

Asepsis related deviations from safe practice in parenteral medication administration in the North West Province

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ABSTRACT

Background: Several studies have been published with regards to the incidence of medication administration errors as a patient safety concern. However, there is limited literature available on the incidence of asepsis-related deviations from safe practice during parenteral medication administration and no information is available on a more rural context of this patient safety concern within South Africa.

Objective: To determine the prevalence of asepsis-related deviations from safe practice during parenteral medication administration within medical and surgical wards of level 2 public hospitals in the North West Province of South Africa.

Design: A cross-sectional descriptive quantitative design with contextual strategies was used in this study.

Setting and participants: All three level 2 hospitals in the North West Province were included. Two medical and two surgical wards from each hospital were sampled randomly, while all the parenteral medication administrators in the selected wards on the day of data collection were included in the study. Five parenteral medication administrations were observed with each medication administrator (n = 300).

Measurements: The incidence of asepsis-related deviations from safe practice during parenteral medication administration was determined by direct observation, using a checklist.

Results: 1033 asepsis-related deviations from safe practice during parenteral medication administration were identified. All areas of the hands not disinfected (n = 287; 95.67%) was the most prevalent deviation, the second most prevalent deviation from safe practice was hands not disinfected for at least 15 seconds (n = 281; 93.67%) and the third most prevalent was not disinfecting the IV bottles and vials (n = 145; 62.23%). Of all the areas of hands not disinfected, the fingernails were most often missed (n = 281; 93.67%), the wrist area was second most missed area (n = 268; 89.33%) and between the fingers were the third most missed areas of the hands (n = 257; 85.67%). There was a practically and statistically significant association found between ward type and hands cleaned for less than 15 seconds (Cramer's V = 0.58; p = 0.000). A weak negative correlation ($r = -0.09$) that was statistically significant (p =

0.034) was seen in the relationship between sterility of needles and IV sets not maintained and percentage occupancy. A slight positive correlation ($r = 0.13$) with a p value of 0.052 indicating a borderline statistical significance was found between hands not disinfected and percentage of required staff available. A positive correlation ($r = 0.12$) with a statistically significant p value at the tenth percentile ($p = 0.074$) was found between palms not disinfected and percentage required staff.

Conclusions: Asepsis-related deviations from safe practice during parenteral medication administration were seen as prevalent in rural public hospitals of South Africa impeding patient safety. Both differences with and similarities to international literature were noted. The context of the study should not be deemed insignificant, as resource restraints and psychological climate could possibly hinder the improvement of patient safety in the public hospitals of the North West Province of South Africa.

Key words: Asepsis, hand hygiene, intravenous, nurse, parenteral medication administration.

UITTREKSEL

Agtergrond: Vele studies rakende die voorkoms van medikasietoedieningsfoute as 'n belemmerende faktor in die konteks van van pasiëntveiligheid is al gepubliseer. Daar is wel net beperkte literatuur beskikbaar oor die insidensie van asepsisverwante parenterale medikasie toedieningsfoute maar daar is geen informasie beskikbaar rakende hierdie pasiëntveiligheidsbekommernis in 'n meer landelike konteks in Suid-Afrika nie.

Uitkoms: Om die voorkoms van asepsisverwante afwykings van veilige praktyk tydens parenterale medikasie toediening te bepaal in die mediese en chirurgiese sale van vlak 2 hospitale in die Noordwes Provinsie van Suid-Afrika.

Ontwerp: In die studie is 'n deursnit beskrywende, kwantitatiewe ontwerp met kontekstuele strategieë gebruik.

Milieu en deelnemers: Drie vlak-2 hospitale in die Noordwesprovinsie is ingesluit. Twee mediese en twee chirurgiese sale van elke hospitaal is lukraak gekies terwyl al die medikasietoedieners van die dag vir data-insameling ingesluit is. Vyf parenterale medikasietoedienings van elke medikasietoediener is geobserveer (n = 300).

Mates: Die voorkoms van asepsisverwante afwykings van veilige praktyk tydens parenterale medikasietoediening is bepaal deur direkte observasie met behulp van 'n afmerklys.

Resultate: 1033 asepsisverwante afwykings van veilige praktyk tydens parenterale medikasie toediening is geïdentifiseer. Alle areas van die hande wat nie ontsmet is nie (n = 287; 95.67%), is die afwyking wat die meeste voorgekom het. Die tweede mees algemene afwyking van veilige praktyk was hande wat nie ten minste vir 15 sekondes ontsmet is nie (n = 281; 93.67%) en die derde algemeenste afwyking van veilige praktyk was intraveneuse bottels en medikasie-flessies wat nie ontsmet is nie (n = 145; 62.23%). Van die spesifieke areas van die hande wat nie ontsmet is nie, was die vingernaels die meeste oorgesien (n = 281; 93.67%), die tweede mees algemeen-gemiste areas was die handgewrigarea (n = 268; 89.33%) en die area tussen die vingers is die derde mees algemeen oorgesien (n = 257; 85.67). 'n Praktiese en statisties betekenisvolle assosiasie is bevind tussen die tipe saal en hande wat nie

ontsmet is vir ten minste 15 sekondes nie (Cramers $V = 0.58$; $p = 0.000$). 'n Swak negatiewe korrelasie ($r = -0.09$) wat statisties betekenisvol was ($p = 0.034$), is gevind tussen steriliteit van intraveneuse-stelle en naalde wat nie gehandhaaf is nie en die presentasie okkupasie van die saal. 'n Effense positiewe korrelasie ($r = 0.13$) met 'n p-waarde van 0.052 wat grenslyn statisties betekenisvol was, is bevind tussen hande wat nie ontsmet is nie en die persentasie vereiste personeel beskikbaar. 'n Positiewe korrelasie ($r = 0.12$) wat statisties betekenisvol is op die tiende persentiel ($p = 0.074$), is gevind tussen handpalms wat nie ontsmet is nie en die persentasie vereiste personeel beskikbaar.

Gevolgtrekkings: Asepsisverwante afwykings van veilige praktyk tydens parenterale medikasietoediening is gesien as algemeen in landelike publieke hospitale van Suid-Afrika, en belemmerend vir pasiëntveiligheid. Die konteks van die studie moet nie as onbeduidend geag word nie, aangesien hulpbronbeperkings en die psigologiese klimaat hiervan moontlik die verbetering van pasiëntveiligheid kan belemmer in die publieke hospitale van die Noordwes Provinsie van Suid-Afrika.

Sleutelwoorde: Asepsis, handhigiëne, intraveneuse, verpleegkundige, parenterale medikasie-administrasie.

LIST OF ACRONYMS

AIDS:	Acquired Immune Deficiency Syndrome
ANA:	American Nurses' Association
DOH:	Department of Health
EN:	Enrolled Nurse
HIV:	Human Immunodeficiency Virus
HREC:	Health Research Ethics Committee
ICN:	International Council of Nurses
IV:	Intravenous
NWU:	North-West University
PN:	Professional Nurse
SANAC:	South African National AIDS Council
SANC:	South African Nursing Council
UNAIDS:	Joint United Nations Programme on HIV/AIDS
WHO:	World Health Organisation

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	II
ABSTRACT	II
UITTREKSEL	IV
LIST OF ACRONYMS	VI
CHAPTER ONE	1
1.1 Introduction and background	1
1.2 Problem statement	5
1.3 Research question	6
1.4 Aim and objectives	6
1.5 Theoretical framework	6
1.5.1 Concept clarification	8
1.5.2 Meta-theoretical assumptions	10
1.5.3 View of the world	10
1.5.4 View of man.....	10
1.5.5 View of health.....	11
1.5.6 View of nursing.....	11
1.6 Research design	12
1.7 Research method and rigour	12
1.8 Ethical considerations	20
1.9 Classification of chapters	22
1.10 Conflict of interest	22
1.11 Summary	23

CHAPTER 2 LITERATURE REVIEW.....	24
2.1 Introduction	24
2.2 Search strategy.....	24
2.3 Domains' relationship with asepsis	24
2.3.1 Context of asepsis in parenteral medication	25
2.3.2 Evaluation of harm done by deviations in asepsis.....	28
2.3.3 Methods for improvement of asepsis	33
2.3.4 Health care workers' influence on asepsis	35
2.3.5 Health care recipients' influence on asepsis	37
2.3.6 Systems' influence on asepsis.....	37
2.3.7 Medication's influence on asepsis.....	41
2.3.8 The need of asepsis during parenteral medication administration.....	42
2.4 Conclusion.....	45
CHAPTER 3 STRUCTURED OBSERVATION METHODS AND RESULTS	46
3.1 Introduction	46
3.2 Method.....	47
3.2.1 Data-collection method	47
3.2.2 Population and sampling	49
3.2.3 Instruments.....	49
3.2.3.1 Checklist for observing asepsis-related deviations from safe practice during parenteral medication administration	49
3.2.3.2 Demographics sheet.....	49
3.2.4 Data realisation.....	50
3.2.5 Data analysis.....	50

3.3	Results	52
3.3.1	Observer’s reflection.....	53
3.3.2	Ward demographics.....	55
3.3.3	Descriptive statistics	57
3.4	Inferential statistics	62
3.4.1	Associations of asepsis-related deviations during parenteral medication administration with nominal variables	62
3.4.2	Correlations between asepsis-related deviations from safe practice and ordinal variables	65
3.5	Discussion	66
3.6	Conclusion.....	71
CHAPTER 4 EVALUATION, RECOMMENDATIONS AND LIMITATIONS OF THE STUDY		72
4.1	Introduction	72
4.2	Evaluation of the study	72
4.3	Relevance of the study.....	74
4.4	Limitation of the study	74
4.5	Recommendations.....	75
4.6	Conclusion.....	79
REFERENCE LIST		80
ADDENDUM A ETHICAL APPROVAL.....		97
ADDENDUM B BLINDED PERMISSION LETTERS		98
ADDENDUM C INFORMED CONSENT		102

ADDENDUM D: CHECK LIST FOR OBSERVATIONS AND WARD DEMOGRAPHICS 106

ADDENDUM E LANGUAGE EDITING CERTIFICATE 107

LIST OF TABLES

Table 1.1: Aseptic technique during parenteral medication administration and the literature support thereof 18

Table 2.1: Summary of medication administration error incidence 27

Table 2.2: Incidence of patient harm..... 29

Table 3.1: Calculation of variables..... 52

Table 3.2: Demographics per ward..... 56

Table 3.3: Incidence of asepsis errors during parenteral medication administration. 59

Table 3.4: Incidence of areas of hands not disinfected 61

Table 3.5: Associations of hospital wards with asepsis-related deviations. 63

LIST OF FIGURES

Figure 1.1: A patient safety model for health care (Emanuel *et al.*, 2008:15). 7

Figure 2.1: Patient safety model applied to study context 25

Figure 3.1: Occupancy versus percentage of required staff available. 57

Figure 3.2: Asepsis-related deviations from safe practice..... 58

Figure 3.3: Incidence of asepsis-related deviations from safe practice during parenteral
medication administration..... 60

Figure 3.4: Areas of hands not disinfected..... 61

Figure 3.5: Incidence of areas of hands not disinfected 62

CHAPTER ONE

1.1 Introduction and background

The World Health Organisation (WHO) states that patient safety is a crucial element of quality of health care and that it is committed to enhancing quality of patient safety (WHO, 2013:1). Adverse events and near-misses are threats to patient safety. Adverse events are defined as injuries related to medical management that include all aspects of care, such as diagnosis and treatment, failure to diagnose or treat, and the systems and equipment (WHO, 2015:9). A near-miss on the other hand is defined as a variation in a normal process that, if continued, could have a negative impact on the patient (Speroni *et al.*, 2013:19). As an adverse event medication administration errors represent one of the major concerns in patient safety (Kim & Bates, 2013:590).

Medication errors are more prevalent than perceived. Internationally Tang *et al.* (2007:451) found that medication errors occur in more than half of the large teaching hospitals (36.1% occurred in the regional hospitals and 12.5% in the local hospitals). Medical wards; surgical wards; and intensive care wards were found to have more medication errors than other wards (Manias *et al.*, 2014:72; Tang *et al.*, 2007:451). Special attention to medication administration in the medical-surgical context is merited.

Within this context, medication errors most often (48%-50%) occur in the administration phase by the nurses who are administering the medications (Fahimi *et al.*, 2008:110; Stavroudis *et al.*, 2010:462; Covvey *et al.*, 2015:266). More confirmation that the administration phase of medication treatment is mostly affected by medication errors, is presented by the National Patient Safety Agency which stated that 41% of serious medication errors transpired during medication administration (Edwards & Axe, 2015:399). This shows that medication administration errors are definitely of concern, as these errors rank higher in both incidence and severity of threat to patient safety.

Deviations from safe practice during medication administration impact on hospital

outcomes financially; lead to patient dissatisfaction, adverse patient outcomes and death (Glaister, 2005:3; Nguyen *et al.*, 2010:224). McLeod *et al.* (2013:278) identified that deviations from safe practice in medication administration are five times more likely to occur in intravenous [IV] medication administration (parenteral medication administration) than in non-intravenous medication administration. Volpe *et al.* (2014:556) and Cheragi *et al.* (2013:229) stated that every so often medication errors occur in parenteral medication administration. The parenteral route of administering medication is used when medication is poorly absorbed via the oral route and it can also provide a rapid response during an emergency (Bruce & Wong, 2001:855). When parenteral medication is poorly prepared and/or wrongly administered it can potentially cause harm to the patient such as infection, thrombus formation and severe hypersensitivity reactions (Bruce & Wong, 2001:855).

Harm in the form of infection represents one of the major complications of hospitalisation, with nosocomial infections accounting for 50% of these complications while the rest represent patient falls, medication errors and other non-infectious adverse events in the United States (Robert & Gaynes 1997:475). A nosocomial infection is defined as an infection acquired at least 72 hours after hospitalisation. It pertains to a secondary disorder associated with hospitalisation but unrelated to the primary condition of the patient (Brooker, 2010:1296). Nosocomial infections have been recognised as a critical problem for centuries, it is the principal source of adverse outcomes in healthcare that is affecting the quality of healthcare.

Furthermore, Murni *et al.* (2013:61) state that nosocomial infections present the most significant cause of morbidity and mortality in healthcare, causing a very high economic burden in both developed and developing countries throughout the world. In medical and surgical wards of developing countries, between 7.2% and 21.6% of patients were affected by nosocomial infections, while this increased to 8.8% and 40.5% respectively of patients in intensive care wards (Murni *et al.*, 2013:61; Pakyz *et al.*, 2014:1130). Nosocomial infection prevalence also increases with bed occupancy, longer hospital stay and in proportion to the number of elderly patients (Labbé *et al.*, 2008:3181-3182). The two preventable aetiologies of nosocomial infections according to Murni *et al.* (2013:61) are the transmission of infections

between patients and health workers and the irrational use of antibiotics.

Focusing on transmission of infections between patients and healthcare workers, safe high-quality healthcare is essential in the prevention of nosocomial infections. Murni *et al.* (2013:74) stated that hand-hygiene practice is most important in reducing overall nosocomial infection rates. Kim and Bates (2013:594) state that not adhering to principals of asepsis is one of the ways in which parenteral medication can be wrongfully administered. Thompson *et al.* (2016:378) reported that not disinfecting hands is the most frequent breach in asepsis and Gokhman *et al.* (2011:483) added that inappropriate aseptic techniques are among the most prevalent parenteral medication administration errors.

Kim and Bates (2013:594) defined basic infection control and safety regulations during parenteral medication administration as: disinfecting hands before medication preparation and administration; disinfecting hands for at least 15-30 seconds; disinfecting all areas of the hands; disinfecting IV bottles, bags and vials before use; maintaining sterility of needles and intravenous sets; and disinfecting the injection site before use. These regulations are necessary in any instrument that might breach the skin as infections can, without difficulty, enter the body through a breach in the skin.

In developed countries infection-control programmes including campaigns to improve hand-hygiene were effective in reducing nosocomial infections. Antibiotic control programmes have also decreased nosocomial infections from antibiotic-resistant gram-negative bacteria successfully. In countries with limited resources the infection control activities need to be effective and of low-cost (Murni *et al.*, 2013:61). According to Murni *et al.* (2013:74) the strongest evidence for reducing overall nosocomial infection rates was hand-hygiene practice. When hand-hygiene is combined with other elementary infection control practices like antibiotic stewardship, the incidence of nosocomial infections in developing countries can be reduced.

Schönfeldt *et al.* (2010:254) state that South Africa is a developing country. Therefore South Africa is also concerned with nosocomial infections being the most

significant cause of morbidity and mortality in health care. In South Africa, limited research has been done regarding asepsis-related deviations in parenteral administration of medication. In one study, Blignaut (2015:160) found that these deviations occurred with high prevalence in one of the provinces of South Africa. In this study 49% of medication administrators did not disinfect their hands prior to medication administration overall. In surgical wards this deviation from safe practice was higher (59%) than in medical wards (40%); however, in this regard parenteral medication administration occurred less than enteral medication administration (21% and 77% respectively). The prevalence of asepsis-related deviations that only affects parenteral medications such as not cleaning intravenous bottles, bags and vials prior to administration was the most common (65%) and it occurred more in surgical wards than in medical wards (68% and 62% respectively) (Blignaut, 2015:160). This shows that asepsis-related deviations in parenteral medication administration are present and need to be addressed.

However, no research with reference to more rural settings in South Africa could be found. According to Cullinen (2006:17); Scherbaum *et al.* (2014:2) and Tabu *et al.* (2012:3-4) the risks for patients in rural areas with regards to nosocomial infections and asepsis-related deviations in parenteral medication administration are greater as these hospitals are more likely to be understaffed with a workload that is burdensome. They also have insufficient funds; and the infection prevention surveillance and control activities focus more on active problems rather than prevention (Reese *et al.*, 2014:598). A lack of resources to provide effective hand hygiene like alcohol hand spray, alcohol swabs and disinfectant soap have been observed in the public hospitals of South Africa and this further aggravates the problem because, as Scherbaum *et al.* (2014:2) report, the prevalence of nosocomial infections increases due to poor hand hygiene, resource and structural constraints. Also, the people who live in rural areas are more likely to live in poverty, be older, uninsured and report poorer health status than urban communities, which further increases their risk of acquiring nosocomial infections (Reese *et al.*, 2014:598).

The North West Province is situated in the north-central area of South Africa and is described as mostly rural with a few urban centres. Broadly speaking, nine-tenths of

the population are Tswana-speaking black South Africans and one-tenth are Afrikaans-speaking white South Africans (Anon, 2014). Van Beuzekom *et al.* (2013:107) state that strategies for improving patient safety should be tailored specifically for a specific setting. This study therefore attempts to investigate asepsis-related deviations in parenteral medication administration within the South African public health setting of the North West Province.

1.2 Problem statement

Patient safety is a crucial element of the quality of health care (WHO, 2013:1). Threats to patient safety are adverse events and near-misses and medication administration errors represent one of the major concerns in patient safety (Kim & Bates, 2013:590; WHO, 2005:9).

Medication administration errors can lead to an increase in morbidity and mortality (Glaister, 2005:3) and are five times more likely to occur in the administration of parenteral medication (McLeod *et al.*, 2013:278). If parenteral medication is poorly prepared and/or wrongfully administered it can potentially cause harm to the patient (Bruce & Wong, 2001:855).

One example of parenteral medication being wrongly administered is when principles of asepsis are not adhered to, like not disinfecting hands during such administration. This is referred to as asepsis-related deviations (Kim & Bates, 2013:592), and may lead to nosocomial infections (Muscarella, 2004:284). Nosocomial infections have been the principal source of adverse outcomes in healthcare and account for 50% of all major complications of hospitalisation in the United States (Robert & Gaynes, 1997:475). The prevalence of nosocomial infections in developing countries ranges between 7.2% and 40.5% while the strongest evidence for reducing nosocomial infection rates are hand-hygiene practice (Murni *et al.*, 2013:68 & 74).

Limited research has been done in South Africa related to asepsis-related deviations in parenteral administration of medication. As Van Beuzekom *et al.* (2013:107) state that strategies for improving patient safety should be tailored specifically for a specific setting. This reiterates the problem that the knowledge of the incidence of asepsis-related deviations in parenteral medication administration, its causes and

the possible preventable interventions is limited within the South African context (Blignaut *et al.*, 2017:3610;3620).

1.3 Research question

The main research question that emanated from the above-mentioned problem statement is:

- What is the prevalence of asepsis-related deviations from safe practice with respect to the administration of parenteral medication within medical and surgical wards of the level two public hospitals in the North West Province of South Africa?

1.4 Aim and objectives

The main aim of this study was to determine the prevalence of asepsis-related deviations from safe practice during parenteral medication administration within medical and surgical wards of level two public hospitals in the North West Province of South Africa.

The following objectives were identified in order to reach this aim:

- To explore and describe the prevalence of asepsis-related deviations from safe practice during parenteral medication administration in medical and surgical wards of level two public hospitals in the North West Province of South Africa by means of direct observation; and
- To determine the relationship between asepsis-related deviations from safe practice and medication administrator qualifications, ward type (medical/surgical), occupancy and staffing levels.

1.5 Theoretical framework

According to Botma *et al.* (2010:187) the research has to be integrated into the broader framework of relevant theory that is appropriate for the study. Following this the theoretical basis is important to make the research results generalisable and meaningful (Botma *et al.*, 2010:187). Brink *et al.* (2013:218) explain that a theory is a set of related statements that explains or describes the phenomena in a systematic

way.

A patient safety model for health care that is used to view patient safety aspects suggested by Emanuel *et al.* (2008:15) was applied as the theoretical framework of this study (Figure 1.1).

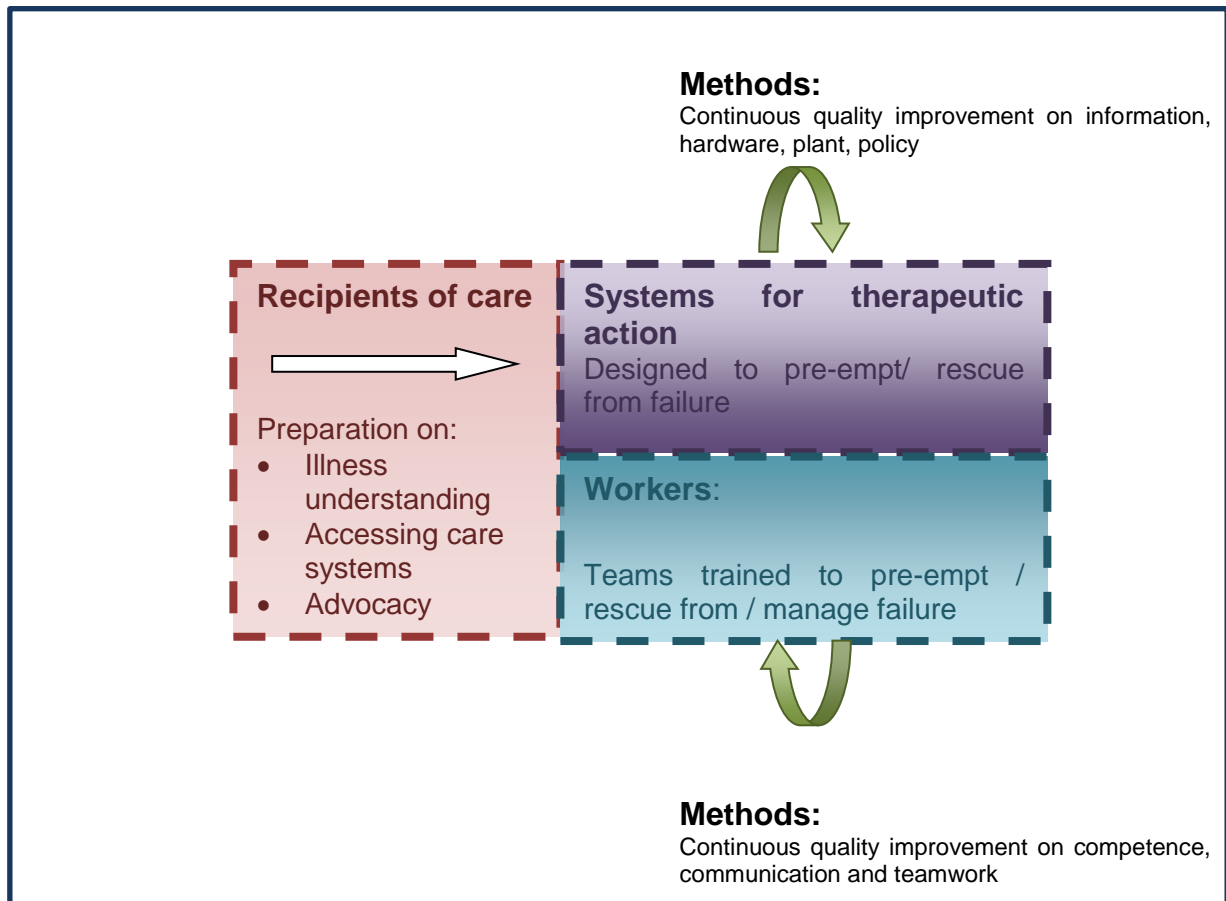


Figure 1.1: A patient safety model for health care (Emanuel *et al.*, 2008:15).

The health care system is divided into four domains: those who receive health care or have a stake in the availability; the infrastructure or the systems for therapeutic interventions thereof; those who work in the field of health care and the methods for feedback and continuous improvement (Emanuel *et al.*, 2008:15). These four domains interact with each other but also with the environment as illustrated by the semi-permeable divisions between them and their outer edges. In this study, although all domains are related to parenteral medication administration, the focus fell on the domain of the workers in health care, specifically medication administrators during a parenteral medication administration round. However, the

observer reflected afterwards that systems' influences cannot be ignored when evaluating a patient safety threat. The fashion in which this model must be applied, will vary by setting and the settings can vary dramatically (Emanuel *et al.*, 2008:16). Thus in this study the model was applied to the South African rural setting by observing the prevalence of asepsis-related deviations in parenteral medication administration in the public health sector.

1.5.1 Concept clarification

- **Professional nurse**

A professional nurse is a person who is registered by the South African Nursing Council as such and is thus authorised in terms of the South African Nursing Act, 2005 (Act 33 of 2005) to practise as a nurse and to administer medication. The practice of a nurse has a broader and less discrete concern than the traditional concern of medicine, in which the nurse acts to promote, maintain and/or restore the patient's health. This practice consists of assessing, diagnosis, planning, treating and evaluating within the framework of the singular concern that is the patient's response to the problem rather than the problem itself (Brooker, 2010:1300). In this research, a professional nurse is a medication administrator.

- **Enrolled nurse**

The enrolled nurse is a person registered by the South African Nursing Council as such and is thus authorised in terms of the South African Nursing Act 2005 (Act 33 of 2005) to practise as an enrolled nurse and to administer medication under direct supervision of a professional nurse. This person is trained to give direct patient care with the basic nursing techniques under the supervision of a professional nurse (Brooker, 2010:1302). An enrolled nurse in this research is thus also a medication administrator.

- **Parenteral medication administration**

This is the administration of medication that bypasses the gastrointestinal tract, such as given by injection (Brooker, 2010:1391). This is a common nursing procedure, where the medication is irretrievable once injected and is absorbed more quickly than oral medication. Therefore the preparation and

administration must be done carefully and accurately. Injections are invasive procedures, therefore aseptic techniques must be used to minimise the risk of infection. Parenteral medications are given intradermal, subcutaneously, intramuscularly or intravenously (Berman *et al.*, 2016:806).

- **Medication administration errors**

According to Ferner and Aronson (2006:1013) this can be defined as mistakes within the treatment process that can lead to, or has the potential to lead to, harm of the patient. For the purpose of this research, the focus is on one such medication administration-related error, namely asepsis-related deviations from safe practice in parenteral medication administration, which may lead to nosocomial infections.

- **Patient safety**

Patient safety is focused on the prevention of error in health care settings. Medication administration safety is but one aspect of patient safe care (Hassen, 2010:1). The focus of patient safety within this study is to provide parenteral medication without causing harm to the patient.

- **Asepsis**

This is the absence of pathogens, where procedures are used to reduce the number of microorganisms and prevent their spread, for example by hand washing (Brooker, 2010:149). In this study asepsis implies that parenteral medication is administered without contamination that threatens patient safety.

- **Disinfecting Hands**

This is when hands are washed with antimicrobial soap and water or antiseptic hand rub is applied to decontaminate hands (WHO, 2009:2).

- **Occupancy**

This is the percentage of bed numbers that indicates the number of patients in a ward in related to its capacity (Hurst, 2002:3). Occupancy will be applied as the number of patients present in the ward on the day of observation.

- **Patient acuity**

Patient acuity is the severity or level of an illness. It is considered as a patient classification system to function as a guideline for nursing staff allocation

(Miller-Keane Encyclopaedia and Dictionary of Medicine, Nursing and Allied Health, 2003:1). Patients with a higher acuity are more susceptible to nosocomial infections (Lucena *et al.*, 2015:238). Thus the patient acuity can also affect asepsis-related deviations during parenteral medication administration.

1.5.2 Meta-theoretical assumptions

Meta-theoretical assumptions can be defined as non-epistemic statements that are not meant to be tested (Mouton & Marais, 1994:192). In this study it consists of the researcher's view of the world, view of man, view of health and view of nursing.

1.5.3 View of the world

The world is the place where man lives temporarily and manages everything thereon. It consists of the internal and external environment in which man functions. The internal environment includes the physical, spiritual and psychological body of man (Vayalilkarottu, 2012:347). The external environment includes the biophysical, socio-cultural, economical and spiritual environments with which man interacts and functions within (Alberti *et al.*, 2003:1173). Interaction between the internal and external environments determines the health status and the challenges that are encountered within this interaction. The environment in this study comprised every element in the surroundings of the medication administrator that influences or impacts his/her life and those of his/her patients.

1.5.4 View of man

The human being is created holistically with spirit, body and soul as a biological, psychological and social being. Man is made up of physical matter that can be seen and touched and also of immaterial aspects which include the soul, spirit, intellect, and emotions (Vayalilkarottu, 2012:347). If disharmony is present in one of these aspects, it will lead to flaws in human behaviour that cause deviations from optimal performance and the conclusion can be made that where a human being is involved, a degree of error is expected (Berman *et al.*, 2016:291-292).

In this study the researcher has focused more on the physical body of man as asepsis-related deviations in parenteral medication administrations cause harm to the human being, although it is also observed how the external environment of the nurse impacts his/her functioning as a medication administrator.

1.5.5 View of health

Health is a continuum of functioning. High-level wellness would be optimal functioning in some or all aspects of being through awareness, education and growth. Poor health is seen as not functioning in some or all aspects of being that can lead to premature death (Berman *et al.*, 2016:292). In this study the focus was on the physical wellbeing of the patient and the safe parenteral administration of medications was seen as an optimal ability of the nurse that leads to high quality safe care.

1.5.6 View of nursing

Nursing is defined by the International Council of Nurses [ICN] (ICN, 2007) as a total autonomous and collaborative care of individuals of all ages, families, groups and communities, whether they are well or sick, irrespective of their setting. I agree with this definition. Nursing can thus be seen as the provision of holistic, safe practice care to all categories of patients, in different wards, with the aim of optimising and improving health and preventing complications and further illness. Nursing is a systematic process that includes promotion of health, prevention of illness and the care of ill, disabled and dying human beings. Key nursing roles include support, reinforcing safe practice environment, research that contributes to shaping health policies and management of patients, the health system and education. Science is essential to clarify the empirical world and to have better control over it. Within the nursing profession, evidence-based knowledge is integrated by means of evidence based practiced to control the delivery of care and to improve patient outcomes (Grove *et al.*, 2013:1-2). Thus, in this study nursing is not only portrayed as administering medication, but also throughout as taking on the research role to better patient outcomes.

1.6 Research design

A cross-sectional study, defined as a study done in one period of time (Brink *et al.*, 2013:101), with a descriptive quantitative design including contextual strategies was used. Botma *et al.* (2010:82) state that quantitative research is an important tool for providing evidence for nursing management, education and practice and for generating knowledge in nursing science. A quantitative design was used in this study to explore and describe what the prevalence is of asepsis-related deviations during parenteral medication administration.

A descriptive design was essential for this study since subjects were observed without someone intervening (Hopkins, 2008:2) and observations were made on specific details (Fouché & De Vos, 2011:96), to describe the prevalence of deviations from safe practice during parenteral medication administration in the North West Province of South Africa.

According to Welman *et al.* (2011:191) human behaviour cannot be understood without appreciating the context in which it takes place. Klopper (2008:68) explained that studies are contextual if the data were to be evaluated in the light of a specific context. In this study, findings were closely bound to one province of South Africa. Thus the behaviour leading to deviations from safe practice was seen in the light of setting-specific challenges and influences.

1.7 Research method and rigour

To acquire an insight into aseptic techniques of the medication administrator during parenteral medication administration, structured observation was used as the research method. Structured observation requires an understanding of the expected series of behaviours in a certain situation. A checklist was used with a list of all the probable behaviours related to aseptic technique so that the researcher was able to identify the correct behaviour during parenteral medication administration (Wood & Kerr, 2010:179).

Population and sampling: The proposed guideline by Kim and Bates (2013:590) of a minimum of 300 cases of medication administration incidences was used for the

determination of sample size. The sampling process and proposed analysis of data were reviewed by a senior statistician and as literature states that 300 observations are enough, no power calculation was required.

The North West Province was purposively selected for this study due to the fact that it is a rural area and similar studies have been done in an urban area in South Africa. The public hospital setting was purposively selected because this setting better represents the health care in a developing country, whereas the private hospitals closely represent a developed country's health care. Due to the vast difference between the South African public and private sectors, the private health sector was excluded from this study as there already are interventions aimed at minimising asepsis-related deviations, which does not necessarily apply to the public sector because of the mentioned difference in the health care systems of the public and private sectors.

The public sector consists of three levels of hospital care services, namely levels 1, 2 and 3. These levels are also referred to as District, Regional and Tertiary hospitals. Level 1/ district hospitals are where inpatient and outpatient services are offered (Cullinen, 2006:16). Also level one hospitals are open 24 hours a day, seven days a week and they have between 30 and 200 beds, a 24-hour emergency service and an operating theatre (Cullinen, 2006:17). These facilities are the first level of referral and personnel are available for basic diagnostic and therapeutic services such as basic laboratory tests and X-rays. These hospitals play a supporting role to primary health care and services as to provide more specialised services (Department of Health [DOH], 2002:8).

Level 2 regional hospitals provide care that requires intervention of specialists and general practitioners. At these facilities at least five of the following eight basic specialities should be provided: medicine, surgery, orthopaedics, paediatrics, obstetrics and gynaecology, psychiatry, diagnostic radiology and anaesthetics (DOH, 2003:28).

Level 3 tertiary hospitals provide sub-specialist support to a number of patients whom they receive from level 2 hospitals. Most of the care in these facilities requires

the expertise of clinicians working as sub-specialists or working in rare specialities like urology, neurology, cardiothoracic surgery etc. (Cullinen, 2006:19).

This research was done in level 2 hospitals in the North West Province due to the fact that regional hospitals are often the most over-burdened of all the levels of hospitals and they are bearing the brunt of the many inadequacies in the district hospitals (Cullinen, 2006:17). Due to the increased workload in these hospitals, asepsis-related deviations during parenteral medication administration might occur more at this hospital level, as business is associated with lower adherence to protocol as a result of nurses developing risky adaptive strategies to cope with the workload (Holden *et al.*, 2014:132).

To ensure a representative and sufficient sample, an all-inclusive sample of the level two hospitals in the North West Province was used. Two medical and two surgical wards from each hospital were selected by fishbowl random sampling. 100 structured observations of parenteral medication administration were done in each of the three level two hospitals of the North West Province (25 observations per ward) to reach the target as proposed by Kim and Bates (2013:590). A maximum of five observations per participant, with a total of 90 participants was anticipated.

Data collection: A check-list was used (see Addendum D) as developed by Kim and Bates (2013:590). The checklist was validated and found to be reliable in South Africa. Prior to the observation informed consent was obtained (see Addendum C). Six items about adherence to basic infection control principles were used during the structured observation of the parenteral administration of medication, which are:

- Disinfecting the hands before administering medication;
- Duration of cleaning (15-30 seconds);
- Area of disinfection (palm, wrist, back of hands, between fingers and all fingernails);
- IV fluid bottles, bags and vials disinfected before use;
- Sterility of needles and IV sets maintained; and
- Disinfecting injection site before administering drugs.

Further notes on staffing levels, medication administrator qualification and bed

occupancy were made on this checklist.

Data analysis: In order to further comply with the contextual strategy proposed, the observer provided an observer's reflection to present the context of the study to the reader. Thereafter numerical data collected were presented. To analyse the data obtained, descriptive statistics were used to produce information on the prevalent types of asepsis-related deviations from safe practice. Descriptive statistics were used to answer the research question, and to describe key research variables such as asepsis-related deviations during parenteral medication administration, qualifications, occupancy and staffing levels (Polit & Beck, 2004:464). In a quantitative descriptive study there is a need for interpretation in the expectations set for this study.

This was applied by pre-selecting the variables namely asepsis-related deviations from safe practice during parenteral medication administration, qualifications, occupancy and staffing levels. The preselected variables were studied and conclusions were drawn from the results of statistical tests (Sandelowski, 2000:336). Regarding inferential statistics, relationships between deviations from safe practice and ordinal variables such as ward type (medical and surgical) and medication administrator rank (professional or enrolled nurse) were investigated by means of Cramer's Vs, as Cramer's V's test a directional hypothesis (Van den Berg, 2016). Correlations between deviations from safe practice and ordinal variables such as staffing levels were assessed. Effect sizes of Cramer's Vs and correlations were seen as small if close to 0.1, medium at 0.3 and large at 0.5. An effect size of 0.5 was deemed practically significant. P-values were calculated and interpreted as statistically significant if smaller than 0.05.

Recruitment and data collection procedure: According to Botma *et al.* (2010:13-15) the target population has to be accessed and informed regarding the study, thereafter the date of the study must be given so as to invite the possible participants to participate in the study. The day before the planned observation in a specific ward, the unit manager of the ward was contacted in order to gain access to the specific ward. The procedure of structured observation was explained to the unit manager

and his/her permission sought. After this procedure, if the unit manager granted permission, the researcher invited the staff to discuss the structured observation procedure with the professional nurse or enrolled nurses allocated as medication administrator of that day and provide him/her with an informed consent form. The researcher confirmed that information was given to the same medication administrator who was administering medication on the day of data collection, thus when the shift changed the following day, the researcher returned on the next day the prospective medication administrator participant was on duty. During this phase of data collection, a medication administrator from each ward served as mediator and was asked to follow up with the possible medication administrator participant and if he/she was willing to complete the informed consent form, the unit manager was asked to sign as a witness. The consent letter was inspected by the researcher on the day of observation, to ensure that participants gave voluntary informed consent. If this letter was completed satisfactorily, the researcher confirmed the participant's understanding and consent to participate in the research study verbally and again emphasised his/her right to withdraw from the study before the observation procedure started. The confidentiality of the results was ensured to the participant verbally as well. When the observations had been completed, the researcher thanked the participants for their time and again reassured them of the confidentiality of the results.

The inclusion criteria for participants included:

- All professional nurses and enrolled nurses registered with the South African Nursing Council; and
- All professional nurses and enrolled nurses administering parenteral medication in the same medical or surgical wards in the level 2 public hospitals of the North West Province of South Africa.

The exclusion criteria for participants were:

- Part-time registered nurses and enrolled nurses as well as student nurses; and
- Registered nurses and enrolled nurses, who are employed on a contract for

shorter than a year in the medical and surgical wards in the level 2 public hospitals of the North West Province of South Africa.

Storage of data: When the observation was complete, the anonymous checklists were sealed in an envelope, and delivered to the statistical consultation offices by the researcher for data capturing. All signed consent documents are kept safe in a locked filing cabinet in the office of the researcher and after completion of the study the consent forms will be kept for five years and destroyed thereafter. The statistician stored the electronic data on a password-protected computer.

Rigour: Rigour is defined by Botma *et al.* (2010:84) as striving for excellence, through scrupulous adherence to detail, discipline and strict accuracy; this is to ensure the research outcome's truth value. When rigour is applied it demands critical examination of each step of the research process to reduce errors and weaknesses. This is essential to ensure that the study's outcomes are an accurate reflection of reality (Botma *et al.*, 2010:84). Through detailed documentation of the research process, objective and systematic data collection, analyses and interpretation of data and the careful maintenance of research records, the accuracy of the research was enhanced as proposed by Botma *et al.* (2010:84).

The face validity (Brink *et al.*, 2013:166), of the tool used to collect data during direct observation was assessed by three experts. They were a head nurse, a charge nurse of the unit and a professor of a college of nursing and it was used in several medication administration error studies with a good validity and reliability report (Kim & Bates, 2013:591). The tool was also previously used and adapted for a South African study (Blignaut, 2015:394) ensuring that it indeed produces accurate results also within this context.

The content validity measures if the instrument in fact measures all the variables that need to be measured (Brink *et al.*, 2013:166). To determine what needs to be assessed with regards to this study, the content of aseptic techniques during parenteral medication administration needs to be determined. Table 1.1 describes the aseptic technique during administration of parenteral medication with a literature support as to why it is necessary.

Table 1.1: Aseptic technique during parenteral medication administration and the literature support thereof

Aseptic technique during parenteral medication administration	Literature support
Disinfecting hands before administering medication.	Hands need to be disinfected to prevent the spread of microorganisms (Endacott <i>et al.</i> , 2009:185).
Cleaning hands for at least 15-30 seconds.	Hands need to be cleaned for at least 15 seconds, as the degree of contamination determines the length of handwashing. The high microorganism count under the nails results in a longer period of time of cleaning hands (Lynn, 2011:128).
Area of washing/disinfecting with alcohol (palm, wrist, back of hands, between fingers and all fingernails)	According to Lynn (2011:128) the palms; backs of hands; each finger; between the fingers; the knuckles; wrists and forearms need to be cleaned by firm rubbing and circular motions.
The port of IV fluid bottles, bags and vials disinfected before use.	Surface bacteria contamination is removed when vials, IV bottles and bags are disinfected with antimicrobial swabs (Lynn, 2011:172; 205).
Sterility of needles and IV sets maintained.	Needles need to be kept sterile to prevent contamination (Lynn, 2011:195). To prevent microorganisms from entering the IV sets, the IV ports are cleaned with antimicrobial swabs (Endacott <i>et al.</i> , 2009:190).
Disinfect injection site before administering drugs.	To prevent micro-organisms from being forced into the tissue, the injection site has to be cleaned with an antimicrobial swab (Lynn, 2011:195).

Validity is the degree to which a measurement represents a true value. It indicates, based on the study's design and interpretation, whether the conclusions of the study

are justified. Validity is not an absolute, but always a matter of degree. The reasons why an inference could be wrong is a threat to validity (Botma *et al.*, 2010:174). As content validity is measured by whether all items of a construct were measured, the above-mentioned table serves as a conformation of content validity. Further adding to the validity, this checklist was used for a similar study in South Africa (Blignaut *et al.*, 2017:3610-3623) from which peer-reviewed conclusions were derived.

To minimise the over-report of observations, the observer discarded checklists if she experienced concentration lapses with resultant uncertainty regarding medication administrators' actions. Furthermore the Hawthorne effect as mentioned by Brink *et al.*, (2013:100) was mitigated by allowing the medication administrator to become familiar with the observer's presence before observations were recorded, by not recording the first three observations done.

Reliability is an indication of the extent of random error in the measurement method. It represents the consistency of the measure achieved. This means that the same results should be produced when a valid measuring instrument is applied to different groups under various circumstances (Botma *et al.*, 2010:177). This measuring instrument was previously used in South Africa. The primary researcher was the only observer to ensure credibility (Sim & Wright, 2002:101). This ensured consistency in observations.

The three aspects that are important in reliability are homogeneity, stability and equivalence. Homogeneity is mostly applicable to pencil and paper tests, showing an internal consistency in test items. However, in this study, the observed items provided no leeway for deviance from what was to be observed, and as only one researcher did the observations, internal consistency is strengthened.

Stability is concerned with consistency, when the same scale or instrument is used to measure the same attribute repeatedly. It is usually applied to technology measures, physical measures and paper and pencil scales (Botma *et al.*, 2010:177). In this study, physical measures in terms of physical actions of medication administrators were measured consistently with the same checklist. To mitigate unstable observing, the observer limited the amount of observations completed daily

to prevent observer fatigue and consequent unreliable observing. Furthermore, the instrument used in this study was used previously and therefore the results were compared with the other studies to measure stability.

According to Botma *et al.* (2010:177) equivalence is when two observers are used to measure the same event and then their data are compared. Equivalence was not applied in this study since there was only one observer. Validity and reliability were implemented throughout the whole study to ensure rigour.

1.8 Ethical considerations

Research ethics is explained by Neale (2009:31) as a generic term for various ways of examining and understanding moral research. A simplified definition of research ethics would be that the welfare and rights of the subject is always placed above the needs of the investigator (Peat *et al.*, 2002:283). Ethics was a major concern for and during this research.

According to Brink *et al.* (2013:34) there are three fundamental ethical principles, namely respect for persons; beneficence; and justice that can be applied in this research. Brink *et al.* (2013:34) state that these principles are based on the human rights of self-determination, privacy, anonymity and confidentiality, fair treatment and to being protected from harm. All of these ethical principles were integrated into the research process and all of them received great consideration throughout the study and adjustments were enforced if any one of these appeared to be violated in the smallest way. All participants were selected fairly due to the recruitment, selection, inclusion and exclusion of participants being just and fair as stated previously in the recruitment and data collection procedure and as proposed by the DOH (2015:16).

One of the threats to ethical observation research is the ethical issues of confidentiality and privacy, due to the thick description of the participant's attitudes, interactions and environment that is often needed (DOH, 2015:17). The field notes were more general about the whole unit being observed and limited on personal characteristics of the medication administer being observed to minimise the risk of a specific participant being tracked down by thick description of observation. It is also

more prudent to negotiate access in relation to setting rather than specific individuals (Saks & Allsop, 2013:111), thus access to the medical and surgical unit and not the specific medication administrator working in that unit were negotiated.

During the structured observation participants were considered as autonomous. They had the right to self-determination, by deciding whether or not to participate in the study without the risk of penalty or prejudicial treatment (Brink *et al.*, 2013:35). The participants also had the right to withdraw from the study at any time or to refuse to divulge information to the researcher (Peat *et al.*, 2002:283). The need for informed consent is emphasized by the DOH (2015:16) and Saks and Allsop (2013:89), therefore informed consent was obtained from all participants prior to the structured observation procedure. Privacy and confidentiality were re-emphasized at this point and 24 hours given to the participant to decide on his/her participation. Before the participant gave consent, he/she was informed about the purpose, requirements and demands of the protocol (Peat *et al.*, 2002:283).

For the participants the risks involved in this phase include anxiety - should the participant feel that his/her mistakes would be made public and he/she would be held accountable for it. To reduce the risk, the participant was reassured repeatedly that results would not be connectable to him/her. Another risk is that the participant lost approximately five minutes of work-time to complete the informed consent. The participant was thanked for this sacrifice. As the benefits that are indirect to the participant include knowledge acquisition, better safety culture in hospitals, recommendations for better practice environment and possibly advocacy for better protocols and policies. The benefits of this study outweighed the risks, in accordance with the guidelines provided by the DOH (2015:16). The risks for loss of reputation to hospitals and wards due to negative results were mitigated by no names being mentioned in results. Results were combined and no specific hospital was implicated.

This study was relevant to generate new knowledge regarding the prevalence of asepsis-related deviations during parenteral medication administration in the level 2 hospitals of the North West Province of South Africa and it can lead to further studies

on interventions to improve patient safety and infection control. The sound research design and methodology of this study reflects scientific integrity as proposed by the DOH (2015:15&16) as with this design the data is valid and the outcomes did address the research objectives.

The requirement of research competence is mentioned by the DOH (2015:16 & 17). The researcher was qualified to do this study due to the fact that she has a degree in Nursing Science (B.Cur) and she completed a Research Methodology module in June 2016 to understand the concepts of ethical research. Experienced help has been used from two supervisors who guided the researcher with this study as they had experience in this field and with the specific methodology.

The proposal was reviewed by the Postgraduate Education and Research Committee (PERC) of the School of Nursing Science. Ethical approval was obtained from the Faculty of Health Science Human Research Ethics Committee of the North-West University (clearance certificate in Addendum A; NWU-00351-16-A1) the North West Provincial Department of Health as well as all the level two hospitals who participated in the study (blinded permission letters provided in Addendum B).

1.9 Classification of chapters

This dissertation comprises the following chapters:

Chapter 1: Overview of the study

Chapter 2: Literature review

Chapter 3: Structured observation methods and results.

Chapter 4: Evaluation, recommendations and limitations of the study.

1.10 Conflict of interest

There was no conflict of interest relevant to this study.

1.11 Summary

Asepsis-related deviations in parenteral medication administration pose a great threat to patient safety. Within the South African context, the extent of this problem is not well defined. A strategy was proposed to determine the incidence of asepsis-related deviations in parenteral medication administration in medical and surgical wards of level 2 public hospitals of the North West Province of South Africa. The research design and research methods proposed were discussed, as well as rigour, ethical considerations as well as classification of proposed chapters of the research. A review of existing literature on the study topic is presented in chapter 2.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

The purpose of a literature review is to contribute to a richer understanding of the nature and significance of the problem at hand. It generates a foundation for the study based on current related knowledge (De Vos *et al.*, 2011:134).

The aim of this section of the study is to investigate known research on all the domains of the patient safety model namely those who work in healthcare, those receiving healthcare, systems for therapeutic actions and continuous quality improvement (Emanuel *et al.*, 2008:15) and their interactions with asepsis-related deviations from safe practice in parenteral medication administration by means of a literature search. The search strategy to obtain this literature will be provided where after a background to the problem of asepsis-related deviations from safe practice in parenteral medication administration will ensue.

2.2 Search strategy

The literature was retrieved by means of EBSCO Host, NWULib guides and ScienceDirect. Google Scholar was used additionally to obtain articles regarding parenteral medication administration errors and related patient safety concerns such as nosocomial infections. Policies and procedures of South African level 2 hospitals were investigated so as to obtain a South African perspective. A plethora of international research is available, though scholarly resources available on asepsis-related deviations in parenteral medication administration in South Africa are limited.

2.3 Domains' relationship with asepsis

Mentioned in chapter one, Emanuel *et al.* (2008:15) suggested a patient safety model which divides the health care system into four domains which interact with each other as well as with the environment around it. The four domains and the context in which these domains function were used as the structure for chapter two.

Asepsis in parenteral medication as the context is discussed, followed by the evaluation of parenteral medication asepsis, the improvement of parenteral medication asepsis lapses, the health care workers' influence on asepsis, and the health care recipients' influence. Thereafter the focus will shift to the system's influence on asepsis and the medications influencing asepsis, ending the chapter off with a reiterative summary of the need for aseptic techniques in parenteral medication administration. Figure 2.1 illustrates the patient safety model as used in this chapter to describe all the influences on asepsis during parenteral medication administration.

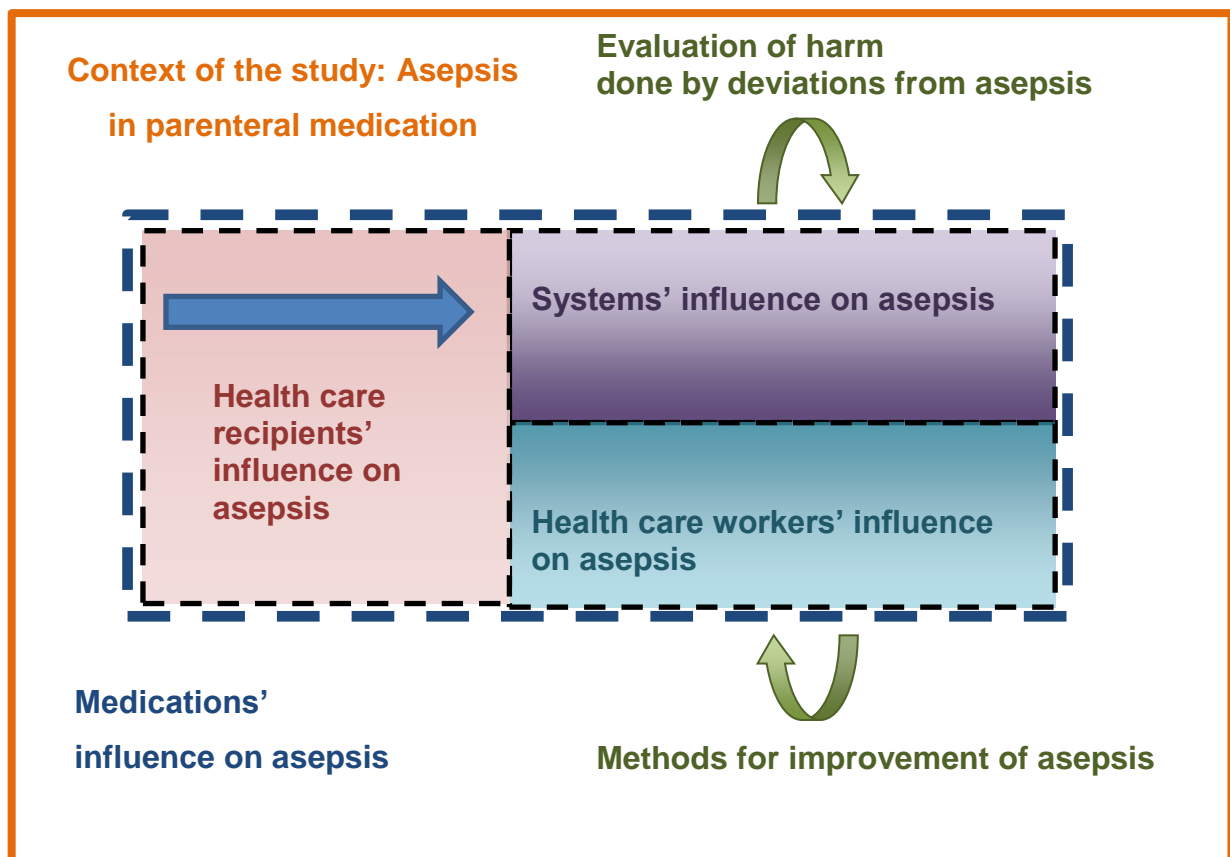


Figure 2.1: Patient safety model applied to study context

2.3.1 Context of asepsis in parenteral medication

Patient safety is a crucial element of the quality of health care while adverse reactions and near misses impede patient safety (WHO, 2013:1). An adverse reaction is defined as any unintended, harmful effect of a therapeutic intervention, medication or a diagnostic test (Brooker, 2010:50). A near miss can be defined as a

variation in a normal process that, if continued, can lead to a negative effect on the patient (Speroni *et al.*, 2013:19 and WHO, 2015:9).

Medication errors form part of the adverse events that have an impact on outcomes financially as well as leading to harm or death of the patient (Ferner & Aronson, 2006:1013). Medication errors can be defined as mistakes within in the treatment process that can lead to harm of the patient or has the potential to lead to harm (Ferner & Aronson, 2006:1013). These errors can occur in the process of prescribing medication, dispensing medication and administrating medication (Glaister, 2005:3; Nguyen *et al.*, 2010:224). Medication errors are more prevalent than generally perceived. Literature provides information on incidences of medication administration errors within different settings. Some of the literature incidence results are presented in table 2.1. Medication administration errors are definitely of concern, as these medication errors rank higher in both the incidence and severity of threat to patient safety than most other adverse events and special attention to medication administration in the medical-surgical context is merited.

Table 2.1: Summary of medication administration error incidence.

Author(s)	Medical/ Surgical ward	Intensive care ward	Oral medication errors	Parenteral medication errors
Cheragi <i>et al.</i> , 2013.				60.78%
Covvey <i>et al.</i> , 2015.	28.6%		50%	
Edwards and Axe, 2015.			41.0%	
Esqué <i>et al.</i> , 2015.				68.1%
Fahimi <i>et al.</i> , 2008.			66.4%	
Manias <i>et al.</i> , 2014.	17.2%	12.3%		
Tang <i>et al.</i> , 2007.	36.1%	33.3%		
Stavroudis <i>et al.</i> , 2010.			48%	
Volpe <i>et al.</i> , 2014.			69.6%	49.7%

When medication is poorly absorbed via the oral route or when a rapid response is needed during an emergency, medication can be administered through the parenteral route. Parenteral medications are administered intradermally, subcutaneously, intramuscularly or intravenously (Berman *et al.*, 2016:806). As parenteral medication administration is an invasive procedure, it poses a risk of infection which could compromise patient safety, operationalised as the intended state of being free from accidental injury (Sorrentino & Alegiani, 2012:92). Medication administration errors are five times more likely to take place in intravenous medication administration than in non-intravenous medication administration according to McLeod *et al.* (2013:278). The American Nurses'

Association (2007:1-3) confirms that most nurses believe that medication errors pose a serious risk for patient harm and that almost half of the errors will most likely occur during the preparation and administration of intravenous medication. A study done in South Africa found a 3% increase in the incidence of medication administration errors in parenteral medication administration versus enteral medication administration (Blignaut, 2015:137).

Adding to the prevalence problem, most patients will receive antimicrobials intravenously as part of their medical treatment (Durlach *et al.*, 2012:220). Vijayakumar *et al.* (2014:50) found that almost all admitted patients will receive medication through the parenteral route and 61% of all the medication administration errors took place during parenteral medication administration. Ding *et al.* (2015:36) further quantify the risk by explaining that patients admitted in the general surgical wards of a large teaching hospital in Beijing, China, received up to 10 intravenous administrations per day.

2.3.2 Evaluation of harm done by deviations in asepsis

Apart from being the most prevalent, medication administration errors related to the parenteral route also lead to the most severe adverse effects. The adverse effects are more severe due to the immediate onset of the intravenous medications' systematic effect, the low therapeutic index and the difficulty of reversing the pharmacological effects after administration (Ding *et al.*, 2015:33; Fahimi *et al.*, 2008:112). Most (81%) of the parenteral medication administration errors took place in high alert medications such as insulin as well as in potassium chloride and sodium chloride used as injection concentrate (Ding *et al.*, 2015:35). However, it is not only the pharmacological action that exacerbates the risk inherent to parenteral medication but also the fact that it is invasive in nature, providing easy access for pathogens to cause infection (Muscarella, 2004:284)

Hughes and Blegen (2008:399) state that it is difficult to reduce medication errors when information regarding the prevalence thereof is absent, inaccurate or contradictory. To further their argument they mentioned that there are 100 undetected errors that do not harm the patient for every detected medication error

that harms a patient. Fahimi *et al.* (2008:114) argued that none of the parenteral medication administrations errors they assessed resulted in patient harm. Ding *et al.* (2015:37) on the other hand found that parenteral medication administration errors took place in nine out of ten cases, the most common error being wrong dosage administration of insulin that resulted in the patient experiencing hypo-/hyperglycaemia. These contradictory findings show the need for better understanding with regards to the level of patient harm brought about by medication errors. Table 2.2 summarises some literature on level of patient harm brought about by medication errors.

Table 2.2: Incidence of patient harm

Author(s)		Patient Harm (%)					
		Near misses	Did- not reach the patient	No harm	Minor harm	Serious harm	Fatal
All medication errors	Covvey <i>et al.</i> 2015.			57%	47,3%	6%	
	Esqué <i>et al.</i> 2015		17%		10,6%		0,6%
	Manias <i>et al.</i> 2014.			55%	3,2%	0,3%	0,04%
	Sorrentino and Alegiani. 2012.	24%	55%	12%		4%	0,4%
Parenteral medication errors	Doherty and McDonnel. 2012.				22%		
	Deters <i>et al.</i> 2009.			33,6%	32,5%	13,6%	1,5%
	Valentin <i>et al.</i> 2014.		71%				0,9%

Parenteral administration errors resulted in more than half of the subsequent serious harm in reported errors. The most frequent errors to take place were wrong time of administration and missed medication. Concerning the type of parenteral administration, 9% of the errors took place during intravenous bolus administrations. During subcutaneous administrations and continuous intravenous administrations

fewer errors were present (Valentin, *et al.*, 2009:931). Fahimi *et al.* (2008:113) argued that 43.4% of errors occurred during bolus administration.

When medication is not prepared in aseptic conditions, there is an increased risk of nosocomial infections (Turpin *et al.*, 2014:956). Hinkle and Cheever (2014:282) state that a breach in asepsis can lead to bacterial phlebitis and Paparella (2011:564) suggest that it can lead to infections like Hepatitis C. Thompson *et al.* (2016:378) agree and add that a breach in hand hygiene and disinfection of the medication vial rubber can especially lead to the spread of infections like Hepatitis B and C.

Gokhman *et al.* (2011:483) found that more than half of medication administration errors came about as a result of inappropriate aseptic techniques. Although differing in incidence, studies concur that the most prevalent deviation from aseptic technique is not disinfecting hands prior to parenteral medication administration (21%-95.4%) (Blignaut, 2015:160-161; Kim & Bates, 2013:594; Rehan *et al.* 2012:178; Thompson *et al.*, 2016:377-378). Other deviations from safe practice include not disinfecting intravenous fluid bags, bottles and vials (8.8%-66%) as well as not disinfecting the injection site (7%-20.1%) (Blignaut, 2015:160-161; Kim & Bates, 2013:594; Rehan *et al.* 2012:178; Thompson *et al.*, 2016:377-378). It can be seen from the above-mentioned findings that asepsis-related deviations during parenteral medication administration are common and the result thereof is of concern as it affects patient safety greatly.

Several factors contribute to the vulnerability of patients to be exposed to medication errors. Errors are more prevalent during the morning medication administration process than in the night shift medication administration (Fahimi *et al.*, 2008:113; Volpe *et al.*, 2014:555; Yihong *et al.*, 2016:893). Parenteral medication errors are more likely to take place when the ward provides a higher level of care to more severely ill patients and uses more parenteral medications like a medical or intensive care ward (Valentin *et al.*, 2009:930; Yihong *et al.*, 2016:892). For this reason, specific priority areas for betterment of asepsis in parenteral medication should be targeted.

The risk for errors during parenteral medication administration is of concern with regards to patient safety, quality of health care and financial implications for the institutions. When contamination of the parenteral medication or the parenteral route takes place it can result in serious patient complications (Muscarella, 2004:284). Bruce and Wong (2001:855) agree that when parenteral medication is poorly prepared and/or wrongfully administered it can lead to harm. It has been found that if aseptic technique is breached during parenteral medication administration, adverse events like infections, thrombus formation, severe hypersensitivity reactions (Berman *et al.*, 2016:806) and bacterial phlebitis and thrombophlebitis can occur (Hinkle & Cheever, 2014:282-283). Also specific nosocomial infections like Hepatitis C can be transmitted (Dorj *et al.*, 2014:2; Muscarella, 2004:284).

In parenteral medication administration infection can be obtained since there is a vulnerable host (the patient), an agent (microorganism) and a conducive environment (Hart, 2007:46).

Nosocomial infections fall under the group of health care associated infections (Berman *et al.*, 2016:672) and can be defined as an infection that is attained at least 72 hours after hospitalisation. It is relating to a secondary disorders associated with hospitalisation but unrelated to the primary condition of the patient (Brooker, 2010:1296). Nosocomial infections result from endogenous sources, where the microorganisms originate from the patients themselves or exogenous sources, where it originates from the hospital environment and hospital personnel (Berman *et al.*, 2016:673). A subgroup of nosocomial infections is iatrogenic infections, which are infections directly resulting from diagnostic or therapeutic procedures (Berman *et al.*, 2016:672). In literature, the term “nosocomial infections” and “health care associated infections” are often used interchangeably to refer to iatrogenic infections, hence iatrogenic infections will be assumed included in the term nosocomial infections in this study.

Nosocomial infections have been recognised as a critical problem for centuries; it is the principal source of adverse outcomes in health care that is affecting the quality of health care. Furthermore, Murni *et al.* (2013:61) elaborate that nosocomial infections

present the most significant cause of morbidity and mortality in health care, causing a very high economic burden in both developed and developing countries throughout the world. Turpin *et al.* (2014:956) agree that when the risks of nosocomial infections are higher, it leads to increased mortality rates and financial expenses. Durlach *et al.* (2012:220) confirm that nosocomial infections are “a major threat to patient safety, Lucena *et al.* (2015:237) add that nosocomial infections lengthens hospitalization, which in turn could add to the financial burden of health care costs. This proves that these infections add to both physical and financial strain with relation to health and health care.

In the United Kingdom one out of ten patients develop an infection during their hospitalisation and in the United States nosocomial infections account for 50% of hospitalisation complications (Robert & Gaynes 1997:475; Scales, 2011:49). In a comparative study between five countries, overall nosocomial infection prevalence was the highest in Argentina with South Africa following at 9.7% (Durlach *et al.*, 2012:221). Murni *et al.* (2013:61) provide more ominous statistics, stating that nosocomial infections affect up to 21.6% of patients in medical wards and 40.5% in intensive care wards.

The most prevalent nosocomial infection is pneumonia and primary bloodstream infections are fourth on the list (Durlach *et al.*, 2012:219). In the comparative study mentioned earlier, South Africa had the highest rate of primary bloodstream infections. Aly *et al.* (2005:1517) report that primary bloodstream nosocomial infections are prevalent in both central venous catheters and peripheral catheters. For this reason, bloodstream infections and causes thereof are a merited concern in patient safety research.

Nosocomial bloodstream infections in hospitalised patients are serious and preventable adverse events (Mercaldi *et al.*, 2013:961). The seriousness of these infections is confirmed by Goto and Al-Hasan (2013:503) stating that bloodstream infections are one of the leading causes of death in European and North American countries. In the United States it was found that bloodstream infections contributes to more deaths than any other infection including pneumonia and influenza combined

(Goto & Al-Hasan, 2013:506). A 35% prevalence of nosocomial bloodstream infections produced mortality rates between 12% and 32% in developed countries (Goto & Al-Hasan, 2013:505).

Bloodstream infections can be caused by various factors. Central intravenous catheters and parenteral nutrition are the leading risk factors for nosocomial bloodstream infections (Durlach *et al.*, 2012:222; Goto & Al-Hasan, 2013:502 and Mercaldi *et al.*, 2013:958). Rao *et al.* (2013:107) focusing specifically on transmission of Hepatitis C as a nosocomial bloodstream infection, found shared supplies, shared environmental surfaces or staff practices to cause breaches in asepsis. Dolan *et al.* (2016:750) and Thompson *et al.* (2016:378) agree and confirm that along with Hepatitis C, Hepatitis B and bacterial pathogens can be obtained through lapses in aseptic technique.

2.3.3 Methods for improvement of asepsis

Although the threat of parenteral medication asepsis lapses can cause severe harm to patients, it could be very easily mitigated. The risk of errors during parenteral medication administration will be greater when infection control policies and procedures are not in place and up to date or when education and training provided for staff are limited (Cheragi *et al.*, 2013:230; Nunkoo & Pickles, 2008:46; Rao *et al.*, 2013:109). These risks can be reduced by adequate infection control measures. Hadaway (2006:59) and Goto and Al-Hasan (2013:506) suggest that the strategies to reduce these risks of infections should be tailored for each setting specifically. Systematic hand washing, training programmes for medication administration (Mercaldi *et al.*, 2013:961) and training programmes for aseptic techniques (Hart, 2007:44; O'Grady *et al.*, 2011:S2) were found to reduce the risks.

O'Grady *et al.* (2011:S8) confirm that contamination of the intravenous route is caused by several factors and the factors relating to asepsis are:

- Skin organisms at the insertion site can migrate into the cutaneous catheter tract and colonize at the catheter tip. This is the most common route of infection for

short-term catheters and therefore the importance of asepsis during insertion and access is vital to prevent infection; or

- The catheter or catheter port is directly contaminated by hands, contaminated fluids or devices.

There are less possible contamination sites when new technologies are applied to reduce the amount of manual manipulation to administer intravenous medications. It results in a lower risk for nosocomial blood stream infections, as manual mixing and administration have more possible contamination sites (Mercaldi *et al.*, 2013:961). If manual mixing is, however, the only option, O'Grady *et al.* (2011:52) advocated that the ports must be vigorously cleaned with antiseptics and only sterile devices must be used to minimise contamination risk when accessing intravenous ports to administer medication or fluid. Dolan *et al.* (2016:573) elaborate that all medication vial ports, the neck of glass ampoules, the intravenous line ports and the skin site for injection should be disinfected with sterile 70% alcohol (an alcohol swab) beforehand and adequate drying time should be allowed. O'Grady *et al.* (2011:S4) agree that the antiseptic used to clean injection sites should have adequate drying time to ensure the effectiveness thereof.

Goto and Al-Hasan (2013:507) report that, when central venous lines are discontinued earlier and proper access techniques are applied, the risk for nosocomial bloodstream infections can be reduced. Pugliese *et al.* (2010:794) proposed several specific access techniques to support the reduction of these bloodstream infections:

- The use of aseptic techniques, through avoiding contamination of sterile equipment and not administering medication from one syringe to multiple patients;
- Only use syringes, needles and cannulas once as these items are single-use items that are sterile;
- Single-dose vials should be used as far as possible and only administered to one patient. If multi-dose vials are used, only sterile syringes, needles and cannulas

should be used and as far as possible one vial should be assigned to one patient; and

- Intravenous fluid infusion and administration sets should only be used for one patient and then discarded appropriately. Intravenous solution bags/bottles should not be used for more than one patient.

These access techniques are aborted in the strategies put in place by means of the Infection Prevention and Control Policies that include hand hygiene and other elementary infection control practices aimed at preventing the spread of nosocomial infections (Department of Health, 2007:6). Having all the correct protocols in place to minimise asepsis lapses in parenteral medication administration, observing asepsis-related practices would add insight into why these protocols are not adequately adhered to.

2.3.4 Health care workers' influence on asepsis

Stavroudis *et al.* (2010:463) found that 68.4% of medication administration errors were caused by human factors. These human factors could be as basic as those working in the health care not doing what they are supposed to, in other words, not following protocol in basic infection control measures (Durlach *et al.*, 2012:220). Rao *et al.* (2013:108) suggested that inadequate hand hygiene and glove use lead to transmission of Hepatitis C. Murni *et al.* (2013:61) add that ineffective hand hygiene increases the prevalence of nosocomial infections and Dolan *et al.* (2016:573) confirm that having non-sterile contact with sterile areas of devices also increase the risk for nosocomial infections. Hart, (2007:44-46), Helder *et al.* (2016:722), Rehan *et al.* (2012:179) and Scales (2011:53) also agree that asepsis-related risks that occur during parenteral medication administration is higher when hand washing techniques are not implemented correctly and when aseptic techniques like keeping the sterile equipment sterile is not implemented.

However, the problem might not be as simple as not following protocol, as other compounding factors might influence asepsis-related outcomes. A breach in knowledge, which could arise from other human factors like insufficient education

and training (Ehsani *et al.*, 2013:4) could be mentioned as the first of these compounding problems. Durlach *et al.* (2012:220) confirm a lack of knowledge to contribute to a higher prevalence of nosocomial infections, while Vaismoradi *et al.* (2014:434) furthermore advocate medication administration education and training to better patient safety. Fatigue is a psychological and physical factor that also contributes to parenteral medication administration errors (Cheragi *et al.*, 2013:230; Ehsani *et al.*, 2013:3-4; Sorrentino & Alegiani, 2012:92). Another psychological factor namely stress was also found to be a cause of lapses in parenteral medication administration safety (Manias *et al.*, 2014:74; Pazokian *et al.*, 2014:248).

Furthermore, the complexity and gaps in the information and communication process of parenteral medication administration can be seen as a risk for asepsis-related deviations. An example of these gaps in the information and communication process is presented by Valentin *et al.* (2009:931) who found that if the nurses administering the parenteral medication labelled the syringes by themselves instead of using the infusions prepared by the pharmacists the risks of errors were lower. When there is no routine checking of medication administrations at nurses' shift change or supervision of trainees the risk of parenteral medication administration related infections is increased (Valentin *et al.*, 2009:930). More communication-related threats to asepsis include missed or mistaken physicians' orders and illegible handwriting (American Nurses' Association, 2007:1).

Nurses contributed to many of the strategies aimed at improving patient safety, as it was perceived that nurses are concerned about the threats to patient safety and nurses have a duty to protect and promote the health and wellbeing of the people in their care (Arries, 2014:3 and Ingram & Murdoch, 2009:56). However, nurses are not solely responsible for maintaining asepsis in wards as Khan *et al.* (2015:513) explain that the interaction between patients and nurses brings along its own risk of nosocomial infection transmission. For this reason, focus is now shifted to those who receive health care.

2.3.5 Health care recipients' influence on asepsis

The patients themselves also have an effect on lapses in parenteral medication administration asepsis. According to Fekadu *et al.* (2017:50) a patient's age is a determinant of parenteral medication administration errors and suggested that a patient from the age of 60 years is twice as much likely to have a parenteral medication administration error. Labbé *et al.* (2008:3182), Reese *et al.* (2014:598), Stausberg (2014:5) and Tehewy *et al.* (2016:38) agree that adverse drug events from parenteral medication administration such as nosocomial infections were likely to occur in patients who were older. Another demographic characteristic of the patient, viz. gender, was mentioned by Vijayakumar *et al.* (2014:50) as being strongly associated with parenteral medication complication.

Longer hospitalisation is often associated with an increased nosocomial infection risk (Labbé *et al.*, 2008:3182; Mercaldi *et al.*, 2013:958; Stausberg, 2014:5). Multiple comorbidities including malnutrition or urinary tract infection, or having undergone invasive procedures such as intubation, surgery, catheterisation or receiving intravenous therapy make a patient more susceptible to nosocomial infections (Durlach *et al.*, 2012:220; Lucena *et al.*, 2015:238; Saptharishi *et al.*, 2016:155). Bae *et al.* (2015:987), Gokhman *et al.* (2011:485) and Saptharishi *et al.* (2016:155) summarise that a patient is in greater risk of acquiring nosocomial infections if the acuity of their illness is greater.

With relation to patient background, Reese *et al.* (2014:598) add coming from a more rural setting, having a poorer health status and living in poverty as exacerbating circumstances in the development of nosocomial infections. Tehewy *et al.* (2016:38) confirm that illiterate patients are a high risk group for medication errors and elaborate that a patient will experience more medication errors when he/ she is not educated and orientated on his entire medication plan.

2.3.6 Systems' influence on asepsis

The leading system influence that produces parenteral medication errors has been found to be interruptions and disruptions (Hemingway *et al.*, 2014:736; Smeulers *et*

al., 2014:279; Volpe *et al.*, 2014:556). Interruptions and disruptions can be defined as phone interruptions, interruptions and disruptions by colleagues and other professionals, noise, busy wards, poor lighting and pressure if a patient is waiting (Hemingway *et al.*, 2014:736). Interruptions are found to be a system influence specifically in parenteral medication administration and therefore distractions must be limited as far as possible during administration (Fell *et al.*, 2016:67).

Interruptions worsen an already heavy workload. Heavy workload is seen as a cause of parenteral medication errors and asepsis-related deviations (Hemingway *et al.*, 2014:739; Labbé *et al.*, 2008:3181; Smeulers *et al.*, 2014:279) as well as having to administer a large number of medications at peak times (Treiber & Jones, 2012:288). The heavy workload could be directly associated with understaffing (Treiber & Jones, 2012:288) and understaffing leads to a high patient to nurse ratio, which can increase the chances of lapses in asepsis (Cheragi *et al.*, 2013:230; Ehsani *et al.*, 2013:3; Paquet *et al.*, 2013:90; Treiber & Jones, 2012:288; Volpe *et al.*, 2014:556). This heavy workload can lead to medication administrators feeling time-pressured and omitting full aseptic procedures, such as not washing hands between patients. A factor related to heavy workload is increased bed count, which might also increase nosocomial infections (Labbé *et al.*, 2008:3181).

Lucero *et al.* (2010:2193) confirm that an increased workload and staff shortage result in unmet nursing care needs and increase the prevalence of adverse events. Unmet nursing care needs have a significant impact on the prevalence of nosocomial infections. Most of the parenteral medication errors occur during routine care of patients and it is confirmed that increased workload leads to a higher risk for adverse events such as a breach in asepsis during parenteral medication administration (Valentin *et al.*, 2009:931; Yihong *et al.*, 2016:892).

Understaffing can lead to the need to work double shifts. When double shifts are worked it can lead to medication errors (Treiber & Jones, 2010:1331) and a correlation has been found between medication errors and overtime (Paquet *et al.*, 2013:90). Error-inducing conditions like a high staff turnover with new staff (especially new graduates) is also of concern regarding aseptic technique during

parenteral medication administration (Treiber & Jones, 2012:288). On the other hand, if staff work well together as a team, asepsis-related deviations will be mitigated, as Bae *et al.* (2015:46) explain that a positive work group learning environment could reduce the prevalence of medication errors.

The risk for infections increases when preparing intravenous medications without the use of a dedicated aseptic area as confirmed by Durlach *et al.* (2012:220) who list hygiene conditions as a factor impacting nosocomial infection risks. In the preparation and administration of intravenous medication, failure to follow appropriate infection control standards leads to an even higher risk (Dolan *et al.*, 2016:572; Paparella & Mandrack, 2016:65). Rao *et al.* (2013:108) agree and state that medication preparation and administration errors that lead to a higher risk for nosocomial bloodstream infections like Hepatitis C are when intravenous medications like heparin is prepared and stored in multiple locations which are not designated aseptic areas while Beaney (2010:1570) suggest that a suitable aseptic environment to prepare medications is necessary to limit the prevalence of parenteral medication errors. Rao *et al.* (2013:108) elaborate on their findings that the risk for nosocomial infections is increased when contaminated sharps are not discarded in the correct way and blood spills are not adequately cleaned. Also when intravenous ports and medication vials are not cleaned with alcohol swabs/ other antiseptic, the risk for nosocomial infections is increased. Another risk factor is manifested when saline flush syringes being prepared in multiple locations which are not aseptic-designated locations (Rao *et al.*, 2013:108).

Although the intent to follow protocol might exist, Durlach *et al.* (2012:220) mention the challenge of non-optimal infrastructure and a lack of equipment as hampering asepsis. Lack of space could lead to an overly-busy environment, which might limit a nurse's ability to adequately maintain asepsis during parenteral medication administration (Smeulers *et al.*, 2014:279; Pazokian *et al.*, 2014:248). Rehan *et al.* (2012:179) also found that in developing countries like India, a heavy patient load and the higher costs of hand sanitizer are some of the barriers of asepsis leading to the spread of infections.

Basic infection regulations and safety regulations during parenteral medication administration were defined by Kim and Bates (2013:594) as disinfecting/washing hands before medication preparation and administration; 15-30 seconds' duration of cleaning; disinfecting/washing all areas of hands; disinfection of intravenous bottles, bags and vials before use; maintaining sterility of needles and intravenous sets and disinfection of the injection site before administering medication. Dolan *et al.* (2016:573) further suggest that intravenous solutions like a bag or bottle should be used for one patient and then discarded and all infusion supplies (syringes, needles and administration sets) should only be used for one person. As for syringes, one syringe must only be used for one patient and then discarded and a sterile syringe and needle should be used for each entry into a vial or intravenous fluid bag while all sharps should be correctly discarded in a sharps container. All medications and parenteral medication administration equipment should be checked to ensure it is sterile and did not expire as this could lead to adverse events like nosocomial infections (Dolan *et al.*, 2016:5720).

The regulations of basic infection control and safety are necessary due to the fact that infections can easily enter the body through a breach in the skin, whether induced or through disease, and therefore asepsis is essential in any supplies that are intended to or might breach the skin (Nunkoo & Pickles, 2008:45). Rosenthal (2006:79) advocated that if policies and procedures regarding asepsis can be kept up to date and staff trained regularly, the prevalence of infection can be reduced. According to Khan *et al.* (2015:513), when there is a lack of compliance with infection control practices, for example when asepsis is breached in any invasive procedures, it will lead to a spread of infections.

In one of the level 2 hospitals of the North West Province of South Africa policies were found to be in place for nurses to apply infection prevention and control (North West Department of Health, 2011:1). The policy was developed by the Nursing Department and the emphasis is on correct hand hygiene, using disinfectants and soap, as well as wearing protective devices to prevent a breach in asepsis. Infection prevention and control education is stressed and the infection control of each ward should be monitored through monthly statistics. Another policy was compiled by the

Infection Prevention and Control Department regarding hand washing so as to reiterate the importance of hand hygiene in prevention and control of infections (North West Department of Health, 2014:1). Although there are many risk factors influencing aseptic technique during parenteral medication administration, there are policies and procedures in place that should be applied to prevent infections from spreading.

2.3.7 Medication's influence on asepsis

It could be argued that a medication itself has an impact on asepsis. It was found that 65% of medication errors included specific medications, with antibiotics the most indicated medications involved in medication errors and sedation and analgesic medications following (Esquè *et al.*, 2015:214). Mercaldi *et al.* (2013:958) argued that antibiotics can be both the treatment and cause of nosocomial bloodstream infections, while Murni *et al.* (2013:61) also warn against the irrational use of antibiotics.

The use of multi-dose heparin vials, which is contaminated through taking it to each patient and not preparing it in an aseptic environment, leads to the spread of infections like Hepatitis C (Centers for Disease Control and Prevention, 2008:875; Rao *et al.*, 2013:107). Multi-dose vials should be limited as it can be contaminated easily and the pathogens can be transferred to all patients using it (Dolan *et al.*, 2016:5720; King & Ogg, 2012:371). Rehan *et al.* (2012:179) agree, reporting a 100% contamination rate in the use of multi-dose vials in that the needle was kept in the vial top. Thus the risk increases with the use of multi-dose vials as the content thereof is directly exposed to the external environment through the dispensing device. The use of multi-dose vials while keeping a needle in the vial top has been observed in the public hospitals of South Africa.

More on multi-dose medications, Paparella (2011:565) reports that a contaminated flush solution spreads pathogens quickly through the whole ward, therefore prepacked flush syringes is recommended and if intravenous solution bags/bottles are used strict asepsis should be applied. The use of a syringe to store medication instead of keeping it in the vial is also a risk as it places the patient at unnecessary

risk of potential infections (Longuet *et al.*, 2016:3; Paparella & Mandrack, 2016:65). Although Beaney (2010:1570) states that medication should not be given 24 hours after preparation in order to prevent contamination and improve asepsis technique, Dolan *et al.* (2016:572) argue that when medications are not administered within one hour of preparation it will breach asepsis in the medication and Longuet *et al.* (2016:3) state that the time between preparation and administration should be kept to a minimum. For example if a vial, infusion bag or bottle with sterile fluid is punctured with a dispensing device (such as a needle) and the dispensing device is left in place to withdraw medication for multiple patients, the risk will be increased for microbial infections. All leftover parenteral medication must also be discarded to prevent contamination and infections (Dolan *et al.*, 2016:573). Lastly, having to work with a variety of medications produces a risk of asepsis breach (American Nurses' Association, 2007).

2.3.8 The need of asepsis during parenteral medication administration

Asepsis is defined as being free from living pathogenic micro-organisms (Brooker, 2010:149). Micro-organisms, generally bacteria and viruses, are the root of infections and the result thereof is local or systematic inflammation and damage (Nunkoo & Pickles, 2008:44). Bacteria are the leading source of infections causing 90% of infections while fungi, viruses, protozoans and mycobacteria, contribute less to these infections (Khan *et al.*, 2015:510).

The overall aim of infection prevention and control (and thus also asepsis) is the prevention of harmful infections (Nunkoo & Pickles, 2008:45). To prevent infection, the agent must be attacked, the host must be strengthened and the environment where preparation and administration of medication takes place must be changed and/or improved (Beaney, 2010:1570; Hart, 2007:46).

Two basic principles are applied to prevent infections, namely hand washing and sanitation to prevent the spread of infections (MacKay *et al.*, 2016:203). Hand hygiene still plays an important role in asepsis technique and if combined with other elementary infection control practices, it can effectively reduce contamination and prevent nosocomial infections (Hadaway, 2006:60; Hart, 2007:44; Ingram &

Murdoch, 2009:50). O'Grady *et al.* (2011:S3) confirm that hands can be washed with conventional soap and water or disinfected with an alcohol-based hand rub both are effective to eliminate micro-organisms that can cause infections. To effectively disinfect hands the WHO prescribed a specific hand wash technique, which consists of eight steps (WHO, 2006 99):

1. Apply enough of the disinfectant product to cover all the areas of the hands (wet beforehand if using water and soap);
2. Rub hands palm to palm;
3. Place right palm over left dorsum with interlaced fingers and rub the areas and vice versa;
4. Rub hands palm to palm with fingers interlaced;
5. Place back of fingers to opposing palms with fingers locked;
6. Rotational rubbing of each thumb clasped in the opposing palm;
7. With clasped fingers rub rotationally, forwards and backwards the opposing palm and vice versa; and
8. Allow hands to dry if using disinfectant hand spray or rinse and dry hands thoroughly if using water and soap.

Another strategy to prevent contamination and infection is the “My five moments for hand hygiene”. The goal of these moments is to help the health care workers to remember when hand hygiene is necessary to prevent contamination and the spread of infection (WHO, 2009:100). The five moments are (WHO, 2009:112):

1. Before touching a patient: as the health care worker may have been in contact with a contaminated surface in the health care area;
2. Before aseptic procedures: hands of the health care worker could be contaminated by any surface in the health care setting and pathogens can be transmitted to a critical site with an infection risk for the patient;
3. After body fluid exposure risk from the patient;
4. After touching a patient; and

5. After touching patient surroundings.

Aseptic techniques can be seen as the specific procedures that are implemented under carefully controlled conditions with the aim to minimise contamination, through preventing the transfer of pathogens from one person to another and/or from the environment to a person (Dolan *et al*, 2016:753; Hart, 2007:43). When aseptic techniques are applied the risk of infection is lowered (O'Grady *et al.*, 2011:S9). Nunkoo and Pickles (2008:45) advocate that the principles of aseptic technique are:

- Before any procedure disinfect hands and use gloves, sterile if appropriate;
- Wear a disposable apron to protect clothing;
- Minimise exposure of any susceptible site;
- All materials that are used must be sterile and the sterile packs must be checked for signs of damage;
- Single-use items must not be reused and non-sterile items must not be mixed in the sterile field; and
- The activity in the immediate surrounding area must be reduced to limit distractions and interruptions.

Medication preparation and administration are the last line of defence before medication errors reach the patient, most errors also occur in these two phases. Since the parenteral route bypasses all the natural barriers of the body making it the most hazardous route of administration the importance of using aseptic techniques is stressed (Ingram & Murdoch, 2009:51). For this reason it is imperative that aseptic techniques be applied when preparing and administering parenteral medication so as to prevent contamination and possible infection (Beaney, 2010:1570; Fahimi *et al.*, 2008:115; MacKay *et al.*, 2016:203).

The ultimate aim of asepsis-related practices is to ensure patient safety. Strategies were developed to pursue the goal of patient safety as there is a need to improve the quality of health care (Arries, 2014:3). In South Africa patient safety is of great concern and therefore policies are in place on national, provincial, district and facility levels (Department of Health, 2007:27) to improve and set a minimum standard for effective prevention and control of infections. To attain the objectives of prevention

and control of infections under the wider aim of patient safety, the emphasis should be on asepsis (Department of Health, 2007:6).

2.4 Conclusion

A review of literature was done as part of the second step of the research process to determine what is known regarding the prevalence of asepsis-related deviations from safe practice during parenteral medication administration, which poses a great threat to patient safety. The known research on all the domains of the patient safety model (Emanuel *et al.*, 2008:15) namely those who work in health care, those who receive health care and the health care system were investigated and discussed. In the next chapter, the incidence of harm measured by means of structured observations will be presented.

CHAPTER 3 STRUCTURED OBSERVATION METHODS AND RESULTS

3.1 Introduction

Patient safety is a crucial element of quality health care within all health care settings (WHO, 2013:1) and in this study we focused on one of the threats to patient safety called asepsis-related deviations from safe practice during parenteral medication administration. Emanuel *et al.* (2008:15) proposed that the health care system can be divided into four domains, which interact with each other and the environment. These four domains are (1) those who receive health care or have a stake in the availability, (2) the infrastructure or the systems for therapeutic interventions thereof, (3) those who work in the health care and (4) the methods for feedback and continuous improvement (Emanuel *et al.*, 2008:15). The patient safety model as discussed in chapter one and two, can vary dramatically in terms of setting when applied (Emanuel *et al.*, 2008:16) and in this study the model was applied to a rural setting within South Africa, where the prevalence of asepsis-related deviations from safe practice in parenteral medication administration was observed within each relevant domain, primarily in the domain of those working in health care, with some systems influences on asepsis taken into account.

When asepsis is breached during parenteral medication administration it can lead to adverse events like infections, thrombus formation and severe hypersensitivity reactions (Berman *et al.*, 2016:806). There is an abundance of research which elaborated on the various adverse events of wrongful parenteral medication administration, with the primary cause being a breach in asepsis during parenteral medication administration (Beaney, 2010:1570; Blignaut, 2015:160-161; Bruce & Wong, 2001:855; Cheragi *et al.*, 2013:230; Dolan *et al.*, 2016:573; Fahimi *et al.*, 2008:113; Hadaway, 2006:59; Hart, 2007:46; Ingram & Murdoch, 2009:51; Khan *et al.*, 2015:513; Kim & Bates, 2013:594; MacKay *et al.*, 2016:203; Mercaldi *et al.*, 2013:961; Nunkoo & Pickles, 2008:45; O'Grady *et al.*, 2011:S8; Pugliese *et al.*, 2010:794; Rao *et al.*, 2013:109; Rehan *et al.*, 2012:178; Rosenthal, 2006:79; Thompson *et al.*, 2016:377-378; Volpe *et al.*, 2014:555; Yihong *et al.*, 2016:893).

According to the WHO (2015:1) the measuring of patient harm is crucial for raising awareness and increasing knowledge to improve the safety of health care and reduce mentioned harm. Harm was measured through determining the incidence of asepsis-related deviations from safe practice during parenteral medication administration. Internationally the incidence of parenteral medication administration errors was found to be fairly high. It was found that 28.9% of medication administrators did not wash their hands before administering medication and specifically to parenteral medication administration, 20,1% of injection sites were not disinfected - these are two aseptic deviations from safe practice recorded as the greatest incidence by Kim and Bates (2013:590). A study done within an urban setting of South Africa found that only 12% of medication administrators washed their hands for long enough and 94% of parenteral medication administrators did not wash all the areas of the hands (Blignaut, 2015:159). Asepsis was seen as the leading error in South Africa out of all the medication administration errors (Blignaut, 2015:160). These statistics, however, are drawn from practices in a developed country and from practices in an urban area of a developing country. As extra resource restraints impact negatively on asepsis practices in rural areas (Scherbaum *et al.*, 2014:2), the aim of this study was to determine the incidence of asepsis-related deviations from safe practice during parenteral medication administration in the medical and surgical wards of the level 2 public hospitals in the North West Province of South Africa, a more rural setting.

3.2 Method

3.2.1 Data-collection method

Data collection was done through structured observation. The direct observational method was used so that the data would not be reliant on the participants' honesty to uncover actions of which the participants themselves might not be aware (Neale, 2009:228). The Hawthorne effect was minimised through giving the medication administrator three medication administrations opportunities to become familiar with the observation prior to starting the recorded observations. Observational collection of data can be experimental or non-experimental (Evans & Rooney, 2011:217). In

this study the investigator did not control the independent variable namely the asepsis-related deviations from safe practice thus classifying the observation as non-experimental. Naturalistic observation was implemented in this study as it has more validity than most other research methods since natural and true behaviours are observed (Jackson, 2012:81). The researcher was as unobtrusive and inconspicuous as possible, while unresponsively recording so as not to alter the behaviour which occurred generally in the natural setting. These are the prerequisites for observation to be categorised as naturalistic (Gravetter & Forzano, 2012:369)

The natural setting was the medical and surgical units during medication administration rounds, where observations were done. The specific behaviour recorded was the application of aseptic techniques during parenteral medication administrations with specific focus on the occurrence of deviations from safe practice. The primary concern within naturalistic studies is the influence of the researcher's expectations in terms of the outcome of the study (Jackson, 2012:83) as researchers might pay more attention to the behaviours that support their hypotheses while perhaps ignoring behaviours that do not support expectations. In this study, to mitigate this risk of bias, the researcher chose to use a standardised checklist which ensured a measure of objectivity to record all positive and negative behaviours during the administration of parenteral medication.

The frequency method as suggested by Gravetter and Forzano (2012:366) was used to quantify data. The frequency method consists of counting the occurrences of each specific behaviour during a fixed time period of observation (Gravetter & Forzano, 2012:366). In this study all the instances of asepsis-related deviations from safe practice were counted and commented on. Further notes on staffing levels, medication administrator qualification and bed occupancy were added to this checklist to later analyse the influence of these health care workers and system influences on aseptic practice.

3.2.2 Population and sampling

The population (N) used in this study were professional and enrolled nurses working in the medical and surgical wards of the level 2 public hospitals in the North West Province of South Africa. For the structured observation, the guideline as proposed by Kim and Bates (2013:590) of a minimum of 300 cases of medication administration incidences was used. The sample (n) was chosen from the population with an all-inclusive sampling method regarding level 2 hospitals in this province to ensure a representative and sufficient sample. In all three the level 2 hospitals, two surgical and two medical wards per hospital were randomly selected by the fish bowl method. None of the sampled ward managers denied access to their wards hence no further ward sampling was indicated. 25 observations were completed in each ward (n = 5 participants per ward, thus n = 60 participants in total). A maximum of five observations was performed on each participant to reach the 300 observational goal.

3.2.3 Instruments

3.2.3.1 Checklist for observing asepsis-related deviations from safe practice during parenteral medication administration

A checklist was used as developed by Kim and Bates (2013:590). Six questions regarding adherence to basic infection control principles were used during the structured observation of the parenteral administration of medication and a space for indicating the rank of the medication administrator was added.

The checklist was used in previous medication administration error studies with peer-reviewed publications. The validity of the instrument was fully discussed in chapter one of this dissertation (section 1.7).

3.2.3.2 Demographics sheet

A demographic sheet was compiled by the researcher in consultation with the supervisors, to gather information regarding the wards where observations were conducted. The information required for this sheet included the number of wards and

the number of beds in the observed wards, occupancies on the day of observation and the number of staff (registered nurses, and enrolled nurses) on the day of observation from the observed unit.

3.2.4 Data realisation

As planned and discussed in section 1.7 the recruitment and data-collection procedures were completed. Permission to do research in each ward was sought from the unit managers, and then the unit managers were informed about the research and given the informed consent letter. The data-collection process was explained and the unit managers were asked to act as mediators in the recruitment process. All the unit managers agreed and distributed the informed consent letters among their staff.

All sampled medication administrators gave informed consent to be observed. The participants' understanding and consent to participate in the research study were verbally confirmed by the researcher before starting with the observations and again the participant was reassured about the confidentiality of the results and their right to withdraw from the study at any time. No medication administrators withdrew from the study at any point.

The observations were performed by only one observer namely the researcher, so as to ensure the validity and credibility of the observation. After the data collection had been completed according to the planned number of parenteral medication administration observations, the observer made sure the participants were not feeling anxious or exploited and again reassured them about the confidentiality of the results and thanked them for participating.

3.2.5 Data analysis

Statistical analyses are indicated for quantitative studies (Brink *et al.*, 2013:178). However, keeping in mind the theoretical framework used as scaffold for this study, the context of the study should not be disregarded (Emanuel *et al.*, 2008:15). For this reason, purely statistical reporting of results was not deemed sufficient and the

researcher addressed the need for data contextualisation by providing a narrative observer's reflection.

Statistical analysis followed, presenting frequencies of asepsis-related deviations from safe care. Descriptive statistics, specifically frequency distribution of data, was presented in the form of pie graphs and histograms. Bruce *et al.* (2008:49) stated that to present the frequency distribution of data a histogram can be used. Frequencies of asepsis-related deviations in medical wards, surgical wards and these wards' totals were presented in histograms.

The relationships between asepsis-related deviations from safe practice, the hospital wards (medical and surgical) and the rank of the medication administrator were investigated by using effect sizes to demonstrate practical significance derived from Cramer's Vs, while statistical significance was indicated by p values. Cramer's V's is an inferential statistical test that is used to test a directional hypothesis (Van den Berg, 2016). In this study, for example, Cramer's V's were used to test whether a certain asepsis-related deviation occurred more in medical wards, or more in surgical wards.

The effect sizes (practical significance) between asepsis-related deviations from safe practice, the hospital wards (medical and surgical) and the rank of the medication administrator (professional and enrolled nurses) were determined by calculating the Cramer's Vs. Furthermore SAS software was used to determine correlations between asepsis-related deviations from safe practice and ordinal variables including occupancy, staffing level and patient to nurse ratio. An effect size is interpreted as small if it is 0.10; medium if it is 0.3 and large if it is 0.5. An effect size is considered practically significant if it is greater or equal than 0.5 (Ellis & Steyn, 2003:52). How these variables were calculated is described in table 3.1.

Table 3.1: Calculation of variables

Formula	Rationale
$\text{Occupancy} = \frac{\text{number of patients}}{\text{number of beds}} \times 100$	This represents the number of patients within relation to the ward capacity (Hurst, 2002:3).
$\text{Staffing level} = \frac{\text{number of staff present}}{\text{number of staff required}} \times 100$	This presents the number of patients per nurse. According to international standards there should be 1 professional nurse for every 5-6 patients Lippincott Solutions (2016:1).
$\text{Patient to nurse ratio} = \frac{\text{number of patients}}{\text{number of beds}} \times 100$	This is done to calculate the number of patients for each nurse, is responsible for.

P values are used to measure differences between groups as a result of chance (Whitley & Ball, 2003:223). Small values (close to 0) imply that the differences are not a result of chance. A p value close to 1 indicates no difference between groups other than difference due to random variation (Whitley & Ball, 2003:223). Statistical significance is derived when the p values are smaller or equal to 0.05 (Ellis & Steyn, 2003:51).

3.3 Results

The observer's reflection will be discussed, followed by the unit demographics and descriptive results for asepsis-related deviations from safe practice during parenteral medication administration. Associations between asepsis-related deviations from safe practice and nominal data (calculated by Cramer's Vs) precede correlations (calculated by regression analysis).

3.3.1 Observer's reflection

Since the start of the observational period, I realised that if I only provided the statistical results of my observations, I would not offer a realistic account of the empirical world of the medication administrator and the context in which the deviations occurred. Therefore, I felt compelled to create the background through an observational reflection.

The delicate/fragile state of the staff was highlighted during the period of collecting data. Most of the professional nurses were drained and had an apathetic way of moving about and completing tasks in the ward. Severe understaffing was present in every ward and most of the participants were over-worked and had to manage with large amounts of stress and responsibility.

The burdensome workload not only affected the staff's attitude, but also impacted on the ward routine. It was observed that in 2/3 of all the wards medication rounds began late as the medication administrators had to help with basic care of the patients before medication could be administered. In the wards where only one professional nurse was present, he/she had to either administer parenteral medication early as to be available for the doctor's rounds or vice-versa.

To add to these divided priorities, the medication administrators could not only focus on the administration of medications as interruptions came frequently. Examples of this are doctors needing assistance or a patient having to be prepared for surgery urgently. In a few instances the professional nurse had to administer parenteral medication and do the doctors' rounds at the same time which led to parenteral medication administrations being done hastily and deviations from safe practice such as not disinfecting hands or not disinfecting vials before use resulted. More frequently the professional nurse was responsible for both parenteral and oral medication administration, which is time-consuming and led to the medication administrator making improvisations like preparing parenteral medications beforehand without applying aseptic techniques or adequate hand hygiene.

At times the professional nurse simply could not attend to all his or her responsibilities. In observing the forced delegation of workload to enrolled nurses, it became clear that they were mostly allocated to administer oral medication. When there are no professional nurses available to administer the parenteral medication, the enrolled nurses have to administer parenteral medication. As the enrolled nurses are not administering the parenteral medication frequently, they tend to pay less attention to aseptic technique either because it is time-consuming and they have a lot of work to do, or because they did not receive adequate training with regards to the importance of asepsis during parenteral medication administration, as per scope prescriptions, enrolled nurses are not supposed to be responsible for medication administration via the parenteral route.

Human resources and time were not the only resource restrictions. Medication, supplies and equipment being out of stock resulted in staff not being able to provide efficient health care as required by the policies and procedures. During the observation period it was noticed that resource constraints added greatly to staff members' job-stress. Compromises on best practices were noted: needles were used for preparing medication for more than one patient or a 200ml Normal Saline intravenous bag was used as diluent for multiple medication administrations instead of the 10ml sterile water for injection. In one of the hospitals the normal saline stock was so limited that the medication administrators were forced to mix two to three different types of medication in one 50ml normal saline bag as they could not spare more than one of these bags per patient. On another occasion the disinfectant hand spray was out of stock, and although more alcohol swabs were used to ensure medication vials, intravenous ports and injection sites were disinfected, hands were not. Exacerbated by the time constraints, hands were left not disinfected, as washing hands between patients meant more nursing tasks were left undone.

On one of the observation days it was noticed that the medical wards, surgical wards and the theatre had a water interruption from 10:00 – 16:00 which made it more difficult for staff to do their duties. Only some of the wards had limited amounts of disinfectant hand spray which made it difficult to apply adequate aseptic techniques. Sterile water as well as normal saline intravenous bags were limited to only using as

prescribed and not as a method of improvising to wash hands. Another way medication administrators improvised was by wearing gloves when disinfecting hands was not possible. On a few occasions gloves were also limited and there were only big gloves available which did not fit the medication administrators and were used only when unavoidable, such as to change wound dressings.

What I concluded during the observation period is that there is a major system problem. The system places a great burden on the health care professionals, who are trying to make ends meet through improvising most of the time at the cost of their own work ethic and job satisfaction. The most severe problem observed is the major staff shortages and secondly the supplies that are out of stock. This leads to an overburdened and burnt-out nursing population struggling to provide safe quality health care to their patients. With results now contextualised, statistical data will be discussed.

3.3.2 Ward demographics

The ward demographics consists of the total bed count, beds occupied, enrolled and professional nurses required for the observed shift and the number of enrolled and professional nurses available. As there was more than one observation opportunity for each of the sampled wards the average of all observation opportunities utilized within a specific ward was generated and presented in table 3.2. According to Lippincott Solutions (2016:1) the professional nurse to patients ratio should be 1:5 or 1:6, while Uys and Klopper (2013:2) explained that, in the South African context, the professional and enrolled nurses divide the workload of administering medication 50/50. Thus the data was interpreted accordingly, assuming the international nurse to patient ratio of 1:6 to be interpreted as 1 professional nurse: 1 enrolled nurse: 12 patients.

Table 3.2: Demographics per ward.

Medical wards							
Hospital	A		B		C		Mean
Ward	1	2	1	2	1	2	
Beds	36	36	31	31	20	31	30.83
Occupancy	34	27	28	31	18	29	27.83
% Occupancy	94.44	75.00	90.32	100.00	90.00	93.55	
Total staff required	6	5	5	5	3	5	4.83
Professional	2	2	2	2	2	2	2
Enrolled	1	1	1	0	1	1	0.83
Total staff	3	3	3	2.0	3	3	2.83
% of required staff available	50.00	60.00	60.00	40.00	100.00	60.00	

Surgical wards							
Hospital	A		B		C		Mean
Ward	1	2	1	2	1	2	
Beds	35	33	24	33	31	27	30.50
Occupancy	32	30	18	27	29	25	26.83
% Occupancy	91.43	90.91	75.00	81.82	93.55	92.59	
Total staff required	5	5	3	5	5	4	4.50
Professional	2	2	2	2	2	2	2
Enrolled	1	1	0	0	2	1	0.83
Total staff	3	3	2	2	4	3	2.83
% of required staff available	60.00	60.00	66.67	40.00	80.00	75.00	

As seen in the above table, the average occupancy was higher in medical wards than in surgical wards. In one ward of hospital A and one ward of hospital C there was a higher occupancy in the surgical wards than the medical wards. The percentage of required staff available was overall higher in surgical wards with the exception of one medical ward in hospital C that had a higher percentage of required staff available than surgical. Figure 3.1 presents the occupancy in relation to percentage of required staff available. The percentage required staff available was calculated for the specific occupancy on the day of observations. For example for the first observation, occupancy was 33 out of 36 beds (91.67%), required staff at 6 patients per professional/enrolled nurse was 6 (33/6) and percentage of required staff available was 3 out of 6 (50.00%). Thus, even when the occupancy and the percentage of required staff available were the same, it did not necessarily imply that there were a sufficient number of staff on the day of observation with regards to the

occupancy of the ward, as percentage of required staff should have been at 100% throughout.

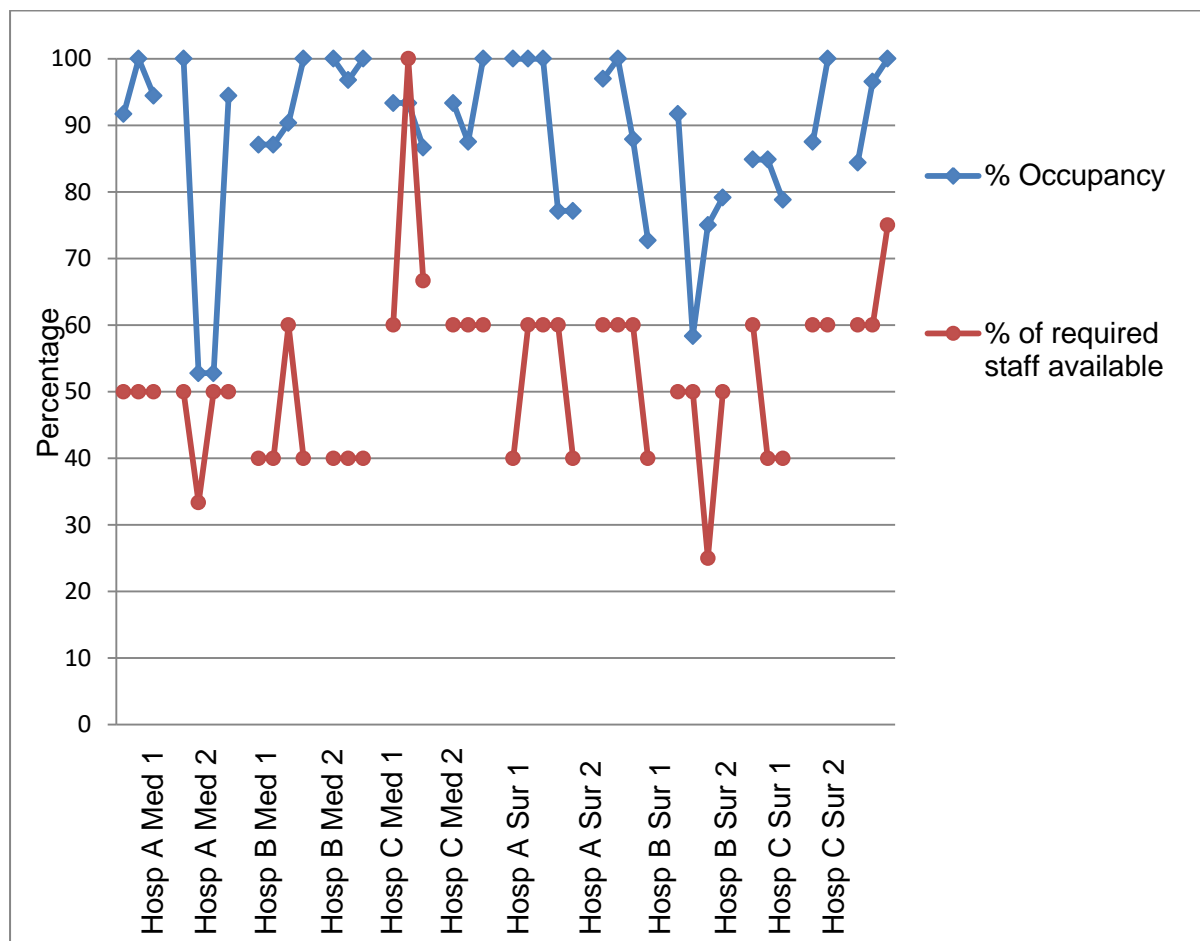


Figure 3.1: Occupancy versus percentage of required staff available.

In the above figure, it is indicated that for Hospital A (where the observations were recorded) the following wards were involved - Med 1 and Med 2 indicate the two different medical wards within the hospital and Sur 1 and 2 represent the two different surgical wards within the hospital. There is a clear distinction noted between occupancy and the percentage of required staff available. There was only one observation during which there were enough staff present for the number of patients in the ward (100% of staff required for the related occupancy).

3.3.3 Descriptive statistics

During the data-collection period 25 observations were conducted per ward in the three level 2 public hospitals of the North West Province of South Africa, leading to a

total of 300 observations. The following variables were observed: hands disinfected before administering medication, hands disinfected for 15-30 seconds, areas of hands not disinfected, the ports of IV fluid bottles, bags and vials disinfected before use, sterility of needles and IV sets maintained and disinfected injection site before administering drugs. The deviation related to the area of washing (palm, wrist, back of hands, between fingers and all fingernails) were present in 287 out of the 300 observations (95.67%) and therefore also discussed separately to provide further detail on problem areas of the hands not disinfected. Altogether there were 1033 asepsis-related deviations from safe practice out of 1698 opportunities for these deviations (60.84%). Figure 3.2 presents the frequency distribution of respective asepsis-related deviations from safe practice in relation to the total of asepsis-related deviations from safe practice found.

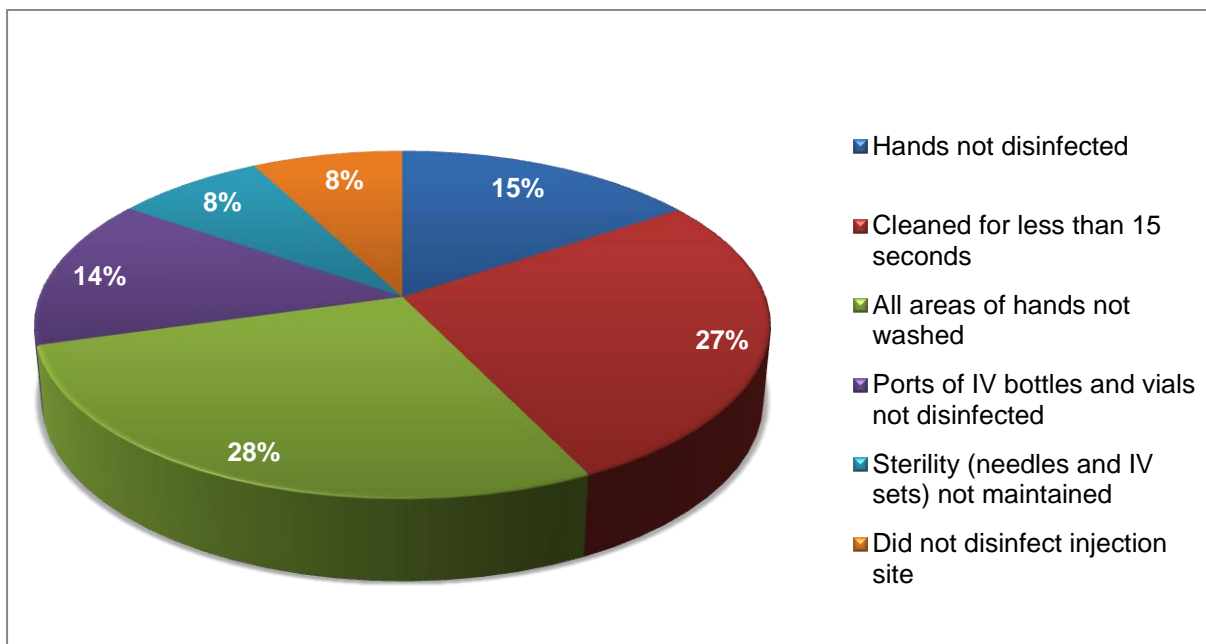


Figure 3.2: Asepsis-related deviations from safe practice.

It is seen in the above figure that all areas of the hands not cleaned were the most prominent deviation from safe practice during parenteral medication administration (28%). Not disinfecting hands for at least 15 seconds in both medical and surgical wards (27%) was the second most prevalent and this was followed by the medication administrator not disinfecting their hands at all (15%).

Table 3.3: Incidence of asepsis errors during parenteral medication administration.

Action not taken	Medical			Surgical			Total		
	Count	n	%	Count	n	%	Count	n	%
Hands not disinfected	150	78	52,00	150	83	55,33	300	161	53,67
Cleaned for less than 15 seconds	150	145	96,67	150	136	90,67	300	281	93,67
All areas of hands not washed	150	146	97,33	150	141	94,00	300	287	95,67
Ports of IV bottles and vials not disinfected	113	77	68,14	120	68	56,67	233	145	62,23
Sterility (needles and IV sets) not maintained	150	42	28,00	149	37	24,83	299	79	26,42
Did not disinfect injection site	131	40	30,53	135	40	29,63	266	80	30,08

In the medical wards there were 528 asepsis-related deviations from safe practice out of 844 opportunities for these deviations (62.56%) and in the surgical wards there were 505 asepsis-related deviations from safe practice out of 854 opportunities (59.13%). Indicated in the above table is the incidence of asepsis-related errors during parenteral medication administration within medical and surgical wards of the level 2 public hospitals in the North West Province of South Africa. All the variables were not measured during each observation period. For example when Enoxaparin sodium 40mg was given the item “IV bottles and vials not disinfected” was not measured during the observation and when a Paracetamol 1g/100ml IV bottle was given the variable “not disinfecting the injection site” was not measured during the observation. Therefore the actual count of observations done on each variable is given in the table.

The most prevalent deviation from safe practice for both medical and surgical wards was all areas of hands not disinfected (n = 287; 95.67%). The second most prevalent deviation from safe practice was not disinfecting hands for at least 15 seconds (n = 281; 93.67%). Third on the list (n = 145; 62.23%) was ports of IV bottles and vials not disinfected. Presented in Fig 3.3 is the difference between the prevalence of asepsis-related deviations from safe practice in medical and surgical wards of the level 2 public hospitals in the North West Province of South Africa.

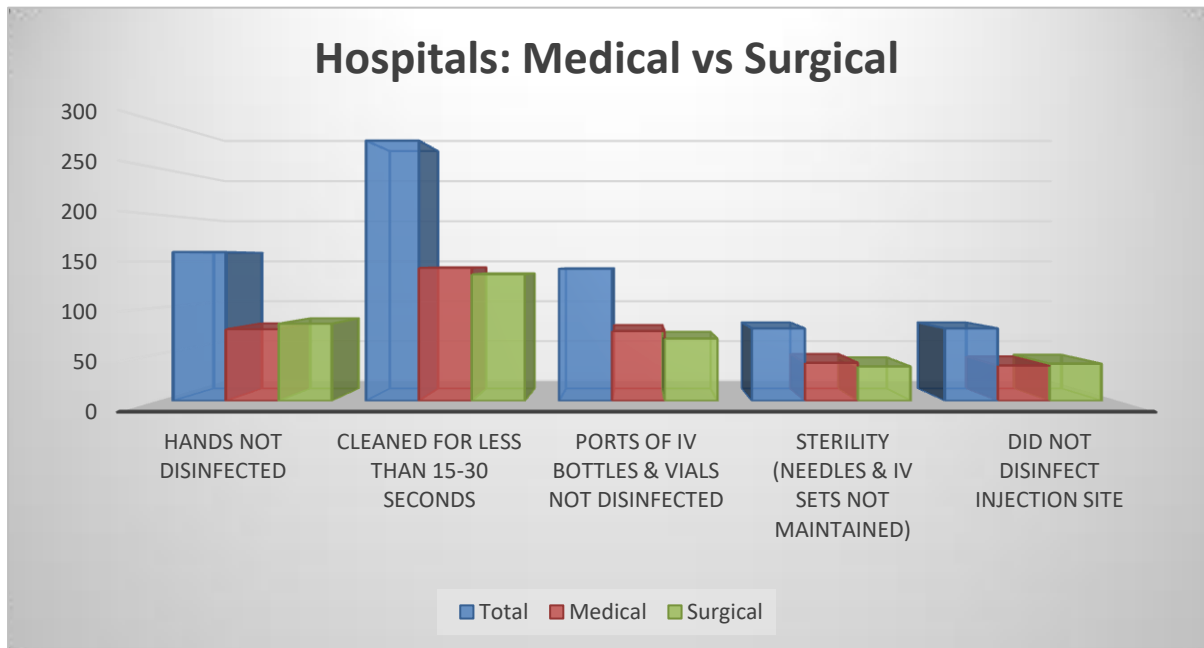


Figure 3.3: Incidence of asepsis-related deviations from safe practice during parenteral medication administration.

Overall the medical wards (n = 382) have more asepsis-related deviations from safe practice than the surgical wards (n = 364) with the exception of the surgical wards having slightly more deviations (n = 5) in the area of not disinfecting hands. To elaborate on the asepsis-related deviations from safe practice observed at the highest incidence, figure 3.4 presents the frequency distribution to clarify which areas of the hands were most often left not disinfected prior to parenteral medication administration with relation to the total of 1160 areas of hands observed to not being washed.

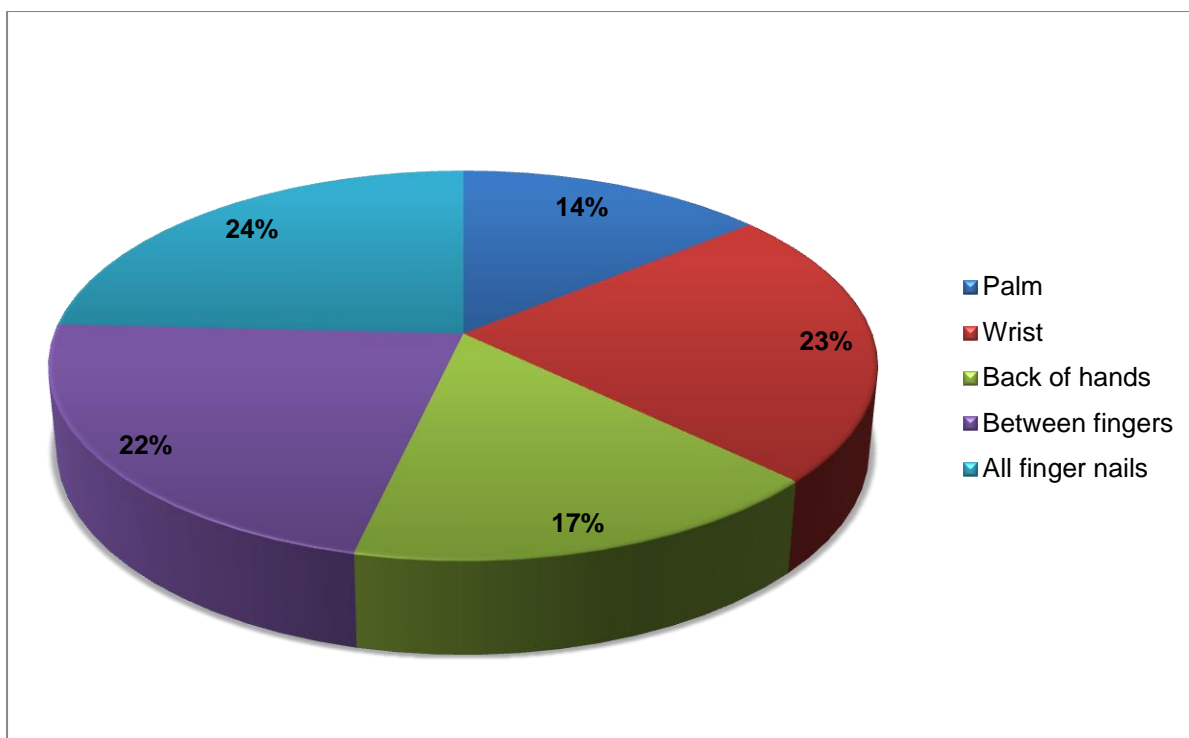


Figure 3.4: Areas of hands not disinfected.

As seen in the above-mentioned figure not disinfecting the fingernails is the area that is most often missed (24%). The second most often missed is the wrists (23%) and the third most missed area was between the fingers (22%). Table 3.4 presents the incidence of different areas of hands not disinfected by the medication administrator.

Table 3.4: Incidence of areas of hands not disinfected

Action not taken	Medical		Surgical		Total	
	n	%	n	%	n	%
		150	100	150	100	300
Palm	78	52,00	85	56,67	163	54,33
Wrist	137	91,33	131	87,33	268	89,33
Back of hands	94	62,67	97	64,67	191	63,67
Between fingers	125	83,33	132	88,00	257	85,67
All fingernails	142	94,67	139	92,67	281	93,67

As mentioned earlier the fingernails were most often not disinfected in both medical and surgical wards (n = 281). The second most prevalent area not disinfected in the medical wards was not disinfecting the wrist area (n = 137) and in the surgical wards it was the area between the fingers (n = 132). The third most overlooked area for the

medical ward is the area between the fingers (n = 125) and for surgical wards it is the wrist area (n = 131). In these areas of disinfecting the hands surgical wards have more errors (n = 584) than the medical wards (n = 576). Figure 3.5 provides an overview of the observed areas of hands not disinfected in both medical and surgical wards.

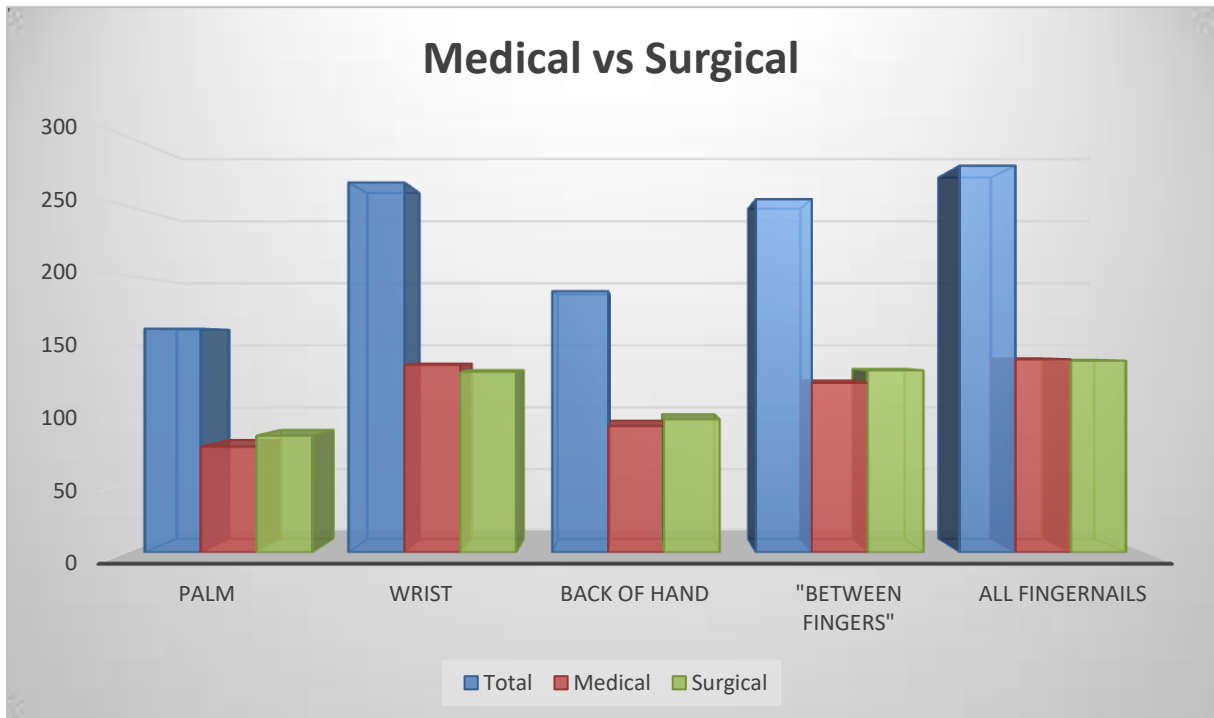


Figure 3.5: Incidence of areas of hands not disinfected

3.4 Inferential statistics

3.4.1 Associations of asepsis-related deviations during parenteral medication administration with nominal variables

Associations between asepsis-related deviations from safe practice and different hospitals, hospital wards, and rank of the medication administrator were explored by means of Cramer's V's. No associations between specific hospitals (A, B or C) with asepsis-related deviations from safe practice could be found. However, some associations between hospital wards (medical or surgical) and asepsis-related deviations from safe practice were noted. These associations are presented in table 3.5.

Table 3.5: Associations of hospital wards with asepsis-related deviations.

		Medical		Surgical		Total		Cramer's V	p value
		n	%	n	%	n	%		
Action not taken									
Hands not disinfected		78	52,00	83	55,33	161	53,67	0,37	0,000
Cleaned for less than 15 seconds		145	96,67	136	90,67	281	93,67	0,58	0,000
Areas not washed / disinfected	Palm	78	52,00	85	56,67	163	54,33	0,38	0,000
	Wrist	137	91,33	131	87,33	268	89,33	0,33	0,001
	Back of hands	94	62,67	97	64,67	191	63,67	0,34	0,000
	Between fingers	125	83,33	132	88,00	257	85,67	0,35	0,000
	All fingernails	142	94,67	139	92,67	281	93,7	0,28	0,015
IV bottles and vials not disinfected		77	68,14	68	56,67	145	62,23	0,42	0,000
Sterility (needles & IV sets not maintained)		42	28,00	37	24,83	79	26,42	0,21	0,263
Did not disinfect injection site		40	30,53	40	29,63	80	30,08	0,45	0,000

Statistically significant associations between ward type and all asepsis-related deviations from safe practice except for “sterility of needles and IV sets not maintained” were determined with p-values below 0.02. However, only one of these associations showed practical significance, namely “hands cleaned for less than 15 seconds” (Cramer’s V = 0.58). Medication administrators in medical wards less often cleaned their hands for an adequate time period (Medical wards’ n = 145; 96.67% and Surgical wards’ n = 136: 90.67%).

Statistically significant associations with large effect sizes related to ward type being medical or surgical included the following:

- IV bottles and vials not being disinfected (Cramer’s V = 0.42). Again medical wards were implicated for more of these deviations at n = 77 (68.14%) versus surgical wards’ n = 68 (56.67%); and
- Injection site not being disinfected (Cramer’s V = 0.45). However, the difference in wards varied between hospitals as the total of both medical and surgical wards with regards to this deviation was 40 (30.53%). This association is thus non-directional.

Statistically significant associations with medium effect sizes related to ward type (medical or surgical), included these asepsis-related deviations from safe practice:

- Hands not infected prior to parenteral medication administration (Cramer's $V = 0.37$). Here, surgical staff less often disinfected their hands than medical staff ($n = 83$; 55.33% and $n = 78$; 52.00% respectively); and
- All areas of the hands not being washed (Cramer's V s ranging from 0.28 to 0.38 for fingernails, between fingers, back of hands, wrists and palms). Medical wards' staff more often lapsed in cleaning their wrists ($n = 137$; 91.33%) and fingernails ($n = 142$; 94.67%) than surgical staff did ($n = 131$; 87.33% for wrists not washed and $n = 139$; 92.67% for nails not cleaned). On the other hand, surgical staff tended to pay less attention to cleaning the palms of their hands ($n = 85$; 56.67%); the back of their hands ($n = 97$; 64.67%); and between their fingers ($n = 132$; 88.00%) than medical staff did ($n = 78$; 52.00% for palms washed; $n = 94$; 62.67% for back of hands washed; and $n = 125$; 83.33% for washed between fingers). As the association showed medical staff to wash parts of their hands better while surgical staff washed other parts of their hands more thoroughly, the overall association between all areas of hands not being washed and ward type was seen as non-directional, not concluding that either ward type's staff were more thorough than the other in cleaning all the sections of their hands.

Although not statistically significant, a medium effect was noted for the association between ward type and sterility of needles and IV sets not being maintained, with a Cramer's V of 0.21. Medical staff were implicated more often for this deviation ($n = 42$; 28.00%) than surgical staff ($n = 37$; 24.83%). No associations between asepsis-related deviations from safe practice and rank of the medication administrator were observed.

3.4.2 Correlations between asepsis-related deviations from safe practice and ordinal variables

Correlations were drawn by means of Regression Analysis on the Statistical Analysis Software (SAS) programme between asepsis-related deviations from safe practice in parenteral medication administration and ordinal variables. These variables included occupancy, patient to nurse ratio and staffing level. A positive correlation indicated that the ordinal variables led to an increase in asepsis-related deviations from safe care, while a negative correlation indicated that the ordinal variable led to a decrease in these deviations. Following this, positive correlations revealed causative variables in asepsis lapses while negative correlations revealed mitigating variables. Only three correlations were detected:

- Sterility of needles and IV sets not maintained and percentage occupancy had a small negative correlation ($r = -0.09$) that was statistically significant ($p = 0.034$). This correlation implies that an increase in the percentage of occupancy causes a decrease in lapses of maintaining sterility of needles and IV sets, thus in this sense occupancy had a mitigating effect on asepsis practices;
- A small positive correlation ($r = 0.13$) was found between hands not disinfected and percentage of required staff available. The p value ($p = 0.052$) indicates a borderline statistical significance. This might indicate that an increase in staff leads to a decrease in hand hygiene practices; and
- Palms not disinfected and percentage required staff has a positive correlation ($r = 0.12$) with a statistically significant p value at the tenth percentile ($p = 0.074$). Related to the previous correlation, an increase in staff leads to a decrease in hand hygiene (i.e. an increase in aseptic related deviations from safe care), this time specifically related to washing of the palms of the hands.

All three of these correlations are counter-intuitive. However, taking into account the observer's reflection, a possible explanation for these findings is that the more despondent staff are will lead to a decrease in staff morale, which could negatively impact a positive safety culture (Pournamdar & Zare, 2016:12389).

3.5 Discussion

Arries (2014:3) stated that health care systems face challenges internationally with regards to quality of care, lack of human resources, patient safety and rising morale distress amongst nurses. In the North West Province of South Africa these identical challenges were observed as the level 2 public hospitals are severely understaffed with a heavy workload and a lack of resources which made it difficult to provide patients with safe and quality care. Valentin *et al.* (2009:143) reported that 32% of parenteral medication errors had workload, stress and fatigue as contributing factors. Cheragi *et al.* (2013:230), Ehsani *et al.* (2013:3-4) and Sorrentino and Alegiani (2012:92) agree that fatigue contributes to parenteral medication administration errors. During the data-collection period fatigue was noticed as all the wards only had an average of 52% of the required staff available.

Under-staffing as seen amongst the professional and enrolled nurses in the level 2 public hospitals of the North West Province is not a new problem. Alp *et al.* (2011:36) stated that under-staffing is one of the major problems in limited resource countries and Ehsani *et al.* (2013:4) added that a shortage of nurses is one of the major causes of medication administration errors. Hemingway *et al.* (2014:739), Smeulders *et al.* (2014:279) and Valentin *et al.* (2009:143) found that a higher patient to nurse ratio will contribute to parenteral medication errors. Treiber and Jones (2012:288) explained that this is because understaffing leads to a higher workload. In the level 2 public hospitals of the North West Province the average patient to nurse ratio was 11:1, which is 2 times more than what is proposed according to international standards (Lippincott Solutions, 2016:1). However, the link between under-staffing and asepsis-related deviations from safe practice was found to be inverse in this study, with more staff available leading to a decrease in hands (and specifically also the palms of the hand) not cleaned prior to parenteral medication administration. Although this correlation had a small effect size, consideration of this matter is merited. With due consideration of the context of the study as sketched in the observer's reflection, it is possible that the nurses' despondency and tardiness might have a peer-pressure effect, rubbing of on other staff. Despondency and lack of interest in the nursing profession in itself, although not measured in this study, have

been previously found to have a negative impact on the medication administration safety (Pournamdar & Zare, 2016:12389) and this therefore could lead to an increase in asepsis-related deviations from safe care. Also, this despondency could possibly explain why an increased number of staff might lead to a more negative work environment. A negative work environment has been proved to lead to a decrease in patient safety (Chiang *et al.*, 2016:363)

The average occupancy is also a predictor for parenteral medication administration errors as it was found in this study to correlate with maintaining sterility of needles and IV sets. The average occupancy observed in the level 2 public hospitals in the North West Province was 87.28% in the surgical wards and 90.08% in the medical wards. These findings are higher than the estimated occupancy of 80% for public hospitals in South Africa (WHO, 2005:1). The increased occupancy observed in medical wards could be due to the high burden of Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS). The Joint United Nations Programme on HIV/AIDS (UNAIDS: 2016) confirms that South Africa has the largest HIV epidemic in the world while the South African National AIDS Council (SANAC, 2017:8) added that the North West Province of South Africa specifically has a high burden of both HIV and TB. According to Statistics South Africa (2016:6) this is a growing problem. The total South African population who are HIV positive (12.7%) in 2015 (2.5%) was higher than it had been in 2014. Often most of these patients are admitted within the medical wards of the public hospitals of South Africa for AIDS-related opportunistic infections (Holmes *et al.*, 2003:652), thus increasing the average occupancy as is seen by the especially increasing medical ward occupancy.

Occupancy in this study presented as a mitigating factor in relation to the incidence of asepsis-related deviations from safe care, in contrast with findings of international literature that indicate an inverse relationship between occupancy and medication administration safety (Cottney & Innes, 2014:68; Oshikoya *et al.*, 2013:72; Vazin & Delfani, 2014:427). As occupancy increased the workload, the small negative correlation between occupancy and asepsis-related deviations from safe practice could be argued to be contingent on the same despondency theory discussed earlier. To explain, occupancy increases the being busy of staff, which decreases

time for interaction with other staff, thus mitigating the inhibiting effect of interaction between despondent nurses might have on the work climate. Again, the more positive the work environment is, the better for medication administration safety.

The type of ward is one of the predictors of asepsis-related deviations from safe care. Surgical wards have a higher rate of medication errors than medical wards according to Rentero *et al.* (2014:398) and Van Wagtendonk *et al.* (2010:1733). Although the medical wards in the level 2 public hospitals of the North West Province had more asepsis-related deviations in parenteral medication administration, it was only higher by 3.45%. Furthermore, associations explored in this study showed that medical wards were often implicated more for deviations from safe aseptic principles. These findings of this study disagree with those stated in international literature. However, these findings were supported by one study done in the Gauteng Province of South Africa which found that in the level 2 hospitals, surgical wards had a 3.6% higher prevalence for asepsis-related deviations during parenteral medication administration than medical wards (Blignaut, 2015:159), proving that there was almost no difference between the medical and surgical wards' asepsis-related deviations from safe practice.

Concluding the discussion on the impact of demographic variables on the incidence of asepsis-related deviations from safe practice, international studies found that the process of care and patient outcomes are directly impacted by staff qualifications (Aiken *et al.*, 2002:6; Paulson, 2004:307). Ehsani *et al.* (2013:4) reported that the qualification of the medication administrator has an influence specifically on parenteral medication administration errors. However, this study found no significant association between the rank of medication administrator and asepsis-related deviations from safe practice during parenteral medication administration. This can be due to the small sample of enrolled nurses (n = 7) versus professional nurses (n = 53), which does not effectively represent the entire population of enrolled nurses administering parenteral medications.

The most prevalent asepsis-related deviation from safe practice was all areas of the hands not being washed at (n = 287; 95.67%). Blignaut (2015:159) also found a high

prevalence (94%) of this deviation in the Gauteng Province. Since there are five hand areas to be disinfected the measurement of all these areas being washed was divided into five sub-observations in this study:

- In 54.33% (n = 163) of observations palms were not disinfected;
- 89.33% (n =268) of the participants' wrists were not disinfected;
- The backs of hands were not disinfected for 63.67% (n = 191) of the observations;
- Between the fingers was missed in 85.67% (n = 257) of the observations; and
- The last and most prevalent area not being disinfected was all fingernails at 93.67% (n = 281).

In this study the fingernails were mostly not disinfected (93.67%), and the second most missed area was the wrist area (89.33%) and the area between the fingers was the third most missed area (85.67%). Whereas Szilágyi *et al.* (2013:1) found in Hungary (a developed country) that the backs of hands were most often missed at 28%, not disinfecting the palm area of the hand was second most often at 18% and not disinfecting the fingertips was the least prevalent at 3.5%. This can be due to the vast difference in the context of the study.

One of the leading asepsis-related deviations from safe practice found was hands not cleaned for at least 15 seconds (n = 281; 93.67%). This correlates loosely with the 88% found by Blignaut (2015:159) in another province of South Africa. There is a vast difference between South Africa and developed countries like South Korea, as Kim and Bates (2013:594) found that only 3.4% of the parenteral medication administrators did not clean their hands for at least 15 seconds prior to medication administration. Due to the burdensome workload and severe understaffing, the staff administer medication hastily which could lead to asepsis-related deviations from safe practice like the above-mentioned.

The medication administrators did not disinfect 62.23% (n=145) of the ports of the IV bottles, bags and vials. These results are higher than international results. Thompson *et al.* (2016:378) found that 21% of supplies were not disinfected and Kim and Bates (2013:594) reported that 18% of supplies were not disinfected.

Comparative local results from the Gauteng Province, (Blignaut, 2015:159) reported a result similar to that of this study at 65% (n=101). Thompson *et al.* (2016:378) stated that lapses in aseptic technique can lead to vial contamination and the spread of infections. Although it was encouraging to see that single dose vials were used, most of the time one needle and/or syringe was used to prepare different medications for different patients as there was limited stock available, thus the risk of spreading infections was increased.

According to Gokhman *et al.* (2011:483) 66% of medication administration errors are caused by inappropriate aseptic techniques. In this study 53.67% of medication administrators did not disinfect their hands prior to administering parenteral medication, thus greatly contributing to these errors. Kim and Bates (2013:594) reported that only 3.4% of medication administrators they observed did not disinfect their hands, while Thompson *et al.* (2016:377-378) found that 37% of medication administrators did not disinfect their hands. Taking a middling stance, Blignaut (2015:159) reported that 21% of parenteral medication administrators in the Gauteng Province South Africa did not disinfect their hands. The high prevalence of this deviation from safe practice observed in the North West Province could be partially explained by the disinfectant hand spray being out of stock during several observations.

Continuing to the next deviation, namely not disinfecting the injection site, a 30.08% the North West Province had an extremely high incidence in comparison with the Gauteng Province at 7% (Blignaut, 2015:159). Internationally Kim and Bates (2013:594) reported a more comparable prevalence at 20.1%, whereas Rehan *et al.* (2012:178) found only 10% of parenteral medication administrators did not disinfect the injection site.

The last deviation being discussed is sterility of needles and IV sets not being maintained. In the North West Province this deviation was the least prevalent (n = 79; 26.42%). However, it was still higher than what had been found in the Gauteng Province (21%). This can possibly be caused by the administrators rushing for time as they have many parenteral medications to give.

The findings of this study show that compliance with aseptic techniques during parenteral medication administration differs vastly from one setting to the next. As Bertsche *et al.* (2015:1) stated that mistakes in hygiene are among the most significant deviations from safe practice during parenteral medication administration, and therefore interventions aimed at minimising lapses in aseptic practices should be tailored according to the specific setting. Tailoring of interventions for specific settings is also one of the prerequisites proposed by Emanuel *et al.* (2008:15) in the patient safety model for health care as was used as the theoretical framework for this study.

3.6 Conclusion

In this section of the study, harm was measured to increase awareness regarding asepsis-related deviations from safe practice. The incidences of asepsis-related deviations from safe practice during parenteral medication administration were determined. All the wards were subject to one or more asepsis-related deviation from safe practice during parenteral medication administration. The most prevalent deviations were all areas of the hands not being washed (95.67%) and not disinfecting hands for 15-30 seconds at 93.67%. Sterility of needles and IV sets maintained was the least prevalent at 26.42%. The factors that aggravated the asepsis-related deviations from safe practice during parenteral medication administration were percentage of required staff available while occupancy served as mitigating factor. The last chapter of the study will provide the evaluation of the study, recommendations and limitations.

CHAPTER 4 EVALUATION, RECOMMENDATIONS AND LIMITATIONS OF THE STUDY

4.1 Introduction

In chapter 3 the results of the study were analysed and discussed so as to address the main aim of the study: *To determine the prevalence of asepsis-related deviations from safe practice during parenteral medication administration within medical and surgical wards of level two public hospitals in the North West Province of South Africa.*

To accomplish this aim, specific objectives were set:

- To explore and describe the prevalence of asepsis-related deviations from safe practice during parenteral medication administration in medical and surgical wards of level two public hospitals in the North West Province of South Africa by means of direct observation; and
- To determine the relationship between asepsis-related deviations from safe practice and medication administrator qualifications, occupancy and staffing levels.

In this chapter the study is evaluated and the significance, recommendations for nursing practice, nursing education, research and policy and the limitations as resulted from the study are presented.

4.2 Evaluation of the study

The study was performed in fulfilment of the requirements for the degree Master of Nursing Science. The aim and objective of this study will subsequently be used to evaluate the study by determining if they realised.

The focus of the study was on asepsis-related deviations from safe practice during parenteral medication administration as a threat to patient safety. Research revealed that there are many contributing causes to asepsis-related parenteral medication

administrations lapses as well as an excess of recommendations on how to minimise asepsis-related deviations from safe practice during parenteral medication administration. Through this study the incidence of asepsis-related deviations from safe practice during parenteral medication administrations was determined in order to identify the problem within the level 2 public hospitals of the North West Province of South Africa.

In the literature review the four domains of the patient safety model for health care, namely health care workers, systems for therapeutic action, recipients of care and the methods for continuous improvement were incorporated as to present a background to the study in terms of incidence and harm following asepsis-related deviations from safe practice as well as possible influencing factors.

During the structured observation (Chapter 3), the incidence of asepsis-related deviations from safe practice during parenteral medication administration was determined in line with the first objective. Inferential statistics were employed to determine the influence of medication administrator qualifications, occupancy and staffing levels on the incidence of asepsis-related deviations from safe practice in parenteral medication administration, in accordance with the second objective.

The deviations from safe practice, namely not disinfecting hands before administering medication; not disinfecting hands for at least 15 seconds; not disinfecting palm, wrist, back of hands, between fingers and all fingernails; not disinfecting IV fluid bottles, bags and vials before use; not maintaining sterility of needles and IV sets; and not disinfecting the injection site before administering medication were quantified, thus objective one was attained. Hands not disinfected for at least 15 seconds was practically and statistically significantly associated with hospital wards with medical wards being implicated most. Sterility of needles and IV sets not maintained was statistically significantly negatively correlated with the percentage occupancy with small effect size ($r = -0.09$; $p = 0.034$) while hands not disinfected was borderline statistically significantly correlated with the percentage of required staff ($r = 0.13$; $p = 0.052$). Palms not disinfected were statistically significantly correlated with the percentage of required staff - the tenth percentile with a small effect size ($r = 0.12$; $p = 0.074$). No correlations were found between

asepsis-related deviations from safe practice and medication administrator qualifications. Thus the second objective was addressed.

4.3 Relevance of the study

Prior to this research limited information was available with regards to asepsis-related deviations from safe practice during parenteral medication administration in the public hospitals of South Africa and no information was available regarding these deviations in the rural areas of South Africa. This study added to the body of knowledge through providing the incidence of the asepsis-related deviations from safe practice observed within the medical and surgical wards of the level two public hospitals of the North West Province of South Africa.

The incidence of asepsis-related deviations from safe practice was very high. It is concluded that asepsis during parenteral medication administration is a challenge that needs to be addressed. The most problematic areas to address are:

- All areas of the hands not cleaned, as this was only done adequately in 4.33% of observations;
- Hands need to be disinfected for at least 15 seconds, which was only disinfected 6.3% of the time; and
- IV bottles and vials not disinfected, that were only disinfected 37.77% of the time.

The medication administrator qualification did not have any significant impact on asepsis-related deviations from safe practice. Counterintuitively, occupancy and low staffing levels mitigated certain asepsis-related deviations from safe practice. Despondency with resultant poor work environments is seen as a possible explanation of these results.

4.4 Limitation of the study

Even though the study contributed to the body of knowledge with regards to the incidence of asepsis-related deviations from safe practice during parenteral

medication administration in the level 2 public hospitals of the North-West Province of South Africa, some limitations were visible in this study:

- In the structured observation phase, the parenteral medication administrations were only observed by one observer. Though parenteral medication administration asepsis-related deviations from safe practice could have been missed due to this, the observer did only maximum 25 observations per day to prevent observers' fatigue. Also, when the observer was not sure about actions taken during observation that observation was cancelled;
- Another limitation of direct observational studies, the Hawthorne effect, was also moderated by the use of only one observer, since one observer is less intimidating than two. The observer further alleviated the Hawthorne effect by allowing the medication administrator to become familiar with the observation prior to starting the recorded observations; and
- The small sample of enrolled nurses affected the study as the sample did not effectively represent the population. Although only seven out of the 60 participants were enrolled nurses there was a difference present in the results and further research should be done on the influence of medication administrator's qualification on the practice of asepsis during parenteral medication administration.

4.5 Recommendations

Burns and Grove (2013:718) defined recommendations as notions that emerged from the present study and previous studies on the same track that can provide direction in the future. Recommendations are provided to improve aseptic techniques during parenteral medication administration in the North West Province of South Africa in nursing practice, research, education and policy.

4.5.1 Recommendations for nursing practice

From this study the following recommendations for nursing practice were derived:

- Safe parenteral medication administration practices should be recognised and rewarded by ward managers and nursing directors;

- Many deviations occur due to diverting from standard procedure such as disinfecting hands and disinfecting vials, intravenous bottles and bags. Therefore medication administrators should keep to existing protocols;
- A major concern seen in all the wards was the lack of disinfecting hands. Handwashing initiatives should be encouraged;
- To raise awareness of aseptic deviations from safe practice during parenteral medication administration, auditing of medication administration should be implemented;
- Nurses and other health care professionals need to build a supportive culture within the medical and surgical units of the North West Province of South Africa in order to assist and limit despondency amongst staff;
- Retraining of medication administrators is necessary to ensure that aseptic practices are up to standard;
- To assist the medication administrator in their tasks, more equipment should be made available, such as reconstitution devices which ease the nurses' workload. The reconstitution devices were available in only one of the three hospitals with limited stock available;
- Basic tasks like getting stock from the pharmacy should be done by a porter so as to limit unnecessary time wastage by nurses; and
- Hospitals need to obtain more supplies such as disinfecting hand spray and non-sterile gloves and distribute these evenly amongst the wards.

4.5.2 Recommendations for nursing research

The following recommendations were derived from this study for nursing research:

- This research focussed on identifying asepsis-related deviations from safe practice during parenteral medication administration. More research is needed in order to formulate interventions to prevent/minimise these deviations;
- This research was done in medical and surgical wards. However, some other wards, like the emergency department or the intensive care ward are at even greater risk of asepsis-related deviations from safe practice during parenteral medication administration. Research is necessary to identify the same

deviations as were identified in this study to see the extent of the problem within other wards;

- Research should be done on the psychological factors impacting on aseptic procedures during parenteral medication administration;
- Research should also be piloted to investigate the role of patients and other multi-professional team members in the incidence of asepsis-related deviations from safe practice during parenteral medication administration;
- Limited research has been done in developing countries with regards to aseptic practices overall. Research should address the knowledge gap on aseptic practices in developing countries; and
- Research should be done on the difference of asepsis-related deviations from safe practice during parenteral medication administration by professional nurses and enrolled nurses.

4.5.3 Recommendations for nursing education

The following recommendations were derived from this study for nursing education:

- Enrolled nurses should receive an introductory course/in-service training with regards to parenteral medication administration, as many of them are forced to administer parenteral medication since there is a major staff shortage;
- Consistent and regular assessment of medication administration competence should be required for both enrolled and professional nurses. This could be done in the form of audits including feedback on the progress; and
- Workshops and in-service training should take place on a regular basis to ensure the competence of the medication administrator and their understanding of safe practice protocol with the emphasis on the importance of aseptic technique.
- Under graduate nursing students should receive a refresher's course with regards to updated parenteral medication administration techniques, risks and safety precautions before graduating.

4.5.4 Recommendations for nursing policy

In this study the following recommendations were brought about for nursing policy:

- A policy for parenteral medication administration auditing should be developed, stressing the importance of asepsis as sepsis-related deviations from safe practice during parenteral medication administration is a major threat to patient safety and necessitates assessment on a regular basis;
- Revise policies which focus on stock control to ensure that these policies do not limit the effectiveness of medication distribution and administration to patients;
- Support systems for overworked nurses should be generated so as to help them deal effectively with stress and to provide strategies to help alleviate the burdensome workload;
- The severe shortage of staff drives us to consider the employment and work schedules of international standards for safe nurse-to-patient ratios and reducing the duration of shifts in accordance with international trends; and
- Campaigns should be mounted with regards to current aseptic technique and infection control policies to create more awareness on asepsis as an essential part of patient safety.

4.6 Conclusion

In this final chapter, the study was evaluated and its significance captured. Limitations were mentioned as were recommendations for nursing practice, nursing research, nursing education and nursing policy. This study has thus successfully addressed all the objectives set at the outset of the study. Asepsis-related deviations from safe practice during parenteral medication administration were seen as being very negative for patient safety. However, the context of the study with reference specifically to resource restraints and psychological climate should not be deemed insignificant in striving towards betterment of patient safety in public hospitals of South Africa.

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ADDENDUM A ETHICAL APPROVAL



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ETHICS APPROVAL CERTIFICATE OF STUDY

Based on approval by **Health Research Ethics Committee (HREC)** on **08/08/2017** after being reviewed at the meeting held on **16/11/2016**, the North-West University Institutional Research Ethics Regulatory Committee (NWU-IRERC) hereby **approves** your study as indicated below. This implies that the NWU-IRERC grants its permission that provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: Asepsis related deviations from safe practice in parenteral medication administration in the North West Province																															
Study Leader/Supervisor: Dr A Blignaut																															
Student: A Erasmus-22820434																															
Ethics number:	<table border="1"><tr><td>N</td><td>W</td><td>U</td><td>-</td><td>0</td><td>0</td><td>3</td><td>5</td><td>1</td><td>-</td><td>1</td><td>6</td><td>-</td><td>A</td><td>1</td></tr><tr><td colspan="3">Institution</td><td colspan="5">Study Number</td><td colspan="2">Year</td><td colspan="5">Status</td></tr></table>	N	W	U	-	0	0	3	5	1	-	1	6	-	A	1	Institution			Study Number					Year		Status				
N	W	U	-	0	0	3	5	1	-	1	6	-	A	1																	
Institution			Study Number					Year		Status																					
Application Type: Single study																															
Commencement date: 2017-08-08																															
Risk: Minimal																															
Continuation of the study is dependent on receipt of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation.																															

Special conditions of the approval (if applicable):

- Translation of the informed consent document to the languages applicable to the study participants should be submitted to the HREC (if applicable).
- Any research at governmental or private institutions, permission must still be obtained from relevant authorities and provided to the HREC. Ethics approval is required BEFORE approval can be obtained from these authorities.

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, please note the following:

- The study leader (principle investigator) must report in the prescribed format to the NWU-IRERC via HREC:
 - annually (or as otherwise requested) on the monitoring of the study, and upon completion of the study
 - without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.
- Annually a number of studies may be randomly selected for an external audit.
- The approval applies strictly to the proposal as stipulated in the application form. Would any changes to the proposal be deemed necessary during the course of the study, the study leader must apply for approval of these amendments at the HREC, prior to implementation. Would there be deviations from the study proposal without the necessary approval of such amendments, the ethics approval is immediately and automatically forfeited.
- The date of approval indicates the first date that the study may be started.
- In the interest of ethical responsibility the NWU-IRERC and HREC retains the right to:
 - request access to any information or data at any time during the course or after completion of the study;
 - to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process.
 - withdraw or postpone approval if:
 - any unethical principles or practices of the study are revealed or suspected,
 - it becomes apparent that any relevant information was withheld from the HREC or that information has been false or misrepresented,
 - the required amendments, annual (or otherwise stipulated) report and reporting of adverse events or incidents was not done in a timely manner and accurately,
 - new institutional rules, national legislation or international conventions deem it necessary.
- HREC can be contacted for further information or any report templates via Ethics-HRECAApply@nwu.ac.za or 018 299 1206.

The IRERC would like to remain at your service as scientist and researcher, and wishes you well with your study. Please do not hesitate to contact the IRERC or HREC for any further enquiries or requests for assistance.

Yours sincerely

Prof LA Du Plessis
Digitally signed by
Prof LA Du Plessis
Date: 2017.08.31
15:06:05 +02'00'

Prof Linda du Plessis

Chair NWU Institutional Research Ethics Regulatory Committee (IRERC)



health
Department of
Health
North West Province
REPUBLIC OF SOUTH AFRICA

[Redacted]

CLINICAL MANAGER'S OFFICE

03th August 2017

To : PHRU

Dear Sir/ Madam

RE : Asepsis related deviations from safe practice in parenteral medication administration in the North West Province

Presenter – Ms. A Erasmus

Date – 19th July 2017

This letter serves to confirm that permission has been granted by [Redacted] Patient Safety Group (PSG) for Asepsis related deviations from safe practice in parenteral medication administration in the North West Province study in [Redacted]. The researcher is requested to submit regular study progress reports and final study report upon completion of the study.

Kind Regards,

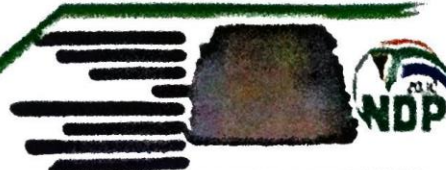
[Redacted Signature]



Healthy Living for All



health
Department of
Health
North West Province
REPUBLIC OF SOUTH AFRICA



OFFICE OF THE CEO

**TO : MS A ERASMUS
NORTHWEST UNIVERSITY
SCHOOL OF NURSING**

FROM : [REDACTED]

DATE : 25 OCTOBER 2017

**SUBJECT : APPLICATION FOR RESEARCH IN PUBLIC HOSPITALS OF THE
NORTH WEST PROVINCE**

This letter serves to inform you (Ms A Erasmus) that the [REDACTED] approves your application to undertake the above mentioned study in [REDACTED], in the [REDACTED].

You are expected to arrange in advanced with the units (through the Office of the Nursing Services Manager) and use this letter of proof that permission granted by the [REDACTED].





health
 Department of
 Health
 North West Province
 REPUBLIC OF SOUTH AFRICA



OFFICE OF THE CLINICAL MANAGER

03 July 2017

TO: Ms Anelle Erasmus
 North West University

FROM: [Redacted]
 [Redacted]
 [Redacted]

Dear Ms A Erasmus

This is to inform you that the [Redacted] (PSG) that sat on 11/05/2017 has given you permission to proceed with your research titled: **Aspsis related deviations from safe practice and parental medication administration.**

We wish you all the best with your study and look forward to sharing in the results of your findings.

Sincerely

[Redacted signature block]

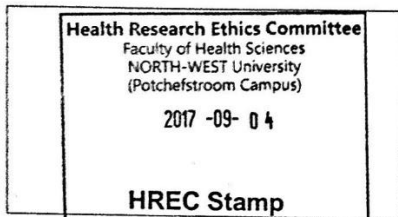
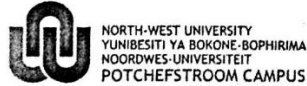
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 2017 -07- 03
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ADDENDUM C INFORMED CONSENT

ANNEXURE B: INFORMED CONSENT



INFORMED CONSENT DOCUMENTATION FOR MEDICATION ADMINISTRATORS IN THE NORTH WEST PROVINCE

TITLE OF THE RESEARCH STUDY: Asepsis related deviations from safe practice in parenteral medication administration in the North West Province.

ETHICS REFERENCE NUMBER: NWU-00351-16-S1

PRINCIPAL INVESTIGATOR: Dr. AJ Blignaut

POST GRADUATE STUDENT: Ms. A Erasmus

ADDRESS:
North West University
Faculty of Health Sciences
Private Bag X6001
Potchefstroom
2531

CONTACT NUMBER: +27 (0) 18 299 1835

You are being invited to take part in a research study that forms part of a Master's degree in Nursing. Please take some time to read the information presented here, which will explain the details of this study. Please ask the researcher or person explaining the research to you any questions about any part of this study that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research is about and how you might be involved. Also, your participation is entirely voluntary and you are free to say no to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part now.

This study has been approved by the Health Research Ethics Committee of the Faculty of Health Sciences of the North West University (NWU-00351-16-S1) and will be conducted according to the ethical guidelines and principles of Ethics in Health Research: Principles, Processes and Structures (DoH, 2015) and other international ethical guidelines applicable to

this study. It might be necessary for the research ethics committee members or other relevant people to inspect the research records.

1 What is this research study all about?

- *This study will be conducted in level 2 public hospitals in the North West Province of South Africa and will involve structured observation with an experienced health researcher trained in nursing. 90 participants will be included in this study.*
 - *We plan to observe the prevalence of sepsis related deviations from safe practice during parenteral medication administration and identify possible relationships between the incidence of these deviations from safe practice and staffing levels, medication administrator qualifications and occupancy.*

2 Why have you been invited to participate?

- *You have been invited to be part of this research because you are a medication administrator who as part of your daily routine administers parenteral medication and therefore are an important role-player in the parenteral medication safety in your ward.*
- *You also fit the research because you are a professional nurse or enrolled nurse registered with the South African Nursing Council, who is qualified to administer parenteral medication.*
- *None of the following exclusion criteria applies to you:*
 - *Being a non-permanent employed registered and staff nurses; or*
 - *Being employed on a contract for shorter than a year.*

3 What will be expected of you?

- *You will be expected to continue with your normal routine in administering medications while being observed by a researcher during one medication round.*

4 Will you gain anything from taking part in this research?

- *There will be no direct benefits for you, if you participate.*
- *The other gains of the study is knowledge acquirement, better safety culture in hospitals, recommendations for better practice environment and possibly advocacy for better protocols and policies.*

5 Are there risks involved in you taking part in this research and what will be done to prevent them?

- *The risks to you in this study are that you might feel anxious about being observed and that you might feel vulnerable to punishment should you make mistakes. However, what is observed will be held strictly confidential, you will not be held liable for any mistakes seen and there will be no way of tracing research results back to your actions. Should you have the need for further discussions after being observed an opportunity will be arranged for you to be counselled.*
- *As this research aim to build knowledge in patient care, there are more gains in joining this study than there are risks.*

6 How will we protect your confidentiality and who will see your findings?

- *Confidentiality of your findings will be protected by not writing any identifying measures on the checklists and not disclosing any information that could be connected to you. Your privacy will be respected by field notes being more general about the whole unit observed and limited on personal characteristics of the medication administer that is*

observed. Your results will be kept confidential by locking away completed checklists and not reporting on specific wards or hospitals. Reporting of findings will be anonymous by not mentioning names of people, wards or hospitals. Only the researchers will be able to look at your findings. Findings will be kept safe by locking hard copies in locked cupboards in the researcher's office and for electronic data will be password protected. Data will be stored for 5 years, where after it will be destroyed by shredding.

7 What will happen with the findings or samples?

- The findings of this study will only be used for this study.

8 How will you know about the results of this research?

- The results of the research will be published in a scientific journal and access to this article will be provided in the form of a printed article for your ward. Should you wish to have access to the full dissertation, this will be provided to you.
- You will be informed of any new relevant findings by the post-graduate student through contact with the nursing manager.

9 Will you be paid to take part in this study and are there any costs for you?

- This study is not funded.
- No you will not be paid to take part in the study because the researcher will conduct the research at your place of work.
- There will thus be no costs incurred by you, if you do take part.

10 Is there anything else that you should know or do?

- You can contact Anelle Erasmus at 078 450 7221 if you have any further questions or have any problems.
- You can also contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 1206 or carolien.vanzyl@nwu.ac.za if you have any concerns that were not answered about the research or if you have complaints about the research.
- You will receive a copy of this information and consent form for your own purposes.

11 Declaration by participant

By signing below, I agree to take part in the research study titled: Asepsis related deviations from safe practice in parenteral medication administration in the North West Province

I declare that:

- I have read this information/it was explained to me by a trusted person in a language with which I am fluent and comfortable.
- The research was clearly explained to me.
- I have had a chance to ask questions to both the person getting the consent from me, as well as the researcher and all my questions have been answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be handled in a negative way if I do so.
- I may be asked to leave the study before it has finished, if the researcher feels it is in the best interest, or if I do not follow the study plan, as agreed to.

ADDENDUM D: CHECK LIST FOR OBSERVATIONS AND WARD DEMOGRAPHICS

CHECK-LIST FOR OBSERVATIONS

Check-list for observing asepsis-related deviations from safe practice in parenteral medication administration per prescription

Did an error or deviation from safe practice occur?		YES	NO
Adherence to Basic infection control principles	Disinfect the hands before administering medication		
	Duration of cleaning (15-30 seconds)		
	Area of washing/disinfecting with alcohol <ul style="list-style-type: none"> • Palm; • Wrist; • Back of hands; • Between fingers; and • All fingernails. 		
	IV fluid bottles, bags and vials disinfected before use.		
	Sterility of needles and IV sets maintained.		
	Disinfect injection site before administering drugs.		

Notes:

Ward type: _____

Medication administrator qualification: _____

Ward demographics

Amount of beds	
Occupancy on day of observation	
Number of staff on day of observation	
Staff required	

ADDENDUM E LANGUAGE EDITING CERTIFICATE

Declaration

This is to declare that I, Annette L Combrink, accredited language editor and translator of the South African Translators' Institute, have language-edited the dissertation by

A Erasmus

With the title

**Asepsis related deviations from safe practice
in parenteral medication administrations in
the North West Province**



Prof Annette L Combrink

Accredited translator and language editor

South African Translators' Institute

Membership No. 1000356

Date: 28 November 2017