ANALYSING THE IMPLEMENTATION OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING GUIDELINES IN SPECIALISED CARE UNITS, IN THE SELECTED HOSPITALS IN KWAZULU-NATAL, SOUTH AFRICA

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SUPERVISOR: DR SIPHO WELLINGTON MKHIZE

Analysing the implementation of Patient Safety Incident reporting and learning Guidelines in specialised care units, in the selected hospitals in KwaZulu-Natal, South Africa

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A thesis submitted to the College of Health, University of KwaZulu Natal in fulfilment of the requirements for the degree Doctor of Philosophy (School of Nursing and Public Health)

This is to certify that the contents of this thesis are the original work of Ms. Thusile Mabel Hycinth Mathe. As the candidate's supervisor, I have approved this thesis for submission

This thesis is presented in manuscript format, Supervisor: Dr S. W. Mkhize

DECLARATION

I . Thusile Mabel Hycinth Mathe (931305833) declare that:

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DECLARATION 2: MANUSCRIPTS

1. Gqaleni T.M.H & Mkhize S.W. (Published). Healthcare professionals' perception of knowledge and implementation of Patient Safety Incident reporting and Learning Guidelines in specialized care units, KwaZulu-Natal. *(SAJCC, 2023 # 559) South African Journal of Critical Care* 2023:39(1): e559. https://doi.org/10.7196/SAJCC.2023.v39i1.559

2. Gqaleni T.M.H & Mkhize S.W. (in review). Patient Safety incident guidelines implementation: A Scoping Review *(Journal of Medical Internet Research ID # 48580)*

3. Gqaleni T.M.H & Mkhize S.W. (Published) Barriers influencing implementation of patient safety incident reporting and learning guidelines in SCUs, KwaZulu-Natal: A qualitative study. *(PLOS ONE Journal ID PONE-D-23-22765)* https://doi.org/10.1371/journal.pone.0289857

DEDICATION

I dedicate this thesis to my late mum, Mrs Khethiwe Mathe for her love, care, nurturing, support, her endless sacrifices and hard work. Thank you for the values you have instilled in me and the guidance that you have imparted to me in all my endeavours. Mum is my pillar of strength and I am truly blessed to have her as my mother. She is my hero and a role model

In loving memory of my late father Mr Malakias Mathe, you are in my thoughts every day and I miss you dearly. Thank you for the love and protection that you had for us growing up. My parents will always be in my heart.

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The language editor for editing my thesis; thank you for the quality of work done in producing the final product of my thesis.

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LIST OF ACRONYMS

ASN: Assistant Nurse Managers

CCU: Critical Care Units

ICU: Intensive Care Units

KZN: KwaZulu-Natal

NDoH: National Department of Health

OM: Operational Nurse Managers

PSIRL: Patient Safety Incident Reporting and Learning guidelines

PSIs: Patient Safety Incidents

RN: Registered Nurses

SCUs: Specialised care units

SPSS: Statistical Package of Social Science

UKZN: University of KwaZulu-Natal

WHO: World Health Organization

IOM: Institute of Medicine

IHI: Institute for Health Improvement

OECD: Organisation for Economic Co-operation and Development

LMICs: low- and middle-income countries

ABSTRACT

Background: Despite the implementation of patient safety strategies, patient safety incidents (PSIs) in specialised care units (SCUs) remain high and are of serious concern worldwide, including in South Africa. Implementing Patient Safety Incident Reporting and Learning (PSIRL) Guidelines is critical in guiding clinical practice and improving clinical outcomes in SCUs. There is limited research on evidence of the implemented PSIRL Guidelines in SCUs at the global level.

Aim: To analyse the implementation of the PSIRL Guidelines in SCUs and to develop a strategy for the effective implementation of the PSIRL Guidelines in selected hospitals in KwaZulu-Natal, South Africa.

Methods: A convergent parallel mixed methods or embedded strategy was used to collect quantitative and qualitative data. A descriptive, non-experimental, cross-sectional survey was used to collect the quantitative data via online questionnaires from March 2021 to May 2021. A purposive sample targeted 237 healthcare professionals. Furthermore, a descriptive, explorative, qualitative approach was used to collect qualitative data from senior healthcare professionals through focus groups and individual interviews, for in-depth information, from August 2021 to October 2021. Content data analysis was performed using Tesch's method of analysis process. The quantitative and qualitative data were analysed separately and then converged to provide a comprehensive analysis of the research problem.

Results: For a quantitative study, a total of 181 questionnaires were returned, yielding a response rate of 76%. Notably, 83% of respondents had high-perceived knowledge of the PSIRL Guidelines, while 98% had low perceptions of the implementation. For the qualitative study, the main themes that emerged during data analysis were ineffective reporting systems affecting the communication of PSI guidelines, inadequate institutional management for the healthcare professionals, insufficient education and training of healthcare professionals and poor human resources affecting the implementation of PSI guidelines. The findings highlighted that there were more major barriers to the implementation of the PSIRL Guidelines.

Conclusion: For the quantitative study, the respondents demonstrated good perceptions of knowledge of the PSIRL Guidelines; however, the perception of the implementation was poor. The qualitative study confirmed that the PSIRL Guidelines are still not successfully implemented in the SCUs and the barriers to implementation were highlighted. For rigorous implementation in South Africa, the study recommends revised PSIRL Guidelines, designed in consultation with the frontline healthcare professionals, consisting of standardised, simple -user-friendly reporting processes as well as an implementation strategy to guide the healthcare professionals.

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Chapter One: Overview of the thesis

1.1 Introduction and background

Globally, increased occurrence of Patient Safety Incidents (PSIs) and near misses have become a public concern, which includes South Africa. This is attributed to the healthcare system that is fraught with PSIs, and critical and high-care units are no exception. Critically ill patients tend to be vulnerable and are exposed to complex environments, therefore higher rates of preventable PSIs are observed (Ahmed, Thongprayoon, Schenck, Malinchoc, Konvalinová, Keegan et al., 2015). Near misses are incidents or situations that have the potential to cause harm but do not reach the patient due to timely intervention, whereas PSI is the harm caused by medical mismanagement, instead of the underlying disease (WHO, 2017). The adverse event terminology was revised by the WHO (2017) guidelines and is now termed Patient Safety Incident (PSI). The WHO (WHO, 2015) described patient safety as more than just a clinical problem, it was a human problem, an economic problem, a system problem, a public problem, and a community problem. Therefore, PSI occurrence is still problematic in specialised care units (SCUs), however, they provide important information on patient safety and the quality of care rendered by the healthcare professionals.

Healthcare professionals are bound to make mistakes from time to time, especially in a complex environment like SCUs (Cleary, Lees and Lopez, 2018). A report from the Institute of Medicine, To Err is Human (1999) as cited in James (2013), declared that between 44,000 and 98,000 people die in the United States each year as a result of PSIs, with high-cost implications. An analysis by the Organisation for Economic Co-operation and Development (OECD) found that 15 percent of all hospital costs in OECD nations were due to patient harm from PSIs. A retrospective review of patients' hospital records across eight lower-middle income countries (Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa and Yemen) estimated the frequency of patient harm at 8.2% with a range of 2.5% to 18.4% per country (Wilson, Michel, Olsen, Gibberd, Vincent, El-Assady et al., 2012). In South Africa, the prevalence of patient harm and its effects on patients, the healthcare system, and the economy are profound (Singh and Mahomed, 2023). Moreover, South Africa lost productivity alone, due to poor quality patient care amounted to between $1.4 to $1.6 trillion each year (National Academies of Sciences and Medicine, 2018). These OECD nations are

a group of 34-member countries, mostly from Europe, which are in partnership with South Africa.

Worldwide, quality of care and patient safety have become vital. Therefore, there is an increasing necessity for the implementation of improvement strategies to continuously improve clinical outcomes in SCUs. One of these initiatives includes the revised WHO (2017) Guidelines for Patient Safety Incident Reporting and Learning Systems (RLS). The main purpose of this guideline was that individuals and the entire health sector should learn from the incidences to prevent reoccurrence, and that reporting was not the only part of implementing an efficient RLS. According to Dhamanti, Leggat and Barraclough (2019), PSI reporting systems provide information on the occurrence of patient safety incidents to mitigate risk, improve the system, learn from the mistakes, and share learning. The whole healthcare sector is expected to implement this system and use the data from the reported incidences to improve the healthcare system (WHO, 2015). Aligning itself with the WHO, the South African National Department of Health (NDoH) developed the National Policy and Guidelines for Patient Safety Incident Reporting and Learning (PSIRL), to establish a uniform national strategy and to guide the healthcare system in handling PSI reporting (NDoH, 2021). This initiative was intended to be implemented by every health establishment to ensure patient safety. Consequently, this strategy was adopted at a provincial level, in the KwaZulu-Natal Department of Health, which aligned itself with a broader vision encapsulated in the NDoH (Mgobozi and Mahomed, 2021). Therefore, this study aimed to analyse the implementation of the PSIRL Guidelines for PSI reporting in the SCUs in selected hospitals, in KwaZulu-Natal, and to develop the PSI implementation strategy.

1.2 Problem statement

Despite the implementation strategies, PSIs in SCUs remain high and are of serious concern, worldwide. Poor implementation of the PSIRL Guidelines might have led to undesirable clinical outcomes, which make it difficult for policymakers and healthcare workers to handle PSIs effectively. Evidence revealed that, in high-income countries, it was estimated that one in every 10 patients was harmed while receiving hospital care (Slawomirski, Auraaen and Klazinga, 2017). This harm might have further increased the length of hospitalisation, utilisation of more healthcare resources, with cost implications. In low- and middle-income countries (LMICs),134 million PSIs occurred in hospitals due to unsafe care, which resulted

in 2.6 million deaths each year (National Academies of Sciences and Medicine, 2018). A study, done in the Eastern Mediterranean Region and Africa, revealed that almost one-third of patients who suffered PSIs died and four out five of those incidences were preventable (WHO, 2015). Furthermore, Vukoja, Riviello, Gavrilovic, Adhikari, Kashyap, Bhagwanjee et al. (2014) affirmed that a needs-assessment should take priority and be expanded to LMICs, as there was lack of standardised processes of care.

In South Africa, a study conducted in KwaZulu-Natal revealed that PSIs were still high (47%), and were serious in nature, which suggests poor implementation of the PSIRL Guidelines, as well as the lack of improvement strategies (Gqaleni and Bhengu, 2018). In addition, the resource-constrained healthcare sector is burdened by a rise in litigation secondary to medical negligence, as the state bears vicarious liability. Moreover, Mgobozi and Mahomed (2021), state that South African public sector has a limited data on the cost of PSI. However, as a proxy estimate the scale of the medico-legal claims can be used to approximate the cost. Kahn (2018) affirmed that by the end of the 2016–2017 fiscal year, government faced contingent liabilities – the cost if all claims were successful – of R56.1bn. That equates to almost a third of the R170.9bn consolidated health budget for 2016–2017. The Eastern Cape health department's contingent liabilities rose from R16.8bn in 2016–2017 to R24.3bn in 2017–2018. In Gauteng, the figure rose from R17.8bn to R22bn over the period, whilst in the Limpopo's province the amount doubled from R2.1bn to R4.35bn. The research shows the cost implications due to litigations secondary to medical negligence and does not indicate how PSIRL guidelines are implemented in SCUs across South Africa, except for KwaZulu-Natal Province.

Failure to effectively implement the PSIRL Guidelines may be due to various contributing factors(Gqaleni and Bhengu, 2020; Nzaumvila, Shabalala, Bongongo, Mabuza and Govender, 2022). These include the external environment, which experiences a lack of technology and government initiatives, economic health care pressures as well as the lack of public awareness. The political climate, influx of refugees due to wars and poverty, and more recently, the pandemic led to overcrowding of health facilities with increased disease burden and complications. The management factors contributing to the failure to effectively implement the PSIRL Guidelines include the lack of employee development, lack of leadership involvement, lack of safety cultures, inadequate human resources with increased patient load, poor communication and coordination. Other factors include the nature of the

work, including the complexity of treatment, lack of knowledge, lack of training, skills development and experience, lack of teamwork, inadequate and dysfunctional equipment, poor handling of PSIs and lack of improvement strategies. Individual characteristics include fatigue, negative attitudes and poor morale. Therefore, these various contributing factors may lead to the poor implementation of PSIRL Guidelines in SCUs.

To curb the occurrence of PSIs, many different approaches, strategies, tools, resources and guidelines were implemented to improve patient safety in SCUs, worldwide. According to Griffin and Resar (2014); Hooper and Tibballs (2014), despite the implementation of different strategies to curb the PSIs, the occurrence remains high, hence being a global concern. As a result, several healthcare institutions implemented intervention strategies to improve patient safety. These intervention strategies ranged from the use of the Trigger Tool for measuring PSIs, where a random sample of in - patient records using 'triggers' were used to identify and measure the rate of PSIs, the use of the Patient Safety tool kit and the checklist, which describe the practical steps on how to implement interventions to build a comprehensive patient safety improvement program. The safety walk rounds provide an informal but structured method for organisational leadership and management to understand front-line safety issues (WHO, 2015). The Institute for Healthcare Improvement (IHI) promoted Intensive Care Unit (ICU) bundles, a straightforward set of evidence-based practices, generally three to five that, when performed collectively and reliably, proved to improve patient outcomes (Marik, Raghunathan and Bloomstone, 2013).

In South Africa, the KwaZulu-Natal Department of Health (KZN DoH) aligned itself with the National Department of Health (NDoH) in the implementation of the PSIRL Guidelines, however, there is no clear evidence of the reduction of PSIs and if these guidelines are adequately implemented in SCUs. It is also not clear if the culture of patient safety and recommended standardisation of PSIRL Guidelines are diligently observed by organisations, to curb the reoccurrence of PSIs. Hence, the aim of this study to analyse the implementation PSIRL Guidelines in SCUs, in selected tertiary hospitals, KwaZulu-Natal. This study aimed to inform policy makers of the need for a review of the reporting and learning guidelines in South Africa and to influence the development of the PSI implementation strategy for the SCUs.

1.3 Purpose of the study

The purpose of this study was to analyse the implementation of PSIRL Guidelines in SCUs and to develop a PSI implementation strategy for effective implementation of the PSIRL Guidelines in the selected hospitals of KwaZulu-Natal, South Africa.

Table 1: Research objectives and questions

1.3.1 Research objectives
Phase 1 To map the evidence of Patient Safety Incident Reporting and Learning guidelines implemented by healthcare professionals in specialized care units globally.
Phase 2 **Phase 2a** To assess healthcare professionals' perceptions on the implementation of the PSIRL Guidelines in SCUs, in KwaZulu-Natal. **Phase 2b** To explore facilitators and barriers in the implementation of the PSIRL Guidelines in SCUs by the healthcare professionals.
Phase 3 **Phase 3a** To develop an implementation strategy for PSI reporting for healthcare professionals in SCUs. **Phase 3b** To evaluate the developed implementation strategy for the healthcare professionals working in SCUs.

1.3.3 Theoretical model

The theoretical model is an organised set of concepts gathered together in a rational system by virtue of their relevance to a common theme (Polit and Beck, 2017). It is a blueprint that will guide the study design, sample selection, data collection strategies and analysis. The model helps to plan and organise the identification of the problem, the review of literature, design of the interventions, analyse the data, and present the findings. Several studies reported the use of Kurt Lewin's Model to create change in the quality of patient care and

patient safety in the SCUs (Abd el-shafy, Zapke, Sargeant, Prince and Christopherson, 2019; Chandrasekaran, Anand, Ward, Sharma and Moffatt-Bruce, 2017; Ciobanu, Latimer and Gillespie, 2018; Hee, Cheng, Ping, Kowang and Fei, 2019). Therefore, in this study, the Kurt Lewin Change Model was adopted and played an important role in guiding the entire process of the research study.

1.3.3.1 Kurt Lewin's Change Model (1947)

Kurt Lewin is widely considered as the founding father of change management, with his unfreeze–change–refreeze or 'changing as three steps', as illustrated in figure 1 (Cummings, Bridgman and Brown, 2016).

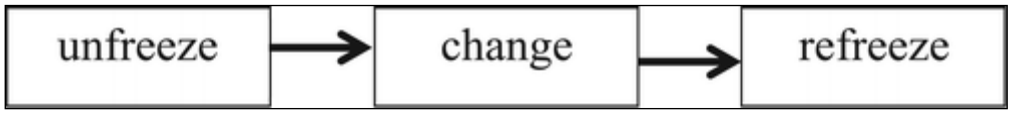

Figure 1: Change as three steps (Cummings et al., 2016)

This model was more suitable for the study as it described the ways of implementing the change process through leaders' knowledge sharing. According to Hussain, Lei, Akram, Haider, Hussain and Ali (2018), this sharing categorises the stages of the change process, and these stages outline the functional significance between organisational change and change implementation. For Lewin, the process of change entailed creating the perception that a change is needed, then moving toward the new, desired level of behaviour and, finally, solidifying that new behaviour as the norm (Cummings et al., 2016). Although Kurt Lewin's model has been criticised for over-simplifying the change process, its foundational significance has remained unquestioned (Cummings et al., 2016). For this study, Kurt Lewin's Change model was relevant as it guided the study on how to refine change; how knowledge sharing affects the change implementation process; how healthcare professionals are involved in change and willing to change; and how the leadership style affected the organisational change process, as illustrated in figure 2.

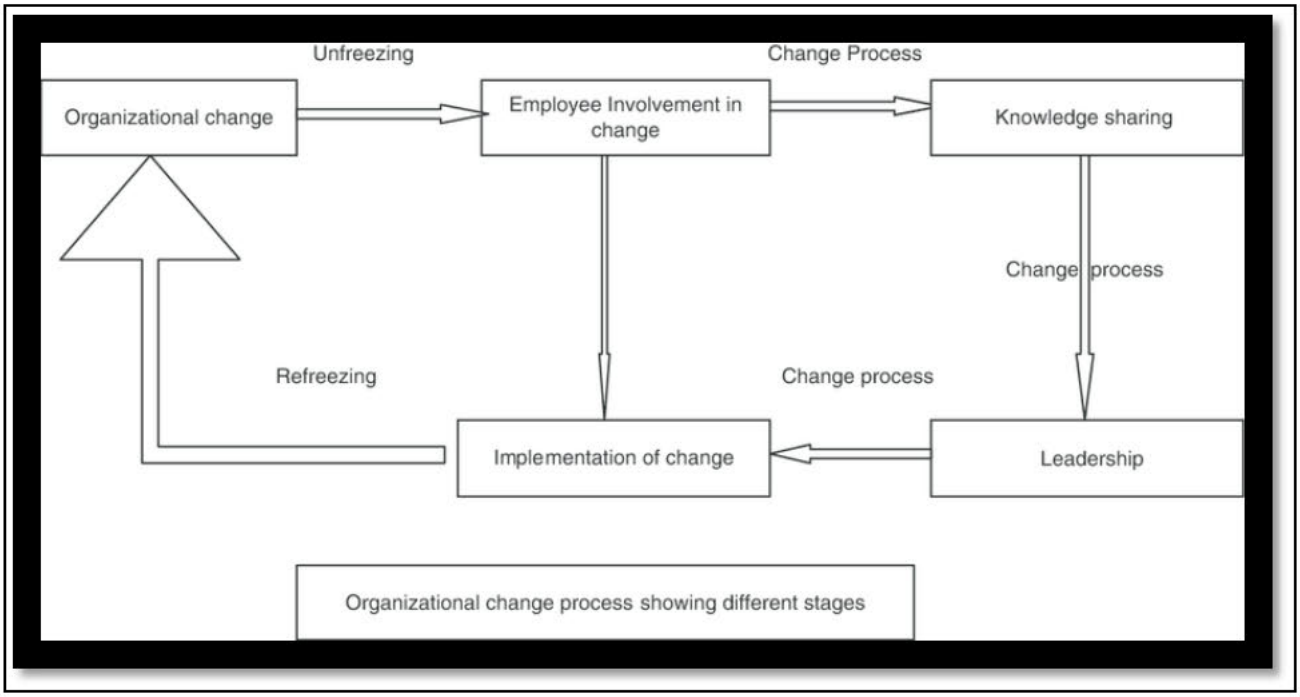

Figure 2: Model of organisational change showing Kurt Lewin's three steps (Lewin, 1947)

1.3.3.2 Application of the model to the study

1.3.3.2.1. Organisational change and unfreezing

Unfreezing means driving changes in organisations for managers and leaders to monitor, evaluate and plan changes using structures for quick responses to the internal or external environment and foresee the pattern of change by individuals, products, and technology (Cummings et al., 2016). For the organisation to change, it should be involved in the activity planning, commitment planning, effective communication and change management structures. Therefore, in this study, the organisation needed to interrogate its own status quo and make plans to effectively implement new strategies, without any resistance. In other words, if there is a need for a change, one cannot just implement the change without the knowledge of others whom the change would affect. Therefore, the first stage becomes important, because it does not only prepare the healthcare professionals for a change, but it also creates awareness. Leadership may need to address both external and internal factors that contribute to poor implementation of the PSIRL Guidelines, as recommended by the South African National Policy and KZN DoH PSIRL Guidelines (NDoH, 2021). Therefore, the leadership and management are supposed to ensure, through consultative processes, that

all healthcare professionals in SCUs are actively involved in the implementation of the PSIRL Guidelines.

Management can also ascertain what barriers and facilitating factors influence the effective implementation of the strategy. Healthcare facilities, including the SCUs are supposed to cultivate patient safety cultures and obtain political support, to solicit approval for the implementation of the newly developed improvement strategy from the Department of Health. According to the NDoH (2021), healthcare facilities are designed to prevent harm and improve the health outcomes for users and healthcare professionals.

1.3.3.2.2 Change

Cummings et al. (2016) suggested that leaders should educate, train, coach, communicate, participate, involve, task support, provide emotional support and incentives, manipulate, co-opt and coerce the employees about change. To avoid organisational resistance there must be active involvement and empowerment of employees with knowledge sharing, as well as in the formulation, planning and implementation stages of change. In this study, an awareness of the PSIRL Guidelines needs to be created and communicated to all the healthcare professionals working in the SCUs. Likewise, this involves careful examination of the implementation of the proposed PSI implementation strategy and assessing if all healthcare professionals are aware, have knowledge and the necessary expertise during the implementation process. The management may need to introduce new strategies, which may help to improve the quality, therefore, knowledge sharing becomes essential through communication, training, workshops, seminars training and continuous personal development.

1.3.3.2.3 Refreezing

According to Cummings et al. (2016), at this stage changes are accepted and become the new norm. People form new relationships and become comfortable with their routines. In this study, refreezing included monitoring and evaluating the effectiveness of the new implementation strategy. Therefore, the organisational change of SCUs was monitored for its success, the effective implementation of the strategy for the healthcare professionals, including enablers and barriers to implementation of the PSIRL Guidelines.

1.4 Significance of the study

Healthcare professionals working in SCUs are expected to provide safe and quality patient care in a complex environment, hence this study aimed to equip institutions and inform management on the implementation strategies identified for effective implementation of the PSIRL Guidelines. The study contributed new knowledge as the results were disseminated to the national and international research communities. Knowledge was also disseminated in a form of international conferences for healthcare professionals working in the SCUs. Manuscripts were submitted to the peer reviewed journals. The findings of this study helped in the development of an implementation strategy for the PSIRL Guidelines for healthcare professionals in SCUs, KwaZulu-Natal (KZN), South Africa.

1.4.1 Clinical practice

The study created a dialogue or an open communication between the senior and middle managers, as well as healthcare professionals working in SCUs of the three selected hospitals, in KZN. More awareness of the PSIRL Guidelines was created through the analysis of the healthcare professional's knowledge and implementations of the PSI reporting guidelines. The study highlighted the gaps, barriers and facilitators of the implementation of these. Healthcare professionals' voices, the study results and recommendations from the healthcare professionals were taken into consideration in the development of the PSI implementation strategy that was evaluated by the experts who were senior and more experienced in clinical practice and academia. The implementation strategy was shared with the healthcare professionals to provide clear guidance on effectively implementing the PSI guidelines, with the objective of reducing the future occurrence of PSIs.

1.4.2 Policymakers

The study generated new knowledge that can be useful for the healthcare professionals working in SCUs, nationally and internationally, to improve their clinical competency in the SCUs. The new knowledge and implementation strategy informed the Department of Health policymakers and guideline developers, to revise and modify the existing PSIRL Guidelines. The new findings further facilitated the consultation of the healthcare professionals at the ground level, where good quality patient care needed to be improved, by effective implementation of the PSIRL Guidelines.

1.5 Operational definitions of terms

1.5.1 Near misses

Near misses mean incidents or situations that have the potential to cause serious physical or psychological injury, or unexpected death, but did not reach the patient due to timely intervention (WHO, 2022). In this study, near misses which often happen in specialised care unit environments need to be monitored and reported, consequently they were included in the analysis of implementation of the PSIRL Guidelines.

1.5.2 Patient Safety Incident (PSI)

Patient Safety Incident means unintended incidents in care that may result in adverse outcomes and may require additional care efforts. According to the (WHO, 2017), these include harm caused by medical management, instead of the disease complications or underlying disease. In this study, PSIs are harm that reached the patient and indicative of quality patient care in SCUs, therefore, were included in the analysis of the implementation of the PSIRL Guidelines.

1.5.3 Patient Safety Incident Reporting Guidelines

Patient Safety Incident Reporting Guidelines are clinical practice guidelines and useful tools to improve the delivery of the best care, based on the best available evidence, for patients. Guidelines must be grounded on the evidence-based medicine paradigm (Lisboa, Cavalcanti and Lobo, 2016). In this study, PSIRL Guidelines are designed to be implemented to ensure patient safety and were analysed for their implementation in SCUs, to improve quality patient care.

1.5.4 Patient safety

Patient safety means freedom from accidental injuries. Initiatives are designed to prevent adverse outcomes from medical errors (WHO, 2011). In this study, patient safety meant an effort made to ensure a safe environment for patients in SCUs resulting in a reduction in morbidity and mortality.

1.6. Literature review

1.6.1 Introduction

The literature review provides a framework for establishing the importance of the study as well as a benchmark for comparing results with other findings. According to Creswell and Creswell (2018), qualitative researchers use literature sparingly. This is usually presented at the end of the study, that is, data is collected in the field before reviewing the literature and it becomes a basis for comparing findings of the qualitative study. On the other hand, quantitative researchers conduct a substantial amount of literature at the beginning of the study to provide direction for the research questions. Therefore, in this study, literature was used in a manner that was suitable for the quantitative strategy, as it is a major part of this study, whilst emerging themes and categories were used for the qualitative study (Creswell, 2018). The literature review was used continuously throughout the study, to compare, contrast and confirm the findings.

A mixed methods approach, and a convergent mixed methods design were used to collect both quantitative and qualitative data. Information was gathered on the following topics: implementation of the PSIRL Guidelines in SCUs, PSI reporting system and management of PSIs, current existing improvement strategies, and patient safety in SCUs. The database search and search engines included: Google Scholar, Cochrane, EBSCOhost, and PubMed/, MEDLINE (Medical Literature Online).

1.6.1.1 Patient Safety Incidents

PSIs and near misses occur more frequently in the healthcare system, and more so in the SCUs. According to the WHO (2022), near-misses are equally important as they indicate the ‘weak areas’ in medical care . A near miss is defined as a situation in which an event or omission arising from clinical care fails to happen, whether as a result of early intervention, therefore not reaching the patient to cause harm (WHO (2022). On the other hand, the WHO (2017) defines PSIs as harm that reaches the patient due to medical management, in contrast to disease complications or underlying disease. PSIs can be classified into categories, for example, hospital-related incidents, patient care-related incidents, medication-related incidents, blood product-related incidents, procedure-related incidents, equipment-related incidents and infrastructure, buildings, fixtures incidents (WHO, 2017). They can be further explained according to patient outcomes as insignificant, minor, moderate, major and

catastrophic (Hooper and Tibballs, 2014). Therefore, the occurrence of preventable PSIs may indicate that quality patient care is sub-optimal, as a result, patients and their families suffer from high mortality and morbidity rates.

One in 10 hospitalised patients experience an adverse event during their stay and that rate does not appear to improve with time (Michel, Brami, Chanelière, Kret, Mosnier, Dupie et al., 2017). The WHO Eastern Mediterranean Region revealed that, on average, healthcare-related harmful incidents affected 8 in 100 patients, and 4 out of 5 incidents were preventable (WHO, 2015). Patient safety is an international concern. Therefore, healthcare professionals should understand the process quantitatively so that worthwhile interventions might be applied to discern and improve performance (Lighter, 2015). According to these literature findings cited above, preventable PSIs still occur in SCUs, and this may be a crucial indicator of poor implementation of the PSIRL Guidelines.

1.6.1.2 Patient safety

The quality of care and patient safety measures are essential in all healthcare facilities and are considered significant for the healthcare systems worldwide, particularly in SCUs (Ochôa da Silva and Aquino Caregnato, 2019). According to the WHO (2017), patient safety means that efforts are made to ensure safe environments for patients, resulting in reductions in morbidity and mortality. Therefore, several studies have indicated that SCUs symbolised a high-risk environment which threatened patient safety, since critically ill patients with multiple co-morbidities, undergoing invasive procedures, were at risk of experiencing PSIs (Brunsveld-Reinders, Arbous, De Vos and De Jonge, 2016). According to Mahomed, Sturm and Moodley (2017), SCUs were designed to accommodate critically ill patients, who are often at increased risk of acquiring healthcare associated infections. Hence, the Institute of medicine (IOM) (1999), encouraged healthcare professionals to confront their human errors to improve and build a safer healthcare system (Ahmed et al., 2015). The IOM main objective of the was to stimulate a national effort to improve patient safety. As a result, healthcare professionals still strive to adhere to the culture of safety to promote quality patient care, especially in SCUs. Hence more improvement strategies need to be explored to mitigate the occurrence of PSIs.

1.6.1.3 PSI implementation strategy

Evidence - based clinical practice guidelines are useful tools to improve delivery of the best care for patients (Lisboa et al., 2016). According to Schünemann, Wiercioch, Etxeandia, Falavigna, Santesso, Mustafa et al. (2014), most national organisations, professional societies, healthcare providers, policy-makers, including the ministries of health, patients and the public were giving more consideration to the healthcare guidelines and their proper implementation. Moreover, McIntosh, Oppel, Mohr and Meterko (2017) affirmed that it was important to identify and implement modifications that were effective in improving the quality of patient care in the specialised healthcare units as there was increased demand, with limited hospital resources. Schünemann et al. (2014) observed that although organisations were offered manuals, a comprehensive list of items and a portal for resources to consider in the planning, development, implementation, evaluation and updating of guidelines did not exist. Therefore, this suggests that implementing the PSIRL guidelines is a process needing team commitment, education, time, and the acceptance of change by all members of the SCUs. Grol, Wensing, Eccles and Davis (2013) described implementation as a planned process, a systematic introduction of innovations of proven value; the aim being that these were given a structural place in professional practice, in the functioning of the organisations or the healthcare structure. Furthermore, Grol et al. (2013) reiterated that effective implementation strategies were needed to ensure that guidelines were incorporated into daily practice. Therefore, implementation strategies are significant in SCUs, as they may effectively facilitate the implementation of PSIRL Guidelines.

Different organisations, including the WHO guidelines, the Institute for Healthcare Improvement (IHI) as well as the IOM, attempted to curb the occurrence of the PSIs. Several methods for monitoring PSIs in the studies were described, such as spontaneous reports with computerised alerts, direct observation, medical records control software, review of clinical processes or a combination of methodologies, according to the purpose defined by the institution. According to Henneman, Gawlinski and Giuliano (2012), surveillance is an important strategy, whereby nurses constantly monitor near misses and implement early interventions to prevent PSIs and to improve patients' outcomes, particularly their safety. Unfortunately, according to Brunsveld-Reinders et al. (2016), little is known on strengths and weaknesses of these systems which make it difficult for SCUs to choose the appropriate PSI reporting improvement strategy to implement.

Implementation of improvement strategies in South Africa should be guided by the existing laws to ensure that the constitutional obligation to deliver quality care to all South Africans as stipulated in Section 47 of the Health Act, 2003, Act No. 61 of 2003 (South Africa, 2003). This clause allows the Minister of Health to prescribe quality standards for the country (Lourens, 2012). Furthermore, Section 24(a) of the Health Act No. 61 of 2003 (South Africa, 2003) stipulates that everyone has a right to an environment that is not harmful to their health or wellbeing, hence quality patient care should be ensured. Also, the healthcare professionals working in SCUs are expected to practice in accordance with legislative framework, for example, the Consumer Protection Act, Act No. 68 of 2008, which calls for the right to good quality and safety. The Nursing Act, Act No.33 of 2005, maintains the professional conduct and practice standards for nurse practitioners, whereby disciplinary action can be taken against the professional nurse.

1.6.1.4 Barriers and facilitators to the implementation of guidelines

There are various factors that either hinder or facilitate the implementation of the guidelines. According to (National Academies of Sciences and Medicine, 2018), failure to adhere to evidence - based practices could be due to a lack of knowledge or awareness of the guidelines. Healthcare professionals do their best to improve the quality of care on a daily basis, however, implementing the evidence-based strategies into daily practices can be difficult. Defects in leadership and management were identified as one of the contributing factors to ineffective implementation of continual improvement (National Academies of Sciences and Medicine, 2018). According to Ritchie, Khan, Moore, Timmings, van Lettow, Vogel et al. (2016), most of these barriers were identified at different levels of the healthcare system. At the health system level, the barriers were a lack of material, funding, resources, lack of communication and awareness to effectively implement the recommended guidelines. At a provider level, the lack of knowledge and skills, inadequate services and continued training as well as lack of communication by the healthcare professionals and lack of interprofessional collaboration as a result of attitudes, ethnic and work cultural differences were identified as barriers in most countries. The barriers at the patient level involved more of a lack of patients' knowledge and lack of financial resources. Moreover, Ritchie et al. (2016), identified a lack of accountability by the healthcare providers due to a hostile environment, dominated by blame and litigation, which created fear to comply with the implementation of the guidelines.

On the other hand, Higuchi, Davies and Ploeg (2017) mentioned several process-related challenges related to increased workload demands. The optimal patient-to-nurse ratio also remained not well understood with competing priorities within the organisation and monitoring difficulties. Moreover, Rasmussen, Pedersen, Pape, Mikkelsen, Madsen and Nielsen (2014) alluded to emotional demands associated with diseased people, acute health crises, constantly changing tasks, unforeseen problems, interruptions and other psychosocial work environment factors that potentially affected the effective implementation of the improvement strategies for patient safety.

Schünemann et al. (2014) confirmed that, although several tools to appraise the reliability of healthcare guidelines existed, guidance on practical steps for developing guidelines was lacking. Brunsveld-Reinders et al. (2016) also affirmed that guidelines on how to develop and apply an incident reporting improvement strategy were scarce, which resulted in the lack of learning and improvement of incident reporting. Although in South Africa PSIRL Guidelines, which are in line with the WHO, have been developed, it is the only PSI reporting guideline available. Therefore, this suggests that healthcare workers might not be well empowered to implement the standardised improvement strategies, as there is a lack of lessons learned from previous and concurrent initiatives, hence the absence of reduction in PSIs.

Spooner, Aitken and Chaboyer (2018) suggested that researchers and clinicians needed to understand the complexities of healthcare settings before implementing practice changes. Strong leadership and supervision, at all levels, are vital to reinforce the patient safety culture. Higuchi et al. (2017) suggested that these should include lessons learned from previous and coexisting initiatives, commitment within the organisation, involvement of staff, senior leaders and steering committee members, organisational values and culture that supported change and external supports for change. Davison, Ndumbe-Eyoh and Clement (2015) confirmed that knowledge translation in healthcare settings was imperative to ensure that clinicians were providing a high standard of patient care that optimised patient outcomes, however, it was also important that the healthcare professionals comprehended the evidence-based interventions to enhance adoption. Ritchie et al. (2016) affirmed that strong ongoing training, effective interprofessional collaboration and effective monitoring and evaluation of implemented improvement strategies contributed to the successful

implementation of the guidelines. Therefore, according to these studies, there are barriers and facilitators of the implementation of patient safety guidelines.

Although different PSI strategies have been put into place, they may still lack standardisation that is suitable for every SCU. Also, most studies conducted used methodologies which were meta-analysis and quantitative approaches, thus lacking the qualitative aspect of the lived experiences of the healthcare professionals, during the actual implementation of the recommended PSI guidelines. Therefore, a mixed method approach may help to gain the depth and breadth of the implementation of the PSI reporting guidelines in SCUs.

Improvement strategies equip the healthcare professionals to effectively implement the guidelines. A clear step by step direction is still lacking, consequently leading to no lessons being learned on how to develop or improve the intervention strategies. Therefore, this study aimed to analyse the PSIRL Guidelines for the purpose of developing an implementation strategy for the PSI reporting in the SCUs.

1.6.1.5 Gaps in the literature review

Continuous literature reviews were conducted, and the researcher identified the following gaps:

- Ineffective implementation of national guidelines for PSIRL since inception (Gqaleni and Mkhize, 2023b; Mgobozi and Mahomed, 2021; Organization, 2020)
- Existing PSIRL Guidelines are haphazard (Nzaumvila et al., 2022).
- Lack of standardised PSI implementation strategy, nationally (Singh and Mahomed, 2023).
- A paucity of literature on the implementation of reporting and learning guidelines, worldwide (Mjadu and Jarvis, 2018).

1.7 Research methodology

1.7.1 Introduction

This section focuses on the research design, the study area, the population, the sample and sampling, the data collection instruments, validity and reliability, as well as trustworthiness.

This section also explains the data collection process, the ethical considerations and data analysis.

1.7.1.1 Mixed methods approach

A mixed methods approach was adopted to conduct this study. According to Creswell and Creswell (2018), mixed methods research is defined as an approach to research in the social, behavioural, and health sciences in which the researcher collects both quantitative and qualitative data, integrates the two, and draws interpretations to understand the research problem. The researcher combines the statistical trends (quantitative data) with stories and personal experiences (qualitative data). Guével and Absil (2023) further affirm that the researcher combines elements of quantitative and qualitative approaches for breadth and depth of understanding and confirmation. The mixed methods approach is not simply the collection of multiple forms of qualitative or quantitative data, but it involves the collection, analysis and integration of both quantitative and qualitative data, to have a comprehensive understanding of the research phenomenon (Creswell and Creswell, 2018)

Burns, Grove and Gray (2015) affirm that when used effectively, mixed methods design combines both the strengths of quantitative, which uses closed-ended questions and qualitative, which uses open-ended questions. The pragmatism philosophical underpinning was adopted for this study, as data was collected from different sources, using different methods of data collection and analysis.

1.7.1.2 Pragmatism philosophy

A research philosophical assumption is described as a worldview, a general perspective on the complexities of the world and is characterised by the way it responds to basic philosophical questions (Polit and Beck, 2017). Research philosophical assumptions guide the researcher on how they see the reality, who they are and how they see the world. The assumption of pragmatism in this research does not rely on one system of philosophy and reality. The assumption looks at many approaches of collecting and analysing data. The researcher assumes that all available approaches to understand the problem must be used. Thus there is a freedom of choice to choose methods, techniques and procedures of research that best meet their needs and purposes.

1.7.2 Research design

Research designs are types of inquiry approaches that provide specific direction for procedures in a research design (Creswell and Creswell, 2018). According to Burns et al. (2015), a research design is a blueprint for conducting a study. In the following section, the researcher provided a detailed overview of the research design and methods used in this enquiry. The convergent mixed methods design was used to collect both quantitative and qualitative data on the implementation of PSIRL Guidelines by the healthcare professionals in SCUs.

1.7.2.1 Convergent mixed methods design

A convergent parallel mixed methods or embedded strategy was used to collect quantitative and qualitative data. This is a form of mixed methods design, whereby the researcher collects both quantitative and qualitative data, roughly at the same time and then merges the two forms of data to understand the phenomenon (Creswell and Creswell, 2018). In this study, a descriptive, non-experimental, cross-sectional survey was used to collect the quantitative data via online questionnaires, whereas qualitative data was collected from focus groups and individual interviews, for in-depth information. The quantitative and qualitative data were analysed separately and then converged to provide a comprehensive analysis of the research problem.

Objective 1: To map the evidence of the PSIRL Guidelines implemented by healthcare professionals in SCUs.

A scoping review was conducted to review literature to seek evidence exists on the implementation of the PSIRL Guidelines by the healthcare professionals and identify gaps in terms of content, context and quality in the implementation of PSIRL, as well as the existing PSI intervention strategies in the SCU.

Objective 2 a: To assess healthcare professionals' perceptions on the implementation of the PSIRL Guidelines in SCUs, in KwaZulu-Natal.

A descriptive, non-experimental, cross-sectional survey was used to collect the quantitative data from the health care professionals via online questionnaires. Quantitative data was collected from the Registrars and Registered nurses who were working in the specialised care units and were actively involved in the implementation of PSIRL guidelines.

Objective 2b: To explore facilitators and barriers in the implementation of the PSIRL Guidelines in SCUs by the healthcare professionals.

A descriptive, explorative qualitative approach was used to collect qualitative data from healthcare professionals working in specialised care units. Therefore, qualitative data was collected from Operational nurse managers, Assistant nurse managers, Consultant medical doctors and Monitoring and evaluation managers who were involved in the implementation of the PSIRL Guidelines in SCUs.

Objective 3a and 3b To develop an implementation strategy for PSI reporting for healthcare professionals in SCUs.

The quantitative and qualitative results were then merged and informed the development of an implementation strategy for PSIRL guidelines for healthcare professionals in SCUs, which was further evaluated by experts.

1.7.3 Study setting

A research setting is an environment, either natural or controlled, in which a study is carried out (Burns et al., 2015). The study was conducted in SCUs of three selected public hospitals in two districts of KZN, South Africa. The KZN province was chosen because of its representative character and had referral hospitals which admit patients from both urban and rural areas. Two hospitals (A and C), situated in the eThekwini District, provide both secondary and tertiary services, and the third tertiary hospital (B) is in the uMgungundlovu district. These districts were chosen because they are the largest in the province, with the most state-owned hospitals equipped with different categories of SCUs, admitting miscellaneous patient profiles, and therefore provided a more comprehensive field for the research project. The settings also employ healthcare professionals who have additional specialist training, with scarce critical care skills, and vast experiences in specialised critical care. Twenty SCUs participated in the study, consisting of both Critical Care units (CCUs) and High Care units. The SCUs were classified according to the services they rendered, for example, neonatal, cardiac and cardiothoracic CCUs and High Care units. The SCUs were further named differently by different hospitals such as surgical, medical, general, medical, surgical trauma unit, neuro/burns unit, but these were grouped into multidisciplinary SCUs in this study.

1.7.4 Study population

Polit and Beck (2017) state that the total population is the entire aggregation of cases, in which the researcher would like to generalise findings. Burns et al. (2015) affirmed that the target group is the entire set of elements or individuals, who meet the sampling criteria. In this study, the total population included all healthcare professionals (762) working in the SCUs. Based on the preliminary information obtained from the three participating hospitals, the total population for the quantitative data collection consisted of the sample frame of all 762 healthcare professionals involved in the implementation of the PSIRL Guidelines in SCUs. The respondents were categorised as follows: Five hundred and twenty-five (525) direct care or bedside RNs, who had CCU speciality and experience, forty-nine (49) Operational Nurse Managers, and one hundred and eighty-eight (188) Registrars, totalling 762, as illustrated on table 1.

Table 2: Total population of the respondents, working in SCUs, that participated in a quantitative study in selected KZN province hospitals.

	Target population *N*=762	**Number of SCUs *N*=20**	**RNs with CCU specialty and CCU Experience *N*=525**	**Operational Nurse managers *N*=49**	**Registrars *N*=188**
Hospital A	395	10	270	30	95
Hospital B	263	6	175	10	78
Hospital C	104	4	80	9	15

SCU= Specialised care units; CCU=Critical Care Units; RN=Registered Nurse

Source: KZN DoH statistics, 2016

1.7.5 Sample and sampling

Sampling is a process of selecting a portion of the population to represent the entire population, so that inferences about the population can be made (Burns et al., 2015).

The researcher adopted the stratified random sampling which is a method that involves the division of the target population into smaller subgroups. The stratification was based on categories of healthcare professionals working in SCUs, i.e. Registered nurses, Registrars and Operational nurse managers.

1.7.5.1 Quantitative sampling

The respondents included both healthcare professionals working day and night shifts in SCUs. For power analysis, and with the help of the statistician, a Raosoft Sample Size Calculator (2004) (Raosoft Inc., USA) assisted in recommending the minimum size of the sample to yield sufficiently valid results. Using the Raosoft parameters of margin error of 5%, a confidence level of 95%, a population size of 762, and a response distribution of 50%, the recommended sample size was 256, as illustrated in table 3. However, the randomised approach was not used as the study was conducted during the COVID-19 pandemic in March to May 2021; therefore, the researcher chose the purposive convenient sampling as the questionnaires were emailed to the available respondents.

Table: 3 The target sample of the healthcare professionals working in the SCUs, in three selected KZN hospitals

	SCUs, *N*=20	RNs, *N*=219	Registrars, *N*=37	Healthcare professionals, *N*=256
Hospital A	10	90	20	110
Hospital B	6	80	10	80
Hospital C	4	49	7	47

SCUs = Specialised care units; KZN = KwaZulu-Natal; RN = Registered Nurse.

Source: Author's own source

1.7.5.2 Qualitative sampling

For qualitative sampling, to solicit rich in-depth information, the purposive sample consisted of healthcare professionals, with high levels of experience in SCUs. There are different views from the literature about the sample size for qualitative studies that determines sample sufficiency. The emphasis is on selecting information- rich participants. The recommendation was that the sample size be determined by data saturation, when the information was repeated, and no new information was emerging from the participants. According to the experience of most qualitative researchers conducting interviews, based on specific research questions, little new information emerges after interviewing more than 20 people (Vasileiou, Barnett, Thorpe and Young, 2018). The researcher used a mixed method approach, and a major part of this study was quantitative in nature, with a smaller qualitative part for in-depth information.

The participants were purposefully selected, and the actual qualitative sample size was forty-one (41) however, data saturation was reached at participant number 18. The three participating settings differed in size, two big and one small, therefore the participating numbers were not the same. The focus group discussion samples comprised of twenty-eight (28) Operational Nurse Managers, a group of ten participants from two settings and eight from one setting. For individual interviews, three Assistant Nurse Managers and three Monitoring and Evaluation Managers participated. Also, seven (7) Consultants participated, of which six (6) were from two settings and one from one setting. All the qualitative interviews were determined by data saturation, when the information was repeated, and no new themes emerged.

1.8 Inclusion and exclusion criteria

For the quantitative study, the criteria for inclusion in the study were all healthcare professionals with more than one year's experience working in the SCUs, both day and night duty. The sample included those with critical care specialities and those who did not, but had specialised care unit experience and were willing to participate. The qualitative study included participants that were all at a senior level and with expertise and experience in SCUs environments and had vast experiences in the handling of the PSIRL Guidelines. Therefore, Operational Nurse Managers, Assistant Nurse Managers, Consultants, Monitoring and Evaluating Managers, who had more than ten years of SCU experience were included in the study. Participants who did not work in the SCUs and those who were not willing to participate in the study, were excluded.

1.9 Research instrument

1.9.1 Quantitative research instrument

For the quantitative approach, a descriptive, cross-sectional survey design was used in this study, whereby data were collected via an online survey. According to Creswell and Creswell (2018), cross-sectional surveys provide quantitative description of trends and attitudes of a population under study. Therefore, in this study, the online questionnaires, with closed-ended questions were designed, using a Likert scale technique, with options ranging from strongly agree to strongly disagree (Polit and Beck, 2017). The Survey Monkey software was used to design the questionnaires which were emailed to the respondents via individual emails, and some were posted on the organisations' intranet, to enhance the

accessibility to all respondents due to COVID-19 pandemic. There was no existing tool for patient safety to measure the study variables for the implementation of Patient Safety Incident reporting and learning guidelines in SCUs to yield high quality data. Therefore, the researcher adapted the South African National Guidelines for Patient Safety Incident Reporting and Learning (WHO, 2017) to align with the research purpose, objectives and research questions of the study. Section A underwent modification to include the different types of Critical Care Units (CCU)s, for example, medical CCU, as well as the work shifts of the healthcare professionals (See annexure F). Section B and C items, the perceptions of knowledge and implementation of PSIRL Guidelines were modified to specifically suit the SCUs. The adapted questionnaire consisted of three sections. Section A included the demographics of the respondents and consisted of five items. Section B analysed the healthcare professionals' perceptions of knowledge of the PSIRL Guidelines and included six items. Responses were rated on a Likert scale from strongly disagree (1) to strongly agree (5), with a higher score associated with good perceptions of knowledge of the PSIRL Guidelines. The overall level of perceptions of knowledge of the PSIRL Guidelines were categorised as follows: 80 - 100% as good knowledge, 60 - 79% as moderate, and <60% as poor knowledge. Section C included the healthcare professionals' perceptions of the implementation of PSIRL Guidelines and was assessed on 12 items. Similarly, responses were rated on a Likert scale from strongly disagree (1) to strongly agree (5), with a higher score associated with positive perceptions of the implementation of PSIRL Guidelines. The categorisation of the overall level of perception of the implementation of the PSIRL Guidelines was as follows**:** 80 - 100% as positive perception and <80% as negative perception.

1.9.2 Qualitative research instruments

For the qualitative approach, focus group discussions and individual interviews were used to collect data. According to (Dilshad and Latif, 2013), a focus group interview provides a setting for a relatively homogeneous group to reflect on the questions asked by the interviewer. The interviews consisted of open-ended questions and data was collected until saturation was reached, that is, no new information emerged. The researcher prepared a written topic guide with a list of probing questions, although the participants were encouraged to speak freely about the topic, to obtain all the information required (Polit and Beck, 2017). The probing questions were influenced by the participants' responses and the interviewer sought clarity to minimise bias and subjectivity (see Annexure G and H). To

further clarify the concepts, the researcher used probing questions, which depended on the participants' responses, allowing the participants to elaborate on their opinions. The researcher took written notes that were used for data analysis and used a reflective journal.

1.9.2.1 Validity and reliability of the research instrument

To prevent bias the tool was designed and discussed with the supervisor and validated by the statistician. The adapted instrument that was used to collect quantitative data was further evaluated by three clinical and three academic experts, who reviewed the content and confirmed it as adequate. The instrument was rigorously pretested on a sample of five experts i.e. 3 clinical experts (Operational manager, Assistant nurse manager, Consultant medical doctor) and 2 academics (Institutions of higher learning) with experience with more than 10 years of experience. The Raosoft calculator with margin era of 5% justified working on a sample size of 256. The tool measures yielded data with sufficient variability. The reliability coefficient was calculated on the sample data of 256 and the scores were deemed reliable. The purpose of pre-testing was to evaluate and refine the tool and the response was that the questions were clear and easily understandable for the respondents. These results from the pretested tool were not included in the main study. The items of the research instrument were aligned with the objectives of the study to ensure content validity. The adapted tool was evaluated by six experts and pretested on five respondents, giving a total of eleven, which consisted of academics and clinical experts. Experts were asked to evaluate individual items and to rate items on a 5-point Likert scale of relevance and their ratings were sufficient. Their responses were consistent, and no ambiguity was identified during the pre-test, indicating the instrument was reliable. The collected data during pretesting was not included in the final analysis. Cronbach's alpha coefficient for the current research tool was 0.9, meaning the instrument was an excellent measure of the variables under study, as indicated by George and Mallery (2019).

1.10 Data collection process

Data collection is a precise systematic method of gathering information, relevant to the purpose of research, addressing both research objectives and questions (Burns et al., 2015). The pragmatism philosophy continuously informed the data collection as different methods of collecting data were used.

1.10.1 Quantitative data collection process

Quantitative data were collected over three months, from March 2021 to May 2021. Observing the Coronavirus Disease 2019 (COVID-19) protocols, the quantitative data were collected through an online survey. Upon obtaining gatekeepers' permissions from the participating institutions, individual email addresses were requested from the respondents. Each respondent was requested to complete the questionnaire online and email it back to the researcher. The researcher created a link and emailed the questionnaires to the respondents or posted them on the organisation's intranet. The respondents had to click on the link, only linked to the researcher's email address; thus, the researcher had access to the response instantly. This approach was also convenient to the healthcare professionals, as it enabled them to respond at their own convenient time. Quantitative data were obtained from Registered Nurses, Registrars and Operational Nurse Managers.

1.10.2 Qualitative data collection process

Qualitative data were collected over three months, from August 2021 to October 2021. The researcher collected qualitative data virtually, using Skype and Zoom meetings. To ensure confidentiality, participants had the option of signing into the interview individually, which prevented unwanted intruders, as well as passwords were used which allowed the host researcher to control who entered the video conference. Focus groups are a recognized way of exploring the opinions, beliefs, and attitudes of a group of people and of enabling people to respond and interact together (Birt, Scott, Cavers, Campbell and Walter, 2016). In addition, participants feel at ease expressing their views when they share similar background with other group members. Focus group discussions were chosen because it addressed a group of people within a short space of time. It encouraged participation of all group members, thus helping the researcher to arrive at subthemes and themes of the study. Focus group sessions were carefully planned discussions that took advantage of a group dynamic and ground rules were established to solicit input from all group members and not to let vocal participants to dominate the discussion (Polit and Beck, 2020). The group discussions were guided by an interview guide, which consisted of topics and probing questions to elicit more detailed information from the group.

The in-depth individual interviews were also chosen as it allows the participants to talk freely about all topics on the guide, the researcher obtains all the detailed information required and gives participants freedom to provides many illustrations and explanations as

they wish (Polit and Beck, 2020). The individual interviews were also guided by an interview guide, which consisted of a broad question, and probing questions, based on the participants' responses.

The researcher used field notes to record information as memos provide a valuable information during data collection over and above audio recorded information. The field notes are helpful to synthesize and understand data after every session, which helped during data verbatim transcription and analysis. Qualitative data was collected from the participants, between 45 to 60 minutes, and this allowed the participants to freely elaborate on their opinions on the phenomenon. According to Dilshad and Latif (2013), interviews are mostly conducted within one and half hours. A reflective journal was used where identified and refined categories, themes and sub-themes and excerpts from the data was coded and recoded.

1.11 Data analysis

According to Polit and Beck (2017), data analysis is the systematic organisation and synthesis of research data. In mixed methods studies, one of the approaches that is recommended is side-by-side comparison. The data analysis was carried out by first analysing the quantitative statistical results and then discussing the qualitative findings, that confirmed the statistical results. According to Creswell and Creswell (2018), by merging the two data, a researcher brings a numeric quantitative database with a text qualitative database. Therefore, in this study, the researcher analysed the quantitative data from the survey that was conducted and reported, as well as the qualitative data from the interviews, and then merged the two databases to understand the research phenomenon better.

1.11.1 Quantitative data analysis

The researcher entered the data onto an Excel spreadsheet (Microsoft, USA), and cleaned and coded it before it was transferred to SPSS 27 (IBM, USA). Descriptive statistics described the demographic characteristics, perceived knowledge, and implementation of the PSIRL Guidelines. Results were presented as frequencies and percentages. With a *p*-value set at 0.05, inferential statistics of the $\chi 2$ test established an association between demographic characteristics and perceived knowledge and implementation of the PSIRL Guidelines. Pearson correlation coefficient (r) examined the relationship between perceived knowledge and implementation in terms of magnitude, strength, and direction.

1.11.2 Qualitative data analysis

Qualitative data analysis involves reflection on the interview interaction and continues during the data analysis (Burns et al., 2015). Thick description from the field notes assisted in analysing the qualitative data as it consisted more detailed information. A reflective journal was maintained by the researcher, to intuit the essence of the phenomenon by remaining open to the meanings attributed to it by those who have experienced it, during the in-depth interviews, to interpret and give meaning expressed by participants (Creswell and Creswell, 2018). Therefore, content data analysis was conducted using Tesch's method of analysis process (Burns et al., 2015), which consists of eight steps as outlined below:

1. Transcribed interviews were read several times and descriptive words were identified for the formulation of thematic statements and concepts that created meaning. Notes were made with ideas that came to mind.
2. Each interview was read through and the underlying meaning behind the scripts was determined. Notes were made on transcripts during the reading process.
3. A list of concepts was made, and similar topics were clustered together. These clustered topics were then mapped as major topics.
4. Raw data comprising transcripts and filed notes were reviewed again in the light of identified topics. The text was coded and organised.
5. Descriptive words were identified in the text and used to describe themes or topics. Related topics were grouped together.
6. A final decision regarding categories was made.
7. A preliminary analysis was made.
8. Excerpts from the data supporting the identified categories and themes was coded and recoded. A reflective journal was used to form themes and sub-themes.

1.11.3 Trustworthiness

According to Polit and Beck (2017), four criteria are used to determine trustworthiness, namely, credibility, dependability, confirmability and transferability. Therefore, in this study, these concepts were applied to ensure trustworthiness.

1.11.3.1 Credibility

According to Polit and Beck (2017), credibility refers to confidence in the truth of the data and its interpretations, that is, the data must reveal what it is searching for. Polit and Beck

(2017) suggest that the study must be conducted in an authentic manner and steps to be taken to demonstrate credibility. In this study, the researcher had a prolonged engagement with the participants during the data collection process and interpretation, which helped to gain an in-depth understanding of the phenomenon under study. The researcher also engaged in frequent debriefing sessions with the supervisor and other experts in the mixed methods approach to broaden the researcher's view of the study and to minimise the researcher's own bias.

1.11.3.2 Dependability

Dependability refers to the stability and consistency of data over time and conditions. According to Polit and Beck (2017), the findings of an inquiry must be able to be repeated and replicated with the same participants in the same context. In this study, the researcher collected data from different sources, online surveys and videoconferencing applications. Data were converged by merging quantitative data collected from Registered Nurses, Operational Nurse Managers and Registrars working in SCUs, with the qualitative data obtained from Assistant Nurse Managers, Consultants and Monitoring and Evaluation Managers. The relevance of the themes that emerged was monitored from the data collected, transcripts were coded and detailed and complete records were kept. Documentation was available for an enquiry audit by the supervisor and by future researchers with the same interest in the same phenomenon.

1.11.3.3 Confirmability

Confirmability refers to objectivity, that is, the potential for congruence between two or more independent people about data's accuracy, relevance, or meaning (Polit and Beck, 2017). Therefore, the findings should not reflect the researcher's bias, but should reveal participants' voices and conditions of inquiry. In this study, the research report conveyed participants' experiences and not the perspectives of the researcher. The themes generated during data collection reflected the tone of the participants. Member checking carried out through range of activities, including, an ongoing way, by deliberate probing during the data collection, to ensure that participants' meanings were understood.

R**eturning the verbatim transcripts to the participants**.

The researcher provided feedback to the participants about emerging interpretation and obtained participant's reactions. Participants reconstructed their narrative through deleting extracts they feel no longer represent their experience, or that they feel presents them in a negative way.

Membership check interview

The researcher asked the participants to review and comment on interpretive notes, thematic summaries and draft of the research report. The researcher focused on confirmation, modification, and verification of the interview transcript. The second interview to discuss data empowered participants as they had the opportunity to remove and add to their data thereby constructing new meanings.

Using synthesised analysed data, the researcher used analysed data from the whole sample and participants were able to see their experiences within the final results.

1.11.3.4 Transferability

Transferability refers to the extent to which findings can be generalised and applied in other settings or groups (Polit and Beck, 2017). In this study, the researcher was responsible for providing a detailed account of the research process, findings and the recommendations, so that the other prospective researchers could evaluate the applicability to their context. Thick and descriptive data which addressed the objectives of the study was collected, as well as a concise research methodology, to provide other researchers an opportunity to replicate the study in similar situations.

1.12. Ethical considerations

(i) Independent reviews

The University of KwaZulu-Natal's Human Science Research Ethics Committee granted ethical clearance (HSSREC/00001651/2020), and the Directorate: Health Research and Knowledge Management Unit (NHRD Ref: Kz_202010_0240), before data collection (see Annexure A and B). After obtaining ethical clearance, the researcher also obtained permission from the relevant selected gatekeepers, prior to data collection. Permission was

also obtained from the Chief Executive Officers, Heads of Departments and Senior Nurse Managers (See Annexure C). Appointments were made with the institutions' Senior Nurse Managers and Operational Nurse Managers and all the participants prior to data collection.

(ii) Informed consent

The principle of autonomy was observed, whereby the respondents were informed about the study, to make an informed decision. For quantitative data collection, the online questionnaire consisted of an information sheet explaining the study purpose, and the respondents had the option of giving consent before they proceeded to fill in the questionnaire (see Annexure D and E). The consent was completed by every respondent without coercion. For qualitative data, a verbal consent to participate and recording the interview voices was obtained from the participants before data collection. Furthermore, a record of verbal permission is on the researcher's recording device. This was further recorded on the interview guides, consisting of the participants' site code, date, start, and end of the interview.

(iii) Respect for the recruited

Respondents were informed that they were not forced to participate and that they had a right to withdraw from the study even if they had already given consent, without any negative consequences, thus ensuring voluntary participation. The online questionnaire allowed the respondent to withdraw at any stage of responding if they felt uncomfortable to continue with the participation. Debriefing of the research study was conducted, highlighting the importance of the study, the purpose and process of the study, as well as assurance of protection of participants' rights and potential risks, including their mitigation were explained. The researcher ensured that the participants were not subjected to any harm, whether physically or psychologically.

(iv) Confidentiality and anonymity

The anonymity of the respondents' responses was ensured as the researcher used online means of data collection and did not see the respondents physically. Names of respondents and their institutions were not mentioned. Confidentiality was ensured by assuring the respondents that their responses were not going to be divulged without their permission. Codes were assigned to each questionnaire so that it was not possible to associate the

questionnaire with the respondents. Additionally, an electronic password that only allowed the researcher access, was created. Virtual interviews were conducted as per participants' availability and convenience. To ensure anonymity, participants' real names were not used. Data collection devices, that is, audiotapes and transcripts were restricted to the researcher, research assistant and the supervisor only.

1.13 Data management

Participants' interview recordings from Skype and Zoom meetings, as well as the questionnaires were allocated a file, and the data analysis document was stored in the researcher's personal computer which is password- protected. Back-up copies were stored in a password- protected memory stick. All data was only accessible to the researcher, research assistant and the supervisor. On the completion of the study, all data collected was stored in a password protected personal computer. Data will be stored for five years and soft copies will be deleted.

1.14 Conclusion

This chapter highlighted the background of the status of the implementation of the PSIRL Guidelines in SCUs. The problem statement also highlighted the gaps in the implementation of these guidelines. The purpose, objectives and research questions of the study indicated the need for the conduction of this study. The literature review provided an overview of the research that has been conducted of this phenomenon. The theoretical model provided guidance which formed the basis of this study. This chapter clearly addressed the research methodology which consisted of the critical steps that were taken in conducting this study. The study research methodology consisted of the research methods and approach, philosophy underpinnings, research design, study population, sample and sampling, research instruments that were used to collect data for both quantitative and qualitative data, data collection process and analysis, trustworthiness, ethical considerations and data managing. The following chapter is a summary of data dissemination.

Table 4: Thesis structure

Chapter 1: Introduction, Background and Research methodology	This chapter described the background information related to Patient safety Incident guidelines in SCUs, in a global and in a South Africa context. It also includes a literature review and the research methodology undertaken in this study.				
Manuscript Number	**Title of the manuscript**	**Research Objectives**	**Research Approach**	**Data Collection**	**Contribution of the Manuscript**
Chapter 2: Manuscript 1	Healthcare professionals' perception of knowledge and implementation of Patient Safety Incident reporting and Learning Guidelines in specialized care units, KwaZulu-Natal. *(published in SAJCC, 2023 # 559) South African Journal of Critical Care* 2023:39(1):e559. https://doi.org/10.7196/SAJCC.2023.v39i1.559	To assess the healthcare professionals' perceptions on the implementation of PSIRL Guidelines in SCUs, in KwaZulu-Natal	Quantitative approach	Cross-sectional survey	The respondents demonstrated good perceptions of knowledge of the PSIRL Guidelines; however, the perception of the implementation was poor. Therefore, a revised implementation strategy coupled with periodic in-service training for healthcare professionals is recommended, to foster and facilitate effective adherence to the PSIRL Guidelines.
Chapter 3: Manuscript 2	Patient Safety incident guidelines implementation: A Scoping Review *(in review at JMIR ID #* 48580*)*	To map the evidence of PSIRL Guidelines implemented by healthcare professionals in specialised care units globally	Mixed methods approach	Document and Desktop analysis	The nature of implemented incident reporting guidelines was online based **(**n=9) and paper-based incident reporting (n=4). The outcomes of the implemented incident reporting guidelines were positive, as evidenced by improved reporting of incidents, including medication errors (n=7) and decreased rate of incidents and errors (3). Other studies showed no change (n=3) in implementing the incident reporting guidelines.
Chapter 4: Manuscript 3	Barriers influencing implementation of patient safety incident reporting and learning guidelines in SCUs, KwaZulu-Natal: A qualitative study. *(PONE-D-23-22765)*	To explore facilitators and barriers in the implementation of PSI reporting guidelines in SCUs by the healthcare professionals.	Qualitative approach	Focus Group and Interviews	This study confirmed that the PSIRL Guidelines are still not successfully implemented in the SCUs and the barriers to implementation were highlighted. For rigorous implementation in South Africa, the study recommends revised PSIRL Guidelines, designed in consultation with the frontline healthcare professionals, consisting of standardised, simple -user-friendly reporting process as well as a better implementation strategy to guide the healthcare professionals
Chapter 5: Develop a PSI implementation strategy for healthcare professionals working in SCUs	This chapter presents a developed PSI implementation strategy for the SCUs. It also discusses the purpose of the implementation strategy, process and research methods that were used, that contributed to its development. The model that was adopted to guide its implementation by the healthcare professionals is also applied.				
Chapter 6: Synthesis, Conclusion, Limitations and Recommendations	The chapter discusses this study's main findings, drawing conclusions from the previous chapters. This chapter highlights how the research objectives were met and how the theoretical model and the research methodology were linked. The thesis concludes with the reference list and the annexures for this study				

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Chapter 2

This manuscript addressed the objective 2a: To assess the healthcare professionals' perceptions of knowledge and implementation of PSIRL Guidelines in specialised care units, in KwaZulu-Natal and the research question.

First publication: Healthcare professionals' perceptions of knowledge and implementation of Patient Safety Incident reporting and learning Guidelines in specialised care units, in KwaZulu-Natal**.**

2.1 SYNOPSIS TO ARTICLE 1

This study adopted a quantitative approach to collect quantitative data, using a descriptive cross- sectional survey design. Data were collected over a period of three months, from March to May 2021. *(published in SAJCC, 2023 # 559) South African Journal of Critical Care* 2023:39(1): e559. https://doi.org/10.7196/SAJCC.2023.v39i1.559

The first author (TMHG) contributed to the conceptualisation of the project, study design, data collection, data analysis, drafting of the manuscript and editing of the manuscript under the guidance of the research supervisor (Dr. SWM). Both authors contributed to reviewing of the draft manuscript and approved the final version of this article.

RESEARCH

Healthcare professionals' perception of knowledge and implementation of Patient Safety Incident reporting and learning guidelines in specialised care units, KwaZulu-Natal

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Background. Despite the implementation of intervention strategies, incidents in specialised care units remain high and are of serious concern, worldwide.

Objective. To assess the healthcare professionals' perception of knowledge and implementation of patient safety incident (PSI) reporting and learning guidelines in specialised care units of three selected public hospitals in KwaZulu-Natal, South Africa.

Methods. The study used a descriptive, cross-sectional survey design. A purposive sample targeted 237 healthcare professionals. An online structured questionnaire collected the data. Descriptive and inferential statistics were used to analyse data.

Results. A total of 181 questionnaires were returned, yielding a response rate of 76%. Notably, 83% of respondents had high-perceived knowledge of the PSI reporting and learning guidelines, while 98% had low perceptions of their implementation. The current unit (p=0.002) and shift of the day (p=0.008) were factors associated with the perception of good knowledge of PSI reporting and learning guidelines, as indicated by a p-value ≤0.05. The respondents' age (p=0.05), current unit (p=0.015), and shift of the day (p=0.000) were significantly associated with the perception of poor implementation of the PSI reporting and learning guidelines.

Conclusion. The respondents demonstrated a good perception of knowledge of PSI reporting and learning guidelines; however, the perception of the implementation was poor. Therefore, a revised implementation strategy coupled with periodical in-service training for healthcare professionals is recommended, to foster and facilitate effective adherence to PSI reporting and learning guidelines.

Keywords. Patient safety, incidents, guidelines, implementation, critical care, healthcare professionals.

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Contribution of the study.
This study highlights the healthcare professionals' perception of knowledge and implementation of the Patient Safety Incident reporting and learning guidelines in specialised care units in South Africa. The results identified weaknesses in the implementation of the guidelines; hence the necessity for the development of effective strategies to improve patient safety.

Despite the implementation of patient safety strategies, patient safety incidents (PSIs) in specialised care units remain high and are of serious concern worldwide.[1,2] According to the World Health Organization (WHO) in 2017, globally, the healthcare system still demonstrates unacceptably high rates of PSIs and preventable deaths.[1,3] In response to curbing the high rate of PSIs, a global effort was made by the WHO member states to develop patient safety strategies, relevant to their nations, to create a safer environment in the healthcare system.[4] The aim of these patient safety guidelines was to guide clinicians to implement evidence-based decisions and improve clinical outcomes. Organisations and movements have been created to focus on patient safety; however, this is not the case in developing countries.[5] Clarity, consistency, and standardisation in patient safety need to be developed.[5]

In South Africa (SA), the implementation of PSI reporting and learning systems guidelines, as recommended by the KwaZulu-Natal Department of Health (KZN DoH) in line with the National Department of Health (NDoH), has provided no clear improvement in the reduction of PSIs. [6] SA hospitals face various challenges, which include a lack of patient safety guidelines implementation.[6] Abraham *et al*. revealed that current documentation and guidelines relating to patient safety were well known and established within the hospital, but full implementation of these guidelines was lacking.[7]

Incorporating guidelines into critical care practice is recognised as a crucial requirement for the optimal care of critically ill patients; [8] however, implementation of guidelines is often insufficient, resulting in frequent poor adherence in specialised critical care units (SCUs).[9,10] In this study, SCUs include critical care and high care units that care for unstable patients with acute, life-threatening illnesses or injuries and involve multiple skills and specialties. Poor knowledge of patient safety and healthcare professionals' inadequate level of education may contribute to the lack of improvement in patient safety.[11,12] Adequately

prepared healthcare professionals with knowledge, attitudes, and skills are necessary to improve patient safety.[3,13] Working experience, information on patient safety during initial education, and information on patient safety during continuing education have been significantly associated with patient safety.[3] There is limited research on healthcare professionals' perception of knowledge and the implementation of PSI reporting and learning guidelines. This study aimed to assess the perception of knowledge and implementation of PSI reporting and learning guidelines by healthcare professionals in SCUs of KZN Province.

Methods

Study design

A descriptive, cross-sectional survey, which was part of the larger mixed-method design, collected quantitative data from the healthcare professionals working in the specialised care units.

Study setting

The study took place in SCUs of three selected public hospitals in two districts of KZN. Two hospitals (A and C), situated in the eThekwini district, provide both secondary, and tertiary services, and the third tertiary hospital (B) is in the uMgungundlovu district. These districts were chosen because they are the largest in the province, with the most state-owned hospitals equipped with different categories of SCUs, admitting miscellaneous patient profiles, and therefore provided a more comprehensive field for the research project. The selected hospitals treated patients from both urban and rural areas. Twenty SCUs participated in the study, consisting of both critical care units (CCUs) and high care units, as illustrated in Table 1.

Population, sample and sampling

The researcher used a purposive sampling strategy to select specialist critical care nurses and registrars working in the SCUs. Critical care nurses undergo a critical-care training course or orientation that includes essential information on the care of critically ill patients.[14] The registrars are qualified medical doctors receiving advanced training in a specialist field of medicine to become a consultant in that specialty.[15] All the healthcare professionals with >1 year's experience working in the SCUs, day and night duty, and willing to participate met the inclusion criteria. The target population comprised 762 healthcare professionals working in the SCUs, who were involved in the implementation of PSI reporting and learning guidelines in the selected SCUs. For power analysis, and with the help of the statistician, a Raosoft Sample Size Calculator (2004) (Raosoft Inc., USA) assisted in recommending the minimum size of the sample to yield sufficiently valid results. Using the Raosoft parameters of margin error of 5%, the confidence level of 95%, the population size of 762, and the response distribution of 50%, the recommended sample size was 237.

Research tool

The researcher adapted the SA National Guidelines for Patient Safety Incident Reporting and Learning[1] to suit the purpose of the study, as to the researcher's knowledge, no previous studies had researched the topic at the time the study was conducted. Section A underwent modification to include the different types of CCUs, for example, medical CCU, as well as the work shift the healthcare professionals were working. Section B and C items, on the perception of knowledge and implementation of PSI reporting and learning guidelines, were modified to specifically suit the SCUs. The adapted questionnaire consisted of three sections. **Section A -** Demographics of the respondents, included five items.

Section B - Healthcare professionals' perception of knowledge of the PSI reporting and learning guidelines, included six items. Responses were rated on a Likert scale from strongly disagree (1) to strongly agree (5), with a higher score associated with good perception of knowledge of PSI reporting and learning guidelines.[16] The overall level of perception of knowledge of the PSI reporting and learning guidelines was categorised as follows: 80 - 100% as good knowledge, 60 - 79% as moderate, and <60% as poor knowledge.

Section C - Healthcare professionals' perception of the implementation of PSI reporting and learning guidelines was assessed on 12 items. Similarly, responses were rated on a Likert scale from strongly disagree (1) to strongly agree (5), with a higher score associated with positive perception of the implementation of PSI reporting and learning guidelines. The categorisation of the overall level of perception of the implementation of the PSI reporting and learning guidelines was as follows**:** 80 - 100% as positive perception and <80% as negative perception.

Validity and reliability

The adapted instrument was sent to three clinical and three academic experts, who reviewed the content and confirmed it as adequate. The experts had a critical care specialty, and a depth of knowledge and skill in implementing PSI guidelines in SCUs, with working experience of more than 10 years. The items of the research instrument were aligned with the objectives of the study to ensure content validity. The instrument was pretested on a sample of five healthcare professionals working in the SCUs of the research setting. The purpose of pre-testing was to ensure the questions were clear and easily understandable for the respondents. Their responses were consistent and no ambiguity was identified during the pretest, indicating the instrument was reliable. The collected data during pretesting was not included in the final analysis. Cronbach's alpha coefficient for the current research tool was 0.9, meaning the instrument was an excellent measure of the variables under study, as indicated by George and Mallery.[17]

Data collection process

The study was conducted through an online survey, following the COVID-19 protocols, collecting quantitative data over a period of 3 months, from March to May 2021. After obtaining ethical clearance, the researcher sought permission from the relevant selected gatekeepers before data collection. The researcher created a link and emailed the questionnaires to the respondents, or posted them on the organisation's intranet. The respondents had to click on the link, only linked to the researcher's email address; thus the researcher had access to the response instantly.

Ethical considerations

The University of KwaZulu-Natal's Human Science Research Ethics Committee (ref. no. HSSREC/00001651/2020) and the Department of Health (NHRD ref. no. Kz_202010_0240) granted ethical clearance before data collection. The online questionnaire consisted of an information sheet explaining the study, and the respondents had the option of giving consent before they proceeded to fill in the questionnaire. Anonymity of the respondents' responses was ensured as the researcher used online means of data collection and did not see the respondents physically. Confidentiality was ensured by assuring the respondents that their responses were not going to be divulged without their permission. Codes

were assigned to each that it was not possible to associate the questionnaire with the respondent. Additionally, an electronic password that only allowed the researcher access was created.

Data analysis

The researcher entered the data onto an Excel spreadsheet (Microsoft, USA), and cleaned and coded it before it was transferred to SPSS 27 (IBM, USA). Descriptive statistics described the demographic characteristics, perceived knowledge, and implementation of the PSI reporting and learning guidelines. Results were presented as frequencies and percentages. With a *p*-value set at 0.05, inferential statistics of the χ^2 test established an association between demographic characteristics and perceived knowledge and implementation of the PSI reporting and learning guidelines. Pearson correlation coefficient (*r*) examined the relationship between perceived knowledge and implementation in terms of magnitude, strength, and direction.

Results

Of the 237 questionnaires distributed, 181 were returned, yielding a response rate of 76%. According to Nulty,[18] a response rate of more than 73% is considered good. Registered nurses (RNs) (*n*=170) and registrars (*n*=11) completed and returned the online questionnaires.

Demographic profile of respondents

The majority (64.7%) of respondents were >40 years of age, and 80% of healthcare professionals had >6 years of experience in SCUs, as illustrated in Table 2.

Healthcare professionals' perception of the knowledge of the PSI reporting and learning guidelines

The scale was based on a Likert scale and only the highest and lowest response for each item is mentioned. Nearly half of the respondents (49.7%) agreed regarding the categorisation of PSI reporting guidelines and 54.1% agreed that each category was further explained by the severity of patient outcome. Approximately 52% agreed regarding consistent surveillance of near misses, and 54.7% agreed regarding prompt reporting of near misses as soon as they become aware of them to promote quality patient care. Although 49.7% agreed regarding timeously reporting and investigation of the root cause analysis (RCA), half of the respondents (50.3%) disagreed that policies and guidelines were understood by RNs/registrars working in SCUs (Table 3).

Healthcare professionals' perception of the implementation of the PSI reporting and learning guidelines

While 44.2% disagreed regarding creation of adequate awareness of the implementation of the PSI reporting guidelines at the institution, only 11.0% strongly affirmed being involved in the implementation. Only 4.4% strongly agreed that Patient Safety Committees had been established and 36.5% disagreed that a simple and quick system of reporting PSIs had been provided by their organisation. Although 47.5% agreed that adhering to the existing PSI reporting system and guidelines was part of staff performance criteria, 42.0% disagreed that adherence of specialised units to PSI reporting occurred. More than half (54.7%) disagreed regarding the existence of implementation of preventive measures to reduce the incidence of PSIs and their reoccurrence, only 4.4% strongly agreed that these measures were effective. While 53.6% agreed regarding analysis of PSI data and immediate action to mitigate harmful consequences of the PSIs, 40.9 % and 54.1 % disagreed regarding existence of support structures and efficient record keeping of PSIs within organisations, respectively (Table 4).

The overall level of perception of knowledge and implementation of PSI reporting and learning guidelines

Table 5 presents the overall perception of healthcare professionals on knowledge of PSI guidelines and implementation scores. Most of the respondents (83.4%) revealed good perception of knowledge on PSI reporting and learning guidelines. In contrast, only 2.2% had a positive perception regarding the implementation of the PSI reporting and learning guidelines.

Table 1. Target population of the healthcare professionals working in the SCUs, in three selected KZN hospitals

	SCUs, *N*=20	RNs, *N*=200	Registrars, *N*=37	Healthcare professionals, *N*=237
Hospital A	10	90	20	110
Hospital B	6	70	10	80
Hospital C	4	40	7	47

SCUs = specialised care units; KZN = KwaZulu-Natal; RN = registered nurse.

Table 2. Demographic information of healthcare professionals working in SCUs, *N*=181

Demographic information	*n* (%)
Gender	
Female	167 (92.3)
Male	14 (7.7)
Age, years	
23 - 29	13 (7.2)
30 - 39	51 (28.2)
40 - 49	64 (35.4)
50 - 59	42 (23.2)
>60	11 (6.1)
Type of unit	
Medical CCU	14 (7.7)
Surgical CCU	11 (6.1)
Cardiothoracic CCU	8 (4.4)
Coronary care unit	10 (5.5)
Neonatal and paediatric CCU	46 (25.4)
Trauma CCU	17 (9.4)
Neuro CCU	5 (2.8)
Renal unit	17 (9.4)
General CCU	27 (14.9)
High care unit	26 (14.4)
Work shift	
Day duty	170 (93.9)
Night duty	11 (6.1)
Years of experience	
2 - 5	35 (19.3)
6 - 10	42 (23.2)
1 1- 15	38 (20.1)
16 - 20	36 (19.9)
>20	30 (16.6)

SCU = specialised care unit; CCU = critical care unit.

Demographic factors associated with the perception of knowledge and implementation communication of the PSI reporting and learning guidelines

Pearson's χ^2 test was used to determine the statistical significance between variables, as illustrated in Table 6. Current unit and shift of the day were factors associated with the perception of knowledge, while age, current unit, and shift of the day were significantly associated with the perception of the implementation of the PSI reporting and learning guidelines, as indicated by a p-value ≤0.05 (Table 6). This means that healthcare professionals working day shift in certain units were able to implement the PSI guidelines.

Discussion

The purpose of this study was to assess the perception of knowledge and implementation of PSI reporting and learning guidelines in SCUs.

Perception of knowledge of the PSI reporting and learning guidelines

This study revealed that the respondents' perception of knowledge of PSI reporting and learning guidelines was good; this could be attributed to formal education as the majority have specialised education and training. One of the common facilitators of patient safety implementation is education and training opportunities.[19,20] Furthermore, work experience, educational qualification, information regarding patient safety during initial education, and having information concerning patient safety during continuing education were factors significantly associated with knowledge of patient safety.[3,21,22] However, respondents confirmed that the policies and guidelines were not well understood. A similar study revealed that unclear policies, guidelines, and structured formats can also lead to considerable variation in the policies.[23,24]

Perception of the implementation of the PSI reporting and learning guidelines

The respondents had the perception of poor implementation of PSI reporting and learning guidelines in their units. A gap in the communication of patient safety was identified; therefore the recommendation was for the implementation of continuing patient safety education programmes in terms of day courses, safety walk-rounds, conferences, and meetings.[11,25] A similar study affirms that principles acquired from safety awareness campaigns and workshops in the hospitals were also not implemented by staff. [7] The study further revealed that healthcare professionals lacked organisational support, patient safety committees, simple incident reporting systems, and adherence to the PSI reporting and learning guidelines.[26,27]

Age, current unit, and shift of the day were significantly associated with the perception of poor implementation of the PSI reporting and learning guidelines. Research has found that a nurse's age, education, position, and nursing experience have a statistically significant association with their knowledge level.[11,28] This may suggest that certain units were active in the implementation of the PSI guidelines, compared with others, and certain shifts of the day enable the healthcare professionals to implement PSI guidelines. Similar studies found some differences between the working units of healthcare professionals related to safety knowledge.[3,28] Since this study was undertaken in various SCUs, some units may have more updates regarding patient safety than others. This could have improved the implementation of PSI guidelines, compared with their counterparts.

The respondents also indicated the existence of preventative measures; however, they were not effective in reducing the reoccurrence of the PSIs in the SCUs. Similar studies affirm that lack of clinical guidelines, lack of an effective and targeted system for proper monitoring of the programmes, not localising patient safety knowledge, and failure to implement planned programmes to prevent and decrease errors, were challenges to implementing patient safety programmes in hospitals.[29,30]

Table 3. Healthcare professionals' perception of the knowledge of PSI reporting and learning guidelines

Questionnaire item	Strongly disagree, *n* (%)	Disagree, *n* (%)	Neutral, *n* (%)	Agree, *n* (%)	Strongly agree, *n* (%)
The PSIs are categorised as per the recommendation of PSI reporting guidelines, for example, hospital-related incidents; patient care-related incidents; medication-related incidents; blood product-related incidents; procedure-related incidents; equipment-related incidents; and Infrastructure/Buildings/ Fixtures incidents	4 (2.2)	13 (7.2)	32 (17.7)	90 (49.7)	42 (23.2)
Each category is further explained by the severity of patient outcome, that is, insignificant, minor, moderate, major, and catastrophic	2 (1.1)	21(11.6)	26 (14.4)	98 (54.1)	34 (18.8)
Consistent surveillance of near misses and PSIs	10 (5.5)	10 (5.5)	36 (19.9)	94 (51.9)	31 (17.1)
Reporting the near misses and PSIs as soon as they become aware to promote quality patient care	14 (7.7)	9 (5.0)	20 (11)	99 (54.7)	39 (21.5)
Reporting and investigation of the root cause analysis (RCA) of the PSI timeously	7 (3.9)	20 (11.0)	22 (12.2)	90 (49.7)	42 (23.2)
The policies and guidelines are well understood by RNs/registrars working in specialised care units	57 (31.5)	91 (50.3)	11 (6.1)	12 (6.6)	10 (5.5)

Table 4. Healthcare professionals' perception of the implementation of PSI reporting and learning guidelines, N=181

Questionnaire item	Strongly disagree, *n* (%)	Disagree, *n* (%)	Neutral, *n* (%)	Agree, *n* (%)	Strongly agree, *n* (%)
Adequate awareness is created of the implementation of the PSI reporting guidelines in the institution	40 (22.1)	80 (44.2)	26 (14.4)	30 (16.6)	5 (2.8)
I was involved only in the implementation of PSI reporting guidelines	18 (9.9)	68 (37.6)	34 (18.8)	41 (22.7)	20 (11.0)
Patient Safety Committees were established, and performing well in the implementation of PSIs reporting guidelines	38 (20.9)	82 (45.3)	31 (17.1)	22 (12.2)	8 (4.4)
The organisation has provided a simple, quick system of reporting PSIs	37 (20.4)	66 (36.5)	30 (16.6)	37 (20.4)	11.0 (6.1)
Adherence to the existing PSI reporting system and guidelines is part of staff performance criteria	14 (7.7)	22 (12.2)	26 (14.4)	86 (47.5)	33 (18.2)
The Specialised Care units adhere to the Patient Safety Incident (PSI) Reporting and Learning Guidelines	69 (38.1)	76 (42.0)	19 (10.5)	11 (6.1)	6 (3.3)
The department implemented preventative measures that were put in place to reduce the incidence of PSIs and prevent their reoccurrence	39 (21.5)	99 (54.7)	26 (14.4)	12 (6.6)	5 (2.8)
The implemented preventative measures are effective in reducing the reoccurrence of PSIs in the unit	39 (21.5)	93 (51.4)	22 (12.2)	19 (10.5)	8 (4.4)
Analysis of PSI data and immediate action to mitigate harmful consequences of the PSIs	5 (2.8)	19 (10.5)	23 (12.7)	97 (53.6)	37 (20.4)
The organisation has a support structure, which consists of the legal framework that assists during the disclosure of PSIs, as recommended by the PSI guidelines	19 (10.5)	74 (40.9)	48 (26.5)	16 (8.8)	24 (13.2)
The experience of the RNs/Registrars in the units is utilised accordingly when implementing the PSI reporting guidelines	22 (12.2)	74 (40.9)	43 (23.8)	33 (18.2)	9 (5.0)
There is efficient record keeping of reported PSIs as per the recommendation of PSI guidelines	28 (15.5)	98 (54.1)	34 (18.8)	16 (8.8)	5 (2.8)

Table 5. Healthcare professionals' overall level of perception of knowledge and implementation of PSI reporting and learning guidelines

Percentage score	*n* (%)	Level of perception of knowledge of PSI guidelines
<60	17 (9.4)	Low
60 - 73	13 (7.2)	Moderate
80 - 100	151 (83.4)	High
Percentage score	n (%)	Level perception of the implementation of the PSI guidelines
<80	177 (97.8)	Low
80 - 100	4 (2.2)	High

Most professionals had >6 years of work experience in the SCUs; it is therefore perceived that with this level of work experience healthcare professionals should have adequate knowledge and skill, which should lead to effective implementation of the PSI guidelines.[13,28]

Limitations of the study

The study took place in three government hospitals only, in one province, which limits the generalisability of the results to private hospitals and other provinces in South Africa. Only the respondent's perceptions of knowledge and implementation of PSI reporting and learning guidelines were elicited, not the actual knowledge and observed implementation. Information bias was quite possible as the respondents might have given more or less information based on a Likert scale. Recall bias was also possible since the respondents were asked to recall information on PSIs.

Conclusion

The respondents demonstrated perception of good knowledge of PSI reporting and learning guidelines; however, perception of the

Table 6. Demographic factors associated with the perception of knowledge and implementation of the PSI reporting and learning guidelines

	χ^2 value	*p*-value	χ^2 value	*p*-value
Variable	Factors associated with the perception of knowledge of the PSI reporting and learning guidelines		Factors associated with the perception of the implementation of the PSI reporting and learning guidelines	
Gender	13.115a	0.217	24.074a	0.769
Age	42.952a	0.679	65.151a	0.050*
Current unit	125.352a	0.008*	322.643a	0.015*
Shift of the day	27.948a	0.002*	69.991a	0.000*
Correlation between the perception of knowledge and implementation of the PSI reporting and learning guidelines (*N*=181)				
			Perceived implementation	
		Pearson correlation	0.255**	
Perception of knowledge				
		Sig. (2-tailed)	0.031	

*Significant p-value at ≤0.05
**Correlation is significant at the 0.01 level (2-tailed).
Additionally, the Pearson correlation coefficient revealed a very weak significant positive linear correlation between knowledge and perceived implementation (r=0.255; *p*=0.031). Thus, translating to increased perceived knowledge correlating to implementation of the PSI learning and reporting guidelines.

implementation of the PSI reporting and learning guidelines was poor. Therefore, a revised implementation strategy coupled with periodical in-service training for healthcare professionals is recommendeded, to foster and facillitate the already available implementation strategies for effective adherence to PSI reporting and learning guidelines. In addition, a situational analysis needs to be conducted to identify barriers that lead to poor perception of implementation of the PSI reporting and learning guidelines, and to devise strategies that are practical in the facilitation of implementation of PSI reporting and learning guidelines.

Declaration. This manuscript is submitted as partial fulfilment of the requirements for a PhD at the University of KZN.

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Conflicts of interest. None.

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CHAPTER 3

Second Publication: Patient Safety Incident Reporting Guidelines implemented: A scoping review.

This review article addresses research objective 1 and research question 1 of this study; to map the evidence of Patient Safety Incident Reporting and Learning guidelines implemented by healthcare professionals in specialized care units globally.

3.1 SYNOPSIS TO ARTICLE 2

Manuscript 2

Implementation strategies guide the healthcare professionals to effectively implement the PSI reporting and learning guidelines, as recommended by the WHO. The manuscript was submitted to Journal of Medical Internet Research in May 2023 to the Journal of Medical Internet Research - currently under review.

The first author (TMH) conceptualized and prepared the review under the guidance of the research supervisor (Dr. SWM). Both authors contributed to reviewing of the draft manuscript and approved the final version of this results paper.

A scoping review methodology, according to the Joanna Briggs Institute, was adopted to map the evidence of the existing PSI implementation strategies. The research questions addressed in this review are: What evidence exists on the implementation of PSI reporting guidelines by the healthcare professionals? What are the gaps in terms of content, context, and quality in the implementation of Patient Safety Incident reporting and learning guidelines in specialised care units? What are the existing implemented PSI intervention strategies in the specialised care units.

Abstract

Background: Implementing PSI reporting guidelines is critical in guiding clinical practice and improving clinical outcomes in specialized units. Limited research on evidence looks at the implemented PSI reporting in specialized units at the global level.

Objective: This review aims to map the evidence of Patient Safety Incident Reporting and Learning guidelines implemented by healthcare professionals in specialized care units globally.

Methods: A scoping review methodology, according to the Joanna Briggs Institute, was adopted. The eligibility criteria were guided by the Population (Healthcare professionals), Concept (Patient Safety Incident Reporting and Learning guidelines), and Context (Specialised units; Global). Articles written in English were searched from relevant databases and search engines. The report was per the Preferred Reporting Items for Scoping Reviews (PRISMA-ScR) checklist.

Results: The thirteen (13) selected articles were published from 2003 to 2020. Most articles are from Netherlands and Switzerland (n=3), followed by South Africa (n=2). The nature of implemented incident reporting guidelines was computer online based **(**n=9) and paper-based incident reporting (n=4). The reporting system was for all the healthcare professionals within the specialized units, focusing on patients, staff members, and families. The outcomes of implemented incident reporting guidelines were positive, as evidenced by improved reporting of incidents, including medication errors (n=7) and decreased rate of incidents and errors (3). Other studies showed no change (n=3) in implementing the incident reporting guidelines.

Conclusion: The implementation of reporting of PSIs in specialized units started to be reported around 2002, however, the frequency of yearly publications remains very low. Although some specialized units are still using multifaceted paper reporting systems in reporting Patient Safety Incidents, the implementation of electronic and computer-based reporting systems is gaining momentum. The effective implementation of an electronic-based reporting system should extend into other units beyond critical care units.

Keywords:

Patient safety incidents; adverse events; harm; near misses; reporting guidelines; implementation guidelines; implementation practices; intervention strategies; critical care units; intensive care units.

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Background

Reducing the occurrence of Patient Safety Incidents (PSIs) in the healthcare system has become a global concern. According to the World Health Organisation (WHO 2017), the healthcare system has still demonstrated unacceptably high rates of PSIs and preventable deaths. Patient safety remains crucial in the improvement of quality patient care and has been defined by the WHO International Classification for Patient Safety (ICPS) as the reduction of the risk of unnecessary and avoidable harm associated with healthcare to an acceptable minimum (Group, Sherman, Castro, Fletcher, Hatlie, Hibbert et al., 2009; Runciman, Hibbert, Thomson, Van Der Schaaf, Sherman, and Lewalle, 2009). Specialized units (critical care and high care units) are no exception as critically ill patients tend to be more susceptible and exposed to a complex environment, therefore incurring high rates of preventable PSIs and death (Ahmed, Thongprayoon, Schenck, Malinchoc, Konvalinová, Keegan et al., 2015). Near misses and PSIs require constant surveillance, to improve patient safety in acute and critical care units (Henneman, Gawlinski and Giuliano, 2012). Near misses are incidents or situations that have the potential to cause harm but did not reach the patient due to timely intervention, whereas a PSI is harm caused by medical mismanagement, instead of the underlying disease (Ochôa da Silva and Aquino Caregnato, 2019; WHO, 2017). PSIs contribute to the cost of care, adding to the burden of the patient and because of malpractice claims, causing mounting and spiralling costs to the healthcare system and for society at large (Oyebode, 2013).

Evidence revealed that in high-income countries, it was estimated that one in every 10 patients was harmed while receiving hospital care (Slawomirski, Auraaen and Klazinga, 2017). This harm might have further increased the length of hospitalization and utilization of more healthcare resources, with cost implications. In low and middle-income countries (LMICs),134 million PSIs occurred in hospitals due to unsafe care, which resulted in 2.6 million deaths, each year (National Academies of Sciences and Medicine, 2018). A study done in the Eastern Mediterranean and Africa revealed that almost one-third of patients who suffered PSIs died and four out of five of those incidences were preventable (WHO, 2015). In South Africa, a study conducted in KwaZulu-Natal revealed that PSIs were still high (47%), and were serious in nature, which might have suggested poor implementation of PSI reporting and learning guidelines and a lack of improvement strategies (Gqaleni and Mkhize, 2023; Gqaleni and Bhengu, 2020). Therefore, mitigation of the occurrences of PSIs

remains an important component in rendering quality patient care and improving clinical outcomes.

Implementation guidelines are critical in guiding the clinical practice and improvement of clinical outcomes. Rosa, Teixeira and Sjoding (2020) affirmed that incorporating evidence into critical care practice is recognised as a crucial requirement for the optimal care of critically ill patients. However, implementation of evidence-based practices is often insufficient, due to many barriers resulting in frequently poor adherence to guideline recommendations in critical care settings (Costa, White, Ginier, Manojlovich, Govindan, Iwashyna et al., 2017; Jeffs, Hayes, Smith, Mamdani, Nisenbaum, Bell et al., 2014; Weiss, 2017). In response to curb the high rate of PSIs, a global effort was made by the WHO Member States to develop the implementation intervention strategies, relevant to their nations to create a safer environment in the healthcare system (WHO, 2015). The World Alliance for Patient Safety first drafted the guidelines for adverse events report and learning systems, which were updated and revised as WHO Guidelines for Patient Safety Incident Reporting and Learning Systems. In South Africa, it was recommended by the NDoH, that every health establishment was expected to adhere to Patient Safety Incident Reporting and Learning system as stipulated in this Guideline (WHO, 2017). A patient safety learning system (sometimes called a critical incident reporting system) refers to structured reporting, collation, and analysis of critical incidents (Ontario, 2017). Nevertheless, failure to reduce the PSI occurrence might be related to the poor implementation of PSI reporting and learning guidelines which might have led to the negative clinical outcomes which made it difficult for the policy makers and healthcare professionals to handle PSI reporting and learning guidelines effectively. There is limited research on evidence that looks at the implementation of PSIs reporting and learning guidelines in specialised units at global level.

Aim and questions of the review

The aim of this review is to map the evidence of PSI reporting and learning guidelines implemented by healthcare professionals in specialised care units (SCUs), globally. The broad question of the review is: What evidence exists on the implementation of the PSI reporting and learning guidelines by the healthcare professionals? What are the gaps in the implementation of PSI reporting and learning guidelines in SCUs?

Methodology

The Joanna Briggs Institute Scoping Review Methods (2020), scoping reviews as described in the 2020 JBI Manual for Evidence Synthesis (Peters, Marnie, Tricco, Pollock, Munn, Alexander et al., 2020), was used to map the available evidence on PSI Reporting and Learning guidelines implemented by healthcare professionals in SCUs. A scoping review protocol was developed and registered with the Open Science Framework (OSF) (https://osf.io/). The Preferred Reporting Items for Systematic Reviews (PRISMA) extended to scoping reviews (PRISMA-ScR): a checklist and explanation guided the reporting, to ensure the review conforms to the reporting standards of a scoping review (Tricco, Lillie, Zarin, O'Brien, Colquhoun, Levac et al., 2018).

Eligibility Criteria

The eligibility criteria were guided by the Population, Concept and Context (PCC) framework as illustrated in Table 1.

Table 1: PCC framework to determine the eligibility

Eligibility criteria	Elements of the study
Population	Heath care workers, Healthcare Provider(s), Healthcare professionals, Health Personnel, Allied healthcare professionals, nurses, ICU nurses, intensive care nurses, critical care nurses, medical doctors
Concept	Implementation, Practices, Intervention strategies, Patient Safety Incident Reporting guidelines, Voluntary Patient Safety Event Reporting, Risk management, Reporting guidelines, Patient safety learning systems, Critical Incident reporting system, Adverse events; errors, critical incident, incident reports, Hospital risk reporting
Context	Specialised care units, ICUs; critical care units; Coronary care unit/Renal units/Burns unit/High care units, Worldwide, Globally, African continent, European continent, Asian continent, American continent, Australasian continent, WHO regions, United Nations regions.

Information sources

In addition to PCC, the following information sources were included: 1) Studies which presented evidence that were published as from January, 2002 from the following data bases: The start date of 2002 was chosen because the PSI guidelines were published around that period; (2) Quantitative, qualitative and mixed methods study designs; (3) Reports, text and opinion papers relating to implementation of PSI Reporting guidelines and (4)Review articles including: systematic, meta-analysis, Integrative and scoping reviews (5) Grey literature sources including academic outputs (theses and dissertations) and ongoing research and (6) Professional organizations such as World Health Organization (WHO).

Exclusion criteria

Studies written in non-English language and articles on implementation of patient safety reporting guidelines in medical, surgical, theatre and emergency departments were excluded. The scoping of articles was done using the Ryyan software by the two reviewers. Articles that had a wrong population, wrong concept and wrong context were eliminated. The screening was done at two levels until the full articles that met the inclusion criteria were reviewed.

Search terms

The following search terms and electronic databases were used to identify articles for the scoping review (Table 2).

Table 2: Search words

MeSh terms	Healthcare professional(s), health plan implementation, hospital risk reporting, globally
Search words	Healthcare workers or healthcare provider or healthcare professionals or health personnel or nurses or ICU nurses or intensive care nurses or critical care nurses or medical doctors AND Implementation or practices or Intervention strategies AND Patient Safety Incident Reporting guidelines or Voluntary Patient Safety Event Reporting or Risk management or Reporting guidelines or Patient safety learning systems or Critical Incident reporting system or Adverse events or errors or critical incident or incident reports or Hospital risk reporting AND Specialised/Specialised care units or ICUs; critical care units or Coronary care unit or Renal units or Burns unit or High care units AND Worldwide or Globally or African continent or European continent or Asian continent or American continent or Australasian continent or WHO regions or United Nations regions

Search strategy

The researchers followed a three-step search strategy to find evidence related to implementation of PSI Reporting and Learning guidelines implemented by healthcare professionals in SCUs. The reviewers involved the research librarian in designing and refining the search. Firstly, two appropriate data bases, namely, MEDLINE (PubMed or Ovid) and CINAHL were searched. Thereafter, an analysis of the text words contained in the title and abstract of retrieved papers, and of the index terms used to describe the articles were followed. A second search was done using all identified keywords and index terms in all the remaining data bases namely PubMed, EBSCO Host, Web of Science, Scopus, African Journals online (AJOL) and Sabinet. A search for grey literature was done to locate unpublished evidence, including academic outputs (theses and dissertations) and ongoing research. Professional organizations such as the WHO were also searched. Lastly, the reference list of identified articles was searched for additional sources. A sample of a complete search strategy for at least one major data base is included an appendix to the protocol.

Source of evidence selection

The process of source selection was done in two stages. The first stage was based on title and abstract examinations using the PCC inclusion criteria, thereafter, full-text examinations followed as the second stage. All the stages of the review were done by two reviewers (TG & GC), independently and any disagreements solved by consensus. A flowchart of review processes (from the PRISMA-ScR statement) detailing the flow from the search, through source selection, duplicates, full-text retrieval, and any additions from third search, data extraction and presentation of the evidence was availed. The Endnote and Ryann software were used for the management of the results of the search.

Data extraction process, presentation, and analysis

Data extraction and verification were done by two reviewers (TG & GC). A logical and descriptive summary of the results that aligns with the specific questions was presented in the form of charting tables. The data included the following key information: authors, year of publication, country where the study was done, populations involved, study methods, guidelines or strategies implemented and outcomes. Analysis of evidence was done through frequency counts of concepts, population and context. A narrative summary was done to

describe the existing evidence on the implementation of PSI Reporting and Learning guidelines by the healthcare professionals working in SCUs.

Results

According to Figure 1, a total of 146 articles were identified from the data bases and the search engine google scholar. Prior to selection process, 6 duplicates were removed to remain with 140 articles for abstract and title screening. After abstract and title screening, 96 articles were excluded based on the following reasons: wrong population (7), wrong concept (30), wrong context (59). This resulted in remaining with 44 articles for full text screening. Three full texts articles could not be retrieved, hence excluded to remain with 41 full text articles for second level screening. Full text screening yielded in the exclusion of 28 articles based on the following reasons: wrong population (n=2), wrong concept (n=13), wrong context (n=9), unclear outcomes (n=4). As shown on Figure 1 below, 13 articles were found to be fitting the inclusion of this scoping review (Kabane et al, 2013; Truter et al, 2017; Kanda, 2011; Muhsein et al, 2017; Fraenkel et al, 2003; Garcia et al, 2020; Snijders et al, 2009; Runsveld-Reinders et al, 2018; Frey & Schwappach, 2010; Pagnamenta et al. 2012; Frey and Schwappach, 2010; Van der Veer et al. 2007; Muhammed, 2014).

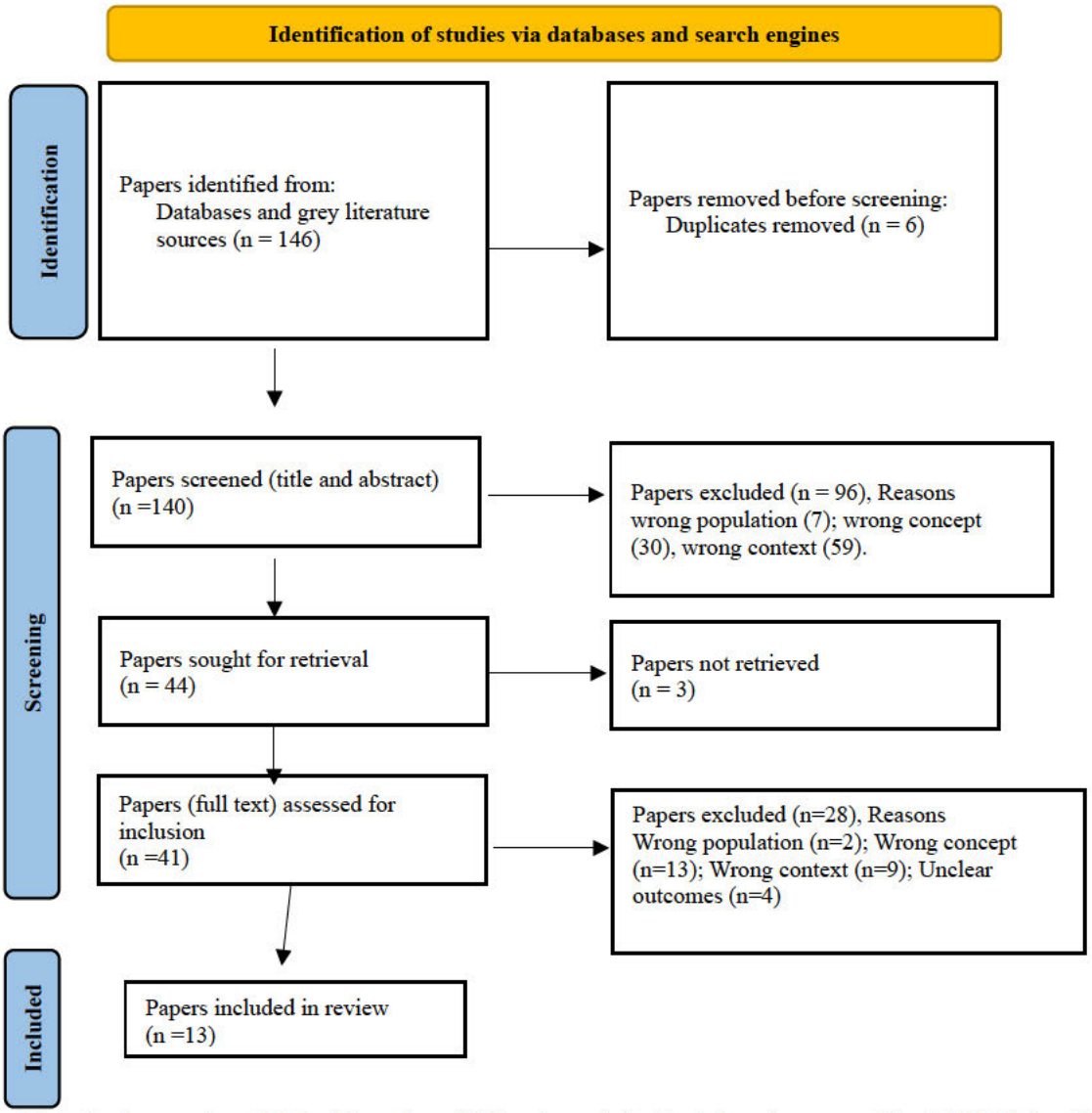

Fig 1: Implementation of PSI and Learning guidelines in specialised units' results presented in a PRISMA flow diagram
Source: Authors own compilation

Publication trends, distribution and characteristics

The articles utilized quantitative (n=9), and review (n=3) methodologies and one was not stated. The most specialised unit were critical care units (n=9). The thirteen (13) selected articles (Table 3) were published in 2003 (n=1), 2007 (n=1), 2009 (n=1); 2010 (n=2); 2011 (n=1), 2012 (n=1), 2013 (n=1), 2014 (n=1), 2017 (n=2), 2018 (n=1) and 2020 (n=1). The articles were identified from four different continents namely Asia (n=2), Africa (n=2), Australia (n=1) and Europe (n=8). Most articles are coming from Netherlands and Switzerland (both with n=3), followed by South Africa (n=2). Others specific countries like Spain, Ireland, Jordan, Australia, and Japan had only one article each.

Table 3: Patient Safety Incident Reporting guidelines implemented by the healthcare professionals (n=13). Most studies report on improving the culture of reporting. WHO, each country has its strategy, for preventing the occurrence of PSIs

Author, year, country	Research design; setting	Patient Safety Incident Reporting guideline				Recommendation
		Nature of PSI guidelines/strategy	Type of healthcare professional	Population recipient	The outcome of the Implementation	
African continent						
Kabane et al., 2013; South Africa	Interventional study	Computerized incident reporting system; Hospital	Healthcare workers	Patients	Increased reporting of incidents is significantly higher in the intervention compared to the control sites. The findings reported for improving the safety culture were largely positive, but only in selected areas. The researcher and the management of the Free State Department of Health are convinced that this model has reduced patient safety risks at its hospitals indeed.	The utilization of the patient safety risk reduction model should serve as a fundamental framework for enhancing patient safety and improving healthcare quality. This model can be effectively utilized by any province or country that is delivering healthcare in a setting with limited resources, with some necessary modifications.
Truter et al., 2017; South Africa	Prospective, quantitative design with a descriptive approach.	Medication error checklist	Neonatal intensive care unit (NICU) staff	Paediatric patients and staff	Higher incidences of medication errors were reported.	It is recommended to implement a formal system for documenting these errors, in addition to regular talks among the interdisciplinary team about preventive measures.
Asian Continent						

Author, year, country	Research design; setting	Patient Safety Incident Reporting guideline				Recommendation
		Nature of PSI guidelines/strategy	Type of healthcare professional	Population recipient	The outcome of the Implementation	
Kanda, 2011; Japan	Not clearly stated; Hospital	An online report input system	All healthcare professionals	Patients	307 and 789 cases were reported within 24 h and 48 h, respectively, indicating that the first report was input mostly without delay by the operational guidelines. Cases that took more than two weeks to be reported would likely have gone unreported had there not been a first report to indicate and confirm that an incident had even occurred.	It is necessary to include specific information about occurrences in this system using unrestricted text, which provides details that cannot be obtained using multiple-choice options like in typical reporting systems.
Muhsein et al., 2017; Jordan	Health Services Executive (HSE) change module; Health Services Executive (HSE) change module	Electronic safety program; Intensive care unit	ICU nursing staff	Adult Patients and staff	Implementing an electronic safety program within Health Services Executive (HSE) change module would protect patient safety and help healthcare providers to be aware of patients' conditions and quality of care.	It is crucial to use electronic safety measures in healthcare centers and hospitals to enhance the quality of patient service. .
Australia Continent						

Author, year, country	Research design; setting	Patient Safety Incident Reporting guideline				Recommendation
		Nature of PSI guidelines/strategy	Type of healthcare professional	Population recipient	The outcome of the Implementation	
Fraenkel et al., 2003; Australia	Longitudinal observational study; adult general intensive care unit	Clinical information system to replace paper-based charts of patient observations, clinical records, results reporting, and drug prescribing	Nursing staff	Patients	A significant reduction in the rates of medication, intravenous therapy, and ventilator incidents. There was a trend toward a reduction in pressure sores. A positive perception of the clinical information system by nursing staff, with less time spent on documentation and more time in patient care. Nursing staff recruitment and retention improved after the clinical information system implementation.	The introduction of a comprehensive clinical information system resulted in significant enhancements in important quality measures, favorable perceptions among nursing staff, and certain positive effects on resources.
European continent						
Garcia, et al., 2020; Spain	Retrospective descriptive analysis; Intensive care unit	Critical patient Transport protocol And its application Through checklists	ICU Doctors; nurses; hospital Managers; representatives From the Quality Unit	ICU patients	The rate of safety-related incidents was less. Over time adherence to protocol compliance increased.	Implementing a critical patient transport policy and utilizing checklists can effectively decrease the occurrence of adverse events and non-damaging mishaps in these patients.
Snijders, et al., 2009; Netherlands	Descriptive survey; NICUs and one pediatric surgical ICU.	a specialty-based, voluntary,	All ICU personnel	Patients	The number of self-reported incidents increased after the intervention. It was positively associated with a non-punitive response to error and negatively associated with overall	The absence of punishment for mistakes, the support from hospital management for patient safety, and the general sense of safety are factors that determine the likelihood of incident reporting in the NICU.

Author, year, country	Research design; setting	Patient Safety Incident Reporting guideline				Recommendation
		Nature of PSI guidelines/strategy	Type of healthcare professional	Population recipient	The outcome of the Implementation	
Snijders, et al., 2009; Netherlands		the nonpunitive incident reporting system			perceptions of safety and hospital management support for patient safety.	
RUNSVELD-REINDERS et al, 2018; Netherlands	Systematic review; Adult intensive care	ICU incident reporting systems	All ICU healthcare professionals	ICU patients	All the IRSs still need to fulfill the WHO checklist criteria. This resulted in an administrative report system rather than the much-desired instrument for practice change. increase of quality as an IRS can only effectively contribute to improving patient safety and quality of care if more attention is given to analyzing incidents and feedback	Healthcare organizations should prioritize the recruitment of skilled professionals who can effectively provide feedback on information and improvement measures, as well as assist in implementing and monitoring the impact of these efforts.
Frey & Schwappach, 2010; Switzerland	Review; Paediatric and adult critical care	Risk scoring of critical incident reports and root cause analysis- are these interventions?	Paediatric and adult critical care staff	Patients	It was just a suggestion that was given.	Integrating system modifications based on event reports and incorporating the knowledge and insights of patients and their families, can enhance patient outcomes.
Pagnamenta et al. 2012 Southern Switzerland	Before-and after-study design. Self-reporting questionnaire and Risk index scores	Multifaceted paper reporting strategy	Health caregivers	Adult ICU patients	Mean risk-index score for medication errors improved, as well as communication. No change for the airway and indwelling lines related AEs	Effective implementation of any risk assessment system requires educational interventions, protocol execution, thorough training, and the use of relevant examples to ensure maximum consistency in scoring.

Author, year, country	Research design; setting	Patient Safety Incident Reporting guideline				Recommendation
		Nature of PSI guidelines/strategy	Type of healthcare professional	Population recipient	The outcome of the Implementation	
Frey and Schwappach ,2010 Switzerland	Literature review	Critical incident monitoring system	ICU personnel	Patients and their families	Hard outcome criteria have shown no improvement in critical incident monitoring, e.g., standardized mortality ratio.	Execution of System Modifications/ Methodology
Van der Veer et al. 2007, Netherlands	Implementation design	ICU Incident registry added to the existing registry	Nurses and physicians	ICU patients	The number of reported events was more than doubled	Further refinement and modifications are necessary. .
Muhammed, 2014 (Dissertation)Ireland	Survey on Patient safety culture	Handoff communication process	ICU nurses	ICU patients	The project evaluation results showed a decline in the percentages of handoff related incidents and improved the nurses' satisfaction.	Further upgrade work are anticipated to be carried out.

Patient safety incident reporting and learning guidelines

The nature of implemented incident reporting and learning guidelines was computer- online based (n=9) and paper-based incident reporting (n=4). The reporting system was for all the healthcare professionals within the SCUs with focus on patients, staff members and families. The outcomes of implemented incident reporting and learning guidelines were positive as evidenced by improved reporting of incidents including medication errors (n=7) and decreased rate of incidents and errors (3). Other studies did not show any change (n=3) in the implementation of the incidents reporting and learning guidelines (See Table 3).

Discussion

The review aimed at mapping the evidence of PSI Reporting and Learning guidelines implemented by healthcare professionals in SCUs, globally. Although the evidence on implementation of PSI reporting and learning guidelines in SCUs comes from 4 different continents (Asia, Africa, Australia, Europe), the number identified for certain countries within each continent is very minimal. Yet globally, there is higher percentage of PSIs in SCUs (Gqaleni & Bhengu, 2020). The implementation of reporting of PSIs in SCUs started to be reported around 2002, however the frequency of yearly publications remains very low. Whilst healthcare systems in developing and developed countries have implemented the patient safety reporting system, challenges still exist to reach full scale (Koike et al, 2022). Incident reporting systems (IRS), as safety culture promoters (Torre-Pérez et al, 2023), serves as a starting point of the learning process to prevent the occurrence of the same incident in the future (Harsul et al, 2020).

Implementation of IRS for risk identification and organizational learning is one way of improving patient safety in healthcare, including specialized settings (Sahlström et al, 2018). The nature of implemented incident reporting guidelines identified in the review were computer based online reporting (Kabane et al, 2013; Kanda, 2011; Muhsein et al, 2017; Fraenkel et al, 2003; Snijders et al, 2009; Van der Veer et al, 2007; Frey and Schwappach, 2010; Runsveld-Reinders et al, 2018), paper based incident reporting (Pagnamenta et al, 2012; Truter et al, 2017; Garcia et al, 2020) and hand off communication (Muhammed, 2014). The use of electronic and computer-based reporting system is gaining momentum due to its effectiveness in increasing the reporting of PSI events, reducing time to make an informed reporting of PSIs and immediate accessibility to information when needed for

analysis (Giles et al, 2005; Van der Veer et al, 2007; Kanda, 2011). Adopting the electronic safety program in specialised units like critical care units will enhance the quality of services that are provided for patients as indicated by Muhsein et al (2017).

Paper based reporting system of PSIs has proved to be inefficient as fewer staff are willing to report the incidents (Gao et al, 2019). However, some SCUs are still using multifaceted paper reporting system in reporting PSIs, errors related to medication and critical transportation of patients with positive results (Pagnamenta et al, 2012; Truter et al, 2017; Garcia et al, 2020). On the other hand, Fraenkel et al (2003) implemented a computerized clinical information system which replaced paper-based charts of patient observations, clinical records, results reporting, and drug prescribing which resulted in the reduction of the occurrence of PSIs, less documentation and more time spent on the patient. According to Ramirez et al (2018), the implementation of a hospital IRS including the systematization of the method and analysis of PSIs by workshop-trained, result in reduction of the frequency of PSIs.

In some cases, reporting of PSIs and handling them at a unit level (SCUs) is not adequate in developing patient safety, hence the need to use multiple methods to strengthen the overall patient safety culture (Sahlström et al, 2018). Van der Veer et al (2007) utilised the concept of multiple methods where the ICU Incident registry was added into the existing registry, and this resulted in double the number of PSIs reported. Additionally, the handoff communication process has proved to lower the numbers of the handoff related incidents and enhancing the satisfaction of nurses (Muhammed, 2014). While much evidence of the current review has revealed the positive outcomes of implementing online or computer-based reporting system in SCUs such as critical care units, the systematic review done by Frey and Schwappach (2010) indicated no improvement in critical incident monitoring after the implementation. Similarly, use of the multifaceted paper reporting strategy highlighted no change for the PSIs related to airway and indwelling lines (Pagnamenta et al, 2012).

Strengths

Scoping reviews ensure high-quality articles are included for data extraction. Publications were emanating from different countries, worldwide, depicting comprehensive available information on the implementation of the reporting guidelines and strategies, which

provided further recommendations. Evidence-based information from the results will be used by the policymakers to improve patient safety culture in SCUs.

Limitations

The review was limited to SCUs only, therefore, pertinent information from other units and other categories of healthcare professionals may have been disregarded. Also, only articles published in English were used, therefore excluding articles published in other languages, whose information may have had a valuable contribution. There is a paucity of literature on the implementation of PSI reporting and learning guidelines worldwide, therefore future research studies need to be conducted, especially in the African continent.

Conclusion and recommendations

Although the evidence on the implementation of PSI reporting guidelines in SCUs comes from 4 different continents (Asia, Africa, Australia and Europe), the number identified for certain countries within each continent is very minimal. Some SCUs are still using multifaceted paper reporting systems in reporting adverse events, however, the implementation of electronic and computer-based reporting systems is gaining momentum. The effective implementation of an electronic-based reporting system should extend into other SCUs beyond critical care units as it increases the reporting of PSIs, reducing time to make an informed reporting of PSIs and immediate accessibility to information when needed for analysis.

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Authors' Contributions

TMHG contributed to the conceptualization of the scoping review, data extraction, analysis of results, drafting, and editing of the manuscript. SWM contributed to the conceptualization, and editing of the manuscript and approved the final version of this results paper.

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Abbreviations

PSIs: Patient Safety Incidents

SCUs: Specialised care units

WHO: World Health Organisation

MeSH: Medical Subject Headings

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Chapter 4

This manuscript addresses objective and research questions 2b: To describe barriers in the implementation of PSI reporting guidelines in specialised care units by the healthcare professionals

Third Publication: Barriers influencing implementation of PSI Guidelines: A qualitative study

4.1 SYNOPSIS TO ARTICLE 3

Manuscript 3

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The first author (T.M.H) conceptualized and prepared the manuscript under the guidance of the research supervisor (Dr. SWM). Both authors contributed to reviewing of the draft manuscript and approved the final version of this article.

Abstract

Background

Globally, increased occurrences of Patient Safety Incidents have become a public concern. The implementation of Patient Safety Incidents incident reporting and learning guidelines is fundamental to reducing preventable patient harm. To improve the implementation of these guidelines in specialised care units in KwaZulu- Natal, the views of healthcare professionals were unearthed.

Aim

This study explores the senior healthcare professional views toward the implementation of Patient Safety Incidents reporting and learning Guidelines in specialised care units.

Methods

A descriptive, explorative qualitative approach was used to collect qualitative data from senior healthcare professionals working in specialised care units. The study was conducted in SCUs of three purposely selected public hospitals in two districts of KwaZulu-Natal. Group discussions and semi-structured interviews were conducted from August to October 2021. Content data analysis was performed using Tesch's method of analysis process.

Results

The main themes that emerged during data analysis were ineffective reporting system affecting the communication of PSI guidelines, inadequate institutional and management for the healthcare professionals, insufficient education and training of healthcare professionals, and poor human resources affecting the implementation of PSI guidelines.

The findings highlighted that there were more major barriers to the implementation of the PSI reporting and learning guidelines.

Conclusion

This study confirmed that the PSI reporting and learning guidelines are still not successfully implemented in the specialised care units and the barriers to implementation were highlighted. For rigorous implementation in South Africa, the study recommends revised PSI reporting and learning guidelines, designed in consultation with the frontline healthcare professionals. These must consist of standardised, simple- user-friendly reporting process as well as a better implementation strategy to guide the healthcare professionals. Continuous professional development programmes may play an important role in the facilitation of the implementation process.

Introduction

Globally, increased occurrence of Patient Safety Incidents (PSIs) and near misses have become a public concern, which includes South Africa (Yali and Nzala, 2022). Near misses are incidents or situations that have the potential to cause harm but do not reach the patient due to timely interventions, whereas a Patient Safety Incident (PSI) is harm caused by medical mismanagement, instead of the underlying disease(WHO, 2017). Unsafe care is one of the top 10 leading causes of death in the worldwide and up to 83% of harm is avoidable (Flott, Fontana and Darzi, 2019). The Institute of Medicine reveals deaths related to PSIs vary from 44 000 to 98 000 people each year with high-cost implications (James, 2013; Lt, 2000; Makary and Daniel, 2016). According to Flott et al. (2019), in 2013, over 420 million hospitalisations around the world resulted in nearly 43 million PSIs. An analysis by the Organisation for Economic Co-operation and Development (OECD) found that 15 percent of all hospital costs in OECD nations are due to patient harm from PSIs, with associated costs ranging between $1.4 to $1.6 trillion, each year (National Academies of Sciences and Medicine, 2018). According to Choi, Pyo, Ock and Lee (2019); Lu, Ko, Chen, Chueh, Chen and Cooper (2022), improving the hospital organization atmosphere is essential to facilitate useful communication of patient safety incidents.

In Swedish and Brazilian health services, barriers and facilitators that influenced patient safety were identified and the relevance of a multifaceted system perspective on patient safety problems and solutions was pointed out (Alves, Carvalho and Albuquerque, 2019; Ridelberg, Roback and Nilsen, 2014). According to (Flott et al., 2019; Lu et al., 2022), patient safety is a multifactorial concept, driven by a complicated array of technical, human and system factors. Several studies have identified barriers influencing the implementation of PSIs reporting in healthcare settings including specialised care units (SCUs). These include underreporting, punitive culture, lack of standardized reporting system, staff

shortages, lack of safety culture, poor processing of incident reports, inadequate engagement of healthcare professionals, limited institutional support of incident reporting systems including inadequate usage of evolving health information technology (Archer, Hull, Soukup, Mayer, Athanasiou, Sevdalis and Darzi, 2017; Gqaleni and Mkhize, 2023a; Gqaleni and Bhengu, 2018; Khoshakhlagh, Khatooni, Akbarzadeh, Yazdanirad and Sheidaei, 2019; Martos Algarra, 2022a; Rashed and Hamdan, 2019; Yali and Nzala, 2022).

In middle and low-income countries (LMICs), almost one-third of patients who suffered PSIs died and four out of five of those incidences were preventable (WHO, 2015). Moreover, 134 million PSIs occur in hospitals due to unsafe care, resulting in 2.6 million deaths, each year (National Academies of Sciences and Medicine, 2018). Also, it is estimated that 75% of PSIs occur in the LMIC contexts, during hospital care and 10-15% of total deaths are as a result of poor quality care (Flott et al., 2019). In South Africa, a study conducted in KwaZulu-Natal reveals a high percentage of serious PSIs (47%) indicating the poor implementation of PSI reporting guidelines and lack of improvement strategies (Gqaleni and Bhengu, 2020). While incidents reporting is considered a cornerstone to patient safety culture and quality improvement in healthcare (Dhamanti, Leggat, Barraclough and Tjahjono, 2019; ELMeneza and AbuShady, 2020), under-reporting in hospitals worldwide is still a challenge(Gong, 2022; Yali and Nzala, 2022; Yusuf and Irwan, 2021).

In South Africa, the implementation of the Patient Safety Incident Reporting and Learning Systems guidelines, as recommended by KwaZulu-Natal Department of Health (KZN DoH), in line with National Department of Health (NDoH 2017) has provided no clear evidence of the reduction of PSIs and if these guidelines are adequately implemented in SCUs. Gqaleni and Mkhize (2023a), affirmed that healthcare professionals' perception of knowledge of PSI reporting and learning guidelines was good, however, the perception of

the implementation was poor. This study further recommended a revised implementation to improve the quality and safety of healthcare in SCUs. For SCUs, to heighten the positive performance and practices of PSIs reporting and learning guidelines, the views of healthcare professionals needed to be unearthed. Therefore, the aim of the study was to explore and describe the views of the senior healthcare professionals regarding the implementation of the Patient Safety Incident reporting and learning guidelines in specialised care units in KwaZulu- Natal.

Materials and Methods

Study design and setting

A descriptive, explorative qualitative approach was used to collect qualitative data from senior healthcare professionals working in SCUs. The study was conducted in SCUs of three purposely selected public hospitals in two districts of KwaZulu-Natal. Two hospitals (A and C), situated in the eThekwini district, provide both secondary and tertiary services, and the third tertiary hospital (B) is in the uMgungundlovu district. The settings consisted of specialised care units that included both Critical Care Units (CCUs), where the most critically ill patients were admitted as well as High Care Units, where the recovering critically ill patients were transferred but still needed specialised care.

Population, recruitment and sampling

Sampling is a process of selecting a portion of the population to represent the entire population, so that inferences about the population can be made (Burns et al., 2015). The target population for this study consisted of senior healthcare professionals, who were involved in the implementation of PSI reporting and learning guidelines in the SCUs. Therefore, the participants that were purposely selected were had expertise and experience in SCUs environments and had vast experience in the handling of PSI reporting and learning

guidelines. The focus group discussions sample comprised of Operational Nurse Managers (OMs). Individual interviews included Assisting Nurse Managers (ANMs), Monitoring, and Evaluation Managers (M&E), and Consultant Medical doctors (CMD).

Inclusion and Exclusion criteria

Operational Nurse Managers, Assistant Nurse Managers, Consultants, Monitoring and Evaluating Managers, who had more than ten years of SCU experience were included in the study. Participants who did not work in these SCUs and those who were not willing to participate in the study were excluded.

Table 1: Inclusion and Exclusion criteria

Inclusion	**Exclusion**
Participants who were Operational Nurse Managers	Participants who were not Operational Nurse Managers
Participants who were Assistant Nurse Managers	Participants who were not Assistant Nurse Managers
Participants who were Consultant Medical doctors	Participants who were not Consultant Medical doctors
Participants who were Monitoring & Evaluation Managers	Participants who were not Monitoring & Evaluation Managers
Working experience of more than 10 years in specialised care units	Participants who did not work in these units and had less than 10 years of experience.
Willingness to participate	Not willing to participate

Recruitment strategy

Appointments were made by the researcher with the institutions' Senior Nurse Managers and Operational Nurse Managers and all the participants prior to data collection. The researcher had a briefing session with the participants prior to data collection and explained the aim of the study and its importance to research. Participants were informed that they were not forced to participate and that they had a right to withdraw from the study even if they had already given consent, without any negative consequences, thus ensuring voluntary participation.

Data collection process

This study was conducted during COVID-19 and the researcher followed the protocols. The data were collected virtually to ensure social distancing, which was reinforced in the boardrooms, including the use of personal protective equipment by the participants. In this study, Skype for individual interviews was used and Zoom was used for the focus group discussions, to collect qualitative data. To ensure privacy, for example, for Skype, participants needed to sign into the interview individually, which prevented unwanted intruders, and for Zoom meetings, passwords were used and the waiting room, which allowed the host researcher to control who entered the video conference. Data was collected over a period of 3 months, from August to October 2021. Information guidelines guided the focus group discussions and individual interviews, which consisted of topics and probing questions to elicit more detailed information from the participants. The researcher prepared one essential question with a list of probing open-ended questions, although the participants were encouraged to speak freely about the topic, to obtain all the information required.

Focus groups discussions, which consisted of Operational Nurse Managers, working in the selected settings, formed homogeneous participants. These participants were also at the

forefront of implementing the PSI reporting and learning guidelines. Individual interviews consisted of senior participants which were heterogenous, namely, Assistant Nurse Managers, Monitoring and Evaluation Managers, and Consultant Medical Doctors to solicit more in-depth information. The probing question were influenced by the participants' responses and the interviewer sought clarity to minimize bias and subjectivity. Data were collected until saturation was reached, that is, no new information emerged. Interviews were conducted and lasted between 45 minutes to 60 minutes, and this allowed the participants to freely elaborate on their opinions on the phenomenon. Participants gave consent to record all the interviews and the researcher transcribed the data verbatim.

Ethical considerations

The University of KwaZulu-Natal's Human Science Research Ethics Committee (HSSREC/00001651/2020), and the Directorate: Health Research and Knowledge Management Unit (NHRD Ref: Kz_202010_0240), granted ethical clearance and permission to conduct the study before data collection. Gatekeepers' permission was also obtained from the Chief Executive Officers, Heads of Department and Senior Nurse Managers. The researcher had a briefing session with the participants, prior to data collection, explaining the aim of the study and its importance to research. Verbal consent to participate and to the recording of the interview voices were obtained from the participants prior to data collection. Furthermore, a record of verbal permission is on the researcher's recording device. This was further recorded on the interview guides, consisting of the participants' site code, date, start, and end of the interview. The participants were informed of their rights to withdraw from the study at any time, without any adverse repercussions. Grove, Burns and Gray (2012) asserted that the researcher must comply with three principles as stated by the Belmont report, namely, the principle of beneficence, the principle

of human dignity, and justice. The participants were informed of their rights to withdraw from the study at any time, without any negative repercussions.

Data analysis

Content data analysis was conducted using Tesch's method of the analysis process (Burns et al., 2015). Transcribed interviews were read several times and descriptive words were identified for the formulation of thematic statements and concepts that created meaning. Notes were made with ideas that came to mind. Each interview was read through and the underlying meaning behind the scripts was determined. Notes were made on transcripts during the reading process. A list of concepts was made, and similar topics were clustered together. These clustered topics were then be mapped as major topics. Raw data comprising transcripts were reviewed again in the light of identified topics. The text was coded and organised. Descriptive words were identified in the text and used to describe themes or topics. Related topics were grouped together. A final decision regarding categories was made. Preliminary analysis was made and excerpts from the data supporting the identified categories and themes was coded and recoded. A reflective journal was used to form themes and sub-themes.

Trustworthiness

During the research process, the researcher applied four criteria, to determine trustworthiness, namely, credibility, dependability, confirmability and transferability (Shenton, 2004).

Credibility. According to Polit and Beck (2017), credibility refers to the confidence in the truth of the data and its interpretations, that is, the data must reveal what it is searching for. The researcher ensured that this study was conducted in an authentic manner and the

researcher had a prolonged engagement with the participants, during the data collection process, which assisted in gaining an in-depth understating of the phenomena under study.

Dependability. In this study the researcher provided detailed information of the research process, findings and recommendations, so that the other prospective researchers could replicate the study to their context. According to Polit and Beck (2017), findings of an inquiry must be able to be repeated and replicated with the same participants in the same context.

Confirmability. Confirmability refers to objectivity, that is, the potential for congruence between two or more independent people about data's accuracy, relevance, or meaning (Polit and Beck, 2017). In this study, the research report conveyed participants' experiences and not the perspectives of the researcher. Themes generated during data collection reflected the tone of the participants.

Transferability. Transferability refers to the extent to which findings can be generalized and applied in other settings or groups (Polit and Beck, 2017). In this study, the researcher was responsible for providing a detailed account of the research process, findings and recommendations, so that the other prospective researchers could evaluate the applicability to their context.

Results

Introduction

Data were collected from the purposively selected participants until data saturation was reached. Data analysis was conducted manually using the eight steps of Tesch's method of analysis. The first section provides the participants' demographics, as illustrated in Table 2 and the second section outlines the findings of the study, thoughts and feelings expressed by

the participants during the in-depth interviews. The names of the participating hospitals and the participants were not divulged to protect their identities.

Table 2: Demographics of participants

Hospital	Gender	Job level
Focus group discussions		
Hospital A	7 Females; 3 Males	Operational managers
Hospital B	8 Females; 2Males	Operational managers
Hospitals C	6 Females; 2Males	Operational managers
Individual interviews		
Hospital A	1 Female	Assistant Nurse Managers
Hospital B	1 Male	Assistant Nurse Managers
Hospitals C	1 Female	Assistant Nurse Managers
Hospital A	1Female; 2 Males	Consultant Medical doctor
Hospital B	1 Female; 2 Males	Consultant Medical doctor
Hospitals C	1 Male	Consultant Medical doctor
Hospital A	1 Female	Monitoring and evaluation Manager
Hospital B	1 Male	Monitoring and evaluation Manager
Hospitals C	1 Female	Monitoring and evaluation Manager

Note: **FGD-** Focus group discussion

OM- Operational Nurse Manager

ANM-Assistant Nurse Manager

M&E- Monitoring and Evaluation managers

CMD- Consultant Medical doctor

Themes and subthemes

The views of some of the participants are presented as direct quotations to support the identified themes and sub-themes.

Theme 1: Ineffective reporting system affecting communication of PSI guidelines

Communication factors are associated with the communication of PSI reporting and learning guidelines as perceived by the healthcare professionals. Participants perceived communication to be ineffective and not user-friendly to implement PSI reporting and

learning guidelines. Most participants stated that the actual structure of the reporting system makes it difficult for the healthcare professionals to effectively implement the guidelines.

Subtheme 1.1: Tedious, long and not simple

The participants indicated that the reporting process was long and intense, tedious and laborious, hence other PSIs were not reported.

> *"It is a long form…the new form is very intense, apart from the report that you're going to write…. not simple at all."* ***(ANM1, Hospital A, Female, from Individual interview)***

> *"The time that it takes to fill in the PSI forms and then the possibility of further meetings down the line, it is essentially inconvenience from the interview process, a very laborious, inconvenient process."* ***(CMD1, Hospital C, Male, from Individual interview)***

Subtheme 1.2: Unclear PSI guidelines and policies

The healthcare professionals also stated that the guidelines were not clear, confusing and not standardised. This was considered a barrier to effective implementation of the guidelines.

> *"The guidelines are not particularly clearer on when an adverse event can be considered as just expected as a consequence of the disease for a particular patient versus a true PSI. Our government is using their own terminology which is unfortunately not based on international standards."* ***(CMD2, Hospital A, Male, from Individual interview)***

Some participants verbalised that there was a mismatch of the guidelines with the actual

work environment.

"Action plans and policies are nice, and they are there, it's something that is there and are nice to read, but when it comes to practicality of it…… guidelines may look good on paper, but they are not effectively implemented." ***(OM2, Hospital A, Female, from FGD)***

Subtheme 1.3: Lack of consultation at the forefront level

Healthcare professionals also reported a lack of consultation at the forefront level and nonclinical involvement during the development phase of PSI reporting and learning guidelines.

"I was never consulted… I just received a directive from the DOH and my concern is that the people that develop these Guidelines are not clinical, they have no understanding of what is happening on the ground, they have no medical training." ***(CMD2, Hospital A, Male, from Individual interview)***

"I didn't have any input, maybe from other managers. I just received a new form from the province informing us what is required." ***(ANM2, Hospital A, Male, from Individual interview)***

Subtheme 1.4: Inadequate feedback to staff and family

Inadequate feedback to staff and family was also identified by the participants as barrier to the implementation of PSI reporting and learning guidelines. Lack of feedback was more from the senior management and was more of a redress meeting. Partial family involvement if a PSI has occurred, near misses are usually overlooked because it is perceived as harm that did not reach the patient.

"So, people might say okay, what do we need to disclose that to the family because it was a near miss. It wasn't a miss. The patient didn't suffer any harm." ***(CMD1, Hospital C, Male, from Individual interview)***

"I've never had feedback. And I've done multiple incident reports reporting over the years, never, ever, ever, ever had…. you would expect documents and feedback. You don't ever get any feedback from them. It is a waste of time because you get nothing back. Then the next time something happens you go…. I'm not going to do it again because what was the point?" ***(CMD1, Hospital B, Female, from Individual interview)***

Theme 2: Inadequate Institutional and management for the healthcare professionals

Most participants expressed a lack of support, especially from the senior management, a disjuncture of the leadership from the challenges experienced by the frontline workers, resulting in poor of teamwork.

Subtheme 2.1: Punitive culture

Most participants reported that there is a punitive culture associated with the implementation of PSI reporting and learning guidelines. This was characterised by fear of the negative repercussions when healthcare professionals attempt to comply, therefore this led to underreporting of most PSIs.

"Sometimes this leads to disciplinary measures. Sometimes you say, I'm going to give you a warning. And the PN will complain that I committed myself by reporting, and now I must face the negative consequences. They even threaten to consult the unions." ***(ANM1, Hospital B, Male, from Individual interview)***

*"Also, people have a view that it is punitive, in a way... so, I have seen different departments threaten each other with PSIs… eh... so if you call something a PSI there is still very much a mindset that this is an accusation... and it is even been recognised between departments to sort of thresh out their politics……. been used between departments as a sort as a blame. Even various people are using it almost punitively…aggressively." (**CMD1, Hospital C, Male, from Individual interview)***

Subtheme 2.2: A hostile environment

Participants described environment as hostile, characterized by hierarchical structure and red tape resulting reluctance in the implementation of PSI guidelines by the healthcare professionals.

*"Registered nurses that fear, they don't want to report that that's why they are under-reporting, because that fear you don't have support. It's always like a threatening environment. All they've learned is that they must keep quiet. And what if I get fired?" **(CMD3, Hospital A, Female, from Individual interview)***

*"To me it's like your call to the court where you're gonna sit and when they discuss this incident you feel that I am... I am on the wrong…" **(OM1, Hospital B, Female, from FGD)***

Subtheme: 2.3 Lack of management support to frontline healthcare workers

In addition, participants expressed a lack of guidance when trying to implement reporting and learning guidelines. Participants verbalised that an enabling environment is crucial, therefore inadequate organisational resources, patient safety committees that are not fully functional, lack of implementation strategies to guide healthcare professionals and learning opportunities were regarded as barriers.

"There is lack of support. Because... we are OMs, we work with staff, and we've got challenges. You need somebody to listen to you, if you say this and this is happening. Instead, you're blamed.... you are criticised... you... you… you really feel bad." ***(OM2, Hospital B, Female, from FGD***

"No one's learning from the previous mistakes and there's always another excuse. You just hit your head against the wall." ***(CMD1, Hospital B, Female, from Individual interview)***

Participants also verbalised that patient safety committees were not existing, and those that were existing were at a development stage.

"But from what I hear they just getting it up and running and getting some processes in order. I think the first steps are happening there… I view it as the start of the process. but I don't know if we've quite got the systems at the unit level… we don't have the unit SOP or patient safety committees on how to deal with a PSI... it is more of an ad-hoc base …" ***(CMD2, Hospital A, Female, from Individual interview)***

"I'm not aware of any Patient Safety committee that exists. I don't even know what happens what the process is after I've handed the form as far as it goes from the ward to the ANM… that's the point of the SOP. I don't know what happens after that, which is bad as well, because we need to know the entire process… it's all… it's all very haphazard". ***(CMD2, Hospital C, Male, from Individual interview)***

2.4.1 Lack of teamwork

Participants reiterated that there should be a learning experience during the implementation of reporting and learning guidelines, not to blame someone. Participants reported that a teamwork approach between departments and collaboration with other

institutions was lacking.

"We rely on nurses on the reporting of the PSI for formal reporting as such, because of a busy environment." ***(CMD2, Hospital A, Male, from Individual interview).***

"Although we morbidity and mortality meetings where we discuss the PSIs as staff, there is still that lack with collaboration with other institutions, we hardly meet…I don't remember us meeting….so there is a gap there." ***(ANM1, Hospital B, Male, from Individual interview)***

Theme 3: Insufficient education and training of healthcare professionals

Participants reported that education and training associated with implementation of PSI reporting and learning guidelines, was multifaceted. The education and training challenges included the actual formal education of registered nurses, lack of training in specialisation of critical care, inadequate in-service training and workshops, to empower the participants on the guidelines. Furthermore, The PSI guidelines were not made freely available and common knowledge to all the disciplines of departments.

Subtheme 3.1: Lack of formal training of healthcare professionals

Participants confirmed that some of the nurses that were allocated to the specialised units did not have the formal training and the skill that is required in this environment.

"In most cases we were not even sure of their training course, as they were training in these schools …mushrooming everywhere, and now come in as ENAs and passed, they now want to be PNs, but still behaving like ENs…running the ward and there is no senior sister. You face these challenges, as they were the ENs recently and that affects

the quality of nurses we employ." ***(ANM2, Hospital A, Male, from Individual interview)***

"People don't know how to identify PSIs are? How do you report…There's a total lack of education here...? So, you can't blame the individuals if they weren't educated in this..... and so I do think there's a major problem." ***(CMD 2, Hospital A, Female, from Individual interview***

Subtheme 3.2: Lack of knowledge on how to construct the report properly

Furthermore, the participants indicated that the reporting system is not user-friendly with terminology that was not easy to understand. Although the participants knew about the classification of PSIs, the reporting process was complex.

"I think the cause is a lack of knowledge of how to write a PSI... Lack of knowledge on how to construct properly... how to report properly, the whole incident... it has to be concise ...it has to be to the point, so if it is not written properly, I send it back…so it's more time needed." ***(ANM1, Hospital A, Female, from Individual interview)***

"Then I mean, I'll say to the doctors you must fill out an incident reporting form and they'll go ...What?... that nobody knows what it is. What to do with it." ***CMD1, Hospital A, Male, from Individual interview)***

Subtheme 3.3: Lack of formal training, in-house training, and continued professional development programme

Participants further indicated that there were insufficient continued professional development programmes to empower the healthcare professionals to construct the report

properly. Participants expected to have a common knowledge for all healthcare professionals and to be familiar with the guidelines.

"The perception that the staff is not adequately trained to identify the PSIs and to disclose to patients and relatives." ***(ANM2, Hospital A, Male, from Individual interview)***

"I think…. even the more senior clinician struggled to decide what is the PSI and what isn't a PSI…ah... so, do you do label something a PSI" ***(CMD1, Hospital C, Male, from Individual interview)***

Subtheme 3.4: Inadequate training of healthcare professionals on PSIs

Some participants reported that some of the items that are in the PSI reporting and learning guidelines were well understood. They explained that some of the PSIs were expected as normal process of the underlying illness.

"Sometimes some of the items that are been included in those PSIs are not particularly appropriate to the ICU, because its normal to follow the normal pathology in ICU." ***(CMD2, Hospital B, Male, from Individual interview)***

Theme 4: Poor human resources affecting the implementation of PSI guidelines

Most participants confirmed that inadequate competent, knowledgeable and experienced was a huge barrier to effective implementation of PSI reporting and learning guidelines. The inadequate staff allocation was exacerbated during COVID-19 pandemic.

4.1 Subtheme: Shortage of staff

Specialised units are busy by nature, and normally a ratio of 1:1, that is comprised of adequate skills mix. Participants stated that it was impossible to achieve this ratio, therefore affecting the implementation of guidelines and compromised quality patient care.

"The... conditions that we are working in are not allowing us to make sure can uhhh…. we try and ensure, but there isn't adequate staff that staff is adequate, I mean people who are who work here every day, and who knows what is happening here and not people that I will be orientating. But the situation is that instead of having staff in this ward to work, according to the guidelines, or the policy we still get people from all over who will come here not knowing exactly what to do. Shortage itself is a big issue (emphatically)You get somebody that has just qualified as PN, she has never worked in a ward, she's just new...new PN She hasn't seen a ventilator she's seeing the ventilator for the first time. She's seeing the monitor for the first time." ***(OM5, Hospital B, Female, from FGD)***

Subtheme 4.2: Inadequate competent a skill mix

Participants also indicated that the staff that was allocated to their departments did not have specialised qualifications in SCU environment.

"You need staff that will understand what is happening…. we don't even have time to orientate them. It's just orientation... You need staff that will understand what is happening…. we don't even have time to orientate them. It's just orientation." ***(OM5, Hospital B, Female, from FGD)***

Subtheme 4.3: High staff turnover and lack of staff retention

Moreover, some participants expressed their frustration on high staff turnover and lack of staff retention.

"There is also an increase in the number of retiring staff and the management is not recruiting for the vacant posts… they are not doing anything new. The staffing challenge is there. It takes too long to replace staff and you must motivate why you need more staff. Although there may be trained and experienced ICU nurses, they are not enough for the number of days and you find yourself not achieving that ratio of 1:" ***(ANM3, Hospital A, Female, Individual interview)***

Subtheme 4.4: Busy environment

Participants indicated that they work in a very environment, looking after vulnerable critically ill patients that require individual attention.

"It is very difficult for staff, especially in this busy critical care where there are staff shortages… to now follow up … because somebody will be having a patient…remember here the ratio here is 1:1 or 1:2." ***(ANM3, Hospital A, Female, Individual interview)***

"We work with sort of skeleton staff. Every day you wonder how people are going to cope with more admissions." ***(OM6, Hospital B, Female, from FGD)***

Discussion

This study sought to explore the views of the healthcare professionals who were at senior level, regarding the barriers and facilitators to implementation PSI reporting and learning guidelines in SCUs. Participants highlighted that although there are stipulated guidelines, they are not effectively executed by the healthcare professionals. They reflected more barriers than facilitators which could be perceived as hindrance to the implementation of these guidelines. All participants acknowledged the importance of the revised improvement strategies to facilitate the rigorous implementation and improvement of quality patient care was essential.

Theme 1: Ineffective reporting system affecting communication of PSI guidelines

In this study, the participants indicated that the difficulty was more on the process of communication of the PSI reporting and learning guidelines. This was at multi-level, amongst the individuals, departments, senior management and the way the whole system is structured. Also, an organisational patient safety culture must be cultivated to create an atmosphere that is conducive to communication of these guidelines. Barriers that were mostly mentioned by the participants included a laborious inconveniencing process, unclear guidelines and policies, not simple and user-friendly, lack of consultation at the coalface and lack of feedback (Alves et al., 2019; Ridelberg et al., 2014; Yali and Nzala, 2022). Several studies confirm that clear, standardised effective communication is key to effective implementation by the healthcare professionals. Although participants in Hospital B demonstrated a positive attitude to the implementation of PSI reporting and learning guidelines, as they stated that they were partially involved during the consultative process, this was not the case in hospital A and C, as they indicated that they were never consulted. The government plays a critical role in monitoring and evaluation of the implemented PSI guidelines, therefore the lack of involvement of the Department of Health in managing incident reporting means that they are not aware of patient safety issues in the hospitals in their regions (Dhamanti, Leggat, Barraclough and Liao, 2021).

Lack of feedback to the staff and patients and uncertainty about what to report does not encourage the healthcare professionals to use the reporting system effectively, hence the participants indicated that there was a lot of undocumented PSIs (Alves et al., 2019; Flott et al., 2019; Gqaleni and Bhengu, 2018). Participants also indicated that there is no learning that takes place, where healthcare professionals can use the PSI as a learning opportunity to prevent recurrences, as they learn from their mistakes. It is important that healthcare professionals do not rely on reporting incidents only, as reports often do not lead to positive

change (Alves et al., 2019). Participants also stated that the feedback to patients and families is partial, only if it is a major event. Martos Algarra (2022b) affirms that patients become first victims and the professionals involved turn into second victims and all of them need adequate support.

Theme 2: Inadequate Institutional and management for the healthcare professionals

Investing in a patient safety culture can be viewed as building an organizational resource, which is beneficial for both , improving the care quality and protecting staff well-being (Lu et al., 2022). There is a need for more effective transformational leadership to facilitate a culture of patient safety incident reporting and effective implementation of PSI reporting and learning guidelines (Yusuf and Irwan, 2021). In this study, participants explained an atmosphere that is hostile, punitive and lack of support of the frontline healthcare workers from the management (Alves et al., 2019; Yusuf and Irwan, 2021). Fear of negative repercussions and litigation were the main barriers of implementation of PSI reporting and learning guidelines (Ontario, 2017). According to Lee, Wu, Weng, Huang, Hsieh and Huang (2016); Ontario (2017), a non-punitive, confidential, independent, expert analysis, timely, system-oriented, and responsive was suggested. A hospital should particularly pay more attention to the confidentiality of case data in the system when establishing an incident reporting system, to avoid disputes and enhance reporting intention. Lack of teamwork and collaboration with other departments and institutions were also mentioned by the participants. A similar study highlighted the lack of collaboration between physicians and other healthcare personnel presented as barriers to improved patient safety due to perceived hierarchical differences (Ridelberg et al., 2014). Participants also stated that, although they had risk management meetings to discuss PSIs, there was a lack of guidance in the form of patient safety committees, implementation strategies and standard operational procedures, that was of common knowledge. A similar study highlighted that the availability and use of

written protocols that provide structure for their work, such as guidelines and standardized care plans, positively influence patient safety (Ridelberg et al., 2014). According to Dhamanti et al. (2021), the lack of commitment to ,and priority of patient safety, the complexity of the bureaucratic structure, and a lack of systematic partnership and collaboration are problems that need to be addressed by systematic improvement.

Theme 3: Insufficient education and training of healthcare professionals

Insufficient education and training, that was expressed by participants, was multifaceted. Participants mentioned poorly qualified healthcare professionals with no skills of working in a specialised care environment. Insufficient skills could act as a barrier to enhanced patient safety. Being a newly graduated nurse was mentioned as a barrier, due to a general lack of experience and the need for learning many new aspects of work (Ridelberg et al., 2014). Also, there was a lack of knowledge on how to identify PSIs, how to construct a written report and adequate in-service training. A similar study confirms that the lack of knowledge about incident reporting systems, and lack of understanding about what constitutes an error was reported as common barriers (Ontario, 2017). The government plays a critical role in ensuring patient safety in healthcare services as they are actively involved in designing the guidelines and development of policies. Therefore, either the government or medical institute managers should collect and analyse the information in the system, reduce the reoccurrence of medical errors through education and training and improvement activities, and enhance the patient safety culture of the hospital (Dhamanti et al., 2021).

Theme 4: Poor Human resources affecting the implementation of PSI guidelines

Participants reported the lack of human resources was not only the insufficient number of the staff allocated to the specialised care units, but the skill mix was also lacking. The

staff shortage was due to increased numbers of the staff at a retirement age, staff resigning for better employment, remuneration and recruitment by other countries for competent staff. This brain drain could be associated with a burnout syndrome, therefore poor implementation of PSI reporting and learning guidelines. The specialised care units are characterised by a busy, stressful environment, with increase in work overload and working with skeleton staff that leads to burnout (Mossburg and Himmelfarb, 2021). Shortage of staff and increased workload was associated with poor implementation of the PSI reporting guidelines (Dhamanti et al., 2021; Lu et al., 2022; Martos Algarra, 2022a). Mossburg and Himmelfarb (2021), affirm that healthcare managers can consider a simpler measure of this resource in ensuring adequate staffing levels across all departments of the institution.

Strengths and limitations of the study

This study provided thought provoking findings as in-depth information was collected from the focus group discussions and individual interviews with participants who were at the managerial positions and were actively involved in the implementation of the PSI reporting and learning guidelines. In addition, the purposive sample from the focus group was homogenous, whereas the individual interviews were heterogenous, which provided the rich array of experiences from various healthcare professionals. To the researchers' knowledge this is the first study to explore the barriers to implementation of PSI reporting and learning guidelines by the healthcare professionals in South African SCUs. Furthermore, the study findings may inform the policy makers and healthcare facilities to revise the PSI reporting guidelines, to be more relevant to the South African context and devise better implementation strategies, to improve patient safety care. In addition, the findings from this study have identified areas that need improvement in patient's safety, therefore its dissemination contributes to the cultivation of patient safety culture

worldwide. The study participants were limited to three major government hospitals in KwaZulu-Natal; however, the sample was representative enough to address the research question. Also, most of the literature that supported this study is from international sources indicating a paucity of South African literature in this topic.

Recommendations

This study was conducted in one province; therefore, it is recommended that further research can be conducted in other provinces. The study analysis and results can be used by national and global stakeholders to improve the implementation of PSI reporting and learning guidelines, as per the WHO recommendations. For rigorous implementation in South African SCUs, the study recommends revised PSI reporting and learning guidelines that consist of standardised, simple -user-friendly terminology as well as a better implementation strategy to guide the healthcare professionals to apply the guidelines effectively. These guidelines need to be designed in consultation with the frontline healthcare professionals and the policymakers. Continuous professional development programmes may play an important role in facilitating the implementation process. Education on PSIs reporting and learning guidelines should be incorporated early in the curriculum of healthcare professionals, so that it becomes common knowledge for all.

Conclusion

This study confirmed that PSI reporting and learning guidelines are still not effectively implemented in the SCUs and the barriers of implementation were highlighted. There is a need to implement these guidelines globally. The study revealed that ineffective reporting system, lack of institutional and managerial support, insufficient education and training of healthcare professionals and poor human resources were the main barriers to effective implementation of PSI and learning guidelines. To effectively improve patient safety, this

study seeks to strengthen collaboration among the healthcare professionals, organisations, within the African continent and globally.

Supporting information

S1 Appendix: Interview guide for the focus group discussion

S2 Appendix: Individual Interview guide

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Chapter 5: The Patient Safety Incident Implementation Strategy

5.1 Introduction

This chapter describes the developed PSI implementation strategy that should be provided to all critically ill patients in SCUs, when needed. A PSI implementation strategy emerged from the data collected for this study to improve outcomes for critically ill patients by means that are achievable in SCUs. Continuous improvement strategies aligned with the WHO Reporting and Learning guidelines and recommendations must be developed and effectively implemented to curb preventable PSIs. According to Ontario (2017), the incident reporting and learning system's main aim is to collate and analyse PSI data, with the aim of implementing systemic solutions to improve patient safety. (Brunsveld-Reinders, Arbous, De Vos and De Jonge, 2016) contend that if more attention is to be given to analysing incidents and feedback, administrative report systems are the preferred instruments for practice change and contribute to improving patient safety and quality of care. However, such a conclusion cannot claim whether the incident reporting system has been truly effective in improving safety practice and patient outcomes (Goh, Tan, Chang, Lee and Zhang, 2021).

In South Africa, the first National Guidelines for PSIRL was implemented on 1 April 2018 and revised in 2022 (WHO, 2022). More specifically, the classification systems were revised to enable meaningful analysis of the reported incidents. However, there are still no clear strategies to assist healthcare professionals in guiding the effective implementation at the grassroots level. Hence, in the first phase of this study, a scoping review was conducted to map the evidence of the PSI reporting guidelines implemented by healthcare professionals in SCUs. The review revealed that the implementation of reporting of PSIs in SCUs commenced around 2002; however, the frequency of yearly publications remained very low. Two objectives informed the implementation of the PSI implementation strategy.

Objective 2 a: To assess healthcare professionals' perceptions on the implementation of the PSIRL Guidelines in SCUs, in KwaZulu-Natal.

Objective 2b: To explore facilitators and barriers in the implementation of the PSIRL Guidelines in SCUs by the healthcare professionals.

The second phase of this study involved the conduction of quantitative research with the healthcare professionals who are at the forefront of implementing the PSIRL guidelines. The study results revealed that the respondents had good perceptions of knowledge of the PSIRL Guidelines; however, the perception of the implementation was poor. The study recommended a revised implementation strategy and periodic in-service training for healthcare professionals to foster and facilitate effective adherence to the PSIRL Guidelines. Furthermore, qualitative research was conducted to unearth the voices of the healthcare professionals. This study confirmed that the PSIRL Guidelines are still not successfully implemented in the SCUs and the barriers to implementation were highlighted. This study further confirmed the need for revised PSIRL Guidelines, designed in consultation with the frontline healthcare professionals. These must consist of standardised, simple -user-friendly reporting processes and better implementation strategies to guide the healthcare professionals. Based on these research results, a PSI implementation strategy was developed.

5.2 Scope of the strategy

The strategy's scope will be applied in a specific setting, a specialised critical care unit. Overall, it is new in its type and offers a unique and original contribution to the researcher's discipline.

5.3 Purpose of the strategy

The main aim of this strategy is to employ a novel and innovative alternative solution to implement the PSIRL Guidelines. PSI implementation strategies help healthcare professionals to focus on their strengths and potential in maintaining good practice standards and reducing risk factors. This strategy is, therefore, specific to improving health outcomes in SCUs. It aims at enhancing the patient's safety in the positive practice environment, thereby ensuring that the following objectives are achieved:

- To address the context and setting of a change effort, to overcome barriers to implementation, and to harness facilitators to implementation.
- To share insights and generalisable knowledge regarding the standardised implementation process that will easily guide the healthcare professionals to effectively implement the PSIRL Guidelines

- To develop a reliable strategy for improving PSI guidelines implementation processes and outcomes and facilitate widespread adoption of the developed implementation strategy.

5.4 Assumptions of the strategy

(Chinn, Kramer and Sitzman, 2021) defined assumptions as the basic givens or accepted truths fundamental to theoretical reasoning. They are a structural component of the theory that is taken for granted or thought to be true without systematically generated empiric evidence and assumed to be true within the strategy because they are reasonable. Based on this assumption Kurt Lewin's (1947) three step model of unfreeze-change- refreeze is adopted (Lewin, 1947) (Refer to Chapter 1 paragraph 1.3.3.2).

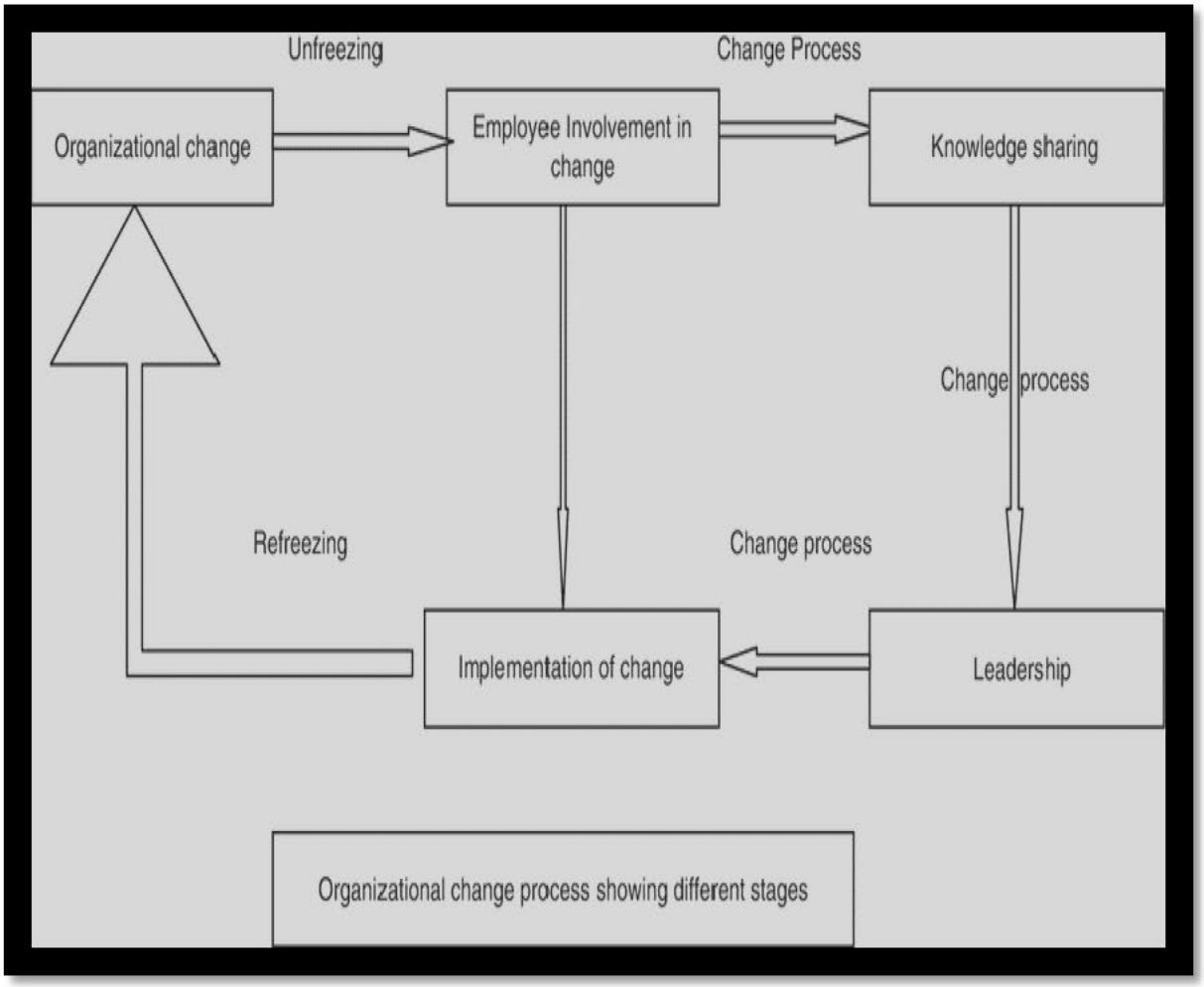

Figure 5: Kurt Lewin's model of organisational change (Lewin, 1947) shows the Kurt Lewin's three steps model: Note: The arrows show different stages of Kurt Lewin's three steps model and not the relationship between variables

5.5 Context of the strategies

(Chinn et al., 2021) emphasise that for the models or strategies to be useful in practice, they must be placed within a context. The context of this strategy is the concept of patient safety and a positive practice environment to improve health outcomes. The implementation strategy incorporates the WHO-recommended action steps for the effective management of PSIs.

5.6 Convergent parallel mixed method

A convergent parallel mixed methods or embedded strategy was used to collect quantitative and qualitative data. According to Creswell and Creswell (2018), convergence means that the researcher collects and converges or integrates different kinds of data bearing on the same phenomenon. The purpose of converging is simultaneously to collect both quantitative and qualitative data, merge the data, and use the results to understand the research problem better. The data collected through quantitative and qualitative research should be able to address the research objectives.

Quantitative data was collected via online surveys, using a descriptive cross-sectional design. The objective was to assess the healthcare professionals' perceptions on the implementation of the PSIRL Guidelines in specialised care units, in KZN. This study revealed that the respondents demonstrated good perceptions of knowledge of the PSIRL Guidelines, however, the perception of the implementation was poor. Therefore, a revised implementation strategy coupled with periodic in-service training for healthcare professionals is recommended, to foster and facilitate effective adherence to the PSIRL Guidelines.

Qualitative data was collected through focus groups discussions and individual interviews to gather in-depth data and to capture certain aspects of the phenomenon. The aim was to explore the facilitators and barriers in the implementation of the PSI reporting guidelines in SCUs by the healthcare professionals. This study findings confirmed that the PSIRL Guidelines are still not successfully implemented in the SCUs and the barriers to implementation were highlighted. For rigorous implementation in South Africa, the study recommended revision of the PSIRL Guidelines, designed in consultation with the frontline healthcare professionals. These must consist of standardised, simple -user-friendly reporting

process as well as a better implementation strategy to guide the healthcare professionals. The themes that emerged include:

- Inadequate Institutional and management support for the healthcare professionals
- Ineffective communication of PSI guideline's affecting the reporting system
- Poor human resources affecting the implementation of PSI guidelines
- Insufficient education and training of healthcare professionals

Therefore, the numeric trends from quantitative research and the qualitative research was integrated to understand the phenomenon and the research problem better. The researcher integrated the quantitative results from the data that were collected from the healthcare professionals using an online survey and the qualitative results from the focus groups and individual interviews. Based on this research outcome the PSI implementation strategy was developed for implementation in SCUs.

Based on this research objective, the PSI implementation strategy was developed for the SCUs. The strategic focus areas include (1) facilitation of patient safety implementation strategy, (2) comprehensive support for the healthcare professionals, (3) functional reporting system, attraction, (4) recruitment and retention of staff, (5) quality, sustainable education and training, (6) effective monitoring and evaluation, (7) a comprehensive budget and (8) improved adherence to the WHO action plans. The developed strategy was evaluated by the experts who have a wealth of knowledge and expertise in the implementation of the PSIRL Guidelines. Experts' comments and recommendations were incorporated into the final design of the implementation strategy. Evaluation tools were emailed to six experts, three were academic and three clinical. The overall objective of the evaluation by experts was to assess the PSI implementation strategy by highlighting the strengths, examining its weaknesses, and exploring opportunities for improving the implementation strategy. The experts were purposefully selected to evaluate the developed implementation strategy, using the evaluation tool.

For the successful implementation of this strategy into the main health system, some of the barriers need to be resolved. The theoretical model is an organised set of concepts gathered in a rational system by their relevance to a common theme. It is a blueprint that guides the study design, sample selection, data collection strategies and analysis. The model helps to plan and organise the identification of the problem, the review of literature,

the design of interventions, analysing the data, and presenting the findings. Hence Kurt Lewin's (1947) three step model of unfreeze-change- refreeze, which was adopted throughout the study, is recommended for implementation by the institutions.

Table 5: PSI Implementation strategy

Strategies, goals and action plan			
Strategy area 1: Patient Safety Implementation strategy			
Goal 1	**Strategic objective**	**Action plan**	**Drivers**
To foster and facilitate effective implementation of PSI reporting and learning guidelines	To establish a standardised implementation strategy that guides clinical practice in specialised care units	1. Conduct situation analysis at the institutional level, to assess the institutions' readiness to implement change as recommended by the PSI implementation strategy.	**Executive and management teams**
		2. Revise the guidelines in consultation with healthcare professionals by the policymaker.	
		3. Share knowledge on standardised information and consultation throughout the province.	
		4. Facilitate quality assurance process, which often feeds in to quality improvement activities: coherence, organizational buy-in and organizational action	
		5. Cultivated Patient safety culture which must be purposely driven by the Department of Health (DOH).	
		6. Appoint champions for each institution, to focus on the effective implementation of the PSI strategy	
		7. Form strong partnerships between the public and private sector	

Strategy area 2: Comprehensive support for the healthcare professionals			
Goal 2	**Strategic objective**	**Action plan**	**Drivers**
To facilitate adequate Institutional and management support	To enhance safe and constructive communication and support for the healthcare professionals	1. Appoint champions at an institutional level in partnership with DOH, to facilitate the implementation and promotion of patient safety.	**Executive and management teams**
		2. Reinforce and enabling environment, that is non-punitive by the leadership.	
		2. Transformational leadership that eliminates red-tape to facilitate the culture of patient safety.	
		3. Consider including PSI reporting and efforts to reduce risks in personal Employee performance management and development system (EPMDS)	
		4. Support staff to implement the guidelines and incentivised for guideline adherence. Incentivise staff that is active in reporting PSIs	
		4. Create a support structure consisting of the legal framework for PSI disclosure.	
		5. Create a functional Patient safety committee, to facilitate the implementation of PSI guidelines and effective feedback.	
		6.Create a platform to deliver feedback on findings of PSI after investigation has been conducted.	
		7. Reinforce a reporting to be system focus, rather than individuals	
		8. Create forums for learning activities, focusing on patient safety.	

		9. Form strong teams through team building exercises amongst the healthcare professionals and other allied healthcare workers through interdepartmental collaborations that will talk to each other to avoid linear implementation process.	
Strategy area 3: Functional reporting system			
Goal 3	**Strategic objective**	**Action plan**	**Drivers**
To re-engineer effective reporting system affecting communication of PSI guidelines	To revise the existing reporting system to create an environment that will enable the healthcare professionals to report PSIs with ease	1. Create a simple, short, and user-friendly system for both doctors and nurses, electronic and eliminating unnecessary paperwork.	**Management and frontline healthcare professionals**
		2. Ensure anonymity for near misses, insignificant and minor PSIs to promote active reporting.	
		3. Facilitate a non-intimidating environment for moderate to severe PSIs by the patient safety committees in	
		4. Use PSIs as a learning opportunity to prevent future occurrences	
		5. Develop a user-friendly application (APP) for healthcare professionals to report at their convenient time.	
		6. Use simple terminology that is familiar to healthcare professionals, eliminate complicated jargon.	
		7. Active participation by the Healthcare professional front liners in guideline development and its implementation.	
		8.Endorse the guidelines and Patient Safety committees to reach a consensus	
		9. Standardise guidelines with clear steps to be followed during the reporting process, widely disseminated and easily accessible for familiarity and clear guidance.	

		Involve patients and families, to actively participate in decision making of their own healthcare plan and activities	
		10. Use motivational strategies, focusing on audit and feedback through monitoring and evaluation.	
		11. Create functional patient safety committees to play a pivotal role in the implementation process	
Strategy area 4: Attraction, recruitment and retention of staff			
Goal 4	**Strategic objective**	**Action plan**	**Drivers**
To attract qualified human resources	To ensure adequate resources required to effectively implement PSI reporting and learning guidelines	1.Effective recruitment of qualified, competent healthcare professionals, from reputable educational institutions and retention of staff.	**Executive and management teams**
		2.Identify retiring staff early and a proper plan for advertisements of vacant posts and establish mentorship programs for the younger healthcare professionals	
		3. Recruit and Retain staff through attractive renumeration package	
		4. Refurbish the decaying infrastructure. State-of-the-art equipment, that is functional and adequately serviced.	
		5. Allocate fair workload, involvement of non-medical staff for administration, and professional support.	

		6. Develop a professional relationship with institutions of teaching and learning and identity staff that needs training in critical care speciality on a rotational basis.	
		7. Ensure good working conditions, that are attractive and safe for the staff	
		8. Plan education and training to be carefully, taking into consideration the different occupations and qualification of healthcare professionals	
Strategy area 5: Quality, sustainable education and training			
Goal 5	**Strategic objective**	**Action plan**	**Drivers**
Strategy area 5: Effective Monitoring and Evaluation			
Goal 5	**Strategic objective**	**Action plan**	**Drivers**
To strengthen monitoring and evaluation of the PSIs	To establish a robust and reliable monitoring and evaluation process for the healthcare professionals	1.Analyse and classify PSIs with an aim of implementing effective action plans, to prevent re-occurrence	
		2. Effective, clear communication from the district quality assurance to specific institutions in terms of implementation of PSI reporting and learning guidelines	
		3. Promote feedback to the reporters, patients and families is critical, to prevent underreporting	
		4. Play a visible, leading role in PSI awareness campaigns	
		5. Vigilant activities aimed at continuous improvements of the PSI implementation strategy	
		6 Centralise the reporting system to minimise loss of PSIs.	

Strategy area 6: Create a comprehensive budget			
Goal 6	**Strategic objective**	**Action plan**	**Drivers**
Clear deliverables that must be specific, measurable, achievable, realistic, and time-bound	To map an achievable budget that will provide enough funding for the implementation process	1. Form strong partnerships with private sector and collaborate with other funding stakeholders.	**Executive and management teams**
		2. Assess available resources and the gaps at the institutional level	
		3. List the required resources, not limited to human resources only, but also infrastructure, training, equipment, space and research	
		4. Monitor and evaluate the budget spent, budget must be well executed and adhered to	
		5. Allocated a contingency fund for possible risks	
		6. Avoid wasteful expenditure	
		7. Allow flexibility and prioritize the critical and core activities that enhance the implementation of the PSI reporting and learning guidelines.	
Strategy area 7: Improved adherence to WHO Action plans			
Goal 7	**Strategic objective**	**Action plan**	**Drivers**
To maintain WHO Six action steps	To incorporate the existing action steps that must not be compromised	Step 1: Identifying PSIs: PSI is identified and reported.	**Middle management and Frontline healthcare professionals**
		Step 2: Immediate action taken: Immediate actions to mitigate the harmful consequences of the incident.	
		Step 3: Prioritisations: A standardised, objective measure of severity is allocated to each incident	
		Step 4: Notification: PSI data should be recorded and analysed to improve patient safety.	

		Step 5: Investigation: All notified incidents require investigation at an appropriate level for root cause analysis (RCA).	
		Step 6: Classification: PSI are classified according their contributing factors, types and outcome	
		Step 7: Analysis: Data is analysed and recommendations are made for change and these changes are implemented	
		Step 8: Implementation of recommendations: Recommendations from the investigations and reviews should be implemented to ensure the development of better systems to ensure improved practices.	
		Step 9: Learning: The fundamental role of PSI reporting systems is to enhance patient safety by learning from failures of the healthcare system.	
		WHO:2022 Continuous monitoring and evaluation of the improvement outcomes	

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Chapter 6: Synthesis, Limitations, Conclusion and Recommendations

6.1 Introduction

The work reported in this thesis responded to the overall process of analysing the implementation of PSIRL Guidelines in specialised care units, in the selected hospitals in KwaZulu-Natal, South Africa, with the aim of designing a suitable implementation strategy. According to the research conducted, the implementation of the PSIRL Guidelines has not been effective, yet it plays a pivotal role in improving positive clinical outcomes evidenced by reduction in the occurrence of PSIs. It was important to have a general analysis of the implementation of PSIRL Guidelines in specialised care units to design an appropriate strategy that suits the healthcare professionals' clinical practice.

6.2. Synthesis of the study

The first chapter comprises of the background, problem statement, the purpose of the study, research objectives and questions, a theoretical model, literature review and research methodology.

The study background provided the context which the researcher took into consideration, prior to the formulation of the research objectives and research questions. The literature review provided information that highlighted the existing strategies for patient safety, although there were fewer articles on the actual implementation of the PSIRL Guidelines, in the South African context. The problem statement clarified the problem at hand and assisted in crafting the purpose of the study. The research methodology mapped the research process through the research approach and design, methods of sampling, tools and data collection methods and data analysis. The data collected resulted in one published article, two manuscripts and a developed implementation strategy. The research objectives were met as explained in the sections below.

6.2.1 Phase 1

Research objective 1 : To map the evidence of PSIRL Guidelines implemented by healthcare workers in specialised care units, globally

A scoping review was conducted, and the results revealed that the reporting of PSIs in specialised units commenced around 2002, however, the frequency of yearly publications

remain very low. There is a paucity of literature on the implementation of PSIRL Guidelines worldwide, as the focus is more on patient safety, reporting and analysis of incidents. Moreover, reporting was more on the administrative analysis of PSIs only and did not bring much change in the reduction of PSIs. Therefore, there is a need for implementing system changes based on incident reports to improve quality patient care.

6.2.2 Phase 2a

Research objective 2: To assess the healthcare professionals' perceptions on the implementation of PSIRL Guidelines in specialised care units, in KwaZulu-Natal.

A descriptive cross-sectional design was followed using the quantitative approach. A purposive sample targeted 237 healthcare professionals. Data was collected through an online structured questionnaire. Cronbach's Alpha coefficient for the current research tool was 0.9, meaning the instrument was an excellent measure of the variables under study. The study took place in SCUs of three selected public hospitals in two districts of KZN.

Descriptive and inferential statistics were used to analyse the collected data. Quantitative data was collected over a period of three months, from March 2021 to May 2021, during the COVID-19 pandemic. A total of 181 questionnaires were returned, yielding a response rate of 76%. Notably, 83% of respondents had high-perceived knowledge of the PSIRL Guidelines, while 98% had low perceptions of the implementation. The current unit (p=0.002) and shift of the day (p=0.008) were factors associated with the perception of good knowledge of the PSIRL Guidelines, as indicated by a p-value $\leq$0.05. The respondents' age (p=0.05), current unit (p=0.015), and shift of the day (p=0.000) were significantly associated with the perception of poor implementation of the PSIRL Guidelines.

The results revealed that respondents demonstrated good perceptions of knowledge of the PSIRL Guidelines; however, the perception of the implementation was poor. Therefore, a revised implementation strategy coupled with periodic in-service training for healthcare professionals is recommended, to foster and facilitate effective adherence to PSIRL Guidelines.

6.2.3 Phase 2b

Research objective 3: To explore facilitators and barriers in the implementation of PSI reporting Guidelines in specialised care units by the healthcare professionals

The qualitative data was collected through focus group discussions and individual interviews, to gather in-depth data and to capture accurate aspects of the phenomenon. The aim was to describe the facilitators and barriers in the implementation of the PSIRL Guidelines in SCUs by the healthcare professionals. A descriptive, explorative qualitative approach was used to collect qualitative data from healthcare professionals working in SCUs of three purposely selected public hospitals in two districts of KwaZulu-Natal. Focus group discussions and semi-structured interviews were conducted from August to October 2021. Content data analysis was performed using Tesch's method of analysis process.

This study findings confirmed that PSIRL Guidelines are still not successfully implemented in the SCUs and the barriers to implementation were highlighted. For rigorous implementation in South Africa, the study recommends revised PSIRL Guidelines, designed in consultation with the frontline healthcare professionals. These guidelines can consist of standardised, simple -user-friendly reporting processes as well as a better implementation strategy to guide the healthcare professionals. The themes that emerged include (1) Inadequate institutional and management for the healthcare professionals, (2) Ineffective communication of the PSI Guidelines affecting reporting system affecting, (3). Poor human resources affecting the implementation of PSI Guidelines,(4). Insufficient education and training of healthcare professionals.

6.2.4 Phase 3

Research objective 4: To develop and evaluate the implementation strategy for PSI reporting for healthcare professionals in specialised care units

Based on this research objective, the PSI implementation strategy was developed for the SCUs. The strategic focus areas include (1) facilitation of patient safety implementation strategy, (2) comprehensive support for the healthcare professionals, (3) functional reporting system, attraction, (4) recruitment and retention of staff, (5) quality, sustainable education and training, (6) effective monitoring and evaluation, (7) a comprehensive budget and (8) improved adherence to the WHO action plans. The developed strategy was evaluated by the experts who have a wealth of knowledge and expertise in the implementation of the PSIRL Guidelines. Experts' comments and recommendations were incorporated into the final design of the implementation strategy. (Refer to Annexure K) For the successful implementation of this strategy into the main health system , some of the barriers need to be resolved. The theoretical model is an organised set of concepts

gathered in a rational system by their relevance to a common theme. It is a blueprint that guides the study design, sample selection, data collection strategies and analysis. The model helps to plan and organise the identification of the problem, the review of literature, the design of interventions, analysing the data, and presenting the findings. Hence Kurt Lewin's (1947) three step model of unfreeze-change- refreeze, which was adopted throughout the study, is recommended for implementation by the institutions.

The implementation strategy fits well in this theoretical model of the study as it described the ways of implementing change processes by leader's knowledge sharing. Unfreezing means driving changes in the organisation for managers and leaders to monitor, evaluate and plan using structures for quick responses to the internal or external environment and foresee the pattern of change by individuals, products and technology. The organisation is required to interrogate its own status quo and make plans to effectively implement new strategies, without any resistance. Part of this analysis has been achieved through the literature review, quantitative and qualitative studies. The next step is at the institutional level, prior the implementation of the strategy, which includes the assessment of the institution readiness to implement the strategy.

For change to take place, the strategy needs to be implemented and the leaders should educate, train, coach, communicate, participate, involve, task support, provide emotional support and incentives, manipulate, co-opt and coerce the employees about the change. This entails active involvement and empowerment of employees on knowledge sharing, and to take responsibility for formulating, planning and implementing effective strategies to avoid organisational resistance. The PSI implementation strategy is designed to facilitate change in the implementation of the PSIRL Guidelines. Effective implementation is expected to reduce the occurrence of avoidable PSIs.

Lastly, during refreezing, changes are accepted and become the new norm. People form new relationships and become comfortable with their routines. This includes monitoring and evaluating the effectiveness of the new implementation strategy. Therefore, organisational change of SCUs should be monitored for its success in effective implementation of the strategy for the healthcare professionals, including the enablers and barriers of implementation of the PSIRL Guidelines.

6.3 Limitations

This study was limited to three major public hospitals in KwaZulu-Natal, therefore excluding other provinces and the private sector, which might have contributed to more informative data. The National Guidelines for PSIRL were developed for all healthcare facilities, however, this study was only limited to SCUs of KZN, therefore some pertinent information from other departments might have been omitted. Most of the literature that supported this study is based on international perspectives while there is a paucity of literature on the South African context. This study was conducted during the COVID-19 pandemic which included the lockdown, making it difficult to secure appointments with the healthcare professionals, as the SCUs were the busiest during this period. It was also difficult to get responses timeously, hence poor response from certain participants, as the study was conducted virtually, to ensure social distance. Communication challenges created by network interruptions made it difficult to connect with the participants and also to observe participants' body language, therefore the researcher relied more on voices, which gave some cues.

6.4 Recommendations and contributions of the study

This study was conducted in one province; therefore, it is recommended that further research be conducted in other provinces. Further research in other departments is recommended as this study was only limited to SCUs. The purpose of this study was to analyse the implementation of PSIRL Guidelines in SCUs and to develop an implementation strategy of these guidelines in the selected hospitals of KZN South Africa. The implementation strategy contribution is to capacitate healthcare professionals in SCUs. A follow-up study analysing the effectiveness of this strategy is recommended. The study research analysis, results, and implementation strategy can be used by global and country stakeholders to improve the implementation of PSIRL Guidelines, as per the WHO recommendations. To assist in implementing this strategy nationally, an aggressive national campaign should be launched in South Africa to educate and encourage healthcare professionals to embrace the vigorous implementation of PSIRL Guidelines to improve quality patient care. This study further contributes to the following domains as discussed in the next sections.

6.4.1 Clinical Practice/ Positive Practice Environment

Nationally and globally, healthcare professionals increasingly understand that healthcare must be based on a combination of scientific evidence, knowledge gained from clinical experience, patient value judgments and preferences. The PSI implementation strategy equips organisations with positive practice environments, resulting in lower turnover and higher retention rates of healthcare professionals. Healthcare professional participation in hospital affairs, establishing nursing foundations for quality care, healthcare professionals' ability, leadership, and support of healthcare professionals, staffing and resource adequacy, and collegial nurse-physician relations are key components of positive practice environments. The culture of the organisation must be one of collaboration across disciplines, teamwork, and one that puts the welfare of the patient first. Patient safety is a collective responsibility. Healthcare professionals must work together with patients, families, and communities, so that patients can be informed advocates in their own care, and every person can receive the safe, dignified, and compassionate care they deserve. These behaviours must be modelled by leaders and executives across the organisation.

A formal evaluation process would then provide the data necessary to decide if the PSI implementation strategy should continue or be expanded, depending on the extent of improvement in the practice environment. Evaluating strategies to enhance the practice environment is critical so that effective strategies can be widely adopted in practice. Creating positive practice environments is therefore an important strategy available to executives and healthcare professional leaders to enhance healthcare professional's retention and improve health outcomes.

6.4.2 Clinical Governance and Policy briefs

Clinical governance is the central element of a framework that supports the delivery of quality. Clinical governance provides the opportunity to understand and learn to develop the fundamental components required to facilitate the delivery of quality care, a no-blame, questioning, learning culture, excellent leadership, and an ethos where staff are valued and supported as they form partnerships with patients. Clinical governance demands the re-examination of traditional roles and boundaries between healthcare professions, between healthcare professionals and patients, and between managers and clinicians and provides the means to show the public that the expected patient care will not tolerate less than best

practice. Therefore, a safe, enabling, and non-punitive environment should be created for healthcare professionals. The PSIRL Guidelines should be used as a learning opportunity and healthcare professionals should obtain support from the leadership and management, especially during the disclosure of the PSI. New approaches are needed for leadership, strategic planning, patient involvement, and management of staff and processes, hence the adoption of the developed PSI implementation strategy is recommended.

Policymakers are to design supportive policies that create an enabling environment for healthcare professionals to implement these guidelines without difficulty and to consider adopting the developed implementation strategy. Policy briefs must be clear, detailed and concise, for easy implementation by healthcare professionals. These briefs must include an analysis of the intervention's impact on the implementation of the Sustainable Development Goals.

6.4.3 Continuous Professional Development for healthcare professionals

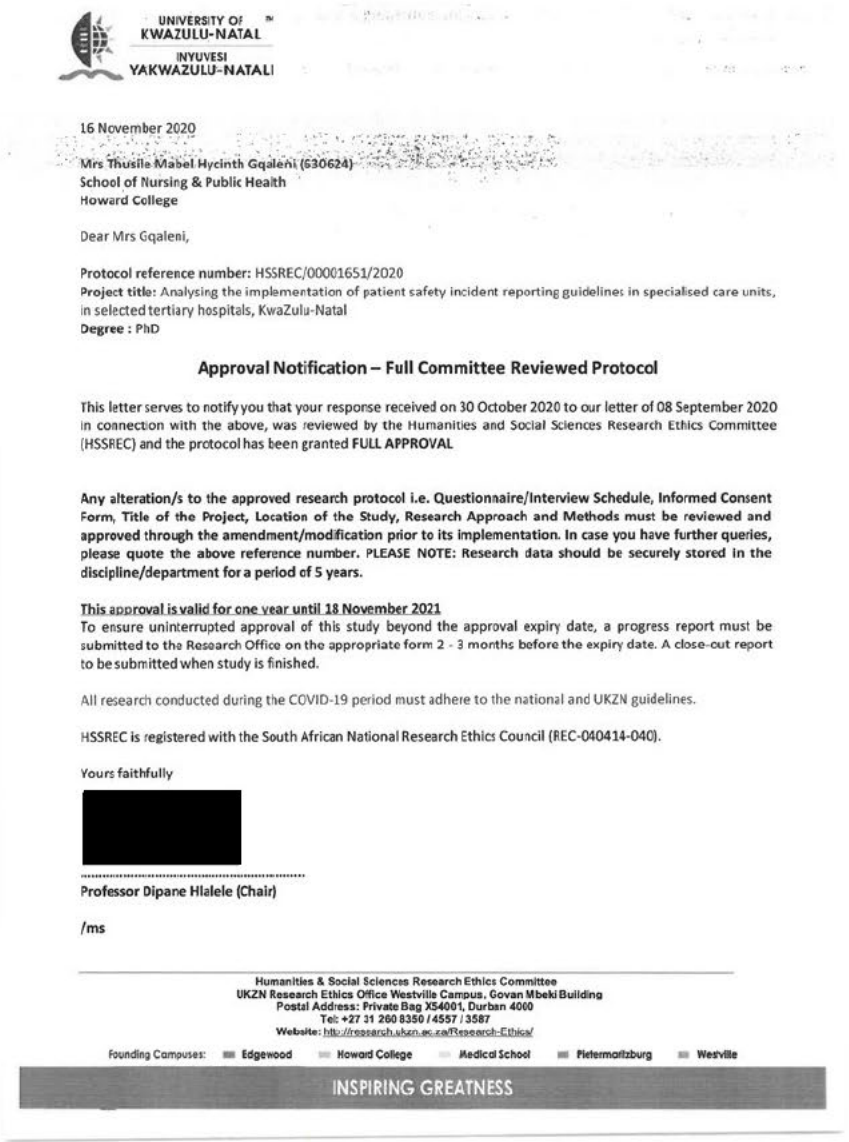
Continuous Professional Development (CPD) can strengthen networks, improve motivation, and empower healthcare professionals; therefore, the positive effects can translate to retention and higher quality care. CPD is important to facilitate and foster the effective implementation of the PSIRL Guidelines and the strategies. Leadership, financial investment, and the mobilisation of material and human resources, including the training of personnel, at the local level, are required. However, to sustain the CPD system buy-in and support from a diversity of stakeholders, consistent funding and resources, and the establishment of robust regulation, monitoring and accreditation structures are required. To promote CPD uptake, some of the recommended strategies include a diversity of options that are easily accessible and available at low-cost and supportive work environments. Funding, structures, qualified human resources to coordinate and manage the CPD system, government support and healthcare professional bodies are pivotal to the success of the PSI implementation strategy.

Furthermore, active promotion, marketing and providing incentives may also alter healthcare providers' attitudes and further lead to participation in CPD activities. The system should also be dynamic wherein modifications and improvements can be introduced continuously.

6.5 Conclusion

This chapter concludes the research process that was conducted in three public hospitals and the findings that informed the development of an implementation strategy. The research methodology was outlined which mapped the research process and the philosophical underpinnings that guided the study. The research outcome consisted of a scoping review, quantitative and qualitative research outcomes, that yielded the development of a PSI implementation strategy.

ANNEXURE A: ETHICAL CLEARANCE CERTIFICATE



UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

16 November 2020

Mrs Thusile Mabel Hycinth Gqaleni (630624)
School of Nursing & Public Health
Howard College

Dear Mrs Gqaleni,

Protocol reference number: HSSREC/00001651/2020
Project title: Analysing the implementation of patient safety incident reporting guidelines in specialised care units, in selected tertiary hospitals, KwaZulu-Natal
Degree : PhD

Approval Notification – Full Committee Reviewed Protocol

This letter serves to notify you that your response received on 30 October 2020 to our letter of 08 September 2020 in connection with the above, was reviewed by the Humanities and Social Sciences Research Ethics Committee (HSSREC) and the protocol has been granted **FULL APPROVAL**

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. In case you have further queries, please quote the above reference number. PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

This approval is valid for one year until 18 November 2021
To ensure uninterrupted approval of this study beyond the approval expiry date, a progress report must be submitted to the Research Office on the appropriate form 2 - 3 months before the expiry date. A close-out report to be submitted when study is finished.

All research conducted during the COVID-19 period must adhere to the national and UKZN guidelines.

HSSREC is registered with the South African National Research Ethics Council (REC-040414-040).

Yours faithfully

[redacted]

.....
Professor Dipane Hlalele (Chair)

/ms

Humanities & Social Sciences Research Ethics Committee
UKZN Research Ethics Office Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Tel: +27 31 260 8350 / 4557 / 3587
Website: http://research.ukzn.ac.za/Research-Ethics/

Founding Campuses: Edgewood Howard College Medical School Pietermaritzburg Westville

INSPIRING GREATNESS

ANNEXURE B: HEALTH RESEARCH & KNOWLEDGE MANAGEMENT UNIT

KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DIRECTORATE:
Health Research & Knowledge Management Unit

Postal Address: Private Bag X9050
Physical Address: 330 Langalibalele Str; PM Burg; 3201
Tel: 0333953189/3123/2805 Fax: 033-3943782
Email address: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

NHRD Ref: KZ_202010_024

Dear Mrs T M H Gqaleni
(UKZN)

Approval of research

1. The research proposal titled **'ANALYSING THE IMPLEMENTATION OF PATIENT SAFETY INCIDENT REPORTING GUIDELINES IN SPECIALISED CARE UNITS, IN THE SELECTED TERTIARY HOSPITALS, KWAZULU-NATAL'** was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

   The proposal is hereby **approved** for research to be undertaken at Inkosi Albert Luthuli Central and Greys hospitals.

2. You are requested to take note of the following:
   a. *All research conducted in KwaZulu-Natal must comply with government regulations relating to Covid-19. These include but are not limited to: regulations concerning social distancing, the wearing of personal protective equipment, and limitations on meetings and social gatherings.*
   b. *Kindly liaise with the facility manager BEFORE your research begins in order to ensure that conditions in the facility are conducive to the conduct of your research. These include, but are not limited to, an assurance that the numbers of patients attending the facility are sufficient to support your sample size requirements, and that the space and physical infrastructure of the facility can accommodate the research team and any additional equipment required for the research.*
   c. *Please ensure that you provide your letter of ethics re-certification to this unit, when the current approval expires.*
   d. *Provide an interim progress report and final report (electronic and hard copies) when your research is complete to* ***HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200*** *and e-mail an electronic copy to hrkm@kznhealth.gov.za*
   e. *Please note that the Department of Health shall not be held liable for any injury that occurs as a result of this study.*

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

[redacted]

Dr E Lutge
Chairperson, Health Research Committee
Date: 29/10/2020

ANNEXURE C: GATEKEEPER APPROVAL LETTERS (Hospital A)

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 800 Bellair Road, Mayville, 4058
Postal Address: Private Bag X08, Mayville, 4058
Tel: 0312401059 Fax: 0312401050 Email: ursulanun@ ialch.co.za
www.kznhealth.gov.za

DIRECTORATE:
Office of The Medical Manager
IALCH

Reference: HSSREC/00001651/2020
Enquiries: Medical Management

16 October 2020

Mrs T M H Gqaleni (630624)
School of Nurs & Public Health
Howard College

Dear Mrs Gqaleni

RE: PERMISSION TO CONDUCT RESEARCH AT IALCH

I have pleasure in informing you that permission has been granted to you by the Medical Manager to conduct research on: **Anlysing the implementation of patient safety incident reporting guidelines in specialized care units in selected tertiary hospitals, KwaZulu-Natal.**

Kindly take note of the following information before you continue:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Kindly ensure that this office is informed before you commence your research.
4. The hospital will not provide any resources for this research.
5. You will be expected to provide feedback once your research is complete to the Medical Manager.

Yours faithfully

[redacted]

Dr L P Mtshali
Medical Manager

pp Dr A-Harrichandparsad
Clinical Care Manager

Fighting Disease, Fighting Poverty, Giving Hope

Gatekeeper Approval for hospital B

health
Department:
Health
PROVINCE OF KWAZULU-NATAL
Private Bag X 9001, Pietermaritzburg, 3200
201 Town Bush Road, Northern Park, Pietermaritzburg, 3201
Tel: 0338973321 Fax: 0338973398

GREY'S HOSPITAL
OFFICE OF THE CEO

To:	**Mrs. T. M. H. Gqaleni** **School of Nursing & Public Health - UKZN**
From:	**Dr. K. B. Bilenge** **CEO - Greys Hospital**
Date:	**12 May 2020**
Re:	**Request for permission to conduct research at Grey's Hospital:** ***Analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal***

Dear Mrs. Gqaleni

Your request to conduct research at Grey's Hospital refers.
Permission to conduct the above study is hereby granted under the following conditions:

- Final ethics approval is a prerequisite for conducting your study at our hospital. Once obtained, please submit a copy of the full and final ethics approval;
- You are also required to obtain approval for your study from the Provincial Department of Health KZN Health Research Unit **prior to commencement**. You will find more information at: *http://www.kznhealth.gov.za/hrkm.htm*
- Confidentiality of hospital information, including staff and patient medical and/or contact information, must be kept at all times; **Patient/staff records are not to be removed from the hospital premises nor are you allowed to photocopy/ photograph them.**
- **You are to ensure that your data collection process will not interfere with the routine services at the hospital (questionnaires and interviews must be done during lunch/tea breaks and outside working hours);**
- You are to ensure that hospital resources are not used to manage your data collection, e.g. hospital staff collecting and/or collating data; photocopying; telephone; facsimile, etc.;
- Informed consent is to be obtained from all participants in your study, if applicable;
- Policies, guidelines and protocols of the Department of Health and Grey's Hospital must be adhered to at all times;
- Professional attitude and behaviour whilst dealing with research participants must be exhibited;
- The Department of Health, hospital and its staff will not be held responsible for any negative incidents and/or consequences, including injuries and illnesses that may be contracted on site, litigation matters, etc. that may arise as a result of your study or your presence on site;
- You are required to submit to this office a summary of study findings upon completion of your research.
- You are requested to make contact with the **Nursing Manager, Mrs. K.T. McKenzie**, and **M&E Manager, Ms. S. Arends**, at Grey's Hospital once you are ready to commence data collection.

Recommended by:

[redacted]

Dr L. Naidoo
Senior Manager: Medical Services

Approved by:

[redacted]

Dr. K. B. Bilenge
Hospital CEO

Hospital approval for hospital C

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

OFFICE OF THE HOSPITAL CEO
KING EDWARD VIII HOSPITAL

Private Bag X02, CONGELLA, 4013
Corner of Rick Turner (Francois Road) & Sydney Road
Tel: 031-3603854, Fax:031-2061457: Email:
www.kznhealth.gov.za

Ref.: KE 2/7/1/(19/2018
Enq.: Miss W.C. Madondo

12 October 2020

Mrs Thulisile Mabel Hychinth Gqaleni (630624)
School of Nurse & Public Health
Howard College

Dear Mrs Thulisile Mabel Hycinth Gqaleni

Protocol: "Analysing the implementation of patient safety incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal"

Permission to conduct research at King Edward VIII Hospital is provisionally granted, pending approval by the Provincial Health Research Committee, KZN Department of Health.

Kindly note the following:-

- The research will only commence once confirmation from the Provincial Health Research Committee in the KZN Department of Health has been received.
- Signing of an indemnity form at Room 8, CEO Complex before commencement with your study.
- King Edward VIII Hospital received full acknowledgment in the study on all Publications and reports a
  nd also kindly present a copy of the publication or
  report on completion.

The Management of King Edward VIII Hospital reserves the right to terminate the permission for the study should circumstances so dictate.

Yours faithfully

[redacted]

SUPPORTED / NOT SUPPORTED

19/10/2020
DATE

DR. S. RAMJI
ACTING SENIOR MEDICAL MANAGER

ANNEXURE D: INFORMATION SHEET

SECTION A No: Code Assigned……

Date: January, 2021

Analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal.

Dear

I am Mrs Thusile Mabel Mathe /Gqaleni, registered for a PhD degree, student number 931305833, also a staff member of the School of Nursing and Public Health at the University of KwaZulu-Natal, Howard college Campus. You are being invited to consider participating in a study that involves research titled **"analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal".** The above mentioned study will be conducted from 11th January 2021 to 16thAugust 2021, in three selected tertiary hospitals. For a quantitative the study 399 respondents will be expected to be enrolled, the questionnaire will take 20 minutes to complete, whereas for a qualitative study, the face to face interviews will take 40 minutes and focus groups will be conducted within one hour.

The purpose of this study is to analyse the implementation of Patient Safety Incident reporting guidelines in specialised care units and to develop an implementation strategy for the PSI reporting in the selected hospitals of KwaZulu-Natal, South Africa. The study does not involve any risks and no costs will be incurred by the participants as a result of participating in the study. I hope that the study will contribute to quality patient care and patient safety in specialised care units.

Your participation in this study is very important, however your participation is voluntary, and you may withdraw at any stage of the study, without any negative repercussions. Your confidentiality and anonymity will be ensured at all times as your name and the name of your hospital will not be required on the questionnaire.

Contact details of Researcher: If you have any questions or need further information on the study do not hesitate to ask my supervisor or me.

Researcher: Tusiwe Mabel Gqaleni (Tel: 260 1559 Email address:gqalenit@ukzn.ac.za)

Supervisor: Dr. Sipho Mkhize (Tel: 031 260 3578 Email address: MkhizeS4@ukzn.ac.za)

OR

The UKZN Humanities & Social Sciences Research Ethics Committee, contact details as follows:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001
Durban
4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604557- Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

ANNEXURE E: INFORMED CONSENT FORM

SECTION B:

TITLE: Analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal

I…….. (Full name of the Participant) hereby confirm that I understand the contents of this document and the nature of the research study and I consent to participating in the research project. I understand the purpose and procedures of the study.

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction. I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any of the benefits that I usually am entitled to.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at (provide details).

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001
Durban
4000

KwaZulu-Natal, SOUTH AFRICA

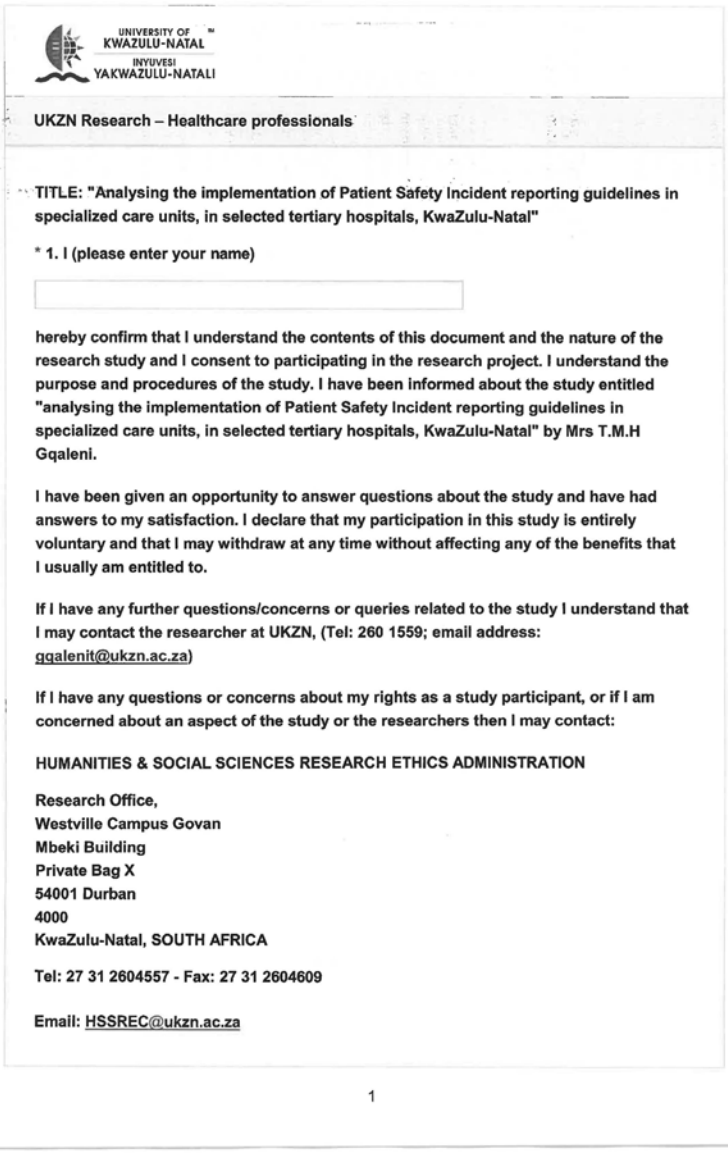
Tel: 27 31 2604557 - Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

Signature of the Participant……... Date……...

Witness Signature…… Date ……...

ANNEXURE F: INSTRUMENT FOR QUANTITATIVE DATA COLLECTION



UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

UKZN Research – Healthcare professionals

TITLE: "Analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal"

*** 1. I (please enter your name)**

hereby confirm that I understand the contents of this document and the nature of the research study and I consent to participating in the research project. I understand the purpose and procedures of the study. I have been informed about the study entitled "analysing the implementation of Patient Safety Incident reporting guidelines in specialized care units, in selected tertiary hospitals, KwaZulu-Natal" by Mrs T.M.H Gqaleni.

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction. I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any of the benefits that I usually am entitled to.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at UKZN, (Tel: 260 1559; email address: ggalenit@ukzn.ac.za)

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office,
Westville Campus Govan
Mbeki Building
Private Bag X
54001 Durban
4000
KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604557 - Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

1

*** 2. I, the abovementioned participant, signed this document electronically, acknowledging I have read and agree to the above.**

- Yes
- No

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INYUVESI YAKWAZULU-NATALI

UKZN Research – Healthcare professionals

Please note that this questionnaire is divided into three sections as follows: **Section A** -Demographics of the respondents, with five items. **Section B** -Healthcare professionals' perception of knowledge of the PSI reporting and learning guidelines, with six items and **Section C** -Healthcare professionals' perception of the implementation of PSI reporting and learning guidelines with 12 items.

SECTION A: DEMOGRAPHIC DATA

*** 1. What is your gender?**

- Male
- Female

*** 2. What is your age?**

- 25-29yrs
- 30-39yrs
- 40-49yrs
- 50-59yrs
- >60yrs

*** 3. Participants' Job level**

- Registered nurse
- Registered nurse with Critical care specialty
- Registrar medical doctor

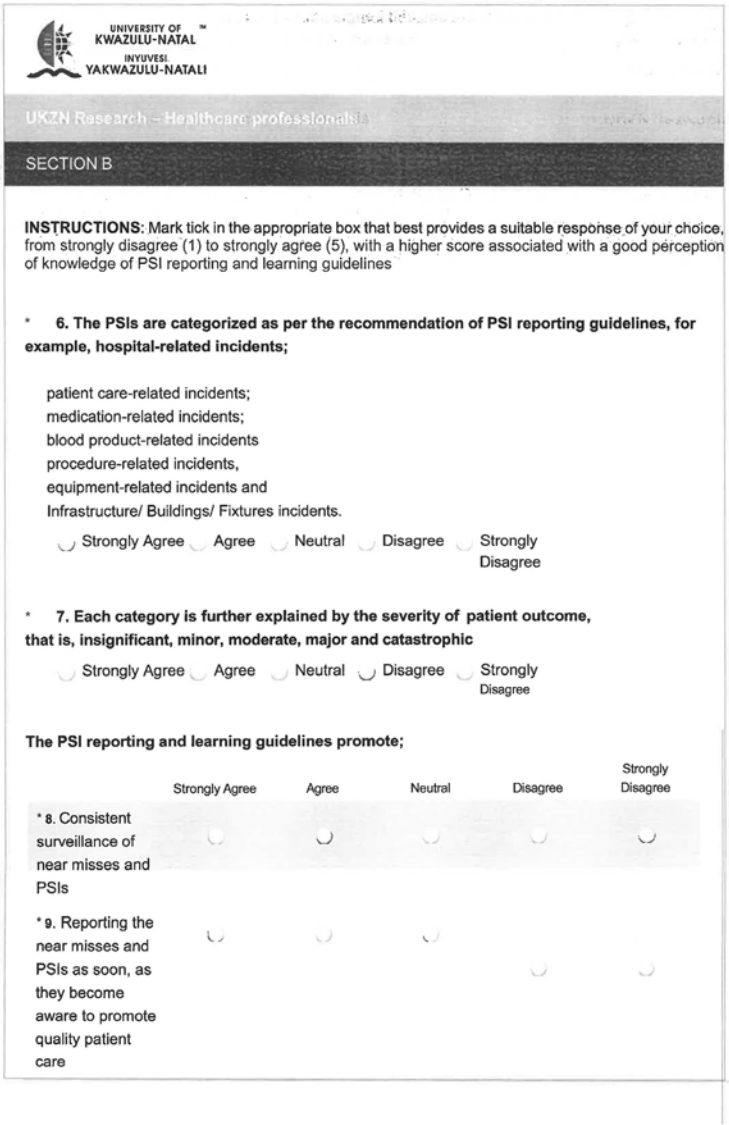
*** 4. Unit where you currently work**

- Medical CCU
- Surgical CCU
- Cardio-thoracic CCU
- Coronary care Unit
- Neonatal and Paediatrics CCU
- Burns Unit
- Trauma Unit
- Neuro CCU
- Renal Unit
- General CCU
- High care unit

5. Shift you are working

- Day duty
- Night duty

3



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SECTION B

INSTRUCTIONS: Mark tick in the appropriate box that best provides a suitable response of your choice, from strongly disagree (1) to strongly agree (5), with a higher score associated with a good perception of knowledge of PSI reporting and learning guidelines

* **6. The PSIs are categorized as per the recommendation of PSI reporting guidelines, for example, hospital-related incidents;**

patient care-related incidents;
medication-related incidents;
blood product-related incidents
procedure-related incidents,
equipment-related incidents and
Infrastructure/ Buildings/ Fixtures incidents.

Strongly Agree Agree Neutral Disagree Strongly Disagree

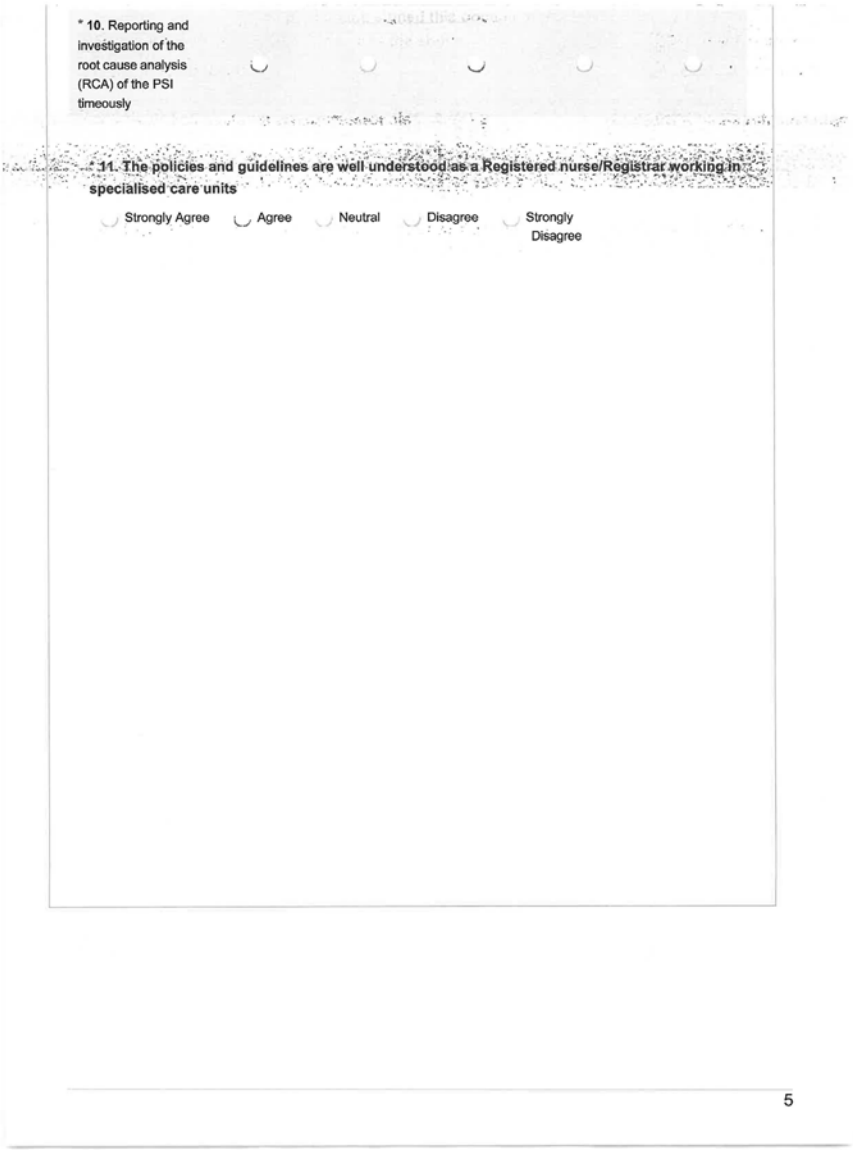
* **7. Each category is further explained by the severity of patient outcome, that is, insignificant, minor, moderate, major and catastrophic**

Strongly Agree Agree Neutral Disagree Strongly Disagree

The PSI reporting and learning guidelines promote;

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
* 8. Consistent surveillance of near misses and PSIs					
* 9. Reporting the near misses and PSIs as soon, as they become aware to promote quality patient care					

4

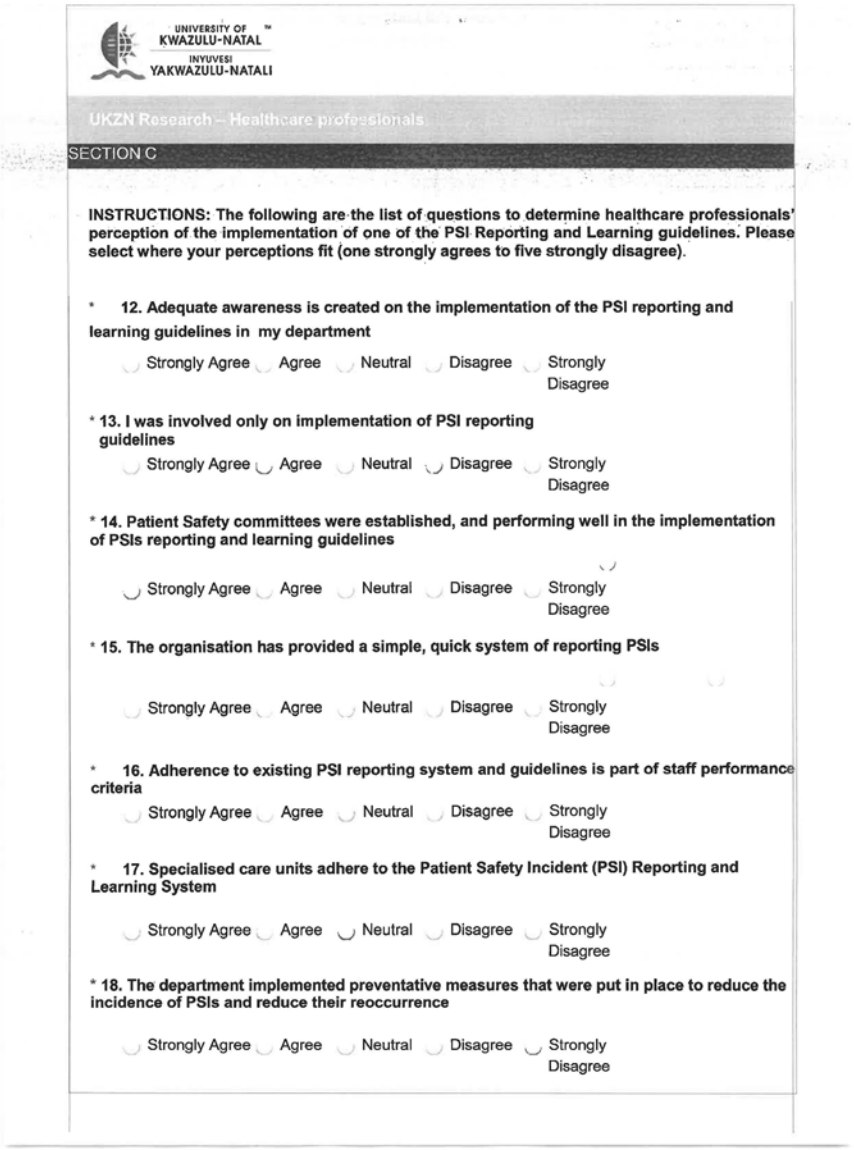


* 10. Reporting and investigation of the root cause analysis (RCA) of the PSI timeously

11. The policies and guidelines are well understood as a Registered nurse/Registrar working in specialised care units

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

5



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UKZN Research – Healthcare professionals

SECTION C

INSTRUCTIONS: The following are the list of questions to determine healthcare professionals' perception of the implementation of one of the PSI Reporting and Learning guidelines. Please select where your perceptions fit (one strongly agrees to five strongly disagree).

* **12. Adequate awareness is created on the implementation of the PSI reporting and learning guidelines in my department**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **13. I was involved only on implementation of PSI reporting guidelines**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **14. Patient Safety committees were established, and performing well in the implementation of PSIs reporting and learning guidelines**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **15. The organisation has provided a simple, quick system of reporting PSIs**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **16. Adherence to existing PSI reporting system and guidelines is part of staff performance criteria**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **17. Specialised care units adhere to the Patient Safety Incident (PSI) Reporting and Learning System**

Strongly Agree Agree Neutral Disagree Strongly Disagree

* **18. The department implemented preventative measures that were put in place to reduce the incidence of PSIs and reduce their reoccurrence**

Strongly Agree Agree Neutral Disagree Strongly Disagree

*** 19. The implemented preventative measures are effective in reducing the reoccurrence of PSIs in the unit**

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

*** 20. Analysis of PSI data and immediate action to mitigate harmful consequences of the PSIs**

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

*** 21. The organization has the support structure, which consists of the legal framework that assist during the disclosure of PSIs, as recommended by the PSI guidelines**

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

*** 22. Experience of the RNs/ Registrars in the units is utilised accordingly when implementing the PSI reporting and learning guidelines.**

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

*** 23. There is efficient record keeping of reported PSIs as per the recommendation of PSI guidelines.**

Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree

Adapted from National Guidelines for Patient Safety Incident Reporting and Learning System (WHO, 2017)

Thank you for taking part in the survey.

ANNEXURE G: SEMI-STRUCTURED INTERVIEW INSTRUMENT

FOCUS GROUP DISCUSSION- OPERATIONAL NURSE MANAGERS

Site code: Date:
Start:
End:

Demographics
Gender:
Employment status:

INTRODUCTION:

Greetings,

Thank you for your time and for agreeing to participate in this study. The information you are going to share will contribute towards improving the implementation of patient safety incident reporting and learning guidelines in specialised care units. This interview is recorded and will take approximately 45 minutes. Thank you for giving me permission to record and I would like to assure you that your institution and your name are not divulged. The information you give will is strictly confidential and only accessible to me, as a researcher and my supervisor, and will be used for research purposes only. A special code has been created for this virtual interview to avoid intruders. Participation is voluntary and please feel free to withdraw at any time, there will be no negative repercussions.

Questions:	Topics:
Which elements in your daily nursing practice influence patient safety?	Culture of Patient Safety
Tell me about your perceived knowledge and implementation of PSI reporting and learning guidelines in your unit	Implementation of PSI guidelines
How are the PSI reporting and learning guidelines implemented? Support from the organisation, e.g. PSI safety committees?	Handling of the PSI process, including classification and severity of patient outcome
What are the barriers and facilitating factors associated with PSI reporting and learning implementation?	Existing improvement strategy

Thank you for your time and participation

ANNEXURE H: INDIVIDUAL INTERVIEW INSTRUMENT

- **ASSISTANT NURSE MANAGERS,**
- **CONSULTANT MEDICAL DOCTORS**
- **MONITORING & EVALUATION MANAGERS**

Site code: Date:

Start:

End:

Demographics

Gender:

Employment status:

INTRODUCTION

Good day Sir/Madam

Thank you for your time and for agreeing to participate in this study. The information you are going to share will contribute towards improving the implementation of patient safety incident reporting and learning guidelines in specialised care units. The interview is recorded and it will take approximately 45 minutes. Thank you for giving me permission to record and I would like to assure you that your institution and your name are not divulged. The information you give will is strictly confidential and only accessible to me, as a researcher and my supervisor, and will be used for research purposes only. A special code has been created for this virtual interview to avoid intruders. Participation is voluntary and please feel free to withdraw at any time, there will be no negative repercussions.

Essential question.

1. Tell me about your experience as a senior manager, in implementing the PSI reporting guidelines, in your department.

2. Probing questions

- How PSI guidelines are communicated to you and the staff?

- How are the PSIs handled and managed in your institution?
- What are the associated factors that may contribute to the poor implementation of PSI reporting guidelines by healthcare professionals?
- What factors do you consider essential for the effective implementation of PSI reporting guidelines for ensuring quality care delivery?

Thank you for participating in my study.

ANNEXURE I: PSI STRATEGY EVALUATION BY EXPERTS

PARTICIPANT 1:

EVALUATION FORM FOR THE PSI IMPLEMENTATION STRATEGY FOR PSI GUIDELINES

THESIS TITLE: ANALYSING THE IMPLEMENTATION OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING GUIDELINES IN SPECIALISED CARE UNITS, IN THE SELECTED HOSPITALS IN KWAZULU-NATAL, SOUTH AFRICA

Instructions:

Thank you for your participation in this study. Kindly complete the checklist by ticking the column that best describes the quality of the PSI implementation strategy.

KEY: SA= Strongly Agree **A**= Agree **U**= Unsure **D**= Disagree **SD**= Strongly Disagree					
	SA	**A**	**U**	**D**	**SD**
Quality of the Content					
The content of the PSI strategy is appropriate for implementation by the healthcare professionals.	SA				
The strategy objectives are clear and specific to the implementation of the PSI reporting and learning guidelines.	SA				
The strategy content is aligned to the scope of practice for healthcare professionals in a South African context.	SA				
The strategy framework is appropriate to support clinical practice.	SA				
The PSI implementation strategy includes theoretical knowledge and practical skills required to implement PSI reporting and learning guidelines successfully.	SA				
The PSI implementation strategy content is relevant to the needs of the healthcare professionals.	SA				
The PSI implementation strategy materials are appropriate, accurate and updated.	SA				
Comments of the validator:					

	SA	A	U	D	SD
Effectiveness of the PSI implementation strategy					
The PSI implementation strategy recommendations explicitly state the population (population of healthcare professionals) to which statements apply.	SA				
The PSI implementation strategy allows for individual and teamwork participation.	SA				
The PSI implementation strategy allows for collaboration with other professionals and departments.		A			
The PSI implementation strategy reflects high expectations of the healthcare professionals.				D	
Comments of the validator: Consider including PSI reporting and efforts to reduce risks in personal Employee performance management and development system (EPMDS)					
Ease of Use					
The PSI implementation strategy presents information in an appealing way, recommendations are precise, unambiguous and user-friendly.		A			
The PSI implementation strategy ensures effective and respectful communication.	SA				
The PSI implementation strategy is comprehensiveness, addresses all aspects that can facilitate the implementation of the PSI strategy to improve health outcomes.	SA				
Comments of the validator: Consider centralizing the reporting process to eliminate loss of PSI's					

THANK YOU FOR YOUR PARTICIPATION.

PARTICIPANT 2:

EVALUATION FORM THE PSI IMPLEMENTATION STRATEGY FOR PSI GUIDELINES

THESIS TITLE: ANALYSING THE IMPLEMENTATION OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING GUIDELINES IN SPECIALISED CARE UNITS, IN THE SELECTED HOSPITALS IN KWAZULU-NATAL, SOUTH AFRICA

Instructions:

Thank you for your participation in this study. Kindly complete the checklist by ticking the column that best describes the quality of the PSI implementation strategy.

KEY: SA= Strongly Agree **A**= Agree **U**= Unsure **D**= Disagree **SD**= Strongly Disagree					
	SA	**A**	**U**	**D**	**SD**
Quality of the Content					
The content of the PSI strategy is appropriate for implementation by the healthcare professionals.		X			
The strategy objectives are clear and specific to the implementation of the PSI reporting and learning guidelines.		X			
The strategy content is aligned to the scope of practice for healthcare professionals in a South African context.			X		
The strategy framework is appropriate to support clinical practice.		X			
The PSI implementation strategy includes theoretical knowledge and practical skills required to implement PSI reporting and learning guidelines successfully.		X			
The PSI implementation strategy content is relevant to the needs of the healthcare professionals.	X				
The PSI implementation strategy materials are appropriate, accurate and updated.			X		
Comments of the validator: Though I am, concerned about the activities that involve DOH and Treasurery (Budget). Unfortunately, there are action plans that are beyond the health professional on the ground, for example, DOH is specifically mentioned, the public private partnership and the issue					

of resources. The Health professionals in the specialised units can only motivate for staff and motivate or order material resources and infrastructure. I wish you had excluded practical skills but practicability, feasibility, applicability or say it was based on current knowledge on PSI and is feasible/practicable/applicable. I cannot understand the expectation because there were no materials listed or cited.

	SA	A	U	D	SD
Effectiveness of the PSI implementation strategy					
The PSI implementation strategy recommendations explicitly state the population (population of healthcare professionals) to which statements apply.		X			
The PSI implementation strategy allows for individual and teamwork participation.	X				
The PSI implementation strategy allows for collaboration with other professionals and departments.	X				
The PSI implementation strategy reflects high expectations of the healthcare professionals.		X			
Comments of the validator: See comments in the text.					
Ease of Use					
The PSI implementation strategy presents information in an appealing way, recommendations are precise, unambiguous and user-friendly.			X		
The PSI implementation strategy ensures effective and respectful communication.	X				
The PSI implementation strategy is comprehensiveness, addresses all aspects that can facilitate the implementation of the PSI strategy to improve health outcomes.		X			
Comments of the validator: I get lost when there are action plans for DOH and Budget including re-imbursement though I think that is meant to be incentives. I think the above quoted are beyond the health professionals at hand. Though the collaborations does not specify issues/areas of collaboration. Sometime I thought they were instructions like to DOH it really seems instructions.					

I think because there is a whole goal of on communication. However, I feel that using the framework specifically would have clearly demonstrated issues that are left out. Listing puts one in a danger of omitting some items unaware.

THANK YOU FOR YOUR PARTICIPATION.

PARTICIPANT 3:

EVALUATION FORM TO EVALUATE THE PSI IMPLEMENTATION STRATEGY FOR PSI GUIDELINES

THESIS TITLE: ANALYSING THE IMPLEMENTATION OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING GUIDELINES IN SPECIALISED CARE UNITS, IN THE SELECTED HOSPITALS IN KWAZULU-NATAL, SOUTH AFRICA

Instructions:

Thank you for your participation in this study. Kindly complete the checklist by ticking the column that best describes the quality of the PSI implementation strategy.

KEY: SA= Strongly Agree **A**= Agree **U**= Unsure **D**= Disagree **SD**= Strongly Disagree					
	SA	**A**	**U**	**D**	**SD**
Quality of the Content					
The content of the PSI strategy is appropriate for implementation by the healthcare professionals.		X			
The strategy objectives are clear and specific to the implementation of the PSI reporting and learning guidelines.		X			
The strategy content is aligned to the scope of practice for healthcare professionals in a South African context.		X			
The strategy framework is appropriate to support clinical practice.		X			
The PSI implementation strategy includes theoretical knowledge and practical skills required to implement PSI reporting and learning guidelines successfully.		X			
The PSI implementation strategy content is relevant to the needs of the healthcare professionals.		X			
The PSI implementation strategy materials are appropriate, accurate and updated.		x			
Comments of the validator: The quality of the content is good and appropriate. Given the staffing and resource constraints currently, it is unclear if even a good strategy is feasible.					

	SA	A	U	D	SD
Effectiveness of the PSI implementation strategy					
The PSI implementation strategy recommendations explicitly state the population (population of healthcare professionals) to which statements apply.	X				
The PSI implementation strategy allows for individual and teamwork participation.	X				
The PSI implementation strategy allows for collaboration with other professionals and departments.	X				
The PSI implementation strategy reflects high expectations of the healthcare professionals.	X				
Comments of the validator: As noted above.					
Ease of Use					
The PSI implementation strategy presents information in an appealing way, recommendations are precise, unambiguous and user-friendly.		X			
The PSI implementation strategy ensures effective and respectful communication.		X			
The PSI implementation strategy is comprehensiveness, addresses all aspects that can facilitate the implementation of the PSI strategy to improve health outcomes.		X			
Comments of the validator: As noted above. The strategy is good but busy clinicians will struggle to implement such a strategy in many settings given staffing and time constraints.					

ANNEXURE J: LANGUAGE EDITING AND PROOF-READING CERTIFICATE

EDITING / PROOFREADING CERTIFICATE

Editor details

DR NELLIE NARANJEE

Doctorate Nursing, MBA, MCur .

Freelance academic editor: Blackford Institute, UK

Contact details

Mobile : [redacted]

Email : [redacted]

Author : Ms Thusile Gqaleni

Title : Analysing the Implementation of Patient Safety Incident Reporting and Learning Guidelines in Specialised Care Units, in the Selected Hospitals in Kwazulu-Natal, South Africa

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STUDENT NUMBER: 931305833

This is to certify that the above dissertation/thesis has been proofread and edited for English language grammar, punctuation, spelling, writing style, clarity, sentence structure and layout. The logical presentation of ideas and the structure of the paper were also checked during the editing process. Neither the research content nor the author's intentions were altered in any way during the editing process.

I am a freelance editor specialising in proofreading and editing academic documents. All amendments were tracked with the Microsoft Word "Track Changes " feature and the document was returned to the author. The author has the option of accepting or rejecting each change individually. The author remains responsible for the correct application of the changes in the text and references. I wish the author all the best.

[redacted]

Dr Nellie Naranjee

28 October 2023

DATE

ANNEXURE K: TURNITIN REPORT

ORIGINALITY REPORT

0 % SIMILARITY INDEX

0% INTERNET SOURCES

0% PUBLICATION S

0% STUDENT PAPERS

PRIMARY SOURCES

1 www.archive.org
Internet Source

2 Submitted to RDI Distance Learning
Student Paper

3 T M H Gqaleni, S W Mkhize. "Healthcare professionals' perception of knowledge and implementation of Patient Safety Incident Reporting and Learning guidelines in specialised care units, KwaZulu-Natal", Southern African Journal of Critical Care, 2023
Publication

4 Submitted to Postgraduate Schools - Limkokwing University of Creative Technology
Student Paper

1 **ANNEXURE L:** SUMMARY OF DATA ANALYSIS

TRANSCRIPT	CODES	SUBTHEMES	THEMES	REMARKS
Focus groups: Operational managers **Hospital A** **Question: Which elements in daily nursing practice influence patient safety?** **Participant 1:** We ensure that there's adequate staffing, making sure that this also uhh...skills mix is uhh.. is ensured, enough ICU trained nurses each day, seven days per the week during the day and during the night.	I ensure that there's adequate staffing, making sure that this also uhh..skills mix is uhh.. is ensured, enough ICU trained nurses each day			**Positive**

Participant 3: I may be short of two nurses, find that the nurses that are brought to you…they even tell you, " I have never nursed a ventilated patient... I've never seen…' she doesn't understand.... she's never seen a ventilator. She's relocated from High care.. Not that she's not willing to work... she is willing.... she may ask you if you have another patient maybe there is not ventilated.... Then you say…I will allocate you, but the sister next to you, is going to assist you. But now you are compromising two patients.... you are compromising her patient, and you compromising this patient as well. So incidents are going to occur.	I have never nursed a ventilated patient... I've never seen…' she doesn't understand.... she's never seen a ventilator. She's relocated from High care.	Inadequate knowledgeable staff Lack of support by Operational Manager	**Lack of management support at the ground level**	**Negative**

	I will allocate you, but the sister next to you, is going to assist you. But now you are compromising two patients.... you are compromising her patient, and you compromising this patient as well.	Work overload		
Participant 4: I just wanted to add in terms of training, ahh… there's been a lot of complaints raised, I know, it's maybe it's out of our control, but since they stopped to take or sending people for post basic training, so as you have a lot of people that have exited through retirement and some got transferred	in terms of training, ahh… there's been a lot of complaints raised, I know, it's maybe it's out of our control, but since they stopped to take or sending people for post basic training, so as you have a lot of people that	Lack of specialised training Change of curriculum for training Lack of skilled staff	**Human resource constraints**	**Negative**

and some resigned, ehh ...the replacement ratio is not the same. So you you lose a skilled person and she gets replaced by maybe maybe no replacement at all. And these people that you've got with no experience they're willing to work but they're not sent for training. Because somehow there's been.... I understand there's been a change of curriculum so everything's is at a standstill for now. So we don't have enough, I mean... skilled people.	have exited through retirement and some got transferred and some resigned, ehh ...the replacement ratio is not the same. So you you lose a skilled person and she gets replaced by maybe maybe no replacement at all. And these people that you've got with no experience they're willing to work but they're not sent for training. Because somehow there's been.... I understand there's been a change of curriculum so everything's is at a standstill for now. So,	Lack of experience Increased Retirement Brain drain Increased staff turnover Lack of staff retention Delayed replacement		

	we don't have enough, I mean... skilled people.			
Hospital B **Assistant Nurse managers** **Question: What are the associated factors that may contribute to the poor implementation of PSI reporting guidelines by the healthcare workers?** **Interview 2**: Because there is this perception that the staff is not adequately trained to identify the PSIs and to disclose to patients and relatives.	perception that the staff is not adequately trained to identify the PSIs and to disclose to patients and relatives.		**Lack of training** **Inadequate in-service training**	

		Inadequate training of healthcare professionals on PSIs Inadequately trained to identify PSIs		**Negative**
Hospital A **Consultants individual Interviews**: **Question: Tell me about your experience as a senior manager, of implementing the PSI reporting guidelines, in your department.** **Individual interview 1** The PSI guidelines haven't been made, freely available and common			**Inadequate communication of guidelines**	

knowledge to all the disciplines of departments. So, it's one of the things from a clinical governance point of view that you have to have a standard operating for patient safetyncident, so… that's the one problem… is that if it is around, I haven't seen it…. So, which is bad because I think every person that works in the unit must be familiar with the relevant standard operating procedures. So something obviously that is important like a patient safety incident… is an important SOP that people need to be familiar with. So that's very difficult then to have an idea of how we follow the guidelines if you don't have an SOP to follow. You can't expect remedial action and education when people don't have	The PSI guidelines haven't been made, freely available and common knowledge to all the disciplines of departments. So, it's one of the things from a clinical governance point of view that you have to have a standard operating for patient safety incident, so… that's the one problem… is that if it is around, I haven't seen it…. So, which is bad because I think every person that works in the unit must be familiar with the relevant	Lack of knowledge of PSI reporting and learning guidelines, Unavailability of SOP Poor communication of PSI guidelines	**Inadequate in-service training** **PSI guidelines not uniform** **Poor understanding of the PSI guidelines and Policies**	**Negative**

anything that they follow This is how it has to be done. The problem is that maybe this SOP does exist...I don't know..... But it needs to be common knowledge we need we need to see this SOP…okay. If something happened, this is what I need to do. Step one, step two, step three, fill out this form here. Yep… Then I mean, I'll say to the doctors you must fill out an incident reporting form and they'll go ...What?... that nobody knows what it is. What to do with it. There are lots of errors , which are reflecting badly on us…unfortunately for us I think is that the current system, that we have now, suboptimal, it is not functioning in the manner it is supposed to function	standard operating procedures. Then I mean, I'll say to the doctors you must fill out an incident reporting form and they'll go ...What?... that nobody knows what it is. What to do with it.	Lack of standardisation of PSI guidelines Lack of knowledge and confusing PSI guidelines not made common knowledge Suboptimal system Dysfunctional	**Ineffective reporting system**	**Negative** **Negative** **Negative** **Negative**