

Medicine stock Management at Primary Health Care facilities in one South African Province

By

Fadzai Eunice Munedzimwe

MNDFAD002

Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

A mini dissertation submitted to the University of Cape Town in partial fulfilment of the requirements
for the Master of Public Health (Health Economics) degree

Supervisor: Dr. Ayako Honda*

Co-supervisor: Ms. Marsha Orgill*

* Health Economics Division, School of Public Health and Family Medicines, Faculty of Health Sciences, University of Cape Town.

The copyright of this thesis vests in the author. No quotation from it or information derived from it is to be published without full acknowledgement of the source. The thesis is to be used for private study or non-commercial research purposes only.

Published by the University of Cape Town (UCT) in terms of the non-exclusive license granted to UCT by the author.

Declaration

I, Fadzai Eunice Munedzimwe, hereby declare that the work on this dissertation/thesis is based on my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature:

Date: 15 August 2017

Dedication

I dedicate this thesis to my family and friends.

Abstract

As nations are encouraged to move towards achieving Universal Health coverage (UHC), access to essential medicines needs to be prioritized. In ensuring access to medicines, an important factor to be considered is the uninterrupted availability of essential medicines at the primary health care (PHC) level which is usually the first point of entry into the health system for patients. If South Africa is to move towards achieving UHC, the government must address the issue of unavailability of medicines due to frequent stock outs at the public health facilities. The increase in prevalence of HIV/AIDS and TB has resulted in an increase in the demand for medicines used in the management and treatment of these diseases. Surveys have revealed the extent of stock outs and shortages of medicines used in the management of HIV and TB in South Africa. It has also been predicted that the burden of disease in relation to these diseases is likely to increase in the coming years therefore, it is important for the South African government to address the issues of stock outs.

Using a qualitative multiple case study approach, we explored the factors which may influence the management of medicine stock thus causing medicine stock outs at four PHC facilities in two of the districts in the study province. A conceptual framework on the factors influencing medicine stock outs at health facilities was developed from reviewing literature on the subject and this was used to guide data collection and analysis. Our findings revealed that the factors influencing the management of medicine stock leading to medicine stock outs include the lack of capacity in terms of human resources and physical resources at the PHC facilities. Insufficient supervision and support from the district level also had an influence as health workers at the facilities did not always follow the recommended procedures for medicine stock management. We also found that there were gaps in communication between the health workers at the facilities and stakeholders at other levels, particularly the pharmaceutical depot from which the facilities obtained their medicines. The inadequate information systems contributed to this gap in communication.

Whilst many studies have focused on the factors that may influence the availability of medicine at higher levels, this study focused on what may influence it at the ground level, the PHC facility level. We anticipate that our findings will inform policy makers on how the availability of medicines at PHC facilities may be improved by focusing on improving the processes in medicine stock management at this level.

Acknowledgements

Firstly, I would like to thank God for allowing me the opportunity to do this work, mom and dad, thank for your continuous prayers and encouragement.

I would like to thank the National Research Fund (NRF) South African Research Chair; Health and Wealth program for funding my studies and this project. A special thank you to Prof Di Mc'Intyre for allowing me time in your busy schedule to brainstorm and for the guidance you provided.

Dr Anbaan Pillay, thank you for meeting with my supervisor and I, for your involvement in this project and particularly for facilitating the approval process with both the National and provincial Departments of Health.

To my supervisors Dr Ayako Honda and Ms Marsha Orgill, I cannot thank you enough for your hard work. There were times when I felt like I would not make it, but your kind words and encouragement kept me going!

Latiefa Adams and Vanessa Daries, thank you for all your help with the co-ordination of my fieldwork. It would not have gone smoothly without you.

Danleen Hongoro, thank you for being my source of sanity and chocolate when I need it. Lastly, I would like to thank my friends and colleagues for being patient and tolerant of me during stressful times.

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
AMC	Average Monthly Consumption
ART	Anti-Retroviral Treatment
ARV	Anti-Retroviral
CCMDD	Central Chronic Medicine Dispensing and Distribution Programme
EML	Essential Medicine List
FGDs	Focus Group Discussions
HIV	Human Immunodeficiency Virus
LMIC	Lower Middle-Income Country
MSH	Management Sciences for Health
NCDs	Non-Communicable Diseases
NHI	National Health Insurance
PD	Pharmaceutical Depot
PHC	Primary Health Care
PTCs	Pharmaceutics and Therapeutics Committees
SDGs	Sustainable Development Goals
SOPs	Standard Operating Procedures
SVS	Stock Visibility Solution
TB	Tuberculosis
TPN	Total parenteral nutrition
UHC	Universal Health Coverage
UN	United Nations
WHO	World Health Organisation

Table of Contents

Declaration.....	ii
Dedication.....	iii
Abstract.....	iv
Acknowledgements.....	v
Abbreviations.....	vi

PART A: PROTOCOL

1	Introduction.....	2
2	Literature review.....	3
3	Study rationale.....	6
4	Conceptual Framework.....	8
5	Research aims and objectives.....	11
	5.1.1 Objectives:.....	11
	5.1.2 Study Question.....	12
6	Methods.....	12
	6.1.1 Study setting.....	12
	6.1.2 Sampling strategy.....	13
	6.1.3 Study design.....	13

6.1.4	Research procedures and data collection methods.....	14
6.1.5	Rigour.....	15
6.1.6	Data analysis.....	16
7	Ethical considerations.....	16
7.1.2	Risks and benefits.....	17
7.1.3	Privacy and confidentiality.....	18
7.1.4	Use of information and publications.....	18
8	Resources/budget.....	20
9	Project Timeline.....	21
10	References.....	22

PART B: LITERATURE REVIEW

11	Introduction.....	26
11.1	Aims and objectives.....	26
11.1.1	Objectives.....	26
11.2	Methods.....	26
12	Structured Literature Review.....	27
12.1	Access to essential medicines.....	27
12.2	Definition of Medicine shortages and medicine stock outs.....	28

12.3	The Impact/Effects of medicine shortages and stock outs.....	29
12.4	Causes of medicine shortages and stock outs.....	32
12.5	Medicines supply systems/chains.....	32
12.6	Procurement and Selection.....	33
12.7	Forecasting.....	34
12.8	Storage of medicines.....	35
12.9	Distribution of medicines.....	36
12.10	Other general causes of medicine shortages and stock outs.....	37
12.11	Strategies to ensure uninterrupted availability of medicines.....	39
12.12	Drug supply management at health facilities and medicines availability.....	41
12.13	Overview of the availability of medicines in South Africa.....	42
12.14	Methods used in research on medicine stock outs.....	43
13	References.....	48
Part C: JOURNAL MANUSCRIPT.....		53
Part D: POLICY BRIEF.....		76
PART E: APPENDICES.....		81
14.1	Appendix 1: Information sheet.....	82
14.2	Appendix B: Consent form.....	83
14.3	Appendix C: Questionnaires.....	84
14.4	Appendix D: Observation and field notes form.....	92
14.5	Appendix E: UCT Ethics Approval letter (HREC).....	94

14.6	Appendix F: Provincial Department of Health Approval.....	96
14.7	Appendix G: Journal instructions for authors.....	97

Index of Tables

Part A; Protocol

Table 1: Budget.....20

Table 2: Timeline.....21

Part B: Literature Review

Table 1: Summary of Articles.....45

Index of Figures

Part A; Protocol

Figure 1: Conceptual framework showing factors influencing the management of medicine stock at PHC clinics which in turn has an influence on the availability of medicines at these facilities..... 8

Figure 2: Illustration of health facilities as cases within the two different district contexts within the same province 10

Part C: Journal Manuscript

Figure 1: Conceptual framework showing factors influencing the medicine stock management at Primary Health Care (PHC) clinics which in turn may influence the availability of medicines at facilities..... 57

Figure 2: Summary of processes to be followed in medicine stock management at clinics as per Standard Operating Procedures for Pharmaceutical Services at PHC level..... 60

Part D: Policy Brief

Figure 1: Conceptual framework showing factors influencing the medicine stock management at Primary Health Care (PHC) clinics which in turn may influence the availability of medicines at facilities. 76

PART A: PROTOCOL

1 Introduction

As medicines are an essential building block in health systems, it is important for countries aiming to strengthen health systems to pay attention to issues related to medicines (Bigdeli et al., 2014). Common weaknesses in this building block are medicine shortages and stock outs which can adversely affect other functions such as service delivery in the health system (Bigdeli et al., 2014). The causes of medicine stock outs are widespread as the supply chain for medicines is a complex process involving many stakeholders (USAID: Deliver Project, 2011). The complexity of the processes used in the supply chain of medicines is partly responsible for the stock outs that occur (Hensen et al., 2011). However, measures can be put in place at the health facility levels where services are delivered to reduce the occurrence of stock outs (USAID: Deliver Project, 2011).

The purpose of the literature review that follows is to frame the research question for the study based on the existing knowledge on the factors influencing medicine stock outs and shortages. It also informed the development of a conceptual framework to be used in guiding the process of data collection.

Peer reviewed articles on research that has been carried out around the topic on medicine stock outs and shortages were searched for using the PubMed database. Most of the articles found focused on medicine stock outs of essential medicines. Only articles in English were considered and these included one systematic review. The abstracts of the articles were read in order to ensure that they contained relevant information for the study topic. The keywords used in the search were "drug stock outs" OR "drug shortages" OR "medicine stock outs" OR "medicine shortages" using the filters "LMICs" OR "Lower and Middle-Income Countries" and "Africa".

2 Literature review

Access to essential medicines

Essential medicines are defined by the World Health Organisation (WHO) as those medicines which respond to the most pertinent health needs of a population (Bigdeli et al., 2014). These medicines are the foundation for most public health programmes that are aimed at reducing morbidity and mortality (Pecoul et al., 1999). Essential medicines and medical technologies have also been widely referred to as the core elements of the health system and are said to have great potential in promoting health equity, achieving Universal Health coverage (UHC) and strengthening health systems as their effects are immediate and long lasting (Barrington et al., 2010; Bigdeli et al., 2014).

The third goal in the Sustainable Development Goals (SDGs) is to ‘ensure healthy lives and promote well-being for all at all ages’ and nations are encouraged to move towards achieving UHC (United Nations Department of Economic and Social Affairs, 2015). In order to move towards UHC, developing countries need to improve access to essential medicines which have remained inaccessible in many Lower and Middle-Income Countries (LMICs) for a long time (Pecoul et al., 1999; Bigdeli et al., 2014; United Nations Department of Economic and Social Affairs, 2015).

Access [to medicines] can be understood using three dimensions; (1) availability, (2) affordability and (3) acceptability (McIntyre, Thiede & Birch, 2009; Magadzire et al., 2014). Access is an important element that needs to be considered when strengthening health systems (Bigdeli et al., 2014; Magadzire et al., 2014). Availability is defined as the fit between the quantity of medicines on hand and the actual need of the medicines (McIntyre, Thiede & Birch, 2009). It speaks directly to the absence of medicine stock outs and shortages. The availability of medicines is critically important in ensuring access to medicines as it would be of no use if medicines were affordable and acceptable but not available.

Unavailability of medicines as a barrier to access to medicines

The WHO states that essential medicines should be available at all times in an adequate health system (Bigdeli et al., 2014). In many Lower and Middle-Income Countries (LMICs), the availability of essential medicines has been poor particularly in the public sector (Bigdeli et al., 2014). In southern Africa, household surveys estimated that approximately 20% of patient visits to public health facilities end with patients unable to receive medicines due to stock outs and shortages (Wagenaar et al., 2014). The unavailability of medicines has been found to be one of the important barriers to accessing essential medicines in South Africa (Magadzire et al., 2014).

Medicine stock outs can be defined as physical unavailability of a medicine required for patient use and medicine shortages are situations where the stock available is less than that required for patient use (Stop Stock Outs Group, 2014). One of the biggest frustrations faced by clinicians working in rural

public facilities is the unavailability of medicines (Stop Stock Outs Group, 2015). The literature reports various causes of medicine stock-outs and shortages which seem to be more pertinent in the lower income countries and smaller public health facilities such as clinics (Schouten et al., 2011; Bateman, 2013; Wagenaar et al., 2014). The causes are linked to problems embedded in the pharmaceutical procurement and distribution systems (Pecoul et al., 1999; Bateman, 2013). It is thus very important to continually assess and improve medicine supply systems to ensure uninterrupted access to medicines (Lufesi, Andrew & Aursnes, 2007). The more complex the medicines supply chain is, the more likely that it will be inefficient and medicine stock outs will occur (Hensen et al., 2011).

Supply chain management of medicines

The medicine supply chain includes procurement, shipping, storage and ultimately dispensing medication to the patients and weakness along this chain can lead to stock outs and shortages (Berger et al., 2007; Lufesi, Andrew & Aursnes, 2007; Harries et al., 2007; Schouten et al., 2011). Factors along this supply chain that are associated with stock-outs and shortages include, manufacturing shortfalls, errors in ordering, delayed or changing procurement strategies, difficulties in transporting, sudden increases in demand for products, inadequate funding and staffing as well as exploitation of national goods (Ketikidis et al., 2006; Berger et al., 2007; Harries et al., 2007; Schouten et al., 2011; Bateman, 2013; Hasselback et al., 2014; Wagenaar et al., 2014; Stop Stock Outs Group, 2015). Open tender systems are widely used to procure medicines as they may be beneficial in terms of costs however it is advised that they be avoided or considered together with other strategies due to the fact that they may result in unforeseen delays that governments have little control over (Kangwana et al., 2009). The reliance of programmes such as malaria programmes on donor funding to purchase medicines can be problematic as this funding is not always a reliable and sustainable source of revenue (Pasquet et al., 2010; Mikkelsen-Lopez et al., 2014). Where governments are not prepared for cases of donors withdrawing funds, stock outs have occurred and it is advised that governments ensure that buffer stock is always available especially for essential medicines for such unforeseen circumstances (Harries et al., 2007; Pasquet et al., 2010; Mikkelsen-Lopez et al., 2014). The aforementioned problems may occur at health facility level or at the central level where facilities order from but there are some which are more specific to health facilities.

Supply chain management of medicines at health facilities

Non-existent or poor stock control including poor forecasting are the major causes of stock outs and shortages reported in literature at the health facility level when stock is available at the central or depot level (Barrington et al., 2010). In a study by Lufesi et. al (2007) in Malawi, some discrepancies were found between the reported stock levels and actual stock on hand at health facilities implying that the health workers were not following protocols on the management of medicine stock. It was suggested that this non-compliance could have been as a result of lack of training and supervision from seniors

such as district pharmacists (Lufesi, Andrew & Aursnes, 2007). Another reported reason for non-compliance to protocol is the capacity of the health facilities themselves to store sufficient stock of medicines including buffer stock. The management of medicines supply is essential for the provision of health care and even more important in lower income countries where resources are scarce as it has also been reported that one of the major areas of wastage in the health system occurs in the use of medicines (World Health Organization, 2010; Schouten et al., 2011).

The effects of unavailability of medicines

The consequences of medicine unavailability are widespread and can have detrimental effects on individual and public health (Harries et al., 2007; Barrington et al., 2010). Unplanned treatment interruptions could lead to an increase in resistance for example to antimicrobials and antivirals which can have the ripple effect of switching to more costly treatment and interventions (Harries et al., 2007; Pasquet et al., 2010). Such adverse effects have been documented from antiretroviral (ART) clinics in sub-Saharan Africa (Harries et al., 2007). Another important consequence of the unavailability of medicines to governments is the loss of confidence in public health systems by citizens (Magadzire et al., 2014; Wagenaar et al., 2014; Honda et al., 2015). Patients may have to travel to alternative facilities including the private sector facilities to source medicines (Pasquet et al., 2010). This may be costly and becomes a barrier to accessing medicines (Magadzire et al., 2014). In order to address the challenges or medicine stock outs and shortages, countries have introduced various systems targeted at the different causes of stock-outs.

Strategies to ensure uninterrupted availability of medicines

As technology advances in Africa, some countries have taken advantage of this and upgraded their medicine management systems from paper based to computer and web-based systems as a measure of mitigating medicines unavailability (Berger et al., 2007; Githinji et al., 2013). The successful implementation of web-based systems has solved the problem in Haiti where obstacles existed with the paper based systems (Berger et al., 2007). This system facilitated communication which is vital for the management of stock levels between stakeholders involved in the processes (Berger et al., 2007). In Kenya, an SMS *for life* was implemented for anti-malarial medicines and it also solved the problems of unavailability of rapid diagnostic tests and anti-malarial medicines by enhancing stock visibility (Githinji et al., 2013).

In South Africa, a software programme, Rx solution has been introduced in some public health facilities to support the regulation of stock control in public health facilities (Health Systems Trust, 2015b). Another programme that has been implemented in South Africa to address the issues of drug stock outs particularly for chronic diseases is the Central Chronic Medicine Dispensing and Distribution Programme (CCMDD) (Health Systems Trust, 2015a). The aim of this programme was to reduce the

burden on Primary Health Care (PHC) clinics and increase the availability of medicines for chronic conditions which are becoming more prevalent in South Africa (Health Systems Trust, 2015a).

The importance of ensuring uninterrupted availability of medicines

A survey revealed that essential medicines used for chronic conditions were more prone to stock-outs than those used for acute conditions (Bigdeli et al., 2014). In the recent past years, there has been a considerable increase in the prevalence of both communicable and non-communicable diseases (NCDs) world-wide (Mayosi et al., 2009; Magadzire et al., 2014). NCDs have become the leading cause of death as reported by the World Health Organization (WHO) report in 2014. This increase has led to an increased demand for essential medicines used to prevent and treat these diseases (Mayosi et al., 2009; Magadzire et al., 2014). The higher demand has placed a huge strain on the health sector of South Africa which serves about 70% of the country's population (Magadzire et al., 2014). It is evident that availability of medicines used to manage these conditions needs to be improved as it has also been predicted that the burden of disease in relation to NCDs and communicable diseases such as HIV/ \AIDS and tuberculosis (TB) is likely to increase in the coming decades (Mayosi et al., 2009; Health Systems Trust, 2015a).

3 Study rationale

The progress on improving access to essential medicines has been slow even though many LMICs have included the access to medicines as part of the right to health in their constitutions as it has been widely acknowledged that medicines are the most effective way of preventing death once disease has been established (Habiya mbere & Wertheimer, 1993; Wagenaar et al., 2014; Bigdeli et al., 2014). Section 27 of the South African constitution states that citizens have the right to access health care therefore it is essential to consider aspects such as the availability of medicines that have a direct impact on access to health care. In South Africa, surveys have revealed the extent of drug stock outs and perceived causes of stock outs by health workers (Stop Stock Outs Group, 2014; Stop Stock Outs Group, 2015; Public Service Commission, 2015). From these reports, it is suggested that one of the reasons why essential medicine stock outs and shortages occur at the PHC level is because of the poor fore-casting and poor management of medicine stock by the clinics (Stop Stock Outs Group, 2015).

In light of the evidence of poor supply chain management of essential medicines in the public health facilities and frequent problems of drug stock-outs or shortages in South Africa, the search for an effective management system is a priority for the current government (Public Service Commission, 2015). A Discrete Choice Experiment (DCE) on improving the public health sector in South Africa revealed that the availability of medicines at health facilities has the greatest impact in the probability that people will attend public health facilities (Honda et al., 2015). South Africa is moving towards

implementing the National Health Insurance (NHI) in the coming years as a bid to move towards achieving UHC. The white paper released mentions the need to address the quality of healthcare of which availability of medicines is one of the areas that need attention. Access to medicine needs to be improved especially in the Primary Health Care (PHC) clinics which are usually the entry point for citizens into the healthcare system for successful implementation of the NHI.

The factors that contribute the most to the occurrence of stock outs of medicines in South Africa include inadequate health workforce particularly pharmacy personnel, poor medicine stock management, and inefficient communication between suppliers, depots and health facilities (Bateman, 2013). The inefficient communication between the depot and health facilities is a problem because in some cases the clinics do not warn the depot well in advance that they will require larger quantities of stock than the usual quantity and thus the depot is unprepared and unable to meet their needs (Bateman, 2013; Stop Stock Outs Group, 2015). Each public health facility including the PHC clinics are required to sign a 'terms of agreement' contract with the pharmaceutical depot which outlines the way in which the two interact in terms of the ordering and supply of medicines.

This study will explore the supply chain management of medicines at clinics in two health districts focussing on the processes involved as well as the way the actors involved in the processes interact as they carry out their roles. It is hoped this research will contribute to policy review and formulation of standard operating procedures for the management of medicines focusing on how to prevent medicine stock outs in public health facilities.

4 Conceptual framework

The conceptual framework in Figure 1. illustrates the factors that influence the medicine stock management processes at health facilities and thus could be responsible for the occurrence of medicine stock outs at clinics. This framework has been informed by the literature review however we are aware that other factors may be found during the study that have not been included in the framework developed for use in this study to guide the collection and analysis of data. We were not able to identify any pre-existing theoretical frameworks that could be used for this study hence empirical literature was used to develop the conceptual framework.

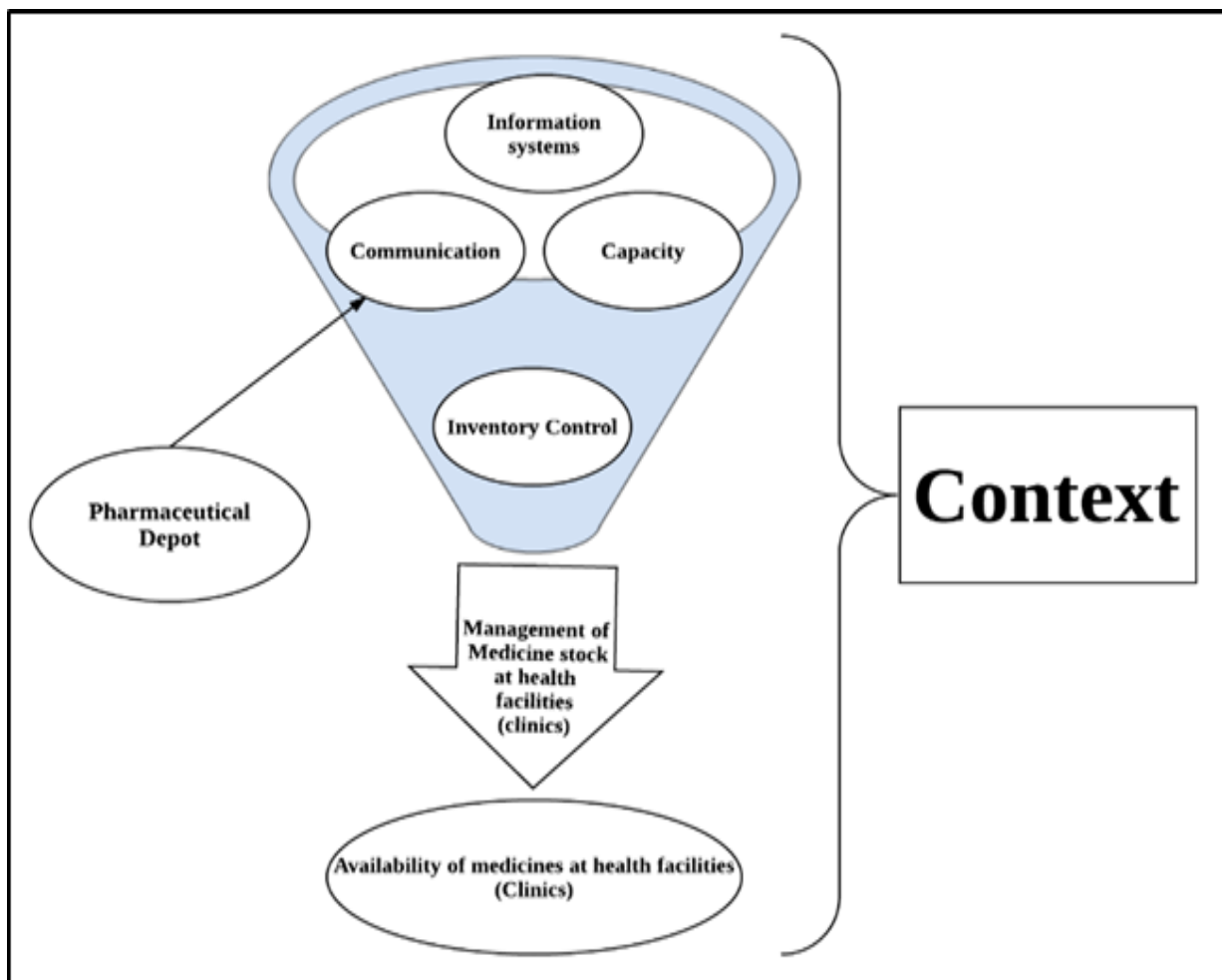


Figure 1: Conceptual framework showing factors influencing the management of medicine stock at PHC clinics which in turn has an influence on the availability of medicines at these facilities.

Ensuring medicines availability is an important goal for health systems as medicines are an important building block in the health system (Bigdeli et al., 2014). Some of the factors influencing the occurrence of stock outs at the health facility level stem from the way in which medicine stock is managed at health

facilities and could be as a result of the inventory control methods used, information and reporting systems used, capacity of the health facilities as well as health workers and communication between key actors in the processes (Harries et al., 2007; Lufesi, Andrew & Aursnes, 2007; Barrington et al., 2010; Githinji et al., 2013). Supply chain management of medicines includes all the processes and activities involved in sourcing medicines from the pharmaceutical depot and ensuring adequate stock levels at the clinics (USAID: Deliver Project, 2011). These are shown in the conceptual framework in Figure 1.

Inventory control of medicines includes the placing of orders from the pharmaceutical depots as well as how the stock levels are maintained at the health facility to ensure uninterrupted availability of medicines (USAID: Deliver Project, 2011). Forecasting is another important aspect of inventory control as it is used to determine the quantities of stock that a facility may potentially use in a certain time period in the future (Harries et al., 2007; USAID: Deliver Project, 2011). If a structured system for forecasting exists, the occurrence of stock outs is likely to be reduced (Harries et al., 2007). In order for facilities to be able to order stock from the depot, communication between the facility and the depot is required. The manner in which clinics communicate with the depot may have an impact on the supply of medicines at the clinics if information is not shared (USAID: Deliver Project, 2011).

Information systems refers to the technologies that may be utilised by health facility staff when managing the levels of medicine stock (Barrington et al., 2010; USAID: Deliver Project, 2011). These may be electronic or paper based which require different levels of skill and expertise to use them well (USAID: Deliver Project, 2011). Information systems may be linked to the way in which information will be shared between the actors involved in ensuring the availability of medicines (USAID: Deliver Project, 2011). Literature suggests that information systems may facilitate efficient communication. The information systems also include the systems used by clinics to report to their district and provincial managers.

The capacity of health workers and health facilities refers to the extent to which the health workers are qualified and able to manage medicine stock as well as the extent to which the facility they work in allows them to do so appropriately (Lufesi, Andrew & Aursnes, 2007). The capacity of the health workers and the health facilities will also enable them to communicate appropriately with the depot, carry out inventory control and use the information and reporting systems available to them. This shows that these factors are interlinked and together influence the process of medicine stock management at a health facility.

There may be other factors which may not be directly linked to the process of medicine stock management but may still influence the process. Such factors may be factors related to the context in which the health facilities are found. Health facilities may be located in different areas such as districts, sub-districts or provinces. These facilities can be said to be embedded in different contexts as shown by

Figure 2. Context is an important aspect when carrying out case study research (Yin, 2003). One of the definitions of a case study states that it is an inquiry about a certain phenomenon within its context especially when there are no clear boundaries between the context and the phenomenon itself (Yin, 2003). This implies that there will always be contextual factors and it is thus important for this study to recognise and consider contextual factors that may have an impact on the management of medicine stock at PHC clinics as part of the in-depth analysis.

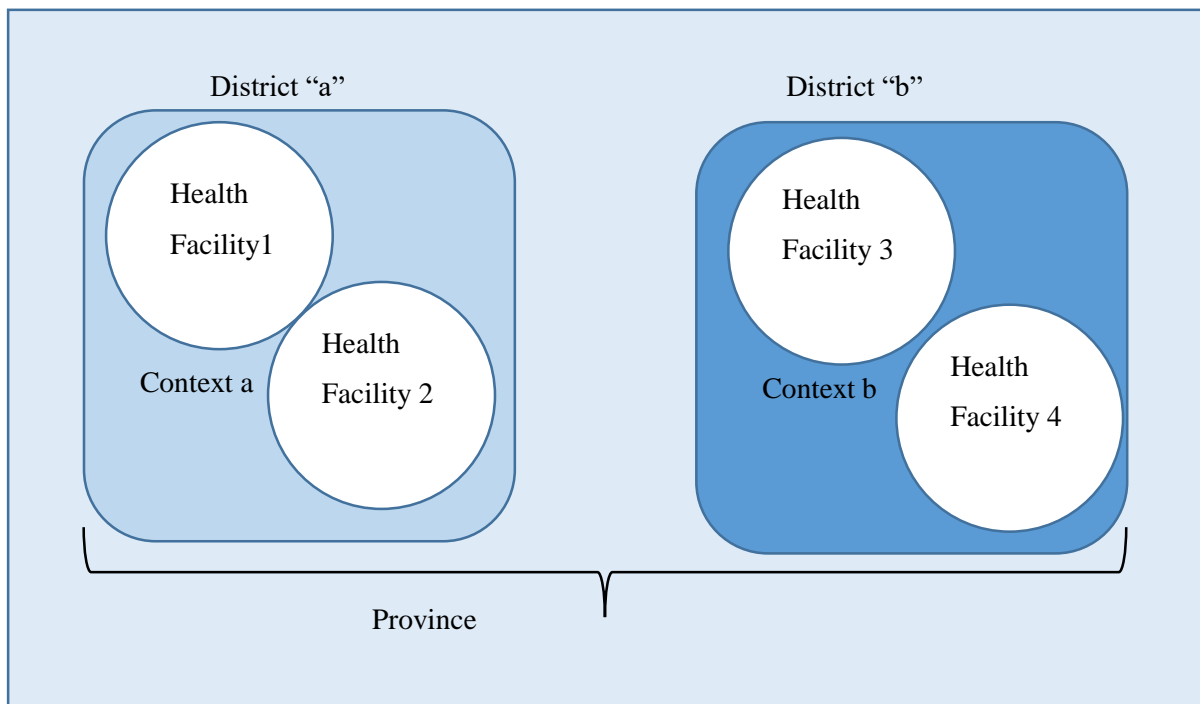


Figure 2 Illustration of health facilities as cases within the two different district contexts within the same province (adapted from Yin, 2003).

In the management of medicine stock at the clinic level, contextual factors which may influence the process include, the geographic location of the clinic, the district as well as provincial management teams, and the disease burden in the district or area served by the clinic (Lufesi, Andrew & Aursnes, 2007; USAID: Deliver Project, 2011; Hasselback et al., 2014). Contextual factors may also influence the actors affecting the manner in which they carry out their roles. These actors include the district pharmacists and the provincial head of pharmaceutical services. Context may be useful in explaining differences or similarities in the cases analysed in a case study.

The geographic location of the two districts illustrated in Figure 1. differs hence the location of clinics may influence the way in which medicine stock is managed in a number of ways. It includes aspects such as whether the clinic is located in a rural or urban area and also speaks to the distance between the facility and the pharmaceutical depot. The location may affect the communication processes between actors and the delivery of medicines from the pharmaceutical depot. It has been reported that medicine

stock outs and shortages are worse in rural areas where there may be transportation and accessibility challenges (Bateman, 2013; Hasselback et al., 2014). A study in Mozambique by Hasselback et. al (2014) reported that the further away facilities were from the depots, stock outs occurred more frequently. This may have been due to difficulties faced by the depots in transporting medicines and accessing the health facilities by road in the more rural areas (Lufesi, Andrew & Aursnes, 2007).

The geographic location may also have an influence on the health workers that are employed at the facilities. Studies have found that health workers are motivated to work in urban rather than rural areas therefore the calibre and capacity of workers found in a health facility may be influenced by the context in which the facility is found (Lufesi, Andrew & Aursnes, 2007). The capacity of the health workers in that region which in-turn influences their ability to follow protocols in inventory control and their ability to use information and reporting systems (Lufesi, Andrew & Aursnes, 2007).

The burden of disease in each district may influence the forecasting process in inventory control as health workers manage medicine stock at the clinics. If there is a higher demand for certain medicines, their chances of going out of stock are increased depending on the methods used to determine re-order quantities (USAID: Deliver Project, 2011).

The head of pharmaceutical services and provincial management team will be the same for both districts in this study however each district will have different district pharmacists as part of its district management team. These actors may be influenced by the afore-mentioned contextual factors influencing the communication between them and the clinics with regards to stock outs. The actors may also be influenced by these factors as they carry out their roles in the management of medicine stock affecting for example their ability to supervise the health workers at the clinics.

5 Research aims and objectives

The aim of this study is to better understand why medicine stock outs occur frequently at public health facilities with a specific focus on the PHC level.

5.1.1 Objectives:

- 1) To examine the medicine stock management process at the clinic, with a particular focus on:
 - Inventory control
 - Capacity of health workers and clinics
 - Communication between the depot and clinics
 - Information and reporting systems used in the processes
- 2) To explore the role that contextual factors may have on the management of medicine stock.

3) To draw policy implications that may improve the management of medicine stock at PHC clinics.

In order to examine these processes, the study will attempt to identify the actors involved in drug procurement and stock management at the PHC clinics, the roles of these actors and the way in which they interact and share information with each other in carrying out their tasks. We will use the standard operating procedures as a tool for analysing our findings, we will test what staff are doing in clinics against the standard operating procedures. This will serve as a basis for reflecting on our findings.

5.1.2 Study Question

What are the processes involved in medicine stock management at PHC clinics in South Africa, focusing on the factors that influence these processes in District A and District B, In the study province as a means to explore and explain how and why stock outs occur at clinics?

6 Methods

6.1.1 Study setting:

South Africa has a total of nine provinces of which the study province has been selected purposively for this study. This selection was based on the fact that in 2014, the study province had the largest proportion of facilities with stock-outs of ARVs and TB medicines (Stop Stock Outs Group, 2015). These medicines are amongst the list of essential medicines that should be found at the PHC level in South Africa (The National Department of Health, 2003). The choice to use ARVs and TB medicines as tracer medicines for this study is based on the reported extent of stock outs of these medicines in the province as well as the high prevalence of HIV in the study province. TB is one of the common co-morbidities of HIV hence the decision to add medicines used to manage and treat the disease alongside ARVs. HIV/AIDS and TB are also amongst the health priorities for the province.

The study province has three districts, District A , District B and District C. These districts are further divided into sub-districts. District A, which is one of the pilot sites for the implementation of the South Africa National Health Insurance and District B which is where the Pharmaceutical Depot is located have been selected purposively as the study sites (Health-e, 2015). District A is one of the deep rural districts where the communities face challenges in accessing health services (Health-e, 2015). District B on the other hand is the economic hub of the study province (District B municipality, 2014). District A has 1 regional hospital, 7 district hospitals, 9 Community Health Centres, 59 clinics, and 27 mobile clinics (Health Systems Trust, 2016). District B on the hand has slightly more public health facilities which include, 1 tertiary hospital, 1 regional hospital, 5 district hospitals, 16 community health centres, 65 clinics and 22 mobile clinics (Health Systems Trust, 2016).

The two districts have been selected purposively to allow for comparisons between districts which may give insight into whether there are any contextual factors such as geographic location and burden of disease which are unique to each district that may influence the occurrence of medicine stock outs. The clinics in District A which is more rural than District B are further away from the depot than the clinics in District B. By choosing these two districts, we will be able to explore if distance from the depot as well as the location in a rural or urban area have an influence on the management of medicine stock ultimately affecting the occurrence of stock outs.

6.1.2 Sampling strategy

The sample size will be determined by the available time and resources for the study. Purposive sampling will be used to identify facilities as cases for inclusion in the study. A total of 2 facilities in each district shall be chosen based on their reported proportions of stock outs according to the data available at the respective district levels. This information on the extent of medicine stock-outs will be sought from the respective district offices. The indicators that will be used to identify the clinics for inclusion in the study are the weekly tracer drug reports which every clinic is requested to submit to their district pharmacist every week. The clinics in each district that reports the most and the least in the average ARVs and TB medicines out of stock on the tracer drug list for the past 3 months will be chosen. For the purpose of this calculation, the numbers of ARVs and TB medicines out of stock will be combined. The reason for choosing the clinics with the most and least medicine stock outs is to enable a comparison of what could be responsible for the difference in the frequent and less frequent occurrence of stock outs.

The case in this study shall be defined as the PHC clinic with an emphasis on the supply chain management of medicines which will be the unit of analysis. Within the supply chain management of medicines at the clinic level, the study will focus on inventory control of medicines including forecasting methods, information and reporting systems, and communication between the depot and clinics. Inventory control includes the processes involved when ordering stock from the pharmaceutical depot and the procedures followed by PHC staff in managing stock levels of medicines at the clinics. In terms of communication, we will focus on how the actors involved at the clinics, within the district and province as well as at the depot communicate with each other as they carry out their respective roles in managing medicine stock. Another aspect that we shall consider is the capacity of the health facilities and health workers to manage medicine stock.

6.1.3 Study design

The study will employ a qualitative multiple case study approach. This study design has been chosen based on the aim and the purpose of this study as advised in literature (Green & Thorogood, 2014). The purpose of the study is both exploratory and explanatory as it aims to find out whether the health

workers at the clinics are following protocols for the management of medicine stock, how the clinics share information and communicate with the pharmaceutical depot as well as other stakeholders in the process of managing stock and then explain how these may be linked to the frequent occurrence of stock outs and shortages within a particular context. The study will also have a descriptive component as it shall describe the processes involved in medicines management at clinics. Case studies are useful where an extensive in-depth description of a phenomenon is needed which is why it has been selected for this study (Yin, 2003; Green & Thorogood, 2014).

The rationale for choosing this methodology is that it will enable collection of a rich source of information in a short time period (Yin, 2003; Green & Thorogood, 2014). Case studies involve studying a particular phenomenon within its context (Yin, 2003). Case studies often make use of a combination of data collection methods and tools (Green & Thorogood, 2014) and one of the unique strengths of this study design is its ability to handle and put together information collected from various sources (Yin, 2003). This will be useful in this study as different sources of evidence and data will be used. Semi-structured in-depth interviews with key informants and documentary analysis will be the main data collection tools.

The conceptual framework developed from the literature will be used to guide data collection (questions will be derived to help us explore and explain the key concepts in the conceptual framework which will ultimately allow us to answer the research questions). Key policy documents will be reviewed such as standard operating procedures (SOPs) for medicines management for the PHC clinic level and depot level, the South Africa National Drug Policy, WHO procurement and supply of pharmaceutical guidelines and other relevant international guidelines on drug stock management. This will help us ensure that we formulate questions on communication, forecasting etc. that are relevant in the South African context. This will also allow us to observe whether standard operating procedures are being followed in our clinic settings.

6.1.4 Research procedures and data collection methods

Qualitative data will be collected in this study. Data will be collected from documents and records at the facilities which include stock cards, weekly tracer drug lists as well as any other stock management records kept at the facility. Provincial and district organograms will be used to identify the key actors in the supply chain management of medicines at PHC level who will serve as key informants in the interviews. The key informants to be interviewed include the pharmaceutical depot manager, the health worker in charge of medicines supply management at the clinics, district pharmacists, and the head of pharmaceutical services in the study province. Snowball sampling shall then be used to identify other informants who are stakeholders in the supply chain management of medicine at clinics as it may not necessarily be the nurse in charge. This will be done in order to gather information from as many perspectives on the management of medicine stock at clinics and the causes of stock outs by covering

all the major actors involved. Initially, a total of 8 actors have been identified and approximately 10 to 15 interviews will be held, depending on the additional informants identified by the initial key informants mentioned above.

Data collected will include information that will help to describe the procedures followed by health workers at the clinics when ordering and receiving medicines from the depot, how stock levels are managed as well as how they respond to cases of stock outs. This will be collected from interviews with the health workers in charge of medicines management at the clinics using semi-structured questionnaires administered by the researcher. The questionnaires will also include questions which will provide information on how the depot interacts and communicates with the clinics and what procedures are followed by the depot in response to cases of drug stock outs at the clinics from the health workers' perspective.

Separate questionnaires for the key informants from the depot, respective district and provincial offices will also be used to collect similar information relevant to their positions. Some questions will be different for different informants as they have different roles in the management of medicine stock. The different groups of informants are vital for this study as there is more than one group of actors involved in managing medicine stock to ensure uninterrupted availability of medicines. It is therefore essential to identify and involve in this study the key actors involved to gather perspectives from more than one angle.

Interviews will be conducted in English using semi-structured questionnaires which will also be in English. These questionnaires will be piloted in order to test their reliability and validity prior to data collection to ensure that the data collected is adequate and appropriate enough to answer the research question. The interviews will be tape-recorded with the consent of the interviewees. The data collected from records at the facilities, interviews and observations will be used to identify and describe the methods of medicines management being utilised at the clinics. This will then be compared against the recommended standard operating procedures and terms of agreement for the supply of medicines signed by the depot and clinics. This data will also provide information on how pharmaceutical depots and clinics manage medicine stock outs as they occur at the clinic level.

6.1.5 Rigour

There are ways in which qualitative researchers are advised to ensure rigour which is also referred to as the trustworthiness of a study (World Health Organisation (WHO), 2012). In case study research, measures to ensure rigour include a clear description of the methods used to collect and analyse data. This may be done in the form of writing up a research protocol detailing the decisions made in developing the study and explaining clearly why these decisions were made (Green & Thorogood, 2014).

In order to ensure confirmability during the phase of research design, a literature review was carried out as advised (World Health Organisation (WHO), 2012). This literature review then informed the development of a conceptual framework to be used to guide data collection. In the data analysis phase, researchers may use different sources of evidence to look for similar and or different experiences within cases as well as across cases (Green & Thorogood, 2014). Where at least two sources of evidence are used, this is called triangulation (Green & Thorogood, 2014). In order to ensure the credibility of the findings during the phase of analysis in this study, we shall use data collected from the interviews, document reviews and observations to compare findings within and across cases.

Purposive selection of cases to include one ‘positive’ and one ‘negative’ case is also a manner in which researchers can ensure rigour (World Health Organisation (WHO), 2012). In this study, the clinics will be selected to ensure that there is one clinic reporting high levels of stock outs and one reporting low levels of stock outs in each district.

6.1.6 Data analysis

Data analysis will be carried out immediately after data collection. The first step in the data analysis will be to transcribe the tape-recorded interviews and type out field notes into electronic documents. This will be done manually. As data will be collected from more than two sources, interviews, document review and observations, the data will be triangulated and this is a way of ensuring rigour in qualitative research (Green & Thorogood, 2014).

The data will be analysed using a thematic content analysis which is the most commonly reported method in qualitative health research (Green & Thorogood, 2014). A thematic content analysis presents the key elements found in a study and groups them into concepts that can be used to summarize and arrange the data in such a way that allows the researcher to put meaning to the findings (Green & Thorogood, 2014). The next step in the thematic analysis will be for the researcher to identify codes and themes across the data set and this shall be guided by the conceptual framework. The codes and themes identified will then be organised using the NVIVO software to enable analysis of the data.

7 Ethical considerations

Ethical review and approval will be sought before the commencement of data collection from the University of Cape Town human research ethics committee as well as both the National and Provincial Department of Health committees. The approval from the National department of Health will be essential to ensure access into the pharmaceutical depots and the health facilities for data collection.

7.1.1 Informed consent process

In as much as the National Department of Health shall provide a letter giving the researcher access into the health facilities, fully-informed consent shall be required from the key informants who will participate in this study. The district managers in each district shall be informed prior to making contact with any potential key informants on the study. Each participant will be provided with a letter of invitation to participate in the research delivered to them prior to the initiation of data collection. In this letter, they shall be given full information of the nature of the research, use of data collection and what participation entails for example the estimated time that the researchers will spend at the facilities as well as how long each interview will take. The participants will also be informed that they have the right to withdraw partially or fully from participation at any stage during the data collection. As the interviews will be tape recorded, the participants will be required to give consent to the recording of the interviews.

The researcher will follow up with the key informants to whom letters were sent telephonically and they will be required to give verbal consent to take part in the research. This verbal consent will be supplemented by a written agreement signed by both the participant and the researcher. This written and signed consent shall be obtained at the health facilities on the day of the interview prior to the interview.

As clinics can be busy places and the choice of venue as well as time of interview can affect the quality of data as well as willingness of health professionals to participate in research, the researcher will make an appointment with the respective key informants and allow them to decide on a time that is least stressful to them as consent will be obtained at their places of work.

7.1.2 Risks and benefits

The risks that may be encountered by the participants in this study are minimal. One of the risks as with all types of research is that of breaching confidentiality which may be feared by the key informants. In order to mitigate this, measures shall be put into place in order to ensure that privacy and confidentiality is maintained at all times.

Since the interviews at the health facilities and depots will be carried out at the informant's place of work, there is the possibility of encountering the risk of lost time for them to carry out their daily duties. In order to mitigate this risk, the researchers shall inform the informants of the estimated time for the interview such that the informants will be prepared and can plan accordingly well in advance. The interviewer shall endeavour to ensure that the interview does not take longer than the proposed time and allow the participants to stop the interview should they wish if it has gone beyond time.

Participants may not be comfortable with the tape recording of the interviews in fear that their voices and words may be recognised if quoted verbatim. In order to address this, the participants will be required to give their consent to the tape recording of the interviews and it will be made clear that the purpose of the tape recording is to ensure that the researcher captures the information they provide as accurately as possible. They will be asked to sign on the consent form specifically if they do consent to being recorded. If the participants are not comfortable with the tape recording, they shall be allowed to opt out of it.

There may be legal and economic risks to the participants which may affect their willingness to disclose certain information pertaining to the way that they do their work for example if they are aware of fraudulent activity. In order to mitigate this risk and inspire confidence into the participants, it shall be emphasised that the findings will not be disclosed to the participants' employers and all responses will be kept anonymous. The participants will be given the option to choose pseudonyms and their permission to use any quotes will be required before they are included in the research report.

There will be no direct benefits to the participants and they will not be offered any remuneration for participation. All participants will be treated fairly and there will be no penalty for refusal to participate as well. A potential social benefit of the research is that the study will potentially inform policy review and formulation of standard operating procedures for the management of essential medicines focusing on how to handle medicine stock outs in public health facilities. Ultimately these may aid the government to deal with the problem of drug stock-outs.

7.1.3 Privacy and confidentiality

The researcher conducting the semi-structured interviews will be trained especially on the importance of maintaining confidentiality and professionalism. In order to maintain confidentiality of the key informants, their names and identification numbers will not be recorded however it will be important to identify whether data was collected from a facility nurse or pharmaceutical depot manager for example. Special codes only known to the researchers will be used for this. That will be the only identification used and it shall not be disclosed. The participants will be given the choice of selecting pseudonyms to be used in the write up in order to preserve the anonymity of the interviewees. The questionnaires and tape records will be kept in a locked cupboard for the duration of the study and the data once entered into spreadsheets will be kept in password protected files. The researchers will be the only ones with access to the keys and passwords. The recordings will then be destroyed as soon as the interviews have been transcribed.

7.1.4 Use of information and publications

The findings of this study will be disseminated through a journal article which will be sent to a peer reviewed journal and a policy brief. These are requirements in the fulfilment of the Master of Public Health, Health Economics dissertation.

8 Resources/Budget

The proposed budget for this study is shown below in Table 1. The study will be funded by the National Research Fund (NRF) South African Research Chair; Health and Wealth program. Unit costs were drawn from the UCT planning and budget guidelines available from: <https://www.uct.ac.za/usr/finance/notices/budgui13.xlsx>. (Accessed 15 March 2016). The duration of the fieldwork study was based on a consideration of the number of facilities to be visited and the number of interviews to be held with the informants.

Table 1: Budget

Category	Description	Unit cost (ZAR)	Number	Total
<i>Travel and accommodation</i>				
Airfare	Flights from Cape Town to City Y and return for two separate field visits, one visit in each district.	2900	4	11600
Per diem accommodation	Accommodation during fieldwork in the study province. Two field visits, ten days per visit spent in each district.	895	20	17900
Per diem meals and incidentals	Meals and incidentals whilst on fieldwork in the study province.	372	20	7440
<i>Transportation</i>				
Per diem car hire	Travel during fieldwork	600	20	12000
Fuel per kilometre	Travel from the airport to the two districts for field visits as well as travel to and from the facilities during field work. City Y-District B: 200x2=400km, City Y-District A: 230x2=460km. Travel to and from facilities +/-400km	3,29	1260	4145,4
<i>Operating expenses, postage, printing, etc.</i>				
Transcription	Total of 20 interviews, half to be transcribed by myself and the other half by a hired transcriber.	1000	10	10000
Printing and stationery	Printing of information sheets, consent forms, pens and notebooks to be used during data collection.			200
Communication	Pre-paid airtime and data to communicate and arrange interviews with participants.	500		500
Total				63785,4

9 Project timeline

The proposed duration of the study is 8 months. Table 2. Shows the timeline for the project.

Table 2: Timeline

Key actions		2016												2017				
		J a n	F e b	M a r	A p r	M a y	J u n	J u l	A u g	S e p	O c t	N o v	D e c	J a n	F e b	M a r	A p r	M a y
1	Prepare research proposal	X	X	X														
2	Submit proposal to Ethics Committee			X														
3	Obtain ethics approval			X	X													
4	Undertake data collection and transcription of interviews					X	X	X										
5	Prepare structured literature review							X	X	X	X	X	X					
6	Submit protocol to UCT Post graduate office													X				
7	Undertake data analysis										X	X	X	X				
8	Prepare research article and policy brief														X	X		
9	Write up dissertation																	X
10	Submit dissertation																	X

10 References

Barrington, J., Wereko-Brobby, O., Ward, P., Mwafongo, W. & Kungulwe, S. 2010. SMS for Life: a pilot project to improve anti-malarial drug supply management in rural Tanzania using standard technology. *Malar J.* 9(298):1-9.

Bateman, C. 2013. Drug stock-outs: Inept supply-chain management and corruption. *SAMJ: South African Medical Journal.* 103(9):600-602.

Berger, E.J., Jazayeri, D., Sauveur, M., Manasse, J.J., Plancher, I., Fiefe, M., Laurat, G., Joseph, S. et al. 2007. Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti. *AMIA Annual Symposium Proceedings.* American Medical Informatics Association. 46.

Bigdeli, M., Peters, D.H., Wagner, A.K. & World Health Organization 2014. Medicines in health systems: advancing access, affordability and appropriate use.

Githinji, S., Kigen, S., Memusi, D., Nyandigisi, A., Mbithi, A.M., Wamari, A., Muturi, A.N., Jagoe, G. et al. 2013. Reducing stock-outs of life saving malaria commodities using mobile phone text-messaging: SMS for life study in Kenya. *PLoS One.* 8(1):e54066.

Green, J. & Thorogood, N. 2014. *Qualitative methods for health research.* Third ed. London: SAGE.

Habiyambere, V. & Wertheimer, A.I. 1993. Essential drugs should be accessible to all people. *World Health Forum.* World Health Organization. 140.

Harries, A.D., Schouten, E.J., Makombe, S.D., Libamba, E., Neufville, H.N., Some, E., Kadewere, G. & Lungu, D. 2007. Ensuring uninterrupted supplies of antiretroviral drugs in resource-poor settings: an example from Malawi. *Bulletin of the World Health Organization.* 85(2):152-155.

Hasselback, L., Crawford, J., Chaluco, T., Rajagopal, S., Prosser, W. & Watson, N. 2014. Rapid diagnostic test supply chain and consumption study in Cabo Delgado, Mozambique: estimating stock shortages and identifying drivers of stock-outs. *Malaria Journal.* 13(1):1-10.

Health Systems Trust 2015a. *Central Chronic Medicine Dispensing and Distribution Programme (CCMDD).* Available: <http://www.hst.org.za/projects/central-chronic-medicine-dispensing-and-distribution-programme-ccmdd> [2015, November 10].

Health Systems Trust 2015b. *Current Projects: Rx Solution.* Available: <http://www.hst.org.za/projects/rx-solution>.

Health Systems Trust 2016. *District and province profiles: Study province.* Available: http://www.hst.org.za/uploads/files/secB_mp.pdf [2016, January 12].

Health-e 2015. *The South African Health News Service. Study province: District A Profile.* Available: [http://www.health-e.org.za/wp-content/uploads/2012/04/District A-District-Profile.pdf](http://www.health-e.org.za/wp-content/uploads/2012/04/District-A-District-Profile.pdf) [2015, November 25].

Hensen, B., Paintain, L.S., Shretta, R., Bruce, J., Jones, C. & Webster, J. 2011. Taking stock: provider prescribing practices in the presence and absence of ACT stock. *Malar J.* 10(218):10.1186.

Honda, A., Ryan, M., van Niekerk, R. & McIntyre, D. 2015. Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment. *Health Policy and Planning.* 30(5):600-611. DOI:10.1093/heapol/czu038 [doi].

Kangwana, B.B., Njogu, J., Wasunna, B., Kedenge, S.V., Memusi, D.N., Goodman, C.A., Zurovac, D. & Snow, R.W. 2009. Malaria drug shortages in Kenya: a major failure to provide access to effective treatment. *The American Journal of Tropical Medicine and Hygiene.* 80(5):737-738. DOI:80/5/737 [pii].

Ketikidis, P.H., Lenny Koh, S., Gunasekaran, A. & Pibernik, R. 2006. Managing stock-outs effectively with order fulfilment systems. *Journal of Manufacturing Technology Management.* 17(6):721-736.

Lufesi, N.N., Andrew, M. & Aursnes, I. 2007. Deficient supplies of drugs for life threatening diseases in an African community. *BMC Health Services Research.* 7:86. DOI:1472-6963-7-86 [pii].

Magadzire, B.P., Budden, A., Ward, K., Jeffery, R. & Sanders, D. 2014. Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa. *BMC Health Services Research.* 14(1):520.

Mayosi, B.M., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. & Bradshaw, D. 2009. The burden of non-communicable diseases in South Africa. *The Lancet.* 374(9693):934-947.

McIntyre, D., Thiede, M. & Birch, S. 2009. Access as a policy-relevant concept in low-and middle-income countries. *Health Economics, Policy and Law.* 4(02):179-193.

Mikkelsen-Lopez, I., Shango, W., Barrington, J., Ziegler, R., Smith, T. & deSavigny, D. 2014. The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners: the case of Tanzania. *Malaria Journal.* 13:181-2875-13-181. DOI:10.1186/1475-2875-13-181 [doi].

District B municipality 2014. *About District B municipality.* Available: <http://www.DistrictBdm.gov.za/index.php/2014-02-25-17-36-25/ndm-background?showall=1&limitstart=> [2015, December 8].

Pasquet, A., Messou, E., Gabillard, D., Minga, A., Depoulosky, A., Deuffic-Burban, S., Losina, E., Freedberg, K.A. et al. 2010. Impact of drug stock-outs on death and retention to care among HIV-infected patients on combination antiretroviral therapy in Abidjan, Côte d'Ivoire. *PLoS One.* 5(10):e13414.

Pecoul, B., Chirac, P., Trouiller, P. & Pinel, J. 1999. Access to essential drugs in poor countries: a lost battle? *Jama.* 281(4):361-367.

Public Service Commission 2015. Consolidated report on service delivery inspections of district hospitals and clinics regarding availability of medicines and medical equipment and the role of health district offices. Public Service Commission.

Schouten, E.J., Jahn, A., Ben-Smith, A., Makombe, S.D., Harries, A.D., Aboagye-Nyame, F. & Chimbandira, F. 2011. Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. *Journal of the International AIDS Society*. 14 Suppl 1:S4-2652-14-S1-S4. DOI:10.1186/1758-2652-14-S1-S4 [doi].

Stop Stock Outs Group 2014. Stop Stock Outs Report 2013 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

Stop Stock Outs Group 2015. Stop Stock Outs Reprt 2014 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

The National Department of Health 2003. Standard Treatment Guidelines and Essential Medicines List for South Africa. Primary Health Care. Third ed. Pretoria: The National Department of Health.

United Nations Department of Economic and Social Affairs 2015. *Transforming our world: the 2030 Agenda for Sustainable Development*. Available: <https://sustainabledevelopment.un.org/post2015/transformingourworld> [2015, October 10].

USAID: Deliver Project 2011. The Logistics Handbook. A practical guide for the supply chain management of health commondities. Second ed. Arlington, USA: USAID.

Wagenaar, B.H., Gimbel, S., Hoek, R., Pfeiffer, J., Michel, C., Manuel, J.L., Cuembelo, F., Quembo, T. et al. 2014. Stock-outs of essential health products in Mozambique ? longitudinal analyses from 2011 to 2013. *Tropical Medicine & International Health*. 19(7):791-801. DOI:10.1111/tmi.12314.

World Health Organisation (WHO) 2012. *Health Policy and Systems Research: A Methodology Reader*. Edited by Lucy Gilson. Geneva, Switzerland.: WHO Library Cataloguing-in-Publication Data.

World Health Organization 2010. The World Health Report [2010]: Health Systems Financing; the Path to Universal Coverage.

Yin, R.K. 2003. The case study as a research strategy. In *Case study research design and methods*. Third ed. London: Sage Publications Inc.

PART B: LITERATURE REVIEW

11 Introduction

The availability of medicines is an essential aspect of access to healthcare especially at the Primary Health Care (PHC) level as this is usually the first point of contact for many individuals with the health care system. The unavailability of medicines at PHC facilities may be due to frequent stock outs of medicines which are caused by various factors. One of these factors being the ways in which medicine stock is managed at the health facility. The following section includes the aims and objectives of the literature review, the methods used and finally the literature review. We start off by giving an overview of access to essential medicines and its importance, we then define medicine stock outs and its impact on patients as well as the health system. We then discuss medicine supply chains detailing at which point medicine stock outs may occur. This is then followed by the functions within the supply chain related to ensuring medicine availability namely, procurement and selection, forecasting, storage and distribution of medicines. The following sections discuss other general causes of medicine shortages and stock outs and is followed by strategies that have been used to address challenges in medicines availability. We then give an overview of medicines availability in the study context, South Africa. Lastly we discuss the methods used in the research papers that were included in this literature review.

11.1 AIMS AND OBJECTIVES

The aim of this literature review was to identify key research that has been conducted on medicine availability, medicine stock management and medicine stock outs. The aim was to identify from the literature what is known on these subjects as well as identify any gaps in this knowledge which could be addressed by further research.

11.1.1 Objectives:

1. To review the literature on the ways in which medicine stock is managed and the occurrence or causes of medicine stock outs identifying any gaps in knowledge.
2. To identify strengths and weaknesses in previously used methods in research carried out to answer similar questions.

11.2 METHODS

Peer reviewed articles published in English were searched for on the availability of medicines and medicine stock management common used databases for public health and medicine which include; PubMed, EBSCOHost, Google scholar, Scopus and Cochrane. Articles from the past three decades were

considered that is from the year 1987. The identified articles were then analysed for relevance (i.e. they focus on the medicine stock management, medicine stock outs or medicine availability) by reading through the abstracts. To further identify additional papers to include in the review, the bibliographies of the papers identified in the step above were reviewed. Grey literature on the subject was included in this review. This was identified by searching through websites of the Management Sciences for Health (MSH), World Health Organisation (WHO), United Nations (UN) and Google. Unpublished articles, reports, conference papers and dissertations were included as grey literature. A review template was developed to extract relevant information from the literature identified for the structured literature review.

12 Structured Literature Review

12.1 ACCESS TO ESSENTIAL MEDICINES

Essential medicines are defined by the World Health Organisation (WHO) as those medicines which respond to the most pertinent health needs of a population (Bigdeli et al., 2014). These medicines are the foundation for most public health programmes that are aimed at reducing morbidity and mortality (Pecoul et al., 1999). The WHO provides a model list for countries to use which consists of basic essential medicines and this list is updated every two years, however the selection of essential medicines may vary from country to country or even provincially. The selection of medicines to be considered on an Essential Medicine List (EML) is usually based on the most prevalent diseases in that region as the selected medicines would have to satisfy the needs of most of that population for them to be deemed ‘essential medicines’ (World Health Organisation, 2017). Other factors considered when selecting essential medicines include the efficacy and effectiveness of the medicines which emanates from evidence based research (World Health Organisation, 2002). The costs and cost-effectiveness of the medicines are also compared to others which may be used to treat the same conditions and these factors are also used to determine which medicines end up on the essential medicines list (World Health Organisation, 2002). It is also important to ensure that those medicines chosen for this list are also readily available (World Health Organisation, 2002).

Essential medicines and medical technologies have also been widely referred to as the core elements of the health system and are said to have great potential in promoting health equity, achieving Universal Health coverage (UHC) and strengthening health systems as their effects are immediate and long lasting (Barrington et al., 2010; Bigdeli et al., 2014). The third goal in the Sustainable Development Goals (SDGs) is to ‘ensure healthy lives and promote well-being for all at all ages’ and nations are being

encouraged to move towards achieving UHC (United Nations Department of Economic and Social Affairs, 2015). In order to move towards UHC, one of the things developing countries need to focus on is improving access to essential medicines which have remained inaccessible in many Lower and Middle-Income Countries (LMICs) for a long time (Pecoul et al., 1999; Bigdeli et al., 2014; United Nations Department of Economic and Social Affairs, 2015).

Access to healthcare, including medicine, can be understood using three dimensions; (1) availability, (2) affordability and (3) acceptability (McIntyre, Thiede & Birch, 2009; Magadzire et al., 2014). Magadzire et al. (2014) and Bigdeli et al. (2014) argue that access [to medicines] is an important element that needs to be considered when strengthening health systems particularly the dimension of availability. The availability of medicines is critically important in ensuring access to medicines as it would be of no use if medicines were affordable and acceptable but not available.

McIntyre, Thiede & Birch (2009) define availability as a dimension of access to healthcare as the fit between the quantity of services and the actual need for those healthcare services. When considering the availability of medicines which form a part of healthcare, this definition could be translated as the fit between the quantity of medicines on hand and the actual need of the medicines (McIntyre, Thiede & Birch, 2009). This definition speaks directly to the absence of medicine stock outs and shortages (McIntyre, Thiede & Birch, 2009).

12.2 DEFINITION OF MEDICINE SHORTAGES AND MEDICINE STOCK OUTS

Many studies that have been carried out on the availability of medicines refer to medicine shortages and medicine stock outs as an important challenge (Harries et al., 2007; Barrington et al., 2010, Magadzire et al., 2014; Wagenaar et al., 2014; Honda et al., 2015). In the literature reviewed, medicine shortages have been defined differently depending on the perspective and context considered (Fox & Tyler, 2003). From the perspective of a health organization, medicine shortages may be understood as a problem in medicine supply that ultimately affects the way in which the pharmacy will prepare a product to be dispensed to a patient or has an influence on the patient care because a prescriber has to choose a different medicine for the patient's treatment (Fox & Tyler, 2003). From the manufacturer's point of view, a shortage refers to the case when the manufacturer is unable to sustain the production of adequate quantities of a certain medicine due to unavailability of raw materials or a problem that would have occurred during manufacture and as a result they produce medicines which are inadequate to meet the demand (Fox & Tyler, 2003).

Wholesalers consider a medicine shortage a case where they experience any difficulty obtaining a medicine from its suppliers (Fox & Tyler, 2003). These suppliers are usually also the manufacturers of the medicines (Fox & Tyler, 2003). This definition of a medicine shortage from the wholesaler's perspective does not distinguish between whether the cause of the shortage is due to previous orders that were not completely fulfilled by the supplier because the supplier did not have sufficient quantities and whether the orders were not fulfilled because the medicines were completely unavailable from their supplier at that point in time (Fox & Tyler, 2003). The Stop Stock Outs Group in South Africa have a simpler definition for a medicine shortage which encompasses all perspectives and they define it as a situation where the stock available is insufficient to satisfy the needs of the clients who need it (Stop Stock Outs Group, 2014). Most literature reports on "medicine shortages" as this is a less negative phrase compared to "medicine stock outs" however it is evident that a medicine shortage may potentially lead to a medicine stock out regardless of whose perspective is considered. In a cross-sectional survey that explored the experiences of health workers responsible for the provision of maternal health care services in Tanzania in relation to drug and supply issues, the nurses reported that medicine stock outs occurred after long periods of medicine shortages (Penfold et al., 2013).

Medicine stock outs have been defined as the physical unavailability of a medicine required for patient use at the point of care when it is required (Stop Stock Outs Group, 2014). This definition is very similar to the definitions of medicine shortages, however the difference between the two definitions is that in some cases stock outs may refer to total unavailability of medicines whereas shortages refer to insufficient medicines that is medicines are not totally unavailable (Stop Stock Outs Group, 2014). We chose to focus on the term 'medicine stock out' as it may include both scenarios when medicines are available but insufficient to meet patient needs as well as when medicines are totally unavailable). It is also clear that both the definitions of medicine shortages and medicine stock outs are similar to that used to define the availability of medicines hence many studies that have explored the factors influencing the availability of medicines have highlighted the need to reduce the occurrence of stock outs and shortages of medicine. In addition to the factors influencing or causing medicine shortages and stock outs, studies have also reported on the impact of the unavailability of medicines highlighting the need for health systems to make it a priority that they ensure the uninterrupted availability of medicines (Schouten et al., 2011; Bateman, 2013; Wagenaar et al., 2014).

12.3 THE IMPACT/EFFECTS OF MEDICINE SHORTAGES AND STOCK OUTS

Research has been conducted on medicine availability and shortages used to treat various conditions including both communicable and non-communicable diseases (NCDs). Of the studies reviewed in this literature review, the studies carried out in the developed world focused on medicines used in treatment of cancer and general antibiotics, whilst in Africa the studies reviewed focused mostly on medicines used to treat communicable diseases such as HIV/AIDs, TB and malaria which are more prevalent in Africa. This shows that medicines availability is an important issue in health systems across the world and it does not only affect a specific group of medicines (USAID: Deliver Project, 2011). Some of the factors influencing the unavailability of medicines may be specific to that area whilst others may be common to both the developing and undeveloped world (Bigdeli et al., 2014).

A survey in various developing countries in 2011 revealed that essential medicines used for chronic conditions and those conditions requiring life-long treatment were more prone to stock-outs than those used for acute conditions (Cameron et al., 2011; Bigdeli et al., 2014). In the recent years, there has been a considerable increase in the prevalence of both communicable and NCDs world-wide (Mayosi et al., 2009; Magadzire et al., 2014). NCDs have become the leading cause of death as reported by the WHO report in 2014. This increase has led to an increased demand for essential medicines used to prevent and treat these diseases (Mayosi et al., 2009; Magadzire et al., 2014). The increased demand has placed a huge strain on the health sector and this contributed to the shortages and stock outs that occur as suppliers fail to meet the increased targets (Mitka, 2011; Magadzire et al., 2014). It is evident that availability of medicines used to manage these conditions needs to be improved in order to prevent the detrimental effects of stock outs as it has also been predicted that the burden of disease in relation to NCDs and communicable diseases such as HIV/AIDS and TB is likely to increase in the coming decades (Mayosi et al., 2009; Health Systems Trust, 2015a).

The consequences of medicine unavailability are widespread and can have detrimental effects on individuals and public health systems as a whole (Harries et al., 2007; Barrington et al., 2010). An important consequence of the unavailability of medicines to governments is the loss of confidence in public health systems by citizens which has been reported in studies in Africa (Magadzire et al., 2014; Wagenaar et al., 2014; Honda et al., 2015). This is even more detrimental in developing countries as most of the population in these countries relies on the public sector for healthcare, for example in South Africa 70% of the population relies on the public health sector for health care services (Magadzire et al., 2014). Apart from this loss of confidence, there may also be cost implications to the health systems in countries due to medicine shortages and stock outs (Fox & Tyler, 2003).

A case study on managing medicine shortages at a hospital in Utah (USA) revealed that shortages of medicines resulted in increased or decreased costs to the health facility (Fox & Tyler, 2003). These experiences in the USA relate to experiences in the private health sector and they may not be the same as in the public sector especially in developing countries (Fox & Tyler, 2003; Cameron et al. 2011). This may be due to the fact in developing countries like South Africa, the public sector is tightly regulated by the government and it may not be possible for them to incur extra costs without them being approved by the government (Cameron et al., 2011). These increase in costs may have resulted from similar aspects which have been reported in other studies such as the increase in paid staff time that resulted from health workers spending more time at work handling shortages of medicines (Fox & Tyler, 2003; Kaakeh et al., 2011). Kaakeh, Sweet et. al (2011) in a study on the impact of drug shortages on health systems in the United States of America reported that there was an increase in the overall amount of human resources needed in times of drug shortages and this would be even more challenging in lower income countries that are facing a human resource crisis (Kaakeh et al., 2011). Pharmacists would spend more time managing the shortages and this included trying to source stock from alternative suppliers, sending information to other members of the health care team such as prescribers that certain medicines are out of stock and updating their data bases with alternative drugs that were available (Kaakeh et al., 2011).

Changing to alternative treatments which cost more than the initial treatment and having to order alternative pack sizes of medicines which may be more expensive have also been reported as reasons for the increased costs to health facilities when they experience medicine shortages or stock outs (Mcbride et al., 2013; McKeever, Bloch & Bratic, 2013). Reimbursement from third party payers such as health insurance schemes may also prove to be a challenge when shortages occur because these payers usually have a set list of medicines that are pre-authorized for treating certain conditions or the insurance schemes prefer generic medicines as a means of containing costs. Once these medicines are unavailable the health facility may run into problems when they make claims where alternative medicines had been used (Fox & Tyler, 2003; Mcbride et al., 2013; McKeever, Bloch & Bratic, 2013). This may also translate into increased direct patient costs as the patients may have to pay a levy for alternative medicines or treatment that have been substituted due to stock outs or shortages (Mcbride et al., 2013). In the private sector, health professionals may also have a wider choice of medicines that they can choose from when their first choices are unavailable as their formularies may be flexible unlike in the public sector where the formularies may only include medicines on the essential medicines list (Cameron et al. 2011). Any medicines outside the essential medicines list would require authorization from higher authorities in the government before the health facilities can order them and use them in

place of those medicines which are unavailable at that time (Cameron et al 2011). This shows us another difference in the way medicine stock outs may impact health facilities in the private and public sectors.

Patients may also incur costs when they need to make alternative plans in order to ensure that treatment is not interrupted (Pasquet et al., 2010). These alternative plans may involve patients being referred out to other health facilities which may result in added travelling costs incurred as the patients travel to alternative facilities including the private sector facilities to source medicines (Pasquet et al., 2010). This may become a barrier to accessing medicines and lead to patient treatment being interrupted (Magadzire et al., 2014; Harding et al., 2014). To date there is no published research that has studied the medicine seeking behaviour of patients as well as the direct cost implications on patients of medicine shortages and stock outs however it is also possible that patients may incur opportunity costs as a result of medicines stock outs (Magadzire et al., 2014; Harding et al., 2014). These opportunity costs could come about as a result of missing paid work to attend health facilities numerous times to check whether their medicines are back in stock (Magadzire et al., 2014; Bateman 2013, Stop Stock Outs Group, 2015). A common practice in South African health facilities when medicines are unavailable is to give the patient a date on which they are to return to the facility to check and collect their medicines if and when they are available which translates to additional visits to the health facility (Bateman 2013; Magadzire et al., 2014).

Unplanned treatment interruptions could lead to an increase in resistance to antimicrobials and antivirals which can have the ripple effect of switching to even more costly treatment and interventions (Harries et al., 2007; Pasquet et al., 2010). It may also result in prolonged treatment periods which could potentially be even more costly as patients would have developed adverse effects due to not having taken their medicines and may need to be hospitalised (McKeever, Bloch & Bratic, 2013). For the working population, this would mean loss in time that could have been spent being productive at work and would then potentially affect the economy of the country (Mcbride et al., 2013; Ankomah et al., 2015). Adverse effects such as drug resistance and treatment failure have been documented from antiretroviral (ART) clinics in sub-Saharan Africa as consequences of medicine unavailability (Harries et al., 2007).

Some of the adverse effects that have been reported in the literature due to medicine shortages and stock outs have led to patient deaths (McBride et al., 2013). These deaths occurred as a result of medication errors that occurred when changing treatment regimens were changed (Mcbride et al. 2013). There is a study where sterile water was unavailable and sepsis occurred in a patient as a result of tap water being

substituted to flush feeding tubes before medicines were administered to the patient through the tubes (Mcbride et al., 2013; McKeever, Bloch & Bratic, 2013). Such medicine errors may occur where the health workers are less familiar with the alternative medicines, for example how they need to be mixed, dosages and directions of use and there is inadequate time to train them on this as the medicine shortage would have occurred unexpectedly (Mcbride et al., 2013). When a patient receives alternative treatment, there is a possibility of having a reaction or side effects that were not present on the previous usual treatment and this too is considered an adverse effect that would have resulted from medicine shortages and stock outs in the literature (McKeever, Bloch & Bratic, 2013; Mcbride et al., 2013; Ankomah et al., 2015).

The effect of medicine unavailability impacts many aspects of the healthcare industry including research and development of new medicines that could benefit the public as it has been reported that clinical trials especially for oncology treatment have been halted due to shortages in supply of medicines or raw materials used to manufacture the medicines. (Mcbride et al., 2013). In oncology, there is often very limited knowledge on treatment alternatives which themselves are limited and for this reason it has been argued that some medicine shortages are more life-threatening than others in as much as the goal is to ensure that all medicines are always available (Mcbride et al., 2013). Medicine shortages and stock outs of some medicines have been argued to be more serious than others even though the goal of health facilities is to ensure that they never occur (Cameron et al., 2011; Mcbride et al., 2013).

12.4 CAUSES OF MEDICINE SHORTAGES AND STOCK OUTS

In order to address the challenges of medicine stock outs and shortages there has been some research carried on the subject and the literature reports various causes of medicine stock-outs and shortages which seem to be more pertinent in the lower income countries and smaller public health facilities such as clinics (Schouten et al., 2011; Bateman, 2013; Wagenaar et al., 2014). The causes are linked to problems embedded in the pharmaceutical procurement and distribution systems (Pecoul et al., 1999; Bateman, 2013).

For a healthcare system to function well it is very important for the medicines supply system to be one that is efficient (World Health Organisation, 2017). It is also important to note that, due to the complexity of health systems, external factors may affect other elements of the health system which, in turn, influence the supply of medicine. Such factors include the lack of human resources, lack of finances that are sustainable, information systems that are not comprehensive, these are cited by the

WHO as essential components of ensuring that the supply of medicines is uninterrupted. It is thus very important to continually assess and improve medicine supply systems to ensure uninterrupted access to medicines (Lufesi, Andrew & Aursnes, 2007). The more complex the medicines supply chain is, the more likely that it will be inefficient and medicine stock outs will occur (Hensen et al., 2011)

12.5 MEDICINES SUPPLY SYSTEMS/CHAINS

The medicine supply chain consists of the selection, procurement, storage, shipping and ultimately distribution of medicines (World Health Organisation, 2017). Any weakness along this chain can potentially lead to stock outs and shortages (Berger et al., 2007; Lufesi, Andrew & Aursnes, 2007; Harries et al., 2007; Schouten et al., 2011; World Health Organisation, 2017). Factors along this supply chain that are associated with stock-outs and shortages reported in the literature include, manufacturing shortfalls, errors in ordering, delayed or changing procurement strategies, difficulties in transporting, sudden increases in demand for products, inadequate funding and staffing as well as exploitation of national goods (Ketikidis et al., 2006; Berger et al., 2007; Harries et al., 2007; Schouten et al., 2011; Bateman, 2013; Hasselback et al., 2014; Wagenaar et al., 2014; Stop Stock Outs Group, 2015).

12.6 PROCUREMENT AND SELECTION

It is recommended that the selection and procurement of medicines in countries and health facilities be based on an Essential Medicines List (EML) in order to ensure that the most basic medicines are available for use by the population (World Health Organisation, 2017). The WHO encourages that this list be reviewed by Pharmaceutics and Therapeutics Committees (PTCs) to ensure that the medicines included on the list are those that will satisfy the needs of most of the population (World Health Organisation, 2017). In many countries, a standard EML will exist and can be used by health facilities to draw up their own list which they would have personalised according to the health needs of the population they serve.

The methods used for procurement differ from country to country. Procurement includes the ways in which suppliers of the selected medicines are chosen (World Health Organisation, 2017). It is essential for health systems to have a set method or system for selecting suppliers which would include how the suppliers are pre-qualified, the establishment of the contract terms between the health system providers and the suppliers as well as managing tenders (Lufesi, Andrew & Aursnes, 2007).

Open tender systems are widely used to procure medicines as they may be beneficial in terms of costs however it is advised that they be avoided or considered together with other strategies because they may result in unforeseen delays that governments have little control over (Kangwana et al., 2009). The prices of medicines may influence the procurement and selection phase of the supply chain as health systems endeavour to make cost-effective decisions as well as to make sure that the medicines remain affordable to the end user especially in the cases where the patients have to pay for their own medicines (Kangwana et al., 2009).

Health financing, also considered one of the elements of the health system has a role to play in the supply of medicines and it is vital for the source of funds that is used to pay for medicines needs to be one that is reliable and sustainable (Pasquet et al., 2010). The reliance of programmes such as malaria programmes on donor funding to purchase medicines can be problematic as this funding is not always a reliable and sustainable source of revenue (Pasquet et al., 2010; Mikkelsen-Lopez et al., 2014). Where governments are not prepared for cases of donors withdrawing funds, stock outs have occurred and it is advised that governments ensure that buffer stock is always available especially for essential medicines for such unforeseen circumstances (Harries et al., 2007; Pasquet et al., 2010; Mikkelsen-Lopez et al., 2014). To ensure that medicine shortages do not occur, accurate quantification of the required medicines is needed and this should be based on past consumption data as well as using the right procurement methods which may be a mix of more than one method (World Health Organisation, 2017).

12.7 FORECASTING

Forecasting in medicine supply systems refers to the techniques that are used to ensure that a facility has enough stock to meet the potential demand for those particular medicines in a specified period of time (USAID: Deliver Project, 2011). If a structured system for forecasting exists, the occurrence of stock outs and shortages is likely to be reduced (Harries et al., 2007). It has been reported that in many cases it is the methods used to forecast or lack thereof by facilities that results in medicine shortages and stock outs occurring (Lufesi, Andrew & Aursnes, 2007; Bigdeli et al., 2014). The Practical Guide for the Supply Chain Management of Health Commodities recommends that the methods used when forecasting be based on past consumption data reflecting on the burden of disease in the area however this data must be reviewed from time to time as some diseases may be seasonal (USAID: Deliver Project, 2011). The constant reviewing of consumption data would ensure that the quantities ordered are always up-to date.

In order to store consumption data over long periods of time, it was found in a study on scaling up ART by Barrington, Wereko-Brobby et al (2010) to be beneficial for the health facility to have a good information system in place. The facilities that did not have information systems that were computerized struggled with forecasting accurately for the patients who needed ART and thus experienced shortages more often (Barrington et al., 2010). Information systems refer to the technologies that may be utilised by health facility staff when managing the levels of medicine stock as well as sharing of information related to medicine stock management (Barrington et al., 2010; USAID: Deliver Project, 2011). These may be electronic or paper based which require different levels of skill and expertise to use them well (USAID: Deliver Project, 2011).

Non-existent or poor stock control including poor forecasting are the major causes of stock outs and shortages reported in literature at the health facility level when stock is available at the central or depot level (Barrington et al., 2010). In a study by Lufesi et. al (2007) in Malawi, some discrepancies were found between the reported stock levels and actual stock on hand at health facilities implying that the health workers were not following protocols on the medicine stock management. It was suggested that this non-compliance could have been because of lack of training and supervision from seniors such as district pharmacists (Lufesi, Andrew & Aursnes, 2007). The management of medicines supply is essential for the provision of health care and even more important in lower income countries where resources are scarce as it has also been reported that one of the major areas of wastage in the health system occurs in the use of medicines (World Health Organization, 2010; Schouten et al., 2011)

12.8 STORAGE OF MEDICINES

Storage in medicine supply systems involves ensuring that the medicines are kept safely and not damaged and this could be at any point in the medicine supply cycle (USAID: Deliver Project, 2011; World Health Organisation, 2017). If medicines are damaged or stolen, this could result in medicine shortages or stock outs occurring at the health facilities as damaged medicines would not be suitable for use (Lufesi, Andrew & Aursnes, 2007).

It is very important that medicines are stored in adequate quantities in order to ensure that the facilities are able to meet the demand and it has been recommended that health facilities also keep “buffer stock” also referred to as “safety stock” at all times as this is one way of preventing medicine shortages (World

Health Organization, 2010; Schouten et al., 2011). In some cases, the health workers at facilities are unable to comply with the recommended guidelines for ordering stock in terms of ordering sufficient quantities of medicines because the capacity of the health facilities themselves is insufficient (World Health Organization, 2010; Schouten et al., 2011). Bulk storage areas would be ideal for keeping this excess stock however the infrastructure at some facilities may not allow for this (Schouten et al., 2011).

12.9 DISTRIBUTION OF MEDICINES

Distribution of medicines refers to the flow of medicines from the warehouse or central store which is the higher level that is responsible for supplying medicines to the facilities where they will be ultimately dispensed to patients (USAID: Deliver Project, 2011). This would include the systems used by the health facilities to order their medicines as well as the transportation of the medicines from the central store to the health facilities (World Health Organisation, 2017). There are two main types of distribution systems which are the push and the pull systems and these can be differentiated by who decides on the quantity of stock to be supplied to the health facility (USAID: Deliver Project, 2011).

The push system also referred to as the ‘‘allocation’’ systems in some literature is whereby the medicine stock is pushed from the higher-level facility such as the central store and they decide on the quantities to be supplied to the lower level facilities i.e. the health facilities such as clinics or hospitals (USAID: Deliver Project, 2011; World Health Organisation, 2017). This means that the higher level would need to calculate quantities for orders from all the facilities and this would be challenging in the larger health systems as it is time consuming (USAID: Deliver Project, 2011). This system is mostly used when new programmes are being initiated or when donors supply stock to health facilities at the lower levels and it does not always take into consideration consumption data on the products supplied (World Health Organisation, 2017). The reasons why consumption data may not be used in deciding on the quantities could be because it is unavailable for example if it is a new program it may not be known how many people will require that medicine if no prior research has been done (World Health Organisation, 2017). It has been reported in the literature especially in the lower income countries that there may not always be information systems that link the lower level to the higher level facilities allowing both levels to view the amount of stock available at the facilities (Harries et al., 2007; Barrington et al., 2010; Schouten et al., 2011; Githinji et al., 2013). This information on stock levels would particularly be useful where the push systems are utilised more than the pull systems as the higher level could then

come up with more accurate quantities of stock to supply to the lower level facilities (USAID: Deliver Project, 2011).

As it is advisable to base quantities for re-supply on consumption data and current stock levels, it may be argued that the pull system also known as the 'requisition' system would be a much better one to use as the lower level facility is the one that decides on the quantity of medicine to be supplied to them (USAID: Deliver Project, 2011). However, this would imply that the health workers at the lower level facilities are skilled and have the time to carry out the necessary calculations to derive the most accurate quantities and it is well known that the health workforce is currently facing a human resource crisis with not enough health workers to serve the populations and this is particularly a problem in the lower income countries (Hongoro & McPake, 2004; USAID: Deliver Project, 2011; World Health Organisation, 2017). In order to bypass the weaknesses and benefit from the strengths in both systems, most health systems use a mix of these systems (Barrington et al., 2010; USAID: Deliver Project, 2011).

Transportation of medicines would also be considered as part of the distribution of medicines and it has been reported that this too may influence the occurrence of medicine shortages as well (World Health Organisation, 2017). In some countries, the health facility itself is responsible for arranging for the transportation of medicines to the facility and this may be a challenge for health facilities that do not have sufficient resources such as drivers and vehicles to collect the medicines from the central store (Hasselback et al., 2014; World Health Organisation, 2017). In these cases, it may be beneficial if the central warehouse transports medicines to the facilities as it is done in other countries however this too may come with challenges which are inevitable due to the inaccessibility of health facilities (Hasselback et al., 2014).

It has been reported that medicine stock outs and shortages are worse in rural areas where there may be transportation and accessibility challenges (Bateman, 2013; Hasselback et al., 2014). A study in Mozambique reported that the further away facilities were from the depots, stock outs occurred more frequently (Hasselback et.al. 2014). This may have been due to difficulties faced by the depots in transporting medicines and accessing the health facilities by road in the more rural areas (Lufesi, Andrew & Aursnes, 2007).

12.10 OTHER GENERAL CAUSES OF MEDICINE SHORTAGES AND STOCK OUTS

Ensuring medicines availability is an important goal for health systems as medicines are an important building block in the health system (Bigdeli et al., 2014). Some of the factors influencing the occurrence of stock outs at the health facility level stem from the way in which medicine stock is managed at health facilities and could be as a result of the inventory control methods used, information and reporting systems used, capacity of the health facilities as well as health workers and communication between key actors in the processes (Harries et al., 2007; Lufesi, Andrew & Aursnes, 2007; Barrington et al., 2010; Githinji et al., 2013).

Literature suggests that information systems may also facilitate efficient communication between various stakeholders involved in the processes of medicine stock management (Githinji et al., 2013). Communication refers to the sharing of information and in the case of medicine stock management, this information relates to medicine stock (Barrington et al., 2007). The information shared between a health facility and the supplier of medicines may include the medicines available for order such that when placing an order, the health facility may make an informed decision on which medicines and quantities of medicines to be ordered for the facility (USAID: Deliver Project, 2011). When the supplier fulfils an order, it would also be beneficial for them to have access to information on what stock is available at the health facility so that they too can make an informed decision on how much to supply them with (USAID: Deliver Project, 2011). This sharing of information on stock levels would eliminate possible cases of stock outs occurring due to stock being under-supplied to the facility (USAID: Deliver Project, 2011). Studies found that where communication between stake holders involved in medicine stock management was efficient, less stock outs occurred (Berger et al., 2007). Strategies to mitigate medicine stock outs in various countries have been moving away from the conventional paper based methods of communication to include on-line and electronic information sharing systems which allow access to real-time information (Berger et al., 2007; Barrington et al., 2010).

Communication with other stakeholders as well as the use of information systems which may be electronic may be related to the capacity of the health workers required to use these information systems (Lufesi, Andrew & Aursnes, 2007). These systems may require certain skills for example if the system is computer based, the ability to use a computer would be essential (USAID: Deliver Project, 2011). The capacity of health workers refers to the extent to which the health workers are qualified and able to manage medicine stock which would include using the resources available to them (Lufesi, Andrew & Aursnes, 2007). The health facility itself, in some cases may limit the health workers if it does not have adequate resources (Lufesi, Andrew & Aursnes, 2007). This speaks to the capacity of the health facility

and includes having adequate human resources as much as physical resources required for the management of medicine stock (Lufesi, Andrew & Aursnes, 2007).

In the medicine stock management at the clinic level, contextual factors which may influence the process include the geographic location of the clinic, the district as well as provincial management teams, and the disease burden in the district or area served by the clinic (Lufesi, Andrew & Aursnes, 2007; USAID: Deliver Project, 2011; Hasselback et al., 2014). Contextual factors may also influence the actors affecting the way they carry out their roles. These actors include the district pharmacists and the provincial head of pharmaceutical services.

The geographic location of health facilities may influence medicine stock management in several ways (Hasselback et al., 2014). The location may affect the communication processes between actors and the delivery of medicines from the pharmaceutical depot. It has been reported that medicine stock outs and shortages are worse in rural areas where there may be transportation and accessibility challenges (Bateman, 2013; Hasselback et al., 2014). A study in Mozambique by Hasselback et. al (2014) reported that the further away facilities were from the depots, stock outs occurred more frequently. This may have been due to difficulties faced by the depots in transporting medicines and accessing the health facilities by road in the more rural areas (Lufesi, Andrew & Aursnes, 2007).

The geographic location may also have an influence on the health workers that are employed at the facilities. Studies have found that health workers are motivated to work in urban rather than rural areas therefore the calibre and capacity of workers found in a health facility may be influenced by the context in which the facility is found (Lufesi, Andrew & Aursnes, 2007). The capacity of the health workers in that region which in-turn influences their ability to follow protocols in inventory control and their ability to use information and reporting systems (Lufesi, Andrew & Aursnes, 2007). facilities by road in the more rural areas (Lufesi, Andrew & Aursnes, 2007).

The causes of medicine stock outs as we have seen can be at various levels within the supply chain even though the impact of stock outs is mostly crucial at the health facility level (Bateman, 2013; Hensen et al., 2011). As the pharmaceutical supply chain is a complex process, there may also be many inter-linkages (Hensen et al., 2011). When addresses the causes of medicine stock outs, it is vital for policy makers to address those causes specific to health facilities such as hospitals and clinics as it would be

of no use if medicines were available from manufacturers as well as warehouses but there were factors at the health facility level which resulted in inefficient medicines supply (Hensen et al., 2011).

12.11 STRATEGIES TO ENSURE UNINTERRUPTED AVAILABILITY OF MEDICINES

Studies have reported different ways of handling medicine stock in case where there are known shortages in order for it to last longer and it has been acknowledged that in order to handle medicine shortages well, healthcare providers need to ensure that they have systematic processes of how to handle shortages and these ways can be in the form of standard operating guidelines or procedures (Kaur et al., 2013; McKeever, Bloch & Bratic, 2013). Just like other resources in healthcare facilities, the rational use of medicines is advised regardless of whether there is a chance that stock outs of that particular medicine may occur. However, when stock is limited, it is even more important to ensure that the limited stock available is utilised in the best possible way and this is commonly referred to as rationing (USAID: Deliver Project, 2011). Rationing of medicine stock may be initiated at the higher level facilities such as the medicine store when they are aware of the medicine shortage or at the lower level health facilities when they have insufficient stock to provide to all their patients (USAID: Deliver Project, 2011; Kaur et al., 2013).

A case study on a hospital in Massachusetts's response to a global shortage of amino acids revealed that when the health workers were aware of the shortages, they began to use the available stock of amino acids sparingly when preparing total parenteral nutrition (TPN) (Kaur et al., 2013). The hospital also then limited the number of people who were handling orders for TPN to the clinical pharmacist and dietician to ensure that there are people who can be held accountable for managing the stock and ensuring that the patients who needed TPN the most were able to get it (Kaur et al., 2013). This case study allowed in-depth exploration of what measures the hospital took and even though the study was only carried out in one place, its findings are recommendable to health facilities (Kaur et al., 2013). Another study on drug shortages in cancer treatment suggests prioritization of patients when there are shortages which can also be considered as rational use of the available resources (McKeever, Bloch & Bratic, 2013). It is recommended that a list of criteria be drawn up considering various things that will enable an independent committee to choose which patients should receive the treatment when it is not adequate for all the patients (McKeever, Bloch & Bratic, 2013; McBride et al., 2013).

As technology advances in Africa, some countries have taken advantage of this and upgraded their medicine management systems from paper based to computer and web-based systems as a measure of mitigating medicines unavailability (Berger et al., 2007; Githinji et al., 2013). The successful implementation of web-based systems has solved the problem in Haiti where obstacles existed with the paper based systems (Berger et al., 2007). This system facilitated communication which is vital for the management of stock levels between stakeholders involved in the processes (Berger et al., 2007). In South Africa, a software programme, Rx solution® has been introduced in some public health facilities to support the regulation of stock control in public health facilities (Health Systems Trust, 2015b; Management Science for Health, 2016, July 16). This programme allows the monitoring, tracking, and ordering of medicine stock as well as movement of stock among health facilities on a computer (Management Science for Health, 2016). Inventory control systems that are well established will help health facilities to ensure that stock outs do not occur as the system will inform them when to order and what quantities to order (USAID: Deliver Project, 2011). The major advantage of these computer based systems is that they are able to generate re-order quantities for the health workers relieving them of the task of doing this for themselves manually (USAID: Deliver Project, 2011). It is also important for these systems to be linked to the higher levels so that the information on medicines availability is available to all the stakeholders involved in the processes of medicine stock management (USAID: Deliver Project, 2011).

There have been some strategies that have been employed in order to improve the reporting of medicine availability by lower level facilities to the higher-level facilities who supply them with stock. In Kenya, an SMS *for life* was implemented for anti-malarial medicines and it also solved the problems of unavailability of rapid diagnostic tests and anti-malarial medicines by enhancing stock visibility (Githinji et al., 2013). With this system, health workers at clinics used their personal cell phone devices to send the weekly facility stock levels via SMS to a central data base which was accessible to those at the higher level such as the district managers (Githinji et al., 2013). The study found that this intervention improved the rate of reporting of the clinics and as a result the district managers could intervene on medicine shortages once identified on the central database by arranging that clinics which had more stock than they needed shared it with those with a shortage and this reduced the occurrence of stock outs (Githinji et al., 2013). This SMS *for life* project is similar to the Stock Visibility Solution (SVS) that has been implemented in 3126 clinics in South Africa by July 2015 also with the hope of improving the reporting of medicine stock levels in a bid to reduce stock outs (Chowles, 2016, July 15).

SVS also uses cell phones to scan barcodes of medicines that are rare available at the health facility and will generate alerts when stock is too high or too low to both the health facility and those with access

to the central database where the information is loaded such as the district managers (Chowles, 2016, July 15). As the programme has only been recently implemented, there has not yet been any published research on how effective it has been in improving the availability of medicines. Another programme that has been implemented in South Africa to address the issues of drug stock outs particularly for chronic diseases is the Central Chronic Medicine Dispensing and Distribution Programme (CCMDD) (Health Systems Trust, 2015a). The aim of this programme was to reduce the burden on PHC clinics and increase the availability of medicines for chronic conditions which are becoming more prevalent in South Africa (Health Systems Trust, 2015a).

12.12 DRUG SUPPLY MANAGEMENT AT HEALTH FACILITIES AND MEDICINES AVAILABILITY

Medicines supply management in health systems occurs at more than one level and the factors that influence this at the health facility level may not always stem from the health facility itself. However, studies have reported that some health facilities may have medicine shortages even though the stock is available at the central level which supplies them with medicines. There is a lack of research that has been carried out at health facility levels such as PHC clinics exploring the processes at the facility and how these may be linked to the occurrence of medicine stock outs levels especially in the lower income settings (Hasselback et al., 2014). The absence of medicines stock outs at these levels should be prioritised in many countries like South Africa where the majority of the population relies on the public sector for health services, these PHC clinics are usually the entry point for citizens into the healthcare system (Bigdeli et al., 2014).

The factors that contribute the most to the occurrence of stock outs of medicines at the facility level include inadequate health workforce particularly pharmacy personnel, poor medicine stock management, and inefficient communication between suppliers, depots and health facilities (Bateman, 2013). The inefficient communication between actors involved in medicine supply at the facilities is also a problem that has been reported (Bateman, 2013; Stop Stock Outs Group, 2015).

12.13 OVERVIEW OF THE AVAILABILITY OF MEDICINES IN SOUTH AFRICA

The health system in South Africa like many other developing countries, consists of two sectors which are the private health sector and the public health care sector. The public health care sector in South Africa is administered by the South African government as it is state funded and it caters for

approximately 70% of the country's population (McIntyre et al., 2009; Public Service Commission, 2015). The public sector therefore carries the major burden of disease which in turn largely consists of the management and treatment of HIV and TB (Stop Stock Outs Group, 2015). Within the public health system, PHC clinics are the foundation and entry point of many into the health care system ((Bigdeli et al., 2014; Public Service Commission, 2015). For treatment that is more sophisticated, patients are referred to district hospitals. Above the district hospital, tertiary and academic hospitals provide advanced health care procedures and treatment (Public Service Commission, 2015). As the PHC clinics are the entry point into the health system, it goes without saying that they need to be made a priority within the health system as in some cases, if patients are satisfactorily treated at this level, they will not require more advanced treatment at the hospital level.

Section 27 of the South African constitution states that citizens have the right to access health care therefore it is essential to consider aspects such as the availability of medicines that have a direct impact on access to health care (Stop Stock Outs Group, 2015). In South Africa, surveys have revealed the extent of drug stock outs and perceived causes of stock outs by health workers (Stop Stock Outs Group, 2014; Stop Stock Outs Group, 2015; Public Service Commission, 2015). From these reports, it is suggested that one of the reasons why essential medicine stock outs and shortages occur at the PHC level is because of the fore-casting and poor medicine stock management by health workers at the clinics (Stop Stock Outs Group, 2015).

The factors that contribute the most to the occurrence of stock outs of medicines in South Africa include an inadequate health workforce particularly pharmacy personnel, poor medicine stock management, and inefficient communication between suppliers, depots and health facilities (Bateman, 2013). The inefficient communication between the depot and health facilities is a problem because in some cases the clinics do not warn the depot well in advance that they will require larger quantities of stock than the usual quantity and thus the depot is unprepared and unable to meet their needs (Bateman, 2013; Stop Stock Outs Group, 2015). Each public health facility including the PHC clinics are required to sign a 'terms of agreement' contract with the pharmaceutical depot which outlines the way in which the two parties interact in terms of the ordering and supply of medicines (Bateman, 2013). The pharmaceutical depot, located in each of the nine provinces in South Africa is responsible for supplying medicines to all the public health facilities in that province (Bateman, 2013). However, the interactions between the depot and health facilities does not always follow the recommendations made in this contract and this negatively affects medicine stock management at the facilities and leads to stock outs of medicines (Bateman, 2013).

In light of the evidence of poor medicine stock management of essential medicines in the public health facilities and frequent problems of drug stock-outs or shortages in South Africa, the search for an effective management system is a priority for the current government (Public Service Commission,

2015). A Discrete Choice Experiment on improving the public health sector in South Africa also revealed that the availability of medicines at health facilities has the greatest impact in the probability that people will attend public health facilities (Honda et al., 2015). South Africa is moving towards implementing the National Health Insurance (NHI) in the coming years as a bid to move towards achieving UHC. The white paper released mentions the need to address the quality of healthcare of which availability of medicines is one of the areas that need attention. Access to medicine needs to be improved especially in the Primary Health Care (PHC) clinics which are usually the entry point for citizens into the healthcare system for successful implementation of the NHI.

12.14 METHODS USED IN RESEARCH ON MEDICINE STOCK OUTS

Of all the articles that were reviewed, one was a systematic literature review and it focused on assessing the evidence to which health care providers, particularly clinicians changed the ways in which they prescribed medicines when certain medicines were out of stock (Hensen et al., 2011). This is one of the commonly cited impacts of medicine shortages and stock outs to the health care worker. There were no other systematic reviews on medicine shortages and stock outs or the factors influencing them which is a disadvantage since systematic reviews are rich sources of literature in that they combine findings from more than one study on a particular subject (Green & Thorogood, 2014). From the literature searches conducted, there was a lack of theoretical frameworks that could be used in this study hence the literature review included mostly empirical evidence.

Most of the studies in the literature reviewed employed mixed methods to answer their research questions and this is advantageous as a way of increasing rigour (Green & Thorogood, 2014). Validating responses can be done by using mixed methods, for example using qualitative methods in order to come up with the questionnaires or the use of focus group discussions (FGDs) in addition to quantitative methods (de Bekker-Grob, Ryan & Gerard, 2012). The causes of medicines availability are best described in a qualitative way therefore it makes sense that most of the studies had a qualitative component in them. Qualitative studies allow for in-depth analyses of phenomena in research which is beneficial when trying to determine the causes of medicines unavailability.

Some of the articles were cross sectional surveys and these have been critiqued for their lack of ability to analyse trends that take place over time which may be useful when considering the causes of medicines unavailability (Green & Thorogood, 2014). This is because these factors are often complex and may not occur at one specific point in time. Another short-coming is that some of the impacts of medicines unavailability may be felt after a long period of time long after the shortage occurred for example. However, cross-sectional studies are still useful and suitable when considering issues in availability of medicines such as the extent of medicines shortages as this can be measured in a specific

period (Green & Thorogood, 2014). They also allow for the exploration of aspects which may lead to further research (Green & Thorogood, 2014). Table 1 summarises the articles reviewed.

Conclusion

A considerable amount of research has been conducted in the area of medicines availability particularly to determine what the likely causes of unavailability are. It is known that the causes of medicines unavailability are mostly embedded in the medicine supply systems, particularly in the procurement and distribution of medicines (Pecoul et al., 1999; Bateman, 2013). The complexity of the processes involved and the involvement of many stakeholders has been reported as having a major influence on the occurrence of medicine shortages and stock outs resulting in medicines being unavailable for patient use (Lufesi, Andrew & Aursnes, 2007). Whilst a lot of the research conducted has focused on the factors that may influence the availability of medicine on a larger scale or at higher levels in the medicines supply chain such as wholesalers and manufacturers, few studies have focused on the lower levels where medicines are physically dispensed to the patient. Non-existent or poor stock control including poor forecasting are the major causes of stock outs and shortages reported in literature at the health facility level when stock is available at the central or depot level and it is very important to continually assess and improve medicine stock management at the health facility level to ensure uninterrupted access to medicines for patients that visit these facilities (Lufesi, Andrew & Aursnes, 2007). This study aims to examine the processes in medicine stock management at PHC facilities to better understand the causes of medicines unavailability at this level.

Table 1: Summary of Articles

Author	Methods	Study Focus and country
1. Ankomah, J. et al, (2015)	Mixed methods, qualitative and quantitative aspects, a strength of this study was that it used different sources of data which were triangulated and this increases rigor.	The causes of unavailability of products in Ghana.
2. Barrington, J et al. (2010)	Pilot study; cross-sectional, mixed methods.	Drug supply management using standard technology in Tanzania.
3. Berger E.J. Et al. (2007)	Qualitative, descriptive.	Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti.
4. Fox, E.R and Tyler, L.S (2003)	Qualitative and descriptive study	Tracking drug shortages and causes in the USA.
5. Githinji, S. et al. (2013)	Cross-sectional evaluation, mixed methods.	This study evaluated whether the SMS based reporting of stock of antimalarial diagnostic tests and medicines resulted in a reduction of stock outs in Kenya.
6. Harding, R. eta al. (2014)	Cross sectional quantitative survey. Used onsite verification via unannounced visits-strength of methods; reliability of data.	Availability of essential drugs for managing HIV-related pain and symptoms in Kenya and Uganda.
7. Harries, et al. (2007)	Descriptive, case study.	Improving procurement and distribution practices of medicines in Malawi.
8. Hasselback, L. et al. (2014)	Cross-sectional survey, mixed methods; case study with quantitative aspects.	Causes of stock outs of Malaria diagnostic tests in Mozambique.
9. Henson, B. et al. (2011)	Systematic literature review	The aim of this review was to assess the evidence on the extent to which prescribing patterns of providers for

		malaria patients differed in the presence and absence of stock.
10. Kaakeh, R., (2011)	Online survey for pharmacists. One weakness is that it used retrospective data based on recall of the participants.	Impact of drug shortages and quantifying human resources required to manage shortages in the USA.
11. Kangwana, B.B., et al. (2009)	Cross-sectional survey. Mixed methods.	Malaria drug shortages in Kenya as a barrier to provide access to effective treatment.
12. Lufesi, N.N.et al. (2007)	Cross-sectional quantitative and retrospective qualitative study	Impact of deficient supplies of drugs for life threatening diseases in Malawi.
13. McBride, A. et al. (2013)	Survey, cross sectional, qualitative	The impact of oncology drug shortages.
14. McKeever, A.E. et al. (2013)	Report	Impact of drug shortages in cancer patients in the USA.
15. Mikkelsen-Lopez, I. et al (2014)	Cross-sectional, quantitative	The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners in Tanzania
16. Holm MR, Rudis MI, Wilson JW. (2015)	Mixed methods	Medication supply chain management through implementation of a hospital pharmacy computerized inventory program in Haiti.
17. Pasquet, A., et al. (2010)	Quantitative cohort study.	Frequency and impact of stock outs of cART in Cote D'Ivoire.
18. Jatau B, et al. (2015)	Cross-sectional evaluation, descriptive	Evaluation of Procurement and Supply Management System for MDR-TB in Nigeria.

19. Schouten, E.J., et al. (2011)	Report	Antiretroviral drug supply challenges in the era of scaling up ART in Malawi.
20. Muhamadi L, et al. (2011)	Case control	Causes of late ART initiation in Uganda.
21. Dorsey ER, et al. (2009)	Quantitative	Selegiline Causes and costs of a generic drug (Selegiline) shortage in the USA.
22. Griffith MM, et al. (2013)	Review article	Managing antimicrobial drug shortages in hospitals in the USA.
23. Windisch R, et al. (2011)	Mixed methods, largely qualitative used grounded theory approach, triangulation of data.	Supply chain management of ART in Uganda and its relation to health systems
24. Mitka, M. (2011)	Report	FDA, US hospital and pharmacy groups report drug shortages a growing problem.
25. McLaughlin MM, et al.	Observational, cross-sectional	Projections for anti-infective drug shortages and time to actual resolution in the USA.
26. Mayimele N et al. 2015	Qualitative, exploratory and descriptive	The role of pharmacists in medicine management at hospital ward level in South Africa.
27. Penfold S, et al. 2013	Mixed methods, cross-sectional survey used Focus Group Discussions (FGDs) and in-depth Interviews (IDIs) with health workers. Member-checking used to increase rigour.	Staff experiences on the impact of equipment and drug supply issues on the provision of maternity services in rural southern Tanzania.
28. Magadzire, B.P. et al. 2014	Cross-sectional, qualitative study, semi-structured interviews.	The perceptions of health workers on how to improve access to essential medicines in South Africa.

13 References

Ankomah, J., Stewart, B.T., Oppong-Nketia, V., Koranteng, A., Gyedu, A., Quansah, R., Donkor, P., Abantanga, F. et al. 2015. Strategic assessment of the availability of pediatric trauma care equipment, technology and supplies in Ghana. *Journal of Pediatric Surgery*. 50(11):1922-1927. DOI:10.1016/j.jpedsurg.2015.03.047 [doi].

Barrington, J., Wereko-Brobby, O., Ward, P., Mwafongo, W. & Kungulwe, S. 2010. SMS for Life: a pilot project to improve anti-malarial drug supply management in rural Tanzania using standard technology. *Malar J*. 9(298):1-9.

Bateman, C. 2013. Drug stock-outs: Inept supply-chain management and corruption. *SAMJ: South African Medical Journal*. 103(9):600-602.

Berger, E.J., Jazayeri, D., Sauveur, M., Manasse, J.J., Plancher, I., Fiefe, M., Laurat, G., Joseph, S. et al. 2007. Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti. *AMIA Annual Symposium Proceedings*. American Medical Informatics Association. 46.

Bigdeli, M., Peters, D.H., Wagner, A.K. & World Health Organization 2014. Medicines in health systems: advancing access, affordability and appropriate use.

Cameron, A., Roubos, I., Ewen, M., Mantel-Teeuwisse, A.K., Leufkens, H.G. & Laing, R.O. 2011. Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. *Bulletin of the World Health Organization*. 89(6):412-421.

Chowles, T. 2016, July 15. *NDoH Deploys SVS mHealth App to Prevent Stock-outs-eHealth News ZA*. Available: <http://ehealthnews.co.za/ndoh-svs-mhealth-stock-outs/> [2017,February 20].

de Bekker-Grob, E.W., Ryan, M. & Gerard, K. 2012. Discrete choice experiments in health economics: a review of the literature. *Health Economics*. 21(2):145-172. DOI:10.1002/hec.1697.

Fox, E.R. & Tyler, L.S. 2003. Managing drug shortages: Seven years' experience at one health system. *American Journal of Health-System Pharmacy*. 60(3):245-245.

Githinji, S., Kigen, S., Memusi, D., Nyandigisi, A., Mbithi, A.M., Wamari, A., Muturi, A.N., Jagoe, G. et al. 2013. Reducing stock-outs of life saving malaria commodities using mobile phone text-messaging: SMS for life study in Kenya. *PLoS One*. 8(1):e54066.

Green, J. & Thorogood, N. 2014. *Qualitative methods for health research*. Third ed. London: SAGE.

Harding, R., Simms, V., Penfold, S., Downing, J., Powell, R.A., Mwangi-Powell, F., Namisango, E., Moreland, S. et al. 2014. Availability of essential drugs for managing HIV-related pain and symptoms within 120 PEPFAR-funded health facilities in East Africa: a cross-sectional survey with onsite verification. *Palliative Medicine*. 28(4):293-301. DOI:10.1177/0269216313498637 [doi].

Harries, A.D., Schouten, E.J., Makombe, S.D., Libamba, E., Neufville, H.N., Some, E., Kadewere, G. & Lungu, D. 2007. Ensuring uninterrupted supplies of antiretroviral drugs in resource-poor settings: an example from Malawi. *Bulletin of the World Health Organization*. 85(2):152-155.

Hasselback, L., Crawford, J., Chaluco, T., Rajagopal, S., Prosser, W. & Watson, N. 2014. Rapid diagnostic test supply chain and consumption study in Cabo Delgado, Mozambique: estimating stock shortages and identifying drivers of stock-outs. *Malaria Journal*. 13(1):1-10.

Health Systems Trust 2015a. *Central Chronic Medicine Dispensing and Distribution Programme (CCMDD)*. Available: <http://www.hst.org.za/projects/central-chronic-medicine-dispensing-and-distribution-programme-ccmdd> [2015, November 10].

Health Systems Trust 2015b. *Current Projects: Rx Solution*. Available: <http://www.hst.org.za/projects/rx-solution>.

Hensen, B., Paintain, L.S., Shretta, R., Bruce, J., Jones, C. & Webster, J. 2011. Taking stock: provider prescribing practices in the presence and absence of ACT stock. *Malar J*. 10(218):10.1186.

Honda, A., Ryan, M., van Niekerk, R. & McIntyre, D. 2015. Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment. *Health Policy and Planning*. 30(5):600-611. DOI:10.1093/heapol/czu038 [doi].

Hongoro, C. & McPake, B. 2004. How to bridge the gap in human resources for health. *The Lancet*. 364(9443):1451-1456. DOI:[http://dx.doi.org/10.1016/S0140-6736\(04\)17229-2](http://dx.doi.org/10.1016/S0140-6736(04)17229-2).

Kaakeh, R., Sweet, B.V., Reilly, C., Bush, C., DeLoach, S., Higgins, B., Clark, A.M. & Stevenson, J. 2011. Impact of drug shortages on US health systems. *American Journal of Health-System Pharmacy*. 68(19):1811.

Kangwana, B.B., Njogu, J., Wasunna, B., Kedenge, S.V., Memusi, D.N., Goodman, C.A., Zurovac, D. & Snow, R.W. 2009. Malaria drug shortages in Kenya: a major failure to provide access to effective treatment. *The American Journal of Tropical Medicine and Hygiene*. 80(5):737-738. DOI:80/5/737 [pii].

Kaur, K., O'connor, A.H., Illig, S.M. & Kopcza, K.B. 2013. Drug shortages as an impetus to improve parenteral nutrition practices. *American Journal of Health-System Pharmacy*. 70(17):1533-1537. DOI:10.2146/ajhp120785.

Ketikidis, P.H., Lenny Koh, S., Gunasekaran, A. & Pibernik, R. 2006. Managing stock-outs effectively with order fulfilment systems. *Journal of Manufacturing Technology Management*. 17(6):721-736.

Lufesi, N.N., Andrew, M. & Aursnes, I. 2007. Deficient supplies of drugs for life threatening diseases in an African community. *BMC Health Services Research*. 7:86. DOI:1472-6963-7-86 [pii].

Magadzire, B.P., Budden, A., Ward, K., Jeffery, R. & Sanders, D. 2014. Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa. *BMC Health Services Research*. 14(1):520.

Management Science for Health (msh) 2016, July 16. Management Sciences for Health Hands over electronic Pharmaceutical Management System to South African Government-Management Science for Health . Available: <http://www.msh.org/news-events/press-room/management-sciences-for-health-hands-over-electronic-pharmaceutical> [2017, February 20].

Mayosi, B.M., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. & Bradshaw, D. 2009. The burden of non-communicable diseases in South Africa. *The Lancet*. 374(9693):934-947.

Mcbride, A., Holle, L.M., Westendorf, C., Sidebottom, M., Griffith, N., Muller, R.J. & Hoffman, J.M. 2013. National survey on the effect of oncology drug shortages on cancer care. *American Journal of Health-System Pharmacy*. 70(7):609-617. DOI:10.2146/ajhp120563.

McIntyre, D., Thiede, M. & Birch, S. 2009. Access as a policy-relevant concept in low-and middle-income countries. *Health Economics, Policy and Law*. 4(02):179-193.

McKeever, A.E., Bloch, J.R. & Bratic, A. 2013. Drug Shortages and the Burden of Access to Care: A Critical Issue Affecting Patients With Cancer. *Clinical Journal of Oncology Nursing*. 17(5):490-495. DOI:10.1188/13.CJON.490-495.

Mikkelsen-Lopez, I., Shango, W., Barrington, J., Ziegler, R., Smith, T. & deSavigny, D. 2014. The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners: the case of Tanzania. *Malaria Journal*. 13:181-2875-13-181. DOI:10.1186/1475-2875-13-181 [doi].

Mitka, M. 2011. FDA, US hospital and pharmacy groups report drug shortages a growing problem. *JAMA: Journal of the American Medical Association*. 306(10):1069-1070. DOI:10.1001/jama.2011.1238.

Pasquet, A., Messou, E., Gabillard, D., Minga, A., Depoulosky, A., Deuffic-Burban, S., Losina, E., Freedberg, K.A. et al. 2010. Impact of drug stock-outs on death and retention to care among HIV-infected patients on combination antiretroviral therapy in Abidjan, Côte d'Ivoire. *PloS One*. 5(10):e13414.

Pecoul, B., Chirac, P., Trouiller, P. & Pinel, J. 1999. Access to essential drugs in poor countries: a lost battle? *Jama*. 281(4):361-367.

Penfold, S., Shamba, D., Hanson, C., Jaribu, J., Manzi, F., Marchant, T., Tanner, M., Ramsey, K. et al. 2013. Staff experiences of providing maternity services in rural southern Tanzania - a focus on equipment, drug and supply issues. *BMC Health Services Research*. 13:61-6963-13-61. DOI:10.1186/1472-6963-13-61 [doi].

Public Service Commission 2015. Consolidated report on service delivery inspections of district hospitals and clinics regarding availability of medicines and medical equipment and the role of health district offices. Public Service Commission.

Schouten, E.J., Jahn, A., Ben-Smith, A., Makombe, S.D., Harries, A.D., Aboagye-Nyame, F. & Chimbwandira, F. 2011. Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. *Journal of the International AIDS Society*. 14 Suppl 1:S4-2652-14-S1-S4. DOI:10.1186/1758-2652-14-S1-S4 [doi].

Stop Stock Outs Group 2014. Stop Stock Outs Report 2013 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

Stop Stock Outs Group 2015. Stop Stock Outs Reprt 2014 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

United Nations Department of Economic and Social Affairs 2015. *Transforming our world: the 2030 Agenda for Sustainable Development*. Available: <https://sustainabledevelopment.un.org/post2015/transformingourworld> [2015, October 10].

USAID: Deliver Project 2011. The Logistics Handbook. A practical guide for the supply chain management of health commodities. Second ed. Arlington, USA: USAID.

Wagenaar, B.H., Gimbel, S., Hoek, R., Pfeiffer, J., Michel, C., Manuel, J.L., Cuembelo, F., Quembo, T. et al. 2014. Stock-outs of essential health products in Mozambique ? longitudinal analyses from 2011 to 2013. *Tropical Medicine & International Health*. 19(7):791-801. DOI:10.1111/tmi.12314.

World Health Organisation (WHO) 2017. *Essential Medicines and Health Products*. Available: <http://www.who.int/medicines/areas/access/supply/en/>.

World Health Organization 2010. The World Health Report [2010]: Health Systems Financing; the Path to Universal Coverage.

World Health Organization 2002. The Selection of Essential Medicines - WHO Policy Perspectives on Medicines, No. 004, June 2002: Selection of essential medicines. Available at: <http://apps.who.int/medicinedocs/en/d/Js2296e/2.html>

Part C: JOURNAL MANUSCRIPT

Proposed Journal: Health Policy and Planning¹

¹Author guidelines for journal manuscript in the appendices.

Taking Stock: A qualitative case study on how medicine stock management at Primary Healthcare facilities in South Africa may affect the availability of medicines.

Munedzimwe Fadzai²

²MPH Student: University of Cape Town, Health Economics Unit, Department of Public Health and Family Medicine, Faculty of Health Sciences, Observatory, Cape Town 7925. +27(084) 550 7119, Fadzai.munedzimwe@gmail.com

Keywords: medicine stock management, medicine stock outs, medicines availability, access to medicines.

Abbreviated running title: Medicine availability at PHC facilities in South Africa.

Key Messages:

- Medicine stock management may influence medicines availability if the processes involved in medicine stock management are not followed appropriately.
- The capacity of the health facility, the capacity of health workers as well as the lack of supervision and oversight from higher levels had an influence on medicine stock management at the facilities.
- Gaps in communication due to insufficient information systems and infrastructure influenced the medicine stock management at the PHC facilities.
- Health workers adapted to the contexts they work in and develop ways of coping with the challenges they face to ensure that patients receive medicines.

Acknowledgements: The project was funded by the National Research Fund (NRF) South African Research Chair; Health and Wealth program and was also supported by the National Department of Health of South Africa.

Word count: 6774 words (including in-text references)

Abstract

The unavailability of medicines due to stock outs is a barrier to accessing essential medicines. Essential medicines most prone to stock outs include chronic medicines and those used to manage communicable diseases such as HIV and TB. A qualitative multiple case study approach was used to examine actual practice on medicine stock management at four PHC facilities in a South Africa province which reported the largest proportion of stock outs of ARVs and TB medicines in 2015 and 2016. Semi-structured interviews were conducted with health workers identified as stake holders in medicine stock management. Questions were guided by themes developed in a conceptual framework from a literature review. Data from these interviews, observations and document reviews was analysed using a multiple coding process to identify common themes in the cases followed by a cross case analysis in NVivo. The main factors influencing the occurrence of medicine stock outs included medicine stock levels not being kept up to date at the facilities and not using the recommended methods of forecasting when placing medicine orders from the pharmaceutical depot. This may have been due to lack of capacity in terms of physical resources as well as human resources both at the PHC facilities and at the district level from which oversight and support of medicine stock management should have come from. Other challenges faced by health workers at the PHC facilities include insufficient information systems which affected their communication between stake holders. Many studies have focused on the factors that influence medicine availability at the higher levels this study focused on what may influence it on the ground, the PHC facility level. Future research could be conducted on using mobile health technologies in medicine stock management particularly to improve the sharing of information between stakeholders in medicine stock management.

Introduction

The unavailability of essential medicines at health facilities is a major barrier to accessing medicines in many Low and Middle-Income Countries (LMICs) particularly at smaller public health facilities such as clinics in rural areas (Schouten et al., 2011; Wagenaar et al., 2014). In southern Africa, household surveys estimated that approximately 20% of patient visits to public health facilities end with patients unable to receive medicines (Wagenaar et al., 2014). As many countries move towards achieving Universal Health Coverage (UHC), the issue of medicine availability continues to require attention (United Nations Department of Economic and Social Affairs, 2015). Thus, there has been a considerable amount of research done to find out what causes the unavailability of medicines.

Medicine stock outs and shortages are defined as situations where medicines are physically unavailable or insufficient for patient use when required (Stop Stock Outs Group, 2014). They may result from manufacturing shortfalls stemming from raw material shortages, sudden increases in demand for products due to epidemics, issues related to the production and regulation of medicines as well as the complex pharmaceutical procurement and distribution systems (Fox & Tyler, 2003; Harries et al., 2007; Bateman, 2013; Wagenaar et al., 2014). At the health facility level, the major causes of medicine unavailability when it is available from the supplier lie in the medicine stock management practices at those facilities (Harries et al., 2007; Barrington et al., 2010). In a study by Lufesi et al (2007) in Malawi, the main challenges were the lack of training and supervision of health workers involved in medicines stock management from seniors such as district pharmacists as well as the inadequate capacity of the health facilities (Lufesi, Andrew & Aursnes, 2007). A survey in various developing countries in 2011 revealed that essential medicines used in the management of chronic conditions and communicable diseases requiring life-long treatment such as HIV were most prone to stock-outs (Cameron et al., 2011; Bigdeli et al., 2014).

In recent years, the world-wide increase in the prevalence of HIV/AIDS and tuberculosis (TB) has increased the demand for anti-retroviral (ARVs) and TB medicines (Mayosi et al., 2009; Magadzire et al., 2014). Since it has been predicted that the burden of disease in relation to these diseases is likely to increase in the coming decades, access to ARVs and TB medicines needs to be increased (Mayosi et al., 2009; Health Systems Trust, 2015). The early initiation of anti-retroviral treatment improves health outcomes, yet one of the challenges that have been reported from programs on the scaling up of anti-retroviral treatments to increase access has been the unavailability of ARVs (Kitahata et al., 2009; World Health Organisation, 2015). In South Africa, surveys have revealed the extent of stock outs of ARVs and TB medicines (Stop Stock Outs Group, 2014; Stop Stock Outs Group, 2015; Public Service Commission, 2015).

HIV and TB management in South Africa has been shifted to the Primary Health Care (PHC) level which is also the entry point for citizens into the healthcare system. The search for an effective medicine stock management system remains a priority for the current government considering that the public sector serves more than 70% of the population in South Africa (McIntyre et al., 2009; Public Service Commission, 2015). A Discrete Choice Experiment on improving the public health sector in South Africa revealed that the availability of medicines at health facilities has the greatest impact in the probability that people will attend public health facilities (Honda et al., 2015). Therefore, improving the availability of medicines at the PHC level would be a good step for the country as it moves towards achieving UHC. The aim of this study was to explore and provide insight into factors influencing the availability of medicines through examining the processes involved in medicine stock management at PHC clinics.

Methods

Conceptual framework

Figure 1 provides a conceptual framework of factors influencing medicine stock management processes at health facilities and, consequently affecting the availability of medicines. These factors include: (1) inventory control, (2) communication, (3) information systems, and (4) the capacity of healthcare providers. Inventory control of medicines at the health facilities includes the maintenance of stock levels and the processes used to order medicines to ensure uninterrupted availability of medicines (USAID: Deliver Project, 2011). Communication refers to the sharing of information in relation to medicine stock management and this may be between health workers at the facility as well as with external stakeholders such as the suppliers of medicines which in our case is the pharmaceutical depot (Harries et al., 2007; Barrington et al., 2010). Information systems include technologies used in managing medicine stock and in sharing information (Harries et al., 2007; Barrington et al., 2010). Capacity of health workers and the health facility refers to the extent to which the health workers are qualified for medicine stock management as well as the extent to which the facility they work in allows them to do so efficiently (Lufesi, Andrew & Aursnes, 2007). Where the health facilities are in different areas, contextual factors unique to these regions may also influence the processes in medicines stock management (Hasselback et al., 2014).

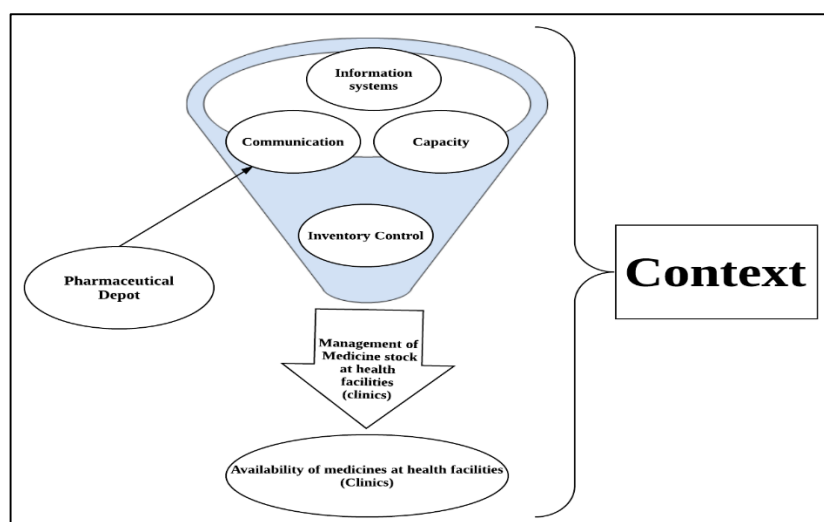


Figure 1: Conceptual framework showing factors influencing the medicine stock management at Primary Health Care (PHC) clinics which in turn may influence the availability of medicines at facilities.

Study Design and Setting

A qualitative multiple case study design was chosen for this study as case studies allow for an in-depth description of a certain phenomenon within a particular context (Yin, 2003; Green & Thorogood, 2014). The study focused on the factors in medicine stock management which may influence the availability of medicines at PHC facilities.

In this study, a primary healthcare facility is a case and medicine stock management is the unit of analysis. As the conceptual framework indicates, the study looks at the four key components of the medicine stock management in primary healthcare facilities, namely: (1) inventory control, including forecasting of medicine stocks, (2) human resource capacity; (3) information and reporting systems; and (4) communication between the depot and clinics.

South Africa has a National government and nine Provincial governments. Across the nine Provinces there are a total of fifty-two health districts. The study province houses three of the fifty-two health districts was selected for this study because in 2014 and 2015 it reported the largest proportion of facilities with stock-outs of ARVs and TB medicines (Stop Stock Outs Group, 2015). These medicines are particularly important in South Africa because of the large burden of disease (Mayosi et al., 2012). The most urban district and the most rural district in the province were selected to give insight into whether any contextual factors specific to that district such as geographic location may influence the medicine stock management.

Four clinics were purposively sampled for investigation, a total of two clinics per district were selected. They were purposively selected with assistance from the district pharmacist in each district using (1)

information on the reported unavailability of medicines by the clinics and (2) the respective district pharmacist's experience in terms of medicine stock management practices at the clinics to include:

- one clinic that had challenges in medicine stock management in each district.
- one clinic that was functioning well in terms of medicine stock management in each district

Data collection

The conceptual framework (Figure 1.), developed from literature reviewed on medicines availability and stock management was used to guide data collection as questions for the in-depth interviews were derived using key concepts from the conceptual framework, which includes inventory control, communication, information systems, capacity and context. The questionnaires (Appendix A) were piloted prior to commencement of data collection. The questionnaires were tested for validation on two nurses and two pharmacists working in similar settings as those in the study but would not participate in the study. Key policy documents related to the medicine stock management at PHC facilities; and district organograms were reviewed to identify key informants for interview as well as to describe the processes in medicine stock management. Provincial and district organograms and snowballing were used to identify the key actors in the medicine stock management at PHC level in both districts. Semi-structured in-depth interviews were carried out in English and were tape-recorded where the interviewees consented. Observation at the facilities on the processes followed by the clinics in medicine stock control using a checklist (Appendix B) and a review of Standard Operating Procedures on stock management was also part of data collection.

Data processing and analysis

Recorded interviews were transcribed verbatim into a word document. These transcripts together with field notes from observations carried out at the clinics and documentary reviews were analysed using a multiple coding process to identify common themes in the cases followed by a cross case analysis. The first coding cycle was a deductive process using themes from the conceptual framework, the second cycle was inductive to identify additional themes not included in the conceptual framework. NVIVO was used to arrange the data and facilitate the coding process. The cross-case analysis involved identifying key concepts from each case following the coding process. The cases were analysed to see if there were any common concepts amongst them as well as to establish if there were any underlying contextual factors which could be responsible for the concepts which were unique to a case. Contextual factors were considered as those which the health workers at the facilities had no control over.

Ethics

This study obtained ethical approval from the University of Cape Town human research ethics committee (HREC Ref: 134/2016). Research approval was obtained from the National and Provincial Department of Health committees. Participation was voluntary and prior to visiting the facilities, letters of invitation with information on the objectives and contents of the study were sent to the key informants. Before the interviews were conducted, written consent was obtained from the participants to participate in the study, for tape recording and the use of their quotations in publications or reports on the study.

Medicine stock management guidelines at PHC clinics in the study province

The provincial government has published a medicine stock management guideline which facilities should ideally follow (see Figure 2). Inventory control at the clinics includes various tasks and processes. Daily, clinic staff which consists mainly of nurses but in some cases, may be pharmacists or pharmacist assistants are required to maintain a running inventory of all medicines by recording stock movement on stock cards. These stock cards should indicate the minimum, maximum and re-order levels. These levels should guide the determining of quantities of medicines to order from the Pharmaceutical Depot (PD).

Every week, clinics are required to report to the district office on medicines availability by indicating which items have been out of stock in the past week.

Ordering of medicines from the PD is done fortnightly following a schedule provided by the PD. Clinics indicate on an order sheet the quantities of the medicines they require and fax it to the PD which processes the order and delivers it to the clinics also on pre-determined dates. Upon delivery, the clinics should check the medicines received in the order. Any discrepancies should be queried with the PD immediately and if needed credits or debits processed. Upon raising the query, if the depot indicates that they have stock of medicines ordered but not received by the clinic, the clinic may make an emergency order through their feeder hospital and arrange for transport to collect the medicines from the PD. If the PD does not have stock, the clinics should inform their clinic supervisor who will cascade the information to other supervisors and the PHC managers at the district level who can advise on steps to be taken from there.

Clinic staff are required to review and re-calculate their stock levels if necessary on a quarterly basis based on the history of consumption in the past three months. District hospitals were responsible for providing pharmacists to supervise and assist the clinics in the medicine stock management.

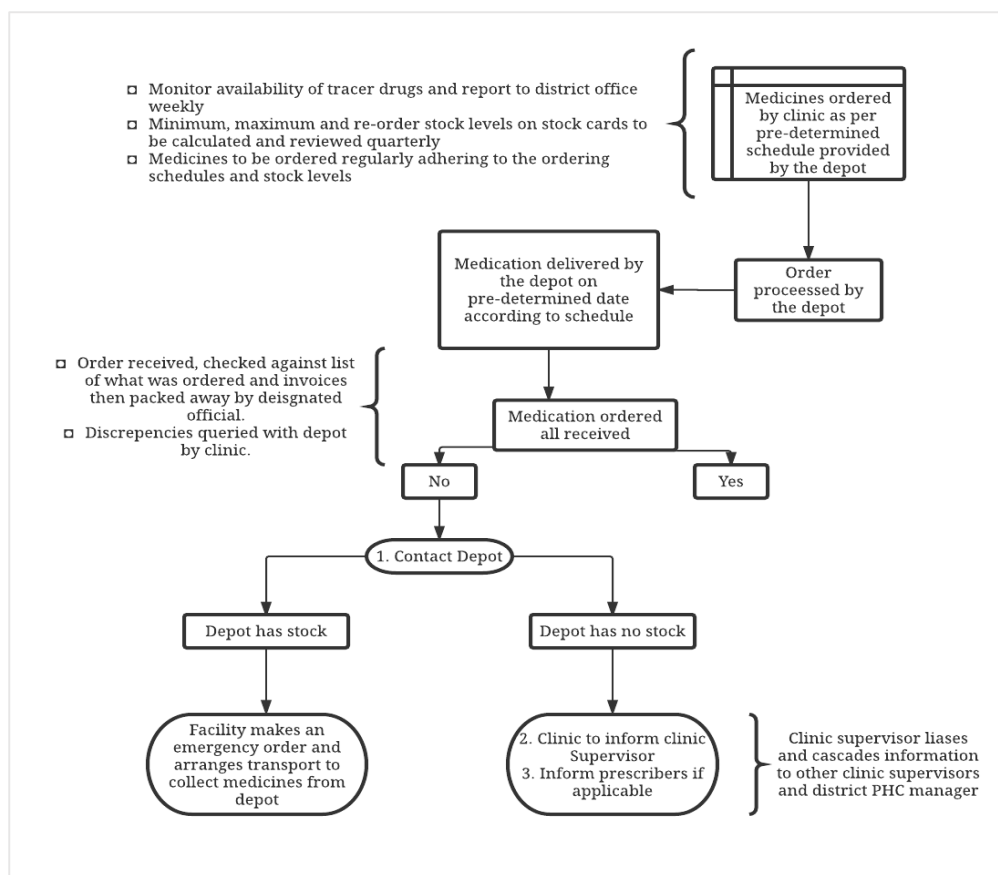


Figure 2: Summary of processes to be followed in medicine stock management at clinics as per Standard Operating Procedures for Pharmaceutical Services at PHC level.

Findings

In this section, the findings on the factors influencing the processes in medicine stock management at the clinics are discussed. First we look at the challenges faced by the health workers at the clinics in medicine stock management then we move on to give the possible factors why the staff are faced with these challenges which may lead to medicine stock outs.

Challenges faced in the inventory control of medicines at the clinics

The clinic staff involved in medicine stock management at two of the clinics did not always record stock movement on the stock cards. This included recording stock received from orders placed at the PD, stock borrowed or lent to other facilities and stock removed from the main bulk storage room to the dispensing room/places. Upon receipt of an order from the PD, the clinic staff did not check the stock received to ensure it matched the invoices and the order they had placed. As a result, medicine stock levels were not always up to date at these clinics. These two clinics were also the ones which according to their district pharmacists reported greater proportions of stock outs.

“When they receive stock as well, they don’t reconcile stock with the invoices and record it on the stock cards, you see.” - (District Pharmacist A)

At all the clinics, none of the clinic staff reviewed and calculated their stock levels every three months using the recommended equation (Min stock=average monthly consumption (AMC) x1.5) even though they were aware that they were supposed to do this. The calculations were time consuming and difficult for the clinic staff to do.

“By right like I said we need to be using that method from Pharmacy and it is strenuous for us because we, because some Clinic they have Pharmacy assistants people who are there to look after the pharmacy so we don't have this person here this clinic is very small so we don't have the pharmacy assistant. So, a nurse needs to see a patient need to go to the pharmacy and check if everything is in order, make orders all of that it gets too much for us.” - (Nurse 2, District A)

Forecasting for medicine stock at the clinics was not done using the recommended methods at all the clinics and sometimes those making orders would not check stock levels before placing orders at the PD to determine re-order quantities but they used their own judgement and experience to determine what quantities to order instead of consulting the re-order levels and calculating the amounts needed.

“To be honest what we do when we are ordering; we go to the pharmacy, we check, oh we have got 50 paracetamol and paracetamol goes fast ok I need to order. Ok we do not do that maths thing you see. - (Nurse 1, district A)

Factors that could influence the availability of medicines

Insufficient human resources and the capacity of nurses managing medicine stock.

Inadequate staffing at clinics and district health offices, and the absence of pharmacists and/or pharmacist assistants at clinics emerged as important factors affecting the ability of clinics to undertake medicine stock management according to recommended guidelines. Not having an adequate number of staff made it difficult for the nurses to carry out their roles in medicine stock management.

“(…) with the staff shortage, it is difficult to do drug management.” (Nurse 2, district B)

Even though some of the nurses had the technical capacity to perform medicine stock management, the lack of staff meant that they could not do so.

“I think the nurses know what they are supposed to but they can’t do it because there is no staff.” (District Pharmacist B)

Nurses had many roles and worked under time constraints as they had other nursing roles. Because of this they did not have time for medicine stock management.

“We find that in other clinics, there are 2 or 3 sisters that are running the whole clinic. Now they have to see patients on a day to day basis, you know. They become so busy in such a way that other drug supply management duties get ignored in the clinic.” (District Pharmacist A)

In both districts, there was a general feeling that pharmacist assistants or pharmacists should be managing medicine supply at the PHC facilities.

“I think that if we had a pharmacy assistant everything would be perfect I am sure that even the pharmacy would be perfect.” (Nurse, PHC 1, District B)

“If all the clinics can have a pharmacy assistant based in the clinic that could decrease some problems.” (PHC supervisor)

Pharmacists and pharmacist assistants would be better than nurses at medicine stock management because their training prior to qualification includes medicine stock management unlike the nurses who have to be trained on it whilst on the job.

“The other thing is that nurses were not trained in drug supply management from school. Even if we can give them training like workshops after school, or after they have qualified, it doesn't make that much of an impact... So, to have somebody who is trained on drug supply management you know, who are custodians of drug supply management it really makes a difference at facility level.” – (District Pharmacist B)

It was observed that the two clinics where a pharmacist or pharmacist assistant were employed had up to date running inventory compared to the clinics where only nurses managed medicine stock. These were also the clinics identified in each district as those facing less challenges in medicines availability and had reported less stock outs per their respective district pharmacists.

Both district pharmacists cited that there were limited funds to employ pharmacist assistants and or extra nurses at PHC facilities. This is one of the reasons why the human resource capacity was not adequate.

Information Systems used in the medicine stock management at PHC facilities get in the way of health workers as they carry out their duties.

Information systems include technologies used in managing medicine stock and in sharing information. Communication systems used included face-to face, written and electronic exchanges of information.

In both districts, it was observed that the information systems used in managing medicine stock were paper based except for one clinic which had the computer based Rx solution® computer program in addition to the paper based methods. The clinic which used Rx solution® was one of the clinics in the district that did not have many challenges with medicines availability. Rx solution® could not be installed at all the clinics as they did not have computers and internet access.

The ordering of medicines from the PD was done manually by clinic staff. An order sheet indicating quantities required was faxed to the depot. A challenge faced by two of the clinics was that they did not have fax machines on-site and had to send the order to their nearest hospital for it to be faxed to the PD from that hospital.

“Ideally you have a fax machine where we fax the form but we do not have. We order then I always go to the hospital, I use my own transport to take the order to the hospital then I fax then I get the confirmation of the fax” (Nurse, PHC 3, district B)

This ordering system also did not allow real-time ordering of medicines from the depot as the clinics had no access to information on what medicines were available at the time they placed the orders. The information systems linking the clinics to the depot were lacking. Internet and computers were not available for use at the clinics which limited the depot in terms of sending out information to the clinics as e-mails are quick and easy to send out to large groups thus affecting communication.

“But the only way that the depot can inform facilities is through circulars and through emails so the hospital people will always receive emails it will depend on how effective they are to cascade it to the PHCs.” (District Pharmacist A)

Communication between health workers at the clinics and other actors outside the PHC facilities.

Communication, which refers to the sharing of information between the PHC facility staff and other actors which include the district pharmacists, hospitals and the pharmaceutical depot included information on medicines that were unavailable at the depot and alternative medicines available or guidelines on what medicines to use as substitutes.

The depot was of the perception that there were no problems in communication between them and the PHC facilities. According to them, they frequently communicated with the clinics.

“On a daily basis, I would say, there is always something that we must write to the clinics. I think weekly there is something going to the clinics, either via the district hospitals or the hospitals but eventually to the clinics.” (Pharmaceutical Depot manager)

Ideally the information should flow from the Head of Pharmaceutical Services or depot to the district pharmacists and hospitals. This flow of information was efficient because both levels had computers with access to the internet allowing them to use emails to communicate and send circulars to the district pharmacists and hospitals. The district pharmacists and hospitals were then responsible for passing the relevant information to the PHC facilities. However, this flow of information was not efficient and this was articulated by all the interviewees, partly because of the lack of information systems that allowed this e.g. computers and internet.

“There is a huge communication gap [between the clinics and the depot]. But between the depot and the hospitals the flow of information is going very very well. Now the forms or let me say the platforms of communications between the depot and the facilities [hospitals], they normally use emails most of the time. And the quickest way that you can send a circular out is via email. So, you find out that hospitals do have information of a particular drug that is out of stock and then it will depend on how effective that particular hospital is in informing the clinics that they are supervising. You see if they are effective enough then the clinics that they are supervising will be aware that maybe 3TC 300mg is out of stock.” (District Pharmacist A)

Due to the challenges in infrastructure, the depot could only send hard copies of the circulars to the clinics when they delivered medicines to them which was every two weeks. This meant that if the information was only relevant at the time the circular was released, the clinics may receive it when it is no longer relevant.

“Well I think with circulars; it takes forever because someone needs to sign and stuff like that ... Sometimes they will come here probably after they were signed last month and you don't know if this is still valid because it was 20 days ago, when it was sent to us.” (Pharmacist, PHC 2, District A)

The depot did not communicate directly with the clinics providing them with reasons why they had not fulfilled the complete orders placed by the clinics. Clinics often had to initiate contact with the depot to find out why they had not received certain medicines that they had ordered.

“You have ordered a set item but when you receive the stock there is nothing and there is no reason. They just put the zero, no stock on the order form but there is no reason why. So now you have to follow up with them and call them asking why have we not receive this.”
(Pharmacist, PHC 2, District A)

Because of all this, some of the clinics felt that the communication between them and the depot was not sufficient.

“If I can rate them, not now, the depot, no man, no they do not communicate with us... in our situation we always find that we are the ones who are always on their case finding out what could have happened with the stock and stuff like that they have never made an effort.” (Nurse, PHC 3, District A)

Supervision and support from the district level in terms of medicine stock management at PHC facilities may be lacking.

The feeder hospitals and district pharmacists were unable to visit the clinics often and thus clinics did not always receive adequate supervision from them to ensure that procedures particularly SOPs in medicine stock management were being implemented. This affected the communication between the clinics and their respective district pharmacists whose role was to co-ordinate medicine supply. The clinics did not always send information on the availability of medicines on a weekly basis as they were required to.

The district pharmacists left it up to the feeder hospitals to ensure that the clinics received support however this did not always happen. The lack of supervision from feeder hospital pharmacists was due to insufficient human resource at the hospitals to send pharmacists to support clinics as well as resources such as vehicles for these pharmacists to use.

“We don't have enough hands, enough people, skilled people to actually do the trainings, to monitor, do monitoring and evaluation at facility levels.” (District Pharmacist A)

Contextual factors that may influence the medicine stock management which are beyond the control of the clinics.

Limited physical resources such as computers, fax machines, and facility vehicles were a challenge for all the clinics except one. These resources would make it easier for clinic staff to fulfil their tasks in managing medicine stock, for example sending orders to the depot.

“Ok we have most of, how can I put it, in other facilities they complain about resources. We are lucky enough to have such resources such as photo copy machines.” (Pharmacist, PHC 2, district A)

Infrastructure and space at the clinics for the storage of medicines was also lacking. This was a major problem at two out of the four clinics, the dispensing rooms were very small and at one clinic medicines were stored in cabinets in the nurses’ consulting rooms. These clinics could therefore not store extra emergency stock

“You see this locker is small we are trying to fit; we are trying but everything should be there and then it is small It cannot accommodate everything... Even our pharmacy room it is small like a toilet it is very small. Only one person can enter in that old building.” (Nurse, PHC 1, district A)

HIV treatment is provided at PHC level and the changing of guidelines to provide ART to all regardless of CD4 count increased the influx of patients visiting clinics for services. Thus, clinics are busier and need to adjust their stock levels to meet the demand for ART.

“The burden of disease comes above our efforts to fight stock outs; it increases the influx of patients into the facilities whilst there are shortages from the supplier or the suppliers are unable to cope with the demand.” (Study province, Head of Pharmaceutical Services)

Clinics that were situated closer to the depot or their feeder hospital found it easier to collect medicines from the depot when they had placed an emergency order compared to those further away.

“With X hospital, yes that is a little bit convenient for me because we are very close so I can jump in the car and quickly go there, and I have my own transport. Many of the other clinics you know the pharmacist assistants maybe don't have their own transport they use taxis or they are too far from X hospital it can be a challenge for them.” (Pharmacist assistant, PHC 4, district B)

How the clinics/health workers have adapted to cope with the challenges faced.

The health workers have relationships with health workers from other facilities which enable them to communicate and borrow stock from each other. Since not all facilities had access to working

telephones, clinic staff used WhatsApp to communicate with each other. This method of communication was fast.

“We have a WhatsApp group, for operational managers and for the whole district team where we discuss, because sometimes others do not have landlines and what, what, but we use the WhatsApp group and we liaise there, and you get help like that” (PHC supervisor)

The clinic staff also made sacrifices, such as working extra time so that they can finish their tasks and ensure that all tasks in medicine stock management have been completed.

“I know of one sister who puts in more time to stock management. She will go to the facility on a Saturday just to make sure that she places her order accurately. So, it's up to the OM or the person responsible for that to do that, but it's not like they have to do that, they just go that extra mile.” (Pharmaceutical Depot manager)

Another sacrifice made was the use of their private vehicles to collect medicines for patients when the clinic itself was unable to provide transport for this.

“The government does not provide cars actually to use around I do not know why it is like that but it's hard because I feel for the person because they become your family all of a sudden you feel for them and then you are like know let me the sacrifice for them once. IL will make a difference. It helps if you have a car because if you didn't have it, it would be a different story, it would be difficult.” (Pharmacist, PHC 2, district A)

Discussion

The study examined actual practice in how primary healthcare facilities manage medicine stock and identified key factors influencing the occurrence of medicine stock outs by specifically looking at: inventory control; human resources available for medicine stock management at primary health facilities; information systems and reporting mechanisms; and communication between clinics and other health systems actors. The factors that may influence the occurrence of stock outs include medicine stock levels not being kept up to date at the clinics and not using the recommended methods of forecasting when placing medicine orders from the PD. This may have been due to lack of capacity in terms of physical resources as well as human resources both at the clinics themselves and at the district level from which oversight and support of medicine stock management should have come from. Other challenges faced by health workers involved in medicine stock management at primary health facilities which may have contributed to the occurrence of stock outs include insufficient information systems which affected communication between primary healthcare facility workers and other

important stake holders such as the district hospital pharmacists and pharmaceutical depot thus limiting the clinic staff from managing medicine stock efficiently.

One of the common practices found at the clinics was that of poor inventory control. Inventory control is a very important aspect of medicine stock management at the health facility level (Githinji et al., 2013; Mikkelsen-Lopez et al., 2014). If stock levels are not up to date then it would be easy to miss items that need to be ordered when they need to be ordered and this often leads to medicine stock running out at the clinics (Mikkelsen-Lopez et al., 2014). In addition to not having stock levels up to date, the health workers were not following the recommended forecasting methods which could have also contributed to the occurrence of stock outs. A structured forecasting system is essential to ensure uninterrupted medicine availability (Harries et al., 2007).

The lack of human resources at public health care facilities is one of the main factors contributing to the frequent unavailability of medicines at PHC clinics. Where there is a shortage of human resources, health workers may be unable to perform their duties adequately (Lufesi, Andrew & Aursnes, 2007). Most of the clinics were not adequately staffed and did not have pharmacist assistants which led to nurses undertaking the medicine stock management. These nurses constantly worked under time constraints, preventing them from following procedures according to the medicine stock management SOP. The nurses felt as though medicine stock management was not meant to be their responsibility but rather that of pharmacy personnel such as pharmacists and pharmacist assistants. Due to the human resource crisis in health care, task-shifting has become a common practice in resource constrained settings (Hongoro & McPake, 2004; Fulton et al., 2011). Task-shifting is the allocation of tasks within the healthcare system to health workers who would not normally do those tasks but can do them (Hongoro & McPake, 2004). It is often less costly to employ these workers (Hongoro & McPake, 2004). Some countries and some disciplines have resorted to the use of mid-level cadres to bridge the gap in human resources (Lehmann, 2008). However, the challenge with task-shifting as we see from our findings is that the nurses were not adequately trained to perform medicine stock management and did not receive sufficient supervision by seniors such as district pharmacists or district hospital pharmacists (Lufesi, Andrew & Aursnes, 2007). Supervision by district pharmacists was reported to have reduced the occurrence of medicine stock outs in a study carried out in Malawi where nurses were responsible for medicine stock management (Githinji et al., 2013).

Another factor that contributed to medicine stock outs was the gap in communication between the personnel at the clinics and those at PD which is essential in managing medicine stock because vital information needs to be shared between them (Barrington et al., 2010). The PD was of the impression that they had communicated to the clinics by sending circulars to them bi-weekly and relying on the district level to pass on urgent circulars they would have received via email (Bateman, 2013). Studies

found that where communication between stakeholders involved in medicine stock management was efficient, less stock outs occurred (Berger et al., 2007). Strategies to mitigate medicine stock outs have included focusing on on-line information systems use in the process of managing medicine stock thus countries are moving from paper based methods of communication and managing medicine stock to electronic systems (Berger et al., 2007; Barrington et al., 2010). In our study, we found that the current information systems limited the health workers in terms of communication. These systems used in ordering did not allow for real-time ordering where the health worker at the facility could instantly know if a medicine they had ordered was out of stock. Access to such information could allow the health worker to immediately place an order for the alternative medicines unlike in the case of the clinics where they would find out when their order had been delivered that the PD did not have stock of that medicines and it may be too late to place an order for alternatives at that time and the clinic runs out of medicine.

One way of addressing the human resource challenge would be the use of more pharmacist assistants at the clinics for medicine stock management. These pharmacist assistants would work under the indirect supervision of pharmacists at the district hospitals. This would allow nurses to focus more on their nursing duties and not have to prioritise when they are pressed for time. The training of PHC nurses at nursing colleges before they are qualified could also include medicine stock management so that they are better equipped to manage medicine stock. Continual professional development on medicine stock management could also be made mandatory for health workers working at the clinics as this would ensure that the health workers' knowledge on medicine stock management is up to date.

To improve communication, the use of cell phones to send circulars from the PD on medicine availability may be useful since it has been identified that the clinics do not have access to emails because they do not have computers unlike at the district level. The NDoH has recently introduced the Stock Visibility Solution (SVS) with the aim of improving the reporting of medicine availability by PHC staff using cell phones to capture and send this information to the district level. This is similar to the *SMS for life* program that improved the availability of rapid diagnostic tests and anti-malarial medicines by enhancing stock visibility in Kenya (Githinji et al., 2013). Since these systems involve the use of cell phones, the pharmaceutical depot could send urgent circulars on medicine availability via SMS to health workers rather than hand delivered circulars. There is an increasing trend in the use of mobile health technologies to facilitate the sharing of information in the healthcare system amongst health workers as well as to patients (Chib, van Velthoven & Car, 2015). Another solution would be to equip the PHC clinics with computers so that the Rx solution for stock management may be implemented there. Linking this system to the depot to allow real time ordering of medicines would also alleviate the problem of finding out that there is no stock at the depot only when the order is delivered at the clinic.

Policy recommendations

To improve the medicine stock management at PHC facilities and avoid medicine stock outs, government could consider the following policy recommendations, which are based on the findings from the study.

- Training of nurses on forecasting methods and other aspects of medicine stock management should be included in the nursing curriculum at nursing colleges.
- Continuous monitoring and supervision of nurses working in medicine stock management by district pharmacists on the implementation of SOPs on medicine stock management.
- Strengthening human resources at PHC facilities by employing more people-particularly pharmacist assistants/ technicians to work at clinics so that nurses are relieved of medicine stock management duties.
- Equipping the PHC facilities with necessary communication infrastructure e.g. computers as this will allow more of them to use Rx solution for medicine stock management and if internet is available, they would be able to use emails to communicate. Rx solution should also be set up with a real-time ordering system linking PHC facilities to the depot. This system would allow them to access information on medicines available for order as they place the order.
- Using cell phones to send circulars on medicine availability via SMS to health workers rather than hand delivered circulars as this would convey the information much faster.

Conclusion

One of the disadvantages of case studies is that the results cannot be generalised as they are specific to a context, however the findings from this study provide insight into areas for government focus to improve medicine availability in South Africa and other countries with similar settings. A major limitation of this study was that the clinics were not consistent in reporting medicine availability to their respective district pharmacists and so the information they had on medicine stock outs at the clinics was incomplete. Therefore, the purposive sampling may have been done using incomplete data. This information would have also added value to our findings as it would then be possible to quantify the occurrence of stock outs and use this as a comparison. Other limitations of this study include the fact that PHC staff were warned of the research visits therefore they could have done things a particular way because they were aware that someone would be doing research in the facility. Lastly, the interview questions collected data from the health workers which was based on past experiences which may be subject to recall bias. One of the strengths of this study is that stakeholders from different levels of the health system were interviewed that is from the PHC, district and provincial level. This allowed us to get different perspectives which is valuable in research. More than one source of data was used which allowed for triangulation and this is one of the ways in which qualitative researchers increase rigour.

Whilst many studies have focused on the factors that influence medicine availability at the higher levels such as the suppliers of medicines which in our case would be the pharmaceutical depot, this study focused on what may influence it on the ground, the PHC clinic level. The study is important because if medicine is available at higher levels but challenges are experienced at the lower levels, then medicine stock outs will still occur. Our study provides insight into practical issues that can be addressed at the PHC level in order to improve medicines availability. Future research in medicine stock management in the South African context could be conducted on how mobile health technologies could be utilised to a greater extent in medicine stock management particularly to link the PHC facilities with the pharmaceutical depot and other stakeholders allowing them to freely share information. It would also be beneficial to explore the acceptability of these technologies by the health workers required to use.

References

- Barrington, J., Wereko-Brobby, O., Ward, P., Mwafongo, W. & Kungulwe, S. 2010. SMS for Life: a pilot project to improve anti-malarial drug supply management in rural Tanzania using standard technology. *Malar J.* 9(298):1-9.
- Bateman, C. 2013. Drug stock-outs: Inept supply-chain management and corruption. *SAMJ: South African Medical Journal.* 103(9):600-602.
- Berger, E.J., Jazayeri, D., Sauveur, M., Manasse, J.J., Plancher, I., Fiefe, M., Laurat, G., Joseph, S. et al. 2007. Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti. *AMIA Annual Symposium Proceedings.* American Medical Informatics Association. 46.
- Bigdeli, M., Peters, D.H., Wagner, A.K. & World Health Organization 2014. Medicines in health systems: advancing access, affordability and appropriate use.
- Cameron, A., Roubos, I., Ewen, M., Mantel-Teeuwisse, A.K., Leufkens, H.G. & Laing, R.O. 2011. Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. *Bulletin of the World Health Organization.* 89(6):412-421.
- Chib, A., van Velthoven, M.H. & Car, J. 2015. mHealth adoption in low-resource environments: a review of the use of mobile healthcare in developing countries. *Journal of Health Communication.* 20(1):4-34.
- Fox, E.R. & Tyler, L.S. 2003. Managing drug shortages: Seven years' experience at one health system. *American Journal of Health-System Pharmacy.* 60(3):245-245.
- Fulton, B.D., Scheffler, R.M., Sparkes, S.P., Auh, E.Y., Vujcic, M. & Soucat, A. 2011. Health workforce skill mix and task shifting in low income countries: a review of recent evidence. *Human Resources for Health.* 9(1):1.
- Githinji, S., Kigen, S., Memusi, D., Nyandigisi, A., Mbithi, A.M., Wamari, A., Muturi, A.N., Jagoe, G. et al. 2013. Reducing stock-outs of life saving malaria commodities using mobile phone text-messaging: SMS for life study in Kenya. *PLoS One.* 8(1):e54066.
- Green, J. & Thorogood, N. 2014. *Qualitative methods for health research.* Third ed. London: SAGE.
- Harries, A.D., Schouten, E.J., Makombe, S.D., Libamba, E., Neufville, H.N., Some, E., Kadewere, G. & Lungu, D. 2007. Ensuring uninterrupted supplies of antiretroviral drugs in resource-poor settings: an example from Malawi. *Bulletin of the World Health Organization.* 85(2):152-155.
- Hasselback, L., Crawford, J., Chaluco, T., Rajagopal, S., Prosser, W. & Watson, N. 2014. Rapid diagnostic test supply chain and consumption study in Cabo Delgado, Mozambique: estimating stock shortages and identifying drivers of stock-outs. *Malaria Journal.* 13(1):1-10.

Health Systems Trust 2015. *Central Chronic Medicine Dispensing and Distribution Programme (CCMDD)*. Available: <http://www.hst.org.za/projects/central-chronic-medicine-dispensing-and-distribution-programme-ccmdd> [2015, November 10].

Honda, A., Ryan, M., van Niekerk, R. & McIntyre, D. 2015. Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment. *Health Policy and Planning*. 30(5):600-611. DOI:10.1093/heapol/czu038 [doi].

Hongoro, C. & McPake, B. 2004. How to bridge the gap in human resources for health. *The Lancet*. 364(9443):1451-1456. DOI:[http://dx.doi.org/10.1016/S0140-6736\(04\)17229-2](http://dx.doi.org/10.1016/S0140-6736(04)17229-2).

Kitahata, M.M., Gange, S.J., Abraham, A.G., Merriman, B., Saag, M.S., Justice, A.C., Hogg, R.S., Deeks, S.G. et al. 2009. Effect of early versus deferred antiretroviral therapy for HIV on survival. *New England Journal of Medicine*. 360(18):1815-1826.

Lehmann, U. 2008. Strengthening human resources for primary health care.

Lufesi, N.N., Andrew, M. & Aursnes, I. 2007. Deficient supplies of drugs for life threatening diseases in an African community. *BMC Health Services Research*. 7:86. DOI:1472-6963-7-86 [pii].

Magadzire, B.P., Budden, A., Ward, K., Jeffery, R. & Sanders, D. 2014. Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa. *BMC Health Services Research*. 14(1):520.

Mayosi, B.M., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. & Bradshaw, D. 2009. The burden of non-communicable diseases in South Africa. *The Lancet*. 374(9693):934-947.

Mayosi, B.M., Lawn, J.E., van Niekerk, A., Bradshaw, D., Karim, S.S.A., Coovadia, H.M. & Lancet South Africa team 2012. Health in South Africa: changes and challenges since 2009. *The Lancet*. 380(9858):2029-2043.

McIntyre, D., Goudge, J., Harris, B., Nxumalo, N. & Nkos, M. 2009. Prerequisites for national health insurance in South Africa: results of a national household survey. *SAMJ: South African Medical Journal*. 99(10):725-729.

Mikkelsen-Lopez, I., Shango, W., Barrington, J., Ziegler, R., Smith, T. & deSavigny, D. 2014. The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners: the case of Tanzania. *Malaria Journal*. 13:181-2875-13-181. DOI:10.1186/1475-2875-13-181 [doi].

Public Service Commission 2015. Consolidated report on service delivery inspections of district hospitals and clinics regarding availability of medicines and medical equipment and the role of health district offices. Public Service Commission.

Schouten, E.J., Jahn, A., Ben-Smith, A., Makombe, S.D., Harries, A.D., Aboagye-Nyame, F. & Chimbandira, F. 2011. Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. *Journal of the International AIDS Society*. 14 Suppl 1:S4-2652-14-S1-S4. DOI:10.1186/1758-2652-14-S1-S4 [doi].

Stop Stock Outs Group 2014. Stop Stock Outs Report 2013 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

Stop Stock Outs Group 2015. Stop Stock Outs Reprt 2014 by the Treatment Action Campaign, Doctors without Borders/Medecins San Frontieres, Rural Health Advocacy Project, Rural Doctors Association of South Africa, SECTION27, Southern Africa HIV Clinician's Society civil society groups. South Africa: Stop Stock Outs Group.

United Nations Department of Economic and Social Affairs 2015. *Transforming our world: the 2030 Agenda for Sustainable Development*. Available: <https://sustainabledevelopment.un.org/post2015/transformingourworld> [2015, October 10].

USAID: Deliver Project 2011. *The Logistics Handbook. A practical guide for the supply chain management of health commondities*. Second ed. Arlington, USA: USAID.

Wagenaar, B.H., Gimbel, S., Hoek, R., Pfeiffer, J., Michel, C., Manuel, J.L., Cuembelo, F., Quembo, T. et al. 2014. Stock-outs of essential health products in Mozambique ? longitudinal analyses from 2011 to 2013. *Tropical Medicine & International Health*. 19(7):791-801. DOI:10.1111/tmi.12314.

World Health Organisation 2015. *Guideline on when to start antiretroviral therapy and on pre-exposue prophylaxis for HIV*. Switzerland: World Health Organisation.

Yin, R.K. 2003. The case study as a research strategy. In *Case study research design and methods*. Third ed. London: Sage Publications Inc.

Part D: POLICY BRIEF



INTRODUCTION

The unavailability of essential medicines at health facilities is a major barrier to accessing medicines in many Low and Middle-Income Countries (LMICs) (Schouten et al., 2011; Wagenaar et al., 2014). South Africa has a high burden of disease in relation to HIV and TB and the medicines used to manage these conditions are some of those medicines which are most prone to stock outs (Cameron et al., 2011; Bigdeli et al., 2014; Stop Stock Outs Group, 2015). The availability of medicines used to manage HIV and TB needs to be improved as it has also been predicted that the burden of disease in relation to these communicable diseases is likely to increase in the coming decades (Mayosi et al., 2009; Health Systems Trust, 2015a). One of the challenges that have been reported from programs on the scaling up of anti-retroviral treatments to increase access has been the unavailability of ARVs (Kitahata et al., 2009; World Health Organisation, 2015). Research on improving the public health sector in South Africa revealed that the availability of medicines at health facilities has the greatest impact on the probability that people will attend public health facilities (Honda et al., 2015). The search for an effective medicine stock management system remains a priority for the current government considering that the public sector serves more than 70% of the population in South Africa (McIntyre et al., 2009; Public Service Commission, 2015). Furthermore, the PHC level needs to be prioritised as it is the entry point for citizens into the healthcare system (McIntyre et al., 2009; Bigdeli et al., 2014). In this policy brief, we present the findings from a study that aimed to identify factors influencing the occurrence of medicine stock outs in PHC facilities through examination of medicine stock management practices at PHC facilities.

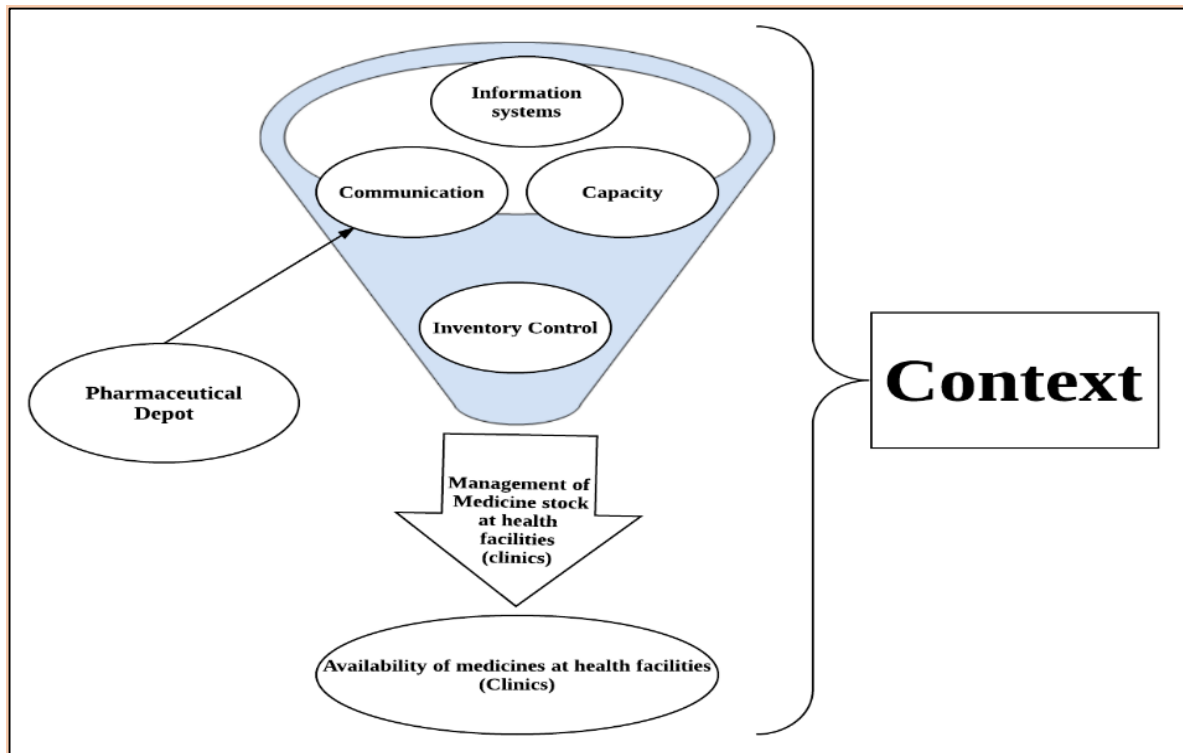
This policy brief was prepared by Fadzai Munedzimwe as part of a dissertation for a Master of Public Health degree at the School of Public Health & Family Medicine of the University of Cape Town. The project was funded by the National Research Fund (NRF) South African Research Chair; Health and Wealth program and was also supported by the National Department of Health of South Africa.

Key Findings

- Medicine stock outs occur because Standard Operating Procedures on medicine stock management are not being followed.
- Standard Operating Procedures are not followed because of the lack of sufficient and adequately trained human resources at the clinics as well as lack of oversight from the district.
- Gaps in communication and lack of infrastructure also affected medicine stock management.
- Health workers adapt to the contexts they work in and develop ways of coping with the challenges they face ensure that patients receive medicines.

Methods

Figure 1. Conceptual framework showing factors influencing the medicine stock management at Primary Health Care (PHC) clinics which in turn may influence the availability of medicines at facilities.



A qualitative multiple case study approach was used to explore the factors which may influence medicine stock management at four PHC facilities. Based on the following selection criteria, two districts were chosen from a province in South Africa: (1) the district that had reported the least and the greatest frequency of stock outs of ARVs and TB medicines and (2) the reported availability of medicines at the facilities in the selected districts. Semi-structured interviews were conducted with key stakeholders involved in medicine stock management at PHC facilities including the facility, district and provincial levels. Observations at the health facilities as well as document reviews were also used to collect data. The main themes raised in the questionnaires were from a conceptual framework (see Figure 1.) developed on the basis of literature

on medicine stock management and the causes of stock outs. The factors that influence the medicine stock management processes at health facilities thus affecting the availability of medicines include the inventory control of medicines, capacity of the health facility and health workers, information systems used and communication between health workers involved in the management of medicine stock.

Findings

What factors influence the availability of medicines at PHC facilities?

- Management of HIV at PHC level and the changing of guidelines to provide ART to all regardless of CD4 count increased the influx

of patients visiting PHC facilities for services. Thus, clinics are busier and need to adjust their stock levels to meet the demand for ART.

“The burden of disease comes above our efforts to fight stock outs; it increases the influx of patients into the facilities whilst there are shortages from the supplier or the suppliers are unable to cope with the demand.” (Head of Pharmaceutical Services)

- The health workers managing medicine stock were aware of the processes they needed to follow as set out in the Standard Operating Procedures. However, they were unable to do so due to the factors identified below. As a result of not following forecasting methods such as placing orders using updated stock levels, medicine stock outs occurred.

“To be honest what we do when we are ordering; we go to the pharmacy, we check, oh we have got 50 paracetamol and paracetamol goes fast ok I need to order. Ok we do not do that maths thing you see.” (Nurse 1, district A)

Why are health workers unable to follow recommended procedures?

- Most of the health facilities examined lack the qualified pharmacists and pharmacy assistants, which results in nurses, who already have a heavy workload, managing medicine stock in spite of a lack of training for this work.

“The other thing is that nurses were not trained in drug supply management from school. Even if we can give them training like workshops after school, or after they have qualified, it doesn’t make that much of an impact... So, to have somebody who is trained on drug supply management you know, who are

custodians of drug supply management it really makes a difference at facility level.” (District Pharmacist)

- There were gaps in communication between health workers at the PHC facilities and external stakeholders such as the pharmaceutical depot which supplied them with medicines and the district hospitals which were responsible for supervising them. As a result of this, the PHC facilities did not receive memos from the depot about medicines availability in time for them to act accordingly.

“There is a huge communication gap [between the clinics and the depot]. But between the depot and the hospitals the flow of information is going very very well. Now the forms or let me say the platforms of communications between the depot and the facilities [hospitals], they normally use emails most of the time. And the quickest way that you can send a circular out is via email. So, you find out that hospitals do have information of a particular drug that is out of stock and then it will depend on how effective that particular hospital is in informing the clinics that they are supervising. You see if they are effective enough then the clinics that they are supervising will be aware that maybe 3TC 300mg is out of stock. (District Pharmacist)

- Infrastructure and space at the clinics for the storage of medicines was also a challenge at two out of the four clinics, the dispensing rooms were very small and at one clinic medicines were stored in cabinets in the nurses’ consulting rooms. These clinics could therefore not store extra emergency stock.

“You see this locker is small we are trying to fit; we are trying but everything should be there and then it is small it cannot accommodate everything... Even our pharmacy room it is small like a toilet it is very small. Only one person can enter in that old building.” (Nurse, PHC 1, district A)

How do the clinics/health workers adapt to cope with the challenges they face?

The health workers have relationships with health workers from other facilities which enables them to

communicate and borrow stock from each other. Since not all facilities had access to working telephones, clinic staff used WhatsApp to communicate with each other. This method of communication was fast.

“We have a WhatsApp group, for operational managers and for the whole district team where we discuss, because sometimes others do not have landlines and what, what, but we use the WhatsApp group and we liaise there, and you get help like that.” (PHC supervisor)

Policy recommendations

To improve the medicine stock management at PHC facilities and avoid medicine stock outs, government should consider the following policy recommendations, which are based on the findings from the study.

- Training of nurses on forecasting methods and other aspects of medicine stock management should be included in the nursing curriculum at nursing colleges.
- Continuous monitoring and supervision of nurses working in medicine stock management by district pharmacists on the implementation of SOPs on medicine stock management.
- Strengthening the human resources at PHC facilities by employing more people-particularly pharmacist assistants/ technicians to work at clinics so that nurses are relieved of medicine stock management duties.
- Equipping the PHC facilities with necessary communication infrastructure e.g. computers as this will allow more of them to use Rx solution for medicine stock management and if internet is available, they would be able to use emails to communicate. Rx solution should also be set up with a real-time ordering system linking PHC facilities to the depot. This system would allow them to access information on medicines available for order as they place the order.
- Using cell phones to send circulars on medicine availability via SMS to health workers rather than hand delivered circulars as this would convey the information much faster.

Conclusion

In conclusion, unlike many studies which focused on medicine availability at higher levels for example manufacturers and suppliers on the availability of medicines, this study provides insight into practical issues that can be addressed at the PHC level in order to improve medicine stock management. This is most important because if medicines are available at the pharmaceutical depot but medicine stock management is inefficient at PHC facilities, stock outs may still occur.

References

- Bigdeli, M., Peters, D.H., Wagner, A.K. & World Health Organization 2014. Medicines in health systems: advancing access, affordability and appropriate use.
- Cameron, A., Roubos, I., Ewen, M., Mantel-Teeuwisse, A.K., Leufkens, H.G. & Laing, R.O. 2011. Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. *Bulletin of the World Health Organization*. 89(6):412-421.
- Health Systems Trust 2015. *Central Chronic Medicine Dispensing and Distribution Programme (CCMDD)*. Available: <http://www.hst.org.za/projects/central-chronic-medicine-dispensing-and-distribution-programme-ccmdd> [2015, November 10].
- Honda, A., Ryan, M., van Niekerk, R. & McIntyre, D. 2015. Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment. *Health Policy and Planning*. 30(5):600-611. DOI:10.1093/heapol/czu038 [doi].
- Kitahata, M.M., Gange, S.J., Abraham, A.G., Merriman, B., Saag, M.S., Justice, A.C., Hogg, R.S., Deeks, S.G. et al. 2009. Effect of early versus deferred antiretroviral therapy for HIV on survival. *New England Journal of Medicine*. 360(18):1815-1826.
- Mayosi, B.M., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. & Bradshaw, D. 2009. The burden of non-communicable diseases in South Africa. *The Lancet*. 374(9693):934-947.
- McIntyre, D., Goudge, J., Harris, B., Nxumalo, N. & Nkos, M. 2009. Prerequisites for national health insurance in South Africa: results of a national household survey. *SAMJ: South African Medical Journal*. 99(10):725-729.
- Public Service Commission 2015. Consolidated report on service delivery inspections of district hospitals and clinics regarding availability of medicines and medical equipment and the role of health district offices. Public Service Commission.
- Schouten, E.J., Jahn, A., Ben-Smith, A., Makombe, S.D., Harries, A.D., Aboagye-Nyame, F. & Chimbwandira, F. 2011. Antiretroviral drug supply challenges in the era of scaling up ART in Malawi. *Journal of the International AIDS Society*. 14 Suppl 1:S4-2652-14-S1-S4. DOI:10.1186/1758-2652-14-S1-S4 [doi].
- Wagenaar, B.H., Gimbel, S., Hoek, R., Pfeiffer, J., Michel, C., Manuel, J.L., Cuembelo, F., Quembo, T. et al. 2014. Stock-outs of essential health products in Mozambique ? longitudinal analyses from 2011 to 2013. *Tropical Medicine & International Health*. 19(7):791-801. DOI:10.1111/tmi.12314.
- World Health Organisation 2015. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Switzerland: World Health Organisation.

14 Part E: Appendices

14.1 APPENDIX 1: INFORMATION SHEET

Medicine stock management at Primary Health Care facilities

Medicines are vital in the provision of healthcare therefore it is essential for them to be available in sufficient quantities at all times. Primary Health Care (PHC) clinics are the entry point for most citizens into the South African health care system and it is of great importance to ensure that medicines are available at clinics. The availability of medicines has been found to be an important deciding factor used by patients when choosing to seek care from health facilities and is therefore a priority for the South African government as it aims to strengthen its health system.

The aim of this study is to better understand the process of managing medicine stock at public health facilities in District A and District B in the study province. The study will have a specific focus on the PHC level by examining the processes used by the clinics to manage medicine stock and how the clinics interact with the pharmaceutical depot in this process. It will also look into factors which may influence the management process.

We would be most grateful if you could take part in this study by sharing your experiences in the management of medicine stock at clinics in the study province. The interview will take about 1 hour. You are free to decide whether or not to participate at any point and time throughout the duration of the study. You may also choose not to answer a particular question(s) and you can stop the interview at any time. The information that you provide will be kept confidential and will be combined with the responses from the other interview participants. No one will know what you, or any other individual have said and no personal details will appear in any reports generated from this research.

We hope that this study will reflect on the opinions from health workers like your-self and inform policy review and formulation of standard operating procedures for the management of essential medicines in public health facilities.

We value your opinion and would be most grateful if you choose to participate in this study. If you require more information on the study, we would be pleased to provide you with more information and answer any questions that you may have with regards to the study and your participation.

Yours sincerely,

Fadzai Munedzimwe

MPH (Health Economics) student, Health Economics Unit,

School of Public Health and Family Medicine, University of Cape Town

Tel: +27 21 406 6558 Email: Fadzai.munedizmwe@gmail.com

14.2 APPENDIX B: CONSENT FORM

Medicine stock Management at Primary Health Care facilities

Consent to participate in interviews and for tape recording

I have been informed about the study ‘Managing medicine stock at Primary Health Care facilities in District A and District B in the study province, South Africa’ and have had the opportunity to ask questions about the study and my involvement in it.

I understand that there will be no consequences as a result of my participating, or not participating in the interviews and recording of the interviews.

I understand that my participation is voluntary and that I am free to withdraw at any time and request that the interview is not tape recorded, without giving a reason.

I understand that the information I provide will be treated in the strictest confidence and that my name will not be used when the information is analysed and reported.

I agree to take part in the interview. Yes/No

I agree to the tape recording of the interview. Yes/No

I agree for my quotations to be used in the publication or report released on the study. Yes/No

Signature of the participant

Date

Interviewer’s name (please print)

Interviewer’s signature

Date

14.3 APPENDIX C: QUESTIONNAIRES

Semi-structured questions for key informant interviews

Individual interviews with health workers in charge of medicine management at PHC clinics.

Capacity of the health workers and facility

- Please provide me with some insight on how medicine stock is managed in the clinic? (Who is involved, how were they appointed, are the sufficient people?)
- Do you think there are enough people involved in the management of medicine stock? If yes, or no, please explain.
- Have you received any specific training or mentoring on inventory control or medicines stock management i.e. on how to use the stock cards or computer systems? (this training may include in-service training/mentorship) How often does this happen? From where/whom do you receive the training/mentoring and when last did it happen? Did the training better equip you to carry out your roles in medicine stock management? If there were any gaps, please mention them.
- How often does the district pharmacist/pharmacists visit the clinic? What is the purpose of these visits? What do you think about the visits? How does this help you in terms of stock management? Is there anything that could be done to improve this? If he never visits, do you think he should visit?
- Do you have telephone lines, internet access, computer systems at the facility in order for you to use to communicate with the depot and other clinics/ district/ provincial offices? Are these in working order? Do they give you any trouble?

Stock management processes/Inventory control, forecasting and information systems

- Can you please show me how and where you record the stock levels of medicines? At each point in time, roughly how much stock of a specific medicine do you keep at your facility? How do you determine these quantities? How often do you review the stock levels to ensure that they are sufficient? (*ask for a copy of stock control sheet/stock card*)
- Can you please explain to me the process you follow when ordering stock?
- How often do you order medicines from the pharmaceutical depot?
- After how long do you receive your order from the depot? Who is responsible for transporting the medicines you have ordered from the depot to your facility?

- Do you receive stock from anywhere other than the depot? If so, where do you receive it from and how to you order it? Why do you receive stock from other sources?
- Who is responsible for receiving stock upon delivery? What is the process for receiving stock at the facility? How do you ensure that what you have ordered is the same as what you have received from the depot?

Relationship and communication with the pharmaceutical depots

- Does the depot inform you if a certain medicine is unavailable and they are unable to supply it? If so how do they inform you? Does the depot give you an indication of when the medicine may be available again?
- What do you think about the way you communicate with the depot? Could you please discuss things that work well and if there are challenges what challenges do you face any challenges in communicating with the depot? What do you think can be done to improve the way in which you interact and communicate with the depot?

Drug stock outs response

- When medicines run out at your clinic or are not delivered from the depot, what is the first thing you do? Who do you contact and how do they respond?
- Do you make any efforts to source medicines that are out of stock from another clinic/hospital? Where would you source medicines that are out of stock at the clinic? Who is responsible for transporting these medicines you have sourced from another clinic/hospital to your clinic?
- If a medicine is out of stock, what do you give the patient? Do you substitute the medicine? What do you base your substitution on? Do you receive any guidelines on which medicines you can substitute with in the case of a nation-wide stock out?

Context

- Does the distance from the depot pose any challenges for medicine stock management? If yes, what are these challenges? Have any of these challenges been resolved in the past?
- Have there been any recent changes to drug stock management in your district?
- Do you feel that if you were closer to the depot things might be better? If yes/ no, why?

- Do you ever experience any challenges with late deliveries from the depot? What is the cause of these late deliveries? Do you experience any transportation challenges with regards to deliveries from the depot?
- What do you think about the location of the clinic in terms of accessibility? What made you choose to work at this facility? Are you still enjoying working here?
- Is it easy or hard to do drug stock management in this facility? What factors help or hinder this in the facility?

Semi-structured questions for key informant interviews

Individual interviews with district pharmacists. (2)

Stock management processes at the clinics.

- Can you please tell me about your role as the district pharmacist in ensuring the availability of medicines at PHC clinics?
- How often do you check the stock levels at the clinics and in what way?
- Do you ever assist or send pharmacists or pharmacist assistants to assist the clinics in managing their stock? How do you or the pharmacists/ pharmacist assistants assist and how often?
- Do you train or ensure that nurses at the clinics are able to manage stock levels? If you do, how often and in what way is this done?
- What do you think influences the medicine stock management process at clinics? What could be done to improve the management of medicine stock at clinics?

Relationship between clinics and the pharmaceutical depots

- How do you communicate with the pharmaceutical depot? What is the purpose of the communication? How often do you communicate?
- Do you communicate with the depot on behalf of the clinics? If so, what is the purpose of this communication?
- Does the depot inform you if a certain medicine is unavailable and they are unable to supply it? If so how do they inform you? Does the depot give you an indication of when the medicine may be available again? Do you disseminate this information to the clinics? How do you do this? What challenges do you face in doing this and how could they be dealt with?
- What do you think about the communication between clinics and (1) the district office (2) the depot?
- What do you think could enable better information sharing and communication?

Drug stock outs response

- How do you find out about medicine shortages and stock outs as they happen at the clinics? How do you respond?
- Do you make any efforts to source medicines that are out of stock at a particular clinic from another facility (clinic/hospital/district)? If so from where?

- If a medicine is out of stock at the depot, do you receive any guidelines on which medicines you can substitute with in the case of a nation-wide stock out? How do you disseminate this information?
- Why do you think medicine stock outs occur at clinics?

Context

- In what ways do you think geographic location influences the availability of medicines at clinics? Do you find that there is a difference between the capacity of health workers to manage medicine stock at the rural and urban clinics? If there is a difference what do you think causes this difference?
- In your opinion, does the burden of disease affect the processes of medicine stock management? If so, how?
- Does the distance between your office and the clinic have any effect on the extent to which you supervise the clinics?

Semi-structured questions for key informant interviews

Individual interviews with the provincial head of pharmaceutical services. (1)

Stock management processes at the clinics.

- Please tell me about your role as the head of pharmaceutical services in the province in ensuring the availability of medicines at PHC clinics?
- Do you check the stock levels at the clinics? How often do you do this? What is the purpose of the checks?
- Do you train or ensure that nurses at the clinics are able to manage stock levels? If so, how often are the nurses trained and in what form is the training (formal or informal e.g mentoring)?
- What factors do you think influence the management of stock at clinics?

Relationship between clinics and the pharmaceutical depots

- How do you communicate with the pharmaceutical depot? How often do you communicate? Do you communicate with the depot on behalf of the clinics? If so, what is the purpose of this communication?
- Does the depot inform you if a certain medicine is unavailable and they are unable to supply it? Does the depot give you an indication of when the medicine may be available again? Do you disseminate this information to the clinics? How do you do this?
- Are you aware of how clinics communicate with the depot? What do you think about this communication and the way in which they interact? Do you see any challenges or enablers of good communication?

Drug stock outs response

- Do the clinics alert you of medicine shortages and stock outs as they happen at the clinics? If not how do you find out about them? How do you respond when you find out?
- Do you make any efforts to source medicines that are out of stock at a particular clinic from another facility? Where would you source these medicines?
- If a medicine is out of stock at the depot, do you prepare any guidelines on which medicines can be used as substitutes? How do you disseminate this information to the clinics?
- In your opinion, what do you think are the enablers of good medicine stock management? What do you think causes stock outs at the clinic level?

Context

- In what ways do you think geographic location influences the availability of medicines at clinics? Do you find that there is a difference between the capacity of health workers to manage medicine stock at the rural and urban clinics? If there is a difference what do you think causes this difference?
- In what way do you think the distance between a facility and the depot is related to the occurrence of drug stock outs?
- In what way is the burden of disease related to the occurrence of stock outs?

Semi-structured questions for key informant interviews

Individual interviews with pharmaceutical depot manager

Stock management processes at the clinics.

- Can you please tell me about your role as the responsible pharmacist at the depot in ensuring the availability of medicines at PHC clinics?
- Please tell me about the process you follow when fulfilling an order from the clinics? Do you use a manual or computer based system for this? Please tell me how it works.
- What factors do you think influence the process of medicine stock management at clinics?
- Do you receive information on stock levels at the clinics? How often and in what way?
- Do you train or ensure that nurses at the clinics are able to manage stock levels/use stock control tools? If so, how often and in what way is this done?
- In terms of DDV's what is your role in ensuring that there is timely delivery of medicines at the clinics? Do you communicate to the clinics about expected delivery dates of stock that they have ordered?
- How are medicines delivered to the clinics? Is there a schedule, route for delivery? Are you obliged to communicate with the clinics with regards to changes in the schedule? Who is responsible for this and how do they ensure that the communication has reached the facilities? How do you ensure that medicines have reached the clinics after their dispatch at the depot?

Relationship between clinics and the pharmaceutical depots

- How do you communicate with the clinics? Email, fax, telephone? Are there dedicated channels for orders, queries etc.?
- Do you communicate with regards to stock levels with the district pharmacist/ head of pharmaceutical services on behalf of the clinics? If so, what is the purpose of this communication?
- What are the strengths and weaknesses in the way in which you communicate with clinics? What do you think can be done to address the weaknesses?

Drug stock outs response

- Do the clinics alert you of medicine shortages and stock outs as they happen at the clinics? If not how do you find out about them? What is your response when you find out?

- Do you make any efforts to facilitate the sourcing of medicines that are out of stock at a particular clinic from another clinic/hospital? Where and how would you source these medicines?
- Who do you inform if a certain medicine is unavailable and are unable to supply it to the clinics? How do you inform them? Do you give you an indication of when the medicine may be available again? Do you send any guidelines on which medicines the clinics can substitute with in the case of a nation-wide stock out? How do you disseminate this information?
- What do you think causes medicine stock outs at the clinics?

Context

- In what ways do you think geographic location influences the availability of medicines at clinics? Do you find that there is a difference between the capacity of health workers to manage medicine stock at the rural and urban clinics? If there is a difference what do you think causes this difference?
- Do you experience any transportation challenges when delivering stock to clinics further away from the depot? (E.g. accessibility)
- Are there any differences that you have noticed in the medicine ordering patterns between clinics in District A and District B? If yes, what do you think causes this?
- In what way is the burden of disease related to the occurrence of stock outs?

14.4 APPENDIX D: OBSERVATION AND FIELD NOTES FORM

District:		Facility Number:	
Storage space (no stock on the floor or in places not ideal as medicine rooms)	Yes	No	
Notes:			
Are stock levels indicated on bins?	Yes	No	
Notes:			
Are stock cards being used in dispensing rooms?	Yes	No	
Notes:			
Are stock cards being used in bulk store rooms?	Yes	No	
Notes:			
Check balance on stock cards with quantity on hand for two random items.	Yes	No	
Notes:			

14.5 APPENDIX E: UCT ETHICS APPROVAL LETTER (HREC)



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room 852-24 Old Main Building
Groote Schuur Hospital
Observatory 7935
Telephone [021] 406 6338 + Facsimile [021] 406 6411
Email: jurnawah.unc@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 March 2016

HREC REF: 134/2016

Dr A Honda

Division of Health Economics Unit
School of Public Health & Family Medicine
FHS

Dear Dr Honda

PROJECT TITLE: MANAGING MEDICINE STOCK AT PRIMARY HEALTH CARE FACILITIES IN
..... -(Masters candidate-F Munedzimwe)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study. This approval is subject to the following:

1. Please add the UCT FHS HREC contact details to the informed consent document.
2. Please ensure that you receive Provincial approval for this study.

Approval is granted for one year until the 30 March 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Fadzai Munedzimwe will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signature removed

PROFESSOR M. BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC/REF:134/2016

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HRREC/REF:134/2016

14.6 APPENDIX F: PROVINCIAL DEPARTMENT OF HEALTH APPROVAL

health
REPUBLIC OF SOUTH AFRICA

Urhfnyango WuzMaphisa

04 May 2016

Ms Fadza Munedzimwe
Health Economics Unit
School of Public Health and
Family Medicine Faculty of Health Sciences, Observatory
University of Cape Town
Cape Town, 7925

Dear Ms F Munedzimwe

**APPLICATION FOR RESEARCH & ETHICS APPROVAL: MANAGING MEDICINE STOCK AT
PRIMARY HEALTH CARE FACILITIES IN AND DISTRICTS IN
. SOUTH AFRICA**

The Provincial Health Research and Ethics Committee has approved your research proposal
in the latest format that you sent.

PHREC REF: RP48_442

Kindly ensure that you provide us with the soft and hard copies of the report once your
research project has been completed.

Kind regards

Signature removed

DEPARTMENT OF HEALTH PLANNING & INFORMATION
2016 -05- 04
PRIVATE B&DATE 1285 1200

14.7 APPENDIX G: JOURNAL INSTRUCTIONS FOR AUTHORS

Health Policy and Planning improves the design, implementation and evaluation of health policies in low- and middle-income countries through providing a forum for publishing high quality research and original ideas, for an audience of policy and public health researchers and practitioners. *HPP* is published 10 times a year.

HPP has a double-blinded peer-review policy. All types of papers are peer reviewed and all article abstracts from each issue are translated into French, Spanish and Chinese.

- [Guidance](#)
- [Types of papers](#)
- [Submission process](#)

Guidance

Improving chances of publication

As well as the high overall quality required for publication in an international journal, authors should take into consideration.

- Addressing *HPP*'s readership: national and international policy makers, practitioners, academics and general readers with a particular interest in health policy issues and debates.
- Manuscripts that fail to set out the international debates to which the paper contributes, and to draw out policy lessons and conclusions, are more likely to be rejected, returned to the authors for redrafting prior to being reviewed, or undergo a slower acceptance process.
- Economists should note that papers accepted for publication in *HPP* will consider the broad policy implications of an economic analysis rather than focusing primarily on the methodological or theoretical aspects of the study.
- Public health specialists writing about a specific health problem or service should discuss the relevance of the analysis for the broader health system. Those submitting health policy analyses should draw on relevant bodies of theory in their analysis, or justify why they have not, rather than only presenting a narrative based on empirical data.
- Primarily focus on one or more low- or middle-income countries.

The editors cannot enter into correspondence about papers considered unsuitable for publication and their decision is final. Neither the editors nor the publishers accept responsibility for the views of authors expressed in their contributions. The editors reserve the right to make amendments to the papers submitted although, whenever possible, they will seek the authors' consent to any significant changes made. The manuscript will not be returned to authors following submission unless specifically requested.

Should you require any assistance in submitting your article or have any queries, please do not hesitate to contact the editorial office at hpp.editorialoffice@oup.com.

Manuscript format and style for all articles

Only articles in English are considered for publication.

Prepare your manuscript, including tables, using a word processing program and save it as a **.doc**, **.rtf** or **.ps** file. Use a minimum font size of 11, double-spaced and paginated throughout including references and tables, with margins of at least 2.5 cm. The text should be left justified and not hyphenated.

The **title page** should contain:

- Title - please keep as concise as possible and ensure it reflects the subject matter
- Corresponding author's name, address, telephone/fax numbers and e-mail address
- Each author's affiliation and qualifications
- Keywords and an abbreviated running title
- 2-4 Key Messages, detailing concisely the main points made in the paper
- Acknowledgements
- A word count of the full article

In the **acknowledgements**, all sources of funding for research must be explicitly stated, including grant numbers if appropriate. Other financial and material support, specifying the nature of the support, should be acknowledged as well.

Figures should be designed using a well-known software package for standard personal computers. If a figure has been published earlier, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. Colour figures are permitted but authors will be required to pay the cost of reproduction.

Please be aware that the requirements for online submission and for reproduction in the journal are different: (i) for online submission and peer review, please upload your figures separately as low-resolution images (.jpg, .tif, .gif or .eps); (ii) for reproduction in the journal, you will be required after acceptance to supply high-resolution .tif files. Minimum resolutions are 300 d.p.i. for colour or tone images, and 600 d.p.i. for line drawings. We advise that you create your high-resolution images first as these can be easily converted into low-resolution images for online submission.

Figures will not be relettered by the publisher. The journal reserves the right to reduce the size of illustrative material. Any photomicrographs, electron micrographs or radiographs must be of high quality. Wherever possible, photographs should fit within the print area or within a column width. Photomicrographs should provide details of staining technique and a scale bar. Patients shown in photographs should have their identity concealed or should have

given their written consent to publication.

When creating figures, please make sure any embedded text is large enough to read. Many figures contain miniscule characters such as numbers on a chart or graph. If these characters are not easily readable, they will most likely be illegible in the final version.

Certain image formats such as .jpg and .gif do not have high resolutions, so you may elect to save your figures and insert them as .tif instead.

For useful information on preparing your figures for publication, go to <http://cpc.cadmus.com/da>.

All **measurements** should be reported in SI units, followed (where necessary) by the traditional units in parentheses. There are two exceptions: blood pressure should be expressed in mmHg and haemoglobin in g/dl. For general guidance on the International System of Units, and some useful conversion factors, see 'The SI for the Health Professions' (WHO 1977).

Manuscript file must include text body. Title Page, Figures and Tables should be uploaded separately.

Manuscript Preparation

Page 1: **Title Page** – as above;

Page 2: **Abstract**. The abstract should be prepared in one paragraph, no headings are required. It should describe the purpose, materials and methods, results, and conclusion in a single paragraph no longer than 300 words without line feeds.

Page 3: **Introduction**. The Introduction should state the purpose of the investigation and give a short review of the pertinent literature, and be followed by:

Materials and methods. The Materials and methods section should follow the Introduction and should provide enough information to permit repetition of the experimental work. For particular chemicals or equipment, the name and location of the supplier should be given in parentheses.

Results. The Results section should describe the outcome of the study. Data should be presented as concisely as possible, if appropriate in the form of tables or figures, although very large tables should be avoided.

Discussion. The Discussion should be an interpretation of the results and their significance with reference to work by other authors.

Abbreviations. Non-standard abbreviations should be defined at the first occurrence and introduced only where multiple use is made. Authors should not use abbreviations in

headings.

References. References must follow the Harvard system and must be cited as follows:

Baker and Watts (1993) found...

In an earlier study (Baker and Watts 1993), it...

Where works by more than two authors are cited, only the first author is named followed by 'et al.' and the year. The reference list must be typed double-spaced in alphabetical order and include the full title of both paper (or chapter) and journal (or book), thus:

Baker S, Watts P. 1993. Paper/chapter title in normal script. Journal/book title in italics **Volume number in bold** : page numbers.

Baker S, Watts P. 1993. Chapter title in normal script. In: Smith B (ed). *Book title in italics*. 2nd edn. Place of publication: Publisher's name, page numbers.

Up to five authors should be cited. If there are more, cite the first three authors and follow with '*et al.*', e.g.:

Baker S, Watts P, Smith B *et al.* 1993. Paper title in normal script. Paper presented at meeting/conference title, place, date. Unpublished document.

Tables All tables should be on separate pages and accompanied by a title - and footnotes where necessary. The tables should be numbered consecutively using Arabic numerals. Units in which results are expressed should be given in parentheses at the top of each column and not repeated in each line of the table. Ditto signs are not used. Avoid overcrowding the tables and the excessive use of words. The format of tables should be in keeping with that normally used by the journal; in particular, vertical lines, coloured text and shading should not be used. Please be certain that the data given in tables are correct. Tables should be provided as Word or Excel files.

Types of papers

Health Policy and Planning welcomes submissions of the following article types

- [Original research](#)
- [Review articles](#)
- [Methodological musings](#)
- [Research in practice](#)
- [Commentaries](#)

- ['How to do \(or not to do\)...'](#) [for example, see [Hutton & Baltussen, HPP, 20\(4\): 252-9](#)] and
- ['10 best resources'](#) [for example, see [David & Haberlen, HPP, 20\(4\): 260-3](#)].
- Supplements

ORIGINAL RESEARCH

Manuscripts should preferably be a **maximum** of **6000** words, excluding tables, figures/diagrams.

The manuscript will generally follow through sections: Title page (as [above](#)), Abstract (no more than 300 words), Introduction, Methods, Results, Discussion, Conclusion, Acknowledgements, References. However, it may be appropriate to combine the results and discussion sections in some papers. Tables and Figures should not be placed within the text, rather provided in separate file/s.

For the reporting of statistical analyses please consider the following additional points:

- Focus the statistical analysis at the research question.
- Report simple analyses first, then only more sophisticated results.
- Provide information about participation and missing data.
- As much as possible, describe results using meaningful phrases (e.g., do not say "beta" or "regression coefficient", but "mean change in Y per unit of X"). Provide 95% confidence intervals for estimates.
- Report the proportions as N (%), not just %.
- Report P values with 2 digits after the decimal, 3 if <0.01 or near 0.05 (e.g., 0.54, 0.03, 0.007, <0.001 , 0.048). Do not report P values greater than 0.05 as "NS".
- Always include a leading zero before the decimal point (e.g., 0.32 not .32).
- Do not report tests statistics (such as chi-2, T, F, etc.)."

For [acknowledgements](#), [figures](#) and [measurements](#) see above.