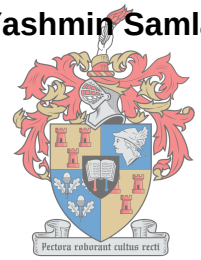
FACTORS INFLUENCING ADVERSE EVENTS RESULTING IN MALPRACTICE LITIGATION IN NURSING PRACTICE IN PRIVATE HOSPITALS IN THE WESTERN CAPE

Yashmin Samlal



Thesis presented in partial fulfilment of the requirements for the degree of Master of Nursing Science in the Faculty of Medicine and Health Sciences Stellenbosch University

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DECLARATION

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Date: March 2018

ABSTRACT

Patient safety is the focus of the healthcare environment. However, the incidences of medical negligence leading to malpractice litigation cases are increasing globally.

The aim of this study was to investigate factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape, which is a sub-study to the principle study “A retrospective analysis of malpractice litigation in nursing practice in South Africa”. The ethics approval for the main study is confirmed by reference number N16/02/027. The research question was “What are the factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape?”

The objectives included:

- Complete an audit analysis of the nursing process
- Categorise the adverse events into principle types
- Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation
- Identify other healthcare team members who may be associated with the adverse events that have resulted in malpractice litigation
- Assess the severity of the adverse events associated with malpractice litigation.

A quantitative, retrospective audit research design was used for the purpose of this study. The study focused on malpractice litigation cases that occurred in private hospitals in the Western Cape.

A convenience sample was applied. Seven attorneys, who had a variety of cases from various private hospitals within the Western Cape, granted the researcher permission to audit a total of 81 trial bundles.

The test-retest method was applied to ensure the instrument included all required information to audit the trial bundles. The main study conducted a pilot study which confirmed reliability of the instrument.

Expert opinions were obtained to ensure validity of the instrument. A rigorous process ensured face and content validity.

The pilot study which is a sub study was conducted for the main study and not repeated in this study.

The individual trial bundles were audited with the use of an audit instrument at the offices of the attorneys who specialised in malpractice litigation cases. With the support of the biostatistician, a descriptive analysis was completed and presented in tables and graphs. Ethical approval (S16/10/204) was granted by the Faculty of Medicine and Health Science at Stellenbosch University.

The researcher found that n=49 (60.5%) of the cases were settled out of court. Clinical manifestations were not recorded in n=62 (76.5%) of the trial bundles. Clinical management was the most common principle type found, n=72 (88.9%). The majority of the adverse events were extreme, n=29 (35.8%) resulting in death or disability.

The recommendations include encouraging continuous professional development, improving supervision in the clinical environment, promoting the 'Just Culture' within the healthcare environment to encourage reporting of adverse events: thereby allowing measures to be put into place to prevent a recurrence of the adverse event.

Keywords: Malpractice, medical negligence, adverse events, misconduct, litigation, patient safety

OPSOMMING

Die veiligheid van die pasiënt is die fokus binne die omgewing van die gesondheidsorg. Nietemin, die voorkoms van mediese nalatigheid wat tot wanpraktyk litigasie-sake lei, is wêreldwyd aan die toeneem.

Die doel van hierdie studie was om faktore te ondersoek wat nadelige gebeurtenisse beïnvloed wat lei tot wangpraktyk-litigasie in die verpleegpraktyk in privaat hospitale in die Wes-Kaap. Dit is 'n substudie vir die hoofstudie. 'n Terugwerkende analise van wanpraktyk-litigasie in die verpleegpraktyk in Suid-Afrika. Die etiese goedkeuring vir die hoofstudie word bevestig deur verwysingsnommer N16/02/027.

Die navorsingsvraag was: "Wat is die faktore wat nadelige gebeurtenisse beïnvloed, wat lei tot wanpraktyk-litigasie in die verpleegpraktyk in privaat hospitale in die Wes-Kaap?"
Die doelwitte was om:

- ‘n Ouditanalise van die verpleegproses te voltooi.
- Die negatiewe gebeure in beginsel tipes te kategoriseer.
- Die faktore wat verband hou met die nadelige gebeuretenisse waarby die verpleegkundige praktisyns betrokke is, wat tot wangedrag litigasie gelei het te bepaal.
- Ander gesondheidsorgspanlede wat geassosieer kan word met die nadelige gebeurtenisse wat tot wanpraktyk-litigasie gelei het te identifiseer.
- Die erns van die nadelige gebeurtenisse wat verband hou met wanpraktyk- litigasie te bepaal.

‘n Kwantitatiewe, retrospektiewe oudit-navorsingsontwerp was gebruik vir die doel van hierdie studie. Die studie het op wanpraktyk litigasie-sake wat in private hospitale in die Wes-Kaap gebeur het, gefokus. ‘n Gerieflike steekproef is uitgevoer. Sewe prokureurs wat ’n verskeidenheid sake van verskillende private hospitale in die Wes-Kaap ondersoek het, het die navorser toestemming gegee om ‘n totaal van 81 hofstukke te oudit.

Die toets- en hertoetsmetode was toegepas om te verseker dat die instrument alle vereiste inligting om die hofstukke te oudit, insluit. ‘n Steekproef is vir die hoofstudie gedoen wat die betroubaarheid van die instrument bevestig het. Vakkundige opinies is ingewin om die geldigheid van die instrument te verseker. ‘n Nougesette proses het sig- en inhoudgeldigheid verseker.

Die loodsstudie wat ’n substudie is, was vir die hoofstudie uitgevoer en is nie in hierdie hoofstudie herhaal nie. Met die ondersteuning van die biostatistikus is ‘n beskrywende analise voltooi en is in tabelle en grafieke aangebied.

Die individuele hofstukke was by die kantore van die prokureurs wat in wanpraktyk litigasie-sake spesialiseer geoudit deur gebruik te maak van ‘n oudit-instrument. Etiese goedkeuring (S16/10/204) is goedgekeur deur die Fakulteit van Medisyne en Wetenskap aan die Universiteit van Stellenbosch.

Die navorser het gevind dat n=49 (60.5%) van die sake buite die hof besleg is. Kliniese manifestasies was nie opgeneem in n=62(76.5%) van die hofstukke nie. Kliniese bestuur was die mees algemene beginseltipe wat bevind was, n-72(88.9%). Die meeste van die nadelige gebeurtenisse was uiterste gevalle n-29 (35.8%) wat tot die dood en gestremdheid gelei het.

Aanbevelings sluit in gedurige professionele ontwikkeling moet aangemoedig word, toesig in die kliniese omgewing behoort verbeter te word, die ‘just culture’ binne die gesondheidsorg omgewing moet bevorder word om die rapportering van nadelige gebeurtenisse aan te moedig; daardeur word maatstawwe in plek geplaas om die herhaling van die nadelige gebeurtenise te voorkom.

Sleutelwoorde: wanpraktyk, mediese nalatigheid, nadelige gebeurtenisse, wangedrag, litigasie, pasiëntveiligheid

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ABBREVIATIONS

COHSASA	Council for Health Service Accreditation of Southern Africa
SANC	South African Nursing Council
WHO	World Health Organisation
SAC	Safety Assessment Code
ICPS	International Classification for Patient's Safety
SAHRC	South African Human Rights Commission
NDOH	National Department of Health
CPR	Cardio Pulmonary Resuscitation
ICU	Intensive Care Unit
NICU	Neonatal Intensive Care Unit
RPN	Registered Professional Nurse

CHAPTER 1
CONTEXTUALISATION AND ORIENTATION OF THE STUDY

1.1 INTRODUCTION

A high level of clinical negligence has resulted in malpractice litigation cases (Pepper & Slabbert, 2011:29). Clinical negligence resulting in malpractice litigation cases has compromised and continues to threaten the quality of care and patient's safety (Pepper & Slabbert, 2011:29).

All healthcare professionals including nurses may be held responsible if the health professional does not function with the appropriate level of skill, knowledge and competence (McQuoid-Mason & Dada, 2012:226).

The general public is growing more aware of the medical negligence risks and this places more pressure on the medical and healthcare profession (Kukreja, Dodwald & Kukreja, 2012:11). Globally radical increases in claims are reported (East, 2011:72).

In 2008 Patel (2008:57) documented that the United States of America (USA) were the world leaders in malpractice litigation claims. They were followed by the United Kingdom (UK) and other European countries, which shows an increase in the number of malpractice litigation claims received. In South Africa, the awareness of medical negligence is also on the increase.

1.2 BACKGROUND

Medical negligence can be described as "a failure to respond as any reasonable person, from the same profession, would in the same or similar situation" (Kverjik & Brous, 2010:63). Medical negligence may further be defined as "unlawful behaviour or conduct by a professional person causing harm or injury to their patients" (Kukreja *et al.,* 2012:11). Patel (2008:57) describes negligence as a form of carelessness, where there is a risk of causing harm to patients. Healthcare professionals, including nurses, who cause harm to a patient through negligence, wrongful acts and omissions, may be held legally responsible for their role in the medical malpractice (McQuoid-Mason & Dada, 2012:174-175). A healthcare professional is expected to function with an appropriate level of skill, knowledge and competence. If the healthcare professional fails to exercise this level of skill, knowledge and competence by subjecting the patient to an adverse event, the healthcare professional may face malpractice litigation (McQuoid-Mason & Dada, 2012:226).

All cases being litigated are referred to as medical malpractice, and all the members of the healthcare team who were involved in caring for the patient are included (Pienaar, 2016:3). As the litigation claims increase year on year, the impact on the medical indemnity insurance also increases (Motsoaledi, 2015). Between 2005 and 2013, the indemnity insurance for neurosurgeons and gynaecologists increased by 573% and 382% respectively. If this continues, the quality of patient care is at risk, as the implications of the high indemnity costs in response to the high claims, will steer potential medical students away from the medical field of study (Motsoaledi, 2015), thus further compromising safe patient care.

Substantiated further, Kukreja *et al.* (2012:11) emphasise that the public is growing more aware of medical litigation, and the potential financial gain, and this adds a lot of pressure to the health care field.

A prevalence of malpractice litigation claims involving the nursing community, both in the public and the private sector, have been identified, but no scientific studies have been conducted in South Africa involving the nursing community.

An investigation, therefore, has become critical to explore malpractice litigation in nursing practice. This study will focus on malpractice litigation in nursing practice in private hospitals in South Africa.

Pepper and Slabbert (2011:30) reported that in South Africa obstetrics, neuro-surgery and spinal surgery are super high risks. This is followed by gynaecology, trauma, orthopaedic and reconstructive surgery which are referred to as high risks. Examples of obstetric complications include excessive use of oxytocics, shoulder dystocia and failure to diagnose pre-natal abnormalities (Down's syndrome and spina bifida for example), (Pepper & Slabbert, 2011:30).

According to Judge Claassen (2016:7), three out of nine provinces in South Africa have medico-legal claims amounting to R30 billion. In 2013-2014, Gauteng Department of Health paid out R256 million on legal costs arising from the plaintiff's attorneys (Claassen, 2016:7). These medical legal payments have not been budgeted for, and the payments are being made from funds allocated to other services, for example the servicing and renewal of medical equipment (Claassen, 2016:7). The use of non-budgeted funds therefore allows for the risk of further claims being instituted (Claassen, 2016:7).

Li *et al.* (2014:2) analysed 1087 malpractice litigation cases in China. Obstetrics and gynaecology, orthopaedics and general surgery accounted for the majority (53%) of the malpractice litigation cases in their study in China (Li *et al.,* 2014:5). Pregnancy and birth related adverse events accounted for sixteen percent of the malpractice litigation cases in China between February 1998 and October 2011 (Li *et al.,* 2014:5).

According to Bjorksten, Bergqvist, Anderson-Karlsson, Benson and Ulfvarson (2016:3) medication errors are the most common type of adverse events worldwide that cause harm to patients, stress to staff and cost the state or private medical system financially. In Sweden, Bjorksten *et al.* (2016:5) completed a study using a population of 583 cases. In their study, it was found that among the 583 cases of medication errors, nine patients died as a result of the medication errors, 29 were seriously harmed (the type of harm was not listed), 64 were moderately harmed (the type of harm was not listed), and 466 cases were not harmed at all.

In 2006 the United States of America (USA) had 12513 malpractice claims resulting in a pay-out value of four billion US dollars (East, 2011:72). A study of death certificates in the USA, completed by Makary and Daniels (2016:1), concluded that medical error is the third leading cause of death in the USA, heart disease is the first leading cause of death, whilst cancer-related deaths is the second leading cause of death. Huang, Sun and Lien (2015:21), confirmed that in the USA, about 2% of nurse practitioners have been identified as primary defendants in malpractice litigation cases.

The United Kingdom received 5470 malpractice litigation claims in 2007, and the total pay-out value for these claims were 633.3 million pounds. In the United Kingdom (UK), the Chief Medical Officer's report states that approximately 10 000 patients experience serious adverse reactions to drugs and hospital acquired infections (Neale, Woloshynowych & Vincent, 2001:322). The most common adverse events occur in vascular surgery and colonic surgery (Neale *et al.,* 2001:323). Neale *et al.* (2001:323) further found that 57% of adverse events were as a result of cognitive error. These adverse events were a result of poor healthcare management rather than disease processes (Neale *et al.,* 2001:322).

Oosthuizen and Carstens (2015:281) identified that human factors are the main focus in adverse events globally; however, there are other factors that must be taken into consideration when faced with an adverse event. Organisational and managerial factors may also contribute to adverse events occurring in health establishments. Human factors include incompetent staff, poor or no clinical monitoring, lack of knowledge, lack of skill required,

staff attitude and staff burn out (Runciman *et al.,* 2010:2-3). Organisational and managerial factors that contribute to adverse events include poor infrastructure, staff shortage, lack of supplies, and availability of operational equipment (Eygelaar & Stellenberg, 2012:1-2).

A study completed in Malawi reported that a combination of lack of trained midwifery staff and inadequate staff mix impacted on the level of care delivered to patients resulting in delays in treatment delivery, poor quality of care delivered and incorrect care being delivered (Bradley, Kamwendo, Chipeta, Chimwaza, Pinho & McAuliffe, 2015:2-3). Bradley *et al.* (2015:7-8) further reported that the staff shortage and lack of knowledge result in errors becoming more frequent and severe, raised stress levels and poor team moral.

As described above, adverse events are continually increasing in the healthcare environment. This has a ripple effect, resulting in malpractice litigation and ultimately costing the country millions of rands.

As a developing country, South Africa cannot afford the loss of revenue due to malpractice. Medical malpractice litigation may be the demise of the health system in South Africa.

1.3 PROBLEM STATEMENT

Gray, Grove and Sutherland (2017:47), define a problem statement as an area of concern where there is a gap in knowledge, needed for nursing practice. The problem statement provides the basis for the research being conducted to obtain essential knowledge and improve the practice concerned.

Despite the increase in adverse events resulting in malpractice litigation cases, there has been no scientific inquiry about malpractice litigation in nursing practice in South Africa which influences quality and safety of patient care.

The medical negligence does not affect the patient alone. The ripple effect that a medical error may have on a patient may result in drastic lifestyle changes for the patient for example divorce, isolation, the inability to maintain a lifestyle, which could result in changes in social habits, amongst other consequences. The financial gain is unable to restore the patient back to a normal society in most cases.

Furthermore, medical negligence has an effect on the nursing staff as the nurse is guided by professional and personal beliefs and obligations (Nursing Act, SANC). The nurse is further guided by Acts and Omissions, R387 (SANC). The nurse not only risks losing her job and

being struck off the register (SANC), but also the possibility of having legal action taken against her bringing her skills and knowledge into question.

The lack of knowledge in legal aspects may hamper the nurses' career and result in the nurse being struck off the register at SANC (Regulation767 of 2014). The nursing profession can only function properly if nurses know the current laws that govern their practice (Howard 2011:30).

1.4 RESEARCH QUESTION

The research question is the foundation of the research study (Lobiondo-Wood & Haber, 2006:28-29). Lobiondo-Wood and Haber (2006:28-29) further explain that the research question should present the problem that is to be researched. The researcher was guided by the following research question: "What are the factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape?"

1.5 RESEARCH AIM

The aim of this study was to investigate factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape.

1.6 RESEARCH OBJECTIVES

The objectives of this research study were to:

- Complete an audit analysis of the nursing process documentation
- Categorise the adverse events into principle types
- Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation
- Identify other healthcare team members that may be associated with the adverse events that have resulted in malpractice litigation
- Assess the severity of the adverse events associated with malpractice litigation.

1.7 CONCEPTUAL FRAMEWORK

Concepts are identified on their importance to what the subject of the study is (Gray *et al.,* 2016:49). A framework explains why a problem in a specific study exists (Castro-Palaganas, 2011:3). The conceptual framework provides guidance to the researcher (Burns & Grove, 2011:238).

This study was guided by the Runciman Model which focuses on patient safety (Runciman, Williamson, Deakin, Benveniste, Bannon & Hibbert, 2006:82-90). The concept of patient safety included the classification of events and incidence, and the Safety Assessment Code (SAC), (New Zealand Incident Management System, 2008:1).

1.7.1 Runciman framework

The World Health Organization summoned Professor W.B. Runciman to draw up a safety model. The International Classification for patient safety (ICPS), (World Health Organisation, 2007:4-5), presented a classification of concepts based on similarities. This classification is applicable across the healthcare spectrum and should be able to stand with existing processes and systems (Runciman, Williamson, Deakin, 2006:82-90). The contributing factors are highlighted as organisational factors, human factors, and environmental and infrastructures. This model includes the Generic Reference Model (GRM), which describes some of the contributing factors to an adverse event occurring as environmental factors, organisational factors and human factors (Runciman *et al.,* 2010:2-3). This is very clearly demonstrated in figure 1.

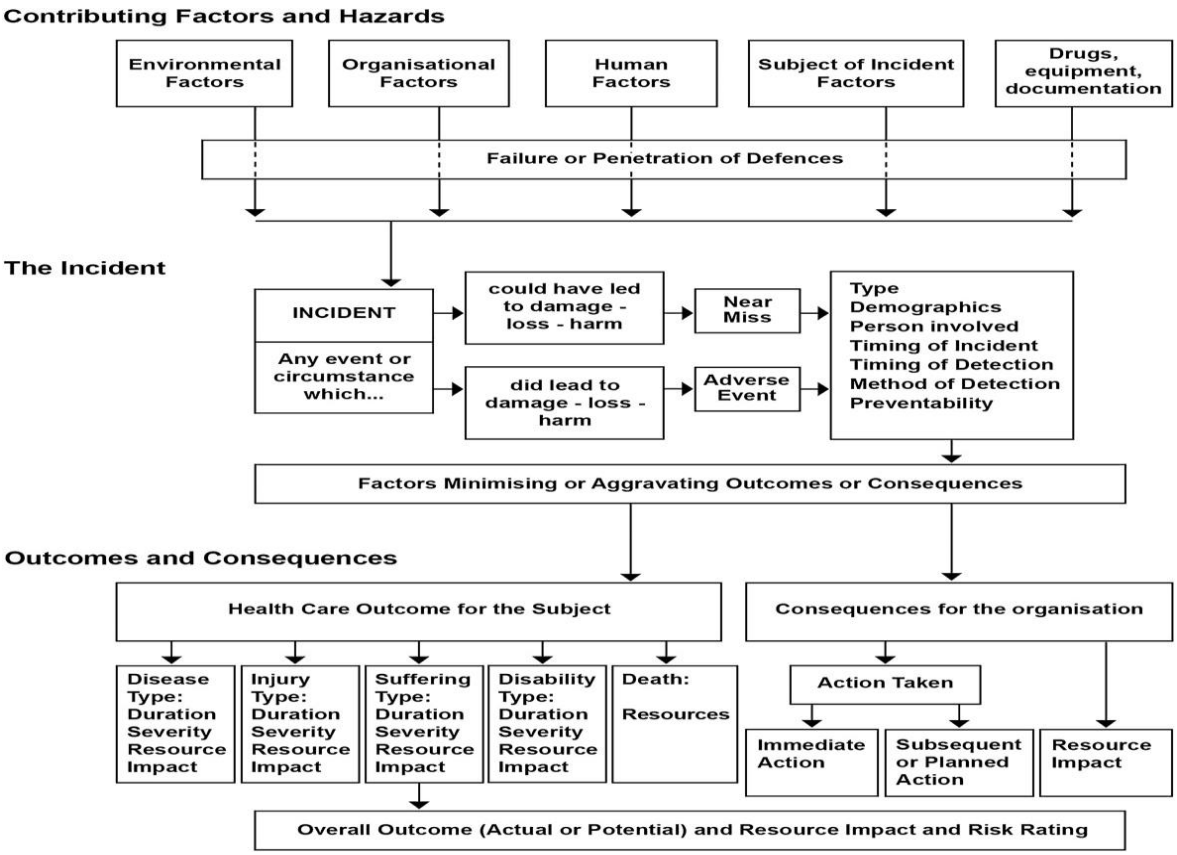

Figure 1: Generic Reference Model

Source: Tracing the Foundations of a conceptual framework for a patient safety ontology (Runciman *et al.,* 2010:2).

- **Patient Safety**

Runciman *et al.* (2010:1) described patient safety as a reduction in the risks of harm in the healthcare environment to an acceptable and minimal level thus rendering the environment free from injury or harm. Factors leading to the adverse events were identified and the adverse events were categorized into principle types, using this classification as a guide to the study.

1.7.2 Safety assessment code (SAC)

The Safety Assessment Code (SAC) is a numerical score system that rates adverse events (New Zealand Severity Assessment Code, 2008:1). This score is based on the frequency of the occurrence, the risk of recurrence and the consequence of the adverse event (New Zealand Severity Assessment Code, 2008:1). This SAC score also determines the level of investigation required to resolve or close the adverse event (New Zealand Severity Assessment Code, 2008:1-2).

- **Severity category**

This score is based on a scale of one to four, with number one being extreme and possibly irreversible, number two being extreme, number three being minor and number four being insignificant (New Zealand Severity Assessment Code, 2008:1-2).

- **Frequency category**

The frequency of an adverse event is generally determined by the severity category. The frequency category is rated on a scale from remote meaning less likely to recur to frequent, which indicates a common error and most likely to recur (New Zealand Severity Assessment Code, 2008:1-2).

The severity of all the adverse events which resulted in malpractice litigation was determined. This allowed the researcher to identify the number of adverse events according to the severity level.

1.8 RESEARCH METHODOLOGY

The research methodology is discussed briefly in this chapter. A more detailed discussion on the research methodology will follow in chapter 3.

1.8.1 Research design

A quantitative, retrospective audit research design was applied for the purpose of this study.

1.8.2 Study setting

The study focused on malpractice litigation cases that have occurred in private hospitals in the Western Cape region. The individual malpractice trial bundles were audited at the various malpractice attorneys' offices.

1.8.3 Population and sampling

For the purpose of this study a convenience sample was applied. The sampling frame was attorneys who specialize in malpractice litigation. At least fifteen attorneys who specialised in medical malpractice litigation cases were consulted with the aim of auditing 100 files in total. The researcher received 7 positive responses from attorneys consulted and was able to audit a total of 81 files (81% of the original sample size).

1.8.3.1 Inclusion criteria

Medical litigation cases which occurred in all private hospital groups in the Western Cape Province were used for the purpose of this study from 2010 to 2016.

1.8.3.2 Exclusion criteria

The researcher excluded medical malpractice litigation cases that have not been finalised or where the hearing was still in progress or any case which had received much media coverage.

1.8.4 Data collection tool

An audit instrument based on identified objectives and aligned to the conceptual framework was used to extract the required data.

1.8.5 Pilot study

No pilot study was completed for the current study, as the main study, "A retrospective analysis of malpractice litigation in nursing practice in South Africa" has received ethics approval, thereby allowing a pilot study to be conducted to test the instrument and the feasibility of the methodology. The ethics approval for the main study is confirmed by reference number N16/02/027.

1.8.6 Data collection

The data collection took place at the various attorneys' offices using the manual extraction tool, and this was later transferred onto an electronic excel. The information extracted was only reviewed by the researcher and the supervisor.

1.8.7 Data analysis

Descriptive analysis was done on the data to determine the frequencies which are presented in tables and graphs.

1.8.8 Reliability and validity

- **Reliability**

The pilot study completed for the main study supports the current study as the sub study is aligned to the main study. The revised instrument was reviewed by the supervisor and the biostatistician to verify that all required information will be captured and measured by the instrument. The test-retest method was used to confirm that the instrument included all the required information.

- **Validity**

Face and content validity was ensured through a rigorous process. The pilot study along with the principal investigator, expert opinions and a biostatistician were consulted before the instrument was found to be reliable and valid.

- **Face Validity**

The instrument used appeared to have measured the data required. This was subjected to experts in quality assurance and writing of standards in healthcare, a biostatistician and the principle investigator of the main study.

- **Content Validity**

The content of the instrument measured all the components, based on the objectives as required. The development and content of the audit instrument were guided by the conceptual framework of this study.

1.9 ETHICAL CONSIDERATIONS

The Belmont report identified beneficence, justice and respect for human dignity as three core principles for an ethical research (Polit & Beck, 2006:87).

1.9.1 Beneficence

This means to do good, promote health and protect the patient's dignity (Pera & Van Tonder, 2012:55). Harming a patient is regarded as a bad deed, irrespective of the situation. According to Polit and Beck (2006:170), beneficence imposes a duty to the researcher to minimize risks and maximize benefits for the participants and the general community.

The data collection process in this study consisted of the auditing of medical litigation bundles and this information was maintained with the utmost anonymity. The researcher can therefore be certain that no harm was generated through the study process.

1.9.2 Justice

Justice is an ethical principle that focuses on resource allocation and fairness (Pera & Van Tonder, 2012:57-58). Justice works together with beneficence in an attempt to produce the most good. Polit and Beck (2006:90) further explain that all information obtained for the purpose of a research study must be kept completely private and confidential, maintaining complete anonymity. Brink, Van Der Walt and Van Rensburg (2012:45) describe anonymity as namelessness, which highlights the researcher's obligation to conceal the identity of the participants of the study.

In this study complete anonymity was maintained. Efforts were made during manual data capturing not to use any identifying notes or numbers. The electronic data capturing and the analysing of the data were done completely anonymously. The names of the attorneys, patients, hospital details and any identifiable information were managed with total confidentiality and anonymity. It is important to note that the researcher had discussed the Ethics Committee's request for a signed permission letter from the attorneys recruited with the supervisor. The decision was then taken not to obtain this letter as it violated the anonymity of the study.

During the course of the study, the researcher was not in contact with any of the patients, staff or their families. All measures were taken to ensure that the confidentiality was maintained i.e. information about the contents of the litigation bundle, the attorneys who represented the cases, the experts who gave evidence and the aspects about the plaintiff, the patient and defendant, and the hospital.

1.9.3 Respect for human dignity

Respect for human dignity includes the right to self-determination and the right to full disclosure of facts (Polit & Becks, 2006:88). These rights give humans the right to decide their own destiny.

The researcher requested a waiver of consent to audit the trial bundles without the consent of the plaintiff or the defendants. This waiver of consent was awarded to the researcher by The Ethics Committee, Faculty of Medicine and Health Sciences at Stellenbosch University. In this study, the plaintiff refers to the patient and the defendant refers to the hospital, doctors and nurses.

Ethics approval from the Faculty of Medicine and Health Sciences at Stellenbosch University was secured. This can be confirmed using the reference number S16/10/204 (Appendix A).

The ethical principles are applicable to all steps of the research process including the research report and publication. The researcher ensured that the principles of the Declaration of Helsinki were maintained throughout the research process and that other applicable international ethical codes for research on humans were adhered to.

The manual data collection tools were stored in a locked cupboard within a double- locked office with only the researcher having access to it. The electronic data was stored on the researcher's computer which contained a security password that was only known to the researcher. Once the electronic data was captured and verified by the researcher's supervisor the manual data collection tool was shredded by the researcher. All the information was periodically shared only with the researcher's supervisor.

The data obtained will be stored for a minimum period of five years for possible inspection, thereafter it will be destroyed. All data will be available to the Health Research Ethical Committee at the Stellenbosch University for inspection and auditing purposes during this five-year period.

1.10 OPERATIONAL DEFINITIONS

Adverse events: Unintended events or harm that may result in outcomes that may require additional care or hospitalisation. Harm implies impairment of structure or functioning of the body and includes disease, injury, suffering, disability and death. Harm may be physical, social or psychological (WHO, 2007:12).

Litigation bundles: All documents used in litigation cases. These documents include expert reports, test results and healthcare professionals' documents (Waterworth, 2010:1).

Malpractice: Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or an official position. Malpractice occurs when negligent or unskillful performance of duties is carried out where skilled professional assistance is required (Paradise, 2004:166-168).

Near-miss events: Events where unwanted consequences could be avoided or prevented (WHO, 2007:12).

Negligence: Negligence may be described as a failure to act as a reasonable person would in the same or a similar situation (Kverjik & Brous, 2010:63).

Patient safety: Reduction in the risks of harm in the healthcare environment to an acceptable minimum and an environment free from harm or injury (Runciman *et al.,* 2010:1)

Risk: The probability that an adverse event will occur (WHO, 2007:12).

Nursing Process: A series of five organised steps to assist the nurse with clinical decision making, problem solving and to deliver safe, quality care (Doenges & Moorhouse, 2013:3-5).

Registered Professional Nurse (RPN): A person registered in a category under section 31(1) in order to practise nursing or midwifery in terms of the Nursing Act, No 33 of 2005 (RSA, 2015).

Midwife: A midwife is a person who is qualified, competent to independently practise midwifery in the manner and the level prescribed and who is capable of assuming responsibility and accountability for such practice according to section 31 subsection 1(b) of the Nursing Act 33 of 2005 (RSA, 2005).

Enrolled Nurse (EN): Previously known as a staff nurse, is a nurse who is qualified to provide basic nursing care under the direct or indirect supervision of the registered nurse and in accordance with her scope of practice (RSA, 2005).

Enrolled Nurse Auxiliary (ENA): An enrolled nurse auxiliary is qualified and competent to practise and deliver elementary nursing care (RSA, 2005).

1.11 CHAPTER OUTLINE

The chapters of the thesis are as follow:

Chapter 1: Foundation of the study

Chapter 1 introduced the study. A description of the rationale, problem statement, research question, research aim and objectives, ethical considerations, operational definitions and study layout were provided. The researcher further gave a brief overview of the methodology of the study.

Chapter 2: Literature review

In this chapter a global literature review is conducted and discussed to obtain a global perspective of the study topic. A conceptual framework of the study is explored.

Chapter 3: Research methodology

An in-depth description of the applied research methodology is discussed in this chapter.

Chapter 4: Data analysis, interpretation and discussion

In this chapter the results of the study objections are revealed, analysed and discussed.

Chapter 5: Conclusions and recommendations

In chapter 5 the results based on the study objectives are concluded, study limitations are identified and recommendations are made based on the scientific evidence obtained during the study.

1.12 SIGNIFICANCE OF THE STUDY

The outcome of this study was to identify and to contribute to reducing the risks that result in nursing malpractice litigation. The study may also assist in identifying potential adverse events and increase the reporting of adverse events, thus reducing the potential harm to the patient, thereby supporting the creation of a just culture within the hospital environment.

1.13 SUMMARY

In this chapter the background of the study was discussed and the study objectives were introduced. The research methodology that guided the study and the data analysis process used was briefly discussed. Ethical considerations were discussed and explained.

1.14 CONCLUSION

Errors are a part of the learning experience. When an error affects another individual negatively, the individual affected may turn to the law to receive compensation. It is important to understand the impact and the effect a negative experience would have on the individuals involved. Medical professionals must take all measures to ensure the safety of their patients, and to continuously be alert that an error is a possibility. By doing this, the medical professional will be encouraged to take necessary precautions when working with patients, either directly or indirectly.

Patient safety is the focus of the healthcare environment, however, the incidence of medical negligence leading to malpractice litigation cases are increasing within South Africa, Africa and internationally. It is important to strengthen the healthcare care environment defences against adverse events resulting in malpractice litigation cases.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

A literature review was done to obtain information on the topic of malpractice litigation in nursing practice. The purpose of a literature review is to get a better understanding of the problem being investigated (De Vos, Strydom, Fouche & Delport, 2011:134). According to Burns and Grove (2011:189), a literature review provides one with theoretical and scientific knowledge about a specific topic. Parahoo (2014:117), further states that a literature review provides a rationale for the current study by highlighting what is known about the specific topic. The literature review is very important in assisting to develop the conceptual or theoretical framework.

In chapter two the researcher presents literature that was critically reviewed in an attempt to acquire a detailed understanding of the adverse events resulting in medical malpractice litigation cases in nursing practice.

The literature review was conducted using the following sources:

- Electronic data bases such as Stellenbosch University electronic library, Pubmed, Cochrane, CINAHL and Google Scholar
- Text and academic books as well as journal articles
- Current newspaper articles and reports

2.2 ADVERSE EVENTS

Sohn (2013:49-50) describes an adverse event as an injury or event occurring during medical management of a patient. As noted in the example provided by Sohn (2013:50), despite the patient being on anti-coagulants and all necessary care was taken the patient still developed a blood clot. This would still be an adverse event but not due to medical error (Sohn, 2013:50), this would be regarded as a risk factor. The World Health Organisation further explained adverse events as unintended event or harm that may result in outcomes that may require additional care or hospitalisation. Harm implies impairment of structure or functioning of the body and includes disease, injury, suffering, disability and death. Harm may be physical, social or psychological (WHO, 2007:12).

2.3 MALPRACTICE

Malpractice takes place when negligent or unskillful performance of duties are carried out where skilled professional assistance is required (Paradise, 2004:166-168).

The Joint Commission on Accreditation of Healthcare Organizations (2003) define malpractice as "improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position; to denote negligent or unskilful performance of duties when professional skills are obligatory." Malpractice is a broader concept and may include negligence.

2.4 INTERNATIONAL PERSPECTIVE

Patel (2008:57) explained that the United States of America, Australia and the United Kingdom have the highest number of medical negligence claims.

In 2006 the United States of America (USA) had 12513 malpractice claims resulting in a pay-out value of four billion US dollars (East, 2011:72). Makary and Daniels (2016:1) who completed a study of death certificates in the USA, concluded that medical error is the third leading cause of death in the USA, heart disease is the first leading cause of death and cancer-related deaths, the second leading cause of death.

Nash, Nash, Leach and Poetker (2011:10-15), reported that the most common reason for a medical malpractice claim in the USA was negligence, followed by lack of complete informed consent and misdiagnosis or failure to diagnosis a patient.

Mariscal (2015:1) described a ‘never event’ as an event that should not have occurred. Mariscal (2015:1) further explained that ‘never events’ occurred more often in the operating theatre and included events, such as wrong-sided surgery, retained surgical products, operating on the incorrect patient or performing an incorrect procedure on a patient. In the USA Mariscal (2015:1-2) reported that 9 744 ‘never events’ were reported. These ‘never events’ could have been prevented had the surgical team completed the surgical time-out correctly.

The United Kingdom received 5 470 malpractice litigation claims in 2007, and the total pay-out value for these claims were 633.3 million pounds. In the United Kingdom (UK), the Chief Medical Officer’s report states that approximately 10 000 patients experience serious adverse reactions to drugs and hospital acquired infections (Neale, Woloshynowych &

Vincent, 2001:322). The most common adverse events occur in vascular surgery and colonic surgery (Neale *et al.,* 2001:323). Neale *et al.* (2001:323) further found that 57% of adverse events were as a result of cognitive error. These adverse events were found to be a result of poor medical management rather than disease processes (Neale *et al.,* 2001:322).

According to Oyebode (2012:327), the UK was estimated to have had 90 000 adverse events per year, 13 500 of these adverse events resulted in the death of patients.

Li, Wu, Sun, Li, Zhao, Lui, Gao, Sun, Zhang and Fan (2014:2) analysed 1087 malpractice litigation cases in China. Obstetrics and gynaecology, orthopaedics and general surgery accounted for the majority (53%) of the malpractice litigation cases in their study in China (Li *et al.*, 2014:5). Pregnancy and birth-related incidences accounted for sixteen percent of the malpractice litigation cases in China between February 1998 and October 2011 (Li *et al.,* 2014:5).

According to Bjorksten *et al*. (2016:3) medication errors are the most common type of adverse events worldwide that cause harm to patients, stress to staff and cost the state or private medical system financially. In Sweden Bjorksten *et al.* (2016:5) completed a study using a population of 583. It was found that among these 583 cases of medication errors, nine patients died due to the medication errors, twenty-nine were seriously harmed (the type of harm was not listed), sixty-four were moderately harmed (the type of harm was not listed), 466 cases were not harmed at all.

A study completed in 21 Dutch hospitals found that human error, especially knowledge-based and rule-based errors were the most common cause of adverse events (*Smits et al.,* 2010:4). Smits *et al*. (2010:4) also identified adverse events resulting from organisational factors were preventable and would leave the patient involved permanently disabled, especially where there were inadequate or unavailable protocols.

A study completed in Malawi reported that a combination of lack of trained maternity staff, staff shortage and inadequate staff mix impacted on the level of care delivered to patients resulting in delays in treatment delivery, quality of care delivered and incorrect care being delivered (Bradley *et al.,* 2015:2-3). Bradley *et al.* (2015:7-8), further reported that the staff shortage, and lack of knowledge result in errors becoming more frequent and severe, raised stress levels and poor team moral.

In Ghana a 27-year-old mother died during child-birth whilst delivering her second baby. The mother was left unattended whilst in labour, which resulted in the baby being delivered onto the hospital floor. During post-delivery, the mother was further neglected by the nursing staff and this resulted in the death of the 27-year-old (Adotevi, 2011:1).

Adeyemo, Oderinu, Olojede, Fashina, Ayodele (2011:153-156) completed a study involving 171 dental surgeons, 13% admitted to extracting an incorrect tooth, while 25% were aware of the protocols in place to prevent the 'never events'. However, one third of the dental surgeons had read the protocol.

Nwosu (2015:1) presented a case study of two wrong-site surgeries in Nigeria. The first case was closed reduction of the incorrect dislocated hip by a senior resident. The second case was wrong-site surgery on the right leg of a patient who had sustained a fracture to the left leg; surgery was performed by an experienced Chief Orthopaedic Consultant. Neither of these cases was reported. According to Nwosu (2015:1-3), both of these cases may have been prevented if the surgical time-out was completed correctly.

2.5 NATIONAL PERSPECTIVE

In South Africa the medical malpractice awareness and the number of medical litigation claims and cases are also on the increase (Patel, 2008:57).

In Gauteng, South Africa 144 mentally ill patients died between 23 March 2016 and 19 December 2016 (Makgoba report, 2017). This case is now known in the media as the Life Esidimeni Disaster (Makgoba report, 2017).

According to the report by Professor Malegapuru Makgoba (2017), 1 371 mentally ill patients were rapidly transferred in large numbers from a structured environment at Life Esidimeni Care Centre with continuous care to 27 sub-standard, unstructured Non-Governmental Organisations (NGO). This was as a result of the Gauteng Department of Health terminating their contract with Life Esidimeni Care Centre on 31 March 2016 (Makgoba report, 2017).

According to a report by the South African Human Rights Commission (SAHRC), approximately 240 cancer patients in public health facilities in Durban, Kwa-Zulu Natal have been compromised due to the state cancer facilities failing to provide treatment as required for these patients. The reason for this was broken or non-functioning radiotherapy machines and a mass exodus of state practising oncologists (SAHRC, 2017).

In a study completed by East (2011:72), a total of 1 186 medical legal cases were analysed. According to the findings in this study the most common cause for litigation in South Africa was neurological damage caused by spinal surgery. This was followed by (in descending order) communication problems, misdiagnosis, gross negligence/unavailability, wrong sided surgery, failed surgery, death, infection, retained instruments, diathermy and other burns, consent and compartment syndrome.

2.6 LEGISLATION

In 1996 the Constitution, through the Bill of Rights gave South Africans the ability to take recourse if they believe that their constitutional rights have been violated (Bill of Rights: 1996). Chapter 2 of the Constitution of the Republic of South Africa, 1996 (Act No. 109 of 1996), includes high quality professional services to be provided with fairness and equality. These services must be efficient, economical and effective. To provide this type of service the Patients' Rights Charter was developed and the Batho Pele Principles were introduced (Van Rensburg & Pelser, 2004:119).

2.6.1 Patients' Rights Charter

The National Department of Health, 2008, introduced the Patients' Rights Charter to promote and protect the rights of all South Africans to ensure safe and effective healthcare service delivery.

The Patients' Rights Charter empowers the community regarding their rights and responsibilities as patients. The function of this Charter is to improve attitudes and service provided in the healthcare environment including nursing staff.

2.6.1.1 Patients' Rights

According to the National Patients' Rights Charter (National Department of Health, 2008), every patient has the right to the following:

- **A healthy and safe environment**

Everyone has the right to a safe and clean environment, which includes clean water supply, sanitation, waste disposal, protection against pollution, infection and all forms of danger. This will ensure physical and mental well-being.

- **Participation in the decision-making process**

Patients have the right to take part in decisions regarding their health.

- **Access to health care**

This right refers to the right to emergency care, treatment and rehabilitation and the explanation of such care to the patient. Persons with special needs are mentioned such as infants, children, pregnant women, the aged, disabled and people living with HIV or Aids. This right compels health care providers to treat patients with dignity, empathy and tolerance and to explain the availability and use of health services to patients in a language understood by them.

- **Treatment by a named health care provider**

Patients have the right to know who is providing health care, thus health care providers should be identified and introduce themselves.

- **Confidentiality and privacy**

All information pertaining to the health and treatment of a patient may only be disclosed with informed consent from the patient, unless it is done under an order of the court. Patients' privacy during examinations and interviews should be protected.

- **Informed consent**

To help patients make informed choices and give consent they have the right to full and accurate information regarding their illness, diagnostic procedures and proposed treatment.

- **Refusal of treatment**

A patient may refuse treatment verbally or in writing provided it does not endanger the health of other persons.

- **Referral for a second opinion**

Patients may request referral for a second opinion to a health provider of their choice.

- **Continuity of care**

Health care professionals may not abandon a patient for whom they have taken responsibility. When patients are discharged, information on follow up services should be given.

- **Complaint about health services**

All patients have the right to complain about health care services and to expect the complaint to be investigated.

2.6.2 Batho Pele Principles

The White Paper, also known as the "Batho Pele", (which is a Sesotho expression meaning "people first"), is a document on the transformation of public service delivery that was published in October 1997, notice 1459 of 1997. The content of this White Paper deals primarily with how public services are provided, and specifically with improving the efficiency of the delivery of services. The document seeks to introduce a fresh approach to service

delivery, an approach that will put pressure on systems, procedures, attitudes and behaviour within the public service and re orientate service delivery in the customers' favour, an approach that puts the people first (South Africa, 1997:12).

The Batho Pele principles (South Africa, 1997) consist of eight service delivery principles, namely:

- **Consultation**

Citizens must be consulted about the level and quality of the public services they receive and, if possible, should be given a choice about the services that are offered.

- **Service standards**

Quality care standards must be visible at national, provincial and departmental levels. These standards must be specific and measurable and relevant to the individual user. Users should be able to judge whether the promised services were received or not.

- **Access**

All citizens must have equal access to the services to which they are entitled.

- **Courtesy**

All healthcare users must be treated with courtesy. Health care staff must ensure that members of the public are treated as customers who are entitled to good service.

- **Information**

Patients must understand the health services they are entitled to receive, their illness, diagnosis and treatment. The White Paper states that health care providers should determine what patients need to know and then decide on the best way to provide the information in a language the patient understands.

- **Openness and transparency**

Citizens should be made aware how national and provincial departments are run and who is in charge.

- **Redress**

Staff should be encouraged to welcome complaints as an opportunity to identify and address problems and improve service delivery. The hospital must have a strategy for providing feedback about complaints that will serve as training opportunity for health care providers.

- **Value for money**

Services must be cost effective and delivered within departmental resource allocations. Waste and inefficiency must be eliminated.

2.6.3 National Health Act 61 of 2003

The National Health Act, 2013 (Act No. 61 of 2003) provides a framework for the Health system in South Africa and is based on the Constitution of South Africa. The aim is to promote and improve the national health system in South Africa, by promoting an essence of shared responsibility among public and private healthcare professionals within the health system (RSA, 2003). The National Health Act aims to provide safe, accessible and efficient health services in South Africa.

2.6.4 Nursing Act 33 of 2005

The nursing profession is governed by the South African Nursing Council (SANC). SANC regulates all training and nursing practice through the Nursing Act, 2005 (Act No. 33 of 2005). Further to this the Nursing Act, 2005 (Act No. 33 of 2005) states that the registered professional nurse must accept responsibility and be accountable for her actions and nursing decisions. This Act further highlight the following:

- The registered nurse is qualified and competent to practise and deliver comprehensive nursing care
- A midwife is qualified and competent to practise midwifery
- An enrolled nurse is qualified and competent to practise and deliver basic nursing care (Act 50 of 1978)
- An auxiliary nurse is qualified and competent to practise and deliver elementary nursing care (Act 50 of 1978).

According to the Nursing Act, 2005 (Act No. 33 of 2005) the functions of the registered professional nurse (RPN) can be further divided into dependent, interdependent and independent roles. The RPN is dependent on the law to practise and may be held criminally liable for acts or omissions resulting in harm to the patient. Searle (2009:113) explains that the RPN has an interdependent function to carry out orders and complete tasks as set out by the multidisciplinary team in order to ensure that patients receive optimal and safe nursing care. Further to the dependent and interdependent function, the RPN has an independent function to assist, implement and review all factors relating to the patient (Searle, 2009:112). The RPN is further responsible to identify unethical, illegal and unsafe practice and to protect the patient from these practices (Searle, 2009:112; SANC, 2005).

2.6.5 Medicines and related substance control Act 101 of 1965

The Medicine and Related Substance Control Act, 1965 (Act No. 101 of 1965) regulates medication intended for human use by requiring registration of the medication. This Act also

allows for a Medicines Control Council to control the use of medication, ensuring that safety is established. The Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) stipulates that all medication should be safe for human use, labelled correctly and dispensed according to the procedure.

2.7 THE SCIENTIFIC NURSING PROCESS

The scientific nursing process is a systematic, goal orientated approach to assess a patient's condition in order to deliver safe nursing (Marawat, 2013:2-5). Waddell (2010:11) described the scientific nursing process as a problem-solving system that guides nursing actions, to provide patient-centered care.

The scientific nursing process consists of five steps:

- Assessment
- Nursing diagnosis
- Planning
- Implementation
- Evaluation

2.7.1 Assessment

Haapoja (2014:5-11) explains that in this phase of the scientific nursing process, the nurse interviews the patient and collects information from the patient. This information could be subjective (based on the patient's experience and feelings) or objective (based on what the patient is presenting with physically and the observations of the nurse (Haapoja, 2014:5-11).

Collection of the subjective data may be completed in an interview process, whereby the nurse interviews the patient and asks a series of questions to obtain the patient's experience of his or her illness (Marawat, 2013, 2-5). It is very important for the nurse at this point, to use knowledge, skill and critical thinking to ensure that the data received is valid and provides a good overview of the symptoms experienced by the patient.

The objective data is collected by the nurse again using her knowledge, skill and critical thinking by conducting tests for example, monitoring of the vital signs, urine testing, neuro-observation necessary, monitoring of the oxygen saturation, and recording of an electro-cardio graph (ECG) (Charbek, 2015:1-6). Charbek (2015:1-6) further indicates that these tests may be done by the nurse and should be interpreted by the nurse. Haapoja (2014:5-11) agrees that this is vital for the correct diagnosis and treatment. Coombs, Curtis & Crookes (2011:368), further explain the importance of taking into consideration the patient's social standing and habits.

To successfully complete this task the professional nurses must have knowledge of the normal values and readings, in order to identify an abnormal result to enable them to be confident to report the abnormalities to the doctor and to other healthcare team members (Waddell, 2010:11).

An accurate assessment of the patient will be able to identify actual and potential problems the patient may be experiencing.

2.7.2 Nursing diagnosis

The nursing diagnosis entails identifying the actual and potential problems the patient may have. This diagnosis differs from the medical diagnosis of the doctor. However, the doctor's medical diagnosis is used to treat the identified symptoms, the potential problems and put measures into place to avoid them from becoming an actual problem. The nursing diagnosis is identified based on the assessment of the patient and the information received from this assessment (Marawat, 2013, 2-5).

Haapoja (2014:5-11) agrees and further explains that an accurate and reliable nursing diagnosis depends on the quality of the assessment of the patient and the knowledge and skill the nurse possesses to be able to identify the signs and symptoms the patient presents with.

2.7.3 Planning

Planning has two components. The first component is what goals have been identified to assist in the patient's healing process and the second what interventions will be taken to reach these goals (Waddell, 2010:11).

The identified goals are determined along with the plan of care to achieve these goals for the specific patient.

A successful plan depends on a good assessment of the patient and once again the nurse's knowledge and skill to identify the actual and potential problems a patient may experience (Haapoja, 2014:5-11).

The care plan is not a fixed plan of care, the care plan changes as the patient's condition changes (Doenges, Moorhouse & Marr, 2012:1-4).

The plan is then formulated by the nurse using critical thinking skills based on the specific patient's condition. Each patient must have an individualised plan of care and not a generic plan (Waddell, 2010:11).

2.7.4 Implementation

The implementation phase is when the nursing care plan as formulated is put into acted upon (Haapoja, 2014:5-11).

Doenges *et al.* (2012:1-4) further explain that in the implementation phase the initial tests completed during the assessment phase will be used to monitor the patient's response to the determined care plan. All nursing care and activities must be documented to provide detailed, evidence-based feedback for all the healthcare team members to provide safe, quality care (Waddell, 2010:11).

2.7.5 Evaluation

In the evaluation phase, using the initial assessment as a base-line for information, the nursing diagnosis, and the planning of care and implementation of the care plan is used to determine if the actions taken were successful or not (Haapoja, 2014:5-11).

If an improvement is noted in the patient's condition, then the nursing care plan is updated to reflect the improvement and this must ideally be documented in the patient's progress report (Doenges *et al.,* 2012:1-4).

If no improvement is noted, the scientific nursing process is recommenced from the assessment phase to reassess, re-plan, re-implement the plan and once again evaluate the outcome (Haapoja, 2014:5-11).

It is important to note that the scientific nursing process is not only completed on admission of the patient, but is completed with every contact one has with the patient. It is a continuous process that is constantly updated and reviewed to ensure that the patient receives the most comprehensive care available to them, in a safe and therapeutic environment (Haapoja, 2014:5-11).

2.8 NEGLIGENCE

Negligence may be described as a failure to act as a reasonable person would in the same or a similar situation (Kverjik & Brous, 2010:63). This was confirmed by Sohn (2013:49) who

explained that negligence is the failure to provide a standard level of care, or to provide sub-standard care.

A case study conducted by Carthey and Clark (2010:7) revealed that evening medication rounds at a hospital were prolonged due to the process of administering controlled or scheduled drugs, as the schedule cupboard was located at the end of the ward.

The process to administer controlled or scheduled drugs is that two trained staff, one of whom must be a registered professional (registered nurse, registered doctor or a registered pharmacist) access the schedule drug cupboard together. The prescribed drug is then counted in the presence of both trained staff, and total stock level of the specific drug is verified with the control book. Thereafter, the correct dosage is locked out of the cupboard and both trained staff members go to the patient to ensure that the five golden rules are adhered to. The five golden rules for medication administration are correct patient, correct medication, correct dose, correct route and correct frequency. Once the medication is administered to the patient, the patient's details are entered into the schedule medication book and both trained staff members sign the schedule book for accountability purposes (Institute for safe medication practice, 2013:1).

Carthey and Clark (2010:7) describes a case study showing the violation of the procedure which increases the risk for a medication error. In the case study, the staff began keeping the schedule drugs in their pocket and administered the medication as per unscheduled drugs without a second trained staff member verifying the doctor's order. Once their medication round was complete, they were then tasked with entering the patient's name in the schedule books and requested staff members to sign, even though they had not witnessed the administration of the drug. Despite the fact that the staff violated the procedure, staff perceived this as a benefit to themselves as there were less distractions while doing medication rounds; it saved time and was less trouble for the staff involved (Carthey & Clark, 2010:8). The risk of an adverse event occurring in this situation is very high as staff were working outside the medication policy.

A study completed in March 2016 by Du Preez (2016:85-97) indicates that human factors cause medication administration errors. Some of the factors noted by Du Preez (2016:85-97) include medication knowledge deficit (67%), lack of training on adverse drug effects (60.8%), work pressure (75%), high nurse patient ratios (63%), distractions (69%) and non-adherence to medication administration policies (64%).

According to The Emergency Medicine Society of South Africa (2010), the resuscitation trolley must be checked at least once a week and a record must be maintained. However, the resuscitation trolley must be checked and replenished immediately after a resuscitation attempt. This includes checking the equipment, medication, defibrillation pads and expiry dates on all products. This practice is further recommended by the United Kingdom Resuscitation Council (2013), the Australian Resuscitation Council (2014) and the New Zealand Resuscitation Council (2014).

In a study based in the Western Cape, Adamson (2012:7-9) found that a number of healthcare institutions did not routinely check their resuscitation trolleys and no accurate documentation was maintained. Adamson (2012:7-9) further found that in some healthcare institutions the resuscitation trolleys were checked regularly, however expiry dates were not confirmed and missing equipment and medication were not replaced. This had a direct impact on the patient's safety especially if a patient urgently required cardiopulmonary resuscitation (CPR) (Adamson, 2012:7-9).

2.9 FACTORS INFLUENCING PATIENT SAFETY

2.9.1 Organisational Factors

Organisational management is a system that defines the lines of communication and authority (Runciman, 2006:48). It further assigns duties, rights, responsibilities and roles of the different levels of staff.

According to Lundstrom, Pugliese, Bartley, Cox and Guither (2002:1), working in an environment that has a visible commitment to safety has a positive impact on the health and safety of the staff.

Many of the adverse events that occur are as a result of environmental and organisational factors (Runciman *et al.,* 2006:23). These factors may include workload management, staff shortages, damaged or faulty equipment, transportation, poor organisation of teams and staff, and inadequate policies and guidelines (Runciman *et al.,* 2006:28-48). The nurse-patient ratio has a significant impact on the risk of adverse events occurring (Du Preez, 2016:89).

A heavy nursing workload, poor application of policies and procedures, new staff who may be unaware of the policies, lack of equipment, and systems failures were identified as

contributing factors to an increased risk for medical legal errors from occurring (Tang, Shei, Yu, Weil & Chen (2007:447-457).

2.9.1.1 Swiss cheese model

In 1990, James Reason proposed the Swiss Cheese Model (Schoenberg *et al*., 2016:116). This model is used in many disciplines to prevent harm from occurring (Schoenberg *et al.,* 2016:117). According to the Swiss Cheese Model, many failures must occur before an error occurs. In medicine, Schoenberg *et al.* (2006:117), indicate that multiple errors must occur to cause harm to the patient. This model uses the analogy of a Swiss cheese, where each slice of cheese may be a barrier. The holes in the cheese are potential errors, circumstances and events that could lead to harm being caused to the patient (Schoenberg *et al.,* 2016:117). Each level may have 'holes' caused by poor design, management, organisational and technical factors. In any situation, there are many structures (referred to as layers in this model) in place to protect the potential victim. These holes continuously change location. There can be many holes in one slice and this may not necessarily cause any problem. The problem occurs when the holes in several slices of cheese line up, allowing hazards to come into contact with the patient, which may result in an adverse event. The Swiss Cheese Model focuses on the person approach, systems approach, latent factors and active factors (Reason, 2000:768-769).

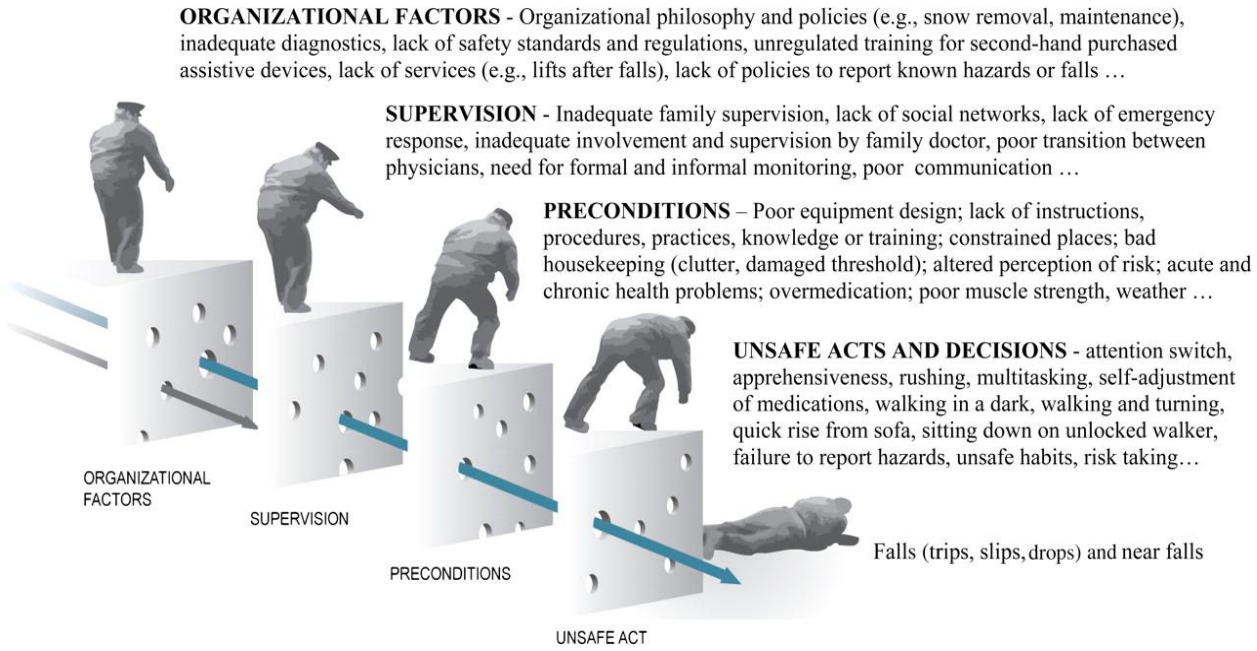

Figure 2.1: Swiss Cheese Model

Source: Introduction to Patient Safety (Schoenberg *et al.,* 2016:117).

- **Person Approach**

Factors such as forgetfulness, negligence, inattention, performing common work out of memory and not following specific instructions lead to unsafe acts. The person approach blames the error on the frontline individuals instead of the institution as this may be more emotionally satisfying. By focusing on the individual, the system of error may not be realised, or fixed, thereby allowing the error to recur regularly in similar circumstances with different individuals.

- **System Approach**

According to Reason (2000:768), errors are expected from individuals in all organisations. The system approach builds defence to avoid an error or reduce the effect of the error. This approach does not blame the individual responsible for the error, but places the attention to how and where the defences failed in the system. It is generally known that errors fall into patterns that recur if the circumstances are similar.

- **Active Failures**

Active failures take place at the frontline of patient care; it has a direct impact on the patient. The consequences of active failures are normally immediate and can be avoided by training and systems. Active failures are not always foreseen and hence may be difficult to avoid.

- **Latent Failures**

Latent failures are present in the system long before the error occurs and this is more likely due to designers, builders, and top management decisions. Poor management, poor decisions and conflicting goals may allow latent failures to occur. Latent failures can be identified and corrected before an error is made. They may be present in the system long before it joins forces with an active failure to create an opportunity for an error to occur.

2.9.2 Environmental Factors

The health care work environment affects the nurse job satisfaction (Peeler, 2015:11). In their study, Hayhurst, Saylor and Stuenkel (2005:283-288), found that managers' positive behaviour increased staff confidence and productivity. This resulted in quality care being delivered, reduced patient complaints and happier patients (Hayhurst *et al.,* 2005:283-288). Environmental characteristics may affect the nurses' perception of job satisfaction (Hayhurst *et al.,* 2005:283-288).

Positive changes in the work environment result in higher employee retention rate, resulting in better teamwork, increased continuity of care, and improved patient outcomes (Lanbrou,

Merkouris, Middleton & Papastavrou, 2014:315-317). Lanbrou *et al.* (2014:305) concluded that when the work environment is conducive to the nurses' needs and safety, their productivity increases and their performance improves.

Kalisch, Lee and Rochman (2010:938-947) found in their study that the nursing schedule, type of patients taken care of, and overtime worked have an impact on the quality of care delivered. Furthermore, Kalisch *et al.* (2010:938-947) also found that good teamwork provided a more satisfying work environment.

2.9.3 Human Factors

Human factors refer to all factors that influence a person and their individual characteristics that in turn influence their behaviour (Carthey & Clark, 2010:3). According to Carthey and Clark (2010:5), common human factors include mental workload, distractions, the physical environment, physical demands, team-work and staff attitude.

In his study, Oyebode (2013:324), provides the following examples of errors that occur as a result of human errors, namely surgery performed on the incorrect side, wound infections, falls, incorrect or improper transfusion, pressure ulcers and burns among many others. Oyebode (2013:324) confirmed in his study that medication error is the most common cause of adverse events worldwide.

2.9.3.1 Interruptions

According to Hughes and Blegen (2008:415) distractions and interruptions can influence thought processes. Petrova (2010:4) confirmed that interruptions can distract a nurse's attention that can result in serious mistakes and negatively impact the patient.

2.9.3.2 Knowledge and Experience

According to Evans (2009:178) inexperienced staff and poor record-keeping contribute to adverse events. A study in Taiwan by Tang *et al*. in 2007 found that 37.5% of adverse events were caused by new staff. Tang *et al.* (2007:447) further found that a lack of experience and a lack of knowledge played a pivotal role in an adverse event occurring.

The educational level of the nursing staff influences the nurses' nursing patterns (Dillies, Van der Stichele, Van Rompaey, Van Bortel & Elseviers, 2010:1077-1079). Safe, quality nursing care is reliant on knowledgeable and competent nurses (Batalden & Davidoff, 2007:2). Skilled and knowledgeable nurses are able to deliver competent nursing care for their patients (Hall, Moore & Barnsteiner, 2008:417). Hall *et al.* (2008:417) further explained that the knowledge, skills and attitudes personified by the nurse can increase job satisfaction.

With regard to legal implications, nursing students are not exposed to any form of legal education; however, many nurses are interested in this topic to assist them to realise what is expected of them (Mathes & Reifsnyder, 2015:261). Being involved in a lawsuit can be a very stressful. If a nurse is found to be guilty of negligent behaviour resulting in an adverse event, the nurse may be legally and civilly charged (SANC, 2005). The lack of knowledge in legal aspects may hamper the nurses' career and result in the nurse being struck off the register at SANC (Nursing Act 33 of 2005).

The nursing profession can only function properly if nurses know the current laws that govern their practice (Howard 2011:30).

2.10 LITIGATION CASES DUE TO ADVERSE EVENTS

Gauteng High Court, 2012, Case number: 10/49971 clearly showed how environmental and organisational factors failed an active 18-month old. The young child was admitted to a public hospital with a diagnosis of croup and a treatment plan for immediate oxygen administration. The hospital did not have adequate oxygen tanks available at the time to administer the oxygen, leaving the child without oxygen for approximately one to two hours. The child was then admitted to the paediatric unit, where his condition worsened to the point where he required intubation. Once the child was intubated, the child had to be admitted to a paediatric intensive care unit (ICU). Unfortunately, this specific hospital did not have an active paediatric ICU resulting in the child being transferred to another public hospital which was located approximately 45 minutes to an hour away from the hospital in question. The child was discharged from the referred hospital some time later, with a diagnosis of Cerebral Palsy and required a 24-hour caregiver (Gauteng High Court, 2012).

Northern Cape High Court, 2014, Case number: 1342/2014 demonstrated how human factors led to a 71-year-old patient having an above knee amputation. The patient had visited his doctor with a painful, swollen, pus-filled toe which had an offensive smell. The doctor treated the patient conservatively despite the seriousness of the condition and the rapid progress of the infection. Three months after failed treatments and the removal of the toenail, the patient was referred to the state hospital for further treatment and management. The proposed treatment as explained to the patient was removal of the toenail, which according to the expert witness should have been done within 48 hours of admission to the hospital. After approximately one month the patient had to have an above-knee amputation

due to complications from the delayed intervention of the infectious toenail (Northern Cape High Court, 2014).

Northern Cape High Court, 2010, Case number: 1744/2010, revealed how human and organisational factors resulted in a patient having numerous surgical interventions and severe pain from September 2001 to 2009. After a fine needle aspiration that led to an open biopsy of the right breast, the surgical team had left a foreign object (needle tip) in the wound. The patient was treated with numerous antibiotics and wound care over the period of eight years for recurrent, intermittent infection in her right breast. Eventually during an admission for an unrelated condition, the current treating doctor requested a mammogram than revealed evidence of the foreign body. After having the foreign body successfully removed, the patient had no further complications to the right breast (Northern Cape High Court, 2010).

KwaZulu-Natal High Court, 2014, Case number: 4401/2014 established that human factors including lack of knowledge and failure to adhere to local policies lead to the blindness of a pre-term infant (28 weeks gestation). At 28 weeks of pregnancy the mother of the pre-term infant was admitted to hospital for prolonged labour and ruptured membranes. A female infant at 28 weeks gestation was born via caesarean section and immediately transferred to the Neonatal Intensive Care Unit (NICU). The baby was then put onto oxygen support and continuous oxygen saturation monitoring. According to the National guidelines on the prevention of blindness in South Africa (DOH, 2002), an infant at 28 weeks gestation should maintain an oxygen saturation between 86 to 92%. The infant maintained a continuous oxygen saturation of 95 to 100% resulting in Retinopathy of Prematurity (ROP) (KwaZulu-Natal High Court, 2014).

2.11 SAFETY ASSESSMENT CODE (SAC)

The outcome of an incident may be loss or in a worst-case scenario, death of a patient. These consequences and outcomes may have a serious impact on the patient, the healthcare professional and the organisation.

The Safety Assessment Code is a numerical score system that rates the severity of an incident. The score is based on the frequency of the occurrence, the risk of recurrence and the consequence of the incident (Government of Western Australia Health Department: 2012). This score will also determine the level of investigation that must be undertaken to resolve or close the incident (South African National Department of Health, 2015:35-44).

2.11.1 Severity Category

The severity category rating is on a scale from one to four. Number one being extreme, meaning the effect of the incident on the patient was drastic and possibly irreversible and number four being minor, meaning the effect on the patient was minimal. This score determines the impact on the patient and the level of investigation required. The severity category will also determine the level of care required, excess length of stay and estimated or actual costs to the institution (South African National Department of Health, 2015:35-44).

2.11.2 Frequency Category

The frequency category is subjective; this is generally determined by the severity category. The adverse event is assessed and the contributing factors are taken into consideration. Recurrent events are documented, measures put into place and the likelihood of recurrence is estimated. The frequency category is rated on a scale from remote, meaning least likely to recur, to frequent which indicates that the error is common and most likely to recur (South African National Department of Health, 2015:35-44).

2.12 JUST CULTURE

Error prevention is only possible if the error is identified and reported. This may encourage learning and may prevent the same error from recurring (Mayo & Duncan, 2004:210). The nurses' ability to identify a potential error or an actual error will determine if this error is reported and acted upon (Mayo & Duncan, 2004:210). To report the error, the nurses must overcome the perceived embarrassment for committing an error that could have been avoided and the potential punitive retaliation from their manager.

A study in Turkey, found that even when nurses are aware of their errors, only 77% are willing to report the errors. The rest of the nurses do not report as they were anxious and concerned about their managers' attitudes and being dismissed from their jobs (Karadeniz & Cakmakci, 2002:111).

Marx (2001:1-28) proposed a new concept known as the "just culture". This new concept encouraged change in the organisational systems in order to reduce the incidences of adverse events. Systems such as work environment, data management systems, and risk management need to be designed with minimal risk for human error. A non-punitive approach to reporting and analysing errors and events must be taken (Clarke, 2006:260). Punitive cultures result in errors and events not being reported and therefore risk areas are not identified and corrective measures are not being introduced (Chiang & Pepper,

2006:393). Chiang and Pepper (2006:393) further imply that managers must encourage a just culture within their units.

In the past the individual nurse could be held responsible for the error without taking into consideration the contributing factors such as fatigue, staff competence, shortage of staff and the work environment (Brenner *et al.,* 2001:510). The 'just culture' encourages change from focusing on the individual involved in the event to focusing on the environment, systems assistance and employee competence. According to Benner (2001:510), the implementation of the 'just culture' has decreased error risks.

Using the 'just culture' in event management identifies the contributing organisational and environmental factors, as well as the nurses' responsibility and accountability (Marx, 2001:5).

Policies and protocols have been implemented to account for the workload, environmental factors, staff needs and competency, and these have been proven to reduce the risk of errors and events (Benner, 2001:510). Leape, Berwick, Clancy, Conway, Gluck, Guest, Lawrence, Morath, O'Leary, O'Neill & Isaac (2009:424-426), confirmed the success of the 'just culture' and further stated that a culture of trust, reporting, transparency and discipline are needed for the delivery of safe, quality patient care.

2.13 MALPRACTICE COSTS

According to Judge N. Claassen (2016:7), three out of nine provinces in South Africa have medico-legal claims amounting to R30 billion. In 2013-2014, Gauteng Department of Health paid out R256 million on legal costs arising from the plaintiff's attorneys. These payments have not been budgeted for, and are being made available from funds allocated to medical equipment renewal and other purposes. The use of non-budgeted funds therefore allows for the risk of further claims being instituted (Claassen, 2016:7).

The highest claim paid out in South Africa was to an 11-year-old, in June 2013, for the amount of R25 million for numerous unsuccessful surgeries relating to insertion of a ventricular peritoneal shunt (Oosthuizen, 2014:183).

There are many reasons which contribute to the increase in medical malpractice litigation claims. The patient who suffers an adverse event may require special devices like wheelchairs and amendments to their accommodation after such an event has occurred. The cost of these life-enhancing devices and life style changes are increasing year by year

and this is factored into the claim for damages when the calculations for the cost of damages are determined (Pienaar, 2016:5).

Oosthuizen and Carstens (2015:277-278) further explain that patients are immensely affected by adverse events. These adverse events often result in additional surgical procedures and increased hospitalisations for the patient. The adverse event may also cause chronic pain for the patient, disability, depression or disfigurement and these results could have a serious effect on the patient's quality of life (Oosthuizen & Carstens, 2015:277-278).

Furthermore, the increasing number and costs of birth related medical litigation cases are resulting in experienced obstetricians and gynaecologists leaving their profession because the frequency and severity of the claims have rendered the obstetricians and gynaecologists uninsurable. Outstanding claims in government and provincial hospitals range between 50 billion to 60 billion rand (Emmet, 2017:1-6).

2.14 SUMMARY

A detailed literature review of medical malpractice was conducted and described in this chapter.

This chapter described the legislation affecting healthcare and the delivery of safe patient care, including the scientific nursing process and factors influencing patient safety and the assessment of the severity of adverse events.

The literature review uncovered factors contributing to adverse events, such as cost cutting, overworked personnel, unskilled staff, inadequate safety measures, poor or lack of attention. These are all barriers to safe, quality care and must be addressed if there is to be a reduction of medical litigation cases in South Africa.

2.15 CONCLUSION

Patient safety is the focus of the healthcare environment, however, the incidence of medical negligence leading to malpractice litigation cases seem to be increasing within South Africa, Africa and internationally. It is important to strengthen the healthcare care environment defences against adverse events resuling in malpractice litigation cases. Strengthening the defences may be achieved by identifying the adverse events and relating factors, discouraging punitive actions and blame culture and encouraging nurses to take

responsibility and accountability for the acts and ommissions and to keep their knowledge base constantly updated.

CHAPTER 3
RESEARCH METHODOLOGY

3.1 INTRODUCTION

The purpose of this chapter is to describe the research methodology that was applied to obtain information regarding factors influencing adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape.

Research methodology is a description of the techniques used by the researcher to collect and analyse the data that is relevant to the topic of research and the research question (Polit & Beck, 2006:15).

3.2 RESEARCH AIM

The aim of this study is to investigate factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape.

3.3 RESEARCH OBJECTIVES

The objectives of this research study were to:

- Complete an audit analysis of the nursing process documentation
- Categorise the adverse events into principle types
- Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation
- Identify other healthcare team members who may be associated with the adverse events that have resulted in malpractice litigation
- Assess the severity of the adverse events associated with malpractice litigation.

3.4 RESEARCH QUESTION

The research question is the foundation of the research study (Lobiondo-Wood & Haber, 2006:28-29). Lobiondo-Wood and Haber (2006:28-29) further explain that the research question should present the problem that is to be researched. The researcher was guided by the following research question:

“What are the factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape?”

3.5 RESEARCH METHODOLOGY

3.5.1 Research design

A research design is the blueprint of how the researcher plans on conducting the research study (Grove, Burns & Gray, 2013:214). Quantitative research is a formal, objective, systematic process in which numerical data are used to obtain information about the world (Burns & Grove, 2005:23).

A quantitative, retrospective audit research design was used for the purpose of this study. A quantitative retrospective study is a study in which data is collected on an outcome of an event (Brink *et al.,* 2012:102). Brink *et al.* (2012:102) further explain that this information is then linked to similar events that have occurred in the past. A quantitative design was applied as it enabled the researcher to access a large number of litigation bundles and allowed the research done to be quantified, resulting in more objective findings and minimising the assumptions (Church & Rogers, 2006:44-52).

3.5.2 Study setting

The study focused on malpractice litigation cases that have occurred in private hospitals in the Western Cape region. The individual malpractice litigation bundles were audited at various attorneys' offices specialising in medical malpractice to maintain privacy and confidentiality.

3.5.3 Population and sampling

Burns and Grove (2011:290) define population as a particular group of individuals who is the focus of the research. Sampling is the process of selecting participants who are a representative of the population being studied (Gray *et al*., 2016:347).

For the purpose of this study a convenience sample was applied. The sampling frame was attorneys who specialise in medical malpractice litigation. At least 15 attorneys who specialised in medical malpractice litigation cases were consulted with the intention of auditing 100 files in total, as recommended by the biostatistician. The researcher received seven positive responses from attorneys in three provinces (Western Cape, Gauteng and Kwa-Zulu Natal). These attorneys had a variety of cases from various private hospitals in the Western Cape. In total 81 trial bundles, that met the criteria of the study, were made available to the researcher for auditing. These trial bundles were from no specific hospital organisation, but from various private hospital groups in the Western Cape Province.

A waiver of consent to complete and audit the malpractice trial bundles was applied for and granted by the Ethics Committee (Faculty of Medicine and Health Sciences) at Stellenbosch University.

3.5.3.1 Inclusion criteria

Medical litigation cases which occurred in all private hospital groups in the Western Cape Province were used for the purpose of this study.

3.5.3.2 Exclusion criteria

The researcher excluded malpractice litigation cases that have not been finalised or where the hearing was still in progress or any case which had received much media coverage.

3.6 DATA COLLECTION TOOL

A questionnaire is defined as a self-report form that is designed to gather information from the respondent (Grove *et al.,* 2013:425).

An audit instrument was designed based on the identified objectives and aligned to the conceptual framework. The instrument was tested and validated during the pilot study of the main study at Stellenbosch University and was used to obtain the required data (Annexure A). The researcher was trained on data collection and assisted in completing the pilot study. The data collection training was done by the principle investigator of the main study. The instrument was slightly adapted as the sample of the pilot study included both private and public cases. The option on the instrument giving the choice between private and public was removed. The audit instrument was reviewed to ensure that accurate, effective data was obtained to reflect data based in the private hospitals in the Western Cape.

The instrument was in English as all malpractice litigation cases are conducted in English and this was confirmed in the pilot study. The instrument was divided into six sections, identified as Section A through to Section F and covered all objectives.

Each section in the instrument addressed the various objectives. Sections A to D on the instrument were based on objective 3.3.1 (to complete an audit analysis of the nursing process documentation). Sections E and F were based on objectives 3.3.2 to 3.3.5 (to categorise the adverse events into principle types, to determine factors associated with the adverse events involving the nurse, to identify other healthcare team members that may be associated with the adverse event and to assess the severity of the adverse event associated with the medical malpractice litigation).

3.6.1 Reliability and validity

- **Reliability**

Reliability refers to the consistency, stability and ability of the instrument to capture and measure the data required for the intended study (Lobiondo-Wood & Haber, 2017:57).

The test-retest reliability method as described in Grove, Burns and Gray (2013:389-390) was applied to ensure that the instrument being used contained all the information required to complete an audit of the adverse event.

The pilot study completed for the main study supported the current study. The sub- study is aligned to the main study. The pilot study confirmed reliability of the instrument; the only information changed on the instrument was the option between private and public. The option was replaced by private as the researcher focused on the private sector in the Western Cape.

The revised instrument was reviewed by the supervisor and the biostatistician to verify that all required information was captured and measured by the instrument.

- **Validity**

Validity refers to the accuracy and truthfulness of the findings (Lobiondo-Wood & Haber, 2017:57-58). Face and content validity were ensured through a rigorous process. The pilot study along with the principal investigator, expert opinions and a biostatistician were consulted before the instrument was found to be valid.

- **Face Validity**

Brink *et al.* (2012:166) describe face validity as based on the intuitive judgement of experts in the field. The instrument must contain questions that at least appear to measure the required data. Burns and Grove, (2005:540), describe face validity as the verification that the instrument measures the necessary data.

The instrument used appeared to have measured the data required. This was subjected to experts in quality assurance and writing of standards in healthcare, a biostatistician and the researcher's supervisor.

- **Content Validity**

Brink *et al.* (2012:126) explain content validity as an assessment of how well the instrument represents all the components of the study.

Content validity ensures that the instrument measures all the known variables that relate to the study (Burns & Grove, 2005:540-541).

The content of the instrument measured all the components, based on the objectives as required. The conceptual framework of this study gave guidance to the development and content of the audit instrument.

Content validity was based on scientific literature as discussed in the literature review. Models and theories guided the content. Expert advice was obtained from experts in quality assurance, writing of standards and a biostatistician to further confirm validity. The researcher's supervisor, who is an expert witness in malpractice litigation cases and a board member for the Office of Health Standards Compliance (OHSC), evaluated the instrument to enhance the face content and content validity. In addition, the validity of this study was supported through the pilot study conducted for the main study.

3.7 PILOT STUDY

A pilot study is a mini-replica of the proposed study, and it is completed in the same manner in which the actual study will be done (De Vos, Strydom, Fouche & Delport, 2011:237). Burns and Grove (2011:509) further explain that the pilot study will also assist in identifying any problems with the design of the study and this also allows the researchers to familiarise themselves with the subjects, the setting and the methodology.

For the purpose of this study, the pilot study was completed on the main study, "A retrospective audit analysis of malpractice litigation in nursing practice in South Africa". The ethics approval for the main study was obtained and confirmed by reference number N16/02/027. The pilot study was conducted in the same manner in which this sub-study was conducted.

3.8 DATA COLLECTION

Data collection is the process to collect data for the proposed study and is dependent on the study design (Burns & Grove, 2011:361).

The data collection process began once ethics approval and a waiver of consent were granted to audit the malpractice litigation bundles. The researcher then arranged appointments with the various attorneys who responded positively to the request to audit the malpractice litigation bundles.

Patient and hospital confidentiality was maintained by auditing the malpractice litigation bundles at the attorney's office. The researcher completed the data collection personally. During this process, the data was captured using an audit instrument and then transferred onto the electronic Excel spread sheet.

The data collection tool was not labelled or marked with any reference to the specific case. For the researcher's convenience the data collection tool was only numbered once the data was loaded onto the electronic Excel spread sheet. This was done for cross checking purposes, to keep track of the amount of number of bundles audited and for when capturing on the Excel spread sheet.

3.9 DATA ANALYSIS

Quantitative data analysis is the technique by which data is converted to a numerical system and analysed statistically (De Vos *et al,* 2011:249). Grove, Burns and Gray (2013:46-48), state that data analysis is the organising and stream-lining of the data collected during the study.

With the support of the biostatistician, a descriptive analysis was done on the data to determine the frequencies which are presented in tables and graphs. Cross tabulations were not possible in this study as the analysis of the pilot study had shown that cases were from no specific hospital groups and no specific medical condition. The results do not identify any name, whether of a defendant (hospital), plaintiff (patient) or lawyers involved in the case. The goal of this study was to identify the factors influencing adverse events which lead to malpractice litigation in nursing practice.

3.10 ETHICAL CONSIDERATIONS

Ethics approval from the Faculty of Medicine and Health Sciences at Stellenbosch University was granted. This is confirmed by the Ethic Committee approval number S16/10/204 (Annexure A). A detailed discussion of the ethical considerations can be found in chapter 1 (paragraph 1.9).

3.11 STUDY LIMITATION

Gray *et al.* (2016:583) describe study limitations as constraints that affect the credibility of the findings.

The limitation identified in this study was that the research was based on auditing medical malpractice bundles. These are considered private and confidential and despite ethical approval from the Faculty of Medicine and Health Science at Stellenbosch University, many attorneys were not keen on providing the researcher access to their medical malpractice bundles.

3.12 SUMMARY

This chapter detailed the research methodology that was used to complete this study. This included the research aim, research objectives, and research question. Further to this, the population and sampling were explained in detail with the data collection methods and process of analysis.

3.13 CONCLUSION

The research methodology employed by the researcher to conduct this study was discussed in detail. Chapter 4 discusses the analysis of data and the interpretation of the findings of this research study.

CHAPTER 4
DATA ANALYSIS AND INTERPRETATION

4.1 INTRODUCTION

Chapter 4 outlines the analysis and interpretation of the data collected for this study. Quantitative data analysis is described by De Vos *et al.* (2011:249) as "the technique by which data is converted to a numerical form and subjected to statistical analysis".

As described in chapter 3, the data captured from the manual data collection tool was transferred onto an electronic Excel spread sheet by the researcher. The biostatistician used the Statistical Package for the Social Sciences (SPSS) to analyse the data. Each column was labelled and coded according to the variable being measured, with 99 representing not applicable and 98 representing data not available.

The data on the manual data collection tool was checked and rechecked by the researcher. The data capturing onto the electronic spread sheet was also checked and rechecked by the researcher before submission to the biostatistician for analysis.

4.2 SECTION A: LITIGATION (QUESTIONS 1-3)

This section includes questions about whether the case was settled out of court or appeared in court, the settled amount in rand, quantum to be paid as decided by the judge.

4.2.1 Question 1 – How was the case presented?

The total number of files audited were n=81. As shown on the figure 4.1, 60.5% of the trial bundles audited were settled out of court.

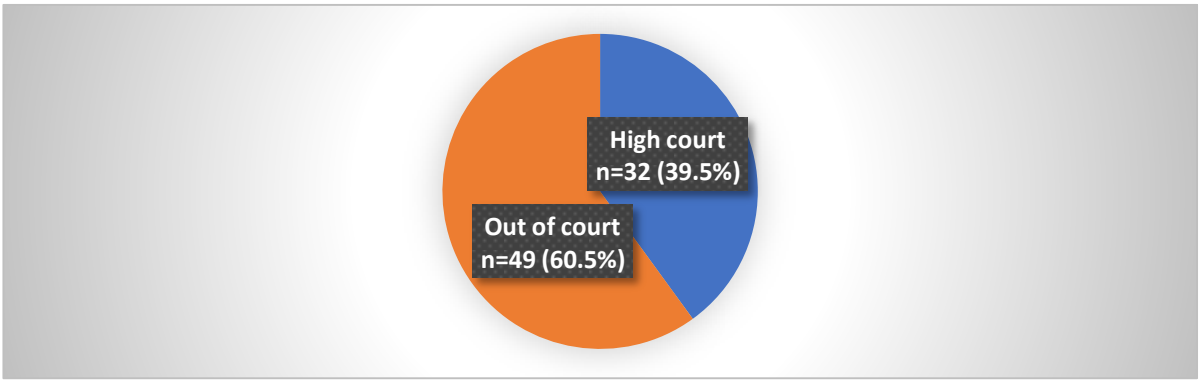

Figure 4.1: Case Presentation (N=81)

4.2.2 Question 2 – If settled out of court, indicate the amount for which the case was settled

The attorneys were not keen to share this information as they believed that this information was private and confidential. One attorney stated that in some cases if the quantum payment is known, one can easily identify either the patient or the hospital involved. After discussion with the attorneys involved and the researcher's supervisor a decision was made not to reveal the out of court settlements.

4.2.3 Question 3 – If presented in court, indicate the amount for which the case was settled

For the reasons mentioned in 4.3.2, the researcher was only able to obtain rand values for eleven trial bundles ranging from R750 000 to R11.1 million the amounts of all of the cases

4.3 SECTION B: DEMOGRAPHIC DATA (QUESTIONS 4-12)

This section describes the patient's age, gender, marital status, dependents, if applicable, employment, social habits and pre-existing medical history.

4.3.1 Question 4 – Age of the patient (N=81)

The ages of the patients who experienced an adverse event that resulted in malpractice litigation ranges from 0-years to 96-years, with the dominant age being 0 years, n=14.

4.3.2 Question 5 – Gender (N81)

The study sample consisted of n=44 (54.3%) females and n=37 (45.7%) males as shown in table 4.1.

Table 4.1: Gender (N=81)

Gender	Frequency	Percentage (%)
Female	44	54.3
Male	37	45.7
TOTAL	N=81	100%

4.3.3 Question 6 – Marital Status (N=81)

Majority of the patients, n=34 (42%), were single. The balance of the marital status is reflected in table 4.2.

Table 4.2: Marital status (N=81)

Status	Frequency	Percentage (%)
Single	34	42.0
Married	29	35.8
Partner	6	7.4
Widow	8	9.9
Widower	4	4.9
TOTAL	N=81	100%

4.3.4 Question 7 - Dependents (N=81)

The dependents per patient varied between 0 to more than 3, with most patients having no dependents, n=32 (39.5%) However, n=9 (11.1%) were undocumented as shown in table 4.3.

Table 4.3: Dependents (N=81)

	Frequency	Percentage (%)
None	32	39.5
One	10	12.3
Two	15	18.5
Three	7	8.6
More than three	5	6.2
Not documented	9	11.1
Not applicable	3	3.7
TOTAL	N=81	100%

4.3.5 Question 8 – Disability on admission (N=81)

Table 4.4 shows that only n=8 (9.9%) patients had a disability on admission, with n=73 (90.1%) not having a disability on admission.

Table 4.4: Disability on admission (N81)

	Frequency	Percentage (%)
Disability-no	73	90.1
Disability-yes	8	9.9
TOTAL	N=81	100%

4.3.6 Question 9 – Indicate whether the patient had any of the following social habits (Smoking, Unsolicited drugs, Alcohol) (N=57)

SMOKING (N=57)

Figure 4.2 shows that n=12 (21%) of the participants smoked.

It may be noted that on admission of a patient, there is a question on the admission document to have prompted the nurse to explore this social habit.

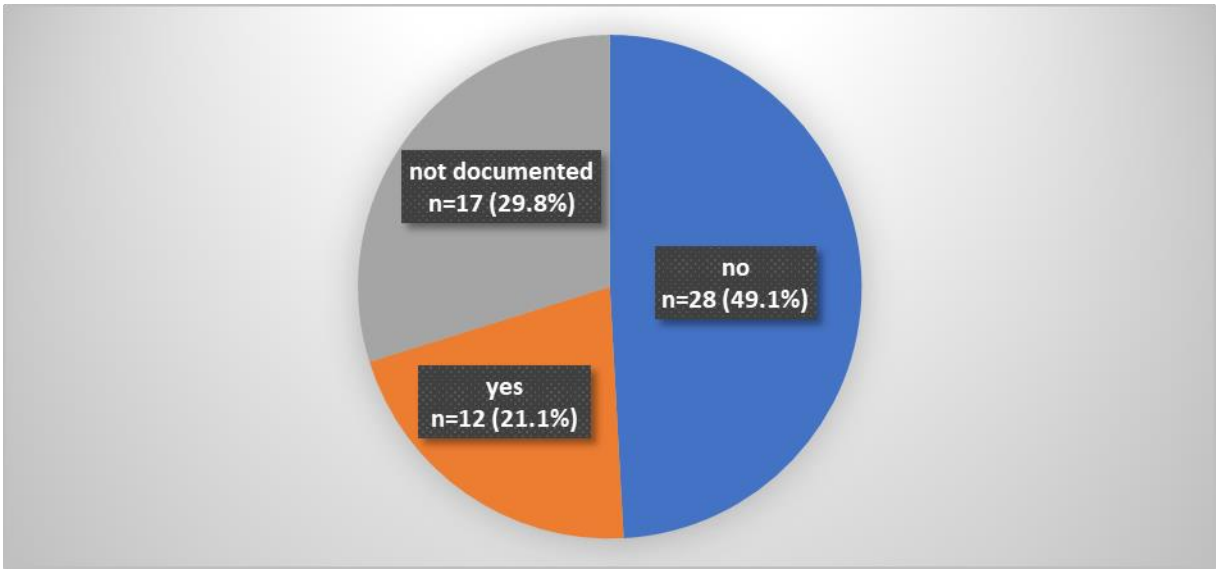

Figure 4.2: Smoking (N=57)

UNSOLICITED DRUGS (N=57)

As shown in figure 4.3, this social habit was not widely explored by the nurse, n=43 (75.4%) was not documented. As may be noted n=14 (24.5%) of the patients responded no to this question. It is important to note that there are no questions through the documentation process to prompt the nurse to question the patient regarding unsolicited drugs.

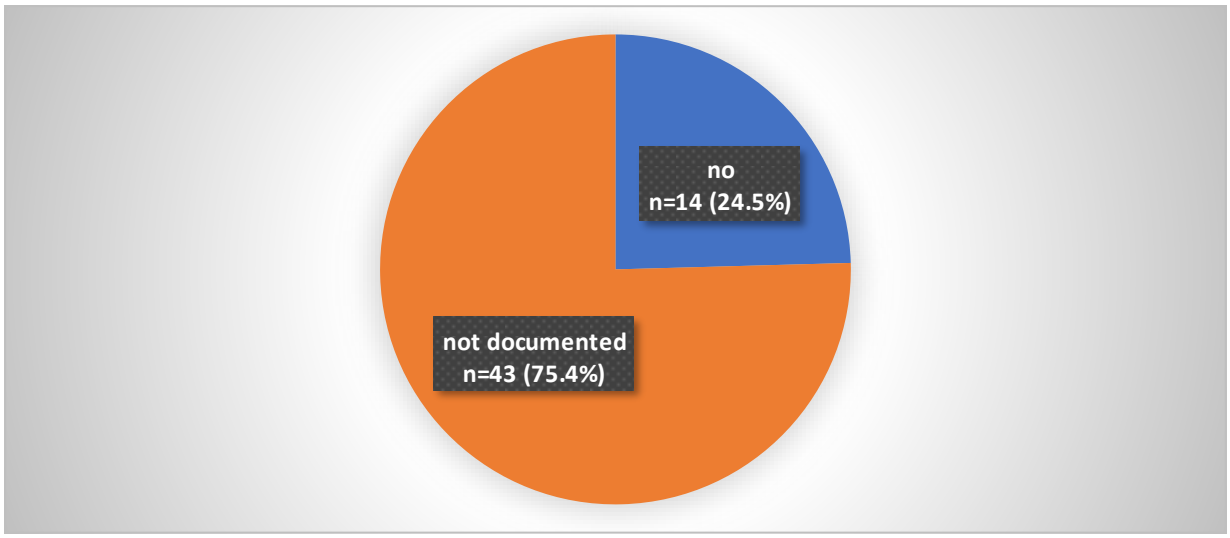

Figure 4.3: Unsolicited Drugs (N=57)

ALCOHOL (N=57)

Figure 4.4 shows n=16 (28.0%) of the patients drank alcohol.

The admission document did have a question to prompt the nurse to explore this social habit.

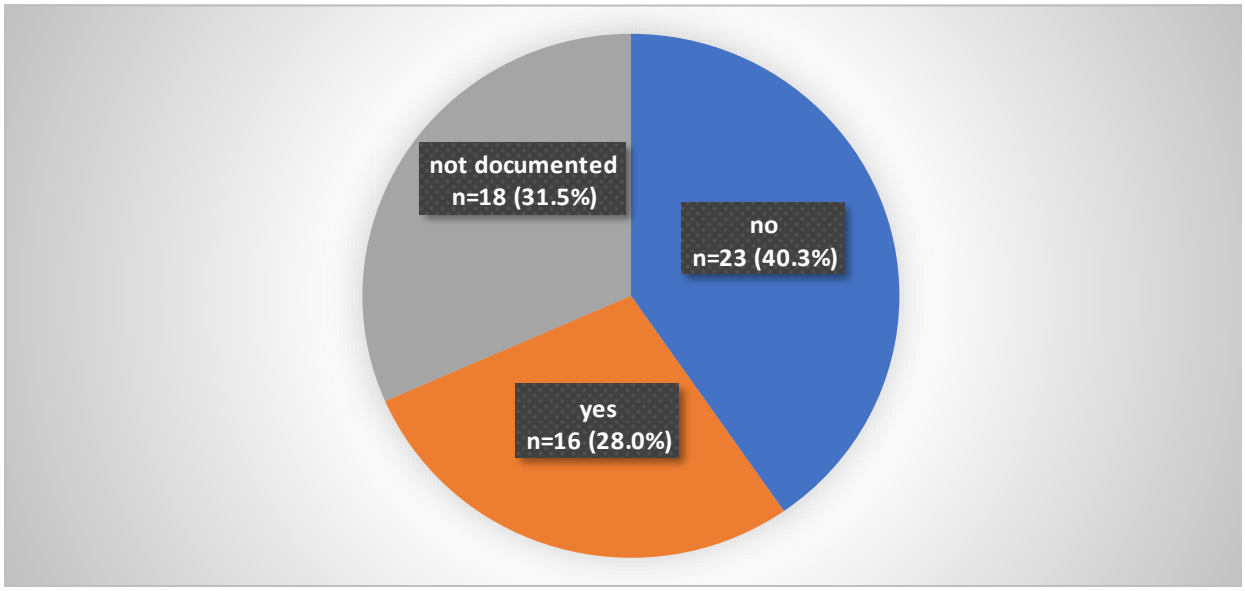

Figure 4.4: Alcohol (N=57)

4.3.7 Question 10 – Any underlying medical condition (Co-morbidity) (N=81)

Figure 4.5 shows that n=44 (54%) of the patients did not have any co-morbidities prior to the adverse event.

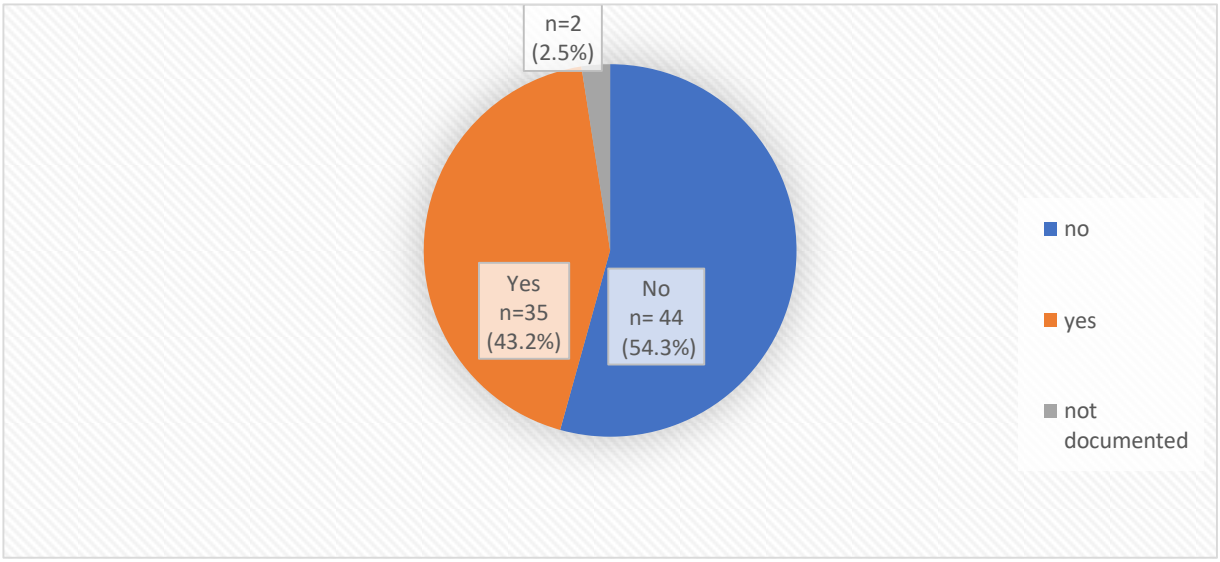

Figure 4.5: Co-morbidity (N81)

4.3.8 Question 11 – Employment at the time of admission to hospital (N=57)

Figure 4.6 indicates that n=28 (49.1%) of the patients were employed prior to the adverse event occurring; n=24 (29.6%) were children and scholars were recorded as not applicable.

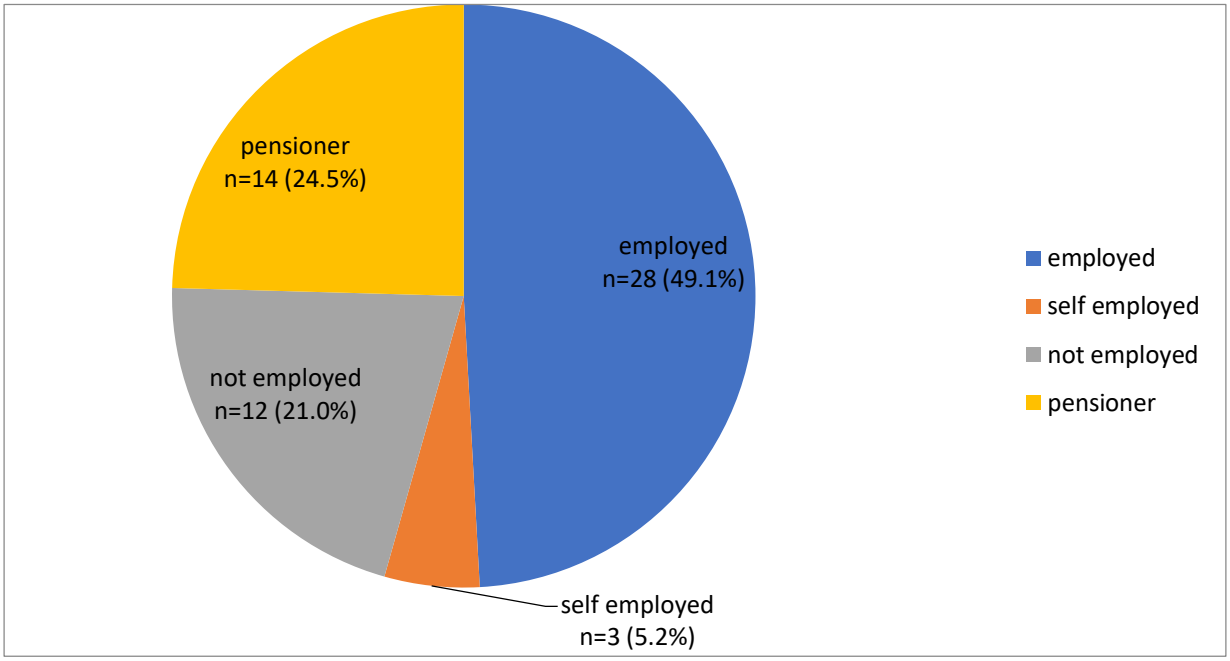

Figure 4.6: Employment (N=57)

4.3.9 Question 12 – Type of Employment (N=57)

The type of employment the patient was involved in prior to the adverse event is shown in table 4.5. The option labelled other included the part time workers and housewives, n=29 (50.9%).

Table 4.5: Type of employment (N=57)

	Frequency	Percentage (%)
Professional	6	10.5%
Technical	1	1.8%
Business	4	7.0%
Administrative	15	26.3%
Tradesman	1	1.8%
Labourer/Unskilled	1	1.8%
Other	29	50.9%
TOTAL	N=57	100%

4.4 SECTION C: HOSPITALISATION (QUESTIONS 13-31)

The hospitalisation section identifies the admission type, diagnosis, care delivered and diagnostic test results. This section will provide information regarding factors leading to the adverse event.

4.4.1 Question 13 – Indicate whether the nursing notes are available to audit (N=81)

Figure 4.7 reflects that the majority of the trial bundles, n=77 (95.1%) audited, had a complete set of nursing notes, in accordance with the phases of the nursing process while n=4 (4.9%) had nursing notes available. It was evident that some of the documentation was missing according to the nursing process.

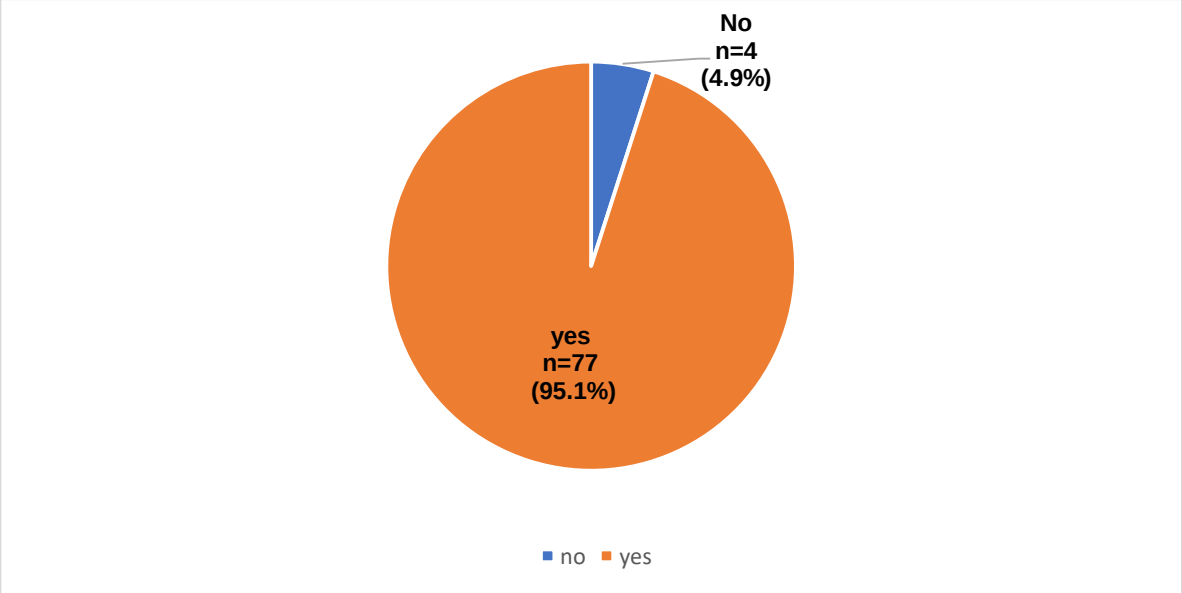

Figure 4.7: Availability of nursing notes (N=81)

4.4.2 Question 14 – Indicate the reason for admission (N=81)

Prior to the adverse event occurring, n=32 (39.5%) of the patients were admitted into the medical ward due to an illness requiring medical care. This was followed by patients being admitted for elective treatment, n=18 (22.2%) as illustrated in table 4.6.

Table 4.6: Reason for admission (N=81)

	Frequency	Percentage (%)
Elective	18	22.2
Planned	12	14.8
Emergency	16	19.8
Sick	32	39.5
Other	3	3.7
TOTAL	N=81	100%

4.4.3 Question 15 – Indicate the discipline to which the patient was admitted prior to the adverse event (N=81)

The majority of the admissions prior to the adverse events occurring were admitted to the medical wards, n=24 (29.6%) and this was followed by the obstetrics, n=12 (14.8%), general surgery, n=10 (12.3%), gynaecology n=7 (8.6%) and trauma n=7 (8.6%).

Table 4.7: Discipline (N=81)

	Frequency	Percentage (%)
Cardiology	1	1.2%
Gynaecology	7	8.6%
Medical	24	29.6%
Obstetrics	12	14.8%
Neonatology	5	6.2%
Neurosurgery	3	3.7%
Neurology	1	1.2%
Orthopaedic	2	2.5%
Ophthalmology	1	1.2%
Paediatrics	2	2.5%
Psychiatric	1	1.2%
Trauma	7	8.6%
General surgery	10	12.3%
Cardiac surgery	1	1.2%
Other	4	4.9%
TOTAL	N=81	100%

4.4.4 Question 16 – Indicate the type of ward/unit the patient was admitted to prior to the adverse event (N=81)

As illustrated in table 4.8, most of the initial admissions were admitted to the general ward, n=38 (46.9%). This was followed by the intensive care unit, n=12 (14.8%) and n=2 (2.5%) to the paediatric ward.

Table 4.8: Type of ward/unit prior to adverse event (N=81)

	Frequency	Percentage (%)
Emergency	11	13.6
General	38	46.9
Paediatrics	2	2.5
ICU	12	14.8
Labour	9	11.1
Post-natal	9	11.1
TOTAL	N=81	100%

4.4.5 Question 17 – Indicate whether the initial assessment including the foetus where applicable was done (N=81)

Table 4.9 indicates that more than n=14 (17.3%) of the initial assessments were incomplete, and n=26 (32.1%) were not done.

Table 4.9: Initial Assessment (N=81)

	Frequency	Percentage (%)
Complete	41	50.6%
Incomplete	14	17.3%
Not documented	26	32.1%
TOTAL	N=81	100%

4.4.6 Question 18 – Indicate the status of the care plan (N=81)

Table 4.10 shows that n=25 (30.9%) of the care plans were not done and n=7 (8.6%) were incomplete.

Table 4.10: Status of care plan (N=81)

	Frequency	Percentage (%)
Complete	49	60.5%
Incomplete	7	8.6%
Not documented	25	30.9%
TOTAL	N=81	100%

4.4.7 Question 19 – Indicate whether the care plan was implemented (N=56)

As illustrated in table 4.11, n=28 (50%) of the care plans were not implemented.

Table 4.11: Implementation of care plan (N=56)

	Frequency	Percentage (%)
Implemented – No	28	50%
Implemented – Yes	28	50%
TOTAL	N=56	100%

4.4.8 Question 20 – Indicate whether special care plans were required (N=66)

Table 4.12 shows that n=32 (48.5%) of the trial bundles audited required special care plans.

Table 4.12: Special care plan required (N=66)

	Frequency	Percentage (%)
No	34	51.5%
Yes	32	48.5%
TOTAL	N=66	100%

4.4.9 Question 21 – Indicate the status of the special care plan (N=32)

The completion of the special care plans as indicated in table 4.13, n=9 (28.1%) were documented and n=4 (12.5%) were incomplete.

Table 4.13: Status of special care plans (N=32)

	Frequency	Percentage (%)
Complete	19	59.4%
Incomplete	4	12.5%
Not documented	9	28.1%
TOTAL	N=32	100%

4.4.10 Question 22 – If yes in question 21, indicate whether the special care plan was implemented (N=23)

Table 4.14 shows that n=15 (65.2%) of the completed and incomplete special care plan were not implemented.

Table 4.14: Implementation of special care plan (N=23)

	Frequency	Percentage (%)
Implemented – No	15	65.2%
Implemented – Yes	8	34.8%
TOTAL	N=23	100%

4.4.11 Question 23 – Indicate whether the vital signs were monitored

Table 4.15 illustrates the completion of the vital signs as noted in the trial bundles.

This research study shows that vital signs monitoring is not being done regularly.

Table 4.15: Vital signs monitored

	DONE		NOT DOCUMENTED	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
Blood pressure (n=69)	56	81.1%	13	18.8%
Pulse (n=81)	66	81.4%	15	18.5%
Foot pulse (n=26)	8	30.7%	18	69.2%
Foetal heart rate (n=14)	6	42.8%	8	57.1%
Respiration (n=81)	59	72.8%	22	27.1%
Temperature (n=81)	62	76.5%	19	23.4%
Fluid balance (n=72)	31	43%	41	56.9%
Weight (n=77)	38	49%	39	50.6%
Neuro-observations (n=34)	5	14.7%	29	85.9%
Post spinal surgery (n=11)	1	9%	10	90.9%
Mental status (n=46)	15	32.6%	31	67.3%
Continuous ECG (n=27)	16	59%	11	40.7%
Continuous oxygen (n=42)	26	61.9%	16	38%
Other (n=8)	1	12.5%	7	87.5%

4.4.12 Question 24 – Indicate whether the following diagnostic tests were done pre-adverse events

As indicated in table 4.16, n=86 (27.7%) of the required diagnostic tests were not done.

Table 4.16: Test – Blood and non-blood tests

	DONE		NOT DOCUMENTED	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
Haemoglucose (n=31)	17	54.8%	14	45.2%
Haemoglobin (n=42)	31	73.8%	11	26.2%
Urine MC+S (n=47)	35	74.4%	12	25.6%
Urea and electrolyte (n=48)	41	85.4%	7	14.6%
Aterial blood gas (n=32)	18	56.3%	14	43.7%
Full blood count (n=54)	44	81.4%	10	18.6%
Liver functions (n=41)	32	78%	9	22%
Other (n=15)	6	40%	9	60%
TOTAL N=310	**224**	**72.3%**	**86**	**27.7%**

4.4.13 Question 25 - Were the patient's results of the diagnostic tests interpreted (N=81)

It is important to note that of the trial bundles audited n=4 (4.9%) of the patients' diagnostic test results were incorrectly interpreted by the registered nurse. Table 4.17 further illustrates that n=60 (74.1%) of these results were not interpreted by the registered nurse.

Table 4.17: Interpretation of patients' diagnostic results (N=81)

	Frequency	Percentage (%)
Correctly interpreted	17	21%
Incorrectly interpreted	4	4.9%
Not interpreted	60	74.1%
TOTAL	N=81	100%

4.4.14 Question 26 – Were the patient' results reported to the doctor (N=81)

In figure 4.8, it is noted that n=55 (68%) of the patients' diagnostic tests were not reported to the doctor.

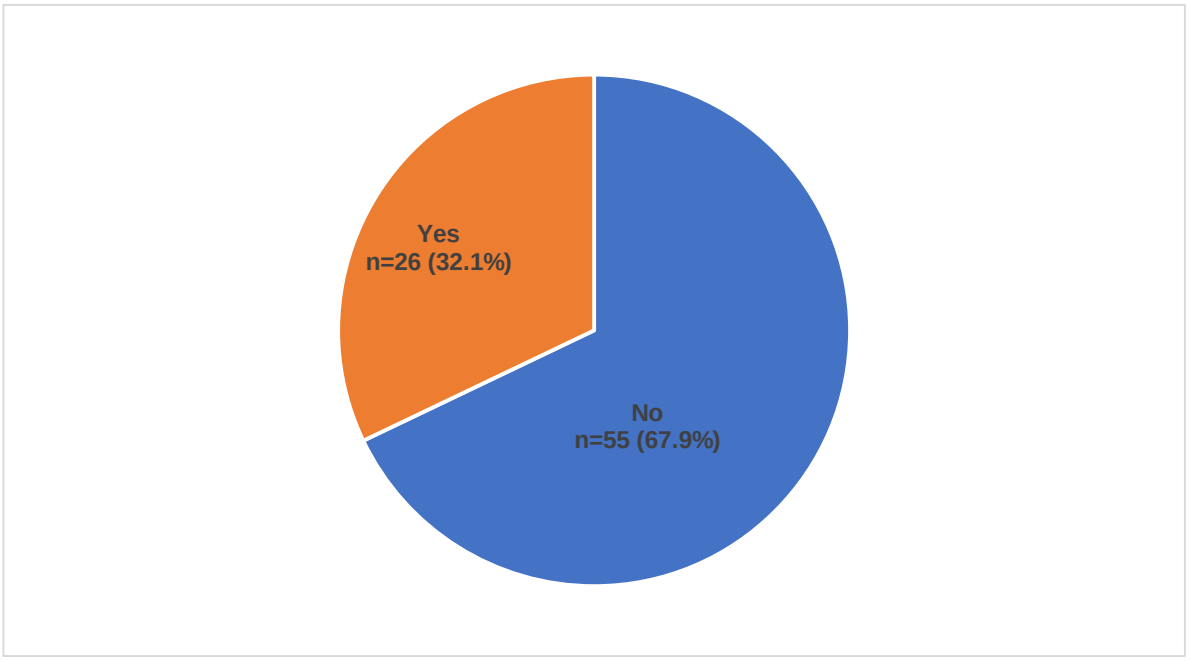

Figure 4.8: Test results reported to doctor (N=81)

4.4.15 Question 27 – If any diagnostic tests on the patients were done, indicate whether action was taken based on the results (N=81)

In figure 4.9, n=64 (79%) of the trial bundles had no action taken based on the test results.

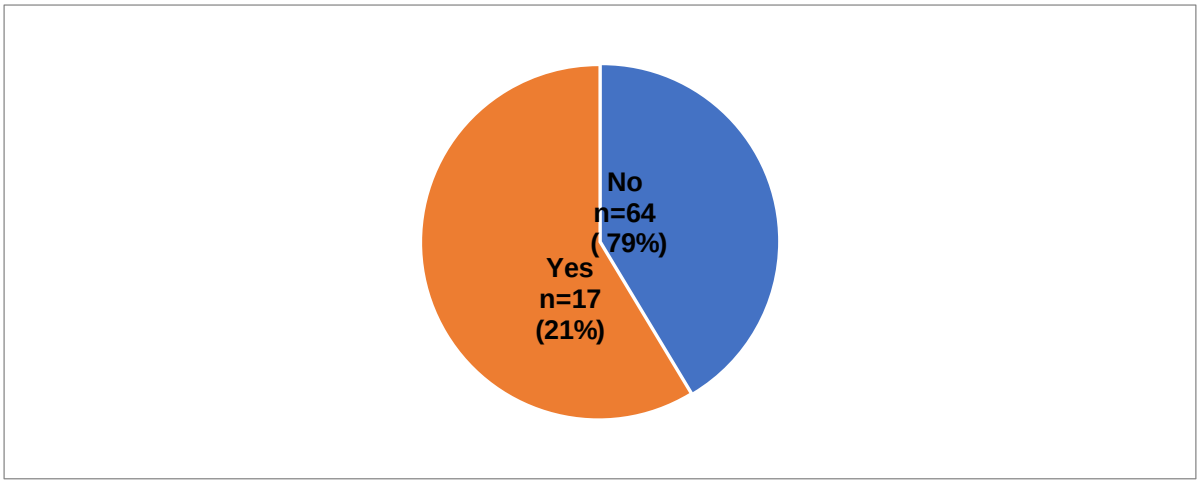

Figure 4.9: Based on results, what action was taken (N=81)

4.4.16 Question 28 - Where applicable, indicate whether the preoperative assessment for surgery was done (N=26)

Table 4.18 represents the perioperative assessments with n=10 (38.5%) being incomplete and n=4 (15.4%) failed to do a perioperative assessment.

Table 4.18: Perioperative assessment done (N=26)

	Frequency	Percentage (%)
Complete	12	46.2%
Incomplete	10	38.5%
Not documented	4	15.4%
TOTAL	N=26	100%

4.4.17 Question 29 - Indicate whether the treatment/technique/management as prescribed was given (N=81)

Figure 4.10 indicates that n=49 (60.5%) of the patients did not receive the treatment as prescribed by the doctor, while n=32 (39.5%) received prescribed treatment.

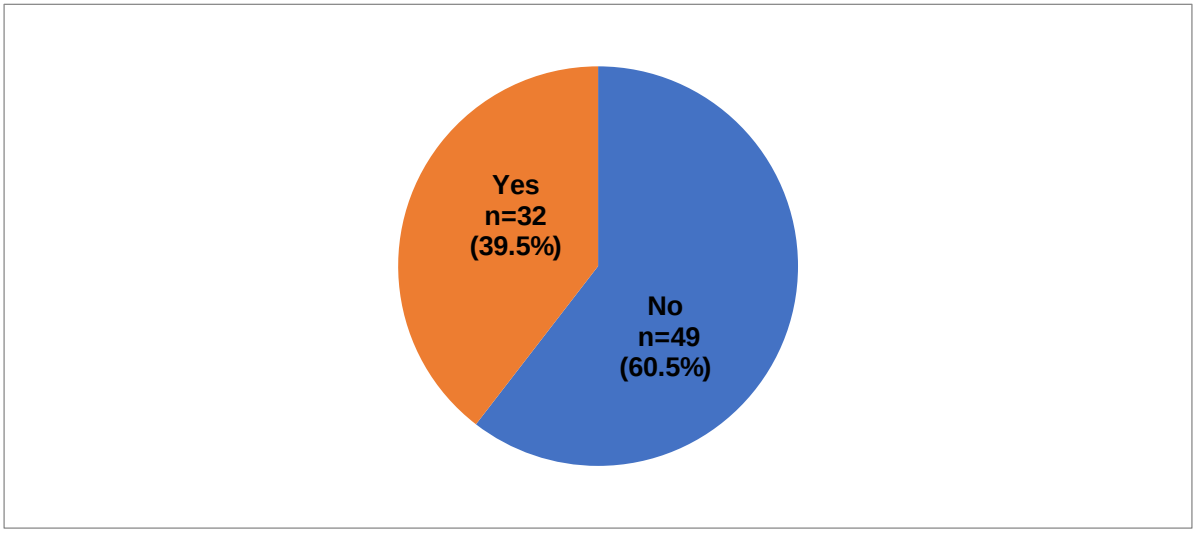

Figure 4.10: Treatment given as prescribed (N=81)

4.4.18 Question 30 - Do the patient's reports (initial, progress, interim and discharge reports) reflect what was done for the patient

Table 4.19 shows that n=62 (76.5%) of the clinical manifestations were not documented, n=64 (79%) discharge reports were not documented and in reports on whether the doctor was contacted n=51 (63%) were not documented.

Table 4.19: Patient's progress reports done (N=81)

	DONE		NOT DOCUMENTED	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
Initial report	64	79%	17	21%
Progress report	46	56.8%	35	43.2%
Clinical manifestations recorded	19	23.5%	62	76.5%
Interim report	31	38.3%	50	61.7%
Doctor contacted report	30	37%	51	63%
Discharge report	17	21%	64	79%

4.4.19 Question 31 - If the patient was discharged, indicate whether specific patient education was given (N=81)

Specific patient education on discharge was not given to n=73 (90.1%) of the patients as illustrated in table 4.20.

Table 4.20: Patient education on discharge (N=81)

	Frequency	Percentage (%)
No	73	90.1%
Yes	8	9.9%
TOTAL	N=81	100%

4.5 SECTION D: OPERATING ROOM (QUESTION 32)

This section is only completed if the adverse event occurred during surgery or as a complication from surgery or is a result of a surgical intervention.

4.5.1 Question 32 – Indicate where applicable whether operating theatre protocols in the operating room were adhered to (N26)

Operating room is a high-risk discipline and table 4.21 shows that a number of operating theatre protocols were not documented.

Table 4.21: Operating room protocols adhered to (N26)

	DONE		NOT DOCUMENTED	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
Swab count	15	57.7%	11	42.3%
Infection control	17	65.4%	9	34.6%
Instrument control	22	84.6%	4	15.4%
Specimen control	17	65.4%	9	34.6%
Diathermy use	17	65.4%	9	34.6%
Surgical pause/Time out	1	3.8%	25	96.2%
Other	4	15.4%	22	84.6%

4.6 SECTION E: ADVERSE EVENTS (QUESTIONS 33-37)

In this section more than one answer was possible. This section describes the adverse event with regard to where the event occurred and the healthcare professionals involved.

4.6.1 Question 33 - Indicate the environment where the adverse event occurred (N=81)

The general wards had the highest number of adverse events with a total of n=23 (28%). This was followed by the operating theatre with n=14 (17.3%), the Intensive Care Unit (ICU) and trauma both with n=12 (14.8%) as shown in table 4.22.

Table 4.22: Environment where adverse event occurred (N=81)

	Frequency	Percentage (%)
General ward	23	28.4
ICU	12	14.8
Operating theatre	14	17.3
Paediatrics	1	1.2
Neonatology	5	6.2
Emergency centre	12	14.8
Obstetrics	8	9.9
Psychiatric	1	1.2
Other	5	6.2
TOTAL	N=81	100%

4.6.2 Question 34 - Describe the adverse event (N=81)

As described in table 4.23, the adverse events were grouped according to the disciplines. Surgical n=15 (18.5%) which included general surgery, dental surgery, ophthalmic surgery, maxilla facial surgery and orthopaedic surgery. Medication errors were noted at n=15 (18.5%), medical errors were n=11 (13.6%) and neurology adverse events were n=10 (12.3%)

Table 4.23 The adverse events (N81)

	Frequency	Percentage (%)
Surgical	15	18.5%
Medical	11	13.6%
Neurology	10	12.3%
Urology	4	4.9%
Obstetrics	8	9.9%
Gynaecology	3	3.7%
New-born and neonatology	9	11.1%
Psychiatric	1	1.2%
Medication errors	15	18.5%
Misdiagnosis	5	6.2%
TOTAL	N81	100%

4.6.3 Question 35 – Indicate the patient outcome(s) as a result of the adverse event (N=81)

As a result of the adverse event n=61 (75.3%) patients had an increased hospital stay, n=46 (56.8%) had their quality of life affected and n=22 (27.2%) of the patients died as a result of the adverse events. This is shown in table 4.24.

Table 4.24: Result of adverse event (N=81)

	Frequency (N)	Percentage (%)
Additional surgery	33	40.7%
Death	22	27.2%
Disabled	9	11.1%
Increased hospital stay	61	75.3%
Quality of life affected	46	56.8%

4.6.4 Question 36 – Healthcare professional(s) or non-healthcare Professionals responsible for adverse event (N=81)

Table 4.25 shows that nursing staff alone contributed to n=35 (43.2%) of adverse events. Nursing and medical staff together contributed to n=41 (52.6%).

Table 4.25: Responsible person (N=81)

	Frequency	Percentage (%)
Nursing	35	43.2%
Medical	3	3.7%
Nursing and medical staff	41	50.6%
Nursing and non-healthcare	2	2.5%
TOTAL	N=81	100%

4.6.5 Question 37 – If nursing or both nursing and medical staff were chosen in question 36, indicate the category (ies) of nurse involved in the adverse event

Table 4.26 indicates that the nurse category most involved in adverse events as confirmed by the trial bundles audited were registered professional nurses, n=77 (95.1%).

Table 4.26: Category of nurse(s) involved

	Frequency	Percentage (%)
Registered professional nurse	77	95.1%
Enrolled nurse	29	35.8%
Enrolled nurse auxiliary	15	18.5%
Midwife	7	8.6%

4.7 SECTION F: PRINCIPLE INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT (QUESTIONS 38-40)

This section refers to the principle incident type, the severity of adverse events and factors contributing to the adverse events.

4.7.1 Question 38 – Indicate the adverse event by Principle Incident type (N=81)

As noted in table 4.27, clinical management, n=72 (88.9%) was the most common principle type noted in trial bundles audited.

Table 4.27: Adverse event by principle type (N=81)

	Frequency (N=81)	Percentage (%)
Administrative	15	18.5%
Clinical management	72	88.9%
Human behaviour	64	79.0%
Organisational	42	51.9%

4.7.2 Question 39 – Indicate the severity of the adverse event according to the Safety Assessment Code (SAC) Matrix (N=81)

Table 4.28 shows that the majority of the adverse events were extreme n=29 (35.8%). On the SAC severity scale extreme is number one and minor being number four.

Table 4.28: Severity of adverse event using the SAC (N=81)

SAC Rating	Description	Frequency (N=81)	Percentage (%)
1	EXTREME	29	35.8%
2	MAJOR	19	23.5%
3	MODERATE	33	40.7%
4	MINOR	0	0%

4.7.3 Question 40 – Indicate which of the following factors contributed to the adverse event

Various contributing factors contributed to the adverse events resulting in medical malpractice litigation as shown in table 4.29. Lack of knowledge was the highest, n=74 (91.4%), followed by the failure to apply guidelines and protocols, n=73 (90.9%) and human factors, n=71 (87.7%).

Table 4.29: Contributing factors to adverse events

	Frequency	Percentage (%)
Clinical manifestations not adhered to	46	56.8%
Poor monitoring	56	69.1%
Failure to apply guidelines/protocols	73	90.1%
Failure to give treatment as prescribed	49	60.5%
Incorrect treatment	18	22.2%
Accumulation of omissions	39	48.1%
Accumulation of errors	57	70.4%
Systems failure	39	48.1%
Behaviour	71	87.7%
Lack of supervision	50	61.7%
Lack of training	44	54.3%
Lack of knowledge	74	91.4%
Other	1	1.2%

4.8 SUMMARY

The results from the data obtained were analysed and presented in tables and graphs. The researcher was able to address and answer the research question namely: “What are the factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape?”

4.9 CONCLUSION

The aim of this study was to investigate factors that influenced adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape.

The researcher was able to successfully audit the trial bundles and therefore meet the study objectives as listed below.

Objective 1: To complete an audit analysis of the nursing process documentation

Objective 2: Categorise the adverse events into principle types.

Objective 3: Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation.

Objective 4: Identify other healthcare team members that may be associated with the adverse events that have resulted in malpractice litigation.

Objective 5: Assess the severity of the adverse events associated with malpractice litigation.

In chapter 5, the results will be discussed and supported by references. The findings and recommendations will be discussed and based on the scientific findings of this study.

CHAPTER 5
DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The previous chapters provided an overview of the study, a detailed literature review, the methodology of the study and an analysis and interpretation of the findings of the study.

This chapter provides a discussion of the results as presented in chapter 4 with concluding remarks, recommendations and overall conclusion to the study.

5.2 DISCUSSION

The aim of this study was to investigate factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape.
The following objectives will be discussed:

- To complete an audit analysis of the nursing process
- Categorise the adverse events into principle types.
- Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation.
- Identify other healthcare team members that may be associated with the adverse events that have resulted in malpractice litigation.
- Assess the severity of the adverse events associated with malpractice litigation.

5.2.1 Objective 1: To complete an audit analysis of the nursing process

The nursing process records were audited to ascertain factors that led to the adverse event. Various factors were explored as illustrated in the data collection tool (Annexure B) and in the previous chapter (chapter 4).

In this study, the researcher found that 60.5% of the cases were settled out of court. The findings of this study are supported by a study of malpractice claims settled in and out of court in 2013 in the United States, which concluded that 96.9% (n=56 850) of the claims were settled out of court and 3.1% were settled in court (Rubin & Bishop, 2013:1).

This study shows that 49.1% of the patients involved in an adverse event were employed. It is interesting to note that 75.3% of these patients had an extended hospital stay, resulting in the patient being off work for longer than anticipated.

This has a potential of impacting on the patient's income and productivity which may lead to an adverse effect on the patient's work life (Walton, Smith-Merry, Harrison, Manias, Iedema & Kelly (2014:1-4). Quality of life was affected in 56.8% of the patients involved in an adverse event. This quality of life change has a ripple effect on the patient, their family, their work and employer and their earning potential, (Walton *et al.*, 2014:1-4).

5.2.1.1 Assessment

It was identified that 32.1% of the initial assessments of the patients who suffered an adverse event were not done, while 17.3% were incomplete.

The assessment phase of the scientific nursing process is critical in identifying abnormalities, chronic conditions and medication, allergies and experiences of the patient. The assessment provides information about the patient that is vital to ensure that an accurate nursing diagnosis is made to ultimately ensure that the patient receives adequate care (Haapoja, 2014:5-11).

The researcher found that social habits of the patients were poorly documented, smoking (29.8%), unsolicited drugs (75.4%) and alcohol (31.5%) were not documented. The assessment documents did not contain questions to adequately explore the patient's social habits. Coombs *et al.,* (2011:368) found that the social situation and social habits of the patient are very important in the healthcare management of the patient.

According to Gowda (2016:1-32), nursing documentation is important for good clinical communication. Appropriate, accurate and completed documentation provides information about nursing assessments, changes in conditions and care provided which are important to support the multidisciplinary team to deliver safe, quality care. Documentation provides evidence of care and is vital for professional and medical legal reasons.

Ohlen (2015:6) further explained that nursing documentation is one of the tools for safe and quality nursing care and for the development of nursing care. Ohlen (2015:6) confirms that in the United States of America, that nurses are required by law to document all nursing interventions.

AlKouri, AlKhatib and Kwafhah (2016:101-104) support this and further state that nursing care that is rendered but not documented can be regarded as nursing care not done.

5.2.1.2 Nursing Diagnosis

The accuracy of the nursing diagnosis is based on the quality of assessment completed. The objective (signs) and the subjective (symptoms) are instrumental in identifying the nursing diagnosis. It is therefore a concern that 17.3% incomplete assessments and 32.1% with no assessments at all were found in the trial bundles, either not done or not documented. If the assessment documents are not completed, it may be deduced that the nursing diagnosis is incorrect. This is evident in this study as 60.5% of the patients did not receive treatment or management as prescribed.

As confirmed in paragraph 2.7 by Haapoja (2014:5-11) an accurate and reliable nursing diagnosis depends on the quality of the assessment of the patient and the nurse's ability to be able to identify the signs and symptoms the patient presents with.

5.2.1.3 Planning

Accurate and reliable planning of the patient's care delivery is vital to a positive outcome for the patient. In this study 30.9% of the trial bundles audited did not have care plans and 8.6% had incomplete care plans. The special care plans were incomplete in 12.5% and not documented in 28.1% of the trial bundles. In addition, the researcher found that 65.2% of the special care plans were not implemented.

A care plan is designed in conjunction with the scientific nursing process (Doenges *et al.,* 2012:4). A special care plan using the same process however is specific to a special condition the patient may have. Doenges *et al*. (2012:5) further explains a care plan as the linking of the nursing diagnosis to specific nursing interventions for specific conditions.

Haapoja (2014:5-11) confirms that the care plan is a reflection of the planning formulated by the nurse, of the actual and potential problems as identified in the assessment and nursing diagnosis. This plan of care is initiated and implemented to achieve these goals for the specific patient.

5.2.1.4 Implementation

In this study the researcher found that 18.8% of the patients did not have their blood pressure monitored. Patients who have had spinal surgery must be monitored closely to detect changes in condition. The researcher found that 90.9% of the patients who required post spinal surgery did not have a complete set of post spinal surgery neuro-observations. In

the trial bundles, neuro-observations were also not followed up regularly, with 85.9% of the patients not receiving the care that was required.

As discussed in paragraph 2.7, Doenges *et al.* (2012:1-4) confirmed that in the implementation phase the initial tests completed during the assessment phase will be used to monitor the patient's response to the determined care plan.

Charbek (2015:5-6) agreed and further explained that monitoring of the vital signs is important as this is the measurement of the body's most basic functions. The vital signs are useful in detecting actual and potential problems.

5.2.1.5 Evaluation

The researcher found that 74.1% of the results were not interpreted by the nurse and 4.9% of the results were incorrectly interpreted by the nurse. The patient had to wait for the doctor to start treatment based on the results. This is especially a concern if one considers a situation where the patient may require immediate action to be taken, to relieve the patient of his symptoms and the doctor only does a ward round once a day. This is even more risky and dangerous to the patient if the doctor has already completed his ward rounds for the day (Charbek, 2015:1-6) and (Haapoja, 2014:5-11).

5.2.1.6 Operating Room

In this study the researcher found that swab counts (42.3%) and instrument counts (15.4%) were not done or not documented. Timeous and accurate count procedures are vital to prevent swab or instruments being left in an operative site.

According to the WHO guidelines for Safe Surgery (2009:73) counting of all swabs, sharps and instruments must be completed before the start of a procedure, before closing of a cavity, before wound closure and at skin closure. These counts must also be completed if there is a change of staff during the operative period.

Goldberg and Feldman (2012:207) confirmed that the surgical count procedures must be standardised and this must include the initial count, the closing count, counts when new items are opened and when relieving theatre staff. The surgical pause or time out was not done in 96.2% of the surgical cases.

Mariscal (2015:2-3) describes a surgical pause as a short meeting in the operating theatre before the first incision of every theatre case when the patient is identified, the surgical procedure and operative side are indicated and the consent is confirmed to prevent surgical errors and to highlight potential risks. The surgical pause or time-out can eliminate wrong-sided surgery, operating on the wrong patient and conducting an incorrect operation. Furthermore, the surgical pause/time-out process highlights patient's allergies and chronic medication, especially medication like anti-coagulants. Specific information about the patient for example preferences is given, the correct equipment is correctly assembled and required supplies are put in place.

As confirmed by Mariscal (2015:1-6) and Nwosu (2015:1-3), a surgical pause is instrumental in reducing the risk of a 'never event' in theatre, if the surgical pause is carried out correctly.

Infection control measures were not carried out in 34.6% of the operating theatre cases. This puts the patient at risk for a surgical site infection or a nosocomial infection.

According to Spagnolo, Ottria, Amicizia, Perdelli and Christina (2013:1), surgical site infections are a result of the quality of the operating theatre. Spagnolo *et al.*, (2013:1-3) further indicate that the multidisciplinary team is responsible for the prevention of surgical site infections and this includes the theatre and technical managers.

In conclusion, objective one was to audit the nursing process. It is evident in this study that the scientific nursing process is not applied adequately and may compromise safe, quality care. Consequently, failing to document, assess patients accurately, inadequate diagnoses and poor management, may lead to malpractice litigation.

5.2.2 Objective 2: To categorise the adverse events into principle types

5.2.2.1 Administrative

The study revealed that in the trial bundles audited, administrative factors accounted for 18.5% of the adverse events.

Nursing administration is defined as the act of managing nursing duties, responsibilities or rules. It further refers to the group of individuals who are in charge of creating and enforcing rules and regulations (Huber, 2016:2). A common complaint from nurses worldwide is that they are forced to work in situations that put patients at risk due to a shortage of staff. This may be due to not wanting to spend money on adequate staffing, thereby raising the nurse-patient ratio (Martsolf *et al.,* 2014:1-3).

Latent failures are present in the organisation long before it joins forces with an active failure and creates an opportunity for an error to occur (Paragraph 2.9.1.1). Latent failures are allowed to occur due to poor management, poor decisions, and conflicting goals (Reason, 2000:769).

5.2.2.2 Clinical Management

Clinical management (88.9%) was the most common category which contributed to adverse events. Clinical management involves diagnosing and managing the symptoms presented by the patient (Butler, 2008:7). The clinical management must be patient specific and it must relate to the specific patient's condition.

Of the trial bundles audited, 76.5% of the clinical manifestations were not documented and in 63% of this was not communicated to the doctor, with 61.7% of the interim reports not documented and thus not done (AlKouri *et al.,* 2016:101-104)

5.2.2.3 Human Behaviour

In this study, the researcher found that 79% of the adverse events were as a result of human behaviour. This included interruptions whilst completing a task, lack of knowledge, lack of experience and attitude.

Human factors refer to all factors that influence a person and their individual characteristics that in turn influence their behaviour (Carthey & Clark, 2010:3). In paragraph 2.6.4, the scope of practice of the nurse is discussed. All nurses being registered or enrolled are responsible and accountable for their actions, behaviours and decisions. Factors such as forgetfulness, negligence, inattention, performing common work out of memory and following specific instructions lead to unsafe acts (Reason, 2000:768).

Results obtained in this study show that 90.1% failed to apply guidelines or protocol. The nurse must ensure that protocols and policies are followed strictly as directed to avoid incidents as described by Adamson (2012:7-9) in paragraph 2.8.

5.2.2.4 Organisational

In this study organisational factors accounted for 51.9% of the adverse events. According to Runciman et al. (2006:23), many of the adverse events occur as a result of environmental and organisational factor. These factors may include workload management, staff shortages,

damaged or faulty equipment, transportation, poor organisation of teams and staff, and inadequate policies and guidelines (Runciman et al. 2006:28-48).

As further explained in para 2.9.1.1 latent failures are present long before an adverse event occurs. Examples of these latent failures are poor management, poor decisions, conflicting goals, old policies and poor access to these policies, no investigations of adverse events or of near-miss events, focus placed on individuals rather than systems (Reason, 2000:769).

In conclusion, in this study the adverse events were categorised into four principle types, administration, clinical management, human behaviour and organisational factors.

5.2.3 Objective 3: Determine factors associated with the adverse events involving the nurse practitioners that have resulted in malpractice litigation

5.2.3.1 Clinical manifestations not responded to

Clinical manifestations refer to the signs and symptoms presented by the patient on admission to the healthcare environment (Oyebode, 2013:323-324).

In this study, 56.8% of the trial bundles reflected clinical manifestations not responded to as a contributing factor to an adverse event.

This may include not reporting results (67.9%), or not noting changes in the patient's condition (76.5%). Ignoring a patient's complaint may also result in clinical manifestations not being responded to. Knowledge of conditions, signs and symptoms, complications and side effects, are very important. If this information is not known to the nurse working with the patient, then the risk of an adverse event occurring is very high (Charbek, 2015:1-6).

5.2.3.2 Poor monitoring

Auditing of the trial bundles revealed that 69.1% of the adverse events occurred as a result of poor monitoring.

Monitoring of a patient is done to obtain a clear and concise understanding of the patient's objective and subjective information. If this is not done effectively and correctly, the risk of not attending to all the patient's signs and symptoms are very high. This practice increases the risk of omissions, errors, misdiagnosis and other risky behaviours.

This research project shows that monitoring of the patient along with observations were not done as prescribed; 18.8% of the patients did not have their blood pressure monitored, 18.5% did not have their pulse monitored, 69.2% did not have foot pulse monitoring done, 27.1% of the patients did not have their respiratory rate monitored, and 23.4% of the patients not having their temperatures taken.

Charbek (2015:1) indicates that vital signs are the measurement of the body's most basic functions and that these vital signs are important in detecting medical problems.

5.2.3.3 Failure to apply guidelines and protocols

The researcher found that 90.1% of the adverse events were due to not following guidelines and protocols.

Protocols and guidelines are put into place for the safety of the patient, to assist the nurse and the healthcare establishment to avoid adverse events. If these are not followed, the nurse places the patient's safety at risk and also that of the hospital and herself.

Ebben *et al.,* (2012:1) further explained that if healthcare professionals, including nursing staff do not adhere to guidelines and protocols patients may not receive appropriate care; consequently, the quality of care delivered is threatened.

5.2.3.4 Failure to give treatment as prescribed

Auditing of the trial bundles revealed 60.5% of the adverse events resulted from failing to provide treatment as prescribed.

Failure to provide treatment as prescribed, can become a factor for many reasons. Knowledge is very important in this regard, because if staff are unaware of the importance of the treatment required, the urgency of completing the treatment is thus not realised. Another reason for not giving treatment as required, may be an organisational or system failure (Runciman *et al.,* 2006:23; Reason, 2000:769).

As discussed in paragraph 2.5, failure to give treatment as prescribed, could result in fatal consequences for the patient, as is evident in the Life Esidimeni Disaster case study discussed (Makgoba, 2017). The second case study discussed in paragraph 2.5, where 240 oncology patients were at a risk of being victims of adverse events due to the Kwa-Zulu

Natal state facilities failing to provide treatment as prescribed and required for these patients.

5.2.3.5 Incorrect treatment

Incorrect treatment accounted for 22.2% of the trial bundles audited. Providing incorrect treatment to a patient can result in an adverse event. Incorrect treatment could be providing an incorrect drug, incorrect ventilation, providing CPR to a patient who has a 'do not resuscitate order', even completing an incorrect test or surgical procedure.

In this study numerous incorrect treatments were noted, for example medication errors (18.5%), wrong-sided surgery (8%), performing CPR on a patient with a 'do not resuscitate' order (25%), no assessments of the patient (32.1%), incorrectly interpreted results (4.9%) or diagnostic testing results not interpreted (74.1%) resulting in incorrect treatment which resulted in an adverse event.

A discussion in para 2.10, reveals how incorrect treatment can have detrimental outcomes for the patient. This is further illustrated in para 2.4 when a neonate is placed on oxygen support and instead of maintaining an oxygen saturation of between 86-92%, the oxygen saturation was maintained at 95-100% resulting in blindness, (Case number: 4401/2014, Kwa-Zulu Natal High Court, 2014).

5.2.3.6 Accumulations of omissions

In this study the researcher found that 48.1% of the adverse events were as a result of accumulation of omissions.

An omission is failing to do the right thing leading to an adverse event or a potential for an adverse event to occur for example omitting to inform the doctor and other staff of a change in a patient's condition. Omitting to administer medical treatment can all be regarded as an omission. Omitting to accurately complete and record of the vital signs and report the findings can affect the outcome of the patient's care (SANC, 2005).

The researcher found, in the trial bundles audited that the observations were not always done. These were blood pressure (18.8%), pulse (18.5%), respiration 27.1% and temperature (23.4%). These are acts of omission of care. This is also discussed in paragraph 2.10, where an 18-month-old diagnosed with croup, required oxygen administration. No oxygen tanks or supply were available leaving the child without adequate

oxygenation for approximately two hours. The child's condition worsened and finally resulted in the child being diagnosed with cerebral palsy due to the lack of oxygen (Case number: 10/49971, Gauteng High Court, 2012).

5.2.3.7 Accumulations of errors

Accumulation of errors accounted for 70.4% of the adverse events audited in the trial bundles.

Errors occur every day without an adverse event occurring. When these errors overlap the risk of an adverse event occurring is increased. This is clearly explained by Reason (2000:769), applying the Swiss Cheese Model, and described in paragraph 2.9.1.1.

Oyebode (2013:323-324) found that shift-work of more than 24 hours were more likely to be associated with medical errors than shifts of less than 24 hours. Furthermore Oyebode (2013:323-324) explained that nursing interruptions whilst completing a task, increased the risk of procedural and clinical errors. Westbrook, Woods, Rob, Dunsmuir and Day (2010:683-690), agree and further state that the frequency of the interruptions was associated with the severity of the error.

5.2.3.8 System failure

In this study 48.1% of the adverse events were as a result of system failure. System failure refers to the inability to identify risky behaviours and situations thus leading to an adverse event (Da Costa Machado Duarte, Conceição Stipp, da Silva and de Oliveira,2015:2-4).

System failure may be eliminated by proper investigations of adverse events, identifying common risks and putting measures in place to prevent the adverse event from recurring. Reporting of adverse events and near-miss events will be helpful to highlight risks that are present within the healthcare environment. Creating a non-punitive reporting culture that is goal focused, rather than person focused will assist in reducing systems failure.

The safest systems are those that acknowledge human error and build in safeguards on a systemic level (Sohn, 2013:1-5). Da Costa Machado Duarte *et al.* (2015:2-4) explained that adverse events are often directly related to system failure, instead of negligence or incompetence.

5.2.3.9 Behaviour

In the trial bundles audited behaviour accounted for 87.7% of the adverse events. As discussed in paragraph 2.8.1.1, forgetfulness, negligence, poor attention, and not following specific instructions lead to unsafe acts (Reason, 2000:768).

5.2.3.10 Lack of supervision

This study confirmed that 61.7% of the trial bundles audited showed a lack of supervision, resulting in an adverse event.

In paragraph 3, it is shown that 37.5% of adverse events were caused by new staff (*Tang et al.,* 2007:447). Jeggel, Traut and Africa (2013:1) believe that support for the new nurse enables the nurse to apply knowledge and skills in the clinical setting.

5.2.3.11 Lack of training

Lack of training accounted for 54.3% of the adverse events. A lack of training leads to a lack of knowledge which in turn results in errors and omissions. Staff may not understand the importance of their actions and omissions thus placing the patient at risk.

In paragraph 2.9.3.2, Batalden et al., (2007:2) confirm that skilled and knowledgeable nurses are able to deliver safe and quality care. This is further confirmed by Hall et al., (2008:417), in paragraph 2.9.3.2.

5.2.3.12 Lack of knowledge

Lack of knowledge 91.4% accounted for most of the adverse events described in the trial bundles audited, which is a critical deficit within the healthcare environment. This occurs when staff work in specific disciplines and may not possess the formal training required to function adequately in the specific department. This renders the staff incapable of identifying risks for example a nurse working in the obstetric unit, but is not a trained midwife may not be able to read a cardiotocography (CTG), thereby will be unable to identify when the baby is at risk. Incidents of this nature may occur in circumstances when the hospital may be short-staffed so staff are moved around the units to ensure coverage. Another reason is that agency staff choose to work in units when they are aware of their lack of training or skill (Runciman *et al.,* 2006:28-48; Tan *et al.,* 2007:447-457).

In conclusion as discussed above, there are various factors that are associated with adverse events involving the nurse practitioners which have resulted in malpractice litigation.

5.2.4 Objective 4: Identify other healthcare team members that may be associated with the adverse events that have resulted in malpractice litigation

Objective four (4) was addressed in section E of the data extraction tool, question 36 and 37. In the trial bundles audited, nursing and medical accounted for 50.6% of the adverse events. Nursing alone accounted for 43.2% of the adverse events.

Being able to identify healthcare professionals involved in adverse events will highlight the fact that risks are present and that the healthcare professional must be vigilant of these risks at all times. Furthermore, identifying these risks may also reduce the recurrence of the adverse events.

As a result of the adverse events 75.3% of the patients had extended hospital stay, the quality of life of 56.8% of the patients were affected, 40.7% of the patients required additional surgery, 27.2% of the patient's died from the adverse event and 11.1% of the patients were left disabled.

In conclusion, despite their professional ethical codes and legal requirements, poor compliance and negligence resulted in adverse events affecting patients directly which resulted in malpractice litigation.

5.2.5 Objective 5: Assess the severity of the adverse events associated with malpractice litigation

In this study 35.8% of the adverse events were classified as extreme and rated one on the Severity Assessment Code. Examples included death (27.2%), disability (11.1%), such as blindness and cerebral palsy. Major events rated two on the severity scale accounted for 23.5% of the adverse events, examples of these are respiratory failure, cardiac failure, and disfigurement. Moderate events, rated three on the severity scale accounted for 40.7% of the adverse events; some examples are administering incorrect medication, post-operative haemorrhage, delayed diagnosis and treatment, delay in commencing CPR and commencing CPR on a patient with a 'do not resuscitate' order.

Bateman (2008:73-74) reported that about 400 of the adverse events reported to the Council for Health Service Accreditation of South Africa (COHSASA) in 2008 may be categorised as SAC one (extreme) or SAC two (major) due to the fact that staff are more comfortable to report more serious adverse events.

In conclusion, the majority of the adverse events resulted in the severity rating of one (extreme). It does appear that the more serious adverse events are challenged through litigation.

5.3 LIMITATIONS OF THE STUDY

The limitations identified in this study were the poor response from the attorneys with regard to auditing the trial bundles. Due to the nature of the information, access to the trial bundles were very difficult, and when this was possible, it was completed under very strict conditions.

5.4 RECOMMENDATIONS

5.4.1 Continuous Professional Development

It is important for nursing staff to keep abreast with the current practices within the nursing community. It is also very important for nursing staff to know and understand the functioning of the body and the pathophysiology. This will assist the nurse in delivering safe, quality care to the patient.

According to Howard (2011:30), in paragraph 2.9.3.2, the nursing profession may only functional effectively if the nurses keep updated on the current laws and practices that govern their practice.

5.4.2 Formal training programmes

Nurses must keep abreast with new trends and procedures. They must take responsibility for their own learning to ensure their competency in completing allocated procedures.

Qualified and experienced nurses may be encouraged to update their skill and knowledge using the formal education system for example for a university qualification.

Current nursing staff that show initiative and interest and have the potential to succeed in a specific discipline should be identified. Identified staff should be encouraged to advance their knowledge by enrolling in formal training programmes in the specific discipline.

Training regarding adverse events must include all healthcare professionals. Therefore, universities and colleges that provide training for the healthcare sector must include training about adverse events, identifying risks that lead to adverse events and malpractice litigation in healthcare.

Batalden and Davidoff (2007:2) found that safe, quality nursing care is reliant on knowledgeable and competent nurses. This is further substantiated by Dillies *et al.* (2010:1077-1079) who found that the level of nursing education influences the nurses' nursing pattern.

5.4.3 In-service and informal training

Training at hospital level is essential for safe nursing practice. Topics for in-service training and discussions may be identified by the clinical risk manager based on types of adverse events experienced within the hospital. Topics may also be identified by the unit manager based on general observations and auditing at ward level. Encouraging staff to identify areas they do not feel competent in and provide training on these topics.

Discussing common conditions, especially medication (effects, contra-indications, side effects and allergens) will assist in reducing this risk from becoming an adverse event. If common problems are noted, bring this problem to the attention of the staff.

Use the morning meeting session to provide in-service training, using posters and pictures to engage all learning styles. Provide staff with factual information, include policies and guidelines.

Regular evaluation of staff is encouraged with follow-up in-service and on-the-spot training. Praise staff that use their knowledge and expertise, and encourage staff who need guidance. Encourage reporting of actual adverse events and near-miss events, as well as correct and effective investigations of the event. Educate staff regarding the assessment code and the ratings, include education on how to decipher these categories and the ranks.

Skills and competencies are rapidly outdated and a need for continuous training in the workplace is necessary (Manuti, Pastore, Scardigno, Giancaspro and Morciano, 2015:01).

5.4.4 Increased supervision

Supervision within the work environment must be available continuously. This will ensure that staff feels safe and comfortable with the knowledge that should they require assistance and guidance, these will be provided. If the nurses feel safe and protected, they will work in a safe and protective manner. Supervision must be provided in a non-threatening, non-interfering manner.

Good supervision is especially important for new staff, new qualified nurses of all categories and student nurses. Supervisors must personally check the patients' records and vital signs instead of only relying on the feedback from the sub-ordinates.

Human behaviour is dependent on various aspects. Experience, attitudes, intrinsic motivation, extrinsic motivation, safety culture, knowledge and confidence are a few variables that dictate a person's behaviour. This is also true for the nurse and their behaviour. Encouragement of good moral behaviour is essential to safe, quality nursing care.

The training of mentors within the hospital with a good knowledge base, positive mannerism and good work ethic is important. These mentors must then go forward and encourage model behaviour.

In paragraph 2.9.2, Hayhurst *et al.* (2005:283-288) found that the managers positive behaviour increased staff confidence and productivity. Hayhurst *et al.* (2005:283-288) further confirmed that good supervision resulted in quality care being delivered, reduced patient complaints and happier patients.

Human factors, including behaviour, present the greatest threat to a potential adverse event (Reason, 2000:80-89).

5.4.5 Recruitment of staff

Measures must be put into place to recruit and retain competent nurses. Recruitment of qualified staff in specialities must be encouraged. Pre-testing of staff knowledge on interviews may also assist in eliminating under-qualified staff. Qualified and experienced nurses may be encouraged to update their skill and knowledge and also to pursue further formal training. Campaigns may be carried out to encourage scholars to study towards a nursing qualification and nursing students may be encouraged to improve their skill and to specialise in specific fields of nursing.

As confirmed in paragraph 2.8, Du Preez (2016:89) confirms that the nurse-patient ratio has a big impact on the risk of adverse events occurring. A study completed by Aiken, Sloane, Bruyneel, Van den Heede, Griffiths, Busse, Diomidous, Kinnunen, Kózka, Lesaffre, McHugh, Moreno-Casbas, Rafferty, Schwendimann, Scott, Tishelman, van Achterberg and Sermeus (2014:1824-1830), found that an increase in the nurses' workload by one patient increased the likelihood of an inpatient dying within 30 days of admission by 7%.

California has passed a law to regulate hospital staffing and set a minimum nurse-patient staffing ratio in 2004. A study completed by Martsolf *et al.* (2014:1-3) noted improvements in patient care, including decreased surgical site infections and decreased falls. Since the law has been passed in California, a reduction in adverse events is evident and patients' stay in hospitalisation has decreased (Martsolf *et al.,* 2014:1-3).

5.4.6 Checking of equipment and stock

Regular and routine checking of equipment and stock levels, including medication and surgical stock are essential for safe patient care. Training must be provided to staff for adequate checking of equipment and the importance thereof must be explained. Once staff are correctly trained they may be allocated to complete routine checks on the equipment and stock levels. If there is a discrepancy, this must be addressed immediately and brought to the attention of the senior supervisor.

Da Costa *et al.* (2015:2-4) noted that identifying existing problems within the processes will be more instrumental in eliminating or reducing adverse events.

5.4.7 Policies and guidelines

Policies and guidelines are put into place to safe guard the patient and to ensure the delivery of safe, quality nursing care. Policies and guidelines must be regularly referred to and easily accessible to the staff. Newly-qualified staff, new staff and students must be given the opportunity to familiarise themselves with the policies and guidelines. If there are changes to a policy and guidelines, in-service training must be done to highlight the changes and the policy must be printed and circulated to all staff involved. Clear and concise protocols and policies must be implemented to avoid incidents as described by Adams (2012:7-9) in paragraph 6.

Ebben *et al.* (2012:1) found that clinical guidelines and protocols are developed to ensure the deliverance of safe, quality care. In most cases, these guidelines and policies are developed and tested using national and international bodies, e.g. World Health Organisation.

Oyebode (2013:330) agreed and explained that guidelines and protocols are used in medical malpractice cases as these guidelines may be a source of standards, provided that these standards are part of a recognised organisation or body.

5.4.8 Audits and monitoring

Auditing of the nursing documentation and general monitoring of procedures will assist in identifying risks. However, it is important to note that auditing and monitoring alone do not provide any benefits. Auditing and monitoring must be followed by feedback and quality improvement projects (QIP) to better the healthcare service delivery. Regular and accurate monitoring may also assist in identifying risks that can be rectified and prevent an adverse event from occurring.

Auditing may be used as a method of measuring care provided, thereby promoting safe, quality care (Esposito & Dal Canton, 2014:2).

5.4.9 Just culture

A 'just culture' must be implemented and encouraged. As discussed in paragraph 2.12, the' just culture' will encourage staff to report adverse events. According to Benner (2001:510) a 'just culture' encourages change from focusing on the individual involved in the event to focusing on the environment, organisation and employee. These may be as a result of active and latent failures as discussed in paragraph 2.9.1.1.

By using the 'just culture' in event management, the contributing organisational and environmental factors are identified, as well as the nurses' responsibility and accountability (Marx, 2001:5).

Leape *et al.* (2009:424-426), confirmed the success of the just culture and further stated that a culture of trust, reporting, transparency and discipline are needed for the delivery of safe, quality patient care.

5.5 FUTURE RESEARCH

A need for future studies on the topic of nursing malpractice litigation should be completed in other provinces in South Africa. This will highlight the severity of nursing malpractice and the impact it has on the South African healthcare system.

5.6 CONCLUSION

The research question, what are the factors that influence adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape was successfully addressed and answered.

The aim of this study was to investigate factors that influenced adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape, and this was successfully completed by the researcher.

An adverse event is not necessarily the result of one person making a mistake at the frontline of healthcare but rather a combination of system or organisational failures, human error and environmental factors (Rafter *et al.,* 2014:274).

If policy makers, hospitals and education do not enforce the prevention of factors which lead to adverse events, the safety and quality of patient care will always be threatened and consequently lead to an increase in medical litigation.

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APPENDICES

APPENDIX A: ETHICAL APPROVAL

UNIVERSITEIT·STELLENBOSCH·UNIVERSITY
jou kennisvennoot • your knowledge partner

Approved with Stipulations

Response to Modifications- (New Application)

06-Mar-2017
Samlal, yasmin Y

Ethics Reference #: **S16/10/204**

Title: **Analysis of adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape**

Dear Mrs yasmin Samlal,

The **Response to Modifications** - ***(New Application)*** received on **01-Mar-2017**, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on **06-Mar-2017**.

Please note the following information about your approved research protocol:

Protocol Approval Period: **06-Mar-2017 -05-Mar-2018**

The Stipulations of your ethics approval are as follows:
1. Before this study commences, signed permission letters from the legal firms are required in which permission is granted to access the cases/case material.
2. No institution should be identifiable based on the way in which they are reported on in any study findings and/or publications or public presentations.

Please remember to use your **protocol number** (**S16/10/204**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired.
The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB 0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes

2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at .

Included Documents:

20170214 MOD2 2nd submission_9 Feb 17 Reference S16_10-204 RESEARCH PROPOSAL_ethics application_revised.docx
20170302 MOD3 Protocol.docx
20170124 MOD Request for expedited review
20170124 MOD Protocol Synopsis
20170123 MOD Checklist
20170302 MOD3 Letter to Ethics Re Corrections Lawyers and Hospitals.pdf
20170124 MOD CV Y Samlal
20170124 MOD Protocol
20170124 MOD Declaration Y Samlal
Investigator declaration Y Samlal (correction).pdf
20170124 MOD Application form
20170124 MOD Checklist
20170214 MOD2 HREC response.docx
20170124 HREC Mods letter
20170124 MOD Response to mods - researcher
20170124 MOD Request for waiver of consent
20170214 MOD2 LETTER_20170209_NEW- Mods2_S1610204.pdf
HREC:Health Research New Application

Sincerely,

Francis Masiye
HREC Coordinator
Health Research Ethics Committee 2

Investigator Responsibilities

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1.Conducting the Research. You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.

2.Participant Enrolment. You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.

3.Informed Consent. You are responsible for obtaining and documenting effective informed consent using **only** the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.

4.Continuing Review. The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period.** Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur.** If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.

5.Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.

6.Adverse or Unanticipated Events. Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HRECs requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch Universtiy Health Research Ethics Committee Standard Operating Procedures www.sun025.sun.ac.za/portal /page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.

7.Research Record Keeping. You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC

8.Reports to the MCC and Sponsor. When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.

9.Provision of Emergency Medical Care. When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.

10.Final reports. When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.

11.On-Site Evaluations, MCC Inspections, or Audits. If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.

APPENDIX B: DATA COLLECTION TOOL

RESEARCH AUDIT INSTRUMENT

TITLE: Factors influencing adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape (S16/10/204)

No:_____ (Office use only)

Audit the malpractice litigation case and complete the following sections.

The audit instrument

Section A: The Litigation (Questions 1 - 3)

1 How was the court case presented?

1	In the High Court (1)	
2	Settled out of Court (2)	

2 If settled out of court indicate the amount for which the case was settled

_____

3 If presented in court indicate the outcome of the judgement specifically the quantum to be paid

---

SECTION B: DEMOGRAPHIC DATA OF THE PATIENT (Questions 4 - 12)

4 Age

5 Gender

1	Female (1)	
2	Male (2)	

6 Marital status

1	Single (1)	
2	Married (2)	
3	Partner (3)	
4	Widow (4)	
5	Widower (5)	
6	Divorced (6)	

7 Dependents

1	None (1)	
2	One (2)	
3	Two (3)	
4	Three (4)	
5	>Three (5)	
6	Not	

8 Any disability on admission

1	Yes (1)	
2	No (0)	

9 Indicate whether the patient had any of the following social habits

	Item	Yes (1)	No (0)	Not documented (98)	NA (99) if a baby/child
1	Smoking				
2	Using unsolicited drugs				
3	Alcohol				

10 Any underlying medical condition on admission e.g. hypertension

1	Yes (1)	
2	No (0)	

11 Choose one of the following: Employment at the time of admission to the hospital

1	Employed (1)	
2	Self-employed (2)	
3	Not employed (3)	
4	Pensioner (4)	
5	NA e.g. child (99)	

12 Choose one of the following: Type of employment

1	Professional e.g. teacher, nurse, pilot, doctor (1)	
2	Technical (2)	
3	Businessman (3)	
4	Administrative (4)	
5	Tradesman (5)	
6	Labourer / Unskilled (6)	
7	Other (7)	
8	Not documented (98)	

SECTION C: HOSPITALIZATION (Questions 13-31)

13 Indicate whether the nursing ward notes are available to audit

1	Yes (1)	
2	No (0)	

14 Indicate the reason for admission

1	Elective surgery (1)	
2	Planned treatment (2)	
3	Emergency (3)	
4	Ill /Sick requires medical care (4)	
5	Other (5)	

15 Indicate the type of discipline (s) to which the patient was admitted before the adverse event

1	Cardiology (1)	
2	Dermatology (2)	
3	Gynaecology (3)	
4	Medical (4)	
5	Midwifery / Obstetrics (5)	
6	Neonatology (6)	
7	Nephrology (7)	
8	Neurosurgery (8)	
9	Neurology (9)	
10	Orthopaedics (10)	
11	Ophthalmology (11)	
12	Paediatrics (12)	
13	Psychiatry (13)	
14	Trauma (14)	
15	Urology (15)	
16	Gen Surgery (16)	
17	Cardiac surgery (17)	
18	Other *(specify) (18)*	

16 Indicate the type of ward / unit to which the patient was admitted before the adverse event

1	Emergency / Casualty (1)	
2	General ward (2)	
3	Paediatrics (3)	
4	ICU (4)	
5	Antenatal ward (5)	
6	Labour (6)	
7	Neonatology (7)	

17 Indicate whether the initial assessment including the fetus where applicable was:

1	Complete (1)	
2	Incomplete (2)	
3	Not documented (98)	

18 Indicate the status of the care plan of the patient: (Includes all types of patients)

1	Complete (1)	
2	Incomplete (2)	
3	No care plan (3)	

19 Indicate whether the care plan was implemented?

1	Yes (1)	
2	No (0)	
3	NA (99)	

20 Indicate whether special care plans were required e.g. for a diabetic patient, patient in labour.

1	Yes (1)	
2	No (0)	

21 Indicate the status of the special care plan of the patient:

1	Complete (1)	
2	Incomplete (2)	
3	No care plan (3)	
4	NA (99)	

22 If yes as indicated in question 21 indicate whether the special care plan was implemented.

1	Yes (1)	
2	No (0)	
3	NA (99)	

23 Indicate whether any of the following vital signs were monitored. (More than one response)

	Item	**Complete (1)**	**Incomplete (2)**	**Not documented (98)**	**NA (99)**
A	Blood pressure				
B	Pulse				
C	Foot pulses				
D	Fetal				
E	Respiration				
F	Temperature				
G	Intake and output				
H	Weight				
I	Neuro observations				
J	Post-spinal surgery				
K	Mental status				
L	Continuous ECG				
M	Continuous oxygen saturation monitoring				
N	Other				

24 Indicate whether the following diagnostic tests were done pre-adverse event where applicable

	Item	Yes (1)	No (0)	NA (99)
A	Haemoglucotest			
B	Haemoglobin			
C	Urine tests			
D	Urea and electrolytes			
E	Blood gasses			
F	Full blood count			
G	Liver functions			
H	Other			

25 Were the results of the diagnostic tests interpreted?

1	Correctly interpreted by the nurse (1)	
2	Incorrectly interpreted (2)	
3	Not interpreted (3)	

26 Were the results reported to the doctor?

1	Yes (1)	
2	No (0)	
3	NA (99)	

27 If any diagnostic tests were done indicate whether action was taken based on the results

1	Yes (1)	
2	No (0)	
3	NA (99)	

28 Where applicable indicate whether the preoperative assessment for surgery was

1	Complete (1)	
2	Incomplete (2)	
3	Not documented (98)	

29 Indicate whether the treatment / technique / management as prescribed was given

1	Yes (1)	
2	No (0)	

30 Do the patient's reports (initial, progress, interim, and discharge) reflect the following about the patient? (More than one response)

	Item	Complete (1)	Incomplete (2)	Not documented (98)	NA 99
1	Initial report				
2	Progress				
3	Clinical manifestations recorded				
4	Interim report				
5	Doctor contacted report				
6	Discharge report				

31 If the patient was discharged indicate whether specific patient education was given

1	Yes (1)	
2	No (0)	
3	NA (99)	

SECTION D OPERATING ROOM (Questions 32)

32 Indicate where applicable whether the following protocols in the operating room were adhered to:

	Item	Yes 1	No 0	NA 99	Not documented (98)
A	Counting swabs				
B	Infection control				
C	Managing instruments				
D	Managing specimens				
E	Use of the diathermia				
F	"Surgical pause" or "Time out"				
G	Other				

SECTION E: ADVERSE EVENT(s) Questions 33 - 37)

33 Indicate the environment where the adverse event(s) occurred

	Item	Yes 1	No 0
A	General ward		
B	ICU		
C	Operating room theatre		
D	Paediatric ward		
E	Neonatology unit		
F	Casualty / Trauma		
G	Labour		
H	Psych		
I	Other *Specify*		

34 Describe the adverse event(s)

_____

_____

_____

_____

35 Indicate the patient outcome(s) as a result of the adverse event. (Could be more than one response)

	Item	Yes 1	No 0
1	Additional surgery		
2	Death		
3	Disabled		
4	Increased hospital stay		
5	Quality of life affected		

36 Healthcare professional(s) or non-healthcare professional responsible for adverse event

1	Nursing (1)	
2	Medical (2)	
3	Both nursing and medical (3)	
4	Non-healthcare professional (4)	
5	Both nursing and non-healthcare professional (5)	
6	Other (6)	

37 If nursing or both nursing and medical were chosen in question 36 indicate the category (ies) of nurses involved in the adverse event

A	Professional nurse (1)	
B	Enrolled nurse (2)	
C	Enrolled nursing assistant	
D	Midwife (4)	

SECTION F: PRINCIPLE INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT (Questions 38 - 40)

38 Indicate the adverse event by Principle Incident type

1	Admin (1)	
2	Clinical management (2)	
3	Human behavior problems	
4	Organizational (4)	
5	Other (5)	

39 Indicate the severity of the adverse event according to the Safety Assessment Code Matrix (SAC)

1	Extreme (1)	
2	Major (2)	
3	Moderate (3)	
4	Minor (4)	
5	Insignificant (5)	

40 Indicate which of the following FACTORS contributed to the adverse event. In this question there could be more than one answer

A	Clinical manifestations not responded to (1)	
B	Poor monitoring (2)	
C	Failing to apply guidelines/ protocols (3)	
D	Failing to give treatment as required (4)	
E	Incorrect treatment (5)	
F	Accumulation of omissions (6)	
G	Accumulation of errors (7)	
H	System failures (8)	
I	Behavioural e.g. attitude (9)	
J	Lack of Supervision (10)	
K	Lack of training (11)	
L	Lack of knowledge (12)	
M	Other *Specify (13)*	

APPENDIX C: DECLARATION BY LANGUAGE EDITOR

Lona's Language Services

English/Afrikaans
Afrikaans/English

3 Beroma Crescent Beroma Bellville
Tel 0219514257
Cell 0782648484
Email illona@toptutoring.co.za

* Translations * Editing * Proofreading
* Transcription of Historical Docs
* Transcription of Qualitative Research
* Preparation of Website Articles

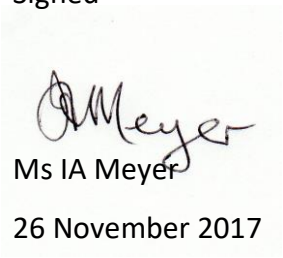
TO WHOM IT MAY CONCERN

This letter serves to confirm that the undersigned

ILLONA ALTHAEA MEYER

has proofread and edited the document contained herein for language correctness.

Signed



Ms IA Meyer

26 November 2017

FOR: **YASHMIN SAMLAL**

TITLE: **FACTORS INFLUENCING ADVERSE EVENTS RESULTING IN MALPRACTICE LITIGATION IN NURSING PRACTICE IN PRIVATE HOSPITALS IN THE WESTERN CAPE**

APPENDIX D: DECLARATION BY TECHNICAL EDITOR

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RUKSHANA ADAMS
COPYWRITING AND EDITING SERVICES

CERTIFICATE OF TECHICAL FORMATTING AND EDITING

This is to certify that the thesis titled

"Factors influencing adverse events resulting in malpractice litigation in nursing practice in private hospitals in the Western Cape"

written by

Yashmin Samlal

Was Reviewed for Technical Formatting and Editing by **RUKSHANA ADAMS**

Date: 29 November 2017
Signature: R. Adams