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DETERMINING MEDICATION PRESCRIPTION AND ADMINISTRATION ERRORS IN A PAEDIATRIC ONCOLOGY WARD IN GAUTENG

by

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Submitted in fulfilment of the requirements for the degree

MNurs (Clinical) in Health Sciences

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DEDICATION

To all the children who bravely battle cancer

and for those who died fighting.

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I would like to thank the following people, without you, none of this would have been possible

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* God - Who has blessed me with this. I hope to be just a small part of Your plan.

"But as for you, be strong and courageous, for your work will be rewarded."

2 Chronicles 15:7

DECLARATION

I, Nadine Puzicha, declare that this dissertation, titled "Determining prescription and medication administration errors in a paediatric oncology ward in Gauteng – an observational study", is my own work. All sources referenced and quoted have been mentioned and acknowledged in a full reference list. Furthermore, I declare that this work has not been submitted for any other degree at any other institution.

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Researcher signature Date

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Witness signature Date

ABSTRACT

Medication errors in paediatric patients are a complex health problem occurring worldwide. Previous work has researched the incorporation of electronic methods in prescribing and administering medication, but little is known about medication errors in hospitalised children in South Africa, where all prescription and administration of medication is done manually.

A quantitative, observational, cross-sectional design was used to conduct this study. The setting for the study was a paediatric oncology ward in a central hospital in Gauteng, South Africa. A convenient sampling method was used, and data was collected using pre-determined structured data sheets. A total of 432 prescribed medications written on prescription charts in the paediatric oncology ward were analysed and 1064 medication administrations were directly observed. This data was used to determine the types, frequencies and contributing factors to prescription and medication administration errors.

During prescription chart analysis, a total error rate of 56% was discovered in the general writing and labelling of prescriptions while a significant number (78%) of all prescriptions were incomplete. Relating to the error type, it was found that 119 of 432 prescribed medications had a prescription error with wrong dose errors being the most prevalent. Contributing factors which increase the incidence of prescription errors were scheduled medications, bed occupancy, day of the week, incomplete prescriptions and illegible writing.

In the direct observation of medication administration, a significant error rate of 93% was found. Documentation errors comprised 63%, making this type of error the most prevalent. Of 1,064 medication administrations observed, 1 in 10 medications were omitted. When considering the “rights of medication” (right patient, medication, dose, route, time), dose errors were the most frequently observed. Contributing factors which increased the incidence of medication administration errors were the type of medication, scheduled medications, route of administration, rank of the administrator, bed occupancy, and the day of the week on which the administration took place.

The findings indicate that supervision and training in both prescription and medication administration would contribute to achieving this goal.

Keywords: Medication errors; Observation; Paediatric; Paediatric Oncology

TABLE OF CONTENTS

CHAPTER 1: ORIENTATION TO THE STUDY

CHAPTER 2: LITERATURE REVIEW

CHAPTER 3: RESEARCH DESIGN AND METHODS

CHAPTER 4: RESULTS AND DISCUSSION

CHAPTER 5: CONCLUSIONS, IMPLICATIONS AND LIMITATIONS

LIST OF REFERENCES

LIST OF ABBREVIATIONS

Abbreviation	Meaning
BCMA	Barcode-assisted medication administration
CPOE	Computerised Prescription Order Entry
eMARS	Electronic medication administration record
FDA	Food and drug administration
HDI	Human development index
IOM	Institute of medicine
ISMP	Institute for safe medication practices
IV	Intravenous
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
NCS	National core standards
NPO	Nil per os
SANC	South African Nursing Council
SOPs	Standard operating procedures
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

LIST OF TABLES

LIST OF FIGURES

LIST OF ANNEXURES

1 ORIENTATION TO THE STUDY

You treat a disease: You win, you lose.
You treat a person, I guarantee you win – no matter the outcome.

- Patch Adams

1.1 INTRODUCTION AND BACKGROUND

Medication errors in paediatric patients are a complex health problem worldwide that involves a variety of health disciplines as well as their ethos of safety (Larose, Levy, Bailey, Cummins-McManus, Lebel & Gravel 2017:7). Medication errors have many potential causes including errors or omissions in prescribing, dispensing and administration. The consequences of such errors can range from those with little impact on a patient to those with very serious effects (Glanzmann, Frey, Meier & Vonbach 2015:1348; Thomas, Gillard, Khor, Hakendorf & Thompson 2015:369).

In paediatric inpatients in high-income countries, the rate of prescription errors ranges between 6.7% and 57.8% (Al-Anazi, Salam & Al-Jeraisy 2015:394; O'Meara & Lyons 2013:1) while in low- to middle-income countries it ranges between 12.5% and 66% (Oberoi, Trehan & Marwaha 2014:2219; Hamza, Sallam & El-Nimr 2013:438). The World Health Organisation (WHO 2014:43) found that 18.45% of medication errors occurred during prescription and 50.01% occurred during medication administration. This demonstrates that prescription and medication administration are the two most common phases in which medication errors occur and was therefore the focus of this study.

Medication errors affect both adult and paediatric patients alike, although the incidence of such errors in the paediatric population involves different risk factors to those of adult patients, necessitating a different and more multifaceted approach (Ruano, Villamañán, Pérez, Herrero & Álvarez-Sala 2016:32). The paediatric oncology population is especially susceptible to prescription errors as most medication dosages are calculated individually according to the patient's age, weight or body surface area (Glanzmann et al 2015:1348). These factors put paediatric patients at a greater risk of having incorrectly prescribed medications administered to them. The identification of medication errors is a responsibility shared by doctors, nurses and pharmacists, as these members of the multi-disciplinary team should be able to identify prescribing errors and avoid the administration of these incorrectly prescribed medications (Star, Nordin, Pöder & Edwards 2013:533). It is also crucial for nurses to be attentive during medication administration to avoid the improper administration of medications, which may have harmful effects on the paediatric patients.

1.2 PROBLEM STATEMENT

In a paediatric oncology unit in a central hospital in Gauteng the researcher observed that paediatric patients were at risk of being harmed due to medications being prescribed and administered incorrectly.

Case examples

Two examples identified by the researcher drove the topic of the study. The first was the misunderstanding of a prescription due to illegible handwriting. A near-miss event occurred when a paediatric patient nearly received a thousand-fold dosage of the medication required when micrograms was mis-prescribed as milligrams. In the second instance, a paediatric patient was given chemotherapy (meant for the intramuscular route) intravenously when the label was not checked and was mistaken for an anti-emetic.

Paediatric patients are at three times' greater risk than adult patients of suffering potential harm by medication which could cause significant impairment (Koumpagioti, Varounis, Kletsiou, Nteli & Matziou 2014:345). Paediatric patients may suffer toxicity, bone marrow suppression, organ failure and ultimately death when receiving incorrectly prescribed or administered medication (Fox, Pontefract, Brown, Portlock & Coleman 2016:456-457).

1.3 AIM AND OBJECTIVES

The aim of the study was to determine prescription and medication administration errors that transpired in a paediatric oncology ward in Gauteng.

In order to achieve the aim, the objectives of the study were to

Objective 1: Identify and describe the frequency and types of prescription and medication administration errors that occurred. (See Chapter 4: Section 4.2.3 and 4.3.4)

Objective 2: Identify factors that contributed to the occurrence of prescription and medication administration errors. (See Chapter 4: Section 4.2.2 and 4.3.3)

1.4 RESEARCH QUESTION

The study wished to answer the following research question:

> What is the frequency and types of prescription and medication administration errors which transpire in a paediatric oncology ward and what are their contributing factors?

1.5 STUDY SETTING

The setting for the study was a 30-bed paediatric oncology ward in an 832-bed central hospital in Gauteng, South Africa. This ward caters for paediatric patients with cancer between the ages of 0-16 years and not only treats patients from Gauteng but accepts referrals from Limpopo and Mpumalanga as well as patients residing in countries outside of South Africa, namely Mozambique, Swaziland and Zimbabwe. Between 2014 and 2016, 250 new cases of paediatric patients with cancer (71 cases in 2014, 98 cases in 2015 and 81 cases in 2016) were referred to and treated in this ward. These numbers made up 20% of all new cases in Gauteng Province and 8.66% of all new cases in South Africa over the three-year period (Reynders 2016, South African Tumour Registry).

The doctors working in the unit consisted of three permanent paediatric oncology specialists, one permanent paediatric oncology fellow, one registrar and two interns, with both the registrar and the interns rotating through the ward bimonthly and monthly, respectively. All doctors, whether permanent or rotating, prescribed medication to the patients. The unit has 30 permanent nurses divided into the following rank categories: 11 Registered Nurses (of which three obtained an additional qualification in oncology and two obtained an additional qualification in child nursing science), 11 Enrolled Nurses and eight Auxiliary Nurses. Of the nurses, only the Registered Nurses and Enrolled Nurses were permitted to administer medication, according to their scopes of practice (SANC 1984). During periods when nursing students rotated (two-12 students per month) through the ward, there might be more than one person administering medication. Enrolled nurses complete a certificate in nursing for the duration of two academic years (SANC 1984) and are thus authorized in terms of their nursing scope of practice, to practise and administer medication under direct supervision of a registered nurse as authorized by Regulation 2598 of 1984; Chapter 5(b). Registered nurses complete a programme for a duration of four academic years (SANC 1984) and may administer medication as authorized by Regulation 2598 of 1984; Chapter 2(b).

The ward is situated on the ground floor of a 108-bed oncology complex and was made up of six different areas. A separate isolation unit consisted of five individual rooms, each with their own bathroom in which barrier nursing was required. Two of the general cubicles accommodated six paediatric patients each (older girls and boys, separately) while the third general cubicle accommodated 11 paediatric patients (toddlers). There were two side rooms which accommodated two paediatric patients each and reverse barrier nursing was often required for these patients. Figure 1.1 depicts the layout of the ward.

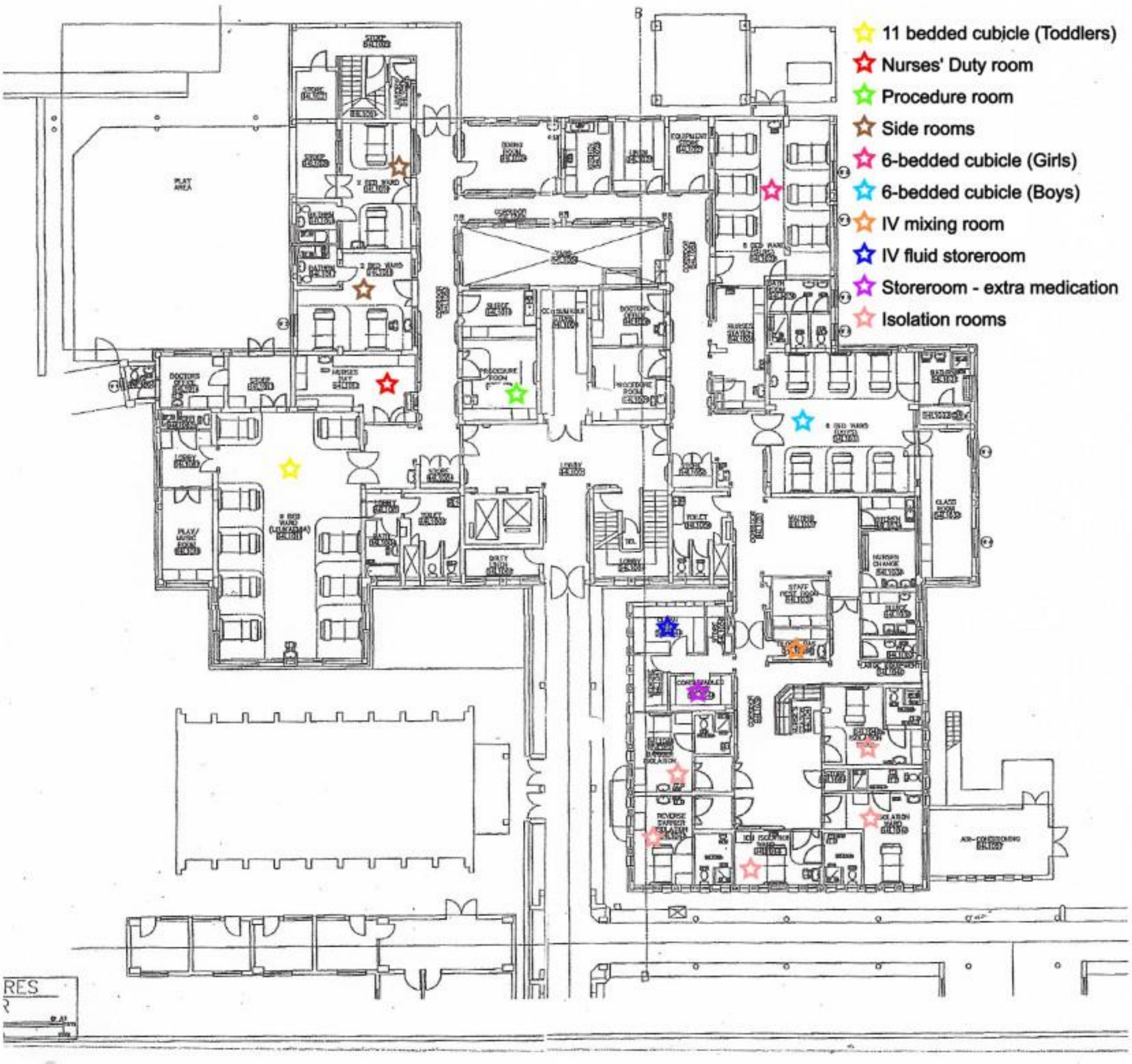

Figure 1.1: Layout of the ward

In the paediatric oncology ward in which the study was conducted, nurses were delegated to medication administration according to the route (oral and intravenous) of administration, with a separate registered nurse delegated to administer chemotherapy. Medication administration was usually performed by three nurses per shift: one (Registered Nurse/Enrolled Nurse) administered the oral medication, one Registered Nurse administered the intravenous medication and one Registered Nurse administered chemotherapy. Oral and intravenous (IV) medications were prescribed manually (hand-written) on a shared prescription chart while chemotherapy was electronically prescribed on a separate prescription chart, which was pre-printed by the consultants according to the patient's treatment protocol.

The locked oral medication trolley was kept in the procedure room near the 11-bed cubicle while extra stock of oral medication was kept in a storeroom in the isolation unit on the opposite side of the ward. The medication trolley was collected during routine times by the administering nurse who pushed the trolley from one side of the ward to the other, administering prescribed medications to all the paediatric patients.

The Registered Nurse administering IV medication walked through the ward at the start of the shift and wrote stickers for all prescribed IV medications. The prescribed medications were found in the prescription charts which were kept in the patient files located at each paediatric patient's bedside. Medications were prepared in the IV mixing room (situated in the isolation unit) where relevant stock of IV medications were kept. Intravenous fluids used for reconstitution were kept in a separate storeroom in the isolation unit while extra stock of IV medication was kept together with the oral medication. All rooms in which medications were kept were situated in the isolation unit, away from patients, in order to ensure patient safety by avoiding paediatric patients from accidentally finding and ingesting any medications. Most IV medications were prepared early in the shift and kept in the refrigerator in the mixing room until the scheduled time at which they needed to be administered. The majority of IV medications used in the paediatric oncology ward were stable for 12-24 hours after reconstitution, provided they were stored between 2-8°C. Augmentin® was the only medication used in the paediatric oncology ward which needed to be administered within 20 minutes of reconstitution and was prepared directly before administration. Any new IV medications prescribed during a shift would be prepared as and when the administering nurse was informed about it.

Chemotherapy was largely prepared by the chemotherapy pharmacy situated in the oncology complex and was collected from the Paediatric Oncology clinic after it had been checked and signed by the consultant on call. The Registered Nurse administering the chemotherapy prepared for administration by unpacking each paediatric patient's chemotherapy into individual trays. Each medication was checked against the prescription to compare dosage, volume of fluid that it was reconstituted in, as well as the time over which it needed to be administered. Certain chemotherapy medications were calculated by the oncology pharmacist and dispensed to the ward in syringes, requiring the administering nurse to reconstitute the medication with the prescribed volume of fluid. Each of these medications were signed off after being checked by the administrator and then signed again once administered. The start and end time of each chemotherapy medication was documented on the prescription.

1.6 SIGNIFICANCE OF THE STUDY

The results of this study could assist the development of interventions to reduce medication errors in the paediatric oncology unit, which can then be shared with other healthcare facilities. The findings should contribute to decreased prescription and medication administration errors which might result in a decreased length of hospital stay, reduced physical and emotional stress on patient and family, and a decreased financial burden for the healthcare facility. The study should increase awareness of medication errors among healthcare professionals and therefore improve the compliance of staff with set practice standards, consequently decreasing prescription and medication administration errors.

1.7 THEORETICAL FRAMEWORK

The 'Swiss cheese model of system accidents' used in risk analysis and risk management was used in this study. The model describes defensive layers, represented as layers of cheese that act as barriers to protect patients from potential hazards (Reason 2000:394). In a series of circumstances brought about by latent conditions and active failures, represented by holes in the cheese, these holes in the defences will line up (see Figure 1.2), leading to a medication error which has the potential to cause serious harm to the patient (WHO 2014:47).

Latent conditions are errors in the system or routine which make humans more inclined to make errors (WHO 2014:45-46) such as inadequate staffing, inexperience and time pressure (Reason 2000:395). These contributory factors play a role in prescription and medication administration errors and by identifying them in the study context, appropriate corrective strategies could be designed in the future, to reduce such errors and improve the safety of patients. Active failures are hazardous acts committed by those (doctors and nurses) who are in direct contact with patients (Reason 2000:395).

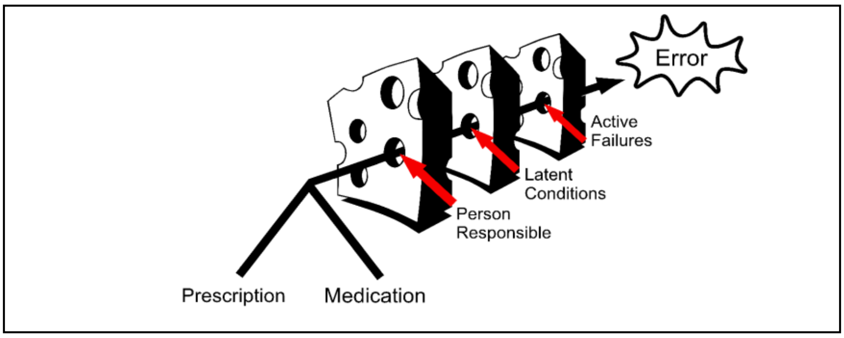

Figure 1.2 Swiss cheese model of system accidents

Adapted from Reason (2000:393)

These failures were human errors caused by acts or omissions and were explored in the study through identifying and describing the frequency and types of medication errors that occurred.

The researcher used the Swiss cheese model of system accidents as applied to prescription and medication administration, to construct the layout of the data sheets as latent conditions and active failures were identified (see Annexure C2 and Annexure D2). This is discussed in detail in Chapter 2, Section 2.10.

1.8 RESEARCH DESIGN AND METHODOLOGY

Grove, Burns and Gray (2012:43) define a research design as “a blueprint for maximizing control over factors that could interfere with a study’s desired outcome”. The selection of the population, sampling process, methods of measurement, and a plan for data collection and analysis are all guided by the type of research design chosen by researcher. This choice is dependent on the problem being studied, the purpose of the study, the appeal for findings to be generalized and the expertise of the researcher (Grove et al 2012:43). In this study, the researcher selected a quantitative, observational, cross-sectional research design to answer the research question.

Quantitative research involves measuring concepts or variables objectively and examining the relationship between them, using numerical or statistical data (Parahoo 2014:43). An observational, cross-sectional design enabled the researcher to determine numerical statistics of prescription and medication administration errors and to examine the relationships between these errors and their contributing factors. Table 1.1 summarises the research design and methods. (See Chapter 3, Section 3.3)

Table 1.1 Overview of research methods used in this study

Research Methods	Application to the study	
	Prescription chart analysis	**Direct observation of medication administration**
Unit of analysis / Study population	*Unit of analysis* – Patient prescriptions served as the data sources for this phase of the study. (See Chapter 3, Section 3.4.2) Between 12 April 2018 and 17 June 2018, 432 prescribed medications written on prescription charts in the paediatric oncology ward were analysed. <u>Inclusion criteria</u> • Any prescription chart written by a designated doctor working in the paediatric oncology ward.	*Study population* – Nurses who were directly observed while administering medications. (See Chapter 3, Section 3.4.3) Between 12 April 2018 and 17 June 2018, 1,064 medication administrations were observed in the paediatric oncology ward. <u>Inclusion criteria</u> • Any registered, enrolled or student nurse who gave voluntary consent to being observed during medication administration.
Sample method	Convenience sampling (a form of non-probability sampling) was used in this study where members of the population had an unequal or unknown chance of being selected. The researcher selected samples that were easily accessible and readily available. (See Chapter 3, Section 3.4.2.2 and 3.4.3.2)	
Sample size	A sample size of 1 281 was chosen to have a 99% confidence interval with a 0.03 margin of error. The total sample size was calculated as 1:3 ratio, as each prescribed medication was administered, on average, three times per day. (See Table 3.1)	

	The researcher was required to collect data for 321 prescribed medications as determined by the statistician. However, as more time was available, data were collected from 432 prescribed medications.	The researcher was required to collect data for 961 medication administrations as determined by the statistician. However, as more time was available, 1064 medication administrations were observed.
Data collection	*Data sheet for prescription chart analysis* (Annexure C2) Section A: General information about medications prescribed Section B: Potential Latent Conditions Section C: Potential Active Failures	*Data sheet for direct observation of medication administration* (Annexure D2) Section A: General information about medication Section B: Person responsible for administration Section C: Potential Latent Conditions Section D: Potential Active Failures
Data analysis	Descriptive statistics were used to describe the types and frequencies of prescription and medication administration errors and were expressed as percentages. Pearson correlation coefficient was used to analyse the data and identify latent conditions which were correlated (either positively or negatively) to the rate of prescription and medication administration errors. (See Chapter 4, Section 4.3 and 4.4)	

Chapter 3 discusses the research design and methodology in detail.

1.9 DEFINITION OF KEY TERMS

In this study, the following key terms are used as defined below.

1.9.1 Medication errors

Medication errors are defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer" (National Coordinating Council for Medication Error Reporting and Prevention) and include prescribing, dispensing, administration and monitoring errors (Hamza et al 2013:436). In this study, medication errors only included prescription and administration errors. **Prescription errors** include one or more of the following: incomplete, incorrect, inappropriate requests at the time of the doctor's orders; illegibility or the need for further clarification; missing route, interval, concentration, rate, dosage or patient information such as age, weight or allergies (Koumpagioti et al 2014:345). This definition was used in the study.

Medication administration errors are defined as "events involving one or more deviation from the doctor's prescription written in the patient's medical record" (Gunningberg, Pöder, Donaldson & Swenne 2014:411). This definition was used in the study.

1.9.2 Nurse

The term 'nurse' includes the registered nurse, enrolled nurse and student nurse as a person registered by the South African Nursing Council (SANC) as such, thus authorised in terms of Regulation 2598 (SANC 1984) to practise as a nurse and administer medication either independently or under direct supervision according to their rank. In this study, registered, enrolled and student nurses were observed during medication administration and the rank of the nurse was identified and recorded during data collection. See Section 1.5 for discussion of the different ranks of nurses as well as their levels of training and scope of practice.

1.9.3 Central hospital

A central hospital refers to a hospital that provides tertiary hospital services and central referral services and may provide national referral services. (Department of Health 2012:5) These hospitals provide training for health care service providers, are attached to a medical school as their main teaching platform and are involved in conducting research. They receive referrals from more than one province and have a maximum of 1 200 beds (Department of Health 2012:5). This definition applied in the study.

1.9.4 Paediatric patient

A paediatric patient is a person under the age of 18 years (Children's Act 2005:12). In this study, medications prescribed and administered to any patient under the age of 18 years were included.

1.9.5 Paediatric oncology

Paediatric oncology is “the term used to encompass all malignant conditions among children with cancer, including blood conditions such as leukaemia” (National Health Services Commissioning Board 2013). In this study, only medications prescribed and administered to paediatric oncology patients were included.

1.10 ETHICAL AND LEGAL CONSIDERATIONS

When studies are conducted using humans as research subjects, it is of utmost importance to ensure that their rights are protected (Polit & Beck 2012:150) and that the needs of the investigator are never placed above the welfare and rights of the participants. Accordingly, the researcher obtained permission and upheld the principles of beneficence, respect for human dignity, and justice.

1.10.1 Permission

The researcher obtained ethical clearance from the Faculty of Health Sciences Research Ethics Committee of the University of Pretoria (Ethics Reference No: 121/2018) and permission from hospital management of the hospital where the study was conducted. The Head of the paediatric oncology unit and the Operational Manager of the unit were informed of the study. (See Annexure A1)

1.10.2 Beneficence

Beneficence refers to the researcher’s responsibility to maximise the benefits (either to participants or to others) and minimise the harm of a study (Polit & Beck 2012:152). Researchers have a responsibility to avoid, prevent or reduce harm (non-maleficence) to the participants. In this study, the participants were not identified in any way as no personal information besides the rank of the administrator was recorded. *Patient harm was minimised as the researcher and fieldworkers delayed the administration of the incorrectly prescribed medication until the doctors had corrected the prescription error.*

1.10.3 Respect for human dignity

Respect for human dignity includes the right to self-determination, which means that people are in control of their actions (Polit & Beck 2012:154).

i) Prescription chart analysis - Consent for the use of hospital records (patient prescription charts) was obtained from the hospital CEO.

ii) Observation of medication administration - The participants were given the choice to participate in the study or not and had the right to ask questions about the study and withdraw at any time, without fear of negative implications. The researcher informed the participants of the purpose and benefits of the study, what was required of them, and that participation was voluntary. The participants signed informed consent forms (see Annexure E for doctors and Annexure F for nurses) indicating voluntary willingness.

1.10.4 Justice

Justice refers to participants' right to fair treatment and privacy (Polit & Beck 2012:155). The participants' privacy was maintained as no personal information was collected during the study. During direct observation of medication administration, the researcher and fieldworkers were not faced with any impending administration which would cause harm to the patient. *However, omitted doses of medication which had not been seen on the prescription charts were recorded and administrators were then immediately asked to return to the patient to administer the omitted medication.* This was done to ensure that the patient had the best chance of reaching the intended treatment outcome.

1.11 LAYOUT OF THE DISSERTATION

The dissertation consists of five chapters as follows:

Table 1.2: Layout of the dissertation

Chapter	Title	Description
Chapter 1	Orientation to the study	Introduces and outlines the study. It gives a brief overview of the research design and methods used.
Chapter 2	Literature review	Discusses the literature reviewed on prescription and medication administration errors for the study.
Chapter 3	Research design and methods	Describes the research design and methodology employed in the study, including validity and reliability, and ethical considerations

Chapter 4	Results and discussion	Discusses the data analysis and interpretation and results; correlations are also made between prescription and medication administration errors and factors that influence them (positively or negatively)
Chapter 5	Conclusion, implications and limitations	Discusses the conclusions reached, briefly refers to the limitations of the study, and makes recommendations for clinical, managerial and educational fields as well as for future research.

1.12 SUMMARY

This chapter discussed the complex health problem of prescription and medication administration errors and how the risk for these errors increases in paediatric patients. The discussion included the study setting, and ward layout, research design and methodology, and ethical and legal considerations. Chapter 2 discusses the theoretical perspective of the study and the literature review conducted for the study.

2 LITERATURE REVIEW

"Some people say they could never work with sick kids, but for me it's the opposite...
They have this will to survive that is so strong.
They never give up. You can't ask for anything more than that.
- Rosemary Livingston

2.1 INTRODUCTION

Chapter 1 described the purpose, research design and methodology of the study. This chapter 2 discusses the rationale for and theoretical perspective of the study, and the literature review conducted for the study. The literature review covered the extent of medication errors and the effects thereof across the world, factors that contribute to these errors as well as the strategies used to overcome the problem. The literature review assisted the researcher to select the theoretical model best suited to the objectives of the study and to guide the development of the data-collection sheets (see Annexure B and Annexure C) used to establish the rate and frequency of medication errors occurring in a selected paediatric oncology ward as well as their contributing factors.

2.2 RATIONALE

A literature review is a summary of what has been published on a specific subject for the purpose of conveying what is currently known about the topic (Grove et al 2012:97; Polit & Beck 2012:94). In the literature review the researcher examined what is known about medication errors and identified existing knowledge gaps. The literature review included not only medication errors in general, but errors made during prescription and administration of medication as well as errors occurring in the general paediatric population, the oncology population and, more specifically, the paediatric oncology population. This will be further discussed under the extent of medication errors. See Sections 2.5.1 – 2.5.3.

2.3 EXPLORING THE LITERATURE

Relevant literature was searched by using EbscoHost (CINAHL, E-journals, Health Source Consumer Edition and MEDLINE) and Google scholar and the following search terms: “medication errors”, “prescription errors”, “medication administration errors”, “medication errors in paediatrics”, “medication errors in pediatrics”, “medication errors in oncology”, “medication errors in paediatric oncology” and “medication errors in pediatric oncology”. Ninety English articles that reported data on medication errors published between 2013 and August 2018 were read. The abstract of each article was browsed and if it appeared to be relevant to the topic of the study, the full article was examined, and appropriate information selected to be included in the literature review. The concept of snowball sampling, which “begins with a few eligible participants and then continues on the basis of participant referrals” (Polit & Beck 2012:276) was also used. References of articles which proved relevant were searched and any reference with a title which seemed appropriate and fell into the allocated timeframe (2013-2017) was downloaded and the same process was used as in the search for the original articles. If the snowballed articles were useful, they were included in the literature review and if not, they were discarded.

2.4 MEDICATION PROCESS

The medication process is susceptible and prone to error as it is a complex five-phase process: (a) prescribing, (b) verifying, (c) preparing/dispensing (d) administering, and (e) monitoring. A medication error can occur in any of these phases (Smeulers, Verweij, Maaskant, de Boer, Krediet, Nieveen et al 2015:2). The medication process starts with a doctor’s decision to prescribe a specific medication for a specific patient with a particular outcome in mind. The prescription is sent to the pharmacy where medications are dispensed by a pharmacist according to the doctor’s prescription. The medications are then sent to the ward and the process ends with the administration of this medication by the nurses and the monitoring of the patient’s response to it to determine whether the medication has had the desired effect (Karavasiliadou & Athanasakis 2014:32). An estimated 100 to 400 prescribing errors occurred per 1,000 patients and 5% to 27% of medication orders for paediatric patients had an error somewhere along the medication process (prescribing, dispensing and administering of medication) (Glanzmann et al 2015:1348).

Each stage of the medication process has a specific role player who may either be responsible for the error made, or the person who intercepts another's error. Junior doctors are more likely to make "simple prescribing errors" which do not often render an adverse event but have the potential to cause harm (Thomas et al 2015:369). Oncologists are no more or less likely to make a mistake during prescribing than any other doctor, but the cost of chemotherapy drug errors can be drastically more distressing as these agents have one of the lowest therapeutic indices and safety margins of any drug class (Hamza et al 2013:436). As pharmacists form part of the medication process, it is not unheard of for errors to occur in the dispensing and mixing of ordered drugs. In a case of medication error in Ohio, USA, a pharmacist mixed chemotherapy in hypertonic saline (23.4% saline) as opposed to 0.9% saline, which caused the paediatric patient to complain of a severe headache and collapse in her mother's arms. She was placed on life support and later declared brain-dead due to an overdose of sodium chloride (Wittich, Burkle & Lanier 2014:1122). Not only doctors and pharmacists are responsible members in the medication process, but nurses too, play a substantial role in medication safety.

The main goal of nursing care is to enhance the quality of patients' lives through maximizing their health and wellbeing (Elliott & Liu 2010:300). It is crucial for nurses to understand the medication prescription so that errors in the preparation and administration of the medications can be prevented (Palmero, Di Paolo, Beauport, Pannatier & Tolsa 2016:117). Nurses play an important role in identifying prescribing errors by confirming an order with the prescriber if there is any uncertainty about the prescription (Whitehair, Provost & Hurley 2014:226). Nurses administering medication are often the last "barrier of defence" in medication delivery (Elliott & Liu 2010:301) and are in a position to catch the errors of others, yet only 2% of errors made by nurses themselves are intercepted (Gunningberg et al 2014:411). It is essential to improve the way that both doctors and nurses manage the medication process during care of paediatric patients to ensure the safe delivery of care (Koumpagioti et al 2014:354).

Patients receive medication as part of their management regime in a hospital (Gunningberg et al 2014:412) and medication errors can occur at any stage of the medication process, during procurement, prescribing, dispensing, administering and monitoring the effects of the drug, but these errors occur most often during the prescription and administration stages (Gunningberg et al 2014:411).The consequences of such errors can range from those with little impact on a patient to those with very serious effects (Glanzmann et al 2015:1348; Thomas et al 2014:369).

2.5 EXTENT OF MEDICATION ERRORS

The WHO estimated that more than 50% of all medications prescribed, dispensed, administered and used were done so incorrectly, although these figures may be largely underestimated due to the underreporting of medication errors (Lapkin, Levett-Jones, Chenoweth & Johnson 2016:846). The Institute of Medicine (IOM) estimated that at least 25% of medication-related injuries were preventable (Radley, Wasserman, Olsho, Shoemaker, Spranca & Bradshaw 2013:470).

Regardless of the evidence, a true indication of medication errors is difficult to quantify largely due to the lack of a standardised definition and terminology. Fernández-Llamazares, Pozas, Feal, Cabañas, Villaronga, Hernández-Gago et al (2013:639) found that studies lacked uniformity when defining medication errors and that there was often vast diversity in the definitions. Another aspect leading to an incomplete and inaccurate overall picture of the actual prevalence of medication errors is that methods and criteria for measuring these errors vary across settings and countries (Mansouri, Ahmadvand, Hadjibabaie, Kargar, Javadi & Gholami 2013:49). This makes the results, in studies detecting medication errors, inconsistent and difficult to compare (Ruano et al 2016:28).

Connor, Ahern, Cuccovia, Porter, Arnold, Dionne et al (2016:117) indicate that 5% to 27% of all medication orders result in a medication error. Over a six-month period, 10,475 medication errors occurred in Australia while in the USA, an annual average of 450,000 preventable medication errors are reported (Hayes, Jackson, Davidson & Power 2015:3064). The IOM reported that medication errors caused between 44,000 and 98,000 deaths per year in USA hospitals alone (Walker 2016:125). In Canada, approximately 70,000 preventable medication errors occur annually resulting in approximately 23,750 deaths, making medication errors the third leading cause of death, after cancer and heart disease (Alabdulhafith & Sampalli 2014:434).

South Africa has no current formal statistics on the incidences of medication administration errors although of the 629 professional nurse misconduct cases between 2003 and 2008, 105 were associated with medication administration (Blignaut, Coetzee, Klopper & Ellis 2017:3; SANC 2013). Some patients, such as paediatric, oncology and paediatric oncology patients, are more susceptible to medication errors (which will be discussed in more detail in the next section). Certain medications are classified as high risk, making it more likely to cause patient harm if an error occurred with these medications.

2.5.1 Medication errors in paediatrics

In 2015, Nelson and Selbst (2015:368) reported that the total rate of *all* medication errors in the paediatric setting ranged between 4% and 30%. Ruano et al (2016:29) found that the risk rate of medication errors is approximately 27% for adult patients and up to 92.3% for paediatric patients. Paediatric patients are more vulnerable than adult patients and, due to their inability to completely metabolise and eliminate drugs, are more likely to experience adverse drug events following a medication error (Palmero et al 2016:114). Silva, Araujo, Arduini, Alonso, Shibata and Troster (2013:1) emphasise that during childhood and adolescence there are important differences in the way in which medication is absorbed, distributed, metabolized and eliminated, making paediatric patients more susceptible to adverse events stemming from medication errors. Small errors, which may be tolerated by adult patients, could cause substantial damage in paediatric patients (Ruano et al 2016:29). Another aspect that makes paediatric patients more susceptible to drug-related adverse events is that many times, doses of drugs in paediatric patients are inferred from adult doses, related only to age, weight and body surface area, while ignoring their pharmacokinetic and pharmacodynamic properties (Silva et al 2013:1).

Paediatric patients may experience up to three times more medication errors than adult patients partly due to the need for weight-based dosing (Manias, Kinney, Cranswick & Williams 2014:1). The risk of overdosing is much higher in paediatric than in adult patients and dosage calculations are more prone to human error due to the need for unit conversion to signify very small doses and the constant need for weight- and surface area-based dosing (Maaskant, Vermeulen, Apampa, Fernando, Ghaleb, Neubert et al 2015:7). The medication process in paediatrics surpasses that of the process for adults as many drugs do not come in paediatric dosages or in paediatric forms. This leads to the necessity of diluting, reformulating (Dedefo, Mitike & Angamo 2016:2), splitting or crushing tablets for children who have difficulty swallowing tablets whole, thereby necessitating additional calculations (Condren, Honey, Carter, Ngo, Landsaw, Bryant & Gillaspy 2014:485) and as a result, increasing the risk of potential medication errors (Niemann, Bertsche, Meyrath, Koepf, Traiser, Seebald et al 2015:102).

In a study conducted by Manias et al (2014:1), the most common type of medication error among paediatric patients was receiving improper dosages and among adult patients was receiving the wrong medication. Tenfold errors are common in paediatric patients due to misplacement of a decimal point, while adult patients experience incorrect doubling of a dosage at the most (Ruano et al 2016:29). These dosing errors frequently cause harm and the significant morbidity and mortality of these errors include 7,000 patient deaths per year in the United States (Rinke, Bundy, Velasquez, Rao, Zerhouni, Lobner et al 2014:339).

An estimated 3% to 37% of medication errors in paediatric intensive care units occurred in the prescription phase and 72% to 75% occurred in the administration phase of the medication process (Haghbin, Shahsavari & Vazin 2016:114). In the UK, a prescription chart review and direct observation of medication administration among paediatric inpatients found errors in 13% of the prescriptions and 19% of the administrations (Star 2013:532). A prescription chart review in Sweden showed a 74% error rate, where prescriptions were incomplete, missing vital information such as route of administration, strength or dosage form (Star et al 2013:532). An average error rate of 74% in prescriptions of paediatric patients was found by Ruano et al (2016:29). According to Manias et al (2014:2), the leading causes of medication errors in paediatrics were poor communication, lack of knowledge, incorrect calculations, performance deficits and not following procedures and protocols. Besides paediatric patients, oncology patients are also a vulnerable group who are inclined to be harmed by medication errors, for reasons which will be discussed in the next section.

2.5.2 Medication errors in oncology

The number of cancer patients, and therefore the amount of chemotherapy being administered, is gradually increasing throughout the world (Ulas, Silay, Akinci, Dede, Akinci, Sendur et al 2015:1699). According to the Institute for Safe Medication Practices (ISMP), chemotherapeutic drugs are classified among the high-risk medications and errors made with chemotherapy can cause dramatic clinical problems due to their high toxicity and low therapeutic indices (Ulas et al 2015:1699). Errors in anticancer drugs pose a major threat to the quality of life of the patients receiving them consequently extra care should be taken during the prescription, calculation and administration of these drugs, to ensure that the right dose of the right medication is given to the right patient at the right time (Mathaiyan, Jain, Dubashi & Batmanabane 2016:2612). In a study in Spain, medication errors were identified among 17.2% of the patients receiving chemotherapy. Of these errors, 75.7% were found in the prescription phase and 1.1% in the administration phase of the medication process (Hamza et al 2013:437). Having stated that both paediatric patients and oncology patients are at greater risk of being harmed by medication errors, the combination of these two vulnerable groups – paediatric oncology patients – requires special attention.

2.5.3 Medication errors in paediatric oncology

Frequent changes in medication dosages in response to changes in weight and height is a common cause of under- or overdosing paediatric patients receiving chemotherapy. Other aspects which play a role in making paediatric patients more susceptible to medication errors include complicated chemotherapy protocols, dependence on caregivers to administer the medication during discharge and complex weekly dosing due to liquid medication being unavailable (Oberoi et al 2014:2218).

Chemotherapy is nephrotoxic, cardiotoxic and carcinogenic, even at therapeutic doses (Hamza et al 2013:436) therefore paediatric patients receiving chemotherapy are at a greater risk of developing complications if medication errors occur. Few studies have examined medication errors among paediatric oncology patients and the researcher found no studies conducted in paediatric oncology in South Africa. Medication errors tend to occur in all settings, in all countries and have the ability to affect all patients. These errors need to be identified and addressed in order to develop strategies to reduce them and to improve the safety of the patients.

2.6 MEDICATION ERRORS

Medication errors can occur anywhere along the line of the medication process, during prescription, dispensing and administration (Koumpagioti et al 2014:345). The WHO (2014:43) found that 18.45% of medication errors occurred during the prescription phase and 50.01% occurred during the administration phase of the medication process. This demonstrates that prescription and administration are the two most common phases in which medication errors occur and were therefore the focus of this study.

2.6.1 Prescription errors

Prescribing errors account for a large percentage of all medication errors and may cause considerable harm to patients (Ryan, Ross, Davey, Duncan, Francis, Fielding et al 2014:1) such as physical and psychological harm, increased length of hospital stay, disability and even death (Mansouri et al 2013:49). A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or increase in the risk of harm when compared with generally accepted practice (Ryan et al 2014:3; Seden, Kirkham, Kennedy, Lloyd, James, McManus et al 2013:3). This includes one or more of the following: incomplete, incorrect, inappropriate requests at the time of the doctor's orders, illegibility or the need for further clarification, missing route, interval, concentration, rate, dosage or patient information such as age, weight or allergies (Koumpagioti et al 2014:345). Pharmacists and nurses should be able to clearly understand each individual medication order in terms of drug name, dosage, frequency, route and indication to safely dispense and administer the drug (Thomas et al 2015:370).

In a review of current literature by Mansouri et al (2013:49) 33% of studies reported errors in prescribing and among these studies, errors ranged from 29.8% to 47.8%, with the most commonly reported error being wrong dose errors. Similar results were obtained in a study conducted in Scotland where errors were found in 36% of patient prescription charts, the most frequent errors identified being medication omissions, inappropriate abbreviations and omission of the prescriber's signature (Ryan et al 2014:6).

2.6.2 Administration errors

The WHO (2014:2) defines a medication error as "a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient". Gunningberg et al (2014:411) define medication administration errors as "events involving one or more deviations from the doctor's prescription written in the patient's medical record", which may occur regardless of whether a prescription error is present or not. Administration errors may be reduced to a certain extent if drugs are prescribed in an intelligible, unequivocal fashion with adequate information backing their clinical purpose (Thomas et al 2015:370). This is not always the case as other factors (lack of knowledge about drugs, inexperience, fatigue, stress, interruptions and high workload) may influence the nurse administering the medication (Ruano et al 2015:29).

Seibert, Maddox, Flynn and Williams (2014:10) indicate at least four different methods in which medication errors can be identified and quantified. The first and most common way is through voluntary reporting of events. This method greatly underreports the quantity, occurrence and outcomes of medication errors as most health care practitioners do not realise that they have made an error until it is recognized by somebody else. The second and third most common methods used to identify medication errors, are computerized monitoring and manual chart review, of which the latter identifies more errors. The fourth and most systematic method, the one which is known as the gold standard of identifying and documenting medication errors, is the direct observation of medication administration. The latter method is seldom used although it generates the most accurate results. Keers, Williams, Cooke, Walsh and Ashcroft (2014:329) corroborate this, stating that direct observation identifies the biggest number and fullest range of errors when compared to that of self-reporting and chart review. This method also does not seem to be influenced by the time in which observations are done or the interventions of the observer. Mansouri et al (2013:49) maintain that direct observation is the most sensitive way of detecting administration errors and the WHO (2014:35) states that it is the most reliable and effective method for detecting and quantifying errors during medication administration. Direct observation was therefore the method of choice for determining prescription and medication administration errors in this study.

Raban and Westbrook (2014:414) state that between 9% and 27% of all medication doses administered contain at least one error. The National Patient Safety Agency of the UK revealed that 50% of all medications administered in hospitals contain some kind of error, such as wrong drug, wrong form of the drug, wrong dose, wrong time or complete omission of the medication (Gunningberg et al 2014:411). In Ethiopia, Feleke, Mulatu and Yesmaw (2015:2) found that the prevalence of errors ranged between 9.4% and 80% of all medication administrations. This increased rate of medication errors in developing countries is attributable to lack of resources, staff shortages and inaccessibility to the latest technology used in developed countries to reduce such errors. Various strategies have been used with the aim of eliminating or at least minimizing both prescribing and administration errors, in order to safeguard patients from the consequences of such errors (Raban & Westbrook 2014:414-421).

2.7 MEASURES TAKEN IN AN ATTEMPT TO OVERCOME MEDICATION ERRORS

Various technologies used as strategies to decrease medication errors come with their own challenges. These strategies include computerized physician order entry (CPOE) for safer prescription of medications (Ruano et al 2016:30); barcode-assisted medication administration (BCMA) systems, smart (computerized) IV infusion pumps connected to a drug library (Ruano et al 2016:32); electronic medication administration records (eMARs) and wireless connectivity and integration with hospital information technology (Seibert et al 2014:209) for safer medication administration.

2.7.1 Reducing prescription errors

Horri, Cransac, Quantin, Abrahamowicz, Ferdynus, Sgro, et al (2014:637) define manual prescriptions as any medication prescription written by hand or typed on a computer in free text while CPOE is a computer-based programme designed to simplify prescribing and reducing prescription errors. Advantages of CPOE are “streamlined relevant drug data information, ease of communication between healthcare professionals, the ability to connect with other programs that improve clinical information and assist in decision making, the alert system, and the mandatory completion of fields such as dose, route and usual doses, cost information and data confidentiality” (Ruano et al 2016:30). Some of the aspects which make CPOE a safer option for prescribing medication than doing so manually are that standardized templates in prescribing are used and warnings can be set to alert the prescriber when deviations from guidelines occur (Baldwin & Rodriguez 2016:59). Although CPOE has been found to reduce prescribing errors in adult patients, the disadvantage of using CPOE in the paediatric population is that having been designed for adults it is not always effective in paediatric patients and can generate new errors (Ruano et al 2016:30).

2.7.2 Reducing administration errors

Administration is the last step in the medication process before the prescribed medication reaches the patient and errors during this phase are more difficult to identify and intercept (Ruano et al 2016:31). The National Core Standards (NCS) for Health Establishments in South Africa, developed in 2011, require protocols with regard to safe administration of medicines to be available (du Preez 2016:1). The ‘five right principles’ of medication administration must be included in these protocols and hospital-specific Standard Operating Procedures (SOPs) may be developed (du Preez 2016:1). While such SOPs have been put in place globally to prevent these errors, new technologies have been established in developed countries to further reduce such occurrences.

Double checking is a safety measure involving two independent healthcare practitioners simultaneously checking medication before it is administered to the patient. This should be the current standard of practice in high-risk patients (such as paediatrics) and with high-risk medications (such as chemotherapy), which may cause injury or death if administered incorrectly (Lapkin et al 2016:849). In a systematic review, Lapkin et al (2016:851) found that there is little evidence to support the clinical benefits of double-checking, especially for low-risk medications and in adult patients, as this practice requires two suitably qualified health care professionals and is therefore time-consuming.

When administering chemotherapy and other drugs, recommended guidelines such as “triple checking” medication during preparation, immediately before administration and afterwards should be followed (Elliott & Liu 2010:304). This may assist in reducing all types of medication administration errors (wrong medication, wrong dose, wrong patient, wrong time, and wrong route). An example of a medication error in chemotherapy, which has occurred more than once, is that Vincristine® (Vinca alkaloid; antineoplastic), a vesicant chemotherapy agent can lead to ulceration, tissue destruction and necrosis if extravasation occurs during intravenous administration (Radhakrishnan, Murali & Mishra 2016:303; Kameo, Silva, Sawada & Hardman 2015:9240). By not following the “triple checking” guideline, this chemotherapy has been unintentionally given as a deep intramuscular injection (identified in the literature reviewed and the ward in which the researcher works) and has the potential to cause great harm (Radhakishnan et al 2016:303).

In 2011, a UK hospital introduced a “no interruption zone” intervention in an attempt to reduce distractions during medication administration. The ‘no interruption zone’ used by nurses during preparation and checking of medications required nurses to wear a vest saying, ‘do not disturb’, in order to deter interruptions (Raban & Westbrook 2014:415). This strategy was later abandoned as it minimized the interaction between nurse and patient (Hayes, Power, Davidson & Jackson 2014:4) and after media suggested that it sent out a message implying that patients should not ‘bother’ the nurses (Raban & Westbrook 2014:415).

Barcode technology is a tool used during the administration of medication in which a series of barcodes are scanned. The patient's barcoded wristband is scanned in order to verify their identity, the prescription is then scanned to ascertain whether the chart belongs to the right patient and then each medication intended to be given is also scanned to ensure that the right drug is given at the right time. This electronic administration has helped decrease the rate of errors, in preventing lapses and slips and alerting the administrator of any medication discrepancies but has not managed to completely eliminate errors (Ruano et al 2016:32).

Smart pumps have software programs incorporated into the operating system, known as dose error reduction systems and drug libraries, which are specific to each unit and developed by a multidisciplinary team of doctors, pharmacists and nurses. Each drug is programmed with its concentration, dosage units as well as the maximum and minimum rates of infusion to prevent under- and over-dosing. This technology makes clinicians aware of incorrectly calculated doses, wrong rate errors and errors with the pump settings, by issuing an alert and allowing for the error to be corrected. 'Inappropriate warnings' or unreliability may persuade clinicians to override and ignore the system alerts in CPOE, barcode technology and smart pumps, opening the door for a medication error to occur (Lapkin et al 2016:853).

Although these technologies have been found to reduce medication errors, they do not eliminate them completely and are largely dependent on maintenance and updating in order to remain accurate (Baldwin & Rodriguez 2016:59). Computer-based systems also introduce their own sources of errors and interruptions associated with scanning malfunctions, computer failures and damaged barcodes (making them unreadable) during the administration of medication (Alabdulhafith & Sampalli 2014:435). The computer-based technologies tend to be available only in high-income countries and strategies more suited to low- and middle-income countries need to be developed to reduce these unfortunate events. If new reliable strategies are not developed, medication errors will continue to have a negative effect on patients, some devastating.

2.8 CONSEQUENCES OF MEDICATION ERRORS

Toxicity, treatment failure, neutropenia, bone marrow suppression, hyperkalaemia, arrhythmias, organ failure, shock, bleeding and infusion reactions are all potential outcomes of medication errors (Fox 2016:455). The WHO estimates that more than half of all medications are either prescribed, dispensed or sold inaptly and that half of the patients take their medications incorrectly leading to misuse, overuse and underuse of both prescription and non-prescription medications (Hamza et al 2013:436). Medication errors involving antibiotics, such as under-dosing, have little effect on infective processes (Bolt, Yates, Mahon & Bakri 2014:78) and may potentially result in severe infection and/or sepsis (Fox et al 2016:456), leading to death. Prolonged use of antibiotics may lead to increased bacterial resistance, necessitating second line treatment and consequently increasing the length of stay and hospital costs (Al-Anazi, Salam & Al-Jeraisy 2015:394; Bolt et al 2014:78). Errors causing the administration of inadequate doses of simple analgesia may lead to supplementing with additional analgesia with undesirable side effects whereas sufficient dosing of the initial analgesia may have served the purpose (Bolt et al 2014:78).

Financial and personal costs, such as emotional stress of the patient, family and administering nurse, increased length of stay, readmissions and increased mortality are all involved in medication errors (Hayes et al 2015:3064). Medication errors that lead to adverse drug events can increase the length of hospital day between 1.7 to 4.6 days (Durham, Suhayda, Normand, Jankiewicz & Fogg 2016:75). It is stated by Walker (2016:125) that compensation for damages and the potential financial support for long-term care of patients who suffered permanent injury may also have a financial impact on the health system and state. Medication safety contributes significantly to morbidity and the cost of healthcare (Acheampong, Anto & Koffuor 2014:117).

Patients exposed to medication errors in British hospitals had an average of 8.6 days added to their admission with an additional cost of £290,268 (±R5.5M) (Elliott & Liu 2010:300). Across Australia, admissions related to medication errors cost an estimated additional $660 million/annum (Hayes et al 2014:3). The consequences of medication errors range from those with little impact on a patient to those with very serious effects (Glanzmann et al 2015:1348; Thomas et al 2014:369). In order to develop strategies to reduce such errors, it is important to identify any contributing factors.

2.9 FACTORS CONTRIBUTING TO MEDICATION ERRORS

Medication errors are not straightforward entities but have many factors which play a role in their occurrence. Contributing factors include excessive workload, inadequate number of nurses, unfavourable working conditions, ample procedures to follow, emotional stress related to problems of the patients and working in shifts, which all increase the risk of making an error (Karadağ, Ovayolu, ParlarKiliç, Ovayolu & Göllüce 2015:893). In addition, the quality of prescriptions, deviations from procedures, such as distractions or interruptions, as well as experience and knowledge of medications all contribute to medication errors (Gunningberg et al 2014:412). Other contributing factors include time pressure, information overload, lack of system feedback, misperception of risk and poor human-system interface (Durham et al 2016:75).

Reason's (2000) Swiss cheese model of accident causation (from this point forward, to be referred to as "Swiss cheese model") has been used as an educational tool and has been beneficial in helping to identify potential threats in healthcare systems before patient harm occurs. For the above-mentioned reasons, the Swiss cheese model was the selected model for this study. A discussion follows in Section 2.10.

2.10 THE SWISS CHEESE MODEL OF ACCIDENT CAUSATION

In Reason's (2000) Swiss cheese model, each slice of cheese represents a control, barrier of defence or safeguard in a system, whose "function it is to protect potential victims from local hazards" (Whitehair et al 2014:226). The slices of cheese represent the "person responsible" (such as the prescribing doctor or the administrating nurse), latent conditions (which are factors contributing to potential prescription or administration errors) and active failures (which often happen at the patient's bedside and may lead to an immediate adverse event (see Sections 2.11.1 and 2.11.2; Figure 2.1).

The Swiss cheese model (Reason 2010) encourages investigators to see the "person responsible" for the active failure, causing the mistake to happen, as one unsafe act in a chain of events, leading up to the error (Li & Thimbleby 2014:117). This approach helps to avoid blame being laid on the individual and focuses on what system errors may have contributed to the medication error. Overlying layers of defences in the healthcare system frequently deter an error before the patient comes to any harm. No error on its own is sufficient to cause harm, but a patient's safety is put at considerable risk when multiple failures occur along the system's defences (Schoenberg, Fondahn & Lane 2016:117) leading to an error reaching the patient.

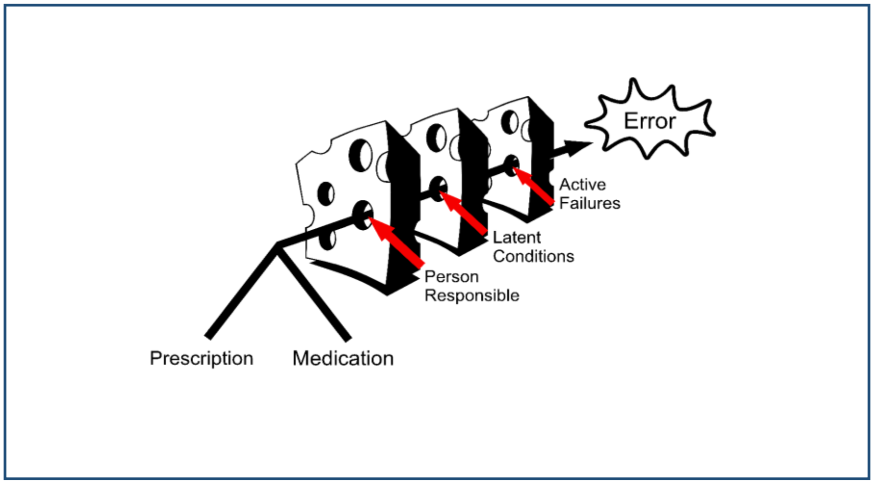

Figure 2.1 Swiss cheese model of system accidents

Adapted from: Reason (2000**:**393)

In a perfect world, these defences would be intact, but in reality, the layers have multiple holes in them - although, unlike in cheese, these holes are constantly opening, closing and moving their location (Reason 2000:769). The existence of a hole in one "slice" does not usually cause an unwanted outcome as the erroneous action will pass through a hole in one layer of defence, but may be blocked by another layer, preventing the medication error from occurring. If the holes in the layers are aligned, the erroneous action will pass through, resulting in a medication error (Karavasiliadou & Athanasakis 2014:33) and potential patient harm. Members of staff are often the last layer of defence in the Swiss cheese model (Ross, Patey & Flin 2014:681), but the only way in which an error can occur, is when latent conditions prepare a situation, causing the holes in the cheese to line up, which is then activated by an active failure (Schoenberg et al 2016:121). In the next section, the first "slice of cheese" – the person responsible – will be discussed.

2.10.1 Person responsible

Thomas et al (2015:376) state that the "safe administration of medications is the consequence of a complex system that requires contributions from many health disciplines and a culture of safety". Humans are imperfect, and errors are unavoidable. It is part of human nature to make errors but so too is finding ways to reduce medication errors (Karavasiliadou & Athanasakis 2014:34). The WHO (2014:6) emphasizes that punishing or blaming one individual member of the health-care team involved in a medication error will not avoid the same error from occurring at a later stage. It is crucial for the root cause in the health-care system to be identified and addressed in order to minimize potential risks in the future. In this study, the person responsible for the safe delivery of medication were the prescribing doctor and the administrating nurse. Sections 2.10.1.1 and 2.10.1.2 will discuss the person responsible in more depth.

2.10.1.1 Prescribing doctor

Of all the types of medication errors, prescribing errors are the most serious as the erroneous request, unless identified and corrected, will be carried out and can lead to significant harm or death (Acheampong et al 2014:127). The WHO (2014:3) states that all doctors, both inexperienced junior doctors and experienced senior doctors, make prescription errors. These errors have an average error rate as high as 8.9%, although junior doctors have been found to have higher error rates in prescribing than senior doctors (Ross et al 2014:681). Junior doctors are closely involved in prescribing in the hospital setting and tend to write the majority of prescriptions (Ross et al 2014:681). These junior doctors also frequently rotate between specialist departments necessitating smooth and speedy adjustments to new groups of commonly prescribed medication for each department (Lavan, Gallagher & O'Mahony 2016:858), increasing the risk of errors.

In a study in West Ethiopia, the most common stage at which errors occurred during the medication process was the prescription phase, accounting for 45.8% of all errors detected (Dedefo et al 2016:4). Medication prescriptions should be legible, explicit and have adequate information supporting the clinical intent of the medications' use. Nurses and pharmacists should be able to understand each order clearly, including the medication, route, dose, frequency, interval as well as identify the prescribing doctor (Thomas et al 2015:370).

2.10.1.2 Administrating nurse

Medication errors are the most predominant nursing error type recorded and associated with 26% to 38% of medication errors occurring in hospitalized patients (Orbæk, Gaard, Fabricius, Lefevre & Møller 2015:203). Nurses spend an average of 15 minutes on each medication administration, which includes preparation, retrieval, administration and documentation (Young, Cochran, Mei, Adkins-Bley, Ciarkowski & Wagner 2015:168), and approximately 16% to 40% of their time administering medication and doing medication-related activities (Hayes et al 2015:3064, Karavasiliadou & Athanasakis 2014:32). Due to the scarcity of safeguards to prevent medication errors, both nurses and patients are put at risk during this stage of the medication process (Keers, Williams, Cooke & Ashcroft 2013:237) and upholding the patient's safety during medication administration remains one of the main nursing responsibilities (Lapkin et al 2016:846).

Young et al (2015:168) define medication administration as "the provision of medications by authorized personnel in a manner that assures proper patient and medication identification and documentation of medication administration in the medical record". Administration of medication is a multifaceted process involving counting, calculating, measuring, mixing and guaranteeing that the right patient receives the right medication in the right dose, at the right time, via the right route, and for the right reason (Lapkin et al 2016:846). Since there are no standard drug strengths and dosages for paediatric patients, nurse training aimed at dosage calculations may aid in reducing certain medication errors in these patients (Acheampong et al 2014:128).

Errors in medication administration are more difficult to identify and intercept than prescription errors and the potential effect thereof on the patient largely depends on the type of drug and the route of administration (Ruano et al 2016:31). Wrong time errors are usually less risky than wrong patient errors. For example, many common medications such as anti-hypertensives and antibiotics have half-lives adequate to maintain the medication's clinical effect, if given an hour or two late. Administering an anti-hypertensive medication or antibiotic to a patient for whom it was not intended, may have more substantial consequences (Radley et al 2013:2).

2.10.2 Latent conditions and active failures

Common factors which cause medication administration errors include failure to verify a patient's identification, environmental factors (such as interruptions during the medication round), poor communication during handover, and inadequate equipment. In addition to these, the characteristics of the administrator (such as years of experience, nurse-patient ratio, years working in the specific unit), poor physical and or mental health of staff, patient-related factors (such as situations which require immediate attention) and the route and time of the drug administration (Keers et al 2014:318) also contribute to medication errors.

Schoenberg et al (2016:121) suggest errors caused by human nature are the source of most failures that lead to adverse events and are often present long before the actual event occurs. According to Schoenberg et al (2016:121), two different errors can precede an adverse event, namely latent conditions and active failures.

2.10.2.1 Latent conditions

Latent conditions are errors which set a situation up to fail and include decisions or actions taken by top level management and procedure writers long before the accident occurs (Reason 2000:769). These decisions and actions lie hidden for many years until an active failure leading to an adverse event causes them to be exposed (Gomes, Silva, de Morais, Chiavone, de Medeiros & Santos 2016:3648; Schoenberg et al 2016:121; Li & Thimbleby 2014:117). The WHO (2014:45) refers to these latent conditions as “service delivery problems” which are failures identified during the investigation of a patient safety incident. Such failures are associated with the way in which a service is provided and the decisions, procedures and systems that make up the whole service delivery process.

The medication process is influenced by many factors, some of which are still not fully understood (Härkänen, Ahonen, Kervinen, Turunen & Vehviläinen-Julkunen 2015:298). Although there may be many more factors which have not yet been exposed, research has revealed several factors that contribute to medication errors.

Organisation-related factors focus on the healthcare system and their relationship and interaction with medication errors. Perceived staffing inadequacy, increased patient load, stress of the nurses, high patient-nurse ratio, new staff or staff’s lack of experience, fatigue, lack of drug knowledge, poorly designed policy, untimely training, poor communication and inadequate physical environment all play a role in medication errors (Härkänen et al 2015:299; Karavasiliadou & Athanasakis 2014:36). The sophistication of medication administration is made more intricate by interruptions, facility layout, time restrictions, the number of medications prescribed per patient as well as the copious procedures and policies that oversee medication administration (Lapkin et al 2016:846). Organisational deficiencies such as unclear and/or unrealistic procedures also cause medication administration errors (Keers et al 2013:253). These factors may not only contribute to an error but may amplify the consequences of the active failure (Li & Thimbleby 2014:117). Latent conditions which may set a situation up to fail includes interruptions and distractions as well as the nurse-patient ratio which will be discussed in the section below.

- *Interruptions and distractions*

An interruption, distraction or disruption is any external event which causes a nurse to turn away from her principal task of administering medication to focus on another task (Lapkin et al 2016:851). Interruptions and distractions are one of the top five factors contributing to medication errors (Karavasiliadou & Athanasakis 2014:36).

Interruptions may occur during any phase of the medication process although interruptions during administration are most significant, as this phase signifies the last opportunity for an error to be detected and corrected before reaching the patient (Prakash, Koczmara, Savage, Trip, Stewart, McCurdie, Cafazzo & Trbovich 2014:884). Over 50% of medication administration encounters are interrupted in some way (Hayes et al 2014:4) and nearly 85% of medication administrations which are interrupted, result in an error. Errors are either procedural, such as not identifying the patient, or clinical, such as giving the medication via the wrong route, at the wrong time or administering the incorrect dosage (Hayes et al 2015:3066). Interruptions are significant role players in medication administration errors (Raban & Westbrook 2014:414) as it takes the administrators attention away from the task at hand and causes attention to be focused elsewhere.

Interruptions consist of having to attend to phone calls, patient care matters or becoming distracted by events happening in the near vicinity of the administrating nurse. Alarm monitors and intravenous pumps as well as other nurses or members of the health care team may also disrupt the administrator. Other interruptions consist of having to go and look for medication that is not on the trolley and unexplained loss of focus (Hayes et al 2015:3067).

- *Nurse-patient ratio*

A high nurse-patient ratio is among the top three contributing factors to medication errors as nurses are expected to accomplish a variety of tasks and duties during a shift and the risk of medication errors increases substantially when a unit is not sufficiently staffed with nurses (Karavasiliadou & Athanasakis 2014:36). This statement is emphasised by Parry, Barriball and While (2015:412) who state that an increase in the nurse-patient ratio raises the incidence of medication administration errors.

The next section discusses active failures, which may lead to instant patient harm.

2.10.2.2 Active failures

Active failures are committed by health professionals who are in direct contact with the patient (Whitehair et al 2014:226) and can appear in different forms such as “slips, lapses, losses, errors and violations of procedures” (Gomes et al 2016:3646). These failures usually occur on the “front line”, such as at the patient’s bedside, and generate immediate adverse events (Schoenberg et al 2016:121). An active failure is a failure in the medication process which leads to or has the potential to lead to patient harm (Mathaiyan et al 2016:2611). The WHO (2014:45) refers to active failures as “care delivery problems” and describes the two essential features as a) “care deviated beyond safe limits of practice” and b) “the deviation had at least a potential direct or indirect eventual adverse outcome for the patient”.

Health care practitioners are human and therefore susceptible to making errors (Karavasiliadou & Athanasakis 2014:34). Human error plays a significant role in medication errors (Elliott & Liu 2010:300) and may be committed by either the doctor prescribing or the nurse administering the medication. Active failures identified in prescription and medication administration are general writing and labelling, and ‘rights’ of medication administration,

General writing and labelling

Prescription errors include illegible handwriting and the use of medical abbreviations, because together with unclear, ambiguous or complicated orders they may also contribute to medication errors (Walker 2016:126; Wittich et al 2014:1118). Frequent errors encountered in prescriptions include omitted signatures and inappropriate abbreviations (Ryan et al 2014:6). The Food and Drug Administration (FDA) together with the Institute for Safe Medication Practices (ISMP) introduced a joint campaign to abolish the use of medical abbreviations, symbols and dose designations which might potentially cause confusion and could result in patient harm (Walker 2016:128). The Joint Commission issued a list of medical abbreviations that could be misunderstood to mean something other than intended and should therefore not be used. To avoid such errors, terms which could be confusing should be written out in full rather than abbreviated (Wittich et al 2014:1119).

The “rights” of medication administration

Medication safety is an important topic as medication errors are common, serious and potentially expensive errors (Smeulers et al 2015:3). There are five well-known “rights” commonly associated with medication administration, namely right patient, right medication, right route, right dose and right time (Walker 2016:126; Blignaut 2015 2015:4 Orbæk et al 2015:2; Wittich et al 2014:112). Nurses are taught about these rights during their training and are encouraged to follow them while administering medication, to prevent any errors from occurring (Edwards & Axe 2015:352).

Right patient

Medication being administered to the wrong patient is a fairly common error. Patients should verbally verify their name and nurses should use alternative methods of identifying each patient (Elliott & Liu 2010:301). Methods to identify patients include confirming their date of birth (Schutijser, Klopotowska, Jongerden, Spreeuwenberg, Wagner & de Bruijne 2018:3), checking the patient’s identity band, and ensuring that it corresponds with the name on the sticker for whom the medication is prescribed (Edwards & Axe 2015:353).

Right medication

As many as 33% of medication errors involve the incorrect drug being administered to a patient (Elliot & Liu 2010:301). It is the responsibility of the nurses to ensure that they are knowledgeable about the medication that they administer and if there is any uncertainty, that they clarify it with the prescribing doctor. Many medications have similar names and medications which share a mechanism of action, chemical constituent or indication for use, often have the same prefix or suffix (Elliott & Liu 2010:301). A safer practice would be to prescribe a medication using the generic name, although this would not avoid confusion if two medications with similar names are both found on the medication trolley. Medications must be viable, properly packaged and within their expiry date and the administrator needs to ensure that the patient is not allergic to the medication being given (Nursing and Midwifery Board of Ireland 2018:15).

Right dose

Dosing errors are the most common type of medication error in paediatrics (Fox et al 2016:454) as doses need to be adjusted according to age, weight and body surface area (Larose, Levy, Bailey, Cummins-McManus, Lebel & Gravel 2017:7). Seibert et al (2014:218) define a ‘wrong-dose error' as any dose that is +- 10% or more of the correct dosage. Larose et al (2017:2) and Nelson and Selbst (2015:369) define an error as a drug prescribed above or below 20% of the recommended dose. Strengths of the formulation need to be specified when prescribing syrup in millilitres in order to be able to detect an error (WHO 2014:29). Dosage errors, both over- and under-dosing, are the most common prescription errors made and intercepted during the prescription phase of the medication process (Fernández-Llamazares et al 2013:645).

Nurses should be vigilant when reading the patient's prescription chart as a decimal point in the wrong place could result in either one tenth or ten times the intended dose being administered (Elliott & Liu 2010:302). Nurses need to have an idea of what the normal dose ranges are for different medications in order to be able to identify a dosage error in the prescription or to recognize when a dosage has been calculated incorrectly before administration (Elliott & Liu 2010:303). Minor errors in calculating drug doses may lead to outcomes which could be life-threatening for a paediatric patient (Karadağ et al 2015:894).

Right route

Medication should always be given via the route for which it was intended. Seibert et al (2014:217) describe wrong route errors as "medications administered to a patient via a route different to the one ordered, such as the intravenous administration of a drug that was prescribed for intramuscular use". Regarding all routes of administration, the intravenous route appears to have the highest rate of errors (Keers et al 2013:252). Many patients have suffered severe neurological consequences (such as quadriplegia) or loss of life when Vincristine® has been administered intrathecally as opposed to intravenously (Elliot & Liu 2010:302) and this error has occurred for decades.

Right time

Administering medication at the right time involves preparing the medication at the right time and should not be done many hours before administration, as this may affect the stability of the medication (Elliott & Liu 2010:302). Dedefo et al (2016:3) define a 'wrong-time error' as "administration of medication outside a predefined time interval from its scheduled administration time". This predefined time varied from +- 30 minutes to +-75minutes from the prescribed administration time (Dedefo et al 2016:3; Keers et al 2013:250). In a systematic review of medication administration errors through direct observation, Keers et al (2013:250) found that 79.7% of the studies reported 'wrong-time errors'. Elliott and Liu (2010:302) found that 'wrong-time errors' accounted for up 31% to 43% of all medication errors.

Postponement of medication administrations may deprive the patient of optimal drug effects and therefore a delay in positive outcomes. The time gap between administrations needs to be adequate in order for the medication to work effectively (Edwards & Axe 2015:353). Medications given before the prescribed times may lead to higher drug concentrations in the bloodstream and unnecessary side effects, resulting in increased length of hospital stay (Gunningberg et al 2014:415). Gunningberg et al (2014:414) found that if patients were not in the bed during the medication rounds, nurses had been known to either leave the medication at the patients' bedside, relying on the correct patient to take their prescribed medication at the right time or to omit the medication completely.

Omission errors

Omission refers to the "failure to give an ordered dose to a patient before the next scheduled dose, if any" (Dedefo et al 2016:3; Seibert et al 2014:217). In the hospital setting, medications are often delayed or omitted for various reasons and although this may not seem like a serious event, this may lead to serious harm or patient death in certain crucial circumstances, such as patients with sepsis (WHO 2014:78). In the UK, omitted medications were the second largest medication errors reported and in China, omission of medication accounted for 33.4% of all medication administration errors (Wang, Jin, Feng, Huang, Zhu, Zhao et al 2015:397).

Poor adherence to medication caused by medication doses being omitted is often related to a decreased therapeutic effect and consequent increased length of hospital stay (Shandilya, Nizamuddin, Faisal, Noor & Abraham 2015:12). Known reasons for medications being omitted include refusal of the patient to take it; the patient being nil per os (NPO) for oral medication or not having intravenous access for IV medication, as well as medications being unavailable (Shandilya et al 2015:13).

When a nurse signs the prescription chart, it provides evidence that the patient has received the medication administered to them (Elliott & Liu 2010:303). Regarding medication administration accuracy, Gunningberg et al (2014:411) found that nurses frequently documented before the administration of the medication opposed to afterwards. This represented an incorrect record of treatment in relation to the time that it was given and due to distractions, stress and heavy workload or patient refusal, could also lead to a complete omission of that drug being administered. Failure to sign for a medication that was administered also poses a risk as another nurse may assume that it was not given and repeat the dose, potentially harming the patient (Elliot & Liu 2010:303).

Kim and Bates (2013:7) found that although medication was administered at a time different to what was ordered, the record indicated that the right time of administration was met. This dishonest record of the actual time of medication administration is not only a medication error but “goes against the general nursing ethics” and should be addressed (Kim & Bates 2013:7).

The standardized five “rights” focus on medication administration at the bedside and do not encompass all causes of drug errors. A drug’s journey is more than what happens only at the bedside therefore more than just the original five “rights” are needed to reduce medication errors (Edwards & Axe 2015:352). Attempts have been made to add extra “rights” to the original five rights of administration in order to further reduce errors (Edwards & Axe 2015:398-406; Elliott & Liu 2010:303). These include the *right reason* for the medication being prescribed and administered should be known and may be verified by the pharmacist or by having protocols in place; the *right documentation* (Smeulers et al 2015:3); the *right form* of the drug, the *right action*, and the *right response* to the medication (Nursing and Midwifery Board of Ireland 2018:15). Patients have the *right to refuse* medication in situations where, for example, they have difficulty swallowing, and nurses have the right to refuse to administer medication if, for example, the prescription is incomplete or ambiguous. Nurses should have the *right knowledge* about what the drug is, how it is expected to work and what the outcome should be. The administrator is responsible for asking the *right questions* in order to ascertain whether they can administer the medication safely. Nurses are expected to offer patients the *right advice* with regard to the expected outcome and any potential side effects and need to be able to determine whether the patient has had the *right response* to the medication administered (Edwards & Axe 2015:358).

The ISMP (2011) states that the “five rights are not a behavioural model for achieving medication safety, but goals for which organizations must accept responsibility and design failsafe ways that they can be achieved”.

2.11 SUMMARY

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP 2014) states that it should be the goal of all healthcare institutions to continuously strive to improve their systems, in order to reduce medication errors and the potential harm they may cause. Medication errors occur throughout the world in all five phases of the medication process and affect all types of patients, including paediatric oncology patients. However, errors occur predominantly in the prescription and administration phase of the medication process and are most prevalent in paediatric patients as their medication doses need to be calculated according to their age, weight and body surface area. Many contributing factors play a role in medication errors and various strategies have been developed to reduce such errors nevertheless these strategies have failed to eliminate the errors.

This chapter discussed the literature review conducted for the study. Chapter 3 discusses the research design and methodology used in the study.

3 RESEARCH DESIGN AND METHODOLOGY

The true character of society is revealed in how it treats its children.

- Nelson Mandela

3.1 INTRODUCTION

Chapter 2 discussed the literature review and the theoretical perspective on which the study was based. This chapter discusses the research design and methodology used to achieve the aim and objectives.

3.2 AIM AND OBJECTIVES

The aim of the study was to determine prescription and medication administration errors that transpired in a selected paediatric oncology ward in Gauteng.

In order to achieve the aim, the objectives of the study were to:

Objective 1: Identify and describe the frequency and types of prescription and medication administration errors that occurred. (Chapter 4, Section 4.2.3 and 4.3.4)

Objective 2: Identify factors that contributed to the occurrence of prescription and medication administration errors. (See Chapter 4, Section 4.2.2 and 4.3.3)

Accordingly, the study wished to answer the following research question:

What prescription and medication administration errors transpire in a paediatric oncology ward?

3.3 RESEARCH DESIGN

Grove et al (2012:43) define a research design as "a blueprint for maximizing control over factors that could interfere with a study's desired outcome". The selection of the population, sampling process, methods of measurement, and a plan for data collection and analysis are all guided by the type of research design chosen by researcher. This choice depends on the problem being studied, the purpose of the study, the appeal for findings to be generalized and the expertise of the researcher (Grove et al 2012:43). In this study, the researcher selected a quantitative, observational, cross-sectional research design to answer the research question.

3.3.1 Quantitative

Quantitative research involves measuring concepts or variables objectively and examining the relationship between them using numerical or statistical data (Parahoo 2014:43). Deductive reasoning which is defined by Polit & Beck (2012:11) as “the process of developing specific predictions from general principles” was used to test for association and the level of significance between medication errors and their contributing factors. Grove et al (2012:25) define deductive reasoning as reasoning which “moves from the general to the specific or from a general premise to a specific situation or conclusion”, by examining specific details which are then used to make a generalization about the universe. The quantitative methodology allowed the researcher to collect data objectively, providing quantifiable results which showed association between medication errors and failures in the system’s defences (Polit & Beck 2012:13). See Section 2.10 for further discussion.

3.3.2 Observational

In nursing research, observation is a process by which data are actively collected about people, behaviours, interactions or events and involves direct observation of individuals in their natural setting (Carlson & Morrison 2009:77) and is frequently paired with document analysis (Allen 2017:1114). The WHO (2014:34-35) recommends that chart review be used to detect prescription errors, in combination with direct observation to detect administration errors, as each method is unable to single-handedly detect all the medication incidents that occur. In a study in South India, Mathaiyan, Jain, Dubashi and Batmanabane (2016:2611) both methods of error identification. The main objective of using observation to collect data is to obtain detailed information which can provide insight about the phenomenon being studied, by providing a first-hand account of witnessed behaviours (Gerrish & Lacey 2010:382), such as how medications are prescribed by doctors and administered by nurses. Observational research summarises the status of an occurrence and includes correlational studies which examine associations among variables without manipulating them (Polit & Beck 2012:233). Humans as observers pose as unique and intelligent measuring tools. Observational research has advantages and disadvantages which will be discussed next.

3.3.2.1 Advantages

Observation research has the advantage of being able to reveal and describe behaviours and practices that occur in actuality as opposed to what people think or say they do. Real-time observations provide researchers with the opportunity to study participants in their natural setting (Allen 2017:1113), while performing their usual routine and do not rely on having to recall information at a later stage which may be misconstrued. As observation is discreet and therefore nonreactive, this method of research is innately more reliable as it is able to generate highly trustworthy data (Given 2008:575). Observer bias is minimised by using a structured data-collection sheet which offers pre-determined aspects on which to focus (Gerrish & Lacey 2010:391-392).

3.3.2.2 Disadvantages

Observational studies are useful for understanding what people do but offer little information about the reasons behind the decisions made and actions taken. When structured observation is the main method of data collection, the underlying meanings behind certain behaviours remain unattainable (Gerrish & Lacey 2010:391-392).

Observational research is generally time-consuming as the observers need to be present for the entire period of observation and data collection (Allen 2017:1114). In cases where fieldworkers are used, training is required to ensure inter-observer reliability and consistency in the results obtained (see Section 3.6.1.1 for description). Some behaviours may be missed if the action takes place out of the field of the observers' vision or during a time outside of the observation period (Gerrish & Lacey 2010:392). Other important behaviours may be missed due to the natural setting providing copious participants, interactions and behaviours on which to focus (Allen 2017:1115). Researchers may, thus, miss significant aspects of the observed setting that would otherwise be useful data for addressing the research questions or may otherwise focus on observations that are ultimately less significant than those they did observe.

Observer bias is another problem observed in observational research. Factors which may hinder observations include observer emotions, prejudices, and values. Personal commitment may cause observers to see what they want to see and may anticipate what *may* be observed as opposed to what *is* observed. Observational biases can be minimised through adequate training and through the use of structured observation data sheets (Polit & Beck 2012:189). Section 3.4.2.4 describes how the challenges of observer bias were overcome. One of the strongest criticisms aimed at observational studies is that of the Hawthorne effect, where the presence of the observer affects the behaviours of the person being observed (see Section 3.5.4.1).

3.3.3 Cross-sectional

In a cross-sectional design exposure and outcome are determined simultaneously for each subject (Carlson & Morrison 2009:77). A cross-sectional design is defined by Maltby, Williams, McGarry and Day (2014:360) as “a research design that provides the researcher with a picture of what might be occurring in a sample or population of people at a particular time” and can be used to investigate relationships between variables. Researchers record information at “a single point in time” and examine and compare single variables without manipulating them (Allen 2017:317). In a cross-sectional research design, time is not considered one of the study variables as *not all data is collected at one exact moment*. However, cross-sectional data are usually collected within a fairly short time frame. In a cross-sectional study, time is thought to have a random effect that yields variation and not bias (Lavrakas 2008:171). A “snapshot” is taken of the population to establish the extent to which the incidence is present (Polit & Beck 2012:227) and this “snapshot” may occur over a period of days, weeks or months. In this study, the researcher used a cross-sectional design to explore the incidence of medication errors during both the prescription and the medication administration phases of the medication process between 12 April and 17 June 2018. The contributing factors and their relationship to the incidence of medication errors were also identified.

Cross-sectional designs have advantages and disadvantages which will be discussed in further detail.

3.3.3.1 Advantages

Cross-sectional designs tend to be relatively cost-effective and easy to conduct. All data are collected at “a single point in time”, eliminating a delay in data collecting efforts which allows researchers to move to data analysis and the reporting of the data fairly quickly (Allen

2017:317). Cross-sectional designs are best to use when attempting to determine the frequency of an occurrence and are useful at distinguishing correlations which can then be studied more meticulously (Lavrakas 2008:171; Mann 2003:268). Cross-sectional designs identify patterns, associations and occurrence rates of a subject of study within a population.

3.3.3.2 Disadvantages

Despite the benefits mentioned above, cross-sectional designs have some challenges and disadvantages. As such designs are carried out at "a single point in time" (Allen 2017:317), they are limited in the sense that they give no explanation of the chain of events between a cause and an outcome. Grove et al (2012:599) concur, stating that cross-sectional designs prohibit changes over time and may not capture the multifaceted phenomena under study. Researchers are not able to interpret or justify what happens before or after the data were collected and are therefore unable to know whether drastic differences would have been found if data were collected at another point in time (Allen 2017:317). Conclusions made from the results of the data collected cannot be construed as causal relationships between causes and outcomes, but only as relationships between the variables (Allen 2017:317; Grove et al 2012:605).

The researcher used a cross-sectional research design for this study as data were collected over a period of just over 2 months (See Section 3.4.2.4 and 3.4.3.4). The results provided the researcher with a picture of what might be occurring during the prescription and medication administration phases at that particular time, in the selected paediatric oncology ward. The researcher examined prescription and medication administrations without manipulating any variables and wished to determine the correlations between any errors and the factors contributing to them.

3.4 RESEARCH METHODOLOGY

Research methods are techniques used by researchers to construct a study, collect data and analyse information to answer a research question (Polit & Beck 2012:12). In this study, structured data sheets were used to collect data (See Annexures C2 and D2). The research methodology consisted of the study setting, population, sample and sampling, eligibility criteria, data collection, and data-collection method.

The study consisted of two separate entities: prescription chart analysis and the direct observation of medication administration which will be discussed further in Section 3.4.2 and 3.4.3.

3.4.1 Study setting

The setting for the study was a selected 30-bed paediatric oncology ward in an 832-bed central hospital in Gauteng, South Africa. (See Section 1.5 for further detail.)

3.4.2 Prescription chart analysis

3.4.2.1 Unit of analysis

A unit of analysis is defined by Polit and Beck (2012:745) as "the basic unit or focus of a researcher's analysis" and is not limited to human subjects but may include hospital records (Polit & Beck 2012:273). For the 'prescription chart analysis' component of the study, the unit of analysis included the prescription charts of any paediatric patient admitted in the paediatric oncology ward during the data collection period.

3.4.2.2 Sample and sampling

The process in which a researcher selects cases which will represent the entire population is known as sampling. The small selected portion of population to be studied is known as the 'sample' (Polit & Beck 2012:275) while the individual units of the population and sample are known as 'elements' (Grove et al 2012:352). Elements can be a human, an event or any other individual unit that the researcher is interested in studying. Choosing a sample reduces the cost, time and manpower needed to conduct the study (Acharya, Prakash, Saxena & Nigam 2013:330). Quantitative researchers develop a 'sampling plan' which stipulates, ahead of the data collection, how many participants are to be selected and how many will be included in the study (Polit & Beck 2012:273). A 'sampling plan' is described by Grove et al (2012:357) as one which defines approaches to be used to obtain a sample for the study and which will improve representativeness, minimize bias and reduce the sampling error.

For this study, convenience sampling was used. Convenience sampling is a form of non-probability sampling where members of the population have an unequal or unknown chance of being selected (Lewis-Beck, Bryman & Futing Liao 2004:197). In convenience sampling, researchers select samples that are easily accessible and readily available (Salkind 2010:255). Convenience samples are not necessarily made up of individuals known to the researcher but entail using the most conveniently available people as participants (Polit & Beck 2012:276). It is an inexpensive method of sampling and usually requires less time in obtaining than other sampling methods (Grove et al 2012:363).

Although convenience sampling is seen as one of the weakest forms of sampling, it is also the most commonly used method in many fields of research (Polit & Beck 2012:277) and is frequently used in nursing studies (Grove et al 2012:362). It is stated by Boslaugh (2008:235), that although it is unfeasible to control the likelihood of selection in a non-probability sample, and therefore a researcher cannot statistically measure the representation of the selected population, this does not necessarily mean that the sample is not representative. The results of the study have known generalisability to the sample itself (Bornstein, Jager & Putnick 2013:361) and should therefore not be taken to be representative of the population. Etikan, Musa and Alkassim (2016:2) point out that in convenience sampling, “one can make only weak statement(s) about some characteristic of the sample itself, rather than a formal inductive inference concerning the population of interest”.

Convenience sampling was the sampling method of choice for this study. The method was suggested by the statistician who stated that although “this method is not recommended in research due to the possibility of sampling error and lack of representation of the population, it is recommended for this study, as the population from where the sample will be drawn, is known and defined within this study”. The researcher wanted a “snapshot” of the prescription and medication administration errors that were happening in the paediatric oncology ward at that particular point in time. As the purpose of this study was not generalisability to the population, but to identify system errors, there was no great concern in drawing inferences from the sample to the population.

A sample size increases the statistical power of the convenience sample (Etikan et al 2016:4) whereby the larger the sample size, the greater the statistical power of the study results. A biostatistician used a precision-based method to calculate the sample size using the following information: a paediatric oncology ward in Gauteng with an average bed occupancy of 66.21%, with each paediatric patient having an average of five prescribed medications, with an average of three administrations per medication, per day.

The method was given as:

$$n = \frac{\frac{z^2.p(1-p)}{e^2}}{1+\frac{z^2.p(1-p)}{e^2N}} \text{…………….. (1)}$$

Where z represents the Z score

p represents probability of success

e represents the margin of error

N is the population size

Figure 3.1 Method used to calculate sample size

In order to have a 99% confidence interval with a 0.03 margin of error, the researcher was required to collect data from 321 prescribed medications. The researcher analysed prescription charts between 12 April and 17 June 2018 of paediatric patients admitted to the paediatric oncology ward and collected data on 432 medications prescribed by the doctors working in the ward at the time of the study (See Section 3.4.2.4 and 3.4.3.4 for detailed information on data collection).

Polit and Beck (2012:284) state that the larger the sample, the more likely the results of the study will be a true representation of the population, where the larger the sampling size, the smaller the margin for sampling errors. In order to identify a sample suitable for data collection, eligibility criteria were defined.

3.4.2.3 Eligibility criteria

Polit and Beck (2012:274) define eligibility criteria as characteristics of the population which make them suitable for the study (inclusion criteria) and include characteristics which the population should not possess (exclusion criteria), which is essential for membership in the target population (Grove et al 2012:352). These specifications are developed from the research problem, the purpose of the research, the literature review, the study variables and the research design (Grove et al 2012:352). The criteria should be determined by theoretical factors to ensure that the resulting sample is an accurate representation of the population construct which the researcher is interested in studying (Polit & Beck 2012:274). Logical reasons for the inclusion and exclusion criteria need to be provided by the researcher and exclusion criteria should be carefully determined as they may affect the generalisability of the study (Grove et al 2012:353). The eligibility criteria for prescription chart analysis were as follows:

- Any prescription chart written by a designated doctor working in the paediatric oncology ward.

3.4.2.4 Data collection

Data collection refers to the methods used to collect data, previously determined by the researcher according to the research question, aims and objectives of the proposed study (Grove et al 2012:507) and the data-collection sheet. Data is collected in an organized fashion with restrictions on what is asked and how answers are described. This is done to minimize bias, increase objectivity and simplify analysis of data collected (Polit & Beck 2012:293). By using data sheets which have pre-determined aspects to be observed, data collectors are forced to stay within the limits of what the study aims to prove and are prevented from incorporating their own ideas of right and wrong into the study. This allows data collectors to remain fair and unbiased, thereby reducing the level of partiality.

- *Development of the data sheets*

The data sheets were developed after an in-depth literature review on the specified topic and were modified to include aspects relevant to the ward in which the study was conducted. Annexure B1 provides the rationale for items included in the data sheet for prescription chart analysis. The first draft of the data sheets (see Annexure C1) was sent to the researcher’s supervisors and to the head of the paediatric oncology ward – a paediatric oncologist, who is an expert in the field. The data sheet was evaluated for its appropriateness and suggestions and additions were offered to improve the first draft. The Ethics Committee suggested removing the designation of the doctors (see Annexure C2). As there are so few doctors working in the paediatric oncology ward, recording their designation would make them easily identifiable. These suggestions were incorporated to develop the final draft of the data sheet (Annexure C2) making it more suitable for the study and to improve the data collection.

Prescription charts were analysed using the final draft of the structured data sheet (see Annexure C2). General information about the medication (Annexure C2 – Section A), such as the name and type of the medication, the route prescribed and whether or not the medication prescribed was a scheduled drug, was recorded. Potential latent conditions (Annexure C2 – Section B; see Chapter 2, Section 2.11.1), such as the number of patients in the ward as well as the number of medications prescribed for each paediatric patient, were noted. The day of the week and the time at which the medication was prescribed were also recorded. Any errors in the general writing and labelling (Annexure C2 – Section C; see Chapter 2, Section 2.11.2.1) were identified and then 432 prescribed medications were analysed for any errors in the prescription of each drug. The data sheet was used, and the medication rights (see Chapter 2, Section 2.11.2.2) were marked off item for item to identify any errors, which were then recorded. Any error identified was rectified, by asking one of the doctors working in the ward to correct the error, before the next administration occurred.

- *Pre-testing the data sheets*

Pre-testing of the data sheets, used in the study, was done to test their validity and reliability thereby ensuring that they provided the data required. The testing was conducted by the researcher and the head of the paediatric oncology ward - a paediatric oncologist, to ensure that the data sheets were efficient and to ensure consistent reporting. The pre-testing took place once ethical approval had been obtained and data collected from the pre-test was not used in the actual study. The testing of the data sheet involved the review of 10 prescription charts of patients admitted in the paediatric oncology ward (using the structured data sheet – see Annexure C2). Based on the outcomes of the pre-tests, no modifications were made to the data sheets.

The process followed in the data-collection phase of the study is described next, with specific consideration to fieldworkers, how they were trained, and challenges involved in using them. Data-collection methods used for both components of the study will be described separately.

- *Fieldworkers*

Green and Baxen (2002:319,320) define a fieldworker as “an objective collector of data” or “a person who collected data on behalf of the researcher”. The researcher approached three registered nurses working in the ward and asked them if they would act as fieldworkers, assisting in the data collection for the study. The researcher recruited staff already working in the ward as they would be more familiar with the ward protocols than any fieldworker recruited from outside the ward. The researcher gave the fieldworkers training on the data sheet, before the start of data collection, which took approximately 1 hour per fieldworker. Each section was explained, and specific aspects to focus on and look out for were emphasised. Examples of different types of errors were given and the fieldworkers had opportunities to ask questions and clarify any aspects of which they were uncertain.

Fieldworkers were included in the study in order to decrease observer bias and to expedite the process of data collection. The use of fieldworkers also comes with certain challenges: different observers may view behaviours differently, resulting in under- or over-reporting of errors. By using structured data sheets and providing the fieldworkers with sufficient training, this challenge was decreased (Blignaut 2015:75). Researchers who depend on fieldworkers necessitate a relationship of trust between themselves and the fieldworkers (van Heerden 2016:92). The researcher had already established a relationship with the fieldworkers and it was important for the fieldworkers to know that the researcher had complete trust in them and that their sensitivity and integrity was relied on during the data-collection process.

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Throughout the study, the data collectors acted as “complete observers” where they were solely focused on observing behaviours and had no interaction with the participants, so as not to influence the phenomena being observed (Gerrish & Lacey 2010:384, 387).

Data were collected for prescription errors using a pre-designed data sheet (see Annexure C2) which was developed from the literature reviewed. Aspects identified for determining errors in prescriptions were included. Using the data sheet, a total of 432 prescribed medications were analyzed by the researcher and one of the fieldworkers. Prescription charts were analyzed once a week, by only one data collector, in order avoid duplicate data being collected. All prescriptions in the ward are renewed once a week (on a Friday) therefore by analysing prescriptions on a weekly basis, the risk of analyzing the same prescription for the same patient would be eliminated.

3.4.2.5 Data analysis

Descriptive statistics used to “reveal characteristics of the sample and to describe study variables” (Grove & Burns 2012:538) were applied to the data in order to summarise variables through frequencies and percentages (%). Frequencies count the number of cases, to determine the incidence of prescription and medication administration errors.

Furthermore, the Pearson product-moment correlation coefficient (Pearson's correlation) was applied to analyse and describe the relationship between two continuous variables. Pearson's correlation is one of the most commonly used statistics and is a measure of the linear relationship between two variables, X and Y, giving a value between +1.0 and -1.0, where 1.0 is a perfect positive correlation, 0.0 (zero) is no correlation, and -1.0 is a perfect negative correlation (Frey 2018:1229). Relationships identified using correlation coefficients should be taken for what they are: associations, not causal relationships. Therefore, when correlational analysis is done, no attempt is made to ascertain independent and dependent variables (Frey 2018:1230).

After analysing prescription charts and collecting 432 entries, the Pearson correlation was used to describe the relationship between the following variables: prescription errors and legible prescriptions, complete prescriptions and scheduled medication.

Data for prescription chart analysis were collected concurrently with that of data for medication administration.

3.4.3 Direct observation of medication administration

3.4.3.1 Population

The population for the medication administration phase of the study consisted of nurses administering medication (see Section 3.4.2.1).

3.4.3.2 Sample and sampling

Convenience sampling was used to sample the population for medication administrations. The researcher was required to observe 961 medication administrations, as recommended by the statistician, to obtain a 99% confidence interval with a 0.03 margin of error. The researcher and fieldworkers observed Registered, Enrolled and student nurses administer a total of 1 064 administrations (see Section 3.4.2.2 for sample size).

3.4.3.3 Eligibility criteria

Registered, enrolled or student nurses who gave voluntary consent to being observed during medication administration.

3.4.3.4 Data collection

Using combinations of data-collection methods, such as observation and data obtained from records, is not uncommon in quantitative research (Polit & Beck 2012:294). The researcher combined data collection from analysing prescription charts and data collection from direct observation of medication administrations, to obtain a broader understanding of medication errors. Since the development of direct observation for studying medication administration errors in 1962, this method has been used in over 40 studies and subsequent research has reliably shown that the observation method is the most accurate in detecting medication errors (Kim & Bates 2013:592). Direct observation provides more accurate results on identified medication errors than incidence reports and self-reporting and can be used to identify the full range of administration errors (Keers et al 2013:238) thus making it one of the methods of choice for this study.

- *Developing the data sheets*

The development of the data sheet for observing medication administration was developed and followed the same process as described in section 3.4.2.4. Annexure B2 includes the rationale for each aspect included in the data sheet for observing medication administration. The first draft of the data sheet can be found in Annexure D1 while the final version can be found in Annexure D2.

The data sheet for observing medication administration was pre-tested through direct observation of ten (10) medication administrations (using Annexure D2). These results were not used in the actual study and based on the outcomes of the pre-test, no modifications were made to this data sheet.

- *Fieldworkers*

The researcher recruited staff already working in the ward as they would be more familiar with the ward protocols than any fieldworker recruited from outside the ward. The researcher gave the fieldworkers training on the data sheet. As part of the training and to ensure their competency, the fieldworkers were asked to observe five (5) medication administrations at the same time as the researcher. The results recorded for these observations were compared and found to be alike, thereby ensuring consistency and reliability. As the fieldworkers were recruited from and were known to the paediatric oncology ward, they were more likely to blend in and be less conspicuous while observing medication administrations than any nurse recruited from the outside. This would therefore diminish the Hawthorne effect (see Section 3.6.5). Initially all three recruited nurses agreed to act as fieldworkers, although one of the nurses discontinued of her own accord, after observing four administrations.

- *Preparing the participants*

The clinical area was prepared prior to the study being conducted, by having a meeting with relevant nurses who were asked to participate (McCormack, Henderson, Wilson & Wright 2009:30-33). To reduce anxiety about being observed and to minimise the Hawthorne effect (see Section 3.5.4.1), an in-depth explanation was given on the study to clarify the process. This included discussions on why the study was being conducted, what it aimed to achieve and how many administrations needed to be observed. Written information about the study was distributed and nurses were informed that ethical approval as well as permission from hospital management had been obtained. Potential participants were assured of the confidentiality and anonymity of the results obtained. Any questions raised about the study were answered honestly and potential participants were given consent forms and asked to sign if they were willing to participate in the study.

Between 12 April and 17 June 2018, the researcher, together with two fieldworkers directly observed the consenting nurses delegated to administration of medication. Observations started when the administrating nurse either entered the procedure room to collect the medicine trolley (oral medication) or started preparing chemotherapy, or when the nurse entered the IV mixing room to prepare the intravenous medication. The observation ended once medication had been recorded for the patient. During this process, the data collectors observed the medication administrator in the ward during medication routine times, passively recording what was observed, without changing the behaviour that would naturally take place in the setting during this routine. Observations were recorded on the structured data sheet (see Annexure D2) and data was collected on any errors that occurred. The number of patients in the ward, number of medications prescribed for each “nurse-patient administration encounter”, number of nurses administering that type of medication as well as any interruptions to the administrating nurse were recorded. The researcher observed 1,064 administrations of medications, each of which was recorded on an individual data sheet.

3.4.3.5 Data-collection method

Administration of medications were observed directly, and a structured, pre-determined data sheet (see Annexure D2) was used to collect data. The researcher collected data from each separate administration of a medication, as opposed to collecting data per "patient-nurse encounter". General information about the medication (see Annexure D2 – Section A), such as the name and type of the medication, the route of administration and whether or not the medication administered was a scheduled drug was recorded. The person responsible (see Annexure D2 – Section B; see Chapter 2, Section 2.10.1.2) for the administration of the medication was identified as well as their rank and whether or not they had any additional qualifications. Potential latent conditions (see Annexure D2 – Section C; see Chapter 2, Section 2.11.1) such as the number of patients admitted to the ward, the number of nurses on duty as well as the number of nurses delegated specifically to medication administration was recorded. The amount of medications prescribed for each paediatric patient to whom the nurse administered medication was noted as well as the day of the week and the time at which the medication was given. Potential active failures (see Annexure D2 – Section D; see Chapter 2, Section 2.11.2.2) collected data on any errors made, with regard to the rights of medication. Any distraction or disruption (see Chapter 2, Section 2.11.1.1), documentation error or omission of any medication was also recorded. By using the pre-structured data sheet, the influence of the data collectors' expectations on the outcome of the study was avoided. This guaranteed a degree of objectivity and narrowed down the aspects of medication errors that were concentrated on.

3.4.3.6 Data analysis

Pearson's correlation analysis was used to analyse the data for medication administrations (see Section 3.4.2.5). Data was collected for 1,064 medication administrations and correlation studies describe the relationship between medication administration errors and type of medication, total number of staff, scheduled medication, rank of the administrator, number of patients and number of administrators.

3.5 RIGOUR

Rigour is related to the study design and determines the quality of research, as good quality research should produce accurate and valid results (Claydon 2015:44). Rigour helps to ensure that all procedures were followed, that any puzzling factors were removed, and that the researcher can be assured that the results are trustworthy (Gerrish & Lacey 2010:24). The two main concepts of rigour are validity and reliability.

3.5.1 Validity

Validity refers to the degree of accuracy which an instrument measures what it is supposed to measure. The data of a researcher is valid if the results obtained through the measurement process of the study are accurate (Yilmaz 2013:318). Validity enhances the rigour of a study and minimises bias and controls perplexing variables (Polit & Beck 2012:236).

3.5.2 Validity of the instruments

The data sheets used for the study were aimed at collecting data on the frequency and types of prescription and medication administration errors that occur in a paediatric oncology ward. Validity of these instruments was ensured by the following methods:

3.5.2.1 Face validity

Face validity is very superficial as it is based on the subjective opinions of people who give their estimation on how well they believe the instrument will measure what it is supposed to measure (Maltby et al 2014:246). Face validity is determined by investigating whether the data sheets *look* like they will measure the objective (Polit & Beck 2012:336). Face validity for the instruments of this study was determined by the head of the paediatric oncology ward – a paediatric oncologist, the operational manager of the ward and the researcher’s supervisors, prior to data collection.

3.5.2.2 Content validity

Content validity refers to the instrument containing all the major elements related to the concept being measured, which were found in the literature or through experts in the field (Grove et al.

2012:294). Content validity is described by Polit and Beck (2012:336) as “the degree to which the instrument has an appropriate sample of items for the construct being measured and adequately covers the construct domain”. The content in the instruments used in this study was extracted from the literature review (see Chapter 2) thereby ensuring its validity.

3.5.3 Validity of the study

Gerrish and Lacey (2010:139) define validity as the “extent to which the results of a study can be generalized to other contexts and populations”. Validity is concerned with whether the inferences made about the observed relationships will remain the same with changes in setting, people, time or outcome measures (Polit & Beck 2012:237).

3.5.3.1 Enhancement of validity

Inferences can be strengthened if the sample or setting chosen for the study is representative of the population and clinical setting in which the findings will be generalised (Polit & Beck 2012:250). An important concept of validity is the replication of results in several sites. Generalisability of results can be made more confidently if several sites obtain similar findings in replicated studies. Systematic reviews are therefore an important aid to validity as they determine the relationships in replicated studies across time, space, people and settings (Polit & Beck 2012:250). Another important concept is that study settings are often “conditioned” to create a standardized environment for data to be collected. If this standardization causes the study environment to be too artificial and too far from what is seen in the “real world”, validity may be jeopardized (Polit & Beck 2012:250). This study had a confidence interval of 99% and a 0.03 margin of accuracy (by using a sample size recommended by a statistician - see Section 3.4.2.2; Table 3.1). The maximum expected difference between the true population parameter and the sample estimate of the parameter was 3%.

Table 3:1 Sample size scenarios to reach required confidence interval and margin of error

	Average bed occupancy	No. of drugs prescribed	Drugs administered	Time period (days)	Total population derived			
Background information	20	5	15	60	4200			
Probability of success	**0.5**							
Confidence interval	**95%**				**99%**			
Margin of Error scenarios	**0.05**	**0.04**	**0.03**	**0.02**	**0.05**	**0.04**	**0.03**	**0.02**
Sample sizes for different margin of errors scenarios	352	525	851	1528	573	832	1281	2087

3.5.3.2 Threats to validity

Threats to validity comprise of ways in which deviations in people, settings, time and conditions may alter the relationships between variables. *Interaction between relationship and people:* an observed outcome with certain people may not yield the same results if applied to other types of people. *Interaction between causal effects and treatment variation:* this may not be applicable as this study did not include treatment (Polit & Beck 2012:251).

3.5.4 Reliability

Reliability refers to the degree of consistency with which a research instrument measures a variable. This means that if the same instrument is used on the same subjects under the same conditions, the given variable will be consistent (Yilmaz 2013:317).

Observer bias (see Section 3.3.2.1) was minimised by using structured data sheets. The data sheets used in this study were verified for reliability through testing (see Section 3.4.2.4). The data collected were therefore pre-determined, and to ensure consistency and inter-observer reliability of the study, the fieldworkers who assisted in the collection of data received training on how to use the data sheets (Gerrish & Lacey 2010:392) prior to the study.

3.5.4.1 Hawthorne effect

A recognised challenge within observational studies is that of the Hawthorne effect (Schutijser, Klopotowska, Jongerden, Spreeuwenberg, Wagner & de Bruijne 2018:8). The Hawthorne effect states that those being observed may be more careful when they are aware that they are being watched (Keers et al 2013:253). The psychological effect of "being singled out, noticed, or made to feel important" have been suggested rationalizations for the Hawthorne effect (Hagel, Reischke, Kesselmeier, Winning, Gastmeier, Brunkhorst et al 2015:957). Another common social psychological explanation of the possible mechanism for the Hawthorne effect is that when those being observed are aware of the observers' presence, they formulate beliefs about the observers' expectations. The desire to conform and be socially accepted causes a change in behaviour of those being observed, to meet the expectations of the observer (McCambridge, Witton & Elbourne 2014:268). However, this argument is problematic as we could not know what the behaviour of the participants would have been, had they not been observed (Gerrish & Lacey 2010:391).

Kim and Bates (2013:3) state that the Hawthorne effect could possibly affect the results of a study as the rate of adherence to standards and procedures could be amplified. In a systematic review of the Hawthorne effect, McCambridge et al (2014:267) stated that if the Hawthorne effect does in fact exist, "studies could be biased in ways that we do not understand well, with profound implications for research".

- *Application to the study*

In this study, observers were aware of the potential Hawthorne effect and were cautious in an attempt not to allow it to influence the results of the study. Nurses being observed were disallowed to view the data sheet to minimise the impact of the Hawthorne effect and observers were non-judgemental and as discreet as possible during data collection. No feedback of the occurrence of any error observed was given, in order to diminish the effect on the nurses' normal practice. However, nurses could have been aware of the aspects on the data sheet as each aspect followed the current medication administration protocol (Schutijser et al 2018:3), which is accessible in the hospital at which the study was conducted. Keers et al (2013:253) state that as long as observers remain non-critical and inconspicuous, participants often revert back to their usual behavioural practices after they become accustomed to being observed.

In line with this statement, the researcher observed that the Hawthorne effect diminished over time. One participant said*, "I know you're watching, and I know I'm not meant to sign before I administer but I'm in a hurry so I'm going to carry on as I usually do".* Another participant administered 500mg of Paracetamol® instead of the 600mg prescribed and said, *"I'm not going to draw up the 4ml of Panado® syrup, I'll just give the 500mg tablet".* During a different observation, a participant told the researcher that she was only going to give half the doses of Lactulose®, Potassium Chloride® and Diabetic phosphate®*, "otherwise it's too much and the child will vomit".* While observing another participant, the researcher asked how much antibiotic was administered to the paediatric patient and the participant started laughing and eventually admitted *"I just gave him 5ml"* while, according to the prescribed dosage, it should have been 3.5ml. Each of these instances were recorded as errors.

The Hawthorne effect is "the tendency of people to behave differently when they know that they are being observed" (Hagel et al 2015:957). The Hawthorne effect was minimised during data collection as the data collectors work in the ward and therefore did not stand out as much as outsiders would have. The researcher and fieldworkers also dressed in nursing uniform to blend in during observation and collection of data.

3.6 SUMMARY

Chapter 3 discussed the research design and methodology, including the setting and the data sheets used to collect data. Chapter 4 discusses the data analysis and interpretation, and results.

4 RESULTS AND DISCUSSION

The only thing necessary for the triumph of evil is for good men to do nothing.

- Edmund Burke

4.1 INTRODUCTION

Chapter 3 described the research design and methodology used in the study. This chapter presents and discusses the descriptive results related to the general information about prescription chart analysis and direct observation of medication administration as a unit, followed by the results of errors identified in prescribed medications and medication administrations, which are discussed separately. Correlations determined by the Pearson's correlation coefficient (see Section 3.4.2.5) then follow. Correlations between prescription errors and the factors which contributed to their occurrence are presented and discussed first, followed by the correlations between medication administration errors and the factors which contributed to their occurrence. The results are presented according to the different "slices of cheese" in Reason's Swiss cheese model, as discussed in section 2.10.

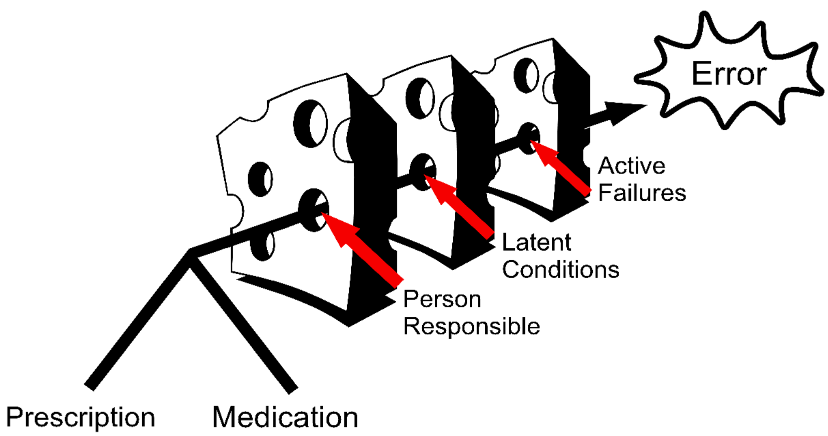

Figure 4.1 Swiss cheese model of system accidents

Adapted from: Reason (2000:393)

Data were collected on medication errors between 12 April 2018 and 17 June 2018 using the data sheet for prescription chart analysis (see Annexure C2) and the data sheet for observing medication administration (see Annexure D2). The results of these two phases of data collection are discussed next.

4.2 PRESCRIPTION CHART ANALYSIS

A total of 432 prescribed medications were reviewed and the results are presented according to the three sections of the data sheet, which is in line with the Swiss cheese model (Reason 2000) used as the theoretical framework for the study (see Figure 4.1):

- Section A**:** General information about medications prescribed
- Section B**:** Potential latent conditions
- Section C**:** Potential active failures

4.2.1 Section A: General information about medications prescribed

Section A covered general information about the medications prescribed in the selected paediatric oncology ward, including types and frequencies of medications prescribed, whether the medication was a scheduled medication or not, and types and frequencies of the different routes of medication prescribed. The results are presented in sections 4.2.1.1 to 4.2.1.3 and discussed together in section 4.2.1.4.

4.2.1.1 Types and frequency of medications prescribed

Paediatric patients treated in the paediatric oncology ward received various types of medications. Some of the medications are used to treat the primary disease (e.g. chemotherapy and steroids), while others are used to treat and manage the complications caused by either the primary disease (e.g. analgesia) or the side-effects of the medications prescribed (e.g. antibiotics, antiemetics, electrolytes and laxatives). Figure 4.2 presents the frequency of the most common types of medication prescribed in the paediatric oncology ward.

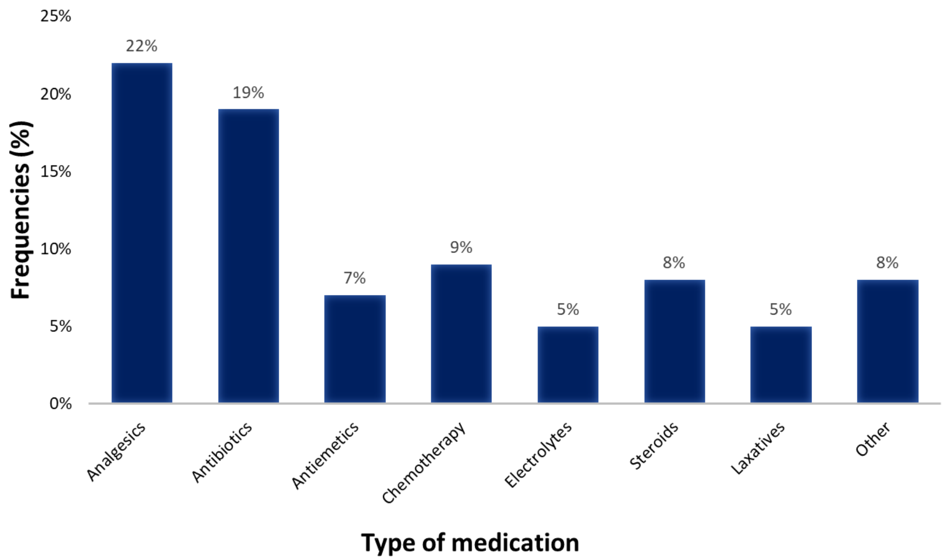

Figure 4.2: Types and frequencies of medications prescribed

A total of 432 (N=432) prescribed medications revealed eight (8) different categories of medication that were prescribed. Of these categories, 22% (n=95) of medications prescribed were analgesics; 19% (n=77) were antibiotics; 9% (n=41) were chemotherapy; 8% (n=34) were steroids and 7% (n=29) were antiemetics. Laxatives (n=20) and electrolytes (n=22) made up 5% of all prescribed medications. See Section 4.2.1.4 for a general discussion.

4.2.1.2 Scheduled medications prescribed

Scheduled medications are often prescribed in the paediatric oncology ward in the form of opioids and sedatives. These medications have a greater risk of causing harm when medication errors occur. Figure 4.3 represents the frequency at which scheduled medications were prescribed.

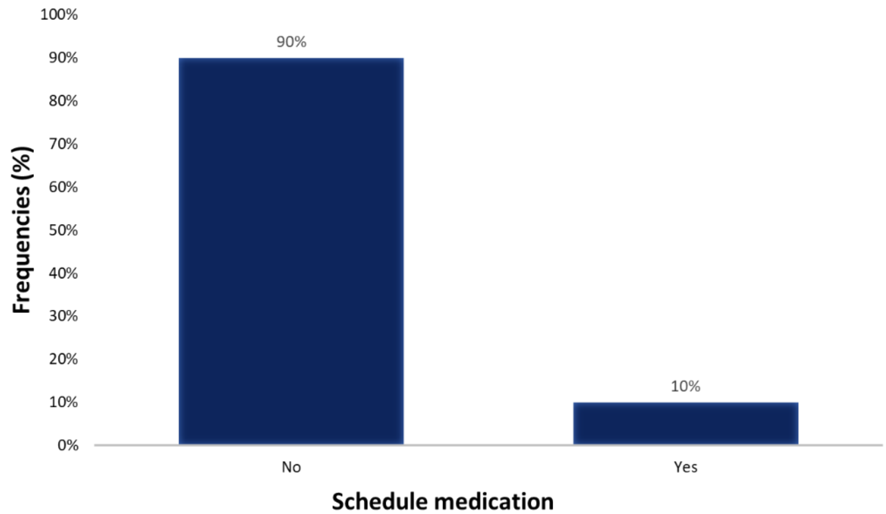

Figure 4.3 Frequency of scheduled medication prescribed

Of the 432 prescribed medications (N=432) analysed, only 10% (n=43) were identified as scheduled medications compared to 90% (n=389) of prescribed medications that were not scheduled medications. See Section 4.2.1.4 for a general discussion.

4.2.1.3 Prescribed route

Certain routes of medication administration have been found to cause greater patient harm when prescribed incorrectly. Figure 4.4 depicts the frequency of different routes prescribed in the paediatric oncology ward.

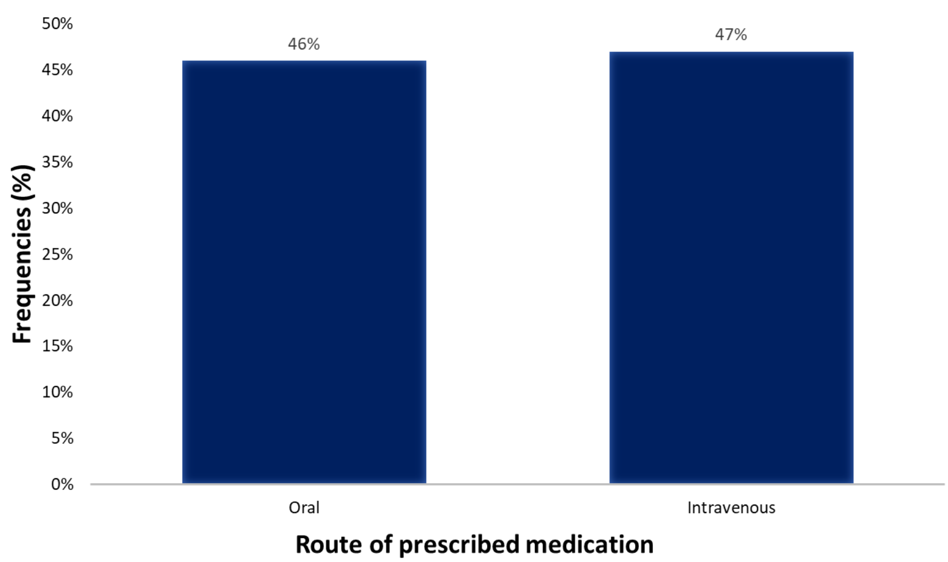

Figure 4.4 Frequency of the route prescribed

Of the 432 prescribed medications (N=432), 47% (n=204) were prescribed for the intravenous route and 46% (n=198) were prescribed for the oral route. Intravenous and oral medication had the same ratio of 1 in 2 for all prescribed medications.

4.2.1.4 Discussion

Type of medication: The results for Section A showed that analgesics (n=95; 22%) and antibiotics (n=77; 19%) were the most commonly prescribed medications.

Scheduled medication: Only 10% (n=43) of all prescribed medications were scheduled medications. These results concurred with Glanzmann et al's (2015:73) findings on medication prescription errors in critically ill children. In a study to determine the prescribing patterns of analgesic drugs across five international paediatric wards, Botzenhardt, Rashed, Wong, Tomlin and Neubert (2016:473) found a 12% frequency of scheduled medications prescribed.

Route of prescribed medication: In this study, intravenous (n=204; 47%) and oral medication (n=198; 46%) were the most frequently prescribed routes of administration.

The WHO (2012) recommends using a two-step strategy to manage persisting pain in paediatric patients with medical illnesses. This two-step strategy was followed by the doctors in the paediatric oncology ward when prescribing analgesia for the patients. This concurred with Botzenhardt et al's (2016:9) findings.

4.2.2 Section B: Potential latent conditions

Section B consisted of three items depicting latent conditions which could lead to potential prescription errors, namely the number of patients in the ward, the number of medications on the prescription chart for each patient, and the day of the week on which each medication was prescribed. The results for each item are presented in Sections 4.2.2.1 to 4.2.2.3 and discussed in Section 4.2.2.4.

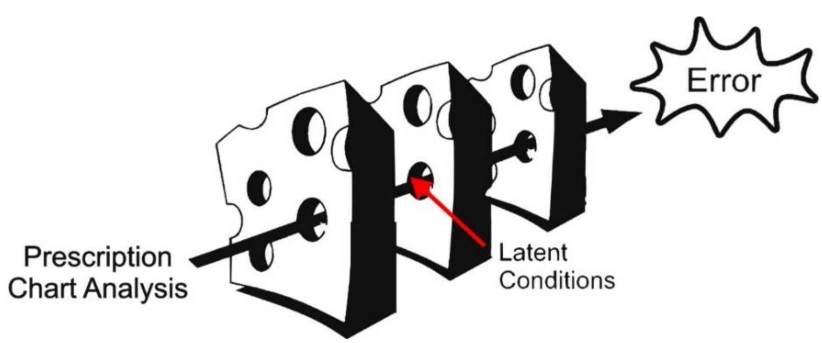

Figure 4.5 Latent conditions in prescription chart analysis

4.2.2.1 Number of patients in the ward

Figure 4.6 presents the number of patients in the ward during the study period.

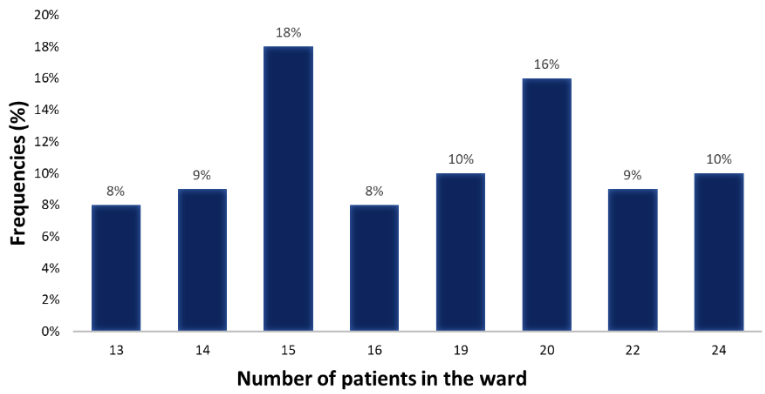

Figure 4.6 Number of patients in the ward when medication was prescribed

The results for the duration of the study indicated that when medications were prescribed, 15 patients occupied the ward 18% of the time, 20 patients occupied the ward 16% of the time; 19 and 24 patients occupied the ward 10% of the time; 14 and 22 patients occupied the ward 9% of the time, and 13 and 16 patients occupied the ward 8% of the time.

4.2.2.2 Number of medications on prescription chart

There was a wide range in the number of medications prescribed for the patients in the paediatric oncology ward depending on the reasons for their admission and how sick they became during the treatment. Figure 4.7 represents the frequencies of the numbers of medications prescribed for each patient.

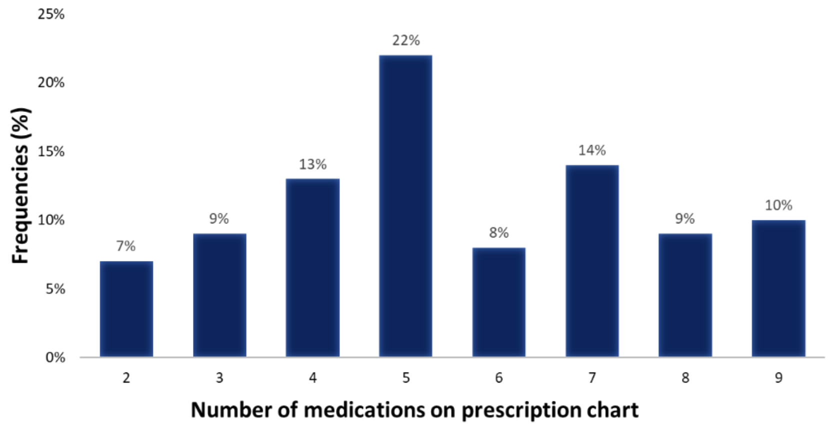

Figure 4.7 Number of medications on prescription charts per patient

Of the total number (N=432) of prescribed medications analysed, 22% (n=97) paediatric oncology patients had a total of five prescribed medications while 14% (n=59) had a total of seven medications prescribed. The number of prescribed medications on prescription charts per paediatric patient ranged between 2 and 17, giving a clear indication of the extent of how ill a patient became during treatment.

4.2.2.3 Day of the week that medication was prescribed

Figure 4.8 illustrates the frequencies at which medications were prescribed on certain days of the week.

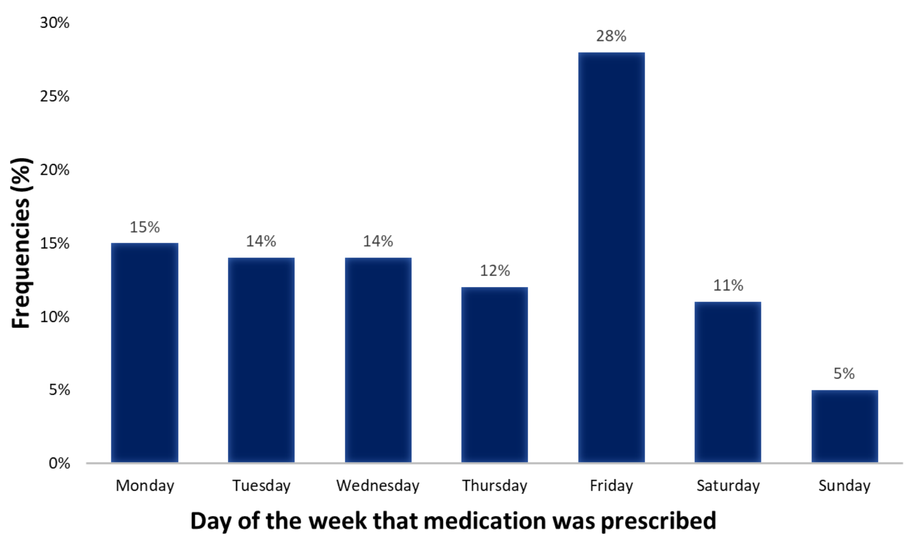

Figure 4.8 Day of the week that medication was prescribed

The results indicated that Fridays had (n=120) 28% of medications prescribed; Mondays had (n=66) 15% of medications prescribed; Tuesdays and Wednesdays each had (n=62) 14% of medications prescribed, and Sundays had (n=23) 5% of medications prescribed.

4.2.2.4 Discussion

Number of patients in the ward: For most (83%) of the study period, the number of paediatric patients in the paediatric oncology ward indicated a bed occupancy of 50% or higher. The researcher found no literature that reported on the number of patients having an association with increased prescription errors.

Number of medications on prescription charts: Polypharmacy refers to the use of five or more medications daily (Masnoon, Shakib, Kalisch-Ellett & Caughey 2017:230), for evading or diminishing undesired effects and complications of treatment. Chemotherapy is given to paediatric oncology patients to slow down the growth of, or completely eradicate cancer causes myelosuppression and other related complications (Soccal, dos Santos & de Campos 2017:17). To treat these complications and the symptoms thereof, numerous medications are used simultaneously, making the occurrence of polypharmacy inevitable (Soccal et al 2017:17; Seden et al 2013:11). It is stated by Glanzmann et al (2015:76-77) that paediatric patients receiving five or more medications during their hospital admission are at three times greater risk of developing an adverse drug reaction than patients receiving four medications or less. Seden et al (2013:9) found that the greatest predictor for prescribing errors was the number of medications on each prescription as each additional medication increased the risk of error by approximately 14%.

Day of the week on which medication was prescribed: In the paediatric oncology ward where the study was conducted, all prescriptions were renewed/transcribed on a Friday to minimise the workload over the weekends and during periods when only one doctor (intern) was on the premises. The majority of admissions to the paediatric oncology ward occurred on Mondays, followed by Tuesdays and Wednesdays, which increased the rate of medications being prescribed on certain days of the week. Seden et al (2013:2) state that higher rates of errors over weekends may be related to lower numbers of senior staff available compared to during a normal working week. However, Manias et al (2014:73) found fewer errors occurred (19.7%) over the weekends compared to the 80.3% of the reported errors on a weekday.

Medications were transcribed by a different individual week to week, which could have caused these results, as not all doctors follow correct prescribing procedures.

4.2.3 Section C: Potential active failures

Section C consisted of two main items, namely the general information on writing and labelling of prescriptions and the "Rights" of the medication prescription. The results of each item are discussed next

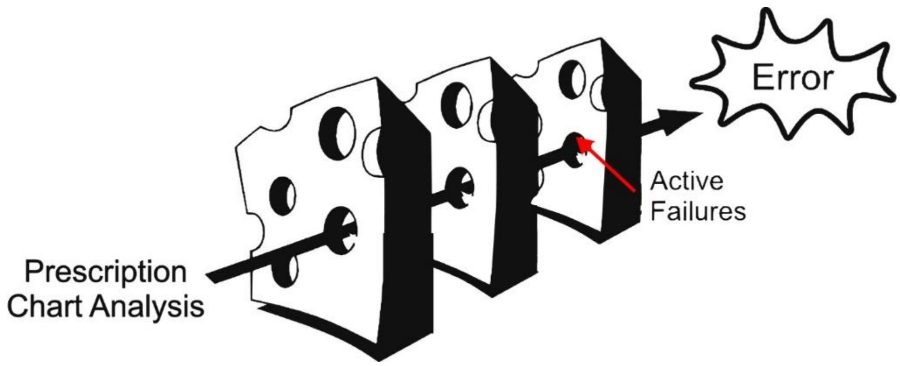

Figure 4.9 Active failures in prescription chart analysis

4.2.3.1 General information on writing and labelling of prescription

Figure 4.10 indicates the frequencies at which any errors in the general information occurred.

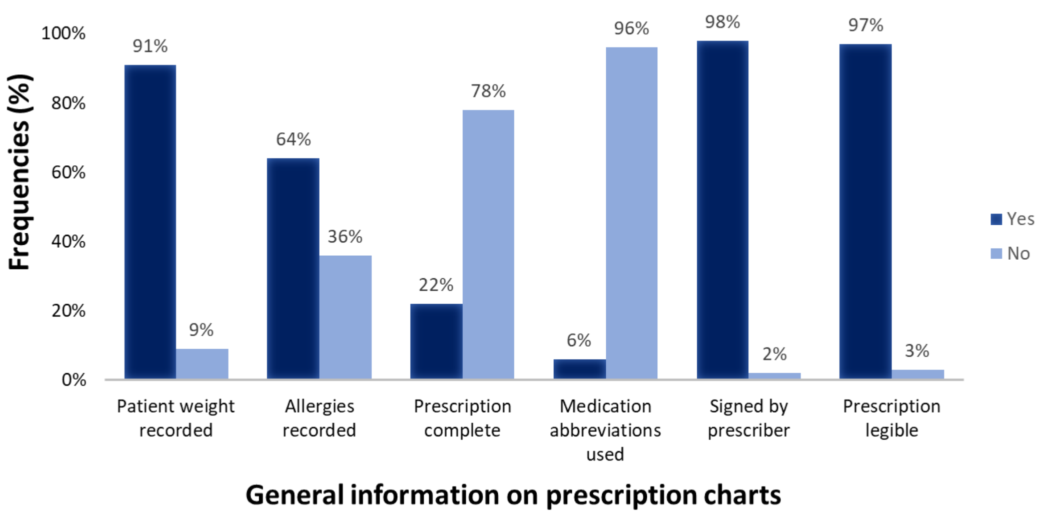

Figure 4.10 General information on writing and labelling of prescriptions

All prescriptions need to have certain general information recorded in order to make them legal and valid. This information includes the weight of the patient, allergies, the use of legible handwriting and the signature of the prescriber. Medication abbreviations should not be used, to avoid confusion which could lead to a medication administration error. The study found that potential failures existed when writing and labelling prescriptions. Overall 78% (n=339) of the total prescriptions were incomplete, either missing the patient's weight, allergies, prescriber's signature, dose, route, interval, date or time that the prescription was written. Of the total number of prescription charts analysed, allergies were not recorded in 36% (n=156); patient's weight was not recorded in 9% (n=38); medication abbreviations were used in 6% (n=25); the writing was not legible in 3% (n=15), and 2% (n=7) did not have the signature of the prescriber.

In their study in nine hospitals in North West England, Seden et al (2013:7) found 20.7% prescription errors. Incomplete prescriptions accounted for 78% of all prescriptions analysed in the current study, which was considerably higher than some of the studies reviewed. Mathaiyan et al (2016:2613) found that 45.5% of prescriptions had information missing while Hamza et al (2013:438) found 30.08% of chemotherapy prescriptions were incomplete. Ryan et al (2014:3) reported that 15.7% prescriptions were incomplete.

This study found inappropriate abbreviations used in 6% of prescribed medications. Mathaiyan et al (2016:2613) found 30.5% inappropriate medication abbreviations while Ryan et al (2014:3) found 4.4%, and Brunetti, Santell and Hicks (2007:577) found 4.7% inappropriate abbreviations. Illegible writing accounted for 3% of prescription errors in the current study and 2% of prescribed medications were not accompanied by the prescriber's signature. Ryan et al (2014:3) found 2% errors due to illegible writing and 2.6% due to no prescriber signature.

4.2.3.2 The "rights" of a medication prescription

Figure 4.11 illustrates the frequencies at which errors were made during prescribing, with regard to the "rights" of medication.

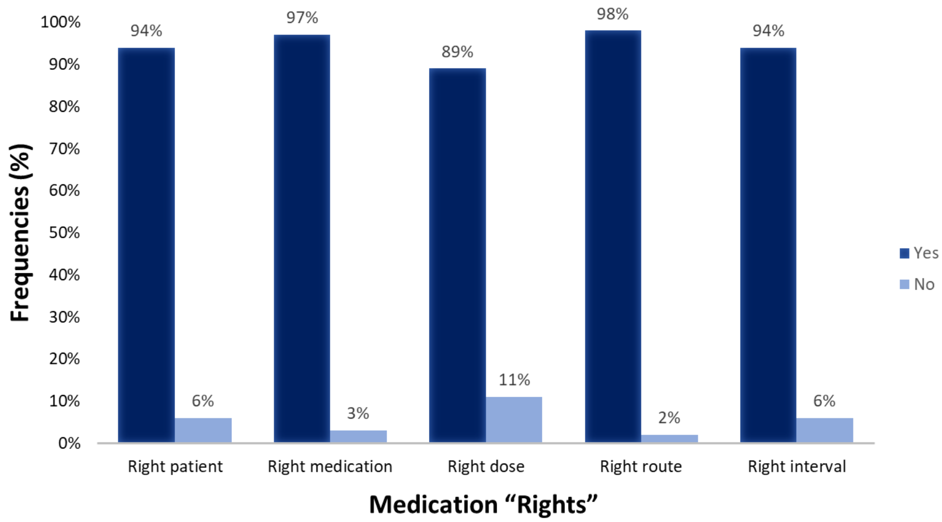

Figure 4.11 Medication "Rights" on prescription chart

A total of (N=432) prescribed medications were analysed and 72% (n=313) of the medications were prescribed correctly. The most frequently occurring prescribing errors were *dosage errors* (11%; n=47); *patient errors* (6%; n=25); *interval errors* (6%; n=27); *medication errors* (3%; n=11) and *route errors* (2%; n=8).

The medication "rights" commonly associated with medication administration state that the right medication should be given at the right dose, to the right patient, at the right time and via the right route. These principles apply to the prescribing of medications as well. There is a greater chance of a medication administration error occurring if the medication has been prescribed incorrectly. This study found a total of 28% prescription errors. Glanzmann et al (2015:1350) found a 14% rate of prescription errors in Europe and Haghbin et al (2016:114) found 14.2% prescription errors in Iran. Other studies found rates of prescription errors between 36% and 66% (Mathaiyan et al 2016:2614; Ryan et al 2014:6; Hamza et al 2013:438). In a systematic review of medication errors in Middle Eastern countries, Alsulami, Conroy and Choonara (2013:1006) found an estimated 3% to 37% rate of prescription errors in paediatric patients. The results from the current study fall within this range.

Alsulami et al (2013:997) found the most common prescription errors were *dosage* and *interval errors*. This study found 11% *dosage errors*. Ryan et al (2014:3) found 12.9% dosage errors and other studies found dosage error rates between 1.7% and 20.6% (Haghbin et al 2016:111;

Glanzmann et al 2015:47; Hamza et al 2013:439; Seden et al 2013:7). *Interval errors* occurred in 6% of prescribed medications in this study. Haghbin et al (2016:111) found 0.97% and Ryan et al (2014:3) found an error rate of 7.7%. The current study found 2% *route errors* for prescribed medications. R*oute errors* are reported to be the least frequent prescribing error and error rates range between 0.71% and 1.2% (Haghbin et al 2016:111; Ryan et al 2014:3; Hamza et al 2013:439).

Patient errors accounted for 6% of the prescription errors in this study where prescriptions either had the incorrect patient sticker or no patient sticker. The results found for *patient errors* was considerably higher than Ryan et al's (2014:3) finding of 0.5% *patient errors*. The researcher found no other studies which reported on *patient errors* in prescribing. The total rate of *medication errors* (3%) in the current study concurred with Ryan et al (2014:3), Glanzmann et al (2015:47) and Haghbin et al's (2016:111) findings of *medication errors* of 1%, 2.1% and 2.34%, respectively.

4.3 DIRECT OBSERVATION OF MEDICATION ADMINISTRATION

A total of N=1,064 medication administrations were observed using Annexure D2, and the results are discussed according to the following sections:

- Section A: General information about medication
- Section B: Person responsible for administration
- Section C: Potential latent conditions
- Section D: Potential active failures

4.3.1 Section A: General information about medication administered

Section A covered the general information about the medications administered in the paediatric oncology ward which were the same as those in section 4.2.1.

4.3.1.1 Types and frequencies of medications administered

Figure 4.12 depicts the types and frequencies of medications administered to the paediatric patients admitted and treated in the paediatric oncology ward.

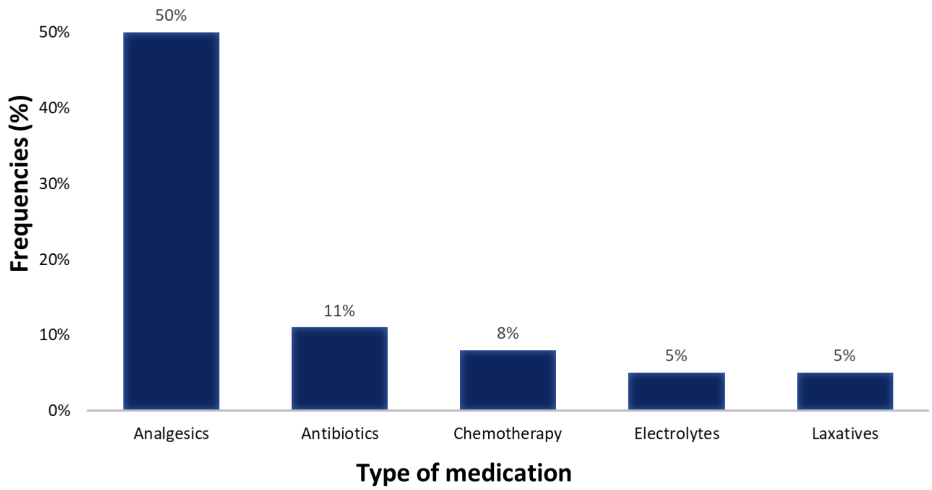

Figure 4.12 Types and frequencies of medications administered

The direct observation of N=1,064 administered medications represented five categories of medications. Of the medications administered, 50% (n= 530) were analgesics; 11% (n=118) were antibiotics; 8% (n=89) were chemotherapy, and 5% (n=51) were electrolytes and laxatives.

4.3.1.2 Scheduled medications administered

Figure 4.13 presents the frequencies at which scheduled medications were administered.

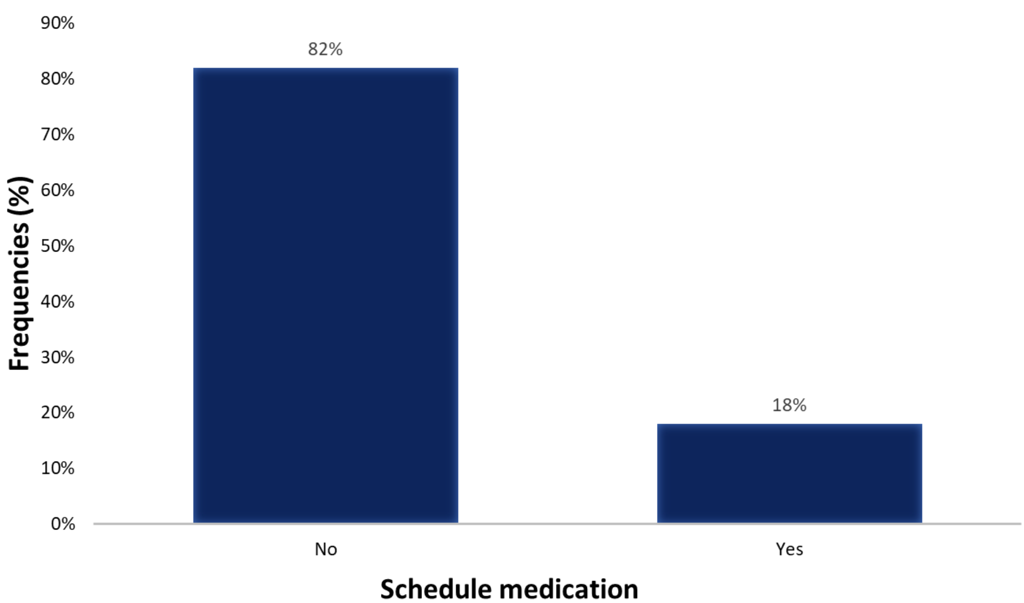

Figure 4.13 Scheduled medications administered

Of the N=1,064 administered medications, 18% (n=188) were scheduled medications and 82% (n=876) were not scheduled medications.

4.3.1.3 Route of administration

Figure 4.14 depicts the frequencies of different routes via which medications were administered in the paediatric oncology ward.

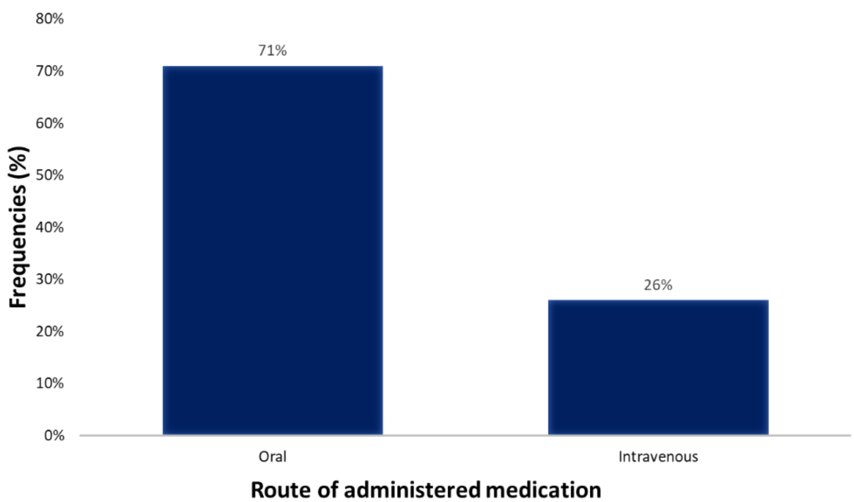

Figure 4.14 Route of administration

Of the N=1,064 scheduled medications administrations observed, 71% (n=757) of medications were administered via the oral route and 26% (n=272) via the intravenous route.

4.3.1.4 Discussion

Type of medication: Antibiotics comprised 11% of all medications administered in the current study. These results were less than the rates of antibiotic administration found in Australia (20.9%), Iran (21%) and Ethiopia (77.8%) (Haghbin et al 2016:113; Hennig, Staatz, Natanek, Bialkowski, Consuelo Llanos Paez & Lawson 2018:2; Feleke et al 2015:4). Electrolytes and laxatives were administered in the current study at 5% of total administrations. A study in 16 Dutch hospitals found that 3.8% of total administrations were electrolytes (Schutijser et al 2018:4). The low rate of scheduled medication administration indicated that the WHO pain ladder guidelines were followed in the paediatric oncology ward.

Route of administration: The oral route (71%) was the most frequently observed route of medication administration in this study, which concurred with Härkänen et al (2015:300) finding that 79.6% of administrations were oral. In addition, Härkänen et al (2015:300) found that 10.4% of medications were administered intravenously compared to 26% of intravenous administrations in the current study. Haghbin et al (2016:113) and Feleke et al (2015:54) reported the intravenous route as the most common route of administration at a rate of 67.2% and 89.4%, respectively.

4.3.2 Section B: Person responsible for administration

The person responsible for the administration of medication to the patients in the paediatric oncology ward has an important task in patient safety.

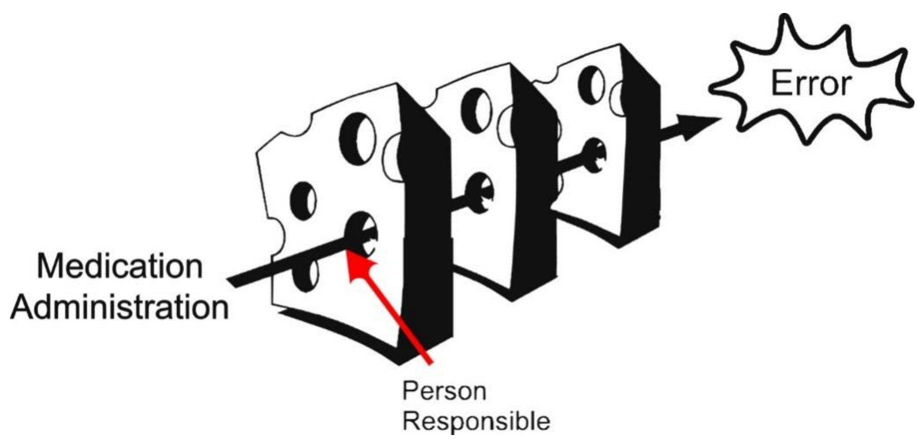

Figure 4.15 Person responsible for medication administration

4.3.2.1 Rank of the administrator

Registered nurses administer all types and routes of medication while enrolled nurses and student nurses only administer oral medication, under the supervision of a registered nurse.
Figure 4.16 shows the frequencies at which the different ranks of nurses administered medication.

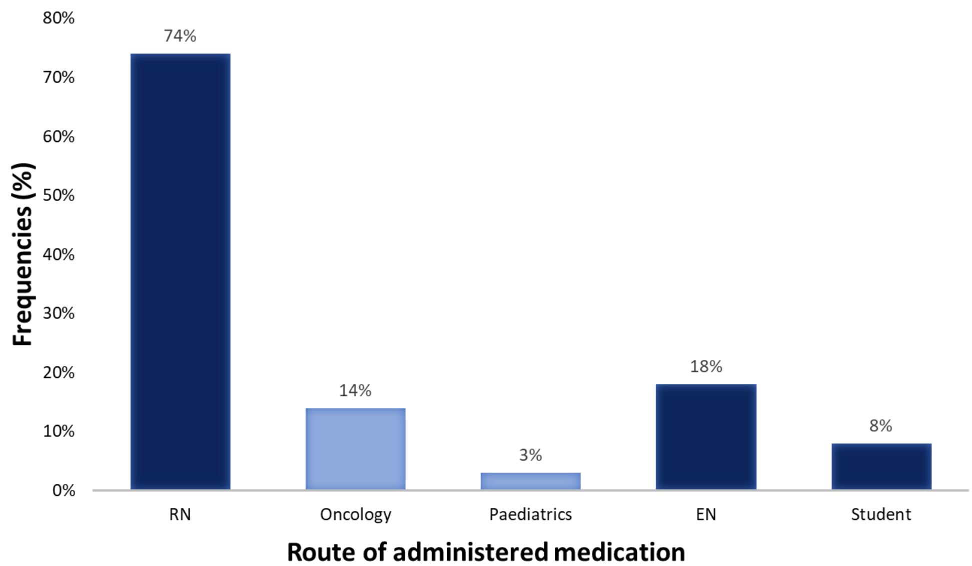

Figure 4.16 Rank of person responsible for administration

The findings indicate that 74% (n=785) of nurses responsible for medication administration were registered nurses, of whom 14% (n=111) of Registered nurses administrators had an additional qualification in oncology and 3% (n=23) of Registered nurses administrators had an additional qualification in child nursing. Enrolled nurses administered 18% (n=185) of medications and student nurses administered 8% (n=85) of the total medication administrations observed.

4.3.3 Section C: Potential latent conditions

Section C consisted of five items to identify any holes in the system's defences or latent conditions which might set a situation up for a potential medication administration error. These items were the number of nurses on duty for each shift on which direct observation took place; the number of patients in the ward; the number of nurses administering the observed medication; the number of medications prescribed to whom medication was administered, and the day of the week that each observation took place.

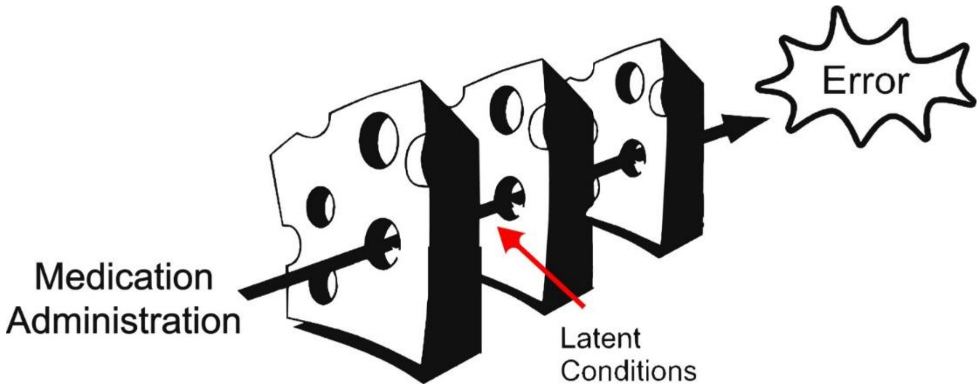

Figure 4.17 Potential latent conditions

4.3.3.1 Number of nurses on duty

Staffing numbers varied from shift to shift with a higher average number of nurses on a day shift verses a night shift. Figure 4.18 illustrates the frequencies of the number of nurses on duty during each shift in which direct observation of medication administration took place.

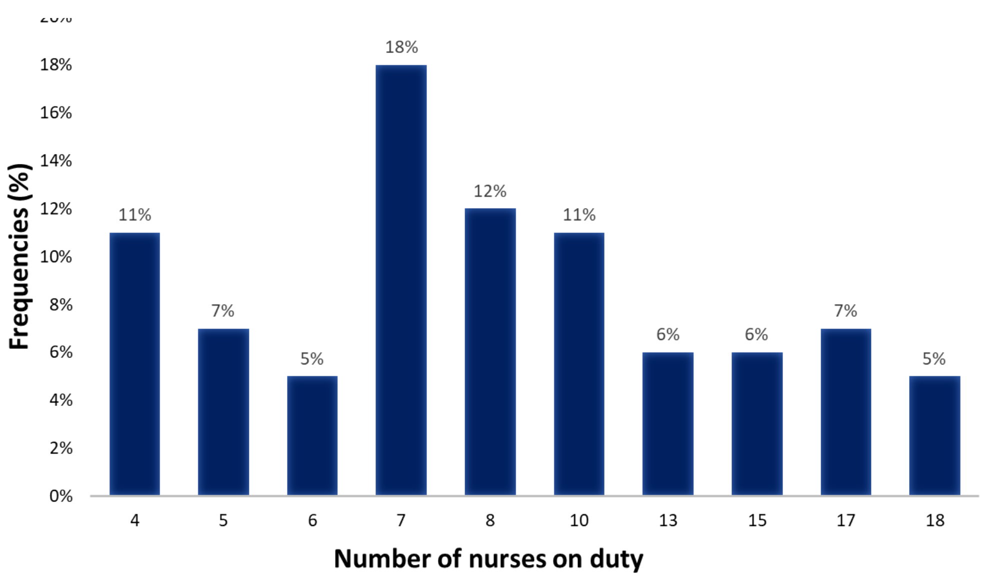

Figure 4.18 Number of nurses on duty

The results indicated that during the study period, the ward had 7 nurses on duty per shift 18% of the time; 8 nurses on duty per shift 12% of the time; 4 and 10 nurses on duty per shift 11% of the time, and between 5 and 18 nurses on duty per shift less than 7% of the time.

4.3.3.2 Number of patients in the ward

Figure 4.19 shows the number of patients in the ward during the study period and is indicative of the bed occupancy.

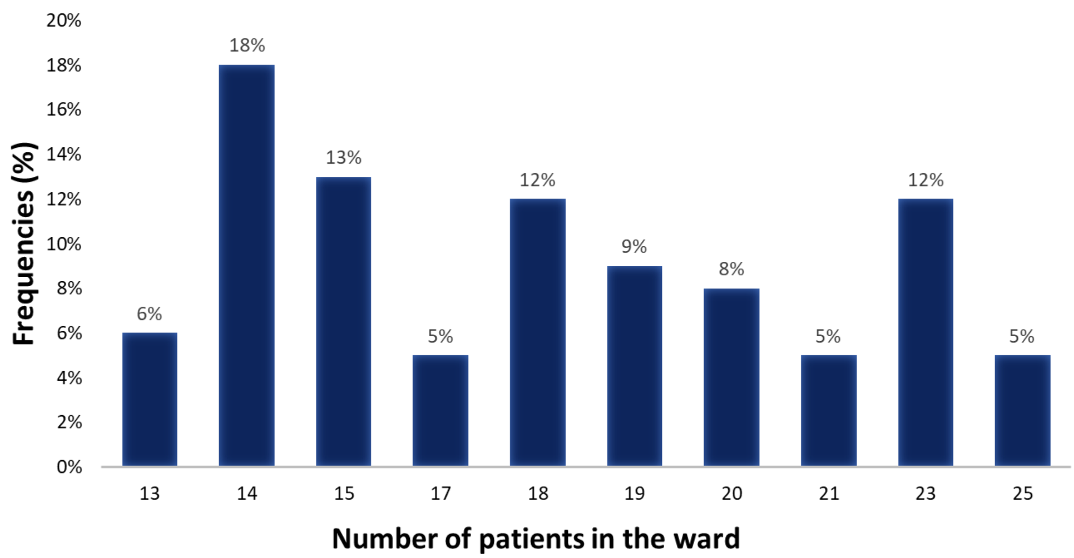

Figure 4.19 Number of patients in the ward during medication administration

At the time during which the study was conducted, the ward had an average of 14 patients 18% of the time; 15 patients 13% of the time, and 18 and 23 patients 12% of the time. The results show that 50% or more of the beds were occupied 74% of the time.

4.3.3.3 Number of nurses administering observed medication

Figure 4.20 illustrates the frequencies at which a nurse was delegated to her specific task alone or whether an additional nurse assisted her.

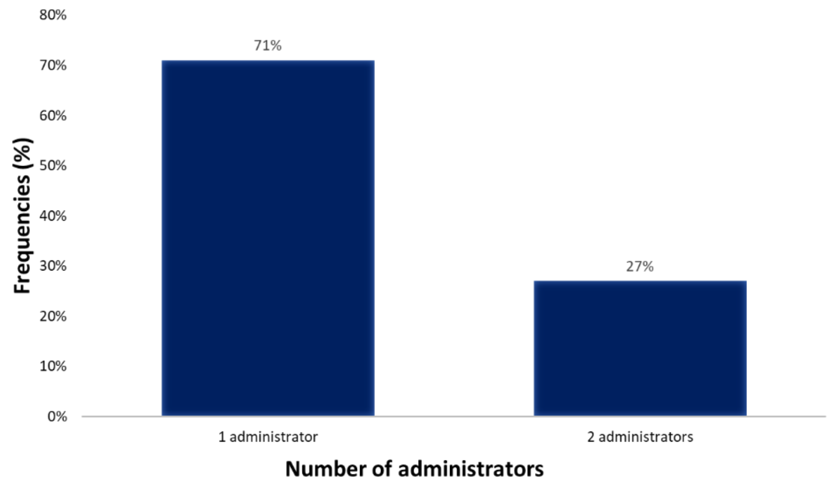

Figure 4.20 Number of administrators per route

Nurses in the paediatric oncology ward were delegated to administer either oral medication, intravenous medication, or chemotherapy on a specific day. The results show that 71% of observations only had one nurse administering medications, while two nurses administered medications 27% of the time.

4.3.3.4 Number of medications prescribed to whom medication was administered

Figure 4.21 indicates the number of medications that each paediatric patient received in 24 hours. The total number of prescribed medications was not limited to one administration each.

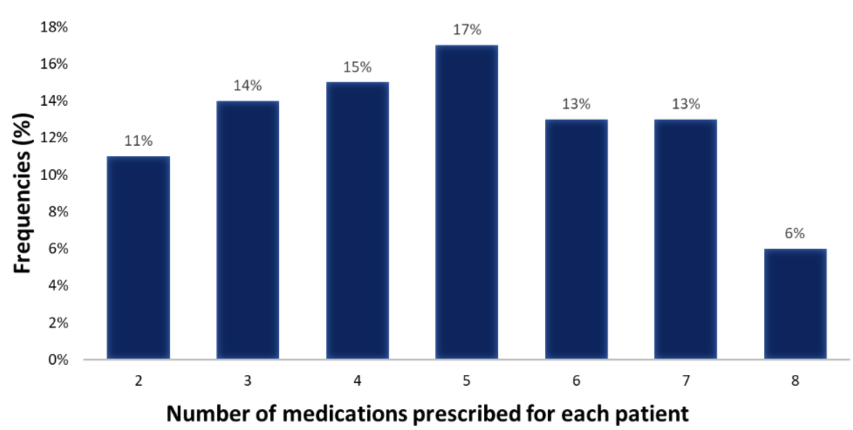

Figure 4.21 Number of medications on prescription chart

The most common number of prescribed medications for one patient was five medications 17% of the time, while four medications were prescribed for a patient 15% of the time. Less than 6% of the time, a patient had either more than eight or only one medication was prescribed.

4.3.3.5 Day of the week that medication was administered

Figure 4.22 illustrates the frequencies at which medications were administered on particular days.

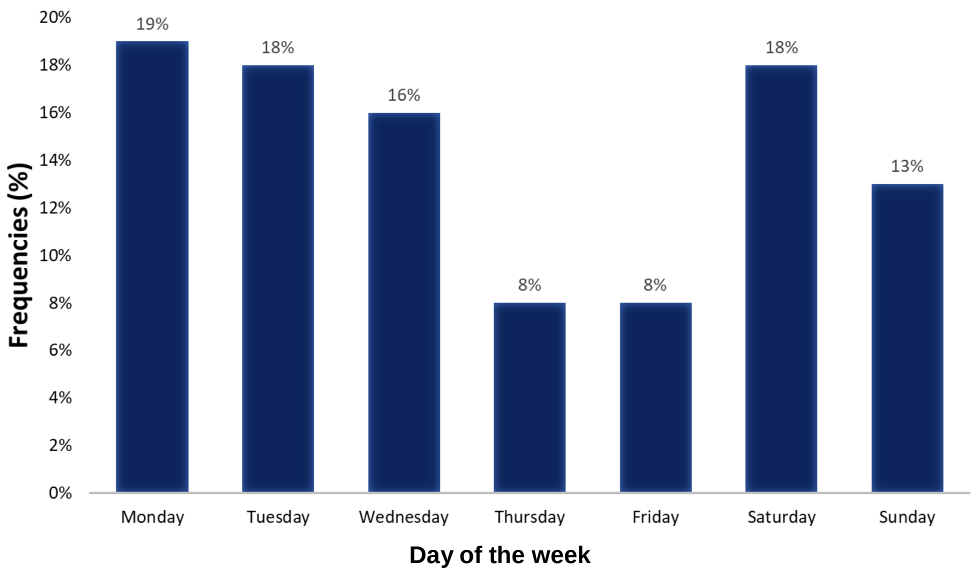

Figure 4.22 Day of the week that medication was administered

Medications were administered to paediatric oncology patients every day of the week. The results show that of the medications, 19% (n=206) were administered on a Monday; 18% on both Saturdays (n=196) and Tuesdays (n=188), and (8%) on Thursdays (n=86) and Fridays (n=85).

4.3.3.6 Discussion

Staffing numbers might sometimes seem excessive based on the bed occupancy of the paediatric ward, but a large number of students rotated through the ward during the study period. These student numbers, frequently up to 13 per shift, often exceeded the number of permanent staff on duty. The administration of different medications (oral route, intravenous route, chemotherapy) was predominantly done by one individual nurse but the number of administrators was increased to two due to the presence of the students. These students were not placed in the ward permanently but spent between 1 and 3 weeks working in paediatric oncology before moving to their next allocated ward. This is not always beneficial as students need training, guidance and supervision, especially when mixing and administering medication in a ward where protocols and dosages are unfamiliar (Blignaut 2015:86). Of all the paediatric patients to whom medications were administered, 57% received a total of five (5) or more medications, with each medication administered between one to six times per day. The number of medications that a paediatric patient receives is a significant factor of medication safety (Glanzmann et al 2015:64) (see section 4.2.2.4 for detailed discussion).

In a study on omitted medications, only medications administered on weekdays were observed to eliminate the confounding effects of low staffing levels over a weekend (Shandilya et al 2015:13). Manias et al (2014:73) determined that fewer errors occurred (19.7%) over the weekends compared to 80.3% reported errors on weekdays. The researcher found no other studies on the day of the week being associated with an increase or a decrease in administration errors.

4.3.4 Section D: Potential active failures

Section D consisted of three items, namely the “Rights” of medication administration, a record of any distractions or interruptions, and whether the researcher intervened in any imminent medication administration errors.

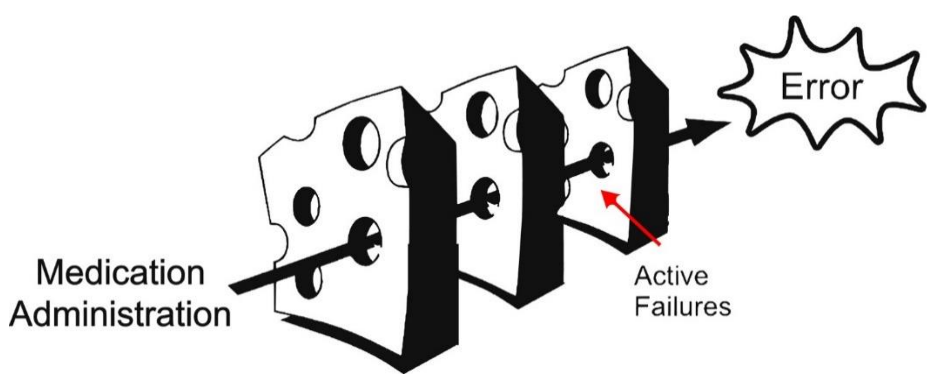

Figure 4.23 Active failures in medication administration

4.3.4.1 The "rights" of medication administration

Medication errors are the most frequent type of nursing error associated with 26% to 38% errors transpiring in hospitalised patients (Orbæk et al 2015:203). There are five well-known rights commonly associated with medication administration, namely right patient, right medication, right route, right dose, and right time. Nurses are taught about these rights during their training and are encouraged to follow them while administering medication to prevent errors occurring. Figure 4.24 illustrates the frequencies at which errors were made according these "right" categories.

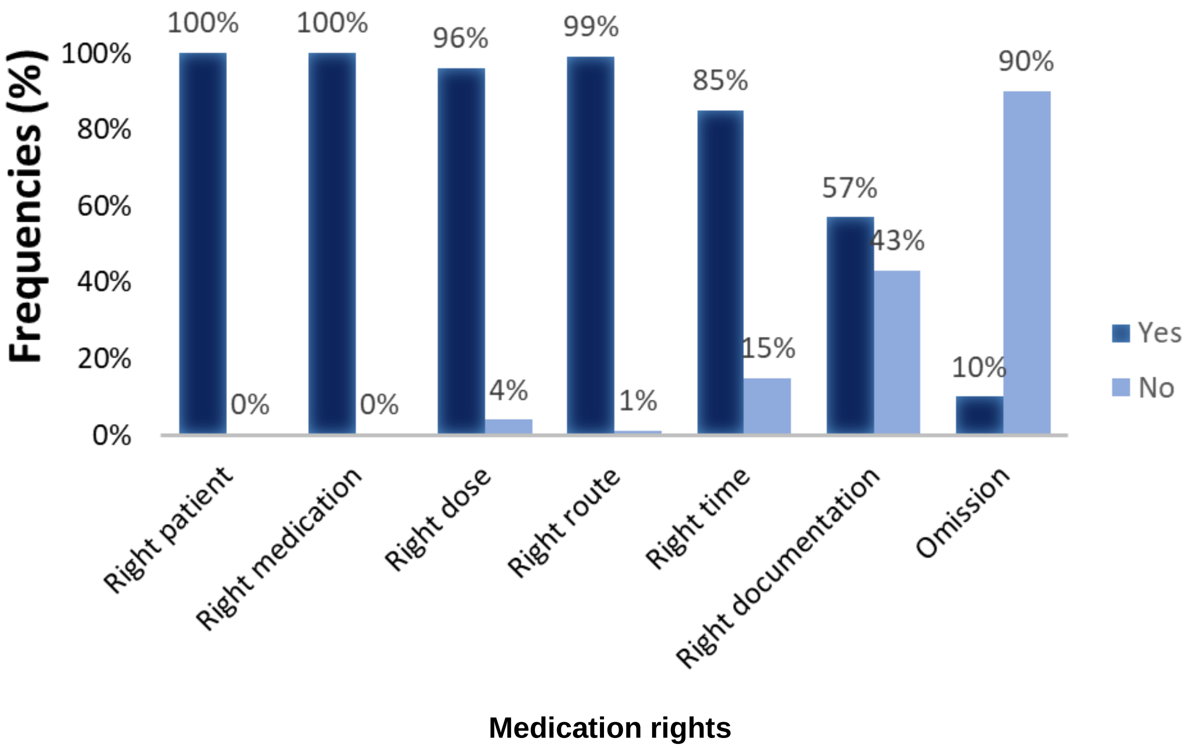

Figure 4.24 "Rights" in medication administration

The direct observation of N=1,064 administered medications revealed 43% (n=453) of administrations contained a documentation error; 10% (n=111) error of omission; 15% (n=158) of medications were administered at the wrong time; 4% (n=40) of medications were given at a higher or lower dose than that prescribed, and 1% (n=6) of medications were administered via the wrong route.

The study found a rate of only 27% correctly administered medications. However, if documentation errors are taken as a separate entity, the rate of correctly administered medication for the current study was 70%, showing an error rate of 30%. Haghbin et al (2016:114) reported a rate of 28.9% while Mathaiyan et al (2016:2614) found a lower rate of 11.2% medication administration errors. *Documentation errors* were found in 43% of all medication administrations which was considerably less than Feleke et al's (2015:4) finding of 87.5%.

In terms of error type, Young et al (2015:168) state that *time errors*, *omission* and *dosage errors* occur most frequently. The most common errors observed in medication administration in the current study were *time errors* (n=158;15%), which concurred with Haghbin et al's (2016:113) finding of 14.1% *time errors*. However, Feleke et al (2015:5) found 53.6% *time errors*.

Medications were omitted in 10% (n=111) of total administrations observed. The literature review indicated a range of 0.58% to 26.8% omission errors (Haghbin et al 2016:111; Feleke et al 2015:5; Härkänen et al 2015:301). Reasons for omissions included patient refusal (n=44; 41%) and the administrator either forgetting or not seeing the medication on the prescription, or the patient's file not being at the bedside (n=23; 21%). Further administrations (n=16; 14%) were omitted due to the administrator withholding medication based on a professional decision that a clinical reason existed for why it should not be administered (e.g. laxatives omitted if patient passed loose stools or antiemetics omitted if the patient was not vomiting and no longer receiving chemotherapy). Only 11% (n=12) of omitted medications were due to unavailability of stock. Shandilya et al (2015:13) found that 47% of omissions were due to patients' refusal and 17% to medication unavailability.

Acheampong et al (2014:128) found that paediatric patients were at greater risk of dosing errors due to inappropriate dosages and strengths available for use in this group of patients. In this study, medication was administered at a dose higher or lower than that which was prescribed in 4% (n=40) of observed administrations. These results concurred with Haghbin et al (2016:111) and Mathaiyan et al (2016:2614) who observed 1.17% and 1.05% *dosage errors*, respectively. Feleke et al (2015:5), however, recorded a *dosage error* rate of 23.1%.

In this study, the patient was not identified in only one observation of the total administrations. Kim and Bates (2013:6) scored observations for *right patient* as either positive or negative depending on whether the administrator checked patients' names on the wristbands or asked patients to verify their names. This resulted in a 94% negative score, although it did not represent 94% of medication being given to the wrong patient. Patients in the paediatric oncology ward are often well known as they return to the ward for their treatment several times over a period of a few months. Nursing staff are familiar with these patients and any mention of the patient or mother's name by the administrator, during the observation, was accepted as positive patient identification in the current study.

In this study, *medication errors* only occurred in four observations. In each of these administrations, the patient did not receive the incorrect medication but rather the medication was given to the patient by a nurse other than the one who had prepared it. This was classified as a *medication error* although it was more a deviation from safe practice, as the administering nurse had no guarantee that the medication had been mixed correctly. Kim and Bates (2013:4) found a comparable low rate of *medication errors* in 1.4% of the observed medication administrations and Blignaut et al (2017:3620) observed 2% of the same deviation from safe practice.

In the current study, only 1% of administrations were associated with *route errors*. These results were consistent with Mathaiyan et al (2016:2614) and Feleke et al (2015:5). *Documentation errors* were found in 63% of administrations in the current study, which was of concern. Härkänen et al (2015:301) recorded only 18.3% *documentation errors*.

4.3.4.2 Distractions and researcher interventions

Distractions are a well-known cause of medication errors and it is within ethical considerations that the researcher would intervene for any medication administration error deemed dangerous. Figure 4.25 indicates the frequencies of distractions and interruptions observed during medication administration as well as any interventions by the researcher.

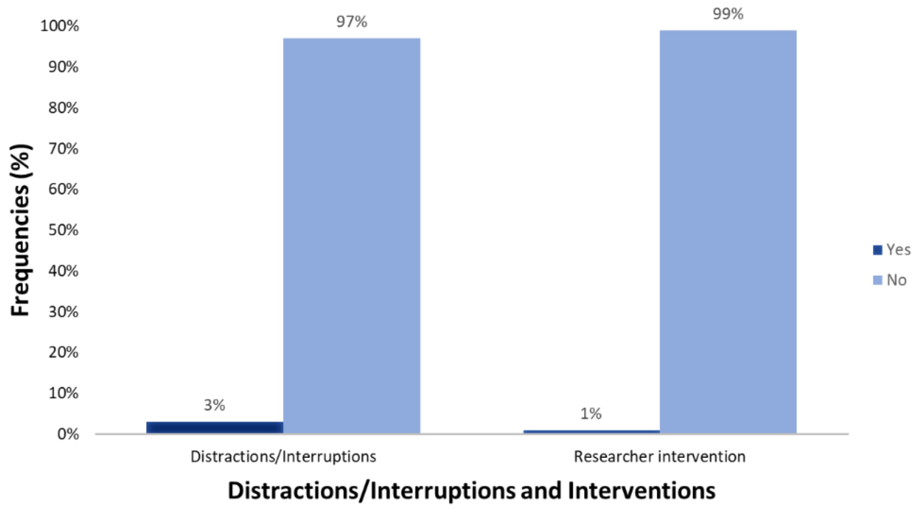

Figure 4.25 Distractions and researcher interventions

The study found that 3% (n=36) of medication administrations were interrupted or that the administrator was distracted in some way. In addition, it was necessary for the researcher to intervene during 1% (n=10) of the medication administrations.

The current study observed only 3% of distractions and interruptions during direct observation of medication administration. In a total of 60 medications administrations, Young et al (2015:172) observed 17% (n=10) interruptions or distractions. Feleke et al (2015:7) emphasise that medication administrations which are interrupted are twice as likely to result in error as those which are not interrupted. Parry et al (2015:412) reviewed studies that examined whether distractions or interruptions contributed to medication administration errors but did not explore how these distractions resulted in error. Several studies reported that distractions and interruptions were associated with increased error rates while others stated that they did not significantly increase the rate of errors (Parry et al 2015:415). In this study, the data collectors worked in the ward in which the study was conducted. Consequently, the distractions may have been under-reported as it tends to be the norm for those who are used to working in the paediatric oncology ward. Moreover, the researcher tried to deal with the interruptions so as not to take the administering nurse away from the task at hand.

The researcher only intervened in 1% (n=10) of the administrations, all of which were omitted doses that the administrator had not seen. Once the administrator moved on to the next patient, the researcher asked for them to return to the patient and administer the omitted dose. It would have been unethical for the researcher to allow the administrator to continue without correcting the error as the patient would have had to wait for the next medication round to receive their medicine thereby reducing the effectiveness of that medication (see Chapter 1: Section 1.10.4). No potentially dangerous administrations were observed.

4.4 CORRELATIONS

Correlational analyses were done using Pearson's correlation coefficient and used to identify factors which contributed to the occurrence of prescription and medication administration errors. The threshold for statistical significance is often set at p = .05 (Frey 2018:1228) and therefore only significant results, with p-values >.05 are presented next. Correlations in prescription errors are presented and discussed first, followed by correlations in medication administration errors.

4.4.1 Prescription chart analysis

Prescription error types were correlated to legible prescriptions, complete prescriptions and scheduled medications. Table 4.1 lists factors contributing to prescription errors.

Table 4.1 Correlations between prescription errors and factors which contributed to their frequency

	Legible prescription	Prescription Complete	Scheduled medication
Dosage error			-0.1496 p=.002
Interval error			-0.1578 p=.001
Patient error	-0.1154 p=.016		
Route error		-0.0953 p=.048	

The study found a negative correlation of 11% between legible prescription and *patient errors* (p=.016) as well as a 9% correlation between complete prescriptions and *route errors* (p=.048). Scheduled medications were negatively correlated with *dosage errors* and *interval errors* (p=0.02 and p=0.01, respectively). Although these correlations were weak, they were statistically significant as seen by p-values of < 0.05.

The above correlations were all negative, indicating that *dosage* and *interval errors* occurred less often in prescriptions when scheduled medications were prescribed. Fewer *patient errors* occurred when prescriptions were legible, and fewer *route errors* were seen when prescriptions were complete.

4.4.2 Direct observation of medication administration

Medication error types were correlated to type of medication, total number of staff, scheduled medication, rank of the administrator, number of patients, and number of administrators. Table 4.2 presents factors contributing to medication administration errors.

Table 4.2 Correlations between medication administration errors and factors which contributed to their frequency

Error type	Type of medication	Total number of staff	Scheduled medication	Registered Nurse	Enrolled Nurse	Student	Number of patients	Number of administrators
Documentation error	-0.14 p<.001	-0.1128 p<.001		0.1710 p<.001	0.1488 p<.001		0.1653 p<.001	
Time error	-0.12 p<.001		-0.1299 p<.001	-0.0660 p=.031	-0.1148 p<.001	-0.0625 p=.042		-0.0628 p=.041
Omission error			0.1674 p<.001					
Dosage error	0.07 p=.018		0.082 p=.008		0.0609 p=.047			

The study found that *documentation errors* were negatively correlated to the type of medication and the total number of staff, but positively correlated to the number of patients and to Registered nurses and Enrolled nurses as the administrators (each with p>.001). *Time errors* were negatively correlated to type of medication, scheduled medication and Enrolled nurses as the administrator (each with p>0.01) as well as to Registered nurses as the administrator (p=.031), student nurses as the administrator (p=.042) and number of administrators. *Omission errors* had a positive correlation to scheduled medications (p>.001). *Dosage errors* were positively correlated to type of medication (p=.018), scheduled medication (p=.008) and Enrolled nurses as the administrator (p=.047). These correlations were significant as seen by the p-value of >0.05.

The above correlations indicated that *documentation errors* decreased when more staff was on duty and increased with higher bed occupancy. *Documentation errors* were also dependent on the type of medication administered and rates were increased when medications were administered by Registered nurses and Enrolled nurses. *Time errors* in medication administration were mostly made by Enrolled nurses as the administrators compared to Registered nurses and student nurses. Fewer *time errors* were seen when the number of administrators was higher, and these errors were also dependent on the type of medication administered. *Omission errors* were mostly seen with scheduled medications as the patients often refused opioids when they did not experience pain. *Dosage errors* were mostly made by Enrolled nurses as the administrators and were dependent on the type of medication and whether it was a scheduled medication or not (see Chapter 1, Section 1.5 for level of education and scope of practice for different nursing ranks).

4.5 SUMMARY

This chapter discussed the general information about prescribed and administered medications. The first objective of the study was to identify and describe the types and frequencies of prescription and medication administration errors that occurred in a paediatric oncology ward in Gauteng. A substantial number of *incomplete prescriptions* were detected, with patient weight and allergies being the most recurrent missing information. *Dosage errors* and *patient* and *interval errors* were the most prevalent errors identified during prescription chart analysis.

Documentation errors were seen in several medication administration observations. *Time errors* were the most frequently detected medication administration error, followed by *omission errors*. The second objective was to identify factors contributing to the occurrence of prescription and medication administration errors. Factors that contributed to prescription errors were found to be scheduled medications, incomplete prescriptions, and illegible prescriptions. Factors which exacerbated the frequency of medication administration errors were type of medication, total number of staff, scheduled medication, number and rank of the administrator and number of patients.

Chapter 5 concludes the study, summarises the results, briefly describes the limitations of the study and makes recommendations for future research.

5 CONCLUSIONS, IMPLICATIONS AND LIMITATIONS

No job is so important & no service is so urgent
that we cannot take the time to perform our work safely.

- Anonymous

5.1 INTRODUCTION

Chapter 4 presented and discussed the results of the study. This chapter presents the conclusions of the study and their implications, briefly discusses the limitations, and makes recommendations for future research based on the findings.

5.2 AIM AND OBJECTIVES OF THE STUDY

The aim of the study was to determine prescription and medication administration errors that transpired in a paediatric oncology ward in Gauteng.

In order to achieve the aim, the objectives of the study were to

Objective 1: Identify and describe the frequency and types of prescription and medication administration errors that occurred. (Chapter 4: Section 4.2.3 and Section 4.3.4)

Objective 2: Identify factors that contributed to the occurrence of prescription and medication administration errors. (See Chapter 4: Section 4.2.2 and Section 4.3.3)

The researcher used a quantitative, observational, cross-sectional research design for the study. Ethics approval was obtained from the University of Pretoria's Faculty of Health Sciences (see Annexure A1) and permission was granted by the relevant hospital (see Annexure A2). Data sheets were developed and used to collect data on 432 prescribed medications (see Annexure C2) during prescription chart analysis and 1,064 medication administrations (see Annexure D2) during direct observation. Convenience sampling was used and prescriptions that met the inclusion criteria were analysed and nurses who gave informed voluntary consent were observed during medication administration.

5.3 CONCLUSIONS

The conclusions reached were based on the results from the data collected (see Chapter 4). The conclusions are discussed separately for prescription chart analysis and direct observation of medication administration, according to the objectives of the study and based on the Swiss cheese model used as the theoretical framework. Implications for decreasing the prevalence of prescription and medication administration errors in the paediatric oncology ward are discussed according to each "layer of cheese" and are sub-divided into clinical, educational and managerial implications. General implications and recommendations for future research are also discussed.

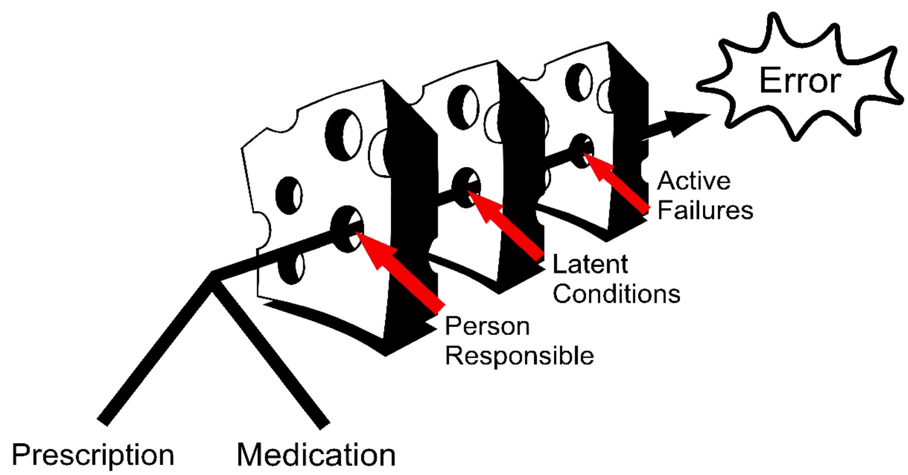

Figure 5. 1 Swiss cheese model of system accidents

Adapted from: Reason (2000:769)

5.3.1 Prescription chart analysis

The data sheet used to analyse prescription charts (see Annexure C2) consisted of three sections:

- Section A**:** General information about medication
- Section B: Potential latent conditions
- Section C: Potential active failures

Section A (General information about prescribed medication) was used to collect data related to the types of medication prescribed, scheduled medication and the prescribed route. Descriptive data of these aspects will be discussed in this section.

Paediatric oncology patients receive many different types of medication during their treatment. While the percentage of chemotherapy prescribed (9%) during the course of the study may appear low, many children remain in hospital for days to weeks after their chemotherapy blocks for the treatment of symptoms and complications caused by the chemotherapy itself. Doctors prescribed analgesics (22%) to manage the patients' pain, antibiotics (19%) for infections caused by neutropenia, electrolytes (5%) to correct imbalances, prophylactic laxatives (5%) to counter the effect of certain analgesia, and blood products (4%) to supplement low blood counts.

Only one in ten prescribed medications were scheduled medications which was found consistent with the literature reviewed. Intravenous (47%) and oral medication (46%) were the most frequently prescribed routes of administration in this study. The majority of chemotherapy treatment and antibiotics as well as all blood products were prescribed intravenously. The bulk of analgesia, steroids, laxatives, and electrolytes were prescribed orally. Other routes of administration were seldom prescribed, and intramuscular and subcutaneous routes of medication administration are painful and should be avoided where possible.

Objective 1: Identify and describe the frequency and types of prescription errors

5.3.1.1 Frequency and types of prescription errors

Section C (Potential active failures) of the data sheet was used to collect data on prescription errors identified. General errors in the writing and labelling of prescriptions and the types and frequencies of prescription errors will be discussed.

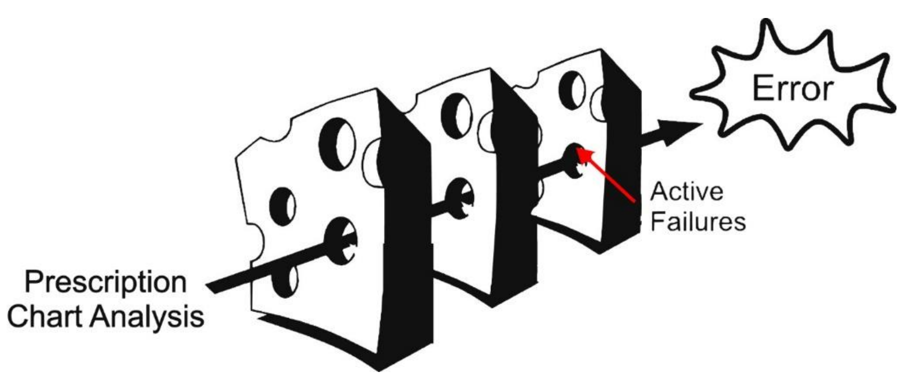

Figure 5.2 Active failures in prescription chart analysis

A significant number of general writing and labelling errors (56%) were found during prescription analysis. These errors were predominantly seen in incomplete prescriptions (78%) and the lack of recorded allergies (36%). The use of medication abbreviations (6%) and lack of the prescriber's signature (2%) were not observed as frequently. These results were inconsistent with the literature reviewed where much lower rates of general writing and labelling errors were observed.

A total of 28% prescription errors were found during prescription chart analysis. Patients admitted to the paediatric oncology ward are at a high risk of medication errors due to the nature of their illnesses, polypharmacy, and the use of high-risk drugs, such as chemotherapy. Paediatric patients in general are particularly vulnerable to dosing errors as many calculations are required due to varying doses in children dependent on the child's age, weight or body surface area. The most prevalent prescription error found was *dose errors* (under- or overdosing), which comprised 11% of the total prescription errors. The recurrent need for weight-based dosing in paediatric patients is the most probable factor contributing to this high rate of error. *Interval errors* (6%) and *patient errors* (6%) were the second most common prescription errors. *Medication errors* (3%) and *route errors* (2%) presented the lowest rate of prescribing errors. These results are consistent with those reported in the literature review.
The implications are presented next.

- Clinical implications
  - Medications should be written in print (capital letters) to make "difficult to read" handwriting more legible. Abbreviations should be avoided, and all medications should be written out in full to evade confusion. Doctors should be encouraged to sign each and every medication prescribed and print their name next to their signature so that the prescriber can be identified. The weight and allergies of the patient should be recorded in every prescription to avoid dosing errors and adverse events in case a patient may be allergic to a medication. All prescriptions should be reviewed for accuracy, completeness and legibility directly after being written.
  - A simple intervention to reduce the number of patient errors would be for doctors to print the patient's name above the sticker on the prescription chart. This would force them to read the patient's name and ensure that the right medication is prescribed for the right patient. Generic names of medications should be used to prescribe, and brand names should be

avoided. Dosing errors could also be reduced if doctors double-checked calculated prescribed doses with a colleague.

- The introduction of standardized prescription charts or the use of IT (Information Technology) systems, which provide electronic prescribing, is recommended.

Objective 2: Identify and describe factors contributing to the occurrence of prescription errors

5.3.1.2 Contributing factors

Section B (Potential latent conditions) of the data sheet was used to collect data on factors which may potentially contribute to prescription errors and included the number of patients in the ward, the number of medications on the prescription chart for each patient as well as the day of the week on which each medication was prescribed.

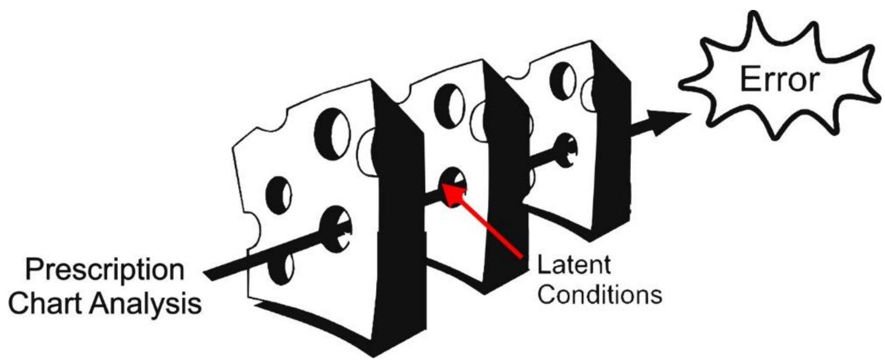

Figure 5.3 Latent conditions in prescription chart analysis

A “polypharmacy” of five or more medications per day were prescribed for 70% of the paediatric oncology patients during the study period, with some children receiving up to 17 different medications in 24 hours. The high prevalence of polypharmacy could increase the frequency of medication errors and drug-drug interactions. The increased rates of medications prescribed on Fridays were due to the renewal of prescriptions while Mondays to Wednesdays saw increased rates of medications prescribed due to the heightened numbers of new admissions to the ward on those days.

Pearson's correlation coefficient was used to determine the factors associated with prescription errors. An increase in *patient errors* was associated with illegible prescriptions while an increase in *route errors* was associated with incomplete prescriptions. The prescription of scheduled medications was associated with a decrease in *dosage* and *interval errors*. The implications follow.

- Clinical implications
  - Clinicians should make every effort to review the prescription charts on a daily basis and stop any medications that are no longer required, in an effort to minimise the presence of "polypharmacy" and thereby decrease the risk of medication errors.
- Educational implications
  - Training and assessment (which includes ongoing monitoring, clear communication and guidance) should be provided for junior doctors on how to prescribe medications to make prescription charts legal and drastically reduce the risk of medication errors caused by potential active failures.

5.3.2 Direct observation of medication administration

The data sheet used to directly observe administration of medication (see Annexure D2) consisted of four sections:

- Section A: General information about medication
- Section B: Person responsible for administration
- Section C: Potential Latent Conditions
- Section D: Potential Active Failures

Each section will be discussed next.

Section A (General information about prescribed medication) collected data related to the types of medication prescribed, scheduled medication, and the prescribed route. Descriptive data of these aspects will be discussed in this section.

Pain in children receiving chemotherapy is common, unrelenting, and felt at high levels of intensity necessitating the need for regular administration of analgesia. Of all medication administrations observed during this study, 50% of medications were analgesia. Febrile neutropenia, regarded as "fever in the presence of neutropenia (neutrophil count of <0.5 x or <1.0 x 10^9/L) with expectation of further decrease" is a common complication of chemotherapy treatment and a major cause of morbidity and mortality requiring swift administration of antibiotics. The results indicated that 71% of the medications were administered orally while 26% were administered intravenously.

Objective 1: Identify and describe the frequency and types of medication administration errors

5.3.2.1 Frequency and types of administration errors

Section D (Potential active failures) of the data sheet focused on identifying medication administration errors by collecting data on the following aspects: the "rights" of medication administration (Right patient, medication, dose, route, time) and documentation errors, omissions, distractions/Interruptions as well as researcher interventions.

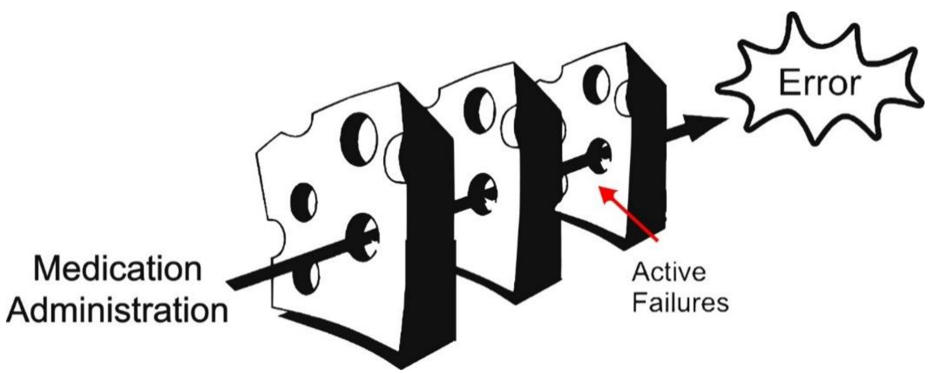

Figure 5.4 Active failures in medication administration

Errors in documentation were the most common error at 63%. While this type of error may not cause as much potential harm as giving the wrong patient the wrong medication, it remains a cause for concern. A substantial amount (15%) of medication was given at the wrong time and 1 in 10 medications was omitted. Wrong medication and wrong route errors occurred seldom, at less than or equal to 1% of administrations and only 1 wrong patient error was observed. The literature discussed in Chapter 4 corroborated the findings of *time errors*, *omission errors* and *dosage errors* being the most frequently observed.

Distractions and interruptions were only observed in 3% of medication administrations. This seemed to have become the norm in the paediatric oncology ward and appeared to be under-reported. Patients in the nearby vicinity will cry and need comforting, IVACs will be alarming and chemotherapy will need to be changed. Parents have questions and student nurses need to be taught. Medications will not be on the medicine trolley and will need to be collected from the storeroom. An intravenous line will be infiltrated and need replacing. The phone will ring, a doctor will request bloods to be taken, an infusion line will be leaking, or a child will start to bleed. The administering nurse will attend to any one of these problems without a second thought, causing an interruption in the administration of medication.

Only 1% of medication administrations required the researcher to intervene. All interventions were to remind the administrator to give omitted doses which had been missed on the prescription chart. No potentially dangerous administrations were observed.

The implications of the medication administration error results are discussed next.

- Clinical implications
    - Strategies such as checklists, signage and wearing “do not disturb” clothing have been tested with varying levels of success. Nurses, patients, relatives, and other staff need to give serious consideration to how to respond to measures implemented in an attempt to separate the medication administrator from the interaction of the larger environment. Non-emergency inquiries from patients and parents, phone calls and alarming machines should be dealt with by other nurses so as not to take the administrator away from the task at hand.
    - Tedious tasks, such as transporting patients to special investigations and collecting medications from the pharmacy, should be done by hospital porters to eliminate removing nurses from the ward and allow them to focus on nursing duties.
    - Reconstitution of medications could be done by the pharmacists, alleviating the nurses in the ward of the extra work and minimising preparation errors.
    - Nurses administering medication should be cautious of attending to problems which are not bound by certain time-frames and manage their time constructively to ensure medications are administered according to the prescribed schedule.
- Educational implications
    - Permanent staff in the paediatric oncology ward should receive regular follow-up training on the potential risks that accompany administration errors. The training should focus on:

- The calculation of medication dosages to ensure that patients are not under- or overdosed and should include competency assessments of any nurse or nursing students administering medication in the ward.
- The importance of administering medications at the right time should be emphasized as giving medication before the prescribed times may lead to higher drug concentrations in the bloodstream and unnecessary side effects, resulting in increased lengths of hospital stay. Delayed administration of medication may deny the child of the optimal drug effect and thereby decrease the positive outcome that was envisioned. Inaccurate recording of the time at which medication was administered may lead to wrong time errors in subsequent doses, especially in medications given prn (per required need).
- The risk of omitted medications, with focus on situations which allow for the omission of a medication
- Documentation errors and the potential harm that may accompany them. These include omitted doses, if medications are signed before administration, due to memory lapses or a child spitting out or refusing the medication. A risk of double dosing occurs if no signature accompanies the administration of the first dose and is then re-administered by a second nurse.

• Management implications
  - Medication administration policies should be revised on a monthly basis and continuous quality improvement efforts should be made by management.
  - Safe medication administration practices should be recognised and awarded to encourage others to pursue the same levels of quality care.
  - Stock control policies should be revised, and it should be ensured that none of the stock levels restrict access to medications which would affect the administration thereof to the patients, having a negative outcome on their care.
  - Medications should always be available and pharmacists on call should be willing to assist when new medications are prescribed out of office hours.

Objective 2: Identify factors contributing to the occurrence of medication administration errors

5.3.2.2 Contributing factors

Factors which may contribute to errors occurring in medication administration were identified using Section B and Section C of the data sheet. Section B identified the person responsible for administration as well as their rank and whether they had an additional qualification or not. Section C included the number of nurses on duty, number of patients in the ward, number of nurses administering observed medications, the number of medications on the prescription chart for each patient as well as the day of the week on which each medication was administered.

- Section B – Person Responsible

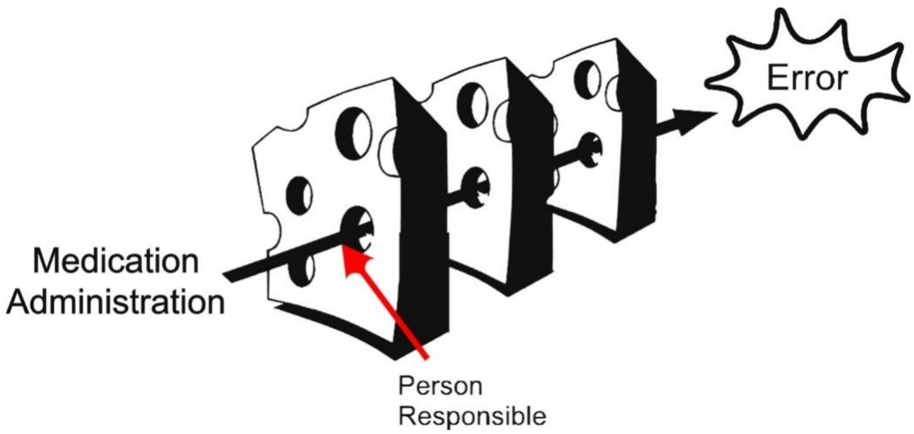

Figure 5.5 Person responsible - medication administration

Registered nurses administered 74% of medications, enrolled nurses 18% and student nurses 8% of all medication administrations observed. Registered nurses were found to administer the most medications as they solely administer intravenous, intramuscular and subcutaneous medications as well as chemotherapy and blood products which do not fall within the scope of practice of the nurses of lower ranks. Of the registered nurses observed, 14% of Registered nurse administrators had an additional qualification in oncology while 3% of Registered nurse administrators had an additional qualification in paediatrics. Dosage errors were positively correlated to Enrolled nurse errors with a p-value of $p=.047$ indicating that dosage errors are more likely to occur when Enrolled nurses administer medication. This result had management implications.

- Management implications
    - Enrolled nurses should be closely supervised when administering medication or should not be authorised to administer medication at all as dosage errors may lead to grave consequences in paediatric patients.

- Section C – Potential Latent Conditions

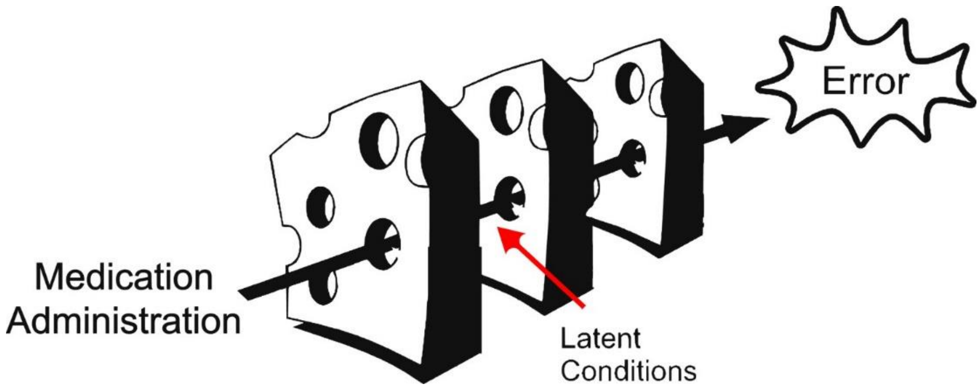

Figure 5.6 Latent conditions in medication administration

The majority of patients received five or more medications per day, which could lead to an increase in the prevalence of medication errors and drug-drug interactions. Admissions into the paediatric oncology ward generally happened on a Monday and a Tuesday in order to start the chemotherapy block early in the week and potentially send the child home again by the weekend. Direct observation of medication administration was not equally divided between days therefore these results may not be an accurate depiction of the average administrations of medication across the days of the week.

Correlation analysis was applied to determine which of these factors had an influence on medication administration errors. Positive correlations in *documentation errors* were seen between bed occupancy and Registered nurses and Enrolled nurses as administrators. Negative correlations in *documentation errors* were seen with higher number of staffing levels. A decrease in *time errors* was correlated to more administrators and to Registered nurses and students as administrators as opposed to Enrolled nurses. *Omission errors* were positively correlated to scheduled medications and *dosage errors* were positively correlated with Enrolled nurses as the administrators, scheduled medications and type of medication. These results had educational and management implications.

- Educational implications
  - Students should only administer medication under the direct supervision of a registered nurse, although situations often occur where this is not possible, and therefore, for the safety of the patients, it should be ensured that students are able to prepare and administer medications accurately and correctly.
  - Clinical facilitators should be made more readily available to take the main responsibility of student supervision from the nurses working in the ward. This is an extra task placed on an already excessive workload.
- Management implications
  - Under-staffing was not highlighted as a problem unique to public hospitals or to South Africa, but it is a problem that affects the holistic care of the patient and potentially affects patient safety. Employment and work schedules should be based on international standards for nurse-to-patient ratios in order to deliver safe patient care. International developments have also aimed to shorten nursing shifts which could be considered in South Africa.

5.4 GENERAL IMPLICATIONS

The results had several general implications for clinical practice and management.

5.4.1 Clinical implications

5.4.1.1 Medication error reporting systems should be put in place to assist in the identification of types and frequencies of errors in the long term. These systems should be self-reported and anonymous. The aim of reporting these errors should not be to place blame on an individual but rather to identify system errors which could be addressed with implementation of carefully thought-through interventions.

5.4.1.2 Clinical pharmacists have proven to be a primary source of valid information regarding the use of medications. Their participation in multi-disciplinary ward rounds has been found to decrease adverse events caused by prescription errors and to increase medication administration accuracy. Effective communication between pharmacists, nurses and doctors should be striven for to effectively transfer messages about medications that are out of stock or have been taken off code.

5.4.2 Management implications

Medication prescription and administration auditing should become a regular activity in the paediatric oncology ward. This should not be a "blaming game" but should be used to point out errors, regardless of how small, in an effort to raise awareness of prescription and medication administration errors.

5.5 LIMITATIONS

The researcher identified the following limitations in this study:

- The generalisability of the results of this study is subject to certain limitations. The study was conducted, and data collected in a single ward, in a single urban hospital in one province in South Africa. The results thus do not represent and cannot be generalised to the greater population.
- Due to the researcher and fieldworkers working in the ward in which the study was conducted, distractions and interruptions may have been under-reported. This would be as a result of the data collectors being aware of how the ward operates and the needs of the patients, regardless of whether they were busy with medication administration or not.
- The Hawthorne effect is a recognised limitation of all observation studies. This effect may have been minimised due to the fact that the nurses administering medication were familiar with the researcher and fieldworkers and were not as intimidated as they might have been should the data collectors have been strangers. The Hawthorne effect was also moderated by data collectors as they dressed in uniform during all observations in an attempt to better blend in to the ward (see Chapter 3, Section 3.4.2.4).
- Data were not collected for the same period of time every day but varied throughout the study period. On some days the data collectors did a certain number of observations while on duty, which resulted in only a few administrations being observed, which may have led to errors being missed later in those medication rounds. On other days the data collectors came in specifically to observe the medication rounds and multiple observations were recorded which may have resulted in inaccurate correlations with the "day of the week".
- Observations of all routes of administration were not observed in equal measure, therefore accurate identification of which route of medication administration most frequently encountered errors could not be made.

5.6 RECOMMENDATIONS FOR FURTHER RESEARCH

Based on the findings, the researcher makes the following recommendations for further research.

- Interventions which could be implemented to reduce the occurrence of medication errors, using pre-test-post-test designs to prove the efficacy of the intervention
- An examination of the potential role of members of the multi-disciplinary team as well as patients and their parents in the reduction of medication errors
- An investigation into/examination of the feasibility and financial implications of the introduction and implementation of new technologies, such as CPOE, barcode technology and smart pumps, in South Africa to decrease the incidence of medication errors.
- Studies should be conducted in which the researcher observes for interruptions in medication administrations only. These results could show how interruptions affect time management and the ability of administrators to continue the delegated task where they left off, without the interruption causing further errors.

5.7 CONCLUSION

This study was conducted in a paediatric oncology ward in a tertiary hospital in Gauteng, South Africa.

During prescription chart analysis, a total error rate of 56% was discovered in the general writing and labelling of prescriptions while a significant number (78%) of all prescriptions were incomplete. Relating to the error type, it was found that 119 of 432 prescribed medications had a prescription error with wrong dose errors being the most prevalent. Contributing factors which increase the incidence of prescription errors were scheduled medications, bed occupancy, day of the week, incomplete prescriptions and illegible writing.

In the direct observation of medication administration, a significant error rate of 93% was found. Documentation errors comprised 63%, making this type of error the most prevalent. Of 1,064 medication administrations observed, 1 in 10 medications were omitted. When considering the "rights of medication" (right patient, medication, dose, route, time), dose errors were the most frequently observed. Contributing factors which increased the incidence of medication administration errors were the type of medication, scheduled medications, route of administration, rank of the administrator, bed occupancy, and the day of the week on which the administration took place.

Medication in a paediatric oncology ward is one of the cornerstones of treatment. Prescription and medication administration errors may potentially result in patient harm. Due to the high workload and inadequate number of nursing staff, there was concern that such errors were taking place unnoticed. This study was conducted to observe the following of procedures to ensure that prescription and medication administrations were safely and efficiently conducted in the selected paediatric oncology ward. Based on the literature reviewed, the researcher anticipated that there would be prescription and medication administration errors. Distractions and interruptions were reported as surprisingly low while documentation errors were significant and unexpected. The benefit of this study was to identify shortcomings in the system's defences which, if understood, could assist in the development of interventions which could lead to reduced error and therefore positive change. The findings indicate that supervision and training in both prescription and medication administration would contribute to achieving this goal.

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ANNEXURE A1

Ethical approval certificate

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 03/14/2020.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

12/04/2018

Approval Certificate
New Application

Ethics Reference No: 121/2018

Title: DETERMINING MEDICATION PRESCRIPTION AND ADMINISTRATION ERRORS IN A PAEDIATRIC ONCOLOGY WARD IN GAUTENG.

Dear Mrs Nadine Puzicha

The **New Application** as supported by documents specified in your cover letter dated 28/03/2018 for your research received on the 4/04/2018, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 11/04/2018.

Please note the following about your ethics approval:

- Ethics Approval is valid for 2 years
- Please remember to use your protocol number (**121/2018**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:

- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers; MBChB; MMed (Int); MPharMed,PhD
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).

☎ 012 356 3084 deepeka.behari@up.ac.za / fhsethics@up.ac.za http://www.up.ac.za/healthethics
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60 / 61, 31 Bophelo Road, Gezina, Pretoria

ANNEXURE A2

CEO permission letter

Permission to access Prescription Charts at Steve Biko Academic Hospital

To: Acting Chief Executive Officer

Steve Biko Academic Hospital
Dr Mathebula

From: The Investigator
Ward 1.1 (Paediatric Oncology)
Steve Biko Academic Hospital
Nadine Puzicha

Re: Permission to do research at Steve Biko Academic Hospital

I, Nadine Puzicha, am the researcher working in Ward 1.1, Paediatric Oncology Unit, at Steve Biko Academic Hospital. I would like to request permission to conduct a study on the Steve Biko Academic Hospital grounds that involves access to patient records.

The request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.

The title of the study is: **DETERMINING MEDICATION PRESCRIPTION AND ADMINISTRATION ERRORS IN A PAEDIATRIC ONCOLOGY WARD IN GAUTENG**

I hereby request access to the following information:

- Prescription charts of patients admitted in the ward during the time at which the study will be conducted.

I intend to publish the findings of the study in a professional journal and/ or at professional meetings like symposia, congresses or other meetings of such a nature.

The personal identity of the patients will be protected as no personal details will be included in the results of the study.

I undertake not to proceed with the study until I have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

Puzicha PN

Nadine Puzicha

Permission to do the research study at Steve Biko Academic Hospital and to access the information as requested is hereby approved.

Acting Chief Executive Officer
Steve Biko Academic Hospital

Dr JS Mangwane

Dr Mathebula

2018/03/26

GAUTENG PROVINSIALE REGERING
DEPT VAN GESONDHEID
STEVE BIKO AKADEMIESE HOSPITAAL
STEVE BIKO ACADEMIC HOSPITAL

2018 -03- 26

PRIVAATSAK/PRIVATE BAG X169
PRETORIA 0001
GAUTENG PROVINCIAL GOVERNMENT
DEPT OF HEALTH

ANNEXURE B1

Rationale for aspects included in data sheet for prescription chart analysis

Annexure B1

Rationale for aspects included in data sheet for Prescription chart analysis

Item	Rationale	Source
Name and type of Medication	The potential effect it may have on the patient largely depends on the type of drug and the route of administration. Medication errors involving antibiotics, such as under-dosing, will have little effect on infective processes and may potentially result in severe infection/sepsis, leading to death. Prolonged use of antibiotics may lead to increased bacterial resistance, necessitating second line treatment and consequently increasing the length of stay and hospital costs. Errors causing the administration of inadequate doses of simple analgesia may lead to supplementing with additional analgesia with undesirable side effects whereas sufficient dosing of the initial analgesia may have served the purpose. According to the Institute for Safe Medication Practices (ISMP), chemotherapeutic drugs are classified among the high-risk medications and errors made with chemotherapy can cause dramatic clinical problems due to their high toxicity and low therapeutic indices.	(Ruano et al. 2016:31) (Bolt, Yates, Mahon & Bakri 2014:78) (Fox, Pontefract, Brown, Portlock & Coleman 2016:456) (Al-Anazi, Salam & Al-Jeraisy 2015:394; Bolt et al. 2014:78) (Bolt et al. 2014:78) (Ulas, Silay, Akinci, Dede, Akinci, Sendur et al. 2015:1699)
Schedule Medication	Different controlled drugs cause dependence or misuse in varying degrees. They are classed according to the extent of harm they may cause when misused	(East Lancashire Health Economy Medicines Management Board [Internet] 2015:2)
Route	Demographic Information	
Number of patients in the ward	A high nurse-patient ratio was classified among the top three contributing factors to medication errors as nurses are expected to accomplish a variety of tasks and duties during a shift and the risk of medication errors increases substantially when a unit is not sufficiently staffed with nurses.	(Karavasiliadou & Athanasakis 2014:36)

	It was also noted that a strong consensus across studies show that the incidence of medication administration errors is raised when there is an increase in the nurse-patient ratio.	(Parry, Barriball and While 2015:412)
Number of drugs prescribed	Significantly higher error rates were associated with (among other factors) having a higher total of number of medications prescribed	(Ryan, Ross, Davey, Duncan, Francis, Fielding, et al. 2014:6)
Day of the week	Demographic information	
Time that drug was prescribed	Demographic information	
Patient weight	An example of essential information necessary on a prescription chart is that of the patient's weight, in order to calculate the medication dosage. Paediatric patients may experience up to three times the amount of medication errors than adult patients partly due to the need to weight-based dosing. The risk of overdosing is much higher in paediatric than in adult patients and dosage calculations are more prone to human error due to the need for unit conversion, to signify very small doses and the constant need for weight- and surface area-based dosing	(Blignaut, Coetzee, Klopper & Ellis 2017:63) (Maaskant, Vermeulen, Apampa, Fernando, Ghaleb, Neubert et al. 2015:7)
Allergies recorded	A prescription chart with a missing allergy status could have a very serious outcome if a medication, to which the patient is allergic, is prescribed. This error could have potentially lethal outcomes if a patient is prescribed a medication to which they previously had severe reaction to (e.g. oedema)	(Seden, Kirkham, Kennedy, Lloyd, James, Mcmanus et al. 2013:4)
Prescription complete	A prescription chart review in Sweden showed a 74% error rate, where prescriptions were incomplete; missing vital information such as route of administration, strength or dosage form.	(Star et al. 2013:532).
Medication abbreviations used	Prescription errors include illegible handwriting and the use of medical abbreviations which may also contribute to medication errors.	(Walker 2016:126, Wittich, Burkle & Lanier 2014:1118)
Signed by Prescriber	Frequent errors encountered in prescriptions are those of omitted	(Ryan et al. 2014:6)

	signatures and inappropriate abbreviations. Nurses and pharmacists should be able to identify the prescribing doctor.	 (Thomas et al. 2015:370)
Prescription legible	Medication prescriptions should be legible, explicit and have adequate information supporting the clinical intent of the medications' use.	(Thomas et al. 2015:370)
Right patient - No sticker - Incorrect sticker	The identity of the patient should always be verified when medications are prescribed. This includes confirming their date of birth, checking the patient's ID band and ensuring that it corresponds with the name on the sticker for whom the medication is intended.	(Schutijser, Klopotowska, Jongerden, Spreeuwenberg, Wagner and de Bruijne 2018:3) (Edwards & Axe 2015:353)
Right medication - Inappropriate drug selection - Duplicate medication	It has been found in literature that as many as 33% of medication errors involve the incorrect drug being administered to a patient. The effect of a duplicate medication being prescribed could range from minor (if the administration of the duplicate medication doesn't pose a great risk for an adverse event) to significant, serious and potentially lethal (if an overdose occurs when duplicated items are co-administered).	(Elliot & Liu 2010:301) (Seden, Kirkham, Kennedy, Lloyd, James, Mcmanus et al. 2013:5)
Right dose	Strengths of the formulation needs to be specified when prescribing syrup in ml in order to be able to detect an error. Dosage errors, both overdosing and under-dosing, have been found to be the most common prescription error made and intercepted during the prescription phase of the medication process.	(WHO 2014:29) (Fernández-Llamazares et al. 2013:645)
Right route	Error rates are likely higher for drugs administered intravenously compared with other routes.	(Wittich, Burkle & Lanier 2014:1118)
Right interval	The time gap between administrations need to be adequate in order for the medication to work effectively.	(Edwards & Axe 2015:353)

ANNEXURE B2

Rationale for aspects included in data sheet for observation of medication administration

Annexure B2

Rationale for aspects included in the Datasheet for observation of Medication Administration

Item	Rationale	Source
Name and type of Medication	The potential effect it may have on the patient largely depends on the type of drug and the route of administration. Medication errors involving antibiotics, such as under-dosing, will have little effect on infective processes and may potentially result in severe infection/sepsis, leading to death. Prolonged use of antibiotics may lead to increased bacterial resistance, necessitating second line treatment and consequently increasing the length of stay and hospital costs. Errors causing the administration of inadequate doses of simple analgesia may lead to supplementing with additional analgesia with undesirable side effects whereas sufficient dosing of the initial analgesia may have served the purpose. According to the Institute for Safe Medication Practices (ISMP), chemotherapeutic drugs are classified among the high-risk medications and errors made with chemotherapy can cause dramatic clinical problems due to their high toxicity and low therapeutic indices	(Ruano et al. 2016:31) (Bolt, Yates, Mahon & Bakri 2014:78) (Fox, Pontefract, Brown, Portlock & Coleman 2016:456) (Al-Anazi, Salam & Al-Jeraisy 2015:394; Bolt et al. 2014:78) (Bolt et al. 2014:78) (Ulas, Silay, Akinci, Dede, Akinci, Sendur et al. 2015:1699)
Schedule Medication	The standard operating procedures developed for the administration of controlled drugs need to include sufficient safety measures to minimise the risk of administration errors.	(National Institute for Health and Care Excellence 2016:1.3.2)
Route	In studies observing all routes of administration, it has been found that the intravenous route appears to have the highest rate of errors.	(Keers et al. 2013:252)
Rank of administrator	Common factors which cause medication administration errors are, among others, characteristics of the administrator (such as years	(Keers, Williams, Cooke, Walsh & Ashcroft 2014:318).

	of experience, nurse-patient ratio, years in the specific unit).	
Number of staff on duty Number of patients in the ward	A high nurse-patient ratio was classified among the top three contributing factors to medication errors as nurses are expected to accomplish a variety of tasks and duties during a shift and the risk of medication errors increases substantially when a unit is not sufficiently staffed with nurses. It was also noted that a strong consensus across studies show that the incidence of medication administration errors is raised when there is an increase in the nurse-patient ratio.	(Karavasiliadou & Athanasakis 2014:36) (Parry, Barriball and While 2015:412)
Number of nurses administering medication	Demographic information	
Number of medications prescribed for patient	The sophistication of medication administration is made more intricate by interruptions, facility layout, time restrictions, and *the number of medications prescribed per patient.*	(Lapkin et al. 2016:846)
Day of the week	Demographic information	
Time that drug was administered	Demographic information	
Right patient - Patient not identified - Patient sticker not checked	Common factors which cause medication administration errors are, among others, failure to verify a patient's identification Patients should verbally verify their name and nurses should use alternative methods of identifying the patient. Such methods include confirming their date of birth, checking the patient's ID band and ensuring that it corresponds with the name on the sticker for whom the medication is prescribed.	(Keers, Williams, Cooke, Walsh & Ashcroft 2014:318). (Elliot & Liu 2010:301) (Schutijser, Klopotowska, Jongerden, Spreeuwenberg, Wagner and de Bruijne 2018:3) (Edwards & Axe 2015:353)
Right medication	It is the responsibility of the nurse to ensure that they are knowledgeable about the medication that they administer and if there is any uncertainty, that they clarify it with the prescribing doctor.	(Elliot & Liu 2010:301)

- Not labelled immediately after preparation - Prepared and administered by different nurses	An error in writing, specifically when labelling medications, could cause medication errors It was found that 72% medications were prepared by another nurse who will not do the actual administration	(Blignaut, Coetzee, Klopper & Ellis 2017:57) (Kim & Bates 2014:4)
Right dose - Calculated incorrectly - Syringe markings not read at eye level	Due to the fact that there are no standard drug strengths and dosages for paediatric patients, nurse training aimed at dosage calculations may aid in reducing certain medication errors in these patients. Nurses should be vigilant when reading the patient's prescription chart as a decimal point in the wrong place could result in either one tenth or ten times the intended dose being administered. Minor errors in calculating drug doses may lead to outcomes which could be life-threatening for a child.	(Acheampong et al. 2014:128) (Elliot & Liu 2010:302) (Karadağ et al. 2015:894)
Right route	In studies observing all routes of administration, it has been found that the intravenous route appears to have the highest rate of errors.	(Keers et al. 2013:252)
Right time - Medication not prepared directly before administration - Given > 1 hour before or/after	Administering medication at the right time involves preparing the medication at the right time and shouldn't be done many hours before administration, as this may affect the stability of the medication. Medications given before the prescribed times may lead to higher drug concentrations in the bloodstream and unnecessary side effects, resulting in increased lengths of hospital stay.	(Elliot & Liu 2010:302) (Gunningberg et al. 2014:415)

prescribed interval		
Documentation - Administering nurse did not record - Actual time not recorded - Recorded before administration - Dosage documented is different to dosage prescribed/ administered	Failure to sign for a medication that was administered also poses a risk as another nurse may assume that it wasn't given and repeat the dose, potentially harming the patient. It has been observed that although medication was administered at a time different to what was ordered, the record shows that the right time of administration was met. A common routine observed during a study done by direct observation of medication administration, was that nurses documented before the administration of the medication as opposed to afterwards. This represents an incorrect record of treatment in relation to the time that it was given and due to distractions, stress and heavy workload or patient refusal, it may also lead to a complete omission of that drug being administered.	(Elliot & Liu 2010:303). Kim and Bates (2013:7) (Gunningberg et al. 2014:411)
Omission of medication	In the hospital setting, medications are often delayed or omitted for various reasons and although this may not seem like a serious event, this may lead to serious harm or patient death in certain crucial circumstances such as patients with sepsis. Poor adherence to medications, caused by medication doses being	(WHO 2014:78)

	omitted is often related to a decreased therapeutic effect and as a result, an increase in length of hospital stay.	(Shandilya, Nizamuddin, Faisal, Noor & Abraham 2015:12)
Distractions/ Interruptions	Interruptions and distractions have been classified as one of the top five factors contributing to medication errors in various studies. Interruptions may occur during any phase of the medication process although interruptions during administration are most significant, as this phase signifies the last opportunity for an error to be detected and corrected before reaching the patient.	(Karavasiliadou & Athanasakis 2014:36) (Prakash, Koczmara, Savage, Trip, Stewart, McCurdie et al. 2014:884)
Did researcher intervene?	The ethical principle of beneficence is defined as the responsibility of the researcher to maximise the benefits (either to participants or to others) and minimise the harm that the study will cause. Researchers have a responsibility to avoid, prevent or minimise harm (non-maleficence) to the subjects.	(Polit & Beck 2012:152)

ANNEXURE C1

Draft of data sheet for prescription chart analysis

Annexure C1: Draft of Data sheet for Prescription chart analysis

General Information						
Error made by:	Consultant		Registrar		Intern	

Prescription Error					
Wrong patient	No sticker on prescription		Wrong interval	Interval incorrect according to ward protocols	
	Incorrect sticker on prescription		Writing and labelling	Patient weight not recorded	
Wrong Medication	Medication not intended for this patient			Allergies not recorded	
				Prescription incomplete	
	Duplicate medication prescribed			Medication abbreviations not accepted	
Wrong dose	Dosage incorrect according to mg/kg (more or less than 10%)			Medication not signed	
				Prescription illegible	
Wrong route	Wrong form of medication for specified route			Contact details of prescriber missing	

Number of Patients in the ward ____

Notes: ____

____

____

____

ANNEXURE C2

Final data sheet for prescription chart analysis

Annexure C2: Final Data sheet for prescription chart analysis

Section A: General Information about medication

Type of Medication

Antibiotics	
Analgesics	
Antiemetics	
Antifungals	
Coagulants	
Chemotherapy	
Other:	

Schedule medication

Yes	
No	

Route

Oral		
Intravenous		
Subcutaneous		
Intramuscular		

Name of Medication:

Section B: Potential latent conditions

Number of patients in the ward	
Number of medications on prescription chart	

Day of the week that medication is prescribed: (Please tick)						
Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Time that medication is prescribed:						

Section C: Potential active failures

		Yes	No
General information on writing and labelling of prescription	Patient weight recorded		
	Allergies recorded		
	Prescription complete		
	Medication abbreviations used		
	Signed by prescriber		
	Prescription legible		

"Rights" of medication prescription				
Right patient	Yes	If no	No sticker on prescription	
			Incorrect sticker on prescription	
Right medica-tion	Yes	If no	Inappropriate drug selection	
			Duplicate medication prescribed	
Right dose	Yes	If no	Dosage incorrect according to mg/kg (more or less than 10% of correct dosage)	
Right route	Yes	If no	Wrong form of medication for specified route	
Right interval	Yes	If no	Interval incorrect according to ward protocols	

Notes:

ANNEXURE D1

Draft of data sheet for observation of medication administration

Annexure D1: Draft of data sheet for observation of medication administration

General Information						
Error made by:	Registered Nurse		Enrolled Nurse		Nursing student	

Medication Administration Error					
Wrong patient	Patient not identified verbally or by wristband		Wrong route	Medication given via wrong route	
	Patient sticker not read on prescription		Wrong time	Medication not prepared directly before administration	
Wrong Medication	Medication not labelled immediately after preparation			Medication given >1 hour before or after prescribed	
	Medication prepared and administered by different nurses		Documentation	Administering nurse did not record	
Wrong dose	Dose calculated incorrectly			Actual time not recorded	
	Markings on syringe not read at eye level			Recorded before administration of medication	
Omission	Medication not given				

Number of Patients in the ward ____

Number of Nurses administering medication ________________________________

Did researcher intervene? If yes, state reason: ______________________________

Interruptions: ____

Notes: ____

ANNEXURE D2

Final data sheet for observation of medication administration

Annexure D2: Data sheet for observation of medication administration

Section A: General Information about medication

Type of Medication		Schedule medication		Route	
Antibiotics		Yes		Oral	
Analgesics				Intravenous	
Antiemetics		No		Subcutaneous	
Antifungals				Intramuscular	
Coagulants					
Chemotherapy					
Other:		Name of Medication:			

Section B: Person responsible for administration

Rank of administrator:

Registered Nurse		Enrolled Nurse			Student Nurse	
Specialised:	Yes		No		Undergrad	
If yes:	Paeds		Onco		Postgrad	

Section C: Potential Latent conditions

Number of nurses on duty	Total		RN:		EN:	
			ENA:		Stu:	

Number of patients in the ward	
Number of nurses administering observed medication	
Number of medications prescribed to whom medication is administered	

Day of the week that medication is administered: (Please tick)						
Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Time that medication is administered:						

Section D: Potential Active Failures

"Rights" of Medication administration				
Right patient	Yes	If no	Patient not identified verbally or by wristband	
			Patient sticker not checked on prescription	
Right medica-tion	Yes	If no	Medication not labelled immediately after preparation	
			Medication prepared and administered by different nurses	
Right dose	Yes	If no	Dose calculated incorrectly	
			Syringe markings not read at eye level	
Right route	Yes	If no	Medication given via wrong route	
Right time	Yes	If no	Medication not prepared directly before administration	
			Medication given >1hr before/after prescribed interval	
Documentation			Administering nurse did not record	
			Actual time not recorded	
			Recorded before administration of medication	
			Dosage documented is different to dosage prescribed	
Omission of medication			If yes: State reason	

Did researcher intervene? If yes, state why	Distractions/Interruptions:

ANNEXURE E

Informed consent (Doctors)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

ANNEXURE E. PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT (DOCTORS)

Version 3: 20 March 2018

STUDY TITLE: DETERMINING MEDICATION PRESCRIPTION AND ADMINISTRATION ERRORS IN A PAEDIATRIC ONCOLOGY WARD IN GAUTENG

PRINCIPAL INVESTIGATOR: Nadine Puzicha

INSTITUTION:

University of Pretoria

Faculty of Health Sciences

Private Bag x 323

Arcadia

0007

CONTACT NUMBER: 083 266 7505

You are being invited to take part in a research study that forms part of my Masters' Degree in Nursing. Please take time to read the information presented, which explains the details of this study. You are welcome to ask the researcher any questions about any part of the study that you do not fully understand. It is important that you clearly understand what this research entails and how you could be involved. Your participation is entirely voluntary, and you are free to decline to participate. If you choose not to participate, it will not affect you negatively in any way. You are free to withdraw from the study at any point, even if you initially agree to take part.

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding investigators in biomedical research involving human subjects. A copy of the Declaration as well as a copy of the hospital approval may be obtained from the investigator should you wish to review it. The researcher or postgraduate students may use the data for secondary data analysis, but all such data will be anonymous and will receive ethical clearance for secondary data analysis.

I……………………………………………………………………………..(Name and Surname) hereby

- ☐ **give consent**
- ☐ **do not give consent** (Please tick the appropriate box)

for the data collected to be used for secondary data analysis should the opportunity arise in the future.

______________________ ______________________

Participant Researcher

<u>What is this research study all about?</u>

This study will be conducted in a Paediatric Oncology unit in the Gauteng Province of South Africa and will involve analysis of prescription charts and individually prescribed medications. The aims of the study are to determine the incidence and types of prescription errors by means of chart analysis and to identify contributing factors to prescription errors within the Paediatric Oncology unit of a public hospital in the Gauteng Province of South Africa.

<u>Why have you been invited to participate?</u>

You have been invited to participate as you prescribe medication and are therefore an important role-player in the medication safety in your ward.

You have complied with the following inclusion criteria: You are a doctor who is qualified to prescribe medication and are willing to participate in the study.

<u>What will your responsibilities be?</u>

You will need to be willing to have any medication that you have prescribed, for the patients in the Paediatric Oncology ward, to be analysed. This will be done between April and July 2018.

<u>Will you benefit from taking part in this research?</u>

There will be no direct benefits for you.

The indirect benefit will be knowledge gain and bargaining for policies to create a better safety culture in hospitals.

<u>Are there risks involved in your taking part in this research?</u>

You may feel anxious about your prescriptions being analysed and may be worried about punishment or exposure to any errors observed. You can be reassured that any observations will be <u>kept strictly confidential</u>. You will not be held liable for any prescribing mistakes made and there will be no way of tracing any research results back to your actions, as the researcher is not interested in any personal details but only in the medication prescription process.

Who will have access to the information?

Anonymity of the information will be assured as the researcher will not write any identifying details on the data sheet used and not divulge any information that could be connected to you. Confidentiality will be ensured by locking away completed data sheets and not reporting on specific individuals. Reporting of findings will be anonymous as no names will be documented. Only the researcher will have access to the data. Data will be kept safe and secure by locking hard copies in a cupboard in the researcher's office and all electronic data will be password protected. Data will be stored for 15 years.

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

No, you will not be paid to take part in the study. The researcher will conduct the research at your place of work and there will be no costs involved for you if you do take part.

Is there anything else that you should know or do?

You can contact Nadine Puzicha at 083 266 7505 if you have any further queries or encounter any problems.

You will receive a copy of this information and consent form for your own records.

How will you know about the findings?

The findings of the research will be shared with you by scientific research article should you be interested.

DECLARATION BY PARTICIPANT

By signing below, I …………………………………..…………. agree to take part in a research study entitled: "Exploring medication errors in a Paediatric Oncology ward in Gauteng".

I declare that:

I have read this information and consent form and it is written in a language which I understand

I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.

I understand that taking part in this study is voluntary and I have not been pressurised to take part.

I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) ....…........…………….. on (date) …………....……….. 20....

....

Signature of participant **Signature of witness**

DECLARATION BY RESEARCHER

I, Nadine Puzicha, declare that:

 I have explained the information in this document to …………………………………..

 I have encouraged him/her to ask questions and took adequate time to answer them.

 I am satisfied that he/she adequately understands all aspects of the research, as discussed above

Signed at (place) ....…........…………….. on (date) …………....……….. 20....

....

Signature of researcher **Signature of witness**

ANNEXURE F

Informed consent (Nurses)

ANNEXURE F: PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT (NURSES)

Version 3: 20 March 2018

STUDY TITLE: DETERMINING MEDICATION PRESCRIPTION AND ADMINISTRATION ERRORS IN A PAEDIATRIC ONCOLOGY WARD IN GAUTENG

PRINCIPAL INVESTIGATOR: Nadine Puzicha

INSTITUTION:

University of Pretoria

Faculty of Health Sciences

Private Bag x 323

Arcadia

0007

CONTACT NUMBER: 083 266 7505

You are being invited to take part in a research study that forms part of my Masters' Degree in Nursing. Please take time to read the information presented, which explains the details of this study. You are welcome to ask the researcher any questions about any part of the study that you do not fully understand. It is important that you clearly understand what this research entails and how you could be involved. Your participation is entirely voluntary, and you are free to decline to participate. If you choose not to participate, it will not affect you negatively in any way. You are free to withdraw from the study at any point, even if you initially agree to take part.

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding investigators in biomedical research involving human subjects. A copy of the Declaration as well as a copy of the hospital approval may be obtained from the investigator should you wish to review it.

What is this research study all about?

This study will be conducted in a Paediatric Oncology unit in the Gauteng Province of South Africa and will involve direct observation of nurses administering medication. The aim of the study is to determine the incidence and types of medication administration errors by means of direct observation and to identify contributing factors to medication administration errors in a Paediatric Oncology unit of a public hospital in the Gauteng Province of South Africa.

Why have you been invited to participate?

You have been invited to participate because you are a medication administrator, who as part of your daily routine, administers medication and are therefore are an important role-player in the medication safety in your ward. You have complied with the following inclusion criteria: You are either a professional or enrolled nurse or nursing student who is qualified to administer medication and are willing to participate in the study.

What will your responsibilities be?

You will be expected to be observed during administration of medication to the patients in the Paediatric Oncology ward. This will be done between April and July 2018.

Will you benefit from taking part in this research?

There will be no direct benefits for you. The indirect benefit will be knowledge gain and bargaining for policies to create a better safety culture in hospitals.

Are there risks involved in your taking part in this research?

You may feel anxious about being observed and may be worried about punishment or exposure to any errors observed but you can be reassured that any observations will be kept strictly confidential. You will not be held liable for any mistakes seen and there will be no way of tracing any research results back to your actions, as the researcher is not interested in any personal details of the administrator, but only in the medication administration process.

Who will have access to the information?

Anonymity of the information provided will be assured as the researcher will not write any identifying details on the data sheet used and not divulge any information that could be connected to you. Confidentiality will be ensured by locking away completed data sheets and not reporting on specific individuals. Reporting of findings will be anonymous as no names will be documented. Only the researcher will have access to the data. Data will be kept safe and secure by locking hard copies in a cupboard in the researcher's office and all electronic data will be password protected. Data will be stored for 15 years. The researcher or postgraduate students may use the data for secondary data analysis, but all such data will be anonymous and will receive ethical clearance for secondary data analysis.

I…………………………………………………………………………….(Name and Surname) hereby

- **give consent**
- **do not give consent** (Please tick the appropriate box)

for the data collected to be used for secondary data analysis should the opportunity arise in the future.

______________________ ______________________

Participant Researcher

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

No, you will not be paid to take part in the study. The researcher will conduct the research at your place of work and there will be no costs involved for you if you do take part.

Is there anything else that you should know or do?

You can contact Nadine Puzicha at 083 266 7505 if you have any further queries or encounter any problems. You will receive a copy of this information and consent form for your own records.

How will you know about the findings?

The findings of the research will be shared with you by scientific research article should you be interested.

DECLARATION BY PARTICIPANT

By signing below, I ………………………………..…………. agree to take part in a research study entitled: "Exploring medication errors in a Paediatric Oncology ward in Gauteng".

I declare that:

I have read this information and consent form and it is written in a language which I understand

I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.

I understand that taking part in this study is voluntary and I have not been pressurised to take part.

I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) ....…........…………….. on (date) …………...……….. 20....

....

Signature of participant **Signature of witness**

DECLARATION BY RESEARCHER

I, Nadine Puzicha, declare that:

I have explained the information in this document to …………………………………..

I have encouraged him/her to ask questions and took adequate time to answer them.

I am satisfied that he/she adequately understands all aspects of the research, as discussed above

Signed at (place) ....…........…………….. on (date) …………...……….. 20....

....

Signature of researcher **Signature of witness**

ANNEXURE G

Letter of clearance from statistician

Date: 29 / 01 /2018

LETTER OF CLEARANCE FROM THE STATISTICIAN

This letter is to confirm that the student, Nadine Puzicha, studying at the University of Pretoria, discussed the Project with the title "Exploring Medication Errors in a Paediatric Oncology Ward in Gauteng" with me.

I hereby confirm that I am aware of the project and undertake to assist with the Statistical analysis of the data generated from the project.
The analytical tool that will be used will be Statistica software to achieve the objective(s) of the study.

Name: Livhuwani Nedzingahe Date: 30 /01/2018

Signature ___________________________ Tel: 076 304 6953

Department or Unit LR Research &Data Analysis Consulting (PTY) LTD

ANNEXURE H

Letter from the editor

Cell/Mobile: 073-782-3923

53 Glover Avenue

Doringkloof

0157 Centurion

21 December 2018

TO WHOM IT MAY CONCERN

I hereby certify that I have edited Nadine Puzicha's master's dissertation, **Determining prescription and medication administration errors in a paediatric oncology ward in Gauteng – an observational study**, for language and content.

IM Cooper

IM Cooper

Iauma M Cooper

192-290-4