Preparation practices for parenteral administration at Doctor George Mukhari Academic Hospital in South Africa

A mini-dissertation submitted by

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DECLARATION

I Phumzile Prudence Skosana declare that the mini-dissertation hereby submitted to the Sefako Makgatho Health Sciences University, for the degree of Master of Pharmacy, in the Department of Pharmacy has not previously been submitted by me for a degree at this or any other university; that it is my work in design and execution, and that all material contained herein has been duly acknowledged.

__________________________________________  ________________
Surname, Initials (Title)                             Date
DEDICATION

I would love to dedicate this piece of work to my mom, the late Zanele Sarah Sangweni. It is actually all because of this powerful woman that I am still standing to complete yet another chapter of my career. She has been my support and source of motivation to always step up and make a difference. I will always and forever love you.

_____________________________
Signed

Phumzile Prudence Skosana
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ABSTRACT

Introduction: Most patients when admitted to hospital require intravenous (IV) medicine due to their critical state and the need to be treated immediately. Intravenous therapy is a complex healthcare technology usually requiring the preparation of the medicine in the clinical areas before administration to the patient. Nurses generally prepare, label and administer intravenous medicines prescribed by doctors.

Aim: The aim of the study was to determine the preparation practices for parenteral medication at Dr. George Mukhari Academic Hospital wards to check the nurse’s knowledge on calculations and labelling requirements for intravenous (IV) medication.

Method: This was an observational, prospective, descriptive and quantitative cross-sectional survey assessing parenteral preparation practices at Dr George Mukhari Academic Hospital (DGMAH), using a checklist and a self-administered questionnaire. It was conducted over a period of five months. The checklist was used to observe whether or not the IV lines put up were labelled according to the Nursing Act and Medicine Control Act requirements. A questionnaire was administered to the nurses to complete that covered the demographics and topics pertaining to preparation of IV medication.

Results: Of the 198 parenteral lines that were observed, only 75 (38%) lines had labels. This was mostly seen in the Intensive Care Unit (ICU). However, eighty six percent of the nurses reported that all IV medication was labelled. The patients’ identity (91%) and the name of the medication (99%) were observed on the 75 labels. 123 nurses responded to the questionnaire with the majority being female (51%) and professional nurses (58%). The medication was prepared on the patients’ counter for 70% and it was just before administration (78%). Only 10% nurses reported that they used resources when reconstituting, where the majority used previous training (70%). The nurses indicated that standard operating procedures (SOP) regarding the preparation of parenterals were available in the wards (67%) and (62%) indicated that these were easily accessible. Fifty five percent of the nurses reported the presence of the standard treatment guidelines in the wards. More than half (58%) of the nurses said they would prefer unit-dosing.

Conclusion: Majority of the observed IV lines did not have labels on them. Of the 75 that had labels, none of them fully complied with all the requirements that are supposed to be on the label. The nurses indicated that training is needed on the calculation but most would prefer unit dosing since it would save them time.
**Recommendations:** Training needs to be conducted for the nurses to re-inforce the need for correct preparation practices with a follow up study on how training will improve the labelling practices.
1.1 INTRODUCTION

This chapter describes the background and the importance for correct preparation of medicine given parenterally. It contains the research aim and objectives. The chapter ends with the importance of conducting this study and a brief outline of the whole dissertation.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

Most patients when admitted to hospital require intravenous (IV) medicine due to their critical state and the need to be treated immediately. As they get better they can be changed to oral preparations (Cheston; May-McCarver; Daniel; Robert; Douglas; Geraldine and John, 2015). Intravenous therapy is a complex healthcare technology usually requiring the preparation of the medicine in the clinical areas before administration to the patient (Cousins; Sabatier; Begue; Schmitt and Hoppe-Tichy, 2005; Taxis and Barber, 2003).

According to the Good Pharmacy Practice it is the role of a pharmacist to oversee the use of medicines from when they are formulated from raw materials to when they are administered to the patient (SAPC, 2010). This however, differs to what happens in practice. In a study carried out in 2008 by the Witwatersrand University students, it was discovered that 86% of the time, it was nurses who administered IV medicines to patients (NDOH, 2008). Nurses generally prepare, label and administer intravenous medicines prescribed by doctors (Taxis and Barber, 2003).

Intravenous therapy use is associated with considerable risks. Patients have experienced adverse effects when medicines were administered through the wrong route (Taxis and Barber, 2003) and medicine errors occurred during the preparation and administration of IV medicines (Cousins et al., 2005; Keer; Williams; Cooke and Ashcroft, 2013; Taxis and Barber, 2003; Valentin; Capuzzo; Guidet; Moreno; Metnitz; Bauer and Metnitz, 2010; Westbrook; Rob; Woods and Parry, 2011). Therefore, it is of importance that the correct procedures are followed when preparing the medicine for administration to help minimise medicine errors.

Medicine errors have been seen in the wards due to some steps of the distribution, preparation and administration process being omitted (Williams, 2010). Steps that were
omitted varied from double checking if the correct medicine is being issued and recording all steps of the preparation and administration process.

In a study by Westbrook et al., in 2011, it was discovered that IV administration has the highest risk and severity of errors due to the wrong rate of administration, wrong volume of mixture and diluents used. The researcher discovered 23% of the medicines were not labelled with the patient's details or the date of constitution. In this study 84 out of 568 IV medicines were given to the wrong patient (Westbrook et al, 2011). Because of so many errors, some facilities have resolved to unit dosing (Murray and Shojania, 2009).

In unit-dose dispensing, medicine is dispensed in a package that is ready to administer to the patient (Murray and Shojania, 2009). In a study by Sinnemaki and partners in 2013 at a primary healthcare institute in Finland, it was discovered that unit-dosing enhances patient safety by limiting errors that can be conducted during the preparation, compounding, reconstitution and labelling of medicine before administration as it would be done by the custodians of medicine who are taught on how to conduct the mentioned procedures (Sinnemaki; Sihvo; Isojarvi; Blom; Airaksinen and Mantyla, 2013). In another study at three commercial hospitals in Canada (2006-2009) it was discovered that when unit-dose dispensing was conducted not only did it enhance patient safety but there were decreased medicine costs and it saved nurses working time (Thibault; Prot-Labarthe; Bussieres and Lebel, 2008).

This survey was motivated by observations by the researcher that most of the parenteral medicines being administered to in-patients were not properly labelled. Therefore, this study aims to investigate practices for parenteral preparations at Doctor George Mukhari Academic Hospital (DGMAH).

1.3 RESEARCH QUESTION

- What parenteral preparation practises are being followed in the wards at DGMAH?
- Do the nurses know the calculations most commonly encountered in the wards?
- Do the nurses know and follow the correct labelling practices?

1.4 AIM OF THE STUDY

The aim of the study was to investigate parenteral preparation practices in the wards at DGMAH.
Chapter 1: Introduction

1.5 **OBJECTIVES OF THE STUDY**

The objectives of the study were the following:

- To determine the profile of the people who prepare parenteral preparations in the wards
- To investigate the nurses’ knowledge on calculations for parenteral preparations commonly encountered in the wards
- To assess the correctness of labelling on parenteral preparations at DGMAH
- To assess whether the wards have the required resources (infrastructure, SOPs, reference books) for preparing admixtures
- To explore the possibility of adopting unit-dose dispensing at DGMAH

1.6 **IMPORTANCE OR SIGNIFICANCE OF THE STUDY**

This study is very important because most patients when admitted to the hospital require some form of intravenous medicine due to the need of being treated immediately to avoid critical cases. It is therefore important for all health care professionals to ensure that the medicines administered to patients are of good quality and will not harm them (Elliott and Liu, 2010).

It is important that this information be gathered to determine current practice and to establish whether there is room for improvement on the preparation practices of nurses.

The data will also help to ascertain whether unit dosing would be a service that pharmacists can offer and how other health care professionals feel about this system.

1.7 **OUTLINE OF THE THESIS**

In this study, the focus was to determine whether parenteral medicines were labelled in the wards and whether it was done correctly. It was also to look at how the nurses in the study wards prepared this medicine before administration to the patient.

This chapter provided a background to the study and the rational of conducting this study. It also includes the research question, aim and objectives of the study.

Chapter 2 describes what has been found in literature regarding preparation of medicines and labelling of parenterals. It also covers medicine errors that can occur whilst preparing
medication, resources and SOPs required when preparing IV medicines. Unit-dosing is briefly discussed to see how other countries are succeeding with it and some of its challenges.

The methods used to select the nurses and the data collection instruments are discussed in Chapter 3.

Chapter 4 outlines the results and the discussion of the data collected.

The summary of the study, outcomes and recommendations are discussed in the final chapter. These will include any limitations encountered during the study and future plans regarding the outcomes of this study.
CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter, all the topics covered by the study are outlined to what was found in the literature starting with parenteral preparations. Areas of importance like Standard Operating Procedures (SOP), resources, labelling and calculations are outlined since they help with reduction of medicines errors. The chapter then ends with brief information on unit dosing.

2.2 PARENTERAL PREPARATIONS

Parenteral preparations are advantageous for admitted patients in that they elicit a rapid effect and the total dose is delivered to the desired area. High concentrations can also be given (Verma; Thakur; Deshmukh; Jha and Verma, 2010). Medicines given via the parenteral route have to be monitored because they can reach toxic levels quicker which can cause fatal effects even leading to death (Vega; Ochoa; and Holder, 2010). They have to be prepared under sterile conditions which can be expensive and they require experienced personnel for administration (Owoso & Humphriss, 2014).

Westbrook et al., (2011), state that giving medicine parenterally poses risk because of the great complexity and multiple steps required in the preparation, administration and monitoring of the patient. They also grouped the most common errors that can occur when preparing and administering IV medicines into the following groups:

- Wrong IV rate
- Wrong mixture of solvent or diluent
- Wrong volume of solvent or diluent
- Drug incompatibility

Elliott and Liu (2010) summarised the important aspects to be covered when administering medicines into the following nine rights: right drug, right dose, right patient, right indication, right route of administration, right time, right response, right action and right documentation.

The most important aspect during parenteral administration is ensuring that the medicine is well prepared and correctly labelled before being administered to the patient in order to avoid making mistakes (Valentin et al., 2010).
2.3 SCOPE OF PRACTICE FOR NURSES

Schellack (2011) explored the interaction of various role players involved in prescribing, supplying, dispensing and administering medicines to patients and found that in the clinical practice setting, be it in hospital or primary care facility, nurses are faced with the challenging task of managing drug preparations and treatment on a daily basis. This was also seen in the United Kingdom where nurses prepare and administer intravenous medicines prescribed by doctors (Taxis and Barber, 2003).

The scope of practice of nurses is clearly described in the following figure by Schellack, 2011).
Chapter 2: Literature Review

Health professionals are always expected to do whatever possible to provide the best service to the community, requiring them to do duties that actually overlap with other
Chapter 2: Literature Review

professions just so the patient gets the best output for their health (Scribante; Muller and Lipman, 1995). There are many areas between professions where an overlap is unavoidable and the grey areas remain. In their study (Scribante et al., 1995) discovered that 50 – 75% of nurses do not have the necessary training to give critically ill patients the required standard of care. They concluded that it is therefore of utter importance that good quality standards are still maintained even in those grey areas, so that patients and society at large will be given the best service to improve the quality of life (Scribante et al., 1995).

2.4 MEDICINE ERRORS

Medicines errors are defined as mistakes associated with medicines and intravenous solutions that are made during the prescription, transcription, dispensing, and administration phases of medicine preparation and distribution (McBride-Henry and Foureur, 2005). This is a preventable event that may cause or lead to inappropriate medicine use or patient harm, while medicines are in the control of the health care professional, patient, or consumer (Strickland and McCarthy, 2014), or a deviation in the preparation or administration of a medicine from the doctor’s prescription, hospital intravenous procedures or manufactures instructions (Cousins et al., 2005).

According to the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 2015) medicine errors cause at least one death every day and injure 1.3 million people each year in the United States of America (Wagenknecht, 2009). These errors can cause serious long term consequences (WHO: 2010). Most medicines errors are due to incorrect timing of administration and improper labelling (Cousins et al., 2005). In a study by Valentin et al., (2010), it was observed that 10.5 out of 100 patients experienced administration errors in the Intensive care unit. These errors posed high potential for serious harm.

Williams (2010) discovered steps that were omitted in the preparation of parenterals that led to errors. These included: no double checking of correct medicine being issued and picked when dispensing; improper labelling of the medicines to be given; improper dose given to the patients; personal hygiene not kept at all times; improper discarding of remaining and expired medicines; not checking the flow for intravenous lines; leading to backflow, and not recording all steps of the administration process when it is performed.

These medicine errors can be very fatal, leading to prolongation of time in hospital, death, increased costs as well as causing harm to the patient (Gordon; Llewellyn and James,
2006). In the study by Gordon et al., (2006), 121 outcomes (41, 3 %) of the errors observed needed immediate intervention and five deaths occurred. The contributing factors to these findings were misidentification, swopping injections, fatigue, distraction and mislabelling.

These errors also contribute negatively to the economy as reported by Chua and partners (2010) at the University of Malaya. The economic consequences are prolonged hospital stay, additional treatment to resolve adverse effects due to the error, additional laboratory tests and monitoring (Chua; Chua and Omar, 2010).

Having a team that monitors that all the steps for drug administration are in-place, including labelling correctly as part of quality assurance, would help to decrease the amount of errors uncounted in the wards (Hughes and Blegen, 2011). Hughes also mentions that to prevent errors from occurring there is a need to improve system of doing things. In a study by Cousins et al., (2005), it was recommended that international procedures for safe IV practices be developed, to improve labelling with clear fonts and having a second person to double check before administration.

The Medicines Errors Prevention and Reduction guidelines by the New Brunswick Pharmaceutical Society of 2009, clearly state that the pharmacist is ultimately responsible for the prevention of errors and the safe provision of care to the patient. All the steps conducted before the actual administration is covered completely when unit-dosing is put to practice (Murray and Shojania, 2009).

### 2.5 LABELLING OF PARENTERALS

According to the Australian National Medicine Policy (Merry; Bedford; Bryce; Crosbie; Price; Quin and Shipp, 2010), the minimum requirements for labelling of large parenteral fluids are as follows:

- All medicine and fluids removed from the manufacturer or hospital pharmacy’s original packaging must be identifiable
- All containers containing medicine leaving hands of the person preparing the medicine must be labelled
- Any medicine or fluid that cannot be identified should be considered unsafe and discarded
Chapter 2: Literature Review

According to Valentin et al., (2010) labelling of parenterals is often not done or is incomplete, omitting information such as the name of the medicine, dose, patient name and the time of preparation.

According to the WHO guidelines for the Safe Injection Global Network (SIGN) campaign (WHO, 2010) the following must appear on an injection label: the patient details, the total amount of active ingredient in the bag or syringe or the concentration of the drug, the total volume in the bag or syringe, the drip rate, the preparation time for mixtures, who the injection is prepared by, the person that checked the drug and route of administration.

In the study by Cousins et al., (2005), they discovered in their observations that labelling errors accounted for 118 of 273 observations (43%). In their conclusion they found that practitioners intending to administer these medicines may be confused over the identity of the medicine, dose, or the intended patient to receive this medicine because there were no proper labels.

Without the correct labels parenterals are difficult to monitor (Mosah; Sahib and AL-Biati H, 2012). Tilluel (2003) found that 28% of the nurses wrote information directly of the final admixture using a felt pen but this could be deleted by continuous handling as seen in many wards. Because of the high chances of toxicity parenterals have to be thoroughly labelled so as to avoid any medicines errors (Porat; Bitan; Shefi; Donchin and Rozenbaum, 2008).

2.6 CALCULATIONS FOR PARENTERAL ADMINISTRATION

Calculation errors are listed as one of the main risks with injectable medicines as outlined in the National Patient Safety Agency (NPSA), (2014). Calculations for the dose and drip rate for some medicines have to be carried out to ensure the correct dose is given at a certain time (Cavell; Jane; Ben; Lisa; Neelam; Stephen and Root, 2014).

Tilluel (2003) describes the need for calculations in the wards as the measurement of a volume of a solution diluted in the delivered infusion in order to obtain the dosage prescribed by the clinician. Therefore, it is important that health professionals who deal with the preparation and administration of medicines are able to do calculations that will be encountered on a daily basis in the wards. Most common calculations that have to be done are the following: conversions, calculating IV drug’s dose /kg, adjustments in renal failure, and calculating drip rate (Cavell et al., 2014).
Chapter 2: Literature Review

In a practice session done by Dr Morautsi (2007) at Witwatersrand University; it was found that pharmacist knew how to do calculation for patients and they never struggled much compared to doctors and nurses. According to Cavell et al., (2014) nurses and doctors need programmes that will help them practice calculations on a regular basis since they will encounter such challenges for their entire profession.

It is alarming to see however that in a study on a population of 299 nurses, 45% of the nurses thought that doing calculations was unnecessary for them (Tilleul; Mons; Schmitt; Laporte and Begue 2003) yet in another study by Brinkcate and Lee (1992), they found that 84% of the flow rates were calculated incorrectly. The same was found when an observational study was done in two major teaching hospitals in Sydney and Australia. The wrong rate of administration was the most frequent error and it accounted for 95 of the 101 which is 94% (Roughead; Semple and Rosenfeld, 2013). Similarly Cousins et al., (2005) found 132 of 273 administrations were given at the wrong rate, usually too quickly and this resulted in pain, phlebitis, irritation and inflammation at the site of administration.

In some institutions, an infusion pump is used. In a study Westbrook et al., (2011) found that, even when available, infusion pumps were rarely used, 17% of 256 infusions, and even when they were used, they did not decrease the number of errors in rate of administration.

2.7 STANDARD OPERATION PROCEDURES

Quality assurance (QA) describes an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item, is of the type and quality needed for the project (Mikel, 2002). These procedures are documented in the form of standard operating procedures (SOPs) (Corke and Haynes, 2015).

The World Health Organisation (WHO, 2010) has a set of SOPs on how parenterals should be administered. They have a “Safe Injection Global Network” (SIGN) campaign that goes on every year where they update their SOPs (WHO, 2010). Their strategy for the safe and appropriate use of injections worldwide has four main objectives: 1. formulating national policies and plans for the safe and appropriate use of injections; 2. ensuring quality and safety of injection equipment; 3. facilitating equitable access to safe injection practices and equipment; and achieving appropriate, rational and cost-effective use of injections. These objectives make it possible not to harm the recipient, not to expose the provider to any avoidable risk and to reduce waste that is dangerous for other people. Therefore it is very
important that written procedures be accessible to all the health professionals in the wards so the quality of care can be consisted and there will be minimized drug error (WHO, 2010).

In a study by Tilleul et al., (2003), they found that 71-85% of the wards lacked written procedures. Tissot; Cornette; Demoly; Jacquet; Barale and Capellier in 1998 also highlighted the lack of knowledge the nurses had in key areas for preparation of medicines, such as the nature and volume of the diluent, rates and schedules for administration and physicochemical incompatibilities.

In a case where there were protocols, Keers et al., 2013 found that they were not adhered to because of some of the following reasons:

- Poorly designed protocols
- Trusting senior colleagues
- Lack of access to suitable administration protocols
- Poor supervision and drug knowledge
- Lack of staff members
- Common accepted practices

The New Brunswick Pharmaceutical Society wrote in their 2009 pharmacy report that if there are clearly defines policies and procedures, staff training, standardized routines and assignment of activities, there can be minimizes potential of error.

The following quote is from a study done by Cousins “Without agreed procedures, it is difficult to teach, maintain and audit safe practices” (Cousins et al., 2005). They further emphasize that it is the responsibility of the individual institutions to audit these procedures and make sure they are implemented.

### 2.8 RESOURCES FOR IV MEDICATION PREPARATION

In order to ensure that the information about medicines is accurate and correct there have to be resources in the wards for medical professionals to refer to when they encounter challenges (Medicines Control Council (MCC) standards, 2011). These resources should be available for the nurses so they can consult when they are not sure of the dose or strength of a certain medicines (MCC, 2005).
In the study carried out in France, most (83%) of the information about the type of diluents and the volume (79%) needed for IV medicines was based on the nurse’s experience as opposed to a minority (25% to 41%) that was based on reliable sources of information such as a national drug compendium and the manufacturer’s leaflet in 41% to 63% (Tilleul et al, 2003). The authors however conclude that, with the number of errors encountered daily, experience and information gathered from a colleague or delivered orally by the manufacturer may not be enough to deliver real quality of care.

The use of the wrong diluent or carrier may cause reduction in the solubility of the medicine powder being reconstituted, which can lead to powder particles being administered to the patient. It can also lead to reduction in stability and activity of the medicine and possible drug precipitations (Cousins et al., 2005). Cousins et al., 2005 further states that providing clinical staff with more readily available information concerning diluents may help to reduce the use of wrong diluents and the importance of using this information can be reinforced as part of intravenous therapy training.

2.9 UNIT-DOSING

Unit-dosing was developed in the 1960s to support nurses in medicines administration and reduce the waste of increasingly expensive medicines (Murray and Shojania, 2009), it is now a standard of practice at hospitals in the United States (Sinnemaki et al., 2013). Medication is dispensed in a package that is ready to be administered to the patient with all the details.

According to Murray and Shojania, (2009) the stepwise process in unit-dispensing is as follows: the doctor will see the patients and write a prescription, prescriptions are sent to the hospital pharmacy, the pharmacist in charge evaluates the prescription and verifies that that medicine is suitable for the patient, medicines are then prepared by the pharmacist technician under direct supervision from the responsible pharmacist, labelling is done by the pharmacist when checking the final product, then medicines is delivered to the wards. On delivery, the medication is ready for administration with the patient’s details on it. Unit dosing was found to minimise all errors that were previously seen upon administration of parenteral medicines (Thibault et al., 2008).

The most important and crucial part of unit-dose dispensing is the labelling step (Murray and Shojania, 2009). This ensures that the right dose is given to the correct person at the
correct rate. According to Thibault et al., (2008) a complete label for a unit dose must contain the following information:

- Brand name
- Generic name
- Dosage
- Dosage form
- Manufacturer name
- Expiry date
- Batch number
- And patient identification number

2.10 SUMMARY

In this chapter, the presented topics of this study are discussed. From the literature, it is crucial that the preparation of parenteral medicines be done correctly and cautiously to prevent any errors to the patients served.

The following chapter describes the methodology of the study in detail.
CHAPTER 3
METHOD

3.1 INTRODUCTION

This chapter describes the study design, site and the population. The methods used to collect the data and analyses are discussed. It identifies the target population looking at the inclusion and exclusion criteria, sample size and the research design. The data collection process is described with the two phase of the study being the observation of IV lines using the checklist and then the response of the nurses using a questionnaire. The data analysis and statistical procedures are also described. The chapter also discusses how reliability and validity were ensured looking also at ethical considerations that were necessary for this study to be conducted.

3.2 STUDY DESIGN

This was an observational, prospective, descriptive and quantitative cross sectional survey assessing parenteral preparation practices at DGMAH. The study was conducted over a period of five months dating from October 2015 to March 2016. The observation phase was five weeks with the rest of the time entailing collection of information using the questionnaire.

3.3 STUDY SITE

This study was conducted in four selected units (Adult Intensive Care Unit, general surgical wards, renal unit and internal medicine) at DGMAH over five months. The general surgery unit has sixteen wards and internal medicine has nine wards. This is a teaching hospital situated next to Sefako Makgatho Health Sciences University.

3.4 STUDY POPULATION

The checklist was used to assess labels on all parenteral lines that were running in the selected wards and for the questionnaires the target population were nurses since they are the ones involved in parenteral preparations and administration of medicines in the surgical, renal, intensive care and internal medicine wards at DGMAH.
3.5 SAMPLE SELECTION

3.5.1 Sample size

The sample size was expected to be 210 as per statistical estimations however only 198 lines were observed for the checklist and 210 questionnaires were handed out. Convenience sampling was used because it uses a population that is easily accessible. It is also much quicker to carry out than random sampling (Latham, 2007). As convenience sampling was used for the observations, 198 IV lines were evaluated in a period of 5 weeks.

The researcher identified patients on parenteral lines that were running whilst in the ward and those were observed and checked for labelling. The nurses available in the wards during data collection were approached and the aim of the study was explained for them to participate. If the nurses consented to the study, they were included.

Inclusion criteria

The following inclusion criteria applied:

- All running parenteral lines during the study period
- Nurses who prepared parenteral medication.
- Nurses in the selected wards who were willing to participate in the study

Exclusion criteria

The following exclusion criteria applied:

- All patients not on parenteral medicines
- Student nurses who are not yet preparing parenterals

3.6 DATA COLLECTION

All data collected was recorded in the data collection instruments. Two data collection instruments were used in this study. The checklist (Appendix 1) which was administered by the researcher and the questionnaire (Appendix 2) which was completed by the nurses in the selected wards.
3.6.1 Parenteral line label evaluation using a checklist

The researcher identified patients on parenteral medicines daily between 08:00 – 16:00 hours. Using the checklist, the IV medicines were evaluated by determining whether they were labelled and what appeared on the label. This was then ticked off on the checklist. It describes the requirements that were supposed to be on a parenteral label as described by the nurse’s scope of practise and the WHO standards (2010). This was to determine whether the wards complied with these requirements or not. The following was required:

1) Name of the patient and file number
2) Medicine name and concentration
3) Directions on when it should be administered
4) Administration rate (drops per minute)
5) Time of constitution (when applicable)
6) Name or signature of the health professional who prepared the medicines
7) Co-signature or name of another health professional for double checking

3.6.2 Questionnaire

After the observations were completed, the researcher went to the wards and approached the available nurses to complete the questionnaire.

After explaining the aim of the study, the nurses that agreed to participate by completing the consent form were included. The nurses were given time to complete the questionnaire then the researcher collected the forms afterwards. When questions arose, the researcher explained the questions in the simplest way possible without influencing the responses to the questionnaire.

All the questionnaires were in English since the target population were nurses who communicate better in the basic medium of instruction.

A self-administered questionnaire was used to determine the knowledge of nurses on the requirements of parenteral labels, availability of SOPs when calculating doses and preparing
parenterals. In this questionnaire the researcher determined the nurses’ knowledge on parenteral labelling and calculations on drip rates and the correct dose.

The questionnaire was also used to determine the availability of resources for drug information and drug preparation incompatibilities. The nurses’ opinions on their role in the preparation of parenterals and how they prepared them were determined using both close ended and open ended questions. The questionnaire was also used to determine whether the nurses would prefer unit-dose.

3.6.3 Information leaflet

An information leaflet was given to all the nurses. This explained the aim of the study and clarified any concerns that could arise regarding the study. This form was attached to the consent form at enrolment.

3.6.4 Consent form

The consent form was used to obtain permission from the nurses to participate in the study. This was so they knew that their decision to participate was independent and not based on any external influences.

3.7 PILOT STUDY

A pilot study was carried out in the paediatric wards, which did not form part of the study, where 30 nurses were requested to complete the questionnaire and 20 labels were observed. This was only conducted after receiving clearance from the Chief Executive Officer (CEO) at DGMAH. The results of the pilot study were analysed and the researcher made the necessary changes to the questionnaire. This entailed shortening the length of the questionnaire and rephrasing the unit dose question since a lot of the nurses did not know the definition of unit-dosing.

3.8 DATA CAPTURE AND ANALYSIS

The data capturing was done by the researcher on Microsoft Excel™. A coding sheet was developed to capture the questionnaire then random checks were done to ensure accuracy when capturing. Once the data were captured into the MS Excel™ sheet, a clinical statistician was consulted for analysis.
The data were exported to the Statistical Analysis Software (SAS) programme version 9.4 where the different variables were summarised by frequencies and percentages. Then data were presented as tables and graphs. Demographic details were summarised descriptively by frequency tables and graphs. Frequency tables were used to summarise the knowledge of nurses on labelling and reconstitution. These were also done to check the SOPs and resources that are available for correct practices. The answers to open ended questions were summarised into themes which are presented as descriptive statistics. All statistical procedures were performed on IBM SAS Statistics version 9.4 running under Microsoft Windows on a personal computer with the clinical statistician.

3.9 RELIABILITY AND VALIDITY

Reliability measures whether the instrument can produce the same results when used consistently and validity determines whether the research and the measuring instrument truly measure that which they were intended to measure (Struwig & Stead, 2013).

A pilot study was conducted where both instruments were tested. This increased the reliability and validity of the data collected. The researcher identified questions that needed to be explained further or needed to be altered and that was done before the actual study commenced. The pilot study also gave the researcher an opportunity to familiarize themselves with the instruments and the procedures to follow when collecting the data.

Therefore all the questionnaires were administered in the same manner, to ensure that all the nurses understood. This ensured that all the nurses were treated in the same manner thus increasing reliability.

3.10 BIAS

The researcher was the only one giving out the questionnaires to the nurses and collecting them, which helped to eliminate variances in the administration of the questionnaire. To avoid selection bias, the researcher approached available nurses in the wards to find out who prepared parenterals and who was willing to participate in the study. To minimize respondent bias, the researcher conducted the questionnaire in a setting where the respondents were also comfortable. The researcher explained questions in such a manner that personal opinions did not influence the participant’s response. All questionnaires were collected and kept safely locked in the supervisor’s office so no one else could interfere with the results.
3.11 ETHICAL CONSIDERATIONS

Approval was obtained from the Sefako Makgatho Health Sciences Research and Ethics committee (SMUREC) and the CEO of DGMAH gave permission to conduct the study in the wards. The nursing administration also gave permission for the study to be conducted in the ICU. Refer to Appendix 3 for the clearance certificate.

All nurses provided written consent before they participated in the research (refer to Appendix 4) after being told about the study and being given a written information leaflet (refer to Appendix 5).

The questionnaire was anonymous and therefore the identity of the nurses was not disclosed. All data collected was kept confidential between the researcher and the supervisors.

3.12 SUMMARY

This chapter presents the whole process of the study. It includes study site, study design the study sample and the study period. It describes what the data collection instruments were looking at and how the pilot study helped to maintain reliability and validity.

The results and the discussion of the data are presented in the next chapter.
4.1 INTRODUCTION

This chapter presents the results and the discussion of the findings in this study. The results are separated into two sections, the first being the checklist used to observe for the presence of labels on running IV lines and to determine whether the labels met the requirements set. The second section was the questionnaire given to the nurses to complete on the various topics regarding the preparation of parenteral medicines. For the checklist, all results of the observations are reported then discussed. The demographics of all the nurses who completed the questionnaire are then described followed by a discussion on all the variables the study was focusing on. In summary a comparison of some of the variables will be done from what was observed and what was collected in the questionnaire.

4.2 OBSERVATIONS USING THE CHECKLIST

4.2.1 Observed Intravenous lines

A total of 198 IV lines were observed across the three units. The renal unit did not have any of its patients on intravenous lines due to renovations. The patients had been moved to other wards.

Of the 198 IV lines, 75 (38%) were labeled and four (2%) had label information written directly onto the parenteral bag. This is despite the fact that according to the Good Pharmacy Practice (GPP) (SAPC, 2010) and the Medicines and Related Substances Act of (1965 as amended) all medicines being given to the patient have to be labelled. Similar to our study Wesbrook et al., (2011) 227 (40%) administrations had a label and eight percent of the IV lines in that study were also written directly on to the bag of the parenteral or syringe. This is concerning because in a study carried out in Haldwani town in India on General Practitioners and pharmacist on errors in drug labeling and medico-legal awareness, it was found that many doctors (88%) and pharmacist (70%) found missing labels especially on injectable emergency drugs increasing the chances of accidents with toxic effects (Srivastava; Prakash; Kumar Sinha; Gaur and Kumar Prasad, 2013).
4.2.2 Compliance to labeling requirement among wards

Figure 4.1 shows the overall of compliance among the different units to the labelling requirement of a label.

![Graph showing compliance among wards](image)

**Figure 4.1: Overall compliance of the units to labelling requirements (n=198)**

Of the 75 labels observed (38%), the highest compliance to the labelling requirements was 59% which was seen in the ICU, with general surgery being the least compliant with 15%. This indicated that most of the IV medicines were not labelled in the wards, this is concerning as according to Vorster and Berk (2002), labelling errors lead to the wrong identification of the patient, mix-ups of drug identification and giving a drug as a bolus instead of an infusion.

The compliance among the wards was further analyzed by calculating the p-values, using the Fischer exact test. According to the Fischer exact test, there was statistically significant difference among the wards with a p value = 0.006*. The surgical ward had the highest number of running lines checked (84) yet its compliance to labelling of IV lines had the least number of labels which is 15%.

The poor compliance to labelling requirements by the wards put patients at risk. A study by Davis; Wolf; Bass III; Thompson; Tilson; Neuberger and Parker in 2006, looking at the literacy and the miseducation of drug labels, found that due to no labels and incorrect labeling practices, 12 patients received medication not prescribed to them (n=218) and some received the wrong drug (16%) especially cephalosporin (7%) since they had similar names. These medication errors could all be avoided if there were correct labels present.
Chapter 4: Results and discussion

The researcher then looked at how many of the labels met the labeling requirements from each ward. For example if the ward had ten labels observed and only two of the labels had the name of the patient it would mean that ward had 20% compliance to the requirement for patient identification.

ICU was the leading ward with regards to compliance to labelling requirement with an average of 44% compliance followed by internal medicine with 34% then General Surgery with 22% compliance for all the requirements, this was despite the fact that the surgical wards was observed to have the most (insert the total % of iv lines running in the surgical ward) The high compliance to labeling requirement in the ICU can be attributed to nurses fearing for their patient’s safety and it could be due to the nurses not wanting to be blamed for the loss of life (Dannenfeldt, 1982).

In a study carried out in Pietermaritzburg South Africa (2015), the chief indications for referral to ICU were the need for cardiovascular and respiratory support with some other organ failures (Gordon; Allorto and Wise, 2015). In that study by Gordon (2015), none of the labels observed in their ICU contained the route of administration on their patient labels and the drip rate was observed for only 25% of the patients in their ICU. These results were identical to ours since in the ICU at DGMAH none of the labels had a route of administration and 25% of the labels also had the drip rate. In critical patients these two variables should be monitored. Whatever the administered drug characteristics, fast rates of drug administration are associated with pain, phlebitis, and loss of cannula patency leading to exposure to infections on the administration area (Cousins et al., 2005).

The different items required to appear on the label were quantified from the 75 (38%) labels observed.

Figure 4.2 illustrates the items that were observed on the labels across the three wards.
Chapter 4: Results and discussion

Figure 4.2: Label requirements observed across the wards (n=75)

Of the 75 labeled IV lines, 99% had the name of the medication, 91% had the patient's name, surname or hospital number, 83% of the labels had the name or signature of the professional who administered the parenteral and 80% had the date the IV line was put up. This showed good compliance to these labelling requirements and shows that patient identification is an important aspect to the nurses. This could be due to the fact that all medication, regardless of the route of administration, is required to have this information especially the patient identification. It is not specific just for medicines administered parenterally.

All the remaining requirements were below 50% with route of administration (3%) and drip rate (5%) being the lowest.

In a study which explored medicine administration errors in six hospital departments in the United Kingdom, Germany and France, they found that a lack of appropriate labelling was a frequent error, as was the case in our observation (Cousins et al, 2005). Administration rate was incorrect in 48% of the IV line observed. This could have been a challenge in our study as only three percent of the labels had the rate of administration which could result in errors. If the rate is not correct, this will impact negatively on the safety of the patient, as for example fast administration rates of medicines are associated with pain, phlebitis, and loss of cannula patency (Ong and Subasyini, 2013).
Chapter 4: Results and discussion

The use of a witness to confirm labels is intended to reduce the possibility of errors from occurring. To be effective, the witness must understand what the member of staff is doing and they therefore require the same level of training (Oxford Shire Clinical Commissioning Group, 2011). In our study a witness or a double signature was not observed on 63% of the labels. In the study by Gordon et al., (2006), only one percent of the labels observed had a second nurse to countersign as a witness.

In our study, 37% had a witness signature or name, this was similar to 39% (n=264) of the administrations observed by Athanasakis in 2015. Internal medicine wards in our study did not have even one of their labels having a witness. The witness will confirm that the staff member selects the correct medicine, ensures that the patient name on the label attached to the controlled drug is the same as which the staff member intends to give it to, and that the staff member has prepared the right dose, indicate on the prescription. They also ensure that the staff member gives it to the right patient (Good Practice Guidance, 2011).

4.3 DATA COLLECTED BY THE QUESTIONNAIRE

A total of 123 questionnaires were returned and completed for analysis instead of the 210 handed out. This is a 56% response rate. The response rate in this study was better than the 32% reported in most studies (Frohlich, 2011).

4.3.1 Demographics

Of the 123 respondents, 81% were females and only nine percent were males. The other ten percent did not indicate their gender on the questionnaires. This gender distribution showed more females than males which is in line with a study by Nel; Müller and Colyn (2011), which explored the scope of practice of a professional nurses working in the intensive care unit in South Africa, 90% of the respondents were female, this can be attributed to nursing being a female dominated profession.

Table 4.1 is a summary of all the demographics of the respondents.
The nurses were further analyzed by age, rank, and years of experience. The majority of the nurses were in the age group of 20-35 (28%) and 46-55 years (27%). Fifty eight percent were professional nurses with only four chief and matron nurses. The student nurses included in the study were the ones who had qualified as professional nurses in theory and were now doing the practicals. Since they were also preparing the parenterals they were included in the study. This is important since knowledge is expected to increase with rank or profession and with years of experience as seen in the scope of practice for nurses (Nursing Act 33 of 2005).

Forty two percent the nurses had more than 10 years of experience followed by one to five years with 33 %. In a South African study by Scribante et al., (1995) whose aim was to determine the scope of practice of the professional nurses, it was found that 30% of the respondents had one to four years of experience which corresponds to what was found in our study.
4.3.2 Preparation of parenteral systems

4.3.2.1 Preparation area

The World Health Organization states that the injection preparation area must be free of clutter so all surfaces can be easily cleaned (WHO, 2014). The international institute for safe medicine guidelines which were released in 2013 and revised in 2016 state that organizations must provide sufficient space for staff working in compounding areas to ensure that sterility is not compromised (National Medication Safety Task force, 2013).

In our study of the 84 (87%) nurses that said they prepared parenterals, 70% said they used the patients counter to prepare the medicines and 19% said it was done in a separate room. The remaining 11% said they prepared the IV lines on the medication trolley or the main kitchen.

The GPP guidelines state that there must be sufficient and suitable space necessary for ward and clinical services, compounding, pre-packing, parenteral admixture preparation, other aseptic compounding and cytotoxic preparations (SAPC, 2010). The WHO (2013) also states that all medicine must be prepared in a separate aseptic area. This was not the case in the wards since it was reported that they use the patients counter with no aseptic conditions. These are some of the benefits of having a unit dose system put in place (Ding, 2012).

In a study by Scheepers; Busch; Hofbauer; Huse; Kalcher; Landgraf; Neerup Handlos and Walser (2010) it was observed that there were no or just limited regulations concerning reconstitution in European hospitals even though aseptic preparation of parenterals is an important part of patient safety. In a previous study done by the same author they concluded that the best place to prepare in ward medication was on the patients bed counter with no disturbance and avoiding mix-ups of other medication belonging to other patients (2010). This was similar to what we found in our study where the nurses prepared the medication on the patients bed counter.

Preparation of IV medicines on the patient counter as indicated by 70% of the nurses in our study, is a great risk to patients, than when they are prepared in the pharmacy under appropriate standards (Austin; Hand and Elia, 2015). Such practice was found to have resulted in contamination of the drugs (23%) and injection of those drugs into the patient (17%) led to complications for seven percent of the patient in a study by Johnson and Stovinski in 1997. As our results showed that 70% of the nurses use the patients counter, they should therefore be extra careful to avoid contaminations and injecting wrong medication to the patients.
4.3.2.2. Preparation time for the medication

It is safer for the person who has prepared a drug to administer it to the patient after a second in charge or supervisor has double checked the content of the medication immediately (Chedoe; Molendijk; Hospes; Van den Heuvel and Taxis, 2012). In this study 78% percent of the nurses said the parenterals were prepared just before administration. This is good practice as many distractions can occur if the medicines are prepared in advance and not given immediately to the patient leading to administration of the wrong drug to a patient or giving the right drug to the wrong patient. The practice of preparing medicines immediately before administration should be encouraged for patient safety, as re-dosing where the person who mixed the medication has added a drug to the carrier solution but not labelled it and just before administration, the drug is added again has also been reported (Chedoe et al, 2012).

4.3.2.3. Reconstitution of parenterals

Majority of the nurses said they prepared more than five parenterals a day (32%) and only a few said they prepared three to five a day (18%). This shows that parenteral lines are constantly being put up so correct techniques should be used.

Seventy percent of the nurses indicated that their training entailed reconstitution of parenterals, 28% said experience and only ten percent used resources to prepare.

Table 4.2 shows the different responses obtained pertaining to preparation of parenterals.
Table 4.2: Important aspects related to preparation of parenterals

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes %</th>
<th>No %</th>
<th>Sometimes</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the same person who prepares the medication also administer it?</td>
<td>68</td>
<td>8</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>(n=113)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there written procedures on reconstitution?</td>
<td>65</td>
<td>30</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>(n=117)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If procedures for reconstitution are available, are they easily accessible?</td>
<td>61</td>
<td>20</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>(n=100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the procedures for reconstitution updated?</td>
<td>41</td>
<td>43</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>(n=103)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were you trained on reconstitutions?</td>
<td>77</td>
<td>19</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>(n=118)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were you taught on incompatibilities?</td>
<td>11</td>
<td>65</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>(n=112)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there verification by another nurse or a signature by another nurse</td>
<td>46</td>
<td>49</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>before administration of parenterals?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n=116)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you mix more than one medicine in one bag?</td>
<td>17</td>
<td>81</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>(n=121)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In a study done by Manchester pharmacy school (2013), which investigated what guidelines or procedures were being used when preparing parenterals; 76% of the nurses in that study reported that there were no written procedures to the daily routine of parenteral drug preparation and administration (Keers et.al, 2013). Similarly in our study 65% of the nurses reported that the written SOPs for reconstitution were present.

When there are no written procedures many steps can be missed when reconstituting the medicines, Westbrook et al., (2011) reported that medicine errors are avoidable when written procedures are put in place and implemented. Brinkcate and Lee (1992) also recommended after his study that written procedures for the management of intravenous preparations in the wards must be put in place to decrease medical errors. As indicated in Table 4.2, 65% of the nurses reported that written procedures on the reconstitution of parenteral medication were available and these were easily accessible (61%). This still leaves room for improvement.

Seventy seven percent of the nurses in our study reported that they had been trained on reconstitution of parenterals which is a requirement, according to the South African Nursing curriculum of 2015 for nursing. It was however interesting to note that 65% of the nurses in our study reported that they had never been taught on incompatibilities and yet it is prudent not to mix the solutions of parenteral drugs without knowledge of their compatibility (Nagaraju; Deepak; Aruna; Swathi; Reddy; Devi and Purushothaman, 2015). Information regarding drug
incompatibilities is well documented in computer databases, and information leaflets published by pharmaceutical companies. Nagaraju et al., (2015) continues to state that due to the increasing number of drugs developed and modernized each day, it is not possible to predict all incompatibilities but the presence of a clinical pharmacist in a ward may minimize the occurrence and increase patient safety.

The standard operating procedures should be updated often as new information is received every day and as health professionals, dealing with the lives of people, there is a need to keep abreast of the latest guidelines and standards. However, 43% of the nurses in our study indicated that the reconstitution procedures were not updated.

Like all institutions, DGMAH has the responsibility to develop and maintain their own SOPs. Cousins et.al (2005) reported that individual institutions have a responsibility to audit the implementation of their SOPs regularly and to provide feedback to practitioners on those areas of practice that are out of compliance with the procedure. SOPs play a critical role in all service as without agreed procedures of this type it is very difficult to teach, maintain, and audit practices (Ochoa and Vega, 2015).

Figure 4.3 shows the SOPs which were reported to be present in the wards.

![Figure 4.3: SOPs reported to be available in the wards (n= 121)](image)

Figure 4.3 demonstrates which SOPs were available in the respective wards. These SOP’s are related to parenteral drug administration and preparation. As discussed before under reconstitution of parenterals, the preparation area has to be clean and if possible preparation...
has to be done under aseptic conditions. Forty three percent of the nurses said that there was an SOP dealing with cleaning of the medicine preparation area.

In the Australian safety regulations of 2010 regarding the labelling and packaging practices, a checklist as a standard procedure that the administrator was used to tick of the steps being done as they prepare for administration. A similar SOP for hanging up an IV line was reported to be present in the wards by 47% of the nurses in our study.

Since 65% of the nurses mentioned that they had not been taught on incompatibilities, it was not surprising to see that only 11% indicated there are SOPs in the wards pertaining to this.

More than half (62%) of those nurses that reported the availability of written procedures for reconstitution said these procedures were easily accessible. This is very important to ensure that the nurses always have a point of reference and a guide on how to carry out certain duties and tasks.

In a document done by the Ministry of Health South Africa in October 2010, it was indicated that all the Health SOPs must be updated every year. In our study 21% of the nurses indicated that SOPs were revised yearly, 20% said they were reviewed every two years (National Department of Health, 2010).

The third edition of the Royal College of Nursing (2010) lists all the SOPs that should be present in the wards for standards for infusion therapy. The SOPs similar to what was found in our study were the reconstitution SOP, compatibility SOP, labelling SOP and infusion set-up SOP.

4.3.3 Knowledge about labelling requirements

The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented (Medicines and Healthcare Products Regulatory Agency, 2015). According to the Medicine Act 101 of 1965 (as amended) every container of medicine which is intended for administration to humans or is sold shall have a label attached to it. In our study only 83% of the nurses said all parenterals were labelled before being put up. The Nursing Act also emphasizes that, labelling should be done for all medication prior to being put up (Nursing Act 33 of 2005).
Chapter 4: Results and discussion

It is expected that the nurses should know the requirements for correct labelling since it is in their act and curriculum however none of the respondents knew all nine of the criteria that should be on a label.

Figures 4.4 and 4.5 show the number of nurses that were knowledgeable about the labelling and the benefits of labelling medicines correctly.

Figure 4.4: Knowledge for requirements that have to appear on a label (n=121)

It is evident from Figure 4.4 that the nurses knew that the medication must have a label indicating who it is prepared for (80%) and when the parenteral was put up (67%). Limited research has been done to test the nurse’s knowledge on labelling requirements but in their curriculum they are taught on medication labelling worldwide (Nursing curriculum, 2015; Blackman; Hall and Darmawan, 2007; Timby, 2009).

Education on the importance of indicating the route of administration and the drip rate should be provided, since the nurses had the lowest percentage knowledge regarding these aspects of labelling requirements (which were 14% and four percent respectively).

4.3.4 Opinions about the benefits of labelling

The nurse clearly also know the benefits of labelling correctly as indicated in Figure 4.5.
Chapter 4: Results and discussion

Figure 4.5: Benefits of labeling correctly (n=121)

The major benefit for labelling correctly is that it helps to ensure that accurate information is recorded and associated with the correct patient (Sanford, 2012). Similarly the nurses (50%) in our study were of the opinion that correct labelling would ensure the correct identification of the patient, 66% indicated that it will ensure that the correct medicine will be administered and hence help to avoid medical hazards (29%).

Sanford (2012) went on to say that labels bridge the gap between patients and the efficient automated workflow run by different individuals in the health profession. In the same light, 22% of the nurses in our study also indicated that if there is a label all health care professionals will know what is given to a particular patient.

The three other benefits of proper labelling which were listed by nurses in our study were that the label communicated with the next person on what medication the patient is receiving, overdoses will be avoided and therefore there will be less medical errors since the patient will be given what is prescribed. These benefits were in line with other studies previously done. (Cousins et al., 2005; Tilleul et al., 2003; Schellack, 2011).

4.3.5 Knowledge of the requirements that have to appear on the label

Figure 4.6 below summarizes of knowledge level of all the nurses with the requirement of labeling.
Figure 4.6: Compliance of knowledge to labelling requirements (n=123)

In Figure 4.6 the percentages of how many of the requirements the nurses knew was calculated. None of the nurses received 9/9 for the knowledge of all the nine labelling requirements. Only one nurse knew eight of the nine labelling requirements. The next highest level of knowledge was those who received at least five of the nine requirements (18.7%), followed by those who knew six of the requirements (17%).

When looking at how many requirement were known in the entire population of nurses (n=123), on average the nurses know 5/9 of the requirements required to appear on a label. This shows that with more training there can be improvement since the nurses have an idea on labeling practices. The pie chart percentages do not add up to 100% because the remaining 31% of the nurses did not know any of the requirements.

4.3.6 Resources

Figure 4.7 shows that 46% of the nurses in this study indicated they had a resource that showed the different diluents available for reconstitution and the volumes to be added when preparing parenterals. In our study, very few respondents referred to manufactures leaflet (2%). Prescriptions seldom provide all the information the nurses will need to complete their
Chapter 4: Results and discussion

tasks, it is therefore important that the manufactures leaflet and updated resources are made available in the wards for reconstitution. Other resources that were used were the ward protocol signed by the Head of Department (2%) and the MIMS (1 %). It is concerning that the nurses in our study seldom consulted resources when reconstituting IV medicines, as resources provide information to minimize mistakes and errors when reconstituting medicines. This was emphasized by Cousins et al., (2005) when concluding that if staff members are provided with more readily available information regarding diluents, there will be a decrease in loss of solubility and stability of drugs and large fluid preparations.

Resources provide information to minimise making mistakes and medicine errors.

Our results were similar to the study done by Tilleul et al., (2003) which found that a minority of the nurses based their information on reliable sources such as the national drug compendium (25%) and the manufacturers leaflet (41%).

Tilleul et al., (2003) also found that most of the information on drug diluents (83%) and volumes (79%) was instead based on the nurses’ experience. Similar to our study this shows that in the French study, resources were being used minimally and diluents were used according to the knowledge or experience the nurses had.

The resources which were present in the wards that can help when prescribing or when having challenges are presented in Figure 4.7.

![Figure 4.7: Resources available in the ward (n=121)](Image)
In a study by Chedoe et al., (2012) at the University of Groningen in the Netherlands, they found that with written materials like textbooks and procedures along with lectures to the nurses, the medicines errors were massively decreased from 31% - 15 %. According to Figure 4.7 it showed that the nurses in our study had resources to refer to when preparing IV medicines and they had indicated in section 4.3.2 that standard operation procedures were available for reconstitution, what is concerning is that they seldom used them.

4.3.7 Dose and drip rate calculations

Nurses administer most of the medication in the wards, and this requires them to do some form of calculation especially when working with paediatrics and critically ill patients (Tshiamo; Kgositau; Ntsayagae and Sabone, 2015). In our study 91% of the nurses indicated that they carried out dosage calculations, the other examples given were drip rate (7%) and concentration calculations (2%). Similarly, 87% (n=39) of the nurses in the study by Padma; Saritha and Indira (2016) reported that they carried out dosage calculations. In their study Padma et al (2016) further discovered that 46.7% of the nurses had inadequate knowledge of drug dosage calculations, 53% had moderately adequate knowledge and only six percent had adequate knowledge. These findings indicate the importance of nurse education on carrying out calculations.

Twenty eight percent of the nurses in our study indicated that they carry out some form of calculations for eight out of ten prescriptions and 24% said they encountered between two and five out of ten prescriptions requiring calculations. In a study done by Chua et al., (2010) in the paediatric wards, 98% of the nurses indicated that they carried out dose calculations daily. This is because most doses are calculated per body weight for children, not for adults.

This makes it of utter importance that adequate dose calculations is conducted in order to avoid dosing mistakes. According to the College and Association of Registered Nurses of Alberta (2015), if calculations are done incorrectly when administering, medicine toxicity and system failures or under dosing of the patients and no recovery may occur. These risks make it important that nurses are trained on proper dosing calculation.

According to Cavell et al., (2014) nurses and doctors need programmes that will help them practice calculations on a regular basis since they will encounter such challenges for their entire profession. In response to the questions whether or not the nurses thought they needed extra training on calculations, 46% indicated that they needed training. This was in line with the 46, 7% who were found to have inadequate knowledge in the study done by Padma et al., in 2016.
Tshiamo et al., (2015) indicated that even though the curriculum for nurse training may be credited for the presence of tools for assessing medication administration, such tools make no provision for testing proficiency in calculation of medical dosages. This was further emphasized by Elliot and Joyce (2005), when they concluded that a student nurse may graduate from the programme and become a nurse with a degree without having mastered calculations of medication dosage which is a skill that is critical in the prevention of medication error. This then implies that more training should be conducted and continued professional development on calculations for nurses should be emphasized.

Likic and Maxwell (2009) looked at postgraduate nurses and the errors they make in following ward protocols. They concluded that nurses must be assisted to understand that they need to continue learning even after graduation (2009). Singh; Vohora; Chokski; Solanki; Chaudhary and Patel (2012) also said that medication errors have been found to be associated with poor training and inexperience on the part of nursing personnel (2012). Since majority of the nurses participating in our study were post-graduate staff and professional nurses it is important to provide continuous learning and training.

4.3.8 Nurses perception of unit-dosing

Unit dosing is defined as a package that contains a particular dose of drug ordered for a patient that is fully identified and ready for administration (Thibault et al., 2008). Unit-dose preparations are done daily, often manually, by technicians and then checked by pharmacists. These contain thousands of patient-specific dosages of drugs, are sent to the wards daily, for nurses to administer medications to patients (Murray and Shojania, 2009).

Because of so many medication errors, some facilities resolved to unit dosing (Murray and Shojania, 2009). Sinnemaki et al., (2013) discovered that unit-dosing enhances patient safety by limiting errors that can be conducted during the preparation, compounding, reconstitution and labelling of medicine before administration as it would be done by the custodians of medicine who are taught on how to conduct the mentioned procedures. Another author also concluded from his study that it saves nurses working time (Thibault et al., 2008).

When asked if they thought the following duties related to unit dosing were their responsibility, the following results were obtained.
Table 4.3: Responsibility to perform these duties

<table>
<thead>
<tr>
<th>Duties</th>
<th>Yes (n=116)</th>
<th>No (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconstitution (%)</td>
<td>74</td>
<td>15</td>
</tr>
<tr>
<td>Labelling (%)</td>
<td>85</td>
<td>9</td>
</tr>
<tr>
<td>Calculating dose (%)</td>
<td>82</td>
<td>11</td>
</tr>
<tr>
<td>Calculating drip rate (%)</td>
<td>85</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 4.3 shows that of all the duties presented to the nurses regarding the preparation of parenterals, more than 50% thought that it is their work and line of duty. These topics are covered in the curriculum run by the South African National Department of Health under curriculum for nursing Diploma (2015) therefore these are subjects that they were aware of and expected to encounter and carry out within their profession.

In a study by Tilleul et al., (2003), almost half of the nurses (45%) felt that calculations are not necessary for the preparation or the administration of the IV drug infusion. This was the opposite in our study where 82% thought that for both dosage and 85% for drip rate calculations it was their duty. This is a good indication that the nurses want to take responsibility for delivering the correct service and medication into their responsibility.

Even though the nurses thought these were their duties 58% said they would prefer unit-dosing compared to the 27% who did no prefer it. Similarly in a study carried out in Qatar (Zaidan; Rustom; Kassem; Al Yafei; Peters and Ibrahim, 2016) 23 respondents (7%) were also not satisfied with the unit dose system. The nurses who indicated that they preferred unit dosing provided the reasons as indicated in Figure 4.8.
Figure 4.8: Reasons unit dosing is preferred (n=53)

Thirty five percent of the nurses thought unit dosing would save them time and 25% said they would be sure that the correct calculations for the dose had been done’ since pharmacists are well trained in calculations pertaining to medication. In study by Zaidan et al., (2016) where the nurses’ perceptions and satisfaction with the use of automated dispensing cabinets at the Heart and Cancer Centers in Qatar, 94 % (n = 378) of the nurses also indicated that the medication delivery system allowed them to do their job more safely and 87 % (n = 349) agreed that they could administer the right dose of medication at the right time.

One way to minimize medicine errors is to deliver premixed medication from the pharmacy to nursing wards without needing any further preparation by nursing staff (Athanasakis, 2012). The same was confirmed by Gray (2008) who said, error rates were shown to vary from 15% to 20% where administration was based on ward stock, but were reduced to five to eight percent where individual patient supply was provided. The benefits for using the unit-dose system mentioned in the other studies (Athanasakis, 2012; Gray, 2008) were similar to the ones listed by our nurses and all of them lead to decreased medical hazards.

Only seven percent of the nurses chose the correct definition to unit dosing when given a chose out of three different definitions. This could be the reason why the 23 of the nurses did not prefer unit dosing. Forty three percent said unit dosing was administering one medicine at a time to the patients.

The reasons given by the 23 nurses who did not prefer unit dosing are shown in Figure 4.9.
Chapter 4: Results and discussion

Figure 4.9: Reasons unit dosing is not preferred by the nurses (n=23)

The major perceived disadvantage of unit dosing was that pharmacy was taking long to complete the prescriptions (Zaidan et al., 2016), which was a similar concern for 43% of our study nurses. The other reasons given by the nurses in our study were that nurses would not be completely sure that the drug preparation was done correctly (20%) and the time it was prepared since some drugs have to be given immediately after being reconstituted (13%). Another reason for the nurse’s not preferring unit dosing could be the fact that it has not been brought to their exposure. This is seen by the fact that only seven percent of the nurses knew the proper definition of what unit dosing is and that they had not seen a place where it is feasible.

4.3.9 A comparison between the nurse’s knowledge on labelling and what was observed on the labels in the wards.

Labelling practices were the most concerning of all the results obtained. Some contrast was found in the knowledge the nurses showed and what was on the observed labels against the checklist. Figure 4.10 shows the comparison between what was observed on the labels and the knowledge the nurses had on labeling requirements.
Chapter 4: Results and discussion

Figure 4.10: Comparison of what was observed and the knowledge on labelling practices

This figure clearly shows that for most of the labelling requirements, the nurses labeled better than what they indicated to know. The lack of knowledge was demonstrated further as the route of administration and the drip rate were not included on the observed labels.

There was no correlation between the observed results and the responses. Some requirements were seen on the labels yet the questionnaire showed limited knowledge on those requirements. These results are not a true reflection of the entire population of labels since they are results of only 75 labels that were observed (38%). Therefore this could have contributed to the results not correlating.

4.4 SUMMARY

The results discussed above are based on the data collected for five month in three different units, internal medicine, general surgery and intensive care unit, at DGMAH. In total there were 198 parenteral lines observed for labelling requirements and 123 questionnaires were filled and returned for analysis. Majority of the nurses were females that were professional nurses.

The preparation of parenterals needs to be done in the correct manner to avoid any medical errors. More written procedures and resources are needed in the wards. The nurses need to
be more accountable for the lines they put up by putting up labels and co-signing to make sure all the requirements are met.

The use of unit dose systems has both its benefits and down sides according to the nurses and these may need to be addressed if a hospital decides on unit dosing.

The next chapter gives the conclusion to the study. The limitations of the study and recommendations are also outlined in Chapter 5.
5.1 INTRODUCTION

This chapter contains a summary of the results obtained looking at the objectives. The recommendations and limitations of the study are also given with a brief conclusion on the study.

5.2 SUMMARY OF RESULTS

5.2.1 Study population demographics

One hundred and ninety eight IV lines were observed and evaluated to determine labelling practices of nurses using a checklist and 123 nurses responded to the questionnaire. This was done in three units at DGMAH; being the internal medicine, general surgery and the adult Intensive care unit. For the questionnaire, there were more female (81%) than males (9%) nurses. More than half of these were professional nurses (58%).

5.2.2 Labelling

Only 38% of the IV lines observed had labels whereas on the questionnaire 83% of the nurses reported that all their IV lines were labelled. Of the labels observed none complied with the entire labelling requirements set out by the Medicine act 101 of (1965) and the nursing act of 2005. ICU had 59% of their IV lines labelled but none of their labels had the route of administration indicated.

The majority (80%) of the nurses knew that the medicine had to have the patient’s identification but in both observation and knowledge assessment the labels did not have the route of administration and the drip rate. None of nurses obtained 9/9 for the knowledge of the labelling requirements and 23 (18.7 %) of the nurses knew 5/9 of the requirements. Half of the nurses indicated that the benefits for correct labelling were that the correct patient received the correct medicine (66%) which would help to avoid medical hazards (29%).

5.2.2.1 Preparation of parenterals

Seventy percent of the nurses used the patients counter to prepare medicines. Seventy eight percent reported that they prepared the medicines just before administration. The nurses used their training from college (70%) and their experience (28%) when
reconstituting parenterals. Only 10% indicated they use reliable resources. Sixty five percent of the nurses indicated that they have SOPs related to parenteral medicines however 43% (n=123) indicated these SOPs were not updated. Twenty three percent of the nurses indicated that they used their experience or the knowledge they acquired during training (70%) for preparation of parenterals.

5.2.3 Calculations

Twenty eight percent of the nurses in our study indicated they carried out some form of calculations for eight out of ten prescriptions prepared. Examples of the calculations done in the wards were, 91% the dosage calculation. The others were drip rate (7%) and concentration (2%). Forty six percent of the nurses indicated that they needed further training in calculations.

5.2.4 Availability of Resources and SOPs

Most (67%) of the nurses indicated that there were SOPs regarding the preparation of parenterals available in the wards and 62% indicated that these were easily accessible. Sixty five percent of the nurses indicated that they had not been taught on IV medicine incompatibilities and only 11% had the SOP for incompatibilities in their wards.

A resource that provides information on the different diluents and volumes to be used when reconstitution was present in the wards, as indicated by 46% of the nurses.

5.2.5 Unit dosing

Only seven percent of the nurses selected the correct meaning of the term unit-dosing. Fifty eight percent of the nurses however indicated they would prefer unit dosing. The two major reasons for them preferring the unit dose system were that it would save them time (35%) and the correct calculation would be carried out (25%). The reasons given by the 23 nurses (27%) who indicated they did not prefer unit dosing were that they felt that they would not be sure the IV medicines were prepared correctly and 20% were of the opinion that there would be a delay in receiving the medicine from the pharmacy.

5.3 LIMITATIONS OF THE STUDY

The limitations of the study are as follows:
Only the labelling practices were observed using the checklist, all the other topics covered in the questionnaire were information reported by the nurses and not verified to be correct or not.

The researcher also could have requested to see the SOPs and resources indicated to be present to ensure they existed.

This study was only done in one institution and not all the wards were included therefore the findings may not be applicable to other hospitals and wards.

### 5.4 CONCLUSION

This study showed that it is mostly the professional nurses who prepare parenteral medicines in the wards.

Most of the nurses indicated that they do dosage calculation and drip rate for some of the patients. According to the literature found, nurses always need to update their calculations skills even after graduating or receiving their certificate (Cavell et al., 2014). In line with this, 46% of the nurses indicated that they needed more training on calculations.

From what was observed with the checklist, only 75 IV lines had labels but the nurses reported that they label most of their IV medicine (83%). None of the labels observed complied 100% with the requirements set in the Nursing Act. Therefore training needs to be done to improve the labelling practices in the wards at DGMAH. The nurses knew that if labelling is done correctly this will benefit the patient and minimise medical hazards which is key of Batho Pele Principles.

All the wards need written SOPS that nurses can follow so that the standard of care can be quantified. All resources should be made readily available with easy access to the nurses. The nurses reported that they had certain SOPs in the wards like the hanging up an IV line (47%) and for cleaning the preparation area (43%). They also indicated that they use different resources.

Having a team that includes a pharmacist that will monitor that all the steps for drug administration are in-place, including labelling correctly as part of quality assurance, would help to decrease the amount of errors uncounted in the wards (Hughes and Blegen, 2011).

Unit dosing is still a foreign concept to some of the nurses since the majority did not know the definition. However the few who indicated that they would prefer this system reported
that it would really save them time and they would know the correct dose was calculated by
the pharmacist. Therefore, this practice could be explored by institution.

It is the pharmacist’s role to ensure that all aspects pertaining to medicine are followed and
done correctly since they are the custodians of medicine. They therefore need to be
assigned time in the wards to monitor drug management and delivery practices to ensure
that medicines are handled correctly and patients’ lives are safe.

This study will contribute positively in preparation of parenteral medicine everywhere
increasing awareness on the gaps in the system therefore helping in reducing medicine
errors. It will encourage the development of guidelines to be followed on maintaining good
and healthy parenteral services to our patients. Most importantly it will impart knowledge on
other health care professional for the improvement of our services in the wards.

Recommendations have been made which will help us achieve the goal of good safety and
health for our society at large.

5.5 RECOMMENDATIONS

The study showed that there is a lot to improve in the preparation of parenterals. Some
being lack of SOPS, no adequate labelling and further training being needed in calculations.
Therefore the following recommendations were made based on the results of the study:

• A similar study can be conducted to include all the wards at the hospital and also
determine how other hospitals are practicing with regards to preparation of IV
medication. This will help determine whether these results are specific to the wards
selected at DGMAH or can be generalized across all wards in the public and private
sector hospitals.

• A follow-up study could be done to ensure the resources and SOPs that the nurses
indicated as available are actually there.

• Another survey should be conducted to actually test the nurse’s knowledge on
calculations followed by a training session as requested by some of the nurses.

• The researcher could shadow the nurses whilst they prepare parenteral medicines to
have more accurate evidence of the actual practice in the wards as it has been done in
other studies.
• A standard label should be issued by the pharmacy which has all the labelling requirements and the nurses can just complete the required information. This would make it easier not to miss any essential information when labelling parenterals.

• Training programmes need to be developed for the nurses so they keep abreast of current labelling practices/requirements.

• There should be a sterile room or a medicine room in all the wards where medication can be prepared to avoid contamination and distractions.

• Pharmacists need to go to the wards and train the nurses, where they provide pharmaceutical information regarding aseptic preparation of parenterals and develop guidelines on the most common incompatibilities among medicines and frequently used diluents.

• The hospital should assign some staff within the health professionals discipline to go and benchmark at a hospital currently using the unit dose system and see if it would be feasible for DGMAH and its staff. Then a study and trial period could be done in some wards to see if it is possible since this system has been shown to reduce the time for medication administration for the nurses and decrease medicine errors.

5.6 CLOSURE

All the references used in this dissertation will be listed in the next chapter followed by all the appendixes.
REFERENCES


References


## Appendix 1: The Checklist

**Date:**

**Ward:**

**Time in the ward:**

**Bed no:**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Patient identification</td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>Name of the medicine</td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td>Concentration of the medicine</td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Route of administration</td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>Drop rate</td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td>Time parenteral was started</td>
<td></td>
</tr>
<tr>
<td>g.</td>
<td>Professional who put up the parenteral</td>
<td></td>
</tr>
<tr>
<td>h.</td>
<td>If parenteral comes in powder form, time of constitution</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendices

Appendix 2: The Questionnaire

Date:

Ward:

Nurse’s details: Rank

<table>
<thead>
<tr>
<th>Chief</th>
<th>Professional</th>
<th>Staff</th>
<th>Student</th>
</tr>
</thead>
</table>

How many years of experience do you have?

0-5  □  6-10  □  >10  □

Parenteral delivery systems

1. Do you prepare parenterals for patient administration?
   Yes  □  No  □

2. Where do you prepare and reconstitute parenteral medication?
   On the patients counter  □  in a separate room in the ward  □
   Other? __________________________

Reconstitution of parenterals

1. How long before administration are admixtures prepared for a patient?
   Just before administration  □
   When preparing for the dosing time for all the patients  □

2. How many reconstitutions do you do per day?
   1-2  □  3-5  □  >5  □

3. Does the same person prepare the admixture and administer it?
   Yes  □  No  □  Sometimes  □

4. Are there written procedures for drug reconstitution?
   Yes  □  No  □
5. If yes, are they easily accessible?
   Yes ☐ No ☐

6. Are the procedures updated on a regular basis?
   Yes ☐ No ☐

7. Have you been trained on how to do reconstitutions for parenterals?
   Yes ☐ No ☐

8. Are you taught about incompatibilities between some drugs?
   Yes ☐ No ☐
   If yes, please give one example
   ____________________________________________________________
   ____________________________________________________________

9. Is there someone else to double check after reconstitution of parenterals?
   Yes ☐ No ☐

10. Do you have cases where 2 or more drugs are infused together in the same bag?
    Yes ☐ No ☐

11. How do you know about the reconstitution of parenteral medication?
    Experience ☐ training ☐ resources ☐

Labelling

1. Are all parenterals labelled before administration to the patient?
   Yes ☐ No ☐

2. Please list the items required to appear on a parenteral label:

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Item 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
3. List the benefits of labelling parenteral medication correctly.

________________________________________________________________

________________________________________________________________

________________________________________________________________

Standard Operating Procedures

1. Are there standard operating procedures for preparation and administration of parenteral medicines in the ward?
   Yes [ ] No [ ]

2. If yes, are they accessible to all staff members?
   Yes [ ] No [ ]

3. Which of the following SOPs are present in the ward?
   Cleaning of administration site [ ]
   Intravenous drug administration procedures [ ]
   Hanging up the IV line for an infusion [ ]
   Removal of an IV line [ ]
   Monitoring the administration area for infections [ ]
   Incompatibilities when constituting [ ]
   Any other?
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________

4. How often are the SOPs revised?
   Yearly [ ] 6 monthly [ ] every two years [ ]

Resources for information

1. Is there a book or document that gives information on all the diluents and volumes used for reconstitution?
   Yes [ ] No [ ]

2. Which of the following reference are present in the ward?
3. Is there a document that can be referred to for incompatibilities of parenteral solutions with medicines?
   Yes ☐  No ☐

4. How do you get information from steps you are not sure of when preparing parenterals?
   Package leaflet ☐  Consult chief nurse in charge ☐  Look in a safe practice for IV administration text book ☐

**Calculations**

1. How often do you do calculations for the preparation of parenteral medicines?
   8/10 patients ☐  5/10 patients ☐  2/10 patients ☐

2. Which calculations are commonly done in the wards?
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

3. Do you think education on the calculations mentioned above is necessary?
   Yes ☐  No ☐

**Unit-dosing**
1. What do you understand by the term unit-dosing?

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

2. Do you think it is your duty to perform the following duties:
   i. Reconstitution? Yes ☐ No ☐
   ii. Labelling? Yes ☐ No ☐
   iii. Calculating the dose? Yes ☐ No ☐
   iv. Calculating the drip rate? Yes ☐ No ☐

3. Would you be comfortable with getting the medication prepared, labelled and ready for administration from the pharmacy?
   Yes ☐ No ☐

Signature: ___________________________ Date: ___________________________
Appendices

Appendix 3: SMUREC Clearance Certificate

Sefako Makgatho Health Sciences University
Research & Postgraduate Studies Directorate
Sefako Makgatho University Research Ethics Committee
(SMUREC)

Molotlegi Street, Ga-Rankuwa 0298
Tel: (012) 521 5617/3698 | fax: (012) 521 3749
Email: loreto.phin@unu.ac.za
P.O. Box 163 Mebusana 0204

APPROVAL NOTICE - NEW APPLICATION

01 October 2015
Ms PP Jiyane
Department of Pharmacy
P.O. Box 218
Mebedusa 0294

Meeting: 01/2015

SMUREC Ethics Reference Number: SMUREC/H247/2015: PG

The New Application received on 07 September 2015 was reviewed by members of Sefako Makgatho University Research Ethics Committee on 01 October 2015 and was approved on 01 October 2015.

Title: Preparation practices for parenteral administration at Dr George Mukhari Academic Hospital in South Africa

Researcher: Ms PP Jiyane
Supervisor: Dr M Matlala
Co-supervisor: Prof A Gous
Institute: DMU/UG
Department: Pharmacy
School: Health Care Sciences
Degree: MSc Med Clinical Pharmacy

Please note the following information about your approved research protocol:

Protocol Approval Period: 01 October 2015 – 01 October 2016

Please remember to use your protocol number (SMUREC/H247/2015: PG) on any documents or correspondence with the REC concerning your research protocol.

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

After Ethical Review: Please note that a template of the progress report is available in the Research Office and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year if necessary. Annually a number of projects may be selected randomly for an external audit. Translation of the consent document in the language applicable to the study participants should be submitted.

International Organisation (IORG In145319), Institutional Review Board (IRB00005122), Federal Wide Assurance (FWA00009419)
Expiry date: 11 October 2016 and NHREC No. REC 1104060-003

Sincerely,

[Signature]

DR C BAKER
DEPUTY CHAIRPERSON SMUREC

Date: 01/10/2015

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Appendix 4: Nurses Consent Form

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ENGLISH CONSENT FORM

Statement concerning participation in a Research Project

Name of Project: Parenteral medicine administration practises at Dr George Mukhari Academic Hospital in South Africa

I have read the information on the proposed study and understand the information, aims and objectives thereof. I was provided the opportunity to ask questions and given the opportunity to think about being involved. The aim and objectives of the project are sufficiently clear to me. I have not been pressurized or influenced to participate in any way.

I understand that participation in this research project is completely voluntary. This will have no influence on the regular work that I do and will not affect my status at the hospital.

I know that this research project has been approved by the Sefako Makgatho University Research and Ethics (SMUREC) and the CEO of Dr George Mukhari Hospital. I am fully aware that the results of this research project will be used for scientific purposes and may be published. I consent to this, provided that my name is not revealed and my responses will be anonymous.

I hereby give consent to participate in this project

.......................................................... ..........................................................
Name of Nurse Signature

.......................................................... ..........................................................
Place Date Witness

Statement by the Researcher

I provided verbal information regarding this Project. I agree to answer any future questions concerning the Project as best as I am able. I will adhere to the approved protocol.

.......................................................... ..........................................................
Name of Researcher Signature Date Place
Appendices

Appendix 5: Information Leaflet

Dear Potential Participant

Please read this information about the study and feel free to ask any questions should you need any clarity before deciding to take part in the study.

I am a Masters student at the Sefako Makgatho Health Science University. I am conducting a research study under the topic: Preparation practices for parenteral administration at Doctor George Mukhari Academic Hospital in South Africa.

The aim of the study is to investigate parenteral preparation practices in the wards at DGMAH.

The objectives of the study are as follows:

- To determine where and how parenteral medication is prepared in the wards
- To determine the parenteral labelling practices at DGMAH
- To investigate the nurses’ knowledge on calculations for parenteral preparations commonly encountered in the wards
- To investigate whether DGMAH has written SOPs for preparation and labelling of parenterals in the wards
- To determine whether the wards have resources for preparing admixtures and guides on all incompatibilities
- To explore the possibility of adopting unit-dose dispensing in the hospital

The questionnaire is anonymous and no personal information about you will be exposed during and after the study. Everything will remain confidential.

All the results and knowledge gained will be used to make recommendations to the management at Dr. George Mukhari Academic Hospital to provide training about preparation of parenteral medication.

The study will be has been approved by the Sefako Makgatho health science University Research and Ethics Committee.
If you agree to participate in the study, you will be required to sign a consent form to indicate your willingness to participate. You will then complete the questionnaire.

I will really appreciate it if you will take part in this study.

If you have any further questions regarding this study, please feel free to contact me on 012 521 4740.

Thank you.