Challenges faced by Healthcare Professionals in reporting Near Miss Incidents in a Hospital, at the Amathole District, Eastern Cape Province, South Africa

by

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DEDICATION

I dedicate this study to all healthcare professionals who, in their professional bodies, report near miss incidents and mentor new entries into their respective professions. One of the greatest challenges today is delivering safer and quality care in a complex, pressurised and fast-moving healthcare environment. In such circumstances, things can go wrong unexpectedly. Therefore, it is our responsibility as healthcare professionals to keep a sharp eye on near miss incidents, and to deliver the quality healthcare that health users deserve, as promised by the National Department of Health.

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A number of organizations and individuals have contributed to the success of this study. This includes the technical expertise to the development of near miss recommendations. Firstly, I would like to thank the Eastern Cape Department of Health in conjunction with the Amathole District for allowing me to conduct a study in one of their District hospitals, in order to develop some insights about the challenges faced by healthcare professionals when reporting Near Miss incidents.

Secondly, a special thanks to the participants who allowed me to collect the necessary data for the study without expecting anything in return. I hope you will also be interested in reading about my findings.

Thirdly, I am also grateful to the University of Fort Hare for allowing me to conduct this study with them.

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OPERATIONAL DEFINITIONS

Barrier: This is a circumstance or obstacle that keeps people or things apart or prevents communication or progress.

BetterObs: This is a program aimed at promoting safer deliveries, healthier babies, better outcomes all round and consequently decreased opportunities for litigation.

Critical intervention: This is an intervention that is implemented in the management of life-threatening and potentially life-threatening conditions, such as blood transfusions, interventional radiology and laparotomy or other surgical interventions.

Degree of harm: This is the severity and duration of any harm and/or any treatment implications that result from an incident.1

Error: This refers to the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (error of planning). Errors may occur due to commission or omission, and usually reflect deficiencies in the systems of care

Harm: Implies impairment of the structure or function of the body and/or any deleterious effect arising from such impairment, including disease, injury, suffering, disability and death, and may be physical, social or psychological

Harmful incident (adverse event): This is an incident that is related to the medical management of patients which results in harm to a patient.

Hazard: This refers to a circumstance, agent or action which has the potential to cause harm.

Incident outcomes: These are all the impacts on a patient or an organisation that are

wholly or partially attributable to an incident.

Incident type: This is a descriptive term for a category of incidents that are of a common nature, grouped based on shared and agreed features.

Just Culture: This is a culture in which staff feel free to report patient safety incidents without fear of victimisation as a consequence of reporting the incidents.

Litigation: The act, process, or practice of settling a dispute in a court of law.

Medical negligence: The act or omission by a medical professional that deviates from the accepted medical standard of care and results in damages.

Near-miss case: This refers to a patient who nearly died but survived the life-threatening complication

Near miss incident: This refers to an unplanned event that neither reached the patient nor resulted in harm or illness although it had a potential to do so.

No harm incident: This refers to an incident which reached a patient but resulted in no discernible harm.

Patient safety: The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.

Patient safety incident: This is an unplanned or unintended event or circumstance that could have resulted or did result in harm to a patient while in the care of a health facility. This event is thus not due to the underlying health condition or natural progression of disease. An incident can be a near miss, no harm incident or harmful incident (adverse event).

Preventable harm: This refers to an identifiable and modifiable cause and an event whose recurrence can be avoided by the adaptation of a process or adherence to guidelines.

Process indicators: These are indicators used in assessing the use of key interventions for the prevention and management of severe complications.

Severe complications: This refers to potentially life-threatening conditions that include diseases or conditions that may be relevant to an adverse outcome but are not part of the chain of events leading to that particular adverse outcome

System: This refers to a set of interdependent elements (people, processes, equipment) that interact to achieve a common goal.

LIST OF ACRONYMS

Abbreviation	Full meaning
AIDS	Acquired Immunodeficiency Syndrome
APH	Anti-Partum Haemorrhage
COVID-19	Corona Virus Disease
CQI	Continuous Quality Improvement
DoH	Department of Health
DMAIC	Define Measure Analyse Improve Control)
ECDoH	Eastern Cape Department of Health
FSB	Fresh Stillborn
GHPT	Gestational Hypertension
HCP	Healthcare Professionals
HIV	Human Immunodeficiency Virus
HPT	Hypertension
LSS	Lean Six Sigma
MEC	Member of the Executive Council
M&M	Mortality and Morbidity
NDoH	National Department of Health
NMIs	Near Miss Incidents
PSIs	Patient Safety Incidents
PPH	Post-Partum Haemorrhage
QI	Quality Improvement
SA	South Africa
SAC	Severity Assessment Code
SASOG	The South African Society of Obstetricians & Gynaecologists
SPSS	Statistical Package for Social Science
WHO	World Health Organization
NGO	Non-Governmental Organisation
USAID	United States Agency for International Development

ABSTRACT

Background

Recording and investigation of NMIs can provide valuable information on monitoring and enhancing patient safety in the healthcare facilities. This in turn, can reduce the likelihood of medico-legal claims. Regardless of attempts to establish efficient incident reporting systems across the entire healthcare industry, underreporting of errors persists worldwide. Therefore, not only do near miss incidents serve as early warning signs of impending potential failure in the healthcare system, but they also provide a chance for patient safety improvement. With that in mind, this study was undertaken to investigate challenges faced by health care professionals in reporting near miss incidents at a hospital in the Amathole District, in the Eastern Cape province of South Africa.

Aim

The aim of the study was to develop recommendations for healthcare management and healthcare professionals on how to better manage NMIs, and by identifying the challenges faced by health care professionals and the impact they have on the quality of care at one state-funded district hospital.

Setting

The study was conducted with healthcare professionals at a district hospital in the Amathole District, Eastern Cape Province, South Africa.

Methods

This study used a mixed method study design. Purposive and convenience sampling were used for participants' selection for the study. Quantitative data was collected using the WHO Near-Miss Approach while individual and focus group interviews with healthcare professionals were carried out for collecting qualitative data. The maternity and neonatal intensive care units were identified as the two high-risk areas from which most medical negligence claims are lodged. The number of complications that occurred in each month of the year 2019 was determined by using components of the WHO near miss approach. The researcher adopted this approach to serve as a baseline assessment. Data was analysed using both Nvivo Version 10 and SPSS Version 20.

Findings

The challenges that healthcare professionals face in reporting near miss incidents at the study site included lack of knowledge about the reporting tool and system, inability to identify a near miss incident and healthcare professional attitudes and practices. The document review revealed that the NMIs are existent but not reported on the prescribed reporting system, a total of 210 actual incidents had occurred in the maternity and neonatal units of the hospital, which accounts for 62% of the 357 deliveries in the year 2019.

Conclusion

Based on the study result and findings, the healthcare system should shift towards a proactive rather than a reactive approach to medical and clinical errors. Continuously reducing the incidence of all patient safety incidents requires improved prevention strategies and effective strategies for recovery from possible medico-legal claims. The study further suggests that additional focus should be placed on NMI reporting and investigation so that operative improvement plans can be developed, implemented, monitored and evaluated. In essence, these improvement plans should be designed to progress patient care, reduce avoidable PSIs and reduce medico-legal claims.

CHAPTER 1: INTRODUCTION AND BACKGROUND INFORMATION

1.1 INTRODUCTION

Medico-legal claims have been a continuous burden to the South African healthcare system. The number of medico-legal claims filed against both public and private healthcare providers has increased rapidly since 2008 (Taylor, Van Waart, Ranchod & Taylor, 2018). A growing amount of potential damages caused by hospitals and especially birth-related injuries in South Africa has increased the cost of health care and this negatively impact on an already-struggling healthcare system (Taylor, et al., 2018). Contingent liabilities for medical negligence claims cost the public health sector about a third of its 2016-2017 annual budget (R55 billion) by mid-2017 and this amount excluded the associated legal expenditures (Blecher, Daven, Kollipara, Maharaj, Mansfelder, & Gaarekwe, 2017). In the Eastern Cape Province, the contingent liabilities increased by close to 45% from R16.8 billion in 2016-2017 to R24.3 billion in 2017-2018 (Kahn, 2018). Over the same period, Gauteng experienced an increase of 23.6% (R17.8bn to R 22bn) and Limpopo experienced a two-fold increase (107%) from R 2.1bn to R 4.35bn (Kahn, 2018). By the 2019-2020 financial year, medical negligence claims had increased to R105.8 billion at national level and in the Eastern Cape Province, the claims increased from R24 billion to R29 billion, exceeding the health department's budget allocation by R5 billion (South African Law Reform Commission, 2021).

Preventable patient harm is a major global public health issue, and South Africa is by no means an exception. Anything that has the potential to harm a patient is called a near miss incident (NMI), which is often referred to in other literature as a patient safety incident (PSI). The main idea behind the NMI process is to compile near miss experiences into an informed intervention that is aimed at reducing incidence of preventable patient harm. NMI occurs as a result of the interaction between patients and healthcare workers. As a result, the NMI process has to improve the safety of both patients and healthcare workers (World Health Organization, 2017). The NMI reporting system is based on effective patient monitoring and injury prevention. The aim is not only to learn from mistakes, but also to prevent similar mistakes from reoccurring (World Health Organization, 2017). This

chapter provides the background of the study, problem statement, aim and objectives of the study. Furthermore, the research design and methods, and literature control is provided. Finally, the chapter detailed the trustworthiness, ethical considerations, permission and the significance of the study.

1.1.1 BACKGROUND OF THE STUDY

A technical working group of the World Health Organization (WHO) was established in 2007, with the aim of developing standardized definitions and uniform criteria for identifying maternal near-miss cases. Process indicators were developed, adapted, and implemented in a variety of settings. Audits were conducted to assess the quality of care delivered. An evaluation of the gap between actual use and optimal use of interventions was conducted (World Health Organization, 2011). According to World Health Organization (2008), patient safety is a dimension of quality assurance while patient safety practices refer to those processes or structures which, when applied, reduce the probability of avoidable harm, and make errors less likely and reduce the impact of harm when it does occur. In order to achieve this, the National Department of Health (NDoH) introduced the Patient Safety Incident Reporting and Learning Policy as a guide for standardised management of patient incidents in the healthcare sector. The policy describes a PSI as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word “unnecessary” in this definition acknowledges that errors, violations, patient abuse and unsafe acts do occur in the healthcare system. In the context of the above-mentioned policy, unnecessary harm to a patient is referred to as an incident (National Department of Health, 2017)

It is standard practice in healthcare facilities to discuss NMIs during Mortality and Morbidity (M & M) meetings or Quality Management meetings. These meetings should be held with the intention of finding the root cause of the identified problem and possible interventions as opposed to casting the blame on healthcare professionals (National Department of Health, 2017). The South African Society of Obstetricians & Gynaecologists (SASOG) reviews NMIs and PSIs during its monthly meetings and

decides on appropriate patient safety improvement plans, where necessary (Taylor, et al., 2018). The WHO Near-miss Approach in maternal services is intended to be carried out within any healthcare context, in order to improve quality of care. An individual who is an expert in clinical practice is assigned to coordinate activities among patient safety committees in a healthcare facility, or related platforms. The WHO near-miss approach is implemented in three stages, namely baseline assessment, situation analysis, and intervention to improve health care. The near-miss approach is designed to improve clinical practice so that preventable morbidity and mortality can be minimized (World Health Organization, 2011). NMIs are considered as markers of patient safety and offer valuable information if timeously reported and investigated. Any trends identified from the analysis of PSIs reports can be used to improve patient safety and reduce medico-legal claims (Sheikhtaheri, 2014).

Furthermore, the PSI policy designed an incident notification form for identifying the type of patient incident, including NMI. In addition, the PSI policy explains the Near Miss, as an incident which did not reach the patient. Near Miss Incident (NMI) means that the actual incident did not occur but almost happened and was prevented just in time, such that the incident did not result in harm, or illness but had a potential to do so ((Guillod, 2013) (National Department of Health, 2017)). On the same note, the NDoH designed a form for reporting NMIs and PSIs. The form starts with an incident notification section followed by a statement recording section and ends with an incident investigation section. Ideally, the form is supposed to be completed by a healthcare professional, with statements being recorded from witnesses and an investigation being carried out by the operational manager of the unit in conjunction with the management of the quality assurance unit. It is the quality assurance management that then finalises the investigation and reports the incident to higher level (National Department of Health, 2017).

However, there has been a notable increase in medical malpractice cases in South Africa over the last few years. The majority of the cases occurred in obstetrics, neurology, orthopaedics, and paediatrics. For example, there has been a 550% increase in medical

malpractice claims in the private sector over the 17 years from 2005. As a direct result of the high demand for health care services and the inability of service providers to meet the demand, pressure is exerted on the public healthcare system which finds itself having to cater for 86% of the population. Hence, identifying where and when these incidents occurred and determining the causative and avoidable contributing factors would reduce the chance of reoccurrence ((Pepper & Nöthling-Slabbert, 2011), (South African Law Recommission, 2017)). As a result of the medico legal summit and other initiatives, the SASOG rolled out a program called Better-OBS that addressed standardization of protocols and adaptation of policies to local conditions (Taylor, et al., 2018). Peer review mechanisms were set up with the primary purpose of improving the quality and safety of care in maternal and new born cases (Taylor, et al., 2018).

In averting a national crisis in the healthcare industry, risk management initiatives focus on minimising adverse clinical outcomes, by identifying and managing unfounded claims timeously, and mediating fairly and cost-effectively (Taylor, et al., 2018). The WHO technical working group developed a set of indicators for the assessment of the quality of care within a healthcare facility in order to ensure that the evaluation of quality of care with the near-miss approach is comprehensive enough to ensure a quality audit of maternal health care services (World Health Organization, 2018). Those indicators were adopted and incorporated into the South African National Guidelines for PSI reporting and learning (National Department of Health, 2017). The guidelines mandate all health care professionals (HCPs) to report near miss incidents and other patient safety incidents immediately or as soon as they become aware of them. Patient safety and near miss incidents must be tracked and analysed in order to determine the need for any improvements to service delivery (National Department of Health, 2017). Accurate and timeous reporting of NMIs provides healthcare establishments with early warning signals hence, opportunities to address the situation before it gets out of hand (Van Spall, Kassam & Tollefson, 2015).

1.2 PROBLEM STATEMENT

The ultimate goal of a health system is to improve people's health by providing comprehensive, integrated, equitable, quality, and responsive health services ((World Health Organization, 2010); (National Department of Health, 2015)). One of the steps towards improving the health system is to identify NMIs, decrease the occurrence of patient incidents and in turn reduce the chances of medico legal claims against the HCPs. It is evident that the interrogation and analysis of NMIs leads to informed recommendations and sustainable quality improvement plans that will equip HCPs with tools to ultimately eliminate patient safety threats through proactive near miss reporting and prevention of avoidable PSIs. If healthcare facilities become accustomed to immediately reporting and interrogating NMIs, patient safety risks could be substantially reduced in the healthcare system as a whole (National Department of Health, 2017). For these reasons, HCPs are expected to report and record all patient-safety incidents and their outcomes, participate in open disclosure and investigation of the incident, finalise incident reports within 60 working days, and participate in the implementation of recommendations arising from the investigation of incidents, and motivate colleagues to feel free to report incidents (National Department of Health, 2017).

The problem is that NMI remain underreported despite the attempts to establish reporting systems across the entire healthcare industry. A variety of managerial and individual factors influence reporting of healthcare errors, including uncertainty of what to report, lack of feedback, fear of punishment and victimisation ((Archer, Hull, Soukup, Mayer, Athanasiou & Sevdalis, 2017); (Chiang, Lee, Lin & Ma, 2019)). This has unfortunately led to the numerous cases of nursing malpractice which contributed considerably to the increase in civil claims against public and private hospitals in the year 2018 (Stellenberg, Whitaker, Williams & Samlal, 2018). Further investigations revealed that there were numerous instances in which healthcare service providers were not adherent to patient management and monitoring guidelines (Stellenberg, et al., 2018). Of 122 cases of medical negligence studied, 20% had resulted in patient death and 74% were settled out of court (Stellenberg, et al., 2018). The factors contributing to civil claims that were identified included, failure to follow guidelines (91%), lack of knowledge (75%), poor

monitoring of patients (69%), failure to administer prescribed medication (66%), failure to respond to clinical signs (63%) and insufficient training (52%) (Stellenberg, et al., 2018). According to global estimates, at least twenty patients will experience preventable harm while in a healthcare facility and some will suffer long-term disability and even death (Panagioti, Khan, Keers, Abuzour, Phipps & Kontopantelis, 2019).

The Eastern Cape health department is burdened with contingent liabilities that are unbudgeted for (Kahn, 2018). Annual trainings have been conducted on reporting NMIs and other PSIs at the selected district hospital. However, it was observed that, despite annual training at the selected district hospital, near-miss incidents remain unreported. During interviews with the DoH's legal representatives when seeking clarifications on existing medico-legal cases, HCPs became more aware of this issue.

Preventable harm is a serious problem in health care settings (Panagioti, et al., 2019)The fact that NMIs and PSIs continue to go unreported suggests that HCPs might be facing some challenges in that respect. In this regard, this study was conceptualised with the intention of identifying challenges faced by HCPs in reporting near miss and PSIs. Besides identifying the challenges, this study also looked at the potential problems with the reporting process itself.

1.3 AIM OF THE STUDY

The goal of this study was to identify challenges faced by health care professionals that could influence the quality of care at one state-funded district hospital. Importantly, this study aimed at developing recommendations to assist healthcare management and HCPs with the process of NMIs.

1.4 RESEARCH OBJECTIVES

The main objectives of this study were to:

- Determine the prevalence of unreported or late reported NMIs at a hospital, in the Amathole District during the year 2019.

- Identify challenges encountered in reporting NMIs at the selected hospital, in the Amathole District during 2019.
- Determine the NMIs frequency, types and severity of complications that occurred throughout the year 2019 at the selected hospital, in the Amathole District
- To come up with recommendations on the reporting of NMIs at the selected hospital, in the Amathole District.

1.5 RESEARCH QUESTIONS

- What is prevalence of unreported and late reported NMIs at a hospital, in the Amathole District during 2019?
- What are the challenges encountered in reporting NMIs at the selected hospital, in the Amathole District during 2019?
- What is the NMI frequency, types and severity of complications that occurred throughout the year 2019 at the selected hospital, in the Amathole District?
- What are the recommendations on the reporting of NMIs at the selected hospital, in the Amathole District?

1.6 RESEARCH METHODS AND DESIGN

1.6.1 Research methodology

This study used a mixed method approach to address the key research objectives, both qualitative and quantitative methods. A mixed methods approach is described as a research methodology in which two research designs are utilized in order to better represent truth (Gray, Grove & Sutherland, 2017).

1.6.2 Research design

A research design, also called a research strategy, is an attempt to find answers to a particular set of questions (Gray, et al., 2017). This means that the research design describes the process of investigating the central problem.

In relation to the qualitative methodology, the study focused on exploratory-descriptive qualitative research design and a descriptive design on the quantitative methodology was used to investigate further the challenges faced by HCPs in reporting NMIs within a hospital (Gray, et al., 2017).

1.6.3 Population

A research population is generally a large collection of individuals or objects that is the main focus of a scientific enquiry. The common characteristics of the groups distinguish them from other individuals, institutions or objects ((Creswell, 2013); (Gray, et al., 2017)). Therefore, population for this study comprised all HCPs regardless of gender, cultural group, and religious affiliations. These included medical officers, radiographers, pharmacists, operational managers, and professional nurses. These are professionals who are registered with a South African healthcare professional body, and are allowed to report PSIs in their facility.

1.6.4 Sampling

The process of sampling is the selection of individuals, events, behaviours, or other elements for study purposes (Gray, et al., 2017). According to Polit & Beck (2012); Majid (2019) a sample is a subset of a population comprising of only those who are selected to participate in a study while sampling is the process of selecting a portion to represent the entire population. Therefore, convenient and purposive sampling was used for selecting participants. A purposive sample has characteristics that are defined for a purpose that is relevant to the study. A convenience sample is drawn from a source that is conveniently accessible to us ((Brink, et al., 2010); (Andrade, 2021)) The researcher selected, who met the sampling criteria and were willing to participate in the study. Everyone who is registered with a South African healthcare professional body and who is allowed to report patient safety incidents in their facility was eligible to participate in the study regardless of their gender, cultural background, or religious affiliation.

The district hospital was conveniently selected by the researcher because of accessibility

and number of near miss incidents observed. Purposive sampling was further used to identify information-rich participants who could supply the information required to answer the research questions ((Patton, 2015); (Marshall & Rossman, 2016); (Gray, et al., 2017)).

The study population was accessed through relevant stakeholders, including the provincial office of the Eastern Cape Department of Health, district and facility levels, individual participants and the University of Fort Hare. The documentation confirming the permission of these institutions and individuals is attached as annexures A to G.

Moreover, in order to gain access to the participants who met the sample criteria, the researcher arranged gatekeeping with one of the hospital managers (Creswell, 2013). There are various ways to describe a gatekeeper such as, someone or something that regulates access to an institution or organisation; or monitors, selects, and restricts information. As a result, the gatekeeper was provided with the research details, sample criteria and was the one who selected individuals for participation in this study (Singh & Wassenaar, 2016). A gatekeeper acts as a liaison and coordinator between the organisation and the researcher, who is outside the organisation. For example, access to the target sample was controlled by the gatekeeper, who was a trusted source with access to the target group, including information on the availability of subjects (Singh & Wassenaar, 2016).

1.6.5 Method of data collection

The data collection procedure refers to the process of gathering, measuring, and analysing accurate insights in order to find the most relevant research information that enables the researcher to answer stated research questions, test hypotheses, and evaluate outcomes ((Brink, et al., 2013); (Gray, et al., 2017)). The data collection exercise was carried out in two phases: The information collected in the first phase addressed the first two objectives. Information about the number of unreported or late reported NMIs, and the complications were determined using the WHO Near-Miss Approach. In the

second phase, individual and focus group interviews with healthcare professionals were carried out. These interview discussions were designed to identify the challenges and barriers HCPs face in reporting NMIs.

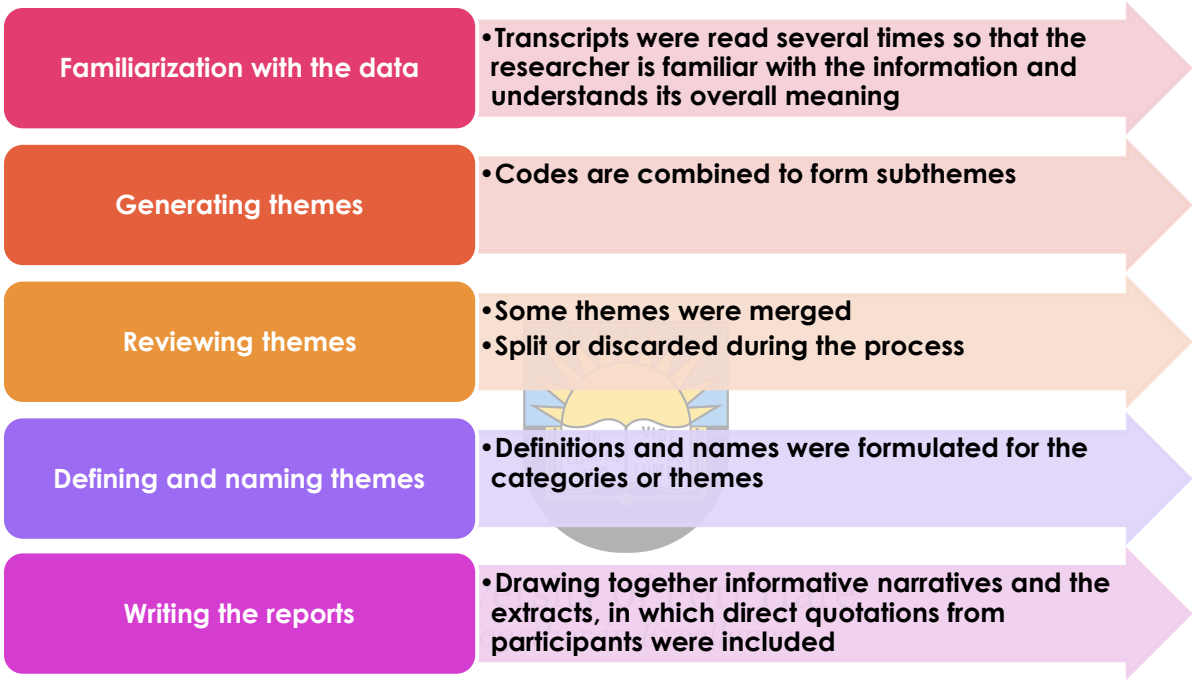
1.6.7 Data analysis

Data analysis is a process of organizing, representing, describing, evaluating, and interpreting data ((Brink, et al., 2013); (Gray, et al., 2017)) Qualitative and quantitative data analysis methods were used in analysing data for this study. Quantitative data analysis refers to analysing the prevalence, relationship, and cause of a phenomenon while, in qualitative research, it refers to the reduction and organization of data, as well as the revelation of meaning through the analysis of data (Gray, et al., 2017). A non-interventional descriptive analysis was used in the quantitative approach to investigate the number of late or unreported near misses (NMIs), using PSI records, maternity records, and minutes from perinatal audit meetings (Gray, et al., 2017). As summarized in figure 1 and attached as Annexure L, descriptive statistics were used to describe sample characteristics ((Kellar, Kelvin & Munro, 2013); (Kaliyadan & Kulkarni, 2019)). Quantitative data was checked, processed, and entered using SPSS version 20 statistical software for further analysis.

In contrast, qualitative data analysis involves integration and synthesis of narrative non-numeric data that are reduced to themes and categories, with the aid of a coding procedure. This analysis does not produce statistical quantities but rather a deeper understanding of the meaning of what people are saying ((Brink, et al., 2013); (McMillan & Schumacher, 2014)). Hence, the data analysis for this study involved reading through transcripts, one at a time, while taking note of the central ideas emanating from responses. Datt & Chetty (2016) state that the emerging ideas are then compared across transcripts and those that are common across transcripts grouped accordingly (Datt & Chetty, 2016). The interviews were transcribed verbatim and translated into English, as some of the interviews were conducted in an African language (IsiXhosa), and organised into themes and sub-themes.

In most qualitative studies, the researcher will identify a philosophical perspective, but may not identify a formal theoretical framework. Theoretical frameworks are used in quantitative and outcome studies, sometimes in qualitative studies, and rarely in mixed methods studies (Gray, et al., 2017). Therefore, a preliminary coding framework was developed, as per Figure 1 below.

Figure 1: Preliminary coding framework



The figure above is the preliminary coding framework summary which represents the Tesch coding steps and direct quotations from the study participants. Using the steps provided by Tesch, to analyse data systematically, the analysis was conducted in the following phases. (i) Familiarization with the data: the transcripts were read several times so that the researcher is familiar with the information and understands its overall meaning. The first task in coding is to generate an initial code for the entire dataset (and its labels) as well as initial coding for important data points (Creswell, 2014).

A preliminary coding framework was developed by synthesizing concepts from previous studies. As the process progressed, new codes were anticipated and compared with the original codes. (ii) Generating themes: codes are combined to form subthemes

(subcategories) that are then boiled down to create themes (categories). (iii) Reviewing themes: some themes were merged, split or discarded during the process. (v) Defining and naming themes: definitions and names were formulated for the categories or themes. (vi) Writing the report: it involved drawing together informative narratives and the extracts, in which examples were chosen to illustrate a particular idea (Creswell, 2014).

During transcription and the analysis process, grammar and repetitions of words were left unchanged, thereby prohibiting the possibility of losing any information. The narratives were similarly left unchanged and were analysed in conjunction with the transcribed interviews. A consensus discussion was held with an independent coder to discuss the results ((Creswell, 2014); (Gnoni & Saleh, 2017)). For further analysis, the transcripts were imported into NVivo V.10, a software package for managing and analysing qualitative research data (Mitchell, Schuster, Smith, Pronovost & Wu, 2016). The results of the study were then triangulated using quantitative and qualitative data to ensure validity and reliability (Gray, et al., 2017) and into the themes that emerged (Marck, Molzahn, Berry-Hauf, Hutchings, Hughes, 2014). The study findings were used to formulate recommendations for improving the reporting of NMIs in the healthcare facilities, in the Eastern Cape. Conversely, field notes, observations, and the experiences of the researcher, as well as direct quotations from participants were analysed, and incorporated into the transcriptions (Creswell, 2014).

1.7 LITERATURE CONTROL

A literature control from national and international publications was done to compare the results to the existing body of knowledge. The literature is reviewed after data collection and analysis so that the information in the literature does not influence the researcher in any way ((Brink, et al., 2010); (Gray, et al., 2017)).

Patient harm occurs across a range of medical settings and differ in severity and outcome. Globally, about 12% of preventable harm is severe and results in long term to permanent disability or death, while 49% of incidents relates to medication and treatment errors (Panagioti, et al., 2019). Besides improving patient care, prevention of preventable patient

harm would directly positively affect cost savings for health care facilities. Preventable patient harm is highest in surgical and intensive care units and is lowest in obstetric units (Panagioti, et al., 2019). In contrast, in South Africa, obstetric units account for the bulk of medico-negligence claims (Taylor, et al., 2018). Maternal health care settings offer antenatal care services geared towards early detection and prevention of harm during pregnancy, labour, and delivery (World Health Organization, 2011). Such services are indicators of the quality of care that is given to the mother and her baby (World Health Organization, 2011). However, the global incidence of fatal patient safety incidents remains high ((Bashir, Kong, Buitendag, Manchev, Bekker & Bruce, 2019).

A study in Malaysia found that most patient safety incidents were not reported and that less than 50% of medication errors are reported (Samsiah, Othman, Jamshed & Hassali; 2016). In Saudi Arabia, about 79% of incidents were not reported as a result of health professionals' concerns with the reporting process (Samsiah, et al., 2016). The same tendency was found in Iran, where nurses were reluctant to report near miss incidents, despite the reporting system being anonymous (Fathi, Hajizadeh, Moradi, Zandian, Dezhkameh, Kazemzadeh & Rezaei, 2017). Presently, there are serious concerns regarding medical negligence in South African healthcare system (Taylor, et al., 2018). If patient safety concerns in obstetric units are not addressed, the South African healthcare system faces a real prospect of paralysis of service delivery (Taylor, et al., 2018).

The Minister of Health held a medico legal summit in 2015 to consider the escalation of medico legal claims in both the public and private sectors. In the discussion document, comparisons were made and the approach to malpractice claims was described in terms of international practice. Poor record generation and keeping, insufficient patient data security, low staff morale and unprofessional behaviour, lack of equipment and human resources, and the defence of cases without merit were identified as causes of the increase in medical malpractice litigation (Dhai, 2015).

There is minimal published literature on the topic of NMIs, specifically about South Africa, not to mention the Eastern Cape province. A retrospective cohort study was conducted

in South Africa for a period of five years to determine the incidence, nature and causes of PSIs in long-term rehabilitative hospital. Various forms of information, including hospital records, adverse health events meetings minutes, quality assurance reports, and patient complaints registers, were reviewed and analysed. According to the findings of the study, there was a low reporting rate of PSIs, regardless of the fact that the incidents demonstrated a variety of patterns over time (Mgobozi & Mahomed, 2021).

According to another retrospective study, which used a screening criterion, medical record review was conducted in acute care hospital settings on adult patients to update recent in-hospital adverse event figures. Researchers selected papers for review based on specific criteria, and it was found that 10% of inpatient stays resulted in adverse events, half of which could have been prevented. Adverse events occurring in the hospital varied considerably, and their incidence was estimated to be a tenth of inpatient stays (Schwendimann, Blatter, Dhaini, Simon, & Ausserhofer, 2018).

Hewitt, Chreim & Forster, 2017, described three main frames used by frontline HCPs that serve as barriers to self-reporting, these include fear of blame, incompetence, and career progression, and other frames that inhibit peer reporting include gossip, position of responsibility and professional boundaries. These authors concluded that blame, incompetence and career progression inhibit healthcare professionals from reporting near miss incidents, naturally. Whereas, the current (National Department of Health, 2017), guideline policy for PSIs states that HCPs should not be victimised solely reporting PSIs, it promotes a Just Culture that supports a learning organisation that investigates incidents instead of blaming individuals.

Nonetheless, the purpose of both the above mentioned study designs is to profile practice patterns, and to figure out possible causal relationships for further analysis (Gray, et al., 2017). Therefore, the current study was a baseline study in which the objective is to establish the status quo. The researcher simply had to listen to participants and develop an understanding of the challenges in reporting near miss incidents and their possible impact to the quality of care, in addition to document review (Creswell, 2014). Among the

benefits of incident reporting and investigation are improved patient satisfaction with health services, reduced avoidable mortality, harm experienced during care, and lower medico-legal costs. (National Department of Health, 2017). As a result, this study did not pose any risks.

The current study culminated with investigating the challenges faced by HCPs in reporting NMIs and the development of recommendations, which hopefully, will motivate healthcare professionals to timeously report near miss incidents and institute interventions and mediation, avoid injury to patients and staff, and prevent the re-occurrence of mistakes, as a way of reducing the financial burden of medical negligence claims.

1.8 TRUSTWORTHINESS

The researcher ensured trustworthiness by using four dimensions of trustworthiness, namely, credibility, transferability, dependability, and conformability. Relevant information about the study was provided, and written informed consent was obtained before conducting the research (Carter & Bryant-Lukosius, 2014). The interviews and other research materials were kept in a safe place throughout the duration of the study (Shenton, 2014). During the interviews, observations and field notes were collected from the different types of participants (Carter & Bryant-Lukosius, 2014). So, direct quotes from participants were preserved in order to ensure conformability by working forward and backwards to interpret findings. Furthermore, a detailed, in-depth report was concluded based on the data collected (Shenton, 2014). Lastly, the existing literature was reviewed after collecting and analysing data to avoid bias ((Brink, H.; Van Der Walt, C.; Van Rensburg, G, 2012); (Datt & Chetty, 2016)).

1.9 ETHICAL CONSIDERATIONS

It is important that any research, especially those involving humans, be ethical in terms of its objectives, methodology analysis (Muller & Bester, 2016). The research study met the ethical requirements as supported by the ethical clearance certificate issued by the

University of Fort Hare ethics committee. The ethics clearance certificate is attached as annexure.

Basic human rights, which include the right to self-determination; privacy; anonymity and confidentiality; informed consent; fair treatment and protection from discomfort and harm were all observed in the execution of this study ((Brink, et al., 2010); (Gray, et al., 2017)). In this study, interviews were conducted in person, anonymously, and recorded. Written informed consent was obtained from all interviewed participants, and all personal information was removed from the interviews ((Brink, et al., 2010); (Gray, et al., 2017)). Anonymity was guaranteed because the participants and health care institution's names were not mentioned in any report, participants were also unknown to the researcher, as a result random codes were generated for each participant ((Creswell, 2013); (Gray, et al., 2017)).

In addition, participants were individually informed about the venue, date and time of data collection and invited to express any concerns they might have. All participants were comfortable with these aspects of the data collection exercise. The participants were not coerced to participate in the study ((Brink, et al., 2010); (Gray, et al., 2017)). A fair and respectful data collection process was followed to reduce the likelihood of subjects withdrawing (McCullagh, Sanon & Cohen, 2014). Data, including the transcribed data, was kept confidential and could only be accessed by the researcher, supervisors, and co-coders. After the acceptance of the research report, the recorder and verbatim transcriptions were destroyed. However, participants can still request a copy of the research report ((Brink, et al., 2010); (McCullagh, et al., 2014))

1.10 PERMISSION

The permission to carry out this study was sought from all the relevant stakeholders, namely, the Eastern Cape Department of Health at provincial, district and facility levels, the individual participants and the University of Fort Hare. All these institutions and individuals granted their permission and the documentary proof to that effect is attached as annexures A to G.

1.11 SIGNIFICANCE OF THE STUDY

The importance of this study is to help provide systems that will profile practice patterns, and to figure out possible causal relationships for further analysis (Gray, et al., 2017). Therefore, the current study was a baseline study in which the objective is to establish the status quo. For instance, the researcher simply had to listen to participants and develop an understanding of the challenges in reporting NMIs and their possible impact to the quality of care. The study findings aims at assisting the NDoH to improve patient satisfaction with health services, reduced avoidable mortality, harm experienced during care, and lower medico-legal costs (National Department of Health, 2017). The current study culminated with the development of recommendations which, hopefully, will firstly motivate HCPs to timeously report NMIs and institute interventions, secondly, to avoid injury to patients and staff, and finally to prevent the re-occurrence of mistakes, as a way of reducing the financial burden of medical negligence claims.

1.13 SUMMARY

This chapter introduced the topic, "Challenges faced by Healthcare Professionals in reporting Near Miss Incidents in a Hospital, Amathole District, Eastern Cape, South Africa" and provided an overview of the phenomenon under study. This study aimed to explore and describe the reasons why HCPs are not reporting NMIs based on information from one district hospital. This chapter further discussed the background of the study and the research problem. The research objectives and questions were also outlined. A summary of research methodology and design, and the permission of this study were provided. Finally, the significance of the study was discussed. Understanding the reasons or factors of relapse will assist in the formulation of recommendations which will assist the health care professionals and managers to adjust the program and prevent or reduce actual PSIs and possible medico legal claims. In the next chapter, the methodology used to address the research questions will be discussed.

1.13 CHAPTER OUTLINE

CHAPTER 1: INTRODUCTION AND BACKGROUND INFORMATION

1.1 INTRODUCTION

1.2 PROBLEM STATEMENT

1.3 AIM OF THE STUDY

1.4 RESEARCH OBJECTIVES

1.5 RESEARCH DESIGN AND METHODS

1.5.1 Population

1.5.3 Method of data collection

1.5.4 Data analysis

1.6 LITERATURE CONTROL

1.7 TRUSTWORTHINESS

1.8 ETHICAL CONSIDERATIONS

1.9 PERMISSION

1.10 SIGNIFICANCE OF THE STUDY

1.11 DEFINITION OF KEY CONCEPTS

1.12 SUMMARY

CHAPTER 2: RESEARCH METHODS AND DESIGN

2.1 INTRODUCTION

The previous chapter gave an overview of the research study. In that chapter, a background to the study was presented together with the statement of the problem, aims, objectives, methodology and ethical considerations. In this chapter, the methodology adopted for the study will be presented in greater detail. The population will be defined and the sampling and data collection procedures will be described. The chapter concludes with an assessment of the data collection process in terms of ethical considerations.

2.2 RESEARCH METHODOLOGY

The key research objectives were addressed using both qualitative and quantitative methods in this study. Using mixed methods means employing two research designs to better represent truth in research (Gray, Grove, Sutherland, 2017). A number of advantages can be gained by researchers who use qualitative and quantitative research methods in their research (Creswell, 2016). This study used parallel mixed methods to examine both types of data throughout the data collection and analysis process, so there are multiple points of convergence (Gray, et al., 2017).

A qualitative research methodology describes life experiences, cultures, and social processes from the perspective of the people involved through scholarly and rigorous analysis (Gray, et al., 2017). This approach involves collecting data in a natural setting that is sensitive to the people and places under study, and the data are analyzed using both inductive and deductive principles to establish patterns or themes ((Creswell, 2013); Renjith, Yesodharan, Noronha, Ladd, George, 2021). Qualitative research allows participants to express themselves and provide richer information on the issues under study ((Creswell, 2013); (Renjith, et al., 2021)). This research method is suitable for studying subjective human experiences and it uses non-statistical methods of analysis ((Borbasi & Jackson, 2012); (Renjith, et al., 2021). Therefore, this approach fits the

purpose of the study, which is to explore the complexities of human experiences through naturalistic inquiry ((Moxham, 2012); (Renjith, et al., 2021)). Since the aim of this study was to explore the challenges that healthcare professionals experience in the clinical setting, qualitative approach is appropriate as it allows for gathering of information on variables that cannot be easily measured.

On the other hand, quantitative research refers to a formal, objective, systematic study process in which data is analyzed numerically in order to answer a research question (Gray, et al., 2017). Research in quantitative methods involves describing variables and concepts, examining their relationships, and determining the effect of interventions on outcomes. As a result, the validity of the relationships that make up a theory can then be evaluated using this method (Chinn & Kramer, 2015).

The researcher hoped to understand attitudes that impact on the reporting of near miss incidents and provide the management with an explanation for the apparent lack of reporting. This detail could only be established by talking directly to the affected people, going to their homes or places of work, and allowing them to tell their stories freely in addition to document review ((Creswell, 2013); (Renjith, et al., 2021)). The research was based on document review and one open-ended question and follow up questions emanating from the responses to the original question (Mitchell, et al., 2016). Rather than generalizing the findings, the purpose of this study was to provide insight into why HCPs face challenges in reporting NMIs (Holtzblatt & Beyer, 2014). The transcription of interviews was done accurately and verbatim in order to avoid changing the meaning. As a final step, a total of two narratives were received and analysed (Shenton, 2014).

Additionally, a qualitative approach allowed for genuine ideas to be collected from participants (Creswell & Creswell, 2018). These ideas were then turned into data and resulted in the creation of valuable content and insights specific to the participating hospital (Creswell & Creswell, 2018). Subsequently, the qualitative method helped the researcher to uncover ideas, incorporate human experience, and access the emotional data that drives decision-making responses (Moxham, 2012). The researcher went to a great extent to explain to participants that every perspective was important and would

contribute to more accurate conclusions of this study. For the quantitative approach, retrospective data was analyzed from PSI records, maternity records, and perinatal audit meeting minutes, using a non-interventional descriptive method primarily to analyze pre-existing data, to investigate the number of late or unreported NMIs (Gray, et al., 2017). A review and recommendations were developed with the intention of improving actual practice.

The researcher utilized experience as a data collector, as well as the advice of experts in qualitative and quantitative research, to ensure she acquired the necessary skills to use each research design. A detailed review of literature on the role of the researcher in qualitative and quantitative research was carried out. That role revolves around accessing the thoughts and feelings of the study participants in a comfortable and relaxed environment, while protecting them and their information. That role is not always easy, especially in situations where participants are expected to give personal and/or confidential information.

Mechanisms for such safeguarding of both participants and their data were clearly articulated to participants and approved by the university research ethics review board, the Eastern Cape DoH Research Committee and the Amathole District before the research began (Sutton & Austin, 2015). In the qualitative approach, all components were organized in to the research design in a way that most likely leads to valid answers to the questions posed. Study protocol provided an outline for conducting a study in a way that maximizes control of variables that could compromise validity (Burns, et al., 2016).

2.2.1 Research Design

All research studies, whether historical, descriptive or experimental, need a plan or general design to direct the enquiry about a problem question. Basically, a research design is an attempt to answer a certain set of questions (Gray, et al., 2017). It is a framework for collecting, analyzing, and interpreting data including the methods and procedure (Ranganathan & Aggarwal, 2018). This includes all the other components of a

study, like variables, hypotheses, experiments, methodology, and data analysis (Creswell & Creswell, 2018). In other words, the research design describes how the researcher will investigate the central problem of the research.

With regard to the qualitative study design, the study focused on exploratory-descriptive qualitative research design. This design is characterized by identifying a specific lack of knowledge that can be addressed only through seeking the viewpoints of the people most affected, with the intent of describing and promoting understanding of for examining health care phenomena (Gray, et al., 2017). Public health in South Africa lacks information about medico-legal claims related to patient safety incidents (Kahn, 2018). More importantly, NMIs may be used as a safety indicator, and if they are included on patient safety incident reports, they will provide valuable insight into trends so that medico-legal liabilities can be avoided (Sheikhtaheri, 2014).

The study was meant to describe the lived experiences of the study participants in order to understand their views. This approach was appropriate for studying the lived experiences of HCPs in reporting of NMIs within their healthcare facility ((Brink, Van Der Walt & Van Rensburg, 2010); (Gray, et al., 2017)).

Consequently, the process required the researcher to become totally connected with the phenomenon under investigation, assisted by the participants' view of their experiences. In order to identify patterns, the researcher compared the data repeatedly until there was a common understanding ((Brink, et al., 2010); (Marshall & Rossman, 2016)).

During this process, the bracketing approach that is commonly used in Phenomenological designs was incorporated in order to assist the researcher with identification and setting aside of any preconceived beliefs and opinions about the phenomenon under investigation. In other words, the researcher eliminated any preconceived ideas and beliefs about the phenomenon under investigation and collected all the data from the participants (Brink, et al., 2010); (Dörfler & Stierand, 2020)

Based on quantitative research, a descriptive design was used to investigate further the challenges faced by HCPs in reporting NMIs within a hospital in the Amathole District, in

the Eastern Cape Province. In quantitative research, a descriptive design is used to address questions about incidence, prevalence, or frequency of occurrence of a phenomenon of interest (Gray, et al., 2017). Hence, a non-interventional descriptive method was used to analyze retrospective data which derived from health records. This was meant to examine various aspects of quality of care using this method primarily to analyze pre-existent data (Gray, et al., 2017). As a result of the mixed research strategies, it was possible to determine the number of unreported or late reported NMIs based on pre-existing data and find out more about participants' experiences, opinions, and behaviours. In essence, the interactive process involved one-on-one interaction with each participant which resulted in more complex and richer information.

2.2.2 Population

An entire collection of objects or people the researcher is particularly interested in and meets the criteria that the researcher is interested in studying is referred to as a population ((Brink, et al., 2013); (Gray, et al., 2017)). The researcher therefore identified the study population as well as the concepts that were expected to constitute the study's major variables, and the relationships among them have been identified. Grey, et al; (2017) argued that the research question in a technical sense does not specify how variables will be measured.

The population was made up of all HCPs, who are between the ages of 21-64 years, whose respective professional bodies permit them to report PSIs, and were willing to participate in the study. The participants included medical officers, radiographers, pharmacists, operational managers, and professional nurses. Therefore, the participants were representative of the study population and included subjects of various ages, ethnic backgrounds, different professional bodies, and socioeconomic levels (McCullagh, et al., 2014). In the second phase of the study, there were a total of 15 participants, 11 of which were females. A total of 15 participants participated in the study, including 9 nursing professionals, 2 medical officers, 2 radiographers, 1 pharmacist, and 1 physiotherapist.

2.2.3 Sampling site and study sample

The study was conducted at a state-funded health care facility in the Amathole District of the Eastern Cape Province. The hospital is a Level 1 district hospital with 180 approved beds and is located in one of the rural towns of the Amathole District, of the Eastern Cape Province (Statistics South Africa, 2011). The hospital renders a wide range of services, including, medical, surgical, pharmaceutical, radiography, physiotherapy, and rehabilitation services. It also renders dietetics and dental services, 72-hour observations for mental health and obstetrics. On average, the maternity unit delivers about 357 babies per annum. The facility head count in the year 2019 was 16 368 out-patients and 19 808 in-patient days. The staff compliment comprised of six doctors, two pharmacists, three radiographers, a dietician, a physiotherapist, 54 professional nurses, and 25 enrolled nurses.

The participants were selected using purposive and convenient sampling methods. The reason for using these two sampling techniques is because they can provide in-depth information needed to achieve the study aim and objectives ((Liamputtong, 2013); (Andrade, 2021)). A purposive and convenient sample of 15 health care workers was selected, based on the inclusion criteria ((Liamputtong, 2013); (Andrade, 2021)). The purpose of sampling is to obtain information about a phenomenon by selecting a sample from a population such that the sample is representative of the population that it was selected from ((Polgar & Thomas, 2013); (Majid, 2019)). Since the researcher had previously worked as a health professional at the same hospital, it was not difficult to establish a good rapport and earn the trust of potential participants. This led to a more open and honest conversation, since the participants did not perceive the researcher as a stranger.

2.2.3.1 Inclusion criteria

An inclusion sampling criteria refers to the requirements for including an element or subject in a sampling process, as identified by the researcher (Gray, et al., 2017). The study participants represented a wide range of ages, ethnicities, professional bodies, and socioeconomic backgrounds (McCullagh, et al., 2014). Only participants who had a

legitimate responsibility to report PSIs met the inclusion requirements. Hence, the participants that were interviewed for the study were multidisciplinary HCPs and comprised of medical officers, radiographers, operational managers, pharmacists, physiotherapists, and professional nurses.

2.2.3.2 Exclusion criteria

In research samples, exclusion criteria are used to exclude certain elements or subjects that may introduce errors in the data and limit the generalization of the study findings (Gray, et al., 2017). Non-clinical staff members who do not report PSIs and their daily jobs does not involve direct patient care were not included in the study. This also included clinical staff members that were not mentioned in the Inclusion criteria.

2.3 TRUSTWORTHINESS

Trustworthiness means to be honest and open about how the research will be conducted. The researcher was honest and explained all the steps she followed when conducting the study, providing authentic information and obtaining written consent from participants prior conducting the study. So, the researcher ensured trustworthiness of the study by using the Lincon and Guba model which sets out the criteria for trustworthiness (Shenton, 2014). The criteria included credibility, transferability, dependability and confirmability.

2.3.1 Credibility

Credibility is confidence in the “truth” of the findings (Shenton, 2014). The researcher ensured credibility of the research by being hands-on during all stages of the study. For example, a good rapport with participants was established to ensure trust between the researcher and the participants. Both data collection and analysis were carried out by the researcher. Moreover, close observation during the interview was maintained to determine non-verbal cues. Subsequently, interviews were conducted until saturation of data was obtained. The interviews were then recorded with participants’ written consent and the researcher ensured that all the recorded information was dated and kept in a safe locked container (Shenton, 2014).

2.3.2 Transferability

Transferability is the extent to which the results of one study can be applied in another setting or sample to develop a detailed database and description (Brink, H.; Van Der Walt, C.; Van Rensburg, G, 2012). The researcher did not allow published literature to influence the results by reviewing the literature after data collection and analysis.

2.3.3 Dependability

The researcher ensured dependability of the study by providing a detailed in-depth report of the findings, so that other researchers can verify them in future. The choice of research design and its implementation were clearly presented and justified (Shenton, 2014).

2.3.4 Confirmability

The researcher guaranteed confirmability by working forward and backward through the research process. This ensured that the interpretation of the findings is sound and complete. In essence, direct quotes of the participants were presented verbatim without any distortion or manipulation (Shenton, 2014).

2.3.5 Triangulation of Data

A combination of contextual information and clarification from participants ensured triangulation. The triangulation approach is used in qualitative research to develop a comprehensive picture of phenomena using multiple methods and data sources. This type of triangulation involved interviewing, observing, and taking notes during data collection. This was done in order to confirm findings and avoid potential bias resulting from personal motives (Carter & Bryant-Lukosius, 2014). Participants were asked to provide a narrative through the planned interviews, to check if they had any additional information to contribute (Creswell, 2013).

The use of multiple methods of data collection about the same phenomenon was followed. The triangulation involved interviews, observation, and field notes during data collection. This reduces the impact of potential bias or personal motivations of the researcher (Carter & Bryant-Lukosius, 2014). Moreover, data source triangulation

involves the collection of data from different types of people, including individuals, groups, families, and communities, in order to gain multiple perspectives and validation. In this study, the subjects were medical officers, radiographers, operational managers, pharmacists, physiotherapist and professional nurses (Carter & Bryant-Lukosius, 2014).

2.4 ETHICAL CONSIDERATIONS

The concept of ethical consideration states that researchers should follow some basic guidelines of behaviour and apply practical strategies that support their actions on the basis of moral principles. Based on moral justification of actions, ethical considerations refer to the standards of behaviour and practical procedures researchers should follow ((Brink, et al., 2013); (Gray, et al., 2017)).

The researcher has read the research Ethics and Regulations, Ethical Principles, the Code of Conduct and the Guidelines in Research of the University of Fort Hare in preparation for this study. The research study was planned in a way that meets ethical acceptability and any doubts regarding ethical procedure was cleared and resolved with appropriate parties. This included: Peer reviews, the academic supervisor and the ethics committee of the University of Fort Hare. Permission to conduct the study was obtained from the ECDoH Research Committee and the Amathole District.

Prior to the interview, the researcher explained all the rights and obligations of the participants during the research process. These included participants' rights to privacy, anonymity and confidentiality, fair treatment, beneficence, and prevention from harm and to withdraw from the study at any stage without suffering any prejudice.

Permission to conduct the research was obtained from each individual participant. These Ethical measures included:

- **Privacy:** The interviews were conducted in private and without interference. Participants were given the opportunity to listen to the recorder to clarify their statements ((Brink, et al., 2010); (Gray, et al., 2017)).

- **Anonymity and Confidentiality:** Anonymity was guaranteed by keeping the identities of both the participants and health care institution anonymous throughout this report. Informed written consent was obtained, and all information that could link the interview to a particular participant was removed. The use, safekeeping and subsequent destruction of the recording was explained to the participants ((Brink, et al., 2010); (Gray, et al., 2017)) Confidentiality was maintained by not linking any information to any specific participating healthcare professional. Only the researcher and the data analyst had access to the recorder and the transcribed data, which was kept in a secure place. Subsequent to the acceptance of the research report, the recorder and verbatim transcriptions were destroyed.

- **Fair treatment, beneficence, and prevention from harm:**

The researcher ensured that she took the responsibility to protect the dignity and welfare of the participants and kept in mind those who would be affected by results of the study. The participants were not coerced in any way to participate in the study ((Lichtman, 2012); (Gray, et al., 2017)). Importantly, no risks were envisaged. The HCPs participated in the research voluntarily and could have withdrawn from the interviews at any time without obligation. As a result, participants were able to express their feelings about the subject under study ((Brink, et al., 2010); (Gray, et al., 2017)). In addition, the researcher ensured that the participants understood the essential points regarding the purpose, content, and process of the study, before consenting to participate ((Brink, et al., 2010); (Gray, et al., 2017)). The participants were therefore granted a written consent and the ethics committee at the University of Fort Hare cleared the study as ethical.

2.5 DATA COLLECTION

Data collection refers to the process of collecting, measuring, and analysing information accurately and using validated procedures ((Brink, et al., 2013); (Gray, et al., 2017)). In this study data was collected in two separate phases, namely, documentary review of hospital records to determine the extent of NMIs reporting in the first phase then individual and focus group interviews in the second phase. In phase 2 of the study, the researcher

invited all HCPs who are required to report NMIs to participate in individual interviews (Carter & Bryant-Lukosius, 2014). Permission to conduct the study was requested and granted from the Eastern Cape Health Department (Annexure E to H).

As part of phase 1 of the study, retrospective data was analyzed using a non-interventional descriptive method, primarily to analyze pre-existing data to determine the number of late or unreported NMs, maternity records, and minutes of perinatal audit meetings (Gray, et al., 2017). The two data collection phases are detailed below.

2.5.1 Phase 1 data collection

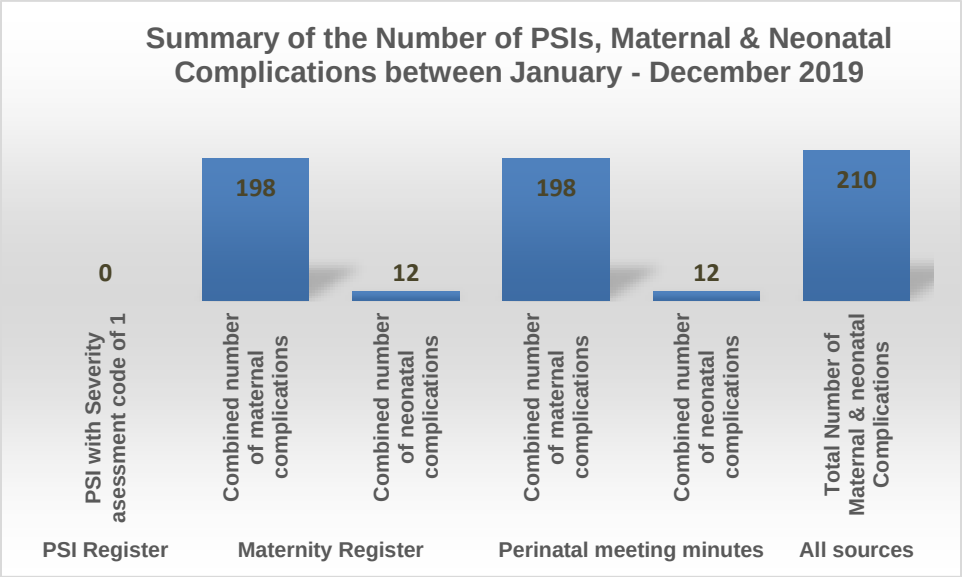
The researcher maintained control over data collection by viewing documents, observing behaviour, and conducting in-depth interviews with participants. The documents were viewed from an access-controlled area, and incidents transcribed from data sources, for the period of January – December 2019, by auditing the paper base PSI register by category of severity assessment code (SAC) 3 reported.

According to (National Department of Health, 2017) the SAC 3 code refers to, no ham or minor harm incidents. There were no SAC 3 incidents recorded on the PSI register. Upon realising that no NMIs were reported for the whole of 2019 from the PSI register, the researcher decided to concentrate on two areas that are high-risk in terms of medical negligence claims. Conversely, the researcher found the quantitative research design chosen particularly useful, as it does not require a specific pattern or format for data collection. The researcher is not constrained by theories or frameworks as long as their investigations take them in a different direction (Kim, Sefcik & Bradway, 2017). These were selected for a closer analysis because most medical negligence claims emanate from these two areas, namely, maternity and neonatal intensive care units (Taylor, et al., 2018).

The researcher proceeded to the maternity register and the perinatal audit meeting minutes for the same period, to audit for maternal and neonatal complications reported

and discussed. A total number of 2010 maternal and neonatal complications were found but not recorded on the PSI register. The data collected from document review is illustrated on figure: 2 below.

Figure 2: Summary of the Number of PSIs, Maternal & Neonatal Complications between January - December 2019



Descriptive statistics were used to describe sample characteristics as summarised in the above figure, and attached as annexure L ((Kellar, et al., 2013); (Kaliyadan & Kulkarni, 2019)). The transcribed data was exported into an Excel spreadsheet, then to the Statistical Package for Social Science (SPSS) version 20, for further analysis.

SPSS is a statistical computer program used for item analysis and correlation analysis of both item-to-item and item-to-total scores. The final step of the study was to triangulate quantitative and qualitative data in order to ensure the validity and reliability of the results (Gray, et al., 2017) into the themes that emerged (Marck, et al., 2014).

The researcher counted the actual number of complications to determine the number of NMIs experienced by mothers and new-borns in the maternity unit for the whole year of

2019. This was achieved by reviewing the maternity register, and the perinatal meeting minutes. Table 1 below lists the maternal complications and the number of cases experienced at the district hospital for 2019. NMIs

Table 1: Maternal complications at the district hospital in the year 2019

Type of complication	**No / year**
Contributory conditions such as maternal health issues such as anaemia or HIV, previous caesarean section, obstructed labour	154
Necessity for blood transfusions, hysterectomy, or other surgical interventions [excluding caesarean sections]	1
Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the mother	1
Maternal deaths irrespective of the duration of pregnancy	0
Maternal near miss [nearly died but survived a complication]	0
Post-Partum Hemorrhage (PPH)	3
Anti-Partum Hemorrhage (APH)	3
Severe Pre-Eclampsia, Eclampsia	1
Gestational Hypertension (GHPT)	35
Ruptured uterus	0
Total number of maternal complications	**198**

Table 1, show that there were 198 maternal complications out of 357 deliveries. Despite being discussed during the perinatal meeting, none of these PSIs were recorded in the PSI register. Health system shortcomings are apparent in the failure to identify NMIs in the maternity unit of the hospital as well as a lack of understanding of the reporting system.

Table 2 below summarizes sample characteristics using descriptive statistics, attached as annexure L. The researcher looked at neonatal complications experienced in the year 2019 on the table below.

Table 2: Neonatal complications at the district hospital in the year 2019	
Type of complication: Neonate	**No/year**
Severe life-threatening neonatal complication such as birth asphyxia, foetal distress	5
Low Apgar scores and prematurity	2
Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the baby	2
Neonatal deaths irrespective of gestation (including FSBs)	3
Maternal near miss [nearly died but survived a complication]	0
Total number of neonatal complications	**12**

Table 2 shows that there were five severe life-threatening neonatal complications. These are: birth asphyxia, foetal distress, two low Apgar scores and prematurity; two admissions to intensive care or transfer to higher levels of care, intubation, and ventilation of the babies, and two neonates who died. Hence, NMI report was found on the patient safety incident reporting system or documents. The lack of reporting of adverse neonatal outcomes is concerning as the healthcare facility.

With regard to the maternal near miss approach, data from the PSI register, the Maternity register, and the minutes from perinatal meetings were categorised (World Health Organization, 2011), transcribed on the observation guide, which is attached as annexure L. This was meant to assist in recording extracted data from the mentioned data sources, and summarized with descriptive statistics in Table 1 and 2. For further analysis, the quantitative data was checked, edited, and entered using SPSS version 20 statistics software. The results of the study were then triangulated using quantitative and qualitative data in order to ensure validity and reliability (Gray, et al., 2017) into the themes that emerged (Marck, et al., 2014).

2.5.2 Phase 2 data collection

The second phase of the study commenced once the number of NMIs at the hospital had been determined. As a result of COVID's strict requirements, data collection dates were

scheduled throughout the year. The reason for this was to minimize the risk of infection, accommodate inter-provincial travel restrictions for the researcher and co-coder, and ensured that the data could be collected at the most convenient time for the participants. Therefore, the dates for data collection were agreed upon with the participants and were set for the 27th – 30th December 2020 for document data review and individual interviews; 12th – 15th April 2021 for confirmation of themes and narratives; and the 23rd – 26th August 2021 for focus group interviews.

Before the interviews could commence, the COVID - 19 pandemic changed the landscape significantly, and the researcher had to adjust the interviewing program to accommodate the participants. Interviews could not proceed as planned, because of the immense pressure on the hospital and staff members hence had to be rescheduled on numerous occasions. The basic structure of the interviews remained the same, however, COVID - 19 prevention measures had to be implemented and this inconvenienced both the interviewer and the interviewees. In that case, it was necessary to refocus the participants during the interview; so the researcher had to continuously guide the participants to stay on the topic under discussion. This made the interviews longer than anticipated.

On the 13th of March 2020, the WHO declared COVID-19 a global pandemic, just after South Africa had detected their first case on the 5th of March 2020. Thereafter, there has been several infection control measures applied across the globe, including South Africa. The infection control measures include, surface cleaning and disinfecting, hand hygiene, screening, protective equipment and clothing (National Department of Health, 2020a). The South African Department of Health recommended that everyone to wear a cloth mask that covers the nose and mouth when in public to reduce the spread through droplets (National Department of Health, 2020a). Therefore, participants were expected to wear a cloth or surgical mask upon arrival for the interview, the researcher was wearing a surgical mask and face shield throughout the interviews. Equally, each participant had access to a surgical mask provided by the researcher if desired. Participants were to wear cloth or surgical masks throughout the interview and sit two metres away from the researcher (National Department of Health, 2020a).

A separate register from the field notes was made available for the researcher to record the participants' names, identity numbers, and responses to the COVID-19 symptom questionnaire and temperature readings. The register was shredded after eleven days post interviews as no one developed any COVID-19 symptoms from the participants. The questions included; fever; cough; sore throat; loss of smell; body aches; nausea; vomiting, diarrhoea, red eyes among others. If any of the responses to the questionnaire is in the affirmative, the participants would not be allowed to participate in the interviews and advised to seek medical assistance (National Department of Health, 2020b). Fortunately, none of the participants had COVID-19 symptoms.

The researcher adopted the WHO recommendation of using a hand rub with 80% concentration of ethanol and 75% concentration of isopropyl alcohol, to ensure superior effectiveness in killing microorganisms. As a result, the researcher provided participants with an alcohol hand rub with 75% alcohol to spray on their hands before and after the interview. The most frequently touched areas, such as arm rests and table edges were wiped down with wet wipes that contain 75% alcohol, before and after each participant to prevent cross contamination of any pathogen (World Health Organization, 2015).

Importantly, phenomenological interviews were conducted to determine the barriers that HCPs experience in reporting NMIs at the district hospital. In essence, the phenomenological interviews were used to obtain in-depth understanding of individual phenomena and richer data from experiences of the participants ((Brink, et al., 2010); (Creswell & Poth, 2018)). Therefore, a phenomenological researcher is free to structure his or her interview in a way that enables a thorough investigation. Phenomenological theory has sufficient structure to examine an experience through interview in an explicit way, which can be done flexibly. Structure in the phenomenological interview method to be explained here is provided by the following key concepts: description, natural attitude, lifeworld, modes of appearing, phenomenological reduction, and imaginative variation (Bevan, 2014).

In addition, volunteers met with the researcher in a space of their choice, which was at the district hospital, away from where COVID-19 patients were admitted; where the research objectives were explained. The informed and written consent for participants was obtained and appointments for interviews were pre booked to avoid intrusion. Intrusiveness is intruding on the participant's time, intruding on their space, and intruding on their personal lives (Lichtman, 2012). It must be noted that the selected venue and time of the interviews had to be changed on numerous occasions, depending on what was transpiring in the hospital. Despite this, the participants did not complain, and attempted to assist the researcher as much they could, regardless of how stressed they were as a result of the pandemic.

Only one question was asked to the participants: "**What challenges did you experience in reporting NMIs**." The researcher used open-ended questions in order to allow participants to express themselves freely and with an opportunity to clarify and express their feelings and emotions. The idea was to make participants feel like they were in a conversation and not an interview or interrogation. Based on the responses, the researcher then asked non-invasive, relevant, and probing follow-up questions to encourage the participants to disclose more information about challenges they faced when reporting NMIs (Shenton, 2014).

The researcher invited all HCPs who have the responsibility to report NMIs for one-on-one interviews. They were informed of a focus group discussion at the end of the one-on-one interviews and invited to participate. This was done so that the data can be triangulated and to determine the challenges and barriers in reporting NMIs (Carter & Bryant-Lukosius, 2014). The data from these interviews was analysed and themes were developed. Once the themes were established, the participants were invited for confirmation of themes, then to a focus group discussion to deliberate the results. During this session, the participants were asked to write down anything they thought was worth bringing to the researcher's attention regarding the barriers they experienced in reporting NMIs (Creswell, 2014).

The researcher conducted the interviews in English, or Xhosa, or both, depending on the participants' preference, although the research questions remained in English. Interviews were recorded; written consent of the participant and field notes were also taken. The researcher observed the participant's non-verbal responses, which could indicate discomfort, irritability or stress (hesitation, laughing or other non-verbal cues) and kept personal notes, which included her own reflections and experiences during the interviews ((Brink, et al., 2010); (Gray, et al., 2017)). Field notes were written soon after each interview. The transcriptions were based on field notes, observations, and the experiences of the researcher, as well as direct quotes from participants. The transcribed interviews were made available to the participants, to ensure the trustworthiness of the data (Carter & Bryant-Lukosius, 2014). The researcher had to rely, to a great extent, on her own instinct to obtain useful, accurate and authentic information, and had to ask more questions than anticipated.

During Qualitative data collection, the researcher used, a voice recorder, observations, and field notes to ensure that all information is captured (Creswell, 2014). The data collection process was based on a combination of sources, namely, interviewing, observing, documenting, and gathering audio-visual information. The data were organized and synthesized into categories and themes that tied together all the data sources (Creswell, 2014). Voice recordings were made with a digital device, allowing transcription of the data to be carried out easily on a computer. In order to ensure better sound quality, the recording device was placed closer to each subject. An audiotape was used to record the interviews, which were easily transcribed as the sound was crisp and clear (Burns, et al., 2016).

Transcripts of the recordings, as well as the recorder, were kept in a secure location for only the researcher and data analyst. After the research report was accepted, the recorder and transcripts were destroyed. Participants were given the opportunity to listen to the recorder to clarify their statements ((Brink, et al., 2010; Gray, et al., 2017)). The researcher was transparent and open at all times and where necessary would ask questions in order to obtain a better understanding of the phenomenon in question. For

further analysis, the transcripts were imported into NVivo V.10, a software package for managing and analysing qualitative research data (Mitchell, et al., 2016).

Throughout the study, the researcher approached the participants without showing or expressing any preconceived ideas about the issue under study. Instead, the participants were allowed to express their opinions and ideas about NMIs reporting while the researcher captured the meaning in their responses (Creswell, 2014). Furthermore, the development of a complex picture was revealed regarding near miss incident relapses. A broad picture of the situation was depicted by identifying multiple perspectives and factors that could explain the phenomenon of non-reporting of NMIs. The development of a comprehensive picture of the non-reporting of NMIs through a visual representation helps to establish a holistic picture (Creswell, 2014).

In addition, the researcher chose the exploratory-descriptive qualitative design to describe the lived experiences of participants concerning the phenomenon as described by participants. This design has strong philosophical underpinnings and typically involves conducting interviews ((Creswell, 2014); (Marshall & Rossman, 2016)). This type of research design culminates the experiences for several individuals who have all experienced the relapse in reporting NMIs (Gray, et al., 2017). This design also allowed the researcher to study the research topic in the area where the phenomenon is occurring. A specific district hospital in the Amathole District, in the Eastern Cape Province, South Africa was chosen as the study site. In this study, rather than generalizing the findings, the aim was to provide an understanding of why health care professionals have difficulty reporting near miss incidents ((Orb, Elsenhauer & Wynaden, 2000); (Holtzblatt & Beyer, 2014)). The premise is that the findings are unique to the study.

The intention was for the participants to provide a narrative, after the individual interviews, follow up with confirmation of themes and finally with focus group to triangulate the data (Carter & Bryant-Lukosius, 2014). The purpose of focus groups is to facilitate deep discussions based on the perceptions, experiences and attitudes of carefully selected participants who have similar experiences or characteristics (Krueger & Casey, 2015). Qualitative research approaches guide researchers in gaining insights into issues that are

uncertain, unclear, and difficult to objectively measure, because these approaches require the collection of narratives grounded in personal or professional experiences from individuals or groups (Seidman, 2013). As with the interviews, no changes were made to the narratives, they were analysed together with the transcriptions (Creswell, 2014). The recorded interviews and narratives were transcribed verbatim and organized into themes and sub-themes (Shenton, 2014).

The participants were asked for clarification and sufficient contextual information was obtained in order to ensure triangulation. A triangulation approach refers to using multiple methods or data sources to gather a comprehensive understanding of phenomena. When a method of triangulation is used, multiple data collection methods are used to gather information about the same phenomenon. The type of triangulation used involved interviews, observations, and field notes during data collection to ensure accuracy of findings, as well as to avoid any potential bias or personal motivations of the researcher (Flick, 2018). The participants and the health care institution's name were not mentioned in any report and the transcribed interviews were coded with numbers to ensure anonymity (Creswell, 2013).

On the whole, explicit qualitative research is conducted as part of an effort to solve or understand an issue. In this study, a variety of qualitative techniques were utilized to describe the perceptions and understanding of participants (Grey, et al., 2017). So, fifteen participants were interviewed in detail and their narrative descriptions were used to organize data into themes and sub-themes. Through these themes and sub-themes, the researcher was able to develop a more detailed understanding of the topic ((Holloway & Galvin, 2017) (Denzin & Lincoln, 2011). The aim of this study was to broaden knowledge about the challenges that health care professionals experience in NMIs reporting as opposed to generalising the findings to a larger external population and develop recommendation to assist healthcare management and HCPs with the process of reporting NMIs. Studying the underlying mechanisms of a phenomenon provides the foundation for the study of potential causative factors, preventing health care professionals from reporting NMIs (Grey, et al., 2017).

As a final step, participants were asked to provide a narrative, post the initial interviews, to ascertain if they had any additional information to contribute and to further confirm the themes and focus groups discussions. Consequently, the participants were contacted telephonically to make appointments through the gatekeeper, and were all willing to participate until the data was saturated. A total of two narratives were received after individual interviews, the data was analyzed and incorporated into the themes that emerged. A narrative analysis enables the participants to share their personal experiences (Creswell, 2013).

The researcher followed these steps in eliciting narrative analysis in the study:

- A list of significant statements was developed from the interviews. The significant statements were listed and each statement was treated with equal worth.
- The statements were then grouped according to meaning, in such that the groups of statements were as close to mutually exclusive as possible.
- The significant statements within each group were further grouped to form subgroups within the group. These subgroups were incorporated to form the sub themes.

The researcher conducted interviews until data saturation occurred. People who have similar perspectives will have similar thought patterns. This becomes evident when the participants repeat the existing themes without any new additional information. The data that is gathered through qualitative research is perspective-based (Saunders, Sim, Kingstone, Baker, Waterfield, Bartlam, Burroughs & Jinks, 2018).

2.5 CONCLUSION

This chapter focused on the research design and methods of data collection used in the study. The sampling techniques, trustworthiness and ethical considerations were also explained. The next chapter will focus on the analysis of the data collected.

CHAPTER 3: DATA ANALYSIS AND PRESENTATION OF RESULTS

3.1 INTRODUCTION

In the previous chapter, the researcher provided an overview of the research design and methods of data collection. Furthermore, the sampling methods, trustworthiness and ethical considerations were explained in detail. This chapter presents data analysis, presentation and findings obtained from the data collection process. Data was collected from a total of 15 participants, 11 of whom were females. Their ages ranged between 21years and 64years. The 15 participants included 9 nursing professionals, 2 medical officers, 2 radiographers, 1 pharmacist and 1 physiotherapist from the selected hospital, in the Amathole District, in Eastern Cape Province. This was a mixed method study and the sample size was actually not determined beforehand, but was depended on data saturation. Everyone in the population was invited to participate voluntary, until a data saturation point was reached. The data saturation was reached after 15 participants.

3.2 RESULTS AND DISCUSSION

A method of open coding was used, and data was analysed according to Tesch's data analysis method (Creswell, 2014). Field notes and transcripts were carefully checked in preparation for data analysis. Grammar and repetition were left unchanged, thereby prohibiting the possibility of losing information ((Creswell, 2014); (Gnoni & Saleh, 2017)). The analysis begins by providing Phase 1: Baseline data analysed quantitatively using SPSS and presented in tables with numerical data set. Qualitative data is thereafter presented in Phase 2 where a thematic analysis was adopted to ensure that responses by each participant were grouped by subject and according to the research question. Therefore, the presentation shows themes and sub-themes of findings from each research question.

3.2.1 Phase 1: Baseline Data

The paper based NMI reporting system was already in operation at the participating district hospital and there were specific people who were tasked with the responsibility to report NMIs. The NDoH designed a form for use by HCPs in reporting NMIs (National Department of Health, 2017). This form is divided into three sections, namely, an incident

notification section, a statement recording section and an incident investigation section. This form should be completed by all HCPs involved, with statements from witnesses, after which an investigation into the incident will be carried out by the relevant professionals.

The incident reporting should be made as soon as the HCPs becomes aware of it, and for serious PSIs, the Quality Assurance unit is expected to send a preliminary report to the district and provincial offices of the Department of Health within 72 hours. The investigation process should be finalised within 60 days of the NMI and PSIs. PSIs are then presented in the patient safety incident committee for further discussions on improvement or mitigation plans on monthly basis or within 72 hours post incident when it comes to serious PSIs. All reports are then forwarded to the district and provincial health offices (National Department of Health, 2017).

The researcher determined the number of unreported or late reported NMIs for the whole of 2019 by reviewing the patient safety incident register, maternity register, and perinatal audit meeting minutes. The registers were archived in an access-controlled area and the minutes were kept in a designated file in the unit manager's office.

3.2.1.1 Baseline data results

According to the PSI reporting system, no NMIs were reported between January and December of 2019. Reporting of a NMIs or PSIs forms the cornerstone of clinical governance as it provides information, guidance and recommendations that can improve patient safety (Bovis, Edwin, Bano, Tyraskis, Baskaran & Karuppaiah, 2018). Under reporting of near miss incident is significant, despite being seen as essential for risk assessment. Mistakes are an inevitable part of medical practice, yet to improve patient safety and good standards of care, errors need to be admitted, reported, and discussed (Bovis, et al., 2018).Therefore, the lack of reporting of PSIs was concerning and the researcher decided to select two high-risk areas, where most medical negligence claims currently stem from, namely, maternity and neonatal intensive care units.

The researcher adopted the WHO-near-miss-approach to serve as a baseline assessment (World Health Organization, 2011). This included identifying all women who presented with acute complications during pregnancy, labour, and birth by reviewing the maternity register, and the perinatal meeting minutes upon discovering that there was no SAC 3, PSIs reported. For each mother, information on the occurrence of selected severe pregnancy-related complications and severe maternal and neonatal outcomes was collected and displayed on Figure 3 below.

Figure 3: Total Maternal and Neonatal Complications

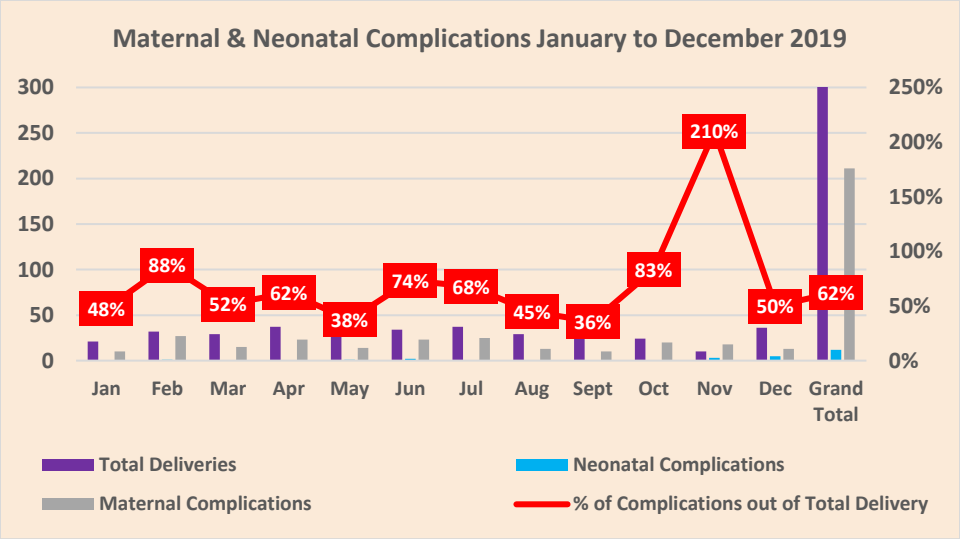


Figure 3 illustrate that NMIs were not reported on the PSI register, even though they were found in the Maternity Register and the Perinatal Meeting Minutes. Fortunately, they were discussed during perinatal meetings, with no PSI investigation. In November alone, the incidents accounted for 210% against the total deliveries, of which the sudden rise of PSIs should have been identified with the development and monitoring of a quality improvement plan. There is an average of 62% of PSIs that occurred compared to the number of total deliveries in the year 2019, with missed opportunities for interventions.

Koehn, Ebright & Draucker (2016) reports that inconsistencies in reporting mechanisms, measurement of events, and lack of accurate statistics on events actually reported by health professionals have prevented events from declining. However, in another study, the increase in PSIs was due to unsupportive leadership, inconsistent investigative

processes, and inconclusive management of events (Daniel, 2021). This is similar to one of the sub themes that emerged from the interviews, which was about the lack of support and feedback in reporting. The South African Department of Health (National Department of Health, 2017) published the National Policy for Patient Safety Incident Reporting and Learning. As part of the management and investigation of events, incident reviews are listed as one of the vital interventions. The researcher continued and counted the actual number of complications, to determine the number of NMIs in the two identified units and the findings are presented in Tables 1 and 2 below.

Table 1: Maternal Complications January 2019 – December 2019

Type of complication: Maternal	**No / year**
Contributory conditions such as maternal health issues such as anaemia or HIV, previous caesarean section, obstructed labour	154
Necessity for blood transfusions, hysterectomy, or other surgical interventions [excluding caesarean sections]	1
Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the mother	1
Maternal deaths irrespective of the duration of pregnancy	0
Maternal near miss [nearly died but survived a complication]	0
Post-Partum Hemorrhage (PPH)	3
Anti-Partum Hemorrhage (APH)	3
Severe Pre-Eclampsia, Eclampsia	1
Gestational Hypertension (GHPT)	35
Ruptured uterus	0
Total number of maternal complications	**198**

Table 1, shows that 198 NMIs occurred in the maternity unit alone, in the period under review. These incidents were not recorded on the incident reporting systems. When a complicated case is not identified early, transfer to higher levels of care is delayed, and so is the adaptation of the nursing care. Special attention should be paid to women with potentially life-threatening conditions because a maternal death or adverse maternal

outcomes are preceded by one or more life-threatening conditions (World Health Organization, 2011).

The table also reveal that out of 357 deliveries, there were a total of 198 maternal NMIs, and 12 neonatal NMIs. For instance, there were 35 women who experienced gestational hypertension (GHPT), 3 women who experienced antepartum haemorrhage (APH), 154 women had contributory conditions such as anaemia or HIV, previous caesarean section and obstructed labour. In addition, there were three women who had experienced postpartum haemorrhage (PPH) and one woman was referred to a higher level of care.

The lack of identification of NMIs in the maternity unit of the selected hospital reflects the shortcomings of the health system in dealing with pregnancy-related complications, and lack of understanding of the reporting system. An experimental study in the USA found that 72.6% of the physician trainees did not understand what the reporting system entailed and why it was necessary (Krouss, Alshaikh, Croft & Morgan, 2019).

For these reasons, training on incidence reporting is necessary for staff to understand the reason why it should be done (Waaseth, Ademi, Fredheim, Antonsen, Brox & Lehnbom, 2019). Furthermore, the researcher analysed the neonatal complications that occurred during the same period. Table 2 below shows the distribution of neonatal complications experienced at the hospital in 2019.

Table 2: Neonatal Complications

Type of complication: Neonatal	No / year
Severe life-threatening neonatal complication such as birth asphyxia, foetal distress	5
Low Apgar scores and prematurity	2
Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the baby	2
Neonatal deaths irrespective of gestation (including FSBs)	3
Maternal near miss [nearly died but survived a complication]	0
Total number of neonatal complications	12

The baseline assessment was extended to neonatal complications on Table 2, by reviewing the maternity register and the perinatal meeting minutes. For each neonate, information on the occurrence of selected complications and neonatal outcomes were collected. Table 2 indicate that there were 5 severe life-threatening neonatal complications such as birth asphyxia, foetal distress, two low Apgar scores and prematurity. Additionally, there were also 2 admissions to intensive care or transfer to higher levels of care, intubation, and ventilation of the babies, and 2 neonates died. No NMI report was found on the PSI reporting system or documents.

The findings of another cross-sectional study on barriers to reporting adverse drug reactions showed that 37% of participants felt they were not obligated to report adverse reactions (Cheema, Haseeb, Khan, Sutcliffe & Singer, 2017). Lack of reporting of near miss incidents suggests a possible lack of accountability at the facility (Varallo, Passos, Nadai & Mastroianni, 2018). The lack of reporting of adverse neonatal outcomes is concerning as this impact negatively on the implementation of remedial actions designed to improve the quality of care.

3.2.2 Phase 2: Interview and Focus Group Data

Phase 2 of this study involved interviewing all HCPs responsible for reporting NMIs. The researcher conducted phenomenological interviews to explore the challenges and barriers HCPs face when reporting NMIs. Phenomenological interviews were conducted to get a deeper understanding of individual phenomena and to collect detailed data from the participants' experiences ((Brink, et al., 2010); (Creswell & Poth, 2018)).

COVID's strict measures dictated that the data collection dates be spread out throughout the year to avoid the risk of infection, accommodate the inter-provincial travel restrictions for the researcher and co-coder, and allow the data to be collected at the most convenient times for the participants. Individual and group interviews were scheduled from 27th - 30th December 2020 along with the review of document data. The dates were selected for the confirmation of themes and narratives on 12th - 15th April 2021, and the focus group interviews were scheduled from 23rd - 26th August 2021.

During interviews, participants' non-verbal responses, (hesitation, laughter, and other non-verbal cues) were observed by the researcher, who kept notes including her own reflections and experiences during the interview (Brink, et al., 2010). As soon as each interview was completed, field notes were written. Field notes, observations, and the researcher's experiences were compiled into the transcripts, along with direct quotes from participants. Data trustworthiness was ensured by making the transcribed interviews available to the participants, a few clarifications were noted, no theme modifications were necessary (Carter & Bryant-Lukosius, 2014). The researcher collected data using a voice recorder, observations, and field notes to ensure that all information is captured (Creswell, 2014). For each interview, the recording device was placed closer to the subject, to ensure better sound quality. Interviews were recorded, allowing for easy transcription; due to crisp and clear sound (Burns, et al., 2016).

The data was analysed using Tesch's data analysis method, using open coding. Preparation for data analysis, involved carefully checking field notes and transcripts. In order to prevent information from being lost, grammar and repetition were not changed (Creswell, 2014). A consensus was reached between the researcher and co-coder regarding code categories and emerging themes. The themes with supporting quotes were shared with a few participants to ensure accuracy and validity. Although clarifications were noted, however, no changes were required to the themes and sub-themes (Eschiti, Lauderdale, Burhansstipanov, Weryackwe-Sanford, Weryackwe & Flores, 2014). A qualitative research software package called NVivo V.10 was used to further analyse the transcripts (Mitchell, et al., 2016)

3.2.2.1 Interview and focus group participants

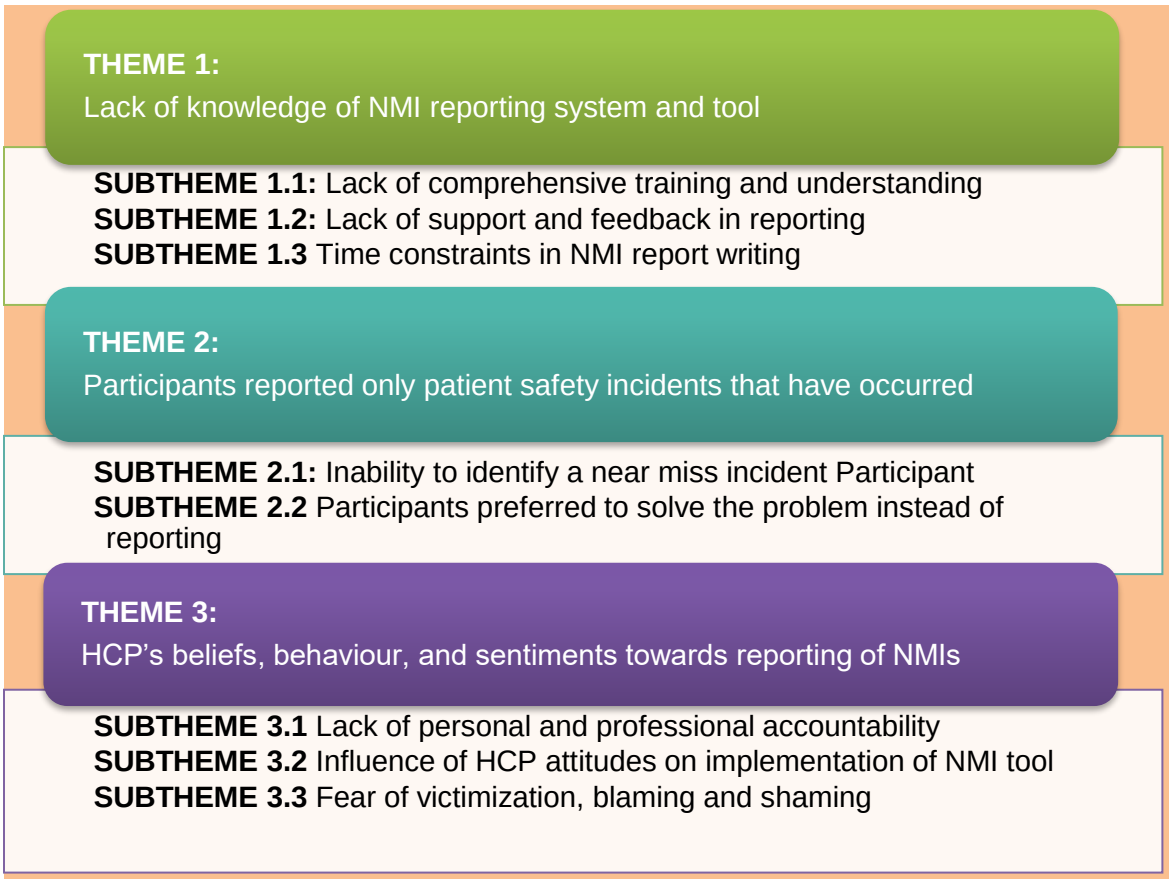
Health professions, particularly nursing, tend to be dominated by women (Waaseth, et al., 2019). While the topic under research was fairly gender neutral, most of the participants were females. Although there were few male voices present as participants, the results were interpreted in a gender neutral manner. The participants were HCPs who were a part of the multidisciplinary team and were registered with a South African HCPs body. They were tasked with the responsibility of reporting NMIs. The participants included medical officers, radiographers, operating managers, pharmacists,

physiotherapists, and professional nurses aged between 21 and 64 years and experience of between 2 and 30 years in their profession.

3.2.2.2 Interview and focus group results

Themes and sub-themes were derived from the data. All the resulting themes and sub-themes were interrelated and are shown in Table 3 below. Fifteen individual interviews were done, thereafter focus groups followed and two participants provided the researcher with narratives after the initial interviews. The narratives were analysed, and the data was added to the data obtained from the interviews. Further individual interviews were conducted to confirm the themes.

Table 3: Summary of themes and subthemes



3.2.2.1 Theme 1: Lack of knowledge of NMI reporting system and tool

There are a NMIs and PSIs reporting form for use by HCPs (National Department of Health, 2017). The form includes three sections, namely, notifying the incident, recording

a statement, and investigating the incident. It is standard practice, that the form is completed by any HCP involved, with statements taken from witnesses, followed by an investigation as a reporting system. Rea & Griffiths (2015) stated that, general practitioners tasked with the responsibility of reporting NMIs displayed an inadequate understanding of what to report, and who to report to. The development and implementation of PSI reporting systems within health care continues to be a fundamental strategy to reduce preventable patient harm and improve the quality of patient care (Archer, et al., 2017).

This study found that the majority of the participants did not know the NMIs reporting tool or system, despite being tasked with the responsibility of reporting near miss incidents. Some participants only knew of the adverse drug reaction reporting tool. All persons tasked with the responsibility of reporting NMIs went through a comprehensive training program. However, these incidents continue to go unreported and it is primarily due to lack of knowledge on the part of those tasked with the responsibility to report.

Table 1 results in the first phase of the study found that, three women had experienced post-partum haemorrhage and one woman had been transferred to a higher level of care, yet these incidents were not recorded on the incident reporting system. In addition, the incidents were not investigated and the circumstances around the post-partum haemorrhage remain unknown.

In the UK, staff members were found to have limited confidence and knowledge of the system for reporting adverse incidents. Few could recall the training they received and even fewer staff members displayed confidence on how the system operates (Bovis, et al., 2018). The direct quotes presented in the text box below demonstrate the lack of knowledge of the reporting system.

Participant 01: *"No, only know of and adverse event, I have never seen the one for near miss, it is the first time I hear about a near miss" "I have never seen it"*
Participant 04: "…to sit and discuss definitions and their meanings, or the tools, the template to report near misses…"
Participant 07: *"No, No I don't remember seeing a reporting tool"*
Researcher: *"Oh I see, is there a reporting system or a reporting tool for NMIs?"*
Participant 11: *"I have never seen it, I don't want to lie"*
Participant 13: *"Nope, I have only seen one for medication, are you sure you are not talking about the ones specific to medication?"*

These results correspond with the findings in Sweden, as in many other countries, (The Organisation for Economic Co-operation and Development, 2018) where it is mandatory for health care professionals to report events that have resulted in a preventable PSI, or that risked doing so, into an incident reporting system (National Department of Health, 2017). Other studies have suggested that this may be due to the incident reporting system that may not be considered user-friendly (Carlfjord, Ohrn & Gunnarsson, 2018) or the staff may feel that too much data is collected (Macrae, 2016). Taking the time to monitor PSIs is important for health care organizations, because of their impact on patients and the opportunities they present for learning and improvement. In addition, a large number of PSIs can be avoided. These are termed preventable adverse events (Schwendimann, et al., 2018), which is referred to as unnecessary harm in the South African context (National Department of Health, 2017).

3.2.2.2.1a Sub-Theme 1.1: Lack of comprehensive training and understanding

All HCPs tasked with the responsibility of reporting NMIs had gone through an initial training session, where the purpose of reporting and the associated documentation and process were explained. The study revealed that lack of training was a barrier to reporting of incidents. In addition, the study found that they also lacked understanding of the importance of such a reporting system. Healthcare workers do not understand the importance of reporting incidents, with the result that the actual reported incidents are a

fraction of the actual number of incidents (Samsiah, et al., 2016). This result is similar to the findings of the current study on figure1, where it was found that 210 actual incidents had occurred in the maternity and neonatal units of the hospital, which accounts for 62% of the 357 deliveries in the year 2019. Even so, none of the NMIs were recorded on the PSI register, for the reviewed period. In this case, HCPs missed an opportunity for learning and patient safety remains compromised. Nurdin & Wibowo (2021) argued that an undetected error compromises the patient safety greatly if the root cause is not investigated. Some of the responses are presented in the text box below.

Participant 01: *"…come to think of it, I have never been trained or guided in reporting a near miss*"
Participant 02: "…*I think training would be beneficial so that we are all clear of the definitions*"
Participant 06: "…*I think if more training would be done, staff members will be encouraged to report…*"
Participant 07: "…*or get trained and mentored comprehensively, so that we are able to incorporate this to our daily routine"*
Participant 10: *"…maybe if we get training it would make sense*"

Although focusing on providing socialization, training, and workshops is a good strategy, this cannot overcome the barriers to incident reporting, especially if hospitals do not implement a feedback process to close the loop in incident analysis management. So, in the absence of action by management in response to the submitted reports, the staff may be hesitant to report future incidents (Varallo, et al., 2018).

3.2.2.2.1b Subtheme 1.2: Lack of support and feedback in reporting

Healthcare failures should be transformed into opportunities to improve patient safety globally. PSIs are largely not reported due to weak patient safety cultures and fear of punishment (Hooper & Tibballs, 2014). A huge barrier to effective reporting and learning is the lack of universally applicable and common standards for collecting, storing, classifying, analyzing, and interpreting incident reports and other clinical data (National Department of Health, 2017). Furthermore, poor leadership support and ambiguity of the report results inhibit the reporting process (Gifford & Anderson, 2010). Error feedback perception also appears to play a significant role in organization-level reporting (Richter, McAlearney & Pennell, 2014). The study results show that HCPs did not feel sufficiently rewarded for reporting errors and do not get support from management when incidents occurred. Those who reported errors stated that they rarely received feedback and lost interest in reporting (Waaseth, et al., 2019).

Majority of the participants mentioned that they lacked support from management in reporting NMIs. This increased the perception that reporting of incidents was not important. Only a few reported that they had ever written an incident report while other participants mentioned that they did not receive feedback after submission of the report.

Literature shows that hospital leaders need to demonstrate a positive attitude towards incident reporting in order to improve the quality of care and patient safety (Nurdin & Wibowo, 2021). When hospital managers are supportive and health professionals are aware and knowledgeable of the reporting system, the ability to manage adverse incidents becomes easier. Studies on reporting NMIs contend that errors occur when a poor safety culture exists in a hospital, and where health professionals lack managerial support (Waaseth, et al., 2019). Private midwives were disillusioned by the lack of support by management when they were involved in a medical negligence claim (Du Plessis, Grobler & Seekoe 2020).

None of the participants verbalised a walk round by a safety quality manager or any other hospital manager. This is in inherent principle of reporting of near miss incidents.

Participants verbalised lacking support in NMI reporting. A group of senior health managers should walk through the facility on a regular basis to observe all service areas, informally address health care professionals and enquire about their knowledge of patient safety and NMIs, to collate, categorise and prioritise issues that needs to be addressed (National Department of Health, 2017). A summary of these rounds is then presented at management meetings for possible resolution of the potential issues. None of the managers, despite being in senior positions and tasked with reporting near miss incidents and patient safety incidents were involved in such meetings or ward rounds.

The walk round exercise is supported by the WHO maternal near-miss approach, which is designed to be a routine activity for quality improvement. Ward rounds and group discussions may stimulate action for change and contribute to the sustainability of actions intended to improve the quality of care given (World Health Organization, 2011).

The responses from participants are presented below:

Participant 02: "*…the other issue is that nothing comes back after reporting, you just keep on reporting and reporting*"

Participant 04: *"…there is no support in reporting...if you report the incident, there is never feedback …"*

Participant 05: *"…but its not easy now, because we don't sit and discuss incidents there is no mentoring and support for quite a while…"*

Participant 06: *"…although reporting is demotivating sometimes, as there is no feedback of what has been done about the incident…"*

Participant 09*: "…the other reason is that even if one reports, there is no report back about the incident"*

The study found that half the participants received no feedback from their leaders after reporting an incident (De Fatima, De Carvalho & De Albuquerque; 2019). The absence of feedback, reward and appreciation contribute to the lack of reporting resulting in continuation of mistakes and errors. On the same note, investigating and understanding the root causes of an incident and discussion of the issue at mortality and morbidity (M&M) meetings are important elements of clinical governance. This contributes in

improving patient outcomes, a higher level of quality of care, value-added attitudes towards patient safety, and help to educate clinical staff (Heslin, Taylor, Hawn, Davies, Heslin, Mims, Morgan, Rabun, Smedley, Morris, Reiff, McGwin, Bland & Rue, 2013).

Additionally, the M&M meetings provide a forum for discussing adverse outcomes. In general, they are capable of improving patient outcomes ((Heslin, et al., 2013); (Pokorna, Muzik, Svancara, & Gregor, 2016)) patient safety attitudes (George, 2017), and they may contribute to the professional development of clinicians (Ferreira, Lynch & Ryder, 2019). In this study, none of the participants verbalised that a root cause analysis was done when an incident was reported and no M&M meetings were held. As a result, systems and processes that need improvement were not identified and improvement of future patient outcomes remains a challenge (Higginson, Walters & Fulop, 2012).

3.2.2.2.1c Sub-theme 1.3: Time constraints in NMI report writing

A study in Norway found that there was a lack of timeous reporting and that healthcare workers were too busy during shifts to report incidents, and although the staff were allowed to report the incident the next day, most of them forgot to do so (Waaseth, et al., 2019). About 22.6% of staff had admitted to having forgotten to report an incident (De Fatima, et al., 2019). A study conducted in the United States found that incidents underreporting was due to lack of training on patient safety reporting and instructions, lack of reporter-friendly classifications and time constraints ((Mjadu & Jarvis, 2018); (Gong, Song, Wu & Hua, 2015)). In another study, Pharmacists did not report incidents because of the perceived lack of time to do so (Cheema, et al., 2017). A study in Iran found that high workload contributes to medication errors among nurses in teaching hospitals (Fathi, et al., 2017). These studies have alluded to the fact that time constraints were a common barrier to incident reporting ((Kasda, 2017) ; (Mitchell, et al., 2016).

Moreover, the global nursing and staff shortages in the health care facilities is a matter of great concern as it contributes to higher levels of near miss incidents (Haddad, Annamaraju & Toney-Buttler, 2022). This is certainly also true in the context of South African health care facilities, especially in the Eastern Cape where this study was

conducted. The Eastern Cape is the poorest province with poor health care systems, high levels of unemployment and low levels of literacy ((Moyo, Mishi & Ncwadi, 2022); (Statistics South Africa, 2017)). Staff shortages are therefore inevitable, as few HCPs remain in a province with such constraints. The inequality of HCPs between the public and private sector, as well as the disparity of public sector health professionals among provinces, has worsened South Africa's health problems (Barron & Padarath, 2017). As a result, insufficient and inadequate health workers lead to physical and mental exhaustion, and even deterioration of their own medical conditions (Tana, 2013). These findings correlate with a study that found that nursing shortages lead to errors, higher morbidity, and higher mortality rates (Wu, Fang, Guan, Fan, Kong & Yao, 2009).

Furthermore, the COVID pandemic contributed to burnout and post-traumatic stress syndrome among health care professionals (Drapeau, Marchand & Beaulliey-Prevost, 2012). The high workloads among HCPs have led to a decrease in scheduled time for reporting NMIs, and most of them report having insufficient time to do so. Some participants in this study alluded to the paperwork that needed to be completed when an incident is reported. Hence there is little chance that HCPs will report an error that compromises patient care. The researcher found that the healthcare workers in this selected hospital were aware that an incident had to be reported as soon as they were aware of it. However, the study results show that no NMIs were reported for the 2019 period. Whereas Table 1 & 2 has shown that NMIs were in existence in the maternity unit. Participants stated that there was not enough time to report NMIs, especially with the current staff shortage in the hospital but acknowledged lack of motivation to do so. Below are the direct quotes from the participants' responses.

Participant 02: "…*there is no time to report although you have witnessed a near miss*"
Participant 04: "*there is also laziness to write because you have to record all these things, it takes time to write the seriousness of the near misses is not there because if we are short staffed and busy writing about something that did not happen ha.a* …."
Participant 05: *"…although reporting takes time, we are so short staffed…"*

Participant 06: *"Firstly Near misses are not reported immediately, it's important to report immediately, it usual takes time to report these kind of incidents…"*

Participant 09: "…*we are so overwhelmed and short staffed, now reporting writing about something that did not happen, mistakes can happen to anyone, and there is no time for all these tasks"*

Participant 12: *"Yes there is [reporting], but clinicians often complain that reporting NMIs takes time, I think it is just laziness, so one always needs to remind them every now and again"*

3.2.2.2.2 Theme 2: Participants reported only patient safety incidents that have occurred

The reporting of PSIs, despite being seen as a crucial component and cornerstone in clinical governance, has a wide variation of staff perception and usage. Reporting can be formal, by means of an instrument or form that needs to be completed, or informal by word of mouth ((National Department of Health, 2022); (Bovis, et al., 2018). Only a few instances are mentioned by these organisations with regard to fixing and reporting of NMIs (Hewitt & Chreim, 2015). The study found that fixing and reporting was an alternative in only a few instances where HCPs dealt with problems they could not resolve. Most of the participants confirmed that they only report PSIs not NMIs. Few had ever reported an NMI and admitted that they had missed opportunities to report incidents because they would have resolved them.

Participant 04: *"Hey, I don't remember, but I do report adverse events and serious adverse events"*

Participant 07: "…I report an incident that has occurred"

Participant 08: "*not really, we report adverse events, not near misses*"

Participant 14: *"Not always, you see as you have just said it with the blood administration, nothing really happened, it was corrected before it happened, and after*

the blood procedure there are many other things to do, there is just no time, unless there was an adverse event"

Participant 15: *"…we correct the issue and move on, it gets busy here at times, unless it was a big deal like PSI's those are mandatory"*

HCPs were found to be more inclined to report more severe errors hence causing more severe harm to their patients ((Farag, Blegen, Gedney-Lose, Lose & Perkhounkova, 2016); (Mansouri, Mohammadi, Adib, Lili, Soodmand; 2019)). According to HCPs, less severe errors did not need to be reported because they were deemed relatively harmless (Soydemir, Seren Intepeler & Mert, 2021); (Dirik, Samur, Seren Intepeler & Hewison, 2019); (Lee, Kim, Lee, Lee, Kim & Kim, 2018)).

The Department of Health in the UK recommends that staff report all adverse outcomes, NMIs, and minor safety issues because it may be a symptom of a larger underlying issue (Barach & Small, 2000). This is the case in South Africa as well, where all incidents are ought to be reported. However, the researcher found the contrary at the participating hospital where the reporting rate was low and inconsistent.

3.2.2.2.2a Sub-theme 2.1: Inability to identify a near miss incident

An incident that fails to reach the patient is an NMI, which means that the actual incident could have occurred but was prevented just in time. It also means that the incident did not result in harm or illness but had the potential to do so. In addition, an unplanned or unintended incident that may have resulted in harm to a patient in a healthcare facility is a PSI. This event is not related to underlying health condition or a natural progression of the disease but to patient safety issues. There are three types of incidents, near misses, no harm incidents, and harmful events (adverse events) (National Department of Health, 2017).

The study found that the participants were unable to define an NMI and needed assistance in writing and reporting. They were under the impression that only serious, unresolved incidents should be reported. These results support the findings of research

carried in another study, which found health care workers, specifically pharmacists, only reported serious incidents and often felt that a resolved issue needed not to be reported ((Chiang, Lee, Lin & Ma, 2019); (Cheema, et al., 2017)). The study also found that when compared with nurses, pharmacists were less likely to report NMIs (Samsiah, et al., 2016). However, any incident has the potential to become a common occurrence. Therefore, training on incidence reporting is required for all staff in order to reinforce the initial training that the health professionals would have received (Waaseth, et al., 2019). Continuous professional development is also necessary at all levels in order to reiterate the importance of patient safety. Some of the responses of the participants are listed in the text box below.

Participant 04: *"Mmhhhh the challenge is that I am not sure what a near miss is, the real definition of it, some incidents I will classify as a near miss whereas it is not at times…"*

Participant 05:

Researcher: *"Please tell me about the challenges you experienced in reporting NMIs."*

Participant: *"Near Miss?"* (Lowering voice)

Researcher: *"Yes Near Miss Incidents"*

Participant: *"Mmmmmh…..Near miss, Near miss….is it a drug reaction?" (Raising eyebrows)*

Participant 08:

Researcher: *"Please tell me about the challenges you experienced in reporting NMIs."*

Participant: *"I am trying to think" (Scratching head)*

Researcher: *"Alright, I will give you time to think" (Silence for sometime)*

Participant: *"Is this about adverse drug reactions?" (Making an Errrrrrr sound before answering)*

Participant 13:

Researcher: *"Please tell me about the challenges you experienced in reporting NMIs."*

Participant: *"Errr, you mean adverse events?" (Relaxed)*

Lack of reporting is attributable to weaknesses in the training programs ((Najafpour, Jafary, Saeedi, Jeddian & Adibi, 2015); (Hamed & Konstantinidis, 2021)). It is more difficult for HCPs to understand the importance of incident reporting due to a lack of necessary training. In view of this, appropriate training on errors and safety requirements are necessary to encourage NMI reporting ((Morello, Lowthian, Barker, McGinnes, Dunt, & Brand, 2013); (Dirik, et al., 2019); (Najafpour, et al., 2015)).

To address this challenge, the National Department of Health developed a form for notifying patients regarding PSIs, including near misses (National Department of Health, 2017). Majority of the participants revealed that they had never even heard of the word near miss. It was only after explanations and examples were given that the participants started to understand that NMIs have the potential to cause harm or illness; even though there were no adverse outcomes they had witnessed. This finding caused great discomfort in the participants and the researcher. The implication of this finding is that the person tasked with reporting NMIs does not have the knowledge and skills to do so.

Professional errors, at risk behaviour and misconduct or negligence contribute to NMIs, and optimal learning is not possible if there is lack of awareness of the incident, or acknowledgement that it ever that it occurred (National Department of Health, 2017). Due to lack of basic knowledge of the definition of NMIs, many near misses continue to go unreported. This therefore means that near-misses and minor incidents that may affect patient safety offer health institutions a unique opportunity to identify potential hazards in the working environment before any major incidents could occur. If the person tasked with reporting of the incident lacks the knowledge and skills to do so, patients' rights to a safe and healthy environment would be infringed upon ((Gong, et al., 2015); (Hooper & Tibballs, 2014); (Schultz, Crock, Hansen, Deakin & Gosbell, 2014)).

As a result, this study found that incident reports are not compiled in general, and that the staff only became aware of a problem once a medical negligence claim had been instituted; or if they were informed of an incident via social media, the press or a tip-off from other practitioners. Prevention of an incident and/or its management can only

happen if the NMI is detected, and not when a patient's family registers a complaint or report an incident on social media.

3.2.2.2.2b Sub-Theme 2.2: Participants preferred to solve the problem instead of reporting

Health care professionals frequently encounter safety problems that they may be able to resolve on the spot (Hewitt & Chreim, 2015). Therefore, reporting of problems such as NMIs, PSIs and workplace challenges was not a priority. The study results show that the majority of HCPs would rather fix the problem and move on with their work. NMIs were seen as not worthy of reporting since they would not have resulted in actual harm to the patient. Instead, HCPs would rather attend to those individual patient safety problems they consider to be unique or rare, according to their personal experiences. HCPs who would have encountered some of the recurrent safety problems would not consider them as worthy of reporting since they would have acquired the skills to address them. Some of the responses given by the participants are shown in the text box below.

Participant 01: *"but I guess it does happen and we don't take it as an incident, I think that's the problem because we don't take it as an incident, because the event that almost happened didn't, it was corrected, Yhaaa"*

Participant 07: "*As I have just said just now, I don't, [report NMI's] it has almost happened mos, which means it was resolved before it becomes an incident, I report an incident that has occurred"*

Participant 13: *"Oh those near misses, we just talk about them casually in the ward we don't write them anywhere, because they are already sorted…"*

In this study, most of the participants believed that if they fixed a problem then it is not worth reporting as it has not caused harm to the patient. They regarded an NMI as an act that almost happened but did not. This kind of practice may be missing key insights and soft intelligence that individuals closest to these incidents might have offered, because if a near miss incident is not reported it can reoccur (Martin, McKee & Dixon-Woods, 2015). In addition, an actual PSI or adverse event may cause irreversible harm or death, whether

it is inevitable or not (Patient Safety Network, 2019). In this study, HCPs considered reporting NMIs a waste of time, since the incident did not actually occur. However, if an NMI is reported and the root cause is explored, quality improvement plans can be developed so that such incidents do not reoccur (Russ, Fairbanks, Karsh, Militello, Saleem & Wears, 2013).

This study found that incident reports were not completed because the HCPs would have solved the problem. Lessons learnt from incident reporting can be used to educate, inform, and prevent other healthcare facilities from experiencing the same adverse events (Pham, Girard & Pronovost; 2013). There are some incidents that HCPs may find difficult to classify as NMIs, such as an extension of a vaginal tear. Some HCPs consider it to be part of normal child birth while others may look at it as an incident worth reporting, possibly caused by inadequately supporting the perineum or controlling bearing down efforts. Considering this disparity in opinions, some professionals may list it as an adverse outcome while others may not. Therefore, a clear definition of the event, the population at risk, and a consistent surveillance system for detection of both the event and the population at risk will assist to clear the confusion (Pham, et al., 2013).

The results show that participants did not know the basic elements of an incident reporting system. Hence incidents that could easily be solved, such as a patient falling off the bed but not getting injured, would go unreported. That being the case, the hospital implemented remedial measures of installing cot sides, without reporting or investing the bed falling incidents.

3.2.2.2.3 Theme 3: HCP's beliefs, behaviour and attitudes towards NMI reporting

Three sub-themes emerged from this theme, namely, lack of professional accountability, professional attitudes, and fear of victimization, blame and shaming. These sub-themes deal with HCPs perspectives, practices and attitudes towards voluntary error reporting. Participants in the study were qualified HCPs who were mandated by the DoH to report near miss and PSIs. However, their views and attitudes towards voluntary reporting of NMIs were negative. In a study in Canada, it was noted that professionals were often not encouraged to report adverse reactions, even if they recognize that early warning signs,

an improved process, and fewer new adverse reactions would occur. So, knowledge alone is insufficient to induce changes in attitude and behaviour (Nichols, Thériault-Dubé, Touzin, Delisle, Lebel & Bussières, 2009); (Hewitt, et al., 2017). Educational interventions have been shown to be effective over time and such interventions should be periodically carried out in order to keep professionals motivated.

Participant 07:
Researcher: *After explaining what an NMI is…*
Participant: *"Oh I get it, I have never reported it and I have never seen anyone reporting it*
Participant 11:
Researcher: *After explaining what an NMI is…*
Participant: "*oh, if nothing happened to the patient, I do not report it"*

Participant 12:
Researcher: *"So, in your entire career have you ever reported an NMI?"*
Participant: *"No, but I have reported several adverse events"*

Participant 13 *"Oh those near misses, we just talk about them casually in the ward, we don't write them anywhere, because they are already sorted, we only write about adverse drug reactions"*
Participant 15: *"… usually these issues are resolved so we don't normally report them"*

Although varied educational interventions were used to improve the reporting of adverse drug reactions, it was observed that about 10.5% of NMIs still remained unreported. Another barrier is related to the culture of reporting among health professionals which requires that only the nursing staff can report patient safety incidents. This leaves out other health professionals who are predisposed to detecting near miss incidents, such as pharmacists (Varallo, et al., 2018).

Additional research is needed in assessing the performance of proposed interventions, in changing the behaviour of professionals and instilling a culture of reporting near miss incidents as well as prioritising and speeding up of risk communication in the hospital (Varallo, et al., 2018).

3.2.2.2.3a Sub-theme 3.1: Lack of personal and professional accountability

Professional accountability is the responsibility for one's actions towards oneself and others (Davis, 2017). Legally and professionally, midwives and nurses are required to take responsibility for their decisions and actions, and the consequences of such decisions. Nurses and midwives are accountable to their patients, their regulators, their employers, and any other supervisory authority that may be relevant. Thus, nurses and midwives should be able to give reasons for their decisions and must justify their choices within the context of legislation, professional standards, evidence-based practice, and professional and ethical conduct (Rubio-Navarro, Garcia-Capilla, Torralba-Madrid & Rutty; 2019). In essence, a midwife or nurse cannot be held accountable without autonomy.

The concept of autonomy can be defined as having the ability to make your own clinical or practice-based decisions, monitoring progress, and having control over a situation, work, or practice. A key component of professional autonomy is the ability to apply various kinds of knowledge in a critical manner, thus providing patients with safe, high-quality health care. Degrees of autonomy can vary depending on several factors, including legislation, organizational dynamics, and individual characteristics ((Bedwell, McGowan & Lavender; 2015); (Davis & Homer, 2016)).

Moreover, the healthcare system should also ensure accountability by all times. Healthcare accountability is a concept that influences the quality of care, decision making, safety standards, and employee values (Rubio-Navarro, et al., 2019). As a result, understanding accountability and its impact in medical practice may improve patient care and working conditions of health care workers. HCPs need to regularly manage accountability in difficult situations. These factors can be impacted upon by the workload

that has become increasingly challenging since the emergence of COVID 19 (Rubio-Navarro, et al., 2019).

The study results show that half of the participants did not accept responsibility for the formal reporting of NMIs. They were very casual about the topic, and it could be deduced that they did not take the issue of NMI reporting seriously. When a deeper understanding was sought, the participants responded frivolously and jokingly. Some participants laughed when asked about their responsibility in reporting the incidents. The participants mentioned that they tend to report errors informally, during informal discussions with colleagues and immediate supervisors, rather than through formal written correspondence (Koehn, et al., 2016).

Based on the responses, the participants were not aware of what and who to report to, or how it impacts the level care provided. This is in line with a UK study which researched general practitioners in the UK. The results showed that the general practitioners lacked a good understanding of the incident reporting system (Rea & Griffiths, 2015). Below is a summary of responses from the participants.

Participant 07:

Researcher: *After explaining what an NMI is…*

Participant: *"Oh I get it, I have never reported it and I have never seen anyone reporting it*

Participant 11:

Researcher: *After explaining what an NMI is…*

Participant: "*oh, if nothing happened to the patient, I do not report it"*

Participant 12:

Researcher: *"So, in your entire career have you ever reported an NMI?"*

Participant: *"No, but I have reported several adverse events"*

Participant 13*: "Oh those near misses, we just talk about them casually in the ward, we don't write them anywhere, because they are already sorted, we only write about adverse drug reactions"*

Participant 15*: "Of cause we talk about these things in the ward to warn each other, even during handover"*

All HCPs are bound by ethical rules in their specific professional practice. These rules have to do with the protection of their patients and the public at large. Health professionals are thus held accountable for their professional acts and omissions. Hence it is important for managers to give direct guidance towards critical focus areas within healthcare facilities (National Department of Health, 2022) . One of the values that encourage HCPs willingness to report inaccuracies is the need for professional accountability (Hewitt, et al., 2017).

In this study, it was found that NMIs were not reported. The majority of participants confided that they did not report NMIs, despite being tasked with the responsibility to do so. Some of the participants indicated that they were using the reporting system, yet they knew about the adverse drug reaction reporting system only. They were embarrassed by their lack of insight as evidenced by their responses and blamed it on lack of training. However, all the participants were trained in the use of the reporting tools when it was introduced and implemented at the hospital. This reflected poorly on their insight and this underpins their lack of understating of the reporting system. The reviewed maternity register also supported the fact that NMIs were not being reported at the study site.

3.2.2.2.3b Subtheme 3.2: Influence of HCP attitudes on implementation of NMI tool

Attitude refers to a reaction to certain circumstances in a particular way, to observe, interpret, or organize opinions in a coherent and connected manner, or to form a particular view on a particular issue ((Bano, AlShammari, Fatima & AlShammar, 2013); (Hewitt & Chreim, 2015). HCPs perception of error severity influenced their attitudes and behaviour

towards voluntary error reporting ((Farag, et al., 2016); (Mansouri, et al., 2019). Attitudes are an important component for effective operation and function of incident reporting systems (Pakorna, Muzik, Svancara & Gregor, 2016). Safety culture is also one important component that can influence HCPs attitudes on the adoption of NMI tools. This type of culture is a combination of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determines an organization's commitment to health and safety management and its style and proficiency (Flott, Nelson, Moorcroft, Mayer, Gage, Redhead & Darzi, 2018).

However, there are difficulties in implementing a patient safety culture. Blaming culture is one example, and is regarded as the most significant cultural barrier to incident reporting ((Noble & Pronovost, 2010); (Navajas & Badia, 2020))Other obstacles included fear of colleagues' reactions, lack of feedback, and the fear of other consequences (Verbakel, Langelaan, Verheij, Wagner & Zwart, 2015). This study found that employees were concerned that if an error occurs, it would be pinned on them.

Participant 01: *"I think we are very busy, so other things, especially if they are not a big deal, we don't take them seriously" and "we just take the serious ones if it happens*

Participant 04: *"…the seriousness of the near misses is not there because if we are short staffed and busy writing about something that did not happen ha, ha"*

Participant 07: *"As I have just said just now, I don't, it has almost happened mos, which means it was resolved before it becomes an incident, I report an incident that has occurred"*

Participant 11:

Researcher: *After explaining what an NMI is…*

Participant: "*oh, if nothing happened to the patient, I do not report it"*

Training programs aim to minimize negative impact on healthcare users (Ljubić, Raković, Dimitrov & Garvanov, 2016). Undergraduate curricula for health care professionals should emphasize the importance of error reporting so that students can have sufficient knowledge and appropriate mind set for practice (Woo & Avery, 2021). Furthermore, healthcare organizations should also devote time and resources to evaluating and, if necessary, revising existing safety training initiatives in order to improve healthcare providers' competency. As a final step, internal workshops on patient safety, risk management, and incident reporting should be incorporated into incoming health care professionals' orientation programs in order to familiarize them with institutional error-management protocols. Workshops may need to be scheduled periodically for employees in order to reinforce adherence to proper standards of error reporting. Incidence reporting will become easier for health care professionals of there are in-service training and workshops (Samsiah, et al., 2016).

3.2.2.2.3c Subtheme 3.3 Fear of victimization, blame and shame

The existence of a system that allows HCPs to openly report incidents without fear is paramount to patient safety (Navajas & Badia, 2020). There may have been lack of reporting of near-misses due to the fear of victimization, blaming, or shaming. Reporting of adverse incidents and outcomes requires a positive organizational culture (Samsiah, et al., 2016). The study found that general practitioners who did not report incidents, cited, among other reasons, shame and fear of being socially isolated (Rea & Griffiths, 2016). For instance, a study carried out in Uganda found that an incident reporting culture that involves punishments and blame impacts negatively on incident reporting (Noame, James, Christine & Mugisha, 2020).

In this study, majority of the participants expressed the view that reporting NMIs would likely result in victimization, and blame. There are three main reasons why frontline HCPs do not favour reporting NMIs, namely, fear of blame, incompetence, and career progression (Hewitt, et al., 2017). There are also three main factors that inhibit peer reporting, namely, gossip, position of responsibility and professional boundaries (Hewitt, et al., 2017). To address this, the basic near-miss approach, implemented by the WHO

in 2017, requires no direct interaction with patients since data are extracted from hospital records without physical interaction with the patient. Equally, no patient interviews are mandatory, but staff members may be required to clarify any doubts they might be having about certain individual cases (World Health Organization, 2017).

In addition, the other strategy to augment the WHO near miss approach is the Lean Six Sigma improvement plan, it does this through defining the problem, selecting measured data elements, analyse the data collected, discuss and implement improvement plans and finally sustain and control the agreed upon plans (Ahmed, 2019). This is to ensure that feedback can be communicated to HCPs. In some healthcare facilities, HCPs who reported NMIs have been required to attend committees or meetings to share their experiences.

HCPs should be encouraged to report incidents without fear of victimisation (National Department of Health, 2017). It is vital that healthcare facilities should console those who commit human error, coach those who are guilty of at risk behaviour and discipline those with reckless behaviour (National Department of Health, 2017). A punitive response can appear in many forms, such as a negative response from a supervisor, not receiving a positive performance review or letter of recommendation, being fired, or being labelled as a complainer or troublemaker, which would be forms of victimisation. Positive feedback after receiving a report of a safety event is an effective counter measure to the fear of a punitive action (Siewert, Brook, Swedeen, Eisenberg & Hochman, 2019). Some of the responses of the participants are shown in the text box below.

Participant 9: *"People do not want an adverse event that is related to them, because they know that the adverse event is related to them therefore, they have to report, reporting include documentation and embarrassment at times and they are not willing to do such things*"

Participant 13: "*oh ok, I have no challenges reporting, but I have not had near misses, but I think the challenge would be one being afraid of victimization or accused of being a hazard in killing patients…*"

Employees may be concerned about the nature of the safety culture at an institution, in addition to fearing punitive action from supervisors or other team leaders. Individuals are usually held responsible for all errors, including system errors, in a retributive manner. The biggest impediment to reporting errors in the health care industry has been punishment for making errors. In this case, HCPs need to be assured that they will not suffer any repercussions for reporting or making errors. In order to achieve a just culture, individuals must not be held responsible for system errors and honest mistakes (Scott, et al., 2019).

3.3 CONCLUSION

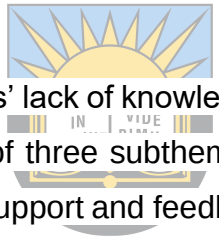
In this chapter, the data analysis obtained from the document review, individual phenomenological interviews, narratives, and focus group discussions was presented. The document review revealed that the NMIs are existent but not reported on the prescribed reporting system as there were a 62% of maternal and neonatal complications out of the total number of deliveries in the 2019 period. The challenges that HCPs face in reporting NMIs were found to fall under three interrelated themes. In the next chapter, the researcher will present quality of healthcare recommendations on reporting NMIs and for the management of incident reporting. The focus of the chapter will be on the development of recommendations and discussion of limitations.

CHAPTER 4: CONCLUSIONS AND RECOMMENDATIONS

4.1 INTRODUCTION

The previous chapter presented the results of the study. The data analysis was on the challenges faced by HCPs in reporting NMIs in a selected hospital at the Amathole District, Eastern Cape Province. The study aimed at determining the prevalence of unreported or late reported NMIs, the frequency, types and severity of complications that occurred throughout the year 2019, and to come up with possible recommendations on the reporting of NMIs at the selected hospital. A near-miss occurs when an incident fails to reach the patient. This chapter will discuss the study recommendations emanating from the results. It is important to note that a consensus discussion was held with the independent coder to discuss the results (Creswell, 2014).

4.2 DISCUSSION



The first theme related to participants' lack of knowledge about the NMI reporting tool and system. This theme was made up of three subthemes, namely, lack of comprehensive training and understanding, lack of support and feedback and time constraints associated with report writing. The second theme revealed that participants reported only the patient safety incidents that have occurred and this theme was made out of two sub themes, namely, inability to identify a near miss incident and participant preference to solve rather than report the incidents. The third and final theme concerned health care professionals' beliefs, behaviour, and sentiments towards reporting of near miss incidents. This theme was made up of three subthemes, namely, lack of personal and professional accountability, influence of health care professional's attitudes in the implementation of an effective reporting tool, and fear of victimization, blame and shaming.

The healthcare system should be shifting towards a proactive rather than a reactive approach to medical and clinical errors. Continuously reducing the incidence of all patient safety incidents requires improved prevention strategies and improved recovery strategies from possible medico legal claims. The study findings suggest that more emphasis should be placed on reporting of near miss incidents. This would have the

benefit of reducing the costs of health care for both the service providers and recipients. Health care systems would benefit from reduced medico legal claims while patients would benefit from improved quality of care (Agency for Healthcare Research and Quality, 2017).

The study findings revealed that while near misses are more common than actual errors, they present more learning opportunities since they expose the healthcare system vulnerabilities without causing harm to patients. Patient safety can be improved through reporting of near misses, reducing the risk of safety issues (Sheikhtaheri, 2014); (Van Spall, et al., 2015). Nearly every day, patients are harmed in healthcare facilities. Wrong medicines are given to patients, the right medicine is given in the wrong dose, treatments are omitted or delayed, and patients in hospital beds develop pressure ulcers or fall and break their femurs. Moreover, diligent and capable clinicians leave objects inside patients after operations, and sadly, many patients die in the care of HCPs (Cross, 2018). The quality of healthcare recommendations in reporting NMIs is discussed next.

4.2.1 Quality of healthcare recommendations in reporting NMIs

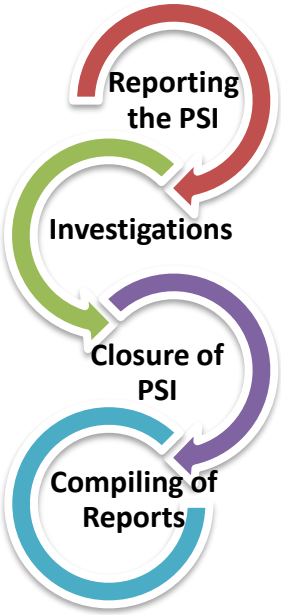
Based on the themes and sub themes that emerged from the study, the findings revealed that there were maternal and neonatal complications that were not reported on the existing PSI system. It is therefore evident that these factors contribute to the negative health outcomes associated with non-reporting of incidents. Considering the similarities in NMI organizational learning behaviour (Feng, Zhang, Tan & Liu, 2021), the problems regarding NMI in healthcare identified in this study may also exist in other healthcare facilities. As a result, the study proposes recommendations of “Recognise it, Say it, Fix it through Continuous Quality Improvement (CQI)” for future improvement. The proposed recommendations will also be meaningful for other healthcare facilities. The recommendations for improvement of the program are illustrated on Figure 4 and will be integrated into the discussions.

Figure 4: Summary of Quality of healthcare recommendations in reporting NMIs

The different components of this model have the potential to encourage and facilitate the adoption and promotion of the Just Culture. The knowledge accumulated through NMI reports can be used to enhance the analysis and interpretation of healthcare institutions reports. Equally, the information on operational risks can be used to strengthen the identification and facilitate effective management of such risks.

The findings discovered that an NMI occurs when an unplanned event does not reach the patient nor results in harm or illness despite having the potential to do so. PSIs, on the other hand, are unplanned or unintended events or circumstances that may result in harm to patients while in health care. The cause of this event can therefore not be traced to the underlying illness or natural progression of the disease (National Department of Health, 2017). The findings for this study firther revealed that, a near miss, a no harm incident, or a harmful incident (adverse event) can be an incident. In order to incoporate the Recognize, Say it, Fix it through CQI model steps, the current reporting system on Figure 5 needs to be augmented.

Figure 5: The existing reporting system (National Department of Health, 2017)



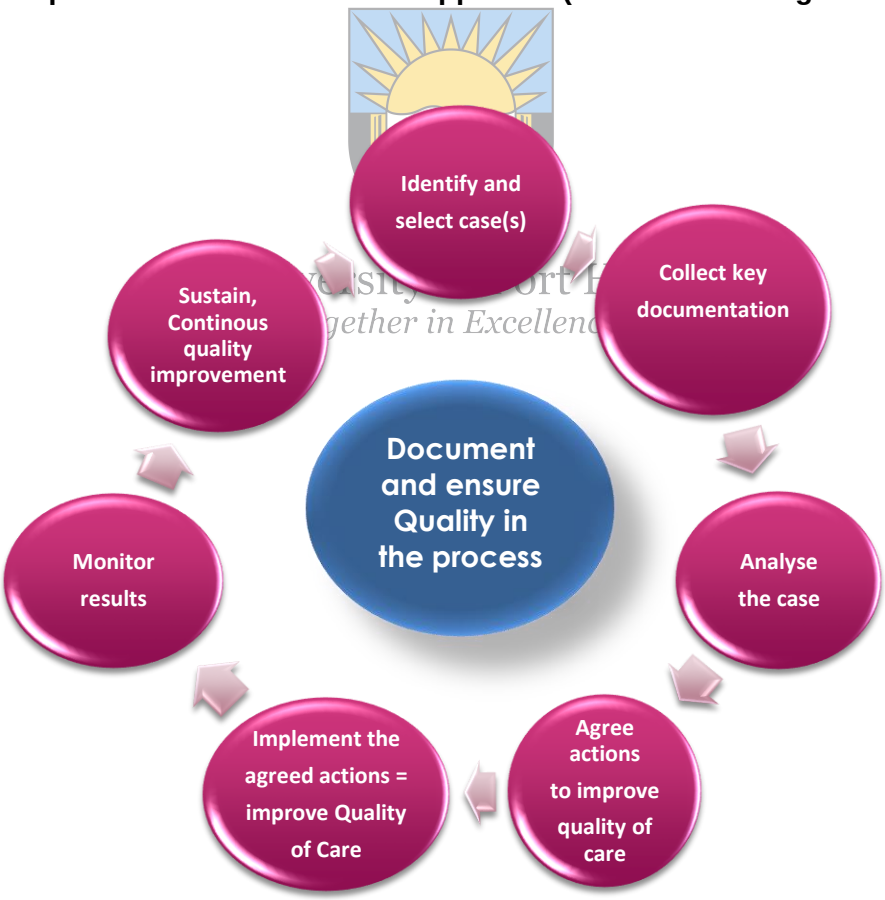
The illustration on Figure 5 shows that HCPs should report incidents as soon as they become aware of them, and within 72 hours of serious PSIs. The illustration also reveals that the Quality Assurance unit is expected to submit a preliminary report to the district and provincial Department of Health offices. In the event of an NMI, PSI, or serious adverse event, the investigation process should be completed within 60 days. When it comes to serious, the PSI committee will discuss improvement or mitigation plans within 72 hours following the incident. Afterwards, district and provincial health offices receive all PSI reports (National Department of Health, 2017).

While the reporting pathway is available in the NDoH guidelines, NMIs still go unreported. Therefore, the findings showed that the steps in achieving the Recognize Say it, Fix it through CQI model are through the review of maternal deaths and identification of preventable contributing factors. This study results stated that this review is central to the improvement of quality of care. A near-miss audit ensures that the analysis of care for critically ill women, identification of deficiencies in the provision of care, and the comparisons within and between institutions and nations is adequately conducted.

Ultimately, this will improve the quality of obstetric care and reduce maternal mortality and morbidity (Meenakshi, Srishti, Anita & Jai, 2017).

Furthermore, the findings for this study confirmed that there were no standard criteria for defining near misses until a few years ago. This caused discrepancies between regional or international comparisons. In 2008, the WHO adopted the definition of maternal near miss and established standard criteria for identifying women with pregnancy-related life-threatening conditions. The WHO definition provides a common basis for conducting maternal near-miss assessments across countries and allows for international comparisons ((Say, Souza & Pattinson, 2009); (Tuncalp, Hindin, Souza, Chou & Say, 2012). The Near-miss Approach steps from the WHO are illustrated in Figure 6.

Figure 6: Steps in the WHO- Near-miss Approach (World Health Organization, 2016)



The complete WHO Near-miss Approach on figure 6, is optimally implemented in three steps, namely, baseline assessment (or re-assessment), situation analysis and intervention. The baseline assessment entails identification and selection of cases and collection of key documents. The situation analysis entails analysis of the cases and the related documentation in order to get a better understanding of the cases. Once the situation analysis is completed, work on the intervention steps would commence. The interventions step entails identification of the appropriate interventions, their implementation and monitoring, and finally, adoption of sustainable continuous quality improvement strategies (World Health Organization, 2016).

The WHO Near-miss Approach focuses on reviewing maternal near-miss cases (women who survived severe complications during gestation, childbirth or within 42 days after termination of pregnancy) in a continuous quality improvement process. The hospital staff involved in case management selects perinatal near-miss cases on a monthly basis, and they systematically evaluate the care provided against guidelines, local protocols, and standards of care. It is important to note that the objective of the assessment review is not to solve a single near-miss case, but rather to critically analyse internal case management procedures and attitudes as well as to identify areas requiring further improvement. Hence, a bottom-up approach is used to identify areas for improvement, and to find and apply solutions to those problems while ensuring local ownership of the process and enhancing team-building. Near miss review cycles are designed with the primary intention of reducing maternal and perinatal mortality (World Health Organization, 2016).

Another step in achieving the Say it, Fix it through CQI model, is reporting of NMIs that should be encouraged through safety walk rounds. Safety walk rounds consist of a core group of senior managers walking through the health facility on a regular basis. Therefore, the rounds take place in six to eight service areas of the health facility. Safety walk rounds are designed to give senior managers an opportunity to assess the extent of near miss and patient safety incidents in the facility. Each round should take at least an hour to complete (National Department of Health, 2017). For instance, operations personnel,

excluding their immediate managers, would be asked about any patient safety incidents. The rounds also provide an opportunity to educate both the facility management and operations staff on NMIs and PSIs where necessary. In this case, employees have the opportunity to be empowered with knowledge on how to prevent and/or deal with near miss and patient safety incidents during their interactions with senior managers during the rounds (National Department of Health, 2017).

Besides safety walk rounds, health facility management and employees are mandated to hold meetings to discuss PSIs, carry out root cause analyses, develop and implement quality improvement plans. It must be noted that in these meetings, NMIs and the potential risks of them developing into patient safety incidents as well as available interventions would be discussed (National Department of Health, 2017). Thereafter, a root cause analysis can be conducted using any quality improvement tool, such as the cause-and-effect diagram, popularly known as the fishbone diagram. This tool is very versatile and can be used in a number of different ways. The cause-and-effect diagram is presented in Figure 7. The head represents the problem or aim and the end of each diagonal bone represents a topic that is relevant to addressing the problem ((Langley, et al., 2009); (Ontario, 2012)).

Figure 7: Cause and effect diagram example

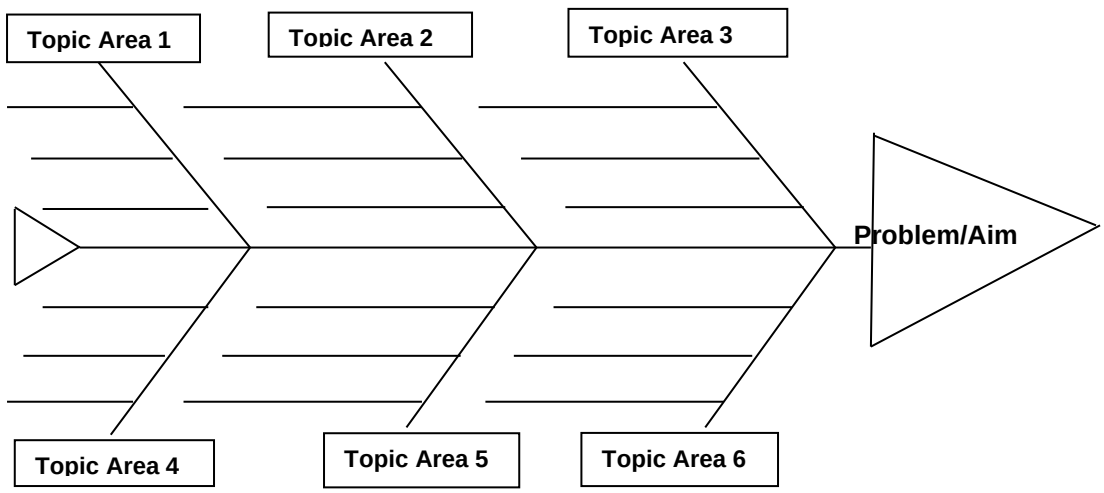


Figure 7, illustrate that brainstorming would be made simple for HCPs once a NMIs has been reported. The topic areas as stipulated in the PSIs guidelines are staff factors, patient factors, and organisational factors, work/environmental factors external factors (National Department of Health, 2017). Therefore, the cause-and-effect diagram can be incorporated into the NMIs and PSIs investigation document.

The study findings revealed that HCPs can identify various signs that could indicate an impending adverse outcome. Once any of these signs are observed, they should be communicated to the team and the measures to ensure patient safety should be taken. It is therefore recommended that HCPs adopt the phrase “See it, say it, fix it through CQI” when it comes to PSIs (Leistikouw, 2017). The root cause analysis is one of the valuable tools available to HCPs when carrying out a detailed analysis of a problem. So, any changes in care and/or improvement plans developed on the basis of a root cause analysis would have a higher likelihood of addressing the causes of an identified NMI. This would mean that, only those PSIs of an unavoidable nature would be experienced since HCPs would have been empowered by the analysis of the NMIs and prevention strategies (National Department of Health, 2022).

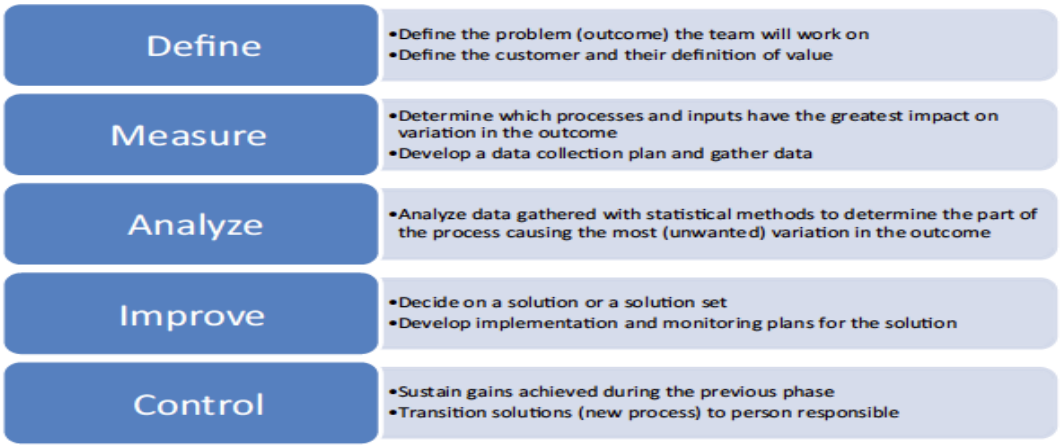
Moreover, it is important HCPs familiarise themselves with the PSI procedures of their healthcare organisation (Leistikouw, 2017). These procedures should be included in the induction package training of each individual who has the responsibility to report a NMIs as well as the health facility annual training plan. Besides having the procedures in the induction package, HCPs would benefit from periodic in-service training on emerging near miss and patient safety incidents (Scott, Dawson, Heavey, De Brún, Buttery, Waring & Flynn, 2021). Such training could focus on updating employees on the changing criteria for identifying NMIs and PSIs, accessing incident reporting tools and incident reporting procedures.

The NDoH encourages individuals, groups and health institutions to conduct research on patient safety issues. Subsequently, the findings of such studies, past and present, are taken into consideration when developing and implementing quality improvement projects

and plans (National Department of Health, 2017). Furthermore, health facilities need to commission research projects aimed at developing and evaluating different quality improvement methodologies; as one way of developing sustainable continuous quality improvement plans in order to enhance quality of care (Langley, et al., 2009).
In the face of shrinking resources, public health leaders are forced to make difficult decisions. Quality improvement interventions are expected to make public health programs, services, or organizations more efficient and effective (Dilley, et al., 2012).

The healthcare industry is one of the most unique in the world and it deals with many complex tasks. As a solution, the Lean Six Sigma, Define, Measure, Analyse, Improve, Control (LSS) (DMAIC) approach is a valuable strategy for improving quality performance in healthcare facilities. This approach provides guidance on how to deal with patient satisfaction within a quality improvement system. Healthcare facilities can use this method to reduce waste, variation, and inequality in their service processes. Figure 8 below shows the DMAIC approach (Ahmed, 2019).

Figure 8: The DMAIC Roadmap (Ahmed, 2019)



It is important to note that the implementation of LSS and DMAIC approaches would assist the healthcare organisations in analysing and evaluating their performance in patient safety, financial outcomes, patient satisfaction and loyalty (Bauer, Vargas, Sellitto, Souza & Vaccaro, 2019); (Gupta, Lteif, Creo, Iqbal, Pittock & Tebben, 2019). However, if projects

are not monitored, the progress, trends and bottlenecks might be missed. As a result, run charts are recommended tools for daily monitoring of progress (Langley, et al., 2009). Run charts are easy to produce, easy to interpret and enable one to understand not only the performance of a process over time but also the extent to which performance fluctuates above and below the target line.

Generally, the findings for this revealed that the challenges faced by HCPs in reporting NMIs at the participating hospital were as follows: Lack of knowledge of the NMIs reporting tool and system; reporting of PSIs only while excluding NMIs and HCPs beliefs, behaviour and sentiments. Furthermore, the findings discovered the challenge of lack of knowledge incorporated barriers in training, support and feedback, and incident reporting time constraints. While the challenge of reporting PSIs only encompassed the inability to identify near misses and the preference by HCPs to solve rather than report an incident. Lastly, the study results revealed challenges on HCPs personal qualities encompassing lack of accountability, personal attitudes and fear of reprimand.

Therefore, the researcher believes that the safety walk rounds encouraged by the health authorities, the root cause analysis, run chart monitoring, and the DMAIC roadmap can be viewed as a summary of a CQI guide that can be used by any health facility in its efforts to improve the quality of patient care (National Department of Health, 2017); (Ahmed, 2019); (Langley, et al., 2009); (Leistikouw, 2017).

4.3 CONCLUSION

In essence, measures for addressing some of the known barriers to use of a system need to be non-punitive, confidential, and independent of regulatory requirements, as well as to provide timely feedback (Schultz, et al., 2014). Hence, reporting, investigating and monitoring of NMIs should not be associated without any punitive action, instead, it should be viewed as a learning opportunity for the organization. HCPs are affected differently by PSIs, and these can last for some time. In response to events, professionals need to be treated with compassion, provided with timely and appropriate care and feedback, and be given the opportunity to heal. The study makes a contribution to the understanding

that incident reviews may unintentionally worsen the emotional distress of participants when conducted in an uncaring, unsympathetic, punitive and poorly timed manner. The healthcare system should strive to limit distress by implementing clear, consistent, non-punitive and transparent processes. If the healthcare facilities want to improve on a just culture, the involved persons require mentoring and emotional support for the duration of the process.

Importantly, healthcare organizations should clarify the roles and responsibilities of NMI reporting and analysis with associated action responsibilities to ensure that the incident reporting system can perform its duties properly. The proposed recommendations of "Recognise it, Say it, Fix it through Continuous Quality Improvement" will also be meaningful for other healthcare facilities. This means that, the healthcare system should shift towards a proactive rather than a reactive approach to medical and clinical errors.

Additionally, to continuously reduce the incidence of all patient safety incidents requires improved prevention strategies and improved strategies for recovery from possible medico-legal claims. Moreover, the study findings suggest that additional focus should be placed on near miss incident reporting and investigation so that effective improvement plans can be developed, implemented, monitored and evaluated. Such improvement plans should be designed to improve patient care, reduce avoidable PSIs and reduce medico-legal claims.

4.4 LIMITATIONS

This study investigated the reasons for the lapses in reporting NMIs at the participating hospital. The purpose of the study was not to generalize the findings to a wider population of health facilities, but rather, to obtain a better understanding of the reasons behind non-reporting of NMIs from a HCPs perspective. The following limitations were identified:

- The process of obtaining ethical clearance from the University of Fort Hare Ethics Committee took longer than envisaged (over a year) due to reorganisation of academic activities from face to face to online.

- The findings of this study cannot be generalised to other settings as only one district hospital was studied.
- The actual conducting of the study was also affected by the COVID-19, which made participants hesitant to engage in face-to-face interviews, resulting in the postponements of interviews dates and times.
- The researcher had difficulty in assessing facial expressions because of the use of facemasks.

4.5 RECOMMENDATIONS FOR FURTHER RESEARCH

- Expanding the scope of the study to include more facilities so that the findings could be generalizable to a wider population of facilities.
- Conducting a cross-sectional with more health care worker categories.
- Determining staff perceptions on the benefits of incident reporting on patient care.

4.6 CHAPTER SUMMARY

This chapter focused on the presentation and discussion of the findings of the study, development of quality of healthcare recommendations in reporting NMIs for reporting of NMIs in the context of a state funded health care facilities. The limitations of the study were also discussed and recommendations for further research were presented. The study provides a basis for guiding future empirical studies that will enhance understanding of the challenges associated with incident reporting in the health care system, and also determinants of NMIs reporting and/or development of interventions targeted at improving incident reporting.

4.7 EXECUTIVE SUMMARY

NMIs can be viewed as markers of patient safety and can provide valuable information if properly reported and investigated. Trends that emanate from incident reports can provide a better understanding of patient safety within a health facility. Based on analysed PSI reports, patient safety can be improved and medico-legal claims would decline. Near miss incidents can be early warning signs of impending failure and, as such, provide opportunities for safety improvement. Even though the majority of incidents go

unreported, the few that get to be reported would have the same desired effects, if properly investigated. Given the benefits of NMIs reporting, this study was undertaken to investigate challenges faced by HCP in reporting NMIs, specifically targeting a district hospital in the Amathole District of the Eastern Cape Province. The goal of the study was to develop recommendations for healthcare management and HCPs on how to better manage NMIs by identifying the challenges faced by HCPs that could impact the quality of care at one state-funded district hospital.

This study used a mixed method study design. Purposive and convenience sampling were used for participants' selection for the study. Quantitative data was collected using the WHO Near-Miss Approach while individual and focus group interviews with healthcare professionals were carried out for collecting qualitative data. Participants were consciously selected based on the relevance of their roles in NMIs reporting besides their willingness to participate in the study. The number of complications that occurred during each month of the year 2019 was determined using components of the WHO-Near-Miss Approach. The information that was obtained served as a baseline assessment of the HCPs reporting situation at the hospital.

The challenges that HCPs face in reporting NMIs at the district hospital included lack of knowledge of the NMIs reporting system and tool, HCPs preference to report PSIs only, and personal perceptions of HCPs towards the incident reporting. Lack of knowledge was characterised by lack of comprehensive training, support and feedback from their seniors, and the time associated with incident report writing. HCPs preference to report PSIs only was characterised by inability to identify a NMIs and preference to solve instead of reporting incidents. Personal perceptions of HCPs included lack of personal and professional accountability, attitudes towards implementation of the NMIs reporting tool, and fear of victimization, blaming and shaming.

The results of the study suggest that the healthcare system should be shifting towards a proactive rather than the current reactive approach to medical and clinical errors.

Reduction in PSIs requires improved prevention strategies and improved strategies for recovery from possible medico legal claims. Based on this study, additional focus should be placed on NMIs reporting and investigation. It is on the basis of the results of the investigations that effective and sustainable improvement plans to improve patient care can be developed. Improvements in patient care would reduce unavoidable PSIs, medico-legal claims would also decrease, and the quality of patient care would improve. NMI reporting is encouraged through the WHO-Near Miss Approach and the Recognise, Say it, Fix it through implementable and effective continuous quality improvement recommendations.

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ANNEXURE A: Application for Ethical Clearance from UFH Ethics Committee

[redacted]

[redacted]

[redacted]

13 December 2019

HREC-Chairerson

Faculty of Science and Agriculture

University of Fort Hare

To: HREC-Chairperson

Re: **Application for Ethical Clearance Certificate**

Dear Sir/Madam

I, Ms. Lindiwe Ntlanganiso (Student Number: [redacted]), write this letter to apply for ethical approval from the Human Research Ethics Committee (HREC) of the University of Fort Hare regarding my proposed research study which reads: **"Challenges faced by Healthcare professionals in reporting Near Miss Incidents, in [redacted] Eastern Cape''**.

Relevant documents are herewith attached for your own perusal. Thank you for your consideration.

Please do not hesitate to contact me should you require any further details.

Kindest regards

[redacted]

Ms. Lindiwe Ntlanganiso

ANNEXURE B: Ethical Clearance Certificate

University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

P.O Box 1054
East London 5200
Tel: +27 (0) 43 704 7368
E-mail: dgoon@ufh.ac.za

ETHICAL CLEARANCE CERTIFICATE
REC-100118-054

Certificate Reference Number:	**Ref # 2020=10=04=NtlanganisoL**
Project title:	**Challenges faced by healthcare professionals in reporting near miss incidents, in [redacted] Eastern Cape**
Nature of Project	Masters of Public Health
Principal Researcher:	Ntlanganiso L
Student Number:	[redacted]
Supervisor:	Prof du Plessis

On behalf of the University of Fort Hare Health Research Ethics Committee (HREC), I hereby give ethical approval in respect of the undertakings contained in the above-mentioned project and research instruments(s). Should any other instruments be used, these require separate authorization. The Researcher may therefore commence with the research as from the date of this certificate, using the reference number indicated above.

Please note that the HREC must be informed immediately of

- Any material change in the conditions or undertakings mentioned in the document
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research

The Principal Researcher must report to the HREC in the prescribed format, where applicable, annually, and at the end of the project, in respect of ethical compliance.

University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

P.O Box 1054
East London 5200
Tel: +27 (0) 43 704 7368
E-mail: dgoon@ufh.ac.za

The HREC retains the right to

- Withdraw or amend this Ethical Clearance Certificate if
  - Any unethical principles or practices are revealed or suspected
  - relevant information has been withheld or misrepresented
  - regulatory changes of whatsoever nature so require
  - the conditions contained in the Certificate have not been adhered to

- Request access to any information or data at any time during the course or after completion of the project.
- In addition to the need to comply with the highest level of ethical conduct principal investigators must report back annually as an evaluation and monitoring mechanism on the progress being made by the research. Such a report must be sent to HREC monitoring@ufh.ac.za.

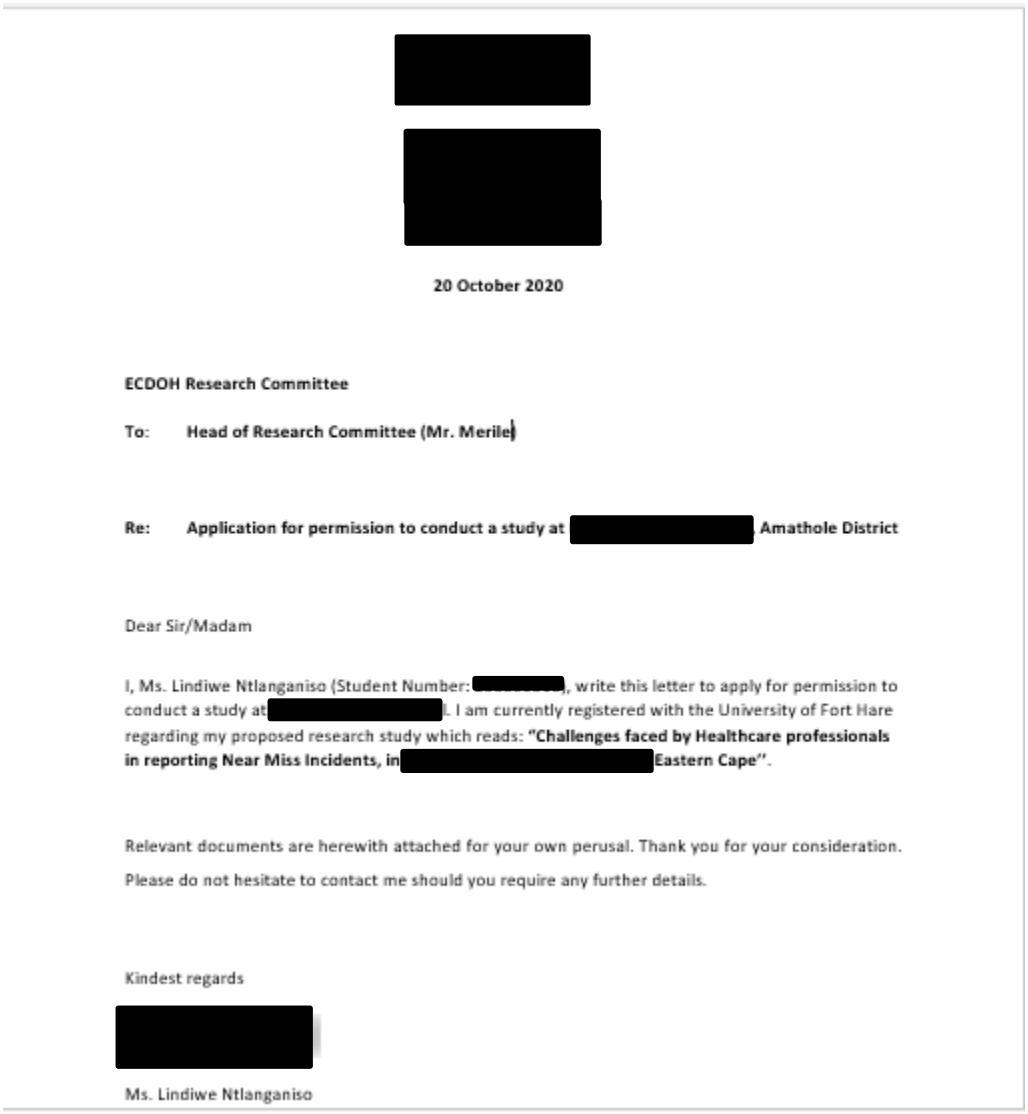
The Ethics Committee wishes you well in your research endeavours.

Yours sincerely

[redacted]

Professor DT Goon
Chairperson: HREC
14 October 2020

ANNEXURE C: Request for Permission conduct study in Eastern Cape province



[redacted]

[redacted]

20 October 2020

ECDOH Research Committee

To: Head of Research Committee (Mr. Merile)

Re: Application for permission to conduct a study at [redacted], Amathole District

Dear Sir/Madam

I, Ms. Lindiwe Ntlanganiso (Student Number: [redacted], write this letter to apply for permission to conduct a study at [redacted]. I am currently registered with the University of Fort Hare regarding my proposed research study which reads: **"Challenges faced by Healthcare professionals in reporting Near Miss Incidents, in [redacted] Eastern Cape"**.

Relevant documents are herewith attached for your own perusal. Thank you for your consideration.

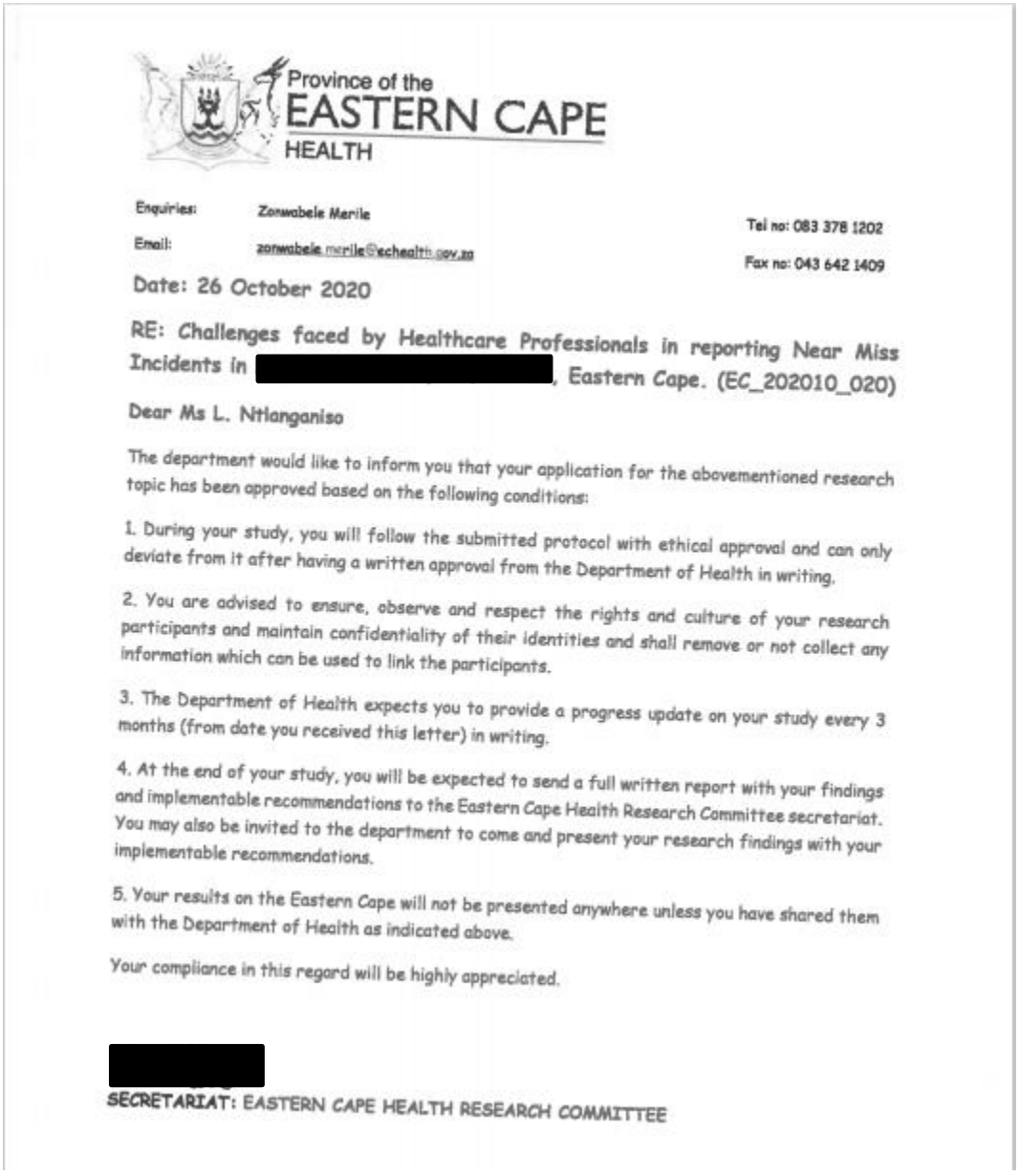
Please do not hesitate to contact me should you require any further details.

Kindest regards

[redacted]

Ms. Lindiwe Ntlanganiso

ANNEXURE D: Clearance Letter from ECDOH Research Committee



Province of the
EASTERN CAPE
HEALTH

Enquiries: Zonwabele Merile
Email: zonwabele.merile@echealth.gov.za
Tel no: 083 378 1202
Fax no: 043 642 1409

Date: 26 October 2020

RE: Challenges faced by Healthcare Professionals in reporting Near Miss Incidents in [redacted], Eastern Cape. (EC_202010_020)

Dear Ms L. Ntlanganiso

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.

2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.

3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.

4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.

5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

[redacted]
SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

ANNEXURE E: Request for permission to carry out study in the Amathole District

[redacted]

[redacted]

09 November 2020

Eastern Cape Department of Health

Amathole District

Dear District Manager (ECDOH, Amathole District)

Application for Data Collection at [redacted] Hospital

I am a student at the University of Fort Hare, registered for Master of Public health. My research topic is: Challenges faced by healthcare professionals in reporting near miss incidents, in [redacted], Eastern Cape. This serves as an application to conduct the study at [redacted] Hospital.

The aim of the study is to investigate the challenges and barriers among Healthcare Professionals that contribute to the lack of reporting near miss incidents that influence the quality of care to patients and which could potentially result in medical negligence claims, formulate guidelines for improvement of reporting (Near Miss Incidents) NMI's to improve the quality of care in the health system.

The inclusion criteria will be healthcare professionals who are required to report NMI's to participate in an individual interview and focus group at the end of individual interviews to triangulate the data and to determine the challenges and barriers in reporting NMI's.

All COVID-19 regulations will be followed, participants will be recorded in a separate register that will be shredded after 10 days of contact. The register will have subject names, identity numbers, COVID-19 symptoms, if any symptoms the subject will be advised to seek medical assistance and will not participate in the interview. Participants and the researcher will be required to wear at least a cloth mask throughout the interview and maintain social distancing. A 70% alcohol hand rub will be available to spray the hands of participants before and after the interview. The most frequently touch areas, such as arm rests and table edges will be wiped down by wet wipes that contain 70% alcohol, before and after each participant to prevent cross contamination of any pathogen.

Please find the attached university and ECDOH ethical clearance documents. I look forward to speaking with you further regarding my request. Thank you in advance.

Yours Sincerely

Lindiwe Ntlanganiso

[redacted].....com

ANNEXURE F: Permission Letter from the ECDOH Amathole District

Province of the
EASTERN CAPE
HEALTH

Room 5 • Ground Floor • Old Medical Center Building • 19 St James St Southernwood • East London • Eastern Cape
Private Bag X0002 • Southernwood East London • 5600 • REPUBLIC OF SOUTH AFRICA
Tel: +27 (0)43 707 6781 • Fax: +27 (0)86445094 • Email: XolaniLmene@echealth.gov.za

Ms L Ntlanganiso
[redacted]
Date: 10 November 2020

Dear Ms Ntlanganiso

RE: PERMISSION TO CONDUCT RESEARCH: CHALLENGES FACED BY HEALTHCARE PROFESSIONALS IN REPORTING NEAR MISS ACCIDENTS, IN [redacted], EASTERN CAPE.

This communique serves to confirm receiving your application dated 9 November 2020 requesting permission to conduct research within Amathole District. This office has no objection in you conducting research as stipulated in your research proposal provided that you adhere to research ethics all the time.

Kindly, make sure that you do not interfere with service delivery when you conduct the interviews with the identified sample.

It will be appreciated that the findings and recommendations will be shared with this office for future planning sessions.

Please do not hesitate to contact this office when you experience any difficulties, when you conduct fieldwork for the abovementioned study.

Your cooperation in this regard will be highly appreciated

Kind Regards
[redacted]
10/11/2020

PERMISSION TO CONDUCT RESEARCH: CHALLENGES FACED BY HEALTHCARE PROFESSIONALS IN REPORTING NEAR MISS ACCIDENTS, IN [redacted] EASTERN CAPE.

Recommended / ~~Not Recommended~~

[redacted]

Mrs. B Hobo

10/11/2020

Date

Secretary: Amathole District Research Committee

Amathole District Dept. of Health

Approved/~~Not Approved~~

[redacted]

Mrs. S Gede

10/11/2020

Date

District Manager

Amathole District Dept. of Health

ANNEXURE G: Letter of Permission to carry out the study at the hospital

[redacted]

[redacted]

01 December 2020

[redacted] **Hospital**

To: The Acting CEO of the Hospital

Re: Application for permission to conduct a study at [redacted] Hospital, Amathole District

Dear Sir/Madam

I, Ms. Lindiwe Ntlanganiso (Student Number: 200800316), write this letter to apply for permission to conduct a study at [redacted] hospital. I am currently registered with the University of Fort Hare regarding my proposed research study which reads: **"Challenges faced by Healthcare professionals in reporting Near Miss Incidents, in [redacted] Eastern Cape''**.

Relevant documents are herewith attached for your own perusal. Thank you for your consideration.

Please do not hesitate to contact me should you require any further details.

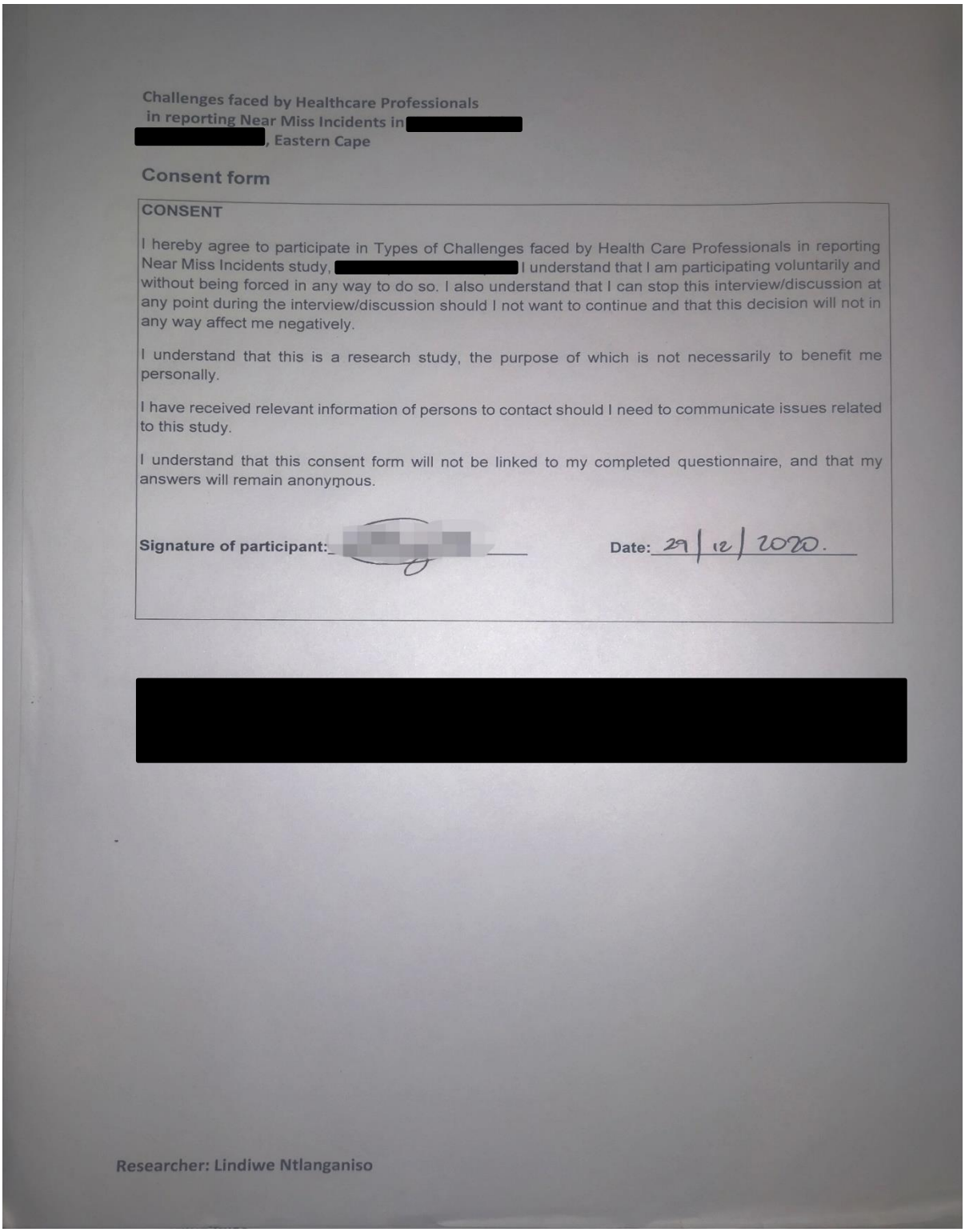
Kindest regards

[redacted]

Ms. Lindiwe Ntlanganiso

[redacted]

ANNEXURE H: Consent Form



Challenges faced by Healthcare Professionals
in reporting Near Miss Incidents in [redacted]
[redacted], Eastern Cape

Consent form

CONSENT

I hereby agree to participate in Types of Challenges faced by Health Care Professionals in reporting Near Miss Incidents study, [redacted] I understand that I am participating voluntarily and without being forced in any way to do so. I also understand that I can stop this interview/discussion at any point during the interview/discussion should I not want to continue and that this decision will not in any way affect me negatively.

I understand that this is a research study, the purpose of which is not necessarily to benefit me personally.

I have received relevant information of persons to contact should I need to communicate issues related to this study.

I understand that this consent form will not be linked to my completed questionnaire, and that my answers will remain anonymous.

Signature of participant: [redacted] **Date:** 29/12/2020.

[redacted]

Researcher: Lindiwe Ntlanganiso

ANNEXURE I: Demographic data and Study Question

INTERVIEW QUESTIONS

This is a phenomenological [open] interview. The researcher starts with normal biographic data to put the participant at ease, and then follows with a central question and sub-questions to obtain deeper understanding of the phenomenon under investigation. This include:

BIOGRAPHICAL DATA

1. COVID screening
2. The participants were asked about their age
3. The type of professional body they are affiliated to

CENTRAL QUESTION:

“Please tell me about the challenges you experienced in reporting NMIs.”

Depending on the responses, the researcher continues with non-invasive, relevant and probing sub-questions which will encourage the participants to disclose more information about challenges experienced in reporting NMIs.

ANNEXURE J: Transcript of an audio-tape interview

Transcription one

Participant 001

Researcher: Good morning, thank you again for consenting to participate in this interview. In this study I want to investigate challenges you experienced in reporting NMIs. I will not mention your name in any documentation, and to help us get started, let me get some more information from you:

Researcher: The participant was wearing a surgical mask and asked to sanitize the hands

Researcher: The participant was asked about Covid-19 symptoms: fever, cough, sore throat, loss of smell, body aches, nausea, vomiting, diarrhea, red eyes, contact with a person with Influenza symptoms or confirmed COVID-19 case, social gathering attendance, high risk exposure with a COVID-19 patient.

Participant: No, not that I know of.

Researcher: The participants of the study should be between the ages of 21 and 64, the age was asked.

Participant: I am 29 years.

Researcher: The participant was asked about the professional body they are affiliated to, to determine if they are mandated to report NMIs.

Participant: South African Nursing Council

Researcher: "What challenges did you experience in reporting NMIs."

Participant: "Near Miss?" *Looking up, trying to think*

Researcher: Yes, Near Miss Incidents

Participant: *There was a few seconds of silence* "Mmmmmh…..Near miss, Near miss….is it a drug reaction?"

Researcher: "No, it is any event that almost occurred but stopped in time before reaching the patient that had a potential to cause harm to a patient, like a patient almost falling but a nurse was next to them and stopped it before time, or giving a patient an injection and then when you confirm the name of the patient you realize that you have the incorrect file and an injection you almost gave was not for the patient you called out, but you realized in time before administering"

Participant: “Oh yhaa, now I understand” *Silence again, the eyes looked like there was a smile behind the mask, putting one finger over the mouth area*

Researcher: “Do you report NMIs?”

Participant: “No, I don’t” *giggling*

Researcher: “Why not?”

Participant: “I have just realized as you are explaining that we have to report those things, we just report the incidents, adverse events, not the near miss” *giggling again* come to think of it, I have never been trained or guided in reporting

Researcher: Can you please elaborate, why you or other HCPs don’t report NMIs?

Participant: “Mmmhhhhh”…*Silence, Looking up, then back to the researcher*

Researcher: Is it because there was no harm to the patient?

Participant: “I think so, I cannot say it happens often, maybe sometimes it does happen, I think its something that happens once in a while, not every now and again”

Participant: “but I guess it does happen and we don’t take it as an incident, I think that’s the problem because we don’t take it as an incident, Yhaaa”

Researcher: “why don’t we take it as an incident?”

Participant: “I think we are very busy, so other things, especially if they are not a big deal, we don’t take them seriously, we just take the serious ones if it happens, but if you are carrying a folder and you want to inject a patient, and realise that the folder you got from the doctor has incorrect patient details inside it, you are busy, when you offer the injection to the patient, the patient doesn’t want it, when you confirm the name its an incorrect patient, it really does happen but I think we take them for granted” *Sigh and a deep breath*

Participant: Sometimes it gets really busy, so if that happens, we take the correct file contents and ensure that we inject the correct patient

Researcher: “is there a reporting tool for NMI’s that you know of”

Participant: “No, only know of and adverse event, I have never seen the one for near miss, it is the first time I hear about a near miss”

Researcher: “any closing remarks, or questions from your side, before I let you go”

Participant: “No, there is nothing” *smiling behind the mask*

Researcher: Thank you, once again for agreeing to participate in this study, I will be back in a few days, if you have anything you want to add, please don't hesitate to tell me

ANNEXURE K: Current near miss incident reporting process

Annexure F: Patient Safety Incident Reporting Form

Section A (notification) - to be completed by manager of section where incident took place. Submit section A and B to next level for notification for SAC 1 incidents
Section B (Statement by staff, patient or significant other)– to be completed by staff, patients or significant other that were directly involved while the incident took place
Section C (investigation) - to be completed by investigator(s) of the incident, in most cases this would be the manager(s) of section where the incident took place

SECTION A - Notification

1. Type of patient safety incident (PSI): Mark with an X		
No harm	Near miss	Harmful (Adverse Event)

2. Patient information		**3. Staff involved**		
Patient name and surname		Name and surname	Contact detail	Department
Patient file number				
Location (department/ward)				
Age				
Gender				
Final diagnosis				

4. Date of PSI				**5. Time of PSI**		
6. SAC rating: Mark with an X	1	2	3	7. Date reported to next level if SAC = 1		8. No of days to report PSI with SAC = 1

9. Method of detecting PSI: Mark with an X	Reported by health professional	Research studies	Surveys on patient experience of care	Inpatient medical review	Review of record on follow-up	External sources			Safety walk rounds	Focused teams	Use of data
						Complaints	Media	Public			

10. Short description of Patient Safety Incident (detailed information available under section B as reported by staff)

11. Immediate resulting action taken to minimise harm

12. Short description of initial disclosure

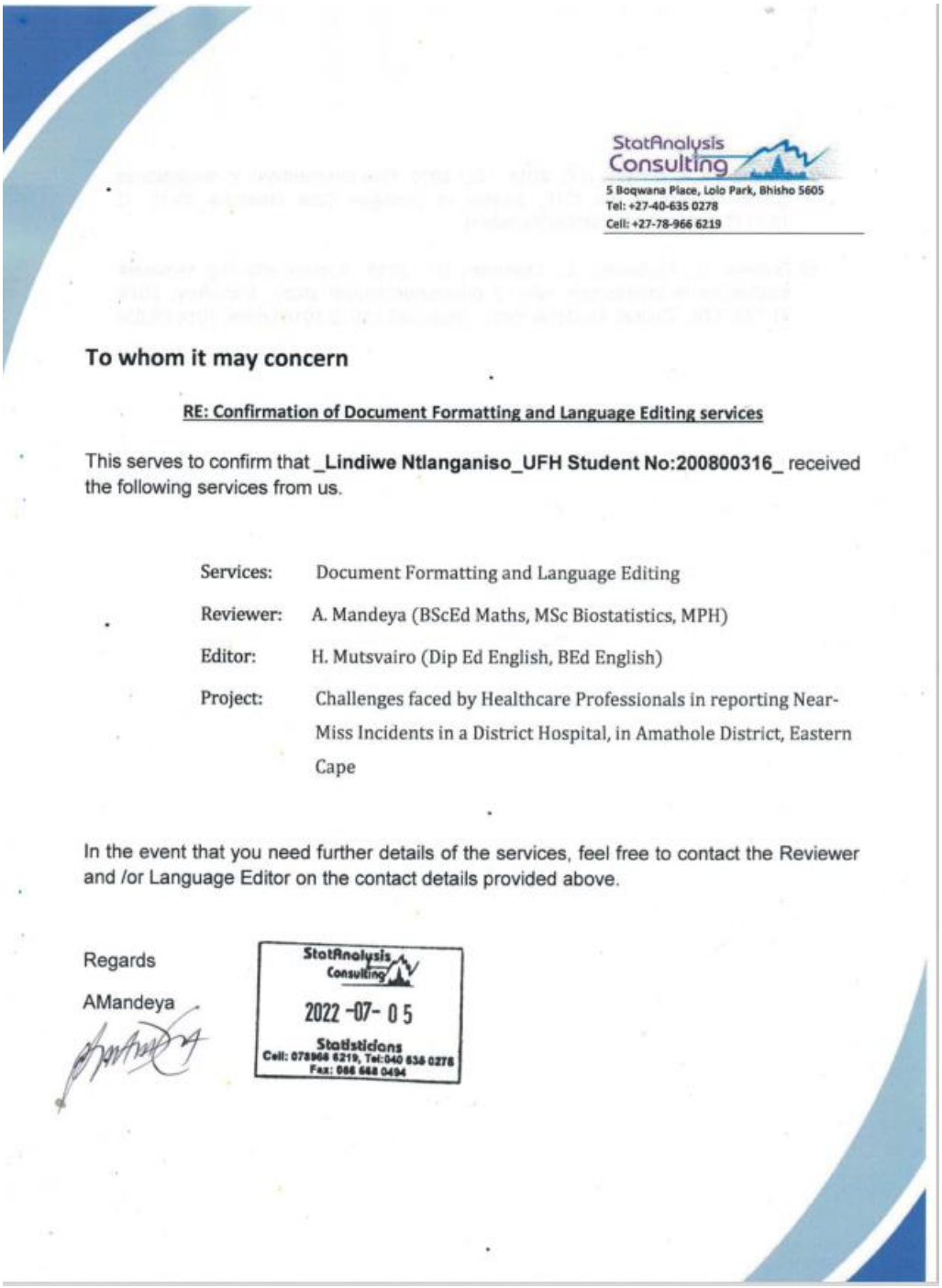
Compiled by: **Designation:** **Signature:** **Date:**

ANNEXURE L: Observation Guide

Site: District Hospital in Amathole District, Eastern Cape		**Date: December 2020**		
Research Issue: Challenges faced by Healthcare Professionals in reporting Near Miss Incidents in a District Hospital, in Amathole District, Eastern Cape				
Observation source	**Area of Observation**	**Method of Data Collection**	**Method of Data Analysis**	**Results**
Patient Safety Incident Register	No harm/Minor Harm incidents	Observation & Measurement	Content Analysis & Descriptive Statistics	**0** = No harm/Minor harm incidents
Maternity Register	Maternal complications	Observation & Measurement	Content Analysis & Descriptive Statistics	**198** = Total Maternal complications
	Neonatal Complications	Observation & Measurement	Content Analysis & Descriptive Statistics	**12** = Total Neonatal complications
Perinatal Audit Meeting Minutes	Maternal complications	Observation & Measurement	Content Analysis & Descriptive Statistics	**198** = Total Maternal complications
	Neonatal Complications	Observation & Measurement	Content Analysis & Descriptive Statistics	**12** = Total Neonatal complications
Maternity Register & Perinatal Audit Meeting Minutes	**Maternal complications**: Contributory conditions such as maternal health issues such as anaemia or HIV, previous caesarean section, obstructed labour	Observation & Measurement	Content Analysis & Descriptive Statistics	**154**
	Necessity for blood transfusions, hysterectomy, or other surgical interventions [excluding caesarean sections]	Observation & Measurement	Content Analysis & Descriptive Statistics	**1**
	Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the mother	Observation & Measurement	Content Analysis & Descriptive Statistics	**1**
	Maternal deaths irrespective of the duration of pregnancy	Observation & Measurement	Content Analysis & Descriptive Statistics	**0**
	Maternal near miss [nearly died but survived a complication]	Observation & Measurement	Content Analysis & Descriptive Statistics	**0**
	Post-Partum Hemorrhage (PPH)	Observation & Measurement	Content Analysis & Descriptive Statistics	**3**
	Anti-Partum Hemorrhage (APH)	Observation & Measurement	Content Analysis & Descriptive Statistics	**3**
	Severe Pre-Eclampsia, Eclampsia	Observation & Measurement	Content Analysis & Descriptive Statistics	**1**

	Gestational Hypertension (GHPT)	Observation & Measurement	Content Analysis & Descriptive Statistics	**35**
	Ruptured uterus	Observation & Measurement	Content Analysis & Descriptive Statistics	**0**
Maternity Register & Perinatal Audit Meeting Minutes	**Neonatal Complications**: Severe life-threatening neonatal complication such as birth asphyxia, foetal distress	Observation & Measurement	Content Analysis & Descriptive Statistics	**5**
	Low Apgar scores and prematurity	Observation & Measurement	Content Analysis & Descriptive Statistics	**2**
	Admission to intensive care or transfer to higher levels of care, intubation, and ventilation of the baby	Observation & Measurement	Content Analysis & Descriptive Statistics	**2**
	Neonatal deaths irrespective of gestation (including FSBs)	Observation & Measurement	Content Analysis & Descriptive Statistics	**3**
	Maternal near miss [nearly died but survived a complication]	Observation & Measurement	Content Analysis & Descriptive Statistics	**0**

ANNEXURE M: Language Editing Certification



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To whom it may concern

RE: Confirmation of Document Formatting and Language Editing services

This serves to confirm that **_Lindiwe Ntlanganiso_UFH Student No:200800316_** received the following services from us.

Services:	Document Formatting and Language Editing
Reviewer:	A. Mandeya (BScEd Maths, MSc Biostatistics, MPH)
Editor:	H. Mutsvairo (Dip Ed English, BEd English)
Project:	Challenges faced by Healthcare Professionals in reporting Near-Miss Incidents in a District Hospital, in Amathole District, Eastern Cape

In the event that you need further details of the services, feel free to contact the Reviewer and /or Language Editor on the contact details provided above.

Regards

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ANNEXURE N: Language Editing Certification

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This is to certify that the Research Dissertation with the title study: **"Challenges faced by Healthcare Professionals in Reporting Near Miss Incidents at a Hospital in the Amathole District, Eastern Cape Province, South Africa"** to be submitted by **Ms Ntlanganiso**, has been proofread and edited by **Usizolwethukini Language Consultants**.

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