Evaluation of the medicine procurement and supply management system in public hospitals in Lesotho

MA Tema

23905719

Dissertation submitted in partialfulfillment of the requirements for the degree *Magister Pharmaciae*in Pharmacy Practice at the Potchefstroom Campus of the North-West University

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Co-supervisor: Ms MJ Eksteen

November 2014



DECLARATION

I, Matsepo Tema, 23905719 hereby declare that	"Evaluation of the medicine procurement and				
supply management system in public hospitals in Lesotho" my own work and all the sources					
used have been indicated and duly acknowle	dged appropriately by means of complete				
references.					
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ABSTRACT

Keywords: Procurement and supply chain, essential medicines, quantification, forecasting, budgeting, distribution

In a well-functioning medicine supply chain management system, procurement forms an integral part that needs to be closely monitored and integrated with other functions. Good procurement practices in the public health sector ensure that good quality efficacious medicines are distributed in the country in the right quantities and at reasonable costs. Pharmaceutical procurement is a major determinant of drug availability and total health costs. It is indicated that medicine expenditure represents the single largest expenditure after salaries and accounts for approximately 20 to 40% of the total healthcare budget, and up to 90% of household budgets in the Sub-Saharan region (MSH, 2012:1). Moreover, effective and efficient public sector procurement systems are essential for the achievement of millennium development goals and the promotion of sustainable development (WHO, 2011:2).

The general aim of the study was to evaluate the current status of procurement and supply chain management systems in the public healthcare hospitals in Lesotho. The study set out to understand the policies, guidelines and practices governing medicine procurement in the public hospitals in Lesotho, and also to outline the impact of procurement activities on the overall operation and effectiveness of the healthcare services. A descriptive, cross-sectional study was conducted, focusing on all levels of medicine procurement and supply management systems in all public hospitals in Lesotho. The study period stretched over nine months, from January 2014 to September 2014.

The study population was inclusive of 17 public healthcare hospitals in the country and the central medical store (CMS). The findings revealed that all hospitals studied (n=17) perform the functions of selection, procurement, quantification, ordering, inventory management, distribution as well as utilisation. Although an essential medicine list (EML) and standard treatment guidelines (STGs) are available for use, public hospitals do not adhere to the use of EML and STGs for medicine procurement (n=17). Therefore, procurement is not limited to medicines on the EML, it is based on the intensity of healthcare services provided, and public hospitals often request medicines that do not occur on the EML, but are necessary to address the different diseases and public health priorities in respective facilities.

According to the Ministry of Health, all public facilities are mandated to procure medicines from the CMS. Public hospitals use their allocated funds for medicine to buy from the CMS, which will, in turn, procure medicines on behalf of the government and distribute to the hospitals as per request, since procurement is pooled at a central level (MOH, 2011:62). However, it was observed that only government facilities (n=11) procure medicines from the CMS only. Facilities that are owned by the Christian health association of Lesotho (CHAL) procure medicines from other places concurrently (n=6). Moreover, CHAL hospitals (n=6) indicated that they are not fully mandated to procure medicines only from the CMS; they can also procure from other agencies based on stock-outs at the CMS, price differences and urgency of obtaining the medicines required. Therefore, procurement practices at government and CHAL hospitals are not similar.

The total expenditure on medicines for government hospitals was 7 088 754.50 Maloti and 121 338 713.05 Maloti in the years 2010/2011 and 2011/2012, respectively. The total expenditure for CHAL hospitals was 2 520 590 Maloti and 3 577 360 Maloti in 2010/2011 and 2011/2012, respectively. According to the findings, variance of budget and expenditure for government hospitals were 15 623 446.50 Maloti in 2010/2011 and 9 490 341.22 Maloti in 2011/2012. Variance of the budget and expenditure for CHAL Hospitals were 912 570 million Maloti in 2010/2011 and 922 640 million Maloti in 2011/2012.

Most hospitals showed a variance of above 50% in 2010/2011. However, in 2011/2012, a shift pattern was observed indicating an improvement in the utilisation of funds allocated. This shift pattern may indicate a possible improvement in procurement practices, including the quantification and budgeting and commitment to procurement plans.

Pharmaceutical management systems require sound policies and a legal framework that will provide a solid foundation for the systems. It is equally important that these policies and regulations are periodically updated to ensure that they address the current health situation in the country and are in line with international standards (MSH, 2012:4). However, some documents are very outdated, and therefore they do not reflect the current health situation in the country as well as procurement trends internationally, and these include national medicine policy, EML and STGs.

In conclusion, the medicine procurement system in public hospitals should be strengthened and should incorporate continuous supportive supervision in order to facilitate and encourage adherence to good procurement practices, and therefore the constant availability of good quality, cost-effective essential medicines in the country.

OPSOMMING

Sleutelwoorde: Verkrygings- en aanbodkettingbestuur, noodsaaklike medisyne, kwantifisering, vooruitskatting, begrotings, verspreiding

In 'n goedfunksionerende medisyne-aanbodkettingbestuurstelsel, is verkryging 'n integrale deel wat noukeurig gemonitor moet word en ook met ander funksies geïntegreer moet word. Goeie verkrygingpraktyke in die openbare gesondheidsektor verseker dat goeie gehalte doeltreffende medisyne in die land in die korrekte hoeveelhede en teen 'n redelike koste versprei word. Farmaseutiese verkryging is 'n belangrike bepaler van medisynebeskikbaarheid sowel as die totale koste van gesondheidsorg. Daar word aangetoon dat besteding op medisyne die grootste enkele besteding na salarisse is, en verteenwoordig ongeveer 20 tot 40% van die totale gesondheidsorgbegroting, en tot soveel as 90% van huishoudelike begrotings in die Sub-Sahara-streek (MSH, 2012:1). Verder is doeltreffende en effektiewe openbare sektorverkrygingstelsels uiters belangrik vir die bereiking van millennium-ontwikkelingsdoelwitte en die bevordering van volhoubare ontwikkeling (WHO, 2011:2).

Die algemene doelstelling van die studie was om die huidige status van die verkryging en aanbodkettingbestuurstelsels in die openbare gesondheidsorghospitale in Lesotho te evalueer. Die studie het gepoog om die beleide, riglyne en praktyke wat medisyneverkryging in publieke hospitale in Lesotho rig, te verstaan, sowel as om die impak van verkrygingsaktiwiteite op die algehele bedryf en effektiwiteit van die gesondheidsorgdienste uit te stip. 'n Beskrywende, deursnee-studie is uitgevoer, met 'n fokus op alle vlakke van medisyneaankope en aanbodbestuurstelsels in alle openbare hospitale in Lesotho. Die studietydperk het oor nege maande gestrek, vanaf Januarie 2014 tot September 2014.

Die studiebevolking het17 openbare gesondheidsorghospitale in die land en die sentrale mediese stoor (CMS) ingesluit. Die bevindinge het getoon dat al die hospitale wat bestudeer (n = 17) is, die funksies van seleksie, verkryging, kwantifisering, bestelling, voorraadbeheer, verspreiding, sowel as gebruik uitvoer. Hoewel noodsaaklik lys van medisyne (EML) en standaard behandeling riglyne (STGs) beskikbaar vir gebruik is, voldoen openbare hospitale nie aan die gebruik van EML en STG's vir medisyneaankope (n = 17) nie. Dus is verkryging nie beperk tot medisyne op die EML nie, dit is gebaseer op die intensiteit van gesondheidsorgdienste, en openbare hospitale vra dikwels medisyne aan wat nie op die EML voorkom nie, maar wat nodig is om die verskillende siektes en openbare gesondheidprioriteite in die onderskeie fasiliteite aan te spreek.

Volgens die Ministerie van Gesondheid behoort alle openbare fasiliteite medisyne vanaf die CMS verkry. Openbare hospitale gebruik hul toegekende fondse vir medisyne om vanaf die CMS te koop, wat op sy beurt medisyne namens die regering verkry en dit na die hospitale versprei soos per versoek, aangesien verkryging op 'n sentrale vlak saamgevoeg word (MOH, 2011:62). Daar is egter waargeneem dat slegs die regeringfasiliteite (n = 11) medisyne vanaf die CMS verkry. Christelike gesondheid vereniging van Lesotho (CHAL) fasiliteite (n = 6) verkry ook medisyne vanaf ander plekke. Verder het CHAL-hospitale (n = 6) aangedui dat hulle nie ten volle gemandateer is om medisyne slegs vanaf CMS te verkry nie; hulle kan ook vanaf ander agentskappe verkry gebaseer op voorraadtekorte, prysverskille en die dringendheid om bepaalde medisynes te verkry.

Die totale besteding op medisyne vir staatshospitale was 7 088 754.50 Malloti en 121 338 713.05 Malloti onderskeidelik in 2010/2011 en 2011/2012. Die totale uitgawes vir CHAL-hospitale was 2 520 590 Malloti en 3 577 360 Malloti in onderskeidelik 2010/2011 en 2011/2012. Volgens die bevindinge, was variansie van die begroting en uitgawes vir staatshospitale 15 623 446.50 Malloti in 2010/2011 en 9 490 341.22 Malloti in 2011/2012. Variansie van die begroting en uitgawes vir CHAL-hospitale was 912 570 miljoen Malloti in 2010/2011 en 922 640. miljoen Malloti in 2011/2012.

Die meeste hospitale het 'n afwyking van meer as 50% in 2010/2011 getoon. In 2011/2012 is 'n verskuiwingpatroon egter waargeneem wat dui op 'n verbetering in die benutting van geallokeerde fondse.

Hierdie verskuiwingspatroon dui op 'n moontlikeverbetering in die verkrygingspraktyke, insluitend die kwantifisering en begroting en verbintenis tot die verkrygingsplanne.

Farmaseutiese bestuurstelsels vereis gegronde beleide en 'n regsraamwerk wat 'n soliede basis vir die stelsels sal bied. Dit is ook belangrik dat hierdie beleide en regulasies gereeld bygewerk word om te verseker dat hulle die huidige gesondheidsituasie in die land aanspreek en belyn is met internasionale standaarde (MSH, 2012 4). Sommige dokumente is egter baie verouderd, en weerspieël dus nie die huidige gesondheidsituasie in die land en internasionale verkrygingstendense nie, en hierdie sluit nasionale medisynebeleid, EML en STG's in.

Ten slotte moet die medisyneverkrygingstelsel in die openbare hospitale versterk word en behoort deurlopende ondersteunende toesig geïnkorporeer te word om die nakoming van goeie verkrygingspraktyke te fasiliteer en aan te moedig, en dus die konstante beskikbaarheid van goeie kwaliteit, koste-effektiewe essensiële medisyne in die land.

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- Cecile van Zyl for text editing the dissertation
- To my family, for all your love, encouragement, prayers and sleepless nights. You have been my pillar of strength.
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- To my colleagues in academia and clinical practice, for your valuable support throughout the early phases of the study.
- To my loving friends, for their constant support and friendship.

LIST OF ABBREVIATIONS

AMC Average monthly consumption

ART Antiretroviral treatment

ARVs Antiretroviral drugs

BOS Bureau of Statistics

CHAL Christian Health Association of Lesotho

CMS Central medical store

DSM Drug supply management

EML Essential medicine list

FEFO First-expiry first-out

FIFO First-in first-out

GOL Government of Lesotho

HPTC Hospital Pharmaco-therapeutic Committee

LFDS Lesotho Flying Doctor Services

LNMP Lesotho National Medicine policy

MOF Ministry of Finance

MOH Ministry of Health

NDSO National Drug Service Organisation

NPTC National Pharmaco-therapeutic Committee

PSM Procurement and supply chain

QEII Queen Elizabeth II Hospital

QMMH Queen Mamohato Memorial Hospital

STGs Standard Treatment Guidelines

UNAIDS United Nations Joint Programme on HIV/AIDS

UNICEF United Nations Children's Fund

UNFPA United Nations Population Fund

WHO World Health Organisation

LIST OF DEFINITIONS

- Average monthly consumption (AMC) is defined as the sum of the monthly consumption during the same period the item was in stock (MOH, 2007c:8). It is an important indicator in the quantification process and should be as accurate as possible (MSH, 2012:384).
- Case mix is as an internationally accepted system which defines disease prevalence in a specified population and therapy required for appropriate management, it contributes towards evidence based management (Kruger, 2010:1)
- Evidence-based treatment refers to a "the process of systematically finding, appraising, and
 using contemporaneous research findings as the basis for clinical decisions". Thus, the
 practice of evidence-based medicine implies that individual clinical expertise is used in
 combination with a systematic review of the best available clinical evidence derived from the
 relevant research (Kruger, 2010:1)
- Evidence-based criteria –synonym of evidence-based treatment
- Lead time is defined as the estimated period from the time a purchase order is made to the time when stock is distributed to the health facilities (MSH, 2012:381).
- Maximum stock level defines that largest amount of stock to be kept in a health facility (MOH, 2007c:9).
- Procurement period is defined as the period from the time a purchase order is made until the next purchase order can prepared (MSH, 2012:381).
- Reorder level defines the stock balance when to place an order (MOH, 2007c:9).
- Safety/buffer stock is defined as the amount of stock that is kept in store to cater for unexpected or sudden increases in consumption patterns or to prevent stock-outs (MSH, 2012:388). It is used to calculate reorder level (MOH, 2007c:9).
- VEN system, it is defined as a pharmaceutical classification system in which medicines are categorised according to their health impact in to vital, essential and non-essential categories (MSH, 2012:335)

MINISTRY OF HEALTH LETTER

National Health Research Edic Committee (NI-REC) via Research Coordination Unit (RCC) Minustry of Health

May 13, 2013.

2O Box 514 Maseru 100

Matsepii A. Tema Magister Phartmaciae candidate North West University

Dear M. A. Tenra,

Re: Evaluation of the <u>Medicine Procurement and Supply Management System in</u> the <u>Public Hospitals in Lesotho (ID 62-2013)</u>

Thank you for submitting the above meetioned proposal. The Ministry of Health Research and Ethics Committee having reviewed your protocol hereby authorizes you to conduct this sortly among the specified population. The study is authorized with the understanding that the protocol will be followed as stated. Departure from the stipulated protocol will constitute a breach of the permission.

We are looking forward to have a progress report and final report at the end of your study.

Sincerely,

Dr. Jill Sanders

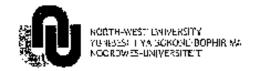
Co-Chairperson of the NH-REC

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ETHICAL APPROVAL FROM NWU



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Ethics Committee Tel + 427 18 299 4852 Amell Fthics@govulec.za

12 July 2013

ETHICS APPROVAL OF PROJECT

The North-West University Ethics Committee (NW. AFC) teachy approves your projecties indicated below. This implies that the NVPC-EC grante its permission that, provided the apecial conditions specified fieldwhere met and pending any other authorisation and may be necessary, the project may be initiated, using the other number below.

> Project title; Evaluation of the medicine procurement and supply management systems in the public hospitals in Lesotho

<u>Salas</u> Bi-Currentin Kir Medalorssami Pelnomiore A Storman Celaboration number:

Approval date: 2013/07/03 Expiry date: 2018/07/02

Special conditions of the approval (if any): None

General conditions:

White this states approved is subject to all declarations, undertailings and agreements transported and signed in the application form, passe note the fallowing:

- The project wader (judge) is investigated) must report in the prescriped format to the NWC-EC: onounity (or as otherwise requested) on the progress of the project,
- without day delay to case of any adverse a rout (or any maker than interrupts across athical principles) during the access of the project.
- The opproval applies striptly to the protection and in the application form. Would any shapes to the protect in desired in the application form. Would any shapes to the project, the project leader must apply for approval of these changes at the NWO EC. Would there be deviated from the project protect without the necessary approval of such changes, the ethics approval is immediately and automatically forfatted.
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The Elitios Committee would like to remain at your service as splendiet good researcher, and wather you wait with your project. Please do not healtate to contact the Ethics Committed for any torkier enquiries or requests for assistance.

Yours sineardy

Prof Amenda Lourens (chair MWU Ethics Committee)

LETTER FROM LANGUAGE EDITOR

To whom it may concern

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18 November 2014

Dear Mr / Ms

Re: Language editing of master's dissertation: Evaluation of the medicine procurement and supply management system in public hospitals in Lesotho

I hereby declare that I language edited the above-mentioned master's dissertation by Miss Matsepo A Tema (student number: 23905719) during November 2014.

Please feel free to contact me should you have any enquiries.

Kind regards

Cecile van Zyl

Language practitioner

BA (PU for CHE); BA honours (PU for CHE); MA (NWU)

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1

LETTER FROM TECHNICAL EDITOR

TO WHOM IT MAY CONCERN

I hereby declare that the dissertation titled

Evaluation of the medicine procurement and supply management system in public hospitals in Lesotho

by

MA Tema

23905719

has been checked and corrected technically, which includes all figures, tables and the layout of the text as well as the aspects of the contents.

Cothuga .

E Oosthuizen

November, 2014

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CHAPTER 1: INTRODUCTION AND STUDY OVERVIEW

1.1 Introduction

This chapter provides an introduction to the study and includes an overview of the background of Lesotho, where the study was conducted. It also includes the significance of the study, research problem, and study objectives (general and specific). The chapter concludes with the division of the chapters

1.2 Background of Lesotho

Lesotho is a small mountainous country completely landlocked by the Republic of South Africa. Lesotho covers an area of approximately 30 355 square kilometres. The country is divided into four ecological zones, namely the lowlands, foothills, mountainous and the Senqu valley (World Bank, 2014). The country is further divided into ten administrative districts.

The country's economy largely depends on subsistence farming, manufacturing, water sold to South Africa, royalties from diamonds, construction and receipts from the Southern Africa Customs Union (MOF, 2008 & World bank, 2014). The gross domestic product (GDP) was 6.8% in the financial year 2012/2013; this was mainly due to agricultural output and construction activities in the country (World Bank, 2014). Moreover, the Lesotho currency, Loti, is equivalent to the South African rand, as a legal tender in the country (World Bank, 2014).

According to the 2006 census report, Lesotho's population is estimated to be 1.8 million, with women accounting for 51% of the total population. The annual population growth rate is estimated to be 0.1% (BOS, 2009). However, recent statistics from the World Bank estimate the population to be 2 million (World Bank, 2014)

According to UNAIDS, Lesotho is classified as a country 'hard hit' by the HIV/AIDS pandemic, with the second highest adult HIV/AIDS prevalence of 23% (UNAIDS, 2013). Despite tremendous measures taken to address the pandemic in the country, there has been no significant change in national adult prevalence rate since 2007, and the number of people living with HIV/AIDS is constantly increasing, from 270 273 in 2007 to 360 000 in 2013 (UNAIDS, 2013).

1.3 Significance of the study

This study provides an outline of the current pharmaceutical procurement system in public hospitals in Lesotho, thereby identifying gaps in the system, constraints and possible actions to be taken. The study focused on the procurement of medicines by the central medical store and public hospitals. Furthermore, the study also assessed financial issues surrounding medicine procurement in the country.

Several studies on the medicine supply chain in Lesotho have revealed that there are gaps in the public procurement of medicines in the country (MOH, 2010a:60& MOH, 2011:63). This created a need to critically identify the main challenges affecting the procurement of medicines in the public sector.

There have also been numerous changes in the healthcare systems that may affect the medicine supply chain in Lesotho, and therefore the availability of medicines to all Basotho at all times.

These include:

- The abrupt closure of the Queen Elizabeth II (QEII) Hospital, which was a government referral hospital and a district hospital for the population of Maseru. The hospital was replaced by the Queen Mamohato Memorial Hospital (QMMH), which is not government managed, but rather a public-private partnership (PPP) initiative managed by a private company. QMMH offers more advanced clinical and diagnostic services in the country. Therefore, procurement activities may need to be adjusted in order to cater for QMMH's specific demands.
- The availability of district pharmaceutical logistics officers. Their role is to provide ongoing supportive supervision and mentoring on medicine supply chain activities in order to strengthen pharmaceutical services.
- The appeal by some laws and acts governing pharmaceutical sector in Lesotho (i.e. Dangerous Medicines Act of 1973 and Lesotho Dental, Medical and Pharmacy Order of 1970).

1.4 Research problem

Several assessments conducted on issues surrounding the management of pharmaceuticals have revealed similar challenges facing medicine supply chain systems in Lesotho. The Lesotho Health Systems Assessment Report (MOH, 2011:63) presented the following challenges:

- Lack of national quantification data for pharmaceutical commodities,
- Weak procurement systems for general medicines,
- Irregular updating of guiding documents, such as the national medicines policy, standard treatment guidelines and essential medicines list,
- · Poor adherence to standard treatment guidelines,
- Delayed payment to the CMS by health facilities, and
- Delayed release of quarterly warrants.

The WHO indicates that failure in any step of the procurement cycle leads to a lack of access to essential medicines and inefficiency in the procurement system (WHO, 1999:7). Among the challenges indicated, the procurement system is the main critical function that needs to be thoroughly evaluated. Furthermore, as indicated, there are gaps within the system in terms of procurement operations (MOH, 2010a:60).

The lack of national quantification data for pharmaceutical commodities is a true resemblance of this challenge, since it reflects the poor procurement practices or non-adherence to procurement policies and may lead to shortages or overstocking. The health systems assessment report revealed that hospitals do not submit quantification to either the MOH or the CMS (MOH, 2010a:12). This occurs as a result of either the availability of inaccurate consumption data or the absence of reliable drug usage data. However, quantification should be based on accurate forecasting and budgeting data. The WHO (2011b:14) indicates that the lack of reliable quantification data is largely due to weaknesses in stock management, consumption and reporting, as well as limited monitoring and evaluation.

A literature search revealed that hospital pharmaco-therapeutics committees (HPTCs) are present in all hospitals and the capacity building of hospital pharmacists in medicine supply chain was carried out. However, both national (NPTC) and hospital committees are reported to be non-functional (MOH, 2010a:12).

This situation, however, raises the following concerns:

- How do public hospitals determine quantities of medicines needed?
- How does the CMS quantify national medicine needs?
- What roles need to be played by both national and hospital drug therapeutics committees?

Failure to access funds promptly leads to stock-outs and procurement inefficiencies. The average medicine availability in Lesotho is reported to be 77.7%, which is slightly below the 80% target availability as set by National Medicine Policy strategic plan of 2005 (MOH, 2010a:6). Nevertheless, there are delays in the transfer of funds from the Ministry of Finance (MOF) to the Ministry of Health (MOH) and to the districts and other cost centres outside the MOH headquarters (MOH, 2010a:64). This occurs frequently during the first and second quarter of each financial year, thereby disrupting service delivery at the concerned cost centres (MOH, 2010a:31). In addition, this challenge affects volume to be purchased, since only small quantities can be requested based on available funds, leading to more expensive purchasing (MOH, 2010a:64).

The health systems assessment report (MOH, 2010a:64) also indicates that there are delays in the payments of unpaid bills owed to the CMS for their procured medicines and medical supplies. These delays also affect the payment of suppliers owed by the CMS. Moreover, these delays can result in vital medicines being out of stock, thereby impacting negatively on overall service delivery and rendering the CMS nearly insolvent.

Medicine procurement is directly and indirectly dependent on the availability of updated policies and functional HPTC, and therefore the proper drug selection, forecasting and quantification of medicines will be possible. The availability of relevant policies and regulations provides a solid foundation for the procurement process (MSH, 2012:12).

There has been continuous support from developmental partners during the past five years, which was aimed at strengthening the pharmaceutical procurement system. Among the main partners, Management Sciences for Health (MSH) provided technical support to the MOH, NDSO, public hospitals and health centres. MSH support includes capacity building of all personnel handling pharmaceuticals, supply chain and monitoring and evaluation training. MSH also provided an information management software system (Rx solution) to the CMS and public hospitals.

In view of these challenges affecting the public procurement of medicines, it was essential to conduct a cross-sectional study to evaluate the current procurement systems in Lesotho and identify gaps that are hindering the effectiveness of the system.

1.5 Research aim and objectives

The research objectives include the general objective and some specific objectives of the research study.

1.5.1 General research aim

The general aim of this study was to evaluate the current status of procurement and supply management systems in the public healthcare hospitals in Lesotho.

1.5.2 Specific research objectives

Specific research objectives consist of two phases, namely a literature review and empirical investigations.

1.5.2.1 Literature objectives were as follows:

- To describe the healthcare system in Lesotho.
- To define the roles and structures in the national pharmaceutical sector.
- To describe the medicine procurement and supply management systems in the public healthcare sector.
- To describe the public healthcare sector procurement systems in Lesotho.
- To compare the Lesotho public healthcare procurement guidelines with the WHO guidelines.

1.5.2.2 Empirical research objectives include the following:

- Identify and assess all levels of medicine procurement and supporting systems.
- Identify and assess financial flows for medicines.
- Identify and analyse existing documents governing the procurement and supply management systems of medicines at public hospitals.
- Determine challenges in the current procurement and supply management systems of medicines in public hospitals and propose recommendations.

1.6 Research methodology

This section provides an outline on how data was collected and analysed. It describes the research design that was employed, study population and design, data collection tools (Appendices A-C) and data analysis.

1.6.1 Research design

A descriptive, cross-sectional study was conducted, focusing on all levels of medicine

procurement and supply management systems in all public hospitals in Lesotho.

The study was conducted in two phases, i.e. a literature review and empirical investigation.

1.6.1.1 Literature review

According to Kumar (2011:37), the review of literature provides a thorough understanding of the

status of the research of the area of study, thereby contributing towards an accurate knowledge of evidence. The literature review focused on the procurement and supply management

systems of medicines in the public health sector.

1.6.1.2 Empirical investigations

Following an intensive review of the literature, the researcher compiled questionnaires.

Structured questionnaires were given to different stakeholders involved in the medicine

procurement and supply chain, namely policy and legal framework, selection, quantification,

procurement, distribution and financing.

1.6.2 Study population

The study population include all public hospitals pharmacies (n=20) and one central medical

store (NDSO) in Lesotho. The study focused on medicine procurement in public hospitals

situated in the ten administrative districts in the country. Each district has at least one public

hospital, either owned by government or by CHAL. In total, there are twenty public hospitals in

Lesotho, representing 8% of healthcare facilities in the country. Although the population is small,

the quality of data collected will clearly reflect the procurement management system in Lesotho,

since most of the intense procurement activities are carried out at both secondary and tertiary

healthcare levels.

1.7 **Ethical considerations**

Permission was sought from the Lesotho Ministry of Health's Ethics Committee (ID 62-2013).

Thereafter, an ethical application was also submitted to the Ethics Committee of the North-West

University (Potchefstroom Campus) for ethical approval (NWU 0006013A1). All data collected

was treated confidential, and all interviewees and study sites were not mentioned by name, but

rather by number. Furthermore, only the researcher and study promoters have access to the

raw data. On the basis of probability, the risk-benefit balance indicates that there are no

foreseeable risks/harms associated with this study; therefore, the benefits outweigh the risks.

A more detailed description of the research methodology will be discussed in Chapter 3.

1.8 Divisions of the chapters

Chapter 1: Introduction and study overview

Chapter 2: Literature review

Chapter 3: Research methodology

5

Chapter 4: Results and discussion

Chapter 5: Conclusions, limitations and recommendations

1.9 Chapter summary

Chapter 1 provided a brief introduction on the country where the study was conducted, the research problem and the study objectives. Furthermore, a brief overview of the research methodology, including ethical considerations, was provided.

CHAPTER 2: LITERATURE STUDY OF MEDICINE SUPPLY IN LESOTHO

2.1 Introduction

This chapter reviews important concepts and principles governing medicine procurement and supply chain management systems.

The specific literature objectives to be discussed are as follows and are depicted in figure 2.1:

- To describe the healthcare system in Lesotho.
- To define the roles and structures in the national pharmaceutical sector.
- To describe the medicine procurement and supply management systems in the public healthcare sector.
- To describe the public healthcare sector procurement systems in Lesotho.
- To compare the Lesotho public healthcare procurement guidelines with WHO guidelines.

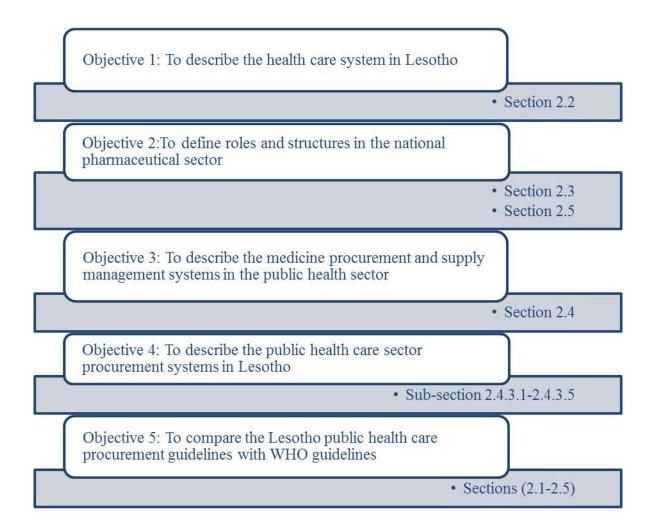


Figure 2.1: Outline of literature objectives with the supply chain framework discussion

2.2 Overview of healthcare structures in Lesotho

The healthcare service delivery system in Lesotho consists of a network of hospitals, health centres and private facilities. The healthcare delivery system is mainly categorised into tertiary, secondary and primary levels. At tertiary level, specialised clinical and diagnostic services are provided, which are not offered at lower healthcare levels. The tertiary level comprises of one referral hospital, Queen Mamohato Memorial hospital (QMMH), and two specialised hospitals, namely the Mohlomi Hospital and the Botsabelo Hospital. The Mohlomi Hospital caters for all mental disorders, while the Botsabelo Hospital provides services for infectious diseases, including leprosy, as well as tropical and respiratory disease. These specialised hospitals receive referrals from all hospital, healthcare centres and private facilities in Lesotho for specified cases only (MOH, 2007a:10).

QMMH is a public-private partnership between the government of Lesotho and the Netcare consortium. The hospital is situated in the Maseru district and attends to all referred cases from all levels of healthcare delivery, including private facilities. It also offers specialised clinical and diagnostic services such as intensive care, paediatrics, surgery, etc. The hospital also serves as a training and research institution offering undergraduate and postgraduate training for different cadres of health professions.

The secondary level comprises of all district hospitals. They attend to referrals from primary health facilities and filter clinics within their catchment areas, as depicted in Figure 2.1. In addition, these hospitals offer comprehensive healthcare services, including hospitalisation, and outpatient clinics, and at least have a functional laboratory on site (MOH, 2007a:10). Each of the ten districts has one government-owned hospital, with the exception of the Thaba-tseka district, which does not have a district hospital owned by government. However, Thaba-tseka has two hospitals owned by the Christian Health Association (CHAL). CHAL has several other public hospitals in Lesotho and provides approximately 50% of health services in the country. There is a memorandum of understanding, signed in 2008, between the Government of Lesotho (GOL) through the Ministry of Health and CHAL on government subvention of hospital and health centre operation costs, such as staff salaries and medicines (MOH, 2007a:10; 2010:39).

The primary healthcare level includes filter clinics, health centres and health posts. Filter clinics act as mini-hospitals and have at least a medical officer and qualified pharmacy staff, either a pharmacist and/or pharmacy technician. In total, there are four filter clinics, of which three are based in the Maseru district and are managed by QMMH. The fourth filter clinic is located in the Leribe district and is managed by the Leribe Hospital (MOH, 2007a:10; 2010:12).

Healthcare centres are community based and provide all primary healthcare services to the population within which they are based and are linked to community or village health workers at health posts. Moreover, health centres are located at the periphery of the mother hospital and are visited by a medical team at regular intervals. These facilities are mostly managed by personnel from the nursing cadre (MOH, 2007a:10; 2010:12).

Health posts are based in the village and are managed by community village health workers and are directly managed and linked to the respective healthcare centres (MOH, 2007a:9). They operate at regular intervals (but not daily) to provide promotive, preventive and rehabilitative care in addition to health education gatherings and immunisation efforts (MOH, 2010:13)

The Lesotho Flying Doctor Service (LFDS) provides medical services in the remote areas of the country. It delivers health services to nine health centres and two village health posts in very hard to reach areas by means of air transport. The medical team visits the facilities once monthly to provide all primary health services, including antiretroviral therapy (ART), care and treatment (MOH, 2007b:9).

In summary, as shown in Table 2.1, there are approximately 217 health facilities in Lesotho, of which 95 are owned by government (GOL), 80 are owned by CHAL, four are owned by the Red Cross, four represent public-private partnerships, and lastly, 34 are privately owned. Out of the 217 health facilities, 21 are hospitals and 196 are health centres and filter clinics (MOH, 2010a:13). There is also an extensive network of private surgeries, nurse-managed clinics and private pharmacies providing clinical care.

Table 2.1: Summary of healthcare facilities in Lesotho

Ownership	Hospitals	Health centres	Filter clinics	Total no. of facilities	Percentage (%) of health facilities
GOL	11	83	1	95	43.8
CHAL	8	72	0	80	36.9
Red Cross	0	4	0	4	1.8
Public-private partnership	1	0	3	4	1.8
Privately owned	1	33	0	34	15.7
Total	21	192	4	217	100

The healthcare referral system in Lesotho

According to the WHO website, a referral system can be defined as a process in which one level of the healthcare system (either primary or secondary levels), having insufficient resources (medicines, equipment, skills) to manage a clinical condition, seeks the assistance of a differently resourced facility at the same or higher level to assist in, or take over the management of the patient. In Lesotho, a referral system begins at a primary healthcare level (health posts, health centre or filter clinic) to a secondary or tertiary healthcare level (district, regional or specialised hospitals). Figure 2.2 clearly outlines the referral process, indicating the relationship throughout the three healthcare levels, i.e. primary, secondary and tertiary (MOH, 2007b:10).

An effective referral system ensures a close relationship between all levels of the health system and helps to ensure that patients receive the best possible care, closest to home. It also assists in making cost-effective use of hospitals and primary healthcare services. Support to health centres and outreach services by experienced staff from the hospital or district health office helps build capacity and enhance access to better quality care (WHO website).

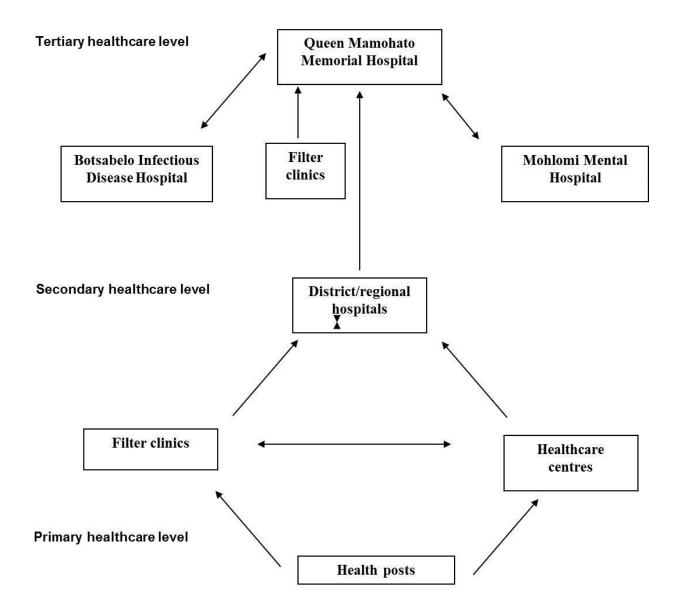


Figure 2.2: Healthcare referral system in Lesotho (adapted from MOH, 2007)

2.3 Overview of the role of the Ministry of Health in medicines procurement and supply management system

The Government of Lesotho (GOL), through the Ministry of Health, is mandated to ensure that the population of Lesotho have access to health services throughout the country. This is through the adoption of the national health policy, which is aimed at ensuring that, by 2020, there is a healthy population, living quality productive lives (MOH, 2004:1). The Minister of Health is therefore responsible for overseeing the overall operations of the ministry with the assistance of the deputy minister, principal and the deputy principal secretaries. The technical aspect of health services lies as the responsibility of the director general of health services and it covers mainly clinical services, primary healthcare, disease control and referral hospitals as depicted in Figure 2.3.

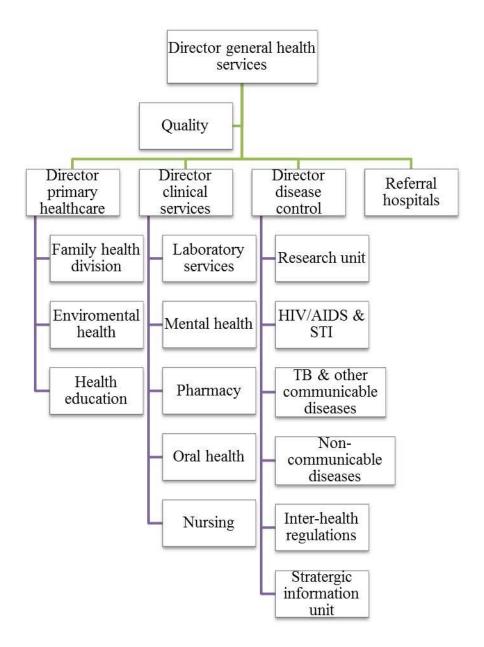


Figure 2.3: Organogram for technical services (adapted from MOH, 2010)

A Directorate of Pharmaceuticals has been established at central level. It has the responsibility for policy, strategic planning, quality control, supervision as well as monitoring and evaluation of pharmaceutical services. The Ministry of Health through this department is committed to ensuring a continuous supply of medicines to all facilities in the country. Indeed, this commitment is through the adoption of the Lesotho National Medicine Policy (LNMP). The overall aim of the policy is to improve and sustain, within available resources, the health of the population of Lesotho by treating, curing, reducing or preventing diseases and conditions through the use of safe, effective, quality, affordable medicines, in both public and private sectors (MOH, 2004:22; 2010a:61)

The department has developed the Lesotho National Medicine Policy, strategic plan, Essential Medicine List (EML), Standard Treatment Guidelines (STGs) and the department is currently in the process of establishing a National Medicine Regulatory Authority and a medicine information centre and an adverse medicine event monitoring system (MOH, 2010a:61).

The main objective of the Lesotho National Medicine policy (LNMP) is to ensure that good quality essential, efficacious and affordable medicines are available to all Basotho at all times in all health facilities in both the public and private sector (MOH, 2005:22).

The objectives of the LNMP are to achieve the following:

- Ensure that medicines of good quality, safety and efficacy are available, at affordable cost, to all Basotho people in both public and private sectors.
- Control, supervise and evaluate the quality of pharmaceuticals.
- Promote the rational use of medicines in the public and private sectors through the provision
 of objective drug information, training and continuous education with an emphasis on better
 diagnosing, prescription writing, dispensing and counselling.
- Promote the local production of good quality essential medicines at affordable cost.
- Be a basis for the development of appropriate medicine legislation and its enforcement.
- Guide the development of appropriate pharmaceutical human resources and ensure their retention and proper deployment in the country.

However, for the country to sustain an uninterrupted supply of good quality, cost-effective medicines in Lesotho, there should be effective and efficient procurement and supply chain management systems in place. These systems are essential towards the achievement of millennium development goals and the promotion of sustainable development (WHO, 2011a:2) and will, among others, ensure availability of essential medicines at every point of need (MSH, 2012:12).

Moreover, Lesotho developed and adopted the Drug Supply Management (DSM) manual and Lesotho Standard Operating Procedures (LESOPs) in 2007. These documents are intended for use in all government- and CHAL-owned facilities. The pharmacy directorate is mandated with the overall responsibilities for the implementation of the DSM system in the country. However, despite these efforts developed to manage the supply chain in Lesotho, there are still some critical challenges that are facing the directorate of pharmaceuticals.

These challenges include:

- Obsolete legislation that does not effectively regulate the pharmaceutical sector.
- Absence of a quality assurance system that ensures quality of medicines within the country.
- Inadequate management systems in the medicines supply chain.
- Absence of updated National Standard Treatment Guidelines (NSTGs) and a National Essential Medicines List (NEML).
- Inadequate management and inequitable distribution of available financial resources.

2.4 Overview of medicine procurement and supply chain management in the Lesotho public health sector

2.4.1 Introduction

Access to healthcare, including essential medicines, is a fundamental human right (MSH, 2012). Therefore, there should be systems in place to ensure that individuals have access to good quality essential medicines whenever they are needed. According to the WHO, access to essential medicines and health products is critical to reach universal health coverage and these items are important to address health problems and improve quality of lives. They form an indispensable component of health systems in the prevention, diagnosis and treatment of disease and in alleviating disability and functional deficiency (WHO, 2011a:2).

Importance of medicine in the health sector (MSH, 2010:12)

Medicine can save lives and improve health

Many incidences of discomfort, disability and premature deaths can be prevented, treated and alleviated through the use of cost-effective medicines.

• Medicines are unique commodities

Medicines are not like ordinary products; consumers often do not choose the medicine since they are not trained to judge medicines and also do not generally know the consequences of not obtaining a needed medicine. Moreover, health practitioners are often not equipped to assess medicines for effectiveness and efficacy, and therefore fear of illness can lead to poor purchase choices by both consumers and practitioners.

Medicines are costly

People do not choose to be sick; therefore, for individuals and households, medicines can account for 60 to 90% of total health spending and is therefore a major out-of-pocket expense. For countries, medicine expenditures are often second only to personnel salaries and benefits, representing as much as 20 to 40% of total national health expenditures.

Medicines promote trust and participation in health services

Generally, it is a common perception that if individuals seek medical help, it is expected that, following all the built-in processes, ultimately medicines will be provided. Therefore, if stock-outs occur regularly, the patients and healthcare workers lose confidence in the system and patient numbers drop (MSH, 2012:455).

• Substantive improvements in the supply and use of medicine are possible.

2.4.1.1 Overview of the drug supply management system

It is important to understand that almost everyone involved in healthcare may directly or indirectly be involved and has something to contribute to the improvement of the management of medicines and medical supplies. In order to ensure a constant supply of essential medicines

at every point of care, the four dimensions of access should be outlined: availability, affordability, accessibility and acceptability (MSH, 2012:19).

Medicine procurement and supply chain management are a set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines, health products, and services in any healthcare setting. These activities are organised according to the functional components of a cycle or a system and may take place at various levels of the health system according to the design of the health system. The components are the same for all health sector levels; however, the procedures and activities within each component may differ (MSH, 2012:19).

Pharmaceutical procurement is a major determinant of drug availability and total health costs. It is indicated that medicine expenditure represents the single largest expenditure after salaries, and accounts for approximately 20 to 40% of the total healthcare budget and up to 90% of household budget in the Sub-Saharan region (MSH, 2012:1). Therefore, an effective procurement and supply chain management system should ensure constant availability of good quality essential medicines, in the right quantities and timely undisturbed distribution at the lowest possible total cost (MSH, 2012:1). Moreover, effective and efficient public sector procurement systems are essential towards the achievement of millennium development goals and the promotion of sustainable development thereby improving universal access to health (WHO, 2011a:2). Millennium development goals are eight goals set by the 191 UN member states and singed as conversions, to be achieved and implemented by the year 2015 (WHO, 2011a:2). These include:

- Goal 1- to eradicate extreme poverty and hunger.
- Goal 2- to achieve universal primary education.
- Goals 3- to promote gender equality and empower women.
- Goal 4- to reduce child mortality.
- Goal 5- to improve maternal health.
- Goal 6- to combat HIV/AIDS, malaria and other disease.
- Goal 7- to ensure environmental sustainability.
- Goal 8- to develop a global partnership for developments.

Although procurement is a critical key process in the drug supply chain, it does not function in isolation. The four basic principles of the drug supply chain are organised in to a cycle that emphasises the interdependence of the functions. These activities are inter-linked to other processes, including selection, distribution, use and management support, as depicted in Figure 2.4. These functions cannot operate in isolation, since the inputs into one function are the outputs from one or more of the other functions. These functions are interlinked and reinforced by appropriate management support systems (WHO, 2004:5).



Figure 2.4: Procurement and supply chain framework (Adapted from MSH, 2012)

Pharmaceutical management systems require sound policies and legal frameworks that will provide a solid foundation for the systems. It is equally important that these policies and regulations are periodically updated to ensure that they address the current health situation in the country and are in line with international standards. Legislative and regulatory frameworks provide a legal basis for the policy and make it enforceable (MSH, 2012:4). However, the Lesotho health systems assessment report revealed that Lesotho has weak pharmaceutical legislation and policies in place (MOH, 2010b:59). To a greater extent, this weakness critically affects almost all basic functions of the procurement and supply chain system, and consequently overall medicine availability in the public healthcare sector.

There are many steps in the procurement process and no matter what model is used to manage the procurement and distribution system, efficient procedures should be in place to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to a lack of access to appropriate drugs and to waste. The absence of a well-managed system can lead to high-cost medicines and poor quality of care (WHO, 1999:12).

2.4.2 Medicine selection

The objective of the national medicine policy (NMP) on the selection of medicine is to ensure that all medicines circulating in the country are selected using evidence-based criteria and procedures (MOH, 2005:22). The selection of medicine is defined as the process of identifying essential medicine to be used to effectively prevent and treat common or prioritised health problems in the country (MSH, 2012:289). The selected items therefore meet the health needs of the majority of the population and should be available in appropriate dosage forms and strengths; these are the essential medicines for the country.

The rationale for the selection of medicine is the use of limited number of essential medicine in the country; therefore, improved supply of medicines, rational prescribing and lower costs (MSH, 2012:281). Moreover, appropriate selection ensures that medicines kept at each health facility address the needs of the local communities (MOH, 2007a:14).

There are currently 216 medicines on the EML of Lesotho. Based on a policy set at national level, drug selection at national level is carried out by the National Pharmaco-therapeutics Committee (NPTC) in consultation with relevant stakeholders. At health facility level, drug selection is performed by the Hospital Pharmaco-therapeutics Committee (HPTC). According to the Lesotho health assessment report (MOH, 2010a:61), the NPTC is said to be in the process of reviewing both STG and EML documents.

Implementing or donor partners i.e. Global fund, UNICEF, UNFPA have specific disease programmes or focus areas, which require the range of drugs to be limited to treat certain conditions. It is crucial that for the selection of commodities to be procured, the national EML, STGs, level of care, and burden disease are taken into account (MOH, 2007a:14).

The selection of medicines is performed according to the Lesotho National Medicines Policy (MOH, 2005) based on the following factors:

- National health priorities
- · Patterns of prevalent disease
- Proven safety and efficacy
- Cost-effectiveness and affordability
- Adequate quality
- When two or more drugs are equivalent, the following aspects are considered:
 - -pharmacokinetic profile
 - -patient compliance
 - -cost of treatment
 - -possibility of reliable supplier
- Type and quality of healthcare level

Each hospital develops its own medicine list based on national EML and STGs. The process considers at least some of the following aspects:

- Case mix
- Evidence-based treatment
- Cost of treatment course
- Level of specialisation (specialised units) and experience of prescribers at the hospital.

2.4.3 Medicine procurement

The medicine procurement system is the major determinant of medicine availability and total medicine costs (MSH, 2010:323). Therefore, medicine procurement is an important part of efficient drug management and supply and is critical for all levels of healthcare institutions and should be based on selected drugs and the availability of financial resources (WHO, 2004:9). Moreover, an effective procurement process should ensure the availability of the right drugs in the right quantities, available at the right time, for the right patient and at reasonable prices, and at recognisable standards of quality (MSH, 2012:10).

Procurement is the actual process of acquiring good quality and cost-effective medicines, including those obtained through purchase, donation or manufacture (WHO, 2004:9). As previously indicated, medicine procurement is a major determinant of drug availability and total health costs. It is indicated that medicine expenditure represents the single largest expenditure after salaries and accounts for approximately 20 to 40% of the total healthcare budget and up to 90% of household budgets in the Sub-Saharan region (MSH, 2012:10).

2.4.3.1 Procurement cycle

Medicine procurement is a complex process involving many functional steps and policies. It is one of the critical, interrelated components of the public healthcare sector supply system (WHO, 2011:2). Therefore, procurement is not simply the act of buying, but encompasses a complex range of operational, business, information technology, safety and risk management, and legal systems, all designed to address an institution's needs. Furthermore, it is indicated that medicine procurement should be conducted within national and institutional policies, rules, regulations and structures that support the overall efficiency of the procurement process (Ombaka, 2009:20). Therefore, effective and efficient public sector procurement systems are essential to the achievement of the Millennium Development Goals and the promotion of sustainable developed in countries (MSH, 2012:323).

According to the WHO (1999:3), in order to manage the procurement and distribution system, there should be efficient procedures be in place to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to a lack of access to appropriate medicines and to waste. In many public supply systems, breakdowns regularly occur at multiple points in this process.

According to the WHO (1999:7), any effective and efficient procurement system should focus on four strategic objectives, namely:

- (1) Procure the most cost-effective medicines in the right quantities
- Development of EML
- Procurement of cost-effective medicines
- Accurate estimates of procurement quantities

- Avoid over- or under-stocking
- (2) Select the most reliable suppliers of high quality medicines
- Reliable suppliers must be pre-selected
- Build reliable quality assurance systems into the procurement process
- (3) Ensure timely delivery
- Procurement and distribution systems must ensure the timely delivery of appropriate quantities to the CMS and district healthcare facilities where commodities are needed
- (4) Achieve lowest possible total costs
- Procurement and distribution systems must achieve the lowest possible total costs
- Evaluate actual purchase price, hidden costs and inventory holding costs

Ideally, an effective medicine procurement process in a health system should (MSH, 2012:324):

- Seek to manage buyer-seller relationships in a transparent and ethical manner;
- Procure the right medicines in the right quantities;
- Procure by generic name;
- Obtain the lowest possible purchase price;
- Ensure that all medicines procured are of recognised quality standards;
- Arrange timely delivery to avoid shortages and stock-outs;
- Ensure supplier reliability and quantification with respect to service and quality;
- Set the purchasing schedule;
- Calculate quantities based on reliable estimates of forecasted actual needs; and
- Monitor procurement performance indicators.

In Figure 2.5, the necessary steps to be followed in an effective procurement system are illustrated. The procurement process is organised into the procurement cycle with functions organised in a chronological order. Any failure occurring in any of the steps can lead to a lack of access to essential drugs and to waste (WHO, 1999:7).

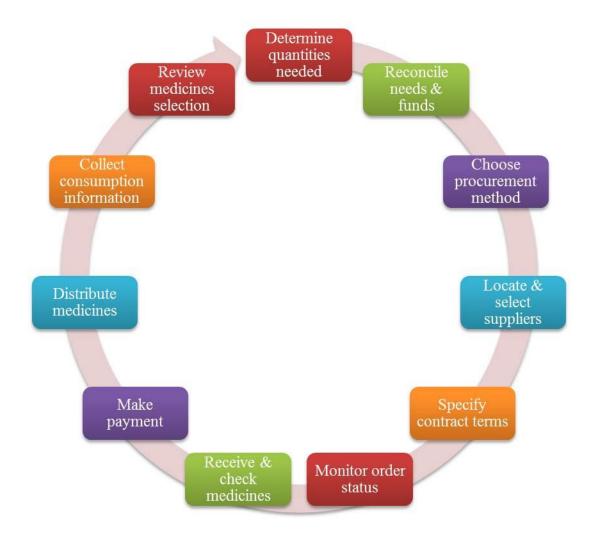


Figure 2.5: Medicine procurement cycle (adapted from MSH, 2012)

2.4.3.2 Medicine procurement in Lesotho

According to the Lesotho National Health Policy (MOH, 2004:2), the procurement of medicine is relatively expensive as the Lesotho public sector market is small, and uncertainty about the quantities of medicine demand of the country create speculation and lead to increases in medicine prices. The objective of the LNMP on the procurement of medicine is to ensure that there is an adequate and regular supply of safe, good quality and efficacious medicine at affordable costs at all times (MOH, 2004:2).

The medicine procurement and supply chain in Lesotho is a hybrid system following both centralised and decentralised models. The choice of procurement model depends on the level at which procurement is conducted and is directed by national policies and procedures. Typically, there are three models for procurement (Thompson, 2009:94):

- **Centralised model:** Main operational functions for decision-making are tightly controlled and situated at one focal point of the organisation. Furthermore, procurement is conducted at the central level by a national procurement unit.
- Decentralised model: Main operational functions are diversely spread across different parts of the organisation. Procurement is conducted by sub-national entities, including regional or provisional authorities and health facilities.
- Mixed model: maintains some central functionality to promote economies of scale. Drug requests for very large quantities are done centrally as bulk purchasing to mitigate costs.

In Lesotho, medicine procurement takes place through a semi-autonomous national procurement agency, named the National Drug Service Organisation (NDSO). The NDSO was established legally as stated in the Finance Act of 1978 and Finance notice of 2007. It is the trading account (financed through a mark-up system) for the Ministry of Finance and is mandated to procure, store and distribute medicines, as well as medical, laboratory and X-ray supplies to all public health facilities in the country (MOH, 2011:22).

The NDSO is mandated to procure medicines on behalf of the Ministry of Health and also to manage the distribution of medicines and other health commodities for several health programmes including HIV/AIDS and opportunistic infections, TB and family planning. Most of these health commodities are donor funded by several development partners working in Lesotho (MOH, 2011:22). Nevertheless, the NDSO sells medicines to private outlets in order to generate an income for operational and/or running costs (MOH, 2010a:62).

The NDSO follows public sector procurement regulations, and procurement is pooled at the national level (i.e. there is centralised procurement for public sector facilities). It uses the WHO pre-quantification scheme when identifying suppliers and the Pharmaceutical Inspection Cooperation Scheme or International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Standards for its prequalification process. Samples are requested from all new suppliers, and these are taken to the South African Bureau of Standards laboratory and/or North-West University's Centre for Quality Assurance Management for testing. Other laboratories are also used for sample testing on an *ad hoc* basis, as identified by the NDSO. Furthermore, the NDSO runs approximately 50 procurements per year, with emergency orders constituting more than 40% of all annual procurements (MOH, 2010a:62).

However, most donor-funded medicines are procured differently, since donor partners have their own procurement guidelines that the government is required to follow when using their funds (MOF, 2007:28). This is designed to promote transparency and an efficient procurement process. However, compliance with the funder's procurement requirements can place an additional burden on the procurement system; therefore, through a global fund coordinating unit, personnel have been employed at national level and the NDSO to offer technical assistance in the management of ARV procurement, distribution and information management (MOH, 2010a:63).

According to the WHO (1999:11), public sector procurement should be limited to an essential medicine list or national/local formulary list, since no public or private healthcare system in the world can afford to purchase all drugs circulating in the market within its given budget. Thus, a limited list of medicines for procurement defines which medicines will be regularly purchased since resources are limited and choices have to be made. Furthermore, a nationally developed formulary or selection based on the essential medicines concept has been used in both industrialised and developing countries' health systems for more than twenty years (WHO, 1999:11). This allows the health system to concentrate resources on the most cost-effective and affordable medicines to treat prevailing health problems. Larger quantities may encourage competition and lead to more competitive medicine prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs.

The NDSO follows set government procurement guidelines (2007), which contain procedures and guidance on all aspects of public sector procurement, including standard documentation (MOF, 2007). Procurement policies within the NDSO involve the following:

- · WHO pre-qualified suppliers for ARVs
- Global Drug Facility for first-line anti-TB medicines
- Procurement services from UNICEF and UNFPA for the procurement of vaccines and condoms
- Limited international bidding for the procurement of some essential medicines from NDSO pre-qualified suppliers.

According to government's procurement guidelines, the following tender processes are used for public sector procurement, as outlined in Table 2.2:

- National competitive tender
- International competitive tender
- Negotiation/direct purchasing

2.4.3.3 Procurement methods

Medicine procurement methods can be categorised into open tender, restricted tender, competitive negotiation and direct procurement (described in table 2.2). Each of these methods can be used with any of the standard reorder frequency models, annually scheduled or perpetual review depending on the procurement contract (MSH, 2012:326). The choice of procurement method is determined by the following:

- National policies and regulations
- Funding(donor requirements)
- Procurement experience
- Management capacity
- Quality assurance capacity
- Impact on product required

Table 2.2: Summary description of different procurement methods used medicine procurement (MSH, 2012)

Procurement method	Description	Advantages	Disadvantages
Open tender	An open tender is a formal procedure whereby quotations are invited from a potential manufacturer or supplier locally or globally subject to the terms and conditions specified in the tender invitation.	 Usually provides lowest costs since there are many bids. New suppliers are identified. 	 High workload is required in evaluating bids and selected suppliers. There is moderate to long lead times.
Restricted tender	In a restricted tender, interested suppliers must be approved in advance, usually through a formal prequalification process that considers adherence to good manufacturing practices, past supply performance, financial viability and other related factors.	 Usually preferred method in small countries (i.e. Lesotho). Favourable prices since there are fewer bids. Moderate workload since suppliers are prequalified; therefore, less work in evaluation of bids. 	 Fewer bids could lead to limited options. A functional prequalification system should be in place.

Procurement method	Description	Advantages	Disadvantages
Competitive negotiation	Competitive negotiations involve approaching a few selected suppliers and requesting price quotations (typically at least three).	Provides short to moderate lead times.	Provides generally higher prices.
		 Less workload since suppliers are already known and prequalified. 	Usually ideal method for private sector procurement
		Buyers may bargain with suppliers to achieve specific price arrangements.	
		Useful for usually high finance value transactions where there is more than one possible supplier.	
International or local shopping	Similar to competitive negotiation.	 Provides short to moderate lead times, Less workload since suppliers are already known and prequalified. 	Bargaining on prices is not permitted
Direct procurement:	This is the simplest but perhaps the most expensive procurement method of all as it involves direct purchase from a single supplier either at quoted prices or negotiated prices.	Easy and quick.Provides short lead times.	 Usually provides the highest prices. Not a cost-effective method for routine orders.
		Suitable for emergency purchasing and low- valued products.	

Procurement method	Description	Advantages	Disadvantages
E- procurement and reverse auction	E-procurement is an Internet-based tendering. Reverse auction is a variation of restricted tenders whereby, through a round-by-round process, the lowest posted bid wins the contract.	Fast and minimal workload.	 This method is rarely used in pharmaceuticals procurement due to quality assurance requirements. Requires Internet capacity.

2.4.3.4 Quantification process

Quantification is basically the first step in the procurement process. The process involves estimating and determining the quantities of specific medicines for procurement and financial means (MSH, 2012:327). An accurate quantification of procurement requirements is needed to avoid stock-outs of some medicines and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract (WHO, 1999:12).

According to the Lesotho health assessment report, the country is faced with challenges of a lack of national quantification data for pharmaceutical commodities (MOH, 2010a:12). This raised a concern to the researcher as to how the country determines quantities of medicines required that need to be procured.

Generally, there are four methods employed in the quantification process and these are summarised in Table 2.3 (MSH, 2012:373). Past consumption is the most reliable way to predict and quantify future needs, provided that the supply chain has been consistently full and that consumption records are reasonably accurate (WHO, 1999:11). Such consumption data must be adjusted in light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance. However, the disadvantage of this method is that any existing patterns of irrational drug use will be perpetuated.

Table 2.3: Quantification methods (MSH, 2012:374)

Method	Description	Uses
Consumption-based	Uses information from past consumption of individual medicines adjusted for stockouts and projections to estimate future needs.	In a normal-function health system to project future needs and is the most reliable method for quantification.
Morbidity-based	Estimates the needs for specific medicines based on the expected number of attendance, incidence of common disease and standard treatment patterns for the disease under consideration.	Normally used for programme scaling, i.e. ART programme scale-up. Also for developing and justifying budgets.
Proxy consumption	Uses data on disease incidence, medicine consumption and/or pharmaceutical expenditure, and extrapolates on service level to be provided.	Mainly used when other quantification methods are unreliable and can be used for comparison of drug use in other supply systems.
Service-level projection	Uses the average medicine cost per attendance of bedday in different types of facilities in a standard system to project medicine cost in similar types of facilities.	To project medicine expenditure in similar types of facilities and also to estimate budgetary needs.

2.4.3.5 Procurement process for public hospitals

According to the LNMP, public sector medicines should be limited to the essential medicine list. No country can afford to purchase all medicines available in the market within the given budget (MSH, 2012:331). However, this is not the case since procurement is currently out of the scope of EML (MOH, 2009b). Accordingly, the procurement of medicines not included in EML should be ordered at the CMS as motivation items whenever they are needed, but the CMS is not mandated to keep the items in stock, but rather to source them when ordered (MOH, 2007b:15).

Ombaka (2009:22) emphasised that medicine procurement in hospitals is the responsibility of the pharmacist or pharmacy staff, although skills beyond basic pharmacy are also required. In order to ensure effectiveness in procurement process, the following nine key issues should be thoroughly exploited:

- Transparency,
- Cost containment,
- · Technical capability,
- Operational principles of good pharmaceutical procurement,
- · Purchasing for safety,
- Ensuring appropriate selection,
- Timely, accurate and accessible information,
- Ensuring quality products, and
- Proper budgeting and financing.

Although all public healthcare facilities are expected to procure all pharmaceuticals from the CMS, some CHAL and Red Cross facilities regularly procure their pharmaceuticals from other private wholesalers in the country. Operationally, for public facilities to procure medicines elsewhere, the CMS should issue authorisation and source approval (MOH, 2010a:62).

Government hospitals follow set government procurement guidelines (2007) and the Lesotho Standard Operations Guidelines for pharmaceuticals (MOH, 2007b). For CHAL hospitals, they do not follow government procurement guidelines, but rather their own guidelines, since the facilities have their own management. However, CHAL facilities follow the standard operations guidelines for the technical aspects of procurement. For the requirements of LESOPs and DSM, hospitals should accurately quantify and forecast their procurement needs and send such information to the Department of Pharmaceuticals, CHAL secretariat and central medical stores (MOH, 2007b). In contrast, hospitals do not submit their quantification data as required, and therefore, the NDSO quantifies national needs using the demander-based consumption method. Accurate quantification and forecasting (appendix F; page 98) are crucial in order to avoid stock-outs, overstocking and also the possibility of obtaining lower prices on an estimated quantity supply contract and economics of scale (MSH, 2012:340).

Procurement process

According to the Lesotho standard operating procures, orders are placed with the NDSO according to the applicable ordering and delivery schedule (appendix E; page 96), and adequate items and quantities are ordered (MOH, 2007c:13). The ordering and delivery schedule indicates the time frame for order processing and has grouped hospitals according to administrative districts and geographic regions.

The following order processing has to be followed, as shown in figure 2.6:

- All hospitals are expected to place orders at least once every month to the NDSO.
- Order items with stock on hand equal to or below the estimated re-order level.
- Narcotics and habit-forming drugs are ordered on a separate order form.
- Identification of items to order and calculation of quantities and also confirmation of funds.
- Compare the stock on hand (on the stock card balance) and the estimated reorder level on the stock card.
- List all items where the stock on hand is equal to or below the reorder level indicated on the stock card
- Use internal requisition voucher which is either computerised or manual based (appendix F; page 98). If this voucher is computer generated, all the stock items, their unit sizes, VEN classification and unit prices are pre-printed. However, unit prices are constantly changing.
- Prepare the requisition voucher in three copies.
- Transfer the required information for these items from the stock cards to the requisition voucher (if using manual system).
- Fill in the information documented on the stock cards for AMC (average monthly consumption), stock on hand and re-order level for each item on the requisition voucher.
- Calculate and fill in the order quantities (in issue units).
- Calculate the cost for each item by multiplying the order quantity with the unit price.
- Add up cost figures for all items to be ordered to calculate the total at the bottom of the page.
- Submit the completed requisition to the head of pharmacy for cross-checking and make any changes required.
- Send the three copies of the completed and checked requisition to the accounts department for confirmation of funds.
- Send the three copies of the completed requisition to procurement unit for generation of a purchase order as per requested items.

- Once purchase order has been generated and authorised accordingly, it is sent to the NDSO as per ordering schedule.
- File the copy of the requisition accordingly.
- Follow up with NDSO whether the order has been received.
- In contrast to government facilities, CHAL facilities send requisitions directly to the NDSO after approval from the accounts department and higher hospital authority.

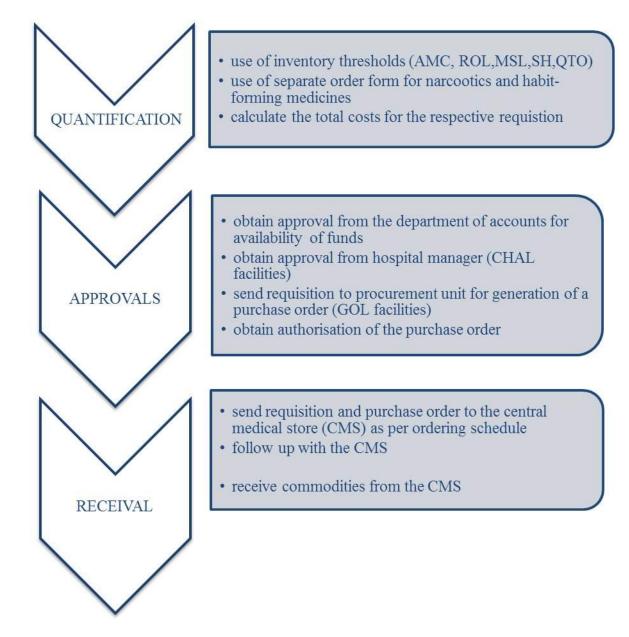


Figure 2.6: Order processing at the public hospital (adapted from MOH, 2007:13)

Figure 2.7 provides a detailed description of purchase order processing for government facilities. It indicates the time frames for each process from the time the requisition is made at facility level up to the time the central medical store delivers the consignment. Basically, it takes an average of one week to process a requisition in to a local purchase order thus, two weeks in total. An additional two weeks is required to serve a purchase and deliver the stock.

Req @ (Hosp & DHMT): This means that during the week indicated (Monday to Friday) the requisitions MUST have been prepared at Hospitals whilst at DHMT the requisitions from the Health Centres MUST have been collected and all ready to be sent to the Procurement Unit in Maseru.

NDSO Delivery: this means that the deliveries by NDSO will be made during the period indicated.

Reg @ PU: This means that during the week indicated (Monday to Friday) the requisitions MUST have REACHED the Procurement UNIT in Maseru and being processed in to the Local Purchase Orders.

LPOs at NDSO: This means that during the 2 weeks in question, Local Purchase Orders, LPOs MUST have reached NDSO and being processed at NDSO for the week that follows.

Figure 2.7: Ordering and delivery process of medicine for GOL hospitals only

How to calculate inventory thresholds

According to the Lesotho standard operating procedures, inventory thresholds should be calculated routinely; this is to ensure that adequate quantities of stock are kept and replenished on time (MOH, 2007c:8). There are several factors that directly influence order quantities, and these include (MSH, 2012:464):

- Average monthly consumption (AMC)
- Lead time
- Safety/buffer stock
- Reorder level and maximum stock level
- Stock position
- Procurement period

In order to determine the average monthly consumption (AMC), a summary of annual monthly issues on the stock card of the item for the previous (12) twelve months is used. Therefore, one should count the number of months the item was in stock during the previous 12 months (exclude number of months the item was out of stock). Those months where the item was out of stock are marked as X in the column of the respective months in the table. Afterwards, all monthly quantities are added and the figure for the annual usage is divided by the number of months the item was in stock; the resulting figure is the AMC. It is important to note that issues to other hospitals, returns to the NDSO, or removal of expired items do not reflect usage in the

hospital. Moreover, on the same stock card, maximum stock levels and reorder levels should also be indicated, they are calculated using a pre-defined factor (MOH, 2007c:8).

Standard operating procedures exist for determining inventory thresholds thereby maintaining minimum and maximum stock levels at all times (MOH, 2007c:8):

Calculating AMC

Average monthly consumption (AMC) = sum of the monthly consumption during the same period / total number of months stock was in stock.

• Calculating maximum stock level

Maximum stock level $(S_{max}) = AMC X 3$

Factor 3 is used to represent months in stock: 1 month stock, 1 month lead time and 1 month of buffer stock. It implies that, even if in any particular month consumption increases (as in outbreaks), the available stock can cater for a two-folds increase.

Calculating re-order level

Re-order level = AMC X 2

Factor 2 is used to represent 1 month stock and 1 month lead time. Re-order level defines the stock balance when to place an order

Calculate order quantity (QTO)

 $QTO = S_{max} - stock$ balance on hand

2.4.4 Medicine distribution and storage

The distribution process entails the receiving and storage of medicines through reliable delivery networks, thereby ensuring a constant supply of medicines to the health facilities (WHO, 2004:10). The activities involved are:

- · Goods received at the port of entry
- Customs clearance
- Stock control
- Delivery to the NDSO and to health facilities thereafter
- Inventory management

MSH (2012:430) indicates that the primary goal of an effective distribution system is to maintain a steady supply of medicines to health facilities where they are needed while still ensuring that resources are used in the most effective way. The distribution process involves the physical flow of goods supported by adequate information flow (MSH, 2012:429).

In Lesotho, the NDSO manages the distribution of pharmaceuticals countrywide through an NDSO delivery system covering all government and CHAL health facilities. It uses the direct model to distribute medicines to the public hospitals; however, for distribution to the health centres, the decentralised model is employed whereby medicines are delivered to the District Health Management Teams (DHMTs) and not to health centres directly, as depicted in Figure 8 (MOH, 2010a:62). However, administrative challenges at the districts affect the distribution of medicines from the DHMT to the respective health centres, and therefore the necessity for the NDSO to directly facilitate the distribution to the health centres (MOH, 2010a:62). Figure 2.8 indicates the flow of both the stock and information from the manufacturer to the NDSO and to the health facilities. This distribution system applies to both government and CHAL facilities.

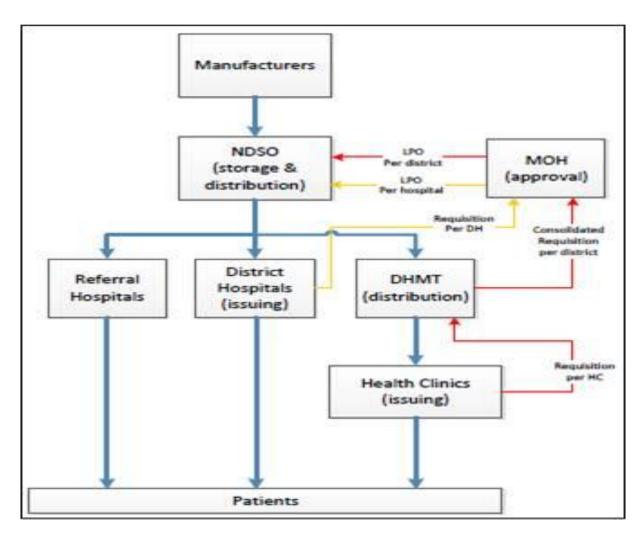


Figure 2.8: Medicine distribution and ordering system (adapted from DSM manual Lesotho)

Standard operating procedures exist for all operations at the NDSO, including procedures for the storage and distribution of medicines for vertical programmes i.e. family planning, nutrition, and disease control. Anti-retroviral medicines and TB products are procured using both government and global fund funds, but the storage and distribution of these commodities are integrated into the central (NDSO) system. These medicines are then delivered to the public hospitals and health centres, following a designed delivery schedule indicating the time frame for order processing and delivery pattern grouping hospitals according to administrative districts and geographic regions as shown in Appendix E (MOH, 2010a:63).

Designing an effective system for a medicine distribution system is complex and very crucial, and therefore it should be cost-effective and should provide an acceptable level of service.

According to principles, an effective distribution system has four major elements (MSH, 2012:429):

- **System type:** It entails geographic and population coverage, number of levels in the healthcare system, pull or push systems, degree of centralisation.
- **Information system:** It describes inventory control, medicines records, consumption reports, information flow.
- Storage: It describes storage system and design, delivery system and layout.
- **Delivery:** It entails collection against delivery, transport management, delivery schedule.

Different models for the distribution of pharmaceuticals are used in different counties and sometimes within the same country, i.e. in the public and private sector (WHO, 2010:236).

These models can also be referred to as distribution systems; they include pull or push systems:

- Pull system: This follows an upward approach whereby the health facilities determine the
 types and quantities of medicines required and place an order with the central medical store
 (supplier). This system is dependent on the demand of the facilities for essential medicines
 (WHO, 2010:236).
- Push system: This follows a downward approach whereby the supplier at either central
 medical store or at national level determines the type and qualities of medicines to be
 supplied to the health facilities. This system is normally used for donor-funded products or
 during disaster relief and for the implementation of scale-up programmes, i.e. access to
 ARVs, TB products, etc. (WHO, 2010:236).

2.4.4.1 Distribution cycle

The distribution process begins when medicines are dispatched by the manufacturer or supplier and ends when consumption information is reported back to the procurement unit, as shown in Figure 2.9 (MSH, 2012:431).

According to MSH (2012:430), a good distribution system should aim to:

- Maintain a constant supply of medicines;
- · Keep medicines in good conditions;
- · Minimise medicine losses due to spoilage and expiry;
- Rationalise medicine storage points;
- Manage transport efficiently;
- Reduce theft and fraud;
- Provide information to forecast medicines needs; and
- Incorporate a quality assurance programme.

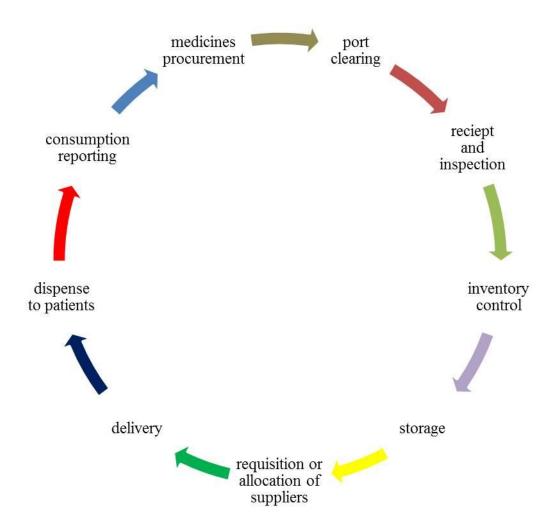


Figure 2.9: Distribution cycle (adapted from MSH, 2012)

2.4.4.2 Inventory management

Inventory management can either be manual or electronic based. Most facilities in the country are currently using the manual system; stock cards or bin cards. Good inventory practices involve the following activities (MOH, 2007b:25):

- Organising stock
 - Alphabetical arrangement
 - First-in-fist-out (FIFO)
 - First-expiry-first-out (FEFO)
 - Expired, damaged and obsolete items should be removed from the shelves and disposed of according to approved procedures.
 - Conducive storage area for pharmaceuticals.

The main objective of inventory control is to supply the right medicine to the right patient at the right time, in the right quantity. Therefore, improved inventory management at facility level has a direct beneficial effect on the whole supply system (MOH, 2007b:26). Moreover, inventory practices can assist in the following:

Budgeting;

- To prevent stock-out;
- To avoid over- or under-stocking;
- To prevent expiration of medicines;
- To monitor stock levels and medicine consumption; and
- Monitoring the rate of medicine consumption, future medicine requirements can be forecast with accuracy.

2.4.5 Medicine use or utilisation

At health facility level, medicines are prescribed following the proper diagnosis of the health problem. The WHO indicates that prescribing should promote the rational use of medicines through the use of STGs and EML (WHO, 2004:29). It is imperative that the four components of the supply chain are interlinked since selection, procurement and distribution are the critical inputs to the rational use of medicines.

Medicine use can be considered either rational or irrational depending on how medicines are used by both health professionals and the public. The medicine use process can be organised into activities that are in a chronological order, as depicted in Figure 2.10; it summarises the main activities in medicine use. The actual use of medicines is influenced by a wide range of factors, including availability, provider experience, economic influences, cultural factors, community beliefs and patient attitudes (MSH, 2012:518).

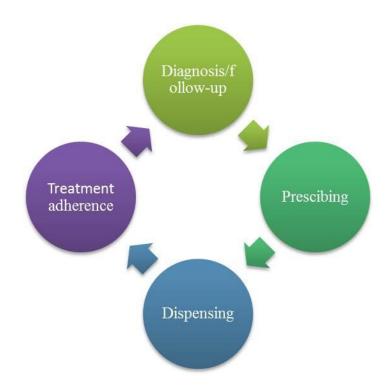


Figure 2.10: Medicines use process (adapted from MSH, 2012)

Rational use of medicine

Rational medicine use is observed if the 5 Rs are maintained:

Right patient

- Right medicine
- · Right quality
- Right quality
- Right time and place

Criteria for rational medicine use (MSH, 2012:517):

- Appropriate indication: prescribing should be based on sound diagnostic criteria using STGs and formularies.
- Appropriate medicines of acceptable standard (efficacy, safety and cost) in the correct dosage and adequate quantity for the required duration of treatment.
- Appropriate patient is identified (no contraindications that exist, likelihood of emergence of adverse drug reactions is minimal)
- · Patient adherence to treatment as directed

Lesotho has mechanisms in place to promote the rational use of medicine, and these include the availability of STGs, EML, HPTCs and the NPTC. However, results from the medicine access survey in 2009 show that the rate of availability of standard treatment guidelines was 53% at hospital level and also most of the HPTCs are not yet fully functional; therefore, continuous mentoring and technical assistance are still required to ensure the improved use of medicines at health facilities (MOH, 2010a:63).

The irrational use of medicine occurs when medicines are used for wrong indications, the use of wrong or ineffective medicine, or the underuse or incorrect use of medicines, and polypharmacy; thus use of more than one medicine unnecessarily (MSH, 2012:518).

Impact of irrational use of medicines:

- Quality of medicine therapy, i.e. polypharmacy.
- Increased healthcare costs, i.e. use of medicines that are prescribed but not needed for the clinical condition.
- More possibility of adverse reactions through inappropriate indication or use.
- Antimicrobial resistance.

2.4.6 Management support

Pharmaceutical management systems require sound policies, as well as a political, legal and regulatory framework that will provide a solid foundation for the systems. It is equally important that these policies and regulations are periodically updated to ensure that they address the current health situation in the country and are in line with international standards. Legislative and regulatory frameworks provide a legal basis for the policy and make it enforceable (MSH, 2012:4). However, the Lesotho health systems assessment report revealed that Lesotho has

weak pharmaceutical legislation and policies in place (MOH, 2010a:59). To a greater extent, this weakness critically affects almost all basic functions of the procurement and supply chain system, and consequently overall medicine availability in the public healthcare sector.

National legislation and regulations provide the necessary legal foundation for procurement procedures, contract enforcement, financial authority, staff accountability and other critical aspects of procurement (WHO, 1999:21). Although the central medical store follows public sector procurement regulations (2007), a common global problem is that the general rules for medicine procurement by the public sector do not take account of the specialised procurement requirements of buying pharmaceuticals. The challenge may be not only to identify the changes that are needed, but also to convince the relevant legal and financial authorities that pharmaceutical procurement does, in fact, require a different approach (WHO, 1999:21).

2.5 Overview of medicine financing

Budgeting and financial functions have a great impact on medicine availability at healthcare facilities, although they are not the only driving forces in procurement and the supply chain system. In Lesotho, all medicines at public healthcare centres are provided free, but at the hospitals, they are provided as part of other services for a hugely subsidised and inclusive fee. Medicine financing is through a recurrent government budget. However, most medicines for country priority diseases such HIV/AIDS and TB are donor funded (MOH, 2010a:38).

The LNMP articulates a need for ensuring more affordable pharmaceutical care through price control mechanisms. Although no legislation currently exists that regulates prices for pharmaceutical services in the private sector, price control mechanisms would be introduced with the enactment of the Medicine Bill (MOH, 2010a:38). This Bill would serve to increase accessibility of essential medicines countrywide, across the population's economic spectrum (MOH, 2010a:38).

It is significantly important to manage the medicine supply chain effectively and efficiently as this is an out-of-pocket expense for taxpayers. In Lesotho, the total health expenditure (THE) on healthcare was 1 133 million Maloti (104.44 million US\$) during 2011, which is approximately 6.44% of the Gross Domestic Product (GDP) and 421.03 Maloti per capita. The total pharmaceutical expenditure (TPE) was 173.7 million Maloti, which is a per capita pharmaceuticals expenditure of 92.31 Maloti. The TPE accounts for 9.88% of the GDP and 15.33% of total healthcare expenditure. Moreover, public expenditure on pharmaceuticals represented 13.4% of the TPE, which is 23.23 Maloti per capita (MOH, 2011:6).

The current financial system (the integrated financial management information system or IFMIS) operates in such a way that every public hospital has its own medicine and medical supplies cost centres where funds are transferred to. Funds are transferred from the Ministry of Finance (MOF) to the Ministry of Health (MOH) headquarters on a quarterly basis as per the approved budget (including the districts and CHAL) (MOH, 2010a:31). However, there is a delay in the transfer of funds from either the MOF to the MOH or the MOH to the districts and other cost centres outside the MOH headquarters, especially during the first and second quarters of each financial year. Therefore, these delays disrupt service delivery at the concerned cost centres, causing delays of payments to the NDSO for medicines and medical supplies delivered to health facilities (MOH, 2010a:31).

The WHO (1999:3) indicates that the procurement system should guarantee access to funds at the time they are needed to avoid drug shortages and procurement inefficiencies. However, in some countries, government funds for procurement are either released irregularly during the financial year, or specify (by finance regulations) that funds must be spent in the year for which they are allocated or be returned to the treasury. Furthermore, limited or irregular funding can lead to delays in payments, worsening procurement problems as suppliers deny credit or insist on advance payments. Indeed, when these scenarios exist, it leads to delays in payments to suppliers, and therefore worsens procurement problems as suppliers deny credit or insist on advance payments. As previously stated, Lesotho is also facing delays in the release of funds from the MOF.

2.6 Chapter summary

Literature on procurement and supply chain management principles as well as medicines financing was reviewed in this chapter. Although procurement is critical in the medicine supply chain, it does not function in isolation; it is interlinked with other key functions, i.e. selection, distribution and use. These functions cannot operate in isolation, since the inputs of one function are the outputs of one or more of the other functions, and therefore any failure in activities with the cycle affects the whole process, thereby disrupting medicine availability and ultimately service delivery

CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

Chapter 3 provides an outline on how data was collected and analysed. It describes the research design that was employed, study population and design, data collection tools (as Appendices A-C) and data analysis technique. Empirical investigations are discussed in this chapter.

3.2 General research aim

The general aim of this study was to evaluate the current status of procurement and supply management systems in the public healthcare hospitals in Lesotho.

3.2.1 Empirical research objectives include the following:

- Identify and assess all levels of medicine procurement and support systems.
- Identify and assess financial flows for medicines.
- Identify and analyse existing documents governing procurement and supply management systems of medicines at public hospitals.
- Determine challenges in the current procurement and supply management systems of medicines in public hospitals and propose recommendations.

3.3 Study design

An observational, descriptive cross-sectional research design was employed in this study. Fathalla (2004:45) stated that this study type may dictate certain research designs. The study design guides the process of data collection, analysis and interpretation of the results. The study objectives can be achieved through a number of alternative designs; therefore, the researcher has to select the appropriate design for the particular study. According to Singh (2006:24) and Fathalla (2004:45), generally, there are two main categories of research design: observational study, and experimental or intervention study. In the observational study, the researchers merely observe and analyse researchable events taking place in the study. They simply observe and record and do not intervene. In the experimental or intervention study, the researchers introduce an intervention and observe or measure the outcome that takes place in the study following the intervention.

According to Fathalla (2004:45), observational studies can either be descriptive or analytical. A descriptive-observational study simply describes the distribution of a characteristic, while an analytical-descriptive study describes associations, and analyses them for possible cause and effect. Furthermore, observational studies may be cross-sectional or longitudinal. In a cross-sectional study, measurements are made on a single occasion, while in a longitudinal study, measurements are made over a period of time. Moreover, a longitudinal observational study may be retrospective or prospective. In a retrospective study, the investigators study present and past events, while in a prospective study, the researchers follow subjects for future events. Fathalla (2004:46) further indicates that experimental or intervention study tests the effect of an

intervention on the events taking place in the study. An experimental or intervention study may be controlled or non-controlled. Controlled studies can further be classified as randomised or non-randomised.

For the purpose of this study, the researcher analysed the characteristics of the observed events and the information was collected at one point in time. Accordingly, questionnaires had a combination of open-ended and closed-ended questions focusing on all levels of medicine procurement and supply management systems in the public hospitals in Lesotho.

3.4 Study population

The study population included all public hospitals pharmacies (19) and one central medical store (NDSO) in Lesotho. Lesotho is divided into ten administrative districts; each district has at least one public hospital either owned by government or by CHAL. In total, there are twenty public hospitals in Lesotho, and these include 11 government hospitals, eight CHAL hospitals and one public-private hospitals (replaced Queen Elizabeth II Hospital, which was a national referral hospital). Although the population is small, the quality of data that was collected clearly reflect the medicine procurement system in Lesotho, since most of the intense procurement activities are carried out at both secondary and tertiary healthcare levels.

The study's focus was on medicine procurement in public hospitals in Lesotho. However, one hospital was excluded from the study; it is public-private facility with very diverse administrative and clinical operations as compared to the other public hospitals. Moreover, out of the 19 public hospitals studied, only 17 hospitals responded to the questionnaires, thereby yielding the response rate at 89.5%, and consequently, conclusions were made on 17 study sites.

3.5 Research method

The research method is defined as a "strategy of enquiry which moves from the assumptions to research design and data collection" (Fathalla, 2004:108). Moreover, it involves the systematic procedure for all the research activities, from the identification of a problem through to drawing conclusions based on the findings (Singh, 2006:79). Research methods employed in this study included the administration of structured questionnaires, and recording or documenting reviews using pre-designed data collection tools. Structured questionnaires were completed by the researcher during the interviews and some were left for completion in other study sites. This occurred mostly at sites where there was either incomplete data provided or the absence of required information at the time of the interview and also time constraints on the side of the respondents. The study sites were divided into regions based on the geographic locations of different hospitals to ease the collection of data. However, during the data collection process, adjustments were made in order to accommodate the diverse demands of the respondents and access to the availability of financial information.

The geographic regions were as follows:

- Central region; it is basically the capital district consisting of five hospitals, including the specialised hospitals;
- Northern region; it covers the three districts of Berea, Leribe and Butha-Bothe, and has six hospitals;

- Southern region; it covers the three districts of Mafeteng, Mohales'hoek and Quthing, and has three hospitals; and
- Mountainous region; it covers the three districts of Mokhotlong, Qachasnek and Thabatseka, and has five hospitals.

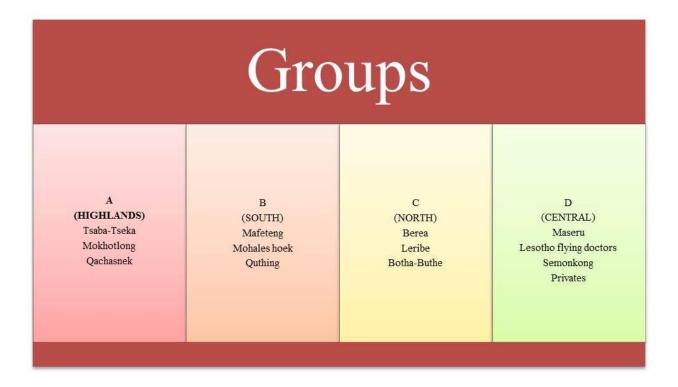


Figure 3.1: Geographic grouping of health facilities per administrative districts

The following process was followed:

- Structured questionnaires were given to different stakeholders involved in the medicine procurement and supply chain, namely policy and legal framework, selection, quantification, procurement, distribution and financing. These stakeholders include: NDSO, MOH and public hospitals.
- Retrospective records were reviewed at MOH and public hospitals to verify responses on the questionnaires.
- Key issues in procurement that public hospitals had with the CMS were verified.
- Retrospective analysis of medicine procurement planning, budget and expenditure.

3.6 Design of the questionnaire

The literature search indicates that a questionnaire is a standardised, structured tool used to collect information in cross-sectional studies (Fathalla, 2004:159 & Burgess, 2001:4). In addition, a questionnaire can be defined as a systematic compilation of questions that are submitted to a sampling population from which information is derived (Singh, 2006:192). The questionnaire is administered in a standard way either by mail, telephone or in person. The self-administered questionnaire approach is inexpensive, less susceptible to interviewer bias and can be administered by mail. Furthermore, Burgess (2001:4) states that participants are more likely to respond to questions in a questionnaire that are more interesting, of value, short, clearly

thought through, and well presented. Therefore, even though respondents might start to fill in the questionnaire, they may give up if they find it hard work to complete, and this may lead to incomplete answers, a high rate of non-response, and biased results (Brink, 2006:150, Fathalla, 2004:59 & Kumar, 2011:153).

There are two major question formats in a questionnaire: the open-ended and closed-ended questions. In open-ended questions, the respondent answers in his/ her own words; conversely, in closed-ended questions, answers are chosen from fixed selected alternative responses. Moreover, a questionnaire provides useful information on knowledge, opinions or attitudes, behaviour and attributes (Brink, 2006:149 & Kumar, 2011: 153).

Ideally, the design of the questionnaire contains three elements (Burgess, 2001:5):

- Determine the questions to be asked.
- Select the question type for each question and specify the wording.
- Design the question sequence and overall questionnaire layout.

A questionnaire should entail the following features (Brink, 2006:197, Fathalla, 2004:104 & Singh 2006:193):

- Professional, well-defined format with a cover letter or an introductory paragraph indicating, firstly, the study title, secondly, aims and objectives of the study, and thirdly, instructions to respondents.
- A cover letter accompanying the questionnaire.
- Informed consent: this is to encourage voluntary participation in the study.
- Appropriate length in order to acquire relevant information.
- Relevant and logical questions that should not be too long.
- Wording of the questions should be unambiguous, clear, simple and precise. Avoid negatives and leading questions.
- Use mostly closed-ended questions for ease of data analysis.
- Use familiar and appropriate language.

Problems associated with the use of questionnaires (Fathalla, 2004:108 & Kumar, 2011:149):

- Planning a questionnaire and its development.
- To get adequate answers or information through questionnaires. Return of questionnaire is always doubtful.
- Incomplete responses.
- The reliability and validity of the data from questionnaires are doubtful.

- Sometimes it is difficult to analyse the data. Only descriptive statistics can be used in this type of data.
- Selection of large and representative sample.

Although there are challenges faced with the use of a questionnaire, there are advantages that may warrant its use. Firstly, the questionnaire permits wide coverage at a minimum expense of both money and effort. It affords wider geographical coverage therefore, it makes for greater validity in the results by promoting the selection of a large and more representative sample. Secondly, the validity of questionnaire data also depends in a crucial way on the validity and willingness of the respondent to provide the information requested. Research has shown that respondents are as a group of superior intelligence (Fathalla, 2004:108). However, the major disadvantages of the questionnaire are the possibility of the misinterpretation of the questions. Misinterpretations are due to the respondent's willingness or impersonality. Mailed questionnaires are usually impersonal. The reliability of the questionnaire is often ignored (Fathalla, 2004:108; Burgess, 2001:4).

For the purpose of this study, three questionnaires were designed for the collection of information at the central medical stores, the ministry of health and at the public hospitals. These questionnaires are interlinked, since deficiency in key criteria at one level directly or indirectly affects activities at other levels in the procurement process.

Basically, questionnaires administered at the ministry of health and central medical store were meant to provide background on the overall activities of the medicines supply chain at the central level. This was aimed at providing knowledge on the four key functions of a medicine supply chain; this information was linked to activities at hospital level and, consequently, what effects they have on medicines procurement at the central level. In summary, the key objective of the questionnaire was to establish gaps in the medicines procurement process and possible intervention strategies to be recommended.

The questionnaires were administered as follows:

- Questionnaire 1: designed for MOH (Appendix A)
- Questionnaire 2: designed for central medical store (Appendix B)
- Questionnaire 3: designed for public hospitals (Appendix C)

For each questionnaire, the following key issues were addressed:

- Medicine selection: The selection of medicines is defined as the process of identifying
 essential medicines to be used to effectively prevent and treat common or prioritised health
 problems in the country (MSH, 2012:289).
- Quantification: Quantification is basically the first step in the procurement process. The
 process involves estimating and determining the quantities of specific medicines for
 procurement, and financial means (MSH, 2012:327).

- Procurement: Procurement is the actual process of acquiring good quality and costeffective medicines, including those obtained through purchase, donation or manufacture
 (WHO, 2004:9). As previously indicated, medicines procurement is a major determinant of
 drug availability and total health costs.
- Ordering: This process involves the requisition of medicines from the supply agency.
- Distribution: The distribution process entails the receipt and storage of medicines through reliable delivery networks, thereby ensuring a constant supply of medicines to the health facilities (WHO, 2004:10).
- Financial resources: This concept refers to available resources for the financing of medicines, and mainly includes government funding.
- Information management: Refers to a pharmaceutical information management system that integrates pharmaceutical data into useful information for decision-making (MSH, 2012:955)

3.7 Data management

Data collected from the study was captured on a Microsoft Excel 2007 spreadsheet and responses from Questionnaire 3 were verified with the responses obtained from the other questionnaires.

3.7.1 Data collection

Data collection was conducted in three phases:

- Phase 1: Structured interviews with MOH. This was to provide insight into the activities conducted at national level.
- Phase 2: Structured interviews with pharmacists in charge of the public hospitals.
- Phase 3 Structured interviews with central medical stores. Although one questionnaire was
 used, all departments that have key roles in medicines procurement at the store will take
 part in the process.

Data used in this study will be stored securely and backed up, which will minimise all possible risks of loss or unauthorised access and will not be accessible to any person except the researchers and study promoters.

3.8 Measurement levels

Singh (2006:226) indicates that there are four levels of measurement that can be used; nominal, ordinal, interval and ratio levels. Ordinal and nominal data are the most common form of measurement scales used in cross-sectional studies. In this study, scales are used to measure responses from quantitative questions and thereafter computed to calculate functional indicators that are characteristically distinctive of good procurement principles. Furthermore, Singh (2006:90) indicates that numerical data can be summarised by calculating their central tendency

and variability by calculating percentage and proportions, and by calculating ratios and rates. Computer software programs facilitated in these calculations.

The following were measured:

Central tendency

- Arithmetic mean (average), which is defined as the sum of values observed divided by the total number of observations in a dataset. It summaries the whole dataset as one.
- Median, is a midpoint at which one half of the observations fall below and one half falls above the value.
- Mode, which is the most frequent measurement in a distribution.

The arithmetic mean, median and mode are used to define the number of purchase orders per annum as well as the service level for the central medical store, and also to present the functionality of the ordering patterns of all studied hospitals (n=17). If the data falls in a 'normal' (evenly spread around the mean) distribution, the mean, median and mode coincide. In 'skewed' distributions (data not evenly spread), they vary and may all be meaningful in the presentation of the data (Singh, 2006:90).

Variability

In addition to knowing the mean value of a series of measurements, it is important to have some understanding about their variation around the mean. There are basically three ways to present the variability of data around the mean: the range, the standard deviation and the percentiles (Singh, 2006:90).

- Range gives the values at the top and at the bottom, but does not give much indication of the spread of observations around the mean.
- Standard deviation (SD) provides information on the spread. It is calculated from a formula that sums the squares of differences between the group mean and each individual value. This sum total is termed the variance. The square root of the variance provides the standard deviation. The greater the differences between the values, the more spread the distribution and the larger the standard deviation. Moreover, mathematicians have calculated that if the observations follow a 'normal' distribution (values evenly spread around the mean), a range covered by one standard deviation above and below the mean will include approximately 68% of the observations. A range of ± 2 SD will cover approximately 95% of observations. A range of 3 SD will cover approximately 99.73% of the observations. Calculating the mean and the standard deviation gives a good summary of the data.
- Percentiles provide another way of looking at variations in distributions. Just as the median is the 50th percentile of a collection of data, the 75th or 95th percentile can be determined and indicates that a particular measurement is larger than 75% or 95% of all the other values. The interquartile range is the distance between the scores representing the 25th and 75thpercentile ranks in a distribution. The percentiles can be applied to data with a skewed, not normal distribution.

In this study, range and standard deviation were used to define the spread of the observations around the mean. Range was used in financial indicators.

Percentages, proportions, ratios and rates

Furthermore, Singh (2006:90) indicates that other forms of measurement may include; percentage, proportion, ratio and rates.

- A percentage is the number of units with a certain characteristic divided by the total number
 of units in the sample and multiplied by 100. Usually, missing data is not included in the
 calculation of percentages. Caution should be exercised when describing percentages
 based on small numbers. In such cases, a small difference may appear as a big difference
 in percentages.
- A proportion is a numerical expression that compares one part of the study units to the whole. A proportion can be expressed as a fraction (for example a proportion of 2/5) or a decimal (for example 0.40)
- A ratio is a numerical expression of the relationship between one set of frequencies and another.

In this study, percentage was mostly used to summarise indicators relating to medicine selection, procurement, quantification and documents reviewed.

3.9 Reliability and validity of data

According to Fathalla (2004:54), an important question in the research design is the decision on how measurements are made to ensure reliability and validity. The core objective is to collect data in a structured way using standardised data collection tools in order to ensure the consistency, accuracy and relevance of data. Errors can occur due to poor reliability and validity, inaccuracy or missing information arising from various points of data collection, and consequently a need to keep errors at a minimum.

Reliability is defined as the consistency and stability in the measure of current knowledge and skills of respondents on a second administration of the same data collection tools. Therefore, reliability deals with the degree of consistency across the same setting at different times (repeatability) for generalisations to be made (Brink, 2006:207 & Fathalla 2004:54).

To ensure the reliability or reproducibility of the results, the following should be considered:

- Measurements made should not vary by observer or between observers (intra- and interobserver consistency).
- Instrument or laboratory variability should be taken into consideration.
- Subject variability should be considered if measurements vary according to the time they are made.

Validity is defined as the extent to which the information is relevant to the conclusions made and is sufficient and accurate to complete in the support of the conclusion (Fathalla 2004:54).

According to Brink (2006:118), validity deals with whether the questionnaire measured what it was intended to measure – how close is the measurement value to the true value.

For the purpose of this study, data was validated through the use of pretested tools and indicators that were developed using the WHO guidelines (WHO, 2011a & b), the MSH manual (MSH, 2012) and in consultation with some of the local pharmacists in the public sector, administration and academia. Furthermore, a pilot study was conducted to adequately test the appropriateness and suitability of all tools designed for the proposed study.

3.10 Ethical considerations

Permission was sought from the Lesotho Ministry of Health's Ethics Committee (ID 62-2013). Thereafter, an ethical application was also submitted to the Ethics Committee of the North-West University (Potchefstroom Campus) for ethical approval (NW 0006013A1). All data collected was treated confidentially, since all interviewees and study sites were not mentioned by name, but rather by identification numbers. Furthermore, only the researcher and study promoters have access to the raw data. On the basis of probability, the risk-benefit balance indicates that there are no foreseeable risks/harms associated with this study, and therefore the benefits outweigh the risks.

Confidentiality

The principle of confidentiality implies that information gathering in qualitative research is based on mutual trust. This trust will be seriously breached by any possibility of break of confidentiality. Confidentiality is an ethical obligation in healthcare research. Since in research, information is likely to be handled by other people involved in the research, steps should be taken to ensure the confidentiality of the records either by limiting access or by replacing identification with code numbers, thereby maintaining anonymity (Fathalla, 2004:64).

Informed consent

This study is based mostly on observation, and generally requires no intervention more invasive than asking questions and reviewing records and documents. Such studies do not carry any physical risk for the research participants. However, they can be intrusive, and therefore ethical considerations include free informed consent, confidentiality and beneficence (Fathalla, 2004:64). The principle of voluntary informed consent implies that participants understand and agree to the reasons for collecting the information. According to Kumar (2011:246), informed consent comprises three major elements, i.e. information, voluntariness and comprehension.

For the purpose of this study, a covering letter was attached to all questionnaires, stating the following:

- Aim and objectives of this study;
- Request to participate in the study;
- Participation in the study is completely voluntary;
- Choice to stop participation at any time;

- Choice not to volunteer or to stop participation, or to refuse to answer particular questions;
- Issues relating to anonymity, privacy and confidentiality; and
- A word of appreciation.

3.11 Statistical analysis

Data collected was captured on a Microsoft Excel spreadsheet (2007), and thereafter procurement indicators were calculated.

3.12 Chapter summary

Chapter 3 outlined the research methods used in the study, including study design, study population and data collection processes. Ethical issues were also addressed regarding the methodology.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Introduction

Chapter 4 provides the results of the empirical investigations of the study and will also focus on the discussion of the study. The results are presented in figures, tables and charts. The chapter is divided into sections covering medicine selection, procurement, distribution and financial resources.

4.2 Outline for the presentation of results

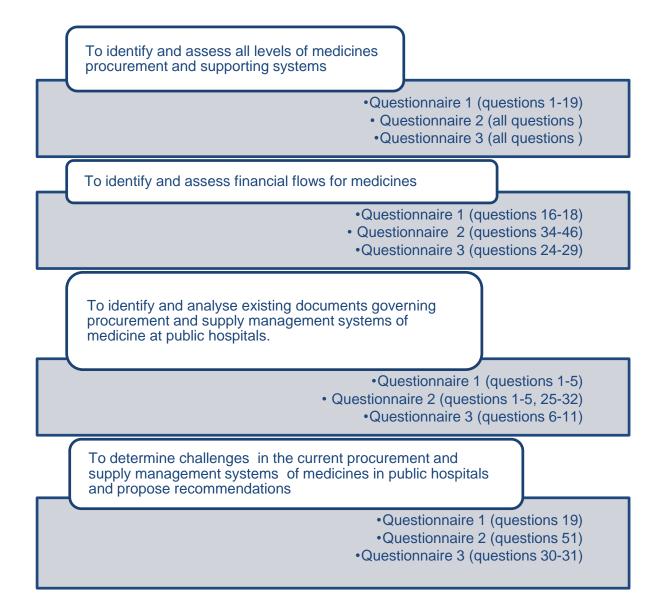


Figure 4.1: Summary linkage of empirical objectives to study questionnaires

4.2.1 Overview of drug supply functions

The drug supply chain is organised into functions that are organised into a cycle, which emphasises their interdependence. These activities are interlinked to other processes, including selection, distribution, use and management support. Therefore, functions cannot operate in isolation, since the inputs from one function are the outputs of one or more of the other functions. These functions are interlinked and reinforced by appropriate management support systems (WHO, 2004:5). A constant supply of medicines at the hospitals promotes effective healthcare, inspires confidence in the health facility and contributes to job satisfaction and self-esteem among staff (MSH, 2012:713).

Table 4.1 describes the drug supply functions at different levels, central medicines store (CMS) and hospital level. It is noted that all hospitals studied perform the following functions: selection, procurement, quantification, ordering, inventory management, distribution as well as utilisation. Public hospitals use their allocated funds for medicine to buy from the CMS, which will, in turn, procure medicines on behalf of the government and distribute to the hospitals as per request, since procurement is pooled at the central level.

The results presented in this study reflect the responses from 17 of the 19 public hospitals. Despite several follow-ups, questionnaires from two hospitals were not received. Therefore, generalisations will be made based on the 17 questionnaires received, resulting in an 89.4% response rate.

The questionnaire from the CMS (questionnaire 2) had a great deal of missing information and some of the questions were not answered. Since the researcher could not verify the responses by acquiring accurate information elsewhere for the questions not answered, it was decided that the questionnaire was considered to be a source of error, and was consequently excluded.

Table 4.1: Drug supply chain functions performed at central and hospital levels

Function	CMS	Public hospital
Selection	√	√
Quantification	V	√
Budgeting	√	√
Procurement	√	
Ordering	V	√
Distribution	V	√
Use		√

4.2.2 Selection

The selection of medicine is defined as the process of identifying essential medicines to be used to effectively prevent and treat common or prioritised health problems in the country (MSH, 2012:289). There are currently 216 medicines on the NEML of Lesotho. Based on policy set at national level, drug selection at national level is carried out by the National Pharmacotherapeutics Committee (NPTC) in consultation with relevant stakeholders. At health facility level, drug selection is conducted by the Hospital Pharmaco-therapeutics Committee (HPTC).

4.2.2.1 Selection based on EML

For the purpose of assessing the selection of medicine, the following parameters were used. Scores obtained will help to determine whether the public hospitals use EML and STGs for medicines selection, whether selection is limited to EML and also whether procurement of medicines is restricted to EML:

4.2.2.2 Availability of EML and STGs

According to the findings of the study, all public hospitals and a CMS had EML and STGs.

4.2.2.3 Availability of a functional HPTC

The findings revealed that out of 17 hospitals that participated in the study, only four hospitals did not have a functional HPTC. Therefore, the availability of HPTC accounts for 76% (n=13) of hospitals.

According to the MSH (2012:886), the purpose and the function of HPTC are to promote the rational use of medicines through the development of policies and procedures for medicine selection, procurement, distribution and use as well as through the education of staff and patients. The response from the thirteen (13) study sites revealed that membership of the committee consists of: medical officer (in charge of the hospital), pharmacist, senior nursing officer, accountant, administrator, dentist, and other relevant disciplines based on the structure and nature of the hospital. It is recommended that membership to the committee should be relatively small and manageable to conduct business effectively; therefore eight(8) to fifteen (15) member committees are sufficient (MSH, 2012:886).

4.2.2.4 Adherence to EML for drug procurement and ordering

The findings indicate that although EML and STGs are available for use in all study sites, public hospitals do not adhere to the use of EML and STGs for medicine procurement (n=17). Therefore, procurement is not limited to medicines on the EML, since, based on the intensity of healthcare services provided, public hospitals often request medicines that do not occur on the EML, but are necessary to address the different diseases and public health priorities in the respective facilities.

According to good pharmaceutical procurement practices (MSH, 2010:331), medicines procurement should be limited to the EML or formulary list. However, these practices differ widely from country to country and are applicable to individual procurement agencies as well as pooled procurement systems. The rationale for limiting procurement to the EML is basically economic, since no country can afford to purchase all medicines available in the market. Therefore, a limited medicines list simplifies the procurement process and leads to reduced and controlled procurement costs.

The study findings indicate that non-adherence with the EML for procurement is linked to common reasons, as universally outlined in the evidence or literature. These reasons also affect the credibility and acceptability of the document. They include the following:

- EML is not accurate; it does not address the current health priorities in the country.
- EML is not up to date (2006 edition).
- Prescribers do not accept EML and STGs.
- Some products from the EML are not readily available in the in the market.

Summary discussion

Medicine procurement is directly and indirectly dependent on the availability of updated policies and procedures and functional HPTC, and consequently the proper drug selection, forecasting and quantification of medicines will be possible (MSH, 2012:1). Therefore, 76% (n=13)

availability of HPTC may indicate progress in the right direction for filtering resourceful information to NPTC, which is currently at advanced stages of review and updating national medicine policy, STGs and EML. As previously mentioned, irregular updating of these documents affects the credibility and acceptability by the end-users (0% adherence).

4.2.3 Procurement

Procurement is the actual process of acquiring good quality and cost-effective medicines, including those obtained through purchase, donation or manufacture (WHO, 2004:9). As previously indicated, medicine procurement is a major determinant of drug availability and total health costs. It is indicated that medicine expenditure represents the single largest expenditure after salaries, and accounts for approximately 20 to 40% of the total healthcare budget and up to 90% of household budgets in the Sub-Saharan region (MSH, 2012:10).

The procurement cycle includes most of the decisions and actions that determine specific medicine quantities obtained, prices paid and quality of medicine received (MSH, 2012:323). In this subsection, procurement activities that will be discussed will relate to quantification and forecasting, ordering, budgeting or financing.

4.2.3.1 Quantification

Quantification is basically the first step in the procurement process. The process involves estimating and determining the quantities of specific medicines for procurement, and financial means (MSH, 2012:327).

According to the Lesotho health assessment report, the country was faced with challenges such as a lack of national quantification data for pharmaceutical commodities (MOH, 2010a:12). This raised a concern to the researcher as to how the country determines quantities of medicines required that need to be procured.

Quantification was measured using responses from the following parameters:

· Quantification at facility level

Hundred percent (n=17) of the hospitals indicated that they quantify for the medicines they procure using the consumption-based method and procedures outlined in the LESOPs and DSM manual. According to the MSH (2012:374), the consumption-based method is the precise approach to quantify medicine usage as it requires the data source to be very reliable, complete, accurate and properly adjusted for stock-outs. Furthermore, out of the 17 study sites, 35% (n=6) of the facilities indicated that they use a functional electronic information system that assists in accuracy, speed and flexibility in quantification and forecasting for medicines. Sixty-five percent (n=11) of the facilities use manual information systems, which have shown to provide inaccurate consumption data, since it is very strenuous and time consuming to extract data manually. Regardless of the information system used, the accuracy of the consumption data remains a challenge.

Availability of procurement plans

The findings revealed that of the 17 hospitals, four did not have procurement plans and two did not respond to the question. Therefore, 65% (n=11) of the facilities had procurement plans in place. The issue of commitment to the implementation of plans remains unknown.

Procurement restricted to CMS

According to the MOH, all public facilities are mandated to procure medicines at the CMS (MOH, 2012:62). However, it is indicated that only government facilities procure medicines at the CMS only; CHAL facilities procure medicines at other places concurrently, including Tripharm agency and Medicare Lesotho. Out of 17 hospitals, 11 were adherent to the mandate. CHAL hospitals (n=6) indicated that they are not fully mandated to procure medicines only at the CMS; they can also procure at other agencies based on stock-outs at the CMS, price differences and urgency of obtaining the medicines in question.

4.2.4 Budgeting

Budgeting and financial functions have a great impact on the availability of medicine at healthcare facilities, although they are not the only driving forces in the PSM system. In Lesotho, all medicines at public healthcare centres are provided free, but at the hospitals, they are provided as part of other services for a hugely subsidised and inclusive fee. Medicine financing is through a recurrent government budget. However, most medicines for country priority diseases, such HIV/AIDS and TB, are donor funded (MOH, 2010a:38).

The current financial system (the integrated financial management information system or IFMIS) operates in such a way that every public hospital has its own medicines and medical supplies cost centres where funds are transferred to. Funds are transferred from the Ministry of Finance (MOF) to the Ministry of Health's (MOH) headquarters on a quarterly basis as per the approved budget (including the districts and CHAL). The central medical store is also financed by the government through a mark-up system (MOH, 2010a:31).

For the purpose of this study, the following parameters were used to assess the availability of funds for procuring essential medicines:

• What was the approved budget for medicines for the financial years 2010/2011 and 2011/2012?

Table 4.2 illustrates the budget and expenditure for public hospitals for the financial years 2010/2011 and 2011/2012. The information was provided by the hospitals and verified at the MOH. For the purpose of this subsection, data presented is for 11 government hospitals and five CHAL hospitals (one CHAL facility did not provide information on the budget and expenditure for the defined periods). Out of the 16 public hospitals studied, only 15 hospitals had knowledge of the availability of funds for the procurement of medicines.

According to the information presented in Table 4.2, the total budget that was released for medicines for government hospitals was 22 712 201.00 Maloti and 21 624 154.27 Maloti in the financial years 2010/2011 and 2011/2012, respectively.

Out of six CHAL hospitals engaged in the study, five provided financial information on their medicine budget and expenditure. However, out of these five facilities, only three provided complete information, while two provided only budget estimates. Based on the information provided, the total budget for the five hospitals was 7 133 160 Maloti and 8 700 000 Maloti for the financial years 2010/2011 and 2011/2012, respectively.

Table 4.2: Budget and expenditure for public hospitals

Name of hospital	Name of hospital Allocated budget(n=11)		Medicines expenditure(n=10)		VARIANCE(n=10)		Percentage variance(n=10)	
	2010/2011	2011/2012	2010/2011	2011/2012	2010/2011	2011/2012	2010/2011	2011/2012
Berea	2074850.00	2200000.00	1172095.45	2043021.81	902754.55	156978.19	43.509389	7.135372273
Botha-Buthe	2500000.00	2000000.00	1874546.91	1190863.89	625453.09	809136.11	25.018124	40.4568055
Botsabelo	411640.00	20000.00	123104.92	15242.34	288535.08	4757.66	70.094034	23.7883
Leribe	4100000.00	3787100.00	469797.85	755308.54	3630202.15	3031791.46	88.541516	80.05575401
Mafeteng	2300000.00	2500000.00	1149914.70	1535043.88	1150085.30	964956.12	50.003709	38.5982448
Mohales hoek	2500000.00	2000000.00	515790.49	1606494.66	1984209.51	393505.34	79.36838	19.675267
Mohlomi	1100000.00	2000000.00	856968.51	1716732.39	243031.49	283267.61	22.093772	14.1633805
Makoanyane	3000000.00	3000000.00	0.00	0.00	3000000.00	3000000.00	0	0
Mokhotlong	1600000.00	1180732.27	400000.00	381793.08	1200000.00	798939.19	75	67.66472047
Qach's nek	1500000.00	1000000.00	478798.38	998905.94	1021201.62	1094.06	68.080108	0.109406
Quthing	1625711.00	1936322.00	47737.29	1890406.52	1577973.71	45915.48	97.063605	2.37127296
Total for GOL hospitals	M22712201.00	M21624154.27	M7088754.50	M12133813.05	M15623446.50	M9490341.22	71.877	39.402
	n=5	n=5	n=3	n=3	n=3	n=3	n=3	n=3
Maluti	0.00	0.00	0.00	0.00				
Scott	1333160.00	1900000.00	690590.00	1219360.00	642570.00	680640.00	48.199016	35.82315789
St.Charles	1500000.00	2000000.00	1350000.00	1878000.00	150000.00	122000.00	10	6.1
St.James	600000.00	600000.00	480000.00	480000.00	120000.00	120000.00	20	20
St.Josephs	1200000.00	1200000.00	0.00	0.00	0.00	0.00	0	0
Tebellong	2500000.00	3000000.00	0.00	0.00	0.00	0.00	0	0
Total for CHAL hospitals	M7133160.00	M8700000.00	M2520590.00	M3577360.00	M912570.00	M922640.00	78.199016	61.92315789

How much of the approved budget was used for medicine procurement in the defined periods?

Total expenditure on medicines for government hospitals was 7 088 754.50 Maloti and 121 338 713.05 Maloti in the years 2010/2011 and 2011/2012, respectively. The total expenditure for CHAL hospitals was 2 520 590 Maloti and 3 577 360 Maloti in 2010/2011 and 2011/2012, respectively. According to the findings, variance of budget and expenditure for government hospitals was 12 623 446.50 Maloti in 2010/2011 and 9490 341.22 Maloti in 2011/2012. Variance of the budget and expenditure for CHAL hospitals was 912 570.00 million Maloti in 2010/2011 and 922 640.00 million Maloti in 2011/2012.

Most hospitals showed a variance of above 50% in 2010/2011. However, in 2011/2012, a shift pattern was observed indicating an improvement in the utilisation of funds allocated. This shift may indicate a possible improvement in procurement practices, including quantification, budgeting and commitment to procurement plans. According to a web-based literature search on healthcare financing and expenditure, variance of below 20% is widely acceptable, and therefore 50% variance indicates challenges in the utilisation of funds (health link website). A variance of over 20% indicates that there are challenges in the utilisation of funds and this relates to poor forecasting and budgeting, under-spending, procurement inefficiencies or difficulty in accessing funds (Health system trust website, 2014).

What approvals are required to access funds at the time of need?

For government facilities, the pharmacist requests confirmation of funds (status of funds) from the accounts department prior to placing an order. Afterwards, the personnel will quantify and complete a requisition and get all approval from accounts. The requisition is sent to the MOH procurement unit for processing to a local purchase order, and the order is authorised by the financial controller and directorate of pharmaceuticals. The order is sent to the CMS for delivery. Ideally, as per ordering and delivery schedule, an order should take at least a week at each section (pharmacy, procurement unit & CMS) and be delivered on the fourth week. It is reported that the length of the entire process is dependent on the availability of personnel at the MOH since requisitions are normally handled there.

For CHAL facilities, once the requisition is made in the pharmacy, it is sent to the accounting department and the hospital manager for approval, and thereafter it is sent to the CMS. The process takes about one week.

What was the payment time and pattern for medicines supplied to the public hospitals?

Out of 17 hospitals, 13 hospitals indicated knowledge of the payment period to the CMS to be 30 days. Two hospitals indicated not to have knowledge of the payment period; rather knowledge of payment is the responsibility of the accounts department. Lastly, two hospitals did not respond to the question. Although 78% (n=13) of facilities are reported to have knowledge of the payment period, only three hospitals indicated payment to the CMS was as per agreement. Ten out of 13 facilities that were not adherent to the payment times reported that there are some challenges inherent in the payment process. For CHAL facilities, payments are dependent on the availability of funds at the defined period and, for government facilities, it is just the lengthy procedure to be followed (funds would be available). Delays in the payment of medicines supplied by the CMS ultimately cause delays in the payment of suppliers to the CMS. Any failure in the procurement process affects the timely and constant availability of essential medicines to the end-users. Moreover, payment to the supplier is very crucial in order to sustain effective drug supply management. This challenge affects volume to be purchased, since only small quantities can be requested based on available funds, leading to more expensive purchasing (MOH, 2010:64).

In summary, the finding revealed that sufficient funds were allocated for all hospitals for the purchase of essential medicines and to carry out procurement activities to completion. However, it was not indicated from the respondents as to actual times when funds were made available for utilisation, since historic reports only indicate summaries of activities in the respective financial years. Therefore, the availability of funds at the appropriate period still remains unknown. Failure to access funds promptly leads to stock-outs and procurement inefficiencies. It is very crucial that budget-related information is readily available in the pharmacy department.

4.2.5 Ordering and distribution

According to the Lesotho standard operating procures, orders are placed with the NDSO according to the applicable ordering and delivery schedule, and adequate items and quantities are ordered (MOH, 2007b:13).

In this subsection, the quantity of purchase orders placed with the CMS is defined. Unfortunately, for most facilities, the response to this parameter described the average number of orders placed in the years 2010/2011 and 2011/2012. They did not separate information for the consecutive years. Table 4.3 illustrates information on ordering patterns and depicted in figures 4.2 and 4.3.

Table 4.3: Hospital ordering pattern

Name of hospital	No of POs placed per annum	No of POs not delivered	% of POs placed and received	NDSO service level (%)
Berea	8	0	100	78
Botha-Buthe	12	2	83.3	80
Botsabelo	4	0	100	80
Mafeteng	8	0	100	70
Makoanyane	8	0	100	75
Mohlomi	4	0	100	90
Mokhotlong	8	0	100	80
Motebang	6	0	100	80
Ntsekhe	8	0	100	80
Qach'snek	8	0	100	90
Quthing	8	0	100	80
Maluti	2	0	100	80
Scott	46	0	100	80
St. Charles	32	0	100	80
St. James	4	0	100	90
St. Josephs	8	0	100	70
Tebellong	20	8	60	90
Totals	Avr=12.11765	N=10	Avr=96.66	Avr=80.0625
STDEV	11.374		10.28	6.299
MEDIAN	8		100	8
MODE	8		100	8

The findings revealed that the average number of orders ranged from four to 46. Out of 17 hospitals, eight placed an average of eight orders (mode =8) in the two consecutive years as illustrated in Table 4.3. Facilities with higher scores (20-46) are basically those that can readily access funds and purchase medicines periodically and when need arises. Hospitals indicated an average of 12±11.4 (median=8) orders placed to the CMS.

Furthermore, table 4.3 indicates that service to the CMS is relatively acceptable, since only 12% (n=2) of the facilities had orders that were not supplied, and therefore 88% (n=14) received all their orders. Furthermore, the supplier obtained an average service level of 80.8±6.3, which is relatively acceptable with a median value of 8.

Figure 4.2 illustrates ordering pattern for government hospitals, it reflects on three key issues; number of purchase orders placed per annum, number of purchase orders not delivered and NDSO service level.

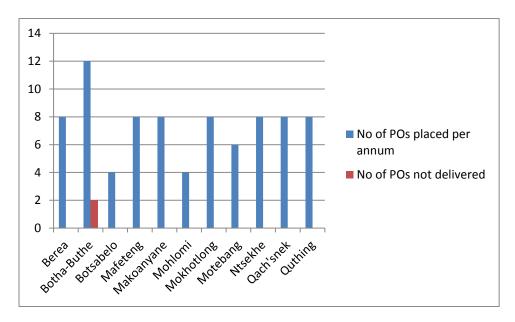


Figure 4.2: Summary of ordering pattern for government facilities

Figure 4.3 illustrates ordering pattern for CHAL hospitals, it reflects on three key issues; number of purchase orders placed per annum, number of purchase orders not delivered and NDSO service level.

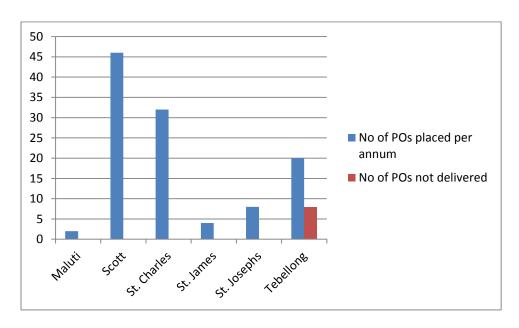


Figure 4.3: Summary of ordering pattern for CHAL facilities

4.3 Chapter summary

In this chapter, the results of the empirical investigations of the study and discussion of the study were outlined.

CHAPTER 5: CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

5.1 Introduction

In this chapter, conclusions are drawn based on the study objectives and recommendations are made from the empirical investigations in Chapter 4. Furthermore, limitations of the study are discussed and certain recommendations are made.

5.2 Conclusions

5.2.1 General research objective

The aim of this study was to evaluate the current status of procurement and supply management systems in the public healthcare hospitals in Lesotho.

5.2.2 Conclusions based on findings from literature review

In this section, the conclusions based on the findings from specific research objectives answered from the literature review will be answered.

5.2.2.1 The first specific research objective was to describe the healthcare system in Lesotho

The healthcare service delivery system in Lesotho consists of a network of hospitals, health centres and private facilities. The healthcare system is mainly categorised into tertiary, secondary and primary levels. There are approximately 217 health facilities in Lesotho, of which 95 are owned by government (GOL), 80 are owned by the Christian Health Association (CHAL), four are owned by the Red Cross, four represent public-private partnerships, and lastly, 34 are private owned. Out of 217 health facilities, 21 are hospitals and 196 are health centres and filter clinics distributed throughout the ten administrative districts in the country (MOH, 2010a:13). There is also an extensive network of private surgeries, nurse-managed clinics and private pharmacies providing clinical care (refer to section 2.2). There is a reliable healthcare system; the Ministry of Health provides continuous support, supervision and leadership.

5.2.2.2 The second specific research objective was to define the roles and structures in the national pharmaceutical sector

The Government of Lesotho (GOL) through the Ministry of Health is mandated to ensure that the population of Lesotho has access to health services throughout the country. The Directorate of Pharmaceuticals was established at the central level, and it has the responsibility of ensuring a continuous supply of medicines to all facilities in the country through the adoption of the Lesotho National Medicine Policy. The overall aim of the policy is to improve and sustain, within available resources, the health of the population of Lesotho by treating, curing, reducing or preventing diseases and conditions through the use of safe, effective, quality, affordable medicines, in both public and private sectors (MOH, 2004:22; 2010a:61). The Directorate of Pharmaceuticals is also responsible for strategic planning, quality control, supervision, as well as the monitoring and evaluation of pharmaceutical services in the country (refer to section 2.3).

5.2.2.3 The third specific research objective was to describe the medicine procurement and supply management systems in the public healthcare sector

Pharmaceutical procurement is a major determinant of drug availability and total health costs. It is indicated that medicines expenditure represents the single largest expenditure after salaries, and accounts for approximately 20 to 40% of the total healthcare budget and up to 90% of household budgets in the Sub-Saharan region (MSH, 2012:1). Medicine procurement in the public health sector follows national and institutional policies and regulations, thereby ensuring the availability of good quality cost-effective essential medicines at all levels of patient care at all times. Moreover, medicine procurement should be limited to an essential medicines list or formulary, since no country can afford to purchases all medicines in the market irrespective of the financial resources available (refer to section 2.4).

5.2.2.4 The fourth specific research objective was to describe the public healthcare sector procurement systems in Lesotho

The medicine procurement and supply chain in Lesotho is a hybrid system, following both centralised and decentralised models. Medicine procurement takes place through a semi-autonomous national procurement agency, named the National Drug Service Organisation (NDSO). The NDSO is mandated to procure medicines on behalf of the Ministry of Health and also to manage the distribution of medicines and other health commodities for several health programmes, including HIV/AIDS and opportunistic infections, TB and family planning

(MOH, 2010a:62). All public healthcare facilities that use government funds are required to procure medicines from the central medical store (refer to section 2.4.3.2).

5.2.2.5 The fifth specific research objective was to compare the Lesotho public healthcare procurement guidelines with WHO guidelines

The WHO guidelines on principles of good procurement practices clearly outline procedures and processes to be followed by procurement agencies in member counties and strategies to be implemented in order to ensure the constant availability of essential medicines at all times. According to the WHO (1999:7), any effective and efficient procurement system should focus on four strategic objectives, namely to procure the most cost-effective drugs in the right quantities; to select the most reliable suppliers of high quality medicines; to ensure timely delivery; and to achieve the lowest possible total costs. According to the Lesotho National Health Policy (MOH, 2004:22), the procurement of medicines is relatively expensive, as Lesotho's public sector market is small, and also, uncertainty about the quantities of medicine demand of the country create speculation and lead to increases in medicines prices (refer to 2.4.3.1). Lesotho's procurement guidelines were found to be in accordance with WHO guidelines on good procurement practices. Thus, the guidelines have been adapted to suit the different settings of healthcare levels in Lesotho, i.e. primary, secondary and tertiary.

5.2.3 Conclusions based on findings from the empirical investigations

In this section, the conclusions based on the findings from specific research objectives answered from the empirical investigations will be answered.

5.2.3.1 The sixth specific objective was to identify and assess all levels of medicines procurement and supporting systems

There are four basic principles of the drug supply chain, i.e. selection, distribution, use and management support. These functions cannot operate in isolation, since the inputs from one function are the outputs of one or more of the other functions (WHO, 2004:5). There are policies and procedures that are in place, providing a guideline for drug supply management in the country. It is noted that all hospitals studied perform selection, procurement, quantification, ordering, inventory management, distribution as well as use (refer to section 4.2.1).

Moreover, pharmaceutical management systems require legislative and regulatory frameworks that will provide a legal basis for the policy and make it enforceable (MSH,

2012:4). However, Lesotho has weak pharmaceutical legislation and policies in place, since the medicines bill (MOH, 2010a:57) has not yet been enacted into a law. To a greater extent, this weakness critically affects almost all basic functions of the drug supply chain, and consequently overall medicines availability in the public healthcare sector.

5.2.3.2 The seventh specific objective was to identify and assess financial flows for medicines

In Lesotho, all medicines at public healthcare centres are provided free, but at the hospitals, they are provided as part of other services for a hugely subsidised and inclusive fee. Medicine financing is through a recurrent government budget (MOH, 2010a:38).

Total expenditure on medicines for government hospitals was 7 088 754.50 Maloti and 121 338 713.05 Maloti in 2010/2011 and 2011/2012, respectively. The total expenditure for CHAL hospitals was 2 520 590 Maloti and 3 577 360 Maloti in 2010/2011 and 2011/2012, respectively.

According to the findings, variance of budget and expenditure for government hospitals was 15 623 446.50 Maloti in 2010/2011 and 9 490 341.22 Maloti in 2011/2012. Variance of the budget and expenditure for CHAL hospitals was 912 570.00 million Maloti in 2010/2011 and 922 640 million Maloti in 2011/2012.

The study concludes that public hospitals had adequate funds for medicine procurement; however, the utilisation of funds was a challenge in the 2010/2011 financial year, since most facilities consumed less than half of the allocated funds. Moreover, the process for payment of supplied medicines to the central medicines is lengthier for government facilities than for CHAL facilities (refer to section 4.2.4).

5.2.3.3 The eighth specific objective was to identify and analyse existing documents governing procurement and supply management systems of medicine at public hospitals

Pharmaceutical management systems require sound policies and legal frameworks that will provide a solid foundation for the systems. It is equally important that these policies and regulations are periodically updated to ensure that they address the current health situation in the country and are in line with international standards (MSH, 2012:4). However, some documents are very outdated, and therefore do not reflect the current health situation in the country and procurement trends in the international world, which include national medicine policy, EML, STGs. (refer to section 4.2.2)

Documents that were studied include:

- Lesotho national medicine policy of 2004: The main objective of the Lesotho National Medicines Policy (LNMP) is to ensure that good quality, essential, efficacious and affordable medicines are available to all Basotho at all times in all health facilities in both public and private sectors (MOH, 2004:22). Although policy is available, it does not have a functional implementation plan and has a weak legislative framework to make it enforceable. A national medicine policy should have a strong legislative and regulatory framework, accompanied by a functioning quality assurance system in order to ensure implementation and enforcement (MSH, 2012:68).
- Essential medicines list (EML) and standard treatment guidelines (STGs) of 2005: It is equally important that enabling policies and regulations be continually developed and reviewed to ensure adherence to the use of STGs by all government and CHAL facilities (MOH, 2005a:2). The study findings revealed hundred percent (n=17) availability of EML and STGs at the public hospitals; however, public hospitals do not adhere to use of EML and STGs for medicine procurement (n=17).
- Lesotho Procurement Manual of 2007: The procurement manual is the unifying reference for all public procurement in Lesotho. It gives procedural guidance and instructions on the many aspects of procurement and contracting, thereby ensuring a uniform standard of basic purchasing procedures (MOF, 2007:11). Therefore, all government hospitals and the central medical store use this manual. The manual also provides a guide on procurement where funding is provided by the donor partners; there may be a requirement to use the donor's own procurement procedures (MOF, 2007:11).
- LESOPs and DSM 2007: The two documents entail procedures and processes to be followed by all public facilities to ensure effective drug management. Hundred percent (n=17) of the hospitals indicated that they quantify for the medicines they procure using the consumption-based method and procedures outlined in the LESOPs and DSM manual. According to the MOH, all public facilities are mandated to procure medicines at the CMS (MOH, 2010:62). However, it is indicated that only government facilities procure medicines at the CMS only; CHAL facilities procure medicines at other places concurrently. Out of 17 hospital, 11 were adherent to the mandate. CHAL hospitals (n=6) indicated that they are not fully mandated to procure medicines only at the CMS; they can also procure at other agencies based on stock-outs at the CMS, price differences and urgency of obtaining the medicines in question.

- Procurement plan: The findings revealed that out of 17 hospitals. Four did not have procurement plans and two did not respond to the question. Therefore, 65% (n=11) of the facilities had procurement plans in place. The issue of commitment to the implementation of plan remains unknown.
- Status of funds: This report can be generated monthly or quarterly following the release of quarterly warrants and also at the end of the financial year to show budget allocation and expenditure committed in that year. Out of 17, only 16 hospitals had knowledge of the availability of funds for the procurement of medicines.

5.2.3.4 The ninth specific objective was to determine challenges in the current procurement and supply management systems of medicines in public hospitals and to propose recommendations

Current challenges in medicine procurement and supply management include the following:

- Weak legislation and legal frameworks governing medicine management in the country.
 This affects the implementation of the LNMP, since it needs sound legislation for it to be enforceable.
- Procurement out of EML; this affects practices and financial functionality. Given the required funds, no country can afford to purchase all medicines circulating in the market (MSH, 2012:331).
- Slow processing of payments to the central medical store.

5.3 Limitations

The study had several limitations that should be taken into account when evaluating the results and conclusions:

- Limited literature was available on medicine procurement in the public and health sectors in Lesotho.
- Due to cost constraints and the topology of the country, it was not possible to visit study sites more than once.
- Most pharmacists at the study sites were reluctant to engage in the study.
- Despite numerous efforts made to follow-up on the questionnaires, only 17 out of 19 hospitals returned the questionnaires, resulting in a response rate of 89.5%.

- Regardless of all approvals obtained to conduct the study, accessing information at the Ministry of Health and the central medical store was a nightmare.
- The study was a large cross-sectional descriptive study that requires administrative support from the Directorate of Pharmaceuticals in order to access required information.
- Some questionnaires were not completed in full; there were many gaps.
- The questionnaire from the CMS (questionnaire 2) had a great deal of missing information and some of the questions were not answered. Since the researcher could not verify the responses by acquiring accurate information elsewhere for the questions not answered, this questionnaire was considered to be a source of error, and was consequently excluded.

5.4 Recommendations

The following recommendations for further research can be made based on the study findings and changes that can be adopted at hospital level:

- If hospitals can budget and forecast accurately, access to funds for medicine
 procurement would not be a challenge at all; the funds are inefficiently used, and not
 appropriately allocated. Inefficiencies arise from underutilisation by health facilities,
 under-spending of budget allocations and the misallocation of resources.
- Hospital pharmacists should take responsibility for the timely payment of supplied medicines and follow up the process to completion.
- Capacitate the public hospitals to carry out the quantification process effectively and efficiently and to have accurate quantification data; also, provide such data to the central medical store.
- Review the EML and STGS every five years. The current documents do not address the current health situation in the country and are not in line with international standards.
- The Directorate of Pharmaceuticals should facilitate the availability of a computerised information system at the public hospitals.
- Further research could be conducted to evaluate procurement practices at the central medical stores and other procurement agencies where CHAL facilities purchase medicines.

5.5 Chapter summary

This chapter included the conclusions based on the literature and empirical investigations. Although public sector procurement practices at the central medical store were not thoroughly exploited, the practices at hospital level have outlined medicine procurement practices in the public hospitals in Lesotho. Therefore, the study objectives have been met. Study limitations and recommendations were included in this chapter.

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APPENDIX A

(To be complied at MOH)

EVALUATION OF THE MEDICINE PROCUREMENT AND SUPPLY MANAGEMENT SYSTEMS IN THE PUBLIC HOSPITALS IN LESOTHO

RESEARCH ENTITY: MEDICINE USAGE IN SOUTH AFRICA
FACULTY OF HEALTH SCIENCES
NORTH-WEST UNIVERSITY: POTCHEFSTROOM CAMPUS

NAME: MATSEPO A TEMA

SUPERVISOR: MRS I KOTZE
CO-SUPERVISOR: DR R JOUBERT
CO-SUPERVISOR: MS MJ EKSTEEN

Dear participant

TITLE: EVALUATION OF THE MEDICINE PROCUREMENT AND SUPPLY MANAGEMENT SYSTEMS IN THE PUBLIC HOSPITALS IN LESOTHO

Medicines procurement is a complex process involving many functional steps and policies. It is one of the critical, interrelated components of the public healthcare sector supply system (WHO, 2011:2). In Figure 2, the necessary steps to be followed in an effective procurement system are illustrated. Therefore, failure occurring in any of the steps can lead to a lack of access to essential drugs and to waste (WHO, 1999:7).

The general objective of this study is to evaluate the current status of procurement and supply management systems in the public healthcare hospitals in Lesotho. The study will outline current pharmaceutical procurement systems in the public hospitals in Lesotho, thereby identifying gaps in the system, constraints and possible actions to be taken. The study will focus on the procurement of medicines by the NDSO and public hospitals. It will also assess financial issues surrounding medicines procurement in the country.

You are kindly requested to participate in the study. Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not

to volunteer or to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, either now, or in the future. All information you supply during the research will be held in confidence and unless you specifically indicate your consent, your name will not appear in any report or publication of the research.

You contribution towards this study will be highly appreciated.						
l	consent to participate voluntarily in the study.					
understand the nature of thi	research and wish to participate.					
Signature	Date					

QUESTIONNAIRE 1: FOR MOH

(3)

(4)

(5)

NB: Please note that in all the questionnaires, monetary value will be presented in Lesotho currency, which is Maloti.

	s questionnaire will be giver lic sector medicines procure	n to the MOH to Identify existing ment.	legal documents governing
Date	ə:		
Nan	ne of institution:		_
Ider	ntity of persons interviewed a	and positions held	
	Identification number	Position	Date of interview
1.			
2.			
3.			
(1)	•	the office of the Director: Phand the supply chain in Lesotho	rmaceuticals in public sector
(2)	le thoro a national occopti	al medicines list (NEML)?	Yes / No

If no, please explain the situation

Does the NEML identify medicines by level of care?

Was the NEML updated within the last 3 years?

Yes

Yes /

No

No

(6)	Are medicines procured in the public health sector limited	imited to national esse			
	medicines list?	Yes	/	No	
(7)	If no, explain the situation				
(8)	Is there a national medicines selection committee?	Yes	/	No	
(9)	If no, skip questions 9 & 10				
(10)	Describe its membership				
(11)	Does the committee have terms of reference (TORs) or SOPs?	Yes	/	No	
(12)	Explain the national drug selection process				
(13)	Is national drug usage data available?	Yes	/	No	
(14)	If yes, describe the process for national quantification				
(15)	Is there a functional national drug therapeutics committee?	Yes	/	No	

	What was the total public health expenditure in the financial years 2010/20 2011/2012?
-	
	What was the total public health expenditure on pharmaceuticals in 2010/20 2011/2012?
-	
	What is the percentage availability of medicines in public hospitals in 2010/20 2011/2012?
	What are the challenges in medicine procurement and the supply chain affecting hospitals?

APPENDIX B

(To be completed at central medical stores)

EVALUATION OF THE MEDICINE PROCUREMENT AND SUPPLY MANAGEMENT SYSTEMS IN THE PUBLIC HOSPITALS IN LESOTHO

RESEARCH ENTITY: MEDICINE USAGE IN SOUTH AFRICA
FACULTY OF HEALTH SCIENCES
NORTH-WEST UNIVERSITY: POTCHEFSTROOM CAMPUS

NAME: MATSEPO A TEMA

SUPERVISOR: MRS I KOTZE
CO-SUPERVISOR: DR R JOUBERT
CO-SUPERVISOR: MS MJ EKSTEEN

Dear participant

TITLE: EVALUATION OF THE MEDICINE PROCUREMENT AND SUPPLY MANAGEMENT SYSTEMS IN THE PUBLIC HOSPITALS IN LESOTHO

Medicines procurement is a complex process involving many functional steps and policies. It is one of the critical, interrelated components of the public healthcare sector supply system (WHO, 2011:2). In Figure 2, the necessary steps to be followed in an effective procurement system are illustrated. Therefore, failure occurring in any of the steps can lead to a lack of access to essential drugs and to waste (WHO, 1999:7).

The general objective of this study is to evaluate the current status of procurement and supply management systems in the public healthcare hospitals in Lesotho. The study will outline the current pharmaceutical procurement system in the public hospitals in Lesotho, thereby identifying gaps in the system, constraints and possible actions to be taken. The study will focus on the procurement of medicines by the NDSO and public hospitals. It will also assess financial issues surrounding medicines procurement in the country.

You are kindly requested to participate in the study. Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer or to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, either now, or in the future. All information you supply during the research will be held in confidence and unless you specifically indicate your consent, your name will not appear in any report or publication of the research.

You contribution towards this study will be highly appreciated						
l	consent to participate voluntarily in the study.	I				
understand the nature of th	s research and wish to participate.					
Signature	<u>Date</u>					

QUESTIONNAIRE 2: FOR NDSO

NB: Please note that in all the questionnaires, monetary value will presented in Lesotho currency, which is Maloti.

This	questionnaire will assess the Co	entral Medical Store.		
Date	9:			
Nam	ne of institution:		_	
Iden	tity of persons interviewed and p	positions held:		
	Identification number	Position	Data of inter	rview
1.				
2.				
3.				
4.				
(a)	STRUCTURE			
(1)	Is NDSO a legal structure?		Yes /	No
If NO	D, skip question 2			
(2)	Name and year of acts, laws			
(3)	When was NDSO established?	?		
(4)	List of product categories that	are managed by this store:		
	a			
	b			
	C			
	d			
	e			
	f			

(5)	Who are your customers?							
(b)	SELECTION OF MEDICINES							
(6)	Do you have a national essential medicines list?	Yes	/	No				
(7)	Please explain the selection process							
(8)	Are medicines procurements limited to NEML?	Yes	/	No				
(9)	If no, please state reason for procuring out of NEML							
(10)	Please indicate categories of medicines that are mostly procured o	ut of N	EML					
(c)	MEDICINE QUANTIFICATION							
(11)	Do you quantify for the medicines you procure for the public hospital	als?						
		Yes	/	No				
(12)	Are quantities of medicines to be procured based on reliable data?							
		Yes	/	No				
(13)	Do you have any supportive data for medicine usage?	Yes	/	No				

4)	If yes, at what level?			
5)	Indicate methods used to assess quantities to be procured (tic	k appropria	te):	
-,	a. Consumption-based method b. Morbidity-based method c. Report and request data d. Funds availability e. Others, specify)-	
6)	Please explain to what extent needs exceed the available bud	get for medi	cines	
(k	MEDICINE PROCUREMENT			
17)	Is there a national public procurement policy?	Yes	/	No
18)	(If yes, please provide a copy) Provide a summary of the policy			
19)	Are there SOPs for conducting public sector medicines procure	ement?		
		Yes	/	No
20)	Do you have a procurement plan?	Yes	/	No
21)	If ves. has the plan been implemented?	Yes	/	No

(23) List all stakeholders involved in the development of a procuren	nent plan		
(24) Explain how you monitor the plan			
Tendering and bidding			
(25) Is the store responsible for the bidding process?	Yes	/	No
(26) Are the documents used for public sector bidding publicly avail	lable?		
	Yes	/	No
(27) Are public sector tender awards publicly available?	Yes	/	No
(28) Which of the following bidding methods are used in procureme	ent (tick app	ropriat	te)?
a. International competitive bidding			
a. International competitive bidding b. Restricted tender			
b. Restricted tender			
b. Restricted tender			
b. Restricted tender c. Open tender			

(29)	Please describe how you select suppliers
(30)	List three main criteria considered in awarding tenders
(31)	What actions are taken to ensure the quality of medicine procured?
(32)	State the monetary value of medicines procured in 2010/11 and 2011/12 (include donor funded drugs)
(e)	ORDERING AND FINANCING
(33)	Indicate how many times procurement was conducted in 2010/2011 & 2011/2012.
(34)	Indicate how many of these were emergency orders.

(35)	Name the types of medicines that were ordered					
(36)	State the total monetary value of the emergency orders for the financial years 2010/2011 & 2011/2012.					
(37)	Explain the ordering process followed by you clients.					
For o	questions 38-39, please refer to the table below.					
	How many orders were made by each public hospital in 2010/11 and 2011/2012?					
(00)	State the total manetary value of orders received					

(39) State the total monetary value of orders received.

	Financial years			
	2010/2011		2011/2012	
Identity of hospitals	Number of orders made	Monetary value of each order	Number of orders made	Monetary value of each order

	Financial years				
Identity of hospitals	2010/2011		2011/2012		
	Number of orders made	Monetary value of each order	Number of orders made	Monetary value of each order	
	•		•		

(40)	What was the total monetary value of wasted medicines at the warehouse in 2010/11 and 2011/12?
(41)	What are the main causes of medicines wastage (loss) at the warehouse?
	a. Expiry b. Damage c. Obsolesce d. Theft e. Other, specify
(42)	Indicate what the planned budget for medicines in 2010/11 and 2011/12 was

(43)	Indicate what the expenditure on medicines was in 2010/11 and 2011/2012.
(44)	Indicate what the revenue collected for medicines in 2010/11 and 2011/12 was
(45)	Describe how the revenue is generated for your medicines budget.
(46)	Describe the payment process by your clients
(47)	Describe the medicines distribution process
(48)	What is the lead time between receiving an order and issuing it to your clients?
(49)	Do you have any information management systems? Yes / No If No. skip question 18.

(50)	List the main data categories that the system can generate.
(51)	What challenges do you experience in the procurement process?

APPENDIX C

(To be completed at the public hospital)

EVALUATION OF THE MEDICINE PROCUREMENT AND SUPPLY MANAGEMENT SYSTEMS IN THE PUBLIC HOSPITALS IN LESOTHO

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understand the nature of this research and wish to participate.					
l	consent to participate voluntarily in the study. I				
understand the nature of thi	research and wish to participate.				
Signature	<u>Date</u>				

QUESTIONNAIRE 3: PUBLIC HOSPITALS

NB: Please note that in all the questionnaires, monetary value will presented in Lesotho currency, which is Maloti.

Hos	pital identity			
Dist	rict	_		
lder	ntification of pharmacist in charge		_	
Qua	lifications	_		
(1)	Where do you receive your medicines from?			
(2)	Does the hospital have a drug therapeutics committee?	Yes	/	No
	If NO, skip 3 & 4.			
(3)	List the composition of the committee.			
(4)	Describe the functions of the committee			
(5)	Describe the selection criteria for essential medicines at the hospital	al		
(6)	Do you procure only medicines that are in the FML or STG?	Yes		No

(7)	If No, please explain the situation										
(8)	Do you quantify for the medicines that you procure?	Yes	/	No							
(9)	If yes, describe the quantification process										
(10)	Is there a public sector procurement policy for medicines?	Yes	/	No							
(11)	Does your facility have a procurement plan?	Yes	/	No							
(12)	If yes, has the plan been implemented?	Yes	/	No							
(13)	If no, please describe the situation										
(14)	Do you place orders as per LeSOPs?	Yes	/	No							
(15)	If no, please explain the difference										
(16)	Describe the procurement process										

(17)	From where do you procure the medicines?
(18)	How many times did you place orders during 2010/11 and 2011/12?
(19)	How many of these orders were emergency orders?
(20)	Were all orders delivered as per agreement?
(21)	What is the delivery agreement?
(22)	If no, how many orders were not delivered as agreed?
(23)	What is the service level for you suppliers?
(24)	What was the budget in 2010/11 and 2011/2012?
(25)	What was the medicines expenditure in the financial years 2010/11 and 2011/12?
(26)	Describe the payment process for medicines supplied
(27)	What is the agreed payment period?
(28)	Are suppliers paid within the agreed period? Yes / No

(29)	If no, please provide reasons										
(30)	Does the facility use an information management system?	Yes	/	No							
(31)	If yes, describe its characteristics or functions										

APPENDIX D

Hospital distribution list by district

District	Number of hospitals	Ownership					
		GOL	CHAL	OTHER			
Maseru	7	3	2	2			
Berea	2	1	1				
Leribe	2	1	1				
Butha-buthe	2	1	1				
Mokhotlong	1	1					
Thaba-tseka	2		2				
Qacha'snek	2	1	1				
Quthing	1	1					
Mohale'shoek	1	1					
Mafeteng	1	1					
Grand total	21	11	8	2			

APPENDIX E

	Sample ordering and delivery Schedule for the period of September 2013 through to September 2014											
	Sept 13- Oct 13				Oct 13 - Nov 13							
Groups	Req @ (Hosp & Req @PU		LPOs at NDSO	NDSO Delivery	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery				
Group A	05/08/13 - 09/08/13	12/08/13 - 16/08/13	19/08/13 - 30/08/13	02/09/13 - 06/09/13	16/09/13 - 20/09/13	23/09/13 - 27/09/13	30/09/13 - 11/10/13	14/10/13- 18/10/13				
Group B	12/08/13 - 16/08/13	19/08/13 - 23/08/13	26/08/13 - 06/09/13	09/09/13 - 13/09/13	23/09/13 - 27/09/13	30/09/13 - 04/10/13	07/10/13 - 18/10/13	21/10/13 - 25/10/13				
Group C	19/08/13 - 23/08/13	26/08/13 - 30/08/13	02/09/13 - 13/09/13	16/09/13 - 20/09/13	30/09/13 - 04/10/13	07/10/13 - 11/10/13	14/10/13 - 25/10/13	28/10/13 - 01/11/13				
Group D	26/08/13 - 02/09/13 - 06/09/13		09/09/13 - 20/09/13	23/09/13 - 27/09/13	07/10/13 - 11/10/13	14/10/13 - 18/10/13	21/10/13 - 01/11/13	04/11/13 - 08/11/13				
	Nov 13 - Dec 13		Nov 13 - Dec 13		Dec 13 - Jan 14							
Groups	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery				
Group A	14/10/13 - 18/10/13	21/10/13 - 25/10/13	28/10/13 - 08/11/13	11/11/13 - 15/11/13	11/11/13 - 15/11/13	18/11/13 - 22/11/13	25/11/13 - 06/12/13	09/12/13- 13/12/13				
Group B	21/10/13 - 25/10/13	28/10/13 - 01/11/13	04/11/13 - 15/11/13	18/11/13 - 22/11/13	18/11/13 - 22/11/13	25/11/13 - 29/11/13	02/12/13 - 13/12/13	16/12/13 - 20/12/13				
Group C	28/10/13 - 01/11/13	04/11/13 - 08/11/13	11/11/13 - 22/11/13	25/11/13 - 29/11/13	25/11/13 - 29/11/13	02/12/13 - 06/12/13	09/12/13 - 20/12/13	23/12/13 - 03/01/14				
Group D	4/11/13 - 08/11/13	$1 \cdot 1 \cdot$		04/12/13 - 10/12/13	11/12/13 - 17/12/13	18/12/13 - 03/01/14	06/01/14 - 10/01/14					
	Jan 14 - Feb 14				Feb 14 - Mar 14							
Groups	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery				
Group A	16/12/13 -	23/12/13 -	30/12/14 -	13/01/14 -	20/01/14 - 24/01/14	27/01/14 -	03/02/14 -	17/02/14 -				

	Sample ordering and delivery Schedule for the period of September 2013 through to September 2014											
	20/12/13	27/12/14	10/01/14	17/01/14		31/01/14	14/02/14	21/02/14				
Group B	18/12/13 - 24/12/14	27/12/14 - 03/01/14	06/01/14 - 17/01/14	20/01/14 - 24/01/14	27/01/14 - 31/01/14	03/02/14 - 07/02/14	10/02/14 - 21/02/14	24/02/14 - 28/02/14				
Group C	27/12/14 - 03/01/14	06/01/14 - 10/01/14	13/01/14 - 24/01/14	27/01/14 - 31/01/14	03/02/14 - 07/02/14	10/02/14 - 14/02/14	17/02/14 - 28/02/14	03/03/14 - 07/03/14				
Group D	13/01/14 - 17/01/14	20/01/14 - 24/01/14	27/01/14 - 07/02/14	10/02/14 - 14/02/14	10/02/14 - 14/02/14	17/02/14 -21 /02/14	24/02/14 - 07/03/14	10/03/14 - 14/03/14				
	Mar 14 - Apr 14				Apr 14 - May 14							
Groups	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery	Req @ (Hosp & DHMT)	Req @PU	LPOs at NDSO	NDSO Delivery				
Group A	17/02/14 - 21/02/14	24/02/14 - 28/02/14	03/03/14 - 14/03/14	17/03/14 - 21/03/14	34/03/14 - 28/03/14	31/03/14 - 04/04/14	07/04/14 - 18/04/14	21/04/14 - 25/04/14				
Group B	24/02/14 - 28/02/14	03/03/14 - 07/03/14	10/03/14 - 21/03/14	24/03/14 - 28/03/14	31/03/14 - 04/04/14	07/04/14 - 11/04/14	14/04/14 - 25/04/14	28/04/14 - 02/05/14				
Group C	10/03/14 - 14/03/14	17/03/14 - 21/03/14	24/03/14 - 04/04/14	07/04/14 - 11/04/14	07/04/14 - 11/04/14	14/04/14 - 18/04/14	21/04/14 - 02/05/14	05/05/14 - 09/05/14				
Group D	17/03/14 - 21/03/14	24/03/14 - 28/03/14	31/03/14 - 04/04/14	14/04/14 - 18/04/14	14/04/14 - 18/04/14	21/04/14 - 25/04/14	28/04/14 - 09/05/14	12/05/14 - 16/05/14				

APPENDIX F

Sample forecasting and budgeting sheet

Drug code	Generic name	Strength	Dosage form	Unit pack	VEN	АМС	Estimated annual requirements (AMC*12)	Adjusted annual requirements	Unit price	Total costs
									Totals	

NB:*

Average monthly consumption during the previous year, adjusted for periods out of stock, is obtained from the stock cards.

Estimated annual requirements are adjusted for expected changes in demand, changes in morbidity patterns, or changes of STGs.

APPENDIX G

Sample internal requisition voucher

Drug code	Generic name	Strength	Dosage form	Unit pack	VEN	AMC	Stock on hand	Re-order level	Order quantity	Unit price	Total costs		
									Totals				
							Requisition prepared by:						
							Date:						
							Requisition approved by:						
							Date:						