population and are asked in such a way that they encourage exploration by the researcher and lead to a comprehensive description of the topic. The stem question always begins with "What is" or "What are", and the topic is a single entity or concept. The key feature of level I questions is that they are based on topics that either have not been studied

before or have not been studied in that specific population (Wood and Ross-Kerr 2010). Second, level II questions have two or more variables in one population and are based on the findings of studies conducted at level I. Once a topic has been thoroughly explored, researchers can identify measurable variables. In research, a variable is defined as anything that varies or changes, that has two or more properties, or that has two or more qualities. Examples of variables include age, gender, height, and weight. Level II questions focus on studying the relationships between two or more variables that have been previously described but never studied together before (Wood and Ross-Kerr 2010). Last, level III questions have cause and effect and are built on the results of previous research. Questions at level three typically start with a significant relationship between variables. At Level III, the question asks Why this relationship exists, and researchers must provide the answer, which always begins with "Because" and ends with a detailed justification. All Level III questions lead to experimental designs (Wood and Ross-Kerr 2010).

The aim and research questions of this study were formulated at a level I knowledge framework. This decision was driven by the fact that the PSI-RLS has not yet been explored within the context of Libya's healthcare sector. Questions at Level I are designed to elicit descriptions of a single topic or a single population that has previously been ignored in the literature (Wood and Ross-Kerr 2010). There may be literature about the topic but not in relation to a specific population, or there may be no literature at all that you can find anywhere on the topic (Wood and Ross-Kerr 2010). Level I studies are exploratory by their very nature; they intend to explore all facets of a topic or a population (Wood and Ross-Kerr 2010).

There is a noticeable absence of studies investigating the correlation between incident reporting and learning. Furthermore, there is no established theory or hypothesis pertaining to PSI-RLS, as evidenced by the findings from the scoping review detailed in Section 2.6. Therefore, to generate new insights, this research will explore the PSI-RLS, as a single concept, within the context of the Libyan healthcare sector. This exploration will be guided by the ensuing research questions, overarching aim, and specific objectives.

3.1.2 Research Questions

I. What are key healthcare policy stakeholder's perceptions and attitudes towards patient safety?

II. What are the consequences of stakeholder perceptions and attitudes of reporting and learning from patient safety incidents?

III. What are the current processes and systems for reporting and learning from patient safety incidents at the national level?

IV. What factors affect the operation of patient safety incidents reporting and learning system?

3.1.3 Aim of the Study

The research aim is to explore patient safety incidents reporting and learning system in the Libyan healthcare sector, in terms of the experiences and perceptions of key healthcare policy stakeholders at the national level.

3.1.4 Objectives

A. To explore perceptions and attitudes of key stakeholders towards patient safety and patient safety incidents reporting and learning system.

B. To explore any national processes and strategies used for reporting patient safety incidents and learning from them.

C. To explore factors affecting the operation of the Patient Safety Incidents Reporting and Learning System.

D. Contribute to the development of knowledge about patient safety and optimise the healthcare sector's system of reporting and learning from patient safety incidents.

3.2 Study Design

This study was conducted over two phases, Phase 1 being the policy analysis and Phase 2 was the semi-structured interviews with key stakeholders at the macro-level. Both phases included notetaking as a third source for collecting data. Collecting data from a multitude of perspectives and sources can help to gain a richer and more nuanced understanding of the PSI-RLS. The policy analysis was conducted before the semi-structured interviews and presented in Chapter Four. The following is the clarification of how the study was conducted.

Considering the scarcity of research on this subject in Libya, there was a clear rationale to initiate an exploration of the experiences related to PSI-RLS among professionals working in this field. Therefore, we do not make presumptions that the PSI-RLS experiences documented in the existing literature can be seamlessly or entirely applicable to the context of the Libyan healthcare sector. As many studies were conducted in social and culture different from Libya. This study is conducted by taking the social and culture perspective of Libyan stakeholders into account. Ovretveit (2009) stated that many health practitioners have come to realise that social, cultural and psychological barriers are often more intransigent than financial obstacles. In addition, a review of safety research has revealed that social science methods are not well-known or widely utilised in healthcare safety research (Ovretveit 2009). Issues for research tend to be defined in ways that align with traditional medical research methods. This leads to a neglect of important issues, much inconclusive research and has often involved unsophisticated social science theory or assumptions (Ovretveit 2009).

Mason (2002) stated that it is imperative that before conducting a research study, the researcher's epistemological and ontological position is clearly identified. This will help the researchers know how their positioning might guide their methodological decisions. Understanding the research paradigm is important for PhD researchers to design rigorous research to answer the research questions. A research paradigm is defined as a basic set of beliefs that guides action (Creswell 2007, p.19). Polit and Beck (2008) contend that a research paradigm is the world view or general philosophical orientation about the world. Creswell (2007) further noted that the world view arises from a discipline's orientation,

students' and supervisors' inclination and previous research experiences. Kuhn (1962) claims that a research paradigm is shared beliefs and agreements among scientists on how to appropriately address and resolve problems. Guba (1990) further elaborates that the selection of a research approach is guided by ontological, epistemological, and methodological considerations. Ontology is 'the nature of reality' (Lincoln and Guba 1985, p.37) while epistemology refers to 'the nature of the relationship between the knower or would-be knower and what can be known' (Guba and Lincoln 1989, p.201). Methodology is 'the process of research' (Creswell 2007, p.17). Ontology, as defined by Hudson and Ozanne (1988), pertains to the nature of knowledge that is created through contextual understanding. On the other hand, epistemology, according to Carson et al. (2001), is how researchers attempt to understand and capture the nature of knowledge. Willig (2012) argued that researchers need to develop a reflexive awareness of the research questions they pose. Furthermore, their selection of methodological approaches is affected by their ontological and epistemological assumptions.

According to Neuman (2014), the ontological assumptions frame reality as either objective or subjective. McManus et al. (2017) stated that the ontology concept can be divided into two main categories: objectivism and subjectivism. The objectivist ontological perspective assures the existence of objective reality, and it can be understood through the laws by which it is legitimised (Kuhn 1962). On the other hand, the subjectivist ontological perspective asserts that knowledge about reality is created by contextual and social understanding (McManus et al. 2017). Objectivism is mostly associated with quantitative methodologies and measurement of reality, while subjectivism is associated with qualitative methodologies and understanding societal viewpoints (McManus et al. 2017). The subjectivist ontological perspective means that the reality is not something that exists independently and is "waiting to be discovered" (Neuman, 2014, p. 94). In this research, reality was seen as based on experiences influenced by participants' inner subjectivity, healthcare context and cultural worldviews.

Epistemologically, positivism and constructivism are two main philosophies for understanding knowledge (McManus et al. 2017). According to Broom and Willis (2007), a positivist philosophical stance is appropriate if the research aims to gather numerical data

and answer questions involving numerical precision using a quantitative method, such as a quantitative survey. In reverse, a constructivist philosophical stance, where there is a shift away from observing participants and recording data objectively, seeks to understand subjective realities constructed by human experiences and beliefs, using a qualitative methodology (Broom and Willis 2007). According to Karp et al. (2016), structuralism is often associated with macro-level analysis, which looks at society as a whole. In contrast, interactionism typically involves micro-level analysis that focuses on individual interactions and the subjective experiences of roles. Structuralists lean towards the idea of roles maintaining social order, while interactionists focus on the potential for change and adaptation within roles (Karp et al. 2016; Bond and Bond 1994). Additionally, context plays a crucial role in the interactionist perspective, as the setting and situation can significantly influence the performance and interpretation of a role. For structuralists, the broader social structure tends to dictate the nature of roles, irrespective of specific contexts (Karp et al. 2016; Bond and Bond 1994). The current study is based on the constructivist philosophy, which is an epistemological position. The researcher has chosen structuralism as the method for interpreting and analysing the data. As a result, the emerging data will be analysed through a philosophical lens, specifically from a structuralist perspective.

Ontology is the study of being and reality. In research, the ontological position pertains to what constitutes reality and what can be known about it. For this research, the researcher adopted the subjectivist ontological perspective. I believe that knowledge about reality is created by contextual and social understanding. Taking a subjectivist stance, the researcher asserts that reality is shaped by human experiences and interactions, leading to the existence of multiple realities.

Epistemology is the study of knowledge and how it is acquired. It deals with the nature, scope, and limits of human knowledge. The researcher adopted a constructivist philosophical stance as the epistemological position of this research. This position emphasizes understanding the meaning and context of human experiences. I used qualitative methods to explore how individuals interpret and make sense of their world. My ontological and epistemological positions have influenced the research approach, including the choice of methods, data collection, and analysis techniques.

As a researcher with a subjectivist and constructivist perspective, I employed qualitative methods for my study. This overall position has informed my research approach. My goal was to understand the perspectives and experiences of participants, as well as the meanings they assign to their actions and interactions related to patient safety and the PSI-RLS in Libyan healthcare. By aligning my research approach with my ontological and epistemological positions, I ensured that my methods were consistent with my fundamental beliefs about reality and knowledge.

According to Silverman (2006), the positivist and constructivist research paradigms are linked with two core methodologies, namely quantitative and qualitative designs. Gabriel (2013) claims that while research design orientation does not adhere to any rigid rules, it is often observed that quantitative study designs predominantly adopt deductive approaches. These approaches are primarily aimed at testing pre-existing theories and hypotheses. On the other hand, qualitative research designs are typically linked with inductive approaches, which strive to generate new hypotheses and theories derived directly from the data. I believe that knowledge can be created and not discovered. This study was conducted employing a qualitative research methodology following an inductive analytical approach, to address the posed research questions.

Theory-informed research is less controversial in the healthcare field. New collaborative data-gathering methods, such as video ethnography, are more likely to be understood and approved when the research plan demonstrates how data collection enhances existing research and theories (Ovretveit 2009). In addition, some qualitative research is more inductive, especially when there is little relevant research or theory available. In these cases, researchers do not use initial theory to guide data gathering but instead use open-ended methods to develop models and theories as the investigation progresses. This type of research is less familiar in the health field (Ovretveit 2009).

Qualitative research focuses primarily on participants' actual or recounted experiences, which are explored through conversations with the principal investigator. This approach is commonly used when little is known about a subject. Additional research using other techniques can then be conducted (Silverman 2001). A quantitative approach has a simplified way of collecting numerical data for data analysis to make inferences (Creswell

2009; Punch 2006). On some occasions, numbers are anticipated to give more information than words, and also in an attempt to understand a phenomenon, there is a need to give an approximation of how much one variable is related to other variables or how different one is from another variable (Creswell 2009). The main difference between quantitative and qualitative methods is that quantitative methods involve numerical data, such as mortality rates, while qualitative methods involve descriptive data, such as observations of people's behaviour or documentary evidence (Taylor and Field 1993). A quantitative approach could have been considered for this research, however, considering the aim of this study a qualitative approach was most suitable.

In this study, a qualitative methodology was employed to deeply explore the experiences of PSI-RLS in the Libyan healthcare sector for the first time. Exploratory research investigates problems that are not clearly defined (Jaeger and Halliday 1998) and is carried out when the problem is at a preliminary stage of understanding. Exploratory research, as the name implies, aims to delve into topics with varying levels of depth, rather than providing definitive solutions to existing problems. Brown (2006) asserts that exploratory research often investigates new or understudied areas, lacking substantial prior research evidence. In the context of the current study, no previous research had been conducted in the study setting. In line with this study, this type of investigation is carried out to ascertain the nature of an issue and provide more insight into it (Singh 2007). Some authors contend that researchers conducting exploratory studies should remain flexible, adjusting their approach based on new discoveries and insights (Saunders et al. 2018). The researcher embraced this mindset in this study.

Qualitative approaches do not encompass a single universally understood position (Caelli et al. 2003). Qualitative research encompasses a wide range of approaches. However, researchers may encounter a situation where their question or topic falls within the qualitative paradigm but does not neatly correspond with well-documented and clearly delineated approaches (Bradshaw et al. 2017). In the health sciences, there has been a rise in the use of qualitative research. However, this has also led to some researchers feeling compelled to categorise their work as specific approaches, such as phenomenology, grounded theory, ethnography, or a narrative study, even if their work does not align with

any of these approaches. In such cases, it may be more appropriate to use an exploratory qualitative approach instead (Neergaard et al. 2009).

The literature has used different terms to describe research that does not conform to traditional qualitative approaches. In recent efforts to clarify generic approaches, Thorne et al. (1997, p.170) define “interpretive description” as a “noncategorical” qualitative research approach. Savin-Baden and Major (2023) refer to a "pragmatic qualitative approach" and Sandelowski (2000, p. 335) explores what she calls “basic or fundamental qualitative description". Merriam (1998, p. 20) refers to this type of research as “basic or generic qualitative research”. “Exploratory research” is the umbrella term used by Brink and Wood (2001, p.85) to describe all description qualitative research and suggest it is a Level 1 research endeavour. This interchangeable use of terms creates ambiguity and confusion in relation to qualitative description research as a methodology in its own right. Reference to “interpretive” as described by Thorne et al. (1997) can cause confusion with phenomenology, for example, and Savin-Baden and Major's (2023) use of a “pragmatic qualitative approach” might suggest that if all else fails, the researcher should adopt a pragmatic approach. As clarified above, many authors merely state that they are reporting on a qualitative study, without defining what that means in the context (Caelli et al., 2003). Nonetheless, Merriam (1998, p. 11) takes the view that generic qualitative research studies are those that epitomise the characteristics of qualitative research but rather than focusing on culture as does ethnography, or the building of theory as does grounded theory, “they simply seek to discover and understand a phenomenon, a process, or the perspectives and worldviews of the people involved”. Qualitative exploration research follows the tradition of qualitative research and aiming to describe the informant's perception and experience of the world and its phenomena (Neergaard et al. 2009).

Qualitative-exploratory research studies assume the broad features of qualitative methodology, without specifically focusing on culture as in ethnography, theory generation in grounded theory methodology, or a participant’s lived experience in phenomenology (Bradshaw et al., 2017). Qualitative-exploratory research seeks to gain insight and grasp events, actions, or diverse participant perspectives (Caelli, Ray, & Mill, 2003; Merriam, 1998). A qualitative-exploratory approach is most suitable when evidence is needed first-

hand from the individuals experiencing the occurrence being investigated and when the available resources and time are constrained (Neergaard et al., 2009).

Qualitative exploratory research, which mainly uses an inductive approach, is suitable for identifying problems, generating hypotheses, forming theories, and developing concepts (Neergaard et al. 2009). The findings from these studies can often be of special relevance to practitioners and policymakers (Caelli et al. 2003). The end goal of exploratory research is to gain new insights, from which new hypotheses might be developed (Jaeger and Halliday 1998). There is no literature available about the topic in the Libyan healthcare context, but the PSI-RLS have been studied in many healthcare contexts. This study aimed to explore and understand PSI-RLS experiences in the Libyan healthcare sector drawing on general principles of qualitative research, which are discussed in later sections, a qualitative-exploratory design was chosen as the most fitting approach for the study.

3.3 **Study Setting**

This study was carried out in Libya, with primary data collected from participants at the macro-level at the MOH in Tripoli. No data was gathered from healthcare facilities. The study participants were selected from stakeholders at the national level, who are important for understanding the process of PSI-RLS in the Libyan healthcare sector.

The research focuses on stakeholders at the macro level rather than on hospitals at the meso and micro levels for three reasons. First, the scoping review results indicate a gap or lack of studies conducted at the macro level. Second, policy analysis reveals that patient safety incidents (medical harm) reported by patients are handled and reviewed by key stakeholders at the national level. Third, a PhD thesis conducted in Libya in 2014 concluded that there seems to be no formal RLS for healthcare staff to report patient safety incidents in Libyan hospitals (Rages 2014, p. 178). Currently, the reporting of patient safety incidents is only known to occur at the macro level. Additionally, patients were not included in the study because Libyan healthcare policy states that patients would be compensated if they suffered harm from healthcare providers. Therefore, there is no logical reason to explore their perception of receiving compensation in case they suffer harm. Furthermore, it is unclear whether reporting processes exist at the meso and micro levels. These may be the

focus of future studies once this study has identified and described processes and mechanisms at the macro level.

3.4 Sample Identification and Sampling Technique

Sampling in research involves selecting the participants or units to be studied (Martínez-Mesa et al. 2016). In quantitative research, random sampling is the most suitable technique as it ensures that each stratum within the population has an equal chance of being selected. On the other hand, qualitative research aims to utilise non-random sampling techniques. This allows qualitative researchers to target specific populations and focus on particular issues to gain a thorough understanding of specific phenomena. The three common sampling approaches in qualitative research are snowballing sampling, convenience sampling, and purposive sampling (Savin-Baden and Major 2023). In the snowball sampling, the researcher relies on participants' referrals to complete the sampling procedure. Convenience sampling allows the researcher to select participants who are readily accessible or available. Likewise, purposive sampling avails of accessible participants, but it provides the additional advantage of facilitating the selection of participants whose qualities or experiences are required for the study (Bradshaw et al. 2017).

Purposive sampling, also called judgment sampling, is a non-random technique that does not need underlying theories or a set number of participant. Purposive sampling is the deliberate choice of a participant due to the qualities the participant possesses (Etikan et al. 2016). In purposive sampling, the researcher chooses what needs to be known and seeks to find individuals who are available and ready to give the information by merit of experience or knowledge (Bernard 2017; Lewis and Sheppard 2006). According to Palinkas et al. (2015), the purposive sampling is one of the most common sampling methods in qualitative research. In addition, Palinkas et al. (2015) revealed that the principles of purposive sampling involve selecting participants with knowledge that will help the researcher obtain rich data related to the phenomenon of interest. This includes choosing expert participants who are knowledgeable about the topic of interest and are willing to participate. Another important point, as added by Creswell and Plano Clark (2011), is that these expert and knowledgeable participants should be able to share their experiences and express their

opinions regarding the research topic. Although non-probability sampling techniques such as purposive and snowball sampling are relevant for qualitative studies and specifically in qualitative exploratory research designs, however, purposive sampling is the most appropriate for this study (Etikan et al. 2016; Parahoo 2014). Purposive sampling was used in this study to ensure participants are chosen based on their ability to answer the research aim.

Identification of participants was done purposively from key healthcare stakeholders that were accessed following permission from the MOH. The MOH is the professional body of the study participants. The target of this sampling approach was to create an extensive range of views among the stakeholders who are involved in the reporting process at the national level. Therefore, participants were MOH staff who have current or recent experience, knowledge and insight into patient safety incidents and/or relevant related stakeholders.

3.5 Sample Size and Data Saturation

According to Onwuegbuzie and Collins (2007), the research question, study objectives, and the chosen design or approach are the main factors that determine the sample size for a study. Braun and Clarke (2013, p.55) suggest that in research aiming to identify patterns across data, a sample size of 15 to 30 individual interviews tends to be common. Dworkin (2012) states that qualitative research typically involves smaller sample sizes compared to quantitative studies, as it aims to gather in-depth data to understand participants' experiences and often generates large volumes of data for transcription and analysis. Additionally, in qualitative studies, smaller samples are used to facilitate in-depth interaction with participants, making the findings more transferable rather than generalisable (Bradshaw et al., 2017).

In this study, 18 participants were recruited from stakeholders and organisations that are supervised by the MOH, namely the Information and Documentation Centre (IDC), Medical Council (MC), Quality and Patient Safety Directorate (QPSD), Medical Insurance Authority (MIA), Medical Manpower Development Center (MMDC), Medical Training Deanery Board (MTDB), Libyan Board of Medical Specialities (BMS) and General Health Council (GHC). The researcher aims to make the sample as integrated as possible with

participants from different professionals and stakeholders in order to provide sufficient details to enhance a rich description of data about the incident reporting and learning system. This decision is informed by the maximum variation sampling in purposive sampling, also known as "Heterogeneous Sampling" (Etikan et al. 2016).

The sample size is a topic of debate in qualitative research (Bradshaw et al. 2017). Due to the lack of expectation for the generalisability of the results and the focus on close interaction with study participants, qualitative samples are often small. In qualitative research designs, the concept of ‘data saturation’ has been acknowledged as a standard for determining sample sizes (Saunders et al., 2018). However, there have been debates about the issues related to the concept of "data saturation" (Malterud et al., 2016; Fusch and Ness, 2015). This idea originated from a characteristic of the grounded theory methodology called "theoretical saturation" (Glaser and Strauss, 2017). Various qualitative research methodologies, however, explain "data saturation" in several ways; it is hardly clearly defined in the research literature (O’Reilly and Parker 2013). According to Allen (2017), data saturation refers to the point in the research process when no new information is discovered in data analysis, and this redundancy signals to researchers that data collection may cease.

A researcher can claim to have achieved data saturation during the data collection process when no new information is obtained from research participants (Coyne 1997). Furthermore, data saturation occurs when further coding is no longer possible because no additional information can be obtained (Guest et al. 2006). Walker (2012) also argues that when enough information is gathered to reproduce a research project, then data saturation can be said to have occurred. The concept of data saturation is often understood as a signal that data collection has been completed (Bradshaw et al. 2017). However, certain qualitative research approaches, such as interpretative phenomenology and hermeneutic phenomenology, challenge the notion of data saturation (Larkin et al. 2021; Ironside 2006). Ironside (2006) points out that these research approaches focus on the unique experiences of each participant, suggesting that it may be difficult to completely gather all the necessary data. In line with this, it has been suggested that determining an appropriate sample size in qualitative study designs should not be based on a fixed rule, but rather on various factors

such as the study design and sampling technique (LoBiondo-Wood and Haber 2021). Therefore, a sample size is sufficient if it adequately fulfills the main objectives of the study, with the aim of gathering cases that are considered to provide a wealth of information (Fawcett and Garity 2008). In this study, the sample size of 18 was determined by not just the study design and sampling strategy, but also a combination of factors such as data saturation and other pragmatic factors such as the time allocated for data collection which was affected by restrictions and lockdowns during the COVID-19 period. For example, data around the absence of a reporting and learning system for healthcare staff became apparent quite early in the data collection and kept reoccurring in the subsequent interviews. The data collection process came to an end once it became clear that no new information was being obtained.

3.6 **Recruitment Plans**

After obtaining ethical approval from the School of Healthcare Sciences at Cardiff University and the MOH in Libya, I sent invitation letters to the stakeholders and the MOH to inform their staff about the study's objectives and to invite them to participate. Interested staff then contacted the researcher expressing their willingness to volunteer and requesting further information about the study. Full contact details and instructions for reaching the stakeholders were already available on their websites. However, the approval from the MOH in Libya to access their staff was sought subsequent to the approval from the School of Healthcare Sciences at Cardiff University.

Additional information was sent to those who volunteered, along with a participant information sheet explaining the purpose of the study and the participant's right to withdraw at any time, even after giving consent to participate. The sheet also outlined their rights and explained what participating in the study would involve. They were given two (2) days to consider whether they wished to volunteer and participate in the study. Those who remained interested in participating informed the researcher via phone, and then the researcher contacted them by telephone for further discussions to address any questions or concerns they might have. During these discussions, a convenient date, time, and venue for the interview were agreed upon with each of the participants. The interviews were conducted over four months, from April 2022 to August 2022.

3.7 Methods of Data Collection

The main data collection sources in qualitative exploratory studies are commonly one-to-one semi-structured in-depth interviews (Stanley 2014). The semi-structured interview approach is commonly utilised in qualitative research and is the most frequent qualitative data source in health services research (Given 2008). This technique usually includes a dialogue between the researcher and participant, guided by a flexible interview protocol and supplemented by follow-up questions, probes and comments (Hardon, et al. 2004). This approach provides participants with a degree of freedom to explain their thoughts and to highlight their areas of particular interest and expertise (Carruthers 1990; Galletta 2013). Semi-structured interviews can be conducted in multiple ways (e.g. face to face, telephone, or remotely) (DeJonckheere and Vaughn 2019). Moreover, semi-structured interviews can provide the opportunity to step into the mind of the participants and discover how they experience the world (DiCicco-Bloom and Crabtree 2006; McCracken 1988).

The semi-structured interview was, therefore, the chosen method for collecting primary data from relevant stakeholders. Face to Face interviews were carried out with participants. All interviews were recorded and transcribed to be prepared for a more thorough analysis.

The semi-structured and open-ended interview guide were based on the research objectives, review of literature, discussions with supervisors and drawing from my professional and cultural insights into working in the field of occupational health and safety in Libya. It is anticipated that this framework may offer specific or general guidance on issues to be tackled in the interviews (Bradshaw et al. 2017). Participants were asked questions related to reporting and learning in the Libyan healthcare sector. The guide of interview questions is presented in Appendix 6.

3.8 Semi-structured Interviews

The interview guide and probes were discussed with my supervisor and piloted with two participants in Libya, in line with Janesick's (2000) recommendation to ensure clarity and the best possible understanding of the interview questions by participants. Based on the pilot study findings, some questions in the guide were revised. For instance, a question that sought to inquire about the patient safety incident reporting and learning systems within

the healthcare sector in Libya had to be changed from “Does the MOH have policies and protocols that support healthcare staff to report patient safety incidents?” to “Please describe any policies and protocols that support healthcare staff to report patient safety incidents”. Hence, the pilot study offered me an opportunity to better construct some of the questions. None of the participants who participated in the pilot study were recruited into the actual research.

Weiss (1994) suggests that researchers should not insist on asking all participants the exact same questions in the exact same manner if they want to explore deeper into a topic or have a more open discussion. The semi-structured interview method allows for flexibility, so new topics that came up during the interviews were readily incorporated into the analysis.

All participants were given the choice to choose a location for the interviews. The in-person interviews took place in a quiet office at the participant’s workplace and lasted between thirty-five to one hundred and five minutes. With the participant's consent, all interviews were audio recorded using a discreet digital recorder. Subsequently, the interviews were transcribed and translated by the researcher.

3.9 **Data Analysis**

The data analysis for this study is explained in two main sections: transcription and translation; data analysis process. The first section, transcription and translation, will be presented initially.

3.9.1 Transcription and Translation

Halcomb and Davidson (2006) explain that interviews can be transcribed in two ways: verbatim or non-verbatim. Verbatim transcription captures every spoken word including sighs, coughs, laughs, errors in spoken words, sentence structure problems and incomplete sentences. In contrast, non-verbatim transcription, also known as clean verbatim, omits stutters, filler speech (“Umm”, “Uh”, “AAAA”), errors in spoken words and non-verbal sounds like coughing and laughing. A verbatim record of the interview is beneficial in facilitating data analysis in research underpinned by theoretical frameworks such as phenomenology, grounded theory, feminism, and ethnography because the closeness between researchers and the text is critical to the research design and philosophical tenets

of the methodology (Halcomb and Davidson 2006). However, verbatim transcription is not always necessary when using some analysis techniques such as thematic or content analysis that seek to identify common ideas from the data (Halcomb and Davidson 2006). Since this study has no theoretical framework but seeks to explore ideas from the data, non-verbatim transcription was more appropriate.

Bailey (2008) suggested that non-verbal interactions such as coughs and noises like "mmm" can be eliminated to avoid data accumulation. Furthermore, Green et al. (2007) highlighted that the researcher can judge the data based on the importance of its contents; therefore, the researcher omitted the non-verbal data as they did not add anything to the data. In addition to that, non-verbatim transcription was chosen for two reasons.

Firstly, during the interviews, which were conducted in Arabic, some participants used English at times. Since English is not their first language, there were errors in their speech. This made some of their sentences difficult to understand when transcribed verbatim. For example, one participant, when asked in Arabic about the process of reporting medical harm by patients, responded in English, saying "Legal is important for people". After further prompting questions to understand what he meant, he explained that he sees justice as an important aspect of patient safety for both patients and healthcare providers.

Secondly, Halcomb and Davidson (2006) asserted that verbatim transcription can be a time-consuming and complex process, with technical dilemmas including human errors such as misinterpretation of the generated data, cultural differences, and language issues. In the current research, the researcher addressed these challenges by taking detailed notes during interviews, allowing for capturing thoughts and interpretations of the data when listening to the recorded interviews. The use of written field notes was argued to be better than verbatim transcribing (Halcomb and Davidson 2006). However, it is worth mentioning that the researcher did not face complex issues of language and communication during the interviews, mainly because all the Arabic-speaking participants spoke Arabic fluently.

After completing each interview, I listened to the recordings closely and then made notes and key codes for them. After I finished the interviews I transcript them. For each interview, I read the transcription while listening to the recording to ensure rigour, trustworthiness and accuracy.

As argued by Halcomb and Davidson (2006) verbatim transcription can be a time-consuming and complex process, however, in the current study, the non-verbatim transcription process was also time-consuming and tedious because the transcribing of the Arabic language of the interviews was from colloquial Arabic to formal Arabic to be ready for translation to English language (See Appendix 7 for an example of a transcript Arabic interview). There was a special challenge in terms of finding words in English to reflect the complex meaning of the original Arabic text. All efforts were made to translate the Arabic idioms used by my participants into appropriate English language.

The repeated listening to the audio recordings during transcription helped with the initial immersion in the data. After completing the non-verbatim transcription process, I translated the transcribed interviews from the Arabic language to the English language to be ready for the data analysis process (See Appendix 8 for an English interview transcript). The translation process was less challenging compared to the transcription process. Software (NVivo 1.6 pro) was utilised to store data during structured coding, analysis, and interpretation of the anonymised transcripts.

3.9.2 Data Analysis Process

Thematic analysis was utilised in analysing the data from interviews. Thematic Analysis (TA) is a method for identifying and interpreting patterns of meaning across qualitative data (Clarke and Braun 2014). In the data analysis, the researcher refines and identifies themes and sub-themes which are considered to function as the key features of the data because those themes are supposed to exactly describe what is happening in the data. In qualitative research, however, it is possible that different researchers might look at the same data differently, and, as a result, could come up with alternative readings and different themes. That is because the process of themes' identification partly depends on the amount and quality of the analytic effort employed by researchers in their analysis, and on their context and position in relation to the research (Howitt, 2013). However, in order to eliminate some of the weaknesses of thematic analysis, there have been attempts to provide methodical guidelines in terms of how to carry it out. Braun and Clarke (2006, p.86) developed a concept for thematic analysis that requires searching across a data set to find repeated patterns of meaning, and, as a result, they proposed a more systematic version that

involves six steps for thematic analysis. Pope et al. (2000) claim that the rigour with which data analysis is conducted determines whether a study yields novel insights into a phenomenon. Braun and Clarke (2006) argue that although qualitative study designs are numerous and diverse, the 'foundational method' in qualitative data analysis is thematic analysis. Thematic analysis typically offers a vivid, intricate, and rich account of data. It is comparatively flexible; not restricted by epistemology or theory, and hence making it a highly essential tool for research (Braun and Clarke 2006). Nevertheless, it should be noted that it is not possible for researchers to entirely exempt themselves from their epistemological and theoretical beliefs, even in their conduct of inductive thematic analysis (Braun and Clarke 2006). The thematic analysis can be deductive or inductive by using a systematic coding approach to identify patterns or themes within data that capture the meaning related to the research question (Braun and Clarke 2006; Braun and Clarke 2013; Braun and Clarke 2021a). Two types of coding approaches are usually adopted in thematic analysis: inductive or 'data-driven' and deductive or 'theory-driven' (Braun and Clark 2013; Vaismoradi et al. 2013; Byrne 2022). In an inductive approach, the codes emerge from the data in response to the specific questions that the participants were asked (Braun and Clark 2013; Byrne 2022). In contrast, the deductive approach tends to create codes that are driven by theoretical frameworks in the research area (Braun and Clark 2013; Byrne 2022). Therefore, the inductive approach results in themes identified within the meaning of what participants have said, while the deductive approach identifies underlying theorised themes (Braun and Clark 2013). Choosing between inductive and deductive (data-led and theory-led) thematic analysis is reliant on how and why the data coding is done. This study's data underwent an inductive thematic analysis because the process of analysing the data was not foreshadowed by preconceived theories and themes were identified using a bottom-up approach. In addition, as concluded from the literature review, the patient safety incident reporting and learning systems is novel and poorly explored area of research in patient safety with no identified underpinning theory, the inductive approach was deemed appropriate to analysis the data of the one-to-one interviews to identify themes that reflect the participants' perspectives without imposing preconceived ideas or theories related to the incident reporting and learning system.

The following section describes the specific process of data analysis undertaken in this study, based on Braun and Clarke (2006) six-phase guide for the thematic analysing, comprising of data familiarisation, generation of initial codes, searching for themes, reviewing themes, defining and naming themes and producing report.

3.9.2.1 Data Familiarisation

Getting familiar with the data is crucial because it helps the researcher understand and absorb any relevant information related to the research questions. Thus, this process goes beyond understanding the superficial meaning of the words into reading the data "actively, analytically and critically" (Braun and Clarke 2013, p. 205). Being able to draw on an understanding of the interview context brings depth to data immersion and enables subsequent interpretation to fully account for the research context beyond interview transcripts (Green et al. 2007). Braun and Clarke (2006) assert that in qualitative analysis, it is imperative that the researcher becomes very familiar with the data by immersing themselves in the data (Braun and Clarke, 2006). When the researcher collects data personally especially through interactions, there is a good chance that the researcher approaches the analysis with some previous knowledge (Braun and Clarke 2006). At this stage, I listened to the audiotapes several times to be immersed in the data to become familiar with all its content and to ensure the accuracy of the data transcription. Furthermore, the transcription of the audio data (excluding non-verbal data, such as coughs and deep breaths) was completed. Indeed, the participants are stakeholders at the macro-level and they are not patients, so omitting non-verbal data such as coughing or breathing will not affect the quality of the data or the process of data transcription. Braun and Clarke (2006) claim that engaging in the data by reviewing the words and meanings critically and analytically enables researchers to gain a good understanding of the collected data and improve the accuracy of the following stages of generating the codes and searching for themes.

3.9.2.2 Generating Initial Codes

The line-by-line coding of data is considered as a formal analysis step in thematic analysis. Coding is an initial process that is working towards theme generation. Boyatzis (1998) states that the most basic form of raw data that can be meaningfully evaluated about an

occurrence is codes, which represent a subset of data that appears important to data analysts. Howitt (2013, p. 176) defined coding as “brief descriptions of small chunks to data”. He added that: “there are no rules to say precisely how this is done but the more conceptual the codings are the better”. Codes can also be defined as features of the data that appear interesting to a researcher and the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon (Braun and Clarke 2006; Boyatzis 1998). This phase involves the production of initial codes from the data. During this phase, initial codes are produced from the data. This step also involves gathering and merging data that is related to each generated code. Additionally, the researcher repeatedly reads the data transcription and takes notes to improve the process of code generation. The approach for developing the codes is determined by whether the themes are motivated by data or theory. In this research, the codes were developed based on the data, not on any theory. The analysis process was inductive and not influenced by any predetermined theories.

Software such as NVivo could be used for coding although it can be done manually as well. This study used a combination of both ways. NVIVO is a qualitative data analysis software that helps to organise, store and analyse unstructured data. In this study, NVivo software was beneficial in organising and analysing the data as the researcher had a fairly large data set to work with. It's important to note that NVivo software aids in the analysis process but doesn't carry out the analysis itself (Yin 2009). However, using the software has advantages such as enhancing rigour and saving time, especially with significant volumes of data (John and Johnson 2000).

In this study, the coding was carried out systematically, line by line. Each set of data received equal attention, and relevant codes were assigned to the parts of the data that were pertinent to the study (Braun and Clarke, 2006).

3.9.2.3 Searching for Themes

Themes are generally broader than the codes as indicated by Braun and Clarke (2006). Furthermore, they defined themes as broader concepts that involve one or more categories depending on the research questions, aim and objectives. The researcher began to search for themes after the process of coding all the interviews. After the coding process was

complete, each set of codes was grouped into categories that included many ideas that shaped the resulting themes. Each theme had a “central organising concept” which included many ideas and aspects related to it (Braun and Clarke 2013, p. 224). This process started with sorting the codes and aligning each code with a likely main theme. Some of the codes were then organised to form early themes and early mind maps were made for these themes. This was important as it helped to establish relationships between generated each set of codes and sub-themes and eventually, broad themes. In doing this, some codes developed into themes and sub-themes. While searching for themes, the researcher revised the transcripts and renamed the codes when necessary to ensure they reflected the meaning across the entire data set. This process involved merging or splitting codes if they referred to similar or different themes, respectively. There were also discarded codes that were not relevant to the research question, such as codes related to the accessibility to healthcare institutions. An initial list of categories from the coding is attached as Appendix 9.

3.9.2.4 Reviewing Themes

During this phase, the researcher reviewed the emerged themes from the previous stage. This was important to ensure the quality of the categorisation made for codes, themes and sub-themes. During this stage, the researcher recognised that some of the themes were not independent themes, and could be categorised under other themes, while several sub-themes could be merged under one sub-theme. For example, the theme perceptions and attitudes toward patient safety incidents reporting and learning system contained several sub-themes but upon review, it became apparent that these subthemes can be centred around two sub-themes which are "reporting patient safety incidents" and “learning from patient safety incidents". The completed proper themes should provide a story that is accurate and reflects the data. This was achieved by ascertaining the internal and external homogeneity of the themes formed in the preceding phase. Patton (1990) defines external homogeneity of a theme as when there is a clear distinction between the theme and others, while internal homogeneity of a theme determines if the data within the theme is coherently meaningful. The researcher that internal and external homogeneity were achieved during this phase. While some themes were merged, others had to be broken up. Once it was confirmed that the generated themes were related to the research questions and that each theme had a central organising concept, the remaining uncoded data was reviewed to ensure

that no information relevant to the identified themes had been omitted. Figures 3.1 below present some excerpts of the analysis process. Other excerpts can be found in Appendix 10. The initial themes and sub-themes resulting from the analysis are attached in Appendix 11.

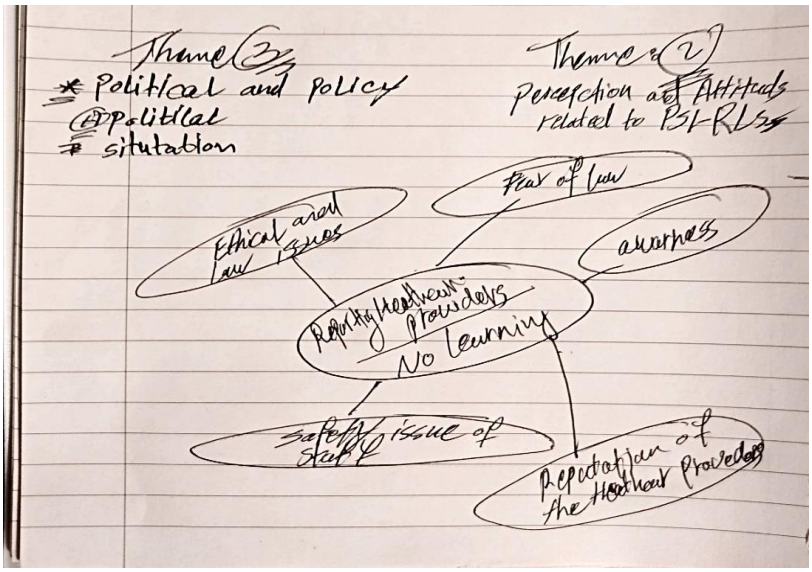

Figure 3-1 Excerpts of the Analysis Process

3.9.2.5 Defining and Naming the Themes

The focus in this phase was on defining themes in such a way as to indicate the aim of each theme. This included creating a synopsis of the core of each theme in the form of a short descriptive sentence so that each theme had an aim and a scope that differentiated it from other themes, while together, the themes created meaningful data and rich information. This phase also involved reviewing the theme names to make sure they were clear and gave the reader a sense of the topic. For example, theme 1 was previously "Understanding perceptions and Attitudes of patient safety". However, upon further refinement based on the content and data it captures, the theme name was changed to "Perceptions and Attitudes Toward Patient Safety".

3.9.2.6 Producing the Report

This is the last stage of the thematic analysis process. After establishing the final themes, the findings were reported using short or long quotations that best represented the themes or subthemes to ensure the validity of the results. According to Braun and Clarke (2006), the last stage of the thematic analysis process involves creating a coherent report that

includes examples with clear data extracts. Additionally, the report should effectively communicate the meaning of the data in a non-monotonous, logical, and reasonable manner. In this step, each theme was examined to extract and clarify all the main aspects surrounding the theme. It is expected that the findings section typically focused on each theme in turn (Braun and Clarke 2013). Throughout this writing phase, my reflections on the extracts within various themes were put together into memos to put certain remarks in perspective. Also, similarities were drawn across themes and compiled for discussion.

3.10 **Rigour of the Study**

Trustworthiness of a study can be defined as the level of confidence in the data, the interpretation of that data, and the methodological approach used to verify the quality of the research (Connelly 2016). Maintaining rigour in research is crucial for producing robust and dependable results that can withstand scrutiny and contribute to advancing knowledge (Creswell and Creswell 2017). Demonstrating the truth of a person's experience and making sure that the researcher presents an honest account of the study participant's experiences and responses are basic requirements in qualitative research (Bradshaw et al. 2017). For example, the process of interviewing may end in biased answers due to the interviewees providing data that they believe the researcher wished to hear (Yin 2013). Therefore, I started the interviews with a neutral introduction to the study, explaining that the research is exploratory and has no preconceived ideas regarding what might considered "right" or "wrong" answers (Gubrium and Holstein 2012).

Over the past few decades, many researchers have been interested in establishing criteria for high-quality qualitative research (Loh 2013). In addition, Ovretveit (2009) stated that social scientists are questioning whether the models and theories developed by researchers are simply reflections of the researchers' own ideas. Hence the attention in recent years to the details of coding and model-building methods and guidelines to ensure rigour in research endeavours. Assessing the quality of qualitative research is a subject of debate due to the subjective nature of the knowledge obtained and the criteria used to evaluate the research method (Mays and Pope 2000). However, in order to establish the trustworthiness criteria, Lincoln and Guba (1985) stated specific criteria that allow the researcher to ensure the rigour of the study. Similarly, Bradshaw et al. (2017) assert that quality in qualitative

research depends on trustworthiness encompassing principles of credibility, confirmability, transferability, and dependability. Therefore, to ensure the trustworthiness of qualitative data, there are four key criteria that the researcher must consider: credibility, transferability, dependability, and confirmability (Lincoln and Guba 1985; Shenton 2004; Connelly 2016; Bradshaw et al. 2017).

To establish credibility in research, it is crucial to develop a trustworthy relationship with the interviewee, involve them throughout the process, and allow them to confirm the accuracy of the findings (Bradshaw et al. 2017). Confirmability can be ensured by using direct quotations from study participants and keeping a record of the data collection and analysis process (Bradshaw et al. 2017). Dependability can be achieved by documenting any changes that occur during the study (Bradshaw et al. 2017). Finally, to ensure transferability, researchers should keep a reflexive journal, use purposive sampling, and provide enough study details to provide a comprehensive description of the data (Bradshaw et al. 2017). This study has implemented these research criteria to ensure the highest quality of the research which are further discussed below.

3.10.1 Credibility

Credibility refers to the extent to which research findings are believable and trustworthy (Lincoln and Guba 1985). According to Lincoln and Guba (1985), enhancing the credibility of the findings can be achieved through prolonged engagement, triangulation, peer debriefing, member checks, and persistent observation.

During the current study, the initial focus of the interview approach was to establish a connection with the interviewee and create a comfortable environment to foster credibility. To enhance the prolonged engagement, the researcher should immerse himself in the context for a better understanding of the culture and build trust with the participants of the study (Lincoln and Guba 1985).

A high degree of construct credibility can be achieved through the use of multiple data sources, a process known as triangulation (Yin 2018). The researcher employed three sources for data collection: policy analysis, one-to-one interviews, and note-taking. The policy analysis was conducted prior to the one-to-one interviews and its findings are

presented in Chapter Four. In the one-to-one interviews, the study involved a wide range of participants and stakeholders, necessitating data triangulation to analyse data from multiple perspectives and enhance the study's credibility. In addition, notes can be documented in various forms such as written text, video recordings, audio recordings, or digitally in Word files. In this research, note-taking was handwritten during interviews, policy analysis, and interview analysis. This practice, endorsed by Kvale and Brinkmann (2009), proved beneficial as it aided the researcher in framing pertinent questions during the conversation. This was particularly significant for subsequent interviews as it allowed the researcher to contemplate and formulate probing questions inspired by the data gathered. The note-taking strategy served multiple purposes in this study. It assisted the researcher in recalling specific information from each policy document and interview that could be utilised for analysis. It also facilitated the creation of initial codes and themes during the interviews (Muswazi and Nhamo 2013). In addition to being a data collection source, note-taking enabled the researcher to amend the topic guide, add prompts, and follow the participant's discussion, thereby fostering a deeper understanding of the research area.

Note-taking and memos were undertaken because this approach helped me systematically organise my thoughts and findings. This organisation proved beneficial during interviews, allowing me to emphasize key data early on and maintain clarity throughout the research process, ensuring that important details were not overlooked.

Undertaken note-taking and memos brought value to the research by supporting transparency and replicability. Detailed notes and memos provide a transparent account of the research process, which is essential for replicability. Other researchers can follow the documented steps to verify findings or build upon the work. Writing memos encouraged me to reflect on the research methods, decisions and biases. This reflective practice can lead to more rigorous and thoughtful research outcomes.

Peer debriefing is a process in which peers provide feedback and comments to a researcher. According to Lincoln and Guba (1985), this process helps the researcher to avoid biased views and maintain research integrity by clearing their mind from emotions. For the current study, in addition to supervisory reviews, Cardiff University conducts two reviews every

academic year. During these reviews, the researcher meets with staff reviewers to discuss the progress of their research and answer any questions. This provides an opportunity for the researcher to make the most of the feedback and comments provided by reviewers while conducting their research. The process ensures that the research conducted is credible and reliable.

Member checking is directed at a judgment of overall credibility (Lincoln and Guba 1985, p. 316). Member checking was carried out by sending a word document file of the interview transcript for confirmation of accuracy. Out of the 18 participants, 12 agreed to receive the interview transcript via WhatsApp, while 6 participants received a hard copy of the transcript. However, none of the participants responded to the submitted interview transcripts. As the researcher did not use the observational method for data collection, persistent observation is not applicable in this research.

3.10.2 Transferability

Transferability refers to the extent to which the findings of a qualitative research can be applied to other populations or situations (Shenton 2004; Cypress 2017). This can be achieved by providing a comprehensive description of the research methods, including the study context, the participants involved, and the procedure used for data collection and analysis to help other researchers understand and replicate the study (Shenton 2004; Cypress 2017). In addition, Lincoln and Guba (1985) proposed that for research findings to be transferable to other contexts, researchers should provide context information in addition to reporting the experiences and behaviours of study participants. This contextual information serves to provide a better understanding and meaning of the reported experiences and behaviours to readers or outsiders.

The chosen research design and method in this study resulted in a detailed and comprehensive account of the data. The data extracts were produced in a deep context, which is thoroughly discussed in the background chapter, methods chapter, and later findings chapters. The examples that were recurrent among the respondents enhanced the transferability of the study, making it possible to apply the findings to other settings.

3.10.3 Confirmability

Confirmability refers to the extent to which the findings are free from potential bias or influence of the researcher, ensuring neutrality (Connelly 2016; Cypress 2017). Confirmability aims to ensure that the research data and interpretation of the results are based on data rather than on the investigator's imagination (Shenton 2004). This can be achieved by maintaining reflexivity throughout the research process, and by providing an audit trail (Shenton 2004; Cypress 2017). Halpern (1983) suggested that process notes can be an audit trail that enhances the confirmability of the research. This includes methodological notes and trustworthiness notes.

For the current study, the researcher took notes on the literature on qualitative research, on conducting qualitative research and on the research methodology (Merriam 1988; Savin-Baden and Major 2023). The note-taking and summarising allowed the researcher a better understanding of conducting qualitative-exploratory research and enhanced the overall quality of the project. Moreover, the study was conducted in accordance with a research protocol that served as a guide for the planning and execution of the study. An audit trail was maintained to demonstrate that the study was carried out as per the plan. Measures were taken to encourage researcher reflexivity and minimize bias, ensuring the confirmability of the findings. All steps and decisions taken from the start of the study till the reporting of the results were transparently described, and the records of the study pathway were kept throughout the study.

3.10.4 Dependability

According to Loh (2013), dependability refers to the consistency and repeatability of research findings. To enhance the dependability of a study, it is recommended to use an audit trail (Lincoln and Guba 1985). An audit trail is a comprehensive record that documents all the stages of a research project, such as how and where the study was conducted, how data was collected and stored, so that other researchers can easily follow the trail (Lincoln and Guba 1985). To ensure dependability in the current study, a thorough description of all research stages was provided. By providing such a detailed account, readers can comprehend the methods used and their effectiveness (Shenton 2004). Furthermore, a record of all supervisory meetings and discussions was maintained to

monitor study progress. Connelly (2016) adds that dependability in research can also be enhanced by having a colleague who is not involved in the research project to help in the data analysis and interpretation. However, in this investigation, an external audit procedure couldn't be used due to budgetary and time limitations.

3.11 **Ethical Considerations**

Jahn (2011) states that ethical values pertinent to research are beneficence and nonmaleficence which embrace the truism 'above all, do no harm'. In April 2022, the research proposal gained ethical approval, after minor amendments, from the Ethics and Review Committee of the School of Healthcare Sciences of Cardiff University (see Appendix 2). Approval granting access to the contact details of stakeholders and the participants was negotiated with the Libyan MOH. In the same month, I applied to the MOH in Libya and gained approval (see Appendix 3). This approval from the Libyan MOH allowed its members to participate in the research and recruitment.

Ethical considerations contribute to the overall quality and integrity of qualitative research. Researchers must address ethical concerns, such as informed consent, confidentiality, and the well-being of participants (Creswell and Creswell 2017). Participants were assured by the researcher that they could decline to answer any question regardless of the reason; this demonstrates the researcher's sensitivity to their psychological well-being (Burns and Grove 2005). In addition, I have emphasised to all participants that participation in this research is voluntary and participants are not subject to any coercion or threat of harm for non-participation.

Participants were informed that they would be represented by a pseudonym instead of their real name. The pseudonyms were used to protect the participants' identities. A written informed consent was required of all research participants for the purposes of anonymity and confidentiality (see Appendix 5 the consent form). All participants were reassured of the maintenance of anonymity and confidentiality throughout the research process.

3.12 **Reflexivity**

Reflexivity, in simple terms, is the process of critically reflecting on oneself as a researcher (Lincoln et al. 2011) and is considered a technique for managing the researcher as an

instrument (Guba and Lincoln 1981). In addition, Berger and Luckmann (2023) stated that reflexivity can simply refer to a concept where an individual's thoughts, actions, or perceptions can influence or shape the reality they are observing or experiencing. Reflexivity involves an awareness that the researcher and the object of study mutually and continually affect each other during the research process (Alvesson and Sköldberg 2000). In qualitative research, the reflective researcher should be open about their shortcomings and strengths by examining their influence on the research (Baillie 2015). As explained above, reflexivity can enhance confirmability, which is important to enable researchers to understand how their position and subjectivity can influence the study (Finlay 2017).

Some researchers wonder about the difference between reflection and reflexivity. According to Hibbert et al. (2010), reflection is like looking in a mirror, where we can observe or examine how we do things or observe our actions. On the other hand, reflexivity is more complicated, it involves thinking about our experiences and questioning how we do things. Haynes (2012) argues that reflexivity is a research approach that goes beyond reflecting on the research process and its outcomes. It involves multiple layers and levels of reflection within the research, including considering the complex relationships between the production of knowledge [epistemology], the processes of knowledge production [methodology], and the involvement and impact of the knowledge producer or researcher [ontology]. By incorporating reflexivity, research processes and outcomes become more open to change and adaptive in response to these multiple layers of reflection. The way researchers understand reflexivity can vary based on personal beliefs about epistemology and ontology (Haynes 2012). On the whole, interpretive researchers consider data to be generated rather than discovered (Silverman 2015; Mason 2002).

3.13 Chapter Summary

A qualitative-exploratory approach was deemed the most appropriate for gaining new insights into the PSI-RLS within Libyan healthcare. This research method employed an inductive approach to the analysis process. Data collection was conducted through three primary sources: policy analysis, one-on-one interviews, and note-taking. The primary method for data collection was through semi-structured one-on-one interviews. Thematic analysis was the chosen method for analysing the interview data. To ensure the rigour of

the qualitative data, the researcher considered four key criteria. The process for obtaining ethical approval for the research was also explained. A reflexive approach was consistently employed throughout the study. The subsequent chapter presents the policy analysis concerning patient safety and PSI-RLS within the Libyan healthcare sector.

4 CHAPTER FOUR – Policy Analysis

4.0 Introduction

The present chapter progresses from the previous chapter's review of the literature on PSI-RLS to explore and review the context of Libyan healthcare policy. Specifically, this chapter will utilise Walt and Gilson's (1994) policy analysis framework to explore which policy documents, if any, address patient safety and patient safety incidents and whether they reference the reporting and learning processes related to these incidents within Libyan healthcare policies. Additionally, the primary aim of this chapter is to address the overall aim of this study, from the theoretical perspective, according to the context of Libyan healthcare policy. Firstly, an overview, aim and background will be presented, before the review method is then described and a result section is provided. Finally, the discussion section and a conclusion will bring the chapter to a close.

4.1 An overview of this chapter

To better understand reporting and learning systems, it is first better to understand the entire process and structure of such systems (Hewitt et al. 2016). There is, however, no formal reporting and learning system in Libyan healthcare, but this review will identify and explore national policy documents to see how patient safety incidents are discussed and whether any reference is made to reporting and learning. A study provides compelling evidence that the lack of policies and standard operating procedures is one of the main contributory factors associated with the occurrence of adverse events (WHO 2010). Reviewing policy documents regarding Libyan healthcare can contribute to increasing theoretical knowledge about patient safety incidents reporting and learning systems. Walt & Gilson's (1994) framework was adopted as a method to achieve the review aim.

4.1.1 Aim

A critical review of patient safety policies which make any reference to incident reporting and learning system in Libyan healthcare. The aim is also to provide a comprehensive understanding of the development of patient safety policies in the context of the Libyan healthcare and the progress, if any, made towards establishing PSI-RLS.

4.1.2 Background on Libya's Healthcare Policies

As previously discussed in chapters one and three, the policy context in Libya has recently been very complex and Libya's healthcare sector has suffered from poor funding, neglect, inadequate development and little modernisation, in addition to the lack of funding for studies estimating harm levels of the Libyan healthcare sector (Elmontsri 2018). Recently, Libya has been ranked among the high-risk countries for COVID-19 in the region by the WHO and access to healthcare has been impacted in many areas by the ongoing war, resulting in limited laboratory testing capacity for COVID-19 amongst other difficulties (Iwendi et al. 2021). However, Libya still has a national health service, and the public sector is the main healthcare provider in Libya (Bogabo et al. 2014).

Healthcare policies in Libya are made by various legislature and executive authorities which have undergone considerable change over the last decade or so. It is important to have a brief overview of these changes to better understand the system complexity of the policy and the governance in the Libyan context. The most important health legislation in Libya was the Public Health law No. 106 of 1973, when the General People's Congress guaranteed the right of citizens to free health services (El Taguri et al. 2008). The governance structure in Libya was also embodied in a legislature and executive authority (Alhashmi 2014). According to the People's Authority regime in Libya, the legislature and executive authority were embodied in the General People's Congress (GPC) and the General People's Committee (GPE) from 1977 to 2011 (Alhashmi 2014; Banks et al., 2016). However, in 2011 radical changes occurred in the Libyan political regime (Alhashmi 2014). The House of Representatives (HOR) became the new legislature established in 2014 (United Nations Support Mission in Libya, 2014). In 2015, the presidency council of the council of ministers was established to be an executive authority in Libya. Moreover, the presidency council consists of a Council of Ministers (COM) chaired by the prime minister, with deputy prime ministers and a number of general ministers being among the membership (United Nations Support Mission in Libya 2016).

4.2 **Policy Analysis Method**

The Walt and Gilson (1994) framework, often referred to as the Health Policy Triangle (HPT), is a widely recognised tool in health policy analysis. The framework has influenced

health policy research in many countries with diverse systems and has been used to analyse a large number of health issues (O'Brien et al. 2020). This framework emphasizes the importance of understanding the complex interplay between four key elements in the policy-making process: context, content, process and actors (Walt and Gilson 1994). The HPT is particularly useful for examining health sector reforms in developing countries, where the interplay of these elements can be complex and dynamic. By using this framework, researchers and policymakers can gain a comprehensive understanding of the factors influencing health policy and develop more effective strategies for reform (Walt and Gilson 1994).

The HPT first presented in the 20th century by Walt and Gilson has been extensively used at local, national, regional, and international levels to assess health policies related to communicable and non-communicable diseases, physical and mental health, antenatal and postnatal care, and human resources, services and systems(Zahidie et al. 2023).

Walt & Gilson's (1994) policy analysis framework has been widely and successfully used for many studies in the healthcare literature. For example, it was utilised in a study conducted by Gilson et al. (2001) to critically review health policy change in three African countries. Moreover, Walt & Gilson's (1994) framework was adopted in another qualitative policy analysis conducted in China, which explored the challenges and enablers in shifting the HIV/AIDS case management services from Centres for Disease Control and Prevention to Community Health Service Centres in urban China (Ma et al. 2015). Walt and Gilson's (1994) framework was selected as the preferred model for analysing healthcare policy because it highlights the importance of the context in which policies are formulated and implemented. This context includes political, economic, social and cultural factors that can influence policy outcomes. Additionally, Libya is classified as a developing country, and this framework is especially useful for analysing the health sector in such nations, where the interaction among the four elements—context, process, actors and content—can be complex and dynamic. In addition, the scoping review in chapter two of this thesis concluded that understanding reporting and learning about patient safety incidents from different dimensions, such as content and process, can facilitate in demonstrating its

structure. Therefore, this rationale contributed to adopting Walt & Gilson's (1994) framework for this review.

- Walt and Gilson (1994) framework

The Walt & Gilson (1994) framework is an analytical model which considers policies regarding four dimensions. Firstly, "actors" are influenced (as individuals and as members of interest groups) by the context within which they live and work, at both the macro-government level and the micro-institutional level. Secondly, "context" is affected by many factors such as uncertainty or instability created by changes in political regimes. Thirdly, the "process" of policymaking (how issues get on to the policy agenda) in turn is affected by actors, their position in power structures, their values, and expectations. Lastly, "content" of the Policy reflects some or all of the above dimensions.

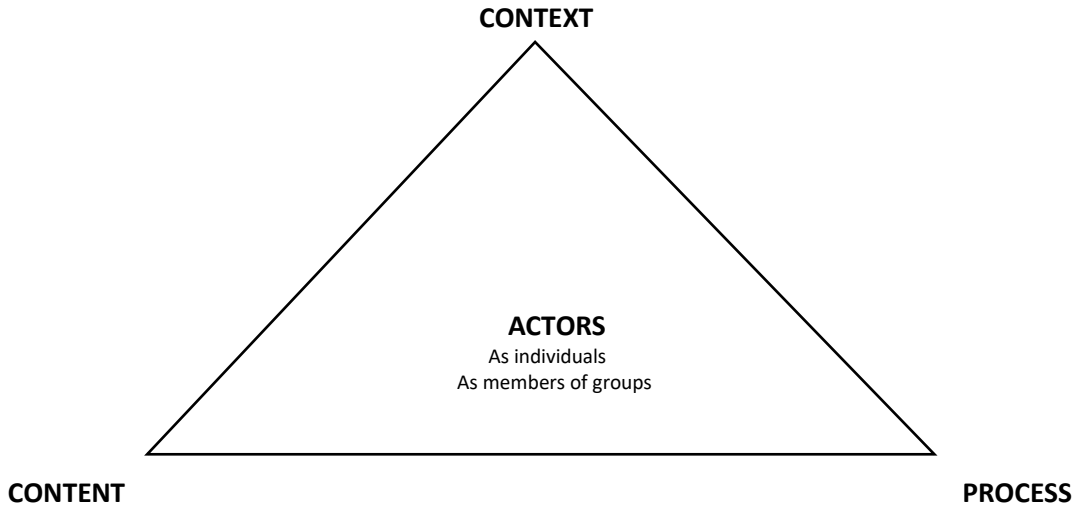

Figure 4-1 A Model for Health Policy Analysis (Walt & Gilson 1994)

- Steps for searching and extracting data

To achieve a manageable yet wide-ranging investigation, a systematic process was followed to obtain the final results for this policy analysis. The search strategy, selection process and data extraction elements of the process are presented separately. Firstly, the search strategy is introduced.

Search strategy

Two meetings were held on January 26 and 28, 2021, between the researcher and the director of the IDC in the Libyan MOH. The meetings aimed to discuss the identification of policy document sources. As a result of these discussions/meetings, the Libyan MOH website was considered to be a national source of data at the macro-level. Furthermore, the website of the IDC of the MOH was also scanned to find various relevant policy documents. To identify useful policy documents specifically for this study, there was a focus on the title and content of the policy documents. No date limit for publication was set for policy document searches to better understand the policy's context over several years. The criteria for the policy documents are shown below.

Inclusion criteria:

- Documents available in Arabic or English.
- Health policy focus.
- Full document accessible.
- Considering national macro-level policies.
- Any document that discusses the context or/and content of patient safety, patient safety incident reporting and learning systems.

Exclusion criteria:

- Studies and research.
- Meso level (such as regional healthcare policies) and Micro-level (such as a hospital or a health centre policies).
- Proposed policies.

Selection process

The searches in the IDC of the MOH website generated 33 hits. The searches were done by scanning the titles, headings and subheadings of those records to check them for eligibility. After the removal of Nine documents, 24 full-text documents were screened against the inclusion and exclusion criteria. After this process, 17 documents did not meet the inclusion criteria and were therefore excluded. A total of 7 policy records were included in this policy analysis.

The excluded documents consisted of policies not related to patient safety or patient safety incident reporting and learning systems, such as policies related to concerning the protection and improvement of the environment and the establishment of the Medical Supply System.

For transparency and rigor, the flowchart of policy documents selection can be seen in Figure 4-2 below, and the following URL https://seha.ly/en/laws-regulations/ is linked to the relevant policy documents and site.

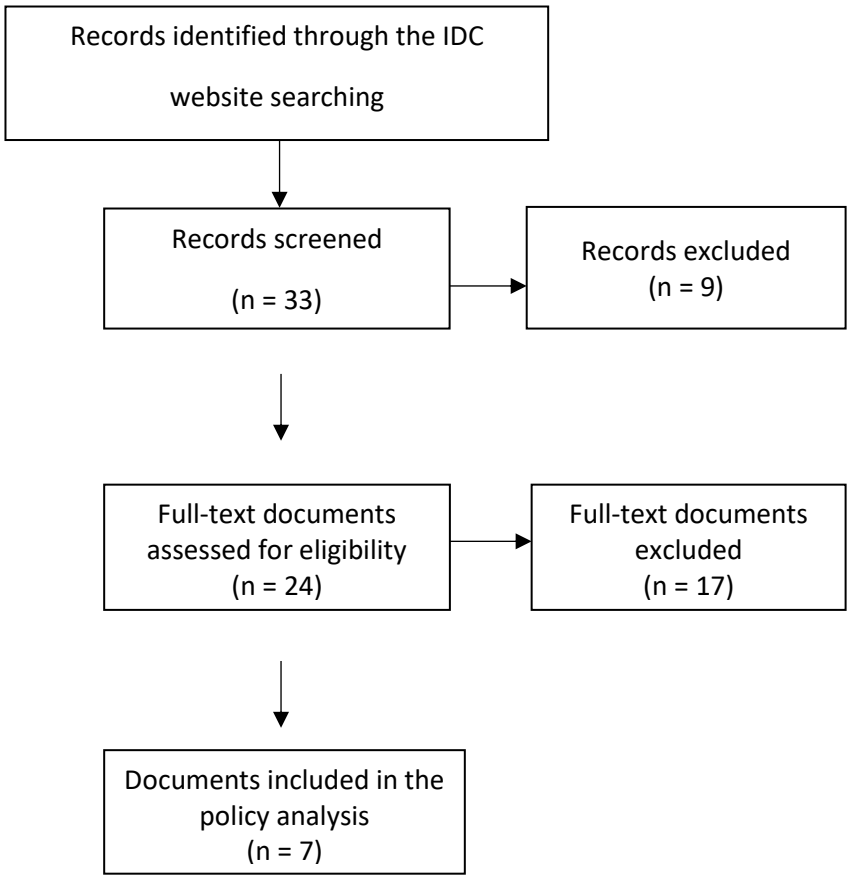

Figure 4-2 Flowchart Representing the Policy Documents Selection Process

Extracting data from the included documents is a good practice, as it aids transparency and rigour (Lockwood et al. 2017). For this policy analysis, the following data were extracted from the included policy documents: authors/policymakers, policy name/year, policy type, what and/or who does the policy seek to address (content/context) and actors addressed in the policy. This data was charted based on the dimensions mentioned in Walt & Gilson's (1994) framework; the data extraction sheet is presented in Table 4-1below.

Table 4-1 Data Extraction Sheet for Policy Documents (continued on the following pages)

Authors/policymakers	Policy name/year	Policy type	What and/or who does the policy seek to address (content/context)	Actors addressed in the policy.
Legislature/The General People's Congress.	Statute No. 17 concerning medical liability/1986.	Statute	➢ Patient safety matters. ➢ Medical harm. ➢ Liability of healthcare providers. ➢ Establishing the Medical Council (MC) and Medical Insurance Authority (MIA). ➢ Formation and the purview of professional courts for proceeding disciplinary trials. ➢ Disciplinary penalties for violators of the provisions of this Statute.	▪ Executive Authority/ The General People's Committee (Council of Ministries). ▪ General People's Committee for Health (Ministry of Health). ▪ Medical Council. ▪ Medical Insurance Authority. ▪ Healthcare providers. ▪ Patients.
Executive Authority/The General People's Committee.	Decree No. 182 regarding the establishment of the Medical Council/1989.	Decree	➢ Working methodology of the medical council. ➢ Reporting medical harm by patients.	▪ General People's Committee for Health (Ministry of Health). ▪ Medical Council. ▪ Judicial Authorities. ▪ Healthcare providers. ▪ Patients.
Executive Authority/The General People's Committee.	Decree No. 556 regarding the organisation of the Medical Insurance Authority (MIA)/1991.	Decree	➢ Organising the structure of the Medical Insurance Authority (MIA) and its functions.	▪ General People's Committee for Health (Ministry of Health). ▪ Medical Insurance Authority. ▪ Medical Council. ▪ Healthcare providers. ▪ Patients.

Authors/policymakers	Policy name/year	Policy type	What and/or who does the policy seek to address (content/context)	Actors addressed in the policy.
Executive Authority/The General People's Committee.	Decree No. 236 regarding the regulation of compensation for physical and moral harms resulting from the professional errors of the practitioners of the medical and paramedical professions, and an estimate of the percentage of impairment for those affected by it/1995.	Decree	➢ Guidelines for the patients or their families to report medical harms. ➢ Regarding the regulation of compensation for physical and/or moral harms. ➢ The methodical work of the impairment evaluation committee and compensation estimation committee.	▪ General People's Committee for Health (Ministry of Health). ▪ Medical Insurance Authority. ▪ Medical Council. ▪ Healthcare providers. ▪ Patients or his guardian or heirs.
Executive Authority/The Presidential Council of the Government of National Accord.	Decree No. 228 regulating the Medical Insurance Authority (MIA) and defining its functions/2021.	Decree	➢ Determining and regulating the competences of the Medical Insurance Authority.	▪ Council of Ministries. ▪ Ministry of Health. ▪ Medical Insurance Authority. ▪ Medical Council. ▪ Healthcare Staff. ▪ Patients.

Authors/policymakers	Policy name/year	Policy type	What and/or who does the policy seek to address (content/context)	Actors addressed in the policy.
Legislature/The General People's Congress.	Statute No. 4 regarding the National Information and Documentation System (NIDS)/1990.	Statute	➢ Establishing the National Information and Documentation System (NIDS). ➢ Collecting data for economic and social purposes. ➢ Conditions of reporting. ➢ Disciplinary penalties for violators of the provisions of this Statute.	▪ Executive Authority/ The General People's Committee (Council of Ministries). ▪ National Information and Documentation System (NIDS). ▪ Staff working in all sectors in Libya.
Executive Authority/The General People's Committee.	Resolution No. 772 to establish sectoral Centres for Information and Documentation/1989	Resolution	➢ Instructions and working methodology of the Information and Documentation Centres.	▪ The General People's Committee (Council of Ministries). ▪ General People's Committee for Health (Ministry of Health). ▪ Information and Documentation Centre (IDC).

Extracting data

Findings from the policy documents were summarised by following the stated framework. Qualitative content analysis was adopted for analysing policy documents. Traditional content analysis is often divided into manifest and latent content analysis. Manifest content analysis looks at the most obvious and straightforward meanings of a text, whereas latent content analysis ferrets out a text's subtler meanings (Ahuvia 2001). Although manifest and latent content analyses examine different aspects of a text, they employ the same traditional content analytic methodologies for research. Both approaches are forms of semantic analysis, meaning they are concerned with interpreting meanings rather than merely analysing the physical text itself (Ahuvia 2001).

According to Graneheim et al. (2017), the first descriptions of content analysis were developed exclusively for a quantitative approach and thus related to a positivistic paradigm. However, later descriptions indicate that content analysis has undergone comprehensive changes, moving from a counting game to a more interpretative approach within the qualitative paradigm. Drisko and Maschi (2016) stated that there are three approaches to content analysis: Basic content analysis, Interpretive content analysis and Qualitative content analysis . Basic content analysis is defined by its use of quantitative analytic methods and typical use of existing documents. Qualitative and interpretive content analysis use non-quantitative analysis techniques (Drisko and Maschi 2016). However, in terms of epistemology, qualitative content analysis can be applicable whether knowledge is believed to be innate, acquired, or socially constructed (Graneheim et al. 2017). Qualitative content analysis comprises descriptions of the manifest content, close to the text, as well as interpretations of the latent content, distant from the text but still close to the participants' lived experiences (Graneheim et al. 2017).

Qualitative content analysis was identified as the appropriate technique for analysing policy documents because the epistemological position of qualitative content analysis is consistent with my belief which I believe that knowledge can be socially constructed. Additionally, qualitative content analysis does not rely on quantitative measures, making it suitable for qualitative studies where numerical data is less relevant. Therefore, the analysis of policy documents employed qualitative content analysis, focusing on both manifest and latent

content. This approach explores official documents related to patient safety and PSI-RLSs, as well as related terms, within the context of the Libyan healthcare sector.

The included policy documents were read in full. While reading electronic full-text documents, initial notes and codes were identified relevant to the aims of the policy review. Then, the full-text documents were re-read line-by-line on hard copies and a table was made to include Important data was coded that related to the four dimensions mentioned. Codes were finalised, and the findings were organised into four dimensions as stated in the framework. Table 4-2 shows example of codes and line-by-line coding for policy documents. The next section discusses the content of the included policy documents.

Table 4-2 Example of Codes and Line-by-Line Coding for Policy Documents

Initial codes	**Article 25: statute No.17 and section 10: decree No. 236**
Actors Healthcare providers (body that undertakes the treatment, doctor, nurses, technicians). Patients. Context Liabilities, harm, professional error.	*"The body that undertakes the treatment of patients and the treating doctor who has the right to direct and supervise shall be liable in solidarity with the nurses, technicians, and others whose work is related to the medical profession for the harms that occur to the patient due to their professional error"* (**Article 25**).
Process of reporting harm via civil avenues Actors harmed party, his guardian, heirs, technical department at the MIA, Medical Council, impairment evaluation committee. Context Injuries, harm, professional error.	*"The harmed party or his guardian or heirs shall submit an application to the Technical Department at the Authority, attaching to the application medical reports on the harmed party's condition. The Technical Department shall study the matter and verify the existence of injuries and harm. When convinced [of the existence of injuries or harm], it shall refer the application to the Medical Council for an opinion on whether there was a professional error or nonexistence. The Technical Department shall receive the Medical Council's recommendations regarding the cases presented to it in which a professional error was found, and the Technical Department shall in turn refer such cases to the Impairment Evaluation Committee"* (**Section 10).**

4.3 Results of the Policy Analysis

There was no one clear policy or document that specifically discussed patient safety incidents, a reporting system, or learning from patient safety incidents in Libyan healthcare. However, the context of patient safety matters and reporting medical harm were referred to and discussed in seven policy documents, the titles of which are presented in table 4-3 below.

Table 4-3 Titles of Included Policy Documents

Policy documents that referred to patient safety matters and reporting medical harm in Libyan healthcare sector.
1. Statute No. 17 year 1986 of the General People's Congress concerning medical liability. **2.** Decree No. 182 year 1989 of the General People's Committee to establish a Medical Council. **3.** Decree No. 556 year 1991 of the General People's Committee to organise a Medical Insurance Authority. **4.** Decree No. 236 of the year 1995 of General People's Committee regarding the regulation of compensation for physical and incorporeal harms resulting from the professional errors of the practitioners of medical and paramedical professions, and estimating the percentage of impairment for those affected by it. **5.** Decree No. 228 year 2021 of the presidential council of the government of national accord regulating the Medical Insurance Authority and redefining its functions. **6.** Statute No. 4 year 1990 of the General People's Congress regarding the National Information and Documentation System. **7**. Resolution No. 772 year 1989 of the General People's Committee to establish Sectoral Centres for Information and Documentation.

There are three types of policies within the included documents. The types of policies are statute, decree and resolution. For clarity and distinction, the following are definitions to assist with identifying the type and content of each policy. There are no specific definitions for each type of policy, but the context of definitions can be concluded as presented below (Legal Information Institute 2020; Reverso Dictionary 2022).

Statute: A law enacted by a legislature.

Decree: An official order that has the force of law.

Resolution: A firm decision to do or not to do something.

To recognise the content of each type of policy, the word 'Article' denotes the content of statutes and the word “Clause”[1] indicates a part of a sentence within an article. The word 'Section' points out the content of the decrees and the word 'Decision' denotes the content of the resolution.

With reference to the policies listed in Table 4.2, there are two statutes, four decrees and one resolution.

- 49 articles within the two statutes, 38 articles regarding statute No. 17 and 11 articles related to statute No. 4.
- Decrees comprise 98 sections: Decree No. 182 contains 10 sections and Decree No. 556 consists of 34 sections. In addition, Decree No. 236 covers 24 sections and Decree No. 228 includes 30 sections.
- Resolution No. 772 contains Nine decisions.

The following is a brief introduction and some content for each policy.

[1] An example of the utilisation of the word Clause is presented on page 117

1. Statute No. 17 year 1986 of the General People's Congress concerning medical liability:

The General People's Congress created this policy in 1986. This statute discussed patient safety matters and the liabilities of healthcare providers in terms of medical harm as a patient safety incident. In addition, the establishment of a Medical Council (MC) and a Medical Insurance Authority (MIA) was mentioned in this policy. Statute No. 17 also stated the disciplinary penalties that may be imposed on violators of its provisions. This statute is a key policy document because articles 1-22 discuss matters of healthcare quality and patient safety, in addition to public safety based on social and cultural backgrounds in Libya. These matters include medication administration, confidentiality, and decision-making regarding discharge from facilities and euthanasia. Articles 7, 11, 12, 13, 16, 18, 19 and 22, extracted below, are examples of the content of Statute No. 17.

Statute No. 17: Article - 07

"The physician's obligation to perform his work is an obligation to exercise care unless the law stipulates otherwise".

Statute No. 17: Article - 11

"A patient shall not be discharged from a treatment facility unless his health condition allows for the discharge or he wishes to be discharged".

Statute No. 17: Article - 12

"A patient's life shall not be ended – even at his request – due to a disfigurement, an incurable or terminal illness, or severe pain, even if the patient requires artificial life support".

Statute No. 17: Article - 13

"The secrets of a patient, known due to the practice of the profession, shall not be disclosed except to judicial authorities in accordance with the law".

Statute No. 17: article - 16

"The dentist's obligation to install dentures is an obligation to achieve a result".

Statute No. 17: Article - 18

"No action or intervention intended to limit procreation shall be undertaken unless there is mutual consent from both spouses and provided that such action does not prejudice the interests of society or such action is decided by a specialised medical committee based on extreme necessity in the case of congenital deformities or mental retardation, or when there is a confirmed risk to the woman's life posed by pregnancy or childbirth".

Statute No. 17: Article - 19

"It is not permissible to abort a pregnant woman or kill a fetus unless it is necessary to save the mother's life".

Statute No. 17: Article - 22

"Medication may be dispensed only in accordance with a written prescription from a licensed doctor, excepting those medications permitted by the Health Secretariat to be dispensed without such a prescription. Medication may not be dispensed if unsuitable in nature, properties, or quantities, or if it is expired or contrary to the prescription".

Statute No. 17 was implemented, and articles 37 and 38 of the statute declare that:

Statute No. 17: Article - 37

"Any provision contrary to the provisions of this Statute is repealed".

Statute No. 17: Article - 38

"This law shall take effect 60 days from its publication date in the Official Gazette".

Box 4-1: Reflective memos

My first impression when I read statute No. 17 was that it is an outdated law that has nothing to do with patient safety. It is a major disaster for the health sector and must be eliminated to improve patient safety in Libya. After a few days, I read it again for the second time and still held the same opinion (that it is the wrong statute), but I was looking for more evidence to support my view. I started writing my findings in the policy. When I read it again for the third time, I highlighted the codes regarding the four dimensions of Walt & Gilson's (1994) framework. For the third time, I still disagreed with the statute.

The fourth time I read this statute, I noted that in Article 25, the statute states that healthcare staff are liable for the medical harm caused by their errors and there are disciplinary penalties for healthcare staff. I concluded that this is definitely a wrong statute. At that time, I still had not recognised the differences between responsibility, accountability, and liability. After extensive research on these terms, I concluded that this is a matter of liability, not accountability because that is the language of statutes or laws.

The fifth time I read this statute, I realized that there are some articles that are very good for patient safety. I found it strange to see a statute providing very good conditions to protect the rights of a certain group of people (patients) while treating another group (healthcare staff) harshly. From this point on, I started to be more careful about such information. I have read this statute in depth and in detail more than 15 times, making notes about every possible point and issue that the statute addresses.

2. Decree No. 182 year 1989 of the General People's Committee to establish a medical council:

The General People's Committee (government) authored decree No. 182 in 1989. This decree was built on statute No. 17. The government further formed and organised how the MC deployed the mandate provided by statute 17 and carried out its specialisation. The MC has the function of determining the extent of the medical liability arising from medical harm. Patients can report medical harm to the MC through judicial authorities. The decree was implemented, and section 10 of the decree states that:

Decree No. 182: Section - 10

"This shall take effect upon the date of its issuance, and it shall be published in the Official Gazette".

3. Decree No. 556 year 1991 of the General People's Committee to organise a medical insurance authority.

The General People's Committee (government) authored this decree in 1991. This policy was built on statute No. 17. The government formed an organisational structure of the MIA and determined its functions. The decree was implemented in 1991 and repealed in 2021 to update the functions of MIA (See decree No. 228 below).

4. Decree No. 236 of the year 1995 of General People's Committee regarding the regulation of compensation for physical and incorporeal harms resulting from the professional errors of the practitioners of medical and paramedical professions, and estimating the percentage of impairment for those affected by it.

The General People's Committee (government) authored this decree in 1995. This policy was built on statute No. 17 and decree No. 556. Patients or their families can submit a request related to medical harm to the MIA. Moreover, this policy has determined the compensation for physical and incorporeal harms resulting from professional errors based on an estimation of the impairment experienced by patients who have been harmed.

Decree No. 236: Section - 2

"This decree shall take effect upon the date of its issuance, and it shall be published in the Official Gazette".

5. Decree No. 228 year 2021 of the presidential council of the government of national accord regulating the medical insurance authority and redefining its functions.

The presidential council of the government authored this decree in 2021. This policy was built on statute No. 17. The government has further redefined the functions of the MIA. New departments and tasks have been added to the authority. For example, the department of insurance awareness development and risk reduction in addition to the department of human resources, administrative affairs, and services were added to the MIA. Decree No. 228 was implemented in March 2021. Section thirty of decree No. 228 states that:

Decree No. 228: Section - 30

> *"This decree shall take effect upon the date of its issuance. Any provision contrary to its provisions is repealed, and all relevant authorities shall implement it*".

6. Statute No. 4 year 1990 of the General People's Congress regarding the National Information and Documentation System.

The policy was created by the General People's Congress in 1990. It outlined the establishment of the National Information and Documentation System (NIDS) of the Libyan state. The NIDS is a central body and functions as a national reporting system for all public sectors. According to Statute No. 04, all sectors, including healthcare, are committed to report their activities to the NIDS. The statute also specifies the penalties for those who violate its provisions. Articles 1 and 11 of Statute No. 4 particularly discuss the establishment of a national reporting system for sectoral activities.

Statute No. 04: Article - 01

> *"The Great Socialist People's Libyan Arab Jamahiriya shall have a national information and documentation system, with a view to providing, handling, and analysing all data, statistics, and documents, and creating a guide to this information so as to facilitate its flow and make it available to all State agencies so they may take sound decisions in light of the indicators to manage and plan its activity, institute the necessary implementation programs, and conduct monitoring*

so as to serve public economic, social, and political purposes for the development of society".

From Article 01 above, "the Great Socialist People's Libyan Arab Jamahiriya" is indicated to the state of Libya. In addition, statute No. 4 empowered the executive authority to declare the necessary decrees to implement this statute, as stated in section 10 below.

Statute No. 04: Article - 10

The General People's Committee shall declare all regulations and decrees necessary to implement the provisions of this statute based on the proposal of the General People's Committee of Planning.

Statute No. 4 was implemented, as stated in Article 11 of the statute.

Statute No. 04: Article - 11

"This Statute shall be published in the Official Gazette and in various media outlets. It shall take effect upon its publication date in the Official Gazette".

7. Resolution No. 772 year 1989 of the General People's Committee to establish Sectoral Centres for Information and Documentation.

The General People's Committee (The executive authority/ government) issued this resolution in 1989. This policy describes the regulations and rules of how the NIDS should be organised. In addition, resolution No. 772 has established sectoral centres for Information and documentation of all sectors in Libya, and how the sectoral centres should report their activities to the NIDS. This policy was issued before statute No. 4. This resolution was implemented, and decision nine of the resolution states:

Resolution No. 772: Decision – 9

"This Resolution shall take effect upon the date of its issuance, and it shall be published in the Official Gazette".

4.4 Discussion and Synthesis

The content of policies is discussed and synthesised in this section. The Walt & Gilson's framework is utilised in this section to achieve the aim of this chapter which is a critical review of policy documents that discuss patient safety incidents and to explore whether any reference is made to reporting and learning system in Libyan healthcare. Below is a brief explanation of contextualising Walt and Gilson's (1994) framework within the Libyan healthcare sector.

Content: This involves actual policies that have addressed patient safety and the PSI-RLS in Libyan healthcare. The content of Libyan healthcare policy has reflected the other three dimensions (context, process and actors).

Process: this aspect involves how policies are developed and implemented. In Libya, it means addressing the gaps in healthcare delivery and ensuring that patient safety policies are adaptable to the country's changing conditions. Libyan healthcare policies are formulated and processed by legislative and executive authorities.

Actors: Key stakeholders include patients and the public, the government and healthcare professionals. Their roles and interactions are vital in shaping and executing patient safety and PSI-RLS.

Context: Libya's healthcare sector has faced significant challenges due to political instability and damage to its infrastructure. Understanding these factors is essential for developing effective policies related to patient safety and incident reporting. The current policy primarily focuses on the legal aspects of patient safety while neglecting ethical considerations. One notable issue is the failure to address near misses within the healthcare sector. The policy mainly emphasises the need for patients or their families to report medical harm, along with prioritising compensation for those who have suffered harm and imposing disciplinary penalties on healthcare providers when relevant. Unfortunately, this approach overlooks the importance of learning from patient safety incidents. The following are details of the four diminutions of Walt and Gilson's framework.

4.4.1 Content and Process

The content analysis of the current policy reflects the content, context and process of making patient safety policies in the Libyan healthcare sector. It also highlights some key actors involved in creating these policies.

The content of the seven policies identified for this review was processed by a legislature and executive authorities. Legislature is a body of persons vested with the power to make, amend and repeal laws. Executive authority is an authority that has the function or purpose of carrying plans, orders and laws into practical effect (Reverso Dictionary 2022). Through the analysis of the documents, the content of the seven policies portrays two concepts. The first concept is specifically for healthcare sector and discusses patient safety matters and the reporting of medical harm. The second concept is for all public sectors and describes a national reporting system in Libya.

The first concept of policy, patient safety matters and reporting medical harm is embodied in statute No. 17 and the four decrees (No. 182, No. 556, No. 236 and No. 228). Moreover, the statute and four decrees as collectively 'five policies' were specifically authored for the healthcare sector. Statute No. 17 was declared by a legislature which was the General People's Congress (GPC). Three decrees (No. 182, No. 556 and No. 236) were proclaimed by an executive authority which was the General People's Committee (GPE). The GPC was a legislature and the GPE was an executive authority (Government) in Libya from 1977 to 2011 (Geneva Centre for Security Sector Governance 2021; Banks et al. 2016; Alhashmi 2014). Decree No. 228 was announced by an executive authority, which was the presidency council of the council of ministers. The presidency council of the council of ministers was established to be an executive authority in Libya since 2015 (United Nations Support Mission in Libya 2016). Furthermore, the House of Representatives (HoR) was established as a legislature in Libya since 2014 (United Nations Support Mission in Libya 2014). As a result of this it is possible to conclude that national legislative and government bodies have played a key role in establishing national structures and process to establish and improve patient safety in Libya.

The second concept of the policy, a national reporting system, is materialised in statute No. 4 and resolution No. 772. In addition, these two policies were not specifically authored for

the healthcare sector but are a requirement of all sectors in Libya. Statute No. 4 was declared by the GPC and resolution No. 772 was proclaimed by the GPE. Figure 4-3 below demonstrates the process of policies via legislature and executive authorities.

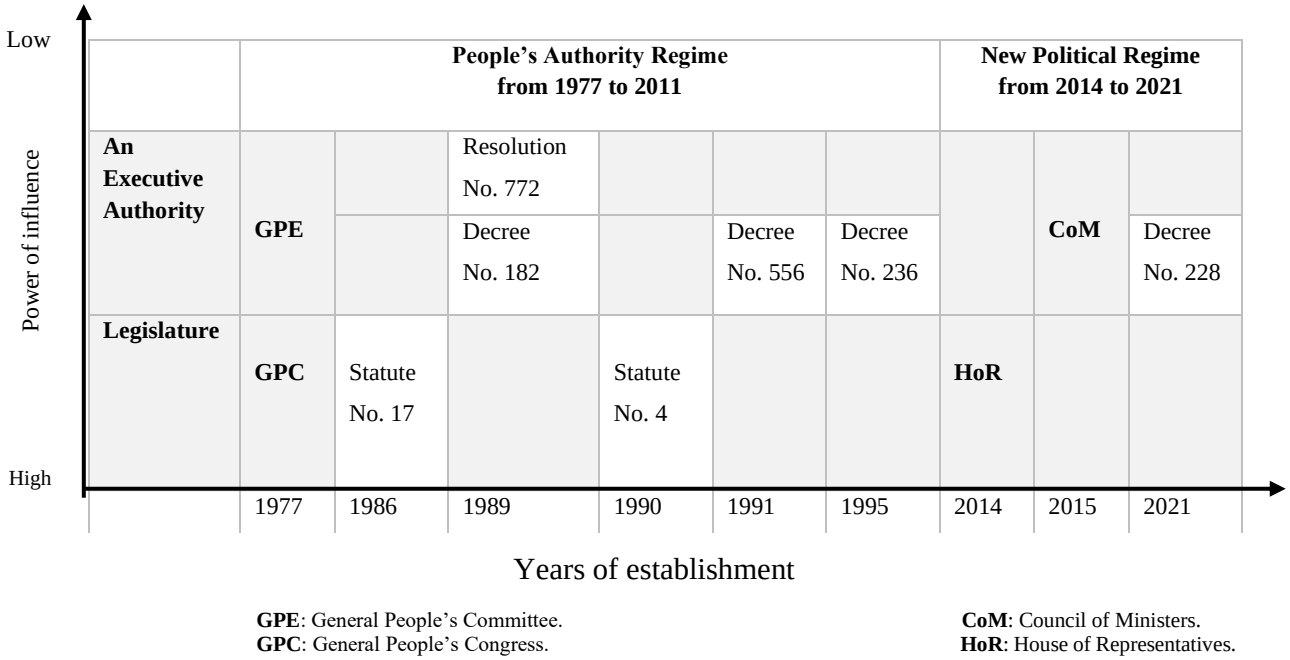

Figure 4-3 Policy-Making Process via Legislature and Executive Authorities in Libya

The figure shows that over a 34-year period statutes/decrees have regularly been produced in the context of patient safety which largely builds on previous policy documents by further specifying and sometimes altering the functions and remits of patient safety governance and processes. The power of influence on healthcare sector and patient safety policies varies between actors. There is a hierarchy of power in the Libyan governance structure, as illustrated in figure 4-3. The legislature is more powerful than the executive authority. The GPC and HoR are more powerful than the GPE and CoM in terms of creating patient safety policies. Therefore, policies created by the legislature are more powerful than the policies issued by the executive authority, in the sense that statutes have greater influence on patient safety and healthcare sector than decrees and resolutions. Also, the decrees have more impact on shaping the structure of the healthcare sector than resolutions because all decrees were authored based on a reference to statute No.17, and resolution

No.772 did not refer the statute No. 17 and statute No. 4. It is important to note that resolution No. 772 should logically be issued as a decree following Statute No. 4, similar to the process for issuing Statute No. 17 and its subsequent four decrees. This is because statutes issued by the legislature empower the executive authority to issue related decrees. However, resolution No. 772 was issued before statute No. 4. Both policies describe the establishment and the method for the national reporting system of all sectors in Libya. This explanation provides a comprehensive understanding of the development and progress of patient safety policies in the context of the Libyan health system.

4.4.2 Actors

The first concept of policy which is patient safety matters and the reporting of medical harm considers patients and the public as key actors according to statute No. 17 and the four decrees subsequent to it, as the MC and the MIA oversee medical harm claims under the supervision of MOH and the government. Healthcare professionals are positioned as expert actors on behalf of the MOH and the government to oversee and determine liability regarding the medical harm within the MC and MIA. However, the healthcare sector, including the healthcare professionals, is positioned as the perpetrators of medical harm within the policy documents, while the patients and public are portrayed as actors who need protection from medical harm and justice delivered where harm has occurred.

4.4.2.1 Patients and Public

Patients and the public are positioned as actors who need some degree of protection from medical harm caused by the healthcare sector and/or healthcare professionals and justice when care goes wrong. However, patients and public have to provide evidence or proof that the error has resulted in harm. Patients and their loved ones have the option to report any medical harm they suffered through either legal or civil avenues. In legal means, decree No. 182 declared that patients can report medical harm through judicial authorities. The judicial authorities in Libya are the judiciary. The judiciary operates as an independent authority and is headed by the Supreme Court, which serves as the highest court in Libya. The members of the Supreme Court are appointed by the legislature. It's important to note that the judiciary is distinct from the Ministry of Justice (MOJ), which work for executing

government policies and regulatory acts and managing the technical aspect of the judicial authorities. Section 3 of decree No. 182 states:

Decree No. 182: Section-3

> *"The Medical Council shall be competent to consider cases referred to it from the judicial authorities concerning the medical and paramedical professions, study and evaluate such cases from a technical perspective, determine the extent of medical liability attaching to the medical error or prove otherwise, and prepare a report to that effect that it shall submit to the authority that referred the case.*
>
> *The Council shall prepare the said report from the facts of the patient's file who suffered the harm. The Council may, as it sees fit, call anyone who supervised the patient at any stage of treatment to appear [before the Council] to hear their statements and obtain the required information from them. The Council may also view, examine, and request any other documents it deems relevant to the case".*

Throughout the civil means, patients or their families can submit a request related to medical harm to the technical department of the MIA. The technical department verifies the case and if they agree that patient safety-related error and harm has occurred, the request is referred to the MC. However, there is no clarification about the required qualifications and staff employed in the technical department whether they are healthcare professionals, legal/lawyers or administrators. These instructions are stated in section 10 of decree No. 236 as shown below.

Decree No. 236: Section - 10

> *"The harmed party or his guardian or heirs shall submit an application to the Technical Department at the Authority, attaching to the application medical reports on the harmed party's condition. The Technical Department shall study the matter and verify the existence of injuries and harm. When convinced [of the existence of injuries or harm], it shall refer*

the application to the Medical Council for an opinion on whether there was a professional error or nonexistence.

The Technical Department shall receive the Medical Council's recommendations regarding the cases presented to it in which a professional error was found, and the Technical Department shall in turn refer such cases to the Impairment Evaluation Committee".

The word Authority mentioned in section 10 above was clarified by decree No. 236, and it refers to "Medical Insurance Authority".

Section 10 considers medical harm as a patient safety incident that should be reported by patients and any proven medical harm results in compensation for the patient. However, the decree makes no reference to the concept of "near misses" at all and only receives reports of claims regard to medical harm. It is essential to consider near misses for avoiding dangerous accidents in the future. Reason (1997, p.119) stated that the investigation of previous near-misses and adverse events gives free lessons to foster the development of defences in the system to protect against more serious occurrences in the future. Also, when medical error and harm is not proved, the policy does not specify that learning should occur when there may be useful experiences to draw upon. As a result, the function of the MC operates around determining liabilities resulting from medical harm and deploying harm where this is proved.

There are no mechanisms and instructions on how this reporting approach can enhance the learning stage in the healthcare sector, to avoid the repetition of medical harm. Learning from defects in healthcare settings has been considered central to efforts aimed at improving patient safety and quality of care (Arabi et al. 2016). Besides that, there is also no consideration for the situations when patients do not report medical harm. There are no clear procedures or processes for medical harm or near misses related to patient safety that are not reported by the patient or their families.

Box 4-2: Notes: Key Insights from Policy Analysis

This part of the policy aroused my curiosity because patients, rather than healthcare staff, report medical harm. This aspect of the findings led to a significant shift in the focus of my study. Originally, my study was a qualitative study of patient safety incident reporting and learning systems in Libya's private healthcare sector. Despite conducting a literature review and scoping study, my focus remained on the private sector. However, after conducting a policy analysis, I realised that Libyan policy stipulates that patients or their families have the right to report medical harm, which falls under the umbrella of patient safety incidents. Consequently, I concluded that there was no need to limit the study to the private sector, as patients have the right to report harm in both the public and private sectors.

4.4.2.2 Government

The government (executive authority) plays an essential role in making policies that shape the healthcare sector. Moreover, the government is the most powerful actor who operates via the MOH, MC and MIA to protect, offer justice and compensate patients, and also to apply disciplinary penalties on professionals who commit medical harm. The government is empowered by article 27 of statute No. 17 to make healthcare policies related to the form of the MC.

Statute No. 17: Article - 27

"A medical council affiliated with the Health Secretariat shall be competent to make determinations of medical liability. Members of the council shall have high-level qualifications in the medical professions and paramedical professions.

On the basis of a proposal by the Secretary of the General People's Committee for Health, the General People's Committee shall issue decrees concerning the formation, regulation, and working methodology of the said council.

Without prejudice with the provisions of this law, the said council shall be subject to the provisions on experts as stipulated in the Law of Criminal Procedure".

From Article 27 above, the legislature used terminologies that are now outdated as they related to the People's Authority Regime (the political regime from 1977 to 2011) to allude to the executive authority, institutions and persons. For instance, the "Health Secretariat" and "the General People's Committee " means the MOH in the current political regime, while the "General People's Committee" is similar to the Council of Ministers and the "Secretary of the General People's Committee for Health" is identical to the Minister of Health.

The clause "On the basis of a proposal by the Secretary of the General People's Committee for Health, the General People's Committee shall issue decrees concerning the formation, regulation, and working methodology of the said council" has empowered the government to form and regulate the MC based on a proposal by the minister of health.

The government announced and implemented decree No. 182 regarding the organisation of the MC in 1989 which is three years after the declaration of statute No. 17. The medical council's remit relates to determining medical liability when medical harms are made and is therefore centrally important to patient safety, or more specifically compensation where patient safety has been compromised, in the healthcare sector.

Likewise, the government was authorised by the legislature to make policies related to the establishment of MIA as stated in articles 31 and 32 of statute No. 17.

Statute No. 17: Article - 31

> *"An authority named the Medical Insurance Authority shall be established as a legal entity. Persons engaged in medical and paramedical professions are obliged to maintain insurance with it against the risks of practising those professions"*.

Statute No. 17: Article - 32

> *"On the basis of a proposal by the Secretary of the General People's Committee for Health, the General People's Committee shall issue a decree to organise the authority referenced in the previous article, regulate how it carries out its functions and invests its resources, and determine the groups*

required to maintain insurance, the cost of premiums, and the payment method, as well as other regulations".

Since then, the government announced three decrees on the subject of the MIA. The first decree is No.556 regarding the organisation of the MIA. Decree No. 556 was announced and implemented in 1991 which is five years after the pronouncement of statute No. 17.

The second decree is No. 236 related to the regulation of compensation for physical and moral harms resulting from the errors of the practitioners of the medical and paramedical professions, and an estimation of the percentage of impairment for those affected by it. Decree No. 236 was announced and implemented in 1995 and that means nine years after the statute No. 17 proclamation.

It is worth it to mention that according to above articles (31 and 32) of statute No. 17, there is mandatory insurance for healthcare staff against the risks of practising medical and paramedical professions. The government has the power to organise the MIA and determine the insurance for the healthcare staff. Section 25 of decree No. 228 stated that.

Decree No. 228: Section-25

"The monthly premium amount for those obliged to maintain insurance with the Authority is determined at five per cent (5%) of the salary. This amount is automatically deducted for the Authority's accounts, with the Ministry of Health covering (60%) sixty per cent and the insured bears (40%) forty per cent".

In 2021, the government updated the competence of the MIA by announcing decree No. 228 which is the third decree regarding the MIA. Decree No. 228 is related to the regulation of the MIA and defining its functions and this decree was announced and implemented in 2021 and that is thirty-five years after the pronouncement of statute No. 17. Sections One and Thirty of this decree states that:

Decree No. 228: Section - 1

"The Medical Insurance Authority established pursuant to the referenced Statute No. 17 of 1986 on Medical Liability shall be regulated and its competences determined in accordance with the provisions of this decree".

Decree No. 228: Section - 30

> *"This decree shall take effect upon the date of its issuance. Any provision contrary to its provisions is repealed, and all relevant authorities shall implement it".*

The government takes full control of the MOH, which in turn oversees the MC and the MIA. All policies related to these two bodies have been announced by the government. Additionally, the government derives the power to establish patient safety policies from statute No. 17 which was declared by the legislature in 1986.

From the perspective of the policy process, all decrees were announced by the government after years of the statute No. 17 proclamation. Moreover, the government has the authority to repeal decrees but not statutes and that can be noted in sections 1 and 30 of decree No. 228 above when the government built its policy (decree No. 228) based on statute No. 17 as stated in section 1, and repealed other policies as stated in section 30.

4.4.2.3 Professionals

Professionals are positioned in the policy documents reviewed as actors who are experts (on behalf of the government within the MC and MIA) to determine whether harm has occurred and the needed compensation for patients. Professionals are also positioned as the perpetrators of harm who the public need protection from and justice delivered. From the perspective of patient safety reporting and learning, there is no mention or detail of how or whether healthcare staff should participate in reporting patient safety incidents or how reports from healthcare staff lead to learning to benefit the healthcare sector. It is clear that policy provides a certain structure which guides some professional actors' actions, but equally there are policy structures and processes relevant to reporting and learning that are not clarified in current policy.

The context of articles 25 and 26 of statute No. 17 imposes liabilities on the Libyan healthcare providers, including MOH, regarding medical harm caused by their professional errors or the utilisation of medical instruments, devices, and pharmaceuticals. The following are articles 25 and 26.

Statute No. 17: Article - 25

"The body that undertakes the treatment of patients and the treating doctor who has the right to direct and supervise shall be liable in solidarity with the nurses, technicians, and others whose work is related to the medical profession for the harms that occur to the patient due to their professional error".

Statute No. 17: Article – 26

"The Health Secretariat, suppliers, manufacturers, distributors and users shall be liable in solidarity for the harm arising from the utilisation of medical instruments, devices, and pharmaceuticals".

In addition, Article 30 of the statute specifies disciplinary penalties that may be imposed on violators of the provisions of statute No. 17, reflecting a blame culture. However, according to Article 29, these penalties can only be imposed through a disciplinary trial, which must be established by a decree from the MOH. As stated in Article 28, the disciplinary trial must be presided over by a judge and include two highly specialised physicians as members.

Statute No. 17: Article- 29

"The decree to refer to the disciplinary trial shall be issued by the General People's Committee for Health or its designated delegate".

Statute No. 17: Article- 30

"The disciplinary penalties that may be imposed on violators of the provisions of this statute are:

1. *Warning.*
2. *Reprimand.*
3. *Deduction from salary for a period not exceeding ninety days per year. The deduction in implementation of this penalty may not exceed a quarter of the monthly salary after the quarter that may be seized or waived by law.*
4. *Deprivation of the annual bonus.*

5. *Deprivation of promotion for a period not less than seven months and not exceeding three years.*
6. *Suspension from practising the profession for a period not exceeding one year.*
7. *Demotion.*
8. *Dismissal from the job or deprivation from practising the profession".*

The consequences of adopting only a legally based approach to understanding and addressing medical harm could affect patient safety culture. For example, patient safety culture is not only a legal matter resulting in guilt and punishment; it also admits and realises that some harm could be caused by system failures, not human error (WHO 2019). The consequences of focusing on the legal approach may shape behaviours of healthcare staff that are counter to patient safety thinking. Other consequences of only focussing on liability and medical harm are that safety learning does not occur and effect the psychological safety of healthcare staff. Patient safety culture considers the psychological safety of healthcare staff as an important aspect of enabling learning behaviour (Edmondson 1999).

The MC and MIA were actors in processing medical errors that cause harm, and they could learn, if any, from patient safety incidents. Still, the policy did not consider the learning mechanism and there are no instructions for extracting lessons that should be utilised for developing the healthcare sector. In addition, the policy does not consider near misses as a patient safety incident.

The first concept of policy which covers the provisions outlined in Statute No. 17 and the subsequent four decrees was declared for the healthcare sector in Libya. These policies indirectly address patient safety within the Libyan healthcare sector. These policies also stipulate how patients and families can report medical harm and how these harms are subsequently processed and deliberated upon members report medical harm. However, these policies do not explicitly define the state of healthcare staff regarding reporting and learning from patient safety incidents. While these policies do not prohibit healthcare staff from reporting patient safety incidents, they also do not mandate them to do so.

Box 4-3: Reflective memos

After reading the policy, I became concerned because Libyan healthcare policy seems to differ significantly from the literature. The context of the policy is very thought-provoking. Reporting patient safety incidents in Libya was notably different from what I had understood. The policy lacked any mention of learning from incidents and I felt that I had analysed a lot of data irrelevant to my study. I began to think that I needed to carefully re-analyse the policy documents and consider if there were any alternative approaches I could have taken to ensure that the data aligned more closely with my study.

Because the healthcare sector in Libya does not currently operate a reporting and learning system where patient safety incidents are provided by staff. The second concept of the policy (which encompasses statute No. 04 and resolution No. 772) could be employed to assist medical and paramedical staff in reporting and learning from patient safety incidents. The second concept outlines a national reporting system in Libya. Although both policies are not specifically tailored for the healthcare sector, they are applicable to all public sectors in Libya, including healthcare. Seventeen sectors were required to report their activity to the NIDS and the MOH was one of those sectors. However, the NIDS does not provide clear instructions about what events should be reported via this system. For instance, there are no explicit guidelines for reporting patient safety incidents through this system. Decision 3 in resolution No. 772 requires all public sectors to gather data and information on their activities through their IDCs.

Resolution No. 228: Decision - 03

> *"All entities and agencies affiliated with the sector are committed to collecting and preparing the data, statistics, information and documents required of them and related to their activity in accordance with the methods, techniques, and instructions issued by the Sectoral Information and Documentation Centre."*

This resolution uses the term "sector" to refer to the healthcare sector, and the "sectoral information and documentation centre" to refer to the information and documentation

centre (IDC) affiliated with the MOH. However, the resolution does not explicitly state whether the sector's activities include information and data related to patient safety incidents. This question remains unanswered. In addition, Article 6 of statute No. 04 could enable healthcare staff to report patient safety incidents through anonymous reporting system.

Statute No. 04: Article – 06

> *"Personal information and data shall not be collected within the framework of the national information system through any means of coercion or deception. The party concerned shall be entitled to view such data and information and to remove or amend anything it deems contrary to reality prior to the documentation of the same. The use of such data or information is limited to purposes of economic and social study. No third party may view it, even a public authority, and it shall not be published in a form that indicates the party to whom it pertains, used for any other purposes, or taken as evidence or grounds for any legal proceeding in contravention of the foregoing*."

The article above emphasises the importance of learning by using anonymous information and data from the public sector solely for economic and social research purposes. It explicitly states that this data should not be utilised for any other intention or as evidence in legal matters. Based on this article, it can be inferred that healthcare staff may use this system to report patient safety incidents anonymously. Since the healthcare sector is part of the public sector, it is eligible to use this system to report patient safety incidents for learning purposes. This will contribute to the development of patient safety in healthcare, benefiting both society and the economy by reducing the negative consequences associated with patient safety incidents. Importantly, these incidents cannot be used as evidence for condemnation or any legal purposes against healthcare providers.

This article emphasises the importance of granting reporters the autonomy to report data and information that could benefit society and the economy. In addition, there is no obligation to report data and information, but it does not discourage reporting. This suggests that reporting patient safety incidents is not mandatory but can be done through voluntary and anonymous reporting systems. The article allows reporters to edit or delete any

information they deem inaccurate before submitting their report. It could be argued that the article encourages speaking up about patient safety incidents. This implies that healthcare providers at micro and meso levels can discuss the report verbally with others to ensure its accuracy and learning value. However, they must not include any personal information about themselves or the patients in the reports submitted to the macro level. For instance, a nurse can choose to report an incident anonymously for learning purposes. She may also discuss it verbally with a colleague to verify the information before submitting it to the macro level.

Theoretically, healthcare providers should be able to report patient safety incidents and learn from them without any barriers. However, there is a need for a policy or a code of conduct in Libya to interpret the current statutes in order to establish a unified framework for the PSI-RLS. The unified framework should clarify the technical and mechanistic aspects of how the concept of PSI-RLS can effectively work in the Libyan healthcare sector. The unified framework should also clarify the reporting process for both patients and healthcare providers.

To summarize, the first concept of the policy indirectly references patient safety through Statute No. 17 and its four subsequent decrees. This concept outlines how patients and their families can report medical harm and how these reports are processed and reviewed. However, Statute No. 17 does not mandate healthcare staff to report patient safety incidents, nor does it prohibit them from doing so. Currently, the healthcare sector in Libya lacks a reporting and learning system for patient safety incidents reported by healthcare providers. Such a system could be started and administered based on the second concept of the policy, specifically Article 6 of Statute No. 4 and Resolution No. 772.

Box 4-4: Reflective memos

Based on the literature review, I strongly believe that it is an ethical action to allow healthcare providers to report and learn from patient safety incidents. After identifying the process of reporting medical harm by patients or their families. I intentionally and actively sought data that could support healthcare providers in reporting patient safety incidents from the first concept of the policy. However, I was concerned about bias because I felt that I might be selecting specific data to prove a preconceived notion in my research. I reassured myself that I am not biased for two reasons. First, I am using the framework proposed by Walt and Gilson (1994) to gather data. Second, after thoroughly analysing and delving into the first concept of the policy, which deals with intricate and underlying ethics, I found it strange that the mentality behind this policy did not take into account crucial data regarding the involvement of healthcare providers in reporting incidents. I discovered that the first concept of the policy is silent on this matter, lacking data to either support or refute the act of reporting incidents by healthcare providers.

Then, I started to pay attention to the second concept of this policy (statute No. 4 and resolution No. 772) that was issued for all public sectors in Libya. I found that the second concept of the policy provides instructions and describes the process of reporting sectoral activities for all public sectors including the healthcare sector. The process for reporting sectoral activities is linear and straightforward. Still, resolution No. 772, which should interpret and clarify the implementation of statute No. 4, was unclear about the meaning of the sectoral activities. This lack of clarity may be due to the fact that resolution No. 772 was not issued based on the final form of statute No. 4, as it was issued about seven months before statute No. 4.

4.4.3 Context

The key and closest Libyan policy to patient safety specifically features in statute No. 17, which is a legal concept, therefore the context of reporting patient safety incidents in Libya currently only clarifies the legal approach. Article 23 of statute No.17 clarify the error and harm as stated below.

Statute No. 17: Article - 23

Medical liability is imposed on any professional error arising from the practice of a medical activity that causes harm to others.

Any breach of an obligation imposed by applicable legislation or established scientific principles of the profession is considered a professional error, all taking into account the circumstances surrounding the available capabilities.

The arising of harm is considered evidence of committing an error or breach of obligation.

It is not permissible to exempt or mitigate medical liability before the occurrence of the harm, and any agreement to that effect is null and void.

This article addresses an error and harm in the context of healthcare in Libya. The first clause discusses how medical liability is attributed to errors that cause harm to people, emphasising that errors are solely attributed to harm. The second clause elaborates on what constitutes an error in the Libyan healthcare sector. In the third clause, the evidence about the occurrence of harm. In the last clause, it is not permissible to exempt or mitigate medical liability for other errors or incidents that did not cause harm. The occurrence of harm is a prerequisite for applying medical liabilities. For instance, medical liability cannot be exempted or mitigated for near misses. Medical liability cannot be assigned to near misses as no harm is inflicted. Near-misses are not recognised as errors in this context. Mahajan (2010) asserts that the usual practice of analysing only those incidents which lead to actual patient harm, in fact, misses big opportunities to learn from near misses, or where an incident was effectively managed without actual harm. Near misses are a vital part of voluntary reporting systems (Flink et al. 2005). Patient safety experts argue that the root causes of near misses and adverse events are similar. Therefore, detecting the root causes of near misses can help us to correct these causes and prevent future adverse events (Sheikhtaheri 2014). Based on the article, it is not possible to find a statement acknowledging the near-miss as an error in a legal document related to the Libyan healthcare because that would conflict with the content of this article.

Medical harms are obliged to result in compensation, and there is no evidence currently that healthcare staff participate in any reporting of patient safety incidents. The public do, however, have the right to report medical errors and receive compensation if they have been harmed and negatively affected. This policy analysis demonstrates that processes and mechanisms for reporting patient safety incidents in Libyan healthcare do not currently

comply with WHO policy that encourages healthcare staff to report patient safety incidents (WHO 2020).

It has been identified that the policy focuses on a legal approach for the public to report patient safety incidents and receive compensation if they have been harmed or negatively affected. However, it fails to address the ethical considerations and potential benefits of reporting such incidents for healthcare providers. Additionally, the policy is designed by statutes and decrees and predominantly written in legal language, focusing on assigning liabilities, blame and disciplinary actions rather than providing a comprehensive ethical framework. As a result, there are questions regarding the effects of such language and processes on patient safety reporting and learning, especially as patient safety culture is characterised by prioritising processes that promote learning from incidents above liabilities, blame or disciplinary actions. Leaving the current policy open only to the legal approach will impede the development of patient safety in Libya. A fear of punishment does not promote incident elimination. Instead, fostering a cooperative, non-threatening, and blame-free environment that encompasses the entire healthcare sector and its members is the primary tenet for effective incident reduction (Liang and Ren 2004).

Feedback regarding medical harm is discussed in the policy, but the feedback existed between patients and specific legal structures and processes (the judiciary , MC and the MIA for obtaining compensation). There are no clear instructions that the feedback regarding medical harm is shared or should be shared with healthcare staff to inform them about their errors. D'lima (2016) emphasised the importance of ensuring that feedback from centralised incident reporting systems is communicated to healthcare providers in a detailed and timely manner. It is also vital to tailor and target such feedback for specific clinical groups and individuals and disseminate it from the institutional level (D'lima 2016).

This is unsurprising considering the ongoing conflict and more recently the Covid-19 pandemic. For example, in the absence of an effectively functioning government (or a split government) there has been little national direction on patient safety of the sort that is needed for a national approach to learning and reporting.

After observing the behaviour of the Libyan healthcare context based on the policy documents, it is possible to conclude that the context has been of survival and adversity not

learning and development. The current context is that there is no national baseline for patient safety and no data available or recorded relating to patient safety incidents. Another critical context is that there is no learning from patient safety incidents and evidence suggests (Wiig 2007) that where there is no learning it is more likely that care is unsafe and safety breaches will continue.

4.5 Reporting Process According to the Libyan Healthcare Policy

The process of reporting patient safety incidents is limited to medical harm by patients and focuses on justice in the form of compensation and applying disciplinary penalties where relevant. Therefore, the process is taking the form of a legal approach involving the MOJ and judicial authority. Whilst the concept of justice is an important requirement and consideration within healthcare policy, it focusing only on justice can be counter-productive for patient safety for the following reasons:

- Absence of learning mechanism process - patient safety continues to be a considerable challenge in the healthcare sector because there is no process of reporting or learning aspects from patient safety incidents.
- The emphasis of policy is only on compensation and punishment via some form of a legal system that threatens about the development of key patient safety concepts such as Just Culture and psychological safety.

Below is a schematic diagram that shows and provides the structure and process of the medical harm reporting approach in Libyan healthcare.

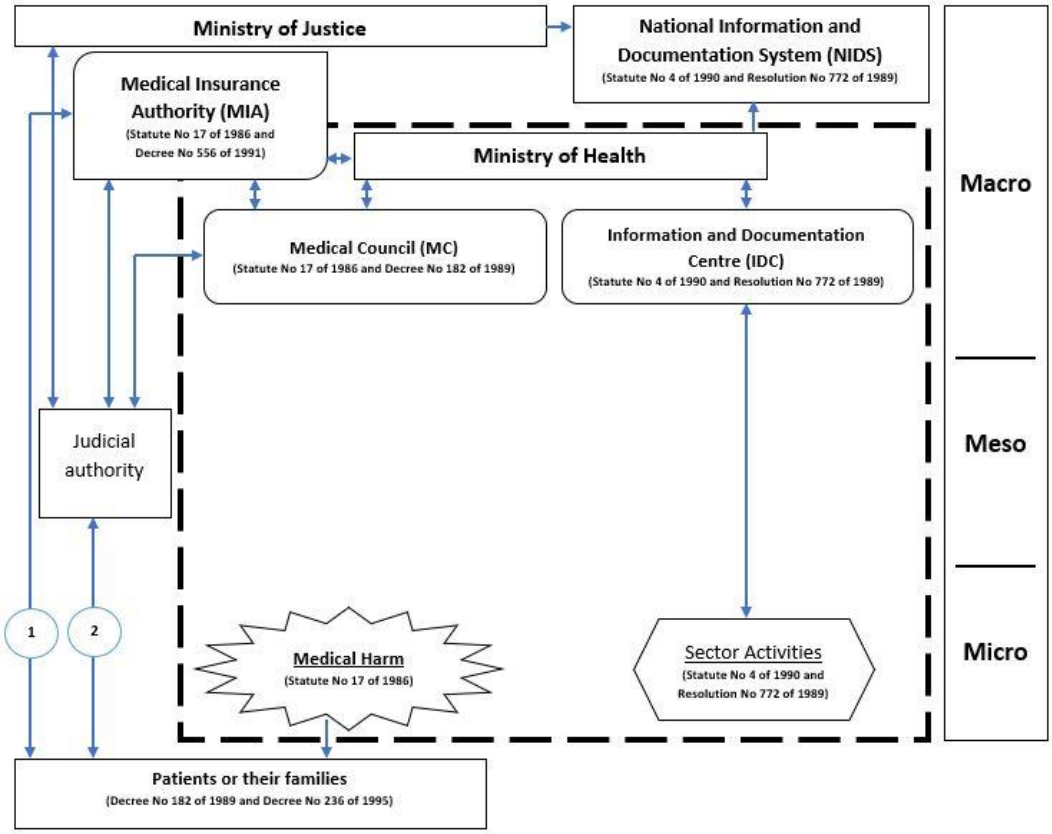

Figure 4-4 Reporting Process According to the Libyan Healthcare Policy

The stippled frame in the shape of a square illustrates the borders of the healthcare sector in Libya. The left, top and bottom sides of the stippled frame demonstrate the involved actors. The right side is the three levels (Micro, Meso and Macro). The arrows explain the process and connections between actors and events. The one-direction arrows mean data flowing in one direction and the two-direction arrows indicate data flowing between actors.

Medical harm is the beginning of a reporting process, and they occur within the borders of the healthcare sector. In the legal approach, patients and their families are stipulated to report medical harm and obtain feedback and decisions through judicial authorities. Those authorities transfer the medical harm case and remain in contact with the MC and the MOJ. The MC reviews cases of medical harm and creates a detailed technical report to determine whether healthcare providers are liable for such harm. Following this, the judicial authorities receive the detailed technical report about the medical harm to adjudicate whether the patient is entitled to compensation or not. It is important to mention that

according to statute No. 17, mainly the judicial authorities are not permitted to punish healthcare providers for the medical harm they cause to patients. There are specific disciplinary penalties, in Statute No. 17, Article 30, that can be applied to healthcare providers through a disciplinary trial, which can be established based on a decree from the MOH or whomever it delegates to do so (Statute No. 17, Articles 28 and 29). In summary, the case of medical harm is usually established by medical expert testimony. The MC does not adjudicate or decide on medical harm in terms of compensation or applying disciplinary penalties. Instead, it offers a detailed technical report that determines whether healthcare providers are liable for medical harm. This detailed technical report from medical experts is offered to the judicial authorities who can then adjudicate whether a patient has the right to compensation due to the medical harm they suffered. Subsequently, the minister of health can decide whether healthcare providers need to undergo a disciplinary trial due to the medical harm they caused.

Moreover, patients and their families can report medical harm in the civil approach to the technical department of the MIA. The MIA acts as the first point of contact (similar to judicial authorities) to receive reports from patients about medical harm and compensates patients for the harm they suffered. The income of the MIA comes from the mandatory insurance for healthcare staff and the MOH budget, which is imposed by statute No. 17. The insurance is meant to protect healthcare staff from risks associated with practising medical and paramedical professions which can cause harm to patients.

Sector activities (activities of the healthcare sector) follow a linear reporting process. The healthcare activities can be reported from frontline staff to senior managers. However, there is no clarification about what healthcare activities should be reported via this system and no policy has clarified the meaning of "healthcare activities". For example, can frontline staff report patient safety incidents via this system?. The IDC has the right to conduct a plan for obtaining data regarding the sector's activities.

The MOH manages the MC and the IDC both financially and administratively. However, the MOH only plays an administrative role for the MIA, which is an independent body in terms of financial disclosure. Therefore, it is shown in the left corner of the stippled frame, not entirely within or outside of the healthcare sector.

This, to my knowledge, is the first time a ‘mapping’ of the policies has been produced regarding the patient safety incidents reporting approach in Libyan healthcare.

4.6 Conclusion

Initially, patient safety policies in Libyan healthcare are framed by a legal perception. Reporting patient safety incidents are limited to medical harms which have been stipulated to be reported by patients or their families. Reporting medical harm significantly focuses on a legal approach, which seeks to apply medical liability to healthcare providers and relevant redress for patients and families who suffered medical harm. Of importance to patient safety in a Libyan context is that there is no evidence that healthcare staff participate in reporting patient safety incidents and also there is no clear mechanism for individual or organisational learning to occur during or following the current reporting process. The legal reporting approach of reporting medical harm may be a barrier to reporting and learning system which will negatively affect patient safety in the Libyan healthcare sector. Libyan healthcare sector currently falls short of the WHO policy recommendations for patient safety and patient safety incidents reporting and learning system.

In addition, it is worth mentioning that conducting this policy analysis faced challenges and limitations. Conducting policy analysis requires a professional person with appropriate skills in law, Arabic language and English language, and mutable knowledge about the healthcare sector, patient safety and management. The translation and interpretation of statutes is a critical issue regarding safety. Some contents of the policy were analysed word by word and sometimes this required the use of dictionaries (both English and Arabic) because the meaning of words in some contexts is strong and does not have an equivalent in English (a group of two or more words could include a subject or/and a necessary predicate). Libyan statutes have been written in the high-standard language. The meaning, word's position in a sentence and the use of grammar can change the context and gives more than one meaning from the perspective of safety. The use of words and grammar in addition to the structure and style of writing were at a very high level. Some contents of the policy are ambiguous and impose a challenge to interpretation. Some sentences are written in a language that opens to more than one interpretation or has a double meaning, so the translation and interpretation can be done in different ways.

Furthermore, legal texts can be particularly challenging due to their complex language and specialised terminology. The structure and style of the Libyan statutes were ambiguous, prompting me to compare translations of this statute from various sources. I sent several articles from the Libyan statutes to two translation offices—one in London and the other in Italy—as well as to a colleague in Saudi Arabia. Including my own translations, there were four versions in total. Each translation varied significantly, resulting in entirely different interpretations. Consequently, I decided to adopt my translations and analyse the related data through a structuralist perspective, incorporating my experience and knowledge of safety.

Lastly, some healthcare policies in the EMRO region are comparable to those in the Libyan healthcare context, particularly regarding medical liability policies. However, the majority of references were in Arabic rather than English. Consequently, these references were excluded, as including them would require additional time for translation.

4.7 Chapter Summary

This policy analysis only provides insights into how things appear on paper and websites. To better understand patient safety, the issue of reporting and learning and how to approach the future this study collected data from key stakeholders and organisations operate within this policy context at the macro level, to see whether interventions and processes are occurring that are not covered in the policies or that have been created in the absence of national policy. The following three chapters are a practical exploration of the PSI-RLS in Libya and the state of healthcare providers regarding the reporting and learning from patient safety incidents.

5 CHAPTER FIVE – Findings: Theme One

5.0 Introduction

As outlined in Chapter 3, this study employed a qualitative design in which data were collected from participants through semi-structured interviews. This chapter aims to address the first research question: "What are key healthcare policy stakeholders' perceptions and attitudes towards patient safety?". This research question is combined into the first objective of this research.

This chapter begins with Table 5.1, which presents the pseudonyms of the participants and stakeholders involved in the reporting process, along with their roles and duties. This is followed by Figure 5-1, which summarises the themes and subthemes identified in the study. The first theme, along with its three subthemes, is then presented. A chapter summary was placed in the end.

Table 5-1 Pseudonyms of Participants and Description of Stakeholders

Pseudonym	**Stakeholders Involved in the Reporting and Learning System**	**Roles and Duties of Stakeholders**
1. Zahra **2. Mohamed** **3. Ibrahim** **4. Fawzia** **5. Fadia** **6. Al Sanusi** **7. Mahmoud** **8. Abdallah** **9. Khalid** **10. Jalal** **11. Massoud** **12. Tareq** **13. Nour**	Ministry of Health (MOH)	Providing healthcare services all over the state.
	▪ Information and Documentation Centre (IDC).	➢ Under the supervision of the MOH. ➢ Collecting information from healthcare institutions.
	▪ Quality and Patient Safety Directorate.	➢ Under the supervision of the MOH. ➢ Ensuring quality and patient safety within healthcare facilities.
	▪ Medical Council (MC).	➢ Under the supervision of the MOH.

		➢ Receiving the medical harm reports that are reported by patients from Judicial Authorities and Medical Insurance Authority. ➢ Reviewing medical harm reported by patients in order to determine medical liabilities.
	Training bodies: ▪ Medical Manpower Development Center. ▪ Medical Training Deanery Board. ▪ Libyan Board of Medical Specialities.	➢ Under the supervision of the MOH. ➢ Providing training courses for healthcare staff.
14. Musa **15. Abu al-Qasaim** **16. Al Zuwy**	Medical Insurance Authority (MIA).	➢ Financially independent, and administratively affiliated with the MOH. ➢ Receiving medical harm reports directly from patients. Patient reporting process via civil avenue. ➢ Making reconciliations with patients regarding medical harm. ➢ Compensate patients regarding medical harm.
17. Salah		➢ Independent body.

18. Ali	General Health Council (GHC).	➢ A newly established body aims to be responsible for the regulation of the health workforce making sure that practitioners are adequately qualified to practice and therefore ensure patient safety and service quality.
Judicial Authorities (Judiciary)		➢ Independent Authorities. ➢ Receiving reports from patients regarding medical harm. Patient reporting process via legal avenue. ➢ Communicating with the medical experts in the Medical Council to obtain clarification of what happened regarding the medical harm. ➢ Making a decision about whether the patient has the right to compensation or not.
Occupational Trials		➢ This trial can only be established by a decree from the Ministry of Health. ➢ Conducting disciplinary trials and enforcing disciplinary penalties according to statute No. 17. ➢ Making a formal decision about the appropriate disciplinary penalties for healthcare providers who cause medical harm.

The findings chapters present the results of the analysis of qualitative data collected through semi-structured interviews with staff involved in reporting patient safety incidents from eight stakeholders. During the interview process, participants discussed their perceptions and experiences of PSI-RLS. The aim of this phase was to capture individual perceptions, opinions, views, and experiences in order to gain an in-depth understanding of patient safety and PSI-RLS. The participants included eight stakeholders involved in reporting patient safety incidents. Although no participants from judicial authorities were interviewed, as they belong to a different sector, they are nonetheless key stakeholders in reporting medical harm.

The findings of the semi-structured interviews are divided into three main chapters, each addressing a new theme. These three core themes primarily explore the perception of patient safety and PSI-RLS at the macro-level of the Libyan healthcare sector. The various themes and subthemes were categorised to provide an understanding of the stakeholders' perceptions of patient safety and incident reporting practice in Libya.

Cultural and social factors were considered to be the main overarching theme as most participants' accounts featured a dialogue about the effect of social and cultural factors on patient safety and PSI-RLS. There are positive and negative social and cultural factors that affect PSI-RLS in Libyan healthcare. Social and cultural aspects were noticeable in the perception and opinions of participants towards patient safety practice in the Libyan context. The analysis revealed the existence of one main overarching theme of cultural and social factors with three themes.

This chapter introduces the first theme, which is 'Perceptions and Attitudes Toward Patient Safety', and includes three subthemes: 'Patient Safety and Law', 'Patient Safety and Stakeholders' Responsibility' and 'Patient Safety and Quality'. Chapter six introduces the second theme, which is "Perceptions and Attitudes Toward Patient Safety Incidents Reporting and Learning System in the Libyan Healthcare Context" and includes two subthemes: "Reporting Patient Safety Incidents in the Libyan Healthcare Context" and "Learning from Patient Safety Incidents in the Libyan Healthcare Context". Finally, Chapter seven presents the third theme, "Organisation of the Healthcare Sector" which

encompasses two sub-themes: “Politics and policies” and “Organisational system”. A summary of the main overarching theme, three themes and their corresponding sub-themes is presented in Figure 5-1.

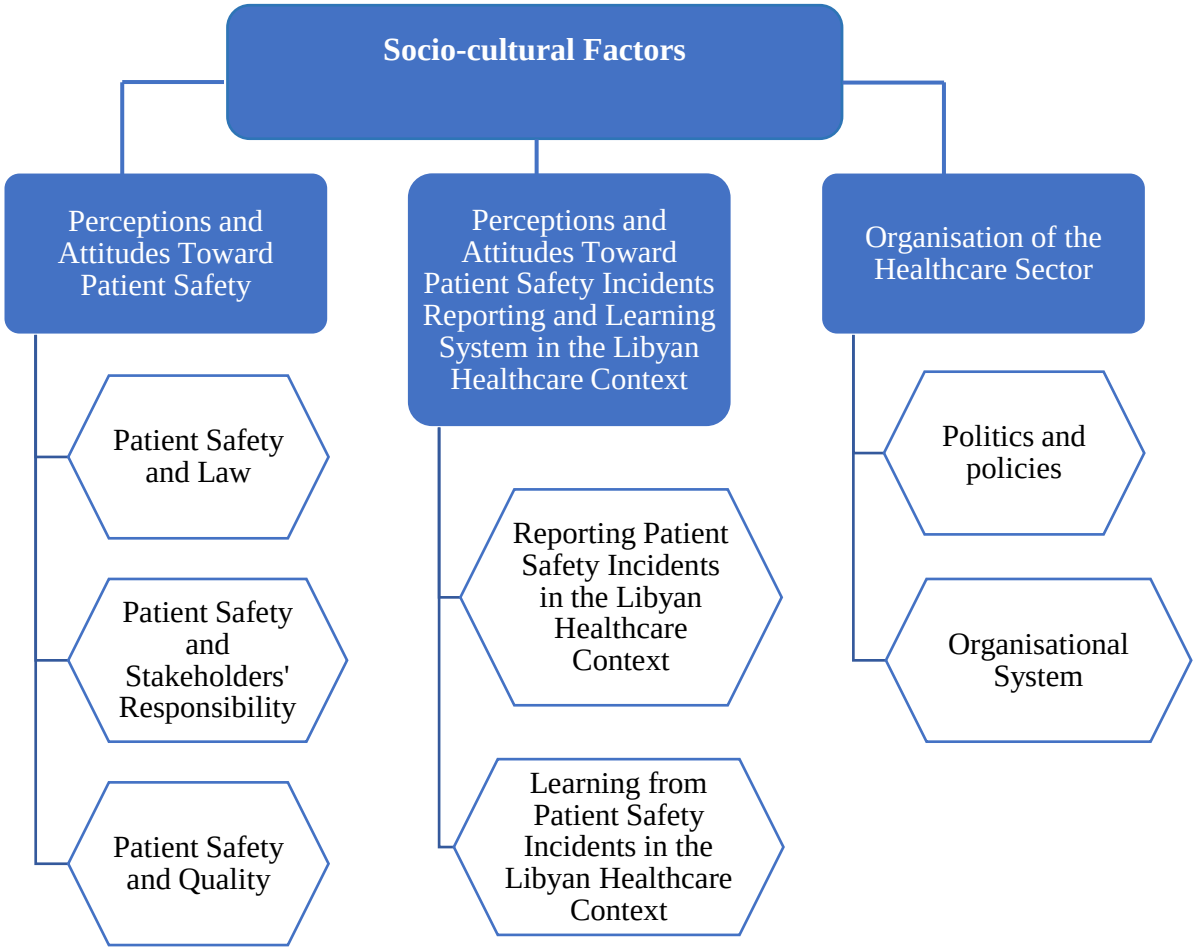

Figure 5-1 Summary of Themes and Subthemes

5.1 Theme One: Perceptions and Attitudes Toward Patient Safety

Key healthcare policy stakeholders in Libya have different perspectives on patient safety based on their individual experiences. Patient safety was described as a public health issue that touches everyone and requires solidarity in addition to laws and oversight, while others view patient safety as a branch that should be linked to the quality of healthcare services. Based on these perspectives and opinions, three subthemes are created to best present the perspectives of key healthcare policy stakeholders regarding patient safety.

- Subtheme One: Patient Safety and Law.
- Subtheme Two: Patient Safety and Stakeholders' Responsibility.
- Subtheme Three: Patient Safety and Quality.

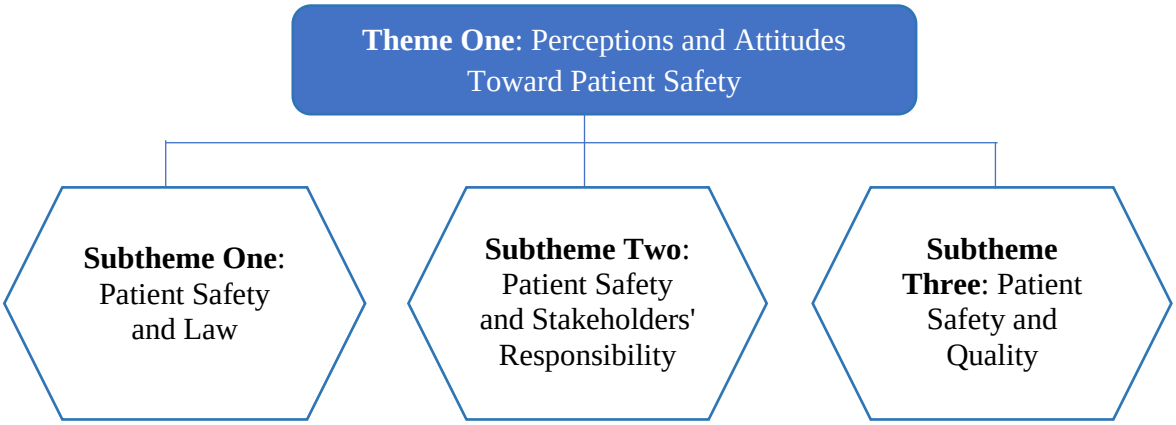

Figure 5-2 Schematic Diagram of Perceptions and Attitudes Toward Patient Safety among Libyan Healthcare Stakeholders

5.2 Subtheme One: Patient Safety and Law

Many participants tend to view patient safety through a legal perspective rather than an ethical one. There was widespread discussion among participants regarding the impacts of law on patient safety. Interviewees discussed their experiences with the statute of medical liability and the consequent effects on patient safety and healthcare staff.

> *Law No. 17 is a strong law that regulates the relationship between healthcare providers and people who receive the services. The law protects the rights of both parties. We are in the process of amending this law because, for more than 30 years of practice, some paragraphs have been observed that need to be added,*

*paragraphs that need to be amended, and paragraphs that need to be changed (**Mahmoud**).*

The interviewee highlights the significance of law No. 17 as a robust legal framework that governs the interactions between healthcare providers and patients. The statement also indicated that law No. 17 protects the rights of both parties, which means that it provides a framework for ensuring that both healthcare providers and patients are treated fairly, and their rights are respected. However, the participant also acknowledges that law No. 17 has been in practice for more than 30 years, and after a long time of its implementation, certain paragraphs within the law require revision to better serve the needs of its intended beneficiaries. Therefore, the statement indicates that there is a process underway to amend law No. 17, with the goal of improving its effectiveness and ensuring that it continues to provide a strong framework for regulating the relationship between healthcare providers and patients.

In addition, Ibrahim states that:

*Libya was at the time one of the first countries to adopt the issue patient safety, and law No. 17 was a shift. It was an actual shift for both patients and staff. The medical staff have recognised that it is a law. By the way, this law is not only to protect patients and against medical staff, on the contrary, the issue was organised to protect the rights of both, and it is sufficient that the law admits that medical error may happen, and for this, medical errors are not a criminal act. The medical staff mentality has changed, and since the issuance of this law, all the procedures have become clear, well -known and explicit (**Ibrahim**).*

This law recognises that medical errors can happen and that healthcare professionals are not necessarily committing a crime when such errors occur. Instead, it takes a more nuanced approach to medical malpractice and seeks to understand the errors, rather than immediately punishing those involved. Change in mentality can help to reduce the fear and stigma that medical professionals may experience when things go wrong. When medical errors occur, it is often not because of malicious intent on the part of the healthcare professional, but rather due to a complex set of circumstances and factors that may be beyond their control. Since the passage of this law, all procedures have become more

transparent and well-known, which can help to prevent misunderstandings and confusion. Overall, this law has helped to organise things and make them more understandable for everyone involved.

Jalal states that:

> *When Health Law No. 06 and Law No. 17 of 1986 were issued, there was a very very very big part of them as an attempt to reduce medical errors and ensure the maintenance of patient safety by all parties involved (**Jalal**).*

Jalal mentions two specific health laws, namely Health Law No. 06 and Law No. 17 of 1986, which were issued with the aim of reducing medical errors and ensuring patient safety.

Box 5-1: Reflective memos

All citations under this subtheme agree that laws are crucial for patient safety, particularly Law No. 17. Initially, I struggled to organise the citations because I could not discern who supported, opposed, or was neutral about these laws. After reviewing the related codes again, I realised that laws benefit both patients and healthcare providers, as they share the responsibility for the safety of patients.

5.3 Subtheme Two: Patient Safety and Stakeholders' Responsibility

There is a belief among some interviewees that patient safety is a critical concern in healthcare that needs solidarity among healthcare providers, patients, and their families in order to achieve patient safety.

Jalal perceives the healthcare sector as a responsible entity for patient safety as claimed below:

> *The Libyan healthcare sector is directly responsible for patient safety. The Libyan healthcare sector greatly appreciates this responsibility. The proof of this is the establishment of a specific institution for quality assurance called the Health Institutions Accreditation Corporation (**Jalal**).*

Khalid also argues that everyone in the healthcare sector is responsible for patient safety.

> ***HJ:*** *Who is supposed to care about patient safety? Or who should be responsible for patient safety?*
>
> ***Khalid:*** *When we talk about patient safety as a principle, it is the responsibility of all those who serve in the healthcare sector, starting from the minister to each healthcare institution, healthcare administration, and ending with the person responsible for hygiene. Everyone directly or indirectly impacts the safety of the patient, and this depends on the degree of contact that person has with the patient.*

Khalid claims ensuring the safety of patients is the collective responsibility of all individuals and entities involved in the healthcare sector. This includes not only the minister or high-level officials but also encompasses healthcare institutions, healthcare administration personnel, and even individuals responsible for hygiene practices.

Khalid emphasises that every person, regardless of their role, directly or indirectly affects the safety of the patient. This means that actions and decisions made by individuals at any level of the healthcare sector can have an impact on patient safety. The extent of the impact may vary depending on the level of contact a person has with the patient. For instance, the minister or high-level officials have the responsibility of setting policies that promote patient safety. Healthcare institutions play a crucial role in implementing these policies and providing a safe environment for patients. Even individuals responsible for hygiene, such as cleaning staff, contribute to patient safety by maintaining a clean and infection-free environment.

Overall, Khalid underscores the shared responsibility of all individuals in the healthcare sector for ensuring patient safety. It emphasises that everyone, from the top-level decision-makers to those in direct contact with patients, has a role to play in patient safety.

> ***HJ:*** *According to your experience, who should be responsible for patient safety in the Libyan healthcare sector?*
>
> ***Salah:*** *The last person to be blamed for patient safety is the patients themselves. Patients may be blamed for not following the instructions provided by healthcare*

providers, who are the final line of defense in protecting patients. However, we should not solely blame the patients, as they may sometimes be unconscious or unaware of the importance of the healthcare services and might unknowingly put themselves at risk. Therefore, even if the patient fails to follow the instructions of healthcare providers, we cannot attribute the medical incidents solely to the patient. The responsibility also lies with the Ministry of Health, which is responsible for providing healthcare services and should focus on spreading awareness and health education. Thus, there is solidarity and shared responsibility among everyone involved, and it would be incorrect to pinpoint a single person as solely responsible for patient safety.

Salah says that patient safety is a collective responsibility that involves the patient, healthcare providers, and the healthcare sector. Blaming the patient alone oversimplifies the issue and disregards the contributions and responsibilities of other involved parties involved. Salah suggests that while it is important for patients to follow instructions provided by healthcare providers, there are various factors that can contribute to patients not adhering to these instructions. As Salah mentions, patients may be unconscious, unaware, or may not fully understand the importance of the instructions given. In addition to the patient's responsibility, healthcare providers also play a crucial role in ensuring patient safety. Furthermore, the healthcare sector and regulatory bodies, such as the MOH, have a responsibility to prioritize patient safety.

HJ: *Okay... Doctor, I would like to ask you about patient safety, from your point of view, who should take care about patient safety?*

Al Sanusi: *Technically, the general concept of patient safety is always related to the quality of service. However, policymakers perceive patient safety as a broad theoretical concept, somewhat separate from the delivery of quality services. This means that it does not solely pertain to the healthcare providers. Patient safety encompasses everything and everyone in the healthcare sector, starting from policies to the final link in the chain of authority or governance in primary healthcare, which is responsible for delivering services to patients. It also includes*

devices, equipment, and buildings that contribute to the provision of services to patients.

Al Sanusi highlights the relationship between patient safety and the quality of healthcare services. While the two concepts are closely connected from a technical standpoint, policymakers often view patient safety as a distinct theoretical concept, somewhat detached from the overall delivery of quality services.

Patient safety encompasses a broad range of factors and extends beyond the actions of healthcare providers alone. It encompasses various elements within the healthcare sector, including policies, governance structures, and the overall chain of authority in primary healthcare. This implies that ensuring patient safety is the responsibility of all stakeholders involved in delivering healthcare services. Furthermore, patient safety encompasses not only human factors but also the physical aspects of healthcare environments. It includes devices, equipment, and buildings that play a role in providing services to patients. These physical components can be designed, maintained, and utilised in a manner that minimizes risks and promotes patient safety.

In summary, patient safety is an all-encompassing concept that goes beyond the actions of healthcare providers. It includes policies, governance, and the physical elements of healthcare environments. All these aspects can work together to ensure patient safety and the delivery of high-quality.

Zahra argues that the responsibility for the safety of patients primarily begins with doctors, as they are responsible for their patient's safety. Her perspective is outlined below:

HJ: *From your point of view, who is primarily responsible for patient safety?*

Zahra: *In the first place, doctors are responsible for the safety of their patients.*

HJ: *okay…. Why doctors are primarily responsible?*

Zahra: *Because they are the ones who receive the patients and diagnose their condition. The doctor is responsible for deciding whether to admit the patient to the hospital or provide care at their home. Additionally, the doctor is responsible for prescribing medication to patients.*

5.4 **Subtheme Three: Patient Safety and Quality**

Patient safety was linked to the quality of healthcare services as stated by two participants Abdallah and:

> *"Let me give you a background of what is happening. Of course, quality in general in the Ministry of Health is centred on patient safety, which is relatively new. In 2009 there was a department that was not working effectively in the past. Four directors of departments passed through it, three of them were excellent, but the concept itself was new, and they used a Libyan quality tool for the accreditation of health institutions, and this tool was divided into four groups: Patient care, Patient safety, Governance and Social responsibility, and it is clear that patient safety is part of quality". (**Abdallah**).*

The quote provides background information on the association between the quality of healthcare services and patient safety in the MOH. The interviewee states that quality in general is focused on patient safety, which is a relatively new concept in Libyan healthcare. This quote highlights the importance of patient safety and the efforts made by the MOH to improve the quality of healthcare services.

Furthermore, Fadia has joined patient safety to the quality of the healthcare services as the other healthcare sectors do.

> *The original specialty of the Ministry of Health is patient safety. This is their priority, and this is their direct specialty. According to the policy, the Quality and Patient Safety Directorate is supposed to be like what the other world works, and the original specialisation of the Quality and Patient Safety Directorate is everything related to the quality of services, patient satisfaction and maintaining his safety, the world goes like this (**Fadia**).*

Box 5-2: Reflective memos

Reflecting on the belief that patient safety requires solidarity among healthcare providers, patients and families, it becomes clear that collaboration is essential. It could be argued that the laws can inexplicitly enhance the need for teamwork among Libyan healthcare providers. This unity fosters a culture of trust and accountability, crucial for high-quality care. Patient safety is inherently tied to the quality of healthcare services, as it ensures that care is effective, efficient, and centred on the patient's well-being. Continuous solidarity and teamwork are vital to achieving patient safety and healthcare quality.

5.5 Chapter Summary

The main themes and subthemes that emerged from the interviews are outlined in this chapter. This chapter addresses the first research question by exploring the first theme, which includes three subthemes. Many participants view patient safety primarily through a legal lens, focusing on compliance with laws designed to prevent harm. Some interviewees emphasized the importance of solidarity among healthcare stakeholders, believing that patient safety is a collective responsibility requiring cooperation and coordination. Another group associated patient safety with the overall quality of healthcare services, arguing that it is integral to providing high-quality care.

6 CHAPTER SIX – Findings: Theme Two

6.0 Introduction

This chapter aims to address the second and third research questions: "What are the consequences of stakeholder perceptions and attitudes of reporting and learning from patient safety incidents?" and "What are the current processes and systems for reporting and learning from patient safety incidents at the national level?". Both questions are integrated into objectives one and two of this research. The second theme derived from the data provides insights into these two research questions. This theme is titled: "Perceptions and Attitudes Toward Patient Safety Incidents Reporting and Learning System in the Libyan Healthcare Context". The researcher delves into two sub-themes that emerged from the second theme. As the chapter progresses, each of these sub-themes will be further explored under headings and their sub-headings. To begin, a brief overview of the second theme will be presented, followed by an in-depth exploration of the two associated sub-themes. Finally, the chapter will conclude with a summary of the second theme.

6.1 Theme Two: Perceptions and Attitudes Toward Patient Safety Incidents Reporting and Learning System in the Libyan Healthcare Context

This theme explores the perceptions and attitudes of key healthcare policy stakeholders towards the patient safety incidents reporting and learning system at the macro-level in Libya. Based on the data gathered from interviewees, there has been a predominant focus on reporting patient safety incidents, with little emphasis on learning from these incidents. As a result, the collected data within this theme is categorised into two distinct subthemes, as shown in Figure 6.1 below.

- Subtheme One: Reporting Patient Safety Incidents in Libyan Healthcare Context.
- Subtheme Two: Learning from Patient Safety Incidents in the Libyan Healthcare Context.

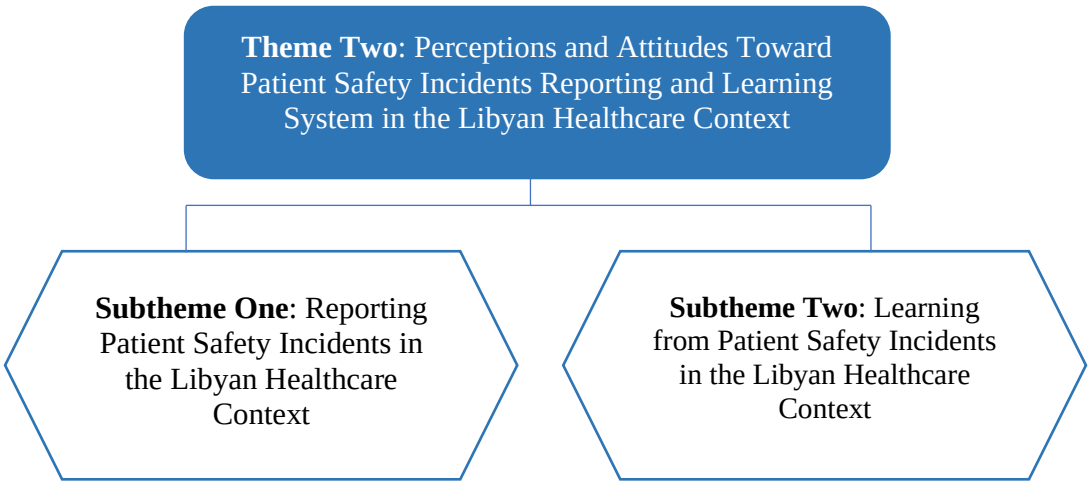

Figure 6-1 Schematic diagram of perceptions and attitudes explored among Libyan stakeholders toward PSI-RLS

Before introducing subtheme two which is about the perceptions and attitudes of key healthcare policy stakeholders regarding the learning from patient safety incidents, the following presentation will include insights on the reporting of such incidents.

6.2 Subtheme One: Reporting Patient Safety Incidents in Libyan Healthcare Context

Many participants believe that patient safety incidents can be reported by two main groups: patients and healthcare personnel. Therefore, the dialogues among participants about reporting patient safety incidents are organised under two key headings, as illustrated in Figure 6-2 below.

- Reporting patient safety incidents by healthcare staff.
- Reporting patient safety incidents by patients.

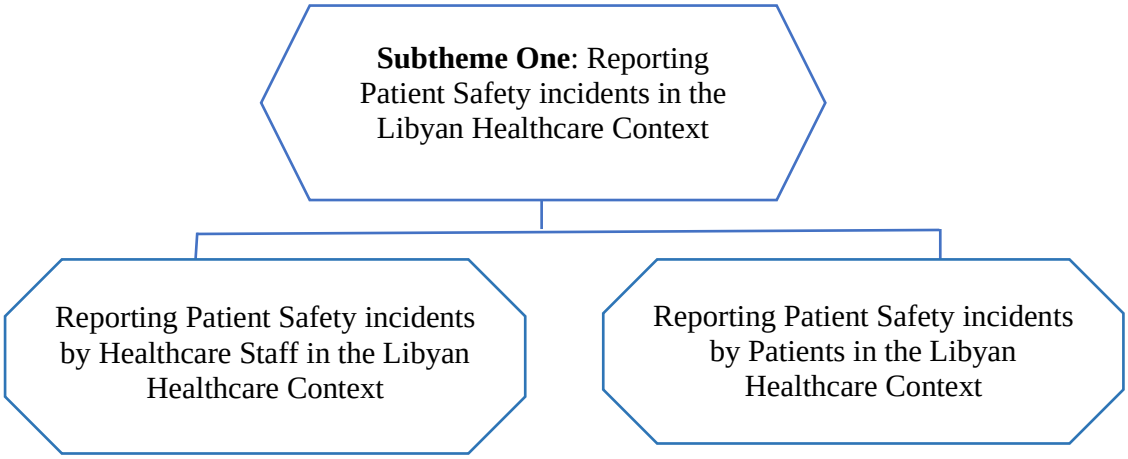

Figure 6-2 Schematic diagram illustrates the states of reporting patient safety incidents in the Libyan healthcare context

The following section explains six factors that influence healthcare staff in Libya to report incidents related to patient safety.

6.2.1 Reporting Patient Safety Incidents by Healthcare Staff in the Libyan Healthcare Context

There was a consensus among participants that there is no official reporting system at the national level for healthcare staff to report patient safety incidents. The Libyan MOH does not have a national reporting system for healthcare staff to report such issues. Although this research is to explore the patient safety incidents reporting and learning system at the macro-level. However, several participants have drawn attention to the reporting process at the institutional level or meso-level. This heading is further explored under six sub-headings as illustrated in Figure 6.2.

I. Ethical Perspectives.
II. Fear of Legal Repercussions.
III. Lack of Awareness.
IV. Tarnish to Reputation.
V. Safety and Security of Healthcare Staff.
VI. Reporting Patient Safety Incidents by Libyan Healthcare Staff at an Institutional Level.

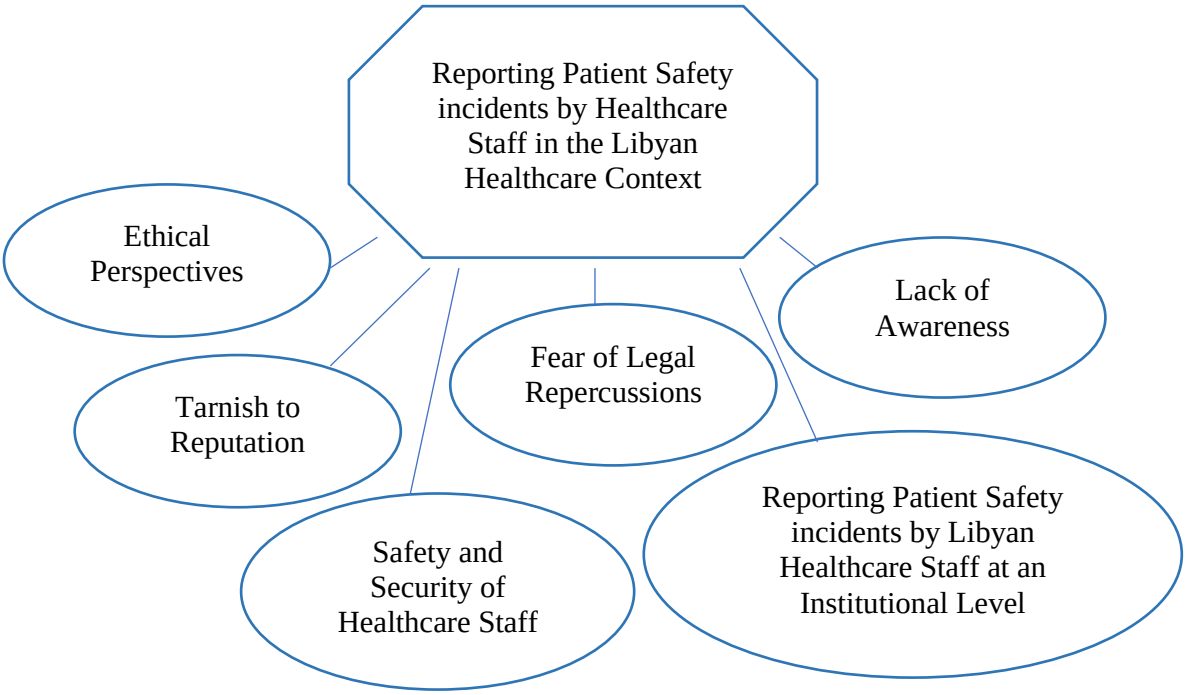

Figure 6-3 Schematic diagram illustrating the key perceptions and attitudes of reporting patient safety incidents by healthcare staff explored among stakeholders.

The perceptions and opinions of the participants regarding reporting patient safety incidents at the institutional level will be presented later, following the exploration of the following five sub-headings.

6.2.1.1 Ethical Perspectives

There is a strong emphasis on professional ethics within the medical field for reporting patient safety incidents by healthcare staff. Some participants believed that reporting patient safety incidents is an ethical matter left to the conscience healthcare staff. The following statements clarify this perspective.

> *Admitting or reporting incidents related to patient safety is completely based on ethical grounds. Currently, there are no established procedures to penalise doctors for their errors. However, addressing medical harm is handled by other parties in accordance with the law (**Al Zuwy**).*

Al Zuwy states that the decision to admit or report patient safety incidents is rooted in ethical considerations. This suggests that individuals should have a sense of ethical responsibility when it comes to reporting and addressing patient safety incidents. Al Zuwy highlights the importance of prioritising ethical responsibility when reporting patient safety incidents. He also mentioned that there are no punishment procedures as reactions to medical errors. In addition, addressing medical harm is overseen by stakeholders according to the law. Al Sanusi added that:

> *When it comes to professional ethics, healthcare providers are supposed to be attentive to the subject of reporting patient safety incidents. If a healthcare worker wants to correct himself, acknowledge his errors, and file a report, it becomes an individual or personal matter that concerns the person. It involves his education level, professional degree, and the oath they have taken. Medical harm may be due to negligence or unexpected complications, and admitting errors is an ethical action. As far as I know, there is no specific law governing this issue, but medical and paramedical unions may have their own guidelines regarding it (**Al Sanusi**).*

Abu al-Qasaim emphasises that reporting patient safety incidents is an ethical matter for medical and paramedical staff.

> ***HJ:** In Libya, I believe that the patient is the one who should report medical harm, do you think healthcare staff such as doctors, nurses, or radiology technicians can admit that they made errors or harm? Let me be clear: in Libya, the right to report medical harm is granted to patients. However, if medical harm occurs and the patient does not want to report or complain, and staff members like nurses have witnessed or noted the harm, can they report this harm?*
>
> ***Abu al-Qasaim:** reporting incidents depends on the ethics of the professionals. If a doctor, nurse, or technician is virtuous and recognises that they work in the medical field dealing with human beings like themselves, then they should report patient safety incidents. After all, they themselves may one day be on the receiving end of medical care. Medical professionals themselves may one day fall under the scalpel. Therefore, they should be wise and capable of understanding the*

consequences of reporting incidents related to patient safety. Based on this, healthcare staff are supposed to report such issues.

HJ: *Does this mean that there are no legal impediments to reporting patient safety incidents?*

Abu al-Qasaim: *Listen, medical staff, including nurses, imaging technicians, and surgeons performing procedures on the heart or brain, are all required to prepare reports. Each person has a role in preparing a report. For example, doctors should write a comprehensive report to help nurses follow up on the patient's pathological condition after leaving the doctor's care. Everything is expected to be documented in the patient's file.*

In the first answer, Abu al-Qasaim highlights the importance of ethical behaviour and the responsibility of professionals in reporting patient safety incidents. He suggests that doctors, nurses, and technicians should possess virtuous qualities and acknowledge that they are dealing with fellow human beings who deserve proper care. Recognising their own vulnerability as potential patients, they should be motivated to report any incidents or problems they observe. Moreover, the idea behind this perspective is that medical professionals should be wise and capable of understanding the potential consequences of reporting patient safety incidents by prioritising the concept of safety first. By reporting incidents, they contribute to safe care and help prevent harm to patients. The belief is that if these professionals ever find themselves in need of medical attention, they would expect the same level of care and responsibility from their colleagues.

In the second response, Abu al-Qasaim did not provide a direct and clear answer to the question. He did not explicitly state whether there are legal impediments to reporting patient safety incidents by staff, giving neither a "yes" nor a "no" response.

In essence, there is a strong emphasis on professional ethics within the medical field for reporting patient safety incidents by healthcare staff. The statement emphasises the moral obligation of medical professionals to act in the best interests of their patients. While there may not be explicit legal impediments to reporting, Abu al-Qasaim suggests that reporting

problems is an integral part of the staff's duty and underscores the importance of ethics in guiding their behaviour.

Abdallah and Fawzia argue that there is a concern among healthcare staff regarding patient confidentiality when reporting patient safety incidents.

> ***HJ:*** *What is the impediment that prevents medical staff from reporting patient safety incidents?*
>
> ***Abdallah:*** *Healthcare staff worry about patient confidentiality when they want to report patient safety incidents or issues. Because there is interference with patient privacy which hinders the reporting or documentation of patient safety incidents by doctors.*

In addition, Fawzia highlighted patient privacy as a barrier to reporting patient safety incidents by healthcare staff.

> *Patient privacy becomes problematic when healthcare staff want to report medical errors or patient safety incidents, particularly for patients with sexual problems or communicable diseases. Patients are afraid that they might be identified in the report, and this is a social-cultural issue prevalent in Libya's healthcare sector (**Fawzia**).*

According to the two above statements, healthcare staff are worried because they understand the importance of maintaining patient confidentiality while also recognising the need to report and address patient safety incidents.

6.2.1.2 Fear of Legal Repercussions

Jalal argues that the fear of legal consequences can be a reason for the reluctance of healthcare staff to report errors or patient safety incidents, as typified in the following account:

> *There is a problem of greed, and the hospital will be exposed to extortion. These patient safety incidents, which should serve as learning opportunities, may be used as a basis for lawsuits. Lawyers will sue for these issues, and healthcare staff will be subjected to abuse and questioning. The main obstacle to reporting*

*patient safety incidents is the fear of health facilities and doctors "to spread their laundry" and they do not want to open the door to problems. So, it is better to be concealed, that is it. This is between me and the God of the Worlds, after which my God will judge me, God is Forgiving and Merciful (**Jalal**).*

Mahmoud also has a legal perspective on non-reporting patient safety incidents. Mahmoud supports Jalal's opinion regarding the fear of legal consequences if healthcare staff report medical harms or errors.

***HJ:** Do you think it is necessary for doctors or medical staff to report medical harms that occur if the patients did not report or sue for these medical harms?*

***Mahmoud:** This is not possible because the doctor cannot put himself in a lawsuit case or sue himself for the medical harm he caused, and therefore condemns himself for causing medical harm when the patient did not report or sue about the medical harm.*

Fadia also holds a legal standpoint concerning the issue of non-reporting of medical harm in private healthcare institutions. She aligns with Mahmoud and Jalal's perspective regarding the apprehension of potential legal ramifications that healthcare institutions or healthcare personnel may face when reporting incidents that cause medical harm.

***HJ:** Well, let's talk about medical harms in the private sector. For example, a medical harm occurred in a private hospital during an operation. Should this harm be reported? and Who should report the harm, the doctor or the patient?*

***Fadia:** Usually, the doctor performing the operation does not admit the medical harms that he makes.*

***HJ:** Is it due to a cultural aspect or something else?*

***Fadia:** The reason doctors do not admit medical harms they make is because of the fear of facing legal action. Sometimes, these harms can even result in work suspension. But personally, I did not hear about someone who was suspended from his job because of medical harm.*

In addition, Fawzia has mentioned that healthcare staff fear punishment when reporting incidents, as she stated below.

> *There is a fear of reprisal or punishment for reporting safety incidents among medical and paramedical staff, which can discourage staff from speaking up or reporting (**Fawzia**).*

According to some participants, the fear of legal consequences acts as a barrier to reporting patient safety incidents among healthcare staff at the hospital level. Additionally, a lack of awareness is mentioned as another barrier to reporting these incidents, as clarified below.

6.2.1.3 Lack of Awareness

Some participants highlighted the lack of awareness as an issue for implementing the PSI-RLS in Libyan healthcare. The following deluge can show that.

> ***HJ:** Do you think the reporting and learning system regarding patient safety incidents exists in Libyan healthcare? Do you have any idea about this system, or have you heard about it at the Ministry of Health?*
>
> ***Khalid:** As a system applied in all healthcare institutions, this does not exist. The reason is the lack of awareness of this concept by the majority of workers in healthcare institutions or even decision-makers in the Ministry of Health.*

Khalid declares that the reporting and learning system is not uniformly implemented across all Libyan healthcare institutions. The primary reason for this absence is the lack of awareness about this concept among the majority of workers in healthcare institutions, including those in decision-making positions. Essentially, many people working in Libyan healthcare institutions are not familiar with the reporting and learning system. They may not be aware of its benefits or how it can improve patient safety. As a result, they have not taken steps to implement it within their respective institutions.

While Khalid climes that the reporting and learning system is not applied in all Libyan healthcare institutions due to a lack of awareness among the majority of workers and

decision-makers, Al Sanusi confirmed that implementing such a system in Libya is related to the degree of awareness among staff in the healthcare sector, as he stated below.

> *Reporting and learning systems are related to the degree of awareness among healthcare staff and the maturity of the health system. Awareness is important, and the reporting system is essential for all parties. It is not limited to patients or doctors, as reporting is their duty (**Al Sanusi**).*

Fawzia asserts that a lack of awareness is one of several reasons why healthcare staff in Libya do not report patient safety incidents.

> ***HJ:** One important aspect of patient safety is the reporting of safety incidents. Could you speak about reporting patient safety incidents among healthcare staff in the Libyan healthcare sector?*
>
> ***Fawzia:** In my experience, I believe that the staff culture of reporting patient safety incidents in Libya is not as robust as it should be. There are several reasons for this. For example, there is a general lack of awareness and education about patient safety and the importance of reporting safety incidents.*

In addition, Jalal argues that there is a lack of awareness of the nature of medical incidents from society and individuals outside the healthcare sector. This makes healthcare providers hesitate to report medical harm.

> *Regrettably, our society lacks awareness of the nature of medical incidents. Greedy lawyers and individuals have been involved in the field of medical errors, prioritising financial gains above all else. It's important to raise awareness about medical errors. During a symposium, I emphasised that the moment medical harm is reported, it marks the beginning of punishment and the imposition of penalties. As a result, the valuable data about medical harm remains unreported by the healthcare providers (**Jalal**).*

Some participants considered tarnishing reputation as a reason for not reporting patient safety incidents, as stated by Zahra and Massoud.

6.2.1.4 Tarnish to Reputation

Zahra and Massoud have linked patient safety incidents to the reputation of healthcare professionals. According to both, medical staff perceive medical errors or patient safety incidents as negatively impacting their professional images. Zahra answers the researcher's question as shown below:

> ***HJ:*** *Is it important for doctors and medical staff to report patient safety incidents?*
>
> ***Zahra:*** *They are supposed to report incidents and learn from them in order to prevent the repetition of these incidents. However, medical staff are concerned about their reputation and professional image, so they often choose to conceal the incidents.*

Zahra claims that healthcare staff are expected to report incidents they encounter during their work. However, she also acknowledges that medical staff often choose to conceal incidents instead of reporting them to protect their reputation. Healthcare providers may be concerned about their reputation and the perception of their competence. They may fear that openly acknowledging incidents could tarnish their professional image. For example, private healthcare providers in Libya may believe that concealing errors is necessary to maintain a good reputation, which can help save their careers or businesses.

Additionally, Massoud supports Zahra's claiming as he stated below:

> *The basic principle of a doctor is to help patients and not intend to commit medical errors or harm. The doctor's goal is to take care of patients and establish a good reputation for themselves. Naturally, the doctor aims to stay away from reporting incidents as much as possible to gain a positive reputation among their patients and the general public (**Massoud**).*

Massoud states that the basic principle of a doctor is to treat patients and minimize the occurrence of medical errors. He suggested that avoiding medical errors is a crucial element in establishing and maintaining a good reputation. Medical professionals make efforts to avoid incidents in order to maintain a positive reputation among their patients and the general public.

6.2.1.5 Safety and Security of Healthcare Staff

The safety and security of healthcare staff is a significant concern in Libyan healthcare institutions. Many participants express their worries regarding the safety and security of healthcare personnel within their work environment when they report patient safety incidents. It appears that family members of patients could potentially pose a threat to the safety of healthcare staff. Moreover, there may be adverse repercussions from healthcare institutions' management when healthcare staff report patient safety incidents. Abdallah states that:

> *When doctors report or document information about patient safety incidents and someone else reads that report and informs the patient's family, it could potentially cause significant harm to the doctor who made the report. This scenario has occurred many times in Libya. Reporting patient safety incidents will create a real burden on staff. This burden, if not from the management of the healthcare facility, will be from the relatives of patients. This is very likely to happen (**Abdallah)**.*

Healthcare staff fear reprisals and confrontations with patient families and hospital management when reporting patient safety incidents. The specific example given by Abdallah illustrates that these concerns are not merely theoretical but have been observed in real-world situations.

In addition, Jalal mentions an example that has a similar context which is related to the fear of staff in healthcare institutions. Jalal also claims that there is no protection for healthcare staff when they report patient safety incidents, as stated in the following statement:

> *There is still apprehension among the staff. If you ask me the reason for this fear, I would say that, for example, when I discuss and write a report about patient safety incidents, there is a possibility that the report will be negatively used against me by someone who does not have a full understanding of its content. Unfortunately, healthcare staff have no protection in such situations (**Jalal**).*

Fadia acknowledged that the safety of healthcare staff is not assured when reporting patient safety incidents.

> *Healthcare staff or doctors can report and admit their errors when they know that their rights and safety are guaranteed* ***(Fadia****).*

Fawzia highlights that staff reluctance to report patient safety incidents stems from a fear of negative reactions from patients and their families.

> *Patients and their families sometimes also play a role in discouraging staff from reporting safety incidents, as they may blame the staff for any negative outcomes and respond with anger or even violence (****Fawzia****).*

As Fawzia stated, there is a fear stemming from the possibility of being blamed for adverse outcomes, which can lead to anger or even violent responses from those affected by the incidents. This dynamic can create a barrier to reporting patient safety incidents among Libyan healthcare staff.

Box 6-1: Reflective memos

Implementing PSI-RLS in Libyan healthcare without addressing staff safety could create more issues than it solves. Policymakers should consider Libya's social and cultural context before introducing such a system. There is a significant concern about the safety of healthcare providers when reporting patient safety incidents. Clear policies are needed to ensure and protect their safety during reporting.

6.2.1.6 Reporting Patient Safety Incidents by Libyan Healthcare Staff at an Institutional Level

Although this study focuses on the national PSI-RLS, however, some participants state that there are individual initiatives to involve healthcare staff in reporting and addressing patient safety incidents at the institutional level. Nevertheless, there is no clear strategy regarding the reporting process and the classification of patient safety incidents that should be reported by healthcare staff. Several interviewees argue that healthcare staff report patient safety incidents at the institutional level (such as hospitals) and such reports neither reach the MOH nor the national level. Ibrahim states that:

*In practice, there is a mechanism of reporting for healthcare staff. There is a hierarchical system in place for reporting incidents and medical complications within hospitals and departments. However, it primarily functions at the hospital level and does not extend to cases reaching the Medical Council at the Ministry of Health. Usually, reports from doctors do not reach the ministry level and are limited to the hospital level (**Ibrahim**).*

Fadia state that the MOH does not engage in regard to reporting patient safety incidents and such incidents are addressed at the hospital level.

***HJ:** Okay... when patient safety incidents occur at a hospital, is there a specific entity or person responsible for reporting these incidents to the Ministry of Health?*

***Fadia:** According to what exists and according to my experience. Patient safety incidents are typically addressed and resolved at the hospital level only. The Ministry of Health does not actively engage in this matter.*

Khalid claims that some leaders or individuals within certain healthcare institutions have become aware of this concept and have recognised its value. Therefore, they attempted to implement reporting systems in their own healthcare institutions.

*Reporting patient safety incidents and learning from them exists on an individual basis. This means that some leaders in certain healthcare institutions have become familiar with this concept and have attempted to implement it within their respective institutions (**Khalid**).*

Moreover, Al Zuwy mentions that events related to patient safety incidents can ideally be discussed within the department. However, he points out that the Libyan healthcare sector currently lacks such system, implying that there may be shortcomings in addressing and discussing patient safety concerns in all Libyan healthcare institutions.

Events such as patient safety incidents are supposed to be reported and discussed within the departments, but unfortunately, such a strategy is not implemented in all Libyan healthcare institutions (***Al Zuwy**).*

The context of the statements above suggests that healthcare institutions, whether private or public, have the autonomy to establish reporting systems that suit their specific nature of work. Some patient safety incidents can be effectively managed at the institutional level. Additionally, mandating incident reporting and learning systems in private healthcare institutions could be perceived as undue interference in their internal management.

6.2.2 Reporting Patient Safety Incidents by Patients in the Libyan Healthcare Context

Several participants highlighted the benefits of involving patients in reporting safety incidents. However, the scope of incidents that patients can report is limited to medical harm. Many participants noted that there is an official national strategy for reporting and reviewing medical harms. Stakeholders at the national level review these incidents. Patients who have suffered harm, or their families, are encouraged to report these incidents. Additionally, patients have the right and autonomy to report medical harm through legal or civil avenues. The practical approach to reporting medical harm by patients closely aligns with established policy. Below are three perspectives on the reporting of medical harm by patients in Libyan healthcare.

I. Patient Rights.
II. Transparency and Trust.
III. Reporting Medical Harm.

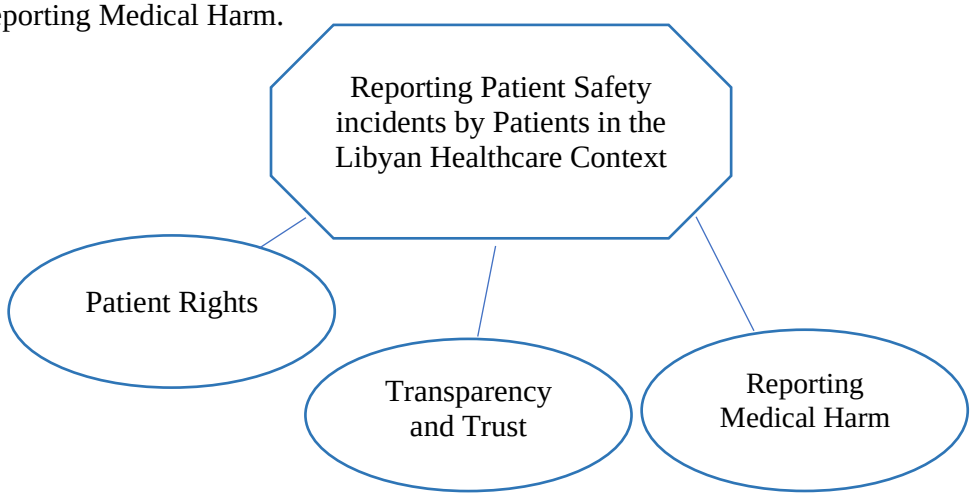

Figure 6-4 Schematic diagram Illustrating the Factors Emphasised by Stakeholders Concerning the Reporting of Patient Safety Incidents by Patients

6.2.2.1 Patient Rights

Khalid argues that giving patients priority to report medical harm not only safeguards their rights and entitlement to compensation, but also empowers them by providing a platform to express their concerns and have their voices heard about healthcare services.

> ***HJ:*** *In Libyan healthcare, what is the purpose of giving the priority to patient to report medical harms?*
>
> ***Khalid:*** *I can tell you two reasons for that. The first reason is to realize the rights of citizens who have suffered harm. It involves determining the causes of the harm to assess whether the patient is entitled to compensation. Of course, these causes are determined by the medical liability authority (Medical Council) during their procedures. This is the first reason. The second reason is to ensure that citizens feel their voices are heard. As you may know, the Libyan system is somewhat difficult and complicated. Therefore, providing an avenue for patients to report medical harm allows them to express their concerns and have their voices acknowledged. It serves as an outlet for patients to communicate their experiences to the healthcare services.*
>
> ***HJ:*** *okay.... this is clear, but do you think this is an important strategy?*
>
> ***Khalid:*** *yes, it is important for patients to be involved in a such topic.*

Khalid highlights two important reasons for giving patients priority to report medical harm. The first reason is to realize the rights of citizens who have suffered harm. If a patient experiences harm due to a medical service, it is crucial to identify the causes of the harm. This assessment helps determine whether the patient is entitled to compensation for the damages they have suffered. In this context, the MC plays a role in investigating and determining the causes of harm during their procedures. By reporting medical harms, patients can initiate the process of assessing their entitlement to compensation and seek justice for the harm they have endured.

The second reason is to ensure that citizens feel their voices are heard within the Libyan healthcare sector. Providing an avenue for patients to report medical harms, allows them to

express their concerns and have their voices acknowledged. This reporting system serves as an outlet for patients to communicate their experiences about healthcare services.

Moreover, Abu al-Qasaim suggests that patients often feel compelled to voice their concerns or complaints because they lack clarity about their medical condition. They may be unsure whether they have experienced any medical complications from their treatment or if they have only received temporary relief through painkillers. This uncertainty can lead to a sense of unease or dissatisfaction, prompting patients to report medical harm in search of potential solutions.

> *The patient is forced to report or complain because he does not know his situation whether he was exposed to complications or treated temporarily with painkillers. Here the Medical Insurance Authority comes as a purely humanitarian subject. Personally, I strive for the patient and not for the doctor. Doctors have clear and proven rights, and the doctor is protected by compensation made by the Authority, but who protects the patient's rights? (**Abu al-Qasaim**).*

The statement portrays the MIA as a humanitarian entity, emphasising its primary role in providing compensation to patients who have suffered harm during medical treatment. By highlighting the humanitarian aspect, it implies that the purpose of the MIA is to alleviate suffering and provide support to patients who have experienced negative outcomes of healthcare.

Abu al-Qasaim expresses his personal standpoint, indicating that his primary concern lies in advocating for patients. This perspective reflects a belief that patients should receive the necessary support, attention, and protection in healthcare settings. Moreover, Abu al-Qasaim claims that doctors have specific rights that are clearly defined and established. These rights likely pertain to various aspects of their profession, such as medical practice, and are typically upheld and protected by laws and regulations.

One important aspect of safeguarding doctors' rights is through compensation provided by the MIA. According to Libyan healthcare policies, there is compulsory insurance for medical and paramedical staff. The MIA is the body that organises this insurance, which is designed to protect staff in case of claims or lawsuits related to their medical harm. This

insurance coverage compensations for patients and helps mitigate financial risks and provides support for legal representation and potential damages.

In the event that a doctor faces a medical harm claim or lawsuit, the MIA typically covers the costs associated with the defense and any potential settlements or judgments. This compensation serves as a safeguard for doctors, helping them navigate legal challenges and ensuring that they are not personally burdened by significant financial liabilities.

BOX 6-2: Note taken after the interview [05 May 2022]

In Libya, healthcare providers are obligated to have insurance to protect them from unintended medical harm. The insurance is managed by MIA, which aims to relieve healthcare providers of liabilities by addressing medical harm resulting from medical errors. It is believed that mandatory insurance can bring tranquillity and stability to healthcare staff. This insurance can provide reassurance and ease the fears of healthcare staff regarding lapses or unexpected harm.

Mahmoud expresses the situation of healthcare if there is no reporting process from patients.

> ***HJ:*** *How the Libyan healthcare sector will be if there are no reports from patients?*
>
> ***Mahmoud:*** *The rights of patients will be lost, and the Libyan healthcare sector will be significantly impacted. We have noticed that some countries do not have medical liability laws, whereas Libyan law is considered ahead of its time and is very sophisticated.*

Mahmoud suggests that if the rights of patients are compromised, it would have a negative impact on the Libyan healthcare sector. He also highlights a comparison between Libya's medical liability law and those of some other countries. Mahmoud further emphasises that Libyan law is considered advanced and sophisticated in terms of medical liability. This suggests that Libya has established a legal framework that protects patients' rights.

Overall, Mahmoud conveys concerns about the potential consequences of losing patient rights in Libya, emphasising the importance of the country's advanced medical liability laws in safeguarding patients.

Fawzia highlights that the reporting by patients is important because it considers patient autonomy and empowerment in the healthcare sector as well as the best source of information on patients' medical issues.

> ***HJ:*** *From your point of view, do you think patients have the right to report medical incidents?*
>
> ***Fawzia:*** *In general, yes, patients have the right to report medical incidents or concerns related to their health or the care they receive. This is considered an important aspect of patient autonomy and empowerment. Patients have first-hand knowledge of their health and are often the best source of information about their medical incidents.*

Fawzia suggests that patients have the right to report medical incidents or concerns for two reasons. First, it is a fundamental aspect of patient autonomy and empowerment. As individuals, patients have a right to be actively involved in decisions about their healthcare and to have their voices heard. Second, patients are the ones who experience their own health conditions and treatments directly. By reporting medical incidents or concerns, patients contribute valuable information that can aid in accurate diagnoses, appropriate treatments, and improved overall care.

6.2.2.2 Transparency and Trust

Salah believes that promoting transparency and trust is the reason for adopting the patient reporting process.

> *Involving patients in reporting medical harm is linked to transparency. The intention is for the patients to have the right to report or complain if they are subjected to medical harm. The ultimate goal is to enhance trust between the patient and the medical and paramedical staff. Doctors should also be open with their patients and provide clear information about medical harm. This will eliminate any doubts between patients and doctors. In this case, the patient will feel confident and*

*satisfied. Therefore, if the patient or one of their family members falls ill, they will not hesitate to visit their doctor again (**Salah**).*

Salah has pointed out the importance of transparency in the healthcare sector, particularly regarding medical harm. The intention behind promoting transparency is to empower patients by giving them the right to report or complain if they experience medical harm. By doing so, the ultimate goal is to build and strengthen trust between patients and the medical staff. To achieve this, it is suggested that doctors should maintain an open and honest relationship with their patients. They should willingly share information about any medical harm that may have occurred, providing clear explanations. This transparency helps to eliminate any doubts or uncertainties that patients may have, allowing them to feel more confident and satisfied with their healthcare experience.

In summary, Salah highlights the significance of transparency in healthcare, emphasising the patients' right to report medical harm and the importance of doctors being open and providing clear information. The aim is to enhance trust between patients and medical staff, leading to increased confidence and satisfaction among patients.

6.2.2.3 Reporting Medical Harm

Patients can report two types of harm: harm caused by systems failures within the healthcare sector and medical complications. The first type refers to defects and systems failures within healthcare institutions or the healthcare sector. Medical harm can be caused by multiple healthcare institutions or factors. Patients go through the entire healthcare service journey, and the complex nature of medical harm occurrence can shift the reporting process from healthcare staff to patients. Abu al-Qasaim states that medical harm can result from various factors and healthcare institutions.

"Patients can report their harm and claim compensation. However, it's important to note that medical harm can occur due to various factors and from different sources. For example, a person might fall ill in Benghazi city, and his family decided to transfer him to Tripoli city. The patient's condition could worsen during the journey to Ajdabiya town. As a result, he might be admitted to the Ajdabiya Hospital. Subsequently, if his condition deteriorates once again in Ajdabiya town, he might be transferred to a hospital in Sirte town, where they could stay for a day

*or more. Finally, upon arriving in Tripoli city and being admitted to a hospital, the patient unfortunately passes away. In such a complex scenario, it becomes challenging to pinpoint a single party responsible for the outcome. The responsibility may be shared among multiple parties, and there may also be a possibility of shifting blame to the patient's companions for any delays in the transfer process. In these cases, if the medical harm is proven, the Medical Insurance Authority compensates the patient for the harm suffered and subsequent death, irrespective of the specific reasons behind the medical harm" (**Abu al-Qasaim**).*

The above statement discusses the process of reporting by patients, providing an example to justify the adoption of this process in Libyan healthcare. The participant described a complex scenario involving multiple parties involved in providing healthcare to the patient. Patients or their families play a crucial role in reporting important and intricate data related to medical harm. The statement emphasises that medical harm is not always straightforward and can have multiple contributing factors. It can arise from various sources and factors, as exemplified by the possibility of harm caused by multiple hospitals or healthcare workers. Furthermore, the statement acknowledges the potential blame that could be placed on the patient's companions for any delays in the transfer process. In cases like these, multiple parties may share responsibility for causing harm. The statement acknowledges the complexity of such scenarios and the difficulty in assigning responsibility to a single party or a single reason for the patient's death due to medical harm.

The given example depicts a situation where a patient falls ill in Benghazi city and is subsequently transferred to different hospitals in various locations (Tripoli, Ajdabiya, Sirte) due to the deterioration of his condition. Tragically, the patient passes away upon arriving in Tripoli city and being admitted to a hospital. This scenario exemplifies the challenges associated with attributing responsibility and determining the reasons for harm because multiple parties are involved in the patient's care. Therefore, from the information reported by the patient or his family, it becomes apparent that the hospital in Tripoli may not bear full responsibility or may not be the main cause of the patient's death. Nevertheless, even in complex situations like the one described, if the medical harm is proven the MIA ensures

compensation for the harm suffered by the patient and their subsequent death. The specific reasons underlying the medical harm are deemed irrelevant in determining the compensation.

Overall, the statement underscores the significance of reports from patients or their families due to the intricate nature of medical harm and the challenges associated with ascribing responsibility and reasons in complex scenarios. Additionally, it emphasises the importance of compensating patients for the harm they have endured, regardless of the specific reasons behind it, while acknowledging the potential involvement of multiple parties in the patient's care.

Medical complications are the second type of medical harm reported by patients. Jalal emphasizes the importance of distinguishing between complications and medical errors because they have different implications. If a medical error is identified, it indicates a failure in care delivery and may result in legal responsibilities for the healthcare providers. On the other hand, when a complication occurs, it may not be directly linked to a specific error or negligence.

Jalal has stated that congenital malformations can be a factor in the increasing medical harms. This is an example of the medical complications reported by patients, as he mentioned below.

> ***HJ:*** *Sometimes patients file a report claiming that they suffered harm, but the experts at the Medical Council state that the healthcare provider is not liable for the harm. This is perplexing because there is harm, yet no one is held liable for it... What does that mean? I want to understand!*
>
> ***Jalal:*** *No, this is not a medical error. It is a deterioration called complications. It is important to understand that this is not a medical error. If there were medical errors, then there would be medical liabilities. Any case that is brought to the attention of the experts at the Medical Council and determined not to be a medical error, with no one being held liable, indicates that it was a complication resulting from the treatment.*

During a seminar at the Ministry of Justice, I provided an example, and I'm ready to repeat it for you. Gallbladder surgery is a common procedure performed in hospitals, and it generally goes smoothly, whether conducted through an endoscope or traditional surgery. Laparoscopic cholecystectomy, in particular, is a widely practiced operation. Due to the extensive training received by many healthcare professionals, errors are not expected to arise frequently. However, in one case involving a patient with a gallbladder condition, congenital malformations were discovered. Specifically, the direct bile ducts connecting the liver to the gallbladder were found to be very small. The gallbladder was successfully removed, but afterward, bile started to leak from these ducts. This situation cannot be considered a medical error because it is a complication resulting from the patient's congenital malformation. The presence of abnormal bile ducts, which cannot be closed in the usual manner, led to these complications. This condition persists until complications arise and cause harm to the patient. Consequently, the patient or their family files a report about medical harm, and the process of penalisation begins. Filing a case against doctors implies that the doctors have initiated punishment, at least psychologically. Therefore, in cases where the accused, who is the doctor or the medical staff at that moment, has not been convicted, it is not a medical error but rather classified as a medical complication.

Jalal emphasises the distinction between medical complications and medical errors, highlighting that not all negative outcomes are the result of medical errors. Understanding this difference can be crucial for assessing accountability and determining liabilities.

Jalal argues that if the case were indeed a medical error, it would entail medical liabilities. When patients report cases of medical harm, these cases will be reviewed by experts at the MC. If these experts determine that the medical harm does not stem from a medical error and that no one can be held liable, it strengthens the indication that it was a complication resulting from the treatments or procedures. This implies that the healthcare professionals followed appropriate procedures of care, but an unfortunate outcome occurred due to complications.

Complications can occur even when everything is done correctly, as they are sometimes inherent risks or side effects associated with certain treatments or procedures. The participant provides an example to illustrate this point. Jalal argues that the gallbladder case cannot be considered a medical error because it is a complication resulting from the individual characteristics of the patient represented in congenital malformation.

In contrast, a medical error refers to harm or negative outcomes for the patient caused by healthcare providers that deviate from accepted standards of care. Overall, Jalal points out that it is essential to differentiate between complications and medical errors because they have different implications. If a medical error is determined to have occurred, it means that there was a failure in the delivery of care, and it may lead to liabilities for the healthcare providers involved. On the other hand, when a complication arises, it is not necessarily attributable to any specific error or negligence.

Al Sanusi has stated that there are type of harm is not liked to the medical error or incidents. In addition, he stated that medical complications are not classified as medical errors.

> *There are medical complications that occur alongside diseases. These complications should not be classified as medical errors. For example, if a patient undergoes an operation and experiences bleeding or other complications, those are considered medical complications. On the other hand, there are medical errors that result from operations, medication administration, or inappropriate patient follow-up. All of these could be categorised under the of medical negligence, which is linked to medical liability (**Al Sanusi**).*

Al Sanusi emphasizes the difference between medical complications and medical errors, highlighting that they should not be considered the same. The text provides an example and further explanation to clarify the distinctions between these two concepts. Medical errors are identifiable events that deviate from the expected standard of care, while medical complications refer to undesired outcomes that may occur despite the healthcare provider's adherence to the standard of care. The statement also mentions medical liability, which pertains to the legal responsibility of healthcare providers for harm caused to patients due to medical negligence.

Although the official reporting process for patients does not capture and recognise near-misses as patient safety incidents, it does have a distinctive attribute: capturing medical complications. Addressing the harms arising from medical complications can improve the processes of medical interventions and enhance patient safety across any healthcare sector. Medical complications can also be a significant source of learning.

6.3 Subtheme Two: Learning from Patient Safety Incidents in Libyan Healthcare Context

There is no organised learning from patient safety incidents at the Macro-Level (national level) in the Libyan Healthcare sector. Despite the existence of an official strategy for patients to report medical harms, which subsequently undergoes review by relevant stakeholders on a national scale, a formalised mechanism for extracting lessons from medical harms at the national level has yet to be established. The concept of systematic learning derived from medical harms remains conspicuously absent within the Libyan healthcare sector's national framework. However, some participants argue that learning from patient safety incidents can happen at the institutional level.

The perceptions of participants about learning from medical harms and patient safety incidents are categorised through two perspectives:

- Learning from medical harms at a national level, and
- Learning from patient safety incidents at an Institutional level.

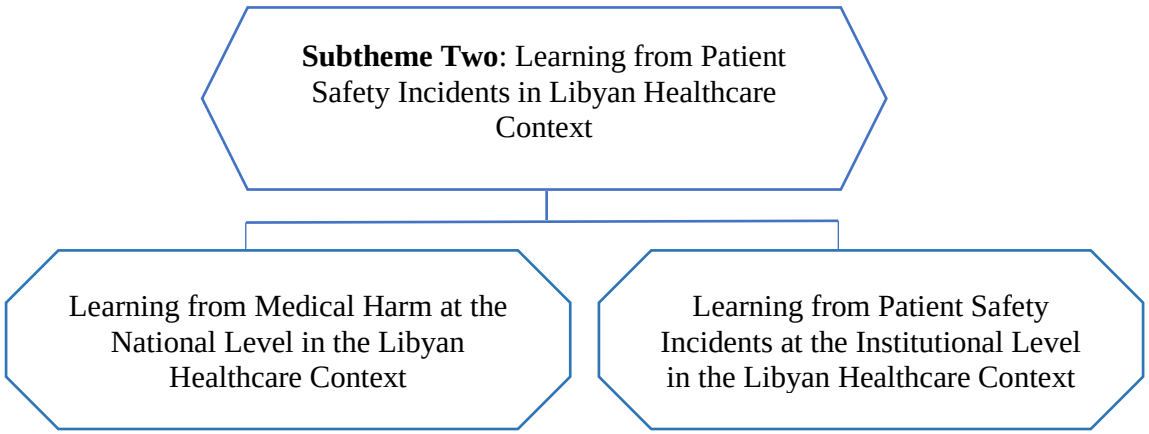

Figure 6-5 Schematic Diagram Illustrates the States of Learning from Patient Safety Incidents in the Libyan Healthcare Context

6.3.1 Learning from Medical Harm at the National Level in the Libyan Healthcare Context

Participants have provided articulate accounts of their experiences regarding the acquisition of knowledge from medical harms at the national level. Numerous participants declared that there is no organised or official mechanism for learning or gaining lessons from medical harms that are addressed at the national level. The following statements clarify that.

> ***HJ:*** *Is there any reaction to correct medical harms reported by patients? For example, fifty to a hundred medical harms are reported every year. Thus, lessons can be extracted that could be useful for reducing or preventing such harm.*
>
> ***Ibrahim:*** *In fact, such procedures do not exist. I do not know who is responsible for that, as the directorates in the ministry are supposed to address this issue. Several symposiums have been held to discuss this topic. The Medical Council can provide information on this matter, as they have organised symposiums to discuss the findings of medical harm.*

Salah confirms that there are no bodies or institutions that use medical harm reports for learning purposes, as declared below.

> ***HJ:*** *Okay ... medical harm reported by patients are reviewed by the Medical Council to determine medical liabilities. Is there any specific party that receives those reports from the Medical Council and learns from them?*
>
> ***Salah:*** *Currently, no. However, the newly established General Health Council will communicate with the Medical Council to address this matter. The Medical Council, also known as the National Council for Determining Medical Liability, is the house of expertise that collects all information regarding medical harm. Therefore, the General Health Council can issue an annual report clarifying the nature of medical harms that occurred in the healthcare sector.*

In addition, Mahmoud confirms that the outcomes of the MC regarding medical harms are not considered as a source of learning.

HJ: *Are there any training programs or procedures carried out based on the outcomes of the Medical Council regarding medical harms?*

Mahmoud: *No, there aren't. Consequently, this has caused the reluctance of doctors to practice the medical profession, especially in the Department of Obstetrics and Gynecology, due to numerous problems in this department. Doctors fear the possibility of making medical harm. Data from the Medical Council indicates that the Department of Obstetrics and Gynecology has the highest number of medical harms related to medical liabilities. Additionally, this department accounts for one-third of all reported cases.*

Abdallah confirmed that there is no learning from patient safety incidents. Additionally, he provided an example of how some healthcare providers perceive patient safety reports.

*There is no culture of learning from patient safety incidents, because even the reports that are submitted, mainly from the director of the Quality and Patient Safety Office to the hospital management, and subsequently transferred to the Ministry of Health, are not intended for the purpose of learning. Some hospitals have made initiatives to send reports every three months, but in general, these reports are not aimed at utilising incidents for learning. Instead, their purpose is to shift embarrassment away from the hospital and to relocate the problems elsewhere. Therefore, we do not have a culture of learning, and addressing this issue requires effort and thoughtful planning in order to establish a mindset of self-learning and continuous development (**Abdallah**).*

Abdallah argues that there is a lack of a learning culture from patient safety incidents because the reports are not used for learning but to avoid embarrassment. To address this, a shift towards self-learning and continuous development is needed.

6.3.2 Learning from Patient Safety Incidents at the Institutional Level in the Libyan Healthcare Context

Two participants argue that healthcare providers can learn from patient safety incidents at both the meso and micro levels. Extracting lessons and learning from these incidents can occur individually at the institutional level.

HJ: *According to the example you mentioned, does that mean there are many patient safety problems, but learning from these problems only occurs at the institutional level? I mean is there a national and formal system for systematic learning?*

Khalid: *The lessons learned are not being applied across all healthcare institutions. However, healthcare institutions are individually making internal changes based on their own learned lessons. This is a customary practice in most healthcare institutions.*

Khalid argues that healthcare institutions can extract valuable lessons and learn from patient safety incidents on an individual basis. Some incidents can be addressed within the healthcare institution and may not require a reaction from higher authorities. Each healthcare facility, such as a hospital or clinic, has the opportunity to analyse and understand the reasons for patient safety incidents that have occurred within their premises. By examining these incidents, healthcare providers can identify areas of weakness in their systems, protocols, or practices that may have contributed to patient safety incidents. This individualized approach allows institutions to tailor their improvement efforts to address specific challenges they face.

In addition, Jalal argues that learning occurs within healthcare facilities, as he stated below.

Jalal: *learning can occur during the daily work within healthcare facilities. For instance, if there are medical errors in hospitals, doctors report and discuss these errors within their respective departments. Some departments hold weekly meetings where doctors share their experiences of encountering medical errors, how they were handled, and what lessons can be learned from them. However, the information discussed in these meetings is not circulated beyond the department. This is the case in all countries, as sharing such information openly can lead to negative consequences from external parties. Hence, this first aspect can be referred to as "learning through daily work." It involves the internal sharing of medical errors within the department. The first part of learning from medical errors is kept unpublished and stays within the departments.*

HJ: *So, you mean this information stays within the healthcare institutions?*

Jalal: *No ... within the departments not the healthcare institutions. It remains within the departments and doesn't reach the level of the overall healthcare institution or its management. Each department maintains its own file, known as an editing file. These files are reviewed on a weekly basis, assessing both successful cases and those that faced challenges. The purpose is to analyse why certain cases were unsuccessful and identify the reasons behind them.*

Jalal suggests that departments at the institutional level can learn from patient safety incidents. The context of the statement emphasizes the importance of having close communication when reviewing incidents and discussing the reports in detail to avoid any misunderstandings. By thoroughly examining the details at the institutional level, healthcare providers can gain a comprehensive understanding of the events leading up to the incidents, the factors involved, and the potential consequences.

6.4 Chapter Summary

This chapter addresses the second and third research questions of this study. The second theme from the data provides insights into these questions. It explores how key healthcare policy stakeholders in Libya view the patient safety incident reporting and learning system at a national level. Two sub-themes emerged from this theme. The chapter illustrates that reporting patient safety incidents is an ethical responsibility that ultimately rests on the conscience of healthcare staff. However, patients and their families also play a crucial role in reporting medical harm. Two types of harm can be Reported by patients those caused by systemic failures in healthcare and those due to medical complications. Currently, there is no organised or official system to learn from medical harm at the national level. Some participants believe that learning from patient safety incidents can happen individually at the institutional level.

7 CHAPTER SEVEN – Findings: Theme Three

7.0 Introduction

This chapter presents the third and final theme of the findings. It also aims to address the last research question: "What factors affect the operation of patient safety incidents reporting and learning system?". This question is integral to the third objective of this research. The final theme derived from the data offers insights into this research question and is titled: "Organisational Structure of the Healthcare Sector". Theme three focuses on the organisational structure of the Libyan healthcare sector and its influence on PSI-RLS. The researcher has organised two subthemes that emerged from theme three. Similar to the second theme, as the chapter progresses, each of these subthemes will be explored in greater detail under separate headings and subheadings. The chapter begins with a concise introduction to the third theme, followed by an in-depth examination of the two related subthemes, and concludes with a summary of the chapter.

7.1 Theme Three: Organisational Structure of the Healthcare Sector

A range of factors were identified from the data that were clustered around the organisational structure of the Libyan healthcare sector and focused on two key areas which are the following subthemes:

- Subtheme One: Politics and Policies.
- Subtheme Two: Organisational System.

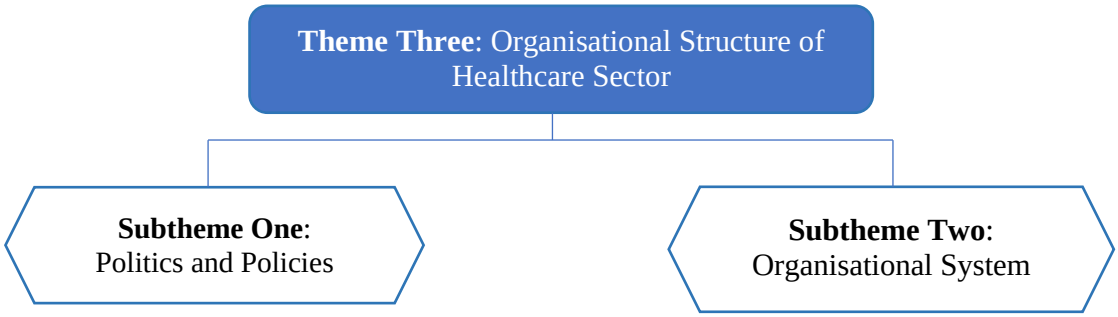

Figure 7-1 Schematic diagram of theme three regarding the organisational structure of the Libyan healthcare sector

The first subtheme "Politics and policies" is going to be presented in detail followed by then the second subtheme.

7.2 Subtheme One: Politics and Policies

The majority of participants declared that the Libyan healthcare sector faces numerous challenges, mainly due to political instability and healthcare policies. These problems have had a detrimental impact on patient safety and establishing patient safety incident reporting and learning system. This introduction paves the way for further details of the problems hindering progress in patient safety initiatives and the development of a reporting and learning system. Data from this subtheme is organised into two headings which are:

- Politics Situation.
- Policy Formulation and Implementation.

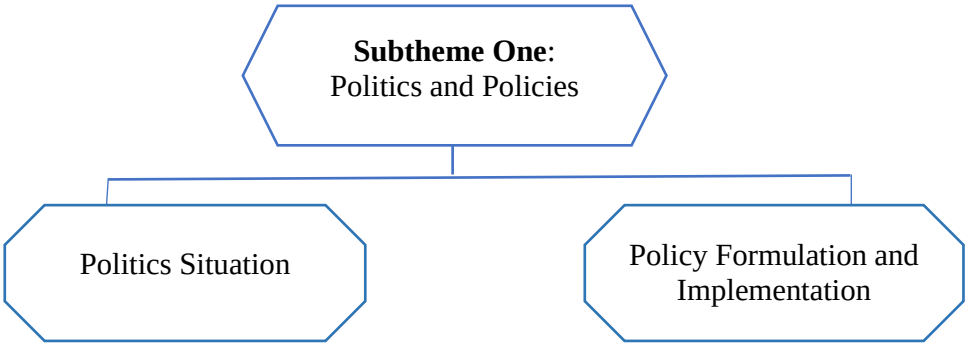

Figure 7-2 Schematic diagram of politics and policies that affect patient safety and PSI-RLS in Libya

I will first introduce the factors associated with the political situation, followed by the issues related to Libyan healthcare policies.

7.2.1 Politics Situation

Two participants highlighted the impact of political instability on patient safety in healthcare institutions as stated below.

> ***HJ:*** *Are there any unique challenges facing the Libyan healthcare sector regarding patient safety incidents?*

> ***Nour:*** *Yes, there are several challenges that impact patient safety and the reporting system in Libya. One of the key issues is the political instability and conflict that the country has experienced. This has had a detrimental effect on the healthcare infrastructure and resources*.

Nour's response suggests that the Libyan healthcare sector faces a unique and significant challenge related to political instability and conflict, which has adverse consequences for patient safety. The scarcity of resources and infrastructure damage could compromise patient safety by limiting access to necessary care and creating conditions where patient safety incidents are more likely to occur.

In addition, Tareq is concerned about the impact of conflicts and insecurity on patient safety in the Libyan healthcare sector as he declared below:

> *Unfortunately, conflicts and insecurity can pose significant challenges to healthcare facilities and patient safety. In Libya, despite the ongoing war, medical facilities have been coping relatively well with the influx of wounded patients. However, it's crucial to ensure that normal health needs continue to be addressed alongside the challenges of conflict (**Tareq**).*

Tareq acknowledges the presence of conflicts and insecurity in Libya, exemplified by the ongoing war in Libya. These conditions create a challenging environment for healthcare facilities and staff, posing risks to patient safety. Despite these challenges, medical facilities are relatively effective in delivering healthcare services. This example possibly highlights the flexibility of healthcare services in conflict times.

7.2.2 Policy Formulation and Implementation

Several participants concern about issues related to policy formulation and implementation in the Libyan healthcare sector that have had a detrimental impact and have hindered the development of PSI-RLS. The following are policy formulation and implementation issues centered around three perspectives:

- Lack of policies,
- Poor implementation of policies, and
- Lack of policy interpretation.

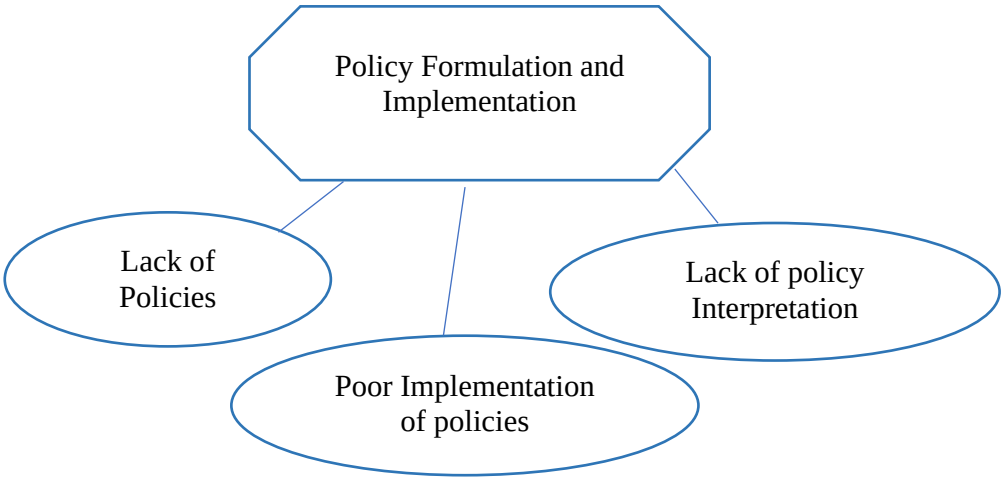

Figure 7-3 Schematic Diagram Illustrating the key Issues related to Policy Formulation and Implementation in the Libyan Healthcare

7.2.2.1 Lack of Policies

Some participants assert the existence of a glaring deficiency in policies concerning patient safety and reporting and learning system, a concern that resonates deeply within the Libyan healthcare sector. This can be noted in Abdallah 's statement as stated below:

> *Without a disclosure policy, patient safety cannot be developed. There must be the courage to speak openly so that progress can be made. However, patient safety incidents often go unaddressed in the policies and strategies of the healthcare sector. (**Abdallah**).*

Abdallah highlights the importance of adopting disclosure policies that encourage healthcare professionals to openly discuss and report patient safety incidents. In addition, healthcare professionals need to have the courage to speak openly about any problems or incidents they observe. Abdallah also states that patient safety problems are often not addressed within the policies and strategies of the healthcare sector.

The below dialogue also emphasised the lack of policies regarding the PSI-RLS in the healthcare sector of Libya.

HJ: *What options are available at the MOH level to implement a Reporting and Learning system that allows doctors, professionals, and nurses to report medical errors or patient safety incidents?*

Al Sanusi: *Yes, yes .... this primarily needs a policy matter rather than a technical strategy. The project has been prepared and is now being implemented. I won't go into a lengthy explanation, but in summary, medical experts, health technicians, and politicians in Libya have convened multiple times to address these issues. The largest conference on this topic took place in 2012.*

Al Sanusi explains that this is primarily a policy matter rather than a technical one. This implies that the fundamental challenge lies in defining the policies, rules, and regulations for reporting and addressing patient safety incidents. The distinction between policy and technical matters is essential because it indicates that the initiative requires more than just technical infrastructure. It necessitates a comprehensive framework involving various aspects such as legal, ethical, and operational aspects.

He mentions that a project related to this issue has already been prepared and is currently in the process of being put into action. He also suggests that there has been discussion and planning involving various stakeholders to address the PSI-RLS at the MOH in Libya.

Khalid states that there are laws but that is not enough to address patient safety incidents, as declared below:

*There are laws, but there is no written policy that explains the details and the package of administrative measures that should be applied or the technical procedures that are required when patient safety incidents occur (**Khalid**).*

Khalid acknowledges the presence of laws related to patient safety. These laws likely address fundamental principles and regulations aimed at patient safety. However, it is important to note that laws often provide a broad framework, outlining general principles rather than specific operational details. Khalid also emphasises the absence of written policies and technical procedures that delve into the specifics of how patient safety incidents should be managed.

7.2.2.2 Poor Implementation of Policies

Some participants believe the policies related to patient safety and the reporting and learning system are not being implemented properly. These participants bring a wealth of firsthand experiences, having witnessed lapses in the policy implementation mechanism, which they argue hinders the implementation of the patient safety reporting and learning system.

> *The medical liability law is very excellent, but its implementation is very weak. Previously, Libya Insurance Company replaced the Medical Insurance Authority, then a decision was issued to open the insurance wide for all insurance companies, private or public. This has caused chaos ...and conflict occurred between insurance companies in Libya (**Mahmoud**).*

The interviewee believes that the law itself is well-designed, but its implementation has been lacking. They go on to explain that there has been a lot of confusion and conflict surrounding the MIA in Libya, particularly since the decision was made to allow all insurance companies, whether public or private, to offer medical insurance. The interviewee indicated that this change has led to chaos and has weakened the effectiveness of the medical liability law.

Khalid adds the distinction between the importance of the reporting and learning system, on the one hand, and the implementation mechanism on the other. He also highlights the challenges associated with the absence of awareness in executing such a system in the Libyan healthcare context. As states below:

> ***HJ:** Do you think the reporting and learning system is important in Libyan healthcare?*
>
> ***Khalid:** Of course, it is important. In terms of significance, it holds great importance. However, when it comes to the implementation mechanism, that's where the problem lies. We often claim that everything in Libya is well-documented, and our issue doesn't lie in writing things down; rather, it lies in executing and implementing them. Why is that? Because this requires a high level of awareness, not just knowledge. This is the biggest challenge we face.*

Khalid responds affirmatively, expressing that the reporting and learning system holds great significance. However, he also highlights a significant challenge when it comes to the implementation mechanism of this system. According to Khalid, Libya may have a well-documented system in place, meaning that healthcare policies are in place, but the main challenge lies in the execution and the practical implementation of those policies.

Khalid goes on to explain that the key challenge is not merely having knowledge or information but having a high level of awareness and perception to effectively implement and act upon those policies. Khalid implies that there may be issues related to the interpretation of knowledge into action within the Libyan healthcare sector.

The subsequent statement offers a clarification of how the policy's implementation mechanism may falter in attaining its intended objectives. Fadia's statement serves as an illustrative instance of the misinterpretation of accountability, thereby adversely impacting the implementation of patient safety reporting and learning system within the healthcare sector of Libya.

7.2.2.3 Lack of Policy Interpretation

Fadia voices concerns regarding the interpretation of policies related to patient safety and the reporting and learning system in the Libyan healthcare sector. She mentioned the misinterpretation of the accountability concept in practical implementation.

> ***Fadia:*** *There is no reporting system, and no reporting occurs due to fear of accountability and Why? Because accountability has been abused. Accountability is seen solely as being associated with punishments, lacking the element of repentance. Reporting patient safety incidents is not perceived as a call for reforms.*
>
> ***HJ:*** *Well... When an error or harm occurs to a patient, can the doctor or nurse report the error without facing consequences?*
>
> ***Fadia:*** *They should be able to report, but as I mentioned earlier, those who handle this matter are financial and administrative affairs, seeking punishment rather than reforms.*

Fadia raises significant concern regarding the lack of a reporting system for healthcare staff and their reluctance to report patient safety incidents. She suggests that one of the primary reasons for this reluctance is the fear of accountability, which has been associated with punishments rather than constructive reforms. Fadia points out that the concept of accountability seems to lack the element of repentance, suggesting that it is primarily punitive in nature.

Fadia acknowledges that medical and paramedical staff should be able to report patient safety incidents, but she reiterates her point that those in charge of managing such matters, specifically in financial and administrative roles, tend to focus on seeking punishments rather than promoting reforms. Fadia suggests the need for a shift in the perspective on accountability, emphasising its importance as a means to drive reforms and improvements in the healthcare sector rather than as a tool for punishment.

According to Fadia's statement, accountability is considered in the Libyan healthcare sector. However, there are no clarifications about the concept of accountability in the Libyan healthcare sector. Accountability must be perceived as a means to drive reforms and improvements, which is the solid basis for patient safety reporting and learning systems. However, accountability is perceived as punitive or as a tool for punishment in the Libyan healthcare sector. This perception leads to a lack of reporting of patient safety incidents, and this reluctance can have negative consequences for patient safety.

Additionally, Al-Zuwy articulates his perspective on the concept of accountability and the role of physicians in safeguarding patient safety. This is evident in his response to the question posed by the researcher, as outlined below.

> ***HJ**: Patient safety incidents can occur due to a lack of or poor-quality equipment. Are healthcare staff accountable in such cases?*
>
> ***Al-Zuwy**: This issue can be viewed from two perspectives and is considered one of the fundamental aspects of patient safety. There are two essential categories in the medical field: life-saving services and non-urgent services. Life-saving procedures follow certain protocols and are performed based on available resources and conditions. Sometimes, full resources may not be available, but it is necessary to*

save a life with the available means. However, when a doctor schedules a non-urgent operation for a patient, such as a non-urgent operation for an appendectomy or a cholecystectomy, and he knows that there is not enough equipment to perform the operation, then the doctor is accountable for any consequences. This is because the equipment needed for the operation is not available and the operation is not urgent. In non-urgent services, no operation should be performed on a patient until all supplies are available and after consulting with the entire medical team. In some cases, doctors may take all necessary precautions, but unexpected harm can still occur. In these cases, the doctor should try as much as possible to justify the harm that occurred.

Box 7-1: Reflective memos

Fadia was very accommodating during the interview. She had previously worked in various hospitals at the micro level before transitioning to the MOH. She raised concerns about the link between accountability and patient safety incidents in the Libyan healthcare sector, believing that current policies do not adequately address this connection. This led me to focus on the differences between responsibility, accountability, and liability, and how these terms are often used interchangeably in Libyan healthcare.

I realised that these terms need clarification in the discussion chapter to improve understanding of their proper usage and the authority required to enforce them. While accountability for patient safety incidents is recognized, Fadia's citation suggests that responses to such incidents at the micro and meso levels are often treated as liabilities. This indicates a misinterpretation of policies at these levels, as they lack the authority to penalize or impose medical liabilities on healthcare staff who report patient safety incidents. Additionally, Al Zuwy's citation (in 7.3.1.1) supports Fadia's concern, noting that hospitals may impose disciplinary penalties, such as blame, on doctors for specific harm.

7.3 Subtheme Two: Organisational System

The organisational system of the Libyan healthcare sector can impact the establishment of patient safety reporting and learning systems. Factors related to the organisational system are centered around three classifications as follows:

- Management and Administration Factors.
- Communications among stakeholders.
- Leadership and Governance Factors.

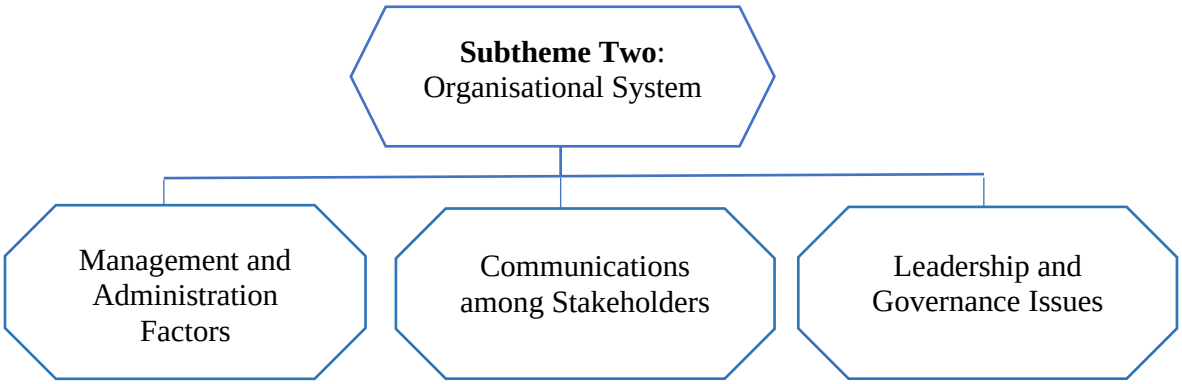

Figure 7-4 Schematic diagram illustrates the factors that influence the organisational system of the Libyan healthcare

7.3.1 Management and Administration Factors

Multiple participants mentioned some management and administrative factors that fail to create an environment conducive to the development of reporting and learning systems. These factors revolved around two perspectives, as illustrated below.

- Existence of a Patient Reporting Process.
- Obligations Framework for Healthcare Providers.

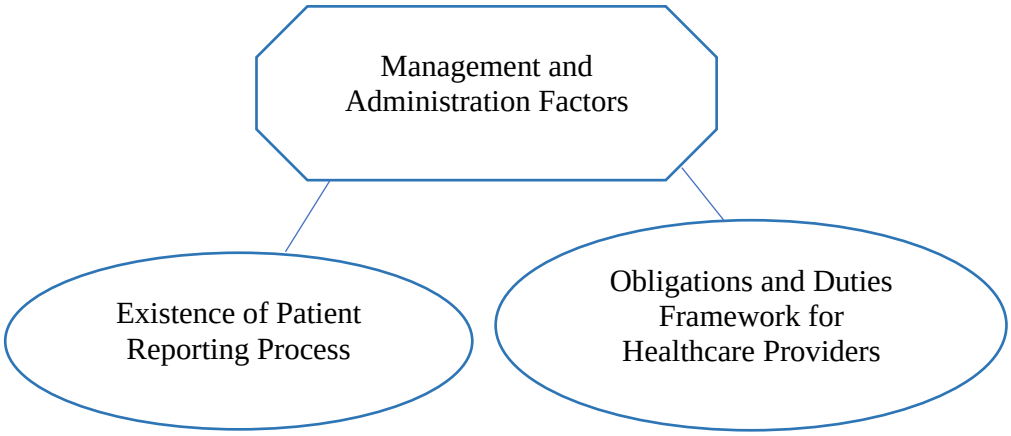

Figure 7-5 Schematic Diagram Illustrates Management and Administration Factors that Affect the Reporting System in Libya

7.3.1.1 Existence of a Patient Reporting Process

The focus is on the process of patients reporting medical harm, with a belief that patients should have priority in reporting such incidents. However, there has been less attention given to the involvement of healthcare providers in reporting patient safety incidents. The presence of a patient reporting process can influence the implementation of the PSI-RLS in some respects. For example, two participants have highlighted the influence of reporting harm by patients on the involvement of healthcare providers in the PSI-RLS in Libya. Both participants mentioned that there are stakeholders responsible for reviewing medical harm reports submitted by patients. Ibrahim expresses his opinion from a macro-level perspective, while Al Zuwy expresses his opinion from a meso-level standpoint.

> *At the Ministry of Health, there is a reliance on the patients' reporting process. The Ministry personnel believe that the committees, organisations, and centers involved in the medical harm reporting process are overseeing all aspects related to the patient and their family (**Ibrahim**).*

Ibrahim argues that the Libyan MOH depends on the patient reporting process which addresses medical harms. He further explains that ministry personnel trust that the stakeholders involved in the patient reporting process are effectively addressing medical harms concerning patients and their families. As a result, less emphasis is placed on implementing reporting and learning system that address patient safety incidents from

healthcare staff. In addition, Al Zuwy shares his viewpoint from a meso-level perspective, as he stated below

> *In hospitals, we do not expect strong actions to be taken against medical personnel for medical harms, as the response to such issues is typically initiated by the harmed party. Since there is no guarantee that harmed party will refrain from filing complaints regarding medical harms, it is not permissible to take action against medical personnel. This is because doing so could result in double actions or penalties being applied on the staff for a single error. The response to harms comes from the patient's side which prevents hospitals from taking direct action against medical personnel who cause harm. This is done to avoid the repetition of procedures for the same error. While some doctors may face disciplinary penalties, such as being blamed, for specific harms, however, the actual response is determined by the patients and the responsible authorities investigating the patient's complaint (**Al Zuwy**).*

Al Zuwy alleges that it is not possible to establish two reporting processes, one through patients and another through staff, to address medical harms. This is because having two separate reporting processes could lead to duplicate actions or penalties for a single medical harm. If both the patient reporting process and the hospital reporting process were to take separate actions against the medical personnel involved in medical harm, it could result in an unjust duplication of consequences. However, at the institutional level, staff members may still be blamed for the medical harm they cause.

Al Zuwy argues that establishing a staff reporting system could conflict with the patient reporting process. He sees the conflict between the two systems in terms of the penalties that may be applied to healthcare staff.

Based on the context of the statement, the institutional level does not have the authority to penalise medical professionals for medical harms that are meant to be processed by patients. Furthermore, the context of the statement suggests that the institutional level does have the autonomy to establish a reporting and learning system for their healthcare staff and institutions.

In addition, Al Sanusi argues that in Libya patients can take legal action in response to medical harm by filing a complaint with the judicial authorities, who then approach the MC for technical opinions regarding medical harm. Alternatively, patients can take a civil approach in response to medical harm by filing a complaint with the Complaints and Appeals department in the General Health Council to address the medical harm. This has mentioned in the statement below.

> ***HJ:*** *Let me give you an example. A doctor met a patient and after the diagnosis, the doctor decides to perform surgery. But unfortunately, a medical harm occurred during the operation. Should the doctor report this harm?*
>
> ***Al Sanusi:*** *This issue is not related to my knowledge in the first place.*
>
> ***HJ:*** *Okay...*
>
> ***Al Sanusi:*** *However, there are organisations that oversee medical harm. Currently, there are two main bodies, in addition to the medical syndicates, that handle this issue. Legally speaking, citizens can file a complaint with the court to start a criminal investigation. Then, the case can be referred to the Medical Council to determine medical liability. Alternatively, citizens can also file a complaint with the Department of Complaints and Appeals in the General Health Council for the civil aspect.*
>
> ***HJ:*** *Does that mean the responsibility to report harm lies with the patients?*
>
> ***Al Sanusi:*** *Yes.*

Al Sanusi eloquently describes the multifaceted reporting process for medical harm through the lens of patients. From the patient's perspective, they have the autonomy to choose the most appropriate avenue for reporting and addressing the harm they have suffered, whether it entails legal channels or civil remedies. In Libya, there are organizations responsible for overseeing medical errors that cause harm and addressing complaints related to them. The two main bodies that receive patient reports or complaints regarding medical harm are the MC and the General Health Council. From a legal standpoint, medical harm is subject to

discussion and interpretation. If a citizen believes they have been a victim of medical harm, they have two options for addressing their harm: the legal or civil approach.

In the legal approach, patients can report or file a complaint with the judicial authorities, who would initiate a legal investigation into the medical harm. They would gather evidence and conduct an inquiry to determine if the case is related to any criminal actions. Simultaneously, the judicial authorities seek technical opinions from the experts at the MC. There are medical professionals or experts in the MC responsible for evaluating medical practices and ensuring professional standards are maintained. In the context of medical harm, the MC will investigate the case to determine the medical liabilities involved. Additionally, patients have another avenue to pursue complaints related to medical harm. They can report their medical harm to the Department of Complaints and Appeals in the General Health Council. This department manages civil aspects of complaints and appeals related to healthcare services. It provides a platform for citizens to voice their grievances and seek resolution for any harm caused by the actions of healthcare providers in a civil approach.

In addition, Ibrahim has explained and clarified two reactions related to the medical harm reported by patients. The first reaction is about determining compensation, and the second reaction is about determining disciplinary penalties. Ibrahim stated that:

> *From a legal perspective, there are two paths for addressing harm if liability is proven. The first path involves the medical council's decision being handed over to the court, which then adjudicates the compensation according to specific regulations. These regulations outline the financial value of different types of damages, such as those affecting the hands, legs, and so on, and even deaths have specific compensation. The Medical Insurance Authority is responsible for paying and compensating the patients in this case.*
>
> *The second path involves disciplinary penalties and the establishment of a professional court in the municipality where the medical harm occurred. According to the legislation, this professional court is headed by a judge with the degree of a consultant and two medical specialists with a job grade*

*of not less than the eleventh degree. The professional court determines disciplinary penalties for healthcare providers based on the extent of the damage. For instance, if providers repeatedly cause harm, they may be isolated from their jobs or removed from the professional record based on the decision of the professional court (**Ibrahim**).*

Note during data analysis: 18 June 2023

The citations from Al Zuwy, Al Sanusi, and Ibrahim discuss the legal consequences healthcare providers face for causing medical harm. Reporting medical harm by patients is perceived as a good process for Libyan healthcare. However, they overlook the ethical aspect, which calls for reforms. Addressing medical harm ethically won't conflict with the legal perspective if the reporting system aims to promote reforms and support learning. This approach can ultimately enhance healthcare providers' understanding of medical harm.

In a dialogue with Salah about healthcare providers' fear of patient litigation over medical harm, I explained that the legal process can hinder providers from reporting and learning from patient safety incidents. However, he stated that litigation is a fundamental right for everyone, as shown below.

***HJ:** Let me express my point of view. The Libyan law grants patients the right to litigate in cases of medical harm, allowing them to obtain compensation if the harm is proven. However, I believe that this strategy can increase the spreading of fear among healthcare staff, discouraging them from discussing and reporting medical errors. This, in turn, hinders their ability to learn from these errors and improves patient safety. Do you consider this to be a detrimental approach?*

***Salah:** firstly, litigation is a fundamental right for everyone. The judiciary ensures fairness and justice, and those who have a legitimate claim will receive the compensation they deserve. Any individual who denies others' rights to justice behaves abnormally. It is only fair that a patient who has*

been harmed by healthcare providers seeks legal recourse. It is essential to convince the patient that, being human, they may be susceptible to medical harm. Hence, any patient who suffers harm due to the actions of healthcare providers has the right to turn to the legal system for resolution.

On the other hand, if a doctor believes that it is better for a patient not to be aware of harm, simply to avoid the possibility of litigation, then that doctor should reconsider their suitability for the medical profession. It is the responsibility of doctors to acknowledge that the nature of their work entails the potential for errors. Therefore, doctors should not shy away from reporting errors during their practice, nor should they fear patient complaints. Moreover, doctors themselves should disclose the occurrence of a medical error to the patient, providing a detailed account before the patient discovers it independently. Doctors should also inform the patient about their right to file a complaint regarding the error.

Salah argues that patients have the right to pursue litigation regarding medical harm to ensure fairness and justice. At the same time, healthcare staff should report medical errors regardless of the litigation process initiated by patients.

While patients' pursuit of litigation and healthcare staff reporting errors may seem like separate reporting processes, they are not mutually exclusive. In fact, they can complement each other. Patients' lawsuits can bring attention to specific cases of medical errors or medical harm that may not be noted by healthcare staff. The two examples provided by Abu al-Qasaim and Jalal illustrates this point (Chapter six, 6.2.2.3), where a patient experienced harm caused by various factors across different hospitals. Similarly, Jalal's case highlights the harm caused by complications arising from the patient's congenital malformation. Both cases were reported by the patients themselves. Therefore, patient reporting can serve as a valuable source of learning that can contribute to improving patient safety.

On the other hand, healthcare staff can report errors, providing valuable data for enhancing patient safety. They can identify patterns, conduct root cause analyses, and implement preventive measures to prevent the recurrence of errors.

In summary, Salah argues that patients have the right to pursue litigation to ensure fairness and justice following medical errors that cause harm. Simultaneously, healthcare staff should actively report patient safety incidents to facilitate learning, accountability, and improvement within the healthcare sector. Both these aspects contribute to a comprehensive approach to addressing patient safety incidents and promoting patient safety.

Jalal agrees that reporting patient safety incidents can by reported by both patients and healthcare providers, as illustrated below.

> ***HJ:*** *Okay, Doctor. I would like to discuss two points: the involvement of patients and the involvement of medical and paramedical staff in reporting errors or incidents that occur in healthcare institutions. Who should be given the priority in reporting incidents: patients, doctors or the nurses?*
>
> ***Jalal:*** *Reporting what? Medical errors or medical complications?*
>
> ***HJ:*** *I mean reporting medical errors and medical harm.*
>
> ***Jalal:*** *Reporting should be done by everyone. When medical errors occur, individuals must be transparent with themselves. As doctors in the workplace, if they engage in a situation where an error occurred, they must report it so that others can learn from such an error.*

Based on the context of the statements in this section (7.3.1.1), it was observed that near misses were not considered in the process of reporting medical harm. The reporting process of medical harm is far from straightforward. This process only focused on actual medical harm and did not encompass near misses in the healthcare sector. The participation of healthcare providers in reporting patient safety incidents has not received much attention. Similar to the perceptions of participants in Chapter Six, there was no reference to learning from harm or patient safety incidents in the reporting process of medical harm by patients.

7.3.1.2 Obligations Framework for Healthcare Providers

Several participants have articulated the framework of healthcare providers' obligations regarding their professional roles and medical harm. Nonetheless, it is evident that legal obligations take precedence in this context, with healthcare providers' duties primarily considered through a legal lens, neglecting clarifications about the ethical obligations of healthcare providers. For example, reporting and learning from patient safety incidents can be clarified as ethical obligations of healthcare providers. There is a prevailing mindset that emphasises legal obligations while overlooking the ethical obligations of healthcare providers in the healthcare sector. The following statements from participants can further elucidate this claim.

> *The definition of a physician's work in Libya is to provide maximum care and diligence, not guarantee the outcome. Legally, doctors are expected to exert their best efforts, but they are not responsible for the inevitable results and are not obligated to heal people (**Al Sanusi**).*

Al Sanusi highlights the legal framework in Libya regarding the role and responsibilities of doctors, emphasising the importance of providing diligent care while recognising that doctors cannot be held accountable for outcomes that are beyond their control or guaranteed success in treating patients.

Al Sanusi describes the legal expectations placed on doctors in Libya regarding their work and the outcomes of their treatments. In Libya, the role of a doctor is understood to involve providing maximum care and diligence. When doctors provide the highest level of care, they are not held accountable for any unfavorable or unavoidable outcomes that may occur. Although doctors are not obligated to achieve a particular outcome, they are still legally required to exert their best efforts. This means that doctors must utilize their knowledge, skills, and experience to provide the most appropriate and effective care to their patients.

Additionally, Al Sanusi mentions that doctors in Libya are not obliged to heal people. While doctors are expected to provide medical treatment and care, they are not legally bound to guarantee a complete recovery or cure for their patients.

*Medical harms committed by doctors are generally viewed as unintentional and lacking criminal intent, except for specific situations defined as criminal under the law, such as abortion and other prescribed acts. Doctors are typically expected to exercise diligence and provide care rather than guarantee specific outcomes, which precludes the presence of criminal intent. Consequently, penalties recourse cannot be viable in such cases (**Al-Zuwy**).*

Al-Zuwy describes the overall perspective of the law regarding medical harms, which are generally characterised as unintentional and lacking malicious intent. Nevertheless, he states that apart from the overall perspective of the law, there are specific situations defined as illegal, such as abortion and other defined acts. He claims that certain acts can be considered unlawful, potentially leading to legal repercussions for doctors.

Al-Zuwy also claims that doctors are typically expected to be assiduous and provide their best care to help patients, rather than guarantee specific outcomes. Consequently, taking punitive action against doctors for medical harm is deemed inappropriate in most cases. Most cases of medical harm in the Libyan context are addressed by giving compensation to patients who suffer harm.

***HJ:** What will be the fate of healthcare staff if they were found liable for medical harm? Are there any penalties against them?*

***Mahmoud:** No, the issue is often dealt with in the civil realm, which pertains to the patient's entitlement to compensation. In most cases, judges adjudicate whether patients have the right to compensation or not, according to the schedule of compensation. The amount of compensation is determined on a case-by-case basis.*

Mahmoud responds by explaining that medical harm in such situations, the focus is usually on resolving the matter in the civil legal system. This means it's about the patient's right to receive compensation for the harm they've suffered. Instead of applying penalties on staff for medical harm, judges typically decide whether patients should receive compensation or not. The amount of compensation varies depending on the circumstances of each case, so it's determined individually for each situation.

Rather than facing punishments, healthcare staff found liable for medical harm will give the right to affected patients to obtain compensation through civil legal proceedings and compensation is made by the MIA. In addition, Mahmoud can give the perspective that the investigations regarding medical harm do not prioritize the negligence in performance which could be made by staff, and not for using punishments as a means of deterrent to prevent medical harm, instead, the investigations prioritize fairness regarding the patient's entitlement to compensation. This strategy focuses on justice and fairness for healthcare staff and patients.

> ***HJ:*** *Based on your experience, do you think healthcare staff who have caused medical harm need to undergo training and update their knowledge to improve their skills? This is for the purpose of enhancing patient safety and reducing medical harm, which will then lead to decreased compensation paid by the Medical Insurance Authority.*
>
> ***Abu al-Qasaim:*** *Believe me, the purpose of addressing and examining medical harms is not to reduce the payment of compensation, but diligence and correct behaviour of the healthcare providers will implicitly reduce the payment of compensation.*

Abu al-Qasaim argues that the main purpose of studying medical errors is not primarily to reduce compensation payments to affected individuals, but rather to promote diligence and correct behavior among healthcare providers. This, in turn, would indirectly lead to a decrease in compensation payments. By fostering a culture of diligence and correct behavior, the occurrence of errors can be reduced, resulting in fewer instances where compensation needs to be paid.

In summary, Abu al-Qasaim claims that by emphasising diligence and correct behavior, the likelihood of errors and subsequent compensation claims can be diminished.

7.3.2 Communications among Stakeholders

Ineffective communication among stakeholders is a pervasive issue that has emerged from data. The absence of organised learning from medical harm that occurred to patients can serve as a clear example of poor communication among stakeholders in Libyan healthcare.

Additionally, some interviewees argued that poor communication has led to difficulties in addressing medical harm reported by patients. Issues related to communication among stakeholders have been categorized into two areas, which are:

- Cooperation and Coordination.
- Overlapping Roles of Stakeholders.

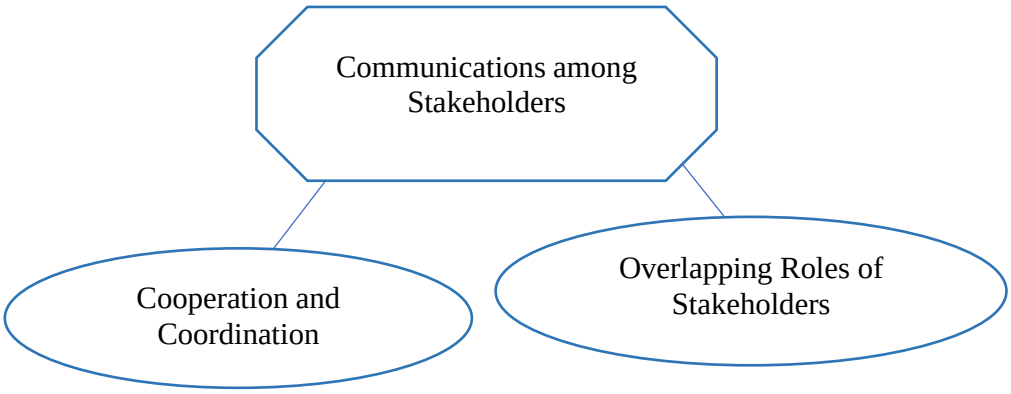

Figure 7-6 Schematic Diagram Illustrates the Factors that Influence Communication among Stakeholders in Libya

7.3.2.1 Cooperation and Coordination

While some participants state that there is cooperation and coordination between stakeholders in addressing the medical harm reported by patients, others describe situations where there is poor communication among the stakeholders.

Mahmoud describes how cooperation and coordination used to be between the MC and judicial authorities in order to address medical harm reported by patients.

> *The Medical Council is a body responsible for preparing technical reports or expertise reports, rather than adjudicating cases of medical harm. Its role is to determine whether there is a medical liability or not. The final decision on cases of medical harm rests with the judiciary. The technical reports from the Medical Council inform the judges whether there is a medical liability or not, in order to assist them in adjudicating cases of medical harm* (***Mahmoud***).

However, Mahmoud states that there is now poor cooperation and coordination with the judicial authorities for addressing medical harm.

> *Judiciaries now rely on different sources of experts to get explanations about medical harm. This means determining medical liabilities is not only more limited to the Medical Council* (***Mahmoud****).*

In addition, Abu al-Qasaim agrees with Mahmoud's opinion. He claims that now the judiciaries do not communicate with the MC to address medical harm.

> *The exists in Libya now is that judiciaries consult with random medical experts and then adjudicate on the medical harms without referring to the experts at the Medical Council (***Abu al-Qasaim**).

Mohamed expresses his opinion about the communication between the MC and healthcare training centers regarding learning from medical harm. He asserts that the training body is working separately from the national stakeholders who address medical harms.

> *We have not reached a stage to communicate with the experts in the medical council regarding medical harm cases that reach them through patients. As a training body, we are supposed to raise the quality of training so that the harms that reach the medical council are reduced. We must raise the level of training in all specialties and in all medical fields, even in dentistry, physicians and technical jobs, and therefore medical harms will be reduced (****Mohamed****).*

Mohamed indicates that their organisation has not yet reached a point where they communicate directly with experts in the MC about medical harm cases reported by patients. Instead, Mohamed emphasises their role as a training body. He states that their primary focus is on improving the quality of training across various medical specialties, including dentistry, physicians, and technical jobs. Mohamed believes that by enhancing the level of training in these fields, they can contribute to a reduction in medical harms overall.

Based on Mohamed's claim, it is clear that there is no cooperation and coordination between the MC and the training body to address the medical harm that has happened to patients. This aligns with the statement made by the interviewee from the MC, who confirmed that there is no direct communication with training bodies regarding the

medical harms that are reported to the MC. The absence of communication means that no lessons can be learned from medical harms.

> *The Medical Council submits all information regarding medical harm to the Ministry of Health, but the Ministry does not take any action, such as forming a committee or providing specific comments or requests. The Ministry of Health has received all the Medical Council's reports from 1990 until 2021. Unfortunately, there seems to be no interest from the ministry (**Mohamed**).*

Mohamed says that there is poor cooperation and coordination between the MC and the MOH in regard to addressing medical harm. Despite receiving this valuable information, the MOH doesn't seem to be doing anything in response. They aren't forming committees to investigate these issues, providing specific feedback on how to prevent similar problems, or making any requests for changes to promote patient safety. In simpler terms, the MC collects information about medical harms and sends it to the MOH, hoping that the ministry will do something to fix the issues and prevent them from happening again. However, the MOH has not shown any interest in taking action on these reports for over three decades, which is a cause for concern because it means that problems in the healthcare sector are not being addressed.

7.3.2.2 Overlapping Roles of Stakeholders

Abu al-Qasaim argues that there is a problem of overlapping powers and suggests the need for clear role boundaries for stakeholders involved in addressing medical harm.

> *We have a problem of overlapping powers. The Medical Insurance Authority must be independent and not subject to any other institution. Moreover, the Medical Council, which is known as the House of Experts or the National Council for the Determination of Medical Liability, is supposed to be the only body that determines medical liabilities for medical harms. The courts or forensic doctors do not have the right to determine medical liabilities (***Abu al-Qasaim**).

Abu al-Qasaim mentions an issue that revolves around conflicting powers and responsibilities within the stakeholders. Specifically, there are concerns regarding overlapping authority and the lack of clear boundaries between different stakeholders. He

stated that there is a need for the MIA to operate independently without being subject to the influence or control of any other organisations. The MC is intended to be the sole body responsible for determining medical liabilities in cases of medical errors. However, there appears to be a current situation in Libya where the courts or forensic doctors possess the authority to decide on matters related to medical errors without referring to the MC.

There is a management problem that lies in the overlapping powers and the lack of adherence to the intended roles and responsibilities among stakeholders. This situation undermines the independence of the MIA and allows the courts, rather than the MC, to decide on matters of medical liability.

7.3.3 Leadership and Governance Issues

Fadia's thoughts aligned perfectly with Abdallah's as they both stressed how deficiencies in leadership and governance can impede the development of a robust patient safety reporting and learning system.

> ***HJ:*** *Is there a policy in the Ministry of Health that clarifies the reporting process at the institutional level such as hospitals or clinics?*
>
> ***Fadia:*** *There are no policies on this issue due to the absence of leadership and a qualified leader. We lack a person with sufficient knowledge who can take charge of this position.*

Fadia claims there is a problem within the MOH. The issue of reporting and learning system is not being effectively addressed due to a lack of leadership and a qualified leader capable of making informed decisions and policies. This absence of leadership and knowledge is impeding the MOH's ability to address this issue appropriately. This, in turn, can result in inefficiencies, missed opportunities, or unresolved problems in the reporting and learning system.

In harmony with Fadia's viewpoint, Abdallah also emphasised the need to fix the defect in governance to enhance patient safety in healthcare institutions. Abdallah states that:

*The problem lies in governance and the method of quality management because there is nothing to convince the hospital director of the principles of quality, including patient safety. This issue appears to be incurable due to a defect in governance and the approach to managing health facilities (**Abdallah**).*

Abdallah argues that the core issue is governance, and the hospital's leadership doesn't seem to prioritize patient safety and high-quality care. This problem is compounded by a lack of effective quality management practices. In addition, Abdallah sees fixing the issue of governance as being as difficult as trying to change the course of a large ship, requiring a concerted effort from many stakeholders within the hospital.

From Abdallah's statement, it appears that there is insufficient understanding of patient safety at the institutional level, such as in hospitals. This deficiency may be due to defects in governance, which could result from the absence of policies that emphasise the importance of patient safety. Therefore, establishing a reporting and learning system could be challenging without implementing policies that highlight the positive outcomes of such a system on patient safety.

***HJ:** The Medical Insurance Authority has a lot of data regarding medical harms because it gives compensation to harmed patients. Why the Medical Insurance Authority does not build a reporting and learning system? by finding out and studying the reasons that led to medical harm, and then developing effective solutions to prevent the recurrence of medical harm?*

***Abu al-Qasaim:** This is the responsibility of the Ministry of Health because this overtime work is expensive and needs to pay money to operate such a system. The Medical Insurance Authority cannot open a school for education. By what right does the Medical Insurance Authority become like private schools? and what is the curriculum?*

From the above statement, Abu al-Qasaim highlights two points: the responsibility of the MOH and cost for operating the reporting and learning system. Abu al-Qasaim claims that establishing a reporting and learning system falls under the purview of the MOH, not the MIA. This may imply that there are no policies clarifying the roles of stakeholders

regarding the reporting and learning system. Abu al-Qasaim also states that operating the reporting and learning system involves costs and requires sufficient financial resources for effective operation. The MOH is responsible for overseeing healthcare services and policies within a country, and implementing a reporting and learning system is part of their mandate to enhance patient safety in the healthcare sector.

7.4 Chapter Summary

To conclude, this chapter wraps up the analysis of the data and the presentation of the results of this study. Participants bring a wealth of firsthand experiences. There are observed shortcomings in Libyan healthcare policy. These shortcomings pertain to the ethical dimensions and codes of conduct related to medical ethics, rather than legal aspects.

Participants assert that there is a significant deficiency in policies regarding patient safety and the reporting and learning system, a concern that resonates deeply within the Libyan healthcare sector. While it is evident that there are healthcare policies related to patient safety in Libya, these policies primarily emphasise the legal obligations of healthcare providers rather than their ethical responsibilities.

It is evident that medical ethics and codes of conduct have not been frequently addressed by participants. A code of conduct is a vital policy for every healthcare sector. Participants did not discuss the code of conduct as a component of medical ethics or as a crucial guideline for medical and paramedical staff within the Libyan healthcare sector. In many healthcare sectors, there are legal and ethical obligations to ensure a safe environment for patients. Legally, the Libyan healthcare sector is governed by various policies, including laws and decrees. However, participants did not reference policies related to medical ethics in this context. Ethically, healthcare providers have a responsibility to prioritise patient safety, and the lack of clear guidelines on medical ethics may lead to moral dilemmas, such as the reporting of patient safety incidents. The absence of comprehensive policies regarding medical ethics can expose healthcare organisations to liability if patient safety is compromised.

8 CHAPTER EIGHT – Discussion

8.0 Introduction

This chapter aims to fulfil the fourth and final objective of this study: to "contribute to the development of knowledge about patient safety and optimise the healthcare sector's system of reporting and learning from patient safety incidents". The chapter will discuss and integrate both the theoretical perspectives of Libyan healthcare policy and the practical insights gathered from participants, supported by relevant literature. First, the chapter will begin with a discussion on the influence of medical liabilities on the reporting of patient safety incidents within the Libyan healthcare sector. Following this, there will be a discussion of the current state of the PSI-RLS in Libyan healthcare. Subsequently, the chapter will explore the ethical theories related to PSI-RLS in the context of Libyan healthcare. The chapter will conclude with a summary that encapsulates the key points discussed.

8.1 Patient Safety Incidents and Medical Liabilities in Libyan Healthcare

Addressing patient safety incidents and medical liabilities can demonstrate how the intervention of medical liabilities influences the PSI-RLS in the Libyan healthcare sector. In simpler terms, the medical liability statute establishes a framework for justice for both healthcare providers and recipients of healthcare services in Libya.

The second subtheme of Theme One, which emerged from interviews, suggests that patient safety is the responsibility of all stakeholders involved in healthcare services, including healthcare providers, patients, and their families. Kennedy (2001) argues that ensuring safety is the responsibility of all staff in their various roles to create a culture of safety and deliver high-quality services within the NHS in the United Kingdom. However, in Libyan healthcare, ensuring safety also requires a legal perspective to protect the rights of healthcare providers and patients, as presented in the first subtheme of theme one.

There is a predominant focus on patient safety incidents from a legal perspective, with less emphasis on the ethical aspect. According to the Hippocratic Oath, medical practice is fundamentally ethical (Berdine 2015). However, much attention has been paid to the legal aspects of medical harm that occurs to patients. At the outset, it is important to reiterate

that, as discussed in Chapter One 1.5.1 and Chapter Two 2.6, medical harm constitutes one of the two events of patient safety incidents. The patient safety incidents examined in this study are classified as either harm or near misses. In other words, patient safety incidents can lead to either harm or no harm, irrespective of the severity of the harm as defined by OSHA.

According to Libyan healthcare policy, specifically statute No. 17, the whole healthcare sector, from Micro to Macro levels, is liable for the medical harm that occurs to patients. This liability encompasses everyone involved in delivering healthcare to patients, from medical and paramedical staff to the MOH. The liability can be applied in the form of compensation or/and disciplinary penalties. The primary focus of this liability is to provide compensation to harmed patients rather than imposing disciplinary penalties on healthcare providers. The compensation can be determined through civil compromise between the patient and the MIA. Legally, the judiciary adjudicates whether patients are entitled to compensation. Whereas disciplinary penalties related to medical harm can only be imposed by a decree from the MOH.

Funding for compensations is sourced from the income generated by mandatory insurance for medical and paramedical staff, as well as a deduction from the MOH budget. The MIA deducts 5% from the healthcare sector: 2% directly from the salaries of medical and paramedical staff, and 3% from the MOH budget. This percentage is subject to change through a governmental decree. However, the mandatory insurance cannot be annulled, as it is mandated by statute No. 17.

Libyan healthcare policy mainly focuses on addressing and reporting medical harm through legal and civil avenues, completely overlooking near misses. Additionally, there is insufficient attention to the ethical aspects of addressing medical harm or patient safety incidents. One key ethical consideration is the importance of learning from these incidents. Furthermore, there is ambiguity and a lack of clarity regarding the involvement of healthcare providers in reporting patient safety incidents.

The findings from the interviews revealed practical perspectives on medical liability associated with medical harm in Libyan healthcare. Many participants acknowledged the importance of the medical liability statute for both patients and healthcare providers. Some

participants argued that there is apprehension among staff at the micro level regarding liability for medical harm. This apprehension was often attributed to a lack of clear policies and inadequate interpretations of existing healthcare policies in Libya. While the law is important, ethical policies are equally essential. According to Cornock (2021), ethics and law are not a single entity, and both are vital to healthcare practice. Ethics and law interact to provide a framework for healthcare practitioners, ensuring they practise according to the shared values of society (Cornock 2021). There is a clear distinction between ethics and laws or statutes in the healthcare sector. It can be argued that ethics help people, while the law protects them. The table 8-1 below provides a concise comparison of the key differences between ethics and statutes (Hendrick 2000; Tingle and Cribb 2013; The Ethics Centre 2016; Xhemajli 2021; Hall et al. 2024).

Table 8-1 Comparison of the key Differences Between Ethics and Statutes

Contexts	***Ethics***	***Statutes/Laws***
Definition	A set of moral principles or values that guide individual behaviour and decision-making.	Formal written laws enacted by a legislative body
Branch	Philosophy: A branch of philosophy that deals with questions of right and wrong, good and bad, and moral duty.	Law: Rules that govern society and regulate behaviours. Created to maintain order, protect rights, and provide a framework for the functioning of society.
Subjectivity	Subjective and can vary between individuals, cultures, and societies.	Objective and uniformly apply to all individuals within a jurisdiction.
Enforceability	Not legally enforceable	Legally binding and enforceable

Legal Consequences	No legal penalties for non-compliance	Non-compliance can lead to legal consequences
Basis	Personal beliefs, societal norms, professional codes of conduct	Legislative process, part of the legal system

Gallagher and Levinson (2005) mentioned that the risks associated with revealing harm to patients, particularly the legal risks, are growing concerns for physicians. This disclosure dilemma is especially acute for private practitioners. Furthermore, even if physicians choose to disclose harm to a patient, they might be uncertain about what exactly to communicate due to the complexity of medical harm (Gallagher and Levinson 2005).

It is widely recognised that the disclosure of harmful medical errors is the right thing for hospitals and physicians to do. It supports ethical obligations and patient safety principles, and it can enhance trust in the patient-physician relationship (Kachalia et al. 2010). However, concerns that disclosure might lead to new claims or complicate subsequent litigation can inhibit the impulse to disclose. Consequently, in practice, disclosure may not occur as often as we would hope (Kachalia et al. 2010).

There is hesitation and apprehension about medical liability in the healthcare sector. Liang and Ren (2004) stated that healthcare providers in the United States fear admitting, reporting, and discussing incidents due to medical liability concerns. Thus, learning opportunities that could save lives are lost. In addition, Kachalia et al. (2010) stated that it is currently unclear whether increased disclosure of medical harm will lead to higher or lower liability. Some doctors and risk managers worry that admitting medical harm may amount to handing over a blank cheque and invite lawsuits and disputes about compensation amounts. Others counter that prompt disclosure may reduce liability because patients primarily seek the facts, a sincere apology, a commitment to prevent the harm from recurring and fair compensation (Kachalia et al. 2010).

Liang and Ren (2004) have suggested that to effectively address the medical liability and insurance issue, we must move beyond superficial symptomatic treatment and instead

address the substantive root cause: reducing incidents to reduce harm. This approach will, in turn, effectively reduce the number of lawsuits and stabilize healthcare access and costs. To effectuate such a goal, healthcare providers need liability reform, an infrastructure conducive to the open discussion of patient safety incidents and an assurance that information collected for safety purposes will not be used against them (Liang and Ren 2004).

It is beneficial to clarify the differences between the terms liability, accountability and responsibility, as these are often used incorrectly in various contexts. Cornock (2014) argue that responsibility means to be responsible for ensuring that something is carried out whilst accountability moves beyond this to encompass the responsibility but adds a requirement that the healthcare provider provides an account of how they undertook the particular task. Liability moves the definition forward by adding a dimension of jeopardy to the definition of accountability. In a strict legal sense once the accountable persons have provided their account, they have fulfilled their duty. However, if the healthcare provider is liable rather than accountable for their action then the account they provide will be judged (Cornock 2014). These three terms can be viewed as a hierarchy, with responsibility being the least onerous, moving through accountability, to liability having the most potential impact (Cornock 2014). Ethically, there is little to choose between being responsible, accountable and liable for our actions. However, responsibility, accountability, and liability each have distinct legal meanings (Ellis and Ellis 2021). Table 8-2 below highlights the differences between liability and accountability (Mahlmeister 1999; Ieraci 2007; Cornock 2011; Saboor 2023), both are essential concepts and need to be considered in the healthcare sector.

Table 8-2 Distinguishing Between Liability and Accountability

Basis	**Accountability**	**Liability**
Definition	Refers to the state of being answerable or responsible for one's actions, decisions, or obligations.	Refers to the legal responsibility or obligation to compensate for harm, damage, or loss caused to someone or something.

Context	A social or moral responsibility that individuals or organisations have towards others.	Primarily used in the legal context.
Scope	Covers actions, decisions, or obligations.	Covers harm, damage, or loss.
Authority	Being answerable to someone or some authority for the outcomes or consequences of one's actions.	Legal consequences or penalties.
Imposition	Can be voluntary or imposed by external factors such as laws, regulations, or social norms.	Arises when there is a breach of legal duty or when someone is found to be at fault or responsible for causing harm or damage.
Focus	Explaining, justifying, or providing an account of actions or decisions.	Legal obligation to pay compensation or bear consequences.
Associated Factors	Often associated with transparency, integrity, and trustworthiness.	Financial or legal consequences.
Nature	Social or moral obligation.	Legal obligation.

The medical liability statute in Libya aims to make the healthcare sector safe for everyone by protecting healthcare practices. It ensures that medical and paramedical staff can practice their professions in safe conditions and that patients receive safe healthcare.

8.2 Reporting Patient Safety Incidents in Libyan Healthcare

ELMeneza and AbuShady (2020) stated that incident reporting is a pillar of safety culture and quality improvement in health care. However, Vincent (2011) argues that reporting systems in most healthcare sectors lack cohesion and integration. Arabi et al. (2016) added that incident reporting systems are often used without a structured review process, limiting their utility to learning from defects and compromising their impact on improving the healthcare sector. Furthermore, Vincent (2011) argues that in many cases, there is little consideration given to whether national reporting systems are equipped to handle incidents that are best addressed institutionally, and vice versa. This often leads to significant frustration and duplication of effort.

As stated in the research aim, this study explores the PSI-RLS in the Libyan healthcare sector, focusing on the experiences and perceptions of key healthcare policy stakeholders. Exploring the process used for reporting patient safety incidents in Libya can contribute to the development of knowledge about patient safety and optimize the healthcare sector's reporting and learning system. The following illustrates the state of the reporting process in Libyan healthcare. Starting with patient involvement in reporting medical harm, followed by the state of reporting patient safety incidents by healthcare providers.

8.2.1 Patient Involvement in Reporting Medical Harm in Libyan Healthcare Sector

Patients and their families are central to reporting medical harm in the Libyan healthcare sector. Liang and Ren (2004) assert that healthcare providers must prioritise integrating the most valuable yet often overlooked stakeholders in healthcare improvement efforts: patients and their families. By partnering with patients, the provider-patient relationship is strengthened, communication is enhanced, safety is promoted and fostering a culture of collective improvement rather than individual blame. Additionally, harmed patients should receive compensation, have the opportunity to express their grievances, and have their suffering acknowledged (Liang and Ren 2004). Furthermore, Kennedy (2001) emphasised the necessity of public involvement in ensuring the competence of healthcare providers in the United Kingdom. He argued that patient and public participation must be embedded in the structures of the NHS and permeate all aspects of healthcare. He also stressed the importance of transparency and openness in the processes that engage the public and

patients. According to Wolf and Hughes (2008), patients can play an essential role in reporting essential information about the occurrence of harm associated with medical interventions. Patient reporting can be an essential part of the reporting system, as it aligns with the concept of patient-centered care. Sherwood et al. (2012) stated that healthcare providers, administrators, and policymakers need to recognise the patient-centred value of "nothing about me without me" and act accordingly.

The Libyan healthcare sector has a formal process for reporting patient safety incidents by patients or the harmed party. However, only incidents involving medical harm are reported through this process, and near misses are not included (See Figure 8.1 below). Reporting medical harm by patients can help identify two key issues that can enhance learning from patient safety incidents and improve patient safety. These issues are medical complications and systems failures occurring within the healthcare sector. Reporting medical harm by patients can help identify systems failures within the healthcare sector, as patients experience the entire healthcare process within the sector. Unlike administrators, providers, and other healthcare professionals who only see their specific roles, patients and their families experience the entire healthcare journey (Liang and Ren 2004). Studies have shown that adverse events or medical harms are commonly associated with failures and/or defects in the design, organisation, operation and management of medical systems, and human error is only part of the problem of lapses in patient safety (WHO 2010). In addition, reporting harm by patients can help identify medical complications occurring due to medical interventions, such as adverse drug reactions. Wolf and Hughes (2008) stated that without the patient's reports of adverse drug reactions, healthcare providers would not be aware of the majority of these reactions. This matches the findings of the scoping review in chapter two. About 25% of the included studies examined healthcare providers' views on the medication reporting system. None of the studies included patients' perspectives on reporting medication harm. Additionally, practical experiences in Libyan healthcare, as detailed in chapter six, section 6.2.2.3, confirm the medical harm caused by complications and system failures.

The mechanism for reporting medical harm in Libya is founded on three key pillars: medical liability, medical harm and compensation. Medical liability statute permits patients

to seek compensation through either civil or legal avenues if they suffer harm due to the actions of healthcare providers. Libyan healthcare providers are liable for the medical harm caused by their actions. However, there is no medical liability on the healthcare provider if the harm is caused by the patient's actions. For example, medical liability does not arise if the harm results from the patient's refusal to receive treatment or failure to follow medical instructions. Patients, experts in the MC, the MIA and the judiciary are all involved in reviewing and deciding on cases of medical harm.

Patients have the autonomy to report medical harm or not, and they can choose to report it through either civil or legal avenues. It can be argued that the patient reporting process in the Libyan healthcare sector is transparent and open. The process for reporting medical harm is non-anonymous, as patients choose to provide full details of their cases. From a safety perspective, this approach can improve the understanding of harm occurrences, thereby enhancing learning. Ethical obligations and patient safety principles support the prompt disclosure of harmful medical errors; such transparency can enhance trust in the patient-physician relationship (Kachalia et al. 2010). The patient reporting approach allows for a comprehensive understanding of harm, thereby enhancing learning from patient safety incidents. However, in Libyan healthcare, there is no macro-level learning from this approach. Near misses are also not reported via this process. Another disadvantage is that patients may choose not to report their medical harm for their own reasons, such as the desire to protect their identities and privacy or because the costs associated with making a claim may outweigh the compensation they would receive. Any medical harm, minor or severe, can be reported by patients. As a result, minor instances of harm may go unreported, leading to numerous cases of medical harm being overlooked. Research has shown that the majority of safety improvements stem from identifying and addressing near misses and minor harmful incidents that occur repeatedly over extended periods of time (Leroy 2011).

When a patient reports medical harm through civil avenues, experts in the MC provide testimony regarding medical liabilities. The compensation amount is then determined through a compromise between the harmed party, the healthcare providers and the MIA (the insurer). When a patient reports medical harm through legal avenues, experts in the MC also provide testimony regarding medical liabilities. However, the judiciary

adjudicates the amount of compensation. Involving stakeholders in reviewing the medical harm can help to understand the medical harm. Vincent (2011) stated that to fully understand an incident, it's important to have the complete story and to have it interpreted by someone who understands the work and the context. This means that healthcare incident reports should be reviewed by clinicians and ideally by individuals who can also identify human factors and organisational issues, to be truly valuable (Vincent 2011). In addition, one of the main challenges in healthcare is the vast number of reported incidents, which results in only a small fraction of incidents being reviewed by experts in the field (Vincent 2011). The following details focus on a process for patients to report medical harm and describe the legal avenue when healthcare providers are liable for medical harm.

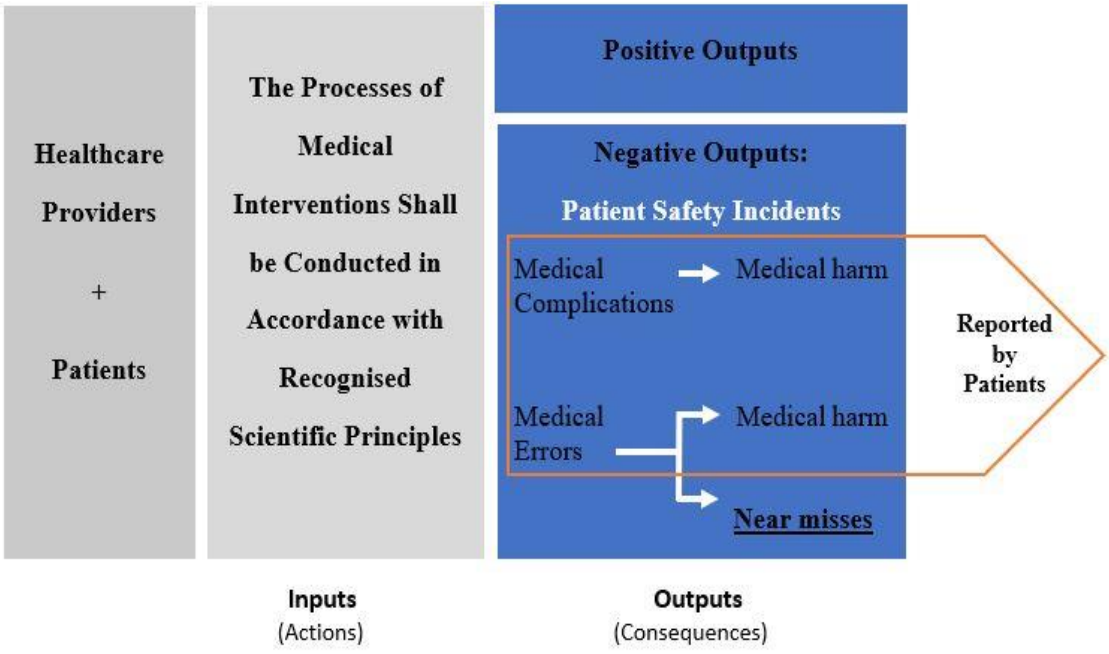

Figure 8-1 Recognised Patient Safety Incidents Reported by Patients

Medical complications are a common type of patient safety incident, mainly reported by patients themselves in the Libyan healthcare sector. These complications are medical harm arising from medical interventions that adhere to recognised scientific principles. One example of a medical complications is adverse drug reactions. Al Qubaisi et al. (2014) stated that adverse drug reactions are deemed preventable and are also considered to be patient safety incidents. According to Kommu et al. (2024), an adverse drug reaction is a

response to a drug which is noxious and unintended, and which occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or the modification of physiologic function. Patton and Borshoff (2018) claim that adverse drug reactions are a significant source of morbidity and mortality, accounting for up to 6% of hospital admissions, with a mortality rate of 2%, and costing the NHS £466 million annually.

In certain instances, patients may experience medical harm even when interventions are executed correctly. While these medical interventions or procedures are generally effective for the majority of patients, some individuals may have adverse reactions to them. In the context of Libyan healthcare, this type of harm is classified as a medical complication. A clear example of that is vaccination programs which may not work 100% with all patients. In such instances, medical harm is primarily raised due to the underlying condition and characteristics of the patient, secondary due to the action of the healthcare provider. However, healthcare providers may still be liable for such harm and are obligated to compensate the harmed patients via their insurer (the MIA). This highlights the importance of continuous learning to reduce the occurrence of medical harm reported by patients. A study conducted in Libya by Ismail and Shedeed (2012) found that iatrogenic complications are a significant issue in the pediatric intensive care unit at Gharian Teaching Hospital. The study reported an incidence rate of 22.9% among admitted cases over a one-year period. Human error (18.4%) followed by machine defects (4.5%) were identified as the most common causes of iatrogenic complications (Ismail and Shedeed 2012). Ignoring this type of harm can lead to its recurrence, increasing the liability of healthcare providers who must compensate patients. At this point, it should be clarified that medical liabilities are not intended to deter healthcare providers from committing medical harms instead, it is to protect the patients' rights. It could be argued that compensation for medical liabilities poses a financial threat to healthcare sector in Libya. Liang and Ren (2004) highlighted that the medical liability crisis significantly impacts the healthcare sector in the United States. Medical liabilities and limited access to insurance for physicians and hospitals have pushed many providers to leave their states, reduce their services or simply retire (Liang and Ren 2004).

In the Libyan healthcare sector, liabilities oblige healthcare providers to provide an explanation when things go wrong (medical harm). Liability focuses on “What happened?” to primarily adjudicate patient entitlement for compensation. It does not consider the reasons why things go wrong or the corrective actions regarding medical harm. Medical liabilities do not interfere in the technical aspects or affairs of the healthcare field and matters of medical background. For example, it cannot allege that the reason for medical harm is negligence. However, it does interfere where there is a risk to the public's safety or social and cultural aspects. Thus, there might be corrective actions with social and cultural backgrounds as stated in the statutes. For instance, Libyan healthcare providers or physicians will be punished for performing euthanasia, even if patients request it, as declared in statute No. 17, article 12 (Chapter Four: section 4.3). Scambler (2008) claims that it is important to draw attention to the social and cultural aspects of even the construction of medical knowledge. He added that the failure to integrate scientific medicine with its social context, or to face some of the difficult implications of its practice, will in the long run detach medicine from its humanitarian mission. In addition, social science approaches can enhance patient safety and contribute to scientific knowledge about safety (Ovretveit 2009).

In 2022, a book documenting cases of medical harm reported by patients was published. The author of this book serves as the chairman of the MC in Libya. The book is formatted in A4 size and is divided into three sections. The first section, spanning pages 1 to 16, discusses the history of medical liability from social and cultural perspectives, the legal framework governing medical liability in Libya, and the administrative, financial and medical challenges within the Libyan healthcare sector that have impacted the operations of the MC. It also offers recommendations for improving medical practice in Libya. The second section, covering pages 16 to 220, presents various cases of medical harm reported by patients or their families. These cases are summarised in a brief, encrypted and anonymous format, encompassing medical harms from the establishment of the MC in 1989 to the end of 2019. The last section of the book, from pages 221 to 230, provides suggestions regarding the code of ethics, conduct and etiquette for the medical profession. Al Montaser (2022) argue that Libya is unique in its medical liability statute which is a civilised achievement that only requires some amendments and developments that the MC

have raised on several occasions since the MC discovered them during practical practice. Unfortunately, the response to these requirements has been much less than what the MC was hoping for. According to Al Montaser (2022, p. 8), a total of 3224 cases were reported by patients through civil and legal avenues. The MC completed and provided testimony for 2400 cases, while 824 cases were not completed due to some issues such as administrative issues in the health sector. A little more than a third (876) of the completed cases had medical liabilities on healthcare providers, whereas about two-thirds (1524) had no liability on the healthcare providers. Below are three cases as an example of medical testimony provided by the medical experts in the MC.

Case One:

"The medical council reviewed the file of one of the cases in its ninth meeting of the year 1998, held on September 08-1998. Upon reviewing the documents recorded therein regarding the birth of the aforementioned child, the council found the following:

The medical team has been requested to attend, but no one did. According to the hospital administration's statement, one of the doctors went on vacation about a year ago and has not returned yet, and the service of the second has ended. The case was in her eighth pregnancy, meaning she had multiple births and fell within the definition of high-risk cases. Additionally, as stated in her medical file, she had high blood pressure, and the pregnancy had passed its due date. The ultrasound report indicated a deficiency in the amount of amniotic fluid. All of this data necessitated rapid intervention to perform a caesarean section to save the mother and her fetus, as both were scientifically exposed to risk. What happened to the child is a rare phenomenon, although no patient has been afflicted with what the case suffered, and with a birth weight less than the average birth weight. In this case, surgical intervention was the optimal treatment, and since that was not done, the council believes that the risks that the case and her fetus were exposed to and the resulting complications constitute a medical liability for the medical team at the hospital" (Al Montaser 2022, p. 110).

Case Two:

"The council reviewed the file of another case in its seventh meeting held on June 24-1997. After studying the case and discussing the information recorded in it, including the hysterectomy performed by the treating physician, the council found the following:

The surgeon who performed the hysterectomy was not at a degree of competence that qualified him to perform such an operation. The complications that the patient suffered after the operation indicate his dereliction and negligence. This holds him liable for the harm that the patient was exposed to as a result of the complications that occurred after the operation" (Al Montaser 2022, p. 111).

Case Three:

"The medical council reviewed the file of one of its cases in its twenty-third meeting for the year 2012, held on December 11-2012. The following is a prepared statement regarding it:

Injury to the sensory nerve (mandibular lingual) when extracting the lower third molar is considered a possible complication that cannot be avoided in many cases. The symptom of numbness may disappear after a period ranging from weeks to months to years. Regarding the patient's complaint of losing the sense of taste, this is something that cannot happen in such cases because the surgical area is very far from the nerve that is responsible for the sense of taste. Therefore, there is no medical liability" (Al Montaser 2022, p. 216).

In case one, the MC has the right to call the medical team to discuss the medical harm. This can be considered accountability as it occurs between healthcare staff and within the healthcare sector. Regardless of the attendance of the medical team, if the experts believe that there are medical liabilities on the healthcare providers, then the healthcare sector is still liable for the medical harm. Therefore, the patient can receive compensation.

In case two, the experts have mentioned their opinion about the cause of the medical harm. They have identified the negligence of the surgeon as the reason for the medical harm. Again, regardless of the cause, the key issue is whether there are any liabilities on the healthcare providers. Their testimony can be used to primarily adjudicate patient entitlement for compensation. Medical testimony in most cases, as mentioned by some participants, is not to punish healthcare providers but rather to ensure patient compensation. In case three, there were no medical liabilities on the healthcare provider.

As the judiciary is an independent authority, they have the autonomy to make their adjudications based on their doctrine. The final decision regarding medical harm reported via a legal avenue will be adjudicated by the judiciary. This means that even if medical testimony indicates liability for the healthcare providers, the judiciary, after considering the patient's statement, may decide otherwise. Conversely, in cases where no liability is found on the part of the healthcare provider, the judiciary may still find them liable. Medical testimony does not go beyond technical medical aspects. Therefore, the judiciary is not obligated to follow a specific opinion or testimony. In other words, the MC cannot bind or compel the judiciary to accept their testimony. Although no judges were interviewed in this study to provide their opinions, but Mahmoud's citation suggests that the judiciary might delve deeper into the medical harm and seek additional medical testimony beyond the MC. Mahmoud stated:

> *Judiciaries now rely on different sources of experts to get explanations about medical harm. This means determining medical liabilities is not anymore limited to the Medical Council* (***Mahmoud****).*

Additionally, the judiciary might have insights that differ from the medical ones. This is crucial for safeguarding the rights of both patients and healthcare providers. This concept is supported by Ibrahim's citation in Chapter 5, Section 5.2, which discusses how the law can protect the rights of both parties. As mentioned earlier, there might be corrective actions with social and cultural backgrounds as stated in the statutes. This means patients are not immune to judicial rulings. For example, the judiciary may seek more evidence to prevent fake claims of compensation or fraud and deception intended to result in financial or

personal gain that may impact medical practices and the healthcare sector, both of which are important for the health and safety of the public and society. Therefore, there might be punishment for fake claims of compensation if there is evidence to support that. Above all, patients or healthcare providers also have the right and autonomy to appeal against judges' rulings.

8.2.2 Healthcare Providers and Reporting Patient Safety Incidents in Libyan Healthcare

Healthcare providers are often so devastated and embarrassed by their medical errors that they may attempt to conceal them or defend themselves by shifting the blame to someone or something else (Wolf and Hughes 2008). Sherwood et al. (2012) emphasise that numerous errors in healthcare settings remain unreported. A major concern clinician have is that self-reporting will result in repercussions. The failure to report errors has implications for both individual clinicians and the organisations they are part of. One significant consequence is the missed opportunity to gain experience of and understand these errors.

Theoretically, Libyan healthcare providers can report and learn from patient safety incidents through the Libyan national reporting system which is an anonymous reporting system, ensuring that patients cannot be identified in such reports. Therefore, this system could help alleviate concerns about medical liabilities when healthcare providers report patient safety incidents. Anonymity is crucial for protecting and enabling reporters to share their experiences without fear of recrimination (Howell et al. 2017). According to Sherwood et al. (2012), the opportunity for anonymous reporting is believed to increase the willingness to report incidents. However, the reports of incidents filed by medical and paramedical staff may not provide comprehensive information, as they are usually submitted anonymously. Vincent (2011) added that the anonymity of the reporter can be a significant disadvantage, as it prevents those managing the reporting system from seeking additional information to clarify the details of an incident. Most reporting systems encourage the submission of a narrative or story of what happened. Focusing only on basic factual details, which is often the case in healthcare, is not very useful as it reveals little about the causes of the incident (Vincent 2011).

Nevertheless, at the institutional or micro level, healthcare providers may choose to include their names in the report to offer further clarifications on patient safety incidents if needed. A study by Shehata et al. (2016) stated that a non-random sample of 50 junior clinical pharmacists from seven different hospitals was selected, and the pharmacists were trained on the process of reporting any medication errors that arose during their work, including near misses. During the 6-month study period, 1200 reports were validated and included in the analysis (with an average rate of 200 reports per month). There were 42 identifiable reporters, all of whom were pharmacists working in governmental and university hospitals, and only 25 reports were submitted anonymously. According to Libyan healthcare policy, patients are stipulated to report medical harm to determine medical liabilities. In such cases, the identity of both parties—the patients and the healthcare providers—needs to exist to establish these liabilities. Therefore, medical liabilities cannot occur if the patient's identity does not exist. In addition, healthcare providers must ensure patient anonymity when reporting patient safety incidents to avoid medical liabilities arising from the disclosure of patient identification, as they are obligated to protect the patient's confidentiality according to statute No. 17: article-13 (See Chapter Four Section 4.3).

From a legal perspective, it could be argued that healthcare providers cannot be held liable based on anonymous medical harms cases. This is because such reports cannot be confirmed as true or false, given that the other party (the patient) is not present to verify them. Additionally, these reports can include both medical harms and near-misses. Medical liabilities cannot be applied based on near misses, as no harm has occurred to patients. Sheikhtaheri (2014) assert that reporters of near misses are not exposed to blame, shame or legal litigation. This may positively influence staff willingness to report these incidents without fear. Additionally, reporters may be rewarded or recognised for their efforts in preventing harm.

Furthermore, medical and paramedical staff at the institutional level have the option to report and learn from incidents without facing repercussions. This approach can enhance patient safety within the hospital and potentially reduce the medical harm reported by patients, thereby avoiding associated consequences. However, as noted by AL Zuwy, healthcare staff members may face practical repercussions, such as blame, when they report

patient safety incidents. This may discourage employees from reporting such incidents and could lead to the concealment of patient safety incidents within the institution.

> *In hospitals, some doctors may face disciplinary penalties, such as being blamed, for specific harms (**Al Zuwy**).*

According to Libyan healthcare policies, disciplinary penalties can be imposed to medical and paramedical staff concerning the safety of patients and the public. These penalties range from a warning to deprivation from practising the profession (Chapter Four: 4.4.2.3). This can be perceived as a barrier to reporting patient safety incidents, similar to some healthcare contexts according to the literature. Wolf and Hughes (2008) claim that clinicians working in a culture of blame and punishment do not report all incidents. However, in Libyan healthcare policies, the imposition of disciplinary penalties is conditioned by medical harm claimed by patients. This harm must be verified by experts in the MC and the judiciary, as outlined in statute No. 17. According to this statute, disciplinary penalties must be administered through a disciplinary trial in a professional court, presided over by a judge and two doctors. Additionally, these penalties can only be imposed by a decree from the MOH, as stipulated in statute No. 17.

> *"The decree to refer to the disciplinary trial shall be issued by the General People's Committee for Health or its designated delegate"* (**Statute No. 17: Article- 29**).

The regulated process of imposing disciplinary penalties can protect medical and paramedical staff, whether in the public or private sector, from arbitrary and unjust blame or punishment regarding patient safety incidents. The MOH does not have the authority to penalise healthcare providers based on their own arbitrary or unjust decisions. Healthcare institutions and management at the meso and micro levels also do not have the right to punish, even to blame, medical and paramedical staff for incidents they made. According to statute No. 17, it is prohibited to penalise medical and paramedical staff for incidents without a decree from the MOH. Furthermore, the judiciary cannot impose penalties on healthcare providers for harm caused unless there is a risk to social and cultural safety, as outlined in the statutes. This process of administering disciplinary penalties protects medical and paramedical staff from disciplinary penalties that may be imposed by the meso and micro levels. The absence of punishment at these levels could be a key factor in

encouraging Libyan healthcare providers to report and learn from patient safety incidents. Regulating and controlling the process of imposing disciplinary penalties related to medical harm could represent a positive step toward enhancing patient safety in the Libyan healthcare sector. However, the lack of structured learning from these incidents can adversely affect both the health sector and patients. Without a learning mechanism, the same harm may recur, resulting in further patient injury and increased compensation costs, which, in turn, lead to higher insurance premiums for healthcare providers.

In the Libyan healthcare sector, mandatory insurance protects healthcare providers against the patients' claims regarding medical harm. The money collected from the healthcare providers is used to compensate patients in case of medical harm. It could be argued that this insurance provides reassurance to healthcare providers to practice their work and compensates patients in case of medical liabilities. However, medical liability does not specify a certain amount of compensation for the harmed party. Insurance premiums may fluctuate depending on the reported harm. A committee determines the percentage of impairment or harm suffered by the patient, and on this basis, the value of compensation is determined by referring to the regulations contained in the law. In a case similar to Libyan healthcare, Liang and Ren (2004) stated that in the world of insurance in the United States, it is axiomatic that patient harm leads to claims. These claims for harm indemnification increase insurer costs, which in turn result in higher premiums for the insured. Therefore, reducing patient harm will lead to fewer claims, lower insurer costs, and ultimately stabilised or even lower premiums for the insured. It is therefore essential that harm be addressed as a root cause of insurance stability (Liang and Ren 2004).

The mandatory insurance in Libyan healthcare can be another advantage that protects healthcare providers from patient claims due to medical harm. Therefore, from an ethical perspective, it is wise to report patient safety incidents and learn from them to reduce the medical harm that could affect patients in the future. From a legal perspective, Libyan healthcare providers should report and learn from patient safety incidents to reduce the harm reported by patients, which will lead to fewer claims, which in turn will lead to lower premiums for the healthcare providers. Wolf and Hughes (2008) stated that the ethical principles of beneficence “doing good” and nonmaleficence “preventing harm” are violated

when incidents are not reported or disclosed. They added that candid reports and disclosure of incidents by healthcare providers might result in greater patient trust and less litigation. Promoting patient safety and preventing harm are fundamental principles of nursing practice, addressed in ethical and professional guidelines worldwide (American Nursing Association 2015; Royal College of Nursing 2010). The main reason for healthcare providers to report incidents is to improve patient safety by recognising that safety can be enhanced through learning from incidents, rather than pretending that they have not happened (Mahajan 2010).

Near misses are not considered patient safety incidents at the national level in the Libyan healthcare sector. However, Libyan healthcare providers have the opportunity to gain experience and learn from near misses, as they do not involve medical liabilities. Healthcare providers need to report and treat near misses as patient safety incidents. Sherwood et al. (2012) stated that near misses are more common than adverse events and provide valuable insights into system weaknesses that could lead to adverse events. According to Leroy (2011), regular screening for near misses, which occur more frequently, is more effective than solely analysing severe incidents.

In some cases, the healthcare providers realise that they caused an incident to the patient by performing a wrong or non-recognised medical intervention, but no harm occurred. This does not mean they were lucky because there is a likelihood of harm occurring and there is still a risk of harm to future patients. Therefore, healthcare providers are accountable for the investigation and learning from these types of incidents which are considered near-misses. Healthcare providers are accountable for investigating and learning from the wrong or non-recognised medical interventions. In addition, healthcare providers are accountable for investigating and learning from medical harm that arises from the right or recognised medical interventions (medical complications). Elmontsri et al. (2018) stated that in developing countries, continuous learning, accountability and mindfulness are critical matters for improving patient safety. Moreover, the creation of a learning organisation is considered as part of the efforts being undertaken to improve patient safety (Elmontsri et al. 2018). Accountability requires justification when things go wrong (medical harm) or could go wrong (near-miss). Accountability to patients and families is a hallmark of a

culture of safety (Sherwood et al. 2012). In addition, accountability cares more about "Why this happens?", to primarily learn from patient safety incidents. It does care about the reasons why things go wrong or could go wrong and then provides reactions to address these patient safety incidents. Healthcare providers should have the opportunity to learn from patient safety incidents 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).

8.2.3 Autonomy for Reporting Patient Safety Incidents

Autonomy in reporting patient safety incidents is a key issue in designing the PSI-RLS. While many believe that reporting should be voluntary, others argue that it should be mandatory. Labib et al. (2019) believe that voluntary reporting is an essential step to improve patient safety. Mekhjian et al. (2004) stated that the importance of an effective voluntary and anonymous event reporting method is universally acknowledged. Hewitt et al. (2017) argue that voluntary incident reporting systems are an approach to improving patient safety, as evidenced by their inclusion in many hospital accreditation programs. In addition, Wolf and Hughes (2008) argued that healthcare providers may not provide detailed descriptions of medical incidents when reporting them mandatorily, since they are motivated by a requirement. However, voluntary reporting may not be the most effective approach, as healthcare providers often have concerns about career-threatening disciplinary actions, as well as possible malpractice litigation and liability. In addition to that there is a concern that with voluntary reporting, the actual frequency of incidents may be much higher than what is reported. Gong (2011) added that voluntary incident reporting systems are a valuable source of adverse events and near misses in the healthcare sector. Unfortunately, such systems usually contain a large amount of incomplete and inaccurate reports, which negatively affect their utility for learning.

The IOM differentiated between mandatory and voluntary reporting of healthcare errors. A voluntary reporting system encourages healthcare practitioners to report incidents, providing valuable information that could help reduce future errors (Wolf and Hughes 2008). Mandatory reporting systems require healthcare practitioners to report incidents that result in patient harm or death (Wolf and Hughes 2008).

Vincent (2011) claims that the IOM recommends establishing a nationwide mandatory reporting system for adverse events involving death or serious harm. Mandatory reporting to a regulatory body serves objectives beyond learning. Such systems demonstrate organization's accountability for harm, provide a minimum level of protection to the public and assurance that harms are fully investigated. Most importantly, such bodies have the power to impose changes across the healthcare sector where necessary. However, in the United States, most hospital leaders believe that a mandatory, non-confidential reporting system run by the state deters reporting of patient safety incidents. Additionally, the majority argue that such a system encourages lawsuits (Wolf and Hughes 2008).

Flink et al. (2005) argue that the development of mandatory reporting systems faces a central conflict that creates a significant barrier. The public wants accountability from physicians and other healthcare providers, while physicians and hospitals are concerned about malpractice liability and damage to their reputations (Flink et al. 2005). Physicians and hospitals prefer voluntary reporting and sharing of information to enhance patient safety, which is beneficial when the main objective is to learn from previous incidents and experiences. However, the public believes that mandatory reporting is essential for ensuring accountability (Flink et al. 2005).

The Anesthesia Patient Safety Foundation (APSF) believes that implementing a mandatory reporting system is quite complex, and there is no evidence to suggest that it leads to significant improvements in practice (Flink et al. 2005). The American Medical Association (AMA) and the American Hospital Association (AHA) oppose mandatory reporting, arguing that any reporting linked to punitive action or public disclosure may turn the reporting process into a mere "numbers game" and drive reporting underground by perpetuating a culture of blame. On the other hand, some argue that the system should be mandatory, while opponents fear that this approach would discourage reporting and create liability issues for healthcare providers (Flink et al. 2005).

In the context of Libyan healthcare, there is no evidence that patient safety incidents are mandatory reported by healthcare providers or patients, either in policy or in practice. According to Libyan healthcare policies and data from interviews, there is no established legal framework that requires the reporting of patient safety incidents. Healthcare providers

and patients are not legally obligated to report patient safety incidents. The following section shows more details about the characteristics and principles associated with the concept of the PSI-RLS in Libyan healthcare.

8.3 Characteristics and Principles of Patient Safety Incidents Reporting and Learning System in Libyan Healthcare

As mentioned in the introduction chapter, reporting systems fulfill one or more of five primary functions (see section 1.5.2). Although Libya currently lacks a formal and effective PSI-RLS within its national healthcare sector, the existing system does serve two main functions:

1. Public accountability;
2. Response to the patients and families involved.

These two functions are most pertinent for Libya, where there is a focus on the legal aspects of patient safety and the reporting of incidents by patients or their families. According to the medical liability statute, patients can receive compensation if the involved stakeholders prove the harm. Therefore, this policy can be seen as fostering a system that encourages public accountability within the Libyan healthcare sector regarding medical harm, while also emphasizing the importance of responding to patients and their families. However, this system does not serve as an effective communications alert route, barometer of risk within healthcare or/and foundation for learning and improvement. This limitation arises from the absence of a code of conduct that would clarify these functions.

In addition, the characteristics and principles of the existing system stem from social and ethical viewpoints. These viewpoints are discussed below.

8.3.1 Social Viewpoint

In the Libyan healthcare sector, there is a national and voluntary approach to reporting medical harm. While reporting such incidents is not compulsory, it is stipulated to be reported voluntarily by the affected parties—patients or their families—rather than by healthcare providers. From this central perspective, understanding the concept of PSI-RLS in Libya can be better understood through a social science lens. For instance, the debate over whether the PSI-RLS should be mandatory or voluntary is addressed by granting

patients the right to voluntarily report medical harm. Meanwhile, healthcare providers in Libya also have the option to voluntarily report patient safety incidents. Viewing the implementation of PSI-RLS through a social science perspective can enhance their effectiveness. Iedema (2009) argues that patient safety research has tended to privilege the formal and structural dimensions of safety at the expense of the social and affective dimensions of safety. Ovretveit (2009) added that the value of social science perspectives and studies for practical action is significant. This is particularly evident in challenging common assumptions and demonstrating why certain strategies, such as voluntary incident reporting, are not achieving their objectives. Moreover, Hewitt et al. (2017) stated that voluntary incident reporting systems are complex sociotechnical systems that can benefit from evaluations using a social science lens.

Scambler (2008) argues that modern medicine may seem distinctly different from other approaches because it is based on the clearly superior rationality of modern science. The evidence supporting this view is compelling, as medical science can diagnose, treat, and cure many afflictions that have affected human beings for thousands of years. However, this approach only tells part of the story. Both medicine and science exist in social contexts which can place limits and challenges to their activities (Scambler 2008).

Compensation for medical harm imposed by medical liability statute can be the foundation for establishing an effective PSI-RLS in Libya. Medical liability states that patients can receive compensation if the harm is proven by the involved stakeholders. This has arguably created a solid foundation for establishing a PSI-RLS in Libya, fostering commitment from both patients and healthcare providers to report patient safety incidents. This system demonstrates the accountability of the Libyan healthcare sector in addressing medical harm. Vincent (2011) stated that reporting incidents is always voluntary, regardless of its goal. He added that reporting systems, whether mandatory or voluntary, only function effectively when the individuals reporting are committed to the system. If they see it as worthwhile, they will report; if not, there will always be reasons why a particular incident does not need to be reported. Geiderman and Marco (2020) argue that mandatory reporting laws raise significant ethical questions because they prioritise public and patient welfare while disregarding both patient autonomy and the physician's duty to protect

confidentiality. This duty entails not disclosing what a patient reveals during their encounter with their physician (Geiderman and Marco 2020).

In Libya, the concept of PSI-RLS allows reporters (patients and healthcare providers) to autonomously report patient safety incidents. Patients or their families can voluntarily report medical harm through civil or legal avenues. Additionally, according to the policy, healthcare providers have the option to report patient safety incidents voluntarily. However, based on practical insights from interviews, healthcare providers are currently not involved in reporting patient safety incidents, and learning is not prioritised in this system. These two issues are the weaknesses of the national PSI-RLS in Libyan healthcare.

This approach acknowledges the challenge of upholding patients' rights to seek justice for medical harm—a right that no healthcare sector can deny. Over and above that, it is equally challenging to mandate healthcare providers to report patient safety incidents because that can disregard both patient autonomy and the physician's duty to protect confidentiality. It could be argued that the approach of reporting medical harm by patients, via civil or legal avenues, occurs in many healthcare contexts but it has been regulated in the Libyan healthcare sector.

8.3.2 Ethical Viewpoint

It is worth reminding that this study does not adhere to a specific theory or theoretical framework, nor does it attempt to confirm or disprove pre-established hypotheses. Instead, the research aims to explore the concept of PSI-RLS in the Libyan healthcare sector. Therefore, the main finding of this study, which is the process of reporting medical harm by patients, will be explored from an ethical perspective. The process of reporting medical harm will be assessed based on three main normative ethics. The following is an in-depth exploration of the ethical approach that guides the process of reporting medical harm within the context of Libya's healthcare sector.

The three major schools of normative ethics are virtue ethics, deontological ethics and consequentialist ethics. These ethics each have their approach to determining what is right and wrong and guide for making ethical decisions. Virtue ethics focuses on the development of personal character. Consequentialist ethics emphasise achieving the right

outcomes. Deontology focuses on the moral obligations and duties of individuals in society (Purtilo and Doherty 2010).

First, virtue ethics which focuses on personal character. The concept of a virtue is the concept of something that makes its possessor good: a virtuous person is a morally good, excellent or admirable person who acts and feels as he/she should (Hursthouse and Pettigrove 2003). This means that individuals with good character are less likely to cause medical harm, linking personal character to medical harm**.** In Libyan healthcare, the process for addressing medical harm does not consider the personal character of the individual who caused the harm. The virtue ethics theory is not followed in Libyan healthcare because healthcare staff can cause harm at any stage of their profession, even if they follow the correct medical interventions for treating patients. Medical complications, such as adverse drug reactions, are examples of this. Therefore, some may think that healthcare staff are bad people because of the medical harm they cause, but in fact, they are not.

Second, the paradigm case of consequentialism is utilitarianism. Consequentialism, as its name suggests, is simply the view that normative properties depend only on consequences. Act consequentialism is the claim that an act is morally right if and only if that act maximizes the good (Sinnott-Armstrong 2019). Utilitarianism suggests that an action is considered immoral if the result is bad. Medical harm is a bad result, so according to utilitarianism, the action (which is the medical intervention) is immoral. However, this is not the case because, in medical complications, the healthcare staff performed the medical interventions correctly and according to known procedures, but harm still occurred. This does not mean that the action of performing the medical intervention was immoral. Thus, in Libyan healthcare, utilitarianism ethics is not followed in the process of addressing medical harm.

Lastly, deontological ethics concerns the means for conducting an action, other than the end of the action. This means that the morality of an action is primally judged on whether it conforms to ethical codes and principles, not on the consequences it produces (Alexander and Moore 2007). This was consistent with Immanuel Kant's moral philosophy which focuses on fairness and the value of the individual and rejects the utilitarian idea that the rightness of an action is a function of how fruitful its outcome is (Alexander and Moore

2007). Immanuel Kant says that the motive (or means) and not the consequence (or end) of an action determines its moral value (Pojman and Tramel 2009). To live ethically, one must never treat another human being as a means to some greater end (Pojman and Tramel 2009). The means of performing an action is an end according to Kant. According to the process of reporting medical harm in Libya, there is a focus on how the action of medical intervention was performed (the mean), not solely on the result of medical intervention (the end).

For instance, when a patient reports medical harm through legal avenues, the judiciary views the healthcare sector as a single entity (or one person) who is liable for causing harm to another person (patient). This perspective is supported by articles 25 and 26 of statute No. 17, which hold the entire healthcare sector liable for any harm that occurs to patients. In other words, one individual (the healthcare provider) interacts with another (the healthcare recipient). The judiciary cares about the means used to treat people without delving into the internal workings or complexities of the healthcare sector. The judiciary primarily investigates the means that were followed to treat the harmed person and does not consider the consequences of the medical action as the solid ground to judge the case. In addition, the judiciary cares about the means used by patients to seek healthcare. The means of delivering and receiving healthcare services are investigated by the judiciary. The judiciary consults medical experts in the MC about the means that were followed to treat the harmed patient. These experts provide testimony from a technical and medical standpoint and medical knowledge ends at this point. Then the judiciary also considers the patient's account of the medical harm and the patient's statement ends at this point. Ultimately, the judiciary evaluates the impact of the means used by healthcare providers on patients, the impact of the means used by patients to seek healthcare services on the healthcare sector and the broader societal implications of both. Therefore, deontological ethics is the best ethical theory that matches the process of addressing medical harm in Libyan healthcare.

Autonomy of reporting is another piece of evidence that the process of reporting medical harm aligns with deontological ethics and Kant's theory. The Libyan healthcare policy allows both patients and healthcare providers to report patient safety incidents based on

their rational judgment. Kant stated, “Our special value comes from our ability to be autonomous, to decide for ourselves how we want to act and then to actually act upon our decisions.” According to Kant, autonomy is crucial for human dignity. He asserts that autonomy (giving oneself a law) “is the ground of the dignity of human nature and of every rational nature.

However, mandatory medical insurance underscores an apparent lack of autonomy among healthcare providers in Libya. However, this requirement can be thoughtfully through the lens of Immanuel Kant’s “Categorical Imperative” (CI). The CI is often regarded as a gold standard of human behaviour because it emphasises universal moral laws and the intrinsic worth of individuals. It serves as a foundational concept in deontological ethics, influencing contemporary notions of justice and fairness (Johnson and Cureton 2004). Kant’s CI is a universal moral law that defines the obligations and duties of all individuals, regardless of their personal backgrounds and beliefs. It provides an ethical framework for understanding our behaviour and how we should interact with others (Sellers and Kirste 2023). Immanuel Kant (1724–1804) asserted that the supreme principle of morality is a principle of practical rationality, which he dubbed the CI. Kant characterised the CI as an objective, rationally necessary and unconditional principle that we must adhere to, despite any natural desires to the contrary (Johnson and Cureton 2004).

Johnson and Cureton (2004) stated that Kant’s theory has significantly influenced modern ethical thought, public policy, and legal systems including the United Nations Universal Declaration of Human Rights. Kant’s CI provides a framework for evaluating the morality of actions based on duty rather than consequences. It suggests that moral actions are those performed out of a sense of duty and adherence to universal moral laws, rather than for personal gain or outcomes (Johnson and Cureton 2004; Uleman 2010). Immanuel Kant’s CI is a cornerstone of his deontological moral philosophy. It serves as a universal moral law that applies to all rational beings, defining their obligations and duties regardless of individual backgrounds or desires (Johnson and Cureton 2004; Uleman 2010). Kant's CI has had a wide-reaching and profound effect on the way society functions today, particularly in terms of policymaking and legislation (Evans 2023). According to Evans (2023), the key components of Kant’s CI are:

- Principle of Universality: This principle states that one should act only according to maxims that can be universally accepted. In other words, you should act in a way that you would want everyone else to act in similar situations.
- Principle of Respect for Persons: This principle emphasises treating individuals as ends in themselves and never merely as means to an end. It highlights the inherent dignity and autonomy of every rational being.

The ends-means formulation states that one should not use people as a means to an end, but should instead treat them as ends in themselves (Evans 2023). For instance, Libyan healthcare providers—regardless of whether the services they deliver are free or paid—should not have an end when interacting with patients, such as healing patients. What is paramount is the ethical nature of the means employed in their actions. According to Kantian ethics, the action outcomes of healthcare providers are not the primary concern, which aligns with the context of the Libyan healthcare sector. Of course, as the statute states, there are situations when the end is a matter, and the outcomes of the healthcare providers will be considered. This is detailed in Statute No.17, Articles 7 and 16, as presented in Chapter Four, section 4.3. In addition, Al Sanusi and Al-Zuwy also support this perspective as shown below.

> *The definition of a physician's work in Libya is to provide maximum care and diligence, not guarantee the outcome. Legally, doctors are expected to exert their best efforts, but they are not responsible for the inevitable results and are not obligated to heal people (**Al Sanusi**).*
>
> *Medical harms committed by doctors are generally viewed as unintentional and lacking criminal intent, except for specific situations defined as criminal under the law, such as abortion and other prescribed acts. Doctors are typically expected to exercise diligence and provide care rather than guarantee specific outcomes, which precludes the presence of criminal intent (**Al-Zuwy**).*

It could be argued that the process for addressing medical harm in the Libyan healthcare sector operates based on Immanuel Kant's ethical principles. These principles advocate for

standardized and normative practices aligned with deontological ethics, emphasising respect for individuals.

8.4 Chapter Summary

The final objective of this study is addressed in this chapter. The medical liability statute in Libya offers advantages concerning patient safety, as well as the protection of medical and paramedical staff and the integrity of healthcare services. Patients are prioritised over healthcare providers when it comes to reporting medical harm. In Libyan healthcare, the process of reporting medical harm is formalised. This reporting mechanism emphasises public accountability within the Libyan healthcare sector rather than focusing solely on learning from medical harm. The process for reporting medical harm in Libya is built upon three key pillars: medical liability, medical harm and compensation. This process helps identify two primary issues that can enhance patient safety in the healthcare sector. First, it facilitates the reporting of medical complications that are often not captured through staff reporting processes. Second, it uncovers systems failures within the healthcare sector, as patients experience the entire journey and interact with various healthcare institutions. In practice, healthcare providers in Libya are not involved in reporting patient safety incidents, despite the fact that Libyan policy allows them the option to do so. The chapter highlighted the challenges related to the involvement of healthcare providers in reporting patient safety incidents within the Libyan healthcare sector. Finally, the chapter concludes with the characteristics and principles of the PSI-RLS in Libyan healthcare.

9 CHAPTER NINE – Conclusion

9.0 Introduction

This chapter concludes the thesis by providing an overview of the study and its main findings. It is followed by a discussion about the contribution to knowledge. The implications for policy and practice are presented, as well as recommendations for the Libyan healthcare sector. Additionally, this chapter highlights the limitations and how the researcher addressed these limitations. Lastly, the researcher provides recommendations for future research.

9.1 Overview of the Study

The research aimed to explore and understand the concept of PSI-RLS in the Libyan healthcare sector through the experiences and perceptions of key healthcare policy stakeholders. The research followed a qualitative-exploratory design and involved two phases of data collection. Data was collected through policy analysis, semi-structured interviews and notetaking as third source of data. Walt & Gilson's (1994) framework was used to conduct the policy analysis phase, whereas the experiences and perceptions of the key healthcare policy stakeholders were explored in-depth through semi-structured interviews. The data analysis stage of the interviews was completed using Braun and Clarke's (2006) model of thematic analysis. The main findings of the interviews were embodied by three main themes, presented in chapters five, six, and seven. The key elements of the findings are integrated into the discussion chapter with reference to the relevant literature.

9.2 Main Findings

The study's findings highlighted both the theoretical and practical perspectives regarding patient safety and PSI-RLS in Libyan healthcare. Three main themes emerged from the interviews: the first theme focused on perceptions and attitudes toward patient safety; the second addressed perceptions and attitudes toward PSI-RLS in the Libyan healthcare context; and the third was the organisational structure of the healthcare sector. The medical liability statute influences patient safety and the PSI-RLS in Libya. The study illustrated

that patients and their families are central to reporting medical harm. Libyan healthcare sector has a national and official reporting process that prioritises patients over healthcare providers for reporting medical harms. However, there is currently no mechanism in place for learning from such reports. Additionally, Libyan healthcare providers do not participate in reporting patient safety incidents at the national level, even though they theoretically have the option to do so. There is a pressing need for a code of conduct for healthcare providers to permit them to report and learn from patient safety incidents. Furthermore, a policy is necessary to establish a unified framework for the PSI-RLS and to confirm that both patients and healthcare providers can report patient incidents.

9.3 Contribution to Knowledge

This research is valuable as it provides a simplified, well-evidenced, and synthesized method to improve patient safety and PSI-RLSs. It can be argued that this study could lead to improvements in patient safety in both practice and policy. Additionally, the study offers various contributions and implications for academics, practitioners, and policymakers, as discussed in previous chapters. These contributions will help us gain a deeper understanding of patient safety and PSI-RLSs. I will discuss the contributions of this study in alignment with the study design and Remenyi et al. (1998) views regarding contributions to the body of knowledge. Repeating what was mentioned in the study design, Neergaard et al. (2009) stated that qualitative exploratory research, which mainly uses an inductive approach, is suitable for identifying problems, generating hypotheses, forming theories, and developing concepts. Jaeger and Halliday (1998) added that the end goal of exploratory research is to gain new insights, from which new hypotheses might be developed. Furthermore, Remenyi et al. (1998) argued that contribution to the body of knowledge can include one or more of the following:

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

Moreover, Hart (2018) noted that originality in research stems from the fact that the research; has not been done before, innovative in style and form, free from imitation or

plagiarism, and authentic. Thus, the scoping review of literature revealed a noteworthy gap in the existing research on PSI-RLSs. This study primarily focuses on the concept of PSI-RLS in Libyan healthcare, which has been unexplored. The literature review also underscores the absence of comprehensive research and an integrated approach to enhancing patient safety in Libya through PSI-RLS. This study found that PSI-RLS needs to be put at the top of the agenda of ethical policies or code of conduct in the MOH in Libya. Ovretveit (2009) argues that perhaps the greatest contribution of the studies is the detailed understanding of the issues in a specific context, and this is one of the values of much qualitative research. In addition, my contributions can be summarised into the following points:

- This study is the first to explore the concept of PSI-RLS in the Libyan healthcare sector at a national level.
- Currently, the Libyan healthcare sector does not have an effective PSI-RLS.
- Healthcare providers are not involved in reporting patient safety incidents at the national level.
- There is no learning from patient safety incidents in the Libyan healthcare sector.
- There is an official process for patients to report medical harm, but this process alludes to the public accountability of healthcare providers rather than focusing on learning from such incidents.
- The reporting process by patients could be adapted for other healthcare sectors to increase learning from medical harm (see section 8.2.1).
- The current healthcare policies are ambiguous and lack clarity, creating an environment focused on survival and adversity rather than learning and development.
- The statute on medical liability ensures that healthcare services are practiced in safe environments, benefiting both healthcare providers and patients in Libya from a sociological standpoint.

9.4 **Implications for Policy and Practice**

The findings of this study highlight important policy and professional practice concerns, besides socio-cultural issues. The main goal of the study was to explore the experiences of

PSI-RLS in the Libyan healthcare sector. While the concept of PSI-RLS in healthcare has been well-acknowledged globally, there is limited knowledge about its implementation in Libyan healthcare. This study provides new knowledge and insights on how PSI-RLS can be promoted in practice within the Libyan healthcare sector. The following is the implication for policies in Libyan healthcare, and then practice implications are presented next.

There is ambiguity surrounding medical liability in Libyan healthcare policies, as there is no clear distinction between what is legal and what is ethical. Although there is a legal policy allowing patients to report medical harm, there is no explicit policy or code of conduct that permits healthcare providers to report patient safety incidents. Therefore, it is important to clarify and confirm that reporting and learning from patient safety incidents is an ethical responsibility for healthcare providers. According to medical ethics principles of non-maleficence and beneficence, healthcare providers have an ethical and moral duty to prevent harm and to benefit patients (Bayazidi et al. 2012). It is important to clarify that both healthcare providers and patients have the option to report patient safety incidents. A unified framework for PSI-RLS is needed, where the code of conduct functions as a proactive process to report and learn from patient safety incidents, while legal policies serve as a reactive process to report and learn from medical harm. By integrating both proactive and reactive processes, the effectiveness of PSI-RLS can be enhanced, leading to a reduction in patient safety incidents and ultimately improving overall patient safety.

According to the first concept of the policy outlined in Statute No. 17 and its four subsequent decrees, healthcare providers are not held liable when they report instances of medical harm. The statute specifies that it is the responsibility of the harmed party to report the medical harm in order to ascertain any potential liabilities for the healthcare provider. In other words, liability may arise only when both parties—the patients and the healthcare providers—engage in the medical harm. Therefore, it is essential to clarify that healthcare providers should not fear medical liabilities when they report incidents related to patient safety.

The data clearly shows a pressing need for a national code of conduct to outline how healthcare providers should report and learn from patient safety incidents. It's undeniable

that the absence of a code of conduct affects healthcare providers' willingness to report patient safety incidents. Therefore, it is crucial for the key healthcare stakeholders to start developing a code of conduct. This code of conduct should provide guidance for healthcare providers on reporting and learning from patient safety incidents to improve patient outcomes and safety in health facilities across the country. Supporting healthcare providers in raising safety concerns at work could potentially enhance the quality of care and ultimately improve patient safety. Without systems in place to address staff concerns, achieving patient safety is impossible. Therefore, there is an urgent need to develop a national code of conduct for patient safety incident reporting and learning at all healthcare levels.

When formulating PSI-RLS policy, it is important to take an inclusive approach to ensure that all relevant stakeholders are involved as this could impact the success of the code of conduct implementation. Some participants have suggested that representatives from meso and micro levels should be involved in top management and ministry levels when making policies regarding the PSI-RLS. Failing to involve the views and opinions of relevant stakeholders may have contributed to the lack of success of healthcare policies in Libya in the past. To improve the success of PSI-RLS policy in Libyan healthcare, the MOH, medical and paramedical syndicates, General Health Council, private healthcare sector, representatives of healthcare professionals and their regulatory bodies and all key stakeholders should be involved in policy discussions at national and local levels to ensure that the guidelines are informed by their advice.

It is not recommended to establish overly detailed policies to avoid taking the absence of some details as an excuse for not reporting patient safety incidents. In addition, there should be room for individual creativity. Kennedy (2001) argues that too great a dependence on guidelines stultifies the creativity of individuals, thus, counterproductive in terms of safety. Safety partly depends on the capacity of individuals to adapt and listen to others when faced with a problem.

This study’s findings have implications not only for policy but also for socio-cultural practices. The concept of PSI-RLS is widely believed to have originated in western culture. As a result, the policy guidelines and structures pertaining to PSI-RLS in most developed

healthcare settings are likely tailored to western culture. Liang et al. (2007) suggested that healthcare professionals in the Arab world are not sufficiently motivated to report incidents for investigation and learning purposes. This lack of encouragement could stem from the fact that healthcare organisations in the region have not implemented such reporting systems. This is potentially due to the absence of necessary regulations that manage and foster patient safety, a practice that is common in developed countries, including the United States. In numerous studies, the responsibility of reporting and learning from patient safety incidents is typically assigned to healthcare providers. However, the Libyan healthcare context presents a different scenario. In Libyan healthcare settings, healthcare providers are not involved in reporting patient safety incidents. Instead, patients assume a crucial role in reporting medical harm. Moreover, near misses, which are critical for learning and improving patient safety, are not reported at the national level in Libya. This lack of reporting results in a missed opportunity for learning from patient safety incidents on a national scale. These observations underscore the necessity for a more inclusive and culturally sensitive approach to patient safety and incident reporting. It is essential to consider the unique cultural context and involve all stakeholders in the policy process to enhance patient safety effectively.

Last but not least, medical and paramedical staff, as well as other healthcare institutions in Libya, need to be encouraged to report and learn from patient safety incidents in the workplace. To achieve this, it is important to establish a culture of psychological safety, a just culture, and a blame-free culture. The findings of this study indicate that the fear of being blamed or victimized by medical liability can be a barrier to reporting patient safety incidents for all Libyan healthcare providers. Therefore, the code of conduct must create a culture of safety that facilitates accountability and learning from patient safety incidents, ensuring that medical and paramedical staff are not unfairly blamed for systemic failures.

9.5 Recommendations for the Libyan Healthcare Sector

Recommendations are crucial elements of research studies and investigation findings as noted by Bryman (2016). Therefore, I share the following recommendations for policymakers and healthcare providers in the Libyan healthcare sector to help improve patient safety and PSI-RLS.

There is apprehension about medical liabilities concerning harm to patients, which could be the main barrier for healthcare providers in the Libyan healthcare sector to report patient safety incidents. In Libya, the legal policies stipulated patients to report medical harm. Therefore, it cannot be assumed that the PSI-RLS guidelines and structures in the existing literature are readily transferable to the Libyan context, given the liability for medical harm in Libya. This necessitates that policymakers in the MOH and other key stakeholders carefully consider this concern when formulating the code of conduct regarding the PSI-RLS to ensure its appropriateness for the Libyan healthcare context. This will ensure that legal policies and the code of conduct work harmoniously within a unified framework, enabling effective operation of the PSI-RLS in Libya. Kadivar et al. (2017) argue that patient safety, being multidimensional and founded on ethical and legal imperatives, requires consideration of both ethical and legal challenges. To ensure effective learning, patient safety incidents should be reported from both the perspective of healthcare providers and patients. When incidents are only reported by providers, it may overlook medical complications and the valuable lessons that can be learned from them. Similarly, patient reports may not capture near misses, which are an important source of learning. To reiterate, a unified reporting system or framework that allows both healthcare providers and patients to report patient safety incidents is essential to enhance learning from such incidents.

It is recommended and would be useful to introduce the concept of medical liabilities and their social effects in health education in Libya. Allan et al. (2016) argued for the necessity for future nurses to be critical, analytical and informed by sociology as well as physiology, psychology and pharmacology. In addition, future nurses should be confident in responding to critiques of current nursing practices and able to work effectively whilst being aware of how the social context of work affects patients, their families, themselves and other healthcare providers equally (Allan et al. 2016).

By incorporating the concept of medical liabilities associated with medical harm into the health education curriculum, future medical and paramedical staff in Libya would be better equipped to understand the legal and ethical implications of their actions. This could potentially lead to improved patient care and reduced instances of medical harm. It would

also help students understand patient rights and the legal processes involved when medical harm occurs. Incorporating this concept into the curriculum could enhance the quality of healthcare services in Libya, promote a culture of patient safety, and reduce legal risks for healthcare providers. This recommendation aims to foster a more responsible and legally aware generation of healthcare professionals. In addition, introducing deontological ethics or deontological theories in healthcare studies would benefit healthcare providers by offering a social perspective of healthcare services and helping them understand the relationship between duty and the morality of their actions.

Accountability should be enhanced in the Libyan healthcare sector. Regarding accountability, clinicians in the United Kingdom have a regulatorily enforced professional requirement to be able to account for their actions. The General Medical Council (GMC) and Health and Care Professional Council (HCPC) codes of conduct specifically require that the clinician must be able to justify once own decisions (Smith 2021). In addition, the Nursing and Midwifery Council (NMC) mandates that a registered nurse should be able to fully explain all aspects of a patient's care (Smith 2021).

In closing, it is recommended to explore the effects of reporting patient safety incidents on the healthcare sector and society using a sociological perspective, which encompasses a variety of disciplines. According to Bond and Bond (1994), sociology is classified as one of the social sciences, which includes psychology, anthropology, economics, politics, and history.

9.6 Limitations and Strengths of the Study

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 is among the limitations which I would like to highlight.

To start with, the data collection for this study was undertaken during the COVID-19 global pandemic. This presented a challenge as I had to travel to Libya to be able to interview

participants and stakeholders for the research. Travelling during the pandemic came with an added risk, extra unbudgeted costs for quarantining as well as multiple covid testing. I even missed two flights due to delayed test results and the need for several types of tests required by airlines. Luckily, the spread in Libya was lower than in the United Kingdom, so face-to-face interviews were still allowed during the data collection period. Although the pandemic affected the workload and working conditions for the healthcare sector in Libya, in addition, the COVID-19 protocols such as wearing face coverings and maintaining a 2-meter distance were followed during the interviews. However, I believe that this did not greatly impact the quality of the data. When I considered conducting online interviews, I faced challenges due to the unreliable electricity and internet in Libya, with frequent power outages lasting more than 15 hours a day. The data collection period was delayed due to the situation in Libya and COVID-19, so I had to adjust the timelines for data collection and conduct the interviews at a different time than originally planned. Despite these obstacles, I was able to go to Libya and access the study settings. I am honored to be the first researcher to conduct all interviews face to face in Libyan healthcare regarding patient safety. Very few studies were conducted in Libya, and they conducted online interviews.

Besides this, the literature review presented a dearth of literature about the concept of PSI-RLS experiences in the Libyan healthcare sector. This study, through the data presented, explored these experiences in a novel way and in some depth. It can be argued that this study offered a good insight into the concept of PSI-RLS in Libyan healthcare through the discussion of stakeholders' understanding, perceptions, and the societal culture around reporting patient safety incidents, workplace reporting barriers, and interventions such as the need for policy and sociocultural interventions. However, it is imperative to note that only stakeholders involved in reviewing medical harm at the macro level were included in this study, hence the researcher cannot overstate the findings to cover reporting and learning experiences at other levels such as reporting and learning systems at the institutional level in Libya.

In addition, the flexibility of the qualitative-exploratory approach, which employed the use of one-to-one semi-structured interviews, allowed study participants to freely talk about

their unique experiences regarding the concept of PSI-RLS without feeling intimidated or perhaps unsafe. However, I acknowledge that using focus group interviews could have facilitated a broader and more interactive discussion on topics such as the influence of Libyan societal culture on reporting medical harm, its incorporation into the law and potential interventions. Additionally, analysing Libyan healthcare policies and the use of interviews were the data collection tools adopted for this study, as the study sought to provide an in-depth understanding of the reporting and learning experiences of Libyan stakeholders at the macro level, therefore, it is not necessarily the generalisability of these experiences to other settings. Although the study focused on the macro level, collecting data from micro and meso levels might have provided broader perspectives on the concept of PSI-RLS. However, it is also important to note that interviewing participants at these lower levels might be challenging though, as existing ambiguities in policies could cause participants to change their behaviour regarding the reporting of incidents. This lack of clarity doesn't help healthcare providers understand how medical liabilities protect people's rights. Therefore, it would be best to conduct a separate study to explore reporting patient safety incidents at these lower levels. The study recruited a group of eight stakeholders who are part of the medical harm reporting process. Although the purposive sampling method used could be considered representative of the Libyan healthcare sector at the macro level, it cannot be denied that involving additional stakeholders in the study might have offered more insights into the experiences related to PSI-RLS in the Libyan healthcare sector.

The study only included participation from the MOH and policy stakeholders, not patients. It would have been beneficial to include the perspective of patients to gain a broader understanding of reporting patient safety incidents in Libyan healthcare. However, due to limited resources and time constraints, it was not feasible to do so. Additionally, prior to this study, truly little was known about the concept of PSI-RLS in Libya, which made it challenging to balance the scope and depth of the study. The broad exploratory design of the study helped to avoid prematurely eliminating potential areas that might have led to the identification of various issues, some of which have been suggested for future research and some addressed in the recommendation section. Despite the discussed limitations, the study has highlighted areas that call for additional polices and further research, as well as the changes needed for socio-cultural and professional practice in the Libyan healthcare sector.

Finally, this study has adopted a structuralist perspective with an exploratory design, which is considered the most suitable methodology for exploring the PSI-RLSs concept in Libyan healthcare. However, the researcher believes that doing a study at micro and meso levels by adopting an interactionist perspective could also yield valuable insights into the concept of PSI-RLSs in the healthcare sector.

9.7 Future Research

This research can help expand the scope of future studies in the field of PSI-RLS in Libya, the EMRO region, and other developing countries. The challenges and findings presented in this thesis may serve as a roadmap for co-designing research initiatives and engaging healthcare providers and patients on issues related to the concept of PSI-RLSs. Below are six research ideas that could be explored in the future.

1. Studies that aim to establish a learning mechanism from medical harms reported by patients could positively impact patient safety in the Libyan healthcare sector. Data on medical harm can be collected from the MOH through MC, MIA and IDC as well as from judicial authorities through the IDC in the MOJ.
2. This research explored the perceptions and experiences regarding the PSI-RLS from the perspective of stakeholders at the national level (macro level). To gain a more comprehensive understanding, it would be beneficial to conduct studies that explore the perceptions and experiences regarding PSI-RLS from the perspective of meso and micro-level staff, including medical and paramedical staff.
3. Studies involving patients and the public's perceptions regarding their involvement in reporting medical harm would provide a broader understanding of the social and cultural issues related to PSI-RLSs in the Libyan healthcare sector.
4. It would be beneficial to conduct a study exploring the barriers and facilitators of reporting patient safety incidents through a social science lens, as suggested by Hewitt et al. (2017). In addition, Ovretveit (2009) stated that social sciences have significantly contributed to the science and practice of patient safety, but there is still more they can offer. Beyond their instrumental role, social science research is important for highlighting assumptions and presenting alternative perspectives on change and safety issues. This study should involve experts with social and cultural

knowledge, such as sociologists and social psychologists, to provide their perspectives on reporting medical harm.

5. Studies that deeply explore the ethical theories related to the healthcare sector and PSI-RLSs would be beneficial. This will help standardise the ethical thinking of healthcare providers, ensuring it aligns with the ethical perspectives of society (See section 8.3 for more clarity).
6. Finally, and overall, conducting studies that focus on the design and characteristics of the reporting incidents, such as voluntary and anonymous reporting systems, would be beneficial. The reporting stage helps obtain accurate and reliable data related to patient safety incidents, which, in turn, provides valuable lessons and ensures the consistency of PSI-RLSs. Therefore, it is more logical to focus on issues related to reporting rather than those related to learning. Addressing reporting issues is key to effective learning. Additionally, significant efforts have been made in the literature review regarding models and strategies for learning from incidents related to patient safety.

10 REFERENCES

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11 APPENDICES

11.0 **List of Appendices**

11.1 APPENDIX 1- Charting of Literature Review Process

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
1.	Anonymous reporting of medical errors from The Egyptian Neonatal Safety Training Network.	ElMeneza	2020	Egypt	A quantitative descriptive review	• Focuses on the learning process of the national online incident reporting system. • Lessons were figured out by analysing reports from medical errors in the neonatal intensive care units (NICU).
2.	Medical Error Reporting: Status Quo and Perceived Barriers in an Orthopedic Center in Iran.	Mahdaviazad	2020	Iran	A quantitative study/ Cross-sectional	• Studying the reporting process and knowledge of healthcare professionals about the adverse events and the attitude toward their own and colleagues' errors. • The barriers to reporting errors were identified.
3.	Closing the Loop with Ambulatory Staff on Safety Reports.	Williams	2020	United States	A quantitative study/ Exploratory survey	• Main area of study is feedback from the Reporting system.
4.	An improved patient safety reporting system increases reports of disruptive behavior in the perioperative setting.	Katz	2020	United States	A quantitative descriptive review	• Upgrading the reporting system by reporting positive behaviours.
5.	Incident Reporting System in Pediatric Intensive Care Units of	Labib	2019	Egypt	Mixed Method/	• Focuses on human being factors by testing the impact of a training program

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
	Cairo Tertiary Hospital: An Intervention Study.				Intervention Study	for reporting events in pediatric intensive care units.
6.	Medication safety spontaneous reporting system: The Lebanese order of pharmacists initiative.	Akel	2019	Lebanon	Quantitative study/ Designing a reporting tool for adverse drug reactions.	• Improving the patient safety culture by creating an electronic platform and providing training sessions for pharmacists. • A reporting system for adverse drug reactions. • Involving healthcare staff and patients.
7.	Medical error reporting among physicians and nurses in Uganda.	Mauti	2019	Uganda	A cross-sectional, quantitative study	• Assessing the whole process of medical error reporting among physicians and nurses. • Some factors that influencing error reporting were identified.
8.	The acceptance of CIRS among orthopedic and trauma surgeons in Germany Significant gap between positive perception and actual implementation in daily routine.	Sterz	2019	Germany	A quantitative descriptive review	• Utilization of the critical incident reporting system (CIRS). • The attitude of the orthopaedic and trauma surgeons of CIRS.
9.	Deployment of Critical Incident Reporting System (CIRS) in public Styrian hospitals: a five-year perspective.	Sendlhofer	2019	Austria	A quantitative study	• Trying to understand the Critical Incident Reporting Systems (CIRS) after 5 years of utilization. • Possible developments were recommended to improve the CIRS.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
10.	The Role of Governments in the Implementation of Patient Safety and Patient Safety Incident Reporting in Indonesia: A Qualitative Study.	Dhamanti	2019	Indonesia	A qualitative Research/ interviews	• The role of the government for undertaking incident reporting according to the National Guideline for Hospital Patient Safety. • Considering the incident reporting at macro-, meso-, and micro-levels, in hospitals.
11.	Implications from China patient safety incidents reporting system.	Gao	2019	China	A quantitative study	• National Patient Safety Incidents Reporting System (NPSIRS). • Explaining the operational mechanism of the NPSIRS. • The pattern and trend of incident reporting. • Describing the characteristics of incidents.
12.	Improving medication safety through implementation of medication error reporting systems in different medical specialities.	Abuelsoud	2018	Saudi Arabia	A quantitative descriptive review	• The effects of Medication Errors Reporting System in internal medicine, paediatrics, and cardiology.
13.	Investigating the Effect of Senior Managers' Compliance in Reporting Nurses' Treatment Errors in Pediatric Wards.	Nazmieh	2018	Iran	A quantitative descriptive review/ Interventional study	• Using a Voluntary Error Reporting form among the nurse staff in the pediatric ward.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
						• The effect of senior managers' compliance in reporting nurses' treatment error.
14.	Barriers to the success of an electronic pharmacovigilance reporting system in Kenya: an evaluation three years post implementation.	Agoro	2018	Kenya	A quantitative study/ questionnaire	• Determining barriers of an electronic pharmacovigilance reporting system.
15.	Effectiveness and limitations of an incident-reporting system analyzed by local clinical safety leaders in a tertiary hospital: Prospective evaluation through real-time observations of patient safety incidents.	Ramírez	2018	Spain	A quantitative descriptive review	• The learning process of the reporting system was the main area of study. • Focus on the effectiveness of the lessons that have been learned and implemented on the reporting systems for possible improvements.
16.	Optimising incident reporting to encourage a 'no blame culture': Analysis of data collected using an anaesthetic incident reporting tool developed in a district general hospital.	Allen	2018	United Kingdom	A quantitative Descriptive analysis	• The Learning and Feedback processes of the reporting system were the main area of study. • Recommendations to introduce some improvements regarding the Learning and Feedback processes of the reporting system.
17.	A systematic review of practical tools or frameworks to help deconstruct safety incidents and learn from them.	Serou	2018	United Kingdom	Systematic review	• Focus on the learning process.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
						• Suggesting some practical tools that can help multi-disciplinary teams deconstruct and learn from safety incidents.
18.	Likelihood of reporting medication errors in hospitalized children: a survey of nurses and physicians.	Rishoej	2018	Denmark	Quantitative Study/ Survey	• The reporting system in the neonatal and paediatric wards. • Concentrating on reporting whether scenarios involving medications should be reported by nurses and physicians.
19.	Implementation and operation of incident learning across a newly-created health system.	Schubert	2018	United States	Quantitative Study/ Descriptive analysis	• Designing a highly sensitive incident learning system to capture as much information.
20.	Canadian Anesthesia Incident Reporting System (CAIRS): The Canadian Anesthesiologists' Society's National Patient Safety Initiative.	Beattie	2018	Canada	A qualitative descriptive review	• Anesthesia Incident Reporting System. • Using WHO recommendations to develop Anesthesia Incident Reporting System.
21.	An Information Enhanced Framework for Reporting Medication Events.	Wang	2018	United States	A qualitative study/ Designing a framework to discover supportive information from FAERS.	• Reporting medications events related to insulin-use. • Discovering supportive information from the FDA Adverse Event Reporting System (FAERS) in order to enhance the reporting of insulin-use events.
22.	Pharmacist-Initiated Medication Error-Reporting and Monitoring	Chalasani	2018	India	Quantitative Study/ A Prospective Observational Study	• A voluntary medication error-reporting.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
	Programme in a Developing Country Scenario.					Implementation of a voluntary medication error-reporting and monitoring programme.
23.	A Hospital Nursing Adverse Events Reporting System Project: An Approach Based on the Systems Development Life Cycle.	Cao	2017	China	A qualitative approach /Prospective study	• Nursing adverse events reporting platform. Describing the use of the Systems Development Life Cycle (SDLC).
24.	Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait.	Alsaleh	2017	Kuwait	A cross-sectional using a paper questionnaire/Research	• Studying the knowledge and the attitude of physicians Adverse Drug Reaction Reporting. • Considering the human being factors by measuring the effectiveness of the formal pharmacovigilance (PV) program to reporting events.
25.	Evaluation of a web-based error reporting surveillance system in a large Iranian hospital.	Askarian	2017	Iran	A quantitative study	• Evaluating the impact of the online Reporting Surveillance System.
26.	A cross-national comparison of incident reporting systems implemented in German and swiss hospitals.	Manser	2017	Germany	A quantitative study	• Studying the reporting and learning systems. • Comparison of the incident reporting systems between German and Swiss hospitals.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
27.	International recommendations for national patient safety incident reporting systems: an expert Delphi consensus building process.	Howell	2017	United Kingdom	Mixed method	• Studying the structure of patient safety incident reporting systems (PSRS).
28.	Sociocultural Factors Influencing Incident Reporting Among Physicians and Nurses: Understanding Frames Underlying Self- and Peer-Reporting Practices.	Hewitt	2017	Canada	Qualitative case study	• Enablers and inhibitors of self-reporting and peer reporting.
29.	Enhancing patient safety event reporting.	Gong	2017	United States	Systematic Review	• The design of the Reporting and Learning System. • Some features were figured out that can help to increase the effectiveness of the reporting and learning systems.
30.	Learning from defects using a comprehensive management system for incident reports in critical care.	Arabi	2016	Saudi Arabia	A quantitative study	• Focuses on a structured process of the incident reporting systems to increase learning opportunities.
31.	Descriptive analysis of medication errors reported to the Egyptian national online reporting system during six months.	Shehata	2016	Egypt	A quantitative descriptive review	• The main area was the learning part. • Some lessons were highlighted by analysing reports received by the local reporting system.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
32.	Barriers to reporting medication errors and near misses among nurses: A systematic review.	Vrbnjak	2016	Slovenia	Systematic review	• The medication errors reporting system was the field of study. • Barriers to nurses' reporting of medication errors were identified.
33.	A mixed Methods investigation of the efficacy of organisational level feedback from incident reporting.	D'Lima	2016	United Kingdom	Mixed Method	• Concentrated on the feedback process from incident reporting systems.
34.	Incident and error reporting systems in intensive care: a systematic review of the literature.	Brunsveld-Reinders	2016	Netherlands	Systematic review	• Focus on the criteria of Reporting and Learning Systems according to WHO draft guidelines.
35.	Using voluntary reports from physicians to learn from diagnostic errors in emergency medicine.	Okafor	2016	United States	A quantitative descriptive review	• Concentrate on Learning from the errors. • Learning from diagnostic errors in emergency medicine.
36.	Implementation of medication errors reporting system by clinical pharmacists at tertiary care teaching hospital: A pilot study.	Ramesh	2016	India	A quantitative study	• Medication errors Reporting system. • Identifying and assess the pattern of occurrence of Medication errors.
37.	Application of Hospital Information Systems-Construction of an Incident Reporting System.	Lee	2016	Taiwan	A qualitative descriptive review	• Incident Reporting System. • Describing the construction of an Incident Reporting System.
38.	Perceptions of reporting practices and barriers to reporting incidents among registered nurses and	AbuAlRub	2015	Jordan	A quantitative study/ Exploratory survey	• Testing the effectiveness of the incident reporting system by evaluating nurses and physicians' awareness.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
	physicians in accredited and nonaccredited Jordanian hospitals.					
39.	Attitudes of physicians in training regarding reporting of patient safety events.	Bussel	2015	United States	A quantitative study/ questionnaire	• To understand the attitudes and experiences of physicians in training with regard to patient safety event reporting.
40.	Barriers to Medical Error Reporting.	Poorolajal	2015	Iran	Cross-sectional study/ Research	• Exploring the prevalence of medical error underreporting and associated barriers.
41.	The German Critical Incident Reporting System for Anesthesiology: CIRSains.	Welker	2015	Germany	A quantitative descriptive review	• Critical Incident Reporting System for Anesthesiology was the main area of study. • Some solutions were suggested for the problems detected during the evaluation process of the system.
42.	How Effective Are Incident-Reporting Systems for Improving Patient Safety? A Systematic Literature Review.	Stavropoulou	2015	United Kingdom	Systematic review	• The effectiveness of Incident-reporting systems as a method of improving patient safety through organisational learning.
43.	Examining the attitudes of hospital pharmacists to reporting medication safety incidents using the theory of planned behaviour.	Williams	2015	United Kingdom	A quantitative study/ A theory of planned behaviour (TPB) survey.	• Medication Errors reporting systems. • The effect of factors within the hospital pharmacists' practice of their reporting a medication safety incident.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
44.	Voluntary Medical Incident Reporting Tool to Improve Physician Reporting of Medical Errors in an Emergency Department.	Okafor	2015	United States	A quantitative descriptive review	• An online incident reporting system. • Designing and implementation of a web-based medical errors-specific incident reporting system.
45.	The incident reporting systems and organisational learning in Indonesian public hospitals.	Dhamanti	2014	Indonesia	Qualitative approach/ Research	• Patient safety incident reporting and organisational learning arising from incidents. • Investigation of the implementation of patient safety incident reporting in public hospitals.
46.	A survey questionnaire - Incident reporting among doctors in a UK hospital.	Nicholas	2015	United Kingdom	Quantitative Study/ questionnaire	• Reporting and learning system. • Assessing awareness, knowledge and attitudes of doctors towards of reporting adverse. • Identifying factors that deter doctors submitting reports.
47.	Investigating Factors Associated with not Reporting Medical Errors From the Medical Team'S Point of View in Jahrom, Iran.	Jahromi	2014	Iran	Quantitative Study	• Medical team's points of view for not reporting medical errors. • Understanding human factors to consider the issues regarding the reporting system.
48.	Analysis of an integrated reporting system in general surgery.	Kumar	2014	United Kingdom	Quantitative Study	• Focus on the modifications to an existing web-based reporting system.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
49.	National critical incident reporting systems relevant to anaesthesia: A European survey.	Reed	2014	United Kingdom	Quantitative Study/ Survey	• National critical incident reporting systems relevant to anaesthesia in six European countries. • Recommendations were suggested for a successful reporting system.
50.	Health Professionals' Beliefs, Attitudes and Experiences of Medication error reporting: A systematic review protocol.	Al Qubaisi	2014	United Kingdom	A systematic review/ protocol	• Medication errors reporting system. • Providing recommendations based on synthesizing the available evidence on health professionals' beliefs, attitudes and experiences of medication error reporting.
51.	Understanding the attitudes of hospital pharmacists to reporting medication incidents: A qualitative study.	Williams	2013	United Kingdom	Qualitative Study/ Research	• Medication errors reporting system. • Presenting the attitudes of hospital pharmacists to report medication incidents.
52.	Improving patient safety one error at a time: Implementing an electronic error-reporting system in a radiation oncology clinic.	Deraniyagala	2013	United States	Quantitative Study/ Survey	• An online error-reporting in the radiation oncology department. • Assessing staff's perception of the new Electronic Error-Reporting. • The department's attitude toward safety issues.
53.	Practical implications of spontaneous adverse drug reaction	Abideen	2013	India	A qualitative descriptive review	• Adverse drug reaction reporting systems.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
	reporting system in hospitals-an overview.					• Evidence-based overview for implementing an efficient and convenient Adverse drug reaction reporting system. • Demonstrating the fundamental concepts of pharmacovigilance.
54.	Medication Error Reporting Rate and its Barriers and Facilitators among Nurses.	Bayazidi	2012	Iran	A quantitative study/ questionnaire.	• Concentrating on Medication Errors Reporting System. • Barriers and facilitators among nurses for reporting medication errors.
55.	Implementation of a critical incident reporting system in a neurosurgical department.	Kantelhardt	2011	Germany	A qualitative descriptive review.	• The critical incident reporting system in a neurosurgical department. • Describing the one-year experience of the system.
56.	A nationwide medication incidents reporting system in the Netherlands.	Cheung	2011	Netherlands	A quantitative descriptive review	• Medication Incidents Registration (CMR) system.
57.	Data Consistency in a Voluntary Medical Incident Reporting System.	Gong	2011	United States	A qualitative study/ Content analysis method	• Voluntary reporting systems. • The effectiveness of human factors at cognitive levels on reporting events.
58.	Development of an online incident-reporting system for	Kanda	2011	Japan	A quantitative descriptive review	• Electronic Incident Reporting on the Internet.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
	management of medical risks at hospital.					• System construction and operation.
59.	Critical incident reporting and learning.	Mahajan	2010	United Kingdom	A qualitative descriptive review	• The essential components of a successful incident reporting system. • Framework for analysing the reported incidents (learning process). • Barriers and enablers to successful incident reporting were presented.
60.	Toward a Human-Centered Voluntary Medical Incident Reporting System.	Gong	2010	United States	A quantitative descriptive review	• Voluntary Reporting Systems. • The role of human-centred and ontology-based on designing voluntary reporting in terms of improving completeness, accuracy, and interoperability.
61.	Improving patient safety incident reporting systems by focusing upon feedback - lessons from English and Welsh trusts.	Wallace	2009	United Kingdom	Descriptive Mixed method/ Research.	• Concentrated on learning and feedback from patient safety incident reporting systems.
62.	Medication error reporting and the work environment in a military setting.	Patrician	2009	United States	A descriptive survey/ Research	• Medication errors reporting system. • Some reasons for medication errors and for not reporting errors were discovered among nurses.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
63.	Establishing a provincial patient safety and learning system: pilot project results and lessons learned.	Cochrane	2009	Canada	Descriptive Mixed method/ Research.	• Description of the results of a pilot study which aimed to foster a culture of safety by using the technology implementation.
64.	Development of the Incident Reporting System Using the Nursing Administrative Database.	Seto	2009	Japan	A qualitative descriptive review	• Incident reporting system. • Developing the incident reporting system utilized the nursing administrative database.
65.	Factors influencing incident reporting in surgical care.	Kreckler	2009	United Kingdom	A questionnaire survey	• Incident reporting in surgical care. • The influence of event outcome on reporting behaviour. • Staff perception of surgical complications as reportable events.
66.	Critical incident reporting: learning from errors to improve patient safety.	Harth	2007	Germany	A qualitative descriptive review	• Focus to understand a successful incident reporting system.
67.	The development of the National Reporting and Learning System in England and Wales, 2001-2005.	Williams	2006	United Kingdom	A quantitative descriptive review	• Recording and learning from reported patient safety incidents.
68.	Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems.	Flink	2005	United States	A quantitative descriptive review	• Patient Occurrence Reporting and Tracking System. • The history, evolution, and implementation of the reporting system.

P	Title	First author's surname	Year	Country	Type of Study/ Methodology	Area of study /key findings
69.	Building a better incident reporting system: perspectives from a multisite project.	Lubomski	2004	United States	A qualitative descriptive review	• A Web-based incident reporting system. • Discussing key issues that emerged during the design and implementation of the online system.
70.	Development of a Web-based event reporting system in an academic environment.	Mekhjian	2004	United States	A quantitative descriptive review	• A Web-based event-reporting system. • Describing the design and implementation of a Web-based event-reporting and the tracking tool that overcomes these difficulties.
71.	Using focus groups to understand physicians' and nurses' perspectives on error reporting in hospitals.	Jeffe	2004	United States	Qualitative study	• Medical error reporting. • A better understanding of physicians' and nurses' perspectives regarding medical error reporting. • Barriers to reporting, and possible ways to increase reporting.

11.2 APPENDIX 2- Ethical Approval from School of Healthcare Sciences of Cardiff University

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
School of Healthcare Sciences
Ysgol y Gwyddorau Gofal Iechyd

Interim Head of School and Dean /Pennaeth yr Ysgol Dros Dro a Deon Professor David Whitaker

Cardiff University
Eastgate House
35-43 Newport Road
Cardiff
www.cardiff.ac.uk

Prifysgol Caerdydd
Ty Eastgate
35 – 43 Heol Casnewydd
Caerdydd
www.caerdydd.ac.uk

26 April 2022

Hamza Jaber
Cardiff University
School of Healthcare Sciences

Dear Hamza

Research project title: A QUALITATIVE STUDY OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING IN LIBYAN HEALTHCARE

SREC reference: REC872

The School Of Healthcare Sciences Research Ethics Committee reviewed the above application via its proportionate review process.

Ethical Opinion
The Committee gave:

> a favourable ethical opinion of the above application on the basis described in the application form, protocol and supporting documentation.

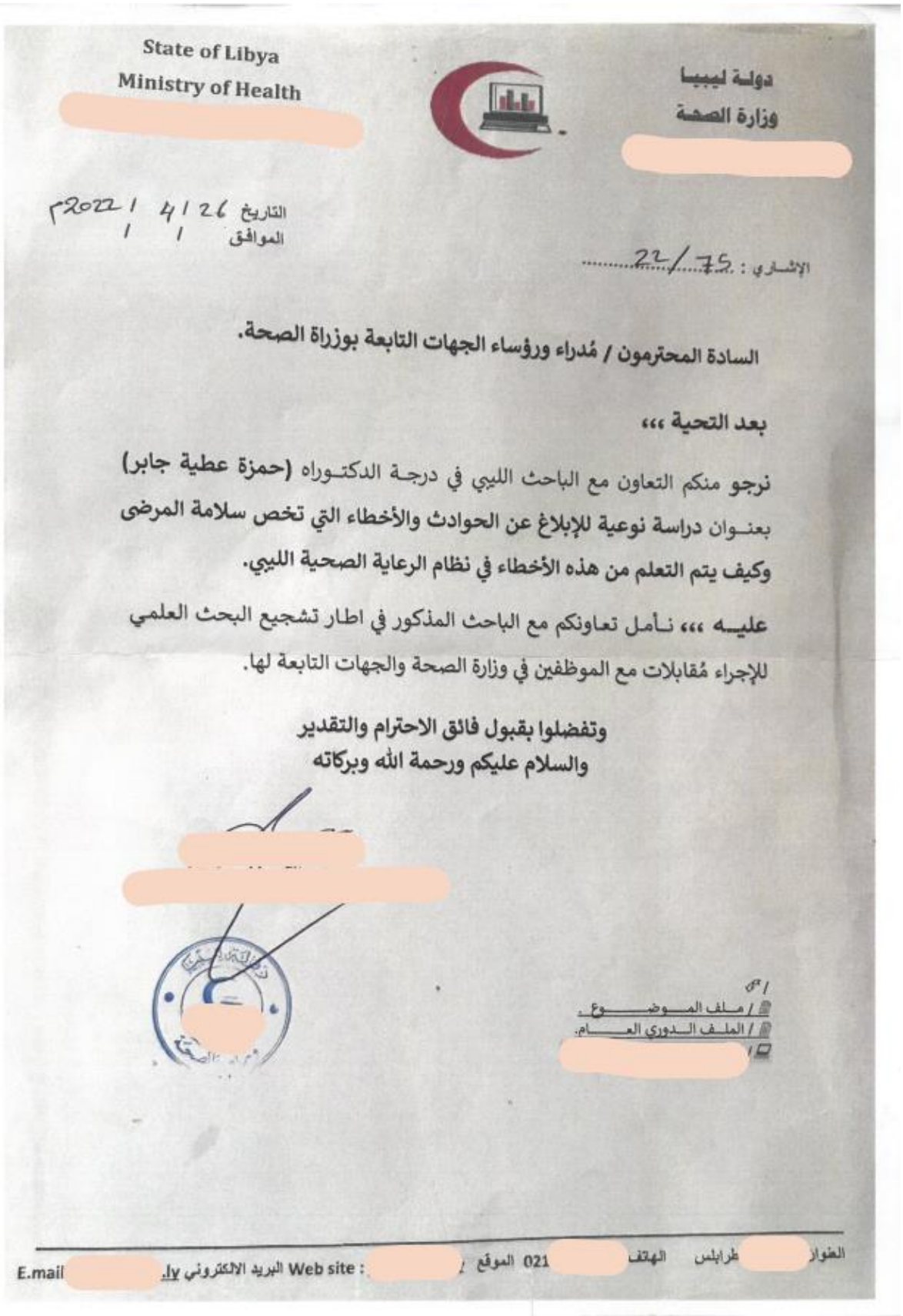
Additional approvals
This letter provides an ethical opinion only. You must not start your research project until all appropriate approvals are in place.

Amendments
Any substantial amendments to documents previously reviewed by the Committee must be submitted to the Committee via HCAREEthics@cf.ac.uk for consideration and cannot be implemented until the Committee has confirmed it is satisfied with the proposed amendments.
You are permitted to implement non-substantial amendments to the documents previously reviewed by the Committee but you must provide a copy of any updated documents to the Committee [via HCAREEthics@cf.ac.uk for its records.

Monitoring requirements
The Committee must be informed of any unexpected ethical issues or unexpected adverse events that arise during the research project e.g.

- End of project report ONLY;
- Annual reports;
- Periodic reports from and/or visits to the Chief/Principal Investigator;
- Oral updates to the Committee (by the Chief/Principal Investigator);
- Establishing a project-specific monitoring provision.

11.3 APPENDIX 3- Approval from the Libyan Ministry of Health



State of Libya
Ministry of Health

دولة ليبيا
وزارة الصحة

التاريخ 2022 / 4 / 26
الموافق / /

الإشـارة : 22/75

السادة المحترمون / مُدراء ورؤساء الجهات التابعة بوزراة الصحة.

بعد التحية ،،،

نرجو منكم التعاون مع الباحث الليبي في درجـة الدكتـوراه (حمزة عطية جابر) بعنـوان دراسة نوعية للإبلاغ عن الحوادث والأخطاء التي تخص سلامة المرضى وكيف يتم التعلم من هذه الأخطاء في نظام الرعاية الصحية الليبي.

عليـه ،،، نـأمل تعاونكم مع الباحث المذكور في اطار تشجيع البحث العلمي للإجراء مُقابلات مع الموظفين في وزارة الصحة والجهات التابعة لها.

وتفضلوا بقبول فائق الاحترام والتقدير
والسلام عليكم ورحمة الله وبركاته

/ ملف الموضـــوع.
/ الملـف الـدوري العـــام.

العنوان: طرابلس الهاتف 021 الموقع / Web site : البريد الالكتروني E.mail .ly

11.4 APPENDIX 4- Participant Information Sheet (PIS)

PARTICIPANT INFORMATION SHEET

[A QUALITATIVE STUDY OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING IN LIBYAN HEALTHCARE]

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

1. What is the purpose of this research project?

Reporting and Learning systems have been considered as a significant strategy to improve patient safety, quality of care, and staff and patient satisfaction in healthcare settings. Very few studies have been conducted in Libya regarding patient safety in the healthcare sector. Learning from patient safety errors can improve patient safety and helps to avoid errors to happen again in the future. However, a comprehensive review of the literature demonstrated that incomplete learning, or a complete absence of learning and lessons, often occurs when patient safety incidents are reported. Furthermore, there were no relevant studies undertaken in Libya or in countries that have experienced comparable adversities.

Therefore, the main aim of this study is to explore patient safety reporting & learning in the Libyan healthcare sector, in terms of the experiences and perceptions of key healthcare policy stakeholders.

The findings of this study will inform healthcare service providers about the barriers and enablers for learning from errors. Moreover, it will enhance understanding of how reporting and learning systems function in the healthcare sector and if necessary, support reporting and learning system performance in the future.

2. Why have I been invited to take part?

You have been invited because you have met the inclusion criteria of this study which include Ministry of Health staff who are have current or recent experience, knowledge and insight in patient safety, healthcare data/information and/or reporting and learning in healthcare. If you do not meet the mentioned inclusion criteria, this means you are excluded and do not need to participate in this study.

3. Do I have to take part?

No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, I will discuss the research project with you. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights.
You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

- An interview will be conducted for about 60 minutes.
- The interview will be at a place of your preference and a time that is convenient for you, and the interviews can be undertaken during or out of the working hours.
- Please note that the researcher will record the interview sessions in an audio format with your permission; this is to ensure that your answers are correctly recalled. Your identity will be kept anonymous, and you will be assigned as a pseudonym during the interview sessions. Also, you can skip any question that you do not want to answer without giving a reason.
- The audio recordings of the interview and related data will be securely saved on a password secured laptop and personal computer. The researcher will return to the UK once data collection is completed and all the data will be transferred to the Cardiff University computer which will be password secured and accessible to only the researcher.

- The audio recording will be transcribed, and your identifying information will be removed from the transcription in order to protect your confidentiality. No one will be able to link the data you have provided to your name or identity. The interview transcripts will bear only your assigned pseudonym and no reference will be made to job title, role or personal information such as gender or age where this information may lead to participants being identified.

5. Will I be paid for taking part?

No payment for this research.

6. What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help us understand the practice of reporting and learning systems in healthcare. This will contribute to the growing body of evidence supporting the advancement of learning from errors in the healthcare sector and the practices of reporting and learning. Your contribution will help us to improve healthcare staff and patient satisfaction in healthcare settings.

7. What are the possible risks of taking part?

- There are no risks or disadvantages to participating in this study.
- You can decline to answer any question without giving reasons.
- A discussion with the ministry of health was arranged prior to holding the interviews to consider available facilities and services that can maintain the welfare of participants.
- There are limits of anonymity/confidentiality in situations where any information revealed to the researcher during interviews indicates there is public interest in revealing issues to third parties. For example, if a study participant shares information that indicates likely or real harm occurring to staff or patients, the researcher will disclose this with appropriate authority internally (e.g. safety team in the participant's organisation) or externally to regulators or relevant authorities within the legal framework of Libya. Nevertheless, it is accepted that best practice is to seek the consent of participants prior to revealing confidential concerns. In situations where study participants feel obliged to report misconduct or wrongdoing, such persons will be referred to the appropriate regulatory body should need be.

8. Will my taking part in this research project be kept confidential?

Yes. All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

The findings will be used for the purpose of the PhD's degree dissertation about an *exploration of the healthcare sector' experience of reporting and learning system in Libya.* The anonymised findings of this study may be published in an internal report or a peer-reviewed publication.

9. What will happen to my Personal Data?

In this research study, no indication of your name would appear in this study. During the data-analysis, the researcher will represent each participant by a pseudonym instead of their real names.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

Adhering to Cardiff University guidelines, the electronic data will be held securely stored in password-protected personal computer. All participants' data will be kept for a minimum period of

5 years after the end of the project, or after publication of any findings based upon the data (whichever is later) afterwards destroyed.

Participants' personal data will be processed after finishing the interview. The researcher will anonymise all the personal data it has collected from, or about, you in connection with this research project. Your consent form will be retained for a minimum period of 5 years and may be accessed, where necessary, by members of the University's governance and audit teams or by regulatory authorities.

Note you can request to withdraw your data, but it will not be possible to withdraw any anonymised data that has already been published or in some cases, where identifiers are irreversibly removed during the course of a research project, from the point at which it has been anonymised.
If the data is still held and can identify its persons, it will be withdrawn.
If the data has already been anonymised, it cannot be withdrawn, but importantly, the person cannot be identified.

10. What happens to the data at the end of the research project?

At the end of the research project data in the form of the audio recorded interview and any personally identifiable information will be destroyed. Anonymised data, such as interview transcripts, will be kept for a period of 15 years to allow for publication of research findings.

11. What will happen to the results of the research project?

We anticipate publishing the findings of the study in a research thesis and within scientific journals. We may utilize some excerpts of what you have explained to illustrate the findings, but pseudonyms will be used, and we will not reveal any details that identify your personally.

There will be an opportunity for a copy of the research results to be sent to you following this study. It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation.

12. What if there is a problem?

If you wish to raise a complaint, you can contact:

The researcher Hamza Jaber: [redacted]@cardiff.ac.uk

If you wish to complain, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact the researcher's supervisors:

Professor [redacted]@cardiff.ac.uk
Dr. [redacted]@cardiff.ac.uk

If your complaint is not managed to your satisfaction, please contact the Director of Research Governance & Active Health Research Theme:

Dr. [redacted]@cardiff.ac.uk

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this research project?

The research is organised by Hamza Jaber (PhD student) under the supervision of Professor Aled Jones and Dr. Dominic Roche from the School of Healthcare Sciences, Cardiff University. The research is currently funded by Libyan cultural attaché (Libyan government).

14. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the School of Healthcare Sciences Research Ethics Committee, Cardiff University.

15. Further information and contact details

Should you have any questions relating to this research project, you may contact the researcher during normal working hours:

Hamza Jaber
Email: [redacted]@cardiff.ac.uk
Phone number: 0044 [redacted]
0021 [redacted]

Thank you for considering to take part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.

11.5 APPENDIX 5- Formal Written Consent Sheet

Appendix 4

Participant ID no:
Do not include box for anonymised samples

CONSENT FORM

Title of research project: A QUALITATIVE STUDY OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING IN LIBYAN HEALTHCARE.

SREC reference and committee: [Ethical Approval from School of Healthcare Sciences of Cardiff University: REC872, Approval from Libyan Ministry of Health- Reference No: 22/75]

Name of Chief/Principal Investigator: [Hamza Jaber]

	Please initial box
I confirm that I have read the information sheet dated 08/04/2022 version 03 for the above research project.	
I confirm that I have understood the information sheet dated 08/04/2022 version 03 for the above research project and that I have had the opportunity to ask questions and that these have been answered satisfactorily.	
I understand that my participation is voluntary and I am free to withdraw at any time without giving a reason and without any adverse consequences (e.g. to medical care or legal rights, if relevant). I understand that if I withdraw, information about me that has already been obtained may be kept by Cardiff University.	
I understand that data collected during the research project may be looked at by individuals from Cardiff University or from regulatory authorities, where it is relevant to my taking part in the research project. I give permission for these individuals to have access to my data.	
I consent to the processing of my personal information such as names and the job position for the purposes explained to me. I understand that such information will be held in accordance with all applicable data protection legislation and in strict confidence, unless disclosure is required by law or professional obligation.	
I understand who will have access to personal information provided, how the data will be stored and what will happen to the data at the end of the research project. If you have specific options to decide how the data can be used, please list them here:	

Version 03 [08/04/2022]

Appendix 4

Participant ID no:
Do not include box for anonymised samples

I understand that after the research project, anonymised data may be published and made publicly available via a data repository and may be used for purposes not related to this research project such as academic research papers and presentations. I understand that it will not be possible to identify me from this data that is seen and used by other researchers, for ethically approved research projects, on the understanding that confidentiality will be maintained.	
The researcher intends to conduct an interview, and I consent to being audio recorded for the purposes of the research project and I understand how it will be used in the research.	
I understand that anonymised excerpts and/or verbatim quotes from my interview may be used as part of the research publication.	
I understand how the findings of the research project will be written up and published.	
I agree to take part in this research project.	

Name of participant (print)	Date	Signature
Hamza Jaber Name of person taking consent (print)	Date	Signature
The Researcher Role of person taking consent (print)		

THANK YOU FOR PARTICIPATING IN OUR RESEARCH

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

11.6 APPENDIX 6- Semi-structured Interview Guide

Stakeholders Semi-structured Interview Guide

Q1. Firstly, I would like to know a little bit about you. Can you tell me a little about your career?

Prompts: When did you qualify? Where have you been employed before (in which positions in the healthcare sector)? Where do you currently work, what is your role and how long have you been doing it? Is anything else you want to add.

Q2. Can you tell me what you know about patient safety?

Prompts: Who should care about patient safety? How important do you think patient safety? Who should be responsible for patient safety?

Q3. Can you tell me what you know about reporting and learning systems in healthcare?

Prompts: Do you think that reporting and learning systems are important for patient safety? Who should report patient safety incedents?

Q4. What is the aim of involving patients to report errors that cause harm?

Prompts: Do you think including or exclude patients to report errors could affect the healthcare sector? How important to include patients to report harm?

Q5. What is the aim of excluding or including healthcare staff to report patient safety incidents?

Prompts: What are the effects of including or excluding healthcare staff in regard to reporting errors or incidents?

Q6. What is the effect of including or exclude both patient and healthcare staff?

Prompts: Do you think excluding both patients and healthcare staff from reporting can affect learning in the healthcare sector?

Q7. What options are available to implement a reporting and learning system type in Libya healthcare?

Prompts: Do you think Libyan healthcare needs a reporting and learning system? If No, why and explain with an example? If yes, to what extent do you think this system is important? and please can you provide an example? /"Then moving to next questions"/ Do you think that a system for reporting and learning from patient safety incidents can be implemented in Libya healthcare? if Yes, how? and if No Why? and who might be responsible for taking this action? Do you think some healthcare policies could be a barrier to the reporting syatem? if Yes, what kind of policies? if No, then in your opinion what are barriers to this system? Do you think policymakers can play roles in implementing a reporting and learning system in Libyan healthcare? If yes, who are policymakers? and how this action can be taken?

Q8. How do you think reporting and learning in the healthcare sector can be developed/enhanced?

Q9. Is there any question you think that I should ask you about it?

Prompts: Please feel free to discuss any questions that are supposed to be asked regarding this topic.

Thank you for your time!

Your participation is highly appreciated!

11.7 APPENDIX 7- Arabic Interview Transcript Sample

11.8 APPENDIX 8- English Interview Transcript

Interview: Abu al-Qasaim:

HJ: Assalamu Alaikum, thank you for participating in my study and for your time today. I have some questions about patient safety and exposure to incidents. Various factors can lead to a patient experiencing a medical error. Once these errors and their causes are identified, the responsible authorities are notified to address and rectify them.

First, let us start with patient safety.

HJ: In your opinion, who is supposed to be responsible for patient safety?

Abu al-Qasaim: In the name of Allah, first you well come, then I can answer your question, and I would like to say that I have seen cases about patient safety many times, regardless of what the law stipulates. In fact, there are some medical errors directly occurring from the patient. It is a medical error, and it was done by the doctor, but it is mainly caused by the patient himself. How so! the information and data provided by the patient is often not true, he may fancy or imagine. For example, if he has heart disease, he may say that he has an issue in his heart, because of a previous conversation between him and colleagues in the street or another doctor or others. Then he repeats in a conversation as if he has information. At this point, the doctor is forced to focus on the patient's words, because the doctor wants to take information from the patient. Then the doctor concludes diseases and therapeutic steps. You know that in medicine that the doctor when he has a pathological condition, he expects six to seven diseases every time an option falls, and this is found in the health law. Therefore, he has two or three reasons based it begins treatment, but with the patient's insistence that he has a certain disease and does not adhere to prescriptions, reports and tests.

HJ: I have seen some people in the medical council have the same idea, and they pointed out that sometimes the papers that can be taken to prove the medical error do not exist.

Abu al-Qasaim: It is often lost or non-existent. Even if the patient has it, they usually don't keep it for more than a few weeks. They might tear it up, write on it, or use it for something else. It can also get lost in the car or at home. It was recommended in the past when the patient's medical file (booklet) was created in which the medical condition is complete. This booklet records the health status of each person I am in my family. I had eight medical manuals. They are very good and any doctor who passes by receives the booklet is writing and proving the case in the booklet and gives the necessary treatment prescription and writes recommendations.... etc. In the same booklet, he may use a page or two and the booklet has a number of pages and even if it is filled it is changed with a second booklet and this is in the proof is good. At the same time even in follow-up and in treatment, because as soon as you appear in front of the doctor you give him the booklet and he browse it and sees the pathological cases etc. The doctor certainly will reach a useful result. The medical error I told you sometimes may be caused by the patient, negligence and the patient's claim to knowledge without knowledge, so that sometimes he may not understand the words that the doctor says to him because he do not want to listen, all the matter that the patients want a specific drug and it will come with a result, that is what the patients want. There are other things, Do I continue?

HJ: Yes, but in short words to finish your idea?

Abu al-Qasaim: Sometimes, doctors request medical tests, but some patients want to perform them at other health centres. Some patients sometimes wish to obtain a certain result to obtain a medical report for treatment abroad at the state's expense or to receive compensation from health insurance.

HJ: Considering that the law in Libya allowed this procedure, the person may resort to circumventing the law to obtain compensation!

Abu al-Qasaim: Circumvention … Yes, so the results of the test are to satisfy the patient only, the doctor needs to satisfy the patient, and if there is no agreement between the patient and the doctor, the relationship between them will worsen and other issues will be involved. I want to inform you about the documentation process in patient files. In Tunisia, a file is opened for a patient as soon as they see a doctor, and all subsequent procedures are based on this file. However, in Libya, many providers, especially private clinics, avoid this practice to prevent being held accountable for medical errors. They often refrain from providing a complete diagnosis due to fear of medical liabilities. In Libya, there is a lack of awareness about medical liabilities. Some doctors pay a nominal annual premium of 200-250 dinars for medical insurance to cover any potential errors. This insurance aims to reduce the financial burden of medical liabilities.

Abu al-Qasaim: I am discussing how medical staff and doctors strive to reduce medical insurance premiums. However, the private sector often avoids difficult situations, transferring critical cases to the public sector when they become intractable. The private sector in Libya is primarily focused on financial gain, turning the profession into a trade. There exists an implicit contract between patients and the private sector. For example, if a clinic advertises that it treats patients, and I, as a patient, enter seeking treatment, an implicit contract is formed. This contract obliges the clinic to treat me, even though it is not written with specific conditions. In the private sector or the general doctors are not required to achieve a result, doctors are not required to ensure a patient's recovery. The responsibility lies with the patient who seeks treatment. There is also no obligation to pay a specific premium for follow-up examinations or analyses aimed at achieving recovery. Sometimes, when recovery is not achieved, patients end up complaining against the doctor.

HJ: We do not want to focus on the doctor alone, for example, the radiology technician, the administrator, or the nurse. For example, whether in the public or private sector, are they primarily responsible for patient safety?

Abu al-Qasaim: Yes, we are primarily responsible for the patient, whether the contract is formal or informal, or if you own a clinic and the patient attended. Let me tell you that the law requires doctors to help if they encounter a medical emergency, even if they are just walking on the street. Failure to do so can result in punishment. For example, if a doctor sees someone having a seizure, an accident, or fainting, they must assist. In cases of fractures, the doctor should stay with the patient until an ambulance arrives. If there is a large wound, the doctor should quickly bandage it to stop the bleeding. If two witnesses can prove that a doctor ignored a medical emergency, the doctor will be investigated. Medicine is a noble profession and not a commercial one.

HJ: In Libya I believe that the patient is the one who should report medical harm, do you think healthcare staff such as doctors, nurses, or radiology technicians can admit that they made errors or harm? Let me be clear: in Libya, the right to report medical harm is granted to patients. However, if medical harm occurs and the patient does not want to report or complain, and staff members like nurses have witnessed or noted the harm, can they report this harm?

Abu al-Qasaim: reporting incidents depends on the ethics of the professionals. If a doctor, nurse, or technician is virtuous and recognises that they work in the medical field dealing with human beings like themselves, then they should report patient safety incidents. After all, they themselves may one day be on the receiving end of medical care. Medical professionals themselves may one day fall under the scalpel. Therefore, they should be wise and capable of understanding the consequences of reporting incidents related to patient safety. Based on this, healthcare staff are supposed to report such issues.

HJ: Does this mean that there are no legal impediments to reporting patient safety incidents?

Abu al-Qasaim: Listen, medical staff, including nurses, imaging technicians, and surgeons performing procedures on the heart or brain, are all required to prepare reports. Each person has a role in preparing a report. For example, doctors should write a comprehensive report to help nurses follow up on the patient's pathological condition after leaving the doctor's care. Everything is expected to be documented in the patient's file.

For example, any symptoms such as high temperature, chills, fainting, or other issues should be written down, not verbally communicated. This is important because the doctor reviews the file upon arrival, and some symptoms may have occurred earlier and resolved by the time the doctor arrives. For example, a patient’s temperature might have risen but returned to normal by the time the doctor checks. Documenting these changes is crucial as the patient’s condition can vary, especially after surgery.

HJ: True, but sometimes other staff, such as nurses, may cause medical errors or harm to patients.

Abu al-Qasaim: Yes, errors can happen due to other staff. I’ve attended some trials, and it’s not just doctors who can make errors; nurses and other staff can too. Everyone is responsible under the management of the health facility and the treating doctor or specialist. When a doctor performs a treatment, they are responsible for their assistants, including other doctors and nurses. These assistants can only act based on the specialist doctor’s instructions. For example, if an injection is needed, the doctor must document and sign the order. The nurse then administers the injection and records it. The judiciary seeks irrefutable evidence because there can be doubts about fairness.

HJ: I want to talk about a point of view which doesn't have to be correct. Let's say that someone is convinced that he does not judge things until after seeing the action "event", so he reacts based on the action. For example, if something is about to fall I do not touch it until after it falls. This is my idea of the law, in the sense that the law does not move except when an event occurs. In medical errors, for example, the law cannot rule unless there is evidence indicating medical harm.

HJ: Is that true?

Abu al-Qasaim: Here I see otherwise, because the occurrence of a medical error sometimes does not cause harm. The law refers to compensation with the intention of reparation. The damage did not happen, today it did not happen but it may happen in the future.

HJ: An important point I want to know is the error that did not cause harm, but the damage may occur in the future. So, the law does not consider the expected harm in the future?

Abu al-Qasaim: this is called caution and caution, as the skilled doctor has to intervene in these matters. Those are the doctors we need to guard against medical harm.

HJ: the law in Libya does not deal with this thing?

Abu al-Qasaim: these things exist in the law, but they are not applied and are invisible. These simple incidents, and you know that major incidents come from minor ones.

HJ: How do small medical errors occur?

Abu al-Qasaim: patients often don't fully understand their own diseases and focus mainly on getting cured because they've paid for treatment. In the past, when healthcare in Libya was free, patients would see multiple doctors and collect various prescriptions without using them properly. This can lead to issues because some medications shouldn't be taken together due to their chemical interactions. A lack of health education means patients might give doctors incorrect information, which can lead to errors. Doctors have to rely on this information to study the patient's condition, even if it's not always accurate.

HJ: Who decides whether the patient or the doctor is right?

Abu al-Qasaim: the patient is always considered right, whether due to ignorance or claiming knowledge. Even if the patient is in a coma or has improper motives, such as seeking a medical report to circumvent the law, the doctor should treat the patient as a medical case, not as a fraudster. If any of the patient's claims indicate a specific goal, the doctor must treat him as a patient, not as an abnormal person or fraudster. Medical education in Libya might differ. Doctors must be culturally qualified, especially as Muslims, to always have an opinion and consider deterrents. If a doctor causes harm, they may face imprisonment, compensation, beating, dismissal, or other penalties, motivating them to work diligently. The goal is to avoid harm and medical problems, not necessarily to achieve a cure.

HJ: Is it important to have a medical committee or council to act as a deterrent in cases of medical harm?

Abu al-Qasaim: Even defaming the doctor can be enough.

HJ: Do you think this point is important for caution?

Abu al-Qasaim: It is crucial to address the lack of professional trials when a doctor makes medical harm. Doctors should be referred directly to a professional court to decide the case and draw conclusions. If the doctor is correct, it should be acknowledged. If the medical condition does not require surgical intervention, it should be avoided in the future and

documented. Additionally, medical liability laws should be taught in universities to avoid confusion between concepts. Sometimes, people compare and suggest going to Tunisia for treatment, claiming it is better than Libya. But let me ask, what is the purpose of going to Tunisia? Healing comes from God. Patients look for reasons, which could be an experienced or a junior doctor. The process is psychological; when you go to Tunisia, what does the doctor do? They smile at you, and the nurse is competent. The patient experiences new faces, new food, and tourism. Our health culture should make hospitals like hotels, with rooms offering good services, kind words, and pleasant smells. Currently, hospital rooms have five to six patients, which leads to bad smells, inappropriate behaviour, strange thoughts, infections, and waste transmission, all affecting patient safety.

HJ: okay...I don't want to take up too much of your time!

Abu al-Qasaim: It's okay, I'm very happy. We are looking for new staff. May God help you. Feel free to reach out anytime, even tomorrow or in a month. Welcome.

HJ: HJ: If patients do not report medical harm and only allow a committee of doctors to do so, it might reduce or eliminate compensation.

Abu al-Qasaim: It means to escape, medical error always exists, and whoever does not work does not make errors. Whoever is not working will not make errors. Proving medical harm to the patient can only be proven by the presence of a specific act, which is a medical error. I will tell you another thing, if the law in Libya becomes optional, all the articles related to it must be completely changed.

HJ: Does this affect the health sector in Libya?

Abu al-Qasaim: Yes, it affects us, and we are by virtue of our culture and we are a new society. We are not a naïve society; Libyans are not naïve - don't take me for the word. Medical education varies, with some studying in Benghazi and others in Tripoli, often without knowing Latin. A medical staff member is not considered a doctor unless fully equipped. We hope to reach a stage where doctors are held accountable for their errors. Currently, doctors are not punished because another party compensates for the harm. Because the penalty was paid in the form of compensation. Meaning that I did harm, and you proved that I made a harm - even though 90% refuse to admit that they made harm. What is the punishment? The penalty is that he pays the money, and the Medical Insurance Authority is there to bear it, this is one of the reasons that will not lead to the development of the health sector in Libya.

Abu al-Qasaim: But I have a different point of view, instead of punishing the doctor...

Abu al-Qasaim: The doctor will not be punished; all the matter is to prove that he made a medical harm only. There is no penalty, even the judiciary rules with a certain financial value of ten thousand, one hundred thousand, two hundred thousand or even a million. The doctor is allowed to leave without any obligation. This is due to the absence of professional trials. They are the ones that specialise in this matter. Even if the doctor is obligated to pay compensation by a judicial ruling, he goes back to the authority as the body charged with protecting him. The medical insurance authority is responsible only for paying compensation. Doctors pay the authority for protection because it is mandatory. If it were

optional, the insurance company would not cover every medical staff member. Each unit must pay premiums and obtain insurance. This is not the case in Libya. For example, in some countries if a doctor, such as a surgeon, approaches the insurance authority, the situation changes. As a surgeon, there is a risk of death. The potential death of a patient cannot be equated to any monetary value. Therefore, insurance may not be provided, or it may come with specific conditions, higher premiums for technical reserves, and increased care. These terms should be clearly stated in the contract, making the responsibility contractual. I have heard that in France it is said that the doctor before entering the surgery in the hospital goes to the insurance company, and bears responsibility in a specific proportion when medical harm occurs. There is something called the item of tolerance, that is, the doctor, for example, bears 50%, and the insurance company 50%.

HJ: Is this to reduce negligence and help to be cautious and vigilant?

Abu al-Qasaim: Yes, it's true. The presence of a deterrent means that if a doctor threatens to raise insurance costs, they take necessary precautions. It's illogical to think that medical insurance covers all costs. In addition, some doctors earn a monthly salary of one thousand dinars and may cause harm in certain situations. Most errors come from beginners, but some surgeons perform two or three surgeries daily and earn six to seven thousand dinars net. Both pay the same insurance premium, which is unfair. Junior doctors should be treated differently than experienced surgeons.

HJ: From what I understand, you sometimes communicate with the Medical Council. If a patient reports medical harm and is granted compensation, do you learn from these cases or hold training sessions to prevent future harm?

Abu al-Qasaim: In the past, there is none, I mean in the past, from 1994 to 2000, the Medical Insurance Authority was an independent body, and I was one of its founders. During that time, we followed up on cases, consulted doctors, and held conferences and meetings in hospitals to explain the law. However, since 2000, when the Medical Insurance Authority was merged with the Libya Insurance Company by a decree, there has been no such activity. Because the subject has become a trade, and from 2000 to 2018 the subject was received by Libya Insurance Company by a decree of the General People's Committee. This decree was legally incorrect because laws can only be cancelled by other laws, not decrees. Medical insurance should be managed by an authority, not private companies, which are profit-driven. The authority operates under professional law, while the private sector follows commercial law. Law 17 works according to the health law, and what is in the health law is applied, and at the same time, it is always referred to the state. The private sector's approach has led to a lack of justice in this matter. We have led a perception for the purpose of pervading the benefit of the medical staff, and the medical assistant, and for the interest itself sector.

HJ: Based on your experience, do you think healthcare staff who have caused medical harm need to undergo training and update their knowledge to improve their skills? This is for the purpose of enhancing patient safety and reducing medical harm, which will then lead to decreased compensation paid by the Medical Insurance Authority.

Abu al-Qasaim: Believe me, the purpose of addressing and examining medical harms is not to reduce the payment of compensation, but diligence and correct behaviour of the healthcare providers will implicitly reduce the payment of compensation. We also have a problem of overlapping powers. The Medical Insurance Authority must be independent and not subject to any other institution. Moreover, the Medical Council, which is known as the House of Experts or the National Council for the Determination of Medical Liability, is supposed to be the only body that determines medical liabilities for medical harms. The exists in Libya now is that judiciaries consult with random medical experts and then adjudicate on the medical harms without referring to the experts at the Medical Council. The courts or forensic doctors do not have the right to determine medical liabilities.

HJ: Does that operate according to the health laws?

Abu al-Qasaim: They are in force, but the National Council for the Determination of Medical Liability, established alongside the Medical Insurance Authority, is responsible for determining medical harm. When there is an allegation of medical harm, we transfer the medical file to the Council because we are not a technical body. The Council reviews the case with its medical staff to decide if there was a medical error and who is liable, whether it be the doctor, nurses, or the institution. The Council then sends a report back to us. If a medical error is found, the patient can choose to resolve the issue peacefully or file a complaint with the judiciary. However, the judiciary is usually only involved in cases of dispute, such as non-payment, prejudice, or procrastination, because these cases can take a long time to resolve, sometimes up to two years.

HJ: I have heard about a case in Tarhuna Hospital, and even in the Al-Khums city from which I am, regarding a woman in childbirth who has a medical harm, and the case was decided by granting her compensation from the Libya Insurance Company. The Tarhuna case lasted more than ten years without being judged.

Abu al-Qasaim: This could lead to conflicts with other laws and result in the loss of women’s rights. In Libya, it is assumed that only one party determines medical errors under mandatory law. The authority pays compensation, while the specialist, technician, or doctor is obliged to pay the insurance authority to cover their medical errors. If there is a dispute, the judiciary intervenes. Without an agreement, the injured party can go to court. For example, if we offer 10,000 diners in compensation, the court might award 200,000 diners instead. We also submit payment requests from the authority to the judiciary using the medical case file. Patients can report their harm and claim compensation. However, it's important to note that medical harm can occur due to various factors and from different sources. For example, a person might fall ill in Benghazi city, and his family decided to transfer him to Tripoli city. The patient's condition could worsen during the journey to Ajdabiya town. As a result, he might be admitted to the Ajdabiya Hospital. Subsequently, if his condition deteriorates once again in Ajdabiya town, he might be transferred to a hospital in Sirte town, where they could stay for a day or more. Finally, upon arriving in Tripoli city and being admitted to a hospital, the patient unfortunately passes away. In such a complex scenario, it becomes challenging to pinpoint a single party responsible for the outcome. The responsibility may be shared among multiple parties, and there may also be a possibility of shifting blame to the patient's companions for any delays in the transfer

process. In these cases, if the medical harm is proven, the Medical Insurance Authority compensates the patient for the harm suffered and subsequent death, irrespective of the specific reasons behind the medical harm.

HJ: Your words are important because they highlight that there is no direct or specific cause for medical harm.

Abu al-Qasaim: The surgeon may face a dangerous situation when treating a patient with no immunity, high blood sugar, high blood pressure, or a deteriorating heart condition. In such cases, immediate medical intervention is necessary. The doctor's role is to help the patient, improve their health, and relieve pain, not necessarily to guarantee a specific outcome. Sometimes, errors are unavoidable. For example, in cases of internal bleeding, a doctor must act quickly to stop the bleeding, even if it involves risky surgery. The doctor understands the risks but must intervene for the patient's sake, knowing that success is not always guaranteed. The doctor must medically and humanely intervene, and the ages are in the hands of God. Medical harm can result from various factors: the doctor, the hospital, the nursing staff, or even improperly stored syringes, or the syringes are exposed to the sun and smuggling from the border. Liability is shared, but proving it is challenging. Libyan law requires proof of medical error to provide compensation for the harmed person. Determining who is liable—whether the doctor or others—is a technical matter decided by professional trials. If a doctor repeatedly causes harm, they should be investigated.

HJ: The Medical Insurance Authority has a lot of data regarding medical harms because it gives compensation to harmed patients. Why the Medical Insurance Authority does not build a reporting and learning system? by finding out and studying the reasons that led to medical harm, and then developing effective solutions to prevent the recurrence of medical harm?

Abu al-Qasaim: This is the responsibility of the Ministry of Health because this overtime work is expensive and needs to pay money to operate such a system. The Medical Insurance Authority cannot open a school for education. By what right does the Medical Insurance Authority become like private schools? and what is the curriculum?

HJ: Can you build on the medical harm reports received by the authority and suggest lessons to improve the technical staff's knowledge?

Abu al-Qasaim: We cannot provide medical information because we are not a qualified authority. We are not academics, a school, or a university. Therefore, using data from us would be unreliable. The information we have is technical administrative information. Handling patients, diseases, germs, bacteria, or wounds should be taught by specialised institutions and overseen by the ministry. However, the authority may offer financial support for this purpose. A few months ago, we provided financial support to the sector. The sector itself knows best how to allocate these funds, despite the presence of state budgets, lack of policies, and minimal authority involvement in such programs. The Ministry of Justice is currently reviewing the law and will make necessary amendments. I frequently communicate with the Ministry and the Committee Chairman, sending memos and agreeing with their requests for my participation. I am dedicated to these issues, we will work to amend or cancel what is necessary and address gaps in the law.

HJ: When amending the law, do you think the Medical Council and the Medical Insurance Authority are essential and should remain unchanged in the Libyan health sector?

Abu al-Qasaim: these two bodies complement each other. The National Council for the Determination of Medical Liability should be independent and not affiliated with the Ministry of Health. I previously suggested it be linked to a judicial body. Historically, the law was issued by the General People's Congress, making it somewhat independent. It is inappropriate for the Ministry of Health to both determine medical errors and handle compensation. It is not true to be the opponent and the judge at the same time. This is a significant issue. The National Council and the Medical Insurance Authority should operate independently of each other and not be under the Ministry of Health's supervision. One should be under the Ministry of Health, while the other should report to Parliament or the Presidential Council.

HJ: Thank you so much for the valuable information. May Allah bless you with health and wellness.

Abu al-Qasaim: I have been involved with these cases since 1994, I mean involved in the medical liabilities. I have attended many trials and prosecutions. I even attended hand-to-hand fights, and the president of the court once threatened me with imprisonment. My primary concern is the patient, not the doctor. I am interested in how to protect patients who have suffered medical harm, which is not classified as a crime or fraud. Please let me say that some medical staff bypass the doctor to prepare reports of medical harm, submit them to the prosecution, obtain a ruling, and then share the compensation. This exploitation occurs due to gaps in the law.

HJ: Your thinking is very deep.

Abu al-Qasaim: I hope you will use this information, even if the world changes or we are absent for a while. I used to work at a company with an excellent salary and many advantages. When the Authority was reinstated in 2018, I resigned from the company and joined the Authority out of a desire to help others, as we had experienced and suffered through this stage. Given my age, I want to continue contributing as long as I can. Our efforts will only stop when we die or age limits us. God willing, you will succeed in this study. The most important thing is credibility; God helps us when we are honest. Believe in yourself and leave the rest to God. When transferring information, proving it, and dealing with people, always be honest. Pay attention to documentation and keep this recording, as you can refer back to it. I consider all my files as valuable sources of information and data that I never discard. What something means today may have a different meaning tomorrow.

HJ: Is there a question I missed that you think I should have asked? Do you have any personal insights that could help my study?

Abu al-Qasaim: I want you to look at the medical liability laws in other Arab countries. Libya was the second country in the Arab world, after Jordan, to develop such laws. I attended the JERASH Conference on Medical Liability in 1994. We were the first country in medical Liability and we worked hard and there are among the first pioneers who died and some of them are present until now.

I hope that they will be in the authority because the founders are better than those who come to practice their work only. Whoever comes to practice his work is only accomplishing a job and takes his salary and goes to his way. But whoever created these laws and regulations and followed them has an idea and his heart on this topic. I am deeply invested in the success and outcomes of this project. Sometimes, we discuss these topics for hours, and I often repeat myself. When someone asks me about a specific point, I provide answers, and they realize they had overlooked it. Based on my experience, I might give you a conclusion that isn't immediately apparent but proves true over time. This subject is like solving mathematical equations.

HJ: Yes, you are right in saying that this issue exists even in graduate studies. Sometimes, you may meet someone and receive information that seems valuable. When you take notes, you realize that this person has a specific idea in mind, which clarifies a concept that was previously unclear to you. When you ask a question, they might respond in a way that addresses the gap you missed. They may say something that dispels any doubts you have, simply because they follow a particular line of thought.

Abu al-Qasaim: But sometimes there may be conflicts when different departments discuss the same subject, leading to unanswered questions because the sources may not be competent. My current position wasn't randomly assigned; it reflects the confidence of the committee chairman and its members in my experience. Thank God I am good at dialogues on this topic. We've touched on several topics that might generate questions. You might even consider a second research project on a different topic. One of my projects aims to protect medical professionals not just from medical errors but in their work environment. Imagine a document that safeguards doctors while they practice, addressing issues like infections, assaults, and injustices. This would allow medical staff to work comfortably and confidently, yielding better results. I aim to shield doctors from legal responsibilities as much as possible because they are technical officials. The law shouldn't concern them since they use their medical expertise to treat and save lives. Primarily, doctors are paramedics who seek to anticipate and prevent errors. For instance, it's better to undergo a full medical examination before contracting a disease. This proactive approach ensures that you are healthy or identifies any potential health issues early on. Achieving this level of care requires a culture of knowledge and the availability of resources.

HJ: Do medical professionals, including doctors, nurses, paramedics, and technicians, have the opportunity to speak up when patient safety incidents occur and participate in the incidents reporting process?

Abu al-Qasaim: If the Medical Council summons them, during the investigation, the doctor is called, and sometimes nurses are called as well. If the patient is not reported, no action is taken. You asked me to be honest, we lack credibility because staff do not want to implicate or accuse themselves. The first thing they do is avoid liabilities. Secondly, the institution they work for may hold them liabilities for their intervention, which could bring problems to the institution. This is the reality we live in and the facts we face every day. All our institutions operate on salaries, including the doctors and the General Syndicate of Doctors, which has no role other than collecting fees for granting permission to practice the profession. They are subject to parliament, as are all unions, but who holds them

accountable? There are doctors like Dr. [Name], Dr. [Name], and others who work tirelessly to satisfy both the private and public health sectors to continue their work. Although they do not follow them, they are obligated to satisfy them to avoid disputes, issues, or complaints. This is considered a kind of theft, not interest because it is unprofessional behaviour.

Returning to the second point, regarding the laws, I want you to verify this information because I am not fully sure. How are contracts in Britain handled during surgical interventions? Although I obtained a qualification in law in 2017.

HJ: This is amazing. I believe that your pursuit of this certificate at this age is more commendable than the certificate itself.

Abu al-Qasaim: I got it by understanding and not memorisation. When I came to the Authority, my motivation was the humanitarian matter in the first place. The first thing I think about, is that if I have some disadvantages or disadvantages, may God forgive me for them when I do this work because I was a young man and prone to error. I just want to tell you that error can happen with anyone. The patient is forced to report or complain because he does not know his situation whether he was exposed to complications or treated temporarily with painkillers. Here the Medical Insurance Authority comes as a purely humanitarian subject. Personally, I strive for the patient and not for the doctor. Doctors have clear and proven rights, and the doctor is protected by compensation made by the Authority, but who protects the patient's rights. Also, the doctor must prepare a detailed report before the patient leaves. This report should be sent to other parties for study, research, and auditing, while also ensuring the patient's rights are respected. There is no harm in granting the doctor the report as long as he is protected by the MIA. Since the doctor has admitted his mistake, he is protected, and in return, he must strive to prepare reports immediately, not after a week. He should ask the patient a deliberate question, such as, "Do you still feel pain?" If the patient says no, the doctor should advise continuing the same medication. However, if the doctor tests again and finds the patient is still sick, further action is needed. In addition, a capable lawyer does not make an enemy out of his opponent; instead, he wins him over without considering him an enemy. This principle applies to doctors, lawyers, engineers, pilots, and other professionals, even if they make mistakes. Errors are inevitable, and incidents in the medical sector are bound to happen. Achieving justice in every situation is challenging.

HJ: You asked me to consider two points: studying the laws and policies and ensuring the doctor's security. Is that correct?

Abu al-Qasaim: It would be beneficial to compare British laws with Libyan laws. In Libya, the laws are mandatory, and injustices can occur. Medical staff, being human, may sometimes make mistakes. Patients seek medical help not out of affection for the doctor, but due to illness and fear of death. Medicine is not just a profession; it is a divine calling.

HJ: Okay, thank you very much for your valuable participation, it was a pleasure to meet you today.

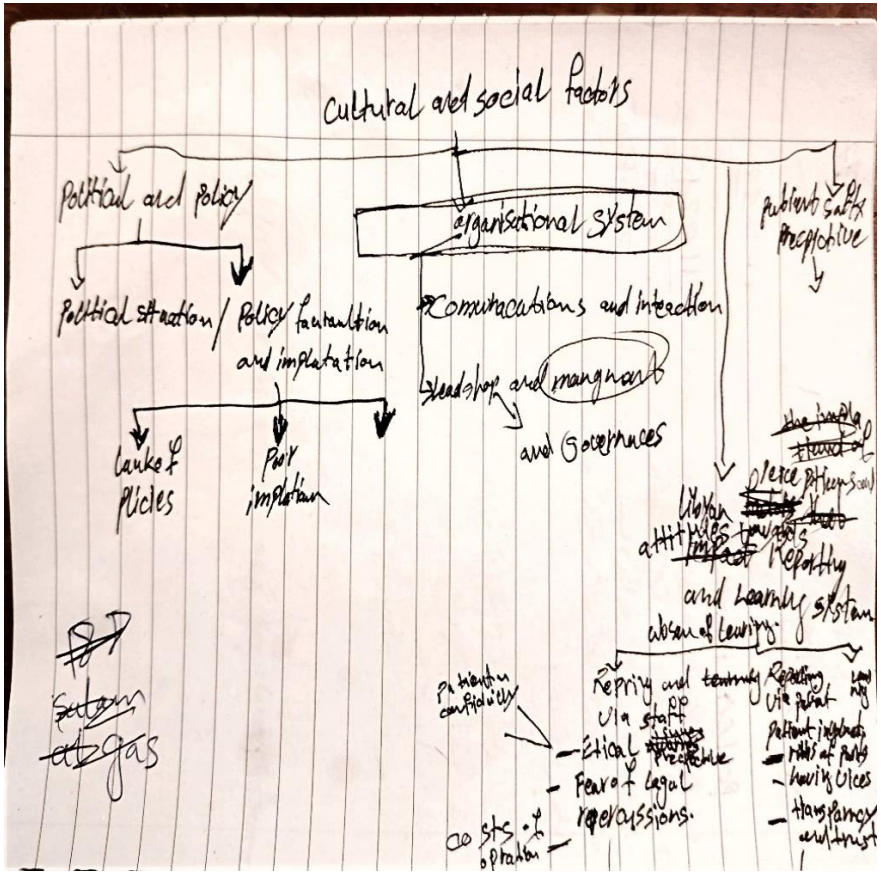
Abu al-Qasaim: You are welcome, any time.

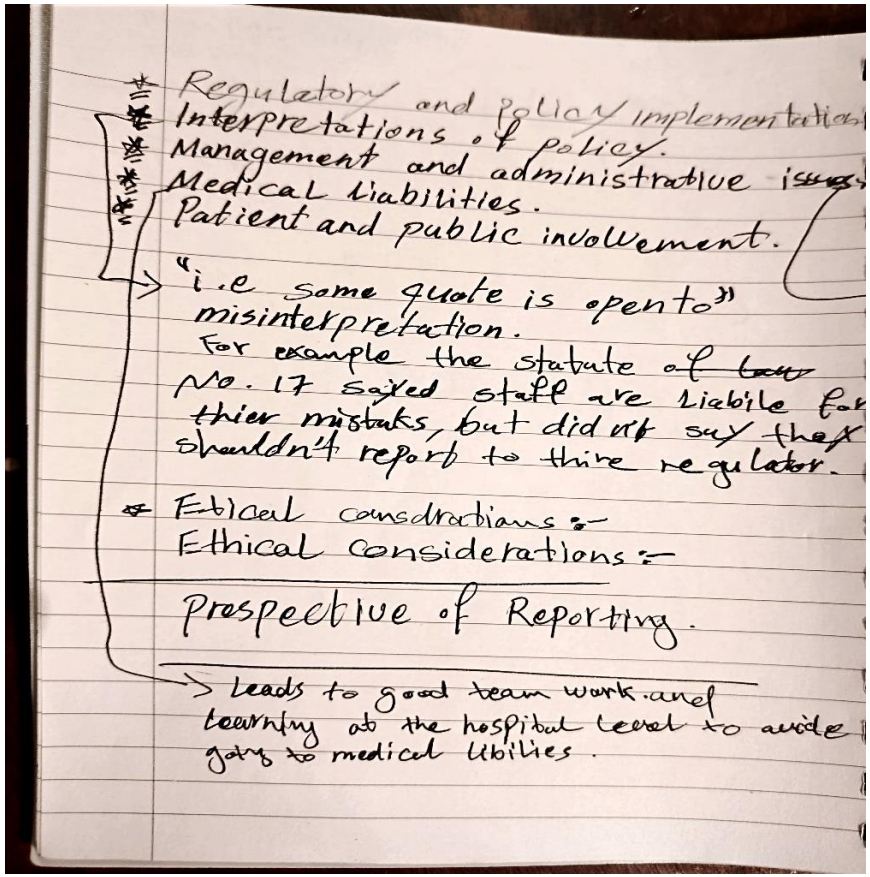
11.9 APPENDIX 9- Initial List of Categories

Initial List of Categories from Thematic Analysis

1. Understanding of reporting patient safety incidents
2. Policies/protocols in place for reporting incidents
3. Power dynamics in the Libyan Healthcare Sector
4. Policy creation feasibility / How a policy might work
5. Mode of reporting harm/ reporting and learning Interventions
6. Fare of medical Liabilities
7. Patient Safety and Justice
8. Poor attention to the ethical benefit of reporting
9. The issue of anonymity
10. Absent of learning
11. Involvement of patients and the public
12. The issue of mandatory or voluntary reporting
13. The issue of autonomy
14. Reporting experiences
15. Lack of awareness on reporting patient safety incidents
16. Barriers to reporting
17. Libyan social and cultural factors
18. Enablers of reporting
19. Systems for reporting medical harm
20. Poor implementation of policies
21. Issue of involving healthcare providers in reporting
22. Promoting reporting incidents by healthcare providers
23. Lack of recognition for near-miss in Libya
24. Efficacy of learning from patient safety incidents
25. Practice challenges in reporting incidents
26. Management and administration issues for reporting incidents
27. Inter-professional reporting experiences
28. Efficacy of reporting
29. The Libyan belief system in reporting harm by patients
30. Fear of punishment
31. Reporting errors not yielding results
32. Lack of leadership on implementing reporting system
33. Ethical belief among stakeholders
34. Workplace culture
35. The role of meso and micro-Levels
36. Reporting harm and psychological safety

11.10 APPENDIX 10- Excerpts of Data Analysis

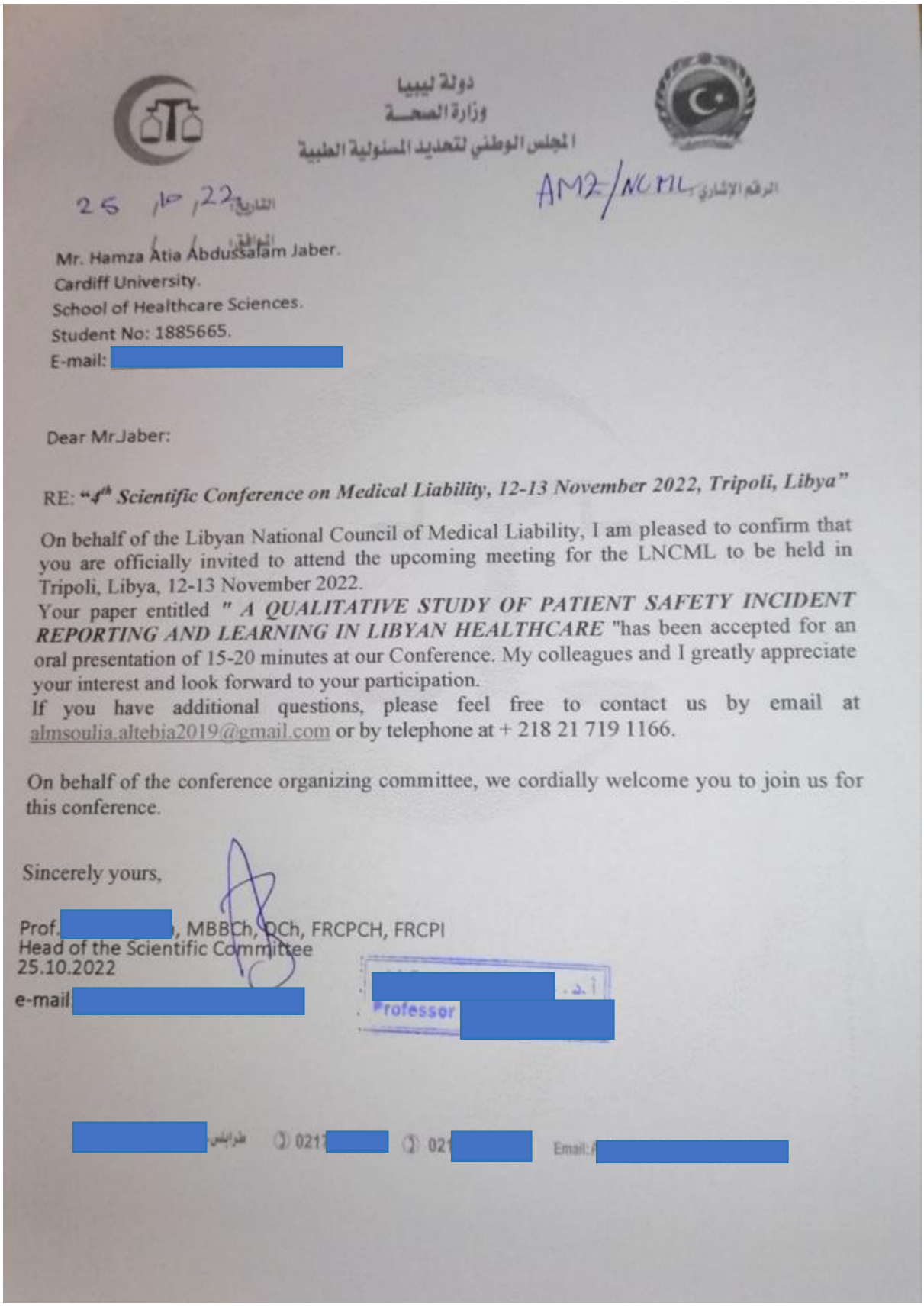




11.11 APPENDIX 11- List of Early Themes and Subthemes

THEMES	SUB-THEMES
Divergence in understanding of patient safety and the concept of PSI-RLS	▪ Laws and medical errors Patients first ▪ Shared responsibilities for patient safety Patients and families/ policymakers/ healthcare institutions ▪ Divergent practices in error reporting and the absence of learning systems to improve safety. No learning at the national level/ Learning at the meso and micro levels
The social-cultural belief and patient safety	▪ Patient Safety and Legal Perspective Reducing medical errors/ intervention of the legal system ▪ Patient safety and quality ▪ Power of law and ethics ▪ Absent of ethical considerations
Barriers and facilitators regarding the concept of PSI-RLS in the Libyan Context	▪ Cultural Factors Liabilities/ lack of learning/ reporting near-misses/blame culture ▪ Patient and Public Involvement Reporting Medical complications/ patient rights ▪ Compensation for Medical Harm Insurance and reassurance/Obligations of healthcare providers/ Protecting healthcare providers
The influence of patient reporting process and Libyan culture	▪ Reporting process by patients ▪ Reporting Medical Harm ▪ Departmental and Local Level Strategies Departmental Meetings: Regular meetings to discuss and address patient safety incidents. Reporting to the Meso Level: incidents can be reported to the intermediate level for appropriate reaction.
The issues of involving healthcare providers in the PSI-RLS	▪ Reporting by Staff Fear of punishments/reputation of healthcare providers /perceived risk of detriment following reporting incidents ▪ Individually-based approach to reporting incidents Lack of awareness/ staff safety/reactions of patients/ Impact of accountability on reporting patient safety incidents.
The structure of the healthcare sector and the implantation of PSI-RLS	▪ The organisation of the Libyan healthcare sector ▪ Communication issues/ leadership issues ▪ Regulatory policies ▪ Absent of policies
Policy planning regarding the concept of PSI-RLS	▪ Implementation of Policies National Intervention: Reporting Policy for Healthcare Providers Institutional Policies: Engaging staff in Reporting Incidents

11.12 APPENDIX 12-An Invitation for the 4th Scientific Conference on Medical Liability in Libya



دولة ليبيا
وزارة الصحة
المجلس الوطني لتحديد المسئولية الطبية

التاريخ: 25 / 10 / 22
الرقم الإشاري: AM2-/NCML

Mr. Hamza Atia Abdussalam Jaber.
Cardiff University.
School of Healthcare Sciences.
Student No: 1885665.
E-mail: [redacted]

Dear Mr.Jaber:

RE: *"4th Scientific Conference on Medical Liability, 12-13 November 2022, Tripoli, Libya"*

On behalf of the Libyan National Council of Medical Liability, I am pleased to confirm that you are officially invited to attend the upcoming meeting for the LNCML to be held in Tripoli, Libya, 12-13 November 2022.
Your paper entitled *" A QUALITATIVE STUDY OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING IN LIBYAN HEALTHCARE* "has been accepted for an oral presentation of 15-20 minutes at our Conference. My colleagues and I greatly appreciate your interest and look forward to your participation.
If you have additional questions, please feel free to contact us by email at almsoulia.altebia2019@gmail.com or by telephone at + 218 21 719 1166.

On behalf of the conference organizing committee, we cordially welcome you to join us for this conference.

Sincerely yours,

Prof. [redacted], MBBCh, QCh, FRCPCH, FRCPI
Head of the Scientific Committee
25.10.2022
e-mail: [redacted]

أ.د. [redacted]
Professor

[redacted] طرابلس ☎ 021[redacted] ☎ 021[redacted] Email: [redacted]

11.13 APPENDIX 13- Awarded Certificate for Participating in the 4th Scientific Conference on Medical Liability in Libya.

دولة ليبيا
وزارة الصحة
المجلس الوطني لتحديد المسؤولية الطبية

هيئة التأمين الطبي
الراعي الرسمي

شهادة شكر وتقدير

السيد المحترم / أ. حمزة عطية جابر

يسرنا وبكل مشاعر الود والتقدير أن نتقدم لكم بجزيل الشكر والإمتنان على
ما بذلتموه من جهد مخلص وبنّاء في إنجاح فعاليات المؤتمر العلمي الرابع
حول المسؤولية الطبية المنعقد خلال الفترة 12-2022/11/13

بارك الله في جهدكم وسدد للعلا خطاكم

أ.د الصديق أحمد الرتيمي
الرئيس الأدوري للمجلس
الوطني لتحديد المسؤولية الطبية

أ.د عبد الله محمد الرايض
رئيس اللجنة التحضيرية

أ.د إبراهيم أحمد المنتصر
رئيس المؤتمر

صدرت في طرابلس
بتاريخ 12/ 11/ 2022

11.14 APPENDIX 14- An Invitation for the 6th Scientific Conference on Medical Liability in Libya.

COUNCIL OF MINISTERS
MEDICAL INSURANCE AUTHORITY
PUBLIC ADMINISTRATION

مجلس الوزراء- هيئة التأمين الطبي
الإدارة العـــامـة

التاريخ: 2024/10/7
الرقم الإشاري 24-836-T-H

Mr Honourable. Hamza Attia Abdulsalam Jaber

Student at Cardif University

After Greetings,

We are honoured to invite you to attend and participate in the Sixth International Conference on Medical Responsibility, which will be held on **(4,3/11/2024)** at the Medical Colleges Complex at the Amphitheatre **(Sanaa Muhaidli) University of Benghazi.** This conference is an important platform for the exchange of knowledge and experience on the issues of medical responsibility and the challenges facing practitioners in this field.

We look forward to accepting the invitation and your valuable participation and enriching the discussions with your experiences

[redacted] **Thank you very much**

A/Counsellor

[redacted]

Honourable Mr./Chairman of the Scientific Committee of the Conference
Honourable Mr. Chairman of the Preparatory Committee for the Conference
Public issued
[redacted]

[redacted].ly/ هيئة التأمين الطبي الإدارة العامة هيئة التأمين الطبي الإدارة العامة-بنغازي [redacted]
092[redacted]

11.15 APPENDIX 15- Awarded Certificate for Participating in the 6th Scientific Conference on Medical Liability in Libya.