Trend in revenue loss due to expired medication at a large urban hospital in Johannesburg, South Africa

A Research Report Submitted to the School of Public Health, University of the Witwatersrand in Partial Fulfilment of the Requirements for the Degree of Master of Public Health

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June 2016

DECLARATION

I, Celeste Charleneton Sauls, hereby declare that the work on which this research is based, hereby submitted to the University of the Witwatersrand for the Degree of Master of Public Health (MPH) is original (except where acknowledgements indicate otherwise). This work nor any part of it has been, is being, or is submitted for another degree at this or any other University.

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Celeste Charleneton Sauls Date

DEDICATION

I dedicate this research report to:

- My husband, Terence Madondo and our lovely son, Terence James ‘TJ’ Madondo
- My parents, Mr. Ephrahim and Lorettha Sauls
- My amazing siblings, Cynthia Jacobs, Olivia Mansingh, Elaine Lewis, Nastassja Scheepers and Ephrahim Sauls
- My late uncle and friend Mr. Christopher Miles
- My late cousin and brother Ashwyn Sauls
- My late niece Laree Lewis

ABSTRACT

Introduction

Limited research has been conducted on the causes and economic impacts of expired medicine, yet medicine costs comprise a significant proportion of healthcare expenditure. Medicines and their management are an important health system function, necessary for improving and maintaining health. However the lack and wastage of essential medicine is still one of the most serious public health problems globally, including South Africa. The high rate of medicine expiry highlights a problem throughout the supply chain and this wastage reduces the quantity of medicines available to patients and therefore the quality of healthcare they receive. This study aimed to estimate the revenue loss due to expired medicines within a hospital setting from January 2011 to June 2014 and explore reasons for this.

Methods

This mixed methods study is a retrospective analysis review of forty-two months of expired medicine reports extracted at a public sector hospital coupled with a qualitative exploration (through semi-structured in-depth interviews) with key stakeholders about possible reasons for the expiration of medicines. In addition, informal observations were conducted across the duration of the fieldwork and recorded in a researcher diary. Ethics and research approvals for the study were obtained from the University of Witwatersrand Human Ethics Committee and the hospital.

Results

32,368 medicines had expired over the study period. These data were drawn from the wards, outpatient departments and pharmacy and consisted of 68 different Anatomical Therapeutic Chemical (ATC) classes. More than 80% of the expired medicines were on the essential medicine list (EML) with antibacterial for systemic use (16%, n=5067) and antivirals for systemic use (15%, n=4970) among the highest classes that expired. The estimated total value of expired medicine for the study period was R838 029; an estimated annual revenue loss of 0.6% of the hospital's total pharmaceutical expenditure; and an average increase in percentage revenue loss of 72% for the study period. Two main themes emerged from the in-depth interviews conducted with key stakeholders; i) Knowledge, understanding and practical application of policies and

procedures related to expired medicines, and ii) Diversion from Ideal: procedures and constraints which may impact implementation. A closer examination to explore the reasons for these diversions - the 'whys'- revealed three thematic areas: mistrust among employees and in the system, fear of being 'caught' yet lack of accountability and, ineffective communication and coordination.

Discussion

Expiry of medicines was highest among essential medicine on the supply-side. Medicines management is not restricted to pharmacists and although adequate tools for quantification and demand planning exist, none of these are focused on the health worker who has no formal training in medicine supply management. The study highlighted the need to identify effective strategies for phasing in and out of pharmaceutical policies and tenders to minimize waste. There is a lack of standard treatment guideline knowledge among prescribers. The extent of expired medicines at patients' homes, patient returns or cost of disposing off expired medicine were not analysed. The relationship between governing documents and daily practices are not well understood by those responsible for managing medicines and accountability is not clearly assigned.

Recommendations and Conclusion

Creating awareness about the risk of medicines expiring and cost impact on service delivery should be communicated to healthcare workers and policy makers. Medicine supply management should be included as part of job descriptions of employees who manage medicines at this hospital to enhance accountability. Employing clinical pharmacists in the wards at tertiary hospitals may improve medicine management. Continuous monitoring and periodic evaluations to identify and address challenges related to medicine wastage is paramount to reduce financial loss and improve health outcomes. Sound coordination and communication is needed between the pharmacy and other departments in the hospital. Additionally, Pharmaceutical and Therapeutics Committees should emphasise the use of Standard Treatment Guidelines.

ACKNOWLEDGMENTS

When I started this journey a few years ago, I promised myself that I would complete it. Though I found myself on numerous occasions wanting to just give up, I just found myself picking up the pieces and carrying on and all thanks to all the people who were there for me.

My achievement would not have been a success without the effort, experiences and mentoring of so many people. For the completion of my research report, I would like to acknowledge:

- Firstly, my Lord and Savior Jesus Christ for carrying me
- My supervisors, Dr. Bronwyn Harris, Centre for Health Policy and Dr. Mandy Maredza, Western Cape Department of Health, for their endless support, motivation, guidance and most of all patience throughout this journey.
- My husband, who has been my pillar and encourager when I felt like giving up. My beloved son, for making me laugh when I felt so overwhelmed
- My parents and siblings for cheering me on
- My sponsor Dr. Denise Evans and
- The hospital staff for their co-operation and willingness in participating in the study.

Contents

i. LIST OF ABBREVIATIONS

ARV	Antiretroviral
ATC	Anatomical Therapeutic Chemical
CEO	Chief Executive Officer
EML	Essential Medicine List
FEFO	First expired first out
FIFO	First in first out
HIV	Human immunodeficiency virus
HREC	Human Research Ethics Committee
ID	Identifier
M&E	Monitoring and Evaluation
MPC	Master Procurement Catalogue
MSM	Medicine Supply Management
NCD	Non-communicable disease
NDP	National Drug Policy
NDoH	National Department of Health
NHI	National Health Insurance
NSN	National Stock Number
OOP	Out-of-pocket
OPD	Out-patient department
PHC	Primary Healthcare
SOP	Standard Operating Procedures
SSP	Stop Stock outs Project
GPP	Good Pharmacy Practice
MSD	Medical Supply Depot
NCS	National Core Standards
NEMLC	National Essential Medicine List Committee
STG	Standard Treatment Guidelines
TB	Tuberculosis
VEN	Vital, Essential, Necessary
WHO	World Health Organisation

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CHAPTER 1: INTRODUCTION AND BACKGROUND

1.1 Introduction

Although medicines comprise a significant proportion of healthcare expenditure, limited research on the causality and economic impact of expired medicines exists (Barraclough and Clark, 2011). Some of the leading causes of expiry of medicines include poor pharmaceutical management, lack of human resources and lack of accountability (World Health Organisation, 1998). Expiry of medicines leads to significant wastage of resources which may result in reduced availability of medicines. This may impact on the quality of healthcare provided to patients and ultimately the loss of confidence in the health system (Nakyanzi et al., 2010). This may also affect the affordability of healthcare for patients by increasing transport costs and out of pocket payments.

In 2010, the World Health Organization (WHO) estimated that approximately 6% of all households and 15% of people across the countries surveyed experienced financial catastrophe[1] due to out-of-pocket (OOP) payments for medicines (Priyanka et al., 2010). OOP payments for medicine is projected to double by 2030 (Barraclough and Clark, 2011, McIntyre et al., 2006). The need to reduce the financial impact on individuals is paramount thus reducing medicine waste is essential.

Wastage of medicines through medicine expiry is a global challenge. In the United States of America and Switzerland, wastage rates have been estimated at 16% and 29% respectively, with more than $1 billion (Toerper et al., 2014) and $436 million (Vogler et al., 2014) lost per annum respectively. Studies looking at revenue loss due to expired medicines are few in developing countries. However, in Uganda in 2006, revenue loss due to expired medicine was estimated to be at least $550,000 for that year (Mwesige, 2006).Though specific published costing data are limited in South Africa, in 2014, the Viennese Sickness Fund reported that medicines worth $8.8 million had expired in the country (Vogler et al., 2014). Furthermore, a few local studies in

[1] Catastrophic health expenditure- health care expenditure resulting from severe illness/ injury that usually requires prolonged hospitalisation and involves high costs for hospitals, doctors and medicines leading to impoverishment or total financial collapse of the household

South Africa conducted at provincial level (Motlanthe, 2010), district level (Tayob, 2012) and hospital level (Dunga, 2013), have pointed to the high levels of wastage due to medicines expiring that may be curtailed with improved management and efficient inventory coordination. For example, between July 2007 and June 2008, medicines worth $66 000 expired across 41 hospitals in the Limpopo province that is an average of 0.07% of pharmaceutical expenditure per month (Motlanthe, 2010).

There are different factors at different levels of the medicine supply management (MSM) cycle that may contribute to the expiration of medicine: manufacturer, supplier, organisation and user level factors (Dias, 2011). All levels are involved in ensuring availability of medicine to patients, however the longer the supply chain, the higher the risk for medicines expiring (Dias, 2011). Most of the operational studies conducted in South Africa have investigated causes of medicines expiring within the context of the pharmaceutical management cycle (figure 1) (Dunga, 2013, Motlanthe, 2010, Tayob, 2012).

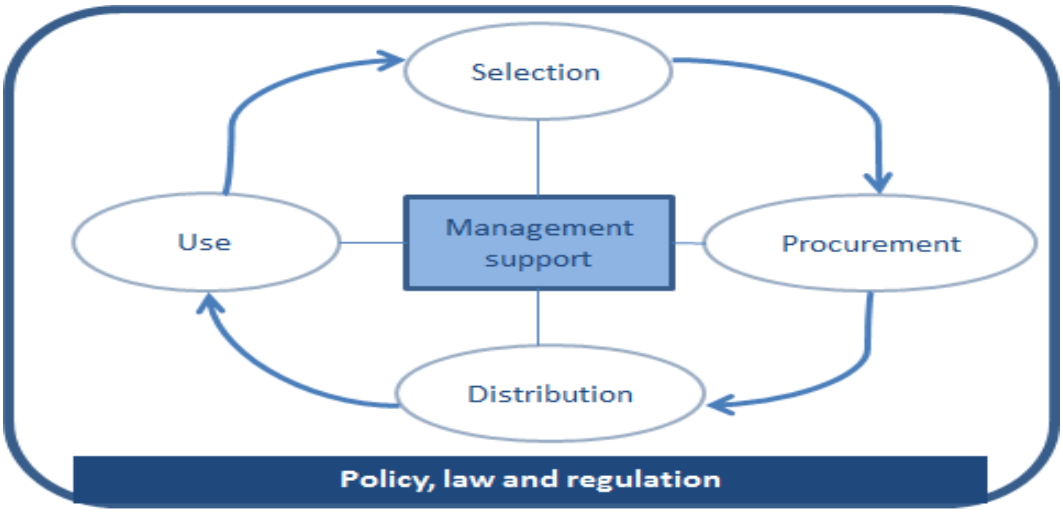

Figure 1: The Pharmaceutical Management Framework (Embrey, 2011)

Nakyanzi and colleagues (2010), Dunga, Motlanthe and Tayob have identified procurement and use as the most critical components in the cycle to avoid medicines expiry. In the South African context selection is a function at the national level, while procurement and use are the main functions at hospital level; strategies may be employed to strengthen these functions at this level. In addition, Motlanthe highlighted management support as a critical component that contributes to medicine expiry and this included lack of internal control measures, lack of training in medicine supply

management, lack or inadequate supervision and monitoring of medicine management systems. The need for accurate and reliable data at hospital level (focus of study) that feed into higher levels at district then province is particularly important to make informed decisions related to procurement and use, which is vital to ensure uninterrupted supply of medicines. Planning and coordination have been identified as the most critical components of organisation level (hospital level) factors which may result in medicines expiring. For example, in Tanzania the lack of planning, coordination, monitoring and evaluation (M&E) resulted in a lack of medicines at the regional level and this caused medicine stock out at the organisational levels in all hospitals and clinics; unexpected demand of medicines that were not accurately forecasted for and; inaccurate calculation from the previous orders (Garraoui et al., 1999).

The abovementioned studies suggest interesting findings in relation to the quantification and causes of medicine expiring. However, only one (Motlanthe) discussed the extent of revenue loss due to expired medicine and explored possible reasons for such loss at a provincial level in South Africa. This study, however, will explore these within a tertiary hospital context; what is here considered to be the organisational context.

This study, based within a hospital ("the organization"), will explore organizational-level factors that contribute to the expiration of medicines. At this level, such factors include M&E, labeling, coordination, medicine procurement, selection, distribution, and use and storage, as well as human resources (Dias, 2011). Even with an excellent supply chain, 'upstream' of the organization, medicines may still expire due to inadequate management, the duration of end-to-end supply or ineffective supply management at the level of the organization. The following figure (figure 2) describes the supply chain of medicines in Gauteng Province in South Africa (the province in which this research is located):

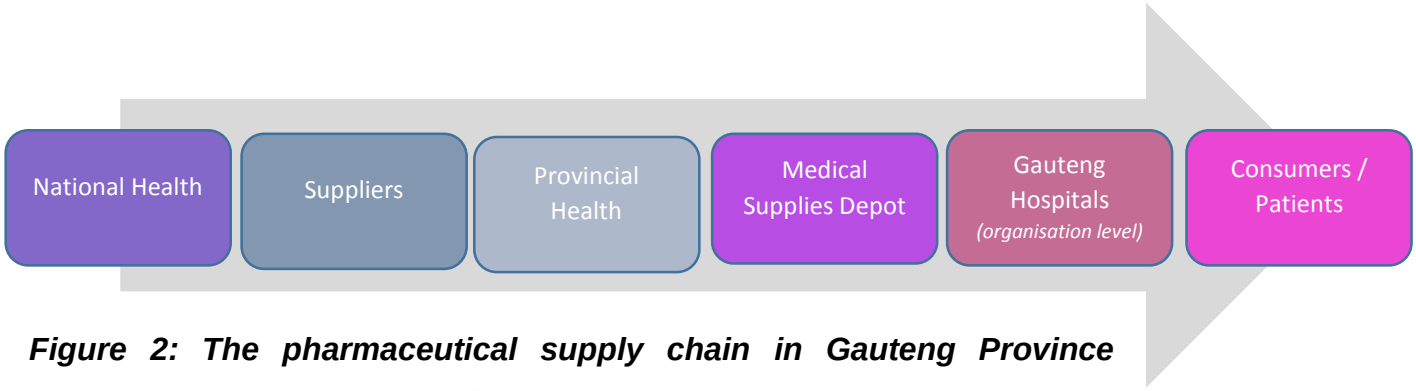

Figure 2: The pharmaceutical supply chain in Gauteng Province *(Kachwee and Hartmann, 2013)*

This study also estimates the potential revenue loss due to expired medicines within the hospital setting. Such information is critical to determine whether the available resources are currently being used efficiently in light of South Africa's healthcare resource scarcity (World Health Organisation, 1998). Moreover, information on *why* medicines expire is important to institutionalise remedial actions to reduce this wastage.

1.2 Background

In South Africa, 80% of the population is dependent on the public sector to provide for their healthcare needs (Price, 2014). Government allocations and donor funds, predominantly Global Fund, are a major source of financing for medicines supply in South Africa (Price, 2014). Yet, there is concern about rising healthcare costs, with budgets becoming more restrictive and slow economic growth rates of 3.3% in 2014 and 3.5% in 2015 (Nene, 2015). In developing countries, medicines comprise the second largest single healthcare cost after human resources (Dias, 2011). More than 30% of the world' population lack the medicines they need and this figure increases to 50% in Africa and Asia (Tumwine, 2010). In these contexts, access to medicines is often used as a proxy for a good healthcare management system (Tayob, 2012). Therefore, persistent and inequitable access barriers to medicines further highlight the need to continuously identify strategies to reduce avoidable waste in the form of medicines expiring in order to retain confidence in the health system by both patients and healthcare providers, and improve equity in access overall.

In South Africa, public health facilities, including pharmacies, are guided by the Public Financial Management Act (PFMA no1 of 1999) of the country. The document highlights the responsibilities associated with ensuring that proper control systems exist for assets and that preventative mechanisms are in place to eliminate theft, loss, wastage and expiry (Public Finance Management Act, 2009). The PFMA emphasises the need for public institutions to avoid unauthorised, fruitless expenditure where expired stock will be recognised as wasteful expenditure by the Department. Whilst it is relatively easy to estimate the direct costs of expired medicines, which are defined as the actual value of the medicines that expire; it is more difficult to quantify the indirect and intangible losses. The latter include the costs of loss of life when individuals fail to access life-saving medicines or loss of productivity when individuals cannot work due to prolonged illness (Kumarasamy et al., 2007, Xu et al., 2003). However, with efficient inventory control, any excess stock identified early can be distributed where it is most needed, before it expires, to reduce the economic losses (Public Finance Management Act, 2009).

The pharmacy is an integral part of any hospital or health facility. A holistic healthcare service can only be provided if the pharmacy is functioning effectively and efficiently (Dunga, 2013). The overall objectives of a public healthcare pharmacy are to promote the rational use of medicines by prescribers, dispensers and patients; and to ensure good dispensing and prescribing practices. Pharmacies should aim to ensure safety, efficacy and quality of medicines; ensure availability and accessibility of medicines to all patients at the facility; and to offer appropriate pharmaceutical services to patients of the hospital (Pharmacist, 2012).

To this end, in the hospital study site of this research, an operational exercise was undertaken in January 2011 to identify and remove all expired medicines from the shelves. Pharmacists and pharmacy assistants visited all inpatient wards, outpatient departments and the pharmacy itself to identify and remove all medicines that had expired or that would expire within six months. Subsequently, it has become practice to conduct monthly medicine audits to ensure the early identification and removal of expired medicine at the hospital. However, once data are collected no further evaluations are conducted to identify strategies to inform future interventions to avoid medicines from expiring.

1.3 Statement of the problem

Medicines and their management are an important health system function to improve and maintain health, however the lack and wastage of essential medicine is still one of the most serious public health problems (Tumwine, 2010). Shortages of essential medicines are experienced in South Africa especially among chronic patients who may experience complications or fatalities (Fokazi, 2012). Reducing medicine expiry is therefore important in contexts of shortages of medicine. Evidence in Africa, as is the case in Uganda (Mwesige, 2006) has shown the cost implication of expired medicines. Globally, expired medicines contribute to the poor performance of health systems, driving up costs and reducing access to quality care for patients (Dias, 2011). Conversely, well managed and controlled medicine supplies that keep wastage to a minimum, may strengthen health system functioning and contribute to public health and trust in healthcare (Dias, 2011, Jha and Roy, 2005, Kachwee and Hartmann, 2013). Although efforts are underway to strengthen South Africa's health system through the reengineering of primary healthcare (PHC) and the piloting of a National Health Insurance (NHI) System (National Department of Health, 2015) – which aim to strengthen supply chain management and deliver healthcare, including medicines through a district-led system, little is known of the economic impact related to, and reasons for, the expiry of medicines in the South African context. Reform of medicine management, as a health system building block, is needed in an effort to holistically strengthen the system.

1.4 Research Question

How much revenue is lost due to expired medicines and what are the reasons for this loss at one tertiary public sector hospital in Johannesburg, South Africa?

1.5 Justification of the study

Poor governance in the pharmaceutical sector is believed to significantly contribute to challenges in pharmaceutical management at different levels of the health system (Anello, 2006). Inefficiencies in medicine management at health facilities have resulted

in multiple forms of irrational practices and waste, in particular medicine expiry. In 2011, expired medicines in South Africa were estimated to be worth R3.4 million, R2.3 million originating in Gauteng Province (Fokazi, 2012). In the study site for this work, an estimated R250, 000 revenue was lost due to medicines expiring in 2010 (Pharmacist, 2012). This information identified a gap in analysing revenue loss due to medicine expiry and possible reasons for such loss, and thus provided the stimulus for this study.

Reducing medicine product waste is an effective strategy to decrease costs, since it does not affect patient care (except in terms of medicine availability), or place limits on the use of higher-cost medicines (Dias, 2011). As a technical exercise, budget evaluations are ideally carried out on current expenditure to ensure current stock is better used. Expired medicine is not the ideal place for budget evaluations as the medicine is no longer usable, however its contents may assist policy makers in identifying high waste medicine products and explore cost saving measures. In addition, the information provided may enhance decision-making in financial and inventory management thereby informing strategies to reduce cost, especially at this vital phase as South Africa is moving toward a NHI, which will focus on efficiency and effectiveness (National Department of Health, 2015).

1.5.1 Aim of the study

The aim of this study is to describe the economic impact related to, and reasons for, the expiry of medicines at a large urban hospital in Johannesburg, South Africa from January 2011 until June 2014.

1.5.2 Study objectives

a. To describe the trend of expired medicine at a large urban hospital in Johannesburg, South Africa from January 2011 until June 2014
b. To determine the average revenue loss due to expired medicine at a large urban hospital in Johannesburg, South Africa from January 2011 until June 2014.
c. To explore possible reasons for revenue loss due to expired medicine at a large urban hospital in Johannesburg, South Africa from January 2011 until June 2014.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Medicine management is a system of processes and behaviours that determines how medicines are ultimately used by or available to patients. In addition, it is an important function for health service delivery to control the costs of medicines, as well as reduce morbidity and mortality, and has a special importance for five main reasons:

a. Medicines save lives and improve health outcomes;
b. Medicines promote trust and participation in health services;
c. Medicines are costly: medicine expenditure represent the largest expenditure over which ministries have yearly discretionary control, which make medicines both important and vulnerable to availability of public funding;
d. Medicines are different from other consumer products: medicines do not conform to the market demand and supply concept. The patient does not choose the medicine prescribed nor is the average prescriber equipped to independently assess the quality, efficacy or safety of each new medicine; and
e. Improvements in the supply and use of medicines are possible (Barraclough and Clark, 2011).

Management is the process for ensuring organisational goals are met through continuous monitoring and effective management of resources (Garraoui et al., 1999). The management function as a whole points to the need to examine the pharmaceutical management process, in particular the planning and organisation that is required for effectively managing medicines. Effective management is the foundation for ensuring the effective medicine management that is required for the reduction of waste, coupled with transparent leadership and governance to ensure accountability. Challenges in effective medicine management highlighted by managers include difficulty in achieving financial sustainability, improving efficiency and reducing pharmaceutical waste (Embrey, 2011). Wastage can interfere with the effective functioning of any pharmaceutical system. It may highlight inadequacies, such as a lack of control, of management both in the pharmacy and at an institutional level which may result in inventory and financial waste.

The overestimation of medicine orders to ensure sufficient stock is a major contributor to wastage of medicines. For example, in a Central American country, inventory records have shown cases of the intentional overstocking of products due to theft (Daniel, 2011a). In a Southeast Asian country, losses caused by wastage are estimated to be more than 30% of the annual medicine budget and; in another country in Central Africa, a hospital pharmacist was seen to routinely allow for losses of approximately 90% on certain medicines when placing an order to ensure that sufficient stock was received (Daniel, 2011b). But as these cases suggest, there may be multiple reasons, including efforts to avoid stock outs that may weaken accountability which may be complex. Knowledge of why wastage occurs may allow for a more nuanced engagement with the problem.

2.2 Pharmaceutical Management

Organisational level factors such as monitoring and evaluation, coordination, communication, information management as well as human resources are embedded in the entire pharmaceutical management framework. The organisational level factors are interlinked and have knock-on effects throughout the pharmaceutical management cycle as illustrated in Table 1:

***Table 1**: Organisational level factors on pharmaceutical management framework*

Pharmaceutical Management Framework	Description of causes and effects	Organisational level factor
Selection	Change in treatment policy without comprehensive planning on implementation impacts	Communication with knock-on effects on all other organisational level and pharmaceutical management components
Procurement	Inappropriate demand planning and quantification. Ensure availability of medicine	Coordination with knock-on effects on all other organisational level and pharmaceutical management components
Distribution	Interrupted supply of medicines due to contract start and end dates that are not in effectively coordinated	Coordination with knock-on effects on all other organisational level and pharmaceutical management components
Use	Prescribing practices in the public vs. private sector. The lack of enforcing the use of standard treatment guidelines	Monitoring and evaluation with knock-on effects on all other organisational level and pharmaceutical management components
Management support systems	Lack of formal training in medicine supply management	Human resources
	Inadequate data which impact decisions on procurement and budgets	Information management

The pharmaceutical management framework is the foundation for pharmaceutical services. The framework consists of four main functions: selection, procurement, distribution and use. These aim to ensure availability of medicines to patients (Embrey, 2011). Each major function builds on the previous function and leads logically to the next. At the core of the pharmaceutical management cycle (Figure 3) are management support systems, which include the planning and organisation of services, financing and financial management, information management, and human resource management (Embrey, 2011). These management support systems should strengthen the pharmaceutical management cycle. As part of management support, managers at all levels of an organisation should be concerned with effectively using resources, as financial sustainability is only achieved when expenditures and financial resources balance and are sufficient to support a given level of demand (Dias, 2011, Embrey, 2011).

In South Africa, pharmacists are responsible for the management of medicines and to oversee the complete medicine distribution cycle - from the prescription according to the diagnosis, through to the choice of medicine, dispensing, preparation and administration of the medicines (Nsovo et al., 2015). Medicines stored in hospital wards remain the responsibility of the designated pharmacist of the hospital and should be managed in accordance with the Medicines and Related Substances Act, Act 101 of 1965, as amended Act 90 of 1997 (Health Professional Council of South Africa, 1997). Wastage may occur at each point within the cycle, however interventions targeting the organisational level factors affecting procurement and use components of the cycle may minimize wastage at the facility. Each function and its related components will be discussed in this section.

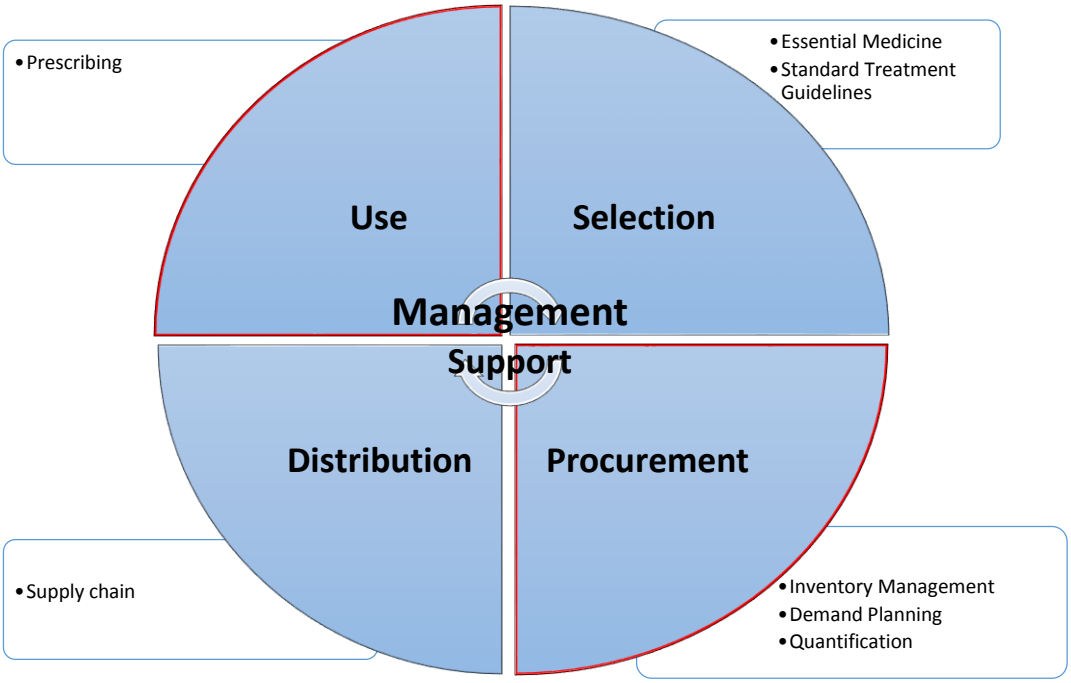

Figure 3: The Pharmaceutical Management Framework Updated *(Embrey, 2011)*.

In South Africa, the National Drug Policy (NDP), which forms part of the National Health Policy, aims at reducing waste by ensuring the availability of appropriate quality medicines in order to serve the healthcare needs of citizens by improving efficiency and cost-effectiveness of the pharmaceutical industry (National Department of Health, 1997). One of the main objectives of the NDP is to achieve access and equity through effective management of the selection, procurement, distribution and use of medicines and medical supplies. The NDP also provides guidelines to pharmacies. These include methods that define minimum and maximum stock levels, guidelines on systematic stock rotation and handling of expired and obsolete stock (National Department of Health, 1997).

2.3 Selection

The selection of essential medicines is one of the core principles of a national medicine policy because it helps to set priorities for all aspects of the pharmaceutical system (WHWorld Health Organisation, 2010). Essential medicines consist of medicines that are deemed to satisfy the healthcare needs of the majority of the population. They are carefully selected and a large part of their selection involves assessing epidemiological

trends in a specified population, thereby identifying which medicines should be available at each level of care on the basis of standard treatment guidelines (STGs) (World Health Organisation, 2002). They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness (WHWorld Health Organisation, 2010). Thus, limiting the selection of essential medicine may lead to improved supply, rational medicine use and reduced cost (Dias, 2011). Most medicine budgets in developing countries are below $30 per person per year, with 38 countries allocating less than $2 per person per year (World Health Organisation, 2002). Overuse or incorrect use of medicines whether essential or non-essential, result in excessive spending on medicines for both patients and the healthcare system which may ultimately waste financial resources (Chalker, 2011).

The basis of medicine selection in South Africa is guided by the WHO Essential Medicine List (EML) model (Dukes et al., 1997). Each province/state and area is different and the priorities may differ considerably, though following the WHO model, the decision about which medicines will be classified as essential is conducted at the National level (Embrey, 2011).

There are multiple reasons to support the use of limited essential medicines (Olson, 2011):

a. Basic health services, including medicines be accessible to everyone;
b. The public sector cannot afford to supply all medicines that are available on the market;
c. Prescribing patterns are influenced by preferences that may differ among prescribers and when the limited number of medicines are available according to the STGs, then it may increase their confidence in the health system;
d. Concentrating procurement and logistic efforts on a limited number of medicines with large quantities may result in economies of scale;
e. Increased patient education and efforts to provide medicine information may improve rational prescribing and use (Brook, 2011, Chalker, 2011, Goosens et al., 2005); and
f. Improved effectiveness and efficiency reduce healthcare costs, in particular medicine cost and more funds are available for alternative more expensive medicines.

The EML has been shown to improve the quality, cost-effectiveness and availability of medicine for healthcare delivery when combined with proper procurement policies and good prescribing practices (WHWorld Health Organisation, 2010). Though the benefits to having an EML are known, nearly 40 years since the introduction of the WHO EML, only a few studies have investigated its impact (Duong et al., 2015). For example, approximately 80% availability of medicines was found in Sudan and Burkina Faso (Bazargani et al., 2014). In contrast, a study by Cameron et al., showed that low and middle income countries still experience low availability of generic medicines and high prices paid by consumers despite national EML policies (Cameron et al., 2009). In Nepal, approximately 50% of the total medicine used by patients in one study was related to inappropriate prescribing of medicines that are not on the EML (Breman et al., 2006). In countries where an EML exist, it serves as a basis for public procurement of medicines which should always be available to ensure access to priority medicine especially for the poor (Bazargani et al., 2014).

Various weaknesses were found in a recent evaluation of the EML in India, including improper selection of medicines, improper principles of medicine selection, non-alignment to National Health, errors in medicine strength and incomplete medicine information (Manikandan and Gitanjali, 2012). These errors directly impact on the selection, procurement and use of medicines which increase medicine wastage. The study further highlighted that expenditures on non-essential medicines, such as multivitamins or cough mixtures, drain limited financial resources that could otherwise be allocated for more essential products, such as vaccines or antibiotics (Barraclough and Clark, 2011).

In South Africa, the National Essential Medicines Committee (NEMLC) consisting of multi-disciplinary technical experts are responsible for the selection of medicines for the EML and development of STGs for use by prescribers in the public sector (National Department of Health, 2012). Each province has a Pharmaceutical and Therapeutics Committee (PTC) that contribute to the selection and promotion of medicine use. STGs exist to assist prescribers on specific treatments for specific clinical problems. In addition to listing essential medicines, the EML indicates at which level of care specified medicines should be used. There is also a formulary system that comprises of a formulary list which is based on the EML, and a formulary manual which contains summary information on each medicine on the formulary list (National Department of

Health, 2012). STGs and the EML are continuously reviewed and updated (National Department of Health, 2012). Therefore, there is need to manage and monitor the process to avoid medicine wastage if any changes occur.

South Africa carries the highest burden of the human immunodeficiency virus (HIV) in the world, with an estimated 6.1 million of its population HIV positive and more than 2 million people on antiretroviral treatment (ARV) (UNAIDS, 2013). Over the past five years, an overall increase in life expectancy has been realised, which is mainly attributed to the country's response to combating the HIV/AIDS pandemic (National Department of Health, 2010). The South African ARV Tender is the largest of its kind in the world, with increased competition and economies of scale enabling the government to significantly reduce the cost of ARVs thereby allowing more patients to receive ARVs and have improved health outcomes (National Department of Health, 2010). A growing proportion of people living with HIV/AIDS also struggle to cope with tuberculosis (TB) and one or several non-communicable diseases (NCDs) such as diabetes, hypertension, cancer and stroke, particularly as they age (Geneau and Hallen, 2012). The need to ensure that medicines are available remains a priority especially where non-adherence may be fatal. Efforts to reduce waste especially in the form of improved management of medicine expiry is paramount as medicine costs are expensive.

2.4 Procurement

Inventory management is the function of supply management that aims to provide sufficient stock of medicines at the lowest costs possible (Dias, 2011). A well-functioning supply management system promotes:

- Good inventory records and procedures, which is the basis for coordinating the flow of products;
- Protection against theft, corruption and expiry; and
- Necessary stock management and quality (Dias, 2011).

Quantification is the main component of inventory management and the first step in the procurement process. It is defined as the process of estimating quantities and costs of products required for a specific health programme during a specific period

and determining when deliveries of the products should be delivered to ensure uninterrupted supply (Dias, 2011). The procurement system is a major element of pharmaceutical availability and related cost (Reuter, 2006). Effective procurement management enables the healthcare provider to provide the right medicine of the right quality to the right patient at the right time, in the right quantity at a reasonable cost (Chalker, 2011).

The quantification of medicine required is conducted to limit stock shortages, minimize excess stock and wastage and to contribute to the provision of quality healthcare. The basis for calculating the appropriate quantity of medicines to be ordered that are within pharmacists' control is average consumption, quantity on hand and re-order level (Dukes et al., 1997). By monitoring the rate of medicine consumption, the healthcare provider can forecast future medicine requirements with accuracy, although there may be challenges. For example, in Tanzania, medicine shortages resulted from unexpected demand, as well as inaccurate consumption data and trends (Barraclough and Clark, 2011). Any improvement made at facility procurement management may benefit the whole medicine supply system; however the reverse is also true. If too much medicine is ordered, it will result in overstocked items which may expire before use – leading to wastage - and if too little is ordered, essential medicines may not be available when needed (Barraclough and Clark, 2011).

Improved medicine availability as a result of better quantification has been seen globally, including more recently, in Kenya and Namibia (Dias, 2011). Though various methods for quantification exist, the quantity and type of medicine required will depend on the disease pattern in the area served by the health facility. Despite availability of numerous tools for the management of medicines, none of these specifically target the health worker who has had no formal training in medicine logistics and supply management systems and yet is expected to participate in the management process (Jha and Roy, 2005). Being trained in medicine supply management (MSM) and actively dispensing with appropriate licencing has also been noted as a gap. For example, a local study conducted at PHC level among nurses found that though 45% acknowledged being trained in MSM, only 16% had the appropriate dispensing licencing (Tayob, 2012).

Medicine shortages is a global challenge affecting both developed and developing countries (Marshall, 2014). The shortage of essential medicine impact the access and availability of health services to patients which may result in poor health outcomes (Bazargani et al., 2014, Duong et al., 2015, Matse, 2005). The South African pharmaceutical sector, guided by the National Drug Policy (1997), currently uses a centralised tendering system to procure essential medicines and medical supplies for the public sector (National Department of Health, 1997). The aim is to enable the majority of the citizens, especially those from previously disadvantaged communities to have access to medicines. Thus, if the quantities issued to facilities are not a true reflection of demand, then the estimates transmitted to the central level may be incorrect. In addition, the inaccurate quantification estimates from facilities, districts and provinces may influence the tendering process. Therefore, disrupt the entire system and may result in the following problems:

- Inaccurate estimates for the tender process;
- Negatively affect the allocated budget; and
- Loss of confidence in the health system by prescribers and patients due to stock outs (National Department of Health, 1997).

2.5 Distribution

The success of the pharmaceutical management cycle is dependent on the ability to reliably and consistently supply medicines to health facilities at all levels of the health system. The consequence of supply interruption can be catastrophic, especially for medicines where non-adherence can be fatal for individuals while increasing resistance - such as antibiotics and ARVs (Clark, 2011). For example, distribution of TB medicine was highlighted as a challenge in Nepal due to the topography and vastness of the area. Medicines were distributed from central level to regional stores then district usually by vehicle or plane. Thereafter, medicines were carried by bicycle or on foot, weather permitting, which impacted on the availability of consistent medicine supply (Clark, 2011).

The medicine supply chain is unique as it consists of large, extended global pipelines, requires high levels of product availability and has high uncertainty in supply and demand (Tayob, 2012). The medicine distribution process should be treated as an

important function of the health system to ensure delivery of items to the intended destination. Medicine distribution through improved management and increased investment of resources to achieve uninterrupted supply may improve medicine availability (Barraclough and Clark, 2011, Clark, 2011). Restrictive resources may be more complex in ensuring the availability and distribution of certain medicines. For example, insulin for type-1 diabetic is expensive and is purchased through country budgets that are already inadequate, whereas ARVs are mainly funded through the Global Fund (Beran et al., 2016). According to Matse, more than 70% of procurement and distribution processes are compromised due to inadequately trained staff. Professionals often lack basic knowledge on management of medicines supplies but are expected to ensure proper purchase, utilisation and appropriate use of those medicines (Matse, 2005). Adequate training of staff on MSM, knowledge of procurement and distribution processes especially its importance in ensuring uninterrupted supply of medicines is one of the key aspects to reducing waste.

There are different approaches that can be used to address resource wastage in the form of medicine expiry. First Expiry First Out (FEFO) is a distribution procedure that ensures that the stock with the earliest expiry date is distributed and used before an identical stock item with a later expiry date is distributed or used (World Health Organisation, 2005). When implemented accurately, FEFO assists with stock management and reduces the chances of medicine expiring. First In First Out (FIFO) is also be useful when no expiry dates on medicine exist, the stock should be distributed on a first priority basis. These two terms may cause some confusion, however FIFO does not mean that stock that came first will expire first, hence the importance of effectively managing stock to minimise the risk of expiry. Even though not the main focus of study, it is also important to acknowledge that storage facilities at health facilities and depots are a vital part of the supply chain, necessary to ensuring that stock is not spoilt.

The current public sector pharmaceutical supply chain in South Africa has seen challenges related to capacity constraints and supply issues which result in stock outs of essential medicine at health facilities (Tayob, 2012). The Stop Stock Outs Project (SSP) conducts annual surveys on the availability of ARV and TB medicines at facilities across the country. The SSP is useful as it is a mechanism that holds management at all levels of care accountable for patient health outcomes. The

provincial depots are constrained by aging infrastructure not designed for the current population and associated disease burdens, combined with the inappropriate processes and systems (Dunga, 2013). This has resulted in high wastage levels, inability to supply medicines to facilities on time and non-payment to suppliers which reduce the overall availability of medicine to the population. In addition, the overall process has further been challenged by the lack of visibility at all levels of care with regards to the elements of supply chain, thus making forecasting for contracts almost impossible which further negatively affect supply issues (Pharmacist, 2012).

2.6 Use

Rational medicine use requires that medicines are prescribed for a particular patient after proper diagnosis of a health problem (Chalker, 2011). The main aspect of rational medicine use includes appropriate diagnosing, prescribing, dispensing, and proper consumption by the patient (Chalker, 2011). Data from developing countries indicate that fewer than 40% of patients are treated according to STGs (WHWorld Health Organisation, 2010). Irrational medicine use occurs globally at all levels of care. For example, the overuse of antibiotics is not a problem limited to developing countries; According to Goosens *et al* (2005) France uses over three times more antibiotics per patient care than does Netherlands.

Irrational medicine use may involve cases where poorly trained prescribers, prescribe irrationally. For example in Kenya a study found inadequately trained prescribers were a major contributor to irrational medicine use (Chalker, 2011). Similarly, a study conducted in Zimbabwe that evaluated practices of dispensing prescribers found that dispensing doctors prescribed 35% more medicine than non-dispensing doctors suggesting irrational prescribing (Trap, 2003). According to Matse, irrational prescribing constitutes 15% of losses that occur in the supply chain in South Africa. Policy makers such as WHO originally hoped that the availability of STGs would change irrational prescribing patterns (Chalker, 2011). However, it has become clear that circulating STGs to all prescribers is not sufficient to see improvement in prescribing patterns. In addition, patients may use medicines irrationally by collecting treatment even when they are not ill, or they may accumulate more medicines than required to avoid anticipated facility stock out periods in future (Bazargani et al., 2014).

The financial and medicine waste related to irrational prescribing may not be monitored and effectively communicated to prescribers and patients (Embrey, 2011).

2.7 Medicine Wastage

Budget restrictions are experienced globally, but more so in public sector hospitals where there is significant focus on improving workflow and reducing expenses (Agnelly, 2014). One of the key criterion in evaluating healthcare systems is expenditure (Kerr and Romine, 2012). Improving inventory efficiencies and reducing medicine waste, while enhancing patient care remain a challenge to hospital pharmacies (Agnelly, 2014). Studies conducted in England and Spain estimated a gross annual prescribed medicine wastage of more than $400 million and $9000 respectively (Coma et al., 2008, Langley et al., 2005). In other studies, though real value could not be assessed, two indicated an enormous burden on pharmaceutical budgets, caused by wastage (Mackridge and Marriott, 2007, Cameron, 1996).

Around the world, expiry costs are often 3% to 5% of pharmaceutical inventory per annum (Dias, 2011). However, in Spain, more than 50% of medicines evaluated in community pharmacies had expired (Coma et al., 2008). Similarly, a study conducted in Nigeria to assess availability of ARVs in treatment centers found that 64% of the facilities had expired ARVs worth more than $146 000 (World Health Organisation, 2003). The national figure for expiry reported in Ethiopia in 2003 was as high as 8% (Tadeg et al., 2014). In South Africa, while expiry costs according to the Gauteng Provincial policy should not exceed 1% of a facility's annual budget (Pharmacist, 2012), the cost of expired medicine in one clinic in a study conducted by Tayob was as high as $8 000, which is equivalent to the average monthly medicine expenditure for one PHC clinic (Tayob, 2012). Similarly, revenue loss across 41 hospitals in Limpopo province was more than $66 000, of pharmaceutical expenditure, i.e an average of 0.07% a month (Motlanthe, 2010).

Medicine wastage, in particular expiry costs, may serve as a proxy for ineffective inventory control and management of financial resources at public health facilities. Even though tools are available for effectively monitoring medicine procurement, use and financial resources, skills and capacity are important pre-conditions. Monitoring

processes may be compromised due to inadequately trained staff or processes that do not take enough account of the local context. The lack of accountability in managing medicines has exposed the public healthcare system in South Africa to wastage, which may directly impact availability of medicines especially to the poor, who are mostly affected by such inefficiencies (Motlanthe, 2010).

CHAPTER 3: METHODOLOGY

3.1 Study Design

This mixed methods study included both quantitative and qualitative components, set in a large tertiary hospital in Johannesburg. The quantitative part consisted of a retrospective data extraction of medicines that were recorded as expired during the period 2011 to mid-2014. The qualitative part comprised semi-structured in-depth interviews with key actors to explore the reasons for the expiration of medicines. In addition, informal observations were conducted across the duration of the fieldwork and recorded in a researcher diary. The quantitative and qualitative components were undertaken concurrently and the data were integrated during the interpretation phase (Creswell, 2006). Using a triangulation approach, the methods were mixed in interpretation and analysis, to contribute to a more holistic understanding of the problem (Creswell, 2006).

3.2 Study Site

The study was conducted at a large urban tertiary hospital in Johannesburg, Gauteng, South Africa. The hospital provides medical and surgical inpatient and outpatient services. The hospital has 347 approved beds and an average medical intake of 45 patients per day. The hospital is home to one of the largest HIV/AIDS treatment clinics in the country, which currently maintains more than 15,000 adult patients on antiretroviral (ARV) therapy. At the time of the study, there were 9 pharmacists and 12 pharmacist assistants. During the study period, expired stock was manually monitored, however an electronic medicine management system, Rx Solution®, is currently used to monitor expired medicines.

3.3 Study Population and Sample

Quantitative record review of medicine audit

The quantitative component of the study consisted of a review of records from a medicine audit aimed to remove all expired stock or medicines that would expire within six months. These medicines were removed from the wards, outpatient departments and pharmacy - and were disposed of or dispensed to the pharmacy outpatient department to ensure usage before expiration. The study sample included all the records of medicines that expired in the wards, outpatient departments, and pharmacy and were recorded at the hospital pharmacy between January 1, 2011 and June 30, 2014.

In-depth interviews with key actors and observations

The qualitative component of the study consisted of semi-structured in-depth interviews with key stakeholders, as well as observation notes made by the researcher. Participants included ward managers, pharmacists and pharmacy assistants who had been working at the hospital for a minimum of 12 months, and were therefore familiar with the medicine management policy. Purposive sampling was used to select the 13 participants for the interview. These participants were chosen because they occupy positions that are central to medicines management and therefore of direct relevance to the study, such as pharmacists and ward managers. Sampling proceeded until the point of saturation, that is, when there was reduced variability in the information received (Barnes et al., 2012). The staff members were asked to participate in an interview to explore possible reasons for medicine expiration, and related trend and revenue loss.

The researcher also kept a diary and conducted informal observations in the wards, pharmacy and outpatient departments. Observations included practices of packaging, storing, naming and recording of medicines.

3.4 Data Collection

Data were collected from July 2014 by the researcher through three mechanisms; i) a data extraction tool which included costs to quantify and classify the type of medicines that had expired. A pre-existing electronic database that had been set up in 2011 to record expired medicines in the different wards was used. However substantial data

cleaning was required because certain fields were either omitted or incomplete in the original database, ii) semi-structured in-depth interviews to explore reasons for medicines expiring, and iii) a researcher diary based on observations to identify gaps between policy and implementation.

a. Data extraction for quantitative information

The data extraction tool (Appendix A) was developed in Microsoft Excel®. Information was compiled on medicines that had expired between January 1, 2011 and June 30, 2014. The original dataset consisted of the medicine name, expiry date, recorded date, unit, expired quantity and unit cost for each item. The dataset was expanded and additional information on national stock number (NSN), route of administration, the VEN classification according to the provincial formulary, anatomical therapeutic class (ATC) code from the WHO classification (Appendix B) and according to the essential medicine list classification were manually added. A full list with ATC codes and definitions is provided in Appendix B. The hospital medicine formulary edition from 2014, the Essential Drug List for hospitals and the National Master Procurement Catalogue (MPC) were used to classify each medicine.

The unit cost per medicine expired was recorded using the cost from the year in which the medicines were recorded as expired. For records, whose unit cost were unknown (four items), the cost in the year which the medicine expired was used. The 2014 year records ran up to June. Therefore, the revenue loss was estimated until June 2014. The researcher assumed that half the budget and expenditure was used by mid-year and proportion loss for 2014 was calculated based on this. The total cost for each year was calculated. The unit costs used were from available invoices or price lists from the pharmacy as well as the Gauteng medical supply depot (MSD).

b. Semi-structured in-depth interviews

Permission to conduct in-depth interviews was requested from the ward managers, ward pharmacy champion, pharmacists and pharmacy assistants (Appendices C). Copies of the permission letter obtained from the hospital Chief Executive Officer (CEO) were shared with all requested to partake in the interviews. The purpose of the research was explained and an information sheet (Appendix D) was provided on the details of the study. Participants were invited to ask questions about the study before an informed consent process was finalised. The interview guide (Appendix E) covered the following topics:

- Participant qualifications
- Ordering of medicines
- Storage of medicines
- Knowledge of drug management
- Reasons for medicine expiration

All in-depth interviews were recorded. Participants were interviewed in English; however they were also encouraged to use words or phrases from other languages where necessary so that nothing of importance was lost. To maintain confidentiality, all participants received unique identifiers during data analysis so statements could not be directly linked to an individual. Furthermore, the participants interviewed reflect persons who directly manage medicines such as pharmacists, pharmacy assistants and nurses.

c. Researcher Diary

The researcher conducted observations immediately after completing each interview. The researcher did not act conspicuous nor attracted any attention that made observations visible .In addition, interviews were conducted in a private room with only one person in each department, no observer effect (McCambridge et al., 2014) was noticed.

3.5 Data Management and Analysis

Statistics included estimate of total value of the expired medicines by therapeutic class and EML classification. Whilst trend tests that test for statistical significance to year on year changes are important, three years is a short time period on which to conduct sophisticated statistical trend analysis (Rosenberg, 1997). However, statistical analysis was conducted to determine the average yearly increase in revenue loss over the time period of analysis using equation for calculating average rate of change, Appendix F. Further, the total value of expired medicines in each year was expressed as a proportion of the total pharmaceutical budget and expenditure to give the percentage loss in revenue. The latter value was compared across the three years of analysis to determine whether there has been a year-on-year proportional increase in

revenue loss relative to the provincial threshold of 1% and the annual hospital pharmaceutical expenditure. Expenditure was used as it was the most stable indicator across the three years, given that the hospital budget was substantially reduced for three years over the study period.

Analysis of in-depth interviews with key actors

All in-depth interviews were typed in Microsoft Word® and analysed in Microsoft Excel®, which was used to help with the coding and thematic content analyses of the data. A code book was developed and analysed deductively (i.e.- from 'pre-established' themes drawn from the literature and conceptual framework) and also inductively allowing for themes to emerge from the participants themselves. Texts were coded across all transcripts and observation notes were drew on as part of the analysis. The information was analysed thematically in a systematic way using an exploratory approach in order to explore in-depth the reasons why medicines expire (Creswell, 2006).

The quantitative and qualitative data sources were integrated by bringing the separate results together in the interpretation of the analysis (Creswell, 2006).

Data validation, reliability and trustworthiness

It is important to ensure methodological rigour and data quality to ensure trustworthiness of any study, especially when using a mixed methods approach. The quantitative data contained in the original dataset were initially captured for another purpose. The medicine that were recorded as expired were already disposed of and the data could not been validated to ensure accuracy and enhance reliability. Therefore, in this study, medicine names and unit costs were corrected during the cleaning of data and the MPC was used to accurately insert or compare medicine names and unit costs. Calculations were also re-ran to ensure accuracy. The qualitative data was collected to support the argument that the inquiry's finds are worth paying attention to. The qualitative data was reduced to themes that describes the research question. The qualitative data were read and coded by more than one person to enhance the reliability of the information (Noble and Smith, 2015). In addition, quotations were used to enhance the trustworthiness and objectivity of the results.

3.6 Ethical Considerations

This study posed minimal risk to the study participants (selected ward managers, pharmacists, and pharmacist assistants) as information was kept confidential and could not be linked to an individual during analysis because unique identifiers (ID) were used. Written informed consent for the interview and recording was sought from all participants before the interview was conducted. All interviews were conducted in an enclosed office at the hospital to ensure privacy. Each participant was assigned a study ID number when data was collected and presented. Only the researcher and supervisors of the study had access to all the information that were password protected and stored in secure cupboards.

The interviews were conducted during normal working hours, and no payment was provided to participants. Though there were no direct benefits to study participants for being included in the study; the hospital and other health facilities in South Africa may indirectly benefit as the information may assist with future planning and management. Information from the study may be useful to improve planning, monitoring and management of medicines.

Permission to conduct the study was sought from the University of the Witwatersrand Human Research Ethics Committee (HREC) (Medical) – M131015 (Appendix G), and the hospital. No data were collected until all permissions were been granted. The data will be destroyed two years after completion and publication of the research report in accordance with ethical guidelines from the HREC**.**

CHAPTER 4: RESULTS

This chapter presents the results from both the quantitative and qualitative components of the study. Descriptive statistics are presented about the characteristics of the expired medicines included Anatomical Therapeutic Chemical (ATC) classification they fall under, type of formulation, single highest unit costs and the VEN classification of medicines and related expiry costs. Findings from the interviews conducted will be presented thematically and observations conducted and aspects observed will be drawn upon.

SECTION A: QUANTITATIVE RESULTS

4.1 Description of medicines

A total of 32,368 unit packs of medicines expired over the study period (January 2011 – June 2014) consisting of 68 different ATC classes.

Expired medicine by ATC classification

Antibacterial for systemic use (16%, n=5067) and antivirals for systemic use (15%, n=4970) constituted the highest classes that expired, followed by medicine used in diabetes mellitus (9%, n=2856) and anti-epileptics (7%, n=2342). Though only 1%, (n=337) of muscle relaxants had expired, this class accounted for more than 10% of the total cost.

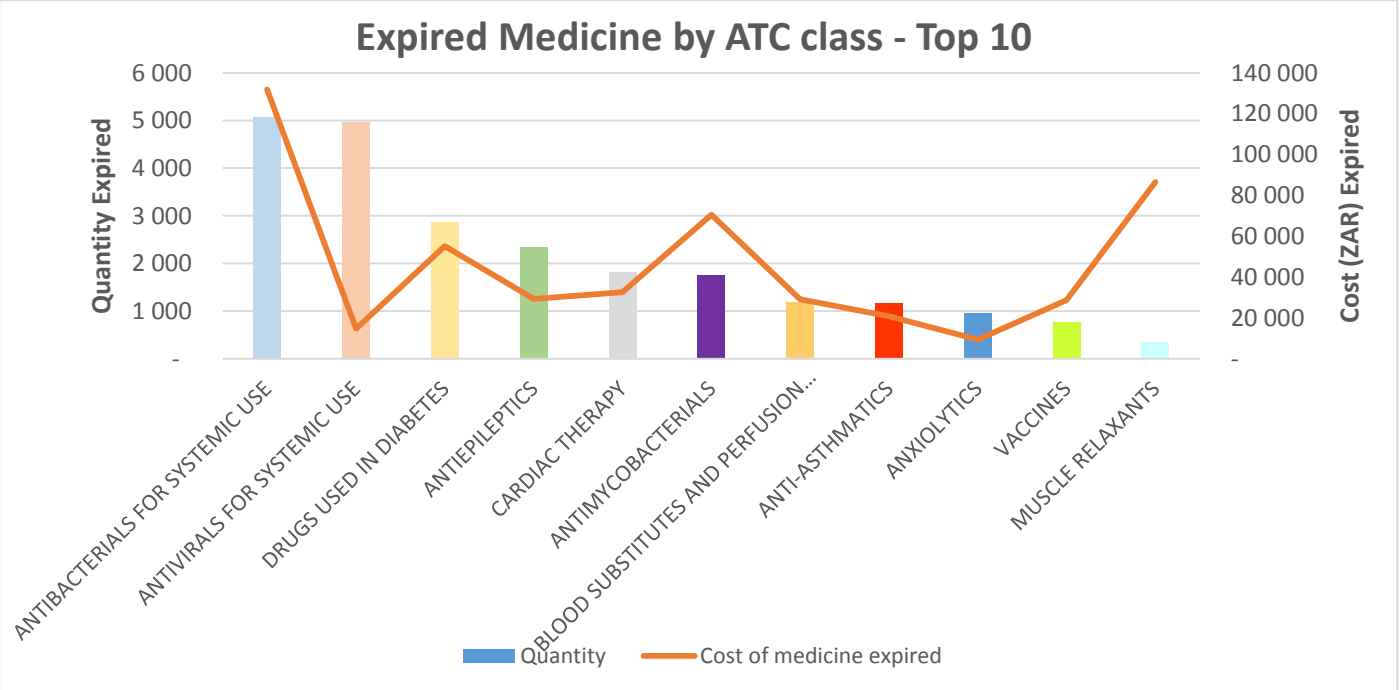

Figure 4: Quantity and cost of medicines that expired by ATC classification

Expired medicine by EML classification and formulation

More than 80% of the medicines that expired were on the EML with antibacterial for systemic use (16%, n=5067) and antivirals for systemic use (15%, n=4970) among the highest classes that expired. Additionally more than 20% of the medicines were injections accounting for the highest unit costs (Figure 5).

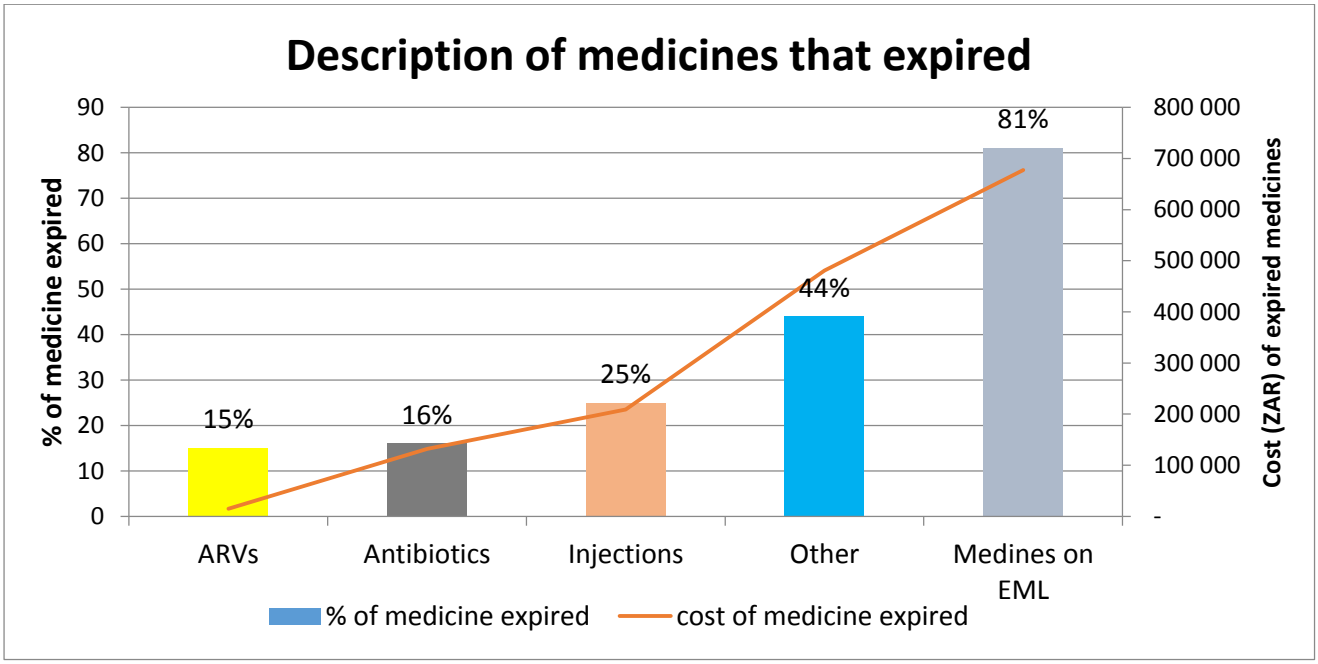

Figure 5: Classes of medicines that expired with corresponding cost

Medicine with highest unit cost

Medicines were ranked by unit cost and Table 2 depicts the top five expired medicines with highest unit costs.

Table 2: Medicine with the highest unit costs

Medicine name	Unit cost (ZAR)
Streptokinase for injection 1500 000IU/vial; 1's	R3 147
Dantrolene sodium for infusion 20mg/70ml; 1's	R1 604
Desmopressin injection 4mcg/ml; 1ml; 1's	R 832
Immunoglobulin human injection; anti-rabies; ampoule;150iu/ml'2ml; 1's	R 592
Sodium Polystyrene Sulphonate Powder; 454g	R 573

Top 5 highest single expired medicines

The Ofloxacin injection value of medicines that expired, accounted for more than 10% (R92 507) over the study period, followed by Dantrolene Sodium for infusion (9%, R82 848) and Acetylcysteine Injection (7%, R59 763).

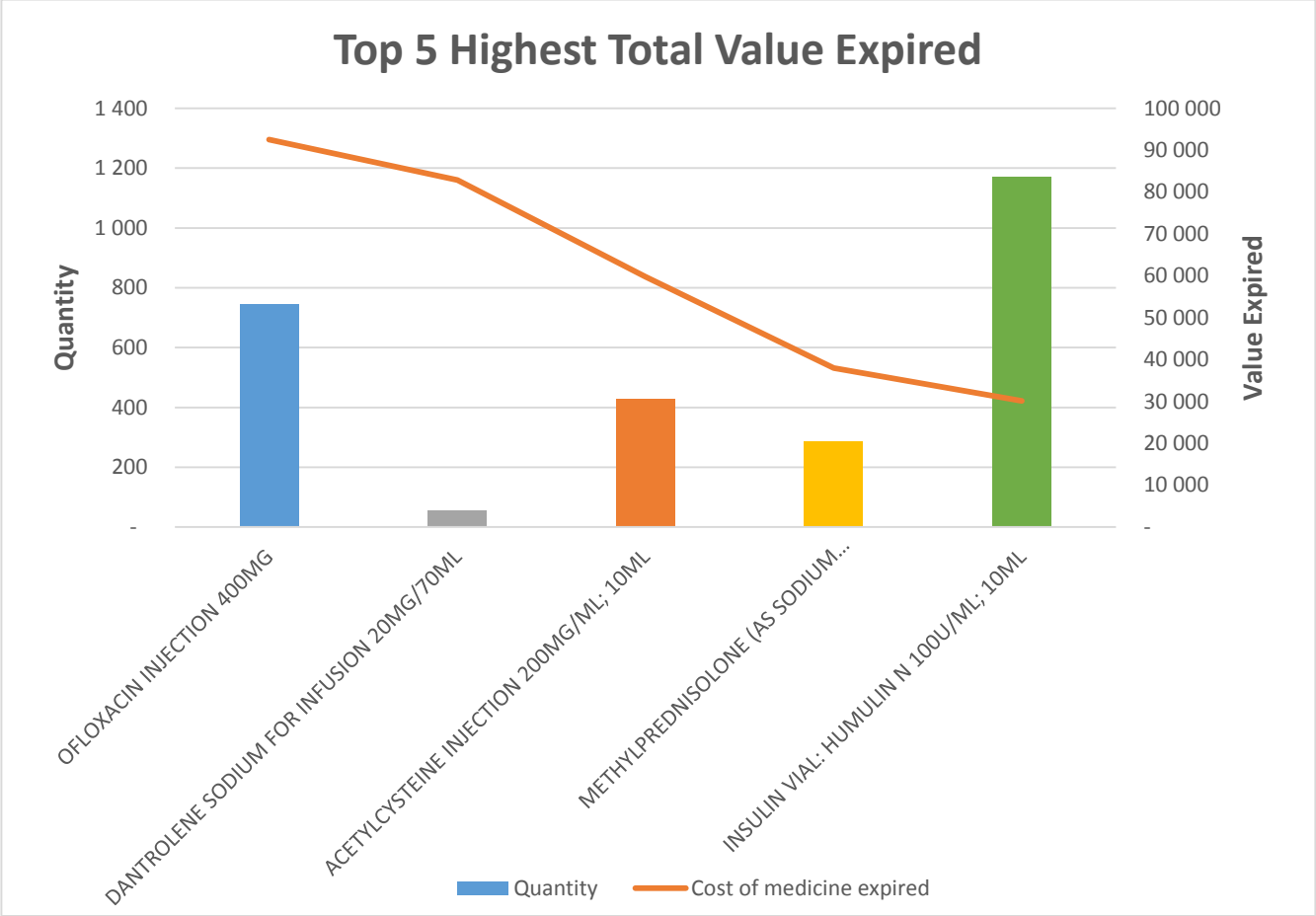

Figure 6: Single highest top 5 medicines that expired with corresponding cost

Medicines were grouped according to their Vital Essential Non-essential (VEN) classification. More than 50% of the medicines that expired were vital (Table 3)

Table 3: Total medicines expired by VEN classification

VEN Classification	Quantity	Value Expired	% of value expired
V	21 066	R433 351	52%
E	5 313	R162 253	19%
N	5 989	R242 425	29%
Total	**32 368**	**R838 029**	

4.2 Total Value Expired over the Study Period

The estimated total value of expired medicine for the study period was R838 029; an estimated annual revenue loss of 0.6% of the hospital's total pharmaceutical expenditure for the period January 2011 to June 2014. The average increase in percentage revenue loss over the study period is estimated to be 72%.

Table 4: Total value of expired medicines over the study period (January 2011-June 2014)

Year	Total value of expired medicines	Total Pharmaceutical Budget	Total Pharmaceutical Expenditure	% loss as proportion of budget	% loss as proportion of expenditure
2011	R196 197	R13 598 000	R39 705 098	1.4%	0.5%
2012	R329 161	R 9 276 000	R38 204 549	3.6%	0.9%
2013	R117 862	R11 382 000	R46 902 168	1.0%	0.3%
2014	R192 809[2]	R17 830 000[3]	R24 506 162[4]	1.1%	0.8%

Overall, these results, emerging from analysis of the three-year database of expired medicines in the hospital, quantify the type and extent of revenue that was lost due to expired medicine over the study period. On the one hand too many vital medicine on the EML expire, but at the same time it is not surprising, given that this is the pool of medicines that should be available. However, any amount of wastage lost is a direct financial loss to the facility. To explore reasons for medicines expiring, that is, the 'hows' and 'whys' (Creswell, 2006) of these trends, qualitative interviews and observations were conducted with actors directly involved in the management of medicines in the hospital.

[2] Revenue loss up to June 2014

[3] Half the budget shown as data on expired medicines for 2014 ran up to June

[4] Half the expenditure shown as data on expired medicines for 2014 ran up to June

SECTION B: QUALITATIVE RESULTS

Interviews were conducted with key actors within the hospital to explore the reasons for medicines expiring. Thirteen interviews were carried out between July and November 2014. Issues explored included the procurement and storage of medicine, overall medicine management and reasons related to expiration of medicines. Interviews lasted for approximately 30 minutes per person. All but one participant (n=12, 92%) were female and the average length of service among participants working at the hospital was 7 years (SD: 6.50). Five (38%) participants were qualified pharmacists, two (40%) of whom had previously worked in the private sector for more than ten years. Participants were drawn from the pharmacy, as well as other relevant wards and units, such as the emergency unit, outpatient departments, theatre, surgical and medical units (as shown in Table 5). This is because medicine management is not restricted to pharmacists and is also managed by nurses and pharmacy assistants as shown in Table 5:

Table 5: Descriptive statistics of participants (N=13)

Variable	**n (%)**
Female	12 (92)
Qualifications of participants • Bachelor of Pharmacy (BPharm) • Professional nurses • Enrolled nurses • Pharmacist assistant - intern • Qualified post basic assistant	 5 (38.5) 3 (23.1) 2 (15.4) 1 (7.6) 2 (15.4)
Mean years in private sector (SD)	3 (4.37)
Mean years at facility (SD)	7 (6.50)
Mean years managing a unit at hospital (SD)	1.5 (2.38)

SD: standard deviation; n: sample

Two main themes emerged; i) Knowledge, understanding and practical application of policies and procedures related to expired medicines, and ii) Diversion from Ideal: procedures and constraints which may impact implementation.

There were a number of different practices in the different units which resulted in the diversion from the ideal management of expired medicines (policy and procedures) and the practiced pathways (actual implementation). It is in the diversions between the two that key gaps, constraints and challenges to managing expired medicines emerge.

Theme 1: Knowledge, Understanding and Practical Application of Policies and Procedures Related to Expired Medicine

Ordering of medicine

According to the Gauteng Provincial Pharmaceutical and Therapeutics Committee (PTC) guidelines, a committee should be in place at every institution for the selection and promotion of rational medicine use (Gauteng Province, 2013). It is recommended that re-order levels are reviewed bi-annually to minimise overstock of items which may result in medicines expiring. This will further enhance the quantification of needs whereby minimum inventory levels are maintained. In the study site, there is a Standard Operating Procedure (SOP) on the ordering, storage and packing of medicine that was developed by the Gauteng Pharmaceutical Services Directorate to be used in facilities in the province (Appendix H). Three participants reported an awareness of *a detailed SOP'* (Participant #4). All participants noted that, when ordering was necessary, a uniform ordering process was always followed amongst all departments *'Main stores - Monday weekly order*', *'We place our order every Monday', 'Order prepared on Sunday and sent to pharmacy on Monday'* (Participants 1, 5 and 12).

Pieced together from different points of view, as described by different participants depending on their location in the hospital, the ideal ordering procedure can be summarised as follows: It is dependent on where the medicines are ordered from. Similarly, the lead time for receiving medicines is also dependent on who the supplier is. All medicines ordered from the depot have a lead time of one week, all direct delivery vouchers (DDV) medicines are received within 21 days and non-essential medicine that are not on contract have a lead time of approximately three (3) months. Most of the medicines (80%) are ordered from the depot and all departments, including those in the pharmacy placed weekly orders. Provision is made for emergency items if weekly order submission to the depot is not submitted on time; however it is restricted

to five items as explained; *'Urgent orders cannot be more than 5 items or big quantities'* (Participant #6).

The system used by main stores to order stock from the depot is computer-based, however all other departments at the hospital use a paper-based system. Though minimum and maximum medicine levels are part of the SOP, this practice is not fully adhered to. Participants emphasized the importance of ordering medicine timeously, however observations revealed that certain medicines exceeded their maximum levels as most departments ordered without considering current stock on hand. All participants explained that they feared stock outs and preferred hoarding stock:

> *'Stock outs are our biggest challenge - when medication is out of stock we have to borrow, which is difficult'* (Participant #5).

This practice resulted in irregular ordering which on the one hand may be seen as the disruption of average monthly consumption, while on the other as a proactive measure for accommodating long holidays which may interrupt supply or an effort to anticipate future failings in the system.

Storage of Medicines

According to the hospital's SOP, the pharmaceutical storage area must be under the control of the responsible pharmacist and delivery of medicines must be made directly to the pharmacy. The responsible pharmacist is not present at all departments all the times, hence different staff are assigned for unpacking and storage of medicines. Who these staff members are and how medicines are received and stored is mainly dependent on the department. The SOP also encourages someone to always be present to receive medicines and ensure the packing and storing thereof. At this facility, a 'Ward Medicine Champion' and pharmacist's assistant is elected to fulfill this role. Observations showed that in some cases the person responsible for packing the stock did not verify the number of items received in relation to the orders placed. Additionally, in some instances the same items were ordered again with the next order placed by the ward.

Implementation of First Expiry First Out (FEFO)

The participants shared similar perspectives regarding the explanation of FEFO and its implementation. Whilst the majority of the participants claimed that they knew what the acronym means, almost half explained FEFO according to principles of First in First out (FIFO). FEFO is a stock rotation method to ensure that medicines with the earliest expiry date are used first, whereas FIFO focuses on using stock that was received first regardless of expiry date. The implication for confusing the two terms (FEFO vs. FIFO) may result in medicines expiring. Although respondents were aware of the acronym, their knowledge itself was incorrect. Although the end result may be the same. Sometimes, medicines that were received first may expire first, and may be used before expiry. This may be different from respondents accurately knowing what to do but not being able to practice this due to constraints or practical issues.

All participants knew who was responsible for monitoring FEFO in their respective units but not all responsible employees understood or were held accountable for ensuring adequate implementation of FEFO. For example, all departments assigned a specific person responsible for monitoring the practice. However there was no training provided or criteria set for an individual to be considered competent. Below are examples of the various perceptions of participants regarding monitoring of the FEFO process;

> *'The pharmacist in charge of the department is responsible for monitoring FEFO'* (Participant #8);
>
> *'The sister in charge is responsible of medication (ward champion) for monitoring the practice'* (Participant #10).
>
> *'Yes, I (ward champion) am in charge of monitoring FEFO but no one checks if I do it correct'* (Participant #9).

The hospital SOP encourages the use of colour coded stickers as a guide to actively practice FEFO. The colour coded sticker provides an estimated timeframe in which certain medicines will expire. This practice was observed in all inpatient wards and outpatient clinics visited. This directly made every person in that unit equally responsible for monitoring medicine expiration dates because each colour coded sticker has a specific expiry date meaning. However, no one can be held individually accountable even if this practice is not adhered to. *'Colour coded stickers are used to mark drugs and it is then packed accordingly. Drug ward champions were chosen at*

each ward and they decided on the colours' (Participant #13). *'FEFO is important to avoid stock from expiring and everyone in the unit should be responsible'* (Participant #3).

Significance of FEFO Process and Policy

According to the SOP, the document should be shared with and signed off by all employees. All participants were aware of the SOP related to practising FEFO, however the SOP was not shared with or signed by all employees *'There is an SOP but only certain departments share the SOP with employees'* (Participant #4). Therefore, employees in these departments cannot be held accountable for not adhering to the SOP. In addition all participants found the practice of FEFO important though the implementation thereof was also explained to be difficult to monitor in certain instances.

> *'In the bulk/main stores, stock is packed in batches and this is linked to expiry and pharmacist pick according to batch therefore easy to ensure FEFO is practiced. Sometimes it is not practiced in the pharmacy in-patient department because it is not easy to monitor as drugs are open and not packed by batch*' (Participant #1).

Along with knowledge pertaining to the policy, the value and significance of monitoring FEFO was highlighted by all participants to;

- reduce expired stock*: 'FEFO is important because it reduces the risk of expired stock* (Participant #1); minimize financial loss: *'It is important because drugs are very expensive and costly to write off one drug. If it is expiring soon, we make a plan - to move it out or double up small strength to get bigger strength'* (Participant #8);
- avoid stock outs due to long ordering lead times*: 'It is important because of different ordering processes and long lead times, some items can be slow movers and FEFO helps organize stock correctly'* (Participant #4) and;
- help identify short dated items: *'It is important because of different ordering processes and long lead times, some items can be slow movers and FEFO helps organise stock correctly'* (Participant #5).

Medicine Management Training

Medicine management training is an important component to enhance stock management. This training emphasises the principles and implications of use, selection, distribution and overall effective management of medicine. Medicine is not only managed by the pharmacist, but includes pharmacy assistants and nurses. Thus, there is need to ensure everyone who manages medicine should undertake medicine management training. Only two participants were confident in reporting that they received medicine management training and are actively implementing it. *'Yes, I have [had] drug management training and it included - supply chain and stock management and financial management training'* (Participant #4).

The remainder of participants reported that they never received medicine management training or had only learnt theory during a module at university or college. All participants acknowledged that training on medicine management is important, however the coordination of such training can be challenging. Participants advised that in-house refreshers should be arranged by the pharmacy department, although a number of reasons were given for the lack of in-house training, including difficulties in finding suitable times: *'…and there is need for in-house refreshers, however it is not easy to organise due to time constraints and staffing'* (Participant #1); *'…there is need for in-house refreshers, especially when new staff starts at the beginning of the year'*, *but this is not conducted due to time constraints* (Participant #2); staff rotations: *'…this is done but there are many rotations which interrupt the trained staff'* (Participant #4); and lack of prioritization: *'…In-house refreshers are important, however it is not done because of low priority associated with drug management'* (Participant #8).

Process of Medicine Management

According to the SOP, there is need to conduct periodic stock takes and monthly stock counts. All participants reported that stock take procedures are conducted as a method to manage their medicines. However different departments follow different processes and have different timeframes for conducting stock assessments, which is decided by the department manager. daily, *'…every day, stock balance is done for scheduled drugs'* (Participant #8), weekly, *and '…mini stock taking done on Fridays' (Participant #5)*. In others, it occurs bi-annually, *'…We have stock taking twice a year (March and September) and this timeframe was chosen by Province'* (Participant #1), or even on

an irregular basis, *'…Stocktaking is done on allocated days, before ordering. Stocktaking done also after receiving stock'* (Participant #13).

During observations, it was evident that all departments conduct some form of stock take based on the data that was captured. However, the aim and reason for these stock takes were unclear among the participants. Additionally, there was a lack of knowledge on how and why a stock take should be conducted. For most, it was seen as merely a packing exercise across all departments, without any specific guideline or format.

Theme 2: Diversion from Ideal: procedures and constraints which may impact implementation

The in-depth interviews suggest that there is knowledge (although not always accurate) of how medicines *should* be managed. However practices often divert from the ideal. A closer examination to explore the reasons for these diversions - the 'whys'- revealed three thematic areas:

- mistrust among employees and in the system,
- fear of being 'caught' yet lack of accountability
- ineffective communication and coordination

1. Mistrust Among Employees and in the System

Ineffective Inventory Management

When exploring the possible reasons why medicines expire, participants mainly attributed it to ineffective inventory management. Ineffective management can be curtailed by identifying internal and external contributing factors that can be used to strengthen intervention. There are aspects within pharmacist control to minimise medicines expiry and these are average consumption, quantity on hand and re-order levels as highlighted in the following extract: *'Sometimes medication is on medication trolley or in the cupboard that is not counted as stock and an order is placed for this drug'* (Participant #9).

There are also aspects out of the control of pharmacists which include storage capacity, procurement period, lead time and minimum order quantity prescribed by policy for example the National Core Standards medicines checklist; as mentioned

'Long lead times make me feel pressure to order more than what I need - service level agreement needs to be re-examined' (Participant #5). Additionally stock is ordered in excess regardless of the minimum and maximum ordering system and re-ordering of available medicines. Participants' orders may be influenced by past experience of either receiving lower quantities or delayed deliveries. It may also become more challenging to borrow medicine from neighboring facilities due to similar system related challenges may be experienced.

Though reasons to minimize overstocking and increase effective management of stock are relevant, there are certain instances that cannot be avoided which further perpetuate this challenge. Over the Easter and Christmas long holidays, the depot have less employees for periods of up to 10 working days which may interrupt the continuous supply of stock. One participant mentioned that *'Holidays interrupt ordering and receiving stock, therefore order excess ahead of time to cater for the holidays*' (Participant #1).

Ineffective/Conflicting Relationships between Stockpiling & Tender Processes

Most participants anticipated the late renewal of tenders and attributed much of the expiration of medicines to this process. Participants mentioned that there is usually a delay in the contract end date of the current supplier and start date of new supplier especially if they are not the same. This therefore resulted in stock hoarding as well as receipt of short dated stock as indicated in the following extracts, *'If the tender is not functional, the company can supply short dated or expired stock - however, short dated items that are not fast moving, are sent back'* (Participant #1), another participant highlighted that *'…pressure to receive short dated stock due to short supply from the pharmacy/depot and unable to dispense this drug before expiry*' (Participant #5).

In addition certain participants mentioned the need for stockpiling, regardless of the implications for transparency and accountability: *'…there is pressure to keep buffer stock for situations when there is no stock'* (Participant #5) and *'…non-payment of suppliers, put pressure to order excess so there is always stock'* (Participant #1). Another participant explained that the public sector is a dumping ground for short dated items, *'Public sector is seen as a dumping ground and are given short dated stock. Short dated stock expires within one year'* (Participant #4).

Rotation of Prescribers

Participants highlighted human resources rotation as an important aspect that impacts on the expiry of medicines. Participants mentioned that doctors are rotated frequently among different hospitals and also between public and private sector resulting in '*overstocking - stock is ordered according to doctor and when the doctor is rotated, the stock will sit'* (Participant #4). Additionally, the high rates of absenteeism at the facility further influences efforts to minimise wastage in the form of medicine expiration:

> *'We never have the full staff complement in the pharmacy because there is someone absent for one or other reason on a daily basis. Staffing - are unable to perform the functions that should be happening'* (Participant #4).

Change in Formulary of Standard Treatment Guidelines

Whenever a change in standard treatment guidelines occurs, usually every two years, stock may not be recommended as per the treatment guideline, however not enough time is given between policy change and implementation. In addition, such changes are not communicated in a timeous manner to other healthcare workers in the facility, and therefore increasing the risk of medicines expiring as explained:

> *'Pharmacy need to communicate if there is a change in drug name or replacement, send out a memo'* (Participant #13).

2. Fear of Being 'Caught' yet Lack of Accountability

Staff Practices

Participants' felts that consequences of irregular practices such as hiding excess stock were not clearly communicated to staff. With this, they suggested that employees are not held accountable for such practices as explained by Participant #4 *'Departments are hiding away excess stock.'* During observations the researcher noticed a box of expired medicines that had been actively hidden in a cupboard for fear of it being found by the pharmacy department during the monthly audit. There are no guidelines or procedures to follow when an employee is caught hiding some medicines. And this

observation was confirmed by one participant who indicated the following; *'If a drug has been removed from the shelf by staff and has not been dispensed to a patient, staff can forget to return it in a timely manner before it expires'* (Participant #12).

3. Ineffective Communication and Coordination

Ineffective Communication

For many in the study, the efficient and effective management of medicine is a challenge due to the lack of communication among different departments. The pharmacy department plays a pivotal role in facilitating communication to provide updates on items that have a slow turnover as well as address knowledge gaps identified. However, this communication is not disseminated timeously and may cause confusion among prescribers. Ineffective communication further forces employees to order higher quantities. Furthermore, the pharmacy department should be held accountable when communication is not effective. Participants had similar views when discussing the level of communication among departments which may directly impact on medicines expiring, and their views are indicated by the extracts;

> *'Lack of communication of available stock to doctors. The supplier will communicate to the pharmacist about unavailable drugs and suggest an alternative, but it is not communicated. When the drug becomes available, drug prescription is not changed'* (Participant #7).

Infrastructural System Issues

Participants mentioned that the use of a manual system makes it difficult to trace stock, for instance one participant mentioned that, *'Manual system makes it hard to track stock once it is released to OPD or the wards*' (Participant #1). Additionally, *'Majority of stock are kept at ward levels and there is no control over their stock due to manual system still practiced*'.

An electronic system called Rx Solution® was recently installed at the hospital. Rx Solution® is a pharmaceutical management system that has various capabilities, of which one includes the ability to minimise the number of expired medicines. However, the roll-out of the system has been limited by lack of necessary equipment in the

hospital as indicated; *'*Rx Solution® *is meant for stock management, however there are no computers'* (Participant #4).

CHAPTER 5: DISCUSSION

The aim of this study was to describe the economic impact related to, and reasons for, the expiry of medicines at a large urban hospital in Johannesburg, South Africa from January 2011 until June 2014. The total estimated value of financial losses due to medicine expiry was R836 029; an estimated annual revenue loss of 0.6% of the total hospital expenditure. This percentage is lower than the allowed percentage in Gauteng Province of 1% (Pharmacist, 2012). However, a 0.6% loss in revenue due to expired medicines presents an opportunity cost as the funds could have been directed to meet other healthcare needs in light of the budgetary constraints that the health system faces. In addition, an average increase in revenue loss of 72% is significant given that budgets are shrinking annually, as is the case at this urban hospital. The annual budget increase for provincial pharmaceutical services is horizontal and the average increase is approximately 16% which is almost five times lower than the average annual increase in revenue lost due to expired medicine (Pharmacist, 2012)

According to this study more than 80% of the medicines that expired were on the essential medicine list (EML), with antibacterial for systemic use (16%, n=5067) and antivirals for systemic use (15%, n=4970) among the highest classes that expired. To explain ‘why’, two main themes emerged, focusing on the ideal management, understanding (policies and procedures) and the practiced pathways (actual implementation). Furthermore, this study found that all the top medicines that expired at this hospital either have high consumption rates or are vital where non-adherence may be fatal. Chronic diseases require long-term compliance to treatment and the expiry of medicines such as anti-diabetics may force patients to either buy or forego treatment. A possible reason for expiry of expensive medicines may be that such expired medicine is only used for emergency cases such as Streptokinase in Cardiac Failure which should be administered within one hour of the event (to a maximum of 12 hours). The consumption at this tertiary hospital may be low and it is possible that patients consulted elsewhere before arriving at this hospital, thus the time window for use of Streptokinase may have passed.

Availability of essential medicines is needed for healthcare delivery and, consistent with other studies, these findings confirmed that expiry of medicines was highest among essential medicine (Nakyanzi et al., 2010). The lack of access to essential medicines due to wastage may cause households to face financial catastrophe by paying out of pocket for medicine in the private sector (McIntyre et al., 2006), making medicine the largest household expenditure item after food (Prinja et al., 2015). Additionally, lack of essential medicines may result in low staff morale and reduce confidence in the health system by patients and healthcare workers (Penfold et al., 2013), which may impact accountability.

Governance and Accountability

In South Africa, there are various documents such as Good Pharmacy Practice (GPP) and the Public Financial Management Act (PFMA), which may assist in the guidance and management of medicines. At facility-level, detailed SOPs provide additional direction and control to ensure delivery of services. The challenge however remains that although a document is developed, its implementation and success is dependent on the custodians of such documents. In this study, the custodians of the policy are all stakeholders who manage medicines, such as pharmacists, pharmacy assistants and nurses, though the pharmacist is responsible for the overall management of medicines at facility level. The scope of practice which determines the activities, responsibilities and accountability of pharmacy assistants practice setting have been developed by the South African Pharmacy Council (Council, 2011). However, pharmacy assistants require in-service training in effectively completing organisational level tasks related to calculating re-order levels, rational procurement and, monitoring and evaluating medicine use. In our study, the need for in-service training was highlighted as important, however suitable times for such training was challenging given the daily turn-over of patients .

Expiry of medicine is serious, as underscored by all guiding documents that seek to minimize the practice. There are additional constraints when the relationship between these documents and daily practices are not understood and accountability is not assigned, key findings of this study. These findings resonate with similar challenges faced by local governments without powers to address important public health determinants or hold implementers accountable see for example, (Livingston et al., 2007, Maclennan et al., 2013). Furthermore, while the hospital PTC may provide

guidance in ensuring accountability, the PTC often does not have powers to enforce accountability (as in this study and elsewhere).

Policy Change

The South African National Core Standards policy was developed by the Office of Health Standards Compliance with the aim of monitoring services using set criteria to benchmark quality of care provided at public healthcare facilities (National Department of Health, 2011). The National Core Standards consist of seven domains and pharmaceutical services is one of the categories in the Clinical Services domain (National Department of Health, 2011). Facilities are audited against the set criteria on a regular basis, which include a list of medicines that should be available in the specified dosage form and pack size. However, the list does not consider the consumption of an item at a specific institution. In this study, pharmacy managers felt forced to ensure that these medicines, (for example: Lamivudine Tablets 150mg; 60`s) are always available in the required quantity, thus increasing the risk of expiry. Furthermore, a key finding is that the medicines expiring with low consumption may be as a result of the minimum quantity set by the National Core Standards criteria that may be too high for this urban tertiary hospital. In addition, at organisational level, the lack of coordination with regards to demand planning and quantification may also be contributing to medicines expiring.

This study, similar to Jha and Roy (2005) found that though adequate tools for quantification and demand planning exist, none of it is focused on the health worker who has no formal training in medicine supply management. On the one hand, even with robust training and adequate investment in skills development related to medicine management, job descriptions may not be aligned with the responsibility of medicine management. Job descriptions do not assign individuals responsibility for managing medicines (beyond the roles of pharmacists) means that there may also be a gap in accountability because individuals are –de facto - “responsible” but without any formal sense of duty. Additionally, without active monitoring at organisational level, the impact may be minimal.

Change in Treatment Policy

There is robust evidence that changing therapies is a significant cause of medicine wastage (WHWorld Health Organisation, 2010). In 2012 Dr Aaron Motsoaledi, South Africa's Minister of Health, announced the award of a new ARV tender – worth approximately R6 billion – that included, for the first time since the start of the ARV programme, the FDC tablet (Clinicians Society of SA HIV, 2013). NDoH provided recommendations on patient priority groups to receive FDC, however at implementation level these priority groups were not optimally adhered too (Clinicians Society of SA HIV, 2013). In this study, this change in treatment policy may be associated to the expiry of ARVs at this urban tertiary hospital. This finding may suggest a lapse of coordination at the organisational level in ensuring the depletion of triple therapy prior to dispensing FDC to patients. Medicine waste may be curtailed by improved management and coordination at the organisational level during procurement phase, thereby only procuring what is needed. However, at a national level, this may require a flexible policy environment that allows for the phasing in and out of new medicines in ways that ease organizational processes.

Limited Knowledge of Standard Treatment Guidelines (STGs)

In this research, more than half of the antibacterials for systemic use that expired were first line therapy for various infections as per the STGs. This finding supports the recent WHO finding that fewer than 40% of patients are treated according to STGs (WHWorld Health Organisation, 2010). This may be due to a lack of STG knowledge among prescribers. In South Africa, prescribers rotate quarterly among facilities within a district with the aim to ensure consistent services are provided and expose prescribers to different all levels of care. Due to the shortage of healthcare workers in Africa (Naicker et al., 2009) and specifically in South Africa (Rispel and Blaauw, 2015), certain prescribers work in both the public and private sectors which may further influence prescribing patterns. External prescribing influence, that is practices beyond the public health system, highlights the need to carefully monitor health system performance at organisational level to prevent poor health outcomes (Rispel and Blaauw, 2015). The quantity of medicines dispensed may therefore not be a true reflection of the demand due to irrational prescribing that may be influenced by these underlying contributing factors.

Medicines are dispensed based on what is prescribed by the doctor. Dispensing data is used to assist pharmacy managers with future planning that may directly impact estimates provided for the tender processes and the allocated budget that this urban tertiary hospital may receive. When medicines are irrationally prescribed and irrationally dispensed, it may lead inaccurate information generated which may either be lower or higher than anticipated, thus increasing the risk of medicine expiry. Medicine expiry may be averted with improved knowledge of STGs among prescribers and accurate data management.

Electronic Inventory Management System

Infrastructure remains a contributing factor to challenges in healthcare systems globally (Hawkes et al., 1994). Some progress has been made at this urban tertiary hospital to support pharmacy product distribution by an electronic stock management system, Rx Solution®, which manages the dispensing of medicines and automates ordering. The system provides significant information to assist managers in making appropriate decisions, such as averting financial loss due to expired medicines and effectively manage inventory. Despite the numerous tools that are available both on Rx Solution® and in each unit, the task of managing medicines in all units, except pharmacy, is dependent on the nursing staff who are already overburdened (Jha and Roy, 2005) and the lack of computers. The use of a computerised inventory management system may improve the operational efficiency but additional challenges may emanate, related to the ability of operating an electronic system. Adequate training is important in ensuring the use of the electronic system.

This study provides critical insight as a step in identifying ways to improve operational efficiency and cost effectiveness in a large urban tertiary public hospital, particularly through the lens of medicine management. In South Africa, the government contributes approximately 40% of all expenditure on health and therefore a yearly increase of 72% in medicine expiring is alarming given that all other wastage forms such theft, pilferage or medicine returns are not included in this figure. This percentage may therefore be even higher if all other forms of wastage are included. This study also highlights that medicines expiring may be curtailed with improved management at the organisational level. Many reasons for medicines expiring in this study are within

the control of the hospital and thus there is an opportunity to implement appropriate interventions and efforts to improve inventory and financial inefficiencies.

LIMITATIONS OF THE STUDY

The study was only conducted in one urban hospital and the results are therefore not statistically generalizable to other similar level hospitals or primary healthcare (PHC) clinics. However, theoretical generalisation is possible through the themes of kknowledge, understanding and practical application of policies and procedures related to expired medicines, and diversion from Ideal: procedures and constraints which may impact implementation. The quality of the quantitative data also imposed a limitation as the expired medicines (between 2011 to mid-2014) were collected for a different purpose and the data were not validated during the hospital audit (carried out in 2010). Furthermore, these data were only captured once by the person who collected the information and there were no quality checks performed on the data to ensure accuracy. The dataset comprised medicines with different formulations making it more challenging to determine the true extent of quantity lost due to expired medicines. The actual date of expiry of medicines that were pre-packed at the facility into smaller unit packs could not be quantified, yet it is important to acknowledge that medicines that have already been opened have a reduced expiry date (Pharmacist, 2012).

No analysis was carried out on the extent of expired medicines at patients' homes (that is, 'downstream' of the organisational-level of medicine supply). There is evidence that both patients and doctors experience medicine expiration in their homes (Nguyen *et al*, 2002). The budget or expenditure were not made available in certain articles referenced which limited the any reference related percentage loss between different articles. In addition, other forms of medicine wastage such as patient returns of non-expired medicines were not analysed. Apart from the actual value of the medicines that expired, additional costs are incurred including costs of collecting and transporting medicines to the accredited disposal area. Such costs were not estimated in this study. The participants were interviewed in one point in time and may have changed positions over time, or might not have had full knowledge of medicine expiry

factors at that point. This is a high volume hospital and staff members were very busy. Thus they may not have provided as much information as they had during the interview as this may have delayed operational activities.

Though analysing the medicine expiring in the pharmacy department is useful, the study looked at the hospital instead of different departments and focused on the types of medicine instead of the different departments. This is certainly an area for future work as such analyses may highlight additional nuances and differences between trained pharmaceutical staff and other staff within the hospital. Additionally, more specific recommendations for different wards may provide more strategic guidelines and procedures for the future.

RECOMMENDATIONS AND CONCLUSION

The key finding of this study is that medicine expiry may be curtailed by enhanced management strategies. Most of these strategies can be adopted and improved at the organisational level, where the biggest impact may be made. The recommendations acknowledged for this study include:

- Continuous monitoring and periodic evaluations to identify and address challenges related to medicine management to reduce medicine wastage;
- Active control over financial resources given that wastage may be enormous and limit availability of medicine;
- Create awareness about the risk of medicines expiring and cost impact on service delivery;
- Enhance distribution mechanisms from suppliers that support the early use of medicines at risk of expiring by the hospital;
- Develop capacity and enhance skills among health workers who manage medicine, to optimally use tools that are aimed at reducing wastage of medicine;
- Improve communication from pharmacy to other units on any changes to STGs and availability of vital medicines;
- Identify innovative ways to ensure the use of STGs;
- Conduct departmental specific expiry reports to provide more strategic guideline to reduce waste.
- Pharmacy management should be aware of medicines with slow or unpredictable turnover at the facility that are most likely to expire;
- Use technology as a tool to improve coordination and provide harmonized procurement and prevent overstocking which may lead to medicine wastage;
- Proactively develop an implementation plan when policy changes or tender changes are announced that may impact medicine expiry; and
- Include MSM as part of job descriptions on employees who manage medicines at this hospital to enhance accountability.
- Consider employing clinical pharmacists at tertiary hospitals to improve medicine management in the wards.

CONCLUSION

This study shows that the majority of medicines that expire at the tertiary hospital are on the EML. Medicine use is only possible if there is access, therefore minimising waste may contribute to access and availability. Sound coordination and communication is needed between the pharmacy and other departments in the hospital. Additionally, Pharmaceutical and Therapeutics Committees should emphasise the use of STGs. Medicine management is not restricted to the role of the pharmacist and, though the tools that exist support individual performance, the application of these tools require personal skills. Rigorous vigilance in medicine management and maintenance of demand planning at hospital level may improve stock management. Accountability can only be effective if it is assigned and practiced. In South Africa, pharmacists are responsible for medicine management, however were confined to the pharmacy in this study and medicine management was extended to nurses. The employment of clinical pharmacists in the wards at this tertiary hospital may improve medicine management in the wards.

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APPENDIX A

Data Extraction Tool

Drug Name	Drug Code	Class of drug	Drug strength	Date manufactured or Batch number	Date procured	Date expired	Date of drug expiration recorded	Unit from which drug was recorded	Method of storage	Unit cost	Route of administration

Appendix B

Anatomical Therapeutic Chemical Classification

ATC code	ATC description
A02	ANTACIDS, DRUGS FOR TREATMENT OF PEPTIC ULCER AND FLATULENCE
A03	ANTISPASMODIC AND ANTICHOLINERGIC AGENTS AND PROPULSIVES
A04	ANTIEMETICS AND ANTINAUSEANTS
A06	LAXATIVES
A07	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A10	DRUGS USED IN DIABETES
A11	VITAMINS
A12	MINERAL SUPPLEMENTS
B01	ANTITHROMBOTIC AGENTS
B02	ANTIHEMORRHAGICS
B03	ANTIANEMIC PREPARATIONS
B05	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
B06	OTHER HEMATOLOGICAL AGENTS
C01	CARDIAC THERAPY
C02	ANTIHYPERTENSIVES
C03	DIURETICS
C05	VASOPROTECTIVES
C07	BETA BLOCKING AGENTS
C08	CALCIUM CHANNEL BLOCKERS
C09	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10	SERUM LIPID REDUCING AGENTS
D01	ANTIFUNGALS FOR DERMATOLOGICAL USE
D02	EMOLLIENTS AND PROTECTIVES
D04	ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.
D06	ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE
D07	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
D08	ANTISEPTICS AND DISINFECTANTS
D11	OTHER DERMATOLOGICAL PREPARATIONS
G01	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS
G02	OTHER GYNECOLOGICALS
G03	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM AND CONTRACEPTION
H01	PITUITARY, HYPOTHALAMIC HORMONES AND ANALOGUES
H02	CORTICOSTEROIDS FOR SYSTEMIC USE
H03	THYROID THERAPY
H04	PANCREATIC HORMONES
J01	ANTIBACTERIALS FOR SYSTEMIC USE
J02	ANTIMYCOTICS FOR SYSTEMIC USE
J04	ANTIMYCOBACTERIALS

J05	ANTIVIRALS FOR SYSTEMIC USE
J05	N/A
J06	IMMUNE SERA AND IMMUNOGLOBULINS
J07	VACCINES
L01	ANTINEOPLASTIC AGENTS
L02	ENDOCRINE THERAPY
L04	IMMUNOSUPPRESSIVE AGENTS
M01	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M03	MUSCLE RELAXANTS
M04	ANTIGOUT PREPARATIONS
M05	DRUGS FOR TREATMENT OF BONE DISEASES
N01	ANESTHETICS
N02	ANALGESICS
N03	ANTIEPILEPTICS
N04	ANTI-PARKINSON DRUGS
N05	ANXIOLYTICS
N06	PSYCHOANALEPTICS
N07	OTHER NERVOUS SYSTEM DRUGS
P01	ANTIPROTOZOALS
P02	ANTHELMINTICS
R01	NASAL PREPARATIONS
R02	THROAT PREPARATIONS
R03	ANTI-ASTHMATICS
R05	COUGH AND COLD PREPARATIONS
R06	ANTIHISTAMINES FOR SYSTEMIC USE
S01	OPHTHALMOLOGICALS
S02	OTOLOGICALS
V03	ALL OTHER THERAPEUTIC PRODUCTS
V04	DIAGNOSTIC AGENTS
V07	ALL OTHER NON-THERAPEUTIC PRODUCTS

APPENDIX C

CONSENT FORM: IN-DEPTH INTERVIEWS

Title of research project: <u>Trend in revenue loss due to expired drugs at a large urban hospital in Johannesburg</u>

The study has been described to me in a language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I understand there will be no reimbursement for participation.

At all times the researcher will keep the source of the information confidential and refer to me and my words by a number or invented name. The written transcripts or notes of the actual interview will only be released to supervisors who will assist in the data analysis, the number or invented name will be used in these transcripts.

I understand the procedure described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form

If you consent to partake in this study please sign here:

_____

Participant signature

_____

Date

_____

Interview's signature

_____

Date

APPENDIX C

CONSENT TO TAPE RECORD INTERVIEWS

If you consent to partake in the study could you please tick an option regarding audio tape-recording:

I have read the project information sheet and it has been clearly explained to me and I understand that it is up to me whether or not the interview is tape-recorded. The purpose of recording the interview is to capture accurately all the information that will be given. It will not affect in any way how the researcher treats me if I do not want the interview to be tape-recorded.

I understand that if my participation is tape-recorded that the recording will be destroyed after compilation and completion of this report. I understand that I can ask the person interviewing me to stop tape recording, and to stop the interview altogether, at any time. I understand that the information that I give will be treated in the strictest confidence and that my name will not be used when the interviews are typed up.

___ Yes, I agree to be **audio taped** during my participation in this study.

___ No, I do not agree to be **audio taped** during my participation in this study.

_____

Interviewee's signature

_____

Interviewer's signature

Date: _____

APPENDIX D

INFORMATION SHEET

Study title: Trend in revenue loss due to expired drugs at a large urban hospital in Johannesburg, South Africa

Hello,

My name is Celeste Sauls. I am studying towards a Master's degree in Public Health at the University of the Witwatersrand. The purpose of the study is to describe the trend and, determine the extent of revenue loss due to expired drugs, and explore possible reasons for such loss. I am inviting you to take part in a research study and would be very grateful if you would agree to answer a few questions about drug stock management at the Organizational level.

By gathering this data, I'm hoping to assist the hospital and other stakeholders to find ways to reduce expired drugs and improve planning as well as monitoring such information. I believe that your ideas and thoughts are important and can contribute to this study. The interview will take around 60 minutes to complete during which I will be asking a few questions and would like you to tell me what circumstances are really like, not what they should be.

If you feel that a question is inappropriate or too sensitive, you are free not to answer it. While answering all the questions will be most useful for our study, you can decide not to answer any questions if you wish. You can stop the interview at any time or ask for clarity when the questions are unclear.

To make the interview easier for me, I will also request if we can tape record the interview. If you do not want the interview to be taped that is your right, and it will not influence the interview or the research in any way. If you give us permission to tape the interview we will listen to the tape and write down everything that you say but not use your name. We will keep the tapes until the full report has been compiled and finalised, after which they will be destroyed.

You will receive no direct benefit from your participation in this study. However, your participation may help the researcher and the hospital better understand what is needed to reduce drugs expiring. Your participation in this study is completely voluntary. If you agree to take part, you can stop at any time if you do not want to carry on being involved. If you refuse to take part or stop at any point during the study, you will not be affected in any way and you will not be discriminated against.

All the information you choose to give me will be kept confidential. Your name will not be used in the research report and no one will be able to link your answers to you. Only my supervisors and I will have access to the information which will be kept in a secure place. All efforts will be made to keep information confidential.

If you have any questions about this study, please feel free to contact me on:

Celeste Sauls
School of Public Health
University of Witwatersrand
Johannesburg
Tel no: 083 749 6896
Email: celestesauls@gmail.com

Similarly you can also contact the Human Research Ethics Committee (Medical) which oversees the ethical aspects of this study. Members of this committee can be contacted through Ms. Anisa Keshav on 011 717 1234.

Appendix E

Trend in revenue loss due to expired drugs at a large urban hospital in Johannesburg, South Africa

Date: _____

Study ID: _____

In-depth Interview (Pharmacists/Pharmacist Assistants/Ward managers)

INTERVIEW GUIDE

Questions in bold (*with prompts below – ONLY if not raised)*

1. **What are your qualifications?**

   _____

2. **How long have you been the ward manager at this place/unit**

   _____

3. **What are your years of experience at this facility?**

   _____

4. **Have you ever worked in the private sector?**

   _____

   a. How many years?

5. **Tell me about how you order and store drugs in this ward?**

   _____

   Prompt if necessary:

   a. Allocated days?

   b. Allocated times?

   c. Ordering forms or computer based?

   d. Do you have any runners?

   e. If no one is available to receive the stock

   f. Reasons for not ordering on specific day?

   g. Responsible for packing drugs?

   h. Open/locked cabinet?

i. Room access controlled/not controlled?

6. **May you please explain what FEFO means to you and your unit?**

_____

Prompt if necessary

a. Why or why not is it important?

b. Where did you find out about FEFO?

c. Who is responsible for actively monitoring this practice?

d. Is it done?

e. How often?

f. Is there a SOP

7. **Tell me about any training you may have had regarding drug management?**

_____

Prompt if necessary

a. Training important?

b. Is there need for in-house refreshers

8. **Tell me about how you manage drugs in your department**

_____

Prompt if necessary

a. Stocktaking

b. What made you choose that timeframe?

c. Monitoring

d. Challenges

9. **Why do you think drugs expire?**

_____

10. **What do you think can be done differently at the hospital, if anything, to limit the number of drugs expiring on the shelves?**

_____

Appendix F

Equation for calculating average rate of change

$$\frac{\left(\sum_{i=2}^{n} \frac{Rate_{year\ i}}{Rate_{year\ i-1}} - 1\right) x100}{n-1}$$

Substitute rate with % revenue loss meaning:

$$\left(\frac{\left(\frac{\%\ loss_{year\ 2}}{\%loss_{year\ 1}} - 1\right)}{} + \left(\frac{\left(\frac{\%\ loss_{year\ 3}}{\%loss_{year2}} - 1\right)}{}\right) + \frac{\left(\frac{\%\ loss_{year\ 4}}{\%loss_{year\ 3}} - 1\right)}{}\right)$$

Appendix G

Study Approval

M131015

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M131015

NAME: (Principal Investigator)	Ms Celeste Sauls
DEPARTMENT:	School of Public Health Medical school
PROJECT TITLE:	Trend in the Revenue Loss Due to Expired Drugs at a Large Urban Hospital in Johannesburg, South Africa
DATE CONSIDERED:	25/10/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ms Bronwyn Harris
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 04/06/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit yearly progress report**.

Principal Investigator Signature M131015Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix H

Standard Operating Procedure on Ordering, Storing and Packing of Medicine

SOPS issued by: Gauteng
Department of Health:
Pharmaceutical Services

SOP 4: PROCUREMENT OF STOCK.

Number of pages: 8

Accountable officers:

The responsible pharmacist at hospital and district pharmacies will be responsible for implementing procedures and control measures for the procurement of stock by the pharmacy. Other responsible officers to whom this SOP applies either directly or indirectly includes the:

Pharmacist, basic and post basic pharmacist assistants.

Clerks, drivers etc.

For district health services where there are no pharmacists or pharmacist assistants rendering the service, then the following substitutions in the SOPS are permissible:

Responsible pharmacist can be substituted with facility manager.

Pharmacist can be substituted with authorised nurse or doctor depending on who is delegated the responsibility.

Pharmacy can be substituted with medicine room.

Policy, references and resource material includes:

Pharmacy Act (Act 53 of 1974) and Regulations as amended.

Medicine and Related Substances Act (Act 101 of 1965), Regulations and Guidelines as amended.

Public Finance Management Act (Act 1 of 1999).

Good Pharmacy Practice in South Africa, Latest Edition.

Provisioning Administration Manual (PAS Manual).

Record of amendments:

Date first issued: June 2000 (Circular Letter 31 of 2000).
Date issued after first review: April 2007 (Circular letter 4 of 2007 and amendments).
Date issued after second review: January 2013.
Area amended: Whole SOP.
New SOP issue authorised by: Senior Manager: Pharmaceutical Services: Ms. N. Thipa

Objective:

To ensure that standardised processes with regards to procurement are applied throughout the province.

Procedure:

1. **How to calculate the Re-order level (ROL)**

Determine the average monthly demand (AMD) for a period of six month.

Determine the appropriate re-order factor (ROF) for your institution using the table below:

Order interval	Lead times in week	Re-order factor	Stock holding in weeks
Once a week	1	0.75	3
Every 2 weeks	2	1.5	6
Every 4 weeks	4	3	12
Every 6 weeks	6	4.5	18
Every 8 weeks	8	6	36

To calculate the re-order level (ROL) multiply the AMD by the

ROF The ROL is re-calculated every six months.

The ROL must be calculated for each item in stock and must be written onto the stock car.

2. **How to use the reorder level**

If the stock holding is above the ROL then do not order stock.

If the stock holding is equal to the ROL then do not order stock, unless due to higher usage e.g. seasonal usage.

If the stock holding is less than the ROL then order the ROL quantity for that item.

3. **Action to be taken before placing an order**

Follow up on all outstanding orders from the medical supplies depot (MSD) and from the suppliers

Check the delivery schedule from MSD to determine when stock may be arriving.

If there are already two backorders for an item, do not place the third order before discussing with the pharmacist in charge of the store. This can lead to overstock at the institutions when all the backorders arrive. MSD reserves the right not to take back any stock that has been repeatedly ordered.

Check the stock on hand (take into considerations the stock issued on the computer system but not yet picked).

Check if the quantity of stock on the shelf matches the quantity of stock on the stock card (modified VA11) or computer printout as an in-process check.

If the quantity of stock on the shelf does not match the quantity on the stock card (modified VA11) or the computer print out, this must be reported to the pharmacist, investigated and corrected.

All discrepancies must be must be recorded on the stock card (modified VA11) or the computer print out while the matter is being investigated.

All findings and corrections made to the stock card (modified VA11) or computer system must be countersigned or authorised by the pharmacist in charge of the store.

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

SOP 7: EFFECTIVE STORAGE OF MEDICINE AND STOCK CONTROL (INCLUDING FEFO AND FIFO).

Number of pages:
3

Accountable officers:

The responsible pharmacist at hospital and district pharmacies will be responsible for implementing procedures and control measures for the effective storage of medicine and stock control in the pharmacy. Other responsible officers to whom this SOP applies either directly or indirectly includes the:

Pharmacist, basic and post basic pharmacist
assistants. Clerks, drivers etc.

For district health services where there are no pharmacists or pharmacist assistants rendering the service, then the following substitutions in the SOPS are permissible:

Responsible pharmacist can be substituted with facility manager.
Pharmacist can be substituted with authorised nurse or doctor depending on who is delegated the responsibility.
Pharmacy can be substituted with medicine room.

Policy, references and resource material includes:

Pharmacy Act (Act 53 of 1974) and Regulations as amended.
Medicine and Related Substances Act (Act 101 of 1965), Regulations and Guidelines as amended. Public Finance Management Act (Act 1 of 1999).
Good Pharmacy Practice in South Africa, Latest Edition.
Provisioning Administration Manual (PAS Manual).

Record of amendments:

Date first issued: June 2000 (Circular Letter 31 of 2000).
Date issued after first review: April 2007 (Circular letter 4 of 2007 and amendments). Date issued after second review: January 2013.
Area amended: Whole SOP.
New SOP issue authorised by: Senior Manager: Pharmaceutical Services: Ms. N. Thipa

Objective:

To effectively store stock and rotate stock by observance of the FEFO and FIFO principles.

Procedure:

1. All storage areas must be large enough to allow for the orderly arrangement of stock and proper stock rotation. It must allow for safe and efficient workflow and effective communication and supervision of pharmacist assistants.

2. All bulk stores must be self-contained, secure, and lockable with access limited only to authorised personnel.

3. Storage areas must have sufficient shelving constructed from a smooth, washable and impermeable material which is easy to clean and maintain and suitable to keep medicine above floor level.

4. There must be appropriate storage facilities for thermo-labile items, see SOP: Cold chain management.

5. There must be appropriate storage facilities for hazardous substances.

6. Appropriate storage facilities for the SS5 and S6 medication must also be available, See SOP: Management of Schedule 5 and schedule 6 medication.

7. All medication must be stored systematically according to dosage forms and in alphabetical order by generic name.

8. The system should allow for ease of counting and identification of the items.

9. Shelves must be labelled with the items generic name.

10. There should be a physical separation or space between each item.

11. Stock must be stored on the shelves or pallets and not directly on the floor.

12. All stock must be packed away using the FEFO (where there is an expiry date) and FIFO (where there is no expiry date) principles.

    All new stock received into the store must be checked for an expiry date.

    Stock nearing expiry should not be received unless it can be used before the expiry date. Short expiry dates must be reported to the pharmacist for a decision.

    All medicines with an expiry date must be arranged in such a way that the short dated stock is stored in front and used first. The order in which these medicines are received into the store is not of importance.

    A system to easily identify short dated stock must be implemented e.g. a colour coding system, to minimise losses.

All medicine without an expiry date must be arranged in such a way that the stock that received first is always in front and used first.

The system of packing stock should allow for ease of counting and identification of items.

13. There must be a stock card (modified VA11) for each medicine in the store, including ARV's. The following must be recorded on the stock card (modified VA11) for all new stock received:
    Date;
    Document number;
    Quantity received;
    New balance;
    Signature;
    Expiry date;
    Batch number (to facilitate batch recall);
    Other relevant information such as batch number, orders placed, expired stock removed etc.10. At least monthly stock counts, expiry date checks and checking for obsolete and unusable stock must be conducted within the bulk store and the satellite pharmacies, wards, consulting rooms etc. and must be handled in accordance to the SOP: Checking for obsolete, expired and unusable stock

11. An audit trail of all stock received, issued, removed must be maintained on the stock card (modified VA11).

SOP 9: CHECKING FOR OBSOLETE, EXPIRED AND UNUSABLE STOCK.

Number of pages: 4

Accountable officers:

The responsible pharmacist at hospital and district pharmacies will be responsible for implementing procedures and control measures for the checking of obsolete, expired and unusable stock in all areas where medicine is kept. Other responsible officers to whom this SOP applies either directly or indirectly includes the:

Pharmacist, basic and post basic pharmacist assistants.

Clerks, drivers etc.

For district health services where there are no pharmacists or pharmacist assistants rendering the service, then the following substitutions in the SOPS are permissible:

Responsible pharmacist can be substituted with facility manager.

Pharmacist can be substituted with authorised nurse or doctor depending on who is delegated the responsibility.

Pharmacy can be substituted with medicine room.

Policy, references and resource material includes:

Pharmacy Act (Act 53 of 1974) and Regulations as amended.

Medicine and Related Substances Act (Act 101 of 1965), Regulations and Guidelines as amended.

Public Finance Management Act (Act 1 of 1999).

Good Pharmacy Practice in South Africa, Latest Edition.

Provisioning Administration Manual (PAS Manual).

Record of amendments:

Date first issued: June 2000 (Circular Letter 31 of 2000).
Date issued after first review: April 2007 (Circular letter 4 of 2007 and amendments).
Date issued after second review: January 2013
Area amended: Whole SOP.
New SOP issue authorised by: Senior Manager: Pharmaceutical Services: Ms. N. Thipa

Objectives:

To ensure that efficient and effective identification and management of obsolete, expired and unusable medication.

To minimise or eliminate losses due to expired, obsolete and unusable stock on the shelves.

To ensure continuous medicine availability at all institutions by ensuring that all stock kept is usable.

To adhere to the PFMA requirements.

Procedure:

1. On a monthly basis identify expired, excessive, slow moving, unusable and obsolete stock within the pharmacy stores, dispensaries, wards and in any area where medication is kept.

2. For expired, unusable and contaminated stock (S1 – S4)

Unusable stock is defined as stock that has been damaged, contaminated, was not stored under the recommended storage conditions, declared unsafe for human use or has expired in terms of the open vial (multi-dose vial) policy.

Check expiry date upon receipt of stock and during the monthly stock counts.

Expired stock must be removed from the usable stock immediately and stored separately and securely until disposed off.

Remove items from the shelves in the presence of a witness:

Either a pharmacist and pharmacist assistant at a licensed and recorded pharmacy or dispensary;

Or a pharmacist assistant and the facility manager or member off health team as delegated at a dispensary or medicine room;

Or by two health care team members in a medicine room, consulting room or ward.

Medicine destined for destruction must be separated into the following six types and clearly labelled:

Solid dosage forms;
Creams, ointment and powders;
Ampoules and liquids
(contained in glass);
Aerosols;
Radioactive medicines;
Cytostatic and cytotoxic medicines and scheduled substances.

All expired stock must be recorded on a VA2 and / or VA27. The following information must appear on the Chronological VA2 and / or VA27 (triplicate):

Alpha code;
Details of the
institution;
Description of
the item;
Quantity expired
or damaged;
Expiry date;
Reason for
expiry or
damage; Value
of the expired
stock;
Signature of person who removed the expired stock and the witness.

Expired stock must be clearly marked as “Expired stock, not to be used”

Update the stock card (modified VA11) with the expired stock removed and record the new balance, with a clear indication of the date and reason for removal on the stock card (modified VA11).

Expired stock returned to the pharmacy store or medicine room, from the wards, clinics or consulting rooms, must be accompanied with the required documentation VA2 and / or VA27 and the expired stock returned is not for credit or exchange.

A copy of all documentation must be retained at the both the receiving and the returning site, in a file labelled “expired, obsolete and unusable stock.

The expired items must be handled in accordance to the SOP: Management and disposal of expired, obsolete and patient returned medication.

The Pharmacy (supplier of stock) within the district, hospital or CHC is required to accept expired and unusable stock from the wards, clinics etc, for destruction purposes only and reserves the right not to exchange the stock or credit returning site. However arrangements can be made within districts for the clinics to dispose of their own expired stock, but all procedures of this SOP and the SOP: Disposal of expired stock must be adhered to.

MSD reserves the right not to accept back expired stock from the institutions, unless it was expired on receipt and MSD had been notified.

3. For expired, unusable and contaminated stock (SS5 and S6)

All relevant procedures for expired stock schedule 1 to schedule 4, applicable to the SS5 and S6 must be applied

Schedule 5 medications should be recorded on a separate VA2 and / or VA 27 as the procedure for destruction for S5 is different from the schedule one to four medicine.

Specified Schedule 5 and S6 expired medication should be recorded on a separate VA2 and / or VA27 as the procedure for destruction of the S6 medication is different from schedule one to four medicine and schedule 5 medicines.

The quantity of the expired stock removed from the pharmacy store or cupboard must clearly be subtracted, using a red pen, in the specified S5 or S6 register and recorded in the separate expired SS5 and S6 register. This is to ensure that on a daily basis the balance in the SS5 and S6 register does not need to account for expired stock. This will require the signature of the pharmacist responsible for the schedule cupboard and a witness.

For expired stock to be returned to the pharmacy within the wards or clinics, check that a corresponding entry in made in the ward or clinic register. All stock received back in the pharmacy must be recorded in the expired stock register for documentation and control purposes.

The expired register for the SS5 or S6 medication must contain the following information: date, description of the item, dosage form, expiry date, batch number, pharmacy, ward or clinic where the stock expired, quantity and the reason for destruction if other than expiry.

4. For obsolete (no longer used at the institution)

On a monthly basis check for obsolete stock.

Prepare a list of items and forward to the pharmacist.

The pharmacist will identify other institutions or areas, which may be able to use the stock. The pharmacist can request MSD to assist with identifying which institutions still use the item not longer used at your facility.

The pharmacist will update the overstock item list and circulate to all pharmacy managers via email, to inform other institutions of stock available for redistribution.

The pharmacist will arrange for the transfer of stock, using the VA5 form, to an institution where the stock can be used.

Update the stock card (modified VA11) accordingly with the transfer out of stock.

Ensure that the stock card (modified VA11) is clearly marked "Obsolete Stock" to prevent reordering of items not used at the institution.

Obsolete stock returned to the pharmacy from the wards or clinics must be accompanied with the required documentation (VA2) and the obsolete stock returned is not for credit or exchange.

MSD reserves the right not to accept back obsolete stock from the institutions.

5. For excess, slow moving items or short dated stock

Short dated stock which can be used by the facility must be clearly marked and put in front of the all the available stock to ensure that it is used first.

Short dated stock (within 4 months of expiry) which will not be used must be clearly identified and marked for redistributed to high usage areas or institutions.

Prepare a list of all stock which has a shelf life shorter than four months, excessive stock and slow moving stock and for forward to the pharmacist.

The pharmacist will identify other institutions that may be able to use the stock.

The pharmacist may request MSD to assist with identifying which institutions still use the item not longer used at your facility.

The pharmacist will update the overstock item list and circulate to all pharmacy managers via email, to inform other institutions of stock available for redistribution.

The pharmacist will arrange for the transfer of stock to another institution, using the VA5 form. Slow-moving and obsolete stock should be identified from the modified VA11 by checking the stock holding, the frequency and quantity of demands (stock on hand divided by average monthly consumption). This will give the total stock holding in months and the pharmacist may then decide on the quantity for redistribution. Overstocking or understocking requires the re-order levels of the medicine to be recalculated in line with usage.

Excess, slow moving or short dated stock returned to the pharmacy store from the wards or clinics must be accompanied with the required documentation (VA2). The stock returned is not for credit or exchange as the stock may be deemed unfit for further use, at the discretion of the pharmacist

MSD reserves the right not to accept back excess, slow moving or short dated stock over ordered i.e. by repeated orders due to dues out of an item