Patient Safety Culture

in Oncology Healthcare Settings

in Malta

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A dissertation submitted in partial fulfilment of the requirements for the Master of Science in Patient Safety and Clinical Risk Management (by Research)

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December 2023

Authenticity Form

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Abstract

Background: In recent decades, there has been a significant increase in patient safety, safety culture and incident reporting publications as well as commitments and efforts to reduce patient harm. A safety culture that can be measured, understood and improved is considered a pillar to the patient safety movement. This is especially emphasised in the realm of oncology healthcare, given its inherent complexity and toxicity of the treatment modalities involved.

Aim: This research study aimed to explore the perceptions of different healthcare professionals of patient safety culture in oncology healthcare settings in Malta. Moreover, this research study aimed to investigate the relationship between safety culture dimensions and safety-related behaviour, specifically reporting of patient safety events.

Design: A retrospective, descriptive and analytical cross-sectional research study was conducted. A mixed-method, concurrent triangulation strategy was employed, following pragmatism principles. Data was collected through a self-administered quantitative questionnaire and a semi-structured focus group interview.

Participants: A total population sampling strategy was employed to recruit participants in the questionnaire-part of the study. Specifically, all full-time and part-time healthcare professionals and management who had been working in Sir Anthony Mamo Oncology Centre for at least 6 months were asked to participate. Out of the 239 questionnaires distributed, 129 questionnaires were returned, achieving a total response rate of 53.97%. On the other hand, maximum variation sampling was employed to recruit participants in the focus group interview. Specifically, the focus group interview comprised of four nursing, two allied healthcare professionals and one health carer working in Sir Anthony Mamo Oncology Centre for at least six months.

Results: Findings from the present research study highlight a number of gaps in the perceptions of safety culture among healthcare professionals working in oncology healthcare settings in Malta, namely in the following components: hospital management support for patient safety (M=2.92, SD=0.784), response to error (M=2.81, SD=0.714), and staffing and work pace (M=2.72, SD=0.833). In addition, findings revealed statistically significant differences in responses across different healthcare professional groups, highlighting the need for adaptivity and individualised approach in prioritising and implementing strategies among diverse healthcare professional groups. Furthermore, higher levels of communication about error and

higher levels of response to error were identified as significant predictors of higher frequency of patient safety event reporting, explaining 38.4% of the total variation in the responses (r= 0.384). Overall, quantitative and qualitative findings aligned. However, qualitative findings indicated mixed findings with regards to communication about error and organisational learning as participants in the focus group interview expressed frustration regarding the effectiveness of incident reporting stating that they often felt that their concerns were met with inaction in terms of feedback and learning from errors. Furthermore, differences in perceptions across healthcare professional groups did not emerge in the qualitative insights gathered. Finally, in addition to the dimensions explored by the quantitative questionnaire, the qualitative insights obtained from the focus group interview revealed a noteworthy component of safety culture, that had not been encapsulated and explored by the questionnaire – that of training and continuous professional development. Participants emphasised its importance in oncology healthcare setting, shedding light on a previously overlooked dimension.

Conclusion: This research study gave an insight into healthcare professionals' perceptions of safety culture as well as the impact of safety culture on incident reporting in the local oncology healthcare settings. The study indicated various deficiencies inherent in the local safety culture. Furthermore, findings highlighted the significance of feedback systems as well as the significance of just culture in error management and their contribution to safety behaviour, specifically incident reporting.

Acknowledgements

I would like to convey my sincere appreciation to my academic supervisor, Dr Patricia Vella Bonanno, and co-supervisor Prof Sandra Buttigieg for their dedication and invaluable guidance all throughout the dissertation. I would also like to thank Prof Liberato Camilleri for his statistical guidance during the data analysis.

My heartfelt thanks go to my loving husband and family whose unwavering support and patience were indispensable throughout this journey.

Finally, my thanks extend to all participants who gave their time and took part in this research project.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CEBMA	Centre of Evidence-Based Management
CSNI	Committee on the Safety of Nuclear Installations
IAEA	International Atomic Energy Agency
INSAG	International Safety Advisory Group
IOM	Institute of Medicine
JBI	Joanna Brigg's Institute
M	Mean
MDH	Mater Dei Hospital
N	Number
OECD	Organisation for Economic Co-operation Development
p	P-value
PASQIT	Patient Safety and Quality Improvement Team
PICOC	Population, Intervention, Comparision, Outcome, Context
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SAMOC	Sir Anthony Mamo Oncology Centre
SD	Standard Deviation
SOPS	Hospital Survey on Patient Safety Culture
SAQ	Safety Attitudes Questionnaire
UM	University of Malta
WHO	World Health Organisation

Chapter 1: Introduction

1.1 Introduction

This introductory chapter presents a historical perspective on patient safety and safety culture. The differences between safety culture and safety climate as well as the importance of incident reporting systems are highlighted. This is followed by information on the local context and patient safety in relation to oncology care. Moreover, the rationale and purpose of the study is also presented followed by the research questions.

1.2 Background to Patient Safety

The World Health Organisation (WHO, 2021) defines patient safety as a healthcare discipline that aims to prevent and reduce risks, medical errors and harm during the provision of healthcare. A central component of the discipline is the continuous improvement based on learning from the occurrences of near-misses, errors and adverse events. Concerns over patient safety within the western healthcare system were raised following a series of research studies (e.g., Brennan et al., 1991; Leape et al., 1991; Leape et al., 1994; Sinclair, 1999; Kennedy, 2001). These reports were usually retrospective case reviews and focused either on single cases (e.g., wrong site surgery) or cases in which a number of patients had been harmed or killed by the same error (e.g., vincristine fatalities) or by the same professional making repeated errors (e.g., the Manitoba and Bristol paediatric cardiac surgery fatalities). For instance, in 1994, Lucian Leape, a Harvard-based surgeon published ‘‘Error in Medicine’’, a seminal paper which summarised evidence showing that error rates in healthcare were very high (Leape, 1994). The influential reports ‘‘To Err is Human: Building a Safer Health System’’, published in 1999 by the Institute of Medicine (IOM; Kohn et al., 1999) as well as ‘‘An Organisation with a Memory’’, published in 2000 by the United Kingdom Department of Health provided further backing to Leape’s (1994) arguments and immediately attracted great attention from the general public as well as politicians (Waterson, 2014). These reports attracted great public attention as they scoped the subject of healthcare safety and patient harm, highlighting how error was routine during the provision of care and was often the cause of unnecessary deaths. In particular, the IOM report published striking statistics stating that between 44,000 and 98,000 people die in the United States yearly, as a result of medical errors (Kohn et al., 1999). Moreover, the IOM report stated that ‘‘the experiences of other industries provide valuable insight about how to begin the process of improving the safety of health care by learning how to prevent, detect, recover and learn from accidents’’ (Kohn et al., 1999). These ‘‘other

industries'', specifically industries operating in high-risk, hazardous environments, adopted a very systematic approach to managing safety (Waterson, 2014).

In recent decades, there has been a significant increase in patient safety publications, research as well as commitments and efforts to reduce patient harm (e.g., IOM, 2007; Francis, 2013; WHO, 2021). Figure 1 summarises some of the most influential reports and events related to patient safety throughout the years. However, despite the progress and increased awareness, levels of unintended patient harm around the world remain unacceptably high. The occurrence of an adverse event due to unsafe medical care is likely one of the ten leading causes of death and disability across the world (Donaldson et al., 2021). In fact, statistics show that approximately one in ten patients are harmed from safety lapses in high-income countries (WHO, 2021). In low- and middle-income countries, estimates suggest that one in four patients is subject to an adverse event while receiving hospital care (WHO, 2021). According to the Organisation for Economic Co-operation and Development (OECD, 2020), globally, unsafe care results in over three million deaths each year. Medication errors, such as incorrect dosages or incorrect infusions and unsafe medication practices such as illegible handwriting, unclear instructions or use of abbreviations are identified as a leading cause of avoidable patient harm (WHO, 2021).

Aside from these alarming statistics, unsafe care and medical errors carry other economic, reputational and litigation consequences. For instance, according to the OECD (2020), in developed countries, the direct cost of treating patients who have been harmed during the provision of medical care is approximately 13% of health expenditure. According to Aitken and Gorokhovich (2012), the cost associated with medication errors alone represent 0.7% of global health expenditure. In addition, reports of avoidable deaths and patient harm frequently feature in media reports, undermining public confidence in the health system (Donaldson et al., 2021).

A safety culture that can be measured, understood and improved is considered a pillar to the patient safety movement (Churruca et al., 2021). In their ''Global Patient Safety Action Plan 2021 – 2030'', the WHO (2021) also highlight the importance of instilling a culture of safety

in the design and delivery of healthcare. The WHO emphasise that a strong safety culture is not only fundamental to reducing medical errors and patients harm, it is also important for providing a safe working environment for healthcare professionals.

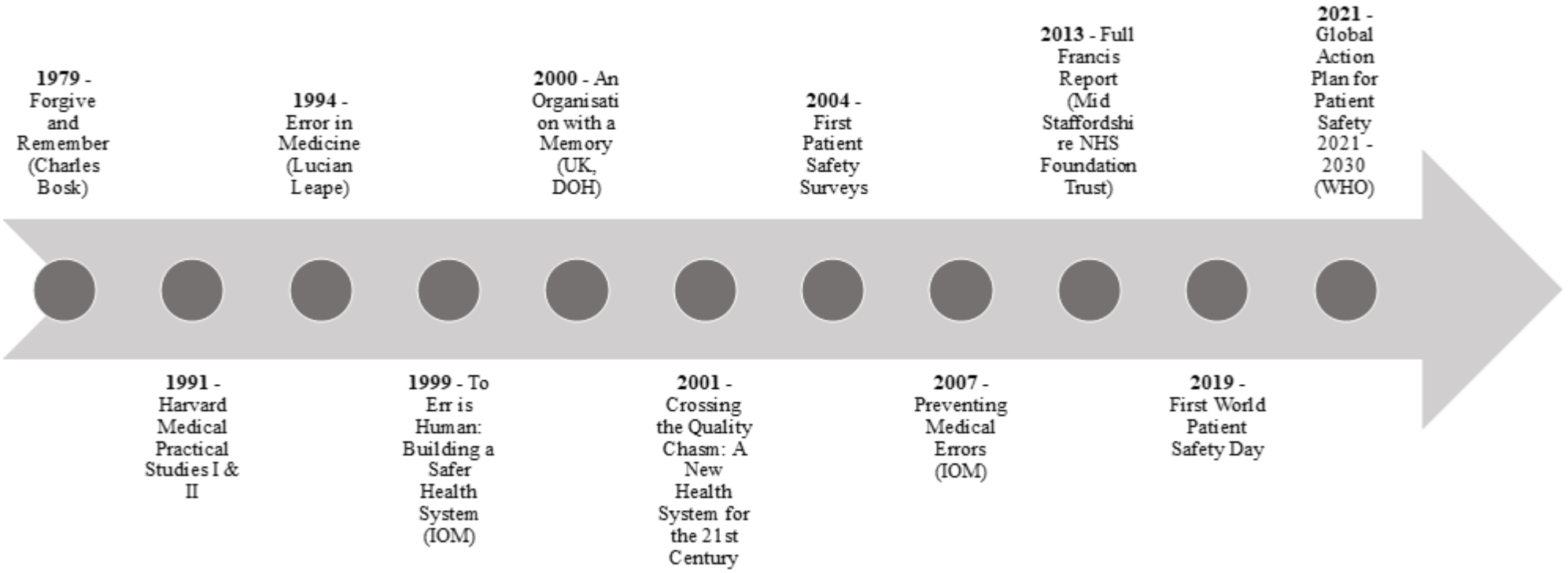

Figure 1: Patient Safety Movement Timeline

1.3 Safety Culture and Safety Climate

Between the period of 1970 and 1990, a series of catastrophic, high-profile accidents occurred. These included the Tenerife Airport disaster (1977), the Three Mile Island nuclear accident (1979), the Space Shuttle Challenger explosion (1986), the Chernobyl nuclear accident (1986), the King's Cross underground station fire (1987), the Herald of Free Enterprise disaster (1987), the Piper Alpha disaster (1988) and the Ladbroke Grove rail crash (1999). These accidents prompted a widespread public debate on appropriate safety management and the role of external bodies within safety critical industries. These accidents also sparked significant interest among the scientific research community to investigate and understand accident causation, especially through the application of the systems approach. A central idea of the systems approach is that complex systems are composed of interrelated components. Therefore, a change in one part or property of the system leads to changes or movements in other parts (Waterson, 2014).

A crucial element which draws on the systems approach is the concept of safety culture. The term ''safety culture'' was first applied following the Chernobyl nuclear disaster in 1986 (Waterson, 2014). The International Safety Advisory Group (INSAG), an advisory group to the International Atomic Energy Agency (IAEA) were tasked with investigating the Chernobyl accident. In their investigation report, the advisory group described the accident as partly arising from a ''poor safety culture''. Since then, extensive amount of research on the topic has been conducted across a range of domains (e.g., rail, aviation, the nuclear industry, construction and healthcare) (Waterson, 2014).

The most widely accepted definition of safety culture is the one proposed by the Advisory Committee on the Safety of Nuclear Installations (CSNI, 1993); ''The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.''

Throughout the years, researchers have continued to develop definitions of safety culture. Table 1.1 summarises some of the safety culture definitions found in the literature. Moreover, despite distinct etymologies, the terms ‘‘safety culture’’ and ‘‘safety climate’’ are often used interchangeably (Flin, 2007; Waterson, 2014). According to Cheyne et al. (1998), safety climate is ‘‘… a temporal state measure of culture, which is reflected in the shared perceptions of the organisation at a discrete point in time’’. Other definitions of ‘‘safety climate’’ found in the literature are summarised and presented in Table 1.2.

From these definitions, as well as many others (see Table 1.1 and Table 1.2), it can be seen that safety culture represents long-term attitudes, values, beliefs and the stable ways in which employees behave. On the other hand, safety climate represents the surface-level manifestation and aspects of the underlying culture during a particular point in time. In other words, safety climate is a temporal phenomenon and represents a ‘‘snapshot’’ of the underlying culture at any one time (Cole et al., 2013). According to Weaver et al. (2013), the difference between safety culture and safety climate is often reduced to a difference in methodology. Denison (1996) argued that quantitative methods can be used to measure safety climate however, safety culture should be measured by qualitative methods because surveys or questionnaires alone cannot fully represent the underlying culture. However, the field of safety culture research is largely dominated by survey studies. According to Waterson (2014), the exploration of safety culture through the sole use of surveys is contrary to the concept of safety culture.

Table 1.1: Definitions of Safety Culture from the Literature (Author's Compilation)		
Author/s	**Domain**	**Definition**
International Safety Advisory Group, 1991	Nuclear	''Safety culture is that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance.''
Cox and Cox, 1991	Industrial gases	''Safety cultures reflect the attitudes, beliefs, perceptions, and values that employees share in relation to safety.''
Ciavarelli and Figlock, 1997	Naval aviation	''Safety culture is defined as the shared values, beliefs, assumptions, and norms which may govern organisational decision making, as well as individual and group attitudes about safety.''
Flin et al., 1998	Offshore oil and gas	''Safety Culture refers to entrenched attitudes and opinions which a group of people share with respect to safety. It is more stable [than safety climate] and resistant to change.''
Cooper, 2000	Theoretical	''Safety culture is a sub-facet of organisational culture, which is thought to affect member's attitudes and behaviour in relation to an organisation's ongoing health and safety performance.''
Wiegmann et al., 2002	General	''Safety culture is the enduring value and priority placed on worker and public safety by everyone in every group at every level of an organisation. It refers to the extent to which individuals and groups will commit to personal responsibility for safety, act to preserve, enhance and communicate safety concerns, strive to actively learn, adapt and modify (both individual and organisational) behaviour based on lessons learned from mistakes, and be rewarded in a manner consistent with these values.''
Goodman, 2003	Healthcare	'''Culture' is a more complex and enduring trait reflecting fundamental norms, values, and assumptions that to some extent reside in societal culture.''
Edwards et al., 2013	General	''Safety culture can be viewed as the assembly of underlying assumptions, beliefs, values and attitudes shared by members of an organisation, which interact with an organisation's structures and systems and the broader contextual setting to result in those external, readily-visible, practices that influence safety.''

Table 1.2: Definitions of Safety Climate from the Literature (Author's Compilation)		
Author/s	**Domain**	**Definition**
Zohar, 1980	Manufacturing	''A summary of molar perceptions that employees share about their work environment.''
Dedobbeleer and Beland, 1991	Construction	''Molar perceptions people have of their work setting.''
Cabrera et al., 1997	Aviation	''The shared perceptions of organisational members about their work environment and, more precisely, about their organisational safety policies.''
Williamson et al., 1997	Manufacturing	''A summary concept describing the safety ethic in an organisation or workplace which is reflected in employees' beliefs about safety and is thought to predict the way employees behave with respect to safety in that workplace.''
Flin et al., 1998	Offshore oil and gas	''Safety climate refers to the perceived state of safety of a particular place at a particular time. It is therefore relatively unstable and subject to change depending on features of the operating environment.''
Cheyne et al., 1998	Manufacturing	''Safety climate can be viewed as a temporal state measure of culture, which is reflected in the shared perceptions of the organisation at a discrete point in time.''
Mearns et al., 2003	Offshore oil	''Safety climate is defined as a 'snapshot' of employees' perceptions of the current environment or prevailing conditions, which impact upon safety.''
Goodman, 2003	Healthcare	''The term 'climate' best describes employee perceptions, beliefs, and attitudes.''
Griffin and Curcuruto, 2016	General	''Safety climate is a collective construct derived from individuals' shared perceptions of the various ways that safety is valued in the workplace ... Safety climate is a multidimensional and multilevel construct: Perceptions about many aspects of the work environment can be shared across teams, organisations, and other collectives.''

Cooper (2000) used the Reciprocal Determinism Model by Bandura (1977) as a framework to explain safety culture. Bandura's (1977) model, which is illustrated in Figure 2 below, consists of three components: person (internal psychological factors), behaviour and situation (external observable factors). Bandura (1977) explains psychosocial functioning through a triadic reciprocal causation, suggesting that an individual's internal psychological factors, their environment as well as the behaviour that they engage in, all interact with each other in a bidirectional manner, as shown in Figure 2. In other words, these factors all operate as interacting determinants that influence each other bi-directionally, in a complex interplay.

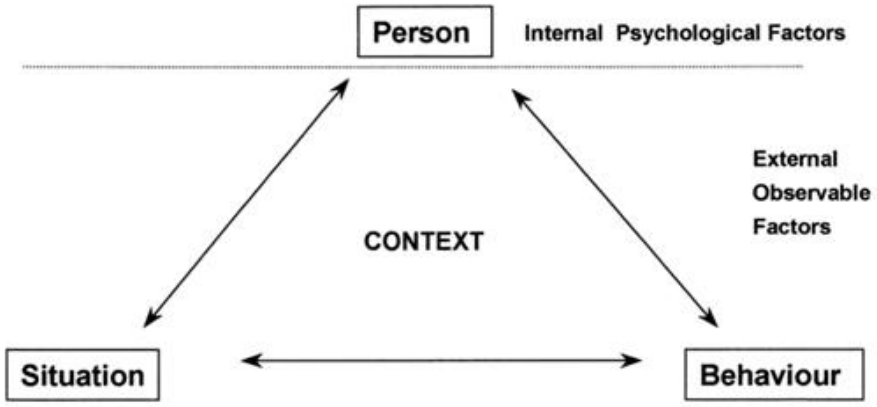

Figure 2: Reciprocal Determinism Model by Bandura (1977)

Cooper (2000) outlines major similarities between Bandura's Reciprocal Determinism Model (1977) and safety culture. First, the elements of the model accurately reflect accident causation relationships identified by a number of researchers (e.g., Heinrich et al., 1980; Reason, 1990). To greater or lesser degrees, accident causation models acknowledge the existence of an interactive or reciprocal relationship between psychological, situational and behavioural factors (e.g., Reason, 1990; 2000). Second, the dynamic nature of the model suits the measurement of human and organisational systems that operate in dynamic environments. This is particularly due to the reciprocal influence of each element on the other two elements, which may not occur simultaneously. Therefore, the model allows for a more nuanced understanding of how different elements interact and influence each other over time. Third, the model also offers a triangulation methodology, encouraging multi-level analyses (Cooper, 2000).

Triangulation refers to the use of multiple methods to investigate a phenomenon (Bowling, 2014). Triangulation allows researchers to take a holistic, multi-faceted view of safety culture, enabling them to investigate the interdependent relationships between psychological, behavioural, and situational factors. In addition, triangulation can be used to test the external validity of the safety culture construct (between-method validation), as well as to crosscheck the reliability or internal consistency of each method involved in the triangulation process (within-method triangulation approach) (Cooper, 2000).

1.3.1 Patient Safety and Patient Safety Culture

The patient safety movement has galvanised significant interest and generated great momentum in healthcare systems which were traditionally accustomed to focus on clinical effectiveness alone. As mentioned, the concept of safety culture originated outside of healthcare. However, a large growing body of evidence highlights the importance of adopting safety culture in healthcare.

Leape and colleagues (1998) argued that many healthcare systems are designed to rely on the error-free performance of healthcare professionals, and enforced by punishment. On the other hand, in industries, in particular in high-reliability organisations, it is appreciated that human error is inevitable. Nearly all adverse events involve a combination of active failures and latent conditions, as illustrated by the Swiss Cheese Model of Accident Causation by Reason (2000) (Figure 3). Active failures are defined as the unsafe acts committed by individual at the sharp end whose actions have immediate adverse consequences. On the other hand, latent conditions refer to less apparent failures that arise from decisions by top-level or senior management of the organisation (e.g., understaffing, heavy workloads, time pressures, equipment procured, design deficiencies, inadequate systems of communications). As the term suggests, latent conditions may lie dormant for years before they combine with an active failure and lead to an accident (Reason, 2000; Flin, 2007; Hoffmann & Rohe, 2010). Furthermore, Reason (2000) uses the analogy of multiple layers of Swiss cheese, where each layer of cheese represents a system or component that can prevent or mitigate the occurrence of an accident whereas the holes in the cheese represent a potential weakness or failure. According to Reason's Swiss Cheese Model, accidents occur when several layers of defences fail simultaneously and allow a hazard to penetrate through and cause an incident. Reason argued that in complex systems,

such as healthcare, failures are often the result of a combination of active errors as well as latent conditions (Reason, 2000). Furthermore, both active failures as well as latent conditions are influenced by the underlying safety culture of an organisation (Flin, 2007).

Around the early 2000s, the first instruments to measure safety culture in healthcare settings were developed, which were mainly adapted those used in other industries (Waterson, 2014). Data from safety culture assessment offers organisations an additional perspective on their safety management systems. It allows the identification of strengths as well as areas for improvements. Safety culture assessments are also carried out to monitor the effectiveness of new initiatives.

Moreover, it can also be used for benchmarking and trends analysis (Flin et al., 2006). Halligan and Zecevic (2011) recommend a continuous process of safety culture assessment, strength and weaknesses identification, improvement interventions or initiatives implementation and revaluation.

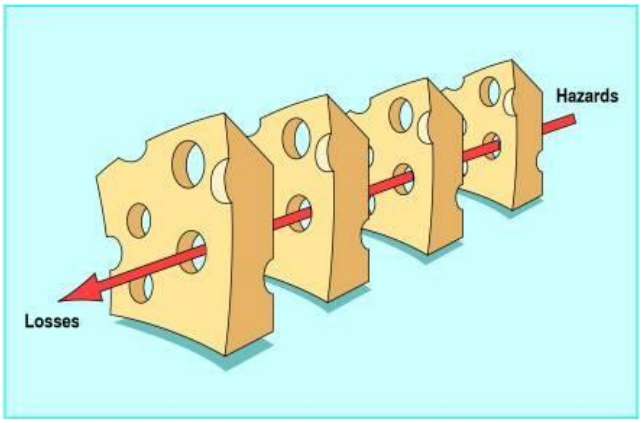

Figure 3: Swiss Cheese Model of Accident Causation (Reason, 2000)

1.3.2 Incident Reporting

Incident reporting is advocated as a crucial measure to improve patient safety in healthcare. Incident reporting refers to the documentation of any adverse events, errors as well as near

misses (Carlfjord et al., 2018). Drawing from the aviation industry as well as other high-risk organisations, the influential report ‘‘To Err is Human: Building a Safer Health System’’ specifically recommended that healthcare organisation institute incident reporting (Kohn et al., 1999). The importance of incident reporting lies in its ability to identify safety hazards or unsafe conditions and consequently, develop preventive measures and interventions to mitigate these hazards in order to minimise the occurrence of future incidents and reduce harm in healthcare (Mitchell et al., 2015).

However, a number limitations and barriers are associated with incident reporting systems, including cultural factors. The fundamental principal behind incident reporting systems is that for organisations to improve their safety performance, managers must be aware of events in their organisation. Therefore, employees must feel comfortable about reporting incidents and near misses without fear of blame and retribution. However, research suggest that there is a prevailing blame culture in healthcare in which frontline healthcare professionals are often blamed for errors. Consequently, this negatively affects healthcare professionals' willingness to report errors (Okpala, 2020). Conversely, a just culture would consider “wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution” (Williams, 2018).

Moreover, Firth-Cozens et al. (2004) found that the perceptions that management does not take action following submitted incident reports as well as a lack of resulting changes, leads to apathy among healthcare professions and reluctance to report incidents. Literature also suggests that the quality of feedback given to employees is critical (Waterson, 2014). This feedback should enable learning, encourage incident and near miss reporting as well as reassures healthcare professionals that the information they provide is being used appropriately (Stavropoulou et al., 2015). Organisations may use multiple means of feedback actions and safety information mechanisms including staff or departmental meetings, training sessions, conferences, updated policies and electronic dissemination (Benn et al., 2009).

1.4 An Overview of Patient Safety in Malta

1.4.1 Patient Safety and Quality Improvement Team

In 2009, the local hospital incident report form was introduced to report near-misses, errors as well as equipment-related incidents. Events had to be reported within 24 hours. Nonetheless, the form was not anonymous (Mangion, 2019). In 2013, the Patient Safety and Quality Improvement Team (PASQIT) was established in Mater Dei Hospital (MDH) to investigate incidents and promote patient safety. This included Sir Anthony Mamo Oncology Centre (SAMOC), which is managed by MDH management set up. The team is made up of healthcare professionals from different professional groups and specialities (Azzopardi Muscat, 2017). In 2015, PASQIT launched the Safety Alert System for Learning. In order to encourage incident and near miss reporting, PASQIT made the Safety Alert form anonymous, voluntary and online (Mangion, 2019). Table 1.3 summarises the reports received by PASQIT over the past five years. In 2018, only 108 reports were received by PASQIT, followed by 71 reports in 2019, 59 reports in 2020 and 144 reports in 2021 (M. Spiteri, personal communication, August 4 2022).

Table 1.3: Incident Reports/Safety Alerts in MDH/SAMOC

Year	Number of Incident Reports/Safety Alerts
2017	149
2018	108
2019	71
2020	59*
2021	144
January – July 2022	99

**Missing data*

(M. Spiteri, personal communication, August 4 2022)

1.4.2 Overview of Local Studies and Data on Patient Safety and Safety Culture

Research on patient safety within the local context is relatively limited. However, a number of research studies, mainly postgraduate dissertations were identified which made a number of important contributions to local healthcare research. In their study Petrova et al. (2010), shed light on nurses' perceptions of medication errors as well as identified factors that may

contribute to these errors in medical wards in Malta. The study found that fear of blame was perceived as a strong barrier to reporting medication errors. Consistent with this finding, a postgraduate study conducted by Baldacchino (2009) explored the patient safety culture in High Dependency Units in MDH and revealed important areas with potential for improvement.

In fact, overall, the study identified 7 weak patient safety dimensions (average percent positive response less than 50%), including ‘‘non-punitive response to error’’ and ‘‘frequency of event reporting’’. Another recent postgraduate study also carried out in MDH identified a number of perceived barriers to incident reporting, including lack of feedback, near misses being viewed as pointless to report, belief that reporting would not lead to system changes (Mangion, 2021). Moreover, the study found that while most nurses were aware of the existing incident reporting system, 28.1% did not know or were not sure how to access the incident reporting form and 29.4% did not know what to do with it once this was completed (Mangion, 2021). Other postgraduate studies also explored the patient safety climate in Intensive Care Units (Teuma Custo, 2016) and in the Obstetrics Departments in MDH (Azzopardi, 2018).

1.4.3 Overview of Media and Union Reports

Moreover, over the years, local media has reported single cases of patient harm as well as healthcare systems issues and concerns. These include the choking incidence in Karen Grech Rehabilitation Centre (Times of Malta, 2013a; Times of Malta, 2019) and more recently the self-harm incident in Mount Carmel Hospital (Times of Malta, 2022a). Moreover, throughout the years, the Malta Union of Midwives and Nurses have also repeatedly reported staff shortages across the Maltese healthcare system and issued multiple directives (e.g., Times of Malta 2013b; 2014; 2015; 2016; 2020; 2022b).

1.5 Patient Safety and Risks in Oncology Care

The lifetime risk of developing cancer is continuously expanding. According to the Ministry for Health (2017), every year, 1800 individuals are diagnosed with cancer in Malta. Moreover, cancer incidence is expected to approach 2500 new diagnoses annually by the year 2030. On the other hand, data shows that cancer survival rates are continuously improving (Ministry for Health, 2017). Oncology care is recognized as highly complex due to diagnostic challenges,

multimodal and multi-speciality treatment strategies (e.g., chemotherapy, radiotherapy, surgery), the nature of the illness and diverse needs of different patients as well as the long-term and late-effects which contribute to morbidity and mortality (Levit et al., 2013). Each treatment strategy carries risks and adverse effects (Donaldson et al., 2021). Moreover, oncology practice is interprofessional and interdisciplinary (Chera et al., 2015) and therefore, it particularly relies on effective communication and care coordination as well as cohesive teamwork (Wynn et al., 2018; Alharbi et al., 2018; Donaldson et al., 2021). In recent years, healthcare systems have seen significant improvements in oncology care stemming from progress in risk assessment, prevention and early detection as well as advances in pharmacotherapies and other treatment modalities (Wynn et al., 2018).

However, high-quality care remains a challenge (Wynn et al., 2018). For instance, medication errors with chemotherapy, a critical component in oncology care, are still common. A literature review found that medication errors involving chemotherapy occur at a frequency ranging from one to four cases per 1000 prescriptions, concerning at least 1 – 3% of adult and paediatric oncology patients (Weingart et al., 2018). Any error or adverse drug reaction involving chemotherapeutic drugs may result in catastrophic consequences in view of the drugs' high toxicity, low therapeutic index as well as the compromised health status of oncology patients (Ranchon et al., 2011). A notable example of this are the multiple case studies involving the accidental intrathecal administration of Vincristine Sulphate (e.g., Dettmeyer et al., 2001; Alcaraz et al., 2002; Qweider et al., 2007; Chotsampancharoen et al., 2016; see Appendix A), among others.

1.5.1 Oncology Healthcare Setting and Services in Malta

- **Sir Anthony Mamo Oncology Centre**

SAMOC is a modern teaching hospital specialised in oncology and haemato-oncology services in Malta. The hospital was officially inaugurated in 2015, following a total investment of nearly 50 million EUR, part-financed by the European Union through the European Regional Development Fund (ERDF 2007 – 2013). This project led to the migration of oncology, haematology and palliative care services. Prior to this investment, these services were mainly provided in Sir Paul Boffa Hospital, separate from Malta's main acute tertiary hospital, MDH.

SAMOC, located adjacent to MDH, accommodates a total of 113 beds and offers both inpatient and outpatient services. It is physically and organisationally connected to MDH. This centre includes six clinical areas for inpatients, including Oncology Adult Ward 1, Oncology Adult Ward 2, Radioisotope Unit, Palliative Care Ward, Haematology Ward and Paediatric/Adolescent Ward as well as an Outpatients Unit, with 12 clinical rooms, a Day-Care Unit, equipped with 24 beds for day-case treatments, a Radiotherapy Department and a Clinical Support Services Unit comprising of occupational therapy, physiotherapy, psychological services, social work services. Other clinical services offered in SAMOC also include a pharmacy with a chemotherapy reconstitution area, a phlebotomy clinic as well as spiritual services (Government of Malta, 2021a).

- **Cancer Care Pathways Directorate**

The Cancer Care Pathways Directorate was established in Malta in 2014. Its purpose is to promote advancement in quality cancer care as well as offer timely access, advice, support, coordination and continuity of care for patients with cancer and their families. At present, the Cancer Care Pathways Directorate offers a number of services including a Fast Track Service, Navigation Service and Survivorship Service (Government of Malta, 2021b). Every year, general practitioners encounter several patients presenting with signs and symptoms suggestive of cancer/malignancy. The establishment of the Fast Track Service allows general practitioners and professionals to refer patients using specific tumour group (e.g., breast cancer, colon cancer, haematology cancer) electronic forms, enhancing a timely review with the aim of providing safer and better access to early treatment. Early detection and diagnosis of cancer is recognized as a key factor to improve patient outcomes and is considered a priority for healthcare systems around the world (Ministry for Health, 2017). In addition to this, the establishment of Navigation Services ensures that newly diagnosed oncology patients are navigated through the complex pathway trajectory of oncology care (Government of Malta, 2021b). A Survivorship Coordinators Team was also established to provide care following completion of treatment. All major treatment modalities can have long-lasting effects which may become apparent shortly after completion of treatment or arise years later. Moreover, it is recognised that the transition from active treatment to the watchful observation phase is particularly stressful for patients in view of the fear of recurrence and changes in roles and relationships.

1.6 Rationale of the Study

I have been working as a nurse for the past five years, including three years in SAMOC in Malta. During the relatively short time that I have spent working in an oncology setting, it became evident to me how particularly vulnerable oncology patients are. Chemotherapy and radiotherapy, among the many treatment modalities, expose the patients to many risks and adverse effects during as well as after treatment. Moreover, the complexities of the disease and treatment regimens require effective communication, care coordination and teamwork to ensure patient safety. In 2020, I enrolled for the Postgraduate Certificate in Patient Safety and Clinical Risk Management course offered by the University of Malta (UM) and subsequently continued my studies by reading for the present course, the Master of Science in Patient Safety and Clinical Risk Management (by research). The course expanded my knowledge on patient safety, systems analysis, risk management and quality improvement scientific techniques in healthcare, and highlighted the importance of establishing a positive patient safety culture. As discussed, investigations into a number of failures and adverse events in healthcare organisations have repeatedly identified a weak safety culture as a contributing factor (e.g., Francis, 2013), revealing the need for and importance of measuring this aspect of organisational culture. In addition to this, a growing body of studies demonstrate the importance of safety culture in healthcare (e.g., Alanazi et al., 2021; Odell et al., 2019; The Health Foundation, 2011). This dissertation has therefore presented me with an opportunity to explore patient safety culture in oncology healthcare settings.

1.7 Purpose of the Study

The aim of this research study was twofold: This research study aimed to explore the perceptions of different healthcare professionals of patient safety culture in oncology healthcare settings in Malta. Moreover, this research study aimed to investigate the relationship between safety culture dimensions and safety-related behaviour, specifically patient safety event reporting. In the absence of any studies exploring the patient safety culture or climate in oncology healthcare settings in Malta, it is anticipated that this research study will provide significant contributions to local healthcare knowledge that could guide patient safety improvement interventions. Rather than considering the findings of safety culture research as an end point, the results should be viewed as a starting point from which action and patient safety changes emerge (Nieva & Sorra, 2003).

The research questions for this present study are as follows:

- How do healthcare professionals working in oncology healthcare settings in Malta perceive patient safety culture?
- Are different healthcare professional groups working in oncology healthcare settings in Malta aligned on their perceptions of patient safety culture?
- What is the relationship between safety culture dimensions and reporting of patient safety events?

1.8 Conclusion

This dissertation is divided in six chapters. This introductory chapter set the scene as it provided a historical perspective on patient safety and safety culture as well as highlighted the difference between safety culture and safety climate. Furthermore, this chapter also emphasised the importance of incident reporting and provided background information on the local context as well as the rationale and purpose of the study. The second chapter presents an overview on safety culture and climate theoretical frameworks. This is followed by a critically-appraised topic (CAT). The main research question presented was as follows; ‘‘What is known in scientific literature about the impact of patient safety culture on incident reporting in hospital settings?’’. The third chapter gives a detailed account of the methodology used for this present study, alongside related ethical considerations. The fourth chapter presents the results achieved whereas the fifth chapter discusses the results with previously published literature. The sixth and final chapter presents a synopsis of the present research study and highlights the key recommendations for health systems management and research extracted from the findings and in line with previously published literature.

Chapter 2: Literature Review

2.1 Introduction

In recent years, there has been an increased focus on measuring and improving safety culture in healthcare (Farokhzadian et al., 2018). First, this chapter commences by outlining theoretical frameworks addressing safety climate and safety culture. Second, this chapter aimed to identify, critically appraise and discuss the findings of the available research studies exploring the relationship between patient safety culture and incident reporting in hospital settings. The main research question presented was as follows; ‘‘What is known in scientific literature about the impact of patient safety culture on incident reporting in hospital settings?’’. A CAT was conducted following the guidelines published by the Centre of Evidence-Based Management (CEBMA) Version 2.0 (2017).

A CAT is a systematic summary of high-quality, most up-to-date available evidence organised around focused research questions and identified through structured methods, with a transparent and reproducible process (Callander et al., 2017). Rapid reviews, such as CATs, are considered as an attractive alternative to traditional systematic reviews (White et al., 2017). Well-conducted meta-analyses and systematic reviews are generally considered as the gold standard in evidence synthesis to inform practice and policy. However, conducting meta-analyses and systematic reviews typically necessitates the involvement of at least two independent researchers and extensive searches across numerous databases as well as grey literature sources. This approach helps ensure the reliability and comprehensiveness of the review process by reducing bias and increasing the likelihood of capturing all relevant studies and evidence. Therefore, due to their rigorous methods, meta-analyses and systematic reviews are considered costly, time-consuming and require a certain level of expertise to conduct (White et al., 2017), making them unfeasible for this study.

In contrast, CATs are considered as a less resource consuming method to address research questions and require only one researcher as opposed to systematic reviews (Callander et al., 2017). CATs impose restrictions or concessions, such as narrowing the timeframe, restricting the number of databases searched or limiting the search to a certain study design, expediting the process so that evidence can be sourced and synthesized in a timelier manner/shorter timeframe. These limits are specified by the authors and should be made explicit and

transparent (White et al., 2017). Therefore, the researcher concluded that conducting a CAT was the most appropriate and suitable method to achieve the aim of this chapter.

2.2 Theoretical Frameworks of Safety Climate and Safety Culture

Throughout the years, a plethora of researchers have addressed safety climate and safety culture in a wide range of industries. A key assumption in literature is that safety culture can affect the overall safety performance (Kalteh, 2019; Morrow et al., 2014). Moreover, numerous research studies suggest that there is a complex, non-linear relationship between safety culture and patient outcomes and that a positive safety culture may, directly or indirectly, result in improved safety outcomes (Alanazi et al., 2021; The Health Foundation, 2011). Griffin and Neal (2000) combined theories of organizational climate with theories of individual performance and proposed one of the first theoretical frameworks illustrating how safety climate relates to safety performance (Figure 4). The model illustrates a link between perceptions of the work environment and individual behaviour. The model shows that safety climate is a higher order factor comprised of more specific first-order factors and illustrates how the influence of safety climate on safety performance is mediated by knowledge, skill and motivation. Furthermore, Griffin and Neal (2000) use the terms ‘‘safety compliance’’ and ‘‘safety participation’’ to clarify the concept of safety performance and differentiate safety behaviours in the workplace. ‘‘Safety compliance’’ describes the core safety activities that need to be carried out by individuals to maintain workplace safety (i.e., active practices). On the other hand, the researchers use the term ‘‘safety participation’’ to describe behaviours that may not directly contribute to workplace safety but help to develop an environment that supports safety (i.e., proactive practices).

Figure 4: Model of Workplace Safety Climate and Safety Performance

(Griffin and Neal, 2000)

Subsequently, Neal and Griffin (2004) also explained that workers' knowledge and motivation are influenced by the safety climate. In turn, this has an impact on their safety behaviour and ultimately on safety outcomes.

Zohar (2003) also proposed a motivational explanatory mechanism, in which behaviour outcome expectancies are set in a mediating position between organisational and group safety climate perceptions and safety behaviours. According to Zohar (2003), safety behaviour must be motivated by intrinsic or extrinsic factors. Zohar (2003) posits that expectation of how managers (or supervisors) will response to particular actions will to a significant extent determine which behaviours are executed, stating that ''whenever safety issues are ignored or made contingent on production pressures, workers will infer low safety priority'' (Figure 5).

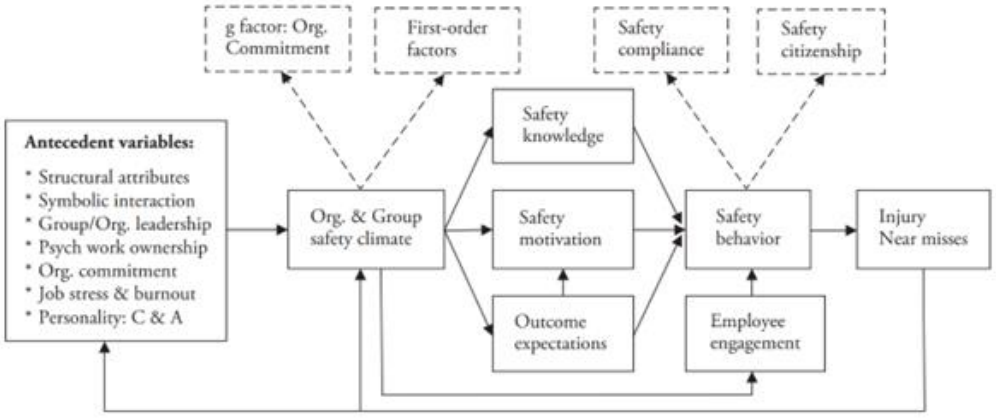

Figure 5: Model of Safety Climate with Antecedent and Outcome Variables (Zohar, 2003)

Flin (2007) amalgamated the two theoretical models by Griffin and Neal (2000) and Zohar (2003). Flin (2007) proposed a simplified and adapted version of these models to illustrate both patient as well as healthcare worker injuries as adverse outcomes (Figure 6).

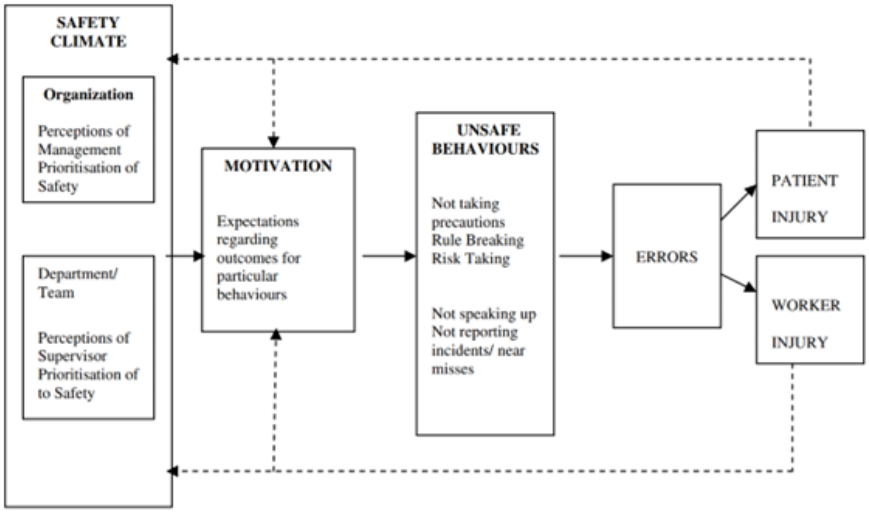

Figure 6: Model of Safety Climate and Injury Outcome (Flin, 2007)

The present research study draws upon insights gained from the theoretical models proposed by Griffin and Neal (2000), Neal and Griffin (2004), Zohar (2003), Flin (2007) and uses the model proposed by Vogus et al. (2010) as an organising framework to investigate the relationship among patient safety culture dimensions and safety-related behaviour, specifically incident reporting.

Vogus and colleagues (2010) posit that safety culture encompasses actions that single out and focus safety-relevant premises and cultural practices that mitigate harm. Following this, Vogus et al. (2010) put forward three practices that lead to safety culture: enabling, enacting and elaborating actions. Evidence suggests that there are at least two ways in which management can enable safer practices on the frontline. First, by directing attention to safety. Second, by creating an environment in which healthcare professionals feel safe to speak up.

One approach to direct attention to safety is to start with perceptions of safety climate. These perceptions reflect how healthcare professionals view patient safety based on their perceptions of their managers' commitment to safety and priority placed on safety (e.g., safety practices or procedures, resource allocation etc...). The degree to which managers are viewed as committed to safety, will significantly shape employees' perceptions of the importance of safety (Neal &

Griffin, 2004). Management who disregards safety procedures whenever facing production delays signals a low commitment to safety (Zohar, 2000). Similarly, in healthcare, management that expects healthcare professionals to work faster during busy times, even if it means taking shortcuts, would translate their poor safety commitment. This is supported by a number of studies, both in healthcare and industry, which have found that management and supervisors' commitment to safety can predict safety-related behaviour, as well as incidents (Zohar, 2000; Zohar & Luria, 2003; De Koster et al., 2011; Wachter & Yorio, 2014; Saleem & Malik, 2022).

Furthermore, within the realm of management support to safety, is the provision of resources, which includes appropriate staffing levels and ensuring a safe pace of work. Some studies have suggested that appropriate staffing levels can impact incident reporting (e.g., Noureldin & Noureldin, 2021). One potential reason for this behaviour may be increased time pressures and workloads. On the same lines, studies conducted by Hashemi et al. (2012) and Dyab et al. (2018) identified lack of time and heavy workload as reasons for errors going unreported.

As stated, Vogus et al. (2010) also describe that safety culture is enabled when leaders create a safe environment in which healthcare professionals are encouraged to speak up and act to resolve threats to patient safety. A punitive response to error, or blame culture, has been recognised as a major barrier to incident reporting in a number of studies (Alhassan et al., 2022; Burlison et al. 2020; Cooper et al., 2017). For instance, Burlison et al. (2020) found that a punitive response to error, among other variables, was significantly associated with voluntary event reporting in the United States. On the other hand, a just culture allows healthcare professionals to feel confident that, in speaking up and reporting near misses or errors, these will foster learning and improvement, rather than disciplinary actions (Waterson, 2014). Wilson (2007) highlights how not all errors will lead to significant harm, contributing to the mentality of 'no harm, no foul'. As a result, these errors are covered up to avoid disciplinary actions. However, it is likely that these same errors could result in more severe consequences and outcomes in the future. In light of this, Wilson (2007) emphasises the importance of establishing a culture of learning to encourage incident reporting and raises the following, essential questions: ''… if we remain unaware of what is broken, how can we address it? How can we proactively prevent the occurrence of these errors?''

Vogus et al. (2010) elaborate that enabling alone is not sufficient to cultivate safety culture. On the other hand, there must be consistent translation or enactment of safety guidelines into meaningful practices by frontline healthcare professionals. Therefore, enacting centres on frontline employees' actions into safety practices. Specifically, teams embedded within the organisation are considered as a critical factor to mitigate incidents and prevent errors (Salas et al., 2020).

Communication failures are recognised as a major causation factor in preventable errors in various healthcare and industries (The Joint Commission, 2016; as cited in Umberfield et al., 2019). Such communication failures may include refraining from speaking up about unsafe conditions or asking safety-related questions to avoid offending individual in more authorities positions or appearing incompetent. Drawing from industry literature, one of the key characteristics in high reliability organisations is deference to expertise. The prevailing norm in many organisations is that authority is closely linked to rank or seniority. On the contrary, high reliability organisations have a fluid decision-making system and value expertise on the problem at hand, irrespective of hierarchical position (Mossburg et al., 2019; Pozzobon et al., 2023). In sum, deference to expertise allows teams to take full advantage of the potential synergy and diverse expertise to enhance collaboration, decision-making and ultimately, improve safety performance and reduce the risks of incidents.

Furthermore, research also suggests that teamwork positively influences employees' safety performance and patient outcomes. For instance, in their study, Hwang and Ahn (2015) found that nurses with higher perceptions of teamwork were more likely to report medical errors. Burlison et al. (2020) found similar results. A study conducted in nine emergency departments found that enhanced teamwork led to a significant decrease in clinical error rates (Morey et al., 2002). This reduction in clinical error rates and adverse events has also been reported in other settings, including in outpatient oncology (Bunnell et al., 2013) and among surgical patients (Neily et al., 2010).

Finally, Vogus et al. (2010) highlights the importance of elaborating a safety culture in which two key themes emerge: reflection and feedback. According to Vogus and colleagues (2010),

a number of structured learning practices can help elaborate a safety culture. Laitinen and Ruohomaki (1996) found that regular safety feedback to employees in construction resulted in elevated safety standards within the workplace. In their study, Richter et al. (2015) analysed datasets from 1052 different hospitals and found that error feedback had the strongest positive effect on error reporting for each healthcare professional group, followed by organisational learning. Burlison et al. (2020) found similar results. Their findings highlight the potential positive outcomes associated with the provision of feedback and communication after an error as well as with the commitment of healthcare organisations to learn from errors and use the data from incident reports for making meaningful changes in the work environment. Collectively, these studies suggest that when employees perceive strong management commitment towards safety, exhibited through feedback practices and organisational learning, the more likely that employees' attitudes will become more positive, and performance will improve.

Against this background, it is hypothesised that safety culture dimensions are positively related to incident reporting in the oncology healthcare setting (see Figure 7 in the following page).

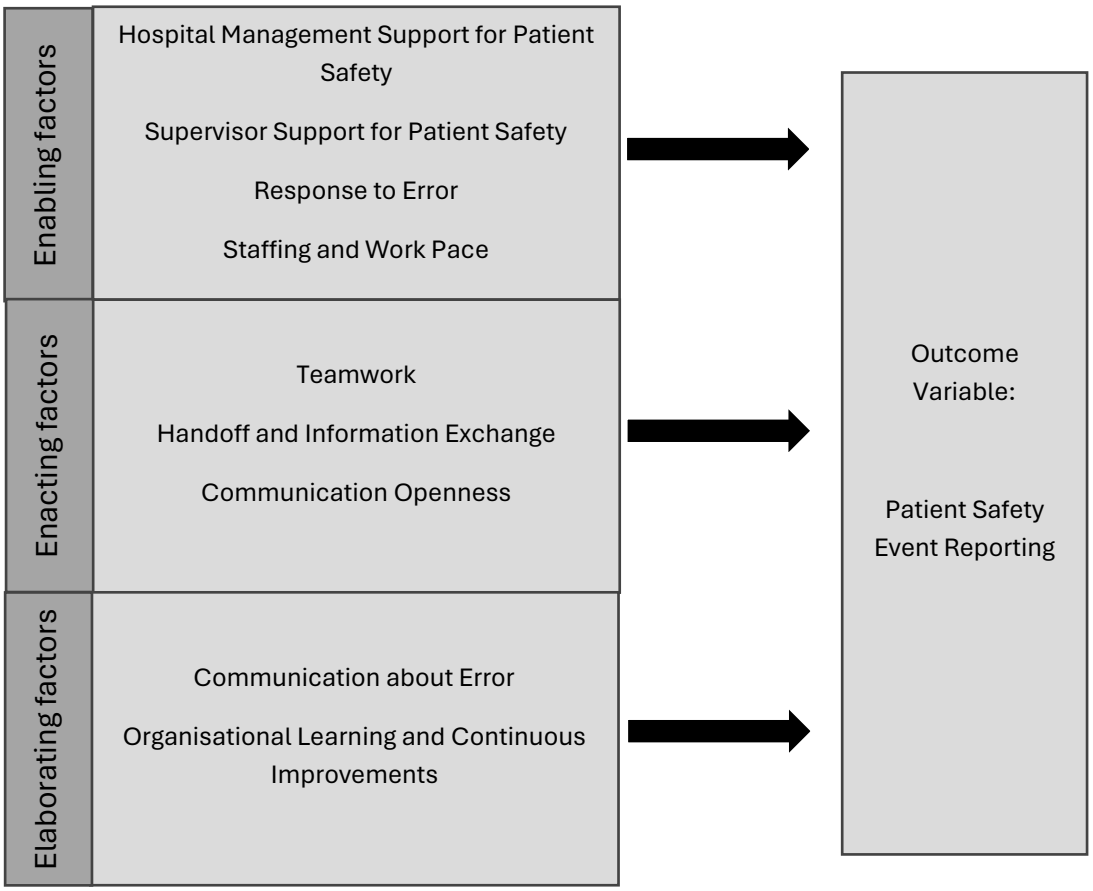

Figure 7: Organising Framework of the Present Research Study

2.3 Critically-Appraised Topic: Patient Safety Culture and Incident Reporting in Hospital Settings

2.3.1 Background

Incident reporting systems provide healthcare organisations with an opportunity to learn from past errors and improve patient safety through the implementation of targeted interventions (Mitchell et al., 2015). However, reporting of errors and near misses can be influenced by a number of factors, including the patient safety culture (Carlfjord et al., 2018).

Patient safety culture refers to the ‘‘product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation’s health and safety management’’ (Advisory Committee on the Safety of Nuclear Installations, 1993). A positive safety culture is characterised by teamwork, commitment to safety at all levels, management support, open communication about safety matters and errors, appropriate levels of staffing and workload as well as the provision of safety equipment or resources and training (Farokhzadian et al., 2018; Waterson, 2014). Furthermore, a positive safety culture emphasises the systems approach, which aims to understand ‘why’ an incident occurred and the reasons behind the unsafe actions and incidents rather than solely focusing on ‘who’ committed the unsafe acts (Farokhzadian et al., 2018). By fostering a systems approach, healthcare organisations encourage an environment in which continuous learning through reporting and discussing clinical risks and incidents is promoted, without fear of blame or punishment (Farokhzadian et al., 2018). As discussed, ‘safety culture’ and ‘safety climate’ are different yet related concepts. The two terms are not used consistently in healthcare literature and are often used inadvertently and interchangeably (Churruca et al., 2021). In view of this, for the purpose of this CAT, the term ‘safety culture’ was used to include assessments of both culture and climate.

Several studies have investigated the relationship between safety culture and safety-related behaviour, including incident reporting – both in industry and in healthcare (Adjekum et al., 2015; Hutchinson et al., 2009; The Health Foundation, 2011). However, findings have been inconsistent. Some studies suggested that a positive patient safety culture is associated with higher frequency of incident reporting (e.g., Abuosi et al., 2022) while others have found no significant relationship (e.g., Culbreth et al., 2021). Therefore, a CAT was conducted to

synthesise the available evidence on the impact of patient safety culture on incident reporting in hospital settings. This CAT explored the existing research studies investigating this relationship, critically appraised the quality of the studies identified and presented an evidence-based synthesis of the impact of patient safety culture on incident reporting in hospital settings.

2.3.2 Research Question

The research question was formulated using the population, intervention, comparison, outcome and context (PICOC) framework (Table 2.1). An initial search was conducted to identify research studies exploring the impact of safety culture on incident reporting in oncology healthcare settings however, this was unsuccessful as it did not yield any studies. Therefore, a second search was conducted. This search was not restricted to any speciality within a hospital setting and included secondary, tertiary, and quaternary levels of care to maximise the results. The primary research question was as follows:

''What is known in scientific literature about the impact of patient safety culture on incident reporting in hospital settings?''

Table 2.1: PICOC Framework

Population	**Intervention**	**Comparison**	**Outcome**	**Context**
Healthcare professionals	Safety culture	Not required for this search	Incident reporting	Hospital settings

2.3.3 Inclusion and Exclusion Criteria

The table in the following page (Table 2.2) describes the inclusion and exclusion criteria which was established for the present study. In summary, research studies were included if they investigated the impact of patient safety culture on the incident reporting in secondary, tertiary, and quaternary hospital settings or units. Studies which were conducted in other settings such as pre-hospital settings, ambulatory settings, primary care centres and hospitals, medical offices or clinics, long-term care settings or nursing home facilities, psychiatric hospitals, and rehabilitation hospitals were excluded. Studies conducted in military hospitals were also excluded. Moreover, studies that did not specify the context (i.e., level of care or speciality) were also excluded. Rationale for each decision is also presented.

Table 2.2: Inclusion and Exclusion Criteria		
Inclusion	**Exclusion**	**Rationale**
Published in peer-reviewed journals	Published in non-peer-reviewed journals, grey literature, editorials, letters or opinion papers, books or book chapters, conference or symposium proceedings	Peer review ensures high-quality research articles
Research articles published in English only	Research articles in languages other than English	English is the language the author is proficient in/Author limitations
Research articles published between 1st January 2012 and 31st December 2022	Research articles published prior to 1st January 2012	Publication date limited to the last 10 years to identify the most current, up-to date evidence as well as a manageable number of studies for review
Research articles available in full text only	Research articles not available in full text	The full text of the research article needs to be analysed for the critically-appraised topic to be robust
Meta-analyses, systematic reviews and primary research	No restrictions on the research design were applied	To maximise the number of research articles on the research topic
Quantitative, qualitative or mixed-methods research articles	No restrictions on the methodology of study were applied	To maximise the number of research articles on the research topic
Research studies examining the relations between patient safety culture and adverse event reporting in hospital settings. That is, studies were included if (a) patient safety culture was included as an independent variable and (b) incident reporting (or near miss reporting) were included as a dependent variable	Research studies that did not examine the relations between patient safety culture and incident reporting (e.g., research studies that examined other patient or employee safety outcomes such as length of stay, readmission rates, job care/satisfaction, sick leave or illness rates)	This criterion is justified by the research title, research questions and research objectives
Hospitals settings (secondary, tertiary and/or quaternary level of care)	Research studies conducted in other contexts such as pre-hospital settings, ambulatory settings, primary care centres and hospitals,	To maintain clear congruence between the research title, research questions, research objectives and inclusion

	medical offices or clinics, long-term care settings or nursing home facilities, psychiatric hospitals, and rehabilitation hospitals. Studies conducted in military hospitals were also excluded.	criteria of the present critically-appraised topic

2.3.4 Search Strategy

Thorough documentation and clear reporting of the search was carried out to provide transparency, verifiability and reproducibility of the results from this CAT. A three-step search strategy was implemented to conduct a comprehensive search. First, a pilot search on the HyDi platform by the UM was carried out using key terms derived from the title of the CAT. Relevant studies were retrieved and an analysis of the title, abstract as well as index terms was carried out to identify all relevant keywords and combination of keywords for this CAT. The alternative keywords and the formulated search string are presented in Table 2.3 and Table 2.4, respectively.

A second search using the identified keywords and terms was undertaken across all included databases. This search was conducted using different databases provided by the UM online library, specifically: CINAHL Complete, Cochrane Database of Systematic Reviews, MEDLINE Complete and PsycINFO. The database Academic Search Ultimate was also searched. Wildcard characters (e.g., ‘‘*’’) were used to search for similar keywords/keyword variations to enhance the flexibility and efficiency of the search. Boolean operators (e.g., ‘‘AND’’) were used to allow for the combination of keywords to search for relevant studies. This search is documented in Table 2.5. Moreover, the following filters were applied to all databases during the search process:

- Scholarly journals, peer-reviewed
- Language: articles in English
- Publication date: articles published between 2012 – 2022

Finally, the reference lists of all included studies were searched for additional relevant studies (i.e., citation searching).

Table 2.3: Alternative Keywords Identified Through the Database Search on CINAHL Complete and MEDLINE Complete

PICOC framework	Main elements	Alternative keywords
Population	Healthcare professionals	Not required for this search
Intervention	Safety culture	Safety culture, safety climate, culture of safety
Comparison	Not required for this search	Not required for this search
Outcome	Intention to report adverse events	Intention to report, reporting intention, adverse event reporting, incident reporting, error reporting, near miss reporting, frequency of reporting, willingness to report, reporting culture
Context	Hospital settings	Not required for this search

Table 2.4: Search String

((‘‘safety culture’’ OR ‘‘safety climate’’ OR ‘‘culture of safety’’)

AND

(‘‘intent* to report’’ OR ‘‘reporting intent*’’ OR ‘‘event reporting’’ OR ‘‘incident reporting’’ OR ‘‘error reporting’’ OR ‘‘near miss reporting’’ OR ‘‘frequency of reporting’’ OR ‘‘willingness to report’’ OR ‘‘reporting culture’’))

Table 2.5: Documentation of the Search *(Date: November 2022)*		
Limiters Applied	**Database**	**Total Number of Hits**
Scholarly journals, peer-reviewed Language: articles in English Publication date: articles published between 2012 – 2022	Academic Search Ultimate	36
	CINAHL Complete	7
	Cochrane Database of Systematic Reviews	0
	MEDLINE Complete	296
	PsycInfo	83

2.3.5 Study Selection

The search of the databases produced a total of 422 articles. The identified articles were all exported to RefWorks. This allowed for better management and organisation of the search and study selection process. The duplicate articles (57) were identified using RefWorks and eliminated, leaving a total of 365 articles. Therefore, the title of the 365 articles was screened for relevance to this CAT. Articles which were not considered relevant to this CAT were removed. In case of doubt, the study was included.

This step resulted in a total of 158 retained articles. The next phase of the study selection process involved reading the abstracts. On screening, 97 out of the 158 studies were excluded as they did not meet the inclusion criteria. This left a total of 61 studies. ResearchGate was used to request the full text articles directly from the authors when these could not be accessed through HyDi. The 61 full text articles were read and compared to the inclusion and exclusion criteria which was established earlier (Table 2.2). This yielded a total of 11 studies which were included in this critically appraised topic review. Additionally, manual searching of the citation list of the included studies was carried out. This step identified another article. Moreover, another article which fit the eligibility criteria of the present CAT was identified from an unstructured search on the research topic and included. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Page et al., 2014) summarising the study selection process is presented in the following page (Figure 8).

2.3.6 Study Characteristics and Data Extraction

This CAT identified and included thirteen studies. The included studies were published between 2012 and 2022. These studies were conducted in Oman, (N= 2), Ghana (N=1), Norway (N= 1), Slovenia (N= 1), United States (N= 2), China (N= 2), South Korea (N= 3) and Israel (N= 1). Out of the thirteen studies included in this CAT, twelve are cross-sectional studies whereas only one study is a longitudinal study. In the following pages, Table 2.6 summarises the overall data extracted from the included studies, including the name of the authors, publication year, country, study purpose, setting of the study, sample, sampling techniques, response rates, study design, and the main findings of each study

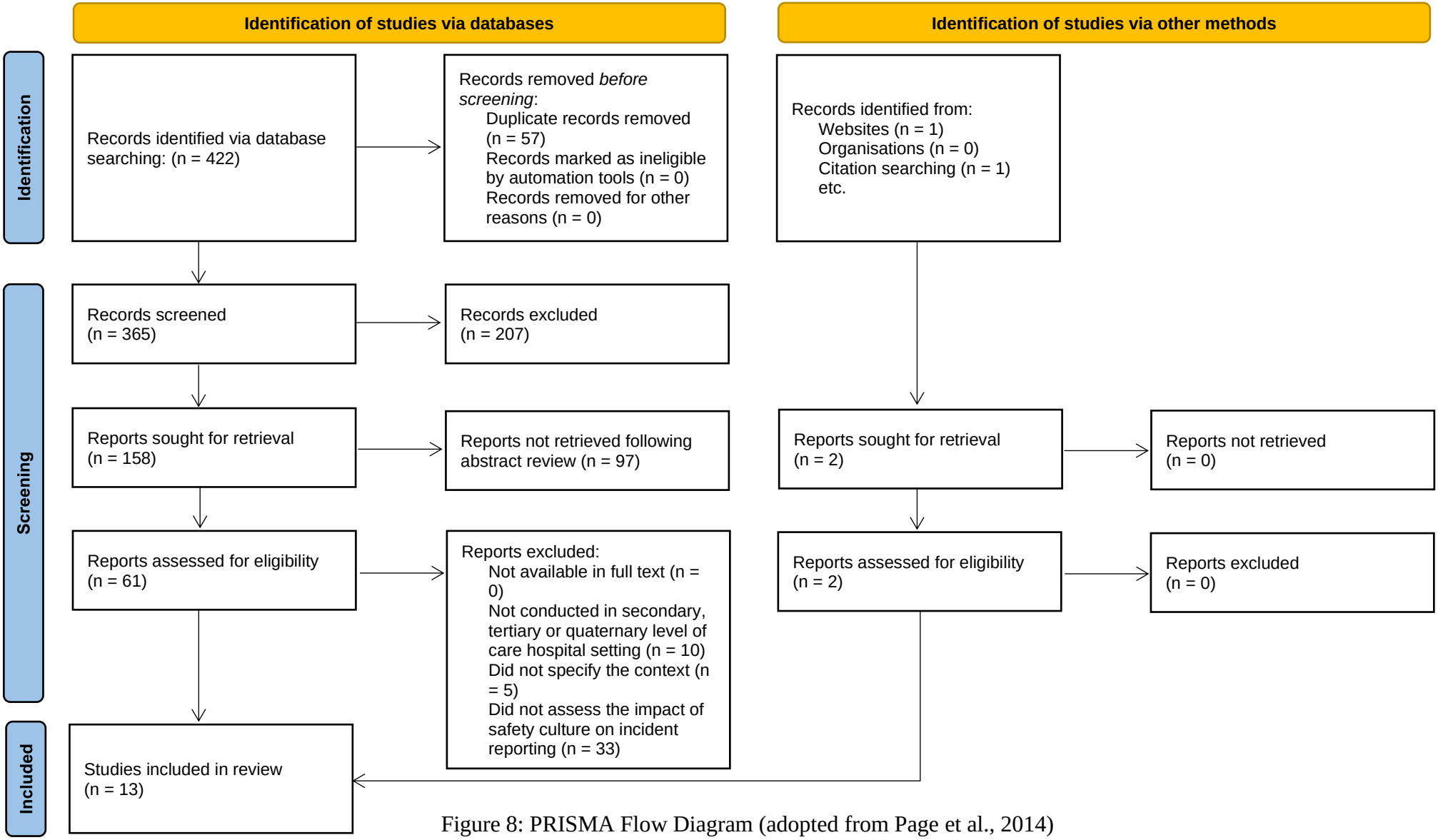

Figure 8: PRISMA Flow Diagram (adopted from Page et al., 2014)

Table 2.6: Data Extraction				
Author/s, Year, Country, Setting	**Aim/Purpose**	**Research Design, Sample**	**Main Findings**	**Relationship**
Al Ma'mari et al. (2019) Oman Two major governmental hospitals (critical care units)	To identify the predictors of critical care nurses' perceptions of patient safety culture and the frequency of event reporting	Cross-sectional study Convenience sampling N= 270/300 Response rate= 90%	Five safety culture variables were predictors of the frequency of events reported namely, openness in communication, income, nonpunitive response to errors, organisational learning and continuous improvement, and feedback and communication about errors (R2 =0.24, adjusted R2 =0.043; F=3.41, *p*= <0.0001)	Positive link
Al Ma'mari et al. (2021) Oman Two main referral hospitals (intensive care units)	To assess if there is a relationship between fatigue, workload, burnout and work environment, and frequency of event reporting; to identify the predictors of the frequency of event reporting among intensive care unit nurses in Oman	Cross-sectional study Convenience sampling N= 270/300 Response rate= 90%	Feedback and communication about errors predicted the frequency of event reporting between nurses working in intensive care units in Oman and it accounted for 21.4% of the variance, with R2= 0.214, F= 12.82 (*p*= <0.01)	Positive link
Alhassan et al. (2022) Ghana Three hospitals (medical units,	To assess the managerial patient safety practices that influence adverse event reporting in three hospitals in the Savannah Region of Ghana	Cross-sectional study Quota sampling N= 210/216 Response rate= 97.2%	Feedback about errors (β= .36, *p*= < 0.001) and non-punitive response to errors (β= .21, *p*= < 0.01) were significant predictors of adverse events reporting	Positive link

obstetrics and gynaecology, emergency units, others)				
Ballangrud et al. (2012) Norway Six hospitals (intensive care units)	To investigate registered nurses' perceptions of the patient safety climate in intensive care units and to explore potential predictors for overall perception of safety and frequency of incident reporting	Cross-sectional study N= 220/302 Response rate= 72%	The following unit level dimensions made significant contributions on the outcome ''overall perception of safety'': supervisor/manager expectation and actions promoting safety, teamwork within hospital units and feedback and communication about error. On the other hand, two dimensions contributed significantly on the outcome ''frequency of incident reporting'', namely: supervisor/manager expectation and actions promoting safety and feedback and communication about error	Positive link
Birk et al. (2016) Slovenia University hospital (including surgical, medical, obstetrics, paediatrics, intensive care, emergency department)	To determine whether safety culture, supervisors and communication between co-workers influence the number of adverse event reports submitted to the heads of clinical departments and to the management of an institution	Cross-sectional study N= 235/400 Response rate= 58.75%	The study found that safety culture, especially regarding department organisation, affects the frequency of AE reporting. If the degree of organization of a department is low, the frequency of adverse event reporting in the department is high and vice versa (t= -2.784, *p*= 0.006).	Positive link
Culbreth et al. (2021) United States	To identify the association between perceptions of safety and culture among neonatal intensive care units' staff	Cross-sectional study Convenience sampling N= 79/132	This study did not identify any significant association between safety attitudes and reporting medical errors in any of the hypothetical vignette scenarios, suggesting that safety climate may not play a significant role in promoting medical error reporting in the neonatal intensive care unit setting	No link

Nine metro hospitals (neonatal intensive care units)	with medical error reporting behaviours	Response rate= 59.8%		
Farag et al. (2019) United States Acute and critical units	To examine the direct, indirect, and total effect of organizational and social factors on nurses' safety motivation (willingness to report medication errors)	Cross-sectional study Systematic random sampling N= 220/500 (144 questionnaires used for the study) Response rate= 44%	The two safety climate dimensions of error feedback (β= 0.38, *p*= < 0.001) and nonpunitive response to error (β= 0.22, *p*= < 0.001) were significant predictors of nurses' willingness to report medication errors	Positive link
Hong and Li (2017) China Four tertiary hospitals	To assess nurses' perceptions towards patient safety culture and adverse event reporting in China and correlate their perceptions with self-reported rates of adverse events	Cross-sectional study Stratified random sampling and total sampling methods N= 919/1251 Response rate= 73.5%	The overall patient safety culture score (Beta= 0.316, *p*= <0.001) and safety climate (Beta= 0.240, *p*= <0.001) emerged to be the strongest predictors for adverse event reporting	Positive link
Jang et al. (2021) South Korea Tertiary hospital	Compares the association between perception of patient safety culture and medication error reporting among early- and mid-career female nurses; addresses the impact of patient safety culture on medication	Cross-sectional, secondary data analysis design N= 311	The study found that early-career nurses with a high patient safety culture are nearly 2.4 times more likely to report medication error compared to those with a low patient safety culture. However, for mid-career nurses, patient safety culture was not associated with medication error reporting	Mixed findings

	error reporting among early- and mid-career nurses			
Lee (2016) South Korea Non-profit tertiary acute hospital affiliated with a university	To identify differences in registered nurses' perceived safety climate and attitudes toward medication error reporting before and after hospital accreditation; to identify the relationship between perceived safety climate and attitude toward medication error reporting among registered nurses in Korea	Longitudinal study Convenience sampling N= 217 pre-accreditation; 373 post-accreditation Response rate= 58% pre-accreditation; 87% post-accreditation	Improving perceptions of safety climate increased participants' medication error reporting. That is, participants' perception of safety climate was positively correlated with their attitude toward medication error reporting (total: r= 0.271, *p*= < 0.001)	Positive link
Lee and Lee (2021) South Korea Four general hospitals	To explore the factors associated with the intention to report medication errors among general hospital nurses	Cross-sectional study Convenient sampling N= 171	The study found a number of significant factors associated with the intention to report medication errors including safety climate (β= 0.26, *p*= 0.001)	Positive link
Toren et al. (2021) Israel Three general hospitals (intensive care units, internal	To determine the extent nurses reported near miss events; to describe the relationship between patient safety culture, professional seniority and intention to report near misses; and to	Cross-sectional study Convenience sample N= 227/370 Response rate= 61.3%	Significant positive correlations were found between intention to report a near miss event and all components of patient safety culture. Variables that significantly predicted intention to report were: feedback and communication about errors, teamwork and reported near misses in the last year	Positive link

medicine or surgical wards)	determine predictors of intention to report near miss events			
Yang and Liu (2021) China Eight tertiary hospitals	To explore the relationship between patient safety culture and nurses' near-miss reporting intention, and examine the potential moderating effect the perceived severity of near misses might have on this relationship	Cross-sectional study Multi-stage random sampling approach N= 920/1100 Response rate= 83.64%	Patient safety culture was positively associated with nurses' near-miss reporting intention. Organisational learning (β= 0.56, *p*= < 0.01) and management support for safety (β= 0.35, *p*= < 0.05) significantly predicted near-miss reporting intention. The study demonstrates that when management was committed to safety and provided support, nurses were more likely to report near misses	Positive link

2.3.7 Critical Appraisal

Critical appraisal is defined as the process of systematically assessing scientific literature for its trustworthiness, value and relevance in a particular context (Mhaskar et al., 2009). The quality of published scientific literature is highly variable, ranging from practice-changing research to poorly conducted or reported research, with serious methodological flaws, biases or limited generalisability which could be harmful to clinical practice (Carpenter et al., 2020). Therefore, critical appraisal of scientific literature is considered as a fundamental skill in clinical practice, allowing academics and healthcare professionals to use research evidence reliably and efficiently. A number of critical appraisal tools exit, providing systematic guidance on assessing the methodological quality of a study. For the present study, the researcher made use of two different critical appraisal tools, chosen according to study design (see Appendix B). Specifically, the Joanna Briggs Institute's (JBI) Checklist for Analytical Cross-Sectional Studies (2020a) and the JBI's Checklist for Quasi-Experimental Studies (2020b) were used.

- **Critical Appraisal of the Cross-Sectional Studies**

The following section presents the critical appraisal of the studies that employed a cross-sectional design (Al Ma'mari et al., 2019; Al Ma'mari et al., 2021; Alhassan et al., 2022; Ballangrud et al., 2012; Birk et al., 2016; Culbreth et al., 2021; Farag et al., 2019; Hong & Li, 2017; Jang et al., 2021; Lee & Lee, 2021; Toren et al., 2021; Yang & Liu, 2021). Table 2.6 gave a summarised description of these studies.

Cross-sectional studies are observational studies which collect and analyse data from a population at one point in time, in contrast to longitudinal studies. Typically, cross-sectional studies are considered as an efficient and economical method to collect data (Wang & Cheng, 2020). Cross-sectional studies are particularly suitable to describe the status of phenomena or relationships among phenomena at a specific point in time (Polit & Beck, 2010) and can be classified as descriptive or analytical (Wang & Cheng, 2020). However, while cross-sectional studies can indicate statistical associations between variables, they cannot alone establish causality (Bowling, 2014). The JBI's Checklist for Analytical Cross-Sectional Studies (2020a) was used as a guidance tool assess the trustworthiness, relevance and results of these studies (see Table 2.8).

A limitation present in all of the above studies is the use of self-report techniques, namely the use of quantitative questionnaires. Questionnaires in healthcare research are important tools used to gather information on individual perspectives in a large cohort, in a systematic and standardised way (Jones et al., 2013). However, several limitations and biases are associated with self-report measures exit including social desirability bias, recall bias, acquiescence response set bias and response style bias (Bowling, 2014).

As mentioned, the included studies used a number of different quantitative questionnaires to assess safety culture and the willingness or frequency of incident reporting. Table 2.7 summarises the different quantitative questionnaires utilised to gather data across the included cross-sectional studies. Five studies used the SOPS questionnaire to assess both safety culture and willingness or frequency of incident reporting (Al Ma'mari et al., 2019; Alhassan et al., 2022; Ballangrud et al., 2022; Birk et al., 2016; Toren et al., 2021). On the other hand, the other studies used multiple questionnaires as well as dichotomous measures to measure safety culture and willingness of frequency of incident reporting such as the Safety Attitudes Questionnaire (SAQ) and hypothetical medical error reporting scenarios.

Overall, Yang and Liu (2021) accounted for the largest sample of participants (N= 920) whereas Culberth et al. (2021), Farag et al. (2019) and Lee and Lee (2021) accounted for the smallest sample of participants (N= 79, N= 144, N= 171, respectively). Sample size and sampling are considered as a major issue in conducting and appraising quantitative research (Polit & Beck, 2010). An inadequate sample size in quantitative studies can increase the risk of bias and limit the generalisability of the findings, undermining the internal and external validity of a study. Moreover, a small sample size can result in lack of statistical power. Statistically significant findings (differences or associations) are difficult to detect with very small sample sizes (Bowling, 2014). On the other hand, a large sample size will be better representative of the population of interest, reduce the impact of random error or chance variation, and produce more precise and accurate results (Polit & Beck, 2010). In addition, in terms of statistical significance, employing a large sample size increases the probability of detecting a statistically significant effect, if one exists. Power calculation, a statistical tool to determine the sample size required to detect a statistically significant effect or difference. Power analysis, also referred to as sample size calculation, is a statistical method used in

research to determine the appropriate sample size required for a study. Its purpose is to estimate the probability of detecting an effect or relationship between variables, given a certain sample size and desired level of statistical significance. Despite this, only five cross-sectional studies conducted a power analysis (Al Ma'mari et al., 2019; Al Ma'mari et al., 2021; Jang et al., 2021; Lee & Lee, 2021; Toren et al., 2021).

Table 2.7: Data Collection Tools across Cross-Sectional Studies

Author, Year	Safety Culture Measure	Incident Reporting Measure
Al Ma'mari et al., 2019	SOPS	SOPS
Al Ma'mari et al., 2021	SOPS (and Maslach Burnout Inventory-Human Services Survey, Fatigue Assessment Scale, Task Load Index and Practice Environment Scale of the Nursing Work Index)	SOPS
Alhassan et al., 2022	SOPS	SOPS
Ballangrud et al., 2012	SOPS	SOPS
Birk et al., 2016	SOPS	SOPS
Culbreth et al., 2021	SAQ	Hypothetical Medical Error Reporting Vignettes
Farag et al., 2019	SOPS (and Multifactorial Leadership Questionnaire, Modified Litwin, Stringer Organizational Climate Questionnaire and Cook and Wall's Organisational Trust Instrument)	SOPS
Hong & Li, 2017	Patient Safety Culture Assessment Scale derived from the SAQ	Adverse Event Reporting Perception Scale
Jang et al., 2021	SOPS	Single-Item Self-Report Measure of Medication Error Reporting
Lee & Lee, 2021	Safety Climate Scale and Nursing Organisation Culture Measurement Tool	Scale of Error Reporting Intention of Nurses
Toren et al., 2021	SOPS	SOPS
Yang & Liu, 2021	SOPS	Investigator-designed instruments

Alhassan et al. (2022) achieved an excellent response rate of 97.2%, the highest response rate from all identified studies. Overall, all cross-sectional studies achieved a good response rate

with the exception of the studies carried out by Farag et al. (2019), Birk et al. (2016) and Culberth et al. (2021), who achieved the lowest response rates of 44%, 58.75% and 59.8%, respectively. The study conducted by Jang et al. (2021) was a secondary analysis of existing data and did not state the sampling method or report response rate. Moreover, Lee and Lee (2021) stated that 201 participants replied to the questionnaires from which 30 were excluded in view of incomplete data however, the researchers failed to report the response rate. Polit and Beck (2010) state that researchers should provide information on response rates as well as about possible nonresponse bias, which can occur when there are differences between the participants and those who refused to participate. While there is no agreed standard for an acceptable minimum response rate, Bowling (2014) suggests that a response rate lower than 60% is considered as suboptimal while a response rate of 75% or higher is considered as good. Schutt (1999, as cited in Draugalis et al., 2008) also indicated that a response rate lower than 60% was unacceptable and Bailey (1987, as cited in Draugalis et al., 2008) asserts that the minimal acceptable response rate was 75%. However, Babbie states that a response rate of 50% is considered as adequate (1990, as cited in Draugalis et al., 2008).

Ballangrud et al. (2012) and Farag et al. (2019) describe how reminders were sent to increase response rates. Moreover, Culbreth et al. (2021) and Farag et al. (2019) mention how compensation was provided to participants after returning the questionnaire whereas Hong and Li (2017) mention that during the data collection period, a researcher visited each hospital at least once as well as maintained communication with nursing managers and the designated link nurses. On the other hand, the other reviewed studies did not mention any strategies to increase their response rates and therefore, reduce nonresponse bias (Al Ma'mari et al., 2019; Al Ma'mari et al., 2021; Alhassan et al., 2022; Birk et al., 2016; Jang et al., 2021; Lee & Lee, 2021; Toren et al., 2021; Yang & Liu, 2021).

According to Polit and Beck (2010), a large sample size cannot correct for a faulty sampling method. Essentially, there are two major categories of sampling methods – probability sampling methods and nonprobability sampling methods. Probability sampling is based on chance events, where each individual of the population has an equal chance of being selected whereas nonprobability sampling is based on the researcher's choice, population accessibility

and availability, where individuals are selected from the population in a non-random manner (Tyrer & Heyman, 2016).

Five studies stated that a convenience sampling method was employed (Al Ma'mari et al., 2019; Al Ma'mari et al., 2021; Culberth et al., 2021; Lee & Lee, 2021; Toren et al., 2021). Convenience sampling, a nonprobability sampling method, entails selecting individuals who are available and willing to participate in a study. However, convenience sampling is regarded as the weakest form of sampling techniques as the available subjects may be atypical of the population and therefore, it is highly susceptible to selection bias and sampling error (Polit & Beck, 2010).

Alhassan et al. (2022) employed a quota sampling method. Quota sampling involves creating a sample that reflects specific quotas of certain characteristics present in the target population. This method allows researchers to ensure that diverse characteristics (e.g., age, sex...) are adequately represented in the study sample (Polit & Beck, 2010). However, except for identifying key strata, this sampling method is procedurally similar to convenience sampling. Thus, it shares many of its weaknesses and limitations. Despite this, quota sampling is still recognised as an efficient method to enhance the representativeness of a nonprobability sample (Polit & Beck, 2010).

As stated previously, the study conducted by Jang et al. (2021) was a secondary analysis of existing data and did not state the sampling method. Furthermore, Ballangrud et al. (2012) and Birk et al. (2016) did not explicitly state was sampling method was employed. However, the authors stated that their study was conducted in a specific hospital, unit or department as well as described participants which were included in the study, suggesting that a consecutive sample was used (Ballangrud et al., 2012; Birk et al., 2016). Consecutive sampling is also a nonprobability sampling method. This technique involves recruiting all individuals who meet the inclusion criteria over a specific time interval. Therefore, it is regarded as a far better approach than sampling by convenience as the risk of bias is greatly reduced (Polit & Beck, 2010).

Conversely, three studies employed a probability sampling method namely, systematic sampling, stratified sampling and a multi-stage random sampling approach (Farag et al., 2019; Hong & Li, 2017; Yang & Liu, 2021, respectively). Probability sampling involves the random selection of elements from a population. Probability sampling is often more costly, timeconsuming and complex than non-probability sampling. However, probability sampling methods are preferred due to their ability to provide representative and unbiased samples, ensuring that findings can be accurately extended to the larger population. This contrasts with non-probability sampling methods, which often introduce selection biases and hinder generalizability.

Finally, all cross-sectional studies discussed their limitations. Researchers have an obligation to the academic community to acknowledge their study's limitations, discuss the implications of the limitations, present possible alternative approaches as well as describe steps taken to mitigate the limitation in a complete and honest manner. A comprehensive presentation of a study's limitations is crucial as limitations represent weaknesses within a study, that may influence the outcome and conclusions of the research (Ross & Zaidi, 2019). This step demonstrates the rigor and transparency of a study as well as it allows other researchers to evaluate the validity and reliability of the findings.

Table 2.8: The JBI's Checklist for Analytical Cross-Sectional Studies (2020a)												
	Al Ma'mari et al., 2019	Al Ma'mari et al., 2021	Alhassan et al., 2022	Ballangrud et al., 2012	Birk et al., 2016	Culbreth et al., 2021	Farag et al., 2019	Hong & Li, 2017	Jang et al., 2021	Lee & Lee, 2021	Toren et al., 2021	Yang & Liu, 2021
Were the criteria for inclusion in the sample clearly defined?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes
Were the study subjects and the setting described in detail?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the exposure measured in a valid and reliable way?	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were objective, standard criteria used for measurement of the condition?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were confounding factors identified?	No	No	No	No	No	No	No	No	No	No	No	No
Were strategies to deal with confounding factors stated?	No	No	No	No	No	No	No	No	No	No	No	No

Were the outcomes measured in a valid and reliable way?	Yes	Yes	Yes	No	Yes	Yes	Yes	Can’t tell	Yes	Yes	Yes	Yes
Was appropriate statistical analysis used?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

- **Critical Appraisal of the Longitudinal Study**

This CAT identified and included only one longitudinal study (Lee, 2016). Table 2.6 presented a summarised description of this study. Longitudinal studies employ continuous or repeated data collection measures to follow individuals over a prolonged period of time, with the number of data collection points and length of time intervals depending on the nature of the study (Polit & Beck, 2010). Therefore, longitudinal studies have the potential to offer a more comprehensive approach to research and allow an understanding of the degree and direction of change over time (Caruana et al., 2015).

The research design employed in Lee's study (2016) exhibits characteristics reminiscent of a quasi-experimental approach. For this reason, the JBI's Checklist for Quasi-Experimental Studies (2020b) was used as a guidance tool to assess the methodological quality and determine to the extent to which the study addressed the possibility of bias in its design, conduct and analysis (see Table 2.9). The study featured a temporal separation of data collection into two distinct phases: a baseline assessment of safety climate and attitudes toward error reporting prior to hospital accreditation, followed by a subsequent evaluation after the accreditation process. However, the study did not feature a control group. In this instance, the pre-test measurement served as the control period. According to Schweizer et al. (2016), quasi-experimental studies may vary in their methodological rigor and can be categorised in three main types, namely designs without control groups, designs with control groups and interrupted time series. The presence of a control group in a quasi-experimental study strengthens the examination of the causal plausibility. The validity of causal inferences is strengthened in quasi-experimental studies with at least one independent control group compared to those without an independent control group (JBI, 2020b). Therefore, it is important to exercise caution when interpreting the findings of a quasi-experimental study that lacks a control group.

The data collection method utilised by Lee (2016) involved a self-report quantitative questionnaire, which are associated with various limitations and biases, including social desirability bias, recall bias, acquiescence response set bias, and response style bias, as outlined by Bowling (2014). Lee (2016) used the safety climate survey developed by Sexton et al. (2006) to examine the hospital safety climate as well as an adapted measure based on the Modified Ulanimo survey (Ulanimo et al., 2007) to identify nurses' attitudes toward

medication error reporting. The internal consistency reliability of the questionnaires was measured using the Cronbach’s Alpha pre-and-post accreditation phases. The safety climate survey achieved coefficient alpha values greater or equal to 0.70, indicating that the instrument in reliable. On the other hand, the medication error reporting questionnaire achieved values between 0.65 and 0.70. This may indicate that the items are not consistently related or that they are measuring multiple, unrelated concepts (Bowling, 2014).

In Lee's (2016) study, a power analysis was undertaken to determine the optimal sample size. Prior to accreditation, the study achieved a 58% response rate, with 217 out of 400 distributed questionnaires returned and analysed. Post-accreditation, the response rate increased to 87%, with 373 out of 450 distributed questionnaires returned and analysed. Consequently, the study included an adequate number of participants to detect differences between the groups over the research period. However, it is important to note the disparity in sample sizes before and after accreditation, which could impact the study's internal and external validity.

The study employed convenience sampling to recruit participants and was conducted within a single hospital. Both the use of convenience sampling and the single-centre setting limit the generalisability of the study's findings (Bowling, 2014). However, it is worth noting that Lee (2016) conscientiously acknowledged most of the study's limitations and provided recommendations for future research.

Table 2.9: Critical Appraisal of the Quasi-Experimental Study	
The JBI's Checklist for Quasi-Experimental Studies (2020b)	Lee (2016)
Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	Yes
Were the participants included in any comparisons similar?	No
Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Can't tell
Was there a control group?	No
Were there multiple measurements of the outcome both pre and post the intervention/exposure?	No
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	No
Were the outcomes of participants included in any comparisons measured in the same way?	Yes
Were outcomes measured in a reliable way?	Yes
Was appropriate statistical analysis used?	Yes

2.3.8 Results

- **Causal Mechanism: How is safety culture assumed to have an effect on incident reporting?**

A causal mechanism is described as the underlying process by which a specific intervention, construct or phenomenon is expected to have an effect on a particular outcome, helping to explain the cause-and-effect relationship between variables. The causal mechanism is often grounded in one or more theories that explain why the assumed effect occurs and under which circumstances. The included studies conceptualised the relationship between patient safety culture and its impact on incident reporting in hospital settings. The presumed casual mechanism following the theories of Griffin and Neal (2000), Neal and Griffin (2004), Zohar (2003), Flin (2007) and Vogus et al. (2010), was that safety culture has a positive impact on incident reporting. Put differently, it was expected that if healthcare professionals perceive a positive safety culture in their organisation, they were more likely or willing to report nearmisses and medical errors.

- **Main Findings**

Overall, this CAT identified a positive relationship between patient safety culture composites and reporting of patient safety events. This indicates that a strong safety culture within healthcare organisations can encourage the reporting of errors or near-misses.

In their longitudinal study, Lee (2016) also found that safety climate was positively correlated with attitudes toward medication error reporting. Furthermore, this relationship grew stronger following the hospital accreditation program (before r=0.167, p= 0.016; after r=0.288, p= <0.001; total r=0.271, p= <0.001). Hong and Li (2017) also found that the overall patient safety culture (p= <0.001) was significantly associated with nurses' adverse event reporting. Furthermore, Hong and Li (2017) analysed a model using multiple linear regression. The model explained 28.2% of the variance in participants' adverse event reporting. The six variables that were included in the model consisted of total work experience (p= 0.003), overall patient safety culture score (p= <0.001), safety climate (p=<0.001), teamwork climate (p= <0.001), overall adverse event reporting perception scale score (p= 0.003) and importance of reporting (p=

0.002). According to the beta values, the overall patient safety culture score (Beta= 0.316, p= <0.001) emerged to be the strongest predictor in the aforementioned model.

In their study, Jang et al. (2021) performed a logistic regression analysis and found that earlycareer nurses with a high patient safety culture were nearly 2.4 times more likely to report medication errors compared to those with a low patient safety culture ($\chi 2$= 20.12, p= 0.017) among early-career nurses. However, for mid-career nurses, patient safety culture was not associated with medication error reporting (p= 0.446).

Lee and Lee (2021) found that safety climate was positively correlated with intention to report medical errors (r=0.35, p= <0.001). Moreover, following a multiple linear regression, the researchers identified that a higher perception of safety climate, among other variables, was a predictor of increased intention to report medical errors (β= 0.26, p= 0.001; R2= 0.25, adjusted R 2= 0.23, F= 11.07, p= <0.001).

Al Ma'mari et al. (2019) conducted a standard multiple regression analysis and found that five variables namely feedback and communication about error, organisational learning and continuous improvement, non-punitive response to error, income and communication openness were predictors of the frequency of events reported (R2= 0.24, adjusted R2= 0.043; F= 3.41, p= <0.0001).

In another study, Al Ma'mari et al. (2021) found that feedback and communication about errors predicted the frequency of event reporting, accounting for 21.4% of the variance, with R2= 0.214, F= 12.82 (p= <0.01). Alhassan et al. (2022) and Farag et al. (2019) also found that communication and feedback about errors was a significant predictor of adverse events reporting (β= 0.36, p= <0.001; β= 0.38, p= <0.001, respectively). Similarly, Toren et al. (2021) found a significant correlation between communication and feedback about errors and intention to report a near miss event (r= 0.30). Furthermore, the authors identified three significant variables that predicted the intention to report near miss events namely, feedback and communication about errors, teamwork and the amount of reported near miss events in the last

year (F [4224] = 14.859, $p<0.001$, explaining 21.1% of the variance of intention to report a near miss event). Ballangrud et al. (2012) also found that feedback and communication about error contributed significantly on the frequency of incident reporting.

Nonpunitive response to error, organisational learning and management support for patient safety were other safety culture composites that impacted incident reporting in some of the included studies. Alhassan et al. (2022) and Farag et al. (2019) found that a nonpunitive response to error was a significant predictor of adverse event reporting ($\beta= 0.22$, $p<0.01$; $\beta= 0.22$, $p<0.001$, respectively). In addition, Yang and Liu (2021) found that organisational learning ($\beta= 0.56$, $p<0.01$) and management support for safety ($\beta= 0.35$, $p<0.05$) significantly predicted near miss reporting intention. Ballangrud et al. (2012) also found that manager expectation and actions promoting safety contributed significantly on the frequency of incident reporting.

Conversely, Culberth et al. (2021) did not identify any significant association between safety attitudes and reporting medical errors in their study, suggesting that safety climate may not play a significant role in promoting medical error reporting in their study context.

2.3.9 Gaps in Literature

The CAT revealed a number of gaps in the literature surrounding the impact of patient safety culture on incident reporting in hospital settings. Particularly noteworthy is the overrepresentation of nurses in the identified studies, consequently possibly overlooking the insights and involvement of other healthcare professionals, including medical doctors, pharmacists, radiographers, and physiotherapists. In addition, there is a limited context diversity in the available literature. The majority of the identified studies focused on tertiary hospitals or intensive care units, with limited focus on specialty units including oncology settings. Furthermore, the available studies do not represent a diverse range of geographical locations, with the majority of the studies focusing on countries outside of Europe (as shown in Section 2.3.6). This could affect the applicability and generalisability of the findings to different healthcare settings locally and internationally. Further gaps in literature include the lack of longitudinal research as well as inconsistency in measurement methodologies.

2.3.10 Limitations

This CAT has a number of limitations. Firstly, concessions were made with regards to the depth and breadth of the search process. The search was limited to five databases which were chosen because they were considered suitable for identifying relevant studies and because these databases were available to the author in their academic setting. Grey literature and unpublished data were excluded whereas only studies published throughout the past 10 years (from 2012 to 2022) in peer-reviewed journals were included. This was done to include the most recent, up-to-date and high-quality research. In view of this, other older publications and other data with important findings may have been excluded. In addition, this CAT searched for and included studies published in the English language only. Therefore, relevant research in other language might have been missed, leading to a biased or incomplete review.

Secondly, this review was conducted by only one researcher. Ideally, multiple researchers would independently screen the studies, to minimise subjective bias. Additionally, the contribution of multiple researchers in the search process would reduce the risk of oversight or errors. However, since this review is part of a dissertation submitted for academic purposes, this was not possible. On the other hand, to minimise the risk of selection bias, a clear and comprehensive search strategy and inclusion and exclusion criteria were established. Moreover, documentation of the search process, including a PRISMA flow diagram was also presented.

A critical appraisal of the included study was conducted. This highlighted a number of noteworthy limitations within the methodology of the studies. Therefore, the results should be interpreted with consideration of these weaknesses. This CAT identified twelve cross-sectional studies, only one longitudinal study was identified and included. As discussed, while cross-sectional studies can indicate statistical associations between variables, they cannot alone establish causality (Bowling, 2014). Furthermore, it is worth emphasizing that the majority of studies examined in this CAT focused on assessing the correlation between patient safety culture and incident reporting within the context of nursing staff, with limited inclusion of other healthcare professionals. Despite this, the studies still provided valuable insights of the effect of safety culture on incident reporting in hospital settings.

2.3.11 Conclusion and Recommendations

This CAT demonstrates the importance of establishing a positive patient safety culture to improve incident reporting in hospital settings. Among safety culture composites, feedback and communication about error was the most commonly cited predictor of incident reporting. Accordingly, efforts to enhance safety culture, in particular establishing a culture in which healthcare professionals are informed about near misses and medical errors, are engaged in discussions to prevent them, and are consistently informed when changes are implemented is of utmost importance. Such measures are instrumental in facilitating and strengthening incident reporting in hospital settings.

Future research should adopt more robust study designs and consider employing mixed methods research approaches, integrating both quantitative and qualitative methodologies. Therefore, this approach would allow a more comprehensive understanding of the research question, ultimately leading to more insightful findings. In addition, future research should adopt more rigorous methodologies, including employing larger sample sizes as well as probability sampling strategies.

2.3.12 Local Research

A separate search was conducted via HyDi, the search interface within the UM's electronic library website. The aim of this search was to identify local studies related to the present research topic. Keywords included: ''safety culture'', ''safety climate''. ''patient safety'' and ''Malta''. This search identified a number of studies with important contributions to patient safety and safety culture literature within a Maltese context. The study characteristics and findings were extracted are presented in the form of a table in the following pages (see Table 2.10).

In sum, in their study, Petrova et al. (2010) identified perceptions of factors that contributed to errors which included poor communication, inadequate staffing levels, tiredness and exhaustion and illegible handwriting. Furthermore, the study by Petrova and colleagues (2010) highlights a fear of blame as a barrier to incident reporting. Mangion (2021) identified other of barriers associated with incident reporting including lack of feedback. In their study, Zammit

(2008; as cited in Mallia et al., 2009) identified underreporting in the local, acute general hospital, revealing that 70% of the participants did not report any incidents in the preceding 12 months. This raises concern since the lack of incident reporting may hinder the identification and resolution of patient safety issues. Similarly, Baldacchino (2009) also identified underreporting in high dependency units in the local general hospital, among other gaps in the safety culture. Conversely, Zammit and Borg (2008; as cited in Mallia et al., 2009) found an overall positive attitude towards patient safety among employees working in local nursing homes for older people. The only major concern reported was that of poor staffing levels (Zammit and Borg, 2008; as cited in Mallia et al., 2009).

Among their main findings, Azzopardi (2018) found that the higher the extent to which a patient safety friendly working environment is perceived as favourable, the lower the perceived unsafe performance in the local obstetrics department. On the same lines, Teuma Custo (2016) found that the higher the extent to which safety procedures are perceived as suitable, the lower clinical incidents in the local intensive care units.

Although a limited number of studies related to patient safety and safety culture literature within a Maltese context were identified, the researcher did not identify studies conducted in local oncology healthcare settings. Therefore, by conducting this study, the researcher can use the findings to benchmark, compare and contrast the findings with the local studies identified as well as with research conducted in other countries.

Table 2.10: Local Research on Patient Safety and Patient Safety Culture		
Author, Year, Purpose	**Setting/Participants, Sample size, Research design, Measurement tool**	**Main findings**
Azzopardi (2018) To test a theoretical framework addressing relationships among patient safety friendly working environment, management support, burnout and their impact on safety performance in the obstetrics department in Malta	Obstetrics department in MDH Doctors, nurses, midwives Participants (N)= 184 Response rate= 73.6% Quantitative (descriptive and analytical) cross-sectional study SAQ	Overall, findings from the study supported the theoretical framework, specifically; ‘‘the higher the extent to which a patient safety friendly working environment is perceived as favourable to the obstetrics team, the lower the obstetric team’s perceived unsafe performance’’ (r= -0.169; *p*= 0.022) and ‘‘burnout mediates the relationship between a patient safety friendly working environment and perceived unsafe performance’’ (β= 0.187; *p*= 0.007) and ‘‘management support has a negative relationship on perceived unsafe performance’’ (r= -0.232; *p*= 0.002)
Baldacchino (2009) To gain an understanding of the patient safety culture pertaining to high dependency units in the local general hospital (in Malta)	High dependency areas in MDH Doctors and nurses Participants (N)= 155/279 Response rate= 56% Quantitative (descriptive) cross-sectional study SOPS	Overall, 7 dimensions were identified as weak patient safety areas (average percent positive response less than 50%); ‘‘non-punitive response to error’’ (19%), ‘‘frequency of event reporting’’ (31%), ‘‘hospital management support for patient’’ (33%), ‘‘teamwork across hospital units’’ (33%), ‘‘hospital handoffs and transitions’’ (35%), ‘‘staffing’’ (37%) and ‘‘feedback and communication about error’’ (42%) Other areas with potential for improvement included: ‘‘overall perceptions of safety’’ (51%), ‘‘organisational learning – continuous improvement’’ (53%), ‘‘communication openness’’ (54%) and ‘‘supervisor/manager expectations and actions promoting patient safety’’ (55%) Only ‘‘teamwork within units’’ was identified as a patient safety culture strength, with a positive percentage of 75 Overall, 33 out of 155 study participants (21%) expressed suggestions and/or comments (section I). The comments strongly support the findings from the quantitative data with

		the main themes focusing on the existing ‘‘blame culture’’, lack of ‘‘management support’’, lack of ‘‘staffing’’ and overwhelming ‘‘workload’’ as well as ‘‘system’’ issues Significant variations between units in 7 dimensions
Deguara et al. (2023) To explore safety culture in a perioperative department from operating theatre practitioners’ perspective	Operating theatre in MDH Nurses Participants (N)= 146/205 Response rate= 71.2% Quantitative cross-sectional study Safety, Communication, Operational Reliability and Engagement (SCORE) questionnaire	The study found a very high perceived level of ‘‘workload’’ (86.3%), ‘‘burnout climate’’ (86.05%) as well as high perceived level of ‘‘personal burnout’’ (63.51%). Conversely, ‘‘work-life imbalance’’ (40.95%) was perceived to be low Participants perceived ‘‘safety climate’’ (46.58%), ‘‘teamwork climate’’ (47.12%), ‘‘advancement’’ (47.68%), ‘‘participation in decision making’’ (48.32%), ‘‘improvement readiness’’ (49.79%) and ‘‘growth opportunities’’ (49.89%) to be of an average level ‘‘Unit leadership’’ (38.49%) was perceived to be the lowest of all safety culture domains explored The study also found that leaders’ recognition of staff feedback and input was associated with improved safety culture perceptions
Mangion (2021) To evaluate nurses’ awareness and knowledge of the local incident reporting system	MDH Nurses Participants (N)= 323/1383 (total population sampling) Response rate= 23% Quantitative (descriptive) cross-sectional study	The majority of charge/deputy nurses (98.8%) and nurses (77.3%) had used the local incident reporting system at least once Less than of half of the participants (48.3%) had filled an incident report form during the last year In contrast, only 11.5% of participants had ever posted an anonymous safety alert form (32.1% charge/deputy nurses; 4.5% nurses) throughout their career, with the largest percentage (22.4%) of safety alert posts coming from nurses with more than 20 years of experience The majority of participants were aware on how to locate/access the incident reporting form as well as what to do with the completed form (71.8%; 70.6%, respectively) However, 20.4% and 23.8% answered ‘‘not quite sure’’ on how to locate or access the incident form and what to do with the completed incident form, respectively

	Incident Reporting Questionnaire (adapted from the study by Evans et al., 2006)	The following statements were the most perceived barriers towards incident reporting: ‘‘If I report something, I never get any feedback on what action is taken’’ (M=3.67, SD= 1.192); ‘‘When the incident does not eventuate or a correction was made then I don't see any point in reporting it’’ (M=3.16, SD=1.241) and ‘‘Adverse incident reporting is unlikely to lead to system changes that will improve the quality of care’’ (M=3.12, SD=1.264) Participants identified/described other perceived barriers towards incident reporting in the open-ended question such as ‘‘disappointment due to lack of feedback’’ (N= 21) and ‘‘blame culture and labelling’’ (N= 18) Findings showed significant differences in the use of incident reporting between nurses in different grades, years of experience and level of education ‘‘Patient falls’’ were the most common incident reported whereas, ‘‘near misses in drug errors’’ were the least incident reported
Petrova et al. (2010) To identify nurses’ perceptions of medication errors including determining perceptions of factors that contribute to errors, barriers to incident reporting and identify possible preventive measures	Eight medical wards in the state general hospital Nurses Participants (N)= 38/43 (convenience sample) Response rate= 88% Quantitative (descriptive) cross-sectional study Self-administered questionnaire (adapted from Wakefield et al., 1996 and Osborne et al., 1996; as cited in Petrova et al., 2010)	The most frequent factors relating to medication errors were nurses’ tiredness and exhaustion (37%) and illegible handwriting (29%) Poor communication between physicians and nurses (M=4.82, SD=1.136) as well as inadequate staffing levels (M=4.68, SD=1.526) had the highest mean values indicating that, nurses considered these factors as most likely to contribute to the occurrence of medication errors Perceived barriers to incident reporting included fear of blame (M=5.29, SD=1.011) and administration focusing on the individual rather than the system as a potential cause of error (M= 5.34, SD=0.966)

Teuma Custo (2016) To test a theoretical framework addressing relationships among safety climate dimensions and their impact on safety performance in intensive care units in Malta	Intensive Care Units in MDH Doctors, nurses, midwives and physiotherapists Participants (N)= 215/260 Response rate= 82.7% Quantitative (descriptive and analytical) cross-sectional study Survey on Patient Safety Climate	Overall, findings from the study supported the theoretical framework and the following generated hypothesis; ‘‘the higher the extent to which safety procedures are perceived as suitable to the intensive care units’ daily work demands and processes, the lower the intensive care units’ clinical incidents’’ (r = -0.269, *p*= ≤ 0.01) and ‘‘the higher the extent to which safety information flow is perceived as clear and unambiguous to the intensive care units’ daily work demands and processes, the lower the intensive care units’ clinical incidents’’ (r = -0.295, *p*= ≤ 0.01) Findings also partially supported the hypothesis stating; ‘‘managerial safety practices mediate the relationship between safety procedure suitability, safety information flow, and clinical incidents’’ (*p*= 0.009, *p*= 0.014 respectively) and ‘‘priority of safety mediates the relationship between safety procedure suitability, safety information flow, managerial safety practices and clinical incidents’’ (*p*= 0.002, *p*= 0.002, *p*= 0.042 respectively)
Zammit (2008; as cited in Mallia et al., 2009) To establish the first patient safety culture assessment in Malta, essential for benchmarking purposes	MDH Stratified representative sample of 400 employees Face to face interview method SOPS	The main safety culture strengths identified were ‘‘communication openness’’ (65%; MDH percentile 50th – 75th) and ‘‘handovers and transitions’’ (44%; MDH percentile 50th – 75th) whereas the amongst areas identified for improvement was ‘‘frequency of events reported’’ (29%; MDH percentile <10th)
Zammit & Borg (2008; as cited in Mallia et al., 2009) To analyse the safety perceptions and attitudes of employees working in	All nursing homes for older people in Malta and Gozo (Government, Church, Private and Public-Private Partnership) 431 healthcare workers	Overall, participants reported a positive attitude towards patient safety The major concern in all settings was lack of ‘‘staffing’’ 77%, 79%, 85% and 95% of state, private-public partnership, private and church healthcare workers respectively, reported that they would recommend the nursing home to their relatives or friends

nursing homes in Malta and Gozo	Face to face interview method SOPS (nursing home)	

2.6 Conclusion

In conclusion, this chapter discussed some of theoretical frameworks surrounding safety climate and safety culture as well as delved into the process of conducting a comprehensive literature search that guided the researcher to explore recent, relevant research articles. The included studies were thoroughly appraised using appropriate critical appraisal tools. Findings from the CAT emphasise the importance of fostering a positive safety culture for effective incident reporting, particularly in the context of feedback and communication about errors. Finally, this chapter outlined research surrounding patient safety, safety culture and safety climate conducted in a local context.

Chapter 3: Methodology

3.1 Introduction

This chapter describes the methodology that was employed in this research study. The chapter presents the research questions as well as the aims and objectives of the research study. Operational definitions of the terms utilised are provided. This is followed by a detailed description of the research design, including the research philosophy, methodological choice, sampling strategies and data collection instruments. Validity and reliability issues, the pilot study and subsequent modifications, the process of data collection, data triangulation and data analysis are also described. Finally, ethical considerations and approvals sought prior to the commencement of the research study are outlined.

3.2 Research Questions

The main research questions for this present study are as follows:

- How do healthcare professionals working in oncology healthcare settings in Malta perceive patient safety culture?
- Are different healthcare professional groups working in oncology healthcare settings in Malta aligned on their perceptions of patient safety culture?
- What is the relationship between safety culture dimensions and reporting of patient safety events?

3.3 Aims and Objectives

For the purpose of this proposed study, the psychological factors represented in Cooper's (2000) adaptation of Bandura's Reciprocal Determinism Model (1977) were measured through a safety culture questionnaire and focus group interview to understand attitudes and perceptions of healthcare professionals related to safety in oncology healthcare settings in Malta. The aim of this research study was twofold: This research study aimed to explore the perceptions of different healthcare professionals of patient safety culture in oncology healthcare settings in Malta. Moreover, this research study aimed to investigate the relationship between safety culture dimensions and safety-related behaviour specifically, reporting of patient safety events.

The objectives of this research study sought to:

- Identify and compare differences and similarities in perceptions of safety culture across different healthcare professional groups working in oncology healthcare settings in Malta
- Explore associations between healthcare professionals' perceptions of safety culture and socio-demographic characteristics
- Investigate the relationship between dimensions of safety culture as manifested through healthcare professionals' perceptions and their impact on reporting of patient safety events
- Compare the findings with published international data as well as with similar local research in other contexts
- Based on the findings, to propose recommendations for practice, healthcare systems management and research

3.4 Operational Definitions

Individuals may have different understandings or interpretation of how key terms or concepts are used in research, which could lead to confusion or miscommunication. Therefore, it is fundamental to outline operational definition in research in a clear, concise and detailed manner. The key concepts that are investigated in this research study are as follows:

- **Perceptions of Safety Culture –** within the framework of the Reciprocal Safety Culture Model by Cooper (2000), ''perceptions of safety culture'' refers to the healthcare professionals' subjective and self-reported internal psychological factors regarding the safety-related norms, practices and values within their organisation (i.e., a perceptual audit)
- **Patient Safety Event –** is defined as any form of healthcare-related incident, error or mistake, irrespective of whether or not it leads to patient harm (Agency for Healthcare Research and Quality, 2021)
- **Incident Reporting –** is defined as a formal recording or documentation of the facts surrounding an occurrence that took place in a hospital setting, for instance: patient injury (WHO, 2005)

3.5 Research Philosophy

Creswell and Creswell (2018) suggest that the research paradigms or philosophical worldviews that the researcher adopts, are made explicit in their research. Research paradigms are based on a set of basic belief systems or standpoints known as ontology, epistemology and methodology (Gubba, 1990). The answer to the ontological, epistemological and methodological questions are considered the starting point of research, and these determine the approach the researcher adopts and guide action (Gubba, 1990). In this research study, a pragmatist research philosophy was adopted. As a philosophical movement, pragmatism began in the United States in late 19th century and its origin is often attributed to the American philosophers Charles Sanders Peirce, William James, George Herbet Mead and John Dewy (Creswell & Creswell, 2018). Understandings of pragmatism as a philosophical school have shifted throughout the years. The following paragraphs highlight some of pragmatism's general characteristics, keeping in mind the risk of over-simplifying the research philosophy.

Tashakkori and Teddlie (2003) define pragmatism as ''a deconstructive paradigm that debunks concepts such as 'truth' and 'reality' and focuses instead on 'what works' as the truth regarding the research questions under investigation. Pragmatism rejects the either/or choices associated with the paradigm wars, advocates for the use of mixed methods in research, and acknowledges that the values of the researcher play a large role in interpretation of results''. As explained by Feilzer (2009), pragmatism ''orients itself towards solving practical problems in the real world''.

Pragmatism, as a research paradigm, is not committed to one philosophy nor it attains any superiority of a single philosophical assumption (Creswell & Creswell, 2018; Kaushik & Walsh, 2019). According to Johnson and Onwuegbuzie (2004), pragmatism seeks the middle ground between philosophical scepticism and dogmatisms. Pragmatism advocates using whatever methodological approach works best for the research problem. In fact, it has been stated as the ''dictatorship of the research question'' (Tashakkori & Teddlie, 2003).

Pragmatist researchers focus on the research problem and draw liberally from both quantitative and qualitative assumptions, utilising all approaches available to understand that problem

(Creswell & Creswell, 2018). Therefore, pragmatist researchers reject traditional dualisms (Robson & McCartan, 2016). As stated by Robson and McCartan (2016), researchers should not ‘‘be the prisoner of a particular method or technique’’. In pragmatism, concern exists with application, that is, what works, as well as with solutions to problems (Creswell & Creswell, 2018), endorsing pluralism and eclecticism (Robson & McCartan, 2016). Consequently, and not surprisingly, pragmatism has been hailed as the foundation of mixed methods research (Pansiri, 2005).

In addition, pragmatist researchers believe that reality is not static (Kaushik & Walsh, 2019) and refute the idea that truth or reality can ever be determined once and for all (Pansiri, 2005). In a pragmatic approach, we are finding the provisional truth, not the ultimate one. What we understand now, may be different in the future. Therefore, pragmatism also endorses fallibilism. That is, current beliefs and conclusions are never viewed as absolute or certain (Robson & McCartan, 2016).

3.6 Methodological Choice

In this research study, mixed methods research was used. From the late 19th century up until the mid-20th century, quantitative research was recognised as the dominant methodology. However, by the second half of the 20th century, there was increased interest and use of qualitative research (Creswell & Creswell, 2018). This created a divisive dispute between academics and researchers, known as the paradigm wars. As a result, purists who believed in paradigm singularity emerged on both sides, arguing that their research approach is superior and that the two approaches could not be used together in view of the difference philosophies associated with them (Kwadwo Antwi & Kasim, 2015).

As the dispute evolved, the mixed methods research approach emerged, variously referred to as the third methodological movement (Tashakkori & Teddlie, 2003), the third path (Gorard & Taylor, 2004), the third research paradigm (Johnson et al., 2007) and the third research community (Teddlie & Tashakkori, 2009). Some researchers argued that both quantitative and qualitative paradigms, with their inherit methods, have their strengths as well as weaknesses and thus, these should be used in tandem to complement each other (Campbell & Fiske, 1959;

Cook & Reichardt, 1979; Sieber, 1973). However, the use of both quantitative and qualitative methods in a single study divided some researchers and was still the subject of controversy. Rossman and Wilson (1985) outlined three different of researchers' perspectives about mixed methods research: purists, situationalists and pragmatists. Purists believe in the dichotomy of research paradigms. Purists argue that quantitative and qualitative approaches derive from different and mutually exclusive ontological and epistemological assumptions. Therefore, according to purists, the two approaches cannot be combined. That is, a synthesis of the two approaches is not possible. The situationalist-view occupies the middle ground. Situationalists believe that both quantitative and qualitative approaches may be used in a single study. However, they do not support integration of the two approaches. That is, each approach is used for different phases of the research or questions within a single study and results are not integrated. On the other hand, pragmatists argue for the integration of methods in a single study. Pragmatists argue that either method can be used to corroborate, elaborate, or initiate findings from the other method (Rossman & Wilson, 1985). Sieber (1973) outlines how quantitative and qualitative approaches can contribute to one another, summarising the case for mixed methods research. As stated by Sieber (1973), while both quantitative and qualitative approaches have their respective strengths, they also have weaknesses which may be overcome by combining both approaches within a single study.

3.6.1 Mixed Methods Research and Patient Safety Culture

Literature highlights the limitations of relying solely on questionnaires for assessing organisational safety culture and emphasises the need for complementary methods to understand the safety culture (Brown et al., 2008; Guldenmund, 2007; Halligan & Zecevic, 2011; Runciman et al., 2008; Waterson, 2014). Despite this, quantitative questionnaires have been the dominant research tool for investigating safety culture in healthcare (Churruca et al., 2021; Halligan and Zecevis, 2011). Halligan and Zecevis (2011) reviewed 139 studies on safety culture in healthcare and found that only 14 studies used a qualitative approach. Similarly, a recent systematic review found that 663 out of 694 studies of safety culture in healthcare exclusively used questionnaires whereas only 31 studies used a qualitative or mixed methods approach (Churruca et al., 2021). Churruca and colleagues (2021) concluded that quantitative questionnaires should be combined with qualitative methods to evaluate such a multi-faceted construct. Moreover, Churruca et al. (2021) points out that this widespread and exclusive use

of quantitative questionnaires to assess the safety culture in healthcare contexts is contrasting with other industries where a mixed methods approach is often applied.

According to Waterson (2014), it is often not possible to understand why healthcare professionals think the way they do from questionnaire results alone. Triangulation of quantitative and qualitative methods is recommended to gather a more accurate understanding (O'Conner et al., 2011; Waterson, 2014). As a result, a pragmatic philosophical, mixedmethods research approach was employed to best address the present research issue and questions.

3.6.2 Mixed Methods Design

A popular classification of purposes of mixed methods research was first introduced by Greene and colleagues (1989), based on their analysis of 57 empirical mixed methods studies. Greene et al. (1989) identified five distinct purposes for mixed methods research namely, triangulation, complementarity, development, initiation and expansion. In the following page, Table 3.1 illustrates and described these purposes and respective rationale for their application (Table 3.1)

As mixed methods research continued to gain momentum, different designs emerged. Tashakkori and Teddlie (2003) noted that nearly 40 different types of mixed method designs are reported in the literature. Creswell (2014) identified six common designs in mixed methods research that fall into two main groups: concurrent and sequential mixed method designs, based on the time and type of data collection and integration. These six designs are also classified into two levels: basic and advanced mixed method designs. The advanced designs are primarily combinations of the basic design. The three basic designs, which are incorporated in the advanced designs, are as follows: convergent, explanatory sequential, and exploratory sequential. These designs are illustrated in Figure 9.

Table 3.1: Mixed Method Designs, adapted from Greene et al. (1989)	
Design and Purpose	**Rationale**
Triangulation: Seeks convergence, corroboration, correspondence of results from the different methods	To increase the validity of constructs and inquiry results by counteracting or maximising the heterogeneity of irrelevant sources of variance attributable especially to inherent method bias but also to inquirer bias, bias of substantive theory and biases of inquiry context
Complementarity: Seeks elaboration, enhancement, illustration and clarification of the results from one method with the results from the other method	To increase the interpretability, meaningfulness, and validity of constructs and inquiry results by both capitalising on inherent method strengths and counteracting inherent biases in methods and other sources
Development: Seeks to use the results from one method to help develop or inform the other method, where development is broadly construed to include sampling and implementation as well as measurement decisions	To increase the validity of constructs and inquiry results by capitalising on inherent method strengths
Initiation: Seeks the discovery of paradox and contradiction, new perspectives of frameworks and the recasting of questions or results from one method with questions or results from the other method	To increase the breadth and depth of inquiry results and interpretations by analysing them from the perspectives of different methods and paradigms
Expansion: Seeks to extend the breadth and range of inquiry by using different methods for different inquiry components	To increase the scope of inquiry by selecting the methods most appropriate for multiple inquiry components

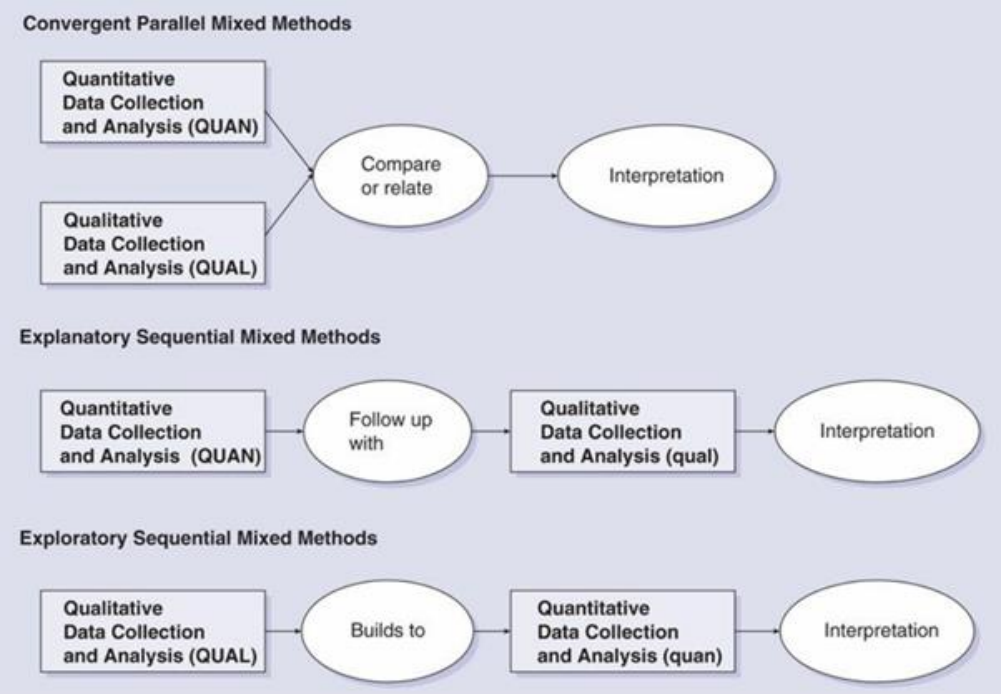

Figure 9: Three Basic Mixed Methods Designs (Creswell, 2014)

3.6.3 The Employed Mixed Methods Design

This research study employed a concurrent triangulation strategy. In a concurrent triangulation approach, quantitative and qualitative data are collected concurrently. Subsequently, these are compared to determine if there is convergence or differences. This comparison is sometimes referred to as confirmation, disconfirmation, cross-validation or corroboration (Creswell & Creswell, 2018). The purpose of this approach is to overcome a weakness inherent in using one method with the strengths of another. While ideally the weight between the quantitative and qualitative methods is equal, it is often impractical and thus, priority may be given to one form of data over the other (Creswell, 2014).

This traditional mixed methods strategy is advantageous as it provides a comprehensive understanding of the research problem by triangulating the findings from both methods as well as increases the validity and reliability of the research results, overcoming the limitations of each method. A concurrent triangulation strategy also allows for the exploration of multiple perspectives, which can aid in identifying factors which could have been overlooked using a

single method. On the other hand, the process of integrating the findings from the two different methods can be challenging and complex (Creswell & Creswell, 2018).

According to Guest and Fleming (2015), there are three important, interrelated dimensions with regards to the integration of quantitative and qualitative date namely, timing, weighting, and purpose. These will be further discussed in the following subsections.

- **Timing**

Timing refers to the temporal relationship between the quantitative and qualitative methods in mixed methods research and can be either concurrent or sequential. Concurrent timing refers to when quantitative and qualitative methods are implemented during a single phase of a study. Conversely, sequential refer to when quantitative and qualitative methods are implemented in two distinctive phases. That is, sequential timing entails using (collecting and analysing) one type of data before using the other data type (Guest & Fleming, 2015). As described above, this research study employed a concurrent triangulation strategy. Therefore, quantitative data and qualitative data were collected and analysed in a parallel manner.

- **Weighting**

In addition to choosing the timing, researchers also need to take into account the relative weight of the quantitative and qualitative approaches in the study. Weight refers to the importance or priority assigned to each method in answering the research question/s. Numerous considerations effect the weight or priority of quantitative and qualitative approaches in a study. Morse (1991) suggests that the research philosophy used to guide the study determines its weighting. For instance, a post-positivist research philosophy requires a quantitative priority, a naturalistic research philosophy requires a qualitative priority whereas a pragmatic research philosophy is dependent on the research question and calls for either equal or unequal priority. Furthermore, Creswell (2003) suggest that practical considerations also influence weighting. That is, more resources are required to conduct a research study that gives equal weighting or priority to quantitative and qualitative methods. Therefore, in view of limited resources, a researcher may choose to give weight to one method and devote fewer resources to the

secondary method. In this research study, significant consideration was given to the quantitative approach due to various practical and contextual factors. The decision to prioritize the quantitative method was influenced by the inherent challenges associated with collecting qualitative data, given the sensitive nature of the research study topic.

- **Purpose**

There can be multiple purposes for employing a mixed methods approach in a research study, as outlined in Table 3.1. In this research study, a mixed method research approach was employed to compare the two datasets (i.e., triangulation) and interpret whether there is convergence, divergence, or contradiction. Furthermore, it was anticipated that the use of qualitative data would provide detailed insights into safety culture that would be difficult to capture using quantitative data alone.

3.7 Procedure (Quantitative Data)

3.7.1 Sampling

The target population is defined as the entire population that the researcher is interested in and to whom the researcher would like to generalise the results of the study (Polit & Beck, 2010). The target population for this study comprised all full-time and part-time healthcare professionals and management who have been working at SAMOC for at least 6 months. Healthcare professionals and management included the following: consultant, resident specialist, higher/basic specialist trainee, pharmacist, pharmacist technician, chief nursing manager, senior nursing manager, deputy/charge nurse, practice/focal nurse, staff nurse, enrolled nurse, radiographer (therapeutic and/or diagnostic), physiotherapist, occupational therapist, phlebotomist/phlebotomy technician, care worker, senior/health carer. A detailed inclusion and exclusion criteria that defines the population's characteristics is presented in Table 3.2.

Table 3.2: Inclusion and Exclusion Criteria for Participants for the Study	
Inclusion	**Exclusion**
Healthcare professionals and management i.e., consultant; resident specialist; higher/basic specialist trainee; pharmacist; pharmacist technician; chief nursing manager; senior nursing manager; charge nurse; deputy charge nurse; practice nurse; focal nurse; staff nurse; enrolled nurse; radiographer (therapeutic and/or diagnostic); physiotherapist; occupational therapist; phlebotomist/phlebotomy technician; care worker; senior/health carer	Support hospital staff (e.g., security; unit clerk; receptionist), medical and health sciences students were excluded
Working in SAMOC in Malta for at least 6 months i.e., haematology ward (adult ward); palliative care unit (adult ward); oncology ward 1 (adult, female oncology ward); oncology ward 2 (adult, male oncology ward); rainbow ward (paediatric haematology and oncology ward); day care unit (adult); oncology outpatients; oncology radiotherapy department; radioisotope unit; chemotherapy reconstitution area; phlebotomy clinic; administration/management offices	Healthcare professionals and management working in other hospitals were excluded Healthcare professionals and management working in SAMOC for less than 6 months were also excluded in view of the limited exposure to the existing safety culture
Over the age of 18 years	Under the age of 18 years
No restrictors were applied on hours of work (e.g., part-time employment or full-time employment)	
No restrictors were applied on other demographic characteristics (e.g., nationality or education level)	
No restrictors were applied to grade or seniority level	

- **Sampling for the Questionnaire**

A total population sampling strategy, or census sampling, was employed to recruit participants for the questionnaire-part of the study. Total populating sampling involves including the whole population with a particular set of characteristics in the research study (Glen, 2018). Despite being a non-probability sampling method, total population sampling greatly reduces sampling bias since it includes all available subjects (Polit & Beck, 2017). Sampling bias is defined as the distortion that arises when a sample is not representative of the population. This occurs when there is an overrepresentation or underrepresentation of some attributes or characteristics of the population from which the sample is drawn (Polt & Beck, 2010). Therefore, a total population sampling method was deemed most appropriate for the present research study.

Following approval from the Data Protection Officer at MDH, the Human Resources Department at SAMOC was contacted. A total of 239 healthcare professionals and management who fit the inclusion criteria (Table 3.2) were invited to participate in the questionnaire study by an intermediary. Given that this sample reflected all healthcare professionals and management working in SAMOC, a sample size calculation was not required.

3.7.2 Self-Administered Questionnaire

Quantitative data was collected through a structured self-administered questionnaire. A structured questionnaire involves the use of fixed or standardised questions which are presented to the participants in the same manner. The use of structured questionnaires in research has various advantages including ease of data collection and analysis. Moreover, structured questionnaires are relatively cost-effective and allow researchers to collect unambiguous data from a large sample of participants (Bowling, 2014). In addition to this, questionnaires tend to be less time consuming and do not have time constraints. That is, respondents can complete the questionnaires when pleased, provided that the deadline is met. Questionnaires are also considered to be non-threatening and less intrusive and offer the possibility of anonymity. Anonymity may be crucial, especially when seeking information on unconventional behaviour (Polit & Beck, 2010). Furthermore, findings from structured questionnaires are not at risk of interviewer bias. Interviewer bias occurs when the interviewer, subconsciously or consciously, influences participants to respond in a certain way (Polit & Beck, 2010).

However, there are also a number of disadvantages to using structured questionnaires in research. According to Bowling (2014), the pre-coded responses in structured questionnaires may not be sufficiently comprehensive. Therefore, in view of the inflexible nature of structured questionnaires, not all answers may be easily accommodated and some respondents may be forced to choose (an inappropriate answer) a pre-coded response that does not fully represent their views. On the other hand, qualitative data collection methods such as interviews may elicit more in-depth information.

The questionnaire was administered in paper form. The use of electronic or online questionnaires as a data collection method is increasing. The proliferation of using electronic

questionnaires may be attributed to several inherent advantages including reduced costs, shorter time required for implementation and ease of data analysis (Wu et al., 2022). However, while online questionnaires are efficient, evidence suggests that response rates are lower when compared to paper questionnaires (Meyer et al., 2022; Palmen et al., 2016). Nonresponse bias stemming from low response rates can lead to biased results if there are differences in characteristics between participants and individuals who declined/refused to participate (Safdar et al., 2016; Bowling, 2014). This study was conducted in a relatively small organisation. Therefore, it was anticipated that logistically, the paper questionnaire distribution and data analysis would be manageable.

The questionnaire was divided into clearly defined sections and was printed clearly and professionally so that it is visually easy to read and comprehend, as suggested by Bowling (2014). A questionnaire information letter covering the details of the research study was also attached to the questionnaire (Appendix C). The information letter was adapted from the sample documents provided by the UM and reflects the requirement of the UM's Research Code of Practice on the information to be provided when obtaining informed consent from research participants. This was given to all sample members to keep for reference. The cover letter highlighted the aims and benefits of the study as well as emphasised the anonymity of the questionnaire.

3.7.3 Hospital Survey on Patient Safety Culture (SOPS)

Several questionnaires are available to measure patient safety culture. For this reason, it was decided to adopt one of the existing safety culture questionnaires to allow for comparison across other studies. As shown in Table 2.7, the Hospital Survey on Patient Safety Culture (SOPS) by the Agency for Healthcare Research and Quality (AHRQ, 2021) is one of the most commonly utilised instruments.

The SOPS was first published in 2004 in the United States by the AHRQ. Since its development, the SOPS has been widely applied to hospitals around the world and has been translated to multiple languages (e.g., Hedsköld et al., 2013; Lee & Dahinten, 2021). The tool has also been adapted to other various settings namely community pharmacies (AHRQ, 2013a), medical offices (AHRQ, 2013b), nursing homes (AHRQ, 2012) and ambulatory surgery centres (AHRQ, 2015). The decision to utilise the SOPS questionnaire (2021) for measuring patient safety culture in this study was based on its level of use, established sound psychometric properties (AHRQ, 2020), as well as widespread use across different healthcare settings globally, including oncology settings (e.g., Sharp et al., 2019; Shu et al., 2015). The adoption of a well-established instrument like SOPS, allows for comparability with existing published literature and facilitates benchmarking with other healthcare organisations.

The questionnaire was utilised to elicit perceptions of patient safety culture from different healthcare professionals in oncology healthcare settings in Malta. Permission to use the tool was sought and granted from the AHRQ (Appendix E). The original English version questionnaire was adopted. All healthcare professionals in Malta read for their undergraduate degree in English or were required to be fluent in the English language prior to their employment. Therefore, translation from English to Maltese or other languages was deemed unnecessary. To avoid misinterpretation, the terms ‘‘Patient Safety’’ and ‘‘Patient Safety Event’’ were defined.

The SOPS was first released in 2004 in the United States by the AHRQ ‘‘for providers and other staff to assess patient safety culture in their hospitals’’. In 2019, the AHRQ released a new updated version. Since its development, the SOPS has been widely applied to hospitals

around the world and has been translated to multiple languages (e.g., Hedsköld et al., 2013; Lee & Dahinten, 2021). The tool has also been adapted to other various settings namely community pharmacies (AHRQ, 2013a), medical offices (AHRQ, 2013b), nursing homes (AHRQ, 2012) and ambulatory surgery centres (AHRQ, 2015).

In total, the SOPS consists of thirty-four items (excluding items on participants' socio-demographic characteristics) related to 12 dimensions within a hospital. The item statements pertaining to each dimension are presented in following tables (see Table 3.3 and Table 3.4) and are categorised as safety culture dimensions at unit or hospital level and safety culture outcomes. Overall, the questionnaire uses a five-point Likert scale ranging either from ''strongly disagree'' to ''strongly agree'' or ''never'' to ''always'', depending on the dimensions. In addition, the questionnaire also assesses the frequency of ''reporting patient safety events'' with two item-measures as well as two single-item measures inquiring about the number of safety events the respondents have reported in the past 12 months ranging from ''none'' to ''11 or more'' as well as an overall rating on patient safety in their work area ranging from ''poor'' to ''excellent''. The SOPS also collects background information on participants, namely staff position, unit/work area, direct interaction or contact with patients, work hours, work tenure and unit tenure.

Finally, in addition to the quantitative questions, the questionnaire concludes with a section for open-ended comments or suggestions. This allows respondents the opportunity to provide feedback on current practices or propose improvements that impact patient safety. Open-ended questions allow respondents to express their thoughts in their own words without restricting their answer to a preestablished response alternative. Therefore, bias resulting from the inflexible nature of structured questionnaires and closed-ended questions is minimised. On the other hand, there are also a few drawbacks associated with open-ended questions and comments in questionnaires. Open-ended questions can be time-consuming to be fill in. Respondents may be unwilling to write responses to open-ended questions and these will likely be ignored. In addition, respondents may feel intimidated to fill in open-ended questions due to the sensitivity of the topic.

Table 3.3: Safety Culture Dimensions Measured by the SOPS Questionnaire, Associated Questionnaire Items and Questionnaire Reliability Statistics (Based on Pilot Test Data by the AHRQ)								
Teamwork 0.76	Staffing and Work Pace 0.67	Organizational Learning; Continuous Improvement 0.76	Response to Error 0.83	Supervisor/Manager Support for Patient Safety 0.77	Communication about Error 0.89	Communication Openness 0.83	Handoffs and Information Exchange 0.72	Hospital Management Support for Patient Safety 0.77
In this unit, we work together as an effective team	In this unit, we have enough staff to handle the workload	This unit regularly reviews work processes to determine if changes are needed to improve patient safety	In this unit, staff feel like their mistakes are held against them (r)	My supervisor, manager, or clinical leader seriously considers staff suggestions for improving patient safety	We are informed about errors that happen in this unit	In this unit, staff speak up if they see something that may negatively affect patient care	When transferring patients from one unit to another, important information is often left out (r)	The actions of hospital management show that patient safety is a top priority
During busy times, staff in this unit help each other	Staff in this unit work longer hours than is best for patient care (r)	In this unit, changes to improve patient safety are evaluated to see how well they worked	When an event is reported in this unit, it feels like the person is being written up, not the problem (r)	My supervisor, manager, or clinical leader wants us to work faster during busy times, even if it means taking shortcuts (r)	When errors happen in this unit, we discuss ways to prevent them from happening again	When staff in this unit see someone with more authority doing something unsafe for patients, they speak up	During shift changes, important patient care information is often left out (r)	Hospital management provides adequate resources to improve patient safety
There is a problem with disrespectful behaviour by	This unit relies too much on temporary,	This unit lets the same patient safety problems keep happening (r)	When staff make errors, this unit focuses on learning rather	My supervisor, manager, or clinical leader takes action to address patient safety concerns that	In this unit, we are informed about changes that are made	When staff in this unit speak up, those with more authority are open to	During shift changes, there is adequate time to exchange all	Hospital management seems interested in patient safety

those working in this unit (r)	float, or PRN staff (r)		than blaming individuals	are brought to their attention	based on event reports	their patient safety concerns	key patient care information	only after an adverse event happens (r)
	The work pace in this unit is so rushed that it negatively affects patient safety (r)		In this unit, there is a lack of support for staff involved in patient safety errors (r)			In this unit, staff are afraid to ask questions when something does not seem right (r)		

Table 3.4 Outcome Measures		
Reporting Patient Safety Events .75	Number of Events Reported Single item response	Patient Safety Rating Single item response
When a mistake is caught and corrected before reaching the patient, how often is this reported?	In the past 12 months, how many patient safety events have you reported?	How would you rate your unit/work area on patient safety?
When a mistake reaches the patient and could have harmed the patient, but did not, how often is this reported?		

3.7.4 Questionnaire Pilot Study and Modifications

A pilot study is defined as a small-scale preliminarily study, or trial run, carried out to test methods and procedures (e.g., data collection instructions and sample recruitment strategies) for their feasibility and suitability, in preparation for the main study (In, 2017). Prior to conducting the main research study, a pilot study was conducted. Nine healthcare professionals were asked to complete the questionnaire. These consisted of two higher specialist trainees, one charge nurse, one practice nurse, three staff nurses and two health carers. The main issue pointed out from the pilot was that reverse score items (e.g., ‘‘In this unit, there is a lack of support for staff involved in patient safety errors’’) could be confusing. However, as explained by Polit and Beck (2010), negatively worded items are important to minimise acquiescence response set bias and therefore, reverse score items were retained. Moreover, question 2 (i.e., ‘‘Think of your ‘unit’ as the work area, department, or clinical area of the hospital where you spend most of your work time. What is your primary unit or work area in this hospital?’’) was eliminated from the questionnaire. As the setting is a relatively small hospital, with 239 staff members who fit the criteria, removal of this question was deemed necessary to ensure anonymity of the participants as well as to maintain the participants’ trust and willingness to participate in the study.

3.7.5 Data Analysis

The data collected from the quantitative questionnaire was inputted in Statistical Package for Social Sciences (IBM SPSS) Version 28. Reverse scoring of negatively worded questions was carried out. The internal consistency of the questionnaire, that is the degree of correlation between different questionnaire items pertaining to one dimension, was measured using the Cronbach’s alpha coefficient and is presented below (Table 3.5). The coefficient alphas for the present study ranged between 0.680 and 0.908. Given that these values were close to or above 0.70, the instrument was deemed reliable. While there is no agreement over the minimum acceptable standards for Cronbach’s alpha for scale reliability, many regard 0.70 as the minimally acceptable level for internal consistency reliability (Bowling, 2014). Descriptive analysis through the use of frequencies and percentages was carried out for demographic data. The Shapiro Wilk test was used to determine whether a score distribution is normal or skewed (non-normal), which indicated that all the ten score distributions were skewed. In view of this, a non-parametric test, specifically the Friedman test was used to compare mean dimension

scores. Following this, the Kruskal Wallis test was used to compare mean dimension scores across healthcare professional groups and other socio-demographic characteristics. Furthermore, the Spearman correlation was used to analyse the relationship between safety culture dimensions and reporting of patient safety events while a parsimonious model which included solely the significant predictors was applied to analyse the predictors collectively.

In addition, percent positive scores of the SOPS questionnaire were also derived to allow for comparison with the SOPS hospital database report (Hare et al., 2022). In summary, this involved determining how respondents answered the questionnaire items as either "strongly agree" or "agree" for positively worded questions and "strongly disagree" or "disagree" for negatively worded questions and deriving an average for each dimension measure. This provided an aggregated view of the positive responses for each dimension in the questionnaire. Finally, responses and comments to the open-ended question were manually extracted into a Microsoft Word document. Subsequently, thematic analysis was carried out to analyse the qualitative data obtained from the questionnaire. This entailed identified common themes or patterns, as well as any inconsistencies (Polit & Beck, 2010).

Table 3.5: Internal Consistency of the Questionnaire in the Present Study

Dimension	**Number of Items**	**Cronbach's Alpha Coefficient**	**Published Cronbach's Alpha (AHRQ, 2021)**
Teamwork	3	0.715	0.76
Staffing and Work Pace	4	0.856	0.67
Organisation Learning – Continuous Improvement	3	0.757	0.76
Response to Error	4	0.875	0.83
Supervisor/Manager Support for Patient Safety	3	0.742	0.77
Communication about Error	3	0.908	0.89
Communication Openness	4	0.680	0.83
Handoffs and Information Exchange	3	0.832	0.72
Hospital Management Support for Patient Safety	3	0.826	0.77
Reporting Patient Safety Events	2	0.851	0.75

3.8 Procedure (Qualitative Data)

3.8.1 Sampling

Purposive sampling was employed to recruit participants for the second phase of the study. Purposive sampling, sometimes also referred to as purposeful or judgemental sampling, is a nonprobability sampling technique widely used in qualitative research, in which the researcher deliberately chooses participants that will best contribute to the information needs of the study (Polit & Beck, 2010). In other words, participants are selected 'on purpose' because they have knowledge that can contribute to the research process, e.g., sample of experts in a case study of an organisation (Bowling, 2014). Various purposive sampling strategies exist such as, maximum variation sampling, sampling confirming and disconfirming cases, typical case sampling, extreme case sampling and criterion sampling (Polit & Beck, 2010). Specifically, maximum variation sampling was employed to recruit participants in the focus group interview. This involved deliberately selecting a diverse range of healthcare professionals in order to capture a broad spectrum of perspectives. Specifically, the focus group interview comprised of 4 nursing, 2 allied healthcare professionals and 1 health carer working in an oncology healthcare setting in Malta for at least 6 months and who are over the age of 18 year.

3.8.2 Focus Group Interview

Individuals develop perceptions and attitudes about any specific construct in relation to their environment, in interaction with other individuals, not in isolation. Safety culture is also a concept that is developed through understanding and making sense of our environment. The policies, procedures and behaviours of others hold a significant role in shaping our own perceptions. In this respect, conducting a focus group is considered a valuable data collection method as it allows the researcher to investigate the participants' different perspective as they take part in a social network and examine the factors that contribute to participants' articulation of opinions (Waterson, 2014).

A focus group is a small group of individuals in the target group of interest, brought together to discuss, or focus on, a specific topic or research issue (Bowling, 2014). The essence of a focus group is the interaction between the study participants to generate the data. In other words, although focus group interviews are considered as a quick and convenient method to gather data from multiple participants simultaneously, focus groups explicitly use group interaction

as part of the method. The group processes can assist participants to explore their views and generate questions in ways that they would find more challenging in one-to-one interviews (Kitzinger, 1996). Focus group interviews have the advantage of using group dynamics to stimulate discussions, generate and explore ideas as well as gain insights in order to explore a topic in greater depth (Bowling, 2014). The focus group interview guide was developed based on the components of the SOPS questionnaire to allow triangulation of the findings and is presented in Appendix F.

The focus group interview lasted approximately two hours and was conducted in a private board room in SAMOC. The session was structured using an interview guide with open-ended questions and other probing questions, allowing participants to freely express their perspectives, while ensuring key safety culture dimensions were covered. The researcher served as the moderator, guiding, and facilitating the discussion throughout the focus group session. This involved directing participants through the conversation, prompting for deeper insights and clarification when necessary, and ensuring that all viewpoints were heard. By taking on this role, the researcher aimed to maintain the flow of the discussion and create a comfortable, private environment conducive to open dialogue.

Prior to the focus group interview, an information letter covering the details of the research study was given to all participants to keep for reference whereas written consent was obtained. The information letter as well as consent form were adapted from the sample documents provided by the UM and reflects the requirement of the UM's Research Code of Practice on the information to be provided when obtaining informed consent from research participants (see Appendix G and Appendix H, respectively).

3.8.3 Data Analysis

Strauss and Corbin (2014) describe analysis as ''... the interplay between researchers and data''. Data analysis involves the interpretation of the data by the researcher. Inevitably, to an extent, this process is influenced by the researcher's subjectivity. Since in qualitative research, the researcher is actively involved in generating, analysing and interpreting data, this subjectivity is particularly pronounced. In order to minimise the potential biases, the audio recording of the

focus group interview was transcribed and analysed alongside the notes taken during the focus group. According to Onwuegbuzie et al. (2009), a transcript-based analysis is the most rigorous as well as time-intensive mode of analysing data. Following this, content analysis was carried out, which involved identifying key themes and concepts that emerge from the transcription and categorising them (Bowling, 2014).

3.9 Ethical Considerations

All research can raise ethical issues. Approval from relevant ethics committees is required before a research study can commence. The following subsections will describe the ethical considerations taken throughout this research study.

3.9.1 Approvals Sought

The researcher sought several approvals prior to data collection (refer to original letters in Appendix I). A letter requesting permission to conduct the study in SAMOC together with a detailed research proposal, participants' information letters and data collection tools were sent either via e-mail or presented during an in-person meeting. Approval to conduct the present study was obtained from the Chief Nursing Manager and Clinical Chairperson of the Haematology and Oncology Department at SAMOC. Moreover, approval was also granted from the Data Protection Officer, Medical Director and Chief Executive Officer at MDH. Subsequently, approval was obtained from the UM's University Research Ethics Committee.

3.9.2 Informed Consent, Anonymity and Confidentiality

Obtaining informed consent is an important procedure to safeguard and protect the study participants' right to self-determination. Informed consent means that participants have been given adequate information on the purpose of the research study, what their participation would entail, that they can comprehend the information given to them and are able to consent or refuse their participation voluntarily (Polit & Beck, 2010).

For the participants' data to be completely anonymous, the researcher cannot link the participants to their data. However, anonymity is rarely possible when conducting qualitative

studies since the researchers often become involved with the participants. When anonymity of the participants is not possible, appropriate confidentiality procedures should be implemented. Polit and Beck (2010) define the promise of confidentiality in research as a pledge that any data collected from participants will not be publicly disclosed or reported in a manner that identifies them.

- **Questionnaire**

All eligible participants were approached by a delegate from the Clinical Chairperson's office, who acted as an intermediary for this study (see Appendix J). The researcher had no contact with the participants, as advised by the Data Protection Office at MDH and the UM's University Research Ethics Committee.

As mentioned, a questionnaire information letter was attached to the questionnaire. Study participants were strongly advised to read the questionnaire information letter thoroughly prior to answering the questionnaire. The information letter explained to study participants the purpose of the study and what their participation would entail. Participants were also informed that their participation was completely voluntary, and that the questionnaire was anonymous. At no point were respondents asked to provide their name or any other personal data which may lead to them being identified. Furthermore, the questionnaire information letter stated clearly that completion and return of questionnaire indicated willingness and consent to participate. Thus, written informed consent was not required.

- **Focus Group Interview**

To recruit participants for the focus group interview, the intermediary selected for this research study approached prospective participants and distributed the focus group information letters, inviting them to participate in a focus group interview (see Appendix G). Similar to the questionnaire information letters, the focus group information letter explained to prospective participants the purpose of the study and what their participation would entail. Participants were also informed that their participation was completely voluntary.

In addition, participants were informed that, should they choose to participate, data collected from the focus group interview would be pseudonymised to protect the confidentiality of the study participants. That is, the identity of the participants would not be noted on transcripts or notes, but instead, a code would be assigned. Moreover, participants were informed that they were free to withdraw from the study without needing to provide any explanation and without any negative repercussions. The researcher only approached participants when they accepted to participate in the focus group interview. Participants were also given verbal information as well as the opportunity to ask any questions about the study. Finally, study participants were asked to sign an informed consent form declaring that they understood the statements of the mentioned form and agree to participate in the study (see Appendix H).

3.9.3 Risk-to-Benefit Assessment and Minimisation of Harm

All research will involve some risks. However, in many cases, the risk is minimal (Polit & Beck, 2010). Due to the sensitive nature of the research topic/study, it was acknowledged that participation in the questionnaire or focus group may entail risks of psychological harm to study participants, however this was considered to be low.

Therefore, the Psychology Department at MDH was contacted and approval to refer study participants who require or request psychological support was obtained (see Appendix K). The service was offered free of charge and was available to all study participants who required or requested psychological support. The contact details of the Psychology Department at MDH were added to the questionnaire and focus group information letters. Moreover, to minimise any risks to participants, data collected from the questionnaire was anonymous whereas data collected from the focus group interview was pseudonymised.

3.9.4 Data Management

Data management (sharing/storing data) can also raise ethical concerns/issues.

- **Questionnaire**

To protect the confidentiality of the study participants, the intermediary distributed the questionnaire and questionnaire information letter in a blank envelope that can be sealed. In addition, unmarked boxes made purposefully to collect the questionnaires were situated in each unit in SAMOC. The questionnaires were stored securely in a locked file cabinet in a secure building.

- **Focus Group Interview**

The codes that link the data to the identity of the participants were stored securely and separately from the data, in an encrypted file on the researcher's password-protected computer. Backup of the data collected was made and was also stored in an encrypted file. Only the researcher had access to this information.

Any hard-copy materials were stored securely in a safe or locked file cabinet in a secure building. Audio recordings were not sent via email, replicated and/or uploaded in any server, cloud storage, site or any other media. Moreover, transcription software was not used to transcribe the interviews. The audio recordings were destroyed after the conversation was transcribed. Under the General Data Protection Regulation and national legislation, participants had the right to access, rectify, and where applicable, ask for the data concerning them to be erased. There were no significant costs associated with processing, storing and managing the data. All data collected will be deleted and destroyed on completion of the study and following publication of results. All data presented to the UM is completely anonymised.

3.10 Conclusion

This chapter presented a detailed overview of the methodology and ethical considerations of the present research study. The following chapter presents the data analysis and subsequent findings from the questionnaire and focus group interview.

Chapter 4: Results

4.1 Introduction

This chapter presents a comprehensive report of the main findings of this research study. The findings were collected through a self-report questionnaire (see Appendix D) and focus group interview (see Appendix F) which assessed perceptions of patient safety culture among different healthcare professionals in oncology healthcare settings in Malta. First, the response rate and demographic data are reported. The subsequent sections present an analysis of the findings, in line with the aims and objectives of this research study.

4.2 Response Rate and Demographic Data

Out of the 239 questionnaires distributed, 129 questionnaires were returned and collected from the boxes made purposefully for this study, situated in each unit in SAMOC, achieving a total response rate of 53.97%. Table 4.1 presents the total population and total response rate (frequency and percentage) across different healthcare professional groups. Enrolled nurses and staff nurses constituted the majority of the participants (N= 55) while radiographers constituted the second-largest group (N= 27). In view of the small number of higher specialist trainees (N= 4), pharmacists (N= 2) and pharmacist technicians (N= 1) who responded to the questionnaire, these were amalgamated together as one group and titled ‘others’ for statistical analyses purposes.

Table 4.2 presents the demographic characteristics of the participants. In summary, 69% of respondents were female whereas 31% of respondents were male. 43.4% of respondents were between 18 to 29 years old, 41.9% were between 30 to 49 years old while 14.7% were over 50 years old. 48.1% of respondents held a postgraduate degree, 33.3% held an undergraduate degree, 14.0% held an undergraduate diploma or advanced diploma whereas 4.7% held an undergraduate certificate. 40.3% of respondents had worked between 1 to 5 years in the oncology hospital while 34.1% had worked between 6 to 10 years, 20.2% had worked 11 or more years while 5.4% had worked less than 1 year in the oncology hospital. 57.4% of respondents had worked between 1 to 5 years in their current unit or work area, 23.3% had worked between 6 to 10 years, 10.9% had worked 11 or more years while 8.5% had worked less than 1 year in their current unit or work area.

The majority of respondents (58.1%) work more than 40 hours per week whereas 40.3% of respondents work between 30 to 40 hours per week. Only 1.6% of respondents worked less than 30 hours per week. Moreover, the overwhelming majority of respondents (94.6%) typically have direct interaction or contact with patients while 5.4% do not.

Table 4.1: Response Rates across Healthcare Professional Groups

Healthcare Professional Groups	Total Population	Response Rate
Overall	239	129 (53.97%)
Nursing		
Enrolled/Staff Nurse	100	55
Focal Nurse/Practice Nurse	16	11
Deputy/Charge Nurse	20	9
Senior/Chief Nursing Manager	4	0
Medical		
Basic Specialist Trainee	0	0
Higher Specialist Trainee	12	4
Resident Specialist	1	0
Consultant	9	0
Pharmacy		
Pharmacy Technician	5	1
Pharmacist	2	2
Allied Health/Other Clinical Position		
Care Worker/Senior/Health Carer	21	11
Phlebotomist/Phlebotomy Technician	5	0
Occupational Therapist	7	0
Physiotherapist	9	9
Radiographer (Therapeutic and/or Diagnostic)	28	27

In view of the small number of participants who held an undergraduate certificate (N= 6), these were amalgamated together with participants who held an undergraduate diploma or advanced diploma and titled as ‘undergraduate certificate, diploma or advanced diploma’. Similarly, participants who worked less than 1 year in the hospital (N= 7) and in the unit or work area (N= 11) were amalgamated together with participants who worked between 1 to 5 years in the hospital and in the unit or work area, respectively. Finally, participants who typically worked less than 30 hours a week (N= 2) were amalgamated together with participants who typically worked between 30 and 40 hours per week and titled as ‘40 hours or less per week’ for statistical analyses purposes.

Table 4.2: Demographic Characteristics of Participants		
Demographic Characteristics	**Frequency (N)**	**Percentage (%)**
Gender		
Male	40	31.0%
Female	89	69.0%
Age		
18-29 years	56	43.4%
30-49 years	54	41.9%
50+ years	19	14.7%
Education level		
Undergraduate certificate	6	4.7%
Undergraduate diploma/undergraduate advanced diploma	18	14.0%
Undergraduate degree	43	33.3%
Postgraduate degree	62	48.1%
Years of experience (hospital)		
< 1 year	7	5.4%
1 to 5 years	52	40.3%
6 to 10 years	44	34.1%
11 or more years	26	20.2%
Years of experience (unit/work area)		
< 1 year	11	8.5%
1 to 5 years	74	57.4%
6 to 10 years	30	23.3%
11 or more years	14	10.9%
Hours (typically worked) per week		
Less than 30 hours per week	2	1.6%
30 to 40 hours per week	52	40.3%
More than 40 hours per week	75	58.1%
Direct interaction/contact with patients		
Yes	122	94.6%
No	7	5.4%

4.3 Mean Analysis and Percent Positive Scores of Safety Culture Dimensions

The Shapiro Wilk test was used to determine whether a score distribution is normal or skewed (non-normal). The null hypothesis specifies that the score distribution is normal and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the score distribution is skewed and is accepted if the p-value is less than the 0.05 criterion. As shown in Table 4.3, all Shapiro Wilk p-values are smaller than the 0.05 level of significance indicating that all the ten score distributions are skewed. For this reason, non-parametric tests will be used to analyse the data further. Specifically, the Friedman test was used to compare

mean dimension scores (Table 4.4). The mean dimension scores range from 1 to 5, where 1 corresponds to ‘never’ or ‘strongly disagree’ and 5 corresponds ‘always’ or ‘strongly agree’. The null hypothesis specifies that the mean subscale scores are similar and is accepted if the pvalue is larger than the 0.05 level of significance. The alternative hypothesis specifies that the mean subscale scores differ significantly and is accepted if the p-value is less than the 0.05 criterion.

The highest mean score achieved across all dimensions was communication openness (M=4.04, SD=0.501), indicating positive perceptions of communication openness across healthcare professionals working in oncology healthcare settings in Malta. This is followed by teamwork (M=4.02, SD=0.550), handoff and information exchange (M=3.84, SD=0.630), supervisor, manager or clinical leader support for patient safety (M=3.79, SD=0.586), organisational learning and continuous improvement (M=3.49, SD=0.778), communication about error (M=3.45, SD=0.872), reporting patient safety events (M=3.22, SD=0.942), hospital management support for patient safety (M=2.92, SD=0.784), response to error (M=2.81, SD=0.714), and staffing and work pace (M=2.72, SD=0.833). These mean dimension scores vary significantly since the p-value (approx. 0) is smaller than the 0.05 level of significance.

Table 4.3: Tests of Normality

	Shapiro-Wilk		
Dimensions	Statistic	Df	P-value
Teamwork	0.897	113	<0.001
Staffing and Work Pace	0.923	113	<0.001
Organisational Learning – Continuous Improvement	0.920	113	<0.001
Response to Error	0.971	113	0.014
Supervisor, Manager or Clinical Leader Support for Patient Safety	0.955	113	<0.001
Communication about Error	0.956	113	<0.001
Communication Openness	0.961	113	0.002
Hospital Management Support for Patient Safety	0.959	113	0.002
Handoff and Information Exchange	0.866	113	<0.001
Reporting Patient Safety Events	0.955	113	<0.001

Table 4.4: Overall Means of Safety Culture Dimensions using Friedman Test

Dimensions	N	Mean	SD	Min.	Max.
Teamwork	113	4.02	0.550	2	5
Staffing and Work Pace	113	2.72	0.833	1	5
Organizational Learning – Continuous Improvement	113	3.49	0.778	1	5
Response to Error	113	2.81	0.714	1	5
Supervisor, Manager or Clinical Leader Support for Patient Safety	113	3.79	0.586	2	5
Communication about Error	113	3.45	0.872	1	5
Communication Openness	113	4.04	0.501	3	5
Hospital Management Support for Patient Safety	113	2.92	0.784	1	5
Handoff and Information Exchange	113	3.84	0.630	1	5
Reporting Patient Safety Events	113	3.22	0.942	1	5

$X^2(9) = 364.992$, p= <0.001

Additionally, the percent positive scores of each dimension were extracted to allow for benchmarking and comparison with other published literature and are presented in Table 4.5. In summary, this involved determining how respondents answered the questionnaire items as either "strongly agree" or "agree" for positively worded questions and "strongly disagree" or "disagree" for negatively worded questions and deriving an average for each dimension measure. In sum, this provided an aggregated view of the positive responses for each dimension in the questionnaire. Overall, participants held positive perceptions of ‘‘teamwork’’ (84.3 positive percent score), followed by communication openness (79.1 positive percent score), handoff and information exchange (75.5 positive percent score), and supervisor, manager or clinical leader support for patient safety (70.0 positive percent score). Conversely, participants held relatively neutral perceptions of organisational learning and continuous improvement (56.6 positive percent score), communication about error (46.6 positive percent score) and negative perceptions of reporting patient safety events (40.0 positive percent score), staffing and work pace (28.2 positive percent score), hospital management support for patient safety (27.9 positive percent score) and response to error (24.1 positive percent score).

Table 4.5: Positive Percent Scores of Safety Culture Dimensions	
Dimensions	**Positive percent score**
Teamwork	84.3
Staffing and Work Pace	28.2
Organisational Learning – Continuous Improvement	56.6
Response to Error	24.1
Supervisor, Manager or Clinical Leader Support for Patient Safety	70.0
Communication about Error	46.2
Communication Openness	79.1
Hospital Management Support for Patient Safety	27.9
Handoff and Information Exchange	75.5
Reporting Patient Safety Events	40.0

4.4 Analysis of Single-Item Measures

Results for the item asking participants to indicate the number of events they reported in the last 12 months are shown in Table 4.6. Notably, 61 participants, or 47.3% of the respondents, did not report any patient safety events in the previous 12 months while another 61 participants, or 47.3% of the respondents, reported between 1 to 2 patient safety events. Only 6 participants (4.7%) had reported 3 to 5 patient safety events whereas only 1 participant (0.8%) reported 6 to 10 patient safety events in the previous 12 months. Although the questionnaire included a ‘‘11 or more’’ category, no respondents selected this as their response.

Table 4.6: Frequency and Percentage of Number of Events Reported

Number of Events Reported	Frequency	Percent
None	61	47.3
1 to 2	61	47.3
3 to 5	6	4.7
6 to 10	1	0.8
11 or more	0	0
Total	129	100

Results for the item asking participants to indicate their perception of patient safety are shown in Table 4.7. Overall, findings revealed positive perceptions of patient safety. Most of the respondents indicated an overall perception of patient safety as ‘‘Very Good’’ (N= 71; 55%),

‘‘Good’’ (N= 35; 27.1%), or ‘‘Excellent’’ (N= 21; 16.3%). On the other hand, only two respondents indicated ‘‘Fair’’ (N= 1; 0.8%) or ‘‘Poor’’ (N= 1; 0.8%) as a patient safety grade.

Table 4.7: Frequency and Percentage of Patient Safety Grade

Overall Perception of Patient Safety	Frequency	Percent
Poor	1	0.8
Fair	1	0.8
Good	35	27.1
Very Good	71	55.0
Excellent	21	16.3
Total	129	100

4.5 Analysis of Differences in Perceptions Across Healthcare Professional Groups

The Kruskal Wallis test was used to compare mean dimension scores between groups of participants clustered by their job position. The mean dimension scores range from 1 to 5, where 1 corresponds to ‘never’ or ‘strongly disagree’ and 5 corresponds ‘always’ or ‘strongly agree’. The null hypothesis specifies that the mean subscale scores vary marginally between the groups and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean subscale scores vary significantly between the groups and is accepted if the p-value is less than the 0.05 criterion.

Several significant differences in responses were observed among different healthcare professional groups across the majority of the safety culture dimensions (p= <0.05) namely, teamwork, staffing and work pace, organisational learning – continuous improvement, response to error, communication about error and hospital management support for patient safety. These are highlighted in Table 4.8 to Table 4.11, Table 4.13 and Table 4.15. In summary, physiotherapists perceive teamwork more positively (M= 4.33, SD= 0.373) when compared to care workers (M= 3.67, SD= 0.516, p= 0.003). Radiographers (therapeutic and/or diagnostic) perceive staffing and workload more positively (M= 3.80, SD= 0.533) when compared to enrolled nurses and staff nurses (M= 2.15, SD= 0.395, p= <0.001). Care workers perceive organisational learning and continuous improvement more positively (M= 4.15, SD= 0.345) when compared to radiographers (M= 2.84, SD= 0.884, p= <0.001). Focal/practice nurses

perceive response to error more positively (M= 3.70, SD= 0.857) when compared to radiographers (M= 2.57, SD= 0.717, p= <0.001). Deputy charge nurses and charge nurses perceive communication about error more positively (M= 4.22, SD= 0.500) when compared to enrolled nurses and staff nurses (M= 3.23, SD= 0.761, p= <0.001). Care workers perceive hospital management support for patient safety more positively (M= 4.00, SD=0.615) when compared to radiographers (M= 2.48, SD= 0.823, p= <0.001). On the other hand, no statistically significant differences were identified in the following dimensions: supervisor, manager or clinical leader support for patient safety (p= 0.138; Table 4.12), communication openness (p= 0.298; Table 4.14), handoff and information exchange (p= 0.52; Table 4.16) and reporting patient safety events (p= 0.146; Table 4.17).

Table 4.8: Analysis of Differences in Teamwork across Healthcare Professional Groups (Kruskal Wallis Test)

Teamwork

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	4.18	0.457	**0.003**
Focal Nurse, Practice Nurse	11	4.27	0.757	
Deputy Charge Nurse, Charge Nurse	9	4.07	0.434	
Care Worker, Health Carer, Senior Health Carer	11	3.67	0.516	
Physiotherapist	9	4.33	0.373	
Radiographer (Therapeutic and/or Diagnostic)	27	3.84	0.636	
Others	7	4.14	0.178	

Table 4.9: Analysis of Differences in Staffing and Work Pace across Healthcare Professional Groups (Kruskal Wallis Test)

Staffing and Work Pace

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	2.15	0.395	**<0.001**
Focal Nurse, Practice Nurse	11	3.52	0.656	
Deputy Charge Nurse, Charge Nurse	9	2.67	0.433	
Care Worker, Health Carer, Senior Health Carer	11	2.50	0.418	
Physiotherapist	9	3.28	0.755	
Radiographer (Therapeutic and/or Diagnostic)	27	3.80	0.533	
Others	7	3.36	0.934	

Table 4.10: Analysis of Differences in Organisational Learning and Continuous Improvement across Healthcare Professional Groups (Kruskal Wallis Test)

Organisational Learning – Continuous Improvement

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.59	0.594	**<0.001**
Focal Nurse, Practice Nurse	11	3.73	0.828	
Deputy Charge Nurse, Charge Nurse	9	3.81	0.556	
Care Worker, Health Carer, Senior Health Carer	11	4.15	0.345	
Physiotherapist	9	3.93	0.641	
Radiographer (Therapeutic and/or Diagnostic)	27	2.84	0.884	
Others	7	3.67	0.694	
Radiographer (Therapeutic and/or Diagnostic)	27	2.57	0.717	
Others	7	2.96	0.728	

Table 4.11: Analysis of Differences in Response to Error across Healthcare Professional Groups (Kruskal Wallis Test)

Response to Error

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	2.70	0.599	**<0.001**
Focal Nurse, Practice Nurse	11	3.70	0.857	
Deputy Charge Nurse, Charge Nurse	9	3.56	0.798	
Care Worker, Health Carer, Senior Health Carer	11	3.02	0.607	
Physiotherapist	9	3.25	0.650	

Table 4.12: Analysis of Differences in Supervisor, Manager or Clinical Leader Support for Patient Safety across Healthcare Professional Groups (Kruskal Wallis Test)

Supervisor, Manager or Clinical Leader Support for Patient Safety

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.85	0.551	0.138
Focal Nurse, Practice Nurse	11	4.03	0.823	
Deputy Charge Nurse, Charge Nurse	9	3.63	0.857	
Care Worker, Health Carer, Senior Health Carer	11	3.45	0.563	
Physiotherapist	9	4.15	0.603	
Radiographer (Therapeutic and/or Diagnostic)	27	3.78	0.443	
Others	7	4.05	0.591	

Table 4.13: Analysis of Differences in Communication about Error across Healthcare Professional Groups (Kruskal Wallis Test)

Communication about Error

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.23	0.761	**<0.001**
Focal Nurse, Practice Nurse	11	3.61	1.332	
Deputy Charge Nurse, Charge Nurse	9	4.22	0.500	
Care Worker, Health Carer, Senior Health Carer	11	4.06	0.905	
Physiotherapist	9	4.11	0.782	
Radiographer (Therapeutic and/or Diagnostic)	27	3.26	0.781	
Others	7	3.86	0.790	

Table 4.14: Analysis of Differences in Communication Openness across Healthcare Professional Groups (Kruskal Wallis Test)

Communication Openness

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.96	0.508	0.298
Focal Nurse, Practice Nurse	11	4.32	0.420	
Deputy Charge Nurse, Charge Nurse	9	3.94	0.410	
Care Worker, Health Carer, Senior Health Carer	11	4.27	0.410	
Physiotherapist	9	3.92	0.375	
Radiographer (Therapeutic and/or Diagnostic)	27	4.08	0.555	
Others	7	4.07	0.426	

Table 4.15: Analysis of Differences in Hospital Management Support for Patient Safety across Healthcare Professional Groups (Kruskal Wallis Test)

Hospital Management Support for Patient Safety

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	2.78	0.545	**<0.001**
Focal Nurse, Practice Nurse	11	3.33	0.365	
Deputy Charge Nurse, Charge Nurse	9	3.37	0.611	
Care Worker, Health Carer, Senior Health Carer	11	4.00	0.615	
Physiotherapist	9	3.22	0.764	
Radiographer (Therapeutic and/or Diagnostic)	27	2.48	0.823	
Others	7	3.29	0.951	

Table 4.16: Analysis of Differences in Handoff and Information Exchange across Healthcare Professional Groups (Kruskal Wallis Test)

Handoff and Information Exchange

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.93	0.613	0.52
Focal Nurse, Practice Nurse	3	2.33	0.882	
Deputy Charge Nurse, Charge Nurse	9	4.00	0.553	
Care Worker, Health Carer, Senior Health Carer	11	3.70	0.605	
Physiotherapist	1	3.00	.	
Radiographer (Therapeutic and/or Diagnostic)	27	3.87	0.371	
Others	7	3.76	0.854	

Table 4.17: Analysis of Differences in Reporting of Patient Safety Events across Healthcare Professional Groups (Kruskal Wallis Test)

Reporting Patient Safety Events

	N	Mean	SD	P-value
Enrolled Nurse, Staff Nurse	55	3.05	0.853	0.146
Focal Nurse, Practice Nurse	11	3.27	0.932	
Deputy Charge Nurse, Charge Nurse	9	3.67	0.612	
Care Worker, Health Carer, Senior Health Carer	11	3.41	1.020	
Physiotherapist	9	3.83	0.750	
Radiographer (Therapeutic and/or Diagnostic)	27	3.30	1.094	
Others	7	3.43	1.018	

4.5 Analysis of Differences in Perceptions Across Other Socio-Demographic Characteristics

The Kruskal Wallis test was used to compare mean dimension scores across socio-demographic characteristics clustered by gender, age, level of education, hospital tenure, unit tenure, hours (typically worked) per weeks, and direct contact with patients. The null hypothesis specifies that the mean subscale scores vary marginally between the groups and is accepted if the pvalue exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean subscale scores vary significantly between the groups, and is accepted if the p-value is less than the 0.05 criterion. Section 4.5.1 to Section 4.5.7 outline the analysis of differences in perceptions across socio-demographic characteristics namely, gender, age, education level, hospital tenure, unit or work area tenure, typical number of hours worked per week and across participants who typically have direct patient contact or interaction and those who do not.

4.5.1 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Gender

As shown in Table 4.18, significant differences in responses were observed in the safety culture dimensions of communication about error and reporting patient safety events among male and female participants. Male participants perceive communication about error more positively (M= 3.78, SD= 0.885) when compared to female participants (M= 3.38, SD= 0.871, p= 0.022).

Similarly, male participants also perceive reporting patient safety events more positively (M= 3.54, SD= 1.065) when compared to female participants (M= 3.15, S= 0.841, p= 0.018).

Table 4.18: Analysis of Differences in Safety Culture Dimensions across Gender (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	Male	40	3.98	0.591	0.112
	Female	89	4.12	0.520	
Staffing and Work Pace	Male	40	2.96	0.895	0.293
	Female	89	2.76	0.837	
Organisational Learning – Continuous Improvement	Male	40	3.69	0.722	0.138
	Female	89	3.47	0.786	
Response to Error	Male	40	2.83	0.754	0.621
	Female	89	2.93	0.755	
Supervisor, Manager or Clinical Leader Support for Patient Safety	Male	40	3.91	0.575	0.245
	Female	89	3.80	0.611	
Communication about Error	Male	40	3.78	0.885	**0.022**
	Female	89	3.38	0.871	
Communication Openness	Male	40	3.96	0.455	0.169
	Female	89	4.08	0.506	
Hospital Management Support for Patient Safety	Male	40	3.05	0.947	0.460
	Female	89	2.93	0.681	
Handoff and Information Exchange	Male	34	3.84	0.378	0.232
	Female	79	3.84	0.714	
Reporting Patient Safety Events	Male	40	3.54	1.065	**0.018**
	Female	89	3.15	0.841	

4.5.2 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Age

As shown in Table 4.19, significant difference in responses were observed in five safety culture dimensions among different age groups. Overall, participants over the age of 50 years perceive teamwork (M= 4.32, SD= 0.451, p= 0.027), organisation learning and continuous improvements (M= 3.82, SD= 0.632, p= 0.011) and hospital management support for patient safety (M= 3.37, SD= 0.597, p= <0.001) more positively when compared to other age groups. On the other hand, participants over the age of 50 years perceive staffing and work pace within their organisation more negatively (M= 2.43, SD= 0.696, p= 0.028) when compared to other age groups. Participants within the age group of 30-49 years perceive communication openness more positively (M= 4.14, SD= 0.480, p= 0.044) compared to other age groups. No statistically significant differences were observed among the age groups and other safety culture dimensions.

Table 4.19: Analysis of Differences in Safety Culture Dimensions across Age (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	18-29 years	56	4.14	0.457	**0.027**
	30-49 years	54	3.93	0.620	
	50+ years	19	4.32	0.451	
Staffing and Work Pace	18-29 years	56	2.78	0.867	**0.028**
	30-49 years	54	3.00	0.858	
	50+ years	19	2.43	0.696	
Organizational Learning – Continuous Improvement	18-29 years	56	3.32	0.763	**0.011**
	30-49 years	54	3.66	0.776	
	50+ years	19	3.82	0.632	
Response to Error	18-29 years	56	2.75	0.668	0.099
	30-49 years	54	3.03	0.773	
	50+ years	19	2.99	0.884	
Supervisor, Manager or Clinical Leader Support for Patient Safety	18-29 years	56	3.83	0.512	0.072
	30-49 years	54	3.75	0.706	
	50+ years	19	4.11	0.431	
Communication about Error	18-29 years	56	3.35	0.842	0.123
	30-49 years	54	3.66	0.917	
	50+ years	19	3.51	0.932	
Communication Openness	18-29 years	56	3.93	0.499	**0.044**
	30-49 years	54	4.14	0.480	
	50+ years	19	4.11	0.459	
Hospital Management Support for Patient Safety	18-29 years	56	2.70	0.647	**<0.001**
	30-49 years	54	3.10	0.856	
	50+ years	19	3.37	0.597	
Handoff and Information Exchange	18-29 years	51	3.87	0.636	0.064
	30-49 years	45	3.73	0.613	
	50+ years	17	4.04	0.633	
Reporting Patient Safety Events	18-29 years	56	3.19	0.892	0.290
	30-49 years	54	3.40	0.963	
	50+ years	19	3.16	0.944	

4.5.3 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Education Level

As shown in Table 4.20, participants who hold an undergraduate certificate, diploma or advanced diploma perceive organisational learning and continuous improvement (M= 4.04, SD= 0.372, p= <0.001) as well as hospital management support for patient safety (M= 3.47, SD= 0.761, p= 0.004) more positively compared to participants who hold an undergraduate and/or postgraduate degree. On the other hand, participants who hold an undergraduate certificate, diploma or advanced diploma perceive staffing and work pace more negatively (M= 2.27, SD= 0.477, p= 0.002) compared to participants who hold an undergraduate degree (M= 2.98, SD= 0.893) or postgraduate degree (M= 2.93, SD= 0.870). No statistically significant differences were observed across educational level and other safety culture dimensions.

Table 4.20: Analysis of Differences in Dimensions across Educational Level (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	Undergraduate Certificate, Diploma or Advanced Diploma	24	4.04	0.576	0.618
	Undergraduate Degree	43	4.03	0.548	
	Postgraduate Degree	62	4.12	0.537	
Staffing and Work Pace	Undergraduate Certificate, Diploma or Advanced Diploma	24	2.27	0.477	**0.002**
	Undergraduate Degree	43	2.98	0.893	
	Postgraduate Degree	62	2.93	0.870	
Organisational Learning – Continuous Improvement	Undergraduate Certificate, Diploma or Advanced Diploma	24	4.04	0.372	**<0.001**
	Undergraduate Degree	43	3.31	0.771	
	Postgraduate Degree	62	3.50	0.805	
Response to Error	Undergraduate Certificate, Diploma or Advanced Diploma	24	2.79	0.650	0.463
	Undergraduate Degree	43	2.83	0.672	
	Postgraduate Degree	62	3.00	0.839	
Supervisor, Manager or Clinical Leader Support for Patient Safety	Undergraduate Certificate, Diploma or Advanced Diploma	24	3.81	0.659	0.863
	Undergraduate Degree	43	3.88	0.493	
	Postgraduate Degree	62	3.82	0.649	

Communication about Error	Undergraduate Certificate, Diploma or Advanced Diploma	24	3.54	0.884	0.834
	Undergraduate Degree	43	3.57	0.950	
	Postgraduate Degree	62	3.45	0.864	
Communication Openness	Undergraduate Certificate, Diploma or Advanced Diploma	24	4.21	0.452	0.104
	Undergraduate Degree	43	3.94	0.494	
	Postgraduate Degree	62	4.06	0.495	
Hospital Management Support for Patient Safety	Undergraduate Certificate, Diploma or Advanced Diploma	24	3.47	0.761	**0.004**
	Undergraduate Degree	43	2.84	0.739	
	Postgraduate Degree	62	2.85	0.728	
Handoff and Information Exchange	Undergraduate Certificate, Diploma or Advanced Diploma	24	3.87	0.604	0.616
	Undergraduate Degree	38	3.80	0.474	
	Postgraduate Degree	51	3.85	0.743	
Reporting Patient Safety Events	Undergraduate Certificate, Diploma or Advanced Diploma	24	3.17	0.985	0.831
	Undergraduate Degree	43	3.23	0.984	
	Postgraduate Degree	62	3.34	0.877	

4.5.4 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Hospital Tenure

No statistically significant differences were observed among healthcare professionals' perceptions of patient safety culture across hospital tenure (Table 4.21).

Table 4.21 Analysis of Differences in Dimensions across Hospital Tenure (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	0 to 5 years	59	4.07	0.463	0.665
	6 to 10 years	44	4.07	0.633	
	11 or more years	26	4.09	0.578	
Staffing and Work Pace	0 to 5 years	59	2.88	0.897	0.769
	6 to 10 years	44	2.76	0.816	
	11 or more years	26	2.81	0.855	
Organisational Learning – Continuous Improvement	0 to 5 years	59	3.46	0.706	0.124
	6 to 10 years	44	3.48	0.933	
	11 or more years	26	3.81	0.543	
Response to Error	0 to 5 years	59	2.86	0.642	0.102
	6 to 10 years	44	2.78	0.843	
	11 or more years	26	3.18	0.786	
Supervisor, Manager or Clinical Leader Support for Patient Safety	0 to 5 years	59	3.86	0.515	0.473
	6 to 10 years	44	3.77	0.496	
	11 or more years	26	3.88	0.889	
Communication about Error	0 to 5 years	59	3.57	0.933	0.733
	6 to 10 years	44	3.42	0.745	
	11 or more years	26	3.49	1.038	
Communication Openness	0 to 5 years	59	4.01	0.448	0.070
	6 to 10 years	44	3.99	0.573	
	11 or more years	26	4.23	0.406	
Hospital Management Support for Patient Safety	0 to 5 years	59	2.91	0.750	0.154
	6 to 10 years	44	2.90	0.861	
	11 or more years	26	3.21	0.626	
Handoff and Information Exchange	0 to 5 years	51	3.91	0.508	0.444
	6 to 10 years	42	3.71	0.701	
	11 or more years	20	3.93	0.738	
Reporting Patient Safety Events	0 to 5 years	59	3.31	0.960	0.836
	6 to 10 years	44	3.23	0.918	
	11 or more years	26	3.27	0.908	

4.5.5 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Unit or Work Area Tenure

As shown in Table 4.22, participants with 11 or more years of experience in their respective unit or work area perceive organisational learning and continuous improvement (M= 3.98, SD=

0.497, p= 0.049) as well as handoff and information exchange (M= 4.13, SD= 0.757, p= 0.027) more positively when compared to participants with a shorter tenure. No statistically significant differences were observed across unit or work area tenure and other safety culture dimensions.

Table 4.22: Analysis of Differences in Dimensions across Unit or Work Area Tenure (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	0 to 5 years	85	4.10	0.491	0.071
	6 to 10 years	30	3.88	0.652	
	11 or more years	14	4.33	0.506	
Staffing and Work Pace	0 to 5 years	85	2.85	0.844	0.126
	6 to 10 years	30	2.63	0.855	
	11 or more years	14	3.07	0.912	
Organisational Learning – Continuous Improvement	0 to 5 years	85	3.46	0.802	**0.049**
	6 to 10 years	30	3.56	0.734	
	11 or more years	14	3.98	0.497	
Response to Error	0 to 5 years	85	2.91	0.760	0.502
	6 to 10 years	30	2.80	0.738	
	11 or more years	14	3.09	0.763	
Supervisor, Manager or Clinical Leader Support for Patient Safety	0 to 5 years	85	3.79	0.549	0.069
	6 to 10 years	30	3.78	0.651	
	11 or more years	14	4.21	0.687	
Communication about Error	0 to 5 years	85	3.56	0.924	0.594
	6 to 10 years	30	3.40	0.846	
	11 or more years	14	3.40	0.818	
Communication Openness	0 to 5 years	85	4.06	0.473	0.391
	6 to 10 years	30	3.93	0.576	
	11 or more years	14	4.18	0.385	
Hospital Management Support for Patient Safety	0 to 5 years	85	2.99	0.791	0.805
	6 to 10 years	30	2.86	0.682	
	11 or more years	14	3.07	0.859	
Handoff and Information Exchange	0 to 5 years	76	3.87	0.601	**0.027**
	6 to 10 years	27	3.64	0.627	
	11 or more years	10	4.13	0.757	
Reporting Patient Safety Events	0 to 5 years	85	3.35	0.929	0.334
	6 to 10 years	30	3.08	0.821	
	11 or more years	14	3.21	1.139	

4.5.6 Differences in Healthcare Professionals' Perceptions of Patient Safety Culture by Typical Number of Hours Worked per Week

As shown in Table 4.23, participants who work more than 40 hours per week perceive teamwork more positively (M= 4.16, SD= 0.509) when compared to participants those work 40 hours or less per week (M= 3.96, SD= 0.576, p= 0.021). On the other hand, participants who work more than 40 hours per week perceive staffing and work pace more negatively (M= 2.39, SD= 0.586) when compared to participants who work 40 hours or less per week (M= 3.43, SD= 0.804, p= <0.001). No statistically significant differences were observed across hours (typically worked) per week and other safety culture dimensions.

Table 4.23: Analysis of Differences in Dimensions across Hours (typically worked) per Week (Kruskal Wallis Test)

		N	Mean	SD	P-value
Teamwork	40 hours or less per week	54	3.96	0.576	**0.021**
	More than 40 hours per week	75	4.16	0.509	
Staffing and Work Pace	40 hours or less per week	54	3.43	0.804	**<0.001**
	More than 40 hours per week	75	2.39	0.586	
Organisational Learning – Continuous Improvement	40 hours or less per week	54	3.38	0.900	0.087
	More than 40 hours per week	75	3.65	0.645	
Response to Error	40 hours or less per week	54	2.90	0.782	0.901
	More than 40 hours per week	75	2.90	0.738	
Supervisor, Manager or Clinical Leader Support for Patient Safety	40 hours or less per week	54	3.88	0.598	0.802
	More than 40 hours per week	75	3.80	0.603	
Communication about Error	40 hours or less per week	54	3.62	0.929	0.184
	More than 40 hours per week	75	3.42	0.860	
Communication Openness	40 hours or less per week	54	4.14	0.467	0.091
	More than 40 hours per week	75	3.98	0.500	
Hospital Management Support for Patient Safety	40 hours or less per week	54	2.87	0.875	0.160
	More than 40 hours per week	75	3.04	0.686	
Handoff and Information Exchange	40 hours or less per week	45	3.84	0.579	0.912
	More than 40 hours per week	68	3.84	0.665	
Reporting Patient Safety Events	40 hours or less per week	54	3.24	0.960	0.967
	More than 40 hours per week	75	3.29	0.912	

4.6 Correlational Analysis

As stated, all Shapiro Wilk p-values are smaller than the 0.05 level of significance indicating that all score distributions violate the normality assumption (see Table 4.3). For this reason, non-parametric tests were used analyse the data further. Specifically, the Spearman correlation was used to analyse the relationship between safety culture dimensions and reporting of patient safety events (Table 4.24).

The Spearman correlation coefficient measures the strength of the relationship between two continuous variables and it ranges from -1 to 1. A correlation coefficient close to 1 indicates a strong positive relationship between the two variables; a correlation coefficient close to -1 indicates a strong negative relationship; while a correlation coefficient close to 0 indicates no relationship between the two variables. The Spearman correlation (non-parametric test) is used to investigate whether a relationship between two variables is significant or not. The null hypothesis specifies that there is no relationship between the two variables and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that there is a significant relationship between the two variables and is accepted if the p-value is less than the 0.05 criterion.

As shown in Table 4.24, a number of safety culture dimensions positively correlate which each other and with incident reporting. Specifically, organisational learning and continuous improvements (p= 0.005), response to error (p= 0.000), communication about error (p= 0.000) and, hospital management support for patient safety (p= 0.013) significantly correlate with reporting of patient safety events.

Table 4.23: Spearman Correlations among Safety Culture Dimensions

			Teamwork	Staffing and Work Pace	OL – CI	Response to Error	S/M/CL Support for Patient Safety	Communication about Error	Communication Openness	Hospital Management Support for Patient Safety	Handoff and Information Exchange	Reporting Patient Safety Events
Spearman's rho	Teamwork	Correlation	1.000	-0.059	0.303	0.079	0.371	0.165	0.225	0.001	0.270	0.011
		P-value	.	0.509	**0.000**	0.373	**0.000**	0.062	**0.010**	0.992	**0.004**	0.903
	Staffing and Work Pace	Correlation	-0.059	1.000	-0.072	0.211	0.150	0.175	0.188	0.026	0.016	0.152
		P-value	0.509	.	0.418	**0.016**	0.090	**0.048**	**0.033**	0.770	0.868	0.085
	OL - CI	Correlation	0.303	-0.072	1.000	0.441	0.305	0.388	0.206	0.617	0.008	0.245
		P-value	**0.000**	0.418	.	**0.000**	**0.000**	**0.000**	**0.019**	**0.000**	0.931	**0.005**
	Response to Error	Correlation	0.079	0.211	0.441	1.000	0.116	0.574	0.158	0.467	0.079	0.500
		P-value	0.373	**0.016**	**0.000**	.	0.189	**0.000**	0.074	**0.000**	0.407	**0.000**
	S/M/CL Support for Patient Safety	Correlation	0.371	0.150	0.305	0.116	1.000	0.220	0.411	0.123	0.256	0.050
		P-value	**0.000**	0.090	**0.000**	0.189	.	**0.012**	**0.000**	0.167	**0.006**	0.572
	Communication about Error	Correlation	0.165	0.175	0.388	0.574	0.220	1.000	0.175	0.350	0.139	0.551
		P-value	0.062	**0.048**	**0.000**	**0.000**	**0.012**	.	**0.048**	**0.000**	0.141	**0.000**
	Communication Openness	Correlation	0.225	0.188	0.206	0.158	0.411	0.175	1.000	0.080	0.418	0.123
		P-value	**0.010**	**0.033**	**0.019**	0.074	**0.000**	**0.048**	.	0.370	**0.000**	0.163
	Hospital Management Support for Patient Safety	Correlation	0.001	0.026	0.617	0.467	0.123	0.350	0.080	1.000	-0.047	0.219
		P-value	0.992	0.770	**0.000**	**0.000**	0.167	**0.000**	0.370	.	0.618	**0.013**
	Handoff and Information Exchange	Correlation	0.270	0.016	0.008	0.079	0.256	0.139	0.418	-0.047	1.000	0.022
		P-value	**0.004**	0.868	0.931	0.407	**0.006**	0.141	**0.000**	0.618	.	0.820
	Reporting Patient Safety Events	Correlation	0.011	0.152	0.245	0.500	0.050	0.551	0.123	0.219	0.022	1.000
		P-value	0.903	0.085	**0.005**	**0.000**	0.572	**0.000**	0.163	**0.013**	0.820	.

The main limitation of the Spearman correlation test is that it investigates the relationship between a dependent variable (reporting of patient safety events) and a sole predictor. However, the aim of many studies is to analyse the predictors collectively. This can be carried out by fitting a regression model and by using a forward procedure; one can identify the parsimonious model which includes solely the significant predictors (Table 4.25). The R-square value measure goodness of fit and ranges from 0 to 1, where a larger R-square value indicates a better model fit. In this application, the R-square value of the two-predictor parsimonious model (0.384) indicates that communication about error and response to error explain 38.4% of the total variation in the responses (reporting of patient safety events scores) (Table 4.26).

Table 4.25: Regression Coefficients of Full Model

Model	Unstandardized Coefficients		Standardised Coefficients	t	P-value
	B	Std. Error	Beta		
Constant	1.049	0.776		1.351	0.180
Teamwork	-0.067	0.158	-0.039	-0.425	0.672
Staffing and Work Pace	0.077	0.096	0.068	0.799	0.426
Organizational Learning – Continuous Improvement	-0.040	0.155	-0.033	-0.259	0.796
Response to Error	0.363	0.137	0.275	2.655	**0.009**
Supervisor, Manager or Clinical Leader Support for Patient Safety	-0.082	0.144	-0.051	-0.568	0.571
Communication about Error	0.511	0.108	0.473	4.729	**<0.001**
Communication Openness	0.085	0.169	0.045	0.502	0.617
Hospital Management Support for Patient Safety	-0.059	0.135	-0.049	-0.439	0.661
Handoff and Information Exchange	-0.070	0.129	-0.047	-0.546	0.586

Dependent Variable: Reporting of Patient Safety Events

R-Square = 0.404

Table 4.25: Regression Coefficients of Parsimonious Model

Model	Unstandardized Coefficients		Standardized Coefficients	t	P-value
	B	Std. Error	Beta		
Constant	0.661	0.320		2.066	**0.041**
Communication about Error	0.472	0.100	0.437	4.718	**<0.001**
Response to Error	0.332	0.122	0.252	2.717	**0.008**

Dependent Variable: Reporting of Patient Safety Events

R-Square = 0.384

4.7 Analysis of Open-Ended Responses

Participants were given the opportunity to provide written comments at the end of the questionnaire. From the 129 questionnaires returned, 33 comments were received. To analyse the qualitative data from the open comments, a thematic analysis was carried out, revealing seven main themes. Three of the main themes identified in the open-ended responses were concordant with the lowest dimension mean scores identified in the quantitative analysis. These consisted of: staffing and work pace, response to error, and hospital management support for patient safety. Three other participants also mentioned the theme of organisation learning and improvements following incident reporting. Furthermore, through the analysis of the open-ended responses, an additional two main theme were identified pertinent to safety culture namely, ‘training’ and ‘structure/environment’.

Therefore, the participants’ comments support the findings from the quantitative data and allowed for a deeper understanding of the perceptions of patient safety culture. Table 4.27 highlights the themes identified, accompanied by the frequency of mention among participants, supported by direct quotations.

Table 4.27: Themes Identified in the Open-Ended Responses of the Quantitative Questionnaire, Supported by Direct Quotations		
Theme	**Number of Participants**	**Direct Quotes**
Staffing and Work Pace	11	‘‘We are extremely short staffed, every single day. It has become exhausting, both physically and mentally. Our patients suffer from both physiological and psychological issues during their treatment and at times I find it very challenging to provide safe medical care as well as support and provide psychological care … I feel rushed in whatever I am doing.’’ ‘‘We need better staffing levels and the workload should be distributed equally’’
Response to Error	6	‘‘... if an error occurs, they [higher management] should evaluate all factors that could have led to that error instead of shifting blame on healthcare professionals.’’
Hospital Management Support for Patient Safety	5	‘‘I wish the hospital management would listen to our concerns when it comes to patient safety and act upon our concerns. It is very frustrating when the same issues occur and no one from higher management does anything about it.’’ ‘‘It is clearly seen that this hospital’s management is more concerned about the number of patients rather than the quality of treatment … Healthcare professionals’ input is never taken into account and it has demotivated the whole department.’’
Training	5	‘‘Training (e.g., how to handle chemotherapy or use CVADs [central venous access devices] should be given to all staff immediately when they start working here … which is not done’’ ‘‘There should be continuous update in emergency training and basic tasks’’
Organisational Learning and Improvements	3	‘‘I feel that in this unit, we are currently trying to encourage the reporting through incident reports more, however, despite this, not much action is taken to address recurrent issues and eventually resolve them.’’
Structure/ Environment	3	‘‘Balcony in our ward is not safe, especially when a patient is given bad news.’’ ‘‘There should be reduced access to the balcony in the ward’’

4.8 Analysis of the Focus Group Interview

The focus group interview consisted of 7 participants, namely: 4 nurses, 1 care worker, 1 physiotherapist and 1 radiographer. The participants were selected from different units and work areas in SAMOC, the only oncology hospital in Malta. Therefore, demographic details of the participants are not presented to safeguard their anonymity. To this end, a pseudonym for each participant is presented in Table 4.28. The focus group interview was conducted in English and therefore, translation was not required.

Table 4.28: Focus Group Interview Participants and Pseudonyms

Healthcare professional group	Pseudonym
Nurse	NUR1
Nurse	NUR2
Nurse	NUR3
Nurse	NUR4
Care Worker	CW
Physiotherapist	PT
Radiographer	RT

A transcript-based analysis of the focus group interview was carried out. Subsequently, seven key themes and concepts emerged from the transcription and were organised according to the enabling, enacting, and elaborating actions proposed by Vogus et al. (2010). Section 4.8.1 to Section 4.8.3 reports the findings related to Enabling Actions, which identified the following themes: (a) Response to Error: Navigating Errors and Accountability; (b) Resource Allocation: Staffing Levels, Work Loads and Working Hours; and (c) Navigating Safety Commitment: Senior and Mid-level Management in Patient Safety. Section 4.8.4 and Section 4.8.5 report the findings related to Enacting Actions, which identified the following themes: (a) Teamwork, Collaboration and Communication Openness Contributing to a Culture of Safety and (b) Transition of Care at the Frontline: Handovers and Information Exchange. Section 4.8.6 and Section 4.8.7 report the findings related to Elaborating Actions, which identified the following themes: (a) The Feedback Loop: Communication about Error and Organisational Learning; and (b) Nurturing a Safety-First Culture through Continuous Professional Development and Competency Enhancement.

4.8.1 Response to Error: Navigating Errors and Accountability

The theme of ‘‘Fostering a Culture of Learning: Navigating Errors, Accountability and Effective Communication in an Oncology Healthcare Setting’’ emerged as a priority among participants in the focus group interview. The insights gathered shed light on a prevalent blame culture within the organisation. Participants highlighted fear of potential repercussions and ‘‘pointing fingers’’ (RT) from writing an incident report. Furthermore, NUR1 stated: ‘‘I think in Malta, in general not just in oncology, there is a strong blame culture. I do not feel comfortable writing an incident report. You always have to be careful what to write and how to phrase it because it will easily turn against you.’’

4.8.2 Resource Allocation: Staffing Levels, Work Loads and Working Hours

Participants shared their perceptions on staffing levels, workloads as well as working hours and their perceived effects on patient safety within their organisation. In particular, the nursing staff expressed great concern over how shortage of staff and high workloads adversely effected the safety and quality of care given to patients – especially within the demanding and complex oncology setting. NUR3 articulated that these factors often created circumstances where nursing staff felt pressured to rush certain aspects of patient care, ultimately exacerbating the potential for lapses. NUR3 stated that ‘‘we do our best not to compromise patient safety, but sometimes, if we are short of staff and you need to do a lot of things patient safety does end up getting compromised with shortcuts.’’

Participants highlight how this situation is also overwhelming for nurses working in the relieving pool of the oncology hospital. NUR2 stated: ‘‘relivers should be trained... unfortunately, they do not rotate and they do not work in each unit very often. So, when we are short of staff in our unit and the management allocated relivers, which have not worked in out unit in a while, sometimes over 6 months, patient safety is obviously compromised... and there is an extra burden on the ward nurses.’’

In addition, the impact of different working hours were discussed. The nursing staff collectively agreed that long working hours (i.e., the standard 12-hour shift) could potentially compromise patient safety. NUR4 expressed: ‘‘towards the end of a 12-hour shift, it can be very difficult to

stay fully alert and concentrated... especially if it is a night shift and you need to administer chemotherapy at 06:00.'' On the other hand, there were different viewpoints regarding the perception that shorter, more frequent shifts (e.g., five eight-hour shifts per week) would present as a superior alternative, as concerns were raised about work-life balance.

4.8.3 Navigating Safety Commitment: Senior and Mid-level Management in Patient Safety

Interestingly, participants often made a distinction between senior and mid-level management during the focus group interview. Their narratives underscored the nuanced roles of both senior and mid-level management in fostering a culture of patient safety in the oncology healthcare setting. Hospital management, or senior-level management, were frequently associated with shaping the organisation's vision for safety through strategic decision-making, setting overarching policies and allocation of resources. On the other hand, mid-level managers were described as important figures in translating these strategic directives into actionable steps at the operational, frontline level.

''I believe that when we speak of short of staff, hospital management have more control over this. Our immediate managers, the NOs [nursing officers] do not have the power to get more, employ more staff. Not even for overtime. They need to ask for permission'' (NUR1).

''...[senior management] do not have experience in the unit, with patients. So, you may mention or suggest something, to implement a change … but they do not understand how crucial that change is because they are not with us in the ward'' (NUR4).

4.8.4 Teamwork, Collaboration and Communication Openness Contributing to a Culture of Safety

Participants discussed the pivotal role of teamwork, collaboration and communication in contributing to a culture of safety in the oncology setting. All participants expressed positive teamwork perceptions among the oncology team. Their narratives shed light on the importance of communication, cross departmental and interdisciplinary collaboration, and a shared

commitment to patient safety. Participants expressed that they felt at ease asking questions to other members of the interdisciplinary team, irrespective of grade or seniority.

‘‘I believe that we have quite good teamwork. Not just between carers and nurses. We ask questions when needed and help each other out even with different professionals’’ (NUR1).

‘‘... when there is something we do not understand, we feel comfortable asking questions’’ (CW).

Furthermore, there were positive perceptions of team building activities and overall agreement that these enhance teamwork among healthcare professionals. NUR4 commented: ‘‘I think it helps – you feel more confident, and it enhances teamwork across units, especially in a small hospital like [the oncology hospital].’’ NUR3 continued: ‘‘I think team building activities help us to build up more confidence between us. We had a recent team building activity organised by [the hospital management]. In my opinion, this was a very effective, positive activity. My suggestion, and the only thing I would have changed, is that I would have included all healthcare professionals [working in the oncology hospital] as this included nurses only.’’ There was overall agreement with this statement among participants.

4.8.5 Transition of Care at the Frontline: Handovers and Information Exchange

In the highly specialised oncology healthcare setting, handovers and information exchange play a critical role in patient safety and care continuity. The theme of ‘‘Transition of Care: Handovers and Information Exchange’’ emerged from the focus group interview, underscoring the importance of a comprehensive and clear handover in the oncology healthcare setting to ensure both patient and healthcare professionals’ safety.

Participants working in the nursing profession expressed the importance of a detailed handover during the beginning and end of each shift which should not just include workload related factors (e.g., which patients are due bloodletting or chemotherapy protocols) but also factors which may not always be given as much importance (e.g., allergies, cardiopulmonary

resuscitation status, infective status etc..). Furthermore, the importance of detailed handover was also highlighted with regards to healthcare professional safety. NUR4 elaborated and gave a generic example when patients undergo a PET [positron emission tomography] scan during the day shift and whilst there are a number of safety precautions that need to be taken, this information is omitted during handoff to the night shift.

4.8.6 The Feedback Loop: Organisational Learning, Initiatives and Continuous Improvements

All participants expressed frustration regarding the effectiveness of incident reporting stating that they often felt that their concerns were met with inaction. In particular, NUR3 mentioned that: ‘‘I believe that, overall, we do write incident reports when necessary. But whenever we write an incident report and send it in, nothing ever happens. We are never given feedback, and very rarely something is implemented to change or avoid that the incident happens again’’. Following this, the PT suggested the implementation of a feedback loop systems within the oncology setting in which hospital management communicate details about the incident, findings from the investigation and actions taken... ‘‘at least in the form of an email’’ (PT). Participants also indicated that they are rarely involved in quality improvement initiatives or changes following an error: ‘‘...very rarely we are involved in the development of initiative or improvements after a mistake’’ (RT). There was general agreement with this statement. However, following this one participant proudly gave an example in which they were involved in the development of a standard operating procedure.

‘‘For instance, we had a problem because sometimes, patients have a reaction to chemotherapy and supposedly by the book we cannot administer chlorphenamine or hydrocortisone before the doctors prescribe them. But, if the patient is feeling very unwell, and with experience you know what to do we go ahead and administer them. But obviously we were not covered so to speak. We needed something to cover us and we discussed with management and they come up with a sheet or policy that we can actually start giving this critical treatment right away. Without the doctors prescribing it. And then it would be prescribed afterwards. So we were informed and included it its development’’ (NUR3).

4.8.7 Nurturing a Safety-First Culture through Continuous Professional Development and Competency Enhancement

This theme delved into the participants' perceptions regarding the significance and pressing need for continuous professional development and competency enhancement in safeguarding both patients' and healthcare professionals' safety as well as fostering professional growth. NUR2 stated: ''I believe that CPD [continuous professional development] courses should be compulsory and updated regularly for both patient safety and us healthcare professionals. What I mean is, for instance, chemotherapy is not being administered or disposed properly... like if gowns or hand hygiene is not done... it will affect both me as well as my colleagues. Not just the patients.''

Participants in the nursing field also expressed that structured training in oncology ''would increase [their] confidence to take care of our patients and improve patient safety'' (NUR1) and emphasised that training should be provided in a timely manner, prior to starting to work in the oncology hospital. Specifically, participants expressed concern regarding introductory training (e.g., accessing and taking care of central venous access devices) being provided after new recruits start working in the local oncology hospital and NUR3 stated that this can be ''... risky for both themselves and the patients. Plus, they are increasing the pressure and workload on the other staff in their unit.''

4.9 Triangulation of Findings

The present research study employed a mixed-methods concurrent triangulation approach to allow a more comprehensive understanding of the research questions. In sum, findings from the questionnaire highlight a number of gaps in the perceptions of safety culture among healthcare professionals working in oncology healthcare settings in Malta, namely perceptions of ''hospital management support for patient safety'' (M=2.92, SD=0.784), ''response to error'' (M=2.81, SD=0.714), and ''staffing and work pace'' (M=2.72, SD=0.833). On the other hand, positive perceptions of enacting factors identified by Vogus et al. (2010) were found namely in the following components: ''communication openness'' (M=4.04, SD=0.501), ''teamwork'' (M=4.02, SD=0.550) and ''handoff and information exchange'' (M=3.84, SD=0.630).

These findings closely relate to the points identified in the focus group interview in which participants highlighted negative perceptions of staffing and workload, a culture of blame, and poor senior managerial support. Conversely, and in convergence with the data identified in the quantitative analysis, participants in the focus group interview cited a positive sense of a well functioning team which fosters open communication among frontline employees. On the other hand, the quantitative and qualitative analysis revealed mixed findings with regards to communication about error and organisational learning as participants in the focus group interview expressed frustration regarding the effectiveness of incident reporting stating that they often felt that their concerns were met with inaction in terms of feedback and learning from errors. Furthermore, while the quantitative data provided valuable information into specific dimensions, the focus group interview uncovered an additional component pertinent to safety culture not captured by the questionnaire. Participants in the focus group interview gave particular weight to training and continuous professional development in the oncology healthcare setting highlighting that formal and structured training in their area increases their confidence in taking care of their patients as well as ensures both healthcare professional and patient safety.

Finally, a clear correlation emerged in the quantitative data analysis, which is consistent with the themes that surfaced during the focus group discussions. Apart from correlations among safety culture dimensions, the quantitative data analysis found that organisational learning and continuous improvements ($p= 0.005$), response to error ($p= 0.000$), communication about error ($p= 0.000$) and, hospital management support for patient safety ($p= 0.013$) statistically significantly correlate with patient safety event reporting. Subsequently, the regression coefficient of the parsimonious model highlights communication about error and response to error as significant predictors of patient safety event reporting, explaining 38.4% of the total variation in the responses. This finding is also evident in the qualitative analysis which revealed how participants expressed frustration with the prevalent blame culture as well as lack of feedback and learning from errors following incidents.

Of note, the quantitative analysis revealed statistically significant difference between perceptions of safety culture and socio-demographic characteristics, including different healthcare professional groups and age groups. For instance, physiotherapists perceived

teamwork more positively (M= 4.33, SD= 0.373) when compared to care workers (M= 3.67, SD= 0.516, p= 0.003) working in oncology healthcare settings in Malta. This finding did not emerge in the qualitative analysis. However, it should be noted that the focus group interview included a limited number of participants and was conducted once. The main findings from the quantitative and qualitative data analysis were amalgamated together in a joint table of findings and are presented in Table 4.29 in the following pages.

4.10 Conclusion

This chapter presented a comprehensive description of the results derived from the quantitative and qualitative data analysis in this research study. Tables were used to further enhance the presentation of key findings and triangulation of data. The following chapter will delve into a detailed discussion of these findings, in relation to the research questions. Additionally, research identified in the CAT as well as other existing research relevant to the research study will be compared and contrasted to the findings obtained.

Table 4.29: Joint Table of Quantitative and Qualitative Results			
	Quantitative Findings (SOPS questionnaire)	**Qualitative Findings (focus group interview and open-ended responses)**	**Concordance /Mixed findings**
Enabling actions	Negative perception of hospital management support for patient safety was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 2.92, SD= 0.784, *p*= <0.001), with the exception of care workers and senior/health carers (M= 4.00, SD= 0.615, *p*= <0.001). Statistically significant differences identified across healthcare professional groups (*p*= <0.001). Positive perception of supervisor, manager or clinical leader support for patient safety was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 3.79, SD= 0.586, *p*= <0.001). No statistically significant differences identified across healthcare professional groups (*p*= 0.138). Negative perception of response to error was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 2.81, SD= 0.714, *p*= <0.001), with the exception of focal/practice nurses and deputy/charge nurses (M= 3.70, SD= 0.857, *p*= <0.001; M= 3.56, SD= 0.798, *p*= <0.001, respectively). Statistically significant differences identified across healthcare professional groups (*p*= <0.001) Negative perception of staffing and work pace was identified across healthcare professionals working in the	Participants in the focus group interview made a distinction between senior and mid-level managers and their separate roles in fostering a culture of safety in the oncology healthcare settings. Overall, negative perceptions of management support, response to error and staffing levels were exhibited. ‘‘I wish the hospital management would listen to our concerns when it comes to patient safety and act upon our concerns. It is very frustrating when the same issues occur and no one from higher management does anything about it.’’ - Direct Quote from the Open-Ended Responses ‘‘... if an error occurs, they [higher management] should evaluate all factors that could have led to that error instead of shifting blame on healthcare professionals.’’ - Direct Quote from the Open-Ended Responses ‘‘We are extremely short staffed, every single day. It has become exhausting, both physically and mentally... I feel rushed in whatever I am doing.’’ - Direct Quote from the Open-Ended Responses	Concordance*

	oncology healthcare setting in Malta (M= 2.72, SD= 0.833, *p*= <0.001), with the exception of radiographers and focal/practice nurses (M= 3.80, SD= 0.533, *p*= <0.001; M= 3.52, SD= 0.656, *p*= <0.001, respectively). Statistically significant differences identified across healthcare professional groups (*p*= <0.001).		
Enacting actions	Positive perception of communication openness was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 4.04, SD= 0.501, *p*= <0.001). No statistically significant differences identified across healthcare professional groups (*p*= 0.298). Positive perception of teamwork was identified across healthcare professionals working in the oncology healthcare setting in Malta (teamwork (M= 4.02, SD= 0.550, *p*= <0.001). Statistically significant differences identified across healthcare professional groups (*p*= 0.003). For instance, physiotherapists (M= 4.33, SD= 0.373), focal/practice nurses (M= 4.27, SD= 0.757) and enrolled/staff nurses (M= 4.18, SD= 0.457) had more positive perceptions of teamwork when compared to care workers and senior/health carers (M= 3.67, SD= 0.516). Positive perception of handoff and information exchange was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 3.84, SD= 0.630, *p*= <0.001). No statistically significant differences identified across healthcare professional groups (*p*= 0.52).	Overall, all participants in the focus group interview expressed positive perceptions of teamwork among the oncology team. Participants expressed that they felt at ease asking questions to other members of the interdisciplinary team, irrespective of grade or seniority: ‘‘...we ask questions when needed and help each other out even with different professionals’’ (NUR1). ‘‘... when there is something we do not understand, we feel comfortable asking questions’’ (CW). Participants working in the nursing profession expressed the importance of a detailed handover in the oncology healthcare setting. While they held a relative positive perception of handover and information exchange among the team they recalled examples in which comprehensive handover is not always given and its impact on both patient and healthcare professional safety.	Concordance*

Elaborating actions	Overall, a neutral perception of communication about error was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 3.45, SD= 0.872, *p*= <0.001). Statistically significant differences identified across healthcare professional groups (*p*= <0.001). For instance, deputy/charge nurses (M= 4.22, SD= 0.500) and physiotherapists (M= 4.11, SD= 0.782) had more positive perceptions of communication about error when compared to radiographers (M= 3.26, SD= 0.781) and enrolled/staff nurses (M= 3.23, SD= 0.761). Overall, a neutral perception of organisation learning, and continuous improvement (within the organisation) was identified across healthcare professionals working in the oncology healthcare setting in Malta (M= 3.49, SD= 0.778, *p*= <0.001). Statistically significant differences identified across healthcare professional groups (*p*= <0.001). For instance, care workers and senior/health carers (M= 4.15, SD= 0.345) had more positive perceptions of organisational learning and continuous improvement when compared to radiographers (M= 2.84, SD= 0.884).	Overall, all participants expressed frustration regarding the effectiveness of incident reporting stating that they often felt that their concerns were met with inaction in terms of feedback and learning from errors. ‘‘I believe that, overall, we do write incident reports when necessary. But whenever we write an incident report and send it in, nothing ever happens. We are never given feedback, and very rarely something is implemented to change or avoid that the incident happens again’’ (NUR3). ‘‘I feel that in this unit, we are currently trying to encourage the reporting through incident reports more, however, despite this, not much action is taken to address recurrent issues and eventually resolve them.’’ - Direct Quote from the Open-Ended Responses In addition, participants in the focus group interview emphasised the importance of the implementation of structured training and continuous professional development in the oncology setting.	Mixed findings
**with the exception of statistically significant difference among socio-demographic characteristics, including different healthcare professional groups*			

Chapter 5: Discussion

5.1 Introduction

The aim of this research study was to explore the perceptions of patient safety culture among different healthcare professionals in oncology healthcare settings in Malta. Moreover, this research study aimed to investigate the relationship between safety culture dimensions and reporting of patient safety events. This chapter presents a comprehensive discussion of the findings aligned with this study's research questions as well as with previously published literature. Section 5.2 addresses the research question: How do healthcare professionals working in oncology healthcare settings in Malta perceive patient safety culture? Section 5.3 addresses the research question: Are different healthcare professional groups working in oncology healthcare settings in Malta aligned on their perceptions of patient safety culture? Section 5.4 addresses the research question: What is the relationship between safety culture dimensions and reporting of patient safety events? In conclusion, Section 5.5 underscores the strengths and methodological limitations that emerged during this research study.

5.2 How do healthcare professionals working in oncology healthcare settings in Malta perceive patient safety culture?

Communication openness and deference to expertise are often found as areas in which the healthcare domain struggles due to its hierarchical nature and professional culture (O'Daniel & Rosenstein, 2008). A well-known example of problematic steep hierarchical gradient is the Elaine Bromiley case, in which a previously healthy woman died from cerebral hypoxia following unsuccessful intubation attempts by two anaesthetists during a routine operation. Subsequently, two of the nurses involved reported that they had known what should have been done but refrained from asserting themselves due to the operating theatre's hierarchical structure. Instead, they had used passive and indirect statements, which had had no effect during the critical situation (Green et al., 2016). In a simulation-based qualitative study involving 44 anaesthesia trainees, it was revealed that the existing steep hierarchical gradient had adverse effects on the well-being of trainees as well as on learning and patient safety. The trainees described conflict avoidance and how they often saw themselves as being in the role of bystanders. Surprisingly, some trainees believed that this steep hierarchy was essential in healthcare, especially during critical moments (Bould et al., 2015). Despite this, the results from the quantitative questionnaire showed that overall, healthcare professionals working in oncology healthcare settings in Malta had a positive perception of ''communication openness'' in their unit (M= 4.04, SD= 0.501; 79.1 percent positive score), which was measured by the

extent to how freely healthcare professionals express or raise concerns about patient safety issues and their ease when asking questions when something does not seem right. This was also evident in the qualitative analysis from the focus group interview in which participants expressed comfort in speaking up and asking questions.

Results from the present study also highlight positive perceptions of ‘‘teamwork’’ (M= 4.02, SD= 0.550; 84.3 percent positive score), the extent to which healthcare professionals work together as an effective team, help each other during demanding periods, and are respectful. This finding was also identified during the focus group interview, in which participants expressed a positive sense of team and collaboration among different members in their organisation. This is in concordance with previously published literature with similar objectives also conducted in different oncology healthcare settings (Adamson 2022b; Alharbi et al., 2018; Legg et al., 2013; Sharp et al., 2019; Zhong et al., 2019) as well as with local studies conducted in high dependency units (Baldacchino, 2009) and nursing homes (Zammit & Borg, 2008; as cited in Mallia et al., 2009). Teamwork on the front lines has been promoted as a strategy to enhanced safety in healthcare as well as other industries (e.g., Dinius et al., 2020; Weaver et al., 2017; Weller et al., 2014). Research suggests that high-performing healthcare teams which exhibit a patient-centred collaborative approach result in improved clinical outcomes (Cuff et al., 2014; Levit et al., 2013). It may be argued that teamwork in the oncology healthcare setting is particularly important in view of its inherent complexities, requiring the collaboration of different healthcare professionals (Alharbi et al., 2018).

Within the realm of teamwork is the coordination and communication required during information exchange and handoffs. Results from the quantitative analysis also highlighted positive perceptions of the dimension ‘‘handoff and information exchange’’ (M= 3.84, SD= 0.630, 75.5 percent positive score), the extent to which important patient information is transferred during transitions between healthcare professionals, shift changes and different units. On the other hand, while participants in the focus group interview expressed general positive perceptions of handoff and information exchange, they also recalled instances in which incomplete handover could have led to both patient and healthcare professional harm.

Similar to high-risk organisations, healthcare settings consist of complex, tightly coupled systems which operate under time-pressured and resource-constrained environment with a potential for high consequences for system failure. Furthermore, the flow of work is distributed across multiple individuals in dedicated roles, contributing their unique expertise and knowledge (Patterson et al., 2004). A recent systematic review highlights the importance of an effective handover. The study found that poor handover was associated with multiple potential adverse events including inaccurate diagnosis, treatment errors, treatment delays, delays in pending investigations as well as lack of availability of necessary equipment (Desmedt et al., 2020). However, the researchers found that there is little evidence delineating what would constitute to a gold-standard handover practice. According to Desmedt and colleagues (2020) most initiatives found in literature focus on facilitating care coordination and communication between healthcare professionals through electronic tools or standardised forms. Furthermore, success in handoff improvements appears limited to specific projects and mainly involves efficiency-related outcomes, or surrogate patient safety measures such as job satisfaction, patient satisfaction and saved nursing time. However, while research seemed to be inconclusive with regards to which interventions or initiatives improve handover, the researchers found that good handover is essential to reduce potential risks or adverse events (Desmedt et al., 2020).

Notably, healthcare professionals working in oncology healthcare settings in Malta have more positive perceptions in the above dimensions of safety culture, when compared to the database published by the AHRQ (Hare et al., 2022). Conversely, participants in this study exhibited more negative perceptions regarding the other dimensions of patient safety culture in comparison to the referenced database (Hare et al., 2022) namely with regards to hospital management support for patient safety, supervisor or management support for patient safety, response to error, staffing and work pace, communication about error, organisational learning and the reporting of patient safety events.

These findings suggest that, while healthcare professionals expressed comfort in collaborating, communicating openly and speaking up among frontline colleagues (i.e., enacting actions), they may lack the same level of comfort or trust in top management. This is further evidenced by poor perceptions of ‘‘hospital management support for patient safety’’ (M= 2.92, SD= 0.784, 27.9 percent positive score). In concordance, data from the open-ended responses as well as

focus group interview also highlight poor perceptions of senior level support towards safety. This finding stands in striking contrast to the AHRQ SOPS hospital database, which demonstrates a still disappointing 64 percent positive score (Hare et al., 2022). Hospital management, gauged by the extent to which management show that patient safety is a top priority and provide necessary resources, is a critical safety culture component (Bastani et al., 2021). In other words, management support can set the tone for a positive safety culture within the organisation.

On the other hand, interestingly, participants held positive perceptions of mid-level managers' support for patient safety, which was gauged by the extent to which managers give weight to employee suggestions aimed at improving patient safety, discourage the use of shortcuts, and actively address concerns related to patient safety (M= 3.79, SD= 0.586, 70 percent positive score). Furthermore, participants in the focus group interview provided further insight and made a clear distinction between senior and mid-level managers and their respective roles in maintaining patient safety and fostering a positive safety culture.

Throughout the years, various research has highlighted the critical role of senior management support in safety performance, safety performance outcomes and fostering a positive safety culture in healthcare as well as other industries (e.g., Zohar, 1980; Michael et al., 2005; Zacharatos et al., 2005; Mearns & Reader, 2008; Watcher & Yorio, 2014; Salem & Malik, 2022; Seo & Lee, 2022). For instance, Salem and Malik (2022) found how safety management practices were linked to employee safety performance through safety consciousness and safety climate in pharmaceutical firms. Watcher and Yorio (2014) found a significant correlation between a number of safety management system practices (e.g., safe work procedures, cooperation facilitation, safety training, communication and information sharing, detection and monitoring, accident investigation, safe task assignment) on both employee engagement levels as well as safety performance outcomes (e.g., accident rates) across multiple industrial sectors.

Hospital management may demonstrate their support towards safety with a number of tools and initiatives, with the one of the most commonly cited being executive walkarounds. A recent systematic review found that longer exposure to leadership walkarounds, combined with

feedback mechanisms, were positively associated with operational and cultural outcomes (e.g., safety attitudes) (Foster et al., 2023). However, the researchers suggest that further evidence is required to establish an association between leadership walkarounds and patient clinical outcomes (Foster et al., 2023).

Furthermore, in the realm of hospital management support for patient safety, the provision of resources extends to human resources. Specifically, staffing levels. Findings from the quantitative and qualitative analysis highlight that overall, healthcare professionals working in oncology healthcare settings in Malta had negative perceptions of ‘‘staffing and work pace’’ (M= 2.81, SD= 0.833, 28.2 percent positive score). This dimension was measured in terms of adequate staffing levels to handle the workload, work pace, appropriate working hours as well as limited or restricting reliance on temporary staff. Participants, especially among the nursing profession, expressed great concern regarding staffing levels, stating that they feel pressured to rush certain aspects of patient care, compromising care with shortcuts and ultimately exacerbating the potential for lapses. Notably, in concordance with the AHRQ SOPS hospital database (lowest scoring dimension with 51 percent positive score among most hospitals in the database, -6% from 2021; Hare et al., 2022), this area exhibited the most negative perceptions (in terms of M score), underscoring the need for potential improvement. Furthermore, this finding is consistent with previously published literature on safety culture in oncology healthcare settings (Alharbi et al., 2018; Sharp et al., 2019; Zhong et al., 2019), with international studies conducted in other contexts (e.g., Oweidat et al., 2023) as well as with local studies conducted in high dependency units (Baldacchino, 2009) and nursing homes (Zammit & Borg, 2008; as cited in Mallia et al., 2009).

Similarly, a qualitative study highlights shortage of staff as a primary challenge for oncology nurses in providing hospice care (Zheng et al., 2021). One participant mentioned that the shortage of human resources led to an increased workload which as consequence, prevented healthcare professionals from providing compassionate care due to lack of time. This statement is also in concordance with a direct quotation from the open-ended responses in the questionnaire: ‘‘… I find it very challenging to provide safe medical care as well as support and provide psychological care … I feel rushed in whatever I am doing.’’

Appropriate staffing is of utmost importance, particularly in healthcare as frontline workers directly interact with patients, influencing the safety and quality of care. In addition, employees at the sharp end are the last line of defence in mitigating errors. Literature highlights the negative consequences of nursing shortages, particularly of permanent employees. According to Dall'Ora and colleagues (2022), there is a plausible casual relationship between low nursing staffing levels and patient mortality. The systematic review of longitudinal studies found that higher nursing staffing levels reduce the risk of patient mortality in acute healthcare settings however, according to the researchers, the limited number of studies identified with a low risk of bias made it difficult to provide generalisable estimates of effect (Dall'Ora et al., 2022). Similarly, Zaranko et al. (2023) found a statistically significant association between the proportion of planned nurse hours that were worked and inpatient mortality in the English National Health Service (OR 0.9883, 95% CI 0.9773 to 0.9996, p= 0.0416). On the other hand, Zaranko and colleagues (2023) did not identify an association for agency nurses or healthcare support workers, indicating that these are not effective substitutes for nursing shortages.

A number of patient acuity tools to assist management in fair and appropriate assignment decision have been developed in a number of contexts. For instance, Brennan and colleagues (2012) assessed the reliability and validity of an oncology acuity tool used among inpatient haematology, oncology and bone marrow transplant units. The researchers identified high inter-rater reliability, moderately strong concurrent validity, and moderate content validity for the acuity tool, meaning that this can provide nurse managers with real-time, reliable and valid measurements of patient care demands. This can be used to inform and assist nurse assignment decisions and create balance in nursing workload, potentially improving both nurse and patient outcomes.

Findings from both quantitative and qualitative analysis also highlight a negative perception of ‘‘response to error’’ (M= 2.72, SD= 0.714, 24.1 percent positive score), highlighting a prevalent perception of blame-culture among healthcare professionals working in oncology healthcare settings in Malta. As expected, ‘‘hospital management support for patient safety’’ was positively correlated to ‘‘response to error’’ (r= 0.467, p= 0.000). Participants in the focus group indicate that ‘‘there is a strong blame culture…’’ (NUR1) and that they ‘‘do not feel comfortable writing an incident report’’ (NUR1). In the open-ended responses, one participant

also suggested that the management ‘‘should evaluate all factors that could have led to that error instead of shifting blame on healthcare professionals.’’ In addition, a poor perception of ‘‘response to error’’ was also identified in previously published literature conducted in oncology healthcare settings (Alharbi et al., 2018; Legg et al., 2013; Zhong et al., 2019) as well as studies conducted in other local contexts (Baldacchino, 2009; Petrova, 2010; Mangion, 2021). Leape et al. (2000) stated how ‘‘punishment drives reporting of errors underground’’. Numerous studies emphasize the negative effects of blame culture in healthcare (Khatri et al., 2009; Jafree et al., 2015). Okpala (2022) conducted a quantitative analysis of 21 research studies and found that blame culture negatively affects the nurses' willingness to report errors. Furthermore, Okpala (2022) found that a blame culture is associated with increased nurse turnover, negatively impacts nurses' well-beings as well as affects nurses' behaviour with regard to patient selection. The latter was evidenced by the fact that almost 60% of nurses working in healthcare settings with a prevailing blame culture tend to avoid uncooperative patients or patients with complicated health conditions (Okpala, 2022).

A body of literature in both healthcare and industry highlight the importance of shifting from a culture of blame to a learning culture and adopting a systematic approach to errors (Murray et al., 2022; Parker & Davies, 2020). Rather than viewing errors in isolation, a systematic approach entails analysing them comprehensively and addressing underlying systemic issues. This involves implementing standardised protocols, robust reporting systems, and thorough root cause analyses to identify the factors contributing to errors and identifying preventative measures (Charles et al., 2016). Despite this, as also evidenced by the findings from the present study, blame culture persists in many healthcare organisations.

Two important safety culture areas related to the elaborating actions proposed by Vogus et al. (2010) measured in the present study were ‘‘communication about error’’ and ‘‘organisational learning and continuous improvement’’, in which the quantitative analysis revealed an overall moderately positive perception among participants (M= 3.45, SD= 0.872, M= 3.49, SD= 0.778, respectively). Furthermore, as expected, ‘‘communication about error’’ was positively correlated with ‘‘organisational learning and continuous learning’’ (r= 0.388, p= 0.000). The dimension ‘‘communication about error’’ was gauged by how staff are informed when errors occur, how staff are involved in discussions on ways to prevent future errors and are informed

when changes are implemented. On the other hand, the dimension ‘‘organisational learning and continuous improvement’’ was measured by how employees perceive the regular review of work processes, the implementation of changes to prevent recurring errors, and the evaluation of these changes. For incident reporting systems to be effective it should not only collect data (i.e., incident reports). However, it should also conduct comprehensive analysis, provide feedback and communicate findings to staff, and implement corrective actions (Farokhzadian et al., 2018).

On the other hand, the qualitative analysis from the present research study revealed mixed findings as participants expressed frustration regarding the effectiveness of incident reporting stating that they often felt that their concerns were met with inaction in terms of feedback and learning from errors. In comparison, Farokhzadian et al. (2018) also found that nurses believed that the absence of actions by management e.g., feedback to staff or follow-up of their report indicates the lack of importance of reporting and highlighted the following direct quotation: ‘‘We completed lots of error reporting forms and sent them to the office of quality improvement, but we did not receive any feedback or corrective action. Thus, we conclude that reporting has no benefit.’’ In particular, the aforementioned excerpt directly compares the sentiments expressed by one participant in the nursing profession during the focus group interview in the present research study: ‘‘…We are never given feedback, and very rarely something is implemented to change or avoid that the incident happens again’’ (NUR3). Subsequently, one participant in the focus group interview suggested the implementation of a feedback loop systems in the local oncology setting in which hospital management can communicate details about incidents, findings from investigations and actions taken.

A study conducted among healthcare professionals providing care to oncology patients in a tertiary healthcare hospital revealed that 36.3% of participants perceived no feedback after reporting an error as a barrier or hindrances to reporting incidences (Bany Hamdan et al., 2023). The study also highlights individualised feedback after submitting a report as an important strategy to increase incident reporting (Bany Hamdan et al., 2023). Furthermore, literature suggests that reinforcing positive safety behaviours with communication and feedback could result to improved safe practices. For instance, audit with feedback is a quality improvement

strategy implemented with the aim of modifying healthcare professionals' professional practice (Ivers et al., 2012; Jamtvedt et al., 2017).

The outcome measure of ''reporting of patient safety events'' assessed the reporting of errors in two main categories: a. near misses i.e., error caught and rectified prior to reaching the patients and b. errors that could have harmed the patient but did not. Findings from the quantitative analysis highlight moderately neutral perception of reporting incidents among healthcare professional working in oncology healthcare settings in Malta (M= 3.22, SD= 0.942, 40.0 percent positive score), yet revealing a relatively lower score than that reported by the AHRQ SOPS hospital database (74.0 percent positive score; Hare et al., 2022). Additionally, quantitative data shows that almost half of the respondents (47.3%) did not report any patient safety events in the previous 12 months whereas only 6 participants (4.7%) had reported 3 to 5 patient safety events and only 1 participant (0.8%) had reported 6 to 10 patient safety events in the previous 12 months.

A number of learning tools and initiatives utilised in high reliability organisations have been transferred to the healthcare setting (Serou et al., 2021). One primary example is that of the introduction of incidents reporting systems. Incident reporting systems play a crucial role in organisation learning and risk reduction as they provide valuable information on hazards and potential risks that may lead to staff or patient harm. The information and data gathered by the incident reporting systems is useful for organisation to implement targeted initiatives or preventive measures with the aim of decreasing the likelihood of future incidents (Serou et al., 2021). Literature highlights numerous distinguishing features embedded in various incident reporting systems aimed at improving their effectiveness. For instance, the IAEA in the United States developed the Safety Reporting and Learning System for Radiotherapy, which enables staff to both submit their own incident reports as well as review reported incidents related to similar technologies, procedures or near misses. This has been useful for organisations which are about to adopt new procedures or introduce new technologies or equipment to review incidents beforehand and learn from other facilities who have implemented similar procedure, technologies or equipment (Trad & Romanofski, 2017). Therefore, this information would enhance quality assurance and safety.

Furthermore, existing literature reveals key insights that point towards several initiatives or interventions aimed at improving incident reporting. Apart from instilling a learning culture and a feedback loop system as discussed above, literature also suggests including patient safety education in undergraduate courses and teaching students to recognise and report errors (Umer Mohsin et al., 2019; Swinfen et al., 2023).

Finally, findings from the qualitative analysis revealed a noteworthy component of safety culture, that had not been encapsulated and explored by the questionnaire – that of training and continuous professional development. Participants highlighted the importance of continuous professional development and competency enhancement specific to the oncology setting in safeguarding both patients' and healthcare professionals' safety as well as fostering professional growth. Engaging in continuous professional development is considered as central for healthcare professionals to deliver high-quality, safe care, and keep pace with the evolving evidence-based practices as numerous research studies highlight the importance of continuous professional development in oncology care as well as other healthcare settings (e.g., Burt & Spowart, 2021; Luconi et al., 2019; Hojati et al., 2023; Main & Anderson, 2023; McBride et al., 2023; Mohammed et al., 2023). For instance, a quasi-experimental study found a reduction of 83% in central line associated bloodstream infection across critical care units six months after the implementation of a new standardised education programme (Burt & Spowart, 2021). Another recent quasi-experimental study found that a training program had statistically significant improvement on totally nurses' knowledge and practice on minimising chemotherapy extravasation (Mohammed et al., 2023). It is noteworthy that other researchers have also utilised other innovative methods such as e-learning to promote oncology and chemotherapy safety standards, suggesting diverse approaches to accommodate different learning styles and enhance accessibility to training in oncology care (Hojati et al., 2023). Moreover, a recent systematic review found that mandatory continuous professional development requirements are a strong motivational factor for their completion and improve healthcare professionals' knowledge and behaviour (Main & Anderson, 2023). Additionally, Main and Anderson (2023) found that interactive continuous professional development is most effective. However, the study concluded that while there was no direct evidence on the ideal quantity of training sessions or courses, there is evidence that complex technical skills may require more frequent continuous professional development (Main & Anderson, 2023).

5.3 Are different healthcare professional groups working in oncology healthcare settings in Malta aligned on their perceptions of patient safety culture?

In the present study, significant differences in responses were observed across socio-demographic characteristics, including among different healthcare professional groups. For instance, radiographers (therapeutic and/or diagnostic) perceive staffing and work pace more positively (M= 3.80, SD= 0.533) when compared to enrolled nurses and staff nurses (M= 2.15, SD= 0.395, p= <0.001) whereas charge nurses and deputy charge nurses perceive communication about error more positively (M= 4.22, SD= 0.500) when compared to enrolled nurses and staff nurses (M= 3.23, SD= 0.761, p= <0.001). This may be explained by various factors such as different workloads, initial training and ongoing safety training. Furthermore, this variation in patient safety culture among different healthcare professionals is consistent and adds to previously published literature conducted in oncology healthcare settings (Adamson 2022a; Adamson 2022b; Alharbi et al., 2018; Fermo et al., 2015) as well as other contexts (Al-Mugheed et al., 2022; Alsabaani, 2020; Tran et al., 2022; Wagner et al., 2019; Willmot and Mould, 2018).

Despite this, the qualitative analysis from the focus group interview did not corroborate this finding. However, it should be noted that the focus group interview included a small number of participants and was conducted only once. Furthermore, some participants may have omitted from voicing their opinion during the focus group interview, allowing other individuals to voice their concerns without expressing opposing contradicting statements.

As stated by Tran et al. (2022), understanding the similarities and differences between different healthcare professional groups allows the implementation of appropriate and focused initiatives. In terms of interventions to address patient safety culture, one ‘‘size’’ does not fit all. Findings from the present study as well as other published literature in various settings highlight the need for adaptivity and individualised approach in prioritising and implementing strategies among diverse healthcare professional groups.

5.4 What is the relationship between safety culture dimensions and reporting of patient safety events?

In the present research study, the author investigated the relationship between safety culture and reporting of patient safety events in oncology healthcare settings. Findings indicate a statistically significant positive correlation between some dimensions of safety culture and the reporting of patient safety events, namely communication about error (rho= 0.551, p= 0.000), response to error (rho= 0.500, p= 0.000), hospital management support for patient safety (rho= 0.219, p= 0.013), organisational learning and continuous improvements (rho= 0.245, p= 0.005). Following this, a collective analysis was conducted by fitting a regression model and employing a forward procedure to identify the parsimonious model including only the significant predictors.

Specifically, higher levels of communication about error (p= <0.001) and higher levels of response to error (p= 0.008) were identified as significant predictors of higher frequency of event reporting, explaining 38.4% of the total variation in the responses (r= 0.384). This result suggests that healthcare professionals who are informed about errors, healthcare professionals who are involved in discussions to prevent them as well as healthcare professionals who are informed about changes that are implemented are more inclined to report patient safety events (t= 4.718, p= <0.001). Furthermore, when healthcare professionals are treated fairly when an error occurs, as well as receive a supportive environment that emphasises learning within their unit, they are more inclined to report patient safety events (t= 2.717, p= 0.008). This finding emphasises the significance of feedback systems as well as the significance of just culture in error management and their contribution to safety behaviour, specifically incident reporting.

Within the local context, Mangion (2021) found that lack of feedback was perceived as the greatest barrier to incident reporting in the acute, general hospital (M= 3.67, SD= 1.192, p<0.001). In addition, this aligns and adds to previously published international literature with similar objectives conducted in different healthcare settings identified in the CAT (Al Ma'mari et al., 2019; Al Ma'mari et al., 2021; Alhassan et al., 2022; Ballangrud et al., 2012; Farag et al., 2019) as well as other industries (Sanne, 2008; Lappalainen et al., 2011; Norman, 2022).

For instance, Al Ma'mari et al. (2021), Alhassan et al. (2022), Ballangrud et al. (2012) and Farag et al. (2019) also found that feedback and communication about errors was a significant predictor of the frequency of events reported among nurses working in tertiary hospital settings ($R2= 0.214$, $F= 12.82$, $p= <0.01$; $\beta= 0.36$, $p= <0.001$; $\beta= 0.437$, $p= 0.000$; $\beta= 0.38$, $p= <0.001$, respectively). This finding suggests that an organisation's failure to provide timely feedback about errors and about actions or changes implemented to prevent future errors translates to healthcare professionals that their incident report is devalued. In turn, this may discourage them from reporting future near misses and adverse events.

Furthermore, a participant in the focus group interview expressed how discouraging it is to write incident reports and not getting feedback and suggested the implementation of regular investigations and audits on reported incidents as well as completed feedback loops to encourage learning from past errors. This closely mirrors the findings of Elder and colleagues (2008). Nurses participating in a qualitative study stated that when there is a lack of adequate feedback following an incident report, they feel like their report went into a ''black hole'' (Elder et al., 2008). Similarly, in the local context, Mangion (2021) presented a participant's perspective, which revealed a sense of frustration and perceived futility. The participant expressed that, despite submitting a number of incident reports, they did not receive feedback or follow-up leading them to perceive the incident reporting system as ''pretty useless''. Additionally, in industry, Lappalainen et al. (2021) found that poor feedback following reported incidents decreased the motivation of maritime employees. The researchers highlighted that, when employees did not receive feedback on past reports, they experienced reluctance to make future incident reports.

It is clear that feedback to frontline employees is an important yet often undervalued area in incident report systems. As evident from published literature, the current consensus is that, unfortunately, the feedback loop of incident reporting is rarely completed (e.g., Elder et al., 2008; Mandavia et al., 2013; Hewitt et al., 2016; Mangion, 2021). In their systematic review, Benn et al. (2009) found that the provision of actionable feedback was highlighted as important in encouraging future incident reporting. Benn et al. (2009) also identified a number of action and information requirements that would constitute to an effective feedback mechanism including aspects such as leadership, the credibility and content of information, dissemination

channels, the capability for rapid action, feedback at multiple levels of the organisation, and feedback that preserves confidentiality, among others. According to Hewitt et al. (2016), data collected from incident reporting systems serves little purpose if its effects are not fed back to the reporter. In their guideline on the establishment and effective use of incident reporting and learning systems, the WHO (2005; 2020) emphasize the importance of feedback as a key element. However, the WHO (2020) also acknowledge the inherent challenge in this domain, given that the volume of incidents often hinders the feasibility of investigating each report individually.

Some authors have described incident reporting systems with feedback loops that have effectively contributed to patient safety. For instance, in a study conducted by Evans et al. (2007), enhancing feedback though newsletters and information dissemination at regular departmental meetings was found to increase incident reporting rates across nursing and medical staff working in tertiary hospital settings. As highlighted by Brunsveld-Reinders et al. (2016), if the management do not take action based on the submitted incident reports, this could lead to apathy and reluctance among healthcare professionals to report near misses and errors.

The second significant predictor of incident reporting was ‘‘response to error’’. As stated above, in concordance with the present research study, a non-punitive response to error is also often cited in literature as a predictor for adverse event reporting in healthcare organisations. For instance, Alhassan et al. (2022) and Farag et al. (2019) found that a non-punitive response to error was a significant predictor of adverse event reporting among nurses working in a tertiary healthcare setting ($\beta = 0.22$, $p = <0.01$; $\beta = 0.22$, $p = <0.001$, respectively). The majority of adverse events in healthcare result from the intricate interplay between frontline individuals' actions and system failures, also referred to as active failures and latent failures, with greater weight given to the latent failures. Reason's (2000) model describes how human error is inevitable however, errors are frequently the result of multiple latent failures within the system and states ‘‘the important question is not who blundered, but how and why the defences failed’’. Despite this, a fear of retribution is thought to explain much of the existing reluctance among frontline healthcare professionals to make use of incident reporting systems (Cooper et al., 2017; Iedema et al., 2011).

In contrast, in the local context, Mangion (2021) found that concerns about disciplinary action and litigation, although still present, were not amongst the major perceived barriers of reporting among nurses working at the acute, general hospital (e.g., 'I am worried about disciplinary action', M= 2.62, SD= 1.254). This may be attributed to contextual differences. It is noteworthy that the present study was conducted in a smaller hospital setting in the local context of Malta. Therefore, it is plausible that the size of the hospital may have played a role, creating a more closely-knit environment potentially leading healthcare professionals to perceive a heightened risk of repercussions for their actions.

5.5 Strengths and limitations

The present study exhibits a number of strengths as well as limitations, both of which will be explicated in this section. First, the researcher employed a descriptive and analytical cross-sectional study design. The cross-sectional nature of the study hindered the identification of trends or changes over time. In addition, establishing causal relationships was not possible. Nonetheless, the researcher managed to gather important insights on perceptions of patient safety culture as well as determine statistical associations between components of safety culture and reporting of patient safety events.

The researcher focused the study on SAMOC, the only oncology hospital in Malta. It is acknowledged that perceptions of patient safety culture vary across different settings. Therefore, some of the findings from this study are not generalisable to other healthcare settings in Malta. On the other hand, this study included various healthcare professionals in the oncology health setting, including nursing staff, radiotherapists, physiotherapists, and other allied healthcare professionals. Including diverse healthcare professionals in the study allowed the researcher to obtain a more comprehensive understanding of the patient safety culture in the oncology context. Furthermore, this approach allowed comparisons across different healthcare professional groups within the oncology multi-disciplinary team, contributing to a nuanced evaluation of safety culture variations among healthcare professionals.

The researcher used a mixed-methods approach to gain a better understanding of healthcare professionals' perceptions on safety culture. The combination of quantitative and qualitative

methodologies allowed for a more comprehensive exploration of healthcare professionals' perceptions, which allowed the identification of factors which could have been overlooked using a single method.

Quantitative data was collected using the SOPS questionnaire (AHRQ, 2019). Notably, the questionnaire was previously validated for reliability and validity (AHRQ, 2018) and the Cronbach's alpha coefficient for the present study ranged between 0.680 and 0.908, indicating that the instrument was reliable. Total population sampling was employed to recruit study participants for the questionnaire. Despite being a non-probability sampling method, total population sampling greatly reduces sampling bias since it includes all available subjects that meet the inclusion criteria (Polit & Beck, 2017). The questionnaire was administered in paper form as it was anticipated to obtain a more favourable response rate. While the use of electronic or online questionnaires as a data collection method is increasing due to several inherent advantages (Wu et al., 2022), evidence also suggests that response rates are lower when compared to paper questionnaires (Meyer et al., 2022; Palmen et al., 2016). Moreover, this study was conducted in a relatively small organisation. Therefore, it was also anticipated that logistically, the paper questionnaire distribution and data analysis would be manageable. Despite these considerations, the study achieved a relatively poor response rate of 53.97%. Although several reminders were sent to the target population throughout the data collection period, this was likely not enough. Unfortunately, non-response bias could not be excluded as the researcher was not able to collect information on non-respondents in view of the anonymous nature of the questionnaire.

The questionnaire was limited with regards to the number of questions posed, overlooking other related areas, particularly in the realm of ongoing training and professional development. Given the expansive nature and multifaceted dimension of patient safety culture, attempting to comprehensively cover all its domains through a 34-item questionnaire is inherently challenging. Despite this, the questionnaire served as a valuable tool for gathering an understanding of perceptions of patient safety culture within its defined scope and investigating the relationship between specific areas of patient safety culture and incident reporting.

As stated above, qualitative data was also collected. This was done through a one-time, semi structured focus-group interview, including 7 different members of the multi-disciplinary team in the oncology setting. It should be noted that patient safety, safety culture and incident reporting are highly sensitive subjects. Therefore, while data collected from the questionnaire was anonymous, data collected during the focus group interview was pseudonymised to protect the confidentiality of the study participants. Despite this, as anticipated, the researcher did not manage to recruit enough participants for multiple or repeated focus group interviews. This can also explain the reason why the majority of research surrounding safety culture utilises quantitative methods.

It is likely that the lack of repeated focus group interviews may have not fully captured the diverse perspectives of participants and restricted the exploration of certain dimensions within the complex topic of patient safety culture. Participants may not have had sufficient time or opportunities to express their views, challenge prevailing opinions or seek clarifications, limiting the depth of data collected and increasing the risk of response bias. In addition, due to the sensitive nature of the topic surrounding safety culture and incident reporting, participants may have refrained from sharing certain experiences or perspectives.

Furthermore, the focus group interview was also subject to sampling and selection bias as the characteristics of the sample may not be fully representative of the wider population and may not capture the diversity of perspectives that could be present with different groups of participants. Finally, the absence of repeated sessions also limited the opportunity for validation and triangulation of findings. Despite this, the focus group interview still managed to elicit valuable and insightful findings.

In conclusion, this research study presented an exploration of patient safety culture among different healthcare professionals in the oncology healthcare setting in Malta. Despite limitations such as potential generalisability constraints as well as a relatively small sample size, the findings contribute significantly to the understanding of safety culture in oncology. The study underscores the need for ongoing efforts to enhance patient safety practices, recognises the inherent differences in perceptions among different healthcare professional

groups and the need for an individualised approach as well as the effects of components of safety culture, in particular communication about error and response to error on incident reporting.

5.6 Conclusion

This chapter discussed the findings of the present research study aligned with the research questions as well as with previously published literature. The methodological strengths and limitations are also outlined. The subsequent and final chapter offers a synopsis of the present research study as well as presents recommendations for health systems managements and future research.

Chapter 6: Conclusion

6.1 Introduction

This chapter presents a synopsis of this research study as well as offers recommendations for health systems management and future research.

6.2 Synopsis of the Research Study

Patient safety culture and incident reporting are integral components of a high-functioning healthcare system. The purpose of the present research study was twofold. First, this research study aimed to explore the perceptions of different healthcare professionals of patient safety culture in oncology healthcare settings in Malta. Second, this research study aimed to investigate the relationship between safety culture dimensions and reporting of patient safety events. While there are increasing international publications exploring the relationship between safety culture dimensions and incident reporting, among other outcomes, research related to this subject is lacking both in the oncology healthcare setting and the local healthcare context.

A critically-appraised topic was carried out to explore literature which investigated the topic of interest. Findings from the critically-appraised topic highlighted the causal mechanism, or relationship, between safety culture and incident reporting in healthcare. Findings indicated that a strong safety culture within healthcare organisations can encourage the reporting of errors or near-misses. Among safety culture sub-dimensions, feedback and communication about error was the most commonly cited predictor of incident reporting.

Subsequently, a retrospective cross-sectional descriptive and analytical research study was conducted, characterised by the collection of data through a mixed-methods, concurrent triangulation approach which included a self-administered, quantitative questionnaire as well as a focus-group interview. For the questionnaire-study, a total population sampling strategy was employed, in which all eligible healthcare professionals working in the oncology healthcare setting in Malta were asked to participate. 129 questionnaires were returned, giving an overall response rate of 53.97%. On the other hand, maximum variation sampling was employed to recruit participants in the focus-group interview. This involved deliberately selecting a diverse range of healthcare professionals in order to capture a broad spectrum of perspectives.

Findings from the quantitative analysis of the present research study revealed a number of fragilities in the perceptions of safety culture among healthcare professionals working in the local, oncology healthcare settings, namely in the following dimensions: hospital management support for patient safety (M=2.92, SD=0.784), response to error (M=2.81, SD=0.714), and staffing and work pace (M=2.72, SD=0.833). Overall, quantitative and qualitative findings aligned. However, participants in the focus group interviews expressed more negative views towards feedback and organisational learning following an incident. In addition to this, consistent with previously published literature, the quantitative analysis revealed statistically significant differences in responses across different healthcare professional groups. However, differences in perceptions across healthcare professional groups did not emerge in the qualitative insights gathered. Furthermore, in addition to the dimensions explored by the quantitative questionnaire, the qualitative insights obtained from the focus group interview revealed a noteworthy component of safety culture, that had not been encapsulated and explored by the questionnaire – that of training and continuous professional development. Participants emphasised its importance in oncology healthcare setting, shedding light on a previously overlooked dimension.

The Spearman correlation identified statistically significant positive correlations between some dimensions of safety culture and the frequency of patient event reporting, namely communication about error, response to error, hospital management support for patient safety, organisational learning and continuous improvements ($p = <0.05$). Furthermore, a regression model and forward procedure were used to identify which factors (i.e., predictors) are most important in explaining the variation in reporting patient safety events. The parsimonious model revealed that communication about errors and response to errors explain 38.4% of the differences in how healthcare professionals working in the local, oncology healthcare settings report patient safety events. Specifically, higher levels of communication about error ($p = <0.001$) and higher levels of response to error ($p = 0.008$) were identified as significant predictors of higher frequency of event reporting, explaining 38.4% of the total variation in the responses ($r = 0.384$). This finding is also evident in the qualitative analysis which revealed how participants expressed frustration with the prevalent blame culture as well as lack of feedback and learning from errors following incidents, which may act as a barrier to reporting

of patient safety events. Essentially, findings highlighted the significance of feedback systems as well as the significance of just culture in error management and their contribution to safety behaviour, specifically incident reporting.

Despite the acknowledged methodological limitations, the findings align well with international published studies particularly in highlighting the significant barriers of insufficient feedback and just culture in incident reporting. In the following sections, recommendations derived from this research study are presented.

6.3 Recommendations

The findings of the present research study suggest action points for health systems management and future research. However, in view of the limitations previously outlined, recommendations for health systems management should only be considered as suggestive rather than conclusive.

6.3.1 Recommendations for Health Systems Management

The present research study identified a number of key areas, that require attention and targeted interventions, namely: staffing and work pace, response to error, hospital management support for patient safety, reporting patient safety events, communication about error, organisational learning and continuous improvement as well as training and continuous professional development. Recognising the imperative role of health systems management in cultivating a positive safety culture in oncology healthcare settings, a number of recommendations based on the findings of the present research study and substantiated by scientific literature, have emerged. It is important to note that, given the identified differences in perceptions across different healthcare professional groups in the quantitative analysis, it is recommended that there is a clear emphasis on the necessity for adaptivity and individualised approach in prioritising and implementing strategies among diverse healthcare professional groups.

- **Staffing and Work Pace**

Regular workload assessments are recommended to ensure appropriate staffing levels in oncology units. Additionally, integrating patient acuity tools, such as that proposed by Brennan et al. (2012), can facilitate the evaluation and management of diverse care needs among oncology patients. These tools are particularly beneficial for informing nurse assignment decisions and ensuring that resources are allocated effectively. By implementing these measures, healthcare organisations can assess and manage the varying levels of care required by patients in the oncology healthcare setting and provide a more balanced staffing approach.

- **Response to Error**

Frequent root cause analyses in response to an error or near miss are recommended. Root cause analyses play a crucial role in understanding factors that have led to an error. Given the preventable nature of many incidents in healthcare, comprehensive root cause analyses have the potential to enhance patient safety (Shah et al., 2022). Additionally, literature highlights the negative effects of blame culture in healthcare and how this effects the willingness to report errors (Okpala, 2022). Therefore, health systems managers are recommended to adopt a systematic approach in response to error and promote a blame-free, learning culture in their organisation. It is essential to cultivate an environment that encourages healthcare professionals to report incidents, near misses or safety concerns without fear that they will be disciplined or personally blamed as a result.

- **Hospital Management Support for Patient Safety**

Senior hospital management needs to show visible commitment towards patient safety. Although other competing priorities exits (e.g., increasing healthcare costs), it is imperative for hospital management to give a prominent status to patient safety within the vision and objectives of the hospital's management and organization. For instance, leadership walk rounds are recommended as an effective intervention in which senior hospital management can obtain feedback from frontline healthcare professionals and show their commitment towards safety (Foster et al., 2023).

- **Reporting Patient Safety Events**

Introducing incident reporting systems to student nurses, medical students, and other health sciences students during their undergraduate education is essential. They should be equipped with the knowledge and skills to identify and report near misses and errors effectively, as highlighted by Umer Mohsin et al. (2019) and Swinfen et al. (2023). It is also recommended to invest further in the current incident reporting system and incorporate user-friendly updates. This recommendation is supported by Trad and Romanofski (2017) who highlighted the benefits of an incident reporting system which users to submit reports and review incidents related to similar technologies, procedures, or near misses. Such a system proves valuable for organisations adopting new procedures or introducing new technologies, facilitating the learning from incidents in similar facilities.

- **Communication about Error**

Health systems managers are advised to provide effective feedback following incident reporting. A closed safety-feedback loop is recommended if healthcare organisations are to learn from incidents and failures in the delivery of care (Benn et al., 2009). Through the transparency and information sharing, the safety-feedback loop addresses the ‘‘black hole’’ identified in the present study as well as other research studies (e.g., Elder et al., 2008; Lappalainen et al., 2021) and therefore, encourages healthcare professionals to further report errors and near misses knowing that their contributions lead to tangible improvements in patient safety.

- **Training and Continuous Professional Development**

Implementing introductory training sessions focused on specific skills pertinent to the oncology setting (e.g., caring for patients with neutropenia, caring for central venous access devices, handling and administrating cytotoxic drugs and caring for patients receiving chemotherapy) which are provided to healthcare professionals prior to commencing their roles in the oncology healthcare setting is recommended. Similarly, establishing a structured, interactive and comprehensive continuous professional development program for healthcare professionals working in the oncology healthcare settings to enhance and update their knowledge and skills is also recommended (Burt & Spowart, 2021; Luconi et al., 2019; Main

& Anderson, 2023; McBride et al., 2022). For instance, a recent quasi-experimental study found that a training program had statistically significant improvement on totally nurses' knowledge and practice on minimising chemotherapy extravasation (Mohammed et al., 2023). It is noteworthy that other researchers have also utilised innovative methods such as e-learning to promote oncology and chemotherapy safety standards, suggesting diverse approaches to accommodate different learning styles and enhance accessibility to training in oncology care (Hojati et al., 2023). These recommendations are underscored by the specialised nature of oncology care, emphasising the critical need for healthcare professionals to be proficient in these areas.

6.3.2 Recommendations for Future Research

The present research study has presented valuable insights into safety culture perceptions in oncology healthcare settings in Malta as well as on the impact of safety culture dimensions on incident reporting. However, in the pursuit of advancing knowledge in the field of safety culture and patient safety, several recommendations for future research have emerged. The following recommendations outline key areas for exploration in future research:

- Future research should further explore the relationship between safety culture, and its specific components, on other patient outcomes (e.g., patient satisfaction, length of hospitalisation, central line-associated bloodstream infections, readmission rates and mortality rates) as well as employee outcomes (e.g., job satisfaction, burnout, staff turnover and injury). Furthermore, future research should investigate the effectiveness of organisational interventions (e.g., leadership walk rounds, feedback mechanisms and crew resource management), new technologies (e.g., electronic health documentation) and training initiatives or programs aimed at enhancing the safety culture in oncology healthcare settings, and their effects on patient as well as employee outcomes. Such research is deemed as feasible by utilising available data (e.g., rehospitalisation rates, key performance indicators, incident reports and root cause analysis) as well as using reliable and valid data collection instruments and can provide significant contributions to both patient care and staff well-being.
- Future research should further explore and unravel the distinct effects of senior management and front-line managers in healthcare settings, discern their respective

influences on safety-related outcomes and gauge the unique contributions of each managerial tier to understand their relative impact on patient and employee outcomes.

- Future research should consider employing longitudinal designs, rather than cross-sectional studies, to establish causality between safety culture and dependant variables.
- Future research should further employ mixed-method research designs (including oneon-one interviews, multiple focus-groups as well as observations) to gain a comprehensive understanding of safety culture among healthcare professionals.
- Finally, future research should also utilize larger sample sizes and strive for improved response rates to minimize bias and enhance the reliability and generalisability of the findings.

6.4 Conclusion

This research study has given readers insight into healthcare professionals' perceptions of safety culture as well as the impact of safety culture on incident reporting in the local oncology healthcare setting. The study indicated various deficiencies inherent in the local safety culture. Strong commitment is required from all stakeholders involved into effectively implementing the suggested recommendations. Furthermore, the study shed light on the significance of feedback following incidents as well as learning culture on the safety behaviour of incident reporting. While acknowledging that substantial shifts in safety culture take time, the potential improvements in overall patient safety validate the collaborative efforts.

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Appendices

Appendix A: Patient Safety Events – Accidental Administration of Vincristine Sulphate

Vincristine Sulphate, commonly known as Vincristine, is a cytotoxic chemotherapeutic agent widely used for a number of malignancies, including acute lymphocytic leukaemia, Hodgkin and Non-Hodgkin lymphoma, neuroblastoma and Wilms tumour. This drug is usually prescribed as a part of multi-drug chemotherapy regimens and is administered intravenously only. Administration through any other route may have fatal consequences for patients (Reddy et al., 2011). However, despite its long-term and extensive use, Vincristine has been repeatedly associated with several cases of preventable medication errors, including accidental intrathecal administration (e.g., Dettmeyer et al., 2001; Alcaraz et al., 2002; Qweider et al., 2007; Chotsampancharoen et al., 2016). According to Gilbar (2020), there have been at least 135 reported cases of accidental Vincristine intrathecal administration. However, Gilbar (2020) also states that the true incidence of inadvertent Vincristine is not known and there are probably many more episodes that have likely gone unreported. Intrathecal administration of Vincristine causes devastating and irreversible neurotoxic effects, usually leading to coma and death. This medication error generally occurs when Vincristine is confused with other drugs which are normally administered intrathecally such as Cytarabine and Methotrexate (Reddy et al., 2011).

Appendix B: Critical Appraisal Tools

JBI CRITICAL APPRAISAL CHECKLIST FOR ANALYTICAL CROSS SECTIONAL STUDIES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5. Were confounding factors identified?	☐	☐	☐	☐
6. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

JBI CRITICAL APPRAISAL CHECKLIST FOR QUASI-EXPERIMENTAL STUDIES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

	Yes	No	Unclear	Not applicable
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	☐	☐	☐	☐
2. Were the participants included in any comparisons similar?	☐	☐	☐	☐
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	☐	☐	☐	☐
4. Was there a control group?	☐	☐	☐	☐
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	☐	☐	☐	☐
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	☐	☐	☐	☐
7. Were the outcomes of participants included in any comparisons measured in the same way?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

Appendix C: Questionnaire Information Letter

L-Università ta' Malta
Faculty of Health Sciences

Department of Health
Systems Management
& Leadership

Patient Safety Culture in Oncology Healthcare Settings in Malta

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''.

The aim of this research study is to provide a baseline assessment of the perceived patient safety culture within the oncology healthcare setting in Malta. This study includes healthcare professionals and management working in an oncology healthcare setting in Malta for at least 6 months. This project is being conducted under the supervision of Dr Patricia Vella Bonanno (Supervisor) and Prof Sandra Buttigieg (Co-Supervisor).

You are invited to complete the survey attached. This will take you approximately 15 minutes to complete. Findings from this study may be used to recommend and implement strategies or initiatives to improve the safety culture in oncology healthcare settings. There are no direct benefits to study participants in taking part. Participation in this study may entail certain risks (e.g., exposing unsafe practices, recalling of adverse events, feelings of stress...). The Psychology Department at Mater Dei Hospital offers free psychological support to all employees and can be contacted on +356 25456900 or +356 25456901. To protect the privacy of the participants, the survey is anonymous. At no point will you be asked to provide your name or any other personal data that may lead to you being identified. Furthermore, you may skip over any questions that you

do not wish to answer. Participation is entirely voluntary, i.e., you are free to accept or refuse to participate.

Completed surveys can be posted in boxes made purposefully for this study. Completion and return of the survey will indicate your willingness to participate in the study. A copy of this information sheet is being provided for you to keep and for future reference.

Thank you for your time and consideration. Should you have any questions or concerns, you may contact myself or my supervisors on the details provided below.

Yours Sincerely,

Kelly Spagnol
kelly.spagnol.14@um.edu.mt
[redacted]

Dr Patricia Vella Bonanno
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Prof Sandra Buttigieg
sandra.buttigieg@um.edu.mt
[redacted]

Appendix D: The Hospital Survey on Patient Safety Culture adapted from the AHRQ

Hospital Survey on Patient Safety (Version 2.0)

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10-15 minutes to complete. If a question does not apply to you or your hospital or you don't know the answer, please select "Does Not Apply or Don't Know."

- *"**Patient safety**" is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of healthcare delivery.*
- ***A "patient safety event" is defined as any type of healthcare-related error, mistake, or incident, regardless of whether or not it results in patient harm.***

Your Staff Position

1. What is your position in this hospital?

Select ONE answer.

Nursing

☐1 Enrolled Nurse, Staff Nurse

☐2 Focal Nurse, Practice Nurse

☐3 Deputy Charge Nurse, Charge Nurse

☐4 Senior Nursing Manager, Chief Nursing Manager

Medical

☐5 Basic Specialist Trainee

☐6 Higher Specialist Trainee

☐7 Resident Specialist

☐8 Consultant

Pharmacy

☐9 Pharmacy Technician

☐10 Pharmacist

Allied Health/Other Clinical Position

☐11 Care Worker, Health Carer, Senior Health Carer

☐12 Phlebotomist/Phlebotomy Technician

☐13 Occupational Therapist

☐14 Physiotherapist

☐15 Radiographer (Therapeutic and/or Diagnostic)

1

SECTION A: Your Unit/Work Area

How much do you agree or disagree with the following statements about your unit/work area?

Think about your unit/work area:	Strongly Disagree ←	Disagree ←	Neither Agree nor Disagree ←	Agree ←	Strongly Agree ←	Does Not Apply or Don't Know ←
1. In this unit, we work together as an effective team	☐1	☐2	☐3	☐4	☐5	☐9
2. In this unit, we have enough staff to handle the workload	☐1	☐2	☐3	☐4	☐5	☐9
3. Staff in this unit work longer hours than is best for patient care	☐1	☐2	☐3	☐4	☐5	☐9
4. This unit regularly reviews work processes to determine if changes are needed to improve patient safety	☐1	☐2	☐3	☐4	☐5	☐9
5. This unit relies too much on temporary, float, or PRN staff	☐1	☐2	☐3	☐4	☐5	☐9
6. In this unit, staff feel like their mistakes are held against them	☐1	☐2	☐3	☐4	☐5	☐9
7. When an event is reported in this unit, it feels like the person is being written up, not the problem	☐1	☐2	☐3	☐4	☐5	☐9
8. During busy times, staff in this unit help each other	☐1	☐2	☐3	☐4	☐5	☐9
9. There is a problem with disrespectful behavior by those working in this unit	☐1	☐2	☐3	☐4	☐5	☐9
10. When staff make errors, this unit focuses on learning rather than blaming individuals	☐1	☐2	☐3	☐4	☐5	☐9
11. The work pace in this unit is so rushed that it negatively affects patient safety	☐1	☐2	☐3	☐4	☐5	☐9
12. In this unit, changes to improve patient safety are evaluated to see how well they worked	☐1	☐2	☐3	☐4	☐5	☐9
13. In this unit, there is a lack of support for staff involved in patient safety errors	☐1	☐2	☐3	☐4	☐5	☐9
14. This unit lets the same patient safety problems keep happening	☐1	☐2	☐3	☐4	☐5	☐9

SECTION B: Your Supervisor, Manager, or Clinical Leader

How much do you agree or disagree with the following statements about your immediate supervisor, manager, or clinical leader?

	Strongly Disagree ←	Disagree ←	Neither Agree nor Disagree ←	Agree ←	Strongly Agree ←	Does Not Apply or Don't Know ←
1. My supervisor, manager, or clinical leader seriously considers staff suggestions for improving patient safety	☐1	☐2	☐3	☐4	☐5	☐9
2. My supervisor, manager, or clinical leader wants us to work faster during busy times, even if it means taking shortcuts	☐1	☐2	☐3	☐4	☐5	☐9
3. My supervisor, manager, or clinical leader takes action to address patient safety concerns that are brought to their attention	☐1	☐2	☐3	☐4	☐5	☐9

SECTION C: Communication

How often do the following things happen in your unit/work area?

Think about your unit/work area:	Never ←	Rarely ←	Some-times ←	Most of the time ←	Always ←	Does Not Apply or Don't Know ←
1. We are informed about errors that happen in this unit	☐1	☐2	☐3	☐4	☐5	☐9
2. When errors happen in this unit, we discuss ways to prevent them from happening again	☐1	☐2	☐3	☐4	☐5	☐9
3. In this unit, we are informed about changes that are made based on event reports	☐1	☐2	☐3	☐4	☐5	☐9
4. In this unit, staff speak up if they see something that may negatively affect patient care	☐1	☐2	☐3	☐4	☐5	☐9
5. When staff in this unit see someone with more authority doing something unsafe for patients, they speak up	☐1	☐2	☐3	☐4	☐5	☐9
6. When staff in this unit speak up, those with more authority are open to their patient safety concerns	☐1	☐2	☐3	☐4	☐5	☐9
7. In this unit, staff are afraid to ask questions when something does not seem right	☐1	☐2	☐3	☐4	☐5	☐9

SECTION D: Reporting Patient Safety Events

Think about your unit/work area:	Never ←	Rarely ←	Some-times ←	Most of the time ←	Always ←	Does Not Apply or Don't Know ←
1. When a mistake is caught and corrected before reaching the patient, how often is this reported?	☐1	☐2	☐3	☐4	☐5	☐9
2. When a mistake reaches the patient and could have harmed the patient, but did not, how often is this reported?	☐1	☐2	☐3	☐4	☐5	☐9

3. In the past 12 months, how many patient safety events have you reported?

- ☐a. None
- ☐b. 1 to 2
- ☐c. 3 to 5
- ☐d. 6 to 10
- ☐e. 11 or more

SECTION E: Patient Safety Rating

1. How would you rate your unit/work area on patient safety?

Poor ▼	Fair ▼	Good ▼	Very Good ▼	Excellent ▼
☐1	☐2	☐3	☐4	☐5

SECTION F: Your Hospital

How much do you agree or disagree with the following statements about your hospital?

Think about your hospital:	Strongly Disagree ←	Disagree ←	Neither Agree nor Disagree ←	Agree ←	Strongly Agree ←	Does Not Apply or Don't Know ←
1. The actions of hospital management show that patient safety is a top priority	☐1	☐2	☐3	☐4	☐5	☐9
2. Hospital management provides adequate resources to improve patient safety	☐1	☐2	☐3	☐4	☐5	☐9
3. Hospital management seems interested in patient safety only after an adverse event happens	☐1	☐2	☐3	☐4	☐5	☐9
4. When transferring patients from one unit to another, important information is often left out	☐1	☐2	☐3	☐4	☐5	☐9
5. During shift changes, important patient care information is often left out	☐1	☐2	☐3	☐4	☐5	☐9
6. During shift changes, there is adequate time to exchange all key patient care information	☐1	☐2	☐3	☐4	☐5	☐9

Background Questions

1. **Gender:**

   ☐a. Male ☐b. Female ☐c. Other: _____

2. **Age:**

   ☐a. 18-29 years ☐b. 30-49 years ☐c. 50+ years

3. **Highest level of education completed/qualification achieved:**

   ☐a. Undergraduate Certificate
   ☐b. Undergraduate Diploma/Undergraduate Advanced Diploma
   ☐c. Undergraduate Degree
   ☐d. Postgraduate Degree
   ☐e. Other, please specify: _____

4. **How long have you worked in this hospital?**

   ☐a. Less than 1 year
   ☐b. 1 to 5 years
   ☐c. 6 to 10 years
   ☐d. 11 or more years

5. **In this hospital, how long have you worked in your current unit/work area?**

   ☐a. Less than 1 year
   ☐b. 1 to 5 years
   ☐c. 6 to 10 years
   ☐d. 11 or more years

6. **Typically, how many hours per week do you work in this hospital?**

   ☐a. Less than 30 hours per week
   ☐b. 30 to 40 hours per week
   ☐c. More than 40 hours per week

7. **In your staff position, do you typically have direct interaction or contact with patients?**

   ☐a. YES, I typically have direct interaction or contact with patients
   ☐b. NO, I typically do NOT have direct interaction or contact with patients

Your Comments

Please feel free to provide any comments about how things are done or could be done in your hospital that might affect patient safety.

Thank you for completing this survey.

Appendix E: Permission Obtained by the AHRQ to Use Questionnaire

L-Università ta' Malta

Kelly Spagnol <kelly.spagnol.14@um.edu.mt>

RE: Permission to use HSOPSC version 2.0 CRM:00730219

Safety Culture Surveys <SafetyCultureSurveys@westat.com> 25 May 2022 at 22:26
To: "kelly.spagnol.14@um.edu.mt" <kelly.spagnol.14@um.edu.mt>
Cc: Howard Holland <HOWARD.HOLLAND@ahrq.hhs.gov>

Dear Kelly Spagnol,

Thank you for the information about your use of the Surveys on Patient Safety Culture™ (SOPS®). Westat, the AHRQ contractor for the Surveys on Patient Safety Culture program (SafetyCultureSurveys@westat.com) are authorized to respond on behalf of the Agency for Healthcare Research and Quality (AHRQ) by Mr. Howard Holland, Director, AHRQ's Office of Communications. We handle the majority of permissions for these tools and their related documents in English, and notify AHRQ of requests for permission to translate these documents.

Based on the description you provided of your project, AHRQ grants you permission to use the Hospital Survey 2.0 in English for your research at the University of Malta in Malta. We understand that this research will be carried out at Sir Anthony Mamo Oncology Center in Malta. AHRQ requests that you note on the survey forms that the form is "reprinted with permission from the Agency for Healthcare Research and Quality (an Agency of the United States Department of Health and Human Services); Rockville, Maryland USA." Additionally, all reports, professional publications, graduate theses, or Web site postings should properly credit AHRQ using the following citation:

Surveys on Patient Safety Culture™. Agency for Healthcare Research and Quality, Rockville, MD USA. https://www.ahrq.gov/sops/index.html

The AHRQ SOPS survey and related materials may be found on the AHRQ website at: https://www.ahrq.gov/sops/index.html. For technical questions, please contact us. We can also put you in touch with other non-U.S. users of the survey (go to https://www.ahrq.gov/sops/international/index.html for more information).

If you have questions about permissions issues, please feel free to contact Mr. Holland (copied on this email).

Sincerely,

Aisha Marsono

****

AHRQ Surveys on Patient Safety Culture™ (SOPS®)Technical Assistance
Westat | 1700 Research Blvd | Rockville, MD 20850
phone: 1-888-324-9749 | fax: 1-888-852-8277 | email: SafetyCultureSurveys@westat.com

Sign up for SOPS updates, news, and events and select "Surveys on Patient Safety Culture" under Quality and Safety topics: https://public.govdelivery.com/accounts/USAHRQ/subscriber/new

How are we doing? To help us assess the quality of technical assistance we provide, we are asking that you please answer a brief questionnaire about the technical assistance you received from your recent inquiry about SOPS. Your participation in this questionnaire is voluntary. Your responses will be confidential and only reported in the aggregate. The questionnaire should take no more than a minute or two.

Thank you for your feedback! Click here to take the questionnaire: https://www.research.net/r/XZYYX3F

---------- Original Message ----------
From: kelly.spagnol.14@um.edu.mt <kelly.spagnol.14@um.edu.mt>;
Received: Wed May 25 2022 04:48:52 GMT-0400 (Eastern Daylight Time)

Appendix F: Focus Group Interview Guide

L-Università ta' Malta
Faculty of Health Sciences
Department of Health Systems Management & Leadership

Patient Safety Culture in Oncology Healthcare Settings in Malta

Focus group guide

General introduction

Good morning/afternoon and welcome to this focus group. My name is Kelly Spagnol and I am presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the University of Malta. My study is titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''.

I would like to thank you all for agreeing to participate in this focus group. Please help yourself to the refreshments at any time throughout this focus group session. I would like to remind you that you were required to sign a consent form prior to participating in this focus group and a copy of the information letter and consent form were also given. Moreover, I would like to emphasise that this focus group session is confidential. Please do not disclose details of who participated and/or of the nature of discussion to others. The discussion will be audio recorded and note-taking will be carried out for reporting purposes.

Ground rules:

- Active participation is encouraged. Participants are encouraged to comment, explain, disagree and share their views and are reminded that there are no right or wrong answers.
- Participants may speak freely however; they should not interrupt each other. Only one person speaks at a time.
- In view of the limited time, the discussion may need to be re-directed (e.g., when the discussion strays too far off topic).

1 of 5

Any questions?

Background

Oncology is recognised for its high degree of complexity and its potential for adverse events. For instance, the narrow therapeutic window of chemotherapy drugs makes any medication error potentially devastating and any error related to cancer care has a potential to cause harm to oncology patients, whose health is already compromised. Moreover, the delivery of care is reliant upon a range of healthcare professionals. Therefore, creating and maintaining a positive patient safety culture is essential.

Open-ended questions

Dimension:	Questions:
General Questions	1. What is the meaning of 'oncology safety'? a. What comes to your mind when you hear the word safety? b. How would you describe the patient safety culture in the oncology healthcare setting? 2. Which factors do you consider important to ensure a patient safety culture in an oncology healthcare setting?
Teamwork	3. How would you describe the way you work in your unit? a. What is the dynamic for working together? b. Do you work in a uni-disciplinary or multidisciplinary way? c. Is interprofessional collaboration promoted? d. To what extent does the way you work have an impact on safety? e. How does your unit address instances of disrespectful behaviour among team members?

	f. Do you think that the oncology healthcare setting would benefit from team building and training initiatives?
Communication Openness	4. How would you describe communication in your unit? a. Do you think open communication is encouraged i. Why do you give this answer? b. How comfortable do you feel asking safety related questions and raising safety concerns (e.g., pointing out an error/speaking up)?
Staffing and Work Pace	5. How would you describe the staffing level and work pace in your unit? a. How do the staffing levels and work pace impact patient safety? b. What is the role of temporary/float/PRN healthcare professionals? i. Are there any challenges or limitations associated with this staffing approach? c. What do you think about your present shift/duties/working hours?
Handoff and Information Exchange	6. What are your thoughts on the amount of time allocated during shift changes to exchange key patient care information (i.e., handover)? a. Can you describe any experience or situation where you have observed patient safety being compromised during shift change, patient transfer to another ward or at the time of admission?
Response to Error	7. What is the standard approach to response to error in your unit? a. What happens when healthcare professionals are involved in a near miss or error? i. Would you like to share some examples

	b. What steps does your unit take to differentiate between blaming the individual and addressing the underlying causes of error (focusing on learning)?
Reporting Patient Safety Events	8. Do you think that all near misses and errors are reported? a. Why do you give this answer? b. If not reported – why do you think that these are not being reported? c. Can you identify any barriers that prevent healthcare professionals from reporting?
Communication About Error	9. What are your thoughts on communication about near misses and error in your unit? a. Could you share how your unit communicates about a near miss or error that has happened? b. How are healthcare professionals engaged in the development of safety solutions and error prevention initiatives with regards to patient safety? c. Can you describe how changes (in response to error) are communicated?
Organisational Learning – Continuous Improvement	10. What are your observations on organisational learning and continuous improvement with regards to patient safety in your unit? a. Do you think that there are continuous improvements? i. What changes has your unit implemented to promote patient safety? b. How does your unit evaluate the effectiveness of its patient safety initiatives/changes (to improve patient safety)?
Supervisor, Manager, or Clinical Leader Support for Patient Safety	11. How does your immediate supervisor/manager/clinical leader in your unit demonstrate commitment to patient safety? a. In what ways are healthcare professionals' suggestions encouraged?

	b. Can you describe your immediate supervisor/manager/clinical leader's approach to working during busy times? i. How is the need for efficiency and ensuring patient safety balanced? c. How does your immediate supervisor/manager/clinical leader respond when patient safety concerns are raised to them? i. Would you like to share some examples?
Hospital Management Support for Patient Safety	12. How does the hospital management demonstrate commitment to patient safety? a. How are safety issues or concerns managed? b. What are your thoughts on the resources provided to maintain or improve patient safety in your hospital?

Concluding remarks

- Is there anything you would like to add about patient safety culture?
- Recap of the most important, pertinent issues discussed during this focus group

Appendix G: Focus Group Interview Information Letter

L-Università ta' Malta
Faculty of Health Sciences
Department of Health Systems Management & Leadership

Patient Safety Culture in Oncology Healthcare Settings in Malta

Invitation to Participate in a Focus Group – Information Letter

Dear Sir/Madam,

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''. This is being supervised by Dr Patricia Vella Bonanno and Prof Sandra C Buttigieg. This letter is an invitation to participate in this study. Below you will find information about the study and about what your involvement in this focus group would entail, should you decide to take part.

The aim of this study is to explore perceptions of patient safety culture within the oncology healthcare setting in Malta. The focus group will consist of 7 to 10 healthcare professionals working within the oncology healthcare setting in Malta. During the focus group, the researcher will ask a set of open-ended questions to initiate and guide a facilitated discussion to explore and gain deeper insights on the perceived patient safety culture in oncology healthcare settings in Malta. The length of the discussion will be between 90 to 120 minutes.

Data collected will be pseudonymised, i.e., the identity of the participants will not be noted on transcripts or notes from the interview, but instead, a code will be assigned. The codes that link the participants' data to their identity will be stored securely and separately from the data collected, in an encrypted file on the researcher's password-protected computer, and only the researcher will have access to this information. Supervisors and examiners will have access to coded data only. However, there may be exceptional circumstances which allow the supervisors and examiners to have access to personal data too, for verification purposes. Any hard-copy materials will be stored securely in a safe or locked file cabinet in a secure building.

Participation in this study is entirely voluntary; in other words, you are free to accept or refuse to participate, without needing to give a reason. You are also free to withdraw from the study at any time, without needing to provide any explanation and without any negative repercussions for you. Please note that, as a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation to access, rectify and where applicable ask for the data concerning you to be erased. Should you choose to withdraw, any data collected from your participation during the focus group will be deleted as long as this is technically possible (i.e., before it is transcribed and submitted to the University of Malta). All data collected will be erased on completion of the study and following publication of results.

If you choose to participate, please note that there are no direct benefits to you. Findings from this study may be used to identify key approaches and strategies that can be taken to improve the patient safety culture in oncology healthcare settings. Participation in this study may entail certain risks (e.g., exposing unsafe practices, recalling of adverse events, feelings of stress...). The Psychology Department at Mater Dei Hospital offers free staff support to all employees and can be contacted on +356 25456900 or +356 25456901. A copy of this information sheet is being provided for you to keep and for future reference.

Thank you for your time and consideration. Should you have any questions or concerns, please do not hesitate to contact me or my supervisors.

Yours Sincerely,

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

[redacted]

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

[redacted]

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

Appendix H: Focus Group Interview Consent Form

L-Università ta' Malta
Faculty of Health Sciences
Department of Health Systems Management & Leadership

Participant's Consent Form

Patient Safety Culture in Oncology Healthcare Settings in Malta

I, the undersigned, give my consent to take part in the study conducted by Kelly Spagnol. This consent form specifies the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study; I have had the opportunity to ask questions and any questions that I had were answered fully and to my satisfaction.
2. I also understand that I am free to accept to participate, or to refuse or stop participation at any time without giving any reason and without any penalty. Should I choose to participate, I may choose to decline to answer any questions asked. In the event that I choose to withdraw from the study, any data collected from me will be erased as long as this is technically possible (i.e., before it is transcribed and submitted to the University of Malta).
3. I understand that I have been invited to participate in a focus group in which the researcher will ask a set of open-ended questions to initiate and guide a facilitated discussion to explore and gain deeper insights on the perceptions of patient safety culture in oncology healthcare settings in Malta. I am aware that the focus group will take approximately 90 to 120 minutes. I understand that the focus group is to be conducted in a place and at a time that is convenient for me.
4. I understand that there are no direct benefits to me from participating in this study. I also understand that findings from this research may help to identify key approaches and strategies that can be taken to improve the patient safety culture in oncology healthcare settings.

5. I understand that my participation in this study may entail certain risks (e.g., exposing unsafe practices, recalling of adverse events, feelings of stress...). I understand that the Psychology Department at Mater Dei Hospital offers free psychological support to all employees and can be contacted on +356 25456900 or +356 25456901.
6. I understand that, under the General Data Protection Regulation (GDPR) and national legislation, I have the right to access, rectify, and where applicable, ask for the data concerning me to be erased.
7. I understand that all data collected will be erased on completion of the study and following publication of results.
8. I have been provided with a copy of the information letter and understand that I will also be given a copy of this consent form.
9. I am aware that, if I give my consent, this focus group will be audio recorded and converted to text as it has been recorded (transcribed).
10. I am aware that focus group discussions should be considered confidential and that I should not disclose details of those participating and/or of the nature of discussions to others.
11. I am aware that my data will be pseudonymised; i.e., my identity will not be noted on transcripts or notes from my interview, but instead, a code will be assigned. The codes that link my data to my identity will be stored securely and separately from the data, in an encrypted file on the researcher's password-protected computer, and only the researcher will have access to this information. Supervisors and examiners will have access to coded data only. However, there may be exceptional circumstances which allow the supervisors and examiners to have access to personal data too, for verification purposes. Any hard-copy materials will be stored securely in a safe or locked file cabinet in a secure building. Any material that identifies me as a participant in this study will be destroyed on completion of the study and following publication of results.
12. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

I have read and understood the statements of this form and agree to participate in this study.

Name of participant: _____

Signature: _____

Date: _____

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

[redacted]

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

[redacted]

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

Appendix I: Approvals Obtained to Conduct the Research Study

Permission obtained from the Chief Nursing Manager at SAMOC

Mr Mario Hili

Chief Nursing Manager

Sir Anthony Mamo Oncology Hospital

Mario Hili
Chief Nursing Manager
SAMOC

18th April 2022

Request for permission to conduct research in Sir Anthony Mamo Oncology Centre

Dear Mr Hili,

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''. This study aims to provide a baseline assessment of the perceived patient safety culture within the oncology healthcare setting in Malta as well as identify recommendations for practice, healthcare systems management and future research. This project is being conducted under the supervision of Dr Patricia Vella Bonanno (Supervisor) and Prof Sandra Buttigieg (Co-Supervisor).

I am hereby seeking your permission to conduct research in Sir Anthony Mamo Oncology Centre. A survey will be distributed to healthcare professionals and management to collect both quantitative and qualitative data. Moreover, a focus group, consisting of approximately 7 to 10 study participants will be conducted to yield deeper insights as well as allow better interpretation of the quantitative results from the survey.

Participation will be entirely voluntary and participants will be free to withdraw at any point, without any repercussions. Data collected from the survey will be anonymous while the data collected from the focus group will be pseudonymised. Data collection will commence once the University Research Ethics Committee approves this research project.

Please find a copy of the research proposal, the survey, the participant information letters and consent form attached to this request. Should you require further information, please do not hesitate to contact me or my supervisors; our contact details are provided below.

Thank you for your kind consideration of this request.

Sincerely,

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

Permission obtained from the Clinical Chairperson of the Haematology and Oncology Department at SAMOC

Dr Nick Refalo

Clinical Chairperson of the Haematology and Oncology Department

Sir Anthony Mamo Oncology Hospital

18th April 2022

Request for permission to conduct research in Sir Anthony Mamo Oncology Centre

Dear Dr Refalo,

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''. This study aims to provide a baseline assessment of the perceived patient safety culture within the oncology healthcare setting in Malta as well as identify recommendations for practice, healthcare systems management and future research. This project is being conducted under the supervision of Dr Patricia Vella Bonanno (Supervisor) and Prof Sandra Buttigieg (Co-Supervisor).

I am hereby seeking your permission to conduct research in Sir Anthony Mamo Oncology Centre. A survey will be distributed to healthcare professionals and management to collect both quantitative and qualitative data. Moreover, a focus group, consisting of approximately 7 to 10 study participants will be conducted to yield deeper insights as well as allow better interpretation of the quantitative results from the survey.

1 of 2

Participation will be entirely voluntary and participants will be free to withdraw at any point, without any repercussions. Data collected from the survey will be anonymous while the data collected from the focus group will be pseudonymised. Data collection will commence once the University Research Ethics Committee approves this research project.

Please find a copy of the research proposal, the survey, the participant information letters and consent form attached to this request. Should you require further information, please do not hesitate to contact me or my supervisors; our contact details are provided below.

Thank you for your kind consideration of this request.

Sincerely,

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

Permission obtained from the Data Protection Officer at MDH

SPTAR MATER DEI

Data Protection Clearance Declaration Form

REF: 117/2022

Full Name: Kelly Spagnol

ID/ Passport: [redacted]

Approval Date from DPO: 29th April 2022

Approval Date from CEO: 29th April 2022

Data Collection Period (From – To): July 2022 – October 2022

MDH Official Approval Names: Dr N Refalo, Mr J Debono

Name of Study / Audit: Patient Safety Culture in Oncology Healthcare Settings in Malta

Applicant's Signature: Kelly Spagnol (May 2, 2022 09:13 GMT+2)

Data Protection Approval Form - Kelly Spagnol

Final Audit Report 2022-05-02

Created:	2022-05-01
By:	Data Protection Approval Form (dpaform.mdh@gov.mt)
Status:	Signed
Transaction ID:	CBJCHBCAABAArsyaekE4krnRgnjYwwxCopa58aAxTNpr

"Data Protection Approval Form - Kelly Spagnol" History

Document created by Data Protection Approval Form (dpaform.mdh@gov.mt)
2022-05-01 - 4:48:31 PM GMT

Document emailed to Kelly Spagnol (kelly.spagnol.14@um.edu.mt) for signature
2022-05-01 - 4:48:43 PM GMT

Email viewed by Kelly Spagnol (kelly.spagnol.14@um.edu.mt)
2022-05-02 - 7:04:13 AM GMT- IP address: 66.249.81.145

Document e-signed by Kelly Spagnol (kelly.spagnol.14@um.edu.mt)
Signature Date: 2022-05-02 - 7:13:39 AM GMT - Time Source: server- IP address: 46.11.15.36

Agreement completed.
2022-05-02 - 7:13:39 AM GMT

Adobe Acrobat Sign

Permission obtained from the Medical Director at MDH

Mr Joseph Debono

Medical Director

Mater Dei Hospital

18th April 2022

Request for permission to conduct research in Sir Anthony Mamo Oncology Centre

Dear Mr Debono,

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''. This study aims to provide a baseline assessment of the perceived patient safety culture within the oncology healthcare setting in Malta as well as identify recommendations for practice, healthcare systems management and future research. This project is being conducted under the supervision of Dr Patricia Vella Bonanno (Supervisor) and Prof Sandra Buttigieg (Co-Supervisor).

I am hereby seeking your permission to conduct research in Sir Anthony Mamo Oncology Centre. A survey will be distributed to healthcare professionals and management to collect both quantitative and qualitative data. Moreover, a focus group, consisting of approximately 7 to 10 study participants will be conducted to yield deeper insights as well as allow better interpretation of the quantitative results from the survey.

1 of 2

Participation will be entirely voluntary and participants will be free to withdraw at any point, without any repercussions. Data collected from the survey will be anonymous while the data collected from the focus group will be pseudonymised. Data collection will commence once the University Research Ethics Committee approves this research project.

Please find a copy of the research proposal, the survey, the participant information letters and consent form attached to this request. Should you require further information, please do not hesitate to contact me or my supervisors; our contact details are provided below.

Thank you for your kind consideration of this request.

Sincerely,

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

Approved

J Debono

Permission obtained from the Chief Executive Officer at MDH

L-Università ta' Malta

Kelly Spagnol <kelly.spagnol.14@um.edu.mt>

Conducting a research study in SAMOC

CEO at Health-MDH <ceo.mdh@gov.mt> 29 April 2022 at 13:04
To: "kelly.spagnol.14@um.edu.mt" <kelly.spagnol.14@um.edu.mt>

Dear Ms Spagnol,

Kindly note that approval has been given by Ms Celia Falzon for you to conduct this study in line with applicable hospital protocols.

Regards

Carmen Farrugia
Personal Assistant To CEO

ISPTAR MATER DEI

T +356 +356 25454102

E carmen.farrugia@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

From: Kelly Spagnol <kelly.spagnol.14@um.edu.mt>
Sent: Friday, 29 April 2022 11:08
To: CEO at Health-MDH <ceo.mdh@gov.mt>
Subject: Conducting a research study in SAMOC

[Quoted text hidden]

10 attachments

Ms Falzon.pdf
94K

Research Proposal PSC.pdf
257K

SOPS 2.0 SURVEY AND LETTER.pdf
275K

Focus group consent form.pdf
182K

Focus group guide.pdf
202K

Focus group information letter.pdf
182K

Mr Debono signed.pdf
46K

Dr Refalo signed.pdf
212K

DPO approval email to forward to CEO.pdf
194K

Mr Hili signed.pdf
836K

Permission obtained from the University of Malta's University Research Ethics Committee

L-Università ta' Malta

Kelly Spagnol <kelly.spagnol.14@um.edu.mt>

The status of your REDP form (FHS-2022-00083) has been updated to Approved

1 message

form.urec@um.edu.mt <form.urec@um.edu.mt> 9 March 2023 at 07:37
To: kelly.spagnol.14@um.edu.mt

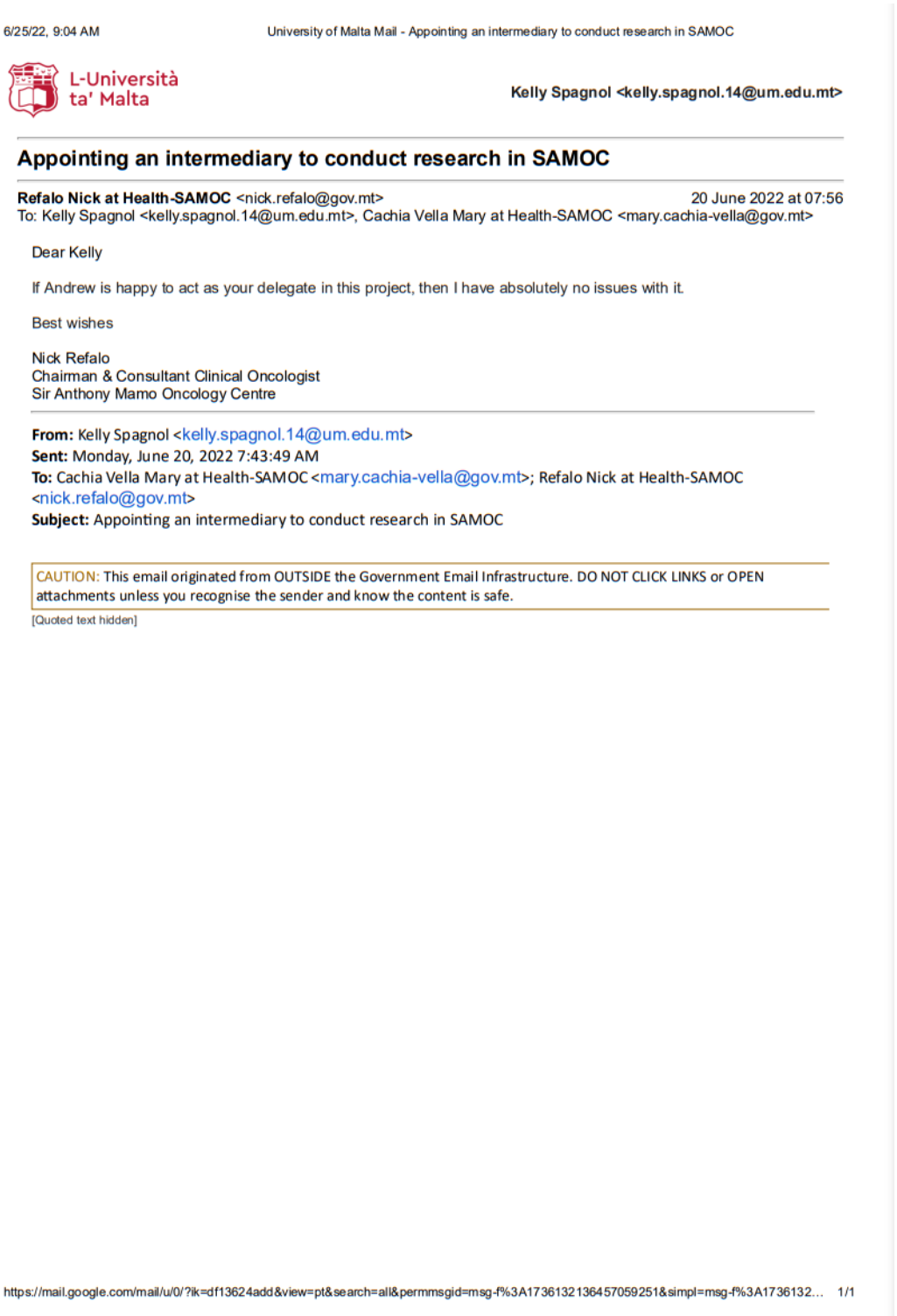
Dear Kelly Spagnol,

Please note that the status of your REDP form (FHS-2022-00083) has been set to *Approved*.

You can keep track of your applications by visiting: https://www.um.edu.mt/research/ethics/redp-form/frontEnd/.

This email has been automatically generated by URECA. Please do not reply. If you wish to communicate with your F/REC please use the respective email address.

Appendix J: Approval for delegate from the Clinical Chairperson's office (at SAMOC) to act as an intermediary for the research study



6/25/22, 9:04 AM University of Malta Mail - Appointing an intermediary to conduct research in SAMOC

L-Università ta' Malta

Kelly Spagnol <kelly.spagnol.14@um.edu.mt>

Appointing an intermediary to conduct research in SAMOC

Refalo Nick at Health-SAMOC <nick.refalo@gov.mt> 20 June 2022 at 07:56
To: Kelly Spagnol <kelly.spagnol.14@um.edu.mt>, Cachia Vella Mary at Health-SAMOC <mary.cachia-vella@gov.mt>

Dear Kelly

If Andrew is happy to act as your delegate in this project, then I have absolutely no issues with it.

Best wishes

Nick Refalo
Chairman & Consultant Clinical Oncologist
Sir Anthony Mamo Oncology Centre

From: Kelly Spagnol <kelly.spagnol.14@um.edu.mt>
Sent: Monday, June 20, 2022 7:43:49 AM
To: Cachia Vella Mary at Health-SAMOC <mary.cachia-vella@gov.mt>; Refalo Nick at Health-SAMOC <nick.refalo@gov.mt>
Subject: Appointing an intermediary to conduct research in SAMOC

CAUTION: This email originated from OUTSIDE the Government Email Infrastructure. DO NOT CLICK LINKS or OPEN attachments unless you recognise the sender and know the content is safe.

[Quoted text hidden]

https://mail.google.com/mail/u/0/?ik=df13624add&view=pt&search=all&permmsgid=msg-f%3A1736132136457059251&simpl=msg-f%3A1736132... 1/1

Appendix K: Permission Obtained from the Psychology Department at MDH (to refer study participants who require or request psychological support

Psychology Department

Mater Dei Hospital

24th June 2022

Request for permission to refer study participant to the Psychology Department (Mater Dei Hospital).

To whom it may concern,

My name is Kelly Spagnol and I am a student at the University of Malta, presently reading for a Master of Science in Patient Safety and Clinical Risk Management with the Department of Health Systems Management and Leadership. I am presently conducting a research study for my dissertation titled ''Patient Safety Culture in Oncology Healthcare Settings in Malta''. This project is being conducted under the supervision of Dr Patricia Vella Bonanno (Supervisor) and Prof Sandra Buttigieg (Co-Supervisor).

A survey will be distributed to healthcare professionals and management to collect both quantitative and qualitative data. Moreover, a focus group, consisting of approximately 7 to 10 study participants will be conducted to yield deeper insights as well as allow better interpretation of the quantitative results from the survey. Participation will be entirely voluntary and participants will be free to withdraw at any point, without any repercussions. Data collected from the survey will be anonymous while the data collected from the focus group will be pseudonymised. Data collection will commence once the University Research Ethics Committee approves this research project.

The aim of this study is to provide a baseline assessment of the perceived safety culture in oncology healthcare settings in Malta as well as identify recommendations for practice, healthcare systems management and future research.

Participation in this study may entail certain risks (e.g., exposing unsafe practices, recalling of adverse events, feelings of stress etc...). Therefore, I am hereby seeking your permission to refer study participants (healthcare professionals and/or management) should they need/request psychological assistance.

Thank you for your kind consideration of this request.

Sincerely,

Kelly Spagnol

kelly.spagnol.14@um.edu.mt

Dr Patricia Vella Bonanno (Supervisor)

patricia.vella-bonanno@um.edu.mt

Prof Sandra C Buttigieg (Co-Supervisor)

sandra.buttigieg@um.edu.mt

[redacted]

P. Sciberras.

Paul Sciberras M.Sc.
Registered Clinical Psychologist
Managing Psychologist
Mater Dei Hospital

24.06.2016.