AN EVALUATION OF OUT OF STOCK MEDICINES IN THE INTENSIVE CARE UNITS AT DR GEORGE MUKHARI ACADEMIC HOSPITAL

A mini-dissertation submitted by

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DECLARATION

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

__________________________________________  ________________________
Surname, Initials (Title)                      Date
DEDICATION

This work is dedicated to thousands of health care professionals in the pharmacy department who by all means are making an impact to the health of patients around them.

To my parents, siblings, and loved ones, for their unrelenting encouragement and support.

Lastly, to my Heavenly Father for granting me the strength and determination throughout the study. The Holy Spirit made it possible for me to accomplish this.
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ABSTRACT

Introduction: Availability of medicines is a key factor in determining access to effective treatment. The availability of medicines is considered a vital part in quality health care service delivery and is regarded as the first priority in the supply of essential medicines. The South African government has shown commitment to improve the quality of health care service delivery with the development of norms and standards. Six fast-track areas for improvement have been identified, including the availability of medicines and supplies to meet patients’ health care needs. Over the last number of years, medicine shortages have been a challenge in the delivery of health care services, globally, as well as in South Africa. Dr George Mukhari Academic Hospital (DGMAH) is no exception to the rule, as the hospital has been experiencing numerous stock-out situations and shortages of medicines, especially over the past two years.

Objectives: The study was aimed at evaluating the practice implications of out of stock medicines at ward level, specifically the adult intensive care units (ICU) and neonatal ICU (NICU), of DGMAH. The objectives of the study were to identify out of stock medicines in the NICU and the adult ICU; to determine reasons for medicine items being out of stock in the ICUs; and to describe the practice implications of out of stock medicines from the perspective of nurses in the ICUs.

Method: This was a descriptive, operational study, conducted over a period of seven months. Data on out of stock medicines were collected from the ICUs on a daily basis as part of usual practice. A step-wise process was followed for each medicine shortage identified and data recorded on a monitoring sheet. Information about the reason/s for the out of stock situation was determined. Actions to obtain the medicine or therapeutic alternative were implemented. Two focus group discussions were conducted with 12 professional nurses designated for medicine management in the ICUs to obtain their perspectives on the practice implications of out of stock medicines. Quantitative data analysis was of a descriptive nature using MS Excel®. Qualitative data were coded and themes developed, using NVivo10®. Ethical clearance for the study was granted by the Sefako Makgatho Health Sciences University and all participant provided written informed consent.

Results: Overall 29 medicine lines were identified as out of stock, of which 19 (65.5%) were from the adult ICU and 10 (34.5%) from the NICU. Alimentary tract and metabolism items (ATC group A; 31.0%) and general anti-infectives’ for systemic use (ATC group J; 27.6%) constituted 58.5% of all out of stock medicine lines. Reasons for stock outs varied and included...
national shortages, supply problems, tender-related challenges, stock outs at the main pharmacy, stock not ordered by the unit as well as challenges obtaining motivational items. Lack of informed communication about out of stock situations was identified as a challenge. Four main themes emerged from the focus group data, namely, (1) out of stock medicines situation; (2) impact of out of stock medicines; (3) actions taken by the nurses; (4) possible suggestions to mitigate the situation.

**Conclusions:** This study showed that there were several out of stock situations, which resulted in inadequate medicine availability in this public sector hospital. Many different factors contributed towards stock outs. Out of stock situations had a negative impact on nurses’ professional practice as well as the quality of care provided to patients. The affected various from the supply system which is poorly managed and lack of informed communication on out of stock items. The findings highlighted the need for a dedicated pharmacist allocated to the ICUs to play an active role in the ward to facilitate better communication and mitigate out of stock situations.

**Recommendations:** A dedicated pharmacist and/or pharmacist assistant allocated to the ICUs to resolve out of stock situations, respond to stock out challenges and facilitate communication between the pharmacy and the wards. Better communication and collaboration within the multi-disciplinary team in handling out of stock situations, will facilitate better patient care. A structured approach of disseminating information on out of stock medicines to the ward, filtered down from NDoH to the pharmacy. Further operational research should focus on pharmacists’ interventions in the wards to assist nurses with medicine shortages.
CHAPTER 1
INTRODUCTION

1.1 INTRODUCTION

This introductory chapter presents the background and rationale for the study. The primary and secondary research questions are provided followed by the aim and objectives. The chapter ends with an outline of the importance of the study.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

South Africa is recognised as a country with extensive Human Immunodeficiency Virus (HIV) infection and Tuberculosis (TB) epidemics (Magadzire et al. 2014). Its health transitioning is characterised by a multiple burden of disease, which includes communicable- and non-communicable diseases (Magadzire et al. 2014). To be able to effectively manage the dual epidemics of HIV infection and TB, it is important that the health care system can deliver essential medicines to the public in need (Stop Stock Outs Project (SSP) 2014). Hence, a well-functioning supply chain of medicines is crucial in responding to the needs of the population and ensuring effective service delivery (WHO 2016).

Accessibility of medicines contributes to the well-being of patients, hence medicines availability cannot be overstated (Romero 2013). According to the World Health Organization (WHO) it was estimated that by the year 2015, 10.5 million lives could be saved if effective interventions were implemented to ensure the availability of medicines (Elamin et al. 2010). Availability of medicines directly affects the quality of health care, and ultimately affects the rational use of medicines. If medicines are consistently unavailable, patient attendance at health care facilities decreases, patients suffer and communities lose confidence in health care services (Dias 2012). Non-availability of medicines further contributes to an increase in mortality, morbidity and the development of resistance, as a result of improper treatment (Mtwara & Mbeya 2011).

The pharmacist plays an integral role in ensuring the effectiveness and efficient supply of medicines within the health care service (Wales et al. 2014). Pharmacists are considered the custodians of medicines, as they provide information on medicines to the public as well as to other health care professionals (Ditonkana & Dambisya 2014). They are also the health care professionals responsible for managing medicines and other pharmaceuticals within an organisation to ensure their effective distribution and appropriate use (Romero 2013).
In the hospital sector, pharmacists are integrally involved in the medicines supply cycle, where they oversee medicines management, from procurement, storage and distribution, up to the point where patients receive their medicines (Dias 2012). Managing the supply of medicines to the wards in a hospital, and ensuring the availability of medicines for in-patients, are vital functions of the pharmacy department (Kachwee & Hartmann 2013).

The South African National Department of Health (NDoH) has shown commitment to improve the quality of health care services, which led to the development of the National Core Standards (NCS) (NDoH 2011). In future, all health care establishments in South Africa will have to comply with these standards, which form the basic requirements for the delivery of safe health care services of a high quality (Whittaker et al. 2011). Based on the NCS, six fast-track areas for improvement have been identified, of which one is the availability of medicines and supplies in the health care service to meet patients’ health care needs (NDoH 2011).

The availability of medicines is considered a vital part in quality health care service delivery. It is regarded as the first priority in the supply of essential medicines, which are those medicines intended to be available in adequate quantities, in appropriate dosage forms and at affordable prices, to satisfy the health care and medicine needs of the majority of patients (Elamin et al. 2010).

One of the health objectives of the National Drug Policy of South Africa is to ensure access to medicines that are available and affordable to those in need (NDoH 1996). Affordability of medicines is defined as free access to medicines and services for patients (Lee & McKerracher 2002). One of the most common issues affecting the availability of medicines in the health care system is the cost of medicines (Romero 2013). In as much as medicines have to be available, affordability of medicines to patients should also be taken into consideration. The unavailability of medicines indirectly also affects the financial resources within the health care system, by increasing the costs of delivering patient care as well as the costs of human resources (Fox et al. 2009).

Over the couple of years, medicine shortages have been a challenge in the delivery of health care services, globally, as well as in South Africa (FIP 2013, Gray 2014). Dr George Mukhari Academic Hospital (DGMAH) is no exception to the rule, as the hospital has been experiencing numerous stock out situations and shortages of medicines, especially over the past two years. Apart from patients’ health being compromised by medicine shortages, health care professionals, especially pharmacists, are also affected due to additional time spent on solving problems caused by out of stock situations (Editorial, 2013).
1.3 RESEARCH QUESTION

Primary and secondary research questions were formulated for the purpose of this study.

1.3.1 Primary research question

What are the practice implications of out of stock medicines in the intensive care units (ICUs) of DGMAH?

1.3.2 Secondary research question

- Which medicines are out of stock in the neonatal intensive care unit (NICU) and the adult intensive care unit (ICU)?
- What are the reasons for out of stock medicines in the NICU and the adult ICU?

1.4 AIM OF THE STUDY

The aim of the study was to evaluate the practice implications of out of stock medicines in the ICUs of DGMAH.

1.5 OBJECTIVES OF THE STUDY

The objectives of the study were as follows:

- To identify out of stock medicines in the NICU and the adult ICU.
- To determine reasons for medicine items being out of stock in the ICUs.
- To describe practice implications of out of stock medicines from nurses’ perspectives in the ICUs

1.6 IMPORTANCE OF THE STUDY

One of the biggest frustrations of health care providers is this short, yet devastating sentence: “Sorry, it’s out of stock” directed at the public, they are supposed to deliver a service to (Stop Stock Out Project (SSP) 2014). Often times the medicines are reported out of stock for several weeks, months or even years. When medicines are not available, it means that trained health care professionals are practicing without some of the most important tools at their disposal (SSP 2014, Lyengar et al. 2016, WHO 2016). The absence of a significant item causes people to suffer pain unnecessarily. Other measurable factors are also affected in terms of hours
Chapter 1: Introduction

wasted when sourcing the out of stock items; patients are left untreated, which in turn affects the confidence of the public, on the health care service (SSP 2014, EAHP 2014, WHO 2016).

In May 2010, South Africa experienced a rampage of shortage of over 80 medicinal items in the public health sector. The severity of the problem varied from province to province, hospital to hospital, depending on the leadership (Nieuwoudt 2010). Since then South Africa has taken some action in managing out of stock situations in the country. To date, the NDoH in collaboration with the Stop Stock Outs National Survey in South Africa have released three annual reports of stock outs in South Africa, in an to attempt to quantify the level of stock outs in the different provinces, identify the causes and finds solutions to unacceptable situations (SSP 2015).

The study aimed at evaluating out of stock medicines at ward level, specifically the intensive care units of DGMAH to have a better understanding of medicine shortages and the reasons for shortages in the wards and in the hospital. The results could be used in the future planning of interventions to mitigate out of stock situations.

1.7 OUTLINE OF THE DISSERTATION

This dissertation includes five chapters. Chapter 1 serves as an introduction to the dissertation, in which the background and rationale for the study and purpose are described. Chapter 2 provides the literature review relating to out of stock medicines, and the extent of the situation in South Africa and from around the world. Chapter 3 contains a detailed description of the methodology related to the study. Chapter 4 presents the results of the study and discussion thereof in the form of two manuscripts which will be submitted for publication in accredited peer-reviewed journals. Chapter 5 concludes the dissertation with the limitations of the study, recommendations for future studies and overall conclusion.
2.1 INTRODUCTION

In this chapter an overview of published literature on the study topic in this particular field is provided. The chapter begins to explore the concepts of essential medicines and the medicines supply management cycle. The chapter further describes how medicines are classified as out of stock and the extent of the problem of medicine shortages globally as well as in South Africa. Factors affecting the availability of medicines and factors contributing to medicines shortages in various provinces of South Africa are discussed. The impact of medicine shortages at large, for the health care provider and for patient care is outlined. Medicines stock out alerts and system for managing medicine shortages are described. The chapter is concluded with a discussion of health care professionals collaboration in the management of medicine shortages.

2.2 ESSENTIAL MEDICINES CONCEPT

The first WHO model list of essential drugs was published in 1977, after discovering that essential medicines in various countries were often inaccessible to the public (WHO 2002). The list of essential medicines, advocated for the principle that some medicines were more essential than others, pointing out that not all medicines are equally useful in all developing countries. The selection criteria is based on the evidence-based approach and revised every two years by the WHO Expert Committee. In the past 25 years, 11 revisions of the list have been published and 156 member states have adopted medicines lists. The name essential drugs list has recently changed to essential medicines list (Laing et al. 2015).

Essential medicines were defined by the WHO, as those medicines that satisfy the priority health needs of the population (WHO 2002, Saouadogo & Compaore 2010). They are selected based on the interest of public health with available resources to achieve maximum health improvements for the population. These medicines should be available at all times, in adequate quantities, appropriate dosage forms with assured quality, safety, efficacy, and at a price an individual and communities can afford (WHO 2002). Essential medicines selection still remains the responsibility of the National Government with regard to public health relevance, evidence of efficacy and safety and comparative cost-effectiveness (Khuluza et al. 2016).
In South Africa, the Essential Medicines Programme was established in terms of the National Drug Policy (NDP) in 1996. The NDP aims to provide equal access to medicines for all South Africans through the Essential Drugs Programme, which will include an Essential Medicines List and Standard Treatment Guidelines, with the aim to promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of medicines by the community. The minimum list includes the medicine needs for a basic health care system, listing the most efficacious, efficient and cost effective medicines for priority conditions. The basis for considering priority conditions, is its estimated future health relevance, and potential for safe and cost-effective treatment (Laing 2015).

2.3 MEDICINE SUPPLY MANAGEMENT CYCLE

Medicines management plays a vital role in ensuring the availability of medicines to the community in need. It forms a pipeline link of the patient and health service providers (Dias 2012). Poor medicines management has been a critical issue particularly in the public sector of developing countries. Management of medicines supply should seriously be taken into consideration to avoid wastage and increase access to health (Dias 2012).

Medicines management essentially involves five key functions namely selection, procurement, management support, distribution and use of medicines. All these require an appropriate management support system in each division (Report 2014).

2.3.1 Selection of medicines

The selection of medicines is usually determined from the National Level, where the Minister appoints the National Essential Medicines List Committee (NEMLC) responsible for selection and revision of the National Essential Medicines Lists within the country (Report 2014). The selection is based on the WHO Essential Medicines List and the National Drug Policy as a model to provide a limited list of medicines in use for the country and the community. The Minister of Health ensures that all health care institutions are catered for, at primary, secondary to tertiary level (Report 2014).

During selection, there are various criteria considered, such as selecting affordable and cost-effective medicines which are safe, of good quality and available to treat most prevalent diseases within the country (Dias 2012).
2.3.2 Medicines procurement

Procurement is a series of steps or processes to ensure the availability of selected medicines (Dias 2012). Procurement of medicines considers the population the health care system provides a service to, disease patterns, monthly consumption statistics, lead time and quality of medicines, which serve as a signal for new orders (Dias 2012). The drug controller should be able to do proper estimation of lead times to avoid stock outs or delayed deliveries (Dias 2012). Procurement is usually done through the medical depot unless permission to buy out other items has been granted to the facility. When ordering from the medical depots, facilities may use the direct delivery voucher (DDV) or “buy out” method, where the medicines are directly delivered to the facility by the supplier or the pharmaceutical company (Report 2014).

2.3.3 Medicines distribution

Distribution is a process by which medicines are transported from a central warehouse to storage depots and health facilities (WHO 2011). The distribution system involves a number of entities at different sequences which differ from one country to another. The different distribution systems depend on geographical factors, population to be served, variability in demand, availability of storage space, maintenance staff and transport facilities (WHO 2011).

The central medical store (CMS) serves as the primary warehousing and distribution point in the medicine supply chain with the aim of ensuring a steady supply of pharmaceuticals to the health care facilities at the right time, in correct quantities and at an affordable price (Dias 2012). A well reputable distribution system ensures that additional storage locations have been calculated to avoid stock outs, over stock situations and product expiry (WHO 2011).

There are two main approaches to ensure an effective distribution system, known as the pull and push systems. These are used to distribute stock from higher level stores to lower level health facilities. In a push system, the CMS or regional medicine stores determine the quantities of medicines that are to be issued to each lower health care facility, based on central estimated allocation quantities (WHO 2011). In a pull system, each health facility determines their own medicine requirements, which is ordered or purchased from a higher level store or warehouse. The pull system often utilises local information about the demand the health care facilities require (WHO 2011).
A well-structured distribution system should be able to achieve the following:

- Sustain a consistent supply of medicines
- Ensure medicines are of good quality
- Minimise medicine losses as a result of spoilage and expiry
- Maintain an efficient transport system
- Reduce fraud and theft
- Prepare forecasting information before hand
- Incorporate a quality assurance programme

The challenge faced with the distribution cycle is to evaluate and improve existing systems in the public health care sector (Dias 2012). Previous inspections have shown that serious delays in distribution were due to late payments of suppliers, which resulted in most suppliers being reluctant to continue business with public sector hospitals (FIP 2013).

### 2.4 SHORTAGES OF MEDICINES

Medicines are classified as out of stock, if the stock required for patients’ use, is physically not available in the health care facility (Dias 2012). Shortage of stock can be described as, when the health care facility does not have enough medicines available for patients until the next order could be received. Another definition of shortage of stock, is when stock on the shelves has reached its minimum levels, which indicates that the product is or will be out of stock within the next few weeks or months (Dias 2012, ASHP 2013, De Weerdt, et al. 2015).

Out of stock, or shortage of stock, could be due to an inadequate budget for procurement of medicines, ineffective distribution systems at national and regional levels, inaccuracy of forecasting from the government, or inaccurate lead times, which could also be due to changes in usage patterns or a shift in prescribing due to other medicines being out of stock (De Weerdt et al. 2015). However, if a good management system for out of stock medicines is practiced, medicines stock outs are normally minimal or rare (Dias 2012, Kaakeh et al. 2011).

Lead time (waiting time) also plays an important role in medicines availability and is referred to as the time between when an order for an item is placed and the time it is received (Dias
Chapter 2: Literature Review

2012). Lead times should be established as they aid in avoiding medicine stock out situations. Depending on the agreement of delivery times, medicines can be delivered in days, weeks, months or even longer, because of unforeseen circumstances such as poor delivery conditions (Dias 2012).

2.5 EXTENT OF THE PROBLEM OF MEDICINE SHORTAGES

Worldwide medicine shortages have been frequent in the past few years, which led South Africa and other international countries to make it a priority to minimise and manage medicines effectively (FIP 2013, WHO 2016). The problem has affected numerous medicines, mostly antiretroviral (ARV) and anti-tuberculosis medicines and to a certain extent, commonly-used medicines such as aspirin (FIP 2013; Magadzire et al. 2014, SSP 2014).

The problem has been intensified and reports have outlined numerous drug shortages which were recorded in 2011, because of challenges not being resolved (Golembiewski 2012, WHO 2016). South Africa's health system is clearly divided into a private sector and a public sector, though medicines reported to be out of stock in some cases from the public sector were also unavailable in private sector facilities, due to the unavailability of active pharmaceutical ingredients (FIP 2013, Kaakeh et al. 2014).

It is evident from various reports that the extent of medicines shortages in South Africa and worldwide is enormous (FIP 2013). Sufficient information on stock shortages should be available to be able to attend to the problem and coordinate the implementation of necessary interventions aimed at reducing numerous stock shortages (FIP 2013, Kaakeh et al 2014).

2.6 FACTORS AFFECTING MEDICINES AVAILABILITY

The following are factors reported to contribute to the unavailability of medicines:

- Manufacturing difficulties: These difficulties might lead to delay in production of products and could be due to changes in the product’s formulation or even limited production capabilities, delaying availability of medicines (Golembiewski 2012, Kaakeh et al. 2014).

- Voluntary recalls: It is mandatory for medicines undergoing certain testing in safety, efficacy and quality before becoming available to consumers, to avoid lack of assurance of the product’s safety and efficacy whilst on the market. The manufacturer might detect
unforeseen problems concerning safety whilst the medicine is on the market, requiring voluntary recall by the manufacturer (Fox et al. 2009).

- Supply and demand: Sudden changes in medicine formularies could lead to unavailability of medicines because of an unexpected increase in demand of certain medicines, which was not anticipated (Golembiewski 2012, Kaakeh et al. 2014, WHO, 2016).

- Economical issues: Changes in the supply chain due to insufficient profits, use of generics and recall expenses, may reduce production of certain medicines (Fox et al. 2009, SSP 2014).

2.7 FACTORS CONTRIBUTING TO OUT OF STOCK SITUATIONS IN VARIOUS PROVINCES IN SOUTH AFRICA

A nationwide survey of medicine stock outs was launched as an independent civil society consortium that monitors and speaks out about medicine stock outs and shortages, with the aim of achieving a stock out free health system (SSP 2013, SSP 2014). The programme aimed to engage with the government in its efforts to improve procurement, distribution and management of essential medicine stocks in the longer term (SSP 2014). The project ensures accountability and transparency to exist along the supply chain of medicines. A survey was conducted amongst different provinces in South Africa to find out the challenges and strategies in place to mitigate them (SSP 2014). A discussion of the situation in the various provinces follow below.

2.7.1 Gauteng Province

In the second annual report of the SSP in South Africa, some of the main reasons for medicine shortages being reported in the Gauteng Province have been identified (SSP 2014). In response to these challenges, the province implemented a number of strategies.

2.7.1.1 Supplier issues

According to the Food and Drug Administration (FDA), medicine shortages resulted from multiple challenges, including production level, due to manufacturing challenges. The situation reflected a global impact of unavailability of active pharmaceutical ingredients (APIs) (SSP 2014, WHO 2016). Industry representatives also claimed that medicine shortages as a result of manufacturing problems, could be linked to underlying problems of active ingredients, lack of global sourcing, and non-compliance with application regulatory
standards (Mica 2013, WHO 2016). The other related challenge faced with suppliers was non-adherence to the contractual lead times. This was agreed to be resolved by strengthening the implementation of a penalty clause in accordance with the general conditions of the supplier contract (SSP 2014). Management supply drug units have also implemented an ongoing system where follow-up is done at the medical supplies depot to engage suppliers on adherence to contractual lead times (SSP 2014).

2.7.1.2. Demand planning systems

Unreliable inventory management systems in the hospitals lead to inaccurate demand planning calculations. Subsequently, implementation of a standardised inventory management system in all institutions is ongoing (SSP 2014, Kaakeh et al. 2014).

2.7.1.3. Contract management

Most of the suppliers have not been awarded tenders to supply items which are listed as EML items. This situation can be resolved by awarding provincial tenders to improve on the supply chain processes involved in the procurement of items not on national contracts (SSP 2014).

2.7.1.4. Forecasting

Time lapse between the guideline changes and the tendering process often creates a gap in making the new medicines guideline available on tenders. These affect the procurement system that operates on a quotation system, is time consuming and does not guarantee continuous availability of the required items (SSP 2014, Kaakeh et al. 2014).

2.7.2 Limpopo Province

The province acknowledged the vast numbers of medicines for which stock outs have been reported within the province. During the period of the stop stock out survey, medicines which were reported as out of stock in facilities were actually available at the depot, which reflect the poor forecasting due to inaccurate data of available medicines (SSP 2014). One of the main contributing factors is infrastructure in most public health care facilities for storage of pharmaceutical items. This results in the ordering of limited stock, and in turn, frequent orders being made (SSP 2014). The province had proposed strategies to implement in order to minimize the shortage of medicines. Some of the plans were to establish mini depots supplying the clinics, and community service pharmacists changing clinics into ideal clinics (SSP 2014).
2.7.3 North West Province

The province is faced with complex factors contributing to the out of stock situation. According to the SSP survey report, one of the underlying factors was unavailability of stock from suppliers. Items such as enalapril tablets and ceftriaxone injections were reported to be out of stock because of the inconsistency of the suppliers (SSP 2014). Remedial actions to be taken include that the depot should keep adequate stock levels so that, in cases where suppliers do not have sufficient stock available the depots are not instantly affected by the situation (SSP 2014, WHO 2016).

2.7.4 Northern Cape

Lack of ownership and responsibility at management positions, insufficient personnel and lack of a credible stock management system were reported as highlights to the rise of out of stock medicines (SSP 2014). The solutions towards challenges were to strengthen increased visibility of stock outs by the management. This includes information regarding inventory management practices for specific items. This could be the amount of operational safety stock held to mitigate against periods of increased demand and the amount of strategic safety stock held to mitigate against disruptions of medicines supply (Mica 2013). This will create an awareness regarding the medicine shortages at the facilities, to improve the service provided (SSP 2014).

2.7.5 Western Cape

Medicines availability was reported to be reliable in the Western Cape. The Cape Medical Depot (CMD) manages the procurement, distribution and it is the warehouse arm of the Department of Health Western Cape for pharmaceuticals and non-pharmaceuticals. The following are strategies that have been implemented to minimise and avoid shortages of medicines (SSP 2015):

- Pre-tender forecasting is accurately estimated and forwarded to the NDoH, for the preparation of tenders
- The CMD has a dedicated finance officer who reports to the CMD Manager and Responsible Pharmacist
- Orders are placed directly to the suppliers and within two weeks suppliers are expected to report and confirm dates of delivery
- Contract penalties are applied on late deliveries by suppliers
CMD pays its suppliers in less than 30 days which makes it an average of 15-20 days

Direct delivery vouchers are followed up by the CMD and original documents are collected by a CMD driver on a set route known by all facilities

2.8 IMPACT OF MEDICINE SHORTAGES

The impact of medicine shortages is a critical issue burdening health systems with additional costs and compromising the health of patients who fail to receive their medicines (Magadzire et al. 2014, WHO 2016). The impact has been reported from high, middle and low income countries. Even though the issue might seem to continue in various countries, however providing information about the incidence and consequences of medicine shortages limit the impact to health care professionals and the patients (WHO 2016).

2.8.1 Consequences for the patient

Patient care is defined as meeting the patient’s basic health care needs, contributing to his/her recovery. When medicines are out of stock, patients’ safety and clinical care are compromised. Medicine shortages or out of stock situations can have a negative impact on the health of the patient, as it can lead to interruption of treatment, defaults or partial intake of medicines (SSP 2013, McLaughlin et al. 2013).

Shortage of medicines can have an even greater effect on the patient’s health when alternative medicines are being prescribed, or issues about the safety of the medicines are being raised due to a less effective response to the medicine by the patient, which may result in adverse patient outcomes (Editorial 2013, Golembiewski 2012, McLaughlin et al. 2013). The use of alternative medicines may also lead to patients developing an increased risk of drug resistance, increased risk of illness and ultimately risk of death (SSP 2013).

Medicines shortages can also impact on other aspects of a patient’s life. An example is, travelling expenses to the health care facility which does not have sufficient medicines, with subsequent perceptions which could result in negativity towards the health care service provided (Editorial 2013).

2.8.2 Functioning of health care providers

Health care providers are affected by medicine shortages in various ways. They are required to spend additional time to manage the shortage of medicines. Managers often have to shift staff or appoint additional staff in order to manage the drug shortages
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(Golembiewski 2012, McLaughlin et al. 2013, Kaakeh et al 2014). Management of human resources becomes a challenge when appropriate measures are not taken to deal with out of stock situations (FIP 2013). According to a survey conducted in 2011, it was reported that pharmacists spend nine hours a week trying to manage medicine shortages (FIP 2013, Kaakeh et al. 2014). Hence when medicines are consistently out of stock, it subsequently results in a straining relationship between the pharmacy department and other health care professionals (FIP 2013).

2.8.3 Cost implications of medicine shortages

Beyond patient care and safety, medicines shortages have an effect on the health system budget for medicines (McLaughlin et al. 2013). According to a survey conducted at the University of Michigan, an annual estimate of R2 592 million was spent on managing medicine shortages in hospitals and health systems (Golembiewski 2012). An increased work load for health care professionals will have direct cost implications for pharmacists, nurses and other health care providers, as more staff will be required. This will result in staff members required to working extra hours to manage shortages of medicines (McLaughlin et al. 2013; Golembieskwi 2012).

Shortage of medicines may also have an effect on health care service budgets (McLaughlin et al. 2013, WHO 2016). In the event where a medicine has to be substituted due to the unavailability of a particular medicine, this could ultimately increase the cost of the medicines for the patient. In such instances additional expenditures should be documented because the cost of providing an alternative medicine might be expensive for the patient (Fox et al. 2009).

Understanding the cost implications of the shortages of medicines is imperative for long-term planning and funding of health care services. It is therefore vital to document the financial implications due to medicine shortages to explain budget variances and to support future budget proposals (Fox et al. 2009). Lack of resources to meet the health care needs of the patient, indirectly influences the costs of making alternative medicines available. This highlights the need for partial economic evaluations to compare costs and consequences of substitution of any medicines, with regards to economic implications (Trask 2011, Kaakeh et al. 2014).

With a cost analysis, it is imperative to determine which costs are important to measure by establishing the perspective of the investigation, which may include those of the patient,
provider, payer and community (Trask 2011). The patient perspective refers to what the patient pays for the product while the societal perspective is broad, because it covers all the expenses carried by the society as a whole. Costs from a provider perspective are regarded as direct costs from hospitalization, supplies, salaries, labour costs and other organizations providing products or services (Trask 2011).

2.9 CONTROLLING EXPENDITURE

Cost analysis has been identified as an effective method in the management of medicines stores (Thawani et al. 2003). It is well known as the “Always Better Control” method of categorizing items based on their capital investment. The method is based on Pareto’s principle of “vital few and trivial many” and grouped accordingly. Group A includes 10-15% items which consume about 70% of the budget, Group B consists of 20-25% of the inventory items which consume 20% of the cumulative cost and Group C includes the remaining 65-70% of the items which account for 10% of the total value (Monton et al. 2014).

Amongst various methods the, ABC analysis has been found to be effective and efficient in cost management, and described as a detailed and precise method to manage medicine stores (Thawani et al 2003). However, the method has limitations in that it can account for only the final value and consumption rate. If the Vital, Essential, Non-essential items (VEN) classification of medicines is coupled together with the ABC analysis, it has shown to be more effective and efficient in medicines management (Monton et al. 2014).

In most instances the VEN is referred as the VED, which is basically the same. The “V” stands for vital items, which are medicines a hospital cannot function without. “E” are essential items which the hospital can function without but may reflect negatively on the quality of services provided by the institution. “D” stands for desirable items, of which the unavailability of these items will not necessarily affect the functioning of the institution (Gupta et al. 2007). VED considers the public health impact of individual items of prime concern, more than the unit price of items. The effective use of this method has shown to improve medicine cost management and waste reduction amongst pharmacies (Monton et al. 2014).

2.10 STRENGTHENING HEALTH SYSTEMS

A health system consists of all organisations, people and actions whose primary goal is to promote, restore or maintain health (Riegelman 2008). It promotes preventive, curative and
rehabilitative interventions through the combination of public health actions taken. In order for a health system to yield desired results. Five key building blocks to strengthen the system are discussed below (Riegelman 2008).

2.10.1 Service delivery

Quality of service varies considerably within the health system, but a good health service delivery is the one that is able to deliver service that is effective, safe and of quality to those in need (Riegelman 2008). Quality of service according to WHO (2007) covers six priority areas which correspond to good service delivery.

In 2011, the South African Association of Hospital and Industrial Pharmacists saw the need to improve the quality of pharmaceutical service by providing a workshop that covered the six priority areas to improving service delivery (Bradley 2011). Improving the quality of health care is one of the central purposes of the NDoH initiatives and corresponds with the NCS. Service delivery can be improved by the management of inventory control from suppliers, and also, development of alternative delivery systems for medicines (Bradley 2011).

2.10.2 Health care force

The health care force includes having sufficient staff members, who are fairly distributed amongst their responsibilities and duties to be able to achieve the best health outcomes with given resources and circumstances (Riegelman 2008). It is noted as one of the most imbalanced issues within the public sector.

In most instances, institutions are faced with unaccountable staff members for their specific duties and this could be due to weak management systems, poor working conditions and limited continuous training (Masamine et al. 2010). This in turn results in poor morale and performance of health workers which impacts on quality and acceptability of the service provided.

2.10.3 Health information systems

Health information systems is one of the most essential and interrelated building blocks for improving health systems (WHO 2010). Health information should be reliable and timely with regards to information concerning health status and health system performance.
With a well-functioning health information system in the hospital, the hospital will be able to identify progress and problems, and resolve them with evidence-based decisions based on different research studies. The results from research could be translated into implementation of health policies to utilize the information for on-going monitoring of plans and programmes as well as resource allocation purposes (Mutale et al. 2013).

### 2.10.4 Health financing

Health systems battle on how to find funds that are needed to meet the standards of service delivery to the community. It is a continuous battle in the health system to provide sufficient funding to meet the highest priorities of service in an efficient and effective manner (Fryatt 2012). Hence, it is the responsibility of the responsible manager to estimate the annual budget and take necessary steps in ensuring that all expenditures remain within the budget (SAPC 2010).

### 2.10.5 Leadership and governance

The quality of leadership and governance is a vital determinant of outcomes in the health service (WHO 2010). Leadership and governance in health systems involves setting strategic policies and regulations in place with effective oversight and accountability from leaders. Accountable personnel are individuals who perform duties to supply service, ensuring that adequate resources are available to deliver service (WHO 2007). Accountability is one of the aspects that concern the management of health professionals and other entities that have the responsibility to deliver and use health services (Mabirizi et al. 2014).

### 2.11 MEDICINE STOCK OUT ALERTS

Currently, the most important early sources of information about existing and potential medicines shortages are manufacturers (Kweder & Dill 2013). Manufacturers should provide reports about existing or potential disruptions in manufacturing to allow implementation of interventions to prevent shortages on time (Kweder & Dill 2013). If such reports were made readily available, South African pharmaceutical companies would have been able to prevent such instances. In South Africa it has been reported that issues concerning medicine shortages were due to active pharmaceutical ingredient supply issues and pharmaceutical companies not accountable to any National management (Gonzalez 2015).
Medicines shortages have been an alarming issue which steered the Minister of Health in South Africa to implement the practice of national buffer stock; whereby medicines are strategically stock-piled with the service provider at the warehouse (Gonzalez 2015). Medicines shortages became so enormous, triggering the United States Food and Drug Administration (FDA) to also find ways to mitigate the impact on patients and the health care system (Kweder & Dill 2013). In the US however the FDA formed a small Drug Shortage Program (DSP) intended to support manufacturers and pharmacies in managing the drug cycle. The DSP along the years has managed to reduce shortages rapidly (Kweder & Dill 2013). The DSP staff worked closely with manufacturing companies such that, they were able to identify an alternative source timely if there was a potential lead of medicine shortage. This was only achieved through co-ordination amongst clinicians, chemists, compliance officers, even international regulators. Even though some of the drug shortages could not be prevented, the FDA somehow managed to explore all avenues to identify alternative manufacturers for temporary importation to resolve the issue (Kweder & Dill 2013).

The FDA further established a website that is daily updated with current medicine shortages, all known alternatives and expected duration of the shortage for health care providers (Kweder & Dill 2013). They do realize that the health care providers are best able to minimize the impact of medicine shortages, hence such information is made readily available for them (Kweder & Dill 2013).

**2.12 MANAGING MEDICINE SHORTAGES**

The management of medicine shortages is expensive to the health system of any country, resulting in additional costs for replacement of medicines and absorbing significant staff time. In December, 2015, a technical consultation was held by WHO executives to discuss bottlenecks and reasons to consider and identify approaches that could be effective at global scale (WHO 2016).

In South Africa the NDoH initiated various interventions to address the weaknesses in the procurement and delivery of medicines. These interventions are aimed at creating a streamlined and efficient supply chain system that supports evidence-based, predictable, reliable medicine supply chain systems. The various interventions implemented are briefly described in this section.
2.12.1 Direct Delivery Strategy (DDS)

The Direct Delivery Strategy (DDS) is a process whereby the health facilities place orders directly to the suppliers contracted by the NDOH. The suppliers then deliver medicines directly to health facilities, rather than depots. This system reduces lead times and improves medicines availability (Zwane 2014, Steel 2016).

2.12.2 Central Chronic Medicine Dispensing and Distribution (CCMDD)

The Central Chronic Medicines Dispensing and Distribution (CCMDD) is a programme which allows the chronic patient who receives medicines every month, on a repeat prescription for a period of six months, to receive their medicines at a pick up point of their convenience. The prescriptions are dispensed centrally using private sector facilities. This system allows resources to be used in a cost efficient manner and reduces congestions in health care services (Zwane 2014).

2.12.3 Control Tower and Provincial Medicine Procurement Units (PMPU)

The Provincial Medicine Procurement Units serve as tactical operational units responsible for managing the procurement of medicines within provinces, using modern delivery method systems. It is regarded as the control tower of the National hub for contracted suppliers in pharmaceutical delivery with efficient and effective monitoring (Zwane 2014, Steel 2016).

2.12.4 Stock Visibility Solution (SVS)

Part of the challenge with the current medicine supply chain, is lack of end-to-end stock visibility due to poor network infrastructure. The NDOH has piloted a system which aims to help health care facilities to have access to stock visibility. The stock visibility system (SVS) is a mobile based solution that provides real time visibility of stock on hand from different health care services (Zwane 2014). The system will enable engagement of stock visibility from the government to increase access to medicines where needed, with the use of a smartphone or an application bundle available to dispensing facilities, to capture stock levels on a daily basis (Steel 2016). The information is synchronized to a mother server from the warehouse which alerts and reports various levels of the supply chain management (Zwane 2014).

The system works by allowing health care professionals, particularly those responsible for dispensing, to report on stock levels on the shelves through a custom-built mobile
application. Based on the reported data on the system, the system will generate a report to the sub-district, district and the provincial managers via sms and email (Zwane 2014, Steel 2016).

Through the use of the SVS, the government will be able to trace the level of stock data from each health care facility. This will also allow the accuracy and efficiency of stock distribution by the pharmacy supply chain management and in turn improve access to quality medicines (Zwane 2014). Weekly and monthly reminders, and automated notifications, are sent to all registered facilities to remind them to submit stock levels, stock received and stock lost (Zwane 2014).

2.12.5 Direct Purchasing

The direct purchasing method enables selected central hospitals to place orders directly with contracted suppliers and manage the full procurement cycle. This method enables facilities to proactively manage their medicine stock levels and to minimise or eliminate stock outs (Zwane 2014).

2.13 COLLABORATION OF HEALTH CARE PROFESSIONALS IN MEDICINES MANAGEMENT

Medicine shortages are a common challenge encountered by pharmacy personnel (Logan et al. nd). This has been an alarming situation which led pharmacists to be proactive in managing the situation through collaborating with other health care professionals (Logan et al.). Collaborative care is commonly known as multidisciplinary, inter-professional, and shared or team care, which are terms often used interchangeably (Agwa & Wannang 2014). A true collaborative care has no hierarchy but is based on the knowledge or expertise brought to the practice. The basis of collaborative care is the belief that quality patient care is achieved by contribution of all health care providers (Agwa & Wannang 2014).

Medicine shortages arise from a variety of different points in the drug procurement process including, but not limited to, manufacturing delays, active ingredient unavailability, supplier issues and increased demand (Logan et al. nd). Frequently medicine shortages occur with little warning and often with no communication to help the pharmacy determine the duration of shortage. The increasing complexity of medicine shortages underscores the need for a strong working relationship between health care workers to optimize patient care (Kelly et al. 2013).
Due to these non-ideal circumstances it is imperative that pharmacists have a proactive plan to manage new and existing shortages. Early identification of medicine shortages and communication to relevant stakeholders improve proper management of the shortage, and hence, collaborative care will help to disseminate information regarding medicine shortages in the facility (Logan et al. nd). Pharmacists have demonstrated their ability to improve care by monitoring adverse events, improving patient health, and reducing health care costs when collaborating with other health care professionals (Kelly et al. 2013).

Standard communication to all health care professionals is of paramount importance for a successful shortage plan (Logan et al. nd). This is well achieved by a set of distribution methods such as emails, intranet posting, regular meetings, and appointing key personnel to disseminate the information. Such information should be clear, concise and timely communicated to health care professionals to help manage the situation (Logan et al. nd). This can only be achieved when pharmacists and other health care professionals make it their responsibility to manage the optimal use of medicines through collaboration (Kelly et al. 2013). Hence, pharmacists and other health care professionals should be up to date on medicine shortages to minimize the frustration and ensure timely treatment for the patients.

According to a study conducted in Johns Hopkins Bayview Medical Center in Baltimore, Maryland, collaborative practice does work. After the hospital had enormous medicine shortages, they made up a joint task force consisting of the head of pharmacy personnel and various subspecialties to provide insight into the impact and feasible alternatives on specific shortages of medicines (Logan et al. nd). The key to this implementation was the vigilance of all staff members in keeping the committee abreast of changes with regards to medicines.

Ideally, health care professionals should have experience with collaborative practice during their undergraduate professional training and can continue to build on these experiences once in practice, which can be done by attending joint continuing education activities and conferences (Kelly et al. 2013). Collaborative practices will enhance patient outcomes, however, time constraints and financial barriers are factors which limit the extent to which health care professionals interact to provide care (Kelly et al. 2013, Agwa & Wannang 2014).

The use of the Drug Information System (DIS) allows communication among health care providers. This helps in sharing information across the health care continuum and may offer additional opportunities for collaboration to be effectively executed (Kelly et al. 2013).
2.14 SUMMARY

Shortage of essential medicines has been documented in most parts of the world with an increasing frequency. These essential medicines are selected based on the interest of public health with available resources to achieve maximum health improvements for the population. The medicines should be safe, effective and of quality to meet the needs of the patients. However, the extent of medicines shortages has affected numerous medicines, mostly antiretroviral (ARV) and anti-tuberculosis medicines.

There are different factors contributing to medicine shortages. Factors include limited number of manufacturers for active pharmaceutical ingredients, voluntary medicine recalls and poor visibility of stock demand. South Africa in collaboration with the SSP have explored and reported a number of reasons behind medicines shortages from various provinces in South Africa in order to alleviate the situation and improve the health services. Medicine shortages do not only affect the health system but patient care is also compromised, causing health care professionals to work under pressure with insufficient resources. Lack of resources to meet the health care needs of the patient indirectly influences the costs of making alternative medicines available. This highlights the need for partial economic evaluations to compare costs and consequences of substitution of any medicines, with regards to economic implications.

The South African government has initiated interventions to address the situation, namely the reduction of lead times for medicines, implementing the direct delivery system to the hospital, stock visibility of medicines to address challenges of stock management and direct purchases to the contracted suppliers. Most importantly is an improved collaboration between the pharmacist and other health care professionals, to improve medicines management.

The following chapter provides a detailed description of the methodology of the study.
3.1 INTRODUCTION

This chapter presents the methodology of this study in detail, starting with a discussion of the study site and the study period. The study design and the study population are described followed by the sample used. The data collection process and instruments are explained in detail. This is followed by a description of the data entry and the data analysis, as well as methods used to ensure the reliability, validity and trustworthiness of the data collected. The chapter concludes with a discussion of the ethical considerations for this study.

3.2 STUDY SITE

The study was conducted at DGMAH, situated in Ga-Rankuwa, Pretoria in the Gauteng Province of South Africa. DGMAH serves as an academic hospital to Sefako Makgatho Health Sciences University. The hospital is composed of 28 clinical departments, rendering all three levels of service namely primary secondary and tertiary levels. It is one of the four academic institutions in the province, and provides a service to the surrounding populations of four sub-districts of approximately 1.7 million people. This excludes the catchment population from the other provinces that it services. DGMAH also receives referrals from Limpopo, North West and Mpumalanga Provinces. In addition, this facility receives referrals from Southern African Development Community (SADC) countries, other tertiary academic hospitals, local specialists and general practitioners. The hospital has 1500 active beds, 20 approved Intensive Care Unit (ICU) beds, 60 high care beds and 17 theatres.

The study took place specifically in the NICU and the adult ICU at DGMAH where medicines are kept as ward stock. The adult ICU at the time of the study had 20 beds with an admission of approximately 87 patients per month and the NICU is a 55 bed unit with an admission of approximately 150 patients per month.

3.3 STUDY DESIGN AND DURATION

This was a descriptive, operational study, conducted over a period of seven months. The study data on out of stock medicines were collected on a daily basis as part of usual practice as quantitative data. Qualitative data were collected with focus group discussions (FGDs),
conducted with nurses in the ICUs, to obtain their perspective on the practice implications of out of stock medicines. Refer to Figure 3.1 for the conceptual framework for the study.

**Figure 3.1:** Conceptual framework for the study
3.4 STUDY POPULATION AND SAMPLE

The study population for this study was the NICU and ICU at DGMAH where pharmaceuticals are kept as ward stock. The ICU at DGMAH, at the time, had 20 beds with an admission of approximately 87 patients per month and the NICU was a 55 bed unit with an admission of approximately 150 patients per month.

3.4.1 Out of stock medicines

In terms of the out of stock items, the target was all the medicines being used in the NICU and the adult ICU. According to the ward medicines stock lists at the time of data collection, there were approximately 70 medicines in use at the NICU and 139 medicines at the adult ICU, with a total of 209 medicines for both wards. The entire medicines list was potentially the population and no sampling occurred, as it was theoretically possible that any of the medicines could be unavailable in the two ICU wards. All out of stock items in the NICU and adult ICU wards over the seven month study period were considered for the purpose of this study. The number of medicines which would be out of stock was however unknown.

The following inclusion criteria applied:

- All out of stock medicines in the ICU units during the study period.

The following exclusion criteria applied:

- All other medicines being available in the ICU units during the study period.

3.4.2 Practice implications of out of stock medicines

For the purpose of describing the practice implications of out of stock medicines, the targeted study population included nurses in both wards.

Purposeful sampling which is commonly used in qualitative studies was used to select 5 – 8 participants for focus group discussion, in each of the two ICUs. This sampling involved the identification and selection of particular individuals who shared characteristics relevant to the study and contributed the most in accomplishing the objectives of the study (Struwig & Stead 2009).

The target population were professional/specialised nurses from both wards, specifically those responsible for medicines management over the past six months. At the time of the study,
there were 27 professional nurses and 56 specialised nurses in the Adult ICU, and, 48 professional nurses in the NICU.

The following **inclusion** criteria applied:

- Nurses designated for medicines management in the past six months

The following **exclusion** criteria applied:

- Nurses who were not designated for medicines management in the past six months (during the study)

### 3.5 DATA COLLECTION INSTRUMENTS AND PROCESS

#### 3.5.1 Out of stock medicines

All the data were collected by the researcher herself who was an academic pharmacist intern. Data collection took place over a period of seven months from September 2015 to March 2016. During the course of data collection, the researcher was working in collaboration with the clinical pharmacist intern stationed at the NICU and the adult ICU. Ward nurses responsible for the medicines room and pharmacy staff responsible for ward medicines, were requested to provide information to the researcher during the time of data collection, if and when it was necessary. Although these health care professionals were only indirectly participating in the study, they were provided with information about the study, after which they were requested to provide written informed consent for their participation. The study information leaflet and consent form was available in English only, as it is the official language of communication at DGMAH (see Appendix 1 and Appendix 2).

Data collection took place in four steps, and was repeated for each item identified as being out of stock during the study period. **Step 1** was the identification of a medicine shortage at any particular point in time. This was either identified by the clinical pharmacist intern, the nurse or the researcher herself. The researcher then recorded the identified out of stock medicine item on a ward medicines monitoring sheet. A study identification number (study ID) was allocated to each identified out of stock medicine for tracking and tracing purposes (see Appendix 3). The reason for the medicine being out of stock was investigated by the researcher in **Step 2**. Information about the reason for the out of stock situation and proposed action plan to obtain the medicine was recorded on the same sheet and followed-up on the action plan (see Appendix 3).
In **Step 3**, depending on the reason for a medicine being out of stock, the researcher had to take the necessary action to obtain the medicine. All actions were recorded and the aim was for the patient to obtain the correct prescribed medicine as the end result, or a therapeutic alternative.

In **Step 4** the researcher ensured that ordered medicines were made available within the expected dates to ensure that patients had safe, effective and quality prescribed medicines available. Throughout the entire process, the researcher ensured effective means of communication with other health care providers to ensure the accomplishment of suggested interventions (see Figure 3.1).

### 3.5.2 Practice implications of out of stock medicines

Two focus group discussions were conducted with nurses, one in the adult ICU and another in the NICU, to explore the practice implications of out of stock situations from nurses’ perspective.

The time and date of the FGDs as well as the number of participants in each FGD, were determined according to availability of the nurses in both wards. The FGD was conducted in an arranged private room with limited disturbance during the discussion. Prior to the commencement of the FGDs, information about the study was provided to the participants and written informed consent was obtained (see Appendix 1 and 2). The FGD was facilitated by an experienced focus group moderator using a focus group discussion guide, comprising of open-ended questions. Probes and further questions were used to verify unclear responses, seek further explanations and encourage participants to elaborate on their responses (see Appendix 4). A digital voice recorder was used to record each of the discussions and the researcher took observational notes during the discussion.

### 3.6 PILOT STUDY

A pilot study was conducted at one of the paediatric wards, prior to the commencement of data collection and after ethical approval was obtained for the study. The aim of the pilot study was to assess the feasibility of the study, whether the data collection instruments were appropriate and to identify any difficulties with the data collection process. Based on the results obtained from the pilot study the data collection instruments were adapted where necessary to ensure that data collected during the actual study was adequate for achieving the objectives of the study.
3.7 DATA ENTRY AND ANALYSIS

3.7.1 Quantitative data on out of stock medicines

Data collected was completed using Statistical Package for the Social Science (SPSS), captured on Microsoft Excel® spread sheets and checked for accuracy and correctness. The number of times each medicine was out of stock and the reasons for medicines being out of stock was summarised descriptively by frequency table.

The Anatomical Therapeutic Class (ATC) index was used to categorise identified out of stock medicines. The ATC codes were obtained from the World Health Organization (WHO) guideline available data base (WHO Collaborating Centre (WHOCC) 2013). The ATC classification system are divided into fourteen main groups which are further divided into five different levels depending on their site of action and therapeutic and chemical characteristics. Out of stock items were classified according to the first level of the ATC index, which is the chemical substance. The frequency of medicine shortages were recorded upon identification by the pharmacist or the nurses during their daily practice.

The out of stock items were further categorised according to their health impact, into Vital, Essential and Non-essential items, referred to as the VEN system. The basic criteria for classifying the VEN analysis was obtained from the National Department of Health master procurement catalogue (2016). Frequency percentages for out of stock medicines, classified according to the VEN system were calculated for each VEN category.

3.7.2 Qualitative data from focus group discussions

The recorded FGDs were transferred from the digital voice recorder to a computer and stored as Windows Media Audio files. Each FGD was transcribed verbatim and saved as an MS Word™ document. Transcripts were imported into a qualitative data analysis software programme, NVivo10™.

Data were analysed using a process of coding into categories and development of themes. The transcripts were read a number of times to explore and obtain an understanding of the data. The researcher used the NVivo10® software to code the data into categories and sub-categories, referred to as “nodes” in NVivo10®. Patterns and connections within and between categories were identified. The data was coded by an independent coder. Codes and categories were compared and discussed by the researcher, independent coder and supervisors to reach consensus. Categories were developed into a framework of key themes.
to provide an accurate reflection and understanding of the perceptions of the participants (Richards, 2005).

3.8 RELIABILITY, VALIDITY AND TRUSTWORTHINESS OF DATA

The data collection instruments were tested during the pilot study, which enhanced validity of the study to yield accurate and producible results. A possible threat to the content validity of the actions taken by the researcher intervention was the unwillingness of the health care workers to aid in the interventions necessary to ensure the availability of the medicine. The collected data were also cross checked with the out of stock report records from the main pharmacy to ensure the validity of the data.

The researcher recognises that this study was only conducted in the ICU units of one public sector academic hospital. The results will therefore not be generalisable to all wards or all hospitals in South Africa. All data entered were cross-checked by the researcher for accuracy and completeness on a daily basis to ensure the reliability of the data entry.

The focus group discussions were conducted by an experienced moderator, which enhanced the trustworthiness of the focus group data. The researcher had continuous review of the process and findings with the supervisors who are experienced in qualitative data analysis to ensure credibility of the results. Dependability was increased by on-going discussions between the researcher, an independent coder and the supervisor to reach consensus regarding code-recode procedures. Continuous self-reflection by the researcher and review of study procedures by the supervisor helped in ensuring conformability of the study.

3.9 BIAS

To avoid selection bias, all out of stock medicines during the data collection period were included in the study. A form of bias that was taken into consideration was time bias, which occurred when the lengths of intervals were analysed at any point in time when the activities were carried out.

Human factors were taken into consideration during the interpretation of the results since the success of the project was dependent on the people working in practice and the amount of medicines that were out of stock during the period. The researcher ensured that that the follow-up period was monitored to reduce bias.
3.10 ETHICAL CONSIDERATIONS

Ethical clearance for the study was obtained from the Sefako Makgatho University Research Ethics Committee (SMUREC) before the commencement of the study (SMREC/H/129/2015:PG) (see Appendix 5). Permission to conduct the study at DGMAH was obtained from the hospital's chief Executive Officer (CEO), the pharmacy manager and the departmental heads of the adult ICU and NICU (see Appendix 6). All focus group participants and participants who were indirectly involved in the study were given information about the study, after which they provided written informed consent. Confidentiality was maintained and all data were made accessible to the researcher and the supervisors only. Data will be kept safe for period of five years.

3.11 SUMMARY

This was a descriptive, operational study that was conducted prospectively, over a period of seven months. The study took place specifically in the NICU and the adult ICU at DGMAH where medicines are kept as ward stock. Data collected on out of stock medicines were collected on a daily basis as part of usual practice as quantitative data. Focus group discussions (FGDs) were conducted with nurses in the ICUs, to obtain their perspective on the describe the practice implications of out of stock medicines as qualitative study.

Quantitative data were captured on MS Excel™ spread sheets and checked for accuracy and correctness. Qualitative data were recorded with a digital recorder, transcripts were imported into a qualitative data analysis software programme, NVivo10™. Data were analysed using a process of coding into categories and development of themes. The transcripts were read a number of times to explore and obtain an understanding of the data

Ethical approval to conduct the study was obtained from SMUREC and was adhered to throughout the study. The researcher recognises that this study was only conducted in the ICU units of one public sector academic hospital. The results will therefore not be generalizable to all hospitals in South Africa.
4.1 INTRODUCTION

The results of the study and the discussion thereof are presented in this chapter in the format of two manuscripts for publication in peer-reviewed accredited journals. The first manuscript will be submitted for consideration of publication to the *Curationis Journal of South Africa*. The author guidelines are available in Appendix 7. The second manuscript will be submitted to the *Journal of Nursing Management*, for which the author guidelines are available in Appendix 8.

The findings of the focus group discussions were presented as a poster at the Public Health Association of South Africa Conference, held in East London, from 19-22 September 2016. A copy of the poster appears in the last section of this chapter.

4.2 MANUSCRIPT 1

The main rationale for this study was based on the challenges experienced with medicine shortages over the past two years at DGMAH and elsewhere (see Chapter 1). Since the conceptualisation of the study, various interventions have been implemented by the Department of Health as well as the hospital, to improve medicines availability. While this was a positive move towards better service delivery for patients, it limited the progress of this study in terms of obtaining sufficient data, especially because the study was conducted specifically in the ICUs.

At the time of the study, an undergraduate BPharm project, which was co-supervised by the researcher, was conducted at the main pharmacy outpatient department (OPD) also to investigate medicines unavailability, but for outpatients. To provide a more comprehensive description of the out of stock situation at DGMAH, the results from the pharmacy OPD (BPharm project) were combined with the results from the ICUs (this MPharm project). The combined results are presented in the manuscript contained in this section, formatted according to the requirements of *Curationis Journal of South Africa* (see Appendix 7). Table 4.1 outlines the roles and contributions of the authors of Manuscript 1, presented in this section.
### Table 4.1: Author contributions for Manuscript 1

<table>
<thead>
<tr>
<th>Author</th>
<th>Affiliation</th>
<th>Role and contribution</th>
</tr>
</thead>
</table>
| Ms Molebogeng Mochabi Matimela | Department of Pharmacy, Faculty of Health Sciences, School of Health Care Sciences, Sefako Makgatho Health Sciences University | MPharm post-graduate student  
First author: Manuscript 1  
Conceptualisation of MPharm study, writing of protocol, data collection, data entry, data analysis and interpretation  
Wrote first draft of the manuscript, including the MPharm and the BPharm study  
Co-supervisor of BPharm study, data analysis |
| Prof Johanna Catharina Meyer | Department of Pharmacy, Faculty of Health Sciences, School of Health Care Sciences, Sefako Makgatho Health Sciences University, South Africa | Supervisor of the MPharm and the BPharm studies  
Conceptualisation of MPharm- and BPharm projects; guidance with protocol- and manuscript writing  
Assisted with data analysis and interpretation  
Revised the manuscript and approved the final version |
| Prof Natalie Schellack | Department of Pharmacy, Faculty of Health Sciences, School of Health Care Sciences, Sefako Makgatho Health Sciences University | Co-supervisor of the MPharm and the BPharm studies  
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Assisted with data analysis and interpretation  
Revised the manuscript and approved the final version |
| T Mohamed; N Ally; MD Mphetu; J Mwazembeni | Department of Pharmacy, Faculty of Health Sciences, School of Health Care Sciences, Sefako Makgatho Health Sciences University, South Africa | Final year BPharm students  
Writing of protocol for BPharm study, data collection, data entry and data analysis (see Appendix 9 for SMU clearance: SMUREC/H/152/2015;UG)  
Revised the manuscript and approved the final version |

### 4.2.1 Letter to the editor

A cover letter to the editor of *Curationis Journal of South Africa*, which will accompany the manuscript, is included in this section.
Prof Fhumulani Mavis Mulaudzi
Editor-in-Chief
Curationis Journal of the Democratic Nursing Organisation of South Africa

Dear Prof Mulaudzi

RE: SUBMISSION OF A MANUSCRIPT FOR PUBLICATION

I am pleased to submit an original research article entitled “Evaluation of medicine shortages in intensive care units and the pharmacy outpatient department at a public sector academic hospital in the Gauteng Province of South Africa” for consideration of publication in Curationis Journal of the Democratic Nursing Organisation of South Africa.

With the submission of this manuscript I would like to declare that the manuscript has not been published elsewhere, accepted for publication elsewhere or under editorial review for publication elsewhere, and that my institution (Sefako Makgatho Health Sciences University) has granted permission for publication of this article.

I further declare that all the authors have critiqued and approved the content of the manuscript and have contributed significantly to the work. The authors have no conflict of interest to disclose and no sponsorship was received for the study.

Thank you for your consideration of our manuscript.

_______________________
Molebogeng Matimela (first author)

Date: __________________

Tel: 012 5214212; Cell: 0836255699
4.2.2 Manuscript 1 for publication

Evaluation of medicine shortages in intensive care units and the pharmacy outpatient department at a public sector academic hospital in the Gauteng Province of South Africa

Significance of work: This manuscript reflects on the range of, and reasons for, out of stock medicines in the intensive care units and pharmacy outpatient department at a public sector academic hospital. It also describes some practical implications for health care professionals to ensure the availability of medicines for inpatients. The findings can be used to identify the most appropriate approaches for mitigating out of stock situations in future.

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**Author contributions:**

MM, JCM and NS designed the research strategy. MM collected data under the supervision of JCM and NS, and wrote the first draft of the manuscript. TM, NA, MDM and JM contributed towards data collection and data analysis. All authors participated in the interpretation of the data, revised the manuscript and approved the final version.
Evaluation of medicine shortages in intensive care units and the pharmacy outpatient department at a public sector academic hospital in the Gauteng Province of South Africa.

Background: Medicine shortages have been a challenge in the delivery of health care services, globally, as well as in South Africa. Shortage of medicines can have a negative impact on patient care and service delivery. Availability of medicines was identified as one of the fast-track areas for quality improvement in preparation for National Health Insurance implementation.

Objectives: This study aimed to conduct an evaluation of the unavailability of medicines for inpatients in the intensive care units (ICUs), and for outpatients collecting their medicines from the pharmacy outpatient department (OPD).

Method: A two-part descriptive and quantitative study was conducted over a period of seven months. Part 1 was operational and took place specifically in the neonatal intensive care unit (NICU) and the adult intensive care unit (ICU), where medicines are kept as ward stock. Part 2 used a cross-sectional design and was conducted at the main pharmacy OPD where patients receive their medicines as per prescription.

Results: In total, 42 medicine lines were out of stock from the adult ICU (19; 44.7%), NICU (10; 24.0%) and pharmacy OPD (13; 30.4%). Categorised according to the Anatomical Therapeutic Classification (ATC), alimentary tract and metabolism items (28.6%), general anti-infectives’ for systemic use (19.0%) and dermatologicals (14.9%) constituted nearly two thirds of all out of stock medicine lines. Essential medicines constituted 40.5% of out of stock medicine lines, 35.7% were vital items and 23.8% were non-essential medicines.

Conclusion: Medicine shortages affect service delivery, however with some advanced planning and interdisciplinary support, health care professionals can take steps to alleviate the harm that may occur from medicine shortages when patients seek care.
Introduction

Availability of medicines is a key factor in determining access to safe, effective and efficient treatment (Paparella & Horsham 2012). Over the last number of years, medicine shortages have been a challenge in the delivery of health care services, globally, as well as in South Africa (International Pharmaceutical Federation (FIP) 2013, Gray 2014). The situation has been a critical issue, and attempts to decrease and manage stock outs and medicine shortages have become a number one priority (FIP 2013).

In 2010 South Africa experienced a rampage of shortage of over 80 medicinal items in the public health care sector (Nieuwoudt 2010). Since then, the severity of the problem varied from province to province, and hospital to hospital, depending on the leadership and management skills practiced within various institutions (Nieuwoudt 2010, Link et al., 2016).

The South African government has shown commitment to improve the quality of health care services, with the development of the National Core Standards (NCS) by the National Department of Health (NDoH 2011). Six ministerial fast-track areas for quality improvement have been identified, including the continuous availability of medicines and supplies in the health care service to meet patients’ health care needs (NDoH 2011). Nonetheless, public sector hospitals in South Africa have been experiencing numerous out of stock situations and shortages of medicines (SSP 2016).

For the last three years, the Stop Stock Outs (SSP) project in South Africa, released an annual report of stock outs in South Africa, in an attempt to quantify the level of out of stocks in different provinces, identify the causes for medicines being out of stock and find solutions to unacceptable situations (SSP 2015). In response to the stock outs, the government has undertaken several initiatives to improve the supply chain for
medicines at various health care facilities, where out of stock situations have remained an undeniable threat to the health of the public (SSP 2015).

When health care facilities experience out of stock situations, the impact goes beyond health; there are cost implications and a waste of human resources, such as time spent on sourcing these out of stock items elsewhere, instead of caring for ill patients (SSP 2015). Hence a need to evaluate the situation and establish reasons for stock outs, which is important to be able to address and manage stock outs at all levels of care, and better inform interventions to address the problem.

**Contribution to field**

This study serves to provide insight into the range of medicine shortages experienced at a public sector academic hospital in the Gauteng Province of South Africa, particularly in the ICUs and the pharmacy OPD. It provides an overview of the range of problems encountered with out of stock medicines, the specific reasons for medicine shortages, as well as the practice implications to make medicines available for quality patient care. The findings can be used to identify the most appropriate approach for future interventions to mitigate and manage out of stock situations in the hospital environment.

**Methods**

**Study setting and design**

The study was conducted at a public sector academic hospital in the Gauteng Province of South Africa. It is the second largest hospital in South Africa and one of the four academic institutions in the province. The hospital has 28 clinical departments, rendering primary-, secondary- and tertiary health care services to approximately 1.7 million people from the surrounding four sub-districts. At the time of the study, the hospital had 46 wards and approximately 1 550 active beds.
This was a two-part study using a descriptive and quantitative methodology. The study design of Part 1 was operational and took place specifically in the NICU and the NICU, where medicines are kept as ward stock. Part 2 of the study used a cross-sectional design and was conducted at the main pharmacy OPD where patients receive their medicines as per prescription.

Definition of key concepts

- **The Anatomical Therapeutic Chemical classification system (ATC):** is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. (WHO 2013).
- **Drug shortage:** A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent (Fox *et al.* 2009).
- **Out of stock medicines:** The medicines required for patients’ use, are physically not available in the health care facility (Dias 2012, Stop Stock Outs Project (SSP) 2015).
- **Shortage of stock:** When the health care facility does not have enough medicines available for patients until the next order could be received (Dias 2012).
- **Vital items:** Medicines which the hospital cannot function without (Gupta *et al.* 2007; Dias 2012).
- **Essential items:** Medicines which the hospital can function without but may reflect negatively on the quality of services provided by the health care facility (Gupta *et al.* 2007; Dias 2012).
- **Non-essential items:** The unavailability of these medicines will not necessarily affect the functioning of the health care facility (Gupta *et al.* 2007; Dias 2012).

Study procedures and sampling

**Part 1: Intensive care units**
Part 1 included medicines kept as ward stock in the NICU and the adult ICU. According to the ward medicines stock lists at the time of the study, there were approximately 209 medicine items in use at the two ICUs, which included approximately 70 items in the NICU and 139 items in the adult ICU. No sampling occurred, as it was theoretically possible that any of the 209 medicine items could be unavailable in one of or both of the two ICUs.

Data collection for Part 1 of the study took place over a period of seven months. The pharmacist worked in collaboration with the nurses responsible for the medicines room in each of the two ICUs. The data collection process took place in four steps as illustrated in Figure 1, with steps being repeated for each item identified as being out of stock during the study period.

**Step 1** of the data collection entailed the identification of a medicine shortage at any particular point in time, when the pharmacist identified an item as being out of stock, or when nurses observed an out of stock item during their daily practice. For the seven month study period, each out of stock medicine item was recorded only once, independent of the number of patients for whom the item was out of stock, the number of times it had been out of stock, as well as the duration it had been out of stock. Hence, for the purpose of this paper, referral is made to an out of stock medicine line. In **Step 2** information about the reason for the out of stock situation and proposed action plan to obtain the medicine was recorded.

Depending on the reason for a medicine being out of stock, necessary actions to obtain the medicine were implemented in **Step 3**. In **Step 4** the identified out of stock medicines or therapeutic alternatives were made available to the ICUs. Throughout the entire process, the pharmacist ensured effective means of communication with other health care professionals to ensure the accomplishment of appropriate interventions. All information collected were recorded on a medicines availability monitoring sheet.
Part 2: Pharmacy outpatients department

Part 2 included adult patients ≥18 years, who arrived at the main pharmacy OPD to collect medicines for their prescriptions. A sample size of 375 patients was estimated at 95% confidence level with an expected frequency of 50% and 5% margin of error. Random sampling was used to select patients as they arrived at the pharmacy OPD. Inpatients, patient cards, to take out (TTO) prescriptions and paediatric patients (<18 years old) were excluded from the sample.

Data collection for Part 2 of the study took place over a period of two weeks by four trained data collectors. Patients were sampled randomly, by selecting every tenth patient, between 08h00 and 16h00 as they arrived at the pharmacy OPD. Possible participants were provided with information about the study and requested to provide written informed consent upon agreement to participate. Medicines availability data were collected during an interview with the patient, once they received their dispensed medication. The number of items prescribed, the number of items dispensed and the actual items being out of stock, were obtained from the patient’s file and prescription, and recorded on a data collection sheet.
Figure 1: Conceptual data collection framework

Data analysis

Data were captured using Microsoft Excel™ and checked for accuracy and correctness. Statistical analysis was of a descriptive nature. The ATC index was used to categorise identified out of stock medicines according to the first level, which is the chemical substance. The frequency of medicine shortages were recorded upon identification by the pharmacist or the nurses during their daily practice.
The out of stock items were further categorised according to their health impact, into Vital, Essential and Non-essential items (VEN system), in line with the NDoH master procurement catalogue (2016). Frequency percentages for out of stock medicines, were calculated for each VEN category. The reasons for medicines being out of stock, were summarised descriptively.

**Ethical considerations**

Ethical clearance for the study was obtained from the Sefako Makgatho University Research Ethics Committee prior to commencement of the study at the ICUs (SMUREC/H/129/2015:PG) and the pharmacy OPD (SMUREC/H/152/2015:UG). Permission to conduct the study within the units at the hospital was obtained from the Chief Executive Officer and pharmacy manager.

**Informed consent**

All participants were provided with information about the study, and upon agreement provided written informed consent. Over the course of the study, health care professionals in the ICUs were requested to provide information regarding out of stock items. Although they were only participating indirectly in the study, they were also requested to provide written informed consent for their participation. Confidentiality was maintained as the information they provided remained anonymous.

**Data protection**

All data will be kept safe for the required period of five years with only the authors having access to the data. After five years the data will be destroyed according to university’s standard operating procedures.
Results

A total number of 42 medicine lines were identified as out of stock for the ICUs and the pharmacy OPD. Nearly half (19; 44.7%) of the out of stock medicines lines were from the adult ICU, followed by the pharmacy OPD with 13 (30.4%) out of stock medicine lines and the NICU accounting for 10 (24.0%) out of stock medicine lines.

At the pharmacy OPD out of stock medicines were identified from 375 patients’ dispensed prescriptions. Ninety (25.2%) of the 375 prescriptions contained one or more out of stock items, totalling 119 items. Most of the prescriptions (64; 71.1%) had only one out of stock item. For the majority of patients, similar items were out of stock, accounting for 13 medicine lines only.

Out of stock medicine lines according to the ATC classification

Table 1 presents a summary of the identified out of stock medicine lines, classified according to the ATC classification, by the main anatomical groups. Alimentary tract and metabolism items (ATC group A; 28.6%), general anti-infectives’ for systemic use (ATC group J; 19.0%) and dermatologicals (ATC group D; 14.9%) constituted nearly two thirds of all out of stock medicine lines.

Table 1: Out of stock medicine lines in the ICUs and pharmacy OPD, according to the ATC classification (n=42)
Out of stock medicine lines according to the VEN classification

Out of stock medicine lines were classified according to the VEN system. Vital items constituted 35.7% and the majority of vital items included medicines from the alimentary tract and metabolism (11.9%). Essential items constituted 40.5%, with the majority of items divided equally between general anti-infectives (7.1%), dermatologicals (7.1%), alimentary tract and metabolic (7.1%) and respiratory system (7.1%). A quarter (23.8%) of the medicine lines were non-essential items, with the majority of items from the alimentary tract and metabolism (9.5%).

Figures 2 to 4 illustrate the distribution of out of stock medicine lines in the ICUs and the OPD pharmacy according to the VEN system and by ATC classification.

<table>
<thead>
<tr>
<th>Sensory organs</th>
<th>0 (0%)</th>
<th>1 (2.4%)</th>
<th>0 (0%)</th>
<th>1 (2.4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>19 (45.2%)</td>
<td>10 (23.8%)</td>
<td>13 (31.0%)</td>
<td>42 (100%)</td>
</tr>
</tbody>
</table>

**Figure 2:** Distribution of vital out of stock medicine lines by ATC class
Figure 3: Distribution of essential out of stock medicine lines by ATC class

Figure 4: Distribution of non-essential out of stock medicine lines by ATC class

Reasons for out of stock items in the ICUs

A number of reasons for medicines being out of stock in the ICUs, and the actions taken by the pharmacist in the unit to address the situation, are listed in Table 2. The
most common reported reasons for out of stock medicines from the nurses, were assumptions made that the pharmacy is out of stock. However, upon investigation and according to the drug controller in the pharmacy, the items were either supply issues, or awaiting delivery from the supplier, hence the need to prescribe a therapeutic equivalent.

Upon investigation it was evident that in some instances the reason for an out of stock situation actually originated from the ward itself. In some instances the unit was out of stock of a certain item/s, because the item was not ordered on time by the designated nurse. Motivational items were also identified as out of stock. These items were not necessarily out of stock at the pharmacy. Due to extensive paper work and a motivation required before these items can be obtained, nurses reported these items as out of stock, because they were not immediately available in the ward, at the time when the item was needed for a particular patient.

As a result of the operational design of the study, if an item was out of stock in the unit but available in the main pharmacy, the pharmacist, in collaboration with the designated nurse responsible for ordering medicines, assisted the unit to order and obtain the item from the main pharmacy.

Service delivery was negatively affected as a result of out of stock situations. The pharmacist and the nurses in the units had to spend time and direct their attention towards sourcing out of stock items elsewhere or obtain an alternative medicine, to prevent treatment interruption and ensure adequate patient care.
Table 2: Reasons for out of stock medicines, and actions taken by the pharmacist in response

<table>
<thead>
<tr>
<th>Reasons for out of stock medicines in the ICUs</th>
<th>Actions taken by pharmacist</th>
</tr>
</thead>
</table>
| Substantial delays from suppliers (e.g. late delivery) and lack of advanced warning regarding items which will be out of stock due to supplier issues | • Make follow-up with relevant procurement units on orders placed and still awaiting delivery  
• Find an interim suitable alternative |
| Item out of stock at the **pharmaceutical depot** | • Follow-up with the drug controller at the pharmacy  
• Find an interim suitable alternative  
• Communicate with nurses regarding the use of an alternative and when the item will be available |
| Extensive paper work and motivation required to obtain **motivational items** | • Complete the appropriate documentation  
• Submit documentation to the main pharmacy, to obtain the item |
| Shortage of medicines due to an item not being on the **tender list** | • Resubmission of acquisition to procurement unit  
• Find an interim suitable alternative |
| Difficulty in obtaining a suitable therapeutic alternative as a result of the **pharmacy being out of stock** | • Pharmacy would source an item from another hospital in the vicinity  
• Follow-up with procurement unit regarding items which are known to be out of stock at the pharmacy  
• Find an interim suitable alternative |
| Orders not placed on time or items not ordered at all, resulting in the **ward being out of stock** | • Complete the ordering form and submit to the main pharmacy  
• Make nurses aware of items being out of stock in the ward, and which should be ordered from the main pharmacy |
| **Emergency** trolley item not replaced and / or not ordered | • Complete the ordering form and submit to the pharmacy  
• Obtain the item from the pharmacy |

**Discussion**

Evaluation of medicines availability enables health care professionals to manage medicines inventory appropriately, maintain required safety stock of high priority medicines and reduce out of stock situations (Pund et al, 2016).

The results of this study showed a variation of out of stock medicines within the ATC classes as well as reasons behind out of stock situations. From the VEN classification, it was evident that the most affected out of stock items at this public sector hospital
were either vital (35.7%) or essential (40.5%) medicines, despite the fact that a hospital cannot function without vital items, which should always be available (Gupta et al. 2007; Dias 2012). Stock outs are not confined to South Africa only, as illustrated by a similar study conducted in Ethiopia, which showed vital item shortages and unavailability in the different regions over a period of six months (Migburu et al., 2016).

Following-up on reported out of stock medicines in the ICUs, indicated complex underlying reasons, varying for the different out of stock medicines. The Pharmacy Department was often held responsible for items being out or stock and charged with the responsibility for managing the out of stock situation. In most instances though, the situation was beyond the control of the Pharmacy Department, such as interruptions in pharmaceutical supplies, similar to what was seen in other settings (Abdelraham 2016).

Different reasons contributed to out of stock situations, of which some were due to internal problems between the suppliers and facilities, while a minority of stock outs were due to national or international shortages, which coincide with some of the reasons for stock outs as reported by the WHO (2016). Each out of stock was related to a specific set of challenges, which included difficulties with sourcing an alternative, delay in obtaining a motivational item, unit being out of stock due to lack of information regarding out of stock items, pharmacy out of stock, unanticipated increase in demand for a particular medicine and an item no longer on the tender list. In some instances medicines were out of stock because of management and logistical problems at provincial depots and not because of supplier issues. These reasons for stock outs were not isolated and similar to what was reported elsewhere. Tenders being awarded to single suppliers, also contributes to shortages because of exclusion of alternative suppliers from the market, resulting in reduced production of particular products (FIP 2013; Gonzalez 2015; SSP 2015; Pund 2016).
In most instances medicines reported as out of stock from the ICUs, were also out of stock at the main pharmacy. There was however lack of communication between the main pharmacy and the ward staff, as ward staff were not always informed regarding out of stock medicines by the pharmacy department. A similar situation was observed in the study conducted by Abdelrahman (2016). A minority of medicines shortages were due to pharmaceutical companies not being able to supply sufficient quantities. This was a worldwide problem, where the inability of manufactures to respond to certain challenges, contributed to the shortages for instance with the benzathine penicillin (WHO 2016). In the event of a medicine shortage due to supply issues, an alternative had to be sourced, which was sometimes not possible.

Apart from patients’ health being compromised by medicines shortages, health care professionals, especially pharmacists, are also affected due to additional time spent on solving problems caused by out of stock situations (FIP 2013). According to a study conducted in 2011, pharmacists reported to be spending nine hours a week trying to manage medicine shortages (FIP 2013; EAHP 2014).

Even though reports on out of stock medicines are still on-going, both at national level and in some provinces, there is hope to manage the situation in health facilities and to actively unite to avoid medicine stock outs in South Africa’s health system (FIP 2013, SSP 2014). Hence monitoring medicines supply chain management should be of paramount to help managers to redistribute medicines across the health facilities as well as to manage emergency orders when necessary (Gray 2014).

An effective way to manage out of stock situations is to use a well structured system of reporting on medicines (Migburu et al., 2016). Rx Solution® is an electronic system which is used to control and manage inventory. It is specifically designed to manage pharmaceutical supplies from procurement to dispensing. Although Rx Solution® was used to a certain extent for inventory control by the pharmacy, a manual
inventory management system was used in the ICUs and all the other wards at the study facility.

**Limitations of the study**

The major limitation of the study was the fact that it was conducted in one hospital and in the ICUs and the pharmacy OPD only, which limits the generalisability of the results. As a result the sample size in terms of out of stock medicine lines was small. Reasons for stock out situations were determined for inpatients only, which further limits the generalisability of the results.

**Recommendations**

Based on the results of this study, a number of recommendations are offered. A pharmacist and/or pharmacist assistant from the pharmacy should be dedicated to each unit, to resolve out of stock situations, respond to stock out challenges in the ward and facilitate communication between the pharmacy and the wards. Better communication and collaboration within the multi-disciplinary team between healthcare professionals in handling out of stock situations, will facilitate better patient care.

The NDoH should continue to provide information on medicine shortages to all health facilities. A structured approach of disseminating information on out of stock medicines from the pharmacy to ward level, especially for medicines without a suitable substitution, is recommended. This will assist in pro-actively identify and put measures in place to respond to medicines shortages (WHO 2015, WHO 2016).

The initiative of split tenders for medicines which are in high demand, should be strengthened, which will enhance the security of supply. Lastly, all hospitals should support the development of an early warning shortage notification system, to identify substitutes, alternative suppliers or other mitigation measures on time (WHO 2016).
Conclusion

This study showed that out of stock medicines is a reality, resulting in inadequate medicines availability for inpatients and outpatients at this public sector health facility. Medicine shortages affect service delivery, however with some advanced planning and interdisciplinary support, health care professionals can take steps to alleviate the harm that may occur from medicine shortages when patients seek care.

Acknowledgements

The authors would like to thank the management of the hospital for the opportunity to conduct research at this facility. We sincerely appreciate the participation of all pharmacy personnel, nurses and patients who made the study possible.

Competing Interests

The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.

Authors’ contributions

MM, JCM and NS designed the research strategy and wrote the manuscript. MM collected data under the supervision of JCM and NS wrote the first draft of the manuscript. T, N, MD and J contributed towards data collection and analysis. All authors participated in the interpretation of the data, revised the manuscript and approved the final version.

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4.3 MANUSCRIPT 2

4.3.1 Letter to the editor

A cover letter to the editor *Journal of Nursing Management*, which will accompany the manuscript is included in this section.
John Daly
Editor-in-Chief
Journal of Nursing Management

Dear Sir

RE: SUBMISSION OF A MANUSCRIPT FOR PUBLICATION

I am pleased to submit an original research article entitled “It’s really affecting us badly because we are the ones with the patient most of the time.’ Intensive care nurses’ perceptions of medicines unavailability at an academic hospital” for consideration of publication in Journal of Nursing Management.

With the submission of this manuscript I would like to declare that the above-mentioned manuscript has not been published elsewhere, accepted for publication elsewhere or under editorial review for publication elsewhere, and that my Institution (Sefako Makgatho Health Sciences University) has granted permission for publication of this article.

I further declare that all the authors have critiqued and approved the content of the manuscript and have contributed significantly to the work. The authors have no conflict of interest to disclose and no sponsorship was received for the study.

Thank you for your consideration of our manuscript.

__________________________
Molebogeng Matimela (first author)
Date: _________________
Tel: 012 5214212; Cell: 0836255699
4.3.2 Manuscript 2 for Publication

**Manuscript Title:** ‘It’s really affecting us badly because we are the ones with the patient most of the time.’ Intensive care nurses’ perceptions of medicines unavailability at an academic hospital

**Word count:** (4657)

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**Acknowledgements**

The authors would like thank the management of the hospital for the opportunity to conduct research at this facility. We sincerely appreciate the participation of all pharmacy personnel, nurses and patients who made the study possible.
Manuscript Title: ‘It’s really affecting us badly because we are the ones with the patient most of the time.’- Intensive care nurses’ perceptions of medicines unavailability at an academic hospital

Abstract

Aim: To explore the practice implications of out of stock medicines from the perspective of nursing staff.

Background: Medicine shortages over recent years have posed challenges to health care service delivery globally. Pharmacists and nurses are affected due to additional time spent solving problems caused by out of stock medicine situations.

Methods: A qualitative descriptive study was conducted in two intensive care units (ICUs). Two focus group discussions were conducted with 12 professional nurses, one in the adult ICU and another in the neonatal ICU, to explore the practice implications of out of stock medicines. Data were coded into categories and developed into a framework of themes.

Results: Essential medicines being out of stock have been a problem for a long period of time, with reasons for unavailability often not known. Unavailability of medicines had a negative impact on patient care. Actions resolving problems resulted in a waste of time and human resources. Taken by nursing and pharmacy staff included sourcing the item from another ward or hospital, or requesting a substitute. Suggested mitigations included a dedicated pharmacist for the units, more effective communication amongst multi-disciplinary team members on out of stock situations and a pro-active approach from the pharmacy.

Conclusion: Active involvement of pharmacists in the ICUs will facilitate more effective management of out of stock medicines as well as communication between the wards and the pharmacy.

Implications for nursing management: A collaborative approach by healthcare professionals can be implemented to actively assist nurses in providing quality health services.

Keywords: Nurses, medicines, out of stock, communication, pharmacy
Chapter 4: Results and Discussion

**Introduction**

Medicine shortages are a worldwide phenomenon. A recent comment in a Belgian pharmacy journal claims that the problem is global – ‘from Afghanistan to Zimbabwe’ – and lists 21 countries affected by a variety of supply problems. Amongst the list of medicine shortages reported around the world, the most significant groups of medicines are generic injectable chemotherapy agents, injectable anaesthetic agents, intravenous nutrition and electrolyte products, enzyme replacement products and radiopharmaceuticals (Gray & Manasse 2012; Stop Stock Outs Project (SSP) 2014; World Health Organization (WHO) 2016).

Access to quality health care is a problem that has plagued South Africa for many years, urging the government to develop the National Core Standards (NCS), which would require compliance by all health establishments in South Africa. Structured according to seven crosscutting domains, the NCS outlined six priority areas for fast track improvement, amongst which waiting times and availability of medicines pertain to pharmaceutical services (National Department of Health (NDoH) 2011).

Most pharmacists in hospital settings are involved with dispensing and distributing medicines, but once medicines are distributed, pharmacists provide very little support to nursing staff with regard to inventory management, to ensure that medicine supplies are adequate and the quality of medicines is maintained (Schellack & Meyer 2010). Availability of medicines is a key factor in determining access to effective treatment. Apart from patients’ health being compromised by medicine shortages, healthcare professionals, especially pharmacists and nurses, are affected due to additional time spent on solving problems caused by out of stock situations (International Pharmaceutical Federation (FIP) 2013; SSP 2015). When medicine shortages occur, nurses and pharmacist are required to act quickly to identify and obtain an alternative, to prevent disruption in patient care (Kaakeh et al. 2011).

In this article, we aim to explore intensive care unit (ICU) nurses’ perceptions about the practice implications of out of stock medicines at an academic hospital in South Africa.
Background

Medicine shortages

Availability of medicines have been a concern towards improving medicine supply, were health care facilities are faced with out of stock situations (SSP 2015). Medicines are classified as out of stock if the stock required for patients’ use is physically not available in the health care facility (Dias 2012; SSP 2015). Shortage of stock can be described as the health care facility not having enough medicines available for patients until the next order could be received, or as stock on the shelves reaching its minimum levels, which indicates that the product is or will be out of stock within the next few weeks or months (Dias 2012; American Society of Health System Pharmacists n.d.; De Weerdt et al. 2015).

Medicine shortage may be related to, but not limited to, manufacturing delays, active ingredient unavailability, supplier issues and increased demand (Logan et al. n.d.). Frequently, medicine shortages occur with little warning and often with no communication to help the pharmacy determine the duration of shortage. The increasing complexity of medicine shortages underscores the need for a strong working relationship between health care workers to optimize patient care (Kelly et al. 2013).

Extent of the effect of medicine shortage on nurses

Studies have reported a global impact of medicine shortages, the situation has been increasing in recent years prompting international concerns (WHO 2016). Although the South African government have implemented some successful initiatives to improve the supply chain for medicines over the past years, the situation remains an undeniable threat to the health of the people of South Africa (SSP 2015). In most hospitals, nurses currently manage inventory in the hospital wards, i.e. ordering, receiving, storage and issuing of medicines (Schellack & Meyer 2010). As such, they are affected by the out of stock medicines situation more closely, as their work requires administration of medicines to patients. Health care professionals, especially pharmacists and nurses, often spend a large amount of time, more than an hour per week, in managing the out of stock medicines and communicating with relevant stakeholders to ensure availability of medicines (Kaakeh et al. 2011; International Pharmaceutical Federation 2013; European Association of Hospital Pharmacists 2014). Nurses constantly need to follow-up with calls to the pharmacy, seeking clarity of the
relevant alternatives provided by the pharmacy (European Association of Hospital Pharmacists 2014).

According to the annual Stop Stock Outs survey report, primary health care facilities in South Africa are expected to report on out of stock medicines on weekly. (Nieuwoudt 2010; SSP 2015). When medicines are not available, it means that trained health care professionals, nurses in particular, practise without some of the most important tools at their disposal (SSP 2014). This results in the absence of significant medicines, causing patients to suffer pain unnecessarily. Other measurable human impacts also occur in terms of hours wasted sourcing out the out of stock items and patients left untreated, which in turn affect the confidence of the public in the health care service (SSP 2014).

**Methodology**

**Setting and context**

This study was conducted at Dr George Mukhari Academic Hospital, situated in Ga-Rankuwa, in the north-western part of Tshwane, Gauteng Province. The hospital gained academic status in 2011, which was followed by the establishment of the new Sefako Makgatho Health Sciences University building on the legacy of the old Medical University of South Africa. It is the second largest hospital in South Africa with approximately 46 wards in total and 1550 active beds. The hospital renders a variety of services including paediatric, dermatological, psychiatric, cancer and surgical treatment with few satellite clinics and pharmacies, for example an antiretroviral clinic and psychiatric clinic.

Medicines in the wards are managed by nurses. Stock is received on a weekly basis from the main pharmacy, although the pharmacy is not actively involved in the day-to-day management of ward stock.

**Participants**

A descriptive study was conducted in the adult and neonatal ICUs, collecting qualitative data in the form of two focus group discussions (FGDs) with nurses to explore the practice implications of out of stock medicines. The study population for the FGDs included professional nurses specifically designated for medicine management in the six months prior to the FGDs. Purposeful sampling was used to recruit 12 participants in total from both units, aimed at the selection of individuals
who shared characteristics relevant to the study and who could contribute most in accomplishing the objectives of the study.
Data collection

Two FGDs were conducted within a week, one in the adult ICU and another in the neonatal ICU, with each FGD lasting approximately 45 minutes. The times and dates of the FGDs were determined according to the availability of the nurses in both wards. The FGDs were conducted in an arranged private room with limited disturbance during the discussions. Prior to the commencement of the FGDs, information about the study was provided to the participants and written informed consent was obtained from all. The FGDs were facilitated by an experienced focus group moderator, using a FGD guide consisting of open-ended questions and observational notes. Probes and further questions were used to verify unclear responses, seek further explanations and encourage participants to elaborate on their responses. A digital voice recorder was used to record each of the discussions.

Data analysis

The recorded FGDs were transferred from the digital voice recorder to a computer and stored as Windows Media Audio files. Each FGD was transcribed verbatim and saved as a Microsoft Word® document. Transcripts were imported into a qualitative data analysis software programme, NVivo 10®. Data were analysed using a process of coding into categories and development of themes. The transcripts were firstly read a number of times to explore and obtain an understanding of the data. The data were coded into categories and sub-categories, referred to as ‘nodes’ in NVivo 10®. Patterns and connections within and between categories were identified. An independent coder also coded the data after which codes and categories were compared and discussed to reach consensus between the two codes. The most relevant themes related to implications were developed into a framework of key themes to provide an accurate reflection and understanding of the perceptions of the participants (Richards 2005).

Results

Four specific themes emerged from the focus group data, namely, (1) out of stock medicines situation; (2) impact of out of stock medicines; (3) actions taken by the nurses; (4) possible suggestions to mitigate the situation. Figure 1 illustrates how the themes related to one another.
Figure 1: Frame work of themes from the study

Out of stock medicines situation

Extent of the problem

It was also evident that the availability of medicines was not consistent. It was evident from the FGDs that the shortage of medicines in the ICUs has been an on-going challenge for the provision of health care. According to the nurses, there were numerous reports of out of stock medicine over the past year. However it appeared as though the extent of the problem was not always the same. One of the nurses
acknowledged that the out of stock situation is better while another felt it was getting worse, as there were many items out of stock. They described the situation as follows:

‘At the moment it’s better but there are still a lot of out of stock medication.’
(Participant 5)

‘The situation of out of stock is getting worse, not better.’ (Participant 6)

Participants furthermore eluded to the fact that the situation was often unpredictable to them, as it is not specifically one item being out of stock. Essential emergency medicines were often out of stock, which was a great concern expressed by the nurses.

‘I cannot say is specifically one item at a time. You find that we are running short of one item this week; the following week it’s another item. For example the past week we had a problem with potassium chloride, this week it is adrenaline, and next week it could be labetalol. So, it’s not one item at a time, and most of the items we really cannot function without in the ICU’. (Participant 7)

Often when medicines shortages are experienced within the hospital health care professionals are prompt to urgently find a suitable available substitute from other wards or nearest hospital, to ensure continuous patient care.

‘There were a lot medicines which were out of stock. Just to name a few it was haloperidol, sodium valproate at some stage, lorazepam and Omnopon®, which is a strong anaesthetic, still being out of stock.’(Participant 7)

‘And there was at one stage we never had adrenaline, we had to borrow from other hospital.’ (Participant 9)

Reasons for out of stock medicines

There were various reasons for medicines being out of stock, however most instances, the pharmacy did not provide clear explanations to the nurses for out of stock situations. Because nurses did not always know why medicines were out of stock, they made their own assumptions such as that it was due to delay in payments of the suppliers by the hospital. This kind of misperception is illustrated by the following narratives:

‘In most instances we only assume amongst ourselves that it is probably due to lack of funds or the hospital did not pay their debts to the suppliers. We assume because we are never told the reasons.’ (Participant 9)
‘They normally do not give us reasons. The only time we were given a reason was
with one of the inotropes. They said it is a supplier issue, and that they are
expecting stock soon. I think it was adrenaline.’ (Participant 7)

Challenges experienced

Lack of communication between the pharmacy department and other health care professionals regarding out of stock medicines was identified as a challenge. On several occasions, nurses did not receive sufficient communication about out of stock situations from the pharmacy. The communication was rather untimely or there was no information communicated to the nurses at all.

‘We don’t know why, there is no communication from the pharmacy.’ (Participant 5)

‘The only communication we receive is on the prescription and usually in the
afternoon where the pharmacist will write out of stock next to the item which is not
available. Then patients end up not getting the treatment that day. Instead of the
pharmacy returning the prescription with no items, they could at least phone us
and let us know, so we can arrange or find an alternative other than writing out of
stock on the prescription.’ (Participant 5)

The unpredictability of medicine shortages and lack of information provided to health care professionals make it increasingly difficult to plan effective coping strategies, however nurses find a suitable way to maneuver through, as stated in below.

‘The sister allocated for ordering medicines usually notify us in our communication
book regarding items that are out of stock.’ (Participant 11)

Ordering of medicines from the pharmacy is done in a standardised manner for all items kept in the ward. Any changes to the ordering lists regarding certain medicines should be communicated to the nurses on time. Participants reported incidents where suddenly an item was no longer available from the pharmacy without a motivation form from the physician. When this was not communicated to them, nurses regarded these items also as out of stock:

‘We have been ordering imipenem as ward stock and all of a sudden we were told
it is now a motivational item. They should have communicated this with us
beforehand, so that we are aware.’ (Participant 5)
It was evident that the ordering and availability of motivational items required extensive paper work. Difficulties were experienced particularly in the late afternoon or after hours, when most patients were admitted. At this time quality services were compromised because consultants were not available in the wards. One of the nurses suggested that at least a certain number of motivational items should be kept in the ICUs to provide for emergency or after hour situations:

‘Motivational items are a problem especially for patients who are admitted after hours. Where do we get the motivational items after working hours? If we can at least have a certain number of motivational items kept in the wards, just in case we have a patient admitted after hours, the motivational letter can then be submitted the following day. If we don’t have anything on the shelf, then it means we cannot serve patients who come as emergency cases.’ (Participant 9)

Out of stock situations and resulting substitution action affect the supply chain management of medicines As a result of lack of communication, nurses highlighted that even the substituted item could be out of stock. One of the nurses explained this kind of challenge:

‘Sometimes even the substituted items are not helpful. You find that the doctors prefer a certain medicine, only to find that it is also out of stock.’ (Participant 11)

Doctors were often received information concerning out of stock items from the nurses this often frustrated the nurses, because certain doctors would prescribe an item which the pharmacist would not agree to.

‘The doctors are not informed regarding items which are out of stock. Usually we inform them regarding items which are out of stock. (Participant 1)

Impact of out of stock medicines

Medicines being out of stock had an impact on the hospital pharmacists, pharmacy department, nurses, and most importantly, the patients. The lost and diverted time spent by health care professionals (pharmacists and nurses) in tracking medicines to meet a patient’s needs, amounts to a waste of human resources and time, as narrated by the nurses. Nurses alluded to the fact that they literally spent hours dealing with out of stock situations:
‘We spent hours dealing with the out of stock situation however it normally depends on the medication that is out of stock will look for it for about two hours.’ (Participant 10)

**Impact on patient care**

It was evident from the discussions that patients faced consequences as a result of medicines being out of stock. Treatment interruption as a result of medicine shortages leads to increased patient suffering, deterioration of the patient condition, development of resistance, missed or delayed treatment, or even death.

‘In one instance one of the patients was on tazobactam and was abruptly stopped because it was unavailable, the patient was on that treatment for only three days, when the medicine was out of stock and an alternative was prescribed. The patient developed resistance and had to go onto colistin, but unfortunately the patient demised.’ (Participant 5)

‘It is not for one patient in a day, it is a number of patients who misses their doses due to an out of stock situation. Something goes wrong with one patient in terms of medication every day.’ (Participant 6)

**Impact on health care professionals**

Nurses faced challenges in finding medicines to treat patients almost every day. This evidently had a negative impact on their work performance as they have to leave their workstation to attend to out of stock medicines situations, to solve the problem. Patients in the ICUs cannot be left unattended, hence nurses have to make arrangements with another nurse who is also attending to a patient, to observe the patient they are responsible for. Nurses voiced their frustration during the FDGs as follows:

‘It is really affecting us badly because we are the ones with the patient most of the time; it is quite frustrating.’ (Participant 5)

‘We run around a lot looking for different out of stock medicines. Normally we usually spent around one hour daily sorting out the out of stock item and that depends if I will be able to get the medicines. We usually call other wards beforehand to find out if they do have that item.’ (Participant 1)
‘Often when you sort out the out of stock situation, you ask another nurse to keep an eye on your patients and you continue when you come back.’ (Participant 1)

**Actions taken in response to out of stock medicines**

When faced with the challenges of out of stock medicines, nurses actively follow-up with the pharmacy department. In most cases, the hospital superintendents are also made aware of the situation, as it helps to speed-up the situation. They inform the doctors to prescribe an alternative, or they source the item from either another ward or another hospital in consultation with the pharmacy staff:

‘The pharmacy staff does try to find alternatives, because it’s quite rare to find any of our medicines from other wards, even if we try sourcing it out from another ward.’ (Participant 6)

‘If an item is out of stock we try by all means to communicate with the doctors to prescribe an alternative to the patient, even though sometimes this causes delayed medicine administration’ (Participant 1)

‘We do regular follow up to check if out of stock items have returned at the pharmacy.’ (Participant 2)

‘We often ensure we that patient prescription card are sent to the pharmacy in the morning to avoid shortage in the ward’ (Participant 3)

‘Usually we make sure that our superintendent is aware of the situation. Running around the hospital, is time consuming. Sorting out, out of stock situations is quite immeasurable in terms of time, because it’s not one item at a time, but around two-three hours, because often messengers are not around.’ (Participant 6)

**Possible solutions to mitigate out of stock situations**

Working in a large healthcare facility can make interaction with other healthcare professionals difficult; however, collaboration between nurses, doctors and pharmacists in medicines management could reduce the impact of out of stock medicines. The nurses gave a clear description on how the pharmacy department can mitigate this problem by assessing the situation within the hospital, determining the reasons for medicines unavailability plan to disseminate the information proactively and implement the plans.
The dissemination of information regarding out of stock medicines can be achieved by having one dedicated pharmacist to attend nurses’ meetings and inform them regarding out of stock items. A pharmacist or pharmacist assistant dedicated to the ICU wards would improve the communication between the nurses and the pharmacists:

‘It would help if we have one pharmacist assistant to come to the ward in the morning during our meeting, at least for five or 10 minutes, to address the out of stock issues.’ (Participant 5)

‘If we can have a contact person, we can call them beforehand, and the person might even help on the phone other than wasting time going to the pharmacy for no help.’ (Participant 6)

Often out of stock situations are as a result of poor communication amongst health care professionals. Effective communication amongst doctors, pharmacists and nurses will facilitate an understanding of medicine shortages:

‘Doctors and pharmacist are encouraged to have regular meetings which can be quarterly with head of departments should at least meet especially for ICU ward, or have a responsible person from the pharmacy for supplying and issuing the medicines should be at the meetings to address the out of stock medicines.’ (Participant 7)

**Discussion**

The main findings from the study highlight significant issues which influence the practice implications of out of stock medicines for health care professionals, especially nurses. Nurses play a vital role in coordinating the administration of medicines as they have the closest interaction with patients in the wards (Smeulers 2014). A study conducted by Popescu et al. (2011) identified that nurses helping and coordinating care with doctors and pharmacists is essential for safe medicines.

The study participants discussed several factors regarding out of stock medicines, with enlightening ideas on how to mitigate the challenges. The reasons for shortages of medicines have been investigated in several studies and include, but are not limited to, the following: limited number of manufacturers for active pharmaceutical ingredients e.g. benzathine penicillin (chronic short supply for several years); poor
visibility of demand; poor adjustments of procurement strategies; and fluctuations of price increases (WHO 2016).

In a large European survey, 21% of hospital pharmacists reported experiencing a shortage of medicines every day, while a further 45% reported experiencing a shortage every week. One in five pharmacists felt that they could not manage the shortages all or most of the time, suggesting that a medicine shortage causes patients to suffer disruption to their treatment (WHO 2016). This coincides with the findings of this study, where nurses alluded that they often spent hours looking for alternatives from the pharmacy when medicines are out of stock.

It is necessary to acknowledge that medicine shortages are a multidimensional problem; thus, healthcare professionals should collaboratively develop proactive coping strategies. At the moment, there is the Stop Stock Out survey project, keeping trends on shortages (SSP 2015), including efforts to respond to and prevent them. In some hospitals, early warnings do exist, but only in a limited number of countries and in certain hospitals (Iyengar et al. 2016). Hence, pharmacists, in collaboration with doctors and nurses, should conduct regular meetings about finding suitable substitutes (Abdelrahman et al. 2016).

Communication amongst health care professionals is a key factor which could help in improving and managing out of stock situations in a timely manner if communicated on time. When health care professionals do not communicate effectively, especially regarding critical information such as out of stock medicines, patients’ safety is at risk for several reasons (Abdelrahman et al. 2016).

To ensure effective communication between the pharmacy and nurses, medicine communication bulletins should be more commonly to available health care professionals. Pharmacy departments should identify an appropriate time on a weekly in the wards with an effort to ensure consistent management of medicine shortages (Kaakeh et al. 2011). When monthly bulletin with a list of medicine shortages with relevant substitutes or alternatives products distributed within the hospitals, it is imperative to ensure an awareness of the information to the health care professionals to help in timely decision making regarding certain out of stock medicines (Abdelrahman et al. 2016). In most instances health care professionals appeared to be less aware of the bulletin, which was meant to provide better information regarding out of stock medicines (Abdelrahman et al. 2016; WHO 2016).

**Implications for nursing management**
Further operational research should focus on pharmacists’ intervention in the wards to assist nurses with medicine shortages. Pharmacists and doctors should engage more to enhance effective communication and this will help nurses manage the out of stock medicines better as communicated to them also. Nurses would benefit from information relevant to the management of out of stock medicines through an effective and proactive pharmacy department.

**Strengths and limitations**

The study was the first of its kind in the ICUs of this hospital. Views expressed reflected those within the intensive care settings of the hospital only, however, data were validated and consensus was reached about the final themes. Although the study took place in only one hospital, which limits the generalisability of the findings, it provides a basis for future research on the practice implications of stock outs and the experiences of nursing staff in dealing with out of stock situations.

**Conclusion**

The findings of this study highlight the need to enhance the interaction and communication between nurses and pharmacists in order to facilitate the management of out of stock medicines. The active role of the pharmacist in the ward will be an intervention to mitigate out of stock situations.

**Acknowledgements**

The authors would like to thank the management of the hospital for the opportunity to conduct research at this facility. We sincerely appreciate the participation of all pharmacy personnel, nurses and patients who made the study possible.

**Source of funding**

This study was funded by the Department of Pharmacy at Sefako Makgatho Health Sciences University.

**Ethical approval**

Ethical clearance for the study was obtained from the Sefako Makgatho University Research Ethics Committee prior to commencement of the study (SMREC/H/129/2015:PG). Permission to conduct the study at the hospital was obtained from the Chief Executive Officer (CEO) and pharmacy manager.

**Authors’ contributions**
Chapter 4: Results and Discussion

MM, JCM and NS designed the research strategy. MM collected the data under the supervision of JCM and NS. MM wrote the first draft of the manuscript. All authors participated in the interpretation of the data, revised the manuscript and approved the final version.

References


### 4.4 POSTER PRESENTATION

The focus group data were also presented as a poster at the Junior Public Health Association of South Africa (JuPHASA) Conference, East London, September 19, 2016:

Matimela MM, Meyer JC, Schellack N. Perceptions of nurses in the intensive care units at Dr George Mukhari Academic Hospital about out of stock medicines.

A copy of the poster is shown on the next page.
Chapter 4: Results and Discussion

Perceptions of nurses in the intensive care units at Dr George Mukhari Academic Hospital about out of stock medicines

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Introduction

Over the past two years, medicine shortages have been a challenge in the delivery of health care services, globally as well as in South Africa. Dr George Mukhari Academic Hospital (DGMAH) is no exception to the rule, as the hospital has been experiencing numerous stock-out situations and shortages of medicines.

Unavailability of medicines can have a negative impact on patient care and health care service delivery. Apart from patients’ health being compromised, medicines shortages, health care professionals, especially pharmacists, and nurses are also affected due to additional time spent on solving problems caused by out of stock situations. This study aimed to explore the practical implications of out of stock medicines from the perspectives of the nursing staff.

Objective

To determine the perceptions of intensive care unit (ICU) nurses at DGMAH about the practical implications of out of stock medicines.

Method

A qualitative, descriptive study was conducted in the two intensive care units (ICUs) of DGMAH, GaRankuwa, Pretoria. The adult ICU currently has 22 beds with an admission of 87 patients per month, while the neonatal ICU has 12 beds with an admission of 120 patients per month.

Two focus group discussions (FGDs) were conducted with 12 nurses, one in the adult ICU and another in the neonatal ICU, to explore the practice implications of out of stock medicines. Participants were professional nurses, designated for medicines management in the past six months. Recorded FGDs were transcribed verbatim and imported into NVivo® for analysis. The transcripts were read a number of times to explore and obtain an understanding of the data. Data were coded into categories and developed into a framework of subthemes.

Ethical clearance for the study was granted by the Sefako Makgatho University Research Ethics Committee (SMUHGEC/126/21/213). All participants provided written informed consent for participation.

Results

Unavailability of medicines

Out of stock situations

- Extent of problem
  - Poor stock levels
  - Stocking errors
  - Essential items out of stock
  - Emergency trolley
  - Electronic trolley
  - Medication errors
  - Anesthetic agents

- Reasons
  - Stocking levels unknown
  - Supply problems
  - Staff shortages

Impact

- Patient care
  - Patient death
  - Staff stress
  - Medication errors

- Nursing staff stress
  - Nursing staff stress levels

Response

- Active time to response
  - No nurse staff available
  - Another ward
  - Another hospital

- Request
  - Request for medication
  - Request for consultation

- Communication
  - Communicate with the pharmacy
  - Internal ward communication

- Results
  - Medication stock levels
  - Patient outcomes

Conclusions

The findings illustrated a number of medicines have been out of stock for a long period in both ICUs. In most instances, reasons for out of stock situation were unknown not specified by the pharmacy. Nurses assumed that out of stock medicines could be supplied from other wards, pharmaceutical items or unavailability of alternatives.

Unavailability of medicines had a negative impact on patient care and could contribute to antibiotic resistance. Reaching out of stock medicines has resulted in waste of time and human resources. Communication from the pharmacy on out of stock medicines was poor.

This drives a need for active and daily service or involvement of pharmacists in the wards to facilitate a better management of out of stock medicines and communication between the wards and the pharmacy.

Recommendations

- A pharmacist dedicated to the ICUs with visits at least once a week to improve communication between the nurses and pharmacists.
- Doctors and pharmacists to have regular meetings on how to comparatively manage medicines shortages and improve quality of care.
- Early warning of out of stock to provide adequate time to plan and manage the remaining medicines.
- Monthly distribution of information to the wards on available, out of stock and alternatives medicines per ordering.

Acknowledgements

- Gratitude to DGMAH for their time and assistance in collecting the study.
- Department of Pharmacy, Sefako Makgatho Health Sciences University for financial support.
CHAPTER 5
LIMITATIONS, RECOMMENDATIONS AND CONCLUSIONS

5.1 INTRODUCTION

Conclusions drawn from the results of the study are provided in this chapter and recommendations are also offered in this chapter based on the results. The chapter ends with limitations to the study.

5.2 LIMITATIONS OF THE STUDY

The major limitation of the study was the fact that it was conducted in one hospital, and in the ICUs and the pharmacy OPD only, which limits the generalisability of the results.

Reasons for stock out situations were determined only for inpatients and participation in the focus group discussions was voluntarily, which further limits the generalisability of the results.

5.3 RECOMMENDATIONS

The following recommendations are made based on the results of the study:

- A pharmacist and/or pharmacist assistant from the pharmacy should be dedicated to each unit, to resolve out of stock situations, respond to stock out challenges in the ward and facilitate communication between the pharmacy and the wards. Nurses would benefit from information relevant to the management of out of stock medicines through an effective and proactive pharmacy department. Frequent and structured meetings are recommended.

- Better communication and collaboration within the multi-disciplinary team in handling out of stock situations, will facilitate better patient care.

- The NDoH should continue to provide information on medicine shortages to all health facilities. A structured approach of disseminating information on out of stock medicines from the pharmacy to ward level, especially for medicines without a suitable substitution, is recommended. This will assist in pro-actively identify and put measures in place to respond to medicines shortages (WHO 2015, WHO 2016).
The initiative of split tenders for medicines which are in high demand, should be strengthened, which will enhance the security of supply. Lastly, all hospitals should support the development of an early warning shortage notification system, to identify substitutes, alternative suppliers or other mitigation measures on time (WHO 2016).

Further operational research should focus on pharmacists’ interventions in the wards to assist nurses with medicine shortages.

5.4 CONCLUSIONS

This study aimed at evaluating the practice implications of out of stock medicines at ward level, specifically the intensive care units. The results showed that there were several out of stock situations in this public sector hospital, which resulted in inadequate medicine availability. The reasons for stock outs varied and included national shortages, supply problems, tender-related challenges, stock outs at the main pharmacy, stock not ordered by the unit, challenges obtaining motivational items, and lack of informed communication on out of stock situations.

Addressing the root causes of stock outs in the supply chain and providing an ongoing evaluation of the out of stock medicines should be undertaken. The information obtained from the evaluation should form the basis for decision-making for better the service delivery. Collaboration and communication within the multi-disciplinary health care team would be important.

The findings of this study highlighted the need to enhance the interaction and communication between nurses and pharmacists in order to facilitate the management of out of stock medicines at ward level. The active role of the pharmacist in the ward will be an intervention to mitigate out of stock situations.
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Struwig, F.W., & Stead, G.B., 2009, Planning, designing and reporting research, South Africa: Pearson Education.


References

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Appendices

Appendix 1: Study information leaflet

An evaluation of out of stock medicines in the intensive care units at Dr George Mukhari Academic Hospital

Dear Colleague

Please read the information provided below concerning this study.

I am a pharmacist intern and a registered Master’s degree student at Sefako Makgatho Health Sciences University. I will be conducting a study at this hospital (Dr George Mukhari Academic Hospital) and will be collecting data at the adult intensive care unit (ICU) and the neonatal intensive care unit.

The aim of the study is to evaluate the practice implications of out of stock medicines in the ICUs of DGMAH. In order to make this study a success, I might need to request information when required. I will need assistance with sourcing the right documents from the right places, and will therefore be asking you if need be.

The study has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC) and the Chief Executive Officer of the hospital.

If you agree to in the study you will be required to provide written consent to indicate your willingness to participate.

Your participation in the study will highly be appreciated. Please feel free to contact me or my supervisor for further information or enquiries about the study.

Regards

Matimela Molebogeng
012 521 4212
Supervisor: Dr JC Meyer (012 521 4567)
Appendix 2: Consent form

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ENGLISH CONSENT FORM

Statement concerning participation in a Research Project.

Name of Research Project

AN EVALUATION OF OUT OF STOCK MEDICINES IN THE INTENSIVE CARE UNITS AT DR GEORGE MUKHARI ACADEMIC HOSPITAL

I have read the information on the aims and objectives of the proposed project and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Project is completely voluntary and that I may withdraw from it at any time and without supplying reasons.

I know that this project has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC), Sefako Makgatho Health Sciences University / Dr George Mukhari Hospital. I am fully aware that the results of this Project will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Project.

............................................................................................................................
............................................................................................................................
Name of /volunteer ............................................ Signature of Volunteer ............................................

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

Statement by the Researcher

I provided written information regarding this Project.

I agree to answer any future questions concerning the Research Project as best as I am able.

I will adhere to the approved protocol.

............................................................................................................................
............................................................................................................................
............................................................................................................................
............................................................................................................................
Name of Researcher ................. Signature ................. Date ................. Place .................
### Appendix 3: Ward medicines availability monitoring sheet

Ward: ______________________

Month: ______________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Study ID</th>
<th>Out-of-stock Item</th>
<th>Reason for out-of-stock (O/S) (√)</th>
<th>Comments and action plan</th>
<th>Follow-up on action plan</th>
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<tr>
<td></td>
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<td></td>
<td>Ward O/S</td>
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<td>Pharmacy O/S</td>
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<td>Not on formulary</td>
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<td>Motivational item</td>
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<td></td>
<td></td>
<td>Not on tender</td>
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<td></td>
<td></td>
<td></td>
<td>Other</td>
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Follow-up on action plan:

<table>
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<th>Outcome</th>
<th>Date</th>
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</table>
Appendices

Appendix 4: Focus group guide

An evaluation of out of stock medicines in the Intensive Care Units at Dr George Mukhari Academic Hospital.

1. Welcome the participants to the discussion and thank them for their willingness to participate.
2. Explain the purpose of the focus group discussion and obtain written consent to take part in the study.
3. Assure participants that there are no wrong or right answers.
4. Encourage participants to speak freely.
5. Explain that the observer (researcher) will make notes and that the discussion will be recorded using a digital voice recorder.

Interviewer to note: Start the digital audio recorder to record the interview. Rephrase questions and prompt for additional information where necessary.

Observer: Make observational notes.

6. Pose the following questions to the group:

- In the past year, please describe the extent of out of stock medicines in the ICU?
  
  Probes:
  o How often did this happen?
  o Which items were mainly out of stock?

- What do you think are the reasons behind the out of stock situations over the past year?

- Please describe the communication/ notification you received in case of an out of stock situation
  
  Probes:
  o When received
  o How often received
  o From whom received

- Please tell me about the impact of out of stock situations on your daily practice and workflow in the unit
Appendices

Probes:

- How much time did you spend on managing the out of stock medicines?
- What effect did the time spent on managing the out of stock have on your normal daily work load?
- Patient care?
- How do you address or what do you normally do in response to an out of stock situation?

Probes:

- Ordering
- Substitution
- Communication with pharmacy?
- Communication with medical practitioners?
- What possible ways can be put in place in future to manage out of stock medicines?

7. The following probes can be used during the discussion to ensure that views are obtained on all the aspects:

- “Anything else?”
- Repeating what the participants have just said, e.g. “Did you say/ Are you saying/ Did you mean / What did you mean by saying that?”
- “Do you have anything to add to what was already said/ Are there any other important topics which were not covered?”

8. Thank the participants for taking part in the discussion.
9. Close the discussion
Appendices

Appendix 5: SMUREC clearance certificate (1)

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

Molotlegi Street, Ga-Rankuwa 0208
Tel: (012) 521 5017/5018 fax: (012) 521 3749
Email: lorato.phri@smu.ac.za
P.O. Box 189 Medunsa 0204

AMENDMENT APPROVAL NOTICE

02 June 2016

Mdl Mthembu
Department of Pharmacy
P.O. Box 218
Medunsa, 0204

MEETING: 15/02/15
15/02/15

SMUREC Ethics Reference Number: SMUREC/12/2015: PG

On the 02 June 2016 SMUREC approved protocol number and charge of title on the following protocol as follows:

Title: An evaluation of the stock of medicines in the intensive care units of Dr George Maritz Academic Hospital

Researcher: W. A. Marwila
Supervisor: Dr JG Meyer
Co-supervisor: Prof N Schellack
Hospital Superintendent: Dr MG Holm (DGMAH);
Other involved IND: W. A. Marwila (Pharmacy - DGMAH), Prof GCoan (CU-DGMAH), Prof Meintjes (DGMAH)
Department: Pharmacy
School: Health Care Sciences
Degree: Honours in Pharmacy

Please refer to the following information about your approved research protocol:


Please remember to use your protocol number (SMUREC/12/2015: PG) on any documents or correspondence with the REC announcing your research protocol. Please note that the REC has the pre-emptive and authority to ask further questions, seek additional information, review further research, or monitor the conduct of the research and the consent process.

After Ethical Review: Please note a reminder of the progress report is submitted to the Research Office and should be submitted to the committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Any new viewpoints may be selected for a formal audit. Transmittal of the consent documents in the language applicable to the study participants should be submitted.

International Organization (ICRC) 091/010881 (IIS): Effective date: 09 December 2015, Federal Wide Assurance (F85910269/45) Effective date: 31 August 2016 and WAREC No: REC 2103138-001

Sincerely

[Signature]

CHAIRPERSON SMUREC

Page 1 of 1
Appendix 6: Letter of request to conduct the study

Pharmacy Manager
Head of Department: Adult Intensive Care Unit
Head of Department: Neonatal Intensive Care Unit
Dr George Mukhari Academic Hospital

Dear Sir / Madam

RE: Request for permission to conduct a study at Dr George Mukhari Academic Hospital

I am a Master of Pharmacy student and academic intern at the Sefako Makgatho Health Sciences University. As part of my post-graduate degree, I am required to conduct a research project. The title of my study is “An evaluation of out of stock medicines in the intensive care units at Dr George Mukhari Academic Hospital”. During the course of the research project, I will be working in collaboration with the pharmacy staff, clinical pharmacist intern stationed at the NICU and the adult ICU and the ward nurses responsible for the medicines room. Their co-operation for the success of the research project will be appreciated.

The study will only be conducted after ethical approval by the Sefako Makgatho University Research Ethics Committee (SMUREC) has been granted.

I hereby kindly request your permission to conduct the research project at Dr George Mukhari Academic Hospital.

Please find attached a copy of my research protocol for your information. Please do not hesitate to contact me or my supervisors should you require further information.

Thank you for your consideration.

Yours in anticipation,

Matimela Molebogeng
MPharm Student
(012) 521 4212

Cc: Prof JC Meyer (Supervisor): (012) 521 4567
    Prof N Schellack (Co-supervisor): (012) 521 3286
Appendices

Appendix 7: Author guidelines - Curationis

Structure and style of your empirical research article

The page provides an overview of the structure and style of your empirical research article to be submitted to the Curationis. The empirical research article provides an overview of innovative research in a particular field within or related to the focus and scope of the journal presented according to a clear and well-structured format (between 3500 and 7000 words with a maximum of 60 references).

- **Language**: Manuscripts must be written in British English.

- **Line numbers**: Insert continuous line numbers.

- **Font**:
  - Font type: Palatino
  - Symbols font type: Times New Roman
  - General font size: 12pt

- **Line spacing**: 1.5

- **Headings**: Ensure that formatting for headings is consistent in the manuscript.
  - First headings: normal case, bold and 14pt
  - Second headings: normal case, underlined and 14pt
  - Third headings: normal case, bold and 12pt
  - Fourth headings: normal case, bold, running in text and separated by a colon.

Our publication system supports a limited range of formats for text and graphics. Text files can be submitted in the following formats only:

- **Microsoft Word (.doc)**: We cannot accept Word 2007 DOCX files. If you have created your manuscript using Word 2007, you must save the document as a Word 2003 file before submission.
• Rich Text Format (RTF) documents uploaded during Step 2 of the submission process. Users of other word processing packages should save or convert their files to RTF before uploading. Many free tools are available that will make this process easier.

**The structure and style of your original article**

**Page 1**

The format of the compulsory cover letter forms part of your submission and is on the first page of your manuscript and should always be presented in English. You should provide all of the following elements:

• **Article title:** Provide a short title of 50 characters or less.

• **Significance of work:** Briefly state the significance of the work being reported on.

• **Full author details:** Provide title(s), full name(s), position(s), affiliation(s) and contact details (postal address, email, telephone and cellular number) of each author.

• **Corresponding author:** Identify to whom all correspondence should be addressed to.

• **Authors’ contributions:** Briefly summarise the nature of the contribution made by each of the authors listed.

• **Summary:** Lastly, a list containing the number of words, pages, tables, figures and/or other supplementary material should accompany the submission.

**Page 2 and onwards**

**Title:** The article’s full title should contain a maximum of 95 characters (including spaces).

**Abstract (first level heading)**

• Do not cite references in the abstract.

• Do not use abbreviations excessively in the abstract.

• The abstract should be written in English.
The abstract should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of five paragraphs labelled Background, Objectives, Method, Results and Conclusion.

- **Background:** *Why do we care about the problem?* The context and purpose of the study (what practical, scientific or theoretical gap is your research filling?).

- **Objectives:** *What problem are you trying to solve?* What is the scope of your work (a generalised approach, or for specific situation). Be careful not to use too much jargon.

- **Method:** *How did you go about solving or making progress on the problem?* How the study was performed and statistical tests used (what did you actually do to get the results). Clearly express the basic design of the study, name or briefly describe the basic methodology used without going into excessive detail. Be sure to indicate the key techniques used.

- **Results:** *What is the answer?* The main findings (as a result of completing the above procedure/study what did you learn/invent/create?). Identify trends, relative change or differences on answers to questions.

- **Conclusion:** *What are the implications of your answer?* Brief summary and potential implications (what are the larger implications of your findings, especially for the problem/gap identified in your motivation?).

**Introduction (first level heading)**

The introduction contains two subsections, namely the background section and the literature review.

- **Problem statement (second level heading):** The setting section should be written from the standpoint of readers, that is, without specialist knowledge in that area and must clearly state and illustrate the introduction to the research and its aims in the context of previous work bearing directly on the subject. The setting section to the article normally contains the following five elements.

  - **Aims of the study/Key focus (third level heading):** A thought provoking introductory statement on the broad theme or topic of the research.
Background (third level heading): Providing the background or the context to the study (explaining the role of other relevant key variables in this study);

Trends (third level heading): Cite the most important published studies previously conducted on this topic or that has any relevance to this study (provide a high-level synopsis of the research literature on this topic).

Research objectives (third level heading): Indicate the most important controversies, gaps and inconsistencies in the literature that will be addressed by this study. In view of the above trends, state the core research problem and specific research objectives that will be addressed in this study and provide the reader with an outline of what to expect in the rest of the article.

Definition of key concepts (third level heading)

Contribution to field (third level heading): Explanation of the study's academic (theoretical and methodological) or practical merit and/or importance (provide the value-add and/or rationale for the study).

Literature review (second level heading): The literature review is the second subsection under the Introduction and provides a brief and concise overview of the literature under a separate second level heading, e.g. literature review. A synthesis and critical evaluation of the literature (not a compilation of citations and references) should at least include or address the following elements, ensure these are in the literature review. Define conceptual (theoretical) definitions of all key concepts; A critical review and summary of previous research findings (theories, models, frameworks, etc.) on the topic; A clear indication of the gap in the literature and for the necessity to address this void; and A clearly established link exists between formulated research objectives and theoretical support from the relevant literature.

Research method and design (first level heading)

This section should include:

Design (second level heading): Describe your experimental design clearly, including a power calculation if appropriate. Note: Additional details can be placed in the online supplementary location.

Materials (second level heading): Describe the type of organism(s) or material(s) involved in the study.
Appendices

- Data collection method/Procedure (secondlevel heading): Describe the protocol for your study in sufficient detail (clear description of all interventions and comparisons) that other scientists could repeat your work to verify your findings.

- Data analysis (secondlevel heading): Describe how the data were summarised and analysed, additional details can be placed in the online supplementary information.

- Context of the study (secondlevel heading): Describe the site and setting where your field study was conducted.

Results (firstlevel heading)

This section provides a synthesis of the obtained literature grouped or categorised according to some organising or analysis principle.

Tables may be used and/or models may be drafted to indicate key components of the results of the study.

- Organise the results based on the sequence of Tables and Figures you will include in the manuscript.

- The body of the Results section is a text presentation of the key findings which includes references to each of the Tables and Figures.

- Statistical test summaries (test name, p value) are usually reported parenthetically in conjunction with the biological results they support, use SI unit.

- Present the results of your experiment(s)/research data in a sequence that will logically support (or provide evidence against) the hypothesis, or answer the question, stated in the Introduction.

All units should conform to the SI convention and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Ethical considerations (firstlevel heading)

Articles based on the involvement of animals or humans must have been conducted in accordance with relevant national and international guidelines. Approval must have been
obtained for all protocols from the author's institutional or other relevant ethics committee and the institution name and permit numbers provided at submission.

- Potential benefits and hazards (second-level heading): What risks to the subject are entailed in involvement in the research? Are there any potential physical, psychological or disclosure dangers that can be anticipated? What is the possible benefit or harm to the subject or society from their participation or from the project as a whole? What procedures have been established for the care and protection of subjects (e.g. insurance, medical cover) and the control of any information gained from them or about them?

- Recruitment procedures (second-level heading): Was there any sense in which subjects might be ‘obliged’ to participate – as in the case of students, prisoners, learners or patients – or were volunteers being recruited? If participation was compulsory, the potential consequences of non-compliance must be indicated to subjects; if voluntary, entitlement to withdraw consent must be indicated and when that entitlement lapses.

- Informed consent (second-level heading): Authors must include how informed consent was handled in the study.

- Data protection (second-level heading): Authors must include in detail the way in which data protection was handled.

**Trustworthiness (first-level heading)**

This refers to the findings of the study being based on the discovery of human experience as it was experienced and observed by the participants.

- Reliability (second-level heading): Reliability is the extent to which an experiment, test, or any measuring procedure yields the same result on repeated trials. Without the agreement of independent observers able to replicate research procedures, or the ability to use research tools and procedures that yield consistent measurements, researchers would be unable to satisfactorily draw conclusions, formulate theories, or make claims about the generalisability of their research.

- Validity (second-level heading): Validity refers to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure. While reliability is concerned with the accuracy of the actual measuring instrument or procedure, validity is concerned with the study’s success at measuring what the researchers set out to measure. Researchers should be concerned with both external and internal validity. External validity refers
to the extent to which the results of a study are generalisable or transferable. Internal validity refers to (1) the rigor with which the study was conducted (e.g. the study's design, the care taken to conduct measurements, and decisions concerning what was and wasn't measured) and (2) the extent to which the designers of a study have taken into account alternative explanations for any causal relationships they explore. In studies that do not explore causal relationships, only the first of these definitions should be considered when assessing internal validity.

Discussion (first level heading)

This section normally contains the following four elements. It is suggested that sub headings are used in this section:

- Outline of the results (second level heading): Restate the main objective of the study and reaffirm the importance of the study by restating its main contributions; summarise the results in relation to each stated research objective or research hypothesis; link the findings back to the literature and to the results reported by other researchers; provide explanations for unexpected results.

- Practical implications (second level heading): Reaffirm the importance of the study by restating its main contributions and provide the implications for the practical implementation your research.

Limitations of the study (first level heading): Point out the possible limitations of the study and provide suggestions for future research.

Recommendations (first level heading): Provide the recommendations emerging out of the current research.

Conclusion (first level heading)

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance, with a recommendation for future research (implications for practice). Provide a brief conclusion that restates the objectives; the research design; the results and their meaning.

Acknowledgements (first level heading)
If, through your study, you received any significant help in conceiving, designing, or carrying out the work, or received materials from someone who did you a favour by supplying them, you must acknowledge their assistance and the service or material provided. Authors should always acknowledge outside reviewers of their drafts and any sources of funding that supported the research.

- Competing interests (secondlevel heading): A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organisations that can potentially prevent you from executing and publishing unbiased research. Authors should disclose any financial competing interests but also any nonfinancial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript. Where an author gives no competing interests, the listing will read ‘The authors declare that they have no financial or personal relationship(s) which may have inappropriately influenced them in writing this article.’

- Authors’ contributions (secondlevel heading): This section is necessary to give appropriate credit to each author, and to the authors' applicable institution. The individual contributions of authors should be specified with their affiliation at the time of the study and completion of the work. An ‘author’ is generally considered to be someone who has made substantive intellectual contributions to a published study. Contributions made by each of the authors listed, along the lines of the following (please note the use of author initials):

J.K. (University of Pretoria) was the project leader, L.M.N. (University of KwaZuluNatal) and A.B. (University of Stellenbosch) were responsible for experimental and project design. L.M.N. performed most of the experiments. P.R. made conceptual contributions and S.T. (University of Cape Town), U.V. (University of Cape Town) and C.D. (University of Cape Town) performed some of the experiments. S.M. (Cape Peninsula University of Technology) and V.C. (Cape Peninsula University of Technology) prepared the samples and calculations were performed by C.S., J.K. (Cape Peninsula University of Technology) and U.V. wrote the manuscript.

References (firstlevel heading)

Begin the reference list on a separate page with no more than 60 references. *Curationis* uses the [Harvard referencing style](#), details of which can be downloaded from the journal website. Note: No other style will be permitted.

All articles published in this journal are licensed under the [Creative Commons Attribution 4.0 International](#) (CC BY 4.0) license.
Appendix 8: Author guidelines – Journal of Nursing Management

Aims and Scope
The Journal of Nursing Management is an international forum which informs and advances the discipline of nursing management and leadership. The Journal encourages scholarly debate and critical analysis resulting in a rich source of evidence which underpins and illuminates the practice of management, innovation and leadership in nursing and health care. It publishes current issues and developments in practice in the form of research papers, in-depth commentaries and analyses.

The complex and rapidly changing nature of global health care is constantly generating new challenges and questions. The Journal of Nursing Management welcomes papers from researchers, academics, practitioners, managers, and policy makers from a range of countries and backgrounds which examine these issues and contribute to the body of knowledge in international nursing management and leadership worldwide.

The Journal of Nursing Management aims to:
Inform practitioners and researchers in nursing management and leadership
Explore and debate current issues in nursing management and leadership
Assess the evidence for current practice
Develop best practice in nursing management and leadership
Examine the impact of policy developments
Address issues in governance, quality and safety.

Journal of Nursing Management employs a plagiarism detection system. By submitting your manuscript to the Journal you accept that your manuscript may be screened for plagiarism.

Essential requirements for papers
Before peer review, all manuscripts are screened by the editors for their suitability for publication in the journal on the basis that they fall within the Journal’s Aims and Scope, and meet the following essential criteria:

- The issue is considered in an international context
- The implications of nursing management and patient outcomes are clear
- The paper adds to the knowledge base in the field
- The paper is written in clear, fluent and simple English
- Collected data should not be more than two years old on submission and there should be no secondary analysis of existing data.

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