Developing a framework to assess healthcare facilities' essential medicine management practices

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Declaration

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Abstract

Access to essential medicines is a fundamental human right; yet, millions of people die each year from diseases that could be treated with modern medicines. A lack of access to essential medicines remains the most serious public healthcare problem globally, with approximately 30% of the world's population not having access to essential medicines. This figure rises to over 50% in the poorest parts of Africa and Asia. Frequent stock-outs and shortages of medicines continue to deny quality healthcare treatment to low-income populations.

Medicine management seeks to find an optimal way to ensure access to essential medicines given various constraints. The absence of adequate assessment tools and frameworks that measure medicine management performance at a facility level, makes it difficult for decision-makers to make informed decisions to improve access to essential medicines.

To address this need, a maturity model was developed to assess essential medicine management performance in public healthcare facilities. A maturity model is a framework that is used to describe the evolution of a system over time through the assessment of its processes. Maturity models provide a well-structured approach to achieving tangible transformation and continuous improvement. The developed model intends to identify opportunities for improvement that extend access to essential medicines.

The maturity model in this study was developed using a three-phase approach that integrated essential medicine management dimensions into maturity model architecture. The model is based on extensive literature reviews on essential medicines, medicine management, and maturity models. The review of literature on essential medicine at facility level helped to define the dimensions of the maturity model. Medicine management literature was also reviewed to identify the key practices that

ensure access to essential medicine in healthcare facilities. Finally, maturity model literature was reviewed to identify the appropriate maturity model architecture which formed the basis of the maturity model developed.

The maturity model was refined and validated by subject matter experts to ensure that the theoretical basis of the model was sound. The validation process found that the developed maturity model adequately measures the performance of essential medicine management at a facility level.

The maturity model developed in this research study provides an alternative assessment method to traditional quantitative performance measurement methods in the healthcare sector and helps healthcare facilities focus on the various practices that drive essential medicine management performance to increase access to essential medicine.

Opsomming

Toegang tot essensiële medisyne word beskou as 'n fundamentele mensereg; tog sterf miljoene mense elke jaar aan siektes wat deur moderne medisyne kon behandel word. 'n Gebrek aan toegang tot essensiële medisyne bly wêreldwyd die ernstigste gesondheidsorgprobleem, met ongeveer 30% van die wêreldbevolking wat nie toegang tot essensiële medisyne het nie. Hierdie syfer styg tot meer as 50% in die armste dele van Afrika en Asië. Die gereelde tekorte en onbeskikbaarheid van medisyne verhoed steeds toegang tot gesondheidsorgbehandeling vir bevolkings met 'n lae inkomste.

Medisynebestuur poog om 'n optimale manier te vind om toegang tot medisyne te verseker, gegewe verskillende beperkings. Daar bestann geen voldoende assesseringsinstrumente of raamwerke wat medisynebestuursprestasie op 'n fasiliteitvlak kan meet nie. Dit is dus moeilik vir besluitnemers om besluite te neem wat toegang tot essensiële medisyne verbeter.

Om hierdie behoefte aan te spreek, is 'n volwassenheidsmodel ontwikkel om essensiële medisynebestuurprestasie in gesondheidsorgfasiliteite te assesseer. 'n Volwassenheidsmodel is 'n raamwerk wat gebruik word om die evolusie van 'n stelsel te beskryf oor 'n tydperke deur die beoordeling van die stelsel se prosesse. Volwassenheidsmodelle is 'n gestruktureerde metode om prosesverbetering te bewerkstellig. Die doel van die volwassenheidsmodel wat in hierdie studie ontwikkel is, is om geleenthede te identifiseer om toegang tot medisyne te verbeter.

'n Omvattende literatuur studie van essensiële medisyne, medisyne-bestuur en volwassenheidsmodelle vorm die basis van die volwassenheidsmodel wat ontwikkel is. Eerstens is essensiële medisyneliteratuur bestudeer om die dimensies van die volwassenheidsmodel te identifiseer. Daarna is 'n literatuurstudie oor medisyne-bestuur uitgevoer om belangrike elemente te

identifiseer wat toegang tot medisyne verbeter. Laastens is literatuur oor volwassenheidsmodelle bestudeer om toepaslike volwassenheidsmodelle-argitektuur te identifiseer wat gebruik is om die raamwerk in hierdie studie te ontwikkel. Die volwassenheidsmodel wat in hierdie studie ontwikkel is, is ontwikkel met behulp van 'n driefase prosedure wat essensiële medisyne-bestuursdimensies in die volwassenheidsmodelle-argitektuur geïntegreer het.

Die volwassenheidsmodel is deur drie kundiges verfyn en bekragtig om te verseker dat die model sy doel bereik het. Die valideringsproses het bevind dat die ontwikkelde volwassenheidsmodel die prestasie van essensiële medisynebestuur op 'n fasiliteitvlak voldoende meet. Die volwassenheidsmodel wat in hierdie studie ontwikkel is, bied 'n nuttige assesseringsmetode wat gesondheidsorgfasiliteite help om op die belangrike praktyke te konsentreer wat toegang tot essensiële medisyne kan verbeter.

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Contents

[1] This literature review focuses only on medicine distribution to inpatients in a healthcare facility.

List of Figures

List of Tables

Nomenclature

Acronyms

B.Pharm	Bachelor of Pharmacy
CMM	Capability maturity model
EML	Essential medicine list
FEFO	First expired, first-out
HAI	Health Action International
HIS	Health information system
HMIS	Health management information systems
INN	International Non-proprietary Name
IST	Information systems and technology
LMICs	Low-and middle-income countries
LMIS	Logistics management information systems
SDGs	Sustainable Development Goals
SEI	Software Engineering Institute
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
STGs	Standard treatment guidelines

UDDS	Unit-dose dispensing system
UN	United Nations
WHO	World Health Organisation
WSS	Ward stock system

Chapter 1

Introduction

The purpose of this research is to develop an assessment framework that can be used to assess essential medicine management performance in public healthcare facilities in sub-Saharan Africa. The intent is to identify opportunities for improvement that extend access to essential medicines. This introductory chapter presents the rationale for the research, the problem under study and the research aim and objectives. The chapter then concludes with a brief discussion on the ethical implications of the study and the outline of this thesis.

Section objectives:	§1.1: To explain the rationale behind the research study; §1.2: To state the problem under study; §1.3: To present the research aim and objectives; §1.4: To present the structure of the document; and §1.5: To discuss the ethical implications of the research.

1.1 Rationale of the Research

Sub-Saharan Africa has the most impoverished healthcare in the world (Conway *et al.*, 2017). This status has been measured by the World Health Organization (WHO) which assesses the state of a nation's health by using three main indicators, namely:

- life expectancy;
- healthy life expectancy; and

- the number of deaths before the age of 70.

The region of sub-Saharan Africa lags far behind other regions globally on all three indicators (Conway *et al.*, 2017). Further, while it accounts for 11% of the world's population it is responsible for 24% of the global disease burden (World Bank Group, 2008). The region has the highest burden of infectious diseases globally. Additionally, in terms of life expectancy, one in four premature deaths from communicable diseases are reported in sub-Saharan Africa (Meyer *et al.*, 2017).

In 2015 at the United Nations (UN) Conference in Rio Janeiro, Brazil, the 2030 Agenda for Sustainable Development was adopted whereby 17 Sustainable Development Goals (SDGs) were established. The focus of this present research is aligned with Goal 3 of the SDGs which resolved to promote healthcare to "[e]nsure healthy lives and promote well-being for all at all ages" (United Nations, 2017). According to the SDGs Report at the time, Goal 3 aims to address major health challenges to (United Nations, 2017):

- improve reproductive, maternal and child health;
- eradicate communicable diseases;
- reduce non-communicable diseases and other health hazards; and
- ensure universal access to safe, effective, quality and affordable medicines and vaccines.

This 2015 resolution, therefore brought essential medicines centre stage as they are known to prevent, treat or alleviate the leading causes of premature death (Embrey, 2012). In 1975, the WHO had already defined *essential medicines* as "indispensable and necessary for the health needs of the population. They should be available at all times, in proper dosage forms, to all segments of society" (Namaya, 2007). Furthermore, access to quality healthcare, including essential medicines had been declared a fundamental human right (WHO, 2002); yet millions of people have continued to die each year due to common conditions which can be prevented or treated with modern medicine. This, according to Embrey (2012), signals a fundamental failure of a healthcare system. Medicine management, therefore, is an important component of an effective and affordable healthcare delivery system (WHO, 2017) as it seeks to find an optimal way to ensure access to medicine given the various

constraints (Iqbal *et al.*, 2017b). Consequently, by improving access to essential medicines and other medical supplies, it is estimated that ten million lives can be saved per year (Kagaruki *et al.*, 2013).

Since medicine is the primary vehicle for healthcare delivery and has a significant impact on the health and well-being of patients around the world (Shrestha *et al.*, 2018) the lack of access to essential medicines remains the most serious public healthcare problem globally. Approximately 30% of the world's population does not have access to essential medicines. This figure rises to over 50% in the poorest parts of Africa and Asia (Kagaruki *et al.*, 2013). Frequent stock-outs and shortages [1] of medical supplies and the reliance on out-of-pocket purchases continue to deny low-income populations quality healthcare treatment (Mackintosh *et al.*, 2018).

In 1977, the WHO introduced the first *Model List of Essential Medicines* in response to requests for assistance from the member states for the selection and procurement of medicine for priority healthcare needs (WHO, 2017). The first Model List contained 224 medical products which could safely and effectively treat the majority of diseases (Dukes & Walkowiak, 2012). Medicines for the list were selected according to disease prevalence, health relevance, evidence of clinical efficacy, safety and cost (WHO, 2010). According to the WHO (2010), the list helps to define the minimum requirements of medicines needed in a basic healthcare system. However, the Model List is not exhaustive but serves rather as a guide for the member states to develop national essential medicines lists (EMLs) which can cater best for the needs of their distinct populations.

In 1978, the International Conference of Primary Health Care, held in Alma-Ata, Kazakhstan, identified the provision of essential medicines as one of the eight building blocks of primary healthcare (Quick *et al.*, 2002). Essential medicines are viewed as an input in a system that needs to be available to allow service delivery (Bigdeli *et al.*, 2013). The availability of medicine is cited in several studies as a key determinant of access and the use of healthcare services which is often a measure of the quality of a healthcare system (Bigdeli *et al.*, 2013). Interruptions in the supply of medicine, therefore, can lead to disease progression, drug resistance due to disease mutation, and death (Wagenaar

[1] The definition of shortage and stock-out used in this thesis is in line with the definition established by the WHO which states that (WHO, 2016): a *shortage* is an event when the supply of medicines, health products, and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs and a *stock-out* is the complete absence of the medicine, health product or vaccine at the point of service delivery to the patient.

et al., 2014). Conway *et al.* (2017) have also stated that the absence of essential medicinal products is particularly problematic when trying to combat the spread of diseases.

The earlier study by Wagenaar *et al.* (2014) had already found that the lack of progress in improving access to essential health products is especially evident in developing counties. Not only are they already burdened with medicine shortages but in recent years there is the new phenomenon of an increasing rate of shortages that has prompted international concern about the long-term supply of essential medicines (Hedman, 2016). Over the past decade in particular, poor performing supply systems have been internationally recognised as a bottleneck that delays the strengthening of healthcare systems (Yadav, 2015). However, as more low- and middle-income countries (LMICs) face significant demographic, epidemiological and economic transitions, they are realising the value of investing in improving their healthcare supply systems (Yadav, 2015). There is now a recognised need to standardise medicine supply system performance assessment by, for example, the use of benchmarking tools and approaches to generate tangible recommendations for the improvement of supply system performance (Yadav, 2015). Therefore, challenges affecting the efficiency of medicine supply systems need to be identified, assessed and prioritised to improve the availability of essential medicines in public healthcare (Musonda *et al.*, 2018).

1.2 Problem Statement

Healthcare facilities procure and consume a wide range of medical products. Over the past few years, however, public healthcare facilities in various developing countries have been experiencing frequent shortages and stock-outs of essential medicines. Previous research has shown that insufficient access to essential medicines has a direct effect on the quality of healthcare delivered. The absence of adequate assessment tools to measure essential medicine management performance at facility level makes it difficult for decision-makers to make informed decisions to remedy the problem.

1.3 Research Aim and Objectives

This research aims to develop an assessment framework to benchmark essential medicines management performance in public healthcare facilities to identify areas for improvement. The framework developed in this study aims to serve as a

complementary assessment method to traditional quantitative methods in the healthcare sector (which focus on collecting data on performance outcomes e.g. number of stock-outs). In particular, it aims to focus on the various practices that drive performance. This has the potential to enable policymakers to better understand the root causes of poor performance. To accomplish the aim of this research, the following objectives have been identified:

1. To identify factors which hinder effective medicine management;
2. To investigate an appropriate approach for structuring/developing the proposed framework;
3. To describe best practices for medicine management;
4. To develop a benchmarking assessment framework to evaluate essential medicine management practices at facility level; and
5. To validate the developed assessment framework.

1.4 Chapter Structure

Table 1.1 below presents the structure of this study with a brief overview of each chapter's content.

Table 1.1: Structure of chapters

Chapter	Chapter description
Chapter 1: **Introduction**	This chapter highlights the need for this research study. It introduces the research problem under study and presents the research aims and objectives which will be used to guide the development of the essential medicine management assessment framework.
Chapter 2: **Literature Review: Background Overview and Research Gap**	This chapter presents an overview of essential medicine supply system challenges and identifies the need for an alternative method of assessing essential medicine management performance at facility level. The chapter also discusses the advantages of benchmarking for process improvement and presents evidence of using maturity models as effective assessment frameworks in the healthcare domain.

Continued on next page

Table 1.1 – *Continued from previous page*

Chapter	Chapter description
Chapter 3: **Research Methodology**	This chapter presents the research methodology used to develop the essential medicine management assessment framework.
Chapter 4: **Literature Review: Maturity Models**	This chapter presents background on maturity models and their application. The chapter also reviews maturity model architecture literature that could potentially be used for the development of the essential medicine management assessment framework.
Chapter 5: **Literature Review: Medicine Management**	This chapter presents the key focus areas for improving access to essential medicines at facility level.
Chapter 6: **Framework**	This chapter presents the essential medicine management assessment framework developed in this study and outlines the framework validation process.
Chapter 7: **Conclusion and Future Work**	The final chapter provides a concise summary of the research conducted and presents research's limitations and recommendations for future work.

1.5 Ethical Implications of Research

There are no significant ethical implications for this study. However, since as human participants were involved during the validation data collection phase, ethical clearance was obtained from the Research Ethics Committee of Stellenbosch University. All participants of the study, therefore, explicitly consented to take part in the study and were assured that their contribution was voluntary and that anonymity would be preserved in these final published research findings.

1.6 Conclusion: Chapter 1

Chapter 1 introduces the research study by establishing the background for the research, presenting the problem statement and presenting the research aim and objectives. The chapter concludes with a brief discussion regarding the ethical implications of the study. Chapter 2 presents a literature review which provides an overview of the challenges for essential medicines supply systems as well as evidence to support the development of an alternative assessment method to evaluate essential medicines management performance at facility level.

Chapter 2

Literature Review: Background Overview and Research Gap

Chapter 1 presented a background on the research problem under study and highlighted the need for improved access to essential medicines in the developing countries of sub-Saharan Africa. Chapter 2 presents an overview of the challenges facing medicine supply systems and introduces the concept medicine management as an approach to improve access to essential medicines. This chapter also presents a review of existing methods of assessing access to medicine and highlights the benefit of using maturity models as a benchmarking assessment tool for evaluating essential medicine management performance.

Section objectives:	§2.1: To highlight challenges facing medicine supply systems; §2.2: To introduce the key functional areas for effective medicine supply; §2.3: To present existing methods of assessing medicine supply management; §2.4: To present the research gap identified; §2.5: To provide evidence of benchmarking as an effective assessment method and decide which benchmarking assessment framework will be developed in this study; and §2.6: To present the outcome of a systematic literature review on maturity models as a useful benchmarking assessment frameworks in the healthcare domain.

2.1 Medicine Supply Systems

In developing countries, medicine is responsible for approximately 40% to 60% of total health expenditure (Shrestha *et al.*, 2018). Medicine supply management, therefore, has been brought to the forefront of many of these countries' healthcare agendas to improve efficiency. The WHO has established that an efficient medicines supply system forms an integral part of a strong healthcare system (WHO, 2017). Recent research has revealed that, depending on the country, supply system inefficiencies occur globally with different causes and challenges (Musonda *et al.*, 2018). It appears, therefore, that under-performing supply systems contribute to high prices and limit the availability of quality healthcare products for effective disease control (Bam *et al.*, 2017). The effectiveness of a medicines supply system, therefore, is considered a reflection of a country's ability to address public healthcare challenges (Uthayakumar & Priyan, 2013).

Medicines supply systems are large and often extend outside the borders of the country and this factor makes them particularly challenging to analyse. In addition, supply management of essential medicines differs from that of other medical supplies due to the nature of the products (Musonda *et al.*, 2018). Supply systems are further made complex by uncertainty in supply and demand and in order to increase the availability and access to medicines, supply systems already in place need to become more robust, agile and flexible (Iqbal *et al.*, 2017b). According to Bam *et al.* (2017), supply systems need to have the ability to withstand unplanned changes in demand caused by external variables without shortages or stock-outs.

According to Yadav (2015), medicine supply systems in developing countries are fraught with problems. Improving medicine supply management requires the vertical and horizontal interconnectivity of human resources, information systems, financing and evidence-informed regulations and policies (Oteba *et al.*, 2018). Figure 2.1 below illustrates the different focus areas of improvement at different levels of a healthcare system.

Figure 2.1: Priority action areas to strengthen medicine supply (Oteba *et al.*, 2018)

Sections 2.1.1 to 2.1.4 provide an overview of medicine supply system challenges in a healthcare system focussing primarily on challenges regarding regulations and polices, financing, information systems and human resources, respectively.

2.1.1 Regulations and Policies

A good policy at a national and facility level is known to have far reaching repercussions and is considered a necessity for optimal system functionality (Conway *et al.*, 2017) and it is governments that have the responsibility of developing laws, policies and standards which regulate medicine in a healthcare system. According to the WHO (1999), however, existing government policies and regulations as well as institutional structures for medicines supply management are frequently inadequate and can hinder the overall efficiency of a healthcare system. Healthcare policies and regulations dictate the state and success of a system and according to Conway *et al.* (2017), poor access to medical products is a result of outdated strategies and policies. It has been established that at facility level, lack of policy or poor policy often results

in functional problems and poor service delivery due to resource mismanagement (Conway *et al.*, 2017).

For any intervention to be successful, the changes implemented often need to be integrated into existing policies, regulations, procedures and practices and rigorously evaluated to avoid replication of unsuccessful approaches (Oteba *et al.*, 2018). In addition, policies and regulations need to be regularly updated to ensure that they address the current health situation in a country and are in line with international standards (Tema, 2014).

2.1.2 Financing

Governments have the responsibility to establish appropriate and reliable funding strategies for public healthcare delivery and to ensure adequate funding is available at all times (Kai Hong, 2016). Sources of financing for medicine include government financing, user fees, health insurance, community co-financing and donor financing. According to Kai Hong (2016), each of these funding sources vary in terms of the efficiency, equity and sustainability. In particular, it has been found that unsustainable sources of funds often lead to medicine shortages and result in the overall inefficiency of a healthcare system (WHO, 1999).

Adequate healthcare financing ensures timely procurement and guarantees the uninterrupted availability of medicines at different levels of a healthcare system (Yadav, 2015). According to the WHO (1999), a system's ability to order medicine when needed and to pay for them on delivery has a positive effect on reducing stock-out rates. Furthermore, the prompt and reliable payments increase suppliers' confidence in a system which allows for better price negotiations (WHO, 1999). The Tema (2014) found that irregular funding leads to delayed payments, which in turn forces suppliers to deny credit and insist on advance payments. Another factor is that limited health budgets also put pressure on manufactures to lower prices which then threatens the quality of the products being produced (Hedman, 2016). Efficient and effective financial management systems are important especially when funding is limited (Barraclough & Clark, 2012).

2.1.3 Information Systems

Timely and accurate information is critical for improved productivity, effectiveness and efficiency of medicine supply management practices to help control costs and also minimise the possibility of a stock-out (Ombaka, 2009). Information systems can be used to identify problems, assess the impact of inventions and monitor and evaluate a system's performance (Oteba *et al.*, 2018). Information included in an information system needs to be of high quality and accurate as it forms the basis for decision making; however, if the quality of information is poor at facility level it makes data related to consumption and stock-outs difficult to analyse. For this particular challenge, a health information system (HIS) is applicable. This system integrates data collection, processing, reporting and use of the information needed to improve health service effectiveness and efficiency through better management (Kagaruki *et al.*, 2013). A strong HIS enables evidence-based decision making for planning, budgeting and allocation of scarce resources and helps practitioners gain insight in to the performance of a healthcare system (Kagaruki *et al.*, 2013).

2.1.4 Human Resources

Human resources need to ensure that medicine supply management practices are carried out effectively, efficiently and in accordance with national policies, laws and regulations (WHO, 1999). Given the impact of medicine supply management activities on the operation and effectiveness of a healthcare system, it is particularly essential that these activities are performed by qualified staff with high professional and ethical standards, using sound procedures based on appropriate policies and regulations (Muhia *et al.*, 2017). According to the WHO (1999), the lack of properly trained staff in key positions contributes to poor access to medicines even when well established policies and regulations are in place. Unfortunately, the lack of career development and generally unattractive public sector salaries restricts the healthcare sector's capacity to attract and retain qualified and competent personnel (Henderson & Tulloch, 2008).

2.2 WHO Medicine Management Cycle

Figure 2.2 below illustrates the WHO Medicine Management Cycle, whereby the cycle represents the main functional areas of effective medicine supply management, namely

selection, quantification, procurement, storage and distribution (WHO, 2017). These functions are organised in a cycle to emphasise their interdependence (Tema, 2014).

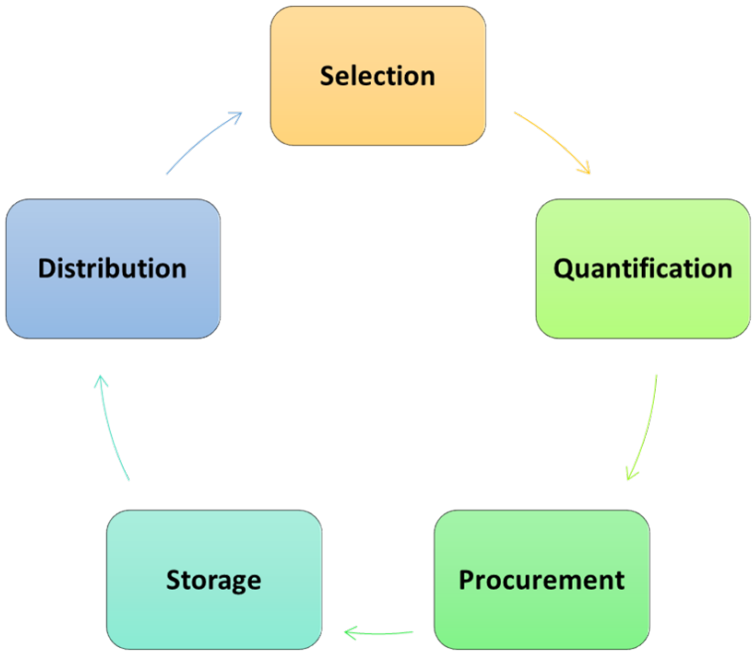

Figure 2.2: The WHO Medicine Management Cycle (WHO, 2017).

According to Embrey (2012), to improve access to essential medicines, the medicine management cycle needs to be reinforced by strong management support systems such as:

- organization;
- sustainable financing;
- information management; and
- human resources management.

The entire medicine management cycle and its support systems, rely on well developed and established policies, laws and regulations which, when supported by good governance, enable sufficient access to essential medicines. The WHO Medicine Management Cycle is discussed in more detail in Chapter 5.

2.3 Assessment Tools

One of the most basic yet significant advances in medicine management has been the introduction of objective standard indicators for assessing, comparing and monitoring the effectiveness medicine management practices (Embrey, 2012). Effective monitoring and evaluating focus on a small set of well-formulated and specific indicators[1] that are directly related to the performance of the system (Miralles *et al.*, 2012). Standard indicators allow a system to compare itself to a target performance level, identify areas of strength and weakness, and to make comparisons with similar systems (Embrey, 2012). Given the complexity of monitoring access to medicines, a range of indicators are used to provide data on medicine availability and price in conjunction with policy indicators (WHO, 2010). The WHO recommends the use of the following core indicators to measure access to essential medicines every three to five years (WHO, 2010):

- **Average availability of 14 selected essential medicines in public and private health facilities.** This indicator is a measure of the average percentage of medicine outlets, where the selection of essential medicines were found on the day of the survey.
- **Median consumer price ratio of 14 selected essential medicines in public and private health facilities.** This indicator measures consumer price ratios, which is calculated as the ratio between median unit prices and Management Science for Health median international reference prices.

Sources of information on access to essential medicines take the form of facility surveys and key informant surveys. Facility surveys on the data related to the availability and use of essential medicines (WHO, 2010). The WHO and Health Action International (HAI) developed a standardised methodology for facility-based surveys on access to essential medicines. The survey collects data on the availability and prices of approximately 50 medicines (14 medicines in use worldwide, 16 regionally specific medicines and 20 medicines of national importance). These data are collected through visits to medicine outlets.

[1] An indicator is a variable that measures change and is generally linked to a system's plans, objectives and targets (Miralles *et al.*, 2012).

Key informant surveys provide information about medicine supply system practices. According to the WHO (2010), surveys with experts who have extensive knowledge about the medicine context in a country can be used to acquire information about medicine selection, procurement, use and policy. This method is low cost and relatively easy to implement: however, one drawback of the method is its subjectivity which introduces measurement errors and affects the comparability of results (WHO, 2010).

The WHO survey package developed in 2002 to monitor and assess the pharmaceutical situation in countries provides a cost-effective means of determining availability of essential drugs, their safety, efficacy and quality (Namaya, 2007). The survey's indicators measure the degree to which a country is meeting the National Drug Policy's objectives of availability, affordability, quality and rational use of essential medicines (Namaya, 2007).

According to Miralles *et al.* (2012), it is important that outcome indicators for medicine management focus on aspects of availability and affordability of essential medicines, as well as quality issues and the appropriate use of medicines. Miralles *et al.* (2012) state that these indicators are typically the most visible and commonly cited for evaluating the success of a supply system's functionality. In sum, systematic and ongoing monitoring is essential:

- to ensure that the performance is on track;
- to improve performance; and
- to achieve long-term goals and results.

2.4 The Research Gap

Given that medicine management practices have a positive or negative effect on access to appropriate healthcare treatment, research into mechanisms that affect healthcare outcomes needs further study to improve the state of healthcare in sub-Saharan Africa (Conway *et al.*, 2017). More recently Mackintosh *et al.* (2018) have concurred that medicine management in LMICs remains understudied and unanalysed.

When analysis of medicine management in the healthcare sector takes place little attention is often paid to medicine supply management practices (Mackintosh *et al.*, 2018). Literature reviews by Kjos *et al.* (2016) and Iqbal *et al.* (2017a) have agreed that

there is a paucity of published literature on medicine supply management activities for public health facilities in developing countries. These activities include the following:

- selection;
- quantification;
- procurement;
- storage; and
- distribution.

The studies mentioned above have also found that there are no adequate performance measures or tools available which assess and evaluate medicine management activities in public healthcare facilities. Many countries do not routinely monitor or report on the performance of their supply systems, which in itself is a significant indicator of sub-optimal performance (Iqbal *et al.*, 2017b). When the existing monitoring does occur it usually takes the form of a periodic survey for only a limited set of indicators with a focus primarily on the availability of essential medicines.

Healthcare processes and the management thereof have a direct impact on the quality of healthcare services delivered (Tarhan *et al.*, 2015). Healthcare organizations are now under constant pressure to achieve better outcomes with fewer resources (Schriek *et al.*, 2016), while simultaneously facing various challenges ranging from operational inefficiencies to high costs and poor quality (Fitterer & Rohner, 2010). The importance of continuously improving healthcare processes to improve the quality of care delivered has been documented in many studies (Schriek *et al.*, 2016). The failure to use a systematic diagnostic method or tools to determine why a healthcare system is under-performing has tended to lead to ad-hoc projects that address only the symptoms of the underlying structural causes (Yadav, 2015).

Since the healthcare domain offers high-risk services to patients daily in a complex, dynamic and multidisciplinary environment it requires the right tools to assess and sustain process improvement interventions. Process improvement is significantly enabled by measurement tools that facilitate benchmarking against best practices (Caralli *et al.*, 2012). Benchmarking the performance of medicine supply management practices provides important information on whether the processes and practices in

place are satisfactorily ensuring access to medicine. Being able to benchmark a system against a recognised standard helps to evaluate the effectiveness of improvement efforts and encourages policy-makers to provide funds for new initiatives to expand and improve the system when the results demonstrate inadequacies within the current system (Kjos *et al.*, 2016).

2.5 Benchmarking

Benchmarking is the process of identifying the highest standards of excellence for products, services or processes and then making the improvements necessary to reach those standards (Elmuti & Kathawala, 1997). According to Ahmed & Rafiq (2002), benchmarking provides a clear signal of success or failure in a system. The process of benchmarking entails analysing one's own performance by highlighting the strengths and weaknesses, and assessing what needs to be done to improve the performance (Salem *et al.*, 2012). The central essence of benchmarking is about learning how to improve organizational activities, processes, and management (Hashim *et al.*, 2012). Benchmarking helps organizations to determine what they could be doing better by setting achievable goals that have already been proven successful (Elmuti & Kathawala, 1997). Benchmarking is also used in a variety of industries as a method of identifying new ideas for process development and is increasingly becoming popular as a tool for continuous improvement (Hashim *et al.*, 2012).

Benchmarking assessment frameworks seek to evaluate the determinants of high performing processes and activities in order to identify "gaps"; gaps are indicative of the potential for improvement in an organization (Ahmed & Rafiq, 2002). This research aims to develop a benchmarking assessment framework to assess the performance of essential medicine management practices at facility level. The framework aims to identify opportunities for improvement while simultaneously providing guidance of which practices need to be improved to extend access to essential medicines. The researcher reviewed three types of benchmarking frameworks in Appendix A for assessing processes; namely: gap analysis, balanced scorecards and maturity models. The aim of the review was to identify a suitable benchmarking framework to develop in this study to achieve this research's aim and objectives.

All three frameworks reviewed have the potential to benchmark medicine management practices at a facility level and have been widely used to assess processes in the healthcare domain; however, for this research, a maturity model will be developed. According to Marra *et al.* (2018), benchmarking frameworks can be valuable when they can be used to identify the sequence of steps needed for process improvement. After the review of the gap analysis and balanced scorecard approaches, the researcher found that those frameworks focus primarily on the "to-be" state of a process or system and do not provide guidance on how to improve the current state. As Hofmann *et al.* (2012) noted, some frameworks focus too much on the fulfilment of requirements but do not help determine how to improve the performance of a system. The researcher found this to be case for the gap analysis and balanced scorecard approaches.

A maturity model will be developed in this study because it measures and thereby support process improvement and facilitates extensive benchmarking and continuous improvement (Gastaldi *et al.*, 2018). Maturity models are an established approach for assessing processes which emphasises the notion of continuous improvement through levels of process formality (Srai *et al.*, 2013) and help organizations to plan and execute process-based transformation (Schriek *et al.*, 2016).

2.6 Maturity Models

An analysis by Wendler (2012) of 237 articles between 1999 and 2010 found that the majority of the literature on maturity models focused primarily on software engineering, information systems, and information communication and technology. It also found that only six of the 237 articles were related to healthcare. The analysis by Wendler (2012) led Söylemez & Tarhan (2016) to identify a lack of maturity models specifically focused on process assessment or process improvement in the healthcare domain.

The following subsections present the methodology used and the outcome of a systematic literature review on maturity models in the healthcare domain.

2.6.1 Methodology Used

The aim of this systematic literature review is to identify literature that proves the usefulness of maturity models in accessing process and practices in the healthcare

domain. According to Carvalho *et al.* (2016) it is important to define a strategy to systematically identify and analyse the literature. The methodology used for this systematic literature review was adapted from the approach by Carvalho *et al.* (2016) as illustrated below in Figure 2.3.

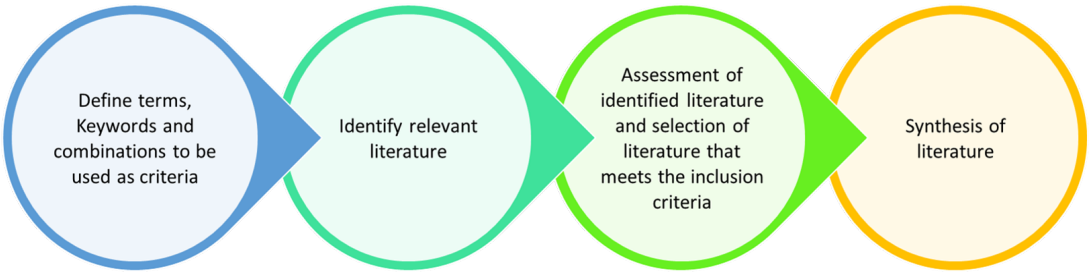

Figure 2.3: Systematic literature review methodology

A description of this fourfold approach is outlined as follows:

Keywords and search criteria. The inclusion and exclusion criteria ensures the quality and similarity of literature required to address the aim of the systematic literature review (Carvalho *et al.*, 2016). The keywords defined as the literature search criteria were:

"health care" or "healthcare"

and

"maturity model" or "capability maturity model"

and

"process" or "process improvement" or "process maturity" or "process assessment" or "process capability"

An initial review of maturity model literature identified a trend in the focus on information systems and technology (IST) maturity models. A similar trend was also noticed during a general search for maturity models literature in the healthcare domain. Owing to the extensive literature on IST maturity models reviewed (both generally and specific to healthcare) in Chapter 4, this systematic literature review excluded the review

IST maturity model literature. The literature included in this review focused specifically on the use of maturity models as process assessment framework in the healthcare domain.

Relevant literature. It is important to identify relevant literature using extensive and reputable databases which efficiently produce objective search results. Two databases were used to identify the relevant literature, namely: Scopus and Web of Science. Scopus and Web of Science are well know and widely used scientific literature databases. Web of Science includes literature from more than 10 000 peer-reviewed journals (Aghaei Chadegani *et al.*, 2013). According to Aghaei Chadegani *et al.* (2013), Scopus is the largest multidisciplinary scientific literature database with more than 49 million publications and over 20 500 peer-reviewed journals.

The keywords were used to search the title, abstract and keywords of publications on Scopus and Web of Science, which identified 72 documents on 2 May 2019.

Assessment and selection of literature. After a review of the document results from the initial search, nine documents were selected based on their adherence to the inclusion and exclusion criteria. Figure 2.4 below illustrates the process of elimination.

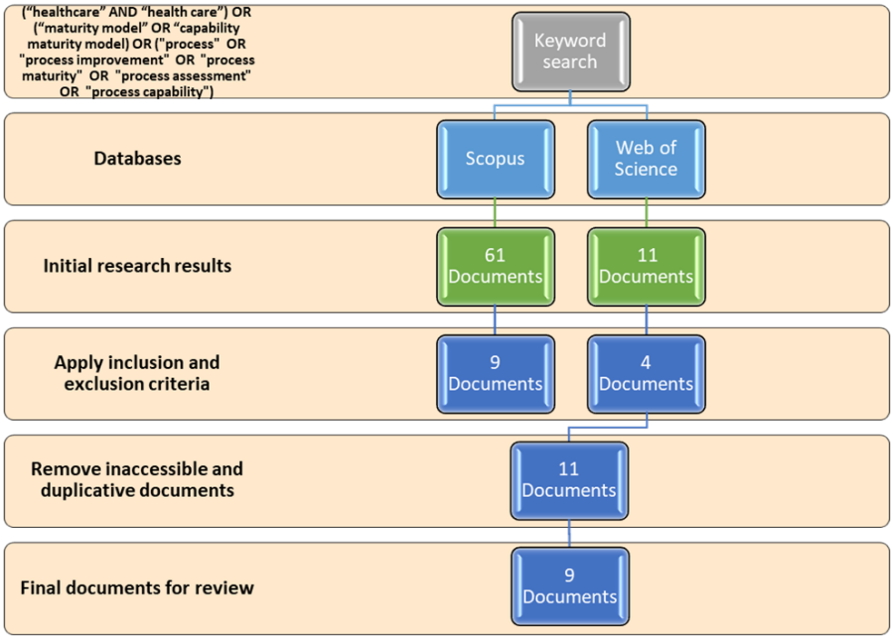

Figure 2.4: Search results 2 May 2019

Literature synthesis A literature synthesis is the process of systematically extracting relevant information from each selected document. The type of data extract should be relevant to the review's aim and objectives (Okoli & Schabram, 2010). The selected literature listed in Table 2.1 below was used to achieve the aim of a systematic literature review by answering the following questions:

1. Are maturity models an appropriate tool/method for assessing process in the healthcare domain?
2. How are maturity models developed in the healthcare domain?
3. How are maturity models validated in the healthcare domain?

Table 2.1: List of selected literature

Author(s)	**Title**
Söylemez & Tarhan (2016)	*The Use of Maturity/Capability Frameworks for Healthcare Process Assessment and Improvement*
Tarhan *et al.* (2015)	*Assessing healthcare Process Maturity: Challenges of using a Business Process Maturity Model*
Fitterer & Rohner (2010)	*Towards assessing the networkability of health care providers: A maturity model approach*
Schriek *et al.* (2016)	*A maturity model for care pathways*
Cleven *et al.* (2014)	*Process management in hospitals: an empirically grounded maturity model*
Gastaldi *et al.* (2018)	*Measuring the maturity of business intelligence in healthcare: Supporting the development of a roadmap toward precision medicine within ISMETT hospital*
Voigt *et al.* (2014)	*'Act on oncology' as a new comprehensive approach to assess prostate cancer centres - Method description and results of a pilot study*
Mettler & Blondiau (2012)	*HCMM - A maturity model for measuring and assessing the quality of cooperation between and within hospitals*
Hofmann *et al.* (2012)	*Act on stroke - optimization of clinical processes and workflow for stroke diagnosis and treatment*

The findings of the systematic literature review are presented in the following subsections.

2.6.2 Maturity Model as an Assessment Framework

Given that the improvement of key processes in the healthcare domain leads to better healthcare outcomes (Hofmann *et al.*, 2012), the first step to enhance the effectiveness and efficiency of a process is to assess the current state of such a process. Assessment frameworks form part of the foundation of process improvement initiatives; they enable process quality to be rated by a consideration of the degree of conformity to a specified standard (Söylemez & Tarhan, 2016).

Many maturity models have been developed to guide process improvement initiatives in the healthcare domain (Schriek *et al.*, 2016). According to Tarhan *et al.* (2015), the quality of healthcare services is influenced by the maturity of the processes that comprise the system. The findings from maturity models are often translated into action plans which result in process improvement (Söylemez & Tarhan, 2016). According to Fitterer & Rohner (2010), process maturity is the basis for improving an organisations capacity to carry out its objectives efficiently and effectively.

Introducing maturity models as an assessment tool brings a total quality perspective to the healthcare domain (Tarhan *et al.*, 2015) and provides a holistic assessment method to improve process maturity (Fitterer & Rohner, 2010). The literature supports the use of maturity models as an effective assessment framework in the healthcare domain, however, Hofmann *et al.* (2012) state that there is a drawback in the fact that each individual organization has to establish its own definition of a quality process. This makes it difficult for the model to be widely used and accepted.

2.6.3 Maturity model architecture

An effective way of designing a new maturity model is by reviewing existing maturity models (Fitterer & Rohner, 2010). According to Söylemez & Tarhan (2016), there is no set guideline for developing maturity models specifically for the healthcare domain as there is a lack of consensus regarding which dimensions and maturity levels are most applicable to the healthcare sector. However, including relevant model elements from existing maturity models allows for the integration of accepted concepts for assessing process maturity (Fitterer & Rohner, 2010). Söylemez & Tarhan (2016) also recommend developing new maturity models based on well validated existing models.

The Capability Maturity Model (CMM) is widely used as the basis for developing new maturity models by adapting its structure and content (Söylemez & Tarhan, 2016). Organizations in the healthcare domain often operate as loosely coupled sets of highly specialised silos which make them different from organizations in other industries, therefore, generic maturity models such a CMM need to be adapted to serve its purpose in a new domain (Schriek *et al.*, 2016). Adaptations to the CMM require changes in dimensions, adopting domain specific terminology, and changing the level of abstraction for each maturity level to incorporate critical core competencies of the new domain (Schriek *et al.*, 2016).

Extensive literature reviews are required to ensure that all the necessary components of a maturity model are included (Gastaldi *et al.*, 2018). Fitterer & Rohner (2010) further suggest that dimensions included in the maturity model should be based on aligning the dimensions to best practices to improve the model's ability to assess process maturity effectively. While the descriptions of maturity levels vary, depending on the domain for which the maturity model is developed, it is important that a consistent scale of maturity is established to ensure the model is adequately able to determine process maturity (Fitterer & Rohner, 2010). According to Fitterer & Rohner (2010), this can be accomplished by developing maturity levels that are comparable to those of the CMM. The CMM architecture is useful in providing guidance on defining dimensions and maturity levels a meaningful sequence (Cleven *et al.*, 2014).

2.6.4 Maturity model validation

It is important to validate a maturity model to ensure that it captures the real-context of the domain appropriately (Fitterer & Rohner, 2010). Validation determines a maturity model's rigour and relevance (Fitterer & Rohner, 2010). Relevance is closely linked to utility which describes the ability of the maturity model to solve the outlined problem (Cleven *et al.*, 2014). Most studies advocate for the validation of maturity models using case studies and implementation. According to Tarhan *et al.* (2015), these methods are preferred because they allow the model to be tested in a real-world setting and, therefore, help to validate the general applicability of a maturity model (Voigt *et al.*, 2014).

Consulting experts in a field is also known to increase the relevance and validity of the maturity model (Gastaldi *et al.*, 2018). Qualitative research methods can be used to gain insight into a practitioner's understanding of a framework and has been proved

to be useful to investigate new ideas and determine the applicability of the model in the "real world" (Cleven *et al.*, 2014). It is, however, important that these experts are key actors in the domain to ensure that their input is meaningful (Fitterer & Rohner, 2010).

2.7 Conclusion: Chapter 2

Chapter 2 provides a brief overview of medicine supply system challenges and introduces the concept of medicine management. The chapter reviews the literature for methods of assessing medicine management performance that improve access to essential medicine. It also identifies the need for the development of a maturity model to benchmark medicine management practices and pinpoint opportunities for improvement. Chapter 3 presents the research methodology used in this study to develop an essential medicine management benchmarking framework.

Chapter 3

Research Methodology

Chapter 2 presented an overview on medicine supply system challenges and identified the need for a benchmarking tool to assess essential medicine management practices at facility level. Chapter 3 presents the research methodology used in this study. The chapter starts by defining the type of research that will be conducted and identifies the research methods that will be used for data collection. The chapter also presents the research approach to develop an essential medicine management maturity model in this study.

Section objectives:	§3.1: To define the type of research that will be conducted in this study; §3.2: To describe the research method used for data collection. §3.3: To provide an overview of the research approach developed by Srai *et al.* (2013) and explain why it was chosen as a guideline for the development of the essential medicine management maturity model; and §3.4: To describe the process of developing an essential medicine management benchmarking framework.

3.1 Research Design

The function of research design is to ensure that the evidence obtained in the research answers the initial research question unambiguously (de Vaus, 2001). Research is often

classified in terms of its purpose (Kothari, 2004). Research designs are typically grouped as exploratory, descriptive or explanatory (Kothari, 2004). Table 3.1 below summarises the research design types.

Table 3.1: Types of research design.

Research design	Description
Exploratory	This research design seeks to achieve new insights into a phenomenon and is often undertaken when few or no previous studies on a subject exist (van Wyk, 2011). The aim of this approach is look for patterns, hypothesis or ideas that can be tested and will form the basis for further research (Neville, 2012).
Descriptive	This research design seeks to provide an accurate and valid representation of the factors or variables that are relevant to the research question (van Wyk, 2011). Quantitative techniques are often used to collect, analyse and summarise data for descriptive research (Neville, 2012).
Explanatory	This research design seeks to identify cause and effect relationships between variables (van Wyk, 2011). Explanatory research can be viewed as an extension of descriptive research as it aims to explain why something is happening (de Vaus, 2001).

The research for this study comprises strong elements of exploratory research that focuses on developing an essential medicine management maturity model. Although essential medicine shortages and stock-outs are not a new phenomenon (see section 1.1) and extensive research continues to be conducted on the subject the tool for this study enables healthcare facilities to benchmark and analyse the performance of their medicine management practices. This capability is to ensure adequate access to essential medicines - the current challenge identified as a gap in the literature in section 2.4.

3.2 Research Method

Research methods refer to a range of techniques and procedures used for the collection of research data that can facilitate inference and interpretation for explanation and prediction (Naicker, 2014). Research methods refer to the tools used to conduct research and can be classified as either qualitative, quantitative or mixed. Quantitative research methods examine numerical data and often make use of statistical tools to

analyse the data collected (Neville, 2012). Quantitative methods allow for the measurement of variables to establish the relations between them. Qualitative research methods, on the other hand, are non-numerical research methods focused on establishing an understanding of a phenomena in their 'natural setting' (Neville, 2012). According to Neville (2012), qualitative research methods are more subjective in nature and focus on reflecting on the less tangible aspects of a search subject. Mixed methods, however, are composed of a combination of qualitative and quantitative research methods.

This research made use of qualitative interviews as a research method for data collection. Qualitative interviews are used when seeking the views and opinions on a topic from an interviewees' perspective (MacDonald & Headlam, 1999). According to Kothari (2004), exploratory investigations which involve original field interviews secure greater insight into the practical aspects of the problem under study. In addition, interviews can be grouped into three main styles, namely: structured, semi-structured and unstructured interviews. These are described as follows:

- **Structured interviews.** Structured interviews involve the use of a questionnaire based on a predetermined and identical set of questions (Neville, 2012). This type of interview is used when the researcher sets out to acquire information where responses are directly comparable (MacDonald & Headlam, 1999).

- **Semi-structured interviews.** Semi-structured interviews list the themes and areas to be covered and there may be some standardised questions; however, the interviewer may omit or add questions depending on the situation and flow of the conversation (Neville, 2012). According to MacDonald & Headlam (1999), semi-structured interviews provide flexibility for the researcher to develop themes and issues by responding to answers provided by an interviewee. Semi-structured interviews are well suited for exploratory research.

- **Unstructured interviews.** Unstructured interviews are considered informal discussions where the interviewer explores a topic in-depth with another person in a spontaneous way (Neville, 2012). This method of interviewing does not follow any predetermined pattern of questions or themes, unstructured interviews are useful when a researcher wishes to explore the full breadth of a topic (MacDonald & Headlam, 1999).

Semi-structured interviews were identified as the most appropriate data collection method as they provided the interviewer with the flexibility to explore the area of study in great detail and allowed the interviewees to fully express themselves without restriction.

3.3 Research Approach Selection

Research approaches are plans and procedures for research that detail the steps from broad assumption to detailed methods of data collection, analysis, and interpretation (Creswell, 2014). According to Creswell (2014), the selection of a research approach should be based on the nature of the research problem, the researcher's experience, and the audience of the study. The research approach used in this study is an adapted research approach proposed by Srai *et al.* (2013).

The study by Srai *et al.* (2013) is based on supply network maturity models, supply networks and sustainability. They describe a three-phase approach for the development of a maturity model. The maturity model developed integrated sustainability dimensions into an established supply network maturity model architecture based on extensive literature reviews on supply network maturity models, supply network and sustainability. The maturity model developed helped organization to benchmark their sustainable supply network practices and identify areas where they could be more efficient with the use of energy and resources while minimising waste (Srai *et al.*, 2013). The study developed an effective tool to measure the sustainability activities of organizations.

Consequently, this study followed the research approach by Srai *et al.* (2013) because it successfully led to the development of an alternative measurement tool to existing quantitative measurement approaches which were complex, resource-intensive and presented significant validation challenges. This challenge, therefore, is similar to that faced in this research. Srai *et al.* (2013) identified that effective sustainable supply networks management led to improved organizational performance. The same principle is also supported by the WHO (2004); namely, that more effective medicine management practices would result in improved access to essential medicines. The maturity model approach for the assessment of an organization's processes, therefore, moves the focus of assessment from process outcomes to evaluating practices within a

process that contribute to the outcomes. Having an appropriate method of evaluating a process has a significant effect on the ability to improve process outcome.

3.4 Research Approach of this Study

This research aims to develop an assessment framework to benchmark essential medicine management performance in public healthcare facilities. The objective of the framework is to identify areas for improvement that ultimately improve access to essential medicines. To address the aim and objectives of this research, an adapted assessment framework development approach proposed by Srai *et al.* (2013) was followed as a guideline. The adapted research approach can be seen in Figure 3.1 below.

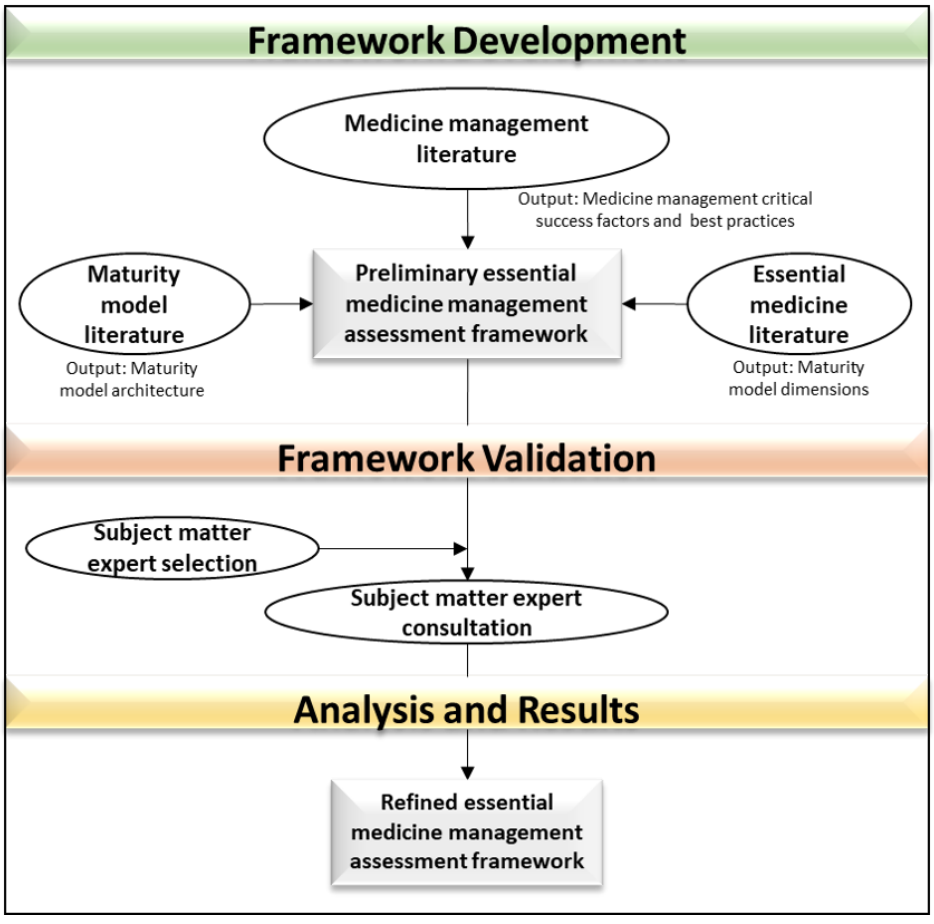

Figure 3.1: Research approach of this study

An overview of the three phases of the research approach used in this study is

provided by the following subsections: framework development, framework validation, and analysis and results.

3.4.1 Framework development

The framework developed in this study assesses the maturity of essential medicine management practices at facility level. While the extensive literature review provided the theoretical foundation (Okoli & Schabram, 2010) to bring the research problem into context, it also formed a firm foundation for advancing knowledge and helped to identify areas where research is needed (Levy & Ellis, 2006).

Essential medicine literature was reviewed to help gain a deeper understanding of this key element in the provision of quality healthcare service delivery. The review of literature on essential medicine at facility level helped to define the dimensions of the assessment framework. Literature on medicine management was reviewed to identify the key practices that ensure access to essential medicine in healthcare facilities. The literature review on medicine management also set out to identify the recognised best practices of medicine management. Maturity model literature was reviewed to identify appropriate maturity model architecture which formed the basis of the assessment framework developed.

Srai *et al.* (2013) has found that incorporating dimensions into maturity model architecture provided a basis for an effective assessment framework. Essential medicine management dimensions found in the literature were integrated into maturity model architecture to develop a preliminary essential medicine management assessment framework.

3.4.2 Framework validation

Validity represents the trustworthiness of the research findings (Naicker, 2014). Ways of ensuring validity include the use of various sources of data and relating the findings of the research to broader theory (Naicker, 2014). Implementation or case studies (as discussed in section 2.6.4) are the best methods for validating maturity models. However, these methods of validation were not feasible for this study due to the time constraints, resources available, and extensive ethical clearance required to conduct comprehensive validation studies in healthcare facilities.

The preliminary essential medicine management assessment framework developed in this study was subject to construct validity (both face and content validity) to ensure that the theoretical basis of the framework was sound. Face validity assesses whether good translations of the constructs have been achieved (De Bruin *et al.*, 2005) and one suggestion is that experts in the field are consulted to judge whether the particular research outcomes address the research's objectives (Kothari, 2004). Content validation, on the other hand, determines how well a domain has been represented (De Bruin *et al.*, 2005). The extent of the literature review and the breadth of the domain covered provides a good measure of content validity.

Triangulation was then applied to strengthen the validity of this study. Triangulation is defined as the use of two or more methods of data collection to examine a particular phenomenon (MacDonald & Headlam, 1999). According to MacDonald & Headlam (1999) triangulation provides additional sources of valuable insight that cannot be obtained from a literature review in that it aims to find consistency in the forms of the data collected. Subject matter experts were consulted to ensure that the appropriate dimensions, maturity level, and best practices were identified to achieve the aim of the maturity model. The following subsections provide an overview of the subject matter expert selection process as well the subject matter expert consultation process.

3.4.2.1 Subject matter expert selection

This research made use of non-probabilistic sampling. In particular, the sampling method used was purposive sampling; a method of sampling that enables the researcher to use their judgement to choose participants best suited to provide the data required for the research study's objectives (Neville, 2012). It involves selecting participants that are especially informed on a specific subject in order to gain a better understanding of a phenomenon (Neville, 2012).

For this study it involved selecting pharmacists with a qualification equivalent to a B.Pharm[1] with a minimum of five years experience in medicine management practices in the public or private healthcare sector.

[1]Bachelor of Pharmacy (B.Pharm) is an undergraduate degree course in the field of pharmacy education.

3.4.2.2 Subject matter expert consultations

The researcher conducted three semi-structured interviews between 20 June 2019 and 31 July 2019 with subject matter experts who provided opinions on the following:

- the research problem;
- the ability of the assessment framework to benchmark essential medicine management practices;
- whether the framework represents medicine management practices in the real-world adequately; and
- whether the solutions proposed by the model are realistic.

The interview questions were predetermined and standardised, each participant was asked identical questions and in the same sequence and the interviews were conducted on a face-on-face basis. The interview questions can be found in Appendix B.

3.4.3 Analysis and Results

The final phase of the research approach dealt with the integration of feedback from the subject matter expert consultations into the preliminary framework where applicable; and presented the final version of the assessment framework.

3.5 Conclusion: Chapter 3

Chapter 3 presents the research design and research methods used in this study. The chapter also presents the research approach used in this study to develop an essential medicine management maturity model. Chapter 4 reviews maturity model literature to gain an understanding of the architectural elements of a maturity model.

Chapter 4

Literature Review: Maturity Models

Chapter 3 presented the research methodology used in this study to develop an essential medicine management maturity model. Chapter 4 introduces the concept of *'maturity'* and provides a brief history of maturity models. The chapter also describes the types of maturity models that can be developed and the type of entities that can be measured using maturity models. Finally, the chapter concludes with an overview of maturity model architecture which could potentially be used to develop an essential medicine management maturity model for this study.

Section objectives:	§4.1: To define *'maturity'* in the context of maturity models and provide a historical overview of maturity models; §4.2: To describe how maturity models are categorised according to their intent; §4.3: To present the types of entities that can be measured with maturity models; and §4.4: To present the maturity model architecture that will be used in this study and explain how the structure of a maturity model contributes to effective process assessment.

4.1 Background

Maturity is defined as "the state of being complete, perfect or ready" (Tarhan *et al.*, 2016). According to Paulk (1993), setting goals for process improvement requires an understanding of the concept of maturity. Maturity in the context of maturity models is defined as a "measure to evaluate the capabilities [1] of an organization" (Cleven *et al.*, 2014).

A maturity model refers to a conceptual model that describes the evolution of organizational capabilities (Gastaldi *et al.*, 2018). Tarhan *et al.* (2015) describes a maturity model as: "a conceptual model that consists of a sequence of discrete maturity levels for a class of processes in a domain and represents the anticipated, desired or typical evolutionary path of these processes". A maturity model is an instrument used to assess and continually improve organizational performance (Tarhan *et al.*, 2015) by determining the gap between the current and desired states of capability maturity (Blondiau *et al.*, 2016). According to Gastaldi *et al.* (2018), maturity models incorporate formality into possible improvement initiatives therefore illustrating a favourable development path towards 'maturity'.

Maturity as an assessment approach originated in the field of quality management (Fitterer & Rohner, 2010). One of the earliest approaches was Crosby's Quality Management Maturity Grid in 1979 which described the typical behaviour exhibited by organization at five levels of maturity for each of the six aspects of quality management (Lahti *et al.*, 2009). The stage-wise framework was used to benchmark organizations on how mature their quality control processes were (Srai *et al.*, 2013). This work formed the foundation for the development of a Capability Maturity Model (CMM) for Software.

Maturity models have been widely applied in different domains since the concept of maturity was popularised by CMMs for Software (Srai *et al.*, 2013). The Software Engineering Institute (SEI) at Carnegie Mellon University developed the five-level CMM for Software in 1987 (Paulk, 1993). The model described how software organization could enhance their software development capabilities by focusing on process improvement

[1] Capabilities refer to an organization's capacity to deploy resources using an organizational process to derive a particular outcome (Srai *et al.*, 2013). Capabilities can be both tangible and intangible processes specific to an organization or industry as a result of complex interaction between resources (Srai *et al.*, 2013).

(Paulk, 1993). The model was initially developed as a reference model for assessing and evaluating software process maturity and as a normative model to guide an organization to move from informal processes to well-organized and controlled software processes (Srai *et al.*, 2013).

The premise behind the development of the CMM was that the quality of a software product is largely determined by the quality of the development and maintenance processes used to build it (Paulk, 1993). The CMM provided a guide on how to gain control of processes and how to work towards a culture of process excellence (Paulk *et al.*, 1993). The CMMs are designed and developed to aid the selection of process improvement strategies by determining the current maturity of a process and identifying the most critical problems to improve the quality of the process (Paulk *et al.*, 1993). According to Paulk *et al.* (1993), focusing on a limited set of activities allows for steady process improvement which enables continuous and lasting gains in process capability.

4.2 Maturity Model Types

Maturity models can be categorised according to their function. De Bruin *et al.* (2005) have identified three categories for maturity models; namely, descriptive, prescriptive and comparative. Table 4.1 summarises the maturity model categories.

Table 4.1: Types of maturity models (De Bruin *et al.*, 2005)

Maturity model	**Description**
Descriptive maturity model	This model is ideal for assessing the 'as-is' state of the maturity of an organization (De Bruin *et al.*, 2005). Descriptive maturity models can be considered diagnostic tools and are suitable for internal, external and longitudinal benchmarking (Van Dyk & Schutte, 2012). It requires a single encounter and makes no provision for improving the maturity of the organization (De Bruin *et al.*, 2005).
Prescriptive maturity model	This maturity model is focused on the performance of an organization and intends to map out strategies to improve the maturity of an organization (De Bruin *et al.*, 2005).
Comparative maturity model	This maturity model enables benchmarking and comparing similar practices across industries or geographical regions (De Bruin *et al.*, 2005).

De Bruin *et al.* (2005) argue that although the above-mentioned maturity models are often seen as distinctly different, they form part of the evolutionary phases of the maturity model life cycle. A maturity model starts in the descriptive phase to gain a deeper understanding of the 'as-is' state of a system. The model then evolves into a prescriptive phase where substantial and repeatable improvements can be made based on the sound understanding of a system as found in the descriptive phase. Finally, for a model to be used comparatively, it has to be applied in a wide range of organizations to attain sufficient data to enable valid comparison.

4.3 Maturity Model Applications

Maturity models have been adopted in various domains as a way to appraise and improve the competence and capacity of an organization or system (Tarhan *et al.*, 2015). According to Lahti *et al.* (2009), the principle idea behind the development of maturity models is to describe the typical behaviour exhibited by an organization at a number of levels of maturity and pinpoint their current maturity level with a view to the next step towards advanced practices. The maturity of an organization's process helps to predict its ability to accomplish its goals; as maturity increases the difference between targeted results and actual results decreases (Paulk *et al.*, 1993). According to Gastaldi *et al.* (2018), maturity models can serve as a common ground for shared learning and improvement interventions. Blondiau *et al.* (2016) have identified three groups of entities in an organization which can be measured using maturity models: process-focused, technology/object focused, and people- focused. These are described as follows:

- **Process-focused**: The concept of process maturity suggests that processes have life cycles which can be assessed by the extent to which a specific process is defined, managed, measured, controlled and effective (Lockamy & McCormack, 2004). It is a measure of how the efficiency or effectiveness of the current process relates to a possible ideal process (Blondiau *et al.*, 2016). The maturity of a process implies that it is well understood, supported by documentation and training, is consistently applied in the organization and is continually being monitored for improvement (Lahti *et al.*, 2009).

- **Technology/ object-focused**: This concept aims to assess to which extent a product, machine or anything similar reaches a defined level of satisfaction (Blondiau *et al.*, 2016). According to Blondiau *et al.* (2016), this is an evaluation of the extent to which technology improves a process.

- **People-focused**: This concept aims to measure the extent to which individual skills are suitable to achieve or support an organizational goal (Blondiau *et al.*, 2016).

The concept of process maturity is becoming increasingly important as organizations start adopting a process view of the organization (Lockamy & McCormack, 2004). As an organization increases its process maturity, institutionalisation takes place via policies, standards and organizational structures (Lockamy & McCormack, 2004). Maturity models provide organizations with the ability to measure and assess their process capability maturity at any given time (De Bruin *et al.*, 2005). This provides organizations with a better understanding of existing capabilities, enables benchmarking, greater efficiency in the utilisation of recourse for improving process capabilities, and presents an opportunity for improved success in a domain (De Bruin *et al.*, 2005).

4.4 Maturity Model Architecture

Maturity models allow organizations to have their practices, processes and methods evaluated against a clear set of artefacts that establish a benchmark (Caralli *et al.*, 2012). These artefacts typically represent best practices and incorporate standards of practice that are important in a particular domain (Caralli *et al.*, 2012). Despite the differences in application, most maturity models conform to the same basic structural design (Lahrmann *et al.*, 2011). All maturity models share the common property of defining a number of dimensions at several levels of maturity with a description of the characteristics of performance at various level of granularity (Gastaldi *et al.*, 2018).

The following subsections discuss the components of a maturity model in more detail: namely, dimensions and levels, and also describe how maturity can be measured in practice.

4.4.1 Dimensions

Dimensions are commonly referred to as capability areas or key process areas depending on the field of study (Lahrmann *et al.*, 2011). Dimensions are a cluster of related activities that, when performed collectively, achieve a set of goals that are considered important to enhance process maturity (Paulk *et al.*, 1993). According to Cleven *et al.* (2014), items considered relevant and somehow related or that can attribute a particular world-view are grouped together into dimensions. A dimension is a means of grouping similar attributes into areas of importance for a domain and for the purpose of the maturity model (Caralli *et al.*, 2012). Attributes represent the core content of a dimension, based on observed practices, standards or expert knowledge and can be expressed as characteristics, indicators or practices (Caralli *et al.*, 2012). Attributes also represent the qualities that are important for supporting process improvement (Caralli *et al.*, 2012).

Dimensions can be broken up into sub-dimensions which enable a richer analysis of an organization to gain a deeper understanding of its relative strengths and weaknesses and to target specific improvement strategies that could enable more efficient resource allocation (De Bruin *et al.*, 2005). A limited set of dimensions are typically selected for a more focused process improvement approach and to ensure long-lasting and continuous improvement (Paulk *et al.*, 1993). Although there are other challenges that affect the process performance, dimensions are selected based on their effectiveness in improving process maturity (Paulk *et al.*, 1993).

4.4.2 Levels

Continuous improvement is based on evolutionary rather than revolutionary steps (Lockamy & McCormack, 2004). Architecturally, maturity models typically have 'level' to represent the transitional states along an evolutionary scale (Caralli *et al.*, 2012). The concept of an evolutionary path implies that progress towards higher maturity level is incremental and is achieved through a set of intermediate states (Gastaldi *et al.*, 2018). According to Lockamy & McCormack (2004), achieving a higher level of maturity establishes a higher level of process capability. Maturity levels, therefore, represent different states through which an organization is transformed as its process improve (Tarhan *et al.*, 2015).

Levels are also defined as archetypal states of maturity for specific dimensions (Lahrmann *et al.*, 2011). Each level has a distinguishing descriptor, clearly providing the intent of the level and a detailed description of its characteristics (Lahrmann *et al.*, 2011). Maturity levels describe fundamental policies, procedures, infrastructure and activities that contribute most to effective implementation and institutionalisation of a dimension (Paulk *et al.*, 1993). Furthermore, they represent the ability to consistently implement processes with a defined scope that contribute to the achievement of the organization's strategic objective (Caralli *et al.*, 2012). According to Wendler (2012), a maturity level describe the development of the examined object in a simplified way.

Furthermore, maturity levels should be sequential in nature and represent a hierarchical progression (Wendler, 2012). A higher level represents better control of output results, improved forecasting of goals, costs and performance, and greater effectiveness in achieving defined goals (Lahti *et al.*, 2009). To be effective, a maturity model must also have an impact on process improvement, and the transition between maturity levels needs to be measurable. Maturity levels should, therefore, be based on empirical data that has been validated in practise to ensure that each level is more mature than the preceding level (Caralli *et al.*, 2012). This can be accomplished through extensive literature reviews into a specific domain's critical success factors and best practices (De Bruin *et al.*, 2005).

In addition, most maturity models follow the potential performance perspective instead of the life cycle approach (Wendler, 2012). Models based on the life cycle perspective have a well-defined 'final' stage of maturity which can be reached by transitioning through maturity levels. However, the potential performance, is primarily focused on the potential improvement which occurs while transitioning through maturity levels, as each level holds an inherent effectiveness and value (Wendler, 2012).

A common design principle in maturity model development is to represent maturity in a number of cumulative stages (De Bruin *et al.*, 2005). Maturity models commonly have between three and six maturity levels with generic descriptions or a summary of the characteristics of each level (Gastaldi *et al.*, 2018). The number of levels differs depending on the maturity model being developed; however, it is important that the levels are distinct and well defined (De Bruin *et al.*, 2005). There are also different possibilities for defining and naming maturity levels (Cleven *et al.*, 2014). It is common practice to label levels with names which are indicative of the intent of the stage and

that provide a summary of the major requirements and measures of the level, especially with aspects that are new and not included in the preceding levels (De Bruin *et al.*, 2005). According to Cleven *et al.* (2014), defining maturity levels is an interpretive task.

Maturity models can be either continuous or staged depending on the maturity levels. Continuous models allow scoring dimensions at different levels (Cleven *et al.*, 2014). This means that the level can be either the (weighted) sum of the individual scores or the individual levels in different dimensions (Lahrmann *et al.*, 2011). Staged models require compliance with all elements of one level before progression to the next level (Lahrmann *et al.*, 2011). They specify a number of goals and key practices to reach a predefined level (Lahrmann *et al.*, 2011). Once goals are achieved they stabilize an important component in a process which improves the process capability (Paulk *et al.*, 1993). According to Gastaldi *et al.* (2018), most maturity models in literature are fixed level models in that they have a fixed number of maturity levels for every dimension.

Many maturity models adopt the generic five maturity levels defined by the CMM with or without adaptation (Cleven *et al.*, 2014). The CMM provide a framework for organizing evolutionary steps in five maturity levels that provide a successive foundation for continuous process improvement (Paulk *et al.*, 1993). Skipping maturity levels is counter-productive as each maturity level builds a foundation from which to achieve the subsequent level; therefore, organizations need to evolve through each level to ensure process excellence is ingrained the company's culture (Lockamy & McCormack, 2004). According to Paulk *et al.* (1993), improvement initiatives may prove ineffective without maturity levels because the necessary foundation for supporting successive improvement is not established. The aim of the levels of the CMM is to provide sufficient levels of abstraction and to describe what the essential attributes normally expected of the process are, rather than overly constrain how a process is implemented (Paulk *et al.*, 1993). Table 4.2 below summarises the five maturity levels of the CMM.

Table 4.2: CMM five maturity levels (adapted from Paulk *et al.* (1993))

Level	**Description**
Level 1: Initial	Processes are characterised as ad hoc and occasionally even chaotic. Few processes are defined and success depends on individual effort.

Continued on next page

Table 4.2 – *Continued from previous page*

Level	Description
Level 2: Repeatable	Basic processes are established. The necessary process discipline is in place to repeat earlier success with similar application.
Level 3: Defined	The processes are documented, standardised and integrated into standard process for the organization. All processes follow the approach with a tailored version of the standard processes.
Level 4: Managed	Detailed measures of the process outcome quality are collected. The process is quantitatively understood and controlled.
Level 5: Optimising	Continuous process improvement is enabled by quantitative feedback from the process and from piloting innovating ideas and technologies.

Maturity levels describe 'what' is to be done and should not be interpreted as mandating 'how' goals should be achieved (Paulk *et al.*, 1993). Various practices can be used to accomplish the requirements of the maturity level. The structure of a maturity level can be used to derive recommendations and strategies for process improvement (Paulk *et al.*, 1993).

4.4.3 Maturity assessment

According to Lahti *et al.* (2009), there are two methods to determine the maturity of an organization. The first is for an organization to self-assess their current maturity level based on the detailed description of the maturity levels of the maturity model; and the second is through the use of an assessment instrument which contains questions based on the key areas of the maturity model. The latter is, however, preferred (Lahti *et al.*, 2009). The focus of the assessment instrument is to determine the state of an organization's current processes and guide the prioritization of process improvement (Paulk *et al.*, 1993).

The instruments used to determine the maturity level of an organization need to be appropriate to the purpose of the model. According to De Bruin *et al.* (2005), it is important to consider the model and the resources available for conducting an assessment. The assessment instrument can be qualitative or quantitative (Lahrmann *et al.*, 2011) but generally takes the form of a questionnaire or survey (Lahti *et al.*, 2009).

The questions included in the instrument should be guided by the dimensions and sub-dimension of the maturity model produced from an extensive review of literature (De Bruin *et al.*, 2005).

The assessment should be performed in an open, collaborative environment by individuals or teams which are knowledgeable about the domain as well the fundamental concepts of the maturity models (Paulk *et al.*, 1993). The assessment process takes the form of interviews and reviews of relevant documents to gain a better understanding of the organization's processes. The assessment instrument should guide the questioning, listening, reviewing and synthesising of the information from the interviews and documents (Paulk *et al.*, 1993). Professional judgement is then used to decide whether an organization's processes satisfy the relevant goals and practices of a defined maturity level (Paulk *et al.*, 1993).

When determining a maturity level, the maturity model acts as a reference framework against which the current status quo of a process is appraised with the assessment instrument (Tarhan *et al.*, 2016). Assessment instruments then investigate strong, weak or missing points in the definition and application of a process with respect to a reference framework (Tarhan *et al.*, 2016). According to Tarhan *et al.* (2016) the findings from the process assessment are usually used to derive the gap with respect to the reference framework, which, in turn, is an input into developing a roadmap for process improvement.

The assessment instruments used for a maturity assessment can take varying forms of scope, detail and precision (Tarhan *et al.*, 2015). It is, therefore, important that the outcome or results of the assessment are easy to interpret (Lahti *et al.*, 2009). A visual representation of maturity allows for fast and easy interpretations and comparison of outcomes. According to Marra *et al.* (2018), presenting information visually, helps personnel in an organisations to share the same visual vocabulary and priorities which improves collaboration to achieve a specific goal.

4.5 Conclusion: Chapter 4

Chapter 4 provides a brief background of maturity models and reviews maturity model architecture that could potentially be used to develop an essential medicine management

maturity model. Chapter 5 will present a review of literature on medicine management practices to identify key focus areas to improve access to essential medicines.

Chapter 5

Literature Review: Medicine Management

Chapter 4 provided an overview of maturity models and presented maturity model architecture which could possibly be used to develop the maturity model in this study. Chapter 5 provides a background of the WHO Medicine Management Cycle and its functional areas. The literature review in this chapter identifies the key practices which need to be analysed and improved in order to improve access to essential medicines at facility level.

Section objectives:	§5.1: To provide a background of the WHO Medicine Management Cycle; §5.2: To present the key focus areas and recommended practices for effective medicine selection at facility level; §5.3: To present the key focus areas and recommended practices for effective medicine quantification at facility level; §5.4: To provide a brief overview of the role of procurement in the medicine supply management; §5.5: To present the key focus areas and recommended practices for effective medicine storage at facility level; and §5.6: To study the different types of medicine distribution systems used at facility level and present the recommended practices for effective and efficient medicine distribution for inpatients.

5.1 Background

A well-functioning healthcare system necessitates supply systems that can ensure consistent availability of affordable high-quality medicines at all healthcare service delivery points (Yadav, 2015). The WHO supports its member states in the maintenance of a constant supply of quality essential medicines and also collaborates with various stakeholders to develop solutions for essential medicine shortages and stock-outs (WHO, 2017). In addition, the WHO provides guidance and advocates for secure and efficient medicine supply systems to improve the availability and access to essential medicines (WHO, 2017). Improved medicine supply systems put organisations in a better position to adapt to changes in the external supply chain environment (Lahti *et al.*, 2009).

According to Yadav (2015), there are countless ways to organise a medicine supply system. Figure 2.2 in section 2.2 illustrates the WHO Medicine Management Cycle, which organises medicine management functions into a cycle; that represents an effective medicine supply management system.

According to Iqbal *et al.* (2017b), the medicine management cycle provides healthcare systems with a road map for continuous improvement. Each functional area builds on the success of preceding functions: therefore, failure in one function could result in lack of access to essential medicines and the inefficiency of the entire system (Tema, 2014). Medicine management is becoming an increasingly important area of study to find ways for the optimal use of a national health budget that offers the best quality healthcare services possible (Devnani *et al.*, 2010).

Medicine supply systems are complex, context specific, diverse, and dynamic (Yadav, 2015). According to Kanyoma & Khomba (2013), the importance of healthcare services have reduced the extent to which industrial supply chain improvement methods and strategies can be applied. Therefore, in order to improve medicine management practices, best practices and critical success factors need to be identified within the healthcare sector. Sections 5.2 to 5.6 below present the key focus areas for improving access to essential medicines at facility level by reviewing literature on selection, quantification, procurement, storage and distribution.

5.2 Selection

Medicine selection is defined as the process of identifying medicines which can effectively prevent and treat common or prioritised health problems in a region (Tema, 2014). According to Pharasi & Miot (2012), the medicine selection process is integral to the successful implementation of access to equitable healthcare plans. Not only does the selection process have a significant impact on the quality and cost of healthcare services delivered; it also ensures that all medicines within a healthcare system are selected based on well-defined selection criteria and according to a well-defined selection process that ensures quality medicines are widely available at affordable prices (Olson, 2012a).

The selection of the most appropriate medicines is dependent on accurate information regarding public health relevance, comparative cost-effectiveness, and pharmaceutical advances (Aitken, 2016). Further, selection of a limited range of essential medicines results in a higher quality of care, better medicine supply management, and more cost-effective use of health resources (Namaya, 2007). The selection of essential medicines should be linked to standard treatment guidelines (STGs) and essential medicine lists (EMLs); as they promote access to quality healthcare delivery and rational use of the medicine by both patients and healthcare professionals (WHO, 2002). Medicine selection based on well developed STGs and EMLs improves prescribing quality which leads to better healthcare outcomes (Hogerzeil, 2004) as well as significant cost savings, especially for high-unit-cost and high-volume medicines that make up a large portion of a medicine budget (Embrey, 2012).

Sub-sections 5.2.1 and 5.2.2 below present the key focus areas for effective essential medicine selection at facility level in terms of selection process and selection criteria, respectively.

5.2.1 Selection process

The WHO advocates for the principle that some medicines are more essential than others (Laing *et al.*, 2003). The WHO found that many medicines in developing countries were not useful, whereas those that were, often did not reach the populations in need (Laing *et al.*, 2003). This led to the development of the first WHO Model List of Essential Medicines in 1977 (Quick *et al.*, 2002) that represents the basic medicine needs of a healthcare system (Namaya, 2007). The Model List promotes availability, accessibility,

affordability, quality and rational use of medicines (Hogerzeil, 2004). The initial Model List contained 186 medicines (Laing *et al.*, 2003) and is revised every two to three years (Dukes & Walkowiak, 2012). To date more than 156 countries around the world have developed national EMLs (Embrey, 2012). According to the WHO (2002), factors that influence the selection of essential medicines include:

- patterns of prevalent diseases;
- treatment facilities;
- training and experience of available personnel;
- financial resources;
- demographics; and
- environmental factors.

An EML, therefore, represents medicines considered to be the optimal treatment choice of a population's healthcare needs (Olson, 2012a). They allow a healthcare system to concentrate on medicines that are the most cost-effective and affordable for treating prevailing health conditions (Hogerzeil, 2004). By contrast, a wide variety of pharmaceuticals available in a healthcare system contribute to inconsistent prescribing (Olson, 2012a). According to the WHO (1999), EMLs allow practitioners to concentrate on a limited[1] number of products which simplifies the supply management activities and reduces inventory carrying costs. Procurement in the public sector should be limited to medicines of EMLs, as no public healthcare system can afford to buy all medicines available on the pharmaceutical market (Barraclough & Clark, 2012) and short and specific lists are easier to manage and procure (Iqbal *et al.*, 2017b). Hogerzeil (2004) adds that limiting the number of medicines used in a healthcare system allows for larger quantities of specific medicines to be purchased which creates an opportunity to achieve economies of scale. In sum, the advantages of an EML are both medical and economic (Hogerzeil, 2004).

Most WHO member states have national EMLs while others also have provincial or institutional lists (WHO, 2002). Development of an EML at facility level is especially

[1] A national EML should only have approximately 300-400 medicines, while district hospitals should each have 150 -200 medicines, and health centres should each have 40-50 drugs (Iqbal *et al.*, 2017b).

important when a national EML is too extensive to be practical (Olson, 2012a) or when it could result in the procurement of a variety of medicines which do not cater to the needs of a population. According to Tema (2014), other common reasons for selecting medicines outside an EML include:

- the EML does not address current health priorities;
- the EML is not regularly updated;
- prescriber do not accept EMLs and STGs; and
- products on the EML are not readily available on the market.

The development of EMLs is the backbone of medicine selection requires wide agreement on its purpose and use (Iqbal *et al.*, 2017b). For one thing, an EML's criteria must be credible and widely accepted by being defined and published (Olson, 2012a). As such, an EML can be improved through consultation with senior specialists and experts which include professional organisations and academic institutions during both its development and use phase (Olson, 2012a). Iqbal *et al.* (2017b) further add that the selection process of essential medicines for EMLs should be an open and transparent system which is regularly updated to maintain its authority and acceptance.

Moreover, as EMLs form the basis for prescribing medicines and training healthcare personnel they need to be closely related to the STGs used to diagnose and treat common diseases at different levels of care in a healthcare system (Namaya, 2007). STGs are disease-orientated guides which reflect a consensus on the first choice of treatment for a range of health conditions (Olson, 2012b). STGs are systematically developed statements that help health practitioners make decisions on the appropriate treatment for various health conditions. The lack of adherence to STGs results in large stock-outs and the frequent expiration of unused medicine (USAID, 2011). All this underscores the fact that an STG should only include medicines on the EML, to ensure a health system procures only the medicines required by the system (WHO, 2002).

The starting point for developing a STG is to identify common diseases, then define a standard treatment for each diagnosis (Olson, 2012b) for the most efficient and cost-effective treatment of diseases (USAID, 2011). There are three types of STGs; namely, individual, selective and comprehensive. Table 5.1 describes these three types below.

Table 5.1: Types of STGs (Olson, 2012b)

Type	Description
Individual	A standard treatment procedure is developed to define various ways to treat one health problem or disease.
Selective	A standard treatment procedure is developed to define various ways to treat a few high priority common health problems or diseases.
Comprehensive	The STG is developed to define various ways to treat the majority of health problems for a population group. The guidelines ensures that practitioners are able to reference and consult the manual, which promotes the standardization of treatments and prescribing in a healthcare system.

Adherence to STGs has significant benefits to supply medicine management practices. According to USAID (2011), if healthcare practitioners adhere to suggested treatment protocols, a smaller range of products need to be available at each facility which makes the management of the supply system easier to manage. If practitioners prescribe the same products for the same conditions in a facility; product demand becomes more stable and predicable which facilitates more accurate quantification outcomes (Iqbal *et al.*, 2017a). Table 5.2 below summarises the benefits of STGs for various stakeholders in a healthcare system.

Table 5.2: Benefits of STGs for different stakeholders (Olson, 2012b)

Stakeholder	Benefits
Health officials	• Allows the identification of cost-effective treatments for common health problems. • Provides a basis for assessing and comparing quality care. • Identifies most effective therapy in terms of quality and combats antimicrobial resistance. • Provides information for practitioners to give to patients concerning the institution's standards of care. • Integrates special programmes at the point of the primary health.
Supply management staff	• Identifies which medicines should be available for the most commonly treated problems. • Facilitates pre-packing of course-of therapy quantities of commonly prescribed items. • Makes medicine demand more predictable, thereby making quantification more reliable.

Continued on next page

Table 5.2 – *Continued from previous page*

Stakeholder	**Benefit**
Healthcare providers	• Provides experts consensus the most effective, economical treatment for specific setting. • Gives providers the opportunity to concentrate on correct diagnosis. • Sets a quality of care standard. • Provides a basis for monitoring and supervision.
Patients	• Ensures most cost-effective treatments are provided. • Improves availability of medicines. • Improves treatment outcomes. • Encourages adherence to treatment through consistency among prescribers at all locations within the healthcare system.

The key to success for a STG is establishing a monitoring and evaluation system to guide updates and revisions to ensure the guideline remains relevant (Olson, 2012b). This is facilitated by mechanisms to allow the users of STGs to report their experiences using the guideline. According to Olson (2012b), monitoring programmes should focus on improving issues of treatment and clinical failure by reporting on clinical failure rates, healthcare worker's compliance with STGs, patient compliance with prescriptions, medicine quality, and antimicrobial resistance estimates. If clinical failure remains high despite a high rate of compliance with STGs, then a review of the STG should be conducted (Olson, 2012b).

At a national level, the essential medicine selection process should be the responsibility of a procurement board which identifies the medicine needs of a population. The level and breadth of expertise used in the selection process can range from a single medical advisor to a multi-disciplinary team of pharmacists, nurses, medical practitioners and other experts in the field of public health or health economics (Pharasi & Miot, 2012).

At a facility level, a multi-disciplinary drug therapeutic committee is established to guide the medicine selection process (Tema, 2014). The team should have clinical, process and methodological knowledge to develop STGs and accompanying EMLs for the selection of medicines in a healthcare system (Pharasi & Miot, 2012). According to the WHO (1999), if such committee does not exist then an ad hoc committee must be established for this purpose. The process of selection should be consultative and

transparent, the selection of medicine should be based on explicitly defined selection criteria and medicines selected must be linked to evidence-based STGs and EMLs (WHO, 2002). To ensure that an EML remains relevant, its review should correspond to changes in the STG (Aitken, 2016). The review process should also make provision for input, comments and also take into account drug resistance, adverse effects and treatment failures (Olson, 2012a). In addition, revised EMLs and STGs should be distributed throughout a healthcare system and should include background information, selection criteria and listings under the therapeutic category and level of care.

5.2.2 Selection criteria

Patients deserve quality medicine (USAID, 2011). Counterfeit medicines make up an estimated 25% of all medicines in developing countries (Conway *et al.*, 2017) and according to Iqbal *et al.* (2017b), approximately 70% of medicines registered in developing countries can be considered duplicative or non-essential. Medicine selection is largely influenced by marketing strategies which aim to manipulate scientific evidence in favour of new, more expensive and on-patent medication (Shrestha *et al.*, 2018). According to Olson (2012a), these medicines often provide no therapeutic advantage over existing medicines available on the market and personal observations or popularity of a product in the market should not be used to justify the selection of medicines.

The WHO's Department of Essential Medicines and Pharmaceutical Policies is responsible for promoting pharmaceutical quality through the development of quality certification schemes and good manufacturing practice standards to ensure the safety and efficacy of the medicines on the Model List (Dukes & Walkowiak, 2012).

Since patients do not have control over which medicines are available in a healthcare facility, it is of central importance that selected medicines adhere to an established set of criteria to ensure that patients have access to quality medicine at affordable price points (Mackintosh *et al.*, 2018). The quality, safety, and efficacy of medicines are typically considered first before cost considerations (Meyer *et al.*, 2017). Finding the right balance between quality and cost is, however, a major challenge (Iannone *et al.*, 2011).

In most countries, pharmaceutical products require evaluation and approval from a governing body (often called a drug regulatory authority) before the product can be

used in the healthcare system (WHO, 2004). In this case, products registered should have been proven to be efficacious, safe, and of adequate quality for the treatment and prevention of diseases. Selecting medicine approved by a well-functioning national regulatory authority of a country helps to ensure the quality of medicines (USAID, 2011).

The selection of high-cost medicine requires thorough evaluation which includes clinical efficacy and effectiveness, cost-effectiveness and budget impact (Pharasi & Miot, 2012). Determining the quality, safety and efficacy of pharmaceutical products requires relevant, recent and unbiased information in the form of summaries of relevant clinical guidelines, systematic literature reviews, important references, and quality assurance standards (Olson, 2012a).

Relative cost-effectiveness is a major consideration when comparing medicines. As advised by the WHO (2002) the total cost of treatment (not only the unit cost of medicine) should be considered and compared to the efficacy of the medicine. For high-volume, low-cost medicine, the selection is generally based on price (Pharasi & Miot, 2012). Quick *et al.* (2002) have also ascertained that medicine price information of assured quality is indispensable for achieving optimum value for money. Akhlaghi (2012) favours two basic ways to determine the purchase price of medicines. The first method involves obtaining data on current medicine prices by referring to guides such as the Management Sciences for Health International Drug Price Indicator, a guide which is updated annually. The second method involves reviewing past purchase prices while taking into account factors such as inflation (both nationally and internationally) and reviewing fluctuations in currency.

Each drug has a chemical name and an International Non-proprietary Name (INN); also known as a generic name. The generic name of a product is the official name of a product regardless of which company or organisation that manufactures it (WHO, 2004). The generic names are used to categorise medicines which all share the same active ingredient (Schellack & Meyer, 2010). Generic names are widely accepted as the standard for describing medicine (WHO, 1999). Generic names are assigned by using the WHO's well-established procedure and provide a standard way of comparing similar product prices and quality. Selecting medicine based on their generic names is often cheaper and allows for the substitution of medicines which will serve the same purpose (Olson, 2012a). In addition, generic name drug programmes are an economic strategy

for drug supply because it increases competition among the producers and reduces prices by up to 60% (Namaya, 2007).

The WHO Model List of Essential Medicines is meant to guide the development of national and institutional EMLs (Namaya, 2007). According to the WHO Expert Committee on the Selection and Use of Essential Medicines, essential medicine should be selected based on the following eight criteria (WHO, 2002):

1. relevance to the pattern of prevalent diseases;
2. proven efficacy and safety;
3. adequate scientific data and evidence of performance in a variety of settings;
4. adequate quality;
5. favourable cost-benefit ratio;
6. desirable pharmacokinetic properties;
7. possibilities for local manufacture; and
8. availability as single compounds.

These WHO selection criteria are often adopted, modified and adapted to local requirements. The WHO Model List of Essential Medicines is a useful reference for selecting medicines and developing selection criteria for a facility as it includes medicines that are widely considered to be safe, efficacious, cost-effective and of acceptable quality (Olson, 2012a). The Model List is updated every two years through a systematic approach guided by the WHO STGs for various diseases by an expert committee made up of clinical pharmacologists and physicians. They evaluate the latest clinical evidence and decide after several rounds of external reviews and consultations on which medicines to add to the list (Aitken, 2016). Undoubtedly, such continuous updates make the Model List a useful resources.

According to Hogerzeil (2004), as the selection criteria for essential medicine becomes more systematic, only medicines listed on well-developed and evidenced-based STGs should be selected. Thus the focus of the selection criteria should not be on the medicine but should be based on its ability to treat patients effectively.

Final selection criteria should be based on thorough discussions and acceptance by a multidisciplinary committee of experts (Olson, 2012a). As the medicine selection process evolves from an experience-based to an evidence-based approach (Laing *et al.*, 2003), it is important that the selection committee has access to information such as summaries of the WHO clinical guidelines, systematic reviews, cost information, and quality assurance standards to ensure that the selection criteria allows for the selection medicine that will treat patients optimally (WHO, 2002).

5.3 Quantification

Quantification is technically the first step in the procurement process (Iqbal *et al.*, 2017b). Quantification is a process of estimating quantities and cost of medicines required in a healthcare system and planning product delivery schedules to ensure the uninterrupted supply of medicine (SIAPS, 2014c). The process is necessary to avoid medicine wastage caused by over-stocking and treatment delays as a result of under-stocking or stock-outs (WHO, 1999). According to USAID (2011), quantification links information on services and commodities from a facility with policies and plans at a national level to estimate the quantities and costs of the commodities required. Quantification is important for informing supply management decisions on product selection, financing, procurement and delivery (USAID, 2011). According to Akhlaghi (2012), quantification may be summed up as being used to:

1. **Calculate order quantities for procurement.** The quantification process needs to be conducted before each scheduled procurement. Accurate estimates of medicine needs ensure that a system is able to avoid stock-outs, emergency purchases and overstocking while maximising the financial resources available.

2. **Estimate budget requirements.** Medicine procurement budgets are often determined by adding a fixed percentage to the previous year's procurement request to allow for contingencies such as financial cuts, population growth or expansion of services. Quantification, however, provides a rational, well-documented approach to ensure that the budgets developed enable the system to acquire the needed medicines to treat and prevent prevalent diseases.

Decentralised quantification at the facility level is known to improve the overall accuracy and validity of the results for quantification at the national level (Akhlaghi, 2012). This is owing to the fact that consumption and service data from each facility are used to inform high level decision-making on the procurement and financing of medicine (USAID, 2008). In the healthcare sector, quantification incorporates both forecasting and supply planning as seen in Figure 5.1 below (SIAPS, 2014c).

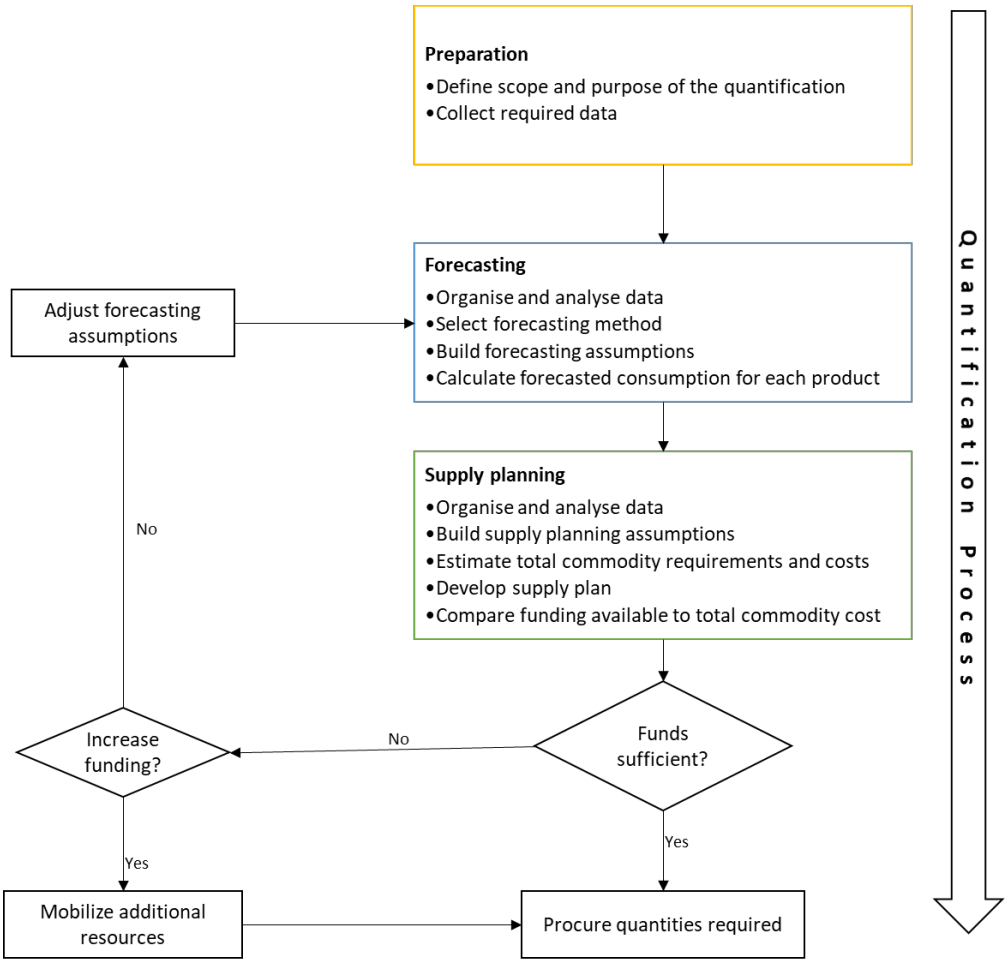

Figure 5.1: Quantification process (adapted from USAID (2008))

There are many factors that inhibit accurate forecasting and effective supply planning in LMIC countries which often lack the necessary technical expertise to do so (SIAPS, 2014c). Lack of adequate training on medicine quantification also has a negative effective on the availability of essential medicine (Tumwine *et al.*, 2010). In addition, poor policy

and misunderstood methodologies may further inhibit the implementation and success of forecasting and supply planning if countries do not have the appropriate tools to address gaps in their quantification capacity and knowledge (SIAPS, 2014c).

Quantification is a complex process and very susceptible to mistakes. Approximately 14% of medicine budgets are lost due to poor quantification (Iqbal *et al.*, 2017a). Even when quantification is done accurately there are various other factors that may further influence the availability of medicines. For example, the quantification process ought to incorporate contextual factors such as funds available, human resources capacity, storage space capacity and capacity to deliver services (Akhlaghi, 2012; Iqbal *et al.*, 2017b). It also relies on access to good quality data, knowledgeable personnel and coordination of key stakeholders to ensure that its outcome is adequate in estimating the medicine needs of a system (SIAPS, 2014c).

In order to maximize effectiveness and usefulness quantification outcomes, it is recommended that quantification be done for a period of two years (USAID, 2008). According to USAID (2008), the two year period allows a facility to: identify gaps in funding, mobilize the needed resources before stock-out occurs, adjust shipment schedules to avoid overstocking and take changes in policies and plans into account. According to USAID (2011), quantification is not a one-time exercise; rather a continuous process that requires ongoing monitoring and routine updates. The output of the quantification process should drive an iterative process of reviewing quantification data and assumptions at least every six months to recalculate the actual total medicine requirements and cost of the system (USAID, 2008).

As mentioned, as the quantification process is used to optimise the use of available resources, then advocate for additional funding when needed, and so inform procurement planning (USAID, 2008). It is, therefore, important that a multidisciplinary team of administrative, planning, clinical and pharmacy staff are closely involved in the provision and management of the quantification process (Iqbal *et al.*, 2017a).

Subsections 5.3.1, 5.3.2 and 5.3.3 present the key focus areas for improving quantification at facility level namely: data management, forecasting and supply planning, respectively.

5.3.1 Data management

Data management involves identifying, collecting, validating, storing, analysing and applying information to make decisions and take action (SIAPS, 2014b). It is an important part of managing ongoing operations, assessing performance over time, and identifying problems and opportunities for improvement (SIAPS, 2014b).

One of the most critical elements in the quantification process is to assess the quality of data (USAID, 2008). Unreliable data continues to hinder effective quantification in most LMICs (Hedman, 2016). Data quality refers to the timeliness, completeness, and accuracy of data (SIAPS, 2014b). A lack of reliable quantification data in a facility can be attributed to poor consumption data reporting and limited monitoring and evaluation of the quantification process (Tema, 2014). Table 5.3 below lists the quantification data required for accurate forecasting (Iqbal *et al.*, 2017a) and supply planning (USAID, 2008).

Table 5.3: Quantification data

Forecasting data	**Supply planning data**
• EMLs • Average consumption • Epidemiological information • Prescription patterns • Minimum and maximum stock levels • Stock on hand • Frequency of stock-outs • Length of the procurement cycle	• Funding and supplier information • Procurement and supplier lead times • Stock on hand • Expiration date of products in stock[1] • Quantity on order [2] • Minimum and maximum stock levels • Procurement and distribution information

Ensuring that only the right data is collected helps to reduce the amount of human and financial resources needed to complete data management activities and improve the accuracy and timeliness of the data collected (SIAPS, 2014b). Therefore, a needs assessment should be conducted to determine which information and data is needed, how it will be used, and what the process is to obtain it.

Another factor that arises is when, despite the availability of high-quality data, systems often struggle to use data to inform decision-making due to a lack of adequately trained personnel (SIAPS, 2014b). Training personnel can help improve the

[1] To assess whether they will be used before expiration
[2] Orders that have not yet been received

capacity for data collection, however, the capacity for analyse and use data in decision-making remains a problem (SIAPS, 2014b). Standard operating procedures, therefore, need to be developed both to train staff on how to adhere to effective data collection practices as well as on how to analyse and use results obtained (SIAPS, 2014b). According to USAID (2008), the reporting rate is a determinant of the quality of data collected: a low reporting rate lessens the quality of data and cannot be used to represent the actual medicine demand of a system. Data should be reported daily by reviewing stock records, invoices from suppliers, and dispensing records (Akhlaghi, 2012).

It is important to identify the best-suited data collection method (whether paper-based or sophisticated software) to ensure data collected is appropriate for its intended use. For this, regular reviews of data collection practices ensure that data collected is still in line with its objective (SIAPS, 2014b). All data used the quantification process needs to be recent, as the older the data, the lower the quality (USAID, 2008). It is also important to review whether historical data has been effective in estimating medicine needs in past quantification periods as the outcome indicates the effectiveness of data collection practices are in place (USAID, 2008).

Quantification committees need to formulate assumptions when data is missing or its quality is questionable, unreliable, outdated or incomplete (Iqbal *et al.*, 2017b). Consumption data and service data, morbidity of data, demographic data, and information on national programmes, policies, strategies, and plans should also be used to inform assumptions for quantification (USAID, 2008). It is, however, important to state clearly and specifically which assumptions are made and on which basis they were made (USAID, 2008).

According to Akhlaghi (2012), conducting accurate quantification without computerization is impossible. Computerised quantification has three main advantages: speed, accuracy, and flexibility (USAID, 2008). The implementation of a health management information systems (HMIS) and logistics management information systems (LMIS) to capture all information required for quantification is essential to improve the accuracy and usefulness of the outcome (Wagenaar *et al.*, 2014). Tools such as Quantimed (a data management software tool) can be used to ease the process of quantification (Akhlaghi, 2012). Quantimed software helps to estimate the total cost of medicines needed to provide healthcare services (USAID, 2011). However, while the

appropriate use of tools is important in the quantification process, ultimately the quality and accessibility data can only produce accurate forecasts and supply plan outputs.

5.3.2 Forecasting

Forecasting is the process of estimating the expected consumption of medicine based on historical consumption data, service statistics data, morbidity data, demographic data and assumptions for a specific time frame (SIAPS, 2014c). It is the process of projecting the future medicine needs of a healthcare system beyond the next purchase order (Akhlaghi, 2012) by using statistical forecasting techniques (Meyer *et al.*, 2017). STGs and EMLs provide evidence-based guidance on which medicines to forecast for a healthcare system (SIAPS, 2014c). Adherence to STGs and EMLs helps to reduce the variability in medicine prescription and allows for better demand forecasting (Iannone *et al.*, 2011).

Owing to the nature of the healthcare sector, forecasting is inherently inaccurate due to the many variables involved, therefore, human judgement is often required (Akhlaghi, 2012). Forecasting is a highly technical process and requires adequate training to conduct accurate forecasts and supply plans (SIAPS, 2014c). The forecasting process is further made complex by the simultaneity of production and consumption of medicines which can lead to high unpredictability and unique demand that are difficult to forecast (Kanyoma & Khomba, 2013). Forecasting methods, which predict the demand perfectly eliminate lag times and also allow for efficient supply planning and resource allocation (Bam *et al.*, 2017).

Consumption data and service data are the most important elements in forecasting medicine needs (WHO, 2017). Consumption data is the historical data on the actual quantities of products that have been dispensed at service delivery points. Service data includes the number of patient visits to a facility, the number of services provided, and the number of people who have received treatment over a period of time (USAID, 2008). Consumption data needs to be adjusted to account for morbidity patterns, seasonal factors, service level, prescribing patterns and patients attendance (WHO, 1999). The disadvantage of using consumption data is that records are often incomplete and do not reflect the demands of the system (WHO, 1999). In such cases, demographic and morbidity data are used to estimate the total unfulfilled need for a

specific treatment. Morbidity data is the estimated incidences and prevalence of specific diseases or health condition and demographic data is data on the proportion of a specific population estimated to be affected by a specific health condition which requires specific treatment (USAID, 2008). The type of forecasting method applied is dependent on the information and resources available (Akhlaghi, 2012).

The consumption method is the preferred choice for medicine forecasting and is considered the most reliable predictor of future consumption (Akhlaghi, 2012). This method uses consumption data to estimate future demand of each product dispensed or consumed during a specific quantification period (USAID, 2008). The method involves analysing historical consumption trends and making assumptions about factors that may influence the demand for medicine over a specified period of time (USAID, 2008). The consumption method uses past consumption data and inventory levels of individual medicines, makes adjustments for stock-outs and projected changes in medicine use to determine the future need (Akhlaghi, 2012).

The accuracy of the consumption method is dependent on the quality of consumption data, inventory records, recording of supplier lead times, projected pharmaceutical costs, information on stock-out periods and anticipated changes in demand (Akhlaghi, 2012). This method does not take into account the appropriateness of past consumption, therefore, it does not always correspond to the population's priority needs; and risks perpetuating the irrational use of medicines (WHO, 1999). The consumption method, therefore, cannot be applied in a system which experiences widespread and long periods of stock-outs as it affects the accuracy of the estimated demand (USAID, 2008). Stock-out information is particularly important in the consumption method as it reflects consumption rates when medicines were not available (Akhlaghi, 2012).

Trained pharmacists should analyse weekly, quarterly or annual forecasting data to estimate the annual demand of a facility (Iqbal *et al.*, 2017b). The major output of the forecasting step is the monthly consumption demand of each product, this information is a key input for the supply planning step (USAID, 2008).

5.3.3 Supply planning

Supply planning estimates the total commodity requirements and costs (USAID, 2011). Supply planning initiates responses to medicines requirements outlined in the forecasting

process (Meyer *et al.*, 2017). Supply plans provide visibility of the supply system and are the final output of the quantification process (Levenger *et al.*, 2013). They detail the actual quantities of each product to be procured as well as the delivery schedule based on funding available and stock levels that account for procurement and supplier lead times as well as safety stock (SIAPS, 2014c). Developing a supply plan entails coordinating the timing of funding with supplier lead times and delivery schedules to ensure a continuous supply of products and to maintain stock levels between an established maximum and minimum levels (USAID, 2008).

A supply plan estimates the total commodities required for the quantification period by calculating additional quantities of products needed to cover the procurement lead time, supply lead time and safety stock and then subtracts the quantities of each product on hand; any quantities that are ordered but not received; and any product that will expire before they are used (USAID, 2008). Deliveries should be scheduled to arrive when the stock reaches the established minimum stock level and the quantities ordered should bring the stock level back up to established maximum stock level (USAID, 2008).

Supply planning software such as PipeLine Software is regarded as the best practice to address the unique considerations of supply planning and monitoring public healthcare programmes (USAID, 2011). PipeLine is a tool that helps to plan optimal procurement and delivery schedules for any type of health commodity and monitor shipments (USAID, 2011).

Apart from the actual purchase price of medicine, other factors need to be taken into account during the supply planning process, such as: hidden costs due to poor product quality, poor supplier performance, short shelf life, and inventory holding costs (WHO, 1999). Good supply planning practices ensure that supplier selection, delivery schedules, product availability, quality, and supplier performance are properly monitored (Ombaka, 2009).

It is also important to consider price, terms, delivery times, dependability, quality of service, return policy and packaging when selecting a suppliers (Iqbal *et al.*, 2017b). Variability in a supply system can be reduced through supplier monitoring (Bam *et al.*, 2017). Long and fluctuating supplier lead times result in stock arriving too late to satisfy demand (Bam *et al.*, 2017). Bam *et al.* (2017) recommend selecting suppliers with shorter and less variable lead times to improve the performance of the supply system as it allows more flexibility when unexpected changes in demand occur. According to the

WHO (1999), information systems in place also need to facilitate tracking and reporting on the performance of suppliers, product defects, and other supply errors should be recorded into the supplier monitoring system.

5.4 Procurement

Procurement is the defined the acquisition of goods and/or service at the best possible cost of ownership, in the right quantity, of the right quality, at the right time, at the right place, and from the right sources for the direct benefit or use of an organisation (Muhia *et al.*, 2017). Effective procurement has a significant impact on safeguarding the availability of medicine (Kanyoma & Khomba, 2013). In a medicine supply system procurement is defined as the process of acquiring good quality and cost-effective medicine (Tema, 2014). According to Ombaka (2009), procurement encompasses a complex range of operational, business, information technology, safety and risk management, and legal systems - all designed to address a healthcare system's needs. Procurement involves all efforts to select appropriate procurement methods, qualify suppliers and products, manage tenders, establish contract terms, assure medicines quality, obtain best prices and ensure adherence to contract terms (WHO, 2017).

The procurement cycle, illustrated in Figure 5.2 below, represents the complex functional steps in the procurement process (Tema, 2014). Given the long procurement cycles, any delay in the functional steps of a procurement cycle creates a wave of uncertainty in the system and results in system-wide stock-outs (Yadav, 2015). According to Yadav (2015), delays are often a result of uncertain and highly variable funding which hinders the start of the procurement cycle.

Figure 5.2: Procurement Cycle (Barraclough & Clark, 2012).

According to Barraclough & Clark (2012), effective procurement is a result of the collaboration between procurement units with adequately trained staff, an appropriate management system and technical policy committees which make the final decision on which medicine to purchase, in what quantities and from which suppliers. The procurement method used in a healthcare system is dependent on national policies and regulations. Tema (2014) outlines three main procurement methods in the public healthcare sector, as:

1. **The centralised model.** In this model the main operational functions for decision-making are tightly controlled and situated at a central level by a national procurement unit.

2. **The decentralised model.** In this model the main operational functions are diversely spread across different parts of the healthcare system. Procurement is

conducted by sub-national entities including regional or provisional authorities and healthcare facilities.

3. **The mixed model.** This model maintains some central functionality to promote economies of scale, therefore, medicine requests for very large quantities are done centrally as bulk purchasing to reduce costs.

Medicine procurement systems are traditionally centralised in many developing countries with little management input from lower levels (Barraclough & Clark, 2012). Procurement practices are often conducted at a national level due to the advantages associated with centralised pooled procurement (Tema, 2014). According to Meyer *et al.* (2017), the strategic use of market intelligence, improved competition, and efficiencies associated with pooled volumes; lower prices can be achieved. Individual hospitals are, therefore, pooled together at a central level, as centralised procurement and decentralised distribution have been found to improve access to medicines at all levels of a healthcare system (Iqbal *et al.*, 2017b). In the centralised procurement model, a central medical store is responsible for the procurement function in a healthcare system. From a healthcare facility viewpoint, the central medical store can be seen as the sole supplier of medicines. Hedman (2016) suggests that a supply system should have at least three suppliers as sourcing for a single supplier increases the exposure to risk and supply failure which can then paralyse the entire system (Kanyoma & Khomba, 2013).

5.5 Storage

According to the WHO (2004), medicine should be stored in a secure area to:

- avoid contamination or deterioration;
- avoid disfiguration of labels;
- maintain the integrity of packaging and so guarantee quality and potency of medicine during shelf-life;
- prevent or reduce pilferage, theft or losses; and
- prevent infestation of pests and vermin.

Storage in medicine supply management, therefore, aims to ensure the physical integrity and safety of products and their packaging in the storage facility until they are dispensed to patients (USAID, 2011). In sum, storage facilities ensure the constant availability and flow of essential medicines in appropriate quantities in a timely and cost-effective manner throughout a healthcare system (SIAPS, 2014d). Poor product traceability, insufficient human resources, poor physical infrastructure, and security remain a big barrier to effective storage practises which may then lead to stock-outs, overstocking and medicine wastage (SIAPS, 2014d).

Storage facilities need to practise appropriate inventory control and have adequate storage capacity to ensure the quality, safety and efficacy of essential medicines during the distribution process (Musonda *et al.*, 2018). Subsections 5.5.1, 5.5.2 and 5.5.3 below present an overview of the key focus areas for improving essential medicine storage: namely, storeroom criteria, storeroom management and inventory control, respectively.

5.5.1 Storeroom requirements

An effective storage facility allows for the efficient flow of supplies (Iqbal *et al.*, 2017b). The dimensions and design of a storeroom need to be appropriate for the storage needs of different types of medicines. According to the WHO (2017), a storeroom should have the following designated areas for:

- receiving stock;
- main storage area;
- expired products;
- inflammable products;
- controlled substances; and
- cold chain products.

A clean and tidy storeroom is easier to manage. The storeroom should be organised and medicines should be easily accessible on good quality shelving (Olson & Savelli, 2012). Shelves should be kept neat and be labelled for each item on it. Keeping products off the floor makes them less susceptible to pests, water and dirt damage (USAID, 2011).

The storeroom should be cleaned and disinfected daily to prevent rodents and insects from infesting the storeroom and damaging products (WHO, 2004). A storeroom should never have waste in it; therefore, a schedule is recommended to establish designated staff responsibilities to maintain a clean and tidy storeroom (Sallet *et al.*, 2012).

In terms of temperatures for storage, most medical supplies can be kept at uncontrolled room temperatures with the basic requirement of a dry, clean and well-ventilated environment and temperatures ranging between 15 to 35 degrees Celsius (Sallet *et al.*, 2012) and out of direct sunlight (USAID, 2011). It is, however, advisable that the manufacturer's storage recommendations are followed since the expiry date provided by the manufacturer assumes that products are stored under the prescribed conditions (Sallet *et al.*, 2012). Certain medicine storage requirements ensure that the physio-chemical quality and shelf-life of the medical products are not affected by environmental conditions (Snow *et al.*, 2003). In such cases, the environmental conditions such as temperature, light, humidity and ventilation then need to be monitored and reported to ensure compliance with medicine storage requirements for effective storage practices (Iqbal *et al.*, 2017b). For less stable medicines, a storeroom also needs to be equipped with an environmental control system (such as an air conditioning system) to regulate and maintain the conditions of the storeroom (USAID, 2011). According to USAID (2011), cold-chain products which require cold storage can be irreparably damaged if the cold chain is broken and this is often the case when electricity supply is unreliable. A storeroom should, therefore, have alternative energy sources such as bottled gas or generator to power a refrigeration system if needed.

In terms of security measures, the storeroom must be secured to prevent theft. A secure storeroom should have double doors or double locks at the entrance and burglar bars on the windows to deter this likelihood (Sallet *et al.*, 2012). A storeroom should, therefore, only be accessible to designated and authorised personnel (Iqbal *et al.*, 2017b); limiting access to the storeroom and tracking the movement of products improves the security of medicine in the facility (USAID, 2011).

Stopping a fire before it spreads can save thousands of dollars in supplies and the storage facility itself (USAID, 2011). The storage facility should be fitted with fire fighting equipment which should be regularly inspected and storeroom personnel should be trained on how to use equipment with regular fire drills (Sallet *et al.*, 2012).

Fire-prevention measures should include a strict no-smoking rule, careful disposal of combustible waste material, and careful handling of flammables (USAID, 2011).

5.5.2 Storeroom management

Storeroom management is concerned with the receiving, inspecting and systematically storing medicines in a storeroom. A well-managed storeroom enables easy identification of medicine which saves time when picking medicines from shelves (WHO, 2004). It also helps to prevent the stock from being lost (Olson & Savelli, 2012). According to Snow *et al.* (2003), when receiving medicines, it is important to:

1. ensure that there is sufficient storage space;
2. prepare and clean the area used for receiving and storing stock; and
3. inspect the packages for damage or expired products.

A clear procedure for receiving stock should also be in place in a storage facility. In an ideal world, all medicines are stored under ideal environmental conditions and according to their specific storage requirements; however, in the real world, the quality of storage practices may vary widely during the distribution of the medicine. It is, therefore, important to inspect the quality of medicine received in storeroom (USAID, 2011). Inspecting for quality assurance includes: inspecting the packaging, integrity of containers, completeness and legibility of labels, and expiry dates to ensure that the medicines have an adequate remaining shelf life (Sallet *et al.*, 2012).

After medicines from suppliers have been inspected on receipt, reporting of potential problems of product quality should be reported (WHO, 1999). If stock is not verified and inspected upon arrival, it increases both the opportunity for theft and poor quality products entering the storeroom (Sallet *et al.*, 2012), as well as the possibility that the amount of product received is not the amount of product ordered. After inspection, therefore, discrepancies must be noted and reported immediately to avoid disputes later.

Another way of avoiding wastage is to store items according to their expiry dates. This is known as the first-expired, first-out (FEFO) rule whereby items which expire earlier should be stored on the shelves in front of those that expire later. While the FEFO prevents wastage it also ensures stock rotation (Snow *et al.*, 2003). In a well-managed storeroom expiry dates are monitored regularly and expired medication is removed from

the storeroom, orders can then be placed regularly and stock is rotated, making wastage due to expiry something that does not occur (Schellack & Meyer, 2010).

The WHO (2004) also recommend the arrangement of medicines in alphabetical order of the generic names and in separate and distinct areas for each dosage form. In addition to an alphabetical order, medicines should be stored according to their frequency of usage (medicines that are fast moving stored close to the entrance of the storeroom for easier access and faster product picking (USAID, 2011)). Furthermore, to avoid spoilage, lightweight items should be stored higher up on shelves while heavy fluids and fragile items should be stored on lower shelves (Snow *et al.*, 2003).

Every product moved into or out of the storeroom should be recorded in a stock-keeping record. Stock records should be available for each dosage form of a medicine in the storeroom for accountability of stock movement (WHO, 2004). Stock records include product name, product description, stock on hand, receipts, issues, losses, adjustments, closing balances and transaction references. Other information that is valuable to have on the stock records include special storage conditions, unit price, item codes and expiry dates. Physical inventory count is the process of counting by hand the number of each product in the storeroom at any given time. Physical inventory helps to ensure for the stock keeping records correspond of the physical stock in the storeroom (USAID, 2011).

Recording the flow of products into and out of the storage is often paper-based, time-consuming and subject to risks of error (SIAPS, 2014d). Without clear processes, paper-based systems limit the visibility of stock in the facility. According to the WHO (1999), even a well-functioning manual inventory control system should be converted to a computerised one. A computerised record-keeping system like the use of a bar coding system enables the efficient tracking of medicines in a facility for data collection (Meyer *et al.*, 2017). Tracking systems allow for an accurate record of inventory components such as expiration dates and physical quantities of medicines. Overall, regular stock-taking, inventory reconciliation, FEFO practices and traceability of medicine supplies have been known to improve the availability of essential medicines (Sallet *et al.*, 2012).

5.5.3 Inventory control

Poor inventory management is one of the biggest challenges facing healthcare facilities (Jurado *et al.*, 2016). Inventory management is a branch of business management concerned with planning and controlling inventory (Iqbal *et al.*, 2017b). Poor inventory

management at a facility level is a major contributor to medicine shortages and stock-outs (Shrestha *et al.*, 2018). The complexity of the problem stems from the stochastic nature of medicine demand which increases the probability of shortages and stock-outs (Jurado *et al.*, 2016). A good inventory management system, therefore, is key to the success of a steady availability of medicines (Muhia *et al.*, 2017).

Inventory control is a branch of inventory management which aims to maintain specific levels of stock in a system (Iqbal *et al.*, 2017b). According to Schellack & Meyer (2010), inventory control in a healthcare facility is responsible for determining: when to order medicine, how much to order and how to maintain appropriate stock levels to avoid overstocking, under-stocking or stock-outs. The effectiveness of inventory control in a facility, therefore, depends on reliable data and information to inform decision-making and improve the availability of medicine (Iannone *et al.*, 2011). Undoubtedly, the regular monitoring and evaluation of stock levels ensures good inventory control.

The challenge is that while increasing stock levels is a proven method of preventing stock-outs; overstocking is not always possible due to budgetary and storage space constraints (Jurado *et al.*, 2016). Kanyoma & Khomba (2013) caution that while stock-outs can lead to treatment delays which can have fatal consequences; overstocking increases inventory holding costs. The failure to control costs, in turn, has long-term negative effects on healthcare delivery as services become unaffordable and unavailable (Kanyoma & Khomba, 2013). To find the balance to this dilemma, Sallet *et al.* (2012) have suggested that the purpose of inventory control at a facility level is to:

- prepare effective orders;
- maintain sufficient safety stock levels within budget limits;
- maintain records in accordance with requirements;
- adjust inventory levels to respond to new morbidity trends and changes in STGs;
- provide appropriate, safe and secure storage; and
- prevent expiry of medicines.

? Some have acknowledged that traditional inventory control models are not always applicable to the healthcare sector due to the nature of essential medicines and the severe consequences of shortages and stock-outs (Uthayakumar & Priyan, 2013). The standard minimum-maximum inventory control system is the most successful inventory control system used for managing health commodities (USAID, 2011). According to Dias *et al.* (2012), it is designed to ensure that stock levels fall within an established desired range. The desired range refers to the maximum and minimum stock levels which are expressed as the number of months of stock; to indicate how long supplies will last (USAID, 2011). When setting the minimum and maximum stock level it important to set the minimum level high enough to avoid stock-outs and the maximum low enough not to increase the risk of expiration or holding costs (Dias *et al.*, 2012). Factors such as lead time and safety stock levels are required to determine the minimum and maximum stock levels of a product. Safety stock refers to stock kept in reserve in the event of an unexpected increase in demand, delayed deliveries or other unexpected events (Akhlaghi, 2012). Implementing safety stock policies helps to reduce stock-outs without excessively high holding costs (Bam *et al.*, 2017). As supplier lead times are variable, the safety stock and minimum stock levels need to ensure that stock-outs do not occur.

A requisitioning system is often used to order medical supplies at facility level (Sallet *et al.*, 2012). It reviews all stock levels at the end of a review period and orders stock quantities which bring the stock level up to the established maximum level for medicines that are at, or have fallen below the allowable minimum stock level for the facility (Jurado *et al.*, 2016). According to Yadav *et al.* (2011), under normal conditions reaching a minimum stock level is when actions to replenish inventory should occur. A review period is the routine interval of time between assessments of stock levels that determines if additional stock is needed (USAID, 2011). According to the WHO (2004), it is advisable to order medicine on a regular basis to prevent shortages and stock-outs. The re-order point is the stock level that indicates when a new order should be placed to last from the period between placing the order and the delivery of the medicine (WHO, 2004). The re-order quantity is based on the desired stock level of a facility for at least two to four months. Adhering to the re-order point ensures that no shortage or stock-outs occur before the arrival of the new order. This ensures that time-consuming and generally expensive emergency orders are rarely placed (USAID, 2011).

Effective inventory control, therefore, needs an efficient information and control system that monitors inventory levels in a storeroom and provides up-to-date information on quantities received and distributed, data on consumption and demand of each product (Serafim *et al.*, 2011).

5.6 Distribution

The medicine distribution process ensures the delivery of medicines from the highest level of a supply system to various levels of need in a healthcare system (SIAPS, 2014a). The key function of medicine distribution is to maintain a constant supply of pharmaceuticals at all levels of a healthcare system (Iqbal *et al.*, 2017b). Most primary healthcare facilities do not have the capacity to properly store large quantities of medicines and have to rely on obtaining periodic shipments through a multi-tiered distribution system (Buckley & Gostin, 2013). The multi-tiered distribution system in developing countries typically consists of international manufacturers and suppliers, national medical stores, regional medical stores, district medical stores, hospitals, and health centres (Buckley & Gostin, 2013). According to the Schöpperle (2013), effective medicine distribution at a national level in developing countries is dependent on reliable transport, storage capacity, timely flow of information for planning and adequate human and financial resources.

Having an efficient and reliable distribution system to move medicines from a central medical store to their point of need remains a critical challenge in many LMICs (SIAPS, 2014a). A poorly designed distribution system is likely to cause stock-outs at healthcare facilities despite the availability of stock at a central medical store (Yadav *et al.*, 2011). A balanced approach that considers the current technical capability, administrative structures and resources available should guide the design and operation of a distribution system (Yadav *et al.*, 2011). According to Namaya (2007), effective medicine distribution aims to keep medicines in good condition throughout the distribution process to:

- minimize losses due to spoilage and expiry;
- maintain accurate records;
- reduce theft and fraud; and

- provide information for forecasting future medicine needs.

Medicine distribution systems at a national level can be characterised as a push or pull system. In the pull system, each healthcare facility requisitions the quantities of medicines needed, based on past consumption and inventory levels (Kagaruki *et al.*, 2013). This system requires accurate quantification at facility level to ensure stock-outs and shortages do not occur (SIAPS, 2014a). As discussed in section 5.3, quantification practices at facility level are often inadequate; therefore the use of the pull system can result in frequent essential medicine shortages and stock-outs.

In the push system, medicine is distributed on a predetermined delivery schedule without an order from a central medical store to a healthcare facility (SIAPS, 2014a). For this system, delivery trucks are loaded with predetermined quantities of medicine based on the population's needs or previous consumption information (Yadav, 2015). The push system works well for a limited range of medicines with relatively steady demand and for facilities which keep sufficient safety stock levels to meet demand between deliveries. The push system is also often used when starting a new medicines programme, where consumption data is not available or the quality of the data cannot be used to produce accurate quantification outcomes (Yadav, 2015). According to the SIAPS (2014a), this system results in fewer shortages and stock-outs and improved information management as a result of the regular intervals of direct deliveries and standardization of the distribution process.

A combination of both push and pull systems can also be used for medicine distribution at national level. The mixed system approach is often used in countries where regional or district medicine stores are subsidiary of a central medical store. The push approach is used to distribute medicine to subsidiary medical stores and the pull approach is used to distribute medicines to healthcare facilities. According to Schöpperle (2013), the choice of system is dependent on a healthcare facility's capacity to conduct accurate quantification.

Sub-section 5.6.1 below presents the different types of distribution systems that can be used for medicine distribution to inpatients in healthcare facilities, while sub-section 5.6.2 presents the recommended practices for effective essential medicine distribution at facility level.

5.6.1 Distribution systems [1]

At facility level, drug distribution is primarily focused on dispensing medicine to patients (WHO, 2004). According to Bigdeli *et al.* (2013), up to 50% of medicines are incorrectly dispensed to patients in LMICs. The accurate and safe distribution of medicines to patients is the main responsibility of a hospital's pharmacy (Iqbal *et al.*, 2017b); which is expected to optimize the medicine distribution system and develop comprehensive policies and procedures for the safe distribution of all medicines and related supplies to inpatients (Alsultan *et al.*, 2012). Embrey (2012) suggests that effective medicine distribution requires, among others, the following practices:

- selecting the appropriate distribution system;
- keeping reliable records of medicine stocks and consumption;
- allocating medicines based on actual treatment needs; and
- reinforcing reporting and supervision arrangements.

Hospitals can distribute medicines to inpatients by operating a central pharmacy or satellite pharmacies. It is important to consider the appropriateness of distribution system in meeting a facility's needs prior to implementation (Anacleto *et al.*, 2006). A safe, organised and efficient distribution system is vital for controlling costs and ensuring medicines are available when needed in a facility (Anacleto *et al.*, 2006). The choice of distribution system implemented should, therefore, be based on the size of the facility and resources available to guarantee an efficient, effective, economical and safe distribution of medicine (Serafim *et al.*, 2011). This can either be accomplished through pharmacy and clinical personnel consultations to identify inefficiencies in the distribution system in order to develop improved practices (Anacleto *et al.*, 2006) or, according to the SIAPS (2014a), facilities could experiment with successfully implemented best practices from other sectors to address challenges and re-design systems in an innovative way.

Medicines can be distributed to patients by using either the ward stock system (WSS), individual order system or unit-dose dispensing system (UDDS). These are each described below:

[1] This literature review focuses only on medicine distribution to inpatients in a healthcare facility.

- In the **ward stock system (WSS)** the hospital pharmacy functions as a warehouse and dispenses bulk containers of medicines on requisition, without review individual patient's prescription for appropriateness of treatment (Olson & Savelli, 2012). In this system, nursing personnel are responsible for effective distribution practices (Cousein *et al.*, 2014); the nursing personnel order bulk supplies from the central pharmacy, the medication is stored in a medicine room or medicine cabinet in the ward and nurses administer medicines for each patient during their administration cycle (Murray & Shojania, 2001). The main advantage of this system is the shorter turnaround time between prescribing and administering medication. However, according to Anacleto *et al.* (2006), the absence of a pharmacist in a clinical role results in higher rates of distribution errors and poor inventory control. In addition, the WSS requires nursing personnel to use approximately 25% of their time for transcribing prescriptions, checking inventory, filling in requests, as well as transporting and separating medicines for various wards (Anacleto *et al.*, 2006) - all of which reduces patient care time (Schellack & Meyer, 2010). Another disadvantage in the WSS is that institutional costs are relatively high due to poor medicine storage practices in the wards and, therefore, often result in high medicine wastage due to expiration and spoilage (McNally *et al.*, 2016).

  According to Olson & Savelli (2012), the WSS is suitable for emergency departments and operating rooms where medication is required immediately after prescription. In life-threatening emergency situations, medications need to be kept in patient care areas as a time-saving measure. This system is also ideal for high-volume, low-cost medicines that do not require a high level of control for preventing theft or medication error. The WSS is the oldest distribution system implemented in hospitals and according to Anacleto *et al.* (2006), has now become obsolete over the years.

- In the **individual order system**, medicines are distributed to patients according to a medical prescription to various wards over a period of 24 hours (Olson & Savelli, 2012). An advantage of the system is that pharmacists review medical prescriptions which improves rational medicine use and reduces inventory levels in hospital wards (Olson & Savelli, 2012). One disadvantage is that distribution

errors remain high when using this system despite the active participation from the pharmacist in the distribution process (Anacleto *et al.*, 2006). As in the WSS, nursing personnel spend a significant amount of time calculating and preparing dosages which results in higher costs for human resource and material handling as well as losses due to theft and inadequate distribution practices.

- The **unit-dose dispensing system (UDDS)** was developed in the 1960s to support nurses with medicine administration (Murray & Shojania, 2001). The system was designed to reduce distribution error rates, costs, losses and theft while improving the productivity of clinical professionals and the quality of healthcare delivered (Anacleto *et al.*, 2006). In the UDDS, a 24-hour medicine supply is distributed in individually packaged unit-doses to each patient (Kjos *et al.*, 2016). The unit-doses are distributed according to a patient's prescription which then limits the nurses' role in the medicine distribution process in the wards (Anacleto *et al.*, 2006).

  A commonly proposed solution to reducing distribution errors and improving distribution efforts is to move from the WSS to the UDDS (Cousein *et al.*, 2014). The UDDS is considered the best distribution method from the patient's perspective (Olson & Savelli, 2012) as it is deemed safer than other hospital distribution systems (Murray & Shojania, 2001). The biggest advantage of UDDS, however, is that it brings a pharmacist into the medicine distribution process which reduces the overall potential for errors (Murray & Shojania, 2001). As a result, this distribution system is generally well accepted and has been widely[1] implemented in hospitals (Murray & Shojania, 2001). According to other researchers (Kjos *et al.*, 2016; McNally *et al.*, 2016), the use of centralised UDDS in hospitals also has further advantages, such as:

  - a reduced total cost of medicine related activities;
  - more efficient use of human resources;
  - improved medicine control and monitoring;
  - fewer medicines in the ward; and
  - an easily adaptable system for computerisation and automation.

[1] The UDDS is used in 90% of hospitals in the United States (McNally *et al.*, 2016).

In principle, a medicine distribution system in a hospital should manage the flow of medicine from the time it enters the pharmacy to when it is dispensed to patients. An effective distribution process, therefore, requires considerable planning, organisation and resources to ensure quality healthcare service delivery (Serafim *et al.*, 2011). One measure of the quality of any distribution system is the incidence of reported medication errors and here the UDDS has been proven to reduce the chance of medication errors as well as saving costs (Alsultan *et al.*, 2012). It is, therefore, the UDDS that is considered best practice for medicine distribution at facility level. The UDDS process will be discussed in more detail in Subsection 5.6.2 that follows.

5.6.2 Distribution process

In the UDDS, doctors prescribe medication to inpatients and prescriptions are sent to a central pharmacy. Local and international accreditation standards recommend that pharmacists review prescriptions for accuracy and appropriateness before dispensing (Alsultan *et al.*, 2012). A pharmacist reviews the orders and instructs technicians to prepare the medicine ordered and then places these orders in a unit-dose cart. Each drawer in the cart is labelled with the patient's name, ward, room and bed number, and contains each patient's medication (Cousein *et al.*, 2014). Then before a cart is sent back to the ward, a pharmacist double-checks each drawer for its prescription accuracy (Murray & Shojania, 2001). It is important that the unit-doses prepared by pharmacy technicians are checked by pharmacists to lower distribution errors and avoid any adverse reactions to medicines by patients (Alsultan *et al.*, 2012). These carts containing patient-specific medicine dosages are transported to wards daily for nursing personnel to administer to patients.

The UDDS is also known to reduce wastage of medicines because those medicines not administered to patients are returned to the pharmacy and put back into storage without concern for identity or contamination (Olson & Savelli, 2012). However, this reduced cost consideration of the UDDS is mainly a trade-off between pharmacy and clinical personnel (Murray & Shojania, 2001). The workload for pharmacy personnel is increased in hospital pharmacies where bulk supplies of tablets and capsules are purchased from manufacturers and repackaged into unit dose packages, however, most medication is commercially available in unit-dose form therefore technicians do not have to waste time re-packaging doses (Murray & Shojania, 2001). In the UDDS,

nursing personnel spend less time on distribution practices, allowing them to attend to other clinical activities. The variable costs in the UDDS include the cost of equipment for hospitals that order supplies in bulk and then repackage the unit-doses themselves. The use of unit-dose dispensing is common in general and surgical wards but is less commonly used in intensive-care units, operating rooms, and emergency wards (Murray & Shojania, 2001).

Human errors have become more prevalent in the distribution of medication due to shortages of well-trained personnel (Alsultan *et al.*, 2012). Hand-written prescription orders are particularly prone to error as they require transcription and can be difficult to read. Electronic prescriptions, however, can help to reduce medication errors by eliminating or reducing such transcribing ambiguities (Alsultan *et al.*, 2012). Not only do electronic prescriptions reduce the workload, errors and costs of the pharmacy but they also facilitate therapeutic conduct by permitting real-time access to basic information regarding the patient and medicine (Serafim *et al.*, 2011). The use of technology in the distribution process improves the efficiency of medicine distribution, assists with cost containment, and decreases the total number of medication-adverse events (Alsultan *et al.*, 2012).

The UDDS is closely linked to the increasing use of automated dispensing devices (Murray & Shojania, 2001). As such, automated UDDSs electronically control and track the distribution of unit-doses for each patient based on the patient's medication profiles (Olson & Savelli, 2012). Other interventions, such as the use of bar codes, have proved to: reduce distribution errors by tracking the use of medicine in the hospital (Cousein *et al.*, 2014), reduce the risk of medication errors, and improve dispensing accuracy (Alsultan *et al.*, 2012). In addition, the implementation of new technology into the medicine distribution processes has also decreased turn-around time for processing medicine orders and increased the accuracy of medication administration to patients (Alsultan *et al.*, 2012).

5.7 Conclusion: Chapter 5

Chapter 5 presents a background overview of the WHO Medicine Management Cycle. A literature review is conducted on the WHO Medicine Management Cycle's functional areas, namely, Selection, Quantification, Procurement, Storage and Distribution. The

aim of the literature study is to identify key focus areas within the functional areas for improving medicine management practices and access to essential medicines at facility level. Chapter 6 presents the essential medicine management assessment framework developed in this study. The chapter describes the framework development process and presents the outcome of the subject matter expert consultations used to validate the framework developed.

Chapter 6

Framework

Chapter 5 presented the best practices for effective medicine supply management aimed at improving access to essential medicines at facility level. Chapter 6 presents the essential medicine management assessment framework developed in this study. The chapter describes the framework development process and presents the dimensions and maturity levels included in the framework along, with the maturity assessment instrument developed. This chapter also presents the outcome of the subject matter expert consultations used to validate and refine the assessment framework developed and concludes with a framework analysis and presentation of the final version of the assessment framework.

Section objectives:	§6.1: To present the dimensions and maturity levels used in the maturity model and describe the maturity assessment procedure; §6.2: To present the outcome of the subject matter expert consultations used to validate the assessment framework developed; and §6.3: To present the refined and validated essential medicine management maturity model and maturity assessment instrument.

6.1 Framework Development

This research study has developed an assessment framework which can be used to benchmark essential medicine management practices at facility level. The assessment framework developed aims to identify inefficiencies in medicine management practices, to identify opportunities for improvement and help to prioritize improvement interventions in order to improve access to essential medicines and the quality of healthcare services delivered. The literature reviews in Chapter 4 and Chapter 5 form the basis of the assessment framework developed in this study. The maturity model was developed by integrating the essential medicine management dimensions into maturity model architecture as outlined in Section 3.4.1. Sub-sections 6.1.1, 6.1.2 and 6.1.3 present the maturity model's dimensions, maturity levels and assessment instrument respectively.

6.1.1 Dimensions

Following the extensive literature review of essential medicines and medicine management practices in Chapter 5, it was decided to use the WHO Medicine Management Cycle's functional areas as dimensions for the maturity model developed in this study. As discussed in Section 2.2, the medicine management cycle represents the key focus areas for efficient medicine supply. The WHO Medicine Management Cycle is typically used to evaluate medicine supply management practices at national level; however, the literature argues that efficient and robust medicine supply management practices at healthcare facility level ensure that the right medicines, in the right quantities, at reasonable prices and recognised quality are continuously available without stock-outs or shortages to patients (Iqbal *et al.*, 2017b).

This study's assessment framework, therefore, is designed to monitor and evaluate these essential medicine management practices at facility level. In terms of procurement, however, Section 5.4 describes how it is more favourable to conduct procurement practices at national instead of at a facility level. The maturity model developed therefore, did not include the procurement functional area as a dimension; as only functional areas applicable to healthcare facility level were included. Table 6.1 below defines the four essential medicine management maturity model dimensions; namely, Selection, Quantification, Storage and Distribution.

Table 6.1: Essential medicine management maturity model dimensions

Dimension	**Description**
Selection	Essential medicine selection at facility level is concerned with identifying essential medicines required to effectively prevent or treat prevalent diseases for a defined population group.
Quantification	Essential medicine quantification at facility level is concerned with estimating the quantities and cost of essential medicines required in a healthcare facility and the planning of delivery schedules.
Storage	Essential medicine storage at facility level is concerned with ensuring the physical integrity and safety of products and their packaging until they are dispensed to patients.
Distribution	Essential medicine distribution for inpatient care, in a healthcare facility, is the process of dispensing medicine from a central hospital pharmacy to inpatients in various wards.

The above four dimensions selected were divided into sub-dimensions to allow for a richer analysis of dimensions. The sub-dimensions highlight the key focus areas to be monitored and evaluated (within the WHO Medicine Management Cycle's functional areas) to improve medicine management performance and access to essential medicines. Table 6.2 defines these essential sub-dimensions of the medicine management maturity model.

Table 6.2: Essential medicine management maturity model sub-dimensions

Dimension	**Sub-dimension**	**Description**
Selection	Selection Process	The selection process for essential medicine selection refers to the well-documented process of identifying the medicines needed in a healthcare facility to prevent and treat prevalent diseases.
	Selection Requirements	The selection criteria for essential medicine selection refers to the attributes that medicines must adhere to; in order to be deemed adequate to prevent and treat prevalent diseases for a healthcare facility's defined population.
Quantification	Data Management	Data management in the process of essential medicine quantification in a healthcare facility is concerned with identifying, collecting, validating, storing, analysing and applying information needed for evidence-based decision making.

Continued on next page

Table 6.2 – *Continued from previous page*

Dimension	**Sub-dimension**	**Description**
	Forecasting	Forecasting, in the process of essential medicine quantification, is the process of estimating the expected consumption of essential medicines based on historic data and assumptions for a specific quantification period for a healthcare facility.
	Supply Planning	Supply planning, in the process of essential medicine quantification, estimates the total essential medicine requirements and cost for a healthcare facility. Supply planning initiates responses to medicine requirements outlined in the forecasting step.
Storage	Storeroom Requirements	The storeroom requirements details the minimum requirements of the storage facilities used to store essential medicine in a healthcare facility.
	Storeroom Management	Storeroom management is concerned with the material receiving, incoming inspections and systematic storage of medicine in a healthcare facility's storeroom.
	Inventory Control	Inventory control in a healthcare facility is responsible for determining when to order medicine, how much to order, and how to maintain appropriate stock levels to avoid overstocking, under-stocking and stock-outs.
Distribution	Distribution Process	The distribution process at facility level is responsible for accurate and safe distribution of medicine to patients as prescribed by healthcare practitioners.

6.1.2 Maturity levels

The maturity model developed contains five CMM-like maturity levels. The maturity levels represent the evolutionary scale and intermediate states through which essential medicine management practices must transition to improve. The maturity level names were adapted from the CMM [1] maturity level names, namely: Initial, Repeatable, Defined, Managed and Optimising, however, the definition of the levels were changed. Each maturity level provides a distinguishing descriptor which describes the intent,

[1]The CMM is a well established and widely applied maturity model that has led to the development of various maturity models in a range of domains. The systematic literature study in Section 2.6.4 found that CMMs are commonly used to guide the design and development of maturity models in the healthcare sector. This supported the researcher's decision to develop CMM-like maturity levels for the maturity model in this study.

characteristics, typical behaviour or requirements of a dimension at a specific level of maturity.

The literature review outlined in Chapter 5 studied the critical success factors and best practices for effective medicine management at facility level to improve access to essential medicines. The findings were used to determine the maturity levels of the dimensions for this study's maturity model. The maturity levels are sequential and represent a hierarchical progression of maturity with *Level 1: Initial* (representing the lowest level of maturity) and *Level 5: Optimizing* (representing the highest level of maturity). Table 6.3 below presents the generalised maturity levels for the essential medicine management maturity model. The detailed maturity levels are presented in the refined maturity model on Page 100.

Table 6.3: Essential medicine management maturity model maturity level

Maturity level	**Description**
Level 1: Initial	The dimension is unmanaged.
Level 2: Repeatable	The dimension is repeatable with the use of arbitrary operational procedures.
Level 3: Defined	The dimension is well-defined with standardised operational procedure.
Level 4: Managed	The dimension is well-managed, and outcomes of operational procedures are predictable.
Level 5: Optimising	The dimension's operational procedures are continuously improving.

6.1.3 Maturity assessment

A maturity assessment instrument was developed to provide an easy and simple method of determining the maturity level of a facility's medicine management dimensions.[1] The assessment instrument investigates strong, weak or missing points in the definition and implementation of a dimension with respect to the maturity model. The maturity assessment instrument provides a detailed account of the maturity level requirements for a dimension at a specific level of maturity; unlike the maturity model developed in this study which only provides a description of the typical behaviour and characteristics of a dimension at a specific level of maturity. The maturity level requirements were determined from the literature review in Chapter 5, which identified

[1]This refers to dimensions defined for this study in Section 6.1.1

the critical success factors and best practices for effective essential medicine management at facility level. The aim of the assessment instrument is to benchmark the state of medicine management practices and guide the prioritization of improvement interventions to increase access to essential medicines.

The maturity level requirements in the assessment instrument aim to provide a sufficient level of abstraction to avoid dictating how a maturity level requirement should be achieved and rather indicate what requirements should be met to improve the facility's medicine management practices and access to essential medicines. A facility's achievement of a maturity level's requirement is dependent on the facility's capacity and resources[1] available. It is important that each facility investigates the best approach to achieve the maturity level requirement. An example to illustrate how the maturity assessment instrument can be used is shown in Appendix C.

The assessment should be performed in an open, collaborative environment by individuals or teams which are knowledgeable about the domain as well as the fundamental concepts of the maturity models. The assessment process takes the form of an interview with senior medicine supply management personnel. The assessment also requires observations to verify if the answers provided in the interview, are accurate. The assessor's professional judgement and knowledge are used to decide whether the facility's practices satisfy the requirements of the maturity level. The assessor is required to read the maturity level requirements from the maturity assessment instrument (see Page 104) for the different dimensions to the interviewee, and the interviewee is required to answer "yes" if the requirement is met and "no" if not. The maturity model so developed is a staged maturity model in which all[2] requirements of a maturity level need to be achieved before progression to higher maturity levels. This transitioning procedure allows for long lasting and continuous improvement. The outcome of the maturity assessment is used to benchmark the facility's essential medicine management practices on the maturity model (see Page 100). The maturity model provides the facility with a description of the dimension at a specific level of maturity. A visual representation of maturity allows for fast and easy interpretations and comparison of outcomes.

[1] Resources include: human resources, infrastructure and financing.

[2] This rule does not apply to Level 1 of the model. All, some or none of the requirements need to be met to achieve this level. Level 1 represents an unmanaged state, therefore not achieving all requirements of this level implies that the dimension is unmanaged.

Each facility should aim to reach Level 5: Optimising. It is inadvisable to skip maturity requirements as each maturity level requires the achievement of the previous level's requirements for continuous improvement. Therefore, although a facility might meet some of the maturity requirements at a higher level of maturity, it must still comply with all the preceding requirements to stabilise the foundation for continuous improvement. The findings from the assessment should be used to derive opportunities for improvement and recommendations for improvement. The structure of the maturity model also provides an indication of which dimensions require the most immediate improvement (i.e. sub-dimensions at Level 1 need to be prioritised for improvement before sub-dimensions at Level 4). As discussed in Section 2.2, the medicine management cycle's functional areas are dependent on the the success of each other; therefore it is important that progression through the maturity levels is even across all the dimensions (i.e. the storage dimension should not reach Level 4 while the selection dimension is at Level 1 because the success of the storage dimension relies on the success of the selection dimension). The essential medicine management maturity model and maturity assessment instrument developed are presented in Section 6.3.

6.2 Framework Validation

Validation in research ensures the integrity of the conclusions drawn and that the research output addresses the research's objectives. The aim of the validation was to ensure the framework is able to adequately assess the performance of medicine management practices in order to identify opportunities for improvement, which can improve access to essential medicines at facility level. As discussed in Section 3.4.2, implementation and case studies are not feasible validation methods for this study, therefore validation using semi-structured interviews with subject matter experts was identified as the most appropriate approach to evaluate the content validity of the assessment framework developed.

Three subject matter experts were interviewed between 20 June 2019 and 31 July 2019. The interview was divided into five sections, namely: interviewee information, research topic, framework, framework assessment and general. Table 6.4 summarises the objectives of the different sections of the interview questions. The complete interview

guide can be found in Appendix B. Each interview [1] was face-to-face interview and lasted approximately an hour.

Table 6.4: Validation process

Interview section	**Objective**	**Section**
Interviewee information	To determine whether the participants meet the inclusion criteria stipulated in Section 3.4.2.1.	§6.2.1
Research topic	To verify that essential medicine shortages and stock-outs are a problem in public healthcare facilities.	§6.2.2
Framework	To determine whether the dimensions and sub-dimensions identified in literature and included in the maturity model are adequate to assess and benchmark essential medicine management practices.	§6.2.3
Framework assessment	To determine whether the maturity level requirements included in the assessment framework aimed at improving access to essential medicine are adequate and that they can be realistically implemented in healthcare facilities.	§6.2.4
General	To determine if the framework developed is useful and easy to understand.	§6.2.5

Sub-sections 6.2.1 to 6.2.5 present the outcome of the subject matter consultations according to the different sections of the interview guide.

6.2.1 Interviewee information

All the participants met the inclusion criteria stipulated in Section 3.4.2.1. All the participants have experience in medicine management in the public and private healthcare sector which allowed them to provide information from both perspectives. Table 6.5[2] presents the profiles of the three participants.

[1] Before an interview, the researcher provided a background on the research study and explained the research's aim and objectives, introduced the concept of maturity models and the usefulness of maturity models as a assessment framework in the healthcare domain. The researcher also explained what would be expected from the interviewee during the interview in terms of the types of questions that would be asked and how they would be asked.

[2] Although all the participants are currently registered pharmacists in Namibia, they have practised in other sub-Saharan African countries including: South Africa, Zimbabwe and Tanzania.

Table 6.5: Participant summary.

Interviewee	Qualification	Years of Experience	Country
Participant 1	Bachelor of Pharmacy	30	Namibia
Participant 2	Bachelor of Pharmacy	14	Namibia
Participant 3	Bachelor of Pharmacy	7	Namibia

6.2.2 Research topic

All participants agreed that essential medicine shortages and stock-outs are a major problem in the public healthcare sector. In particular, Participant 1 and Participant 2 indicated that poor quantification is one of the major causes of essential medicine shortages and stock-outs in the public sector. Participant 1 attributed the erratic availability of essential medicines in public healthcare facilities to the shortages and stock-out of essential medicine due to poor management of resources and a lack of accountability all the way from the highest level of the healthcare system to the lowest level. Participant 2 and Participant 3 both attributed the shortages and stock-outs to poor medicine management practices at central medical store level from where public healthcare facilities order essential medicine. Participant 3 added that central medical stores fail to ensure the availability of medicines in the country which makes it impossible for healthcare facilities to acquire the medicines ordered, which results in shortages and stock-outs.

All participants noted an increase in the number of patients forced to buy essential medicines from private healthcare facilities due to stock-outs of medicine in public healthcare facilities. Participant 2 stated that the current[1] supply system practices are inadequate because they fail to ensure the availability of medicine hence the increased frequency of medicine shortages and stock-outs in the public sector.

6.2.3 Framework

All participants agreed that the dimensions and sub-dimensions included in the framework are the key focus areas for effective medicine supply management and are sufficient to benchmark essential medicine management practices at facility level.

[1]The current system in place referred to by Participant 2 is the healthcare system in Namibia.

6.2.4 Framework assessment

This section of the interview took the form of a questionnaire, in which the interviewer read the maturity requirements identified from the literature and asked the participant if the maturity requirement was useful and whether it would be realistic to implement or achieve in practise. Participants were given the opportunity to provide comments on how the maturity level requirements could be adjusted or changed to make the requirement achievable based on their experience in the field. The outcome of this section of the interview is presented in the following paragraphs according to the four dimensions of the maturity model. Only maturity level requirements which needed to be changed or adjusted are presented in the discussion of the outcome (i.e. maturity level requirements which the participants agreed with are not discussed in this section, but rather presented in the final assessment framework in Section 6.3.).

Selection

- Participant 2 and Participant 3 agreed with the maturity level requirement that requires the selection process to be based on disease prevalence; however, Participant 1 argued that determining the disease prevalence of a population is difficult to do at facility level, as it requires a lot of resources to determine accurately. Participant 1 suggested that facilities identify the most prominent diseases for the population group it serves, by monitoring the "movement" of specific medicines which would imply the most prominent diseases for the population and help to determine which medicines are required in the facility.

- Participant 1 and Participant 2 did not think it feasible to procure only medicines that appear on a facility's EML as it would restrict the doctors' ability to prescribe what they consider to be the best treatment for a specific condition. Both participants, therefore, think that a facility's EML should be flexible and adaptable to changes in disease prevalence. Participant 3, however, argued that procurement from a well-constructed EML should be sufficient to cater to all the medical conditions that a facility treats.

- All participants thought that considering cost as a selection criterion for essential medicine selection in the assessment framework would increase the possibility of

procuring poor quality medicine based on their low cost price. Participant 2 stated that higher quality products are often more expensive, hence it is better to make a selection based on the cost-effectiveness of the medicine.

- Participant 2 said that although the selection criteria of a facility should be closely linked to the WHO's essential medicine selection criteria, at facility level it is not useful to consider desirable pharmacokinetic properties, possibility for local manufacture and availability as a single compound. Participant 2 went on to state that those criteria should be the responsibility of a National Drug Regulatory Authority body as it requires specialised professional skills to determine whether medicines meet those criteria.

Quantification

- o Participant 1 and Participant 2 believe it is essential to have an electronic data management system for effective quantification as the margin for human error is bigger for manual systems. Participant 3, however, stated that manual data management systems are able to produce "accurate" quantification results, although it requires commitment from the facility's personnel to keep the records up to date.

- Participant 1 stated that it is not feasible to validate the quality of data each time data is collected. Instead, it was recommended that facilities select a data management system that sends alerts or warnings when poor quality data is submitted into the system to prevent the time-wasting exercise.

- Participant 1 stated that although forecasting using forecasting software is important, personnel conducting the forecasting exercise need to be knowledgeable and experienced in order to account for changes in demand and disease prevalence accordingly and produce accurate forecasts.

- Participant 1 and Participant 2 did not think it is feasible to forecast the demand for each and every medicine required in a healthcare facility, as such an exercise becomes too exhaustive. Instead they recommended that forecasts should only be prepared for fast moving and expensive medicines.

Storage

- All the participants recommended the maturity level requirement which stipulate that facilities should ensure that medicine is stored in a dry, clean and well ventilated area with temperatures ranging from +15 to +25 degrees Celsius should be changed or adjusted as the aforementioned environmental conditions need to be adhered to by law. Participant 1 suggested that the maturity level requirement require healthcare facilities to monitor the environmental conditions in a storeroom regularly and keep records to ensure compliance on a consistent basis. Participant 2 and Participant 3 said that regulating temperature in a storeroom is important and recommended that a thermometer is placed in various areas in the storage facility and monitored twice a day minimum as some medicines are sensitive to extreme temperatures.

- Participant 1 said that stock cards in the storeroom are redundant if a facility has an adequate information system in place to capture the movement of medicine in and out of the facility and increases the administrative work for the personnel. However, Participant 2 and Participant 3 believed that using stock cards to track the movement of essential medicines is an important back-up system that helps increase the accuracy of the stock data as the electronic tracking system can be validated and reconciled with the stock-card records.

- All participants agreed that physical stock counts should be conducted to reconcile stock records to ensure that the records correspond with the stock on hand and they insisted that the framework should specify that stock counts should be conducted at least every quarter.

- All the participants believed that an alternative energy source in a healthcare facility is ideal; however, it is not so feasible to implement due to the high cost of the alternative energy source infrastructure.

- Participant 1 recommended that the inventory control sub-dimension include a maturity level requirement that requires healthcare facilities to have an information system that notifies personnel when inventory levels have reached a reorder point. According to Participant 1, this is an effective way to ensure that orders are placed in time to avoid shortages and stock-outs.

Distribution:

- All the participants agreed that the unit-dose system is the best system to distribute medicines to inpatients in a healthcare facility. However, they stated that the implementation of such a system requires significant changes to the current systems in place in public healthcare facilities[1]. According to Participant 1 the implementation of the unit dose distribution system would require significant capital investment and human resources to operate efficiently, both of which are limited in the public sector.

- Participant 2 agreed with the maturity level requirement that stipulates that medicine distribution should be initiated by the presentation of a prescription to the pharmacy. However, the participant recommended that the prescriptions should be accompanied by a patients' files (health history) to ensure that the medicines dispensed treat the medical condition most effectively.

6.2.5 General

- All participants indicated the assessment framework was easy to understand. Participant 3 further stated that the maturity assessment instrument compliments the maturity model well and made identifying the level of maturity a lot easier than if the maturity model was presented on its own.

- Participant 1 stated that for the model to be effective in identifying the shortcomings of medicine management practices, the assessment must be conducted by honest individuals to ensure that the maturity level that is identified is the actual maturity level of the facility. Participant 1 suggested an evaluation by an external and knowledgeable person would ensure the objectivity of the assessment results. According to Participant 1, in order to improve access to essential medicines in public healthcare facilities the dimensions identified need to be improved. However, such improvements would require the financial resources available to be allocated properly.

[1]This response is based on the subject matter expert's experience and does not imply that all public healthcare facilities have the same inpatient distribution system in place.

- Participant 2 thought that the assessment framework has the potential to be useful if the healthcare facilities prioritize achieving the maturity level requirements of the different dimensions. According to Participant 2, in order to improve access to medicine, this assessment exercise should be conducted at all levels of the healthcare system.

The subject matter consultation outcomes above were used to make changes to the assessment framework developed, in order to address the identified shortcomings of the model. The analysis of the subject matter expert consultation outcomes is presented in Section 6.3.1.

6.3 Analysis and Results

A preliminary maturity model and maturity assessment instrument was developed, and validated by subject matter experts in this chapter's Section 6.1 and 6.2, respectively. Subsections 6.3.1 and 6.3.2 present the analysis of the subject matter expert consultations and the validated and refined assessment framework, respectively.

6.3.1 Subject Matter Expert Feedback and Analysis

The feedback from the subject matter expert consultations was analysed and incorporated into the assessment framework developed, to address the shortcomings identified. The feedback from the subject matter consultations in Section 6.2.4 was compared to findings in the literature to determine maturity levels requirements should be kept, removed or changed. Table[1] 6.6 presents the outcome of the analysis.

[1]This table presents a summarised version of the feedback provided by the subject matter experts. The full feedback responses are presented in Section 6.2.4

Table 6.6: Analysis of subject matter expert feedback

Maturity level requirement	**Subject matter expert feedback**	**Decisions made**
Dimension: Selection		
The selection process is based on the observed disease prevalence of the population group in which the facility operates.	Participant 1 stated that determining the disease prevalence of a population is difficult at facility level.	Disease prevalence influences the type of essential medicines selected for a system as discussed in Section 5.2.1. Determining the disease prevalence for a defined population is important. If a facility relies on the disease prevalence being determined at a national level; it runs the risk of procuring medicine that will not be used and will potentially result in higher losses from medicine expiry. The maturity level requirement does not state how the facility should determine the disease prevalence for the population group but rather emphasises the fact that medicine selected and made availability in the healthcare facility should enable the treatment of the most common diseases encountered. The researcher therefore decided to keep the maturity level requirement in the assessment framework.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	Subject matter expert feedback	Decisions made
Procurement of medicine is based on and limited to the facility's EML.	Participant 1 and Participant 2 do not think it is feasible to procure only medicines that appear on a facility's EML.	The benefits of limiting the procurement of medicines in the public sector to medicines on an EML is discussed in Section 5.2.1. This requirement is a level 4 maturity requirement dependent on achievement of the preceding maturity level requirements to be feasible. The researcher agrees with Participant 3 that a well constructed EML should be sufficient to cater for all the medical conditions treated by the facility. The level 5 maturity requirement for selection process requires healthcare facilities to update and revise its EML continuously through consultation with a multidisciplinary team of healthcare professionals. This provides an opportunity to add medicine according to observed changes in the disease prevalence and treatment needs of the facility. The researcher therefore decided to the keep the maturity level requirement in the assessment framework.
Essential medicine selection is based on the cost of the medicine.	All participants agreed that cost should be removed, as a selection criteria for essential medicine selection.	Given risk of increasing the probability of selecting cheap but poor quality products, the researcher removed cost as a maturity level requirement and replaced it with cost-effectiveness, as recommended by Participant 2.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	Subject matter expert feedback	Decisions made
The facility's selection criteria is closely linked to the WHO's essential medicine selection criteria: relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, adequate quality, favourable cost-benefit ratio, desirable pharmacokinetic properties, or the possibilities for local manufacture and availability as a single compound.	Participant 2 stated that at facility level it is not useful to consider desirable pharmcokinetic properties, possibility for local manufacture and availability as a single compound.	According to Participant 2, ensuring desirable pharmcokinetic properties as well as the possibility for local manufacture and availability as a single compound is the responsibility of a national drug regulatory authority. The literature encourages the use of the WHO's essential medicine selection criteria as guideline for developing EMLs and criteria as presented in Section 5.2.2. However, given that it should only used as a guideline and that "All essential medicines selected are approved by a national drug regulatory authority." is already included as maturity level requirements in the framework. This maturity level requirement was changed in the framework.
Dimension: Quantification		
The facility makes use of information technology to manage data.	Participant 3 stated that manual data management systems are able produce "accurate" quantification outputs.	Section 5.3.1 emphasises the importance of computerised systems for accurate quantification. Although responsible personnel can carry out manual quantification practices to produce accurate results, the efficiency and accuracy of computerised quantification cannot be compared to a manual system. Therefore, the researcher has decided to keep this maturity level requirement.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	Subject matter expert feedback	Decisions made
The facility has a system to analyse and validate the information and data required for quantification.	Participant 1 stated that it is not feasible to validate the quality of data each time data is collected.	Accurate quantification data is fundamental for producing forecasts and supply plans to ensure fewer medicine shortages or stock-outs occur. Although the researcher does agree with Participant 1 that validating data is time-consuming, ensuring the quality of the data used for quantification is important. The maturity level requirement does not stipulate how, and how often the data should be analysed and validated. The facility could possibly collect random samples for data quality tests, however, the quality of data must be ensured. Validating the data collected is also a quality assurance measure for the data collection process in place and it is therefore important that this maturity level requirement is kept in the assessment framework.
Essential medicine forecasts are developed with the use of forecasting software.	Participant 1 stated that although using forecasting software is important, personnel conducting the forecasting exercise need to be experienced and knowledgeable to account for changes in demand and disease prevalence.	This maturity level was not changed because having trained personnel responsible for performing forecasting is part of the maturity level requirements for forecasting. Both requirements need to be met to achieve Level 2 of maturity for forecasting.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	Subject matter expert feedback	Decisions made
Demand estimates are made for each type of essential medicine.	Participant 1 and Participant 2 did not consider it feasible to forecast the demand for each and every medicine required in a healthcare facility.	Given limited healthcare budgets in the public sector, it is important that foresting is done for all medicine, as highlighted in Section 5.3. The researcher has decided to include this maturity level requirement because forecasting outputs give direct input for supply planning and procurement. Therefore, to prevent shortages and stock-outs, the expected demand for each medicine must be calculated for adequate planning.
Dimension: Storage		
Storeroom is dry, clean and well ventilated with temperatures between +15 and +25 degrees Celsius.	All the participants recommended that this maturity level requirement be changed or adjusted to require healthcare facilities to monitoring the environmental conditions in a storeroom regularly and keep records to ensure compliance on a consistent basis.	The researcher has decided to keep the current maturity level requirement as it is and create an additional requirement which requires healthcare facilities to monitor their environmental conditions in the storeroom. Although it seems redundant to keep this maturity level requirement, Section 5.5 found that the medicine is often not stored according its basic storage requirements which leads to medicine losses. Defining the environmental conditions requirements first ensures that the right conditions are monitored.
Each medicine is accompanied by a stock card.	Participant 1 said that having stock cards is redundant and increases the administrative work for the personnel.	The maturity level requirement was included in the assessment framework as the researcher agrees with Participant 2 and Participant 3, that stock cards serve as a good back-up system. It is also useful for a system which still use manual data management and for validating computerised data management systems.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	Subject matter expert feedback	Decisions made
Stock records are reconciled with physical stock counts.	All participants recommended that the framework should specify that stock counts should be conducted at least every quarter.	This maturity level requirement was adjusted to include the recommendations made by the participants.
The facility has alternative energy sources in the event of power shortages.	According to all the participants, having an alternative energy source is preferred, but often times is not feasible to implement due to the high cost of alternative energy source infrastructure.	This maturity level requirement is currently a Level 4 requirement, but was changed to a Level 5 requirement which is indicative of best practices. The maturity level requirement was kept because of the high costs related to medicine losses due to uncontrolled environmental conditions during electricity outages. Although most medicine can be kept in uncontrolled temperatures, cold chain products have a high risk of damage. Healthcare facilities are required to have back-up electrical supply to clinical areas due to the nature of the services the facility renders. Therefore back-electricity supply should also be provided to the facility's storage area.
	Participant 1 recommended that the inventory control sub-dimension include a maturity level requirement which requires facilities to have an information system that sends notifications when inventory levels reach a recorder point.	The recommended maturity level requirement was added to the assessment framework.

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Table 6.6 – *Continued from previous page*

Maturity level requirement	**Subject matter expert feedback**	**Decisions made**
Dimension: Distribution		
Facility makes use of the unit-dose dispensing system to distribute medicine to inpatients.	All the participants agreed that the unit-dose dispensing system is the best way to distribute medicine; however, they stated that implementation of this system requires significant changes to the current systems in place.	Section 5.6.2 provides evidence to support the use of the unit-dose dispensing system as the most effective medicine distribution system for inpatients. Although significant initial investment is required, the assessment framework cannot recommend an alternative system which does not ensure effective distribution due to financial constraints. This maturity level requirement was included because it provides the best method for effective distribution aimed at improving access to medicines at facility level.
Medicine distribution process is initiated by an order in the form of a prescription.	Participant 2 recommended that the distribution process is initiated by a prescription and patient files (health history).	This maturity requirement was adapted to include patient files as a requirement, along with prescriptions, as recommended by Participant 2 as it would help to ensure that the medicines dispensed treat the diagnosed condition most effectively and prevent distribution errors.

From the subject matter expert consultations, the researcher inferred that the assessment framework developed has the potential to benchmark the state of medicine management practices in healthcare facilities in order to identify opportunities for improvement.

6.3.2 Essential Medicine Management Assessment Framework

The maturity model developed in this study is a staged, descriptive, fixed process-focused maturity model, which can be used to benchmark essential medicine practices at facility level in order to identify opportunities for improvement to improve access to essential medicines. The validated and refined essential medicine management maturity model and maturity assessment instrument is presented on Page 100 and 104 respectively. The name of the framework stems from the fact that the dimensions of the model are based on the functional areas of the WHO Medicine Management Cycle and are rooted in the principles of improving access to essential medicine in the public healthcare sector.

Dimension	Sub-dimension	Maturity level				
		Level 1: Initial	Level 2: Repeatable	Level 3: Defined	Level 4: Managed	Level 5: Optimising
Selection	Selection process	The healthcare facility does not have an essential medicine selection process or the process in place is inadequate.	The healthcare facility's selection process is based on observed disease prevalence.	The healthcare facility's selection process is based on a well-developed essential medicine list and standard treatment guidelines.	The healthcare facility has a formally defined and well-managed selection process that considers various factors to ensures the selection of essential medicines meet the facility's needs.	The healthcare facility's selection process is conducted according to a set policy and procedure which is based on accurate information regarding public health relevance, comparative cost-effectiveness and pharmaceutical advances and is the responsibility of a multi-disciplinary team of healthcare professionals.
	Selection criteria	The healthcare facility does not have an essential medicine selection criteria or the criteria in place is inadequate.	The healthcare facility only selects medicine authorised by a national drug regulatory authority for selection.	The healthcare facility considers cost-effectiveness and quality as the criteria for essential medicine selection.	The healthcare facility's selection criteria is in line with the WHO essential medicine selection criteria.	The healthcare facility has an extensive evidence-based selection criteria developed through consultation of a multi-disciplinary team of healthcare professionals

Dimension	Sub-dimension	Maturity level					
		Level 1: Initial	Level 2: Repeatable	Level 3: Defined	Level 4: Managed	Level 5: Optimising	
Quantification	Data management	The healthcare facility does not practice data management or data management practices are inadequate.	The healthcare facility collects the necessary data and information required for quantification, using a standardised data collection method.	The healthcare facility's data management system produces reliable and complete, quality data in a useful form and in real time.	The healthcare facility's data management system produces records which are used to inform supply management decision-making.	The healthcare facility's data management is the responsibility of well-trained personnel who continuously review the data management practices to ensure that the data collected enables the accurate quantification.	which ensures access to quality and cost-effective medicines.
	Forecasting	The healthcare facility does not forecast its essential medicine needs or the forecasting process in place is inadequate.	The healthcare facility forecasts the demand of each essential medicine required in the facility using quality consumption data.	The healthcare facility's forecasts incorporate evidence-based adjustments for changes in morbidity patterns, seasonal factors, services levels, prescribing patterns, and patient attendance	The healthcare facility's forecasting process is an iterative process that is monitored and evaluated for improved accuracy in its ability to predict the essential medicine's needs of the facility.	The healthcare facility's multi-disciplinary team identifies inefficiencies in the forecasting process to improve the accuracy of the forecasting outcome.	

					to determine its medicine needs.	
	Supply planning	The healthcare facility does not develop supply plans or supply planning process is inadequate.	The healthcare facility's supply planning process determines the quantities, cost and delivery schedules of essential medicines based of the outcomes of the forecasting process.	The healthcare facility considers supplier performance and financial resources available to ensure the facility's inventory levels remain between the desired maximum and minimum inventory levels.	The healthcare facility continuously reviews the supply plans to incorporate changes in demand and the availability of financial resources.	The healthcare facility's multi-disciplinary team continuously review the supply planning process to identify opportunities for improvement.
			Maturity level			
Dimension	**Sub-dimension**	**Level 1: Initial**	**Level 2: Repeatable**	**Level 3: Defined**	**Level 4: Managed**	**Level 5: Optimising**
Storage	Storeroom requirements	The healthcare facility does not have a designated area to store essential medicines or the storeroom does not have the adequate infrastructure for effective storage.	The healthcare facility stores essential medicines in a weather proof storeroom with adequate storage infrastructure and fixtures to ensure the integrity and safety of the essential medicines stored.	The healthcare facility's storeroom has an efficient layout which facilitates effective storeroom management practices.	The healthcare facility's storeroom is constantly monitored for compliance with storeroom requirements.	The healthcare facility stores all medicine according to their manufacturers' storage specifications.
	Storeroom management	The healthcare facility's storeroom is	The healthcare facility's storeroom management	The healthcare facility's storeroom	The healthcare facility and monitors evaluates	The healthcare facility continuously

		unmanaged, or the storeroom management practices are inadequate.	practices ensure that only quality essential medicines enter the storeroom.	management practices ensure the systematic arrangement of essential medicine to ensure minimal inventory loss due to expiry and damage.	storeroom management practices based on its ability to maintain the integrity of essential medicines before distribution.	reviews storeroom management practices to identify opportunities for improving the facility's storage capabilities.
	Inventory control	The healthcare facility does not have an inventory control system in place or the system in place is inadequate.	The healthcare facility regularly monitors inventory levels to inform inventory control decisions.	The healthcare facility uses the standard minimum-maximum inventory control system.	The healthcare facility's inventory control practices prevent under-stocking, over-stocking and stock-outs.	The healthcare facility's inventory control practices are continuously reviewed to identify opportunities for improvement.
Dimension	**Sub-dimension**	**Level 1: Initial**	**Level 2: Repeatable**	**Level 3: Defined**	**Level 4: Managed**	**Level 5: Optimising**
		Maturity level				
Distribution	Distribution process	The healthcare facility distributes medicine to inpatients without a formally defined distribution process or the defined distribution process is inadequate.	The healthcare facility operates a central pharmacy system which distributes medicines to patients upon review of prescriptions and patient records.	The healthcare facility uses the unit-dose dispensing system to distribute medicines to inpatients.	The healthcare facility's distribution process is efficient and the facility experiences fewer distribution errors.	The healthcare facility's clinical and pharmacy personnel continuously review the distribution process to identify inefficiencies and identify improved distribution practices that can be implemented in the facility.

Dimension		
Selection		
Sub-dimension		
Selection process		
Maturity level requirement	**Answer (Yes/No)**	**Maturity Level**
The facility is responsible for its own essential medicine selection.		Level 1
The facility has a defined process for the selection of essential medicines.		
The selection process is based on the observed disease prevalence of the population group the facility treats.		Level 2
The facility has a comprehensive, evidence-based, standard treatment guideline (STG) for the most cost-effective treatment of diseases.		Level 3
The facility has an essential medicine list (EML) based on its comprehensive STG.		
The facility has a multidisciplinary team of healthcare professionals responsible for the development of STGs and EMLs and ultimately the essential medicine selection process.		
The multidisciplinary team considers patterns of prevalent diseases, the type of treatment facility, the training and experience of available personnel, financial resources, demographics and environmental factors in the selection of essential medicines.		
The facility's STGs are adhered to by all practitioners.		Level 4
The procurement of medicine is based on and limited to the facility's EML.		
The facility assesses the performance of the selection process by reporting on its ability to select essential medicines that meet the needs of the facility.		
The selection process is formally documented in the form of a guideline or policy which is in line with the country's National Health Act.		Level 5
The facility's EML and STGs are updated every two to three years.		
The multidisciplinary team of healthcare professionals continuously review the selection process to identify opportunities for improvement.		
The facility observes cost saving due to a limited list of medicines procured.		
Dimension		
Selection		
Sub-dimension		
Selection criteria		
Maturity level requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a selection criterion for essential medicines.		Level 1
All essential medicines selected are approved by a national drug regulatory authority.		Level 2
The facility selects essential medicines according to their International Non-proprietary Name (INN) (generic names).		Level 3

The facility selects essential medicines based on their quality and cost-effectives.		
The facility considers the total cost of treatment not only the unit cost of medicine.		
The facility's selection criterion is based on relevant, recent and unbiased information.		
The facility's selection criterion was developed by a multi-dispensary committee of healthcare professionals.		
The facility's selection criterion is closely linked to the WHO essential medicine selection criteria: relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, adequate quality and favourable cost-benefit ratio.		Level 4
The facility's essential medicines selection criterion is evidence based.		Level 5
All medicines in the facility adhere to the selection criteria.		
The facility's selection criteria are continuously reviewed to identify opportunities for improvement.		
Dimension		
Quantification		
Sub-dimension		
Data management		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a data management system in place.		Level 1
The facility conducted a needs assessment to determine the type of information and data required for quantification.		Level 2
The facility has a standardised data collection process which is conducted according to formally defined standard operation procedures.		
The facility makes use of information technology to manage data.		
The data is collected in a timely manner.		
The facility has a system to analyse and validate the information and data required for quantification.		
The facility's data management is the responsibility of trained personnel.		
The data is available in real-time and presented in a useful form.		Level 3
The data meets established quality standards of timeliness, completeness and accuracy.		
The facility's data management system enables reasonably accurate quantification outcomes on a consistent basis.		Level 4
The facility's data is used to inform supply management decision-making.		
The facility's data management processes are continuously reviewed to identify opportunities for improvement.		Level 5
Dimension		
Quantification		

Sub-dimension		
Forecasting		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility is responsible for forecasting its own essential medicines needs.		Level 1
All medicines forecasted form part of the facility's essential medicines list.		Level 2
The facility's forecasts are developed using forecasting software.		
Demand estimates are made for each essential medicine.		
The facility makes use of the consumption method to forecast essential medicines demand.		
Forecasting is conducted by well-trained personnel.		
The consumption data used for forecasting is adjusted to account for morbidity patterns, seasonality factors, service level, prescribing patterns and patient attendance.		Level 3
The assumptions made during the forecasting process are evidence based and informed by consumption data, service data, morbidity data, demographics data, policies, strategies and plans.		
The forecasting process is a collaborative effort by a multi-disciplinary team of administrative- and planning staff along with both clinical- and pharmacy staff.		
The forecasting outcomes are reviewed and updated every six months to incorporate changes in demand.		Level 4
The forecasting process predicts the facility's medicine demands with marginal lag time.		
The multi-disciplinary team reviews the forecasting process continuously to identify opportunities for improvement.		Level 5
Dimension		
Quantification		
Sub-dimension		
Supply planning		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility is responsible for developing its own supply plans.		Level 1
The supply plans developed are based on the outcome of the forecasting process, inventory levels and funding available.		Level 2
The supply plans determine the quantities, cost and delivery schedules of essential medicines.		
The supply plans incorporate supplier lead times and performance.		
Supply planning is conducted by well-trained personnel.		
Supply plans consistently ensure that inventory levels remain between the facility's established maximum and minim levels.		Level 3

Supply planning is a collaborative effort by a multi-disciplinary team of administrative- and planning staff along with both clinical- and pharmacy staff.		
The data used for supply planning is adjusted to account for morbidity patterns, seasonal factors, services levels, prescribing patterns and patient attendance.		
The facility makes use of supply planning software to improve the accuracy of the supply planning process.		
The assumptions made during supply planning are evidence based and informed by consumption data, service data, morbidity data, demographics data, policies, strategies and plans.		
The facility monitors the performance of suppliers based on pricing, terms, delivery times, dependability, quality service, return policy and packaging.		Level 4
Supply plans are reviewed every six months and adjustments are made to incorporate changes in the availability of financial resources and demand.		
Supply planning practices ensure orders are consistently delivered on time and in full.		
The multi-disciplinary team reviews the supply planning process to identify opportunities for improvement.		Level 5
Dimension		
Storage		
Sub-dimension		
Storeroom requirements		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a designated weatherproof room to store essential medicines.		Level 1
The storeroom is dry, clean and well ventilated with temperatures between +15 and +25 degrees Celsius.		
The storeroom is fitted with equipment to control environmental conditions.		
The environmental conditions of the storeroom are monitored and reported.		
Narcotics and controlled products are kept in a locked area.		
The storeroom is fitted with fire-fighting equipment and personnel is trained on how to use this equipment.		Level 2
The storeroom is fitted with shelves.		
Each shelf contains stock cards and labels of the medicines on it.		
The storeroom is only accessible to authorised personnel.		
The storeroom has security measures to avoid theft.		
Essential medicines are not exposed to direct sunlight and never stored on the floor.		
The storeroom has designated areas for: receiving stock, a main storage area, expired products, controlled substance, and cold chain products.		Level 3
The storeroom is routinely monitored for compliance to storeroom requirements.		Level 4

The facility has alternative energy sources in the event of power shortages.		Level 5
All medicines are stored according to the conditions specified by their manufactures.		
Dimension		
Storage		
Sub-dimension		
Storeroom management		
Statement	**Answer (Yes/No)**	**Level**
The facility's storeroom follows a defined procedure for receiving, inspecting and storing essential medicines.		Level 1
Stock is inspected for quality upon arrival in the storeroom.		Level 2
There is a clear procedure to report discrepancies of medicines received.		
Essential medicines are systematically arranged according to the FEFO rule.		Level 3
Stock records are kept and updated regularly.		
The stock records are reconciled with physical stock takes at least every quarter.		
Storeroom management is conducted by trained personnel.		
The facility has effective guidelines in which contain standard operation procedures for receiving stock, quality assurance inspections and systematic storage practices.		Level 4
The facility has an information system in place to track movement of medicines in the storeroom.		
The facility does not experience excessive essential medicine losses due to expiry, poor quality products or theft.		Level 5
Essential medicines maintain their effectiveness and shelf life throughout the storage period.		
The facility’s storeroom management practices are continuously reviewed to identify opportunities for improvement.		
Dimension		
Storage		
Sub-dimension		
Inventory control		
Statement	**Answer (Yes/No)**	**Level**
The facility has an inventory control system in place.		Level 1
The facility has standard operating procedures for monitoring stock levels.		Level 2
The facility regularly monitors inventory levels.		
The facility's inventory records are complete, reliable and accurate and are used to inform inventory control decisions.		
Monitoring inventory levels is the responsibility of well-trained personnel.		

The facility has a well-calculated minimum and maximum inventory level that consistently ensures few shortages and stock-outs.		Level 3
The safety stock and lead times are considered when determining minimum and maximum inventory levels.		
The facility's reorder quantity is based on the desired inventory levels for two to four months of inventory.		
The facility has an information system in place which sends notifications when inventory levels reach the established reorder quantity.		
The medicine review period ensures medicines do not fall below established minimum stock levels.		
The inventory control system considers the facility's storage capacity and financial resources available.		
Personnel responsible for inventory control have received adequate inventory management training.		
The facility's safety stock policy is adequate to withstand increase in demand.		Level 4
The order quantities consistently last for the period between when orders are placed and when orders arrive.		
Inventory control system prevents the facility from being over-or-under-stocked.		
Inventory control practices are continuously reviewed and updated through consultation with various stakeholders to identify opportunities for improvement.		Level 5
The system rarely places emergency orders.		
Dimension		
Distribution		
Sub-dimension		
Distribution process		
Statement	**Answer (Yes/No)**	**Level**
The facility has defined process for distributing essential medicines to inpatients.		Level 1
The medicine distribution process is initiated by an order in the form of a prescription which is accompanied by each patient's medical records.		Level 2
The facility distributes medicines in unit-doses from the facility's central pharmacy.		
The facility makes use of the unit-dose dispensing system to distribute medicine to inpatients.		Level 3
The medicine distributed is only for a 24-hour period.		
The facility's personnel are well-trained and efficient in preparing unit-dose carts.		
The facility has effective guidelines which contain standard operation procedures for distributing medicines.		

The medicine is only distributed after the review of a prescription and patient records by pharmacists.		
Reliable records are kept to monitor the consumption of medicines.		
Distribution data is collected in a timely manner.		
The turnaround time between receiving an order and administering medication is short.		Level 4
The facility experiences fewer distribution errors and medicine losses due to spoilage.		
The distribution process is formally defined in a facility policy and consistently applied.		Level 5
Pharmacy and clinical personnel consultation help to identify inefficiencies in the distribution system and opportunities for continuous improvement.		

6.4 Conclusion: Chapter 6

Chapter 6 presents the essential medicine management assessment framework. The framework developed is validated by subject matter experts to ensure that the dimensions and maturity levels included are adequate for benchmarking essential medicine management practices at facility level. The aim is to identify opportunities for improvement for better access to essential medicines. Changes to the model according the recommendations by subject matter experts were included in the assessment framework to ensure that the model's shortcomings were addressed. Chapter 7 provides a research overview and presents the objective attained by the research study. The chapter also presents the research study limitations and recommendations for future work.

Chapter 7

Conclusion and Future Work

Chapter 6 presented the validated essential medicine management assessment framework that can be used to benchmark essential medicine management practices at facility level. This is to identify opportunities to improve access to essential medicines. Chapter 7 is the final chapter of this research study and presents a summary of the research and discusses how the objectives the research were attained. The chapter concludes with a presentation of the research's limitations and recommendations for future work.

Section objectives:	§7.1: To present an overview of the research conducted; §7.2: To discuss how the research's objectives of this study were achieved; §7.3: To present the research study's limitations; and §7.4: Provide recommendations for future research.

7.1 Research Summary

The purpose of the research presented in this thesis is to develop an assessment framework that can be used to assess essential medicine management performance in public healthcare facilities in sub-Saharan Africa. The aim is to identify areas for improvement and extend access to essential medicines.

Chapter 1 serves as an introduction for the research study and presented the rationale for the research, the problem under study and the research aim and objectives. The chapter also presented a brief discussion on the ethical implications of the study and the document outline.

Chapter 2 presents a literature review which provided an overview of challenges facing medicine supply systems and introduces the concept of medicine management as an approach to improving access to essential medicines. The chapter also presented a review of existing methods of assessing access to medicine which provided evidence to support the need for the development of an alternative assessment method for evaluating essential medicine management performance at facility level. Finally, Chapter 2 also highlighted the benefits of using a maturity model as a benchmarking assessment tool for evaluating essential medicine management performance.

Chapter 3 presents the research methodology used in this research study. The chapter defines the type of research conducted and identifies the research methods used for data collection. Chapter 3 also presents the research approach applied for the development of the essential medicine management assessment framework.

Chapter 4 introduces the to concept of *maturity* and provides a brief historical overview of maturity models. The chapter also describes the types of maturity models that can be developed and the type of entities that can be measured using maturity models in practice. Finally, Chapter 4 reviews maturity model architecture literature to gain an understanding of the architectural elements of a maturity model, that is used to guide the development the essential medicine management assessment framework in this study.

Chapter 5 presents a literature review of the functional areas of the WHO Medicine Management Cycle namely, selection, quantification, procurement, storage, and distribution. The literature review focuses on identifying recommended practices for key elements within the WHO Medicine Management Cycle's functional areas to improve access to essential medicines and ensure effective medicine supply management practices at facility level.

Chapter 6 presents the essential medicine management assessment framework developed in this study. The chapter describes the framework development process and presents the dimensions and maturity levels included in the maturity model. It also describes how the maturity of essential medicine management practices can be measured. Chapter 6 also presents the outcome of the subject matter consultations used to validate the assessment framework developed and concludes with a framework analysis and results which show the changes made to the model according to the recommendations from subject matter experts to address the model's shortcoming.

Chapter 7, the final chapter of this research study, provides a research overview and presents the objectives attained by the research study. The chapter also presents the research study limitations and recommendations for future work.

7.2 Attainment of Research Objectives

The aim of this study, as outlined in Chapter 1, is to develop an assessment framework that can benchmark essential medicine management performance in public healthcare facilities in order to identify opportunities for improvement. To accomplish this aim, five research objectives were identified. Table 7.1 summarises the research objective of this study and each chapter in which they were addressed.

Table 7.1: Research objectives

No.	Objectives	Chapters
1.	Identify factors which hinder effective medicine management.	§1 & §2
2.	Investigate an appropriate approach for structuring/developing the proposed framework.	§2 & §4
3.	Describe best practices for medicine management.	§5
4.	Develop a benchmarking assessment framework to evaluate essential medicine management practices.	§6
5.	Validate the developed assessment framework.	§6

The following paragraphs describe how the research objectives were achieved:

1. **Objective 1** is achieved in Chapters 1 and 2 by conducting literature reviews on essential medicines and medicine supply management challenges to identify the key factors at facility level that hinder effective medicine management practices and thereby contribute to medicine shortages and stock-outs.

2. **Objective 2** is achieved in Chapters 2 and 4 by conducting literature reviews on the effectiveness of benchmarking to assess process performance and facilitate continuous improvement. A review is conducted on benchmarking assessment frameworks in the literature and the maturity model was chosen as the most appropriate tool to do this assessment at facility level. A systematic literature review is conducted to determine the appropriateness of using maturity models for assessing processes in the healthcare domain. The literature on maturity

model architecture is also reviewed to guide the development of the essential medicine management assessment framework developed.

3. **Objective 3** is achieved in Chapter 5 by conducting a literature review on the key practices for effective medicine management and identifying the recommended practices and focus areas that improve access to essential medicines.

4. **Objective 4** is achieved in Chapter 6 by integrating the essential medicine dimension identified in the literature into the maturity model architecture. The essential medicine management assessment framework developed is designed to enable healthcare facilities to assess the medicine management practices using an easily understood framework that can identify areas for improvement to prioritise improvement interventions and access to essential medicines.

5. **Objective 5** was achieved in Chapter 6 through consultation with subject matter experts to identify the shortcomings of the assessment framework developed and ensure its ability to benchmark medicine management performance at facility level.

This framework provides a complimentary assessment method to traditional quantitative methods in the healthcare sector which focus on collecting data on performance outcomes. The assessment framework developed in this study focuses on the various practices that drive essential medicine management performance. It can potentially be used by policymakers to better understand the root causes of poor performance which result in essential medicine shortages and stock-outs.

7.3 Research Limitations

The research has several limitations that need to be taken into account when reviewing the results, namely:

- The majority of the literature available on medicine management focuses on improving medicine management practices at a national level. The literature was therefore adapted to a facility level context. The process of adapting literature presents the potential of misrepresenting the medicine management dimensions for facility level.

- The maturity model developed in this study can only be used to assess medicine management practices for a healthcare facility that operates using a central pharmacy system and does not include the assessment of medicine distribution to outpatients or emergency wards.
- The ethical clearance and institutional clearance required to validate the essential medicine management framework through implementation or case studies could not be obtained, instead the maturity model was validated by subject matter experts. While this form of validation is used in practice; however, only three subject matter experts took part in the study. This research, therefore, cannot be regarded as a representative sample. Although the subject matter experts confirmed the validity of the model it does not necessarily prove its general usability in practice. Furthermore, all of the interviewed subject matter experts have experience in the same developing Southern African country. Thus, the results may not be generalisable to other sub-Saharan African countries.

7.4 Recommendation for Future Research

Various challenges regarding medicine management at facility level were identified in the literature and became apparent during the subject matter expert consultations. The recommendations for future research identifies research problems that aim to improve access to essential medicine at facility level but lie outside the scope of this research study.

1. There is a constant need for the development of assessment frameworks to evaluate the performance of healthcare processes to improve the quality of healthcare services in public healthcare facilities. As mentioned in Section 2.2, effective medicine management relies on good management support systems which include financing, information systems, human resources, and regulations and policies. These support systems, however, happen to be some of the main challenges for effective medicine supply systems. The researcher recommends further research into the development of a benchmarking framework to assess the performance of these support systems at facility level. This is required to identify opportunities for improvement and ultimately improve access to essential medicines.

2. Research should also be conducted into the effects of contextual factors such as the size of the healthcare facility, number of employees, and number of patients treated on medicine management performance.

3. There is a need for continuity and comparability in performance measures at all levels of the healthcare system. This would ensure that the effects of performance improvement effort at a national level filters down to facility level. Having a standard measure for reviewing medicine management for a whole health system could potentially foster a culture of learning and continuous improvement. Therefore, research could be conducted to develop an essential medicine management assessment framework to assess medicine management performance at a national level.

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Appendices

Appendix A

Review of benchmarking frameworks

Appendix A presents a brief overview of assessment frameworks considered for benchmarking medicine management practices at a facility level. The review considers three assessment frameworks, namely: gap analysis (section A.1), balanced scorecards (section A.2) and maturity models (section A.3).

A.1 Gap analysis

The gap analysis is considered one of the first steps of an accurate and complete benchmarking process (Marra *et al.*, 2018). The gap analysis is a technique used for identifying discrepancies in a system to achieving its set objectives (Amalfitano *et al.*, 2018). It is used to identify the difference between the current and proposed state of an organization and its functionalities- this difference is called a "gap" (Marra *et al.*, 2018). The gap analysis was developed in the 1980s to study quality in the service industry by analysing the difference between customer's expectations and their perceptions of a service (Amalfitano *et al.*, 2018). According to Amalfitano *et al.* (2018), a gap analysis is usually conducted to improve compliance to a set of requirements or standards. The usefulness of the information retrieved from a gap analysis is dependent on how an evaluation is conducted (Zuhaira *et al.*, 2017). Since its initial use in the service industry, the gap analysis has been applied in various domains, including business process management and supply chain management

(Marra *et al.*, 2018). The gap analysis is widely used in management studies to determine the potential for process improvement in a system.

According to (Zuhaira *et al.*, 2017), comparing an organization's current system to a best-practices system to identify gaps is cumbersome, time-wasting and rarely delivers accurate, precise or detailed results. The gap analysis identifies gaps by analysing prominent problems in a system and comparing them to their optimized solutions. This approach provides insight and understanding of a system's problem areas (Zuhaira *et al.*, 2017). The gap analysis defines the "to-be" state of a system by determining the best practices of a system in the domain understudy (Ahmed & Rafiq, 2002). Making comparisons against the best practices of a domain or stated aims of an organization allows it to assess the nature of the leap needed to match or surpass its work class competitors (Ahmed & Rafiq, 2002). According to Tontini & Søilen (2014), the gap analysis helps organizations prioritise resource allocation for process improvement interventions needed to enhance and mature their systems.

A.2 Balanced scorecards

The balanced scorecard is a well-known performance measurement tool that provides organizations with the ability to measure their performance from different perspectives at the same time (Salem *et al.*, 2012). The balanced scorecard was developed by Kaplan and Norton in 1992 to reflect on the inadequacy of traditional management systems, which are highly dependent on financial measures (Salem *et al.*, 2012). According to Pandey (2005), financial measures alone are not sufficient to guide performance for creating value and are highly dependent on non-financial measures. Salem *et al.* (2012) also noted that traditional management systems that incorporated non-financial measures often did not take into account an organization's strategy.

The balanced scorecard focusses on executing an organization's strategy by evaluating the cause and effect relationship between its strategic objectives (Asan & Tanyaş, 2007). It combines both financial and non-financial performance measures into a single scorecard that focuses on the linkage between organizational processes, decisions and results (Pandey, 2005). According to Gomes & Liddle (2009), the balanced scorecard aims to translate the vision and strategy of an organization into objectives, measures, and targets from four perspectives, namely:

1. **Financial perspective:** The financial perspective determines whether the organization's financial strategy contributes to achieving positive performance results (Broccardo, 2015). The financial perspective provides a common language for analysing and comparing organizations (Pandey, 2005).

2. **Customer perspective:** The customer perspective requires an organization to know how it should create value for its customers if it is to succeed (Pandey, 2005).

3. **Internal process perspective:** The internal process perspective helps organizations to determine their competencies and processes and identify where it must excel to improve its performance (Bose & Thomas, 2007).

4. **Learning and growth perspective:** The learning and growth perspective emphasizes employee training and building an organizational culture that facilitates individual self-improvement, as well as, corporate development and growth (Tontini & Søilen, 2014).

The process of translating strategy into action involves turning the organization's strategic vision into clear and understandable objectives for the four perspectives discussed above (Bose & Thomas, 2007). Each of these perspectives provide relevant feedback on how well the organization's strategic plan is executed in order to make adjustments where inefficiencies are identified (Salem *et al.*, 2012). Each perspective of the balanced scorecard includes (Pandey, 2005):

- **Objectives:** The organization specifies major objectives to be achieved under each perspective.

- **Measures:** Measures are the indicators that determine progress towards reaching an objective.

- **Targets:** Targets are the values for the measures.

- **Initiatives:** Initiatives are the actions that need to be performed to achieve the organization's objectives and targets.

Balanced scorecards are a strategic performance measurement frameworks that help organizations translate their strategies into a set of goals and objectives, with

implementation tracked through multiple performance measures (Bose & Thomas, 2007). Balanced scorecards provide a simple, systematic, and easy-to-understand approach for performance measurement, review, and evaluation on a continuous basis and provide quick feedback for control and evaluation Pandey (2005). According to Pandey (2005), balanced scorecards also guide strategy formulation, implementation, and communication.

A.3 Maturity model

Maturity models provide a structured approach for improving organizational capabilities[1] (Brookes *et al.*, 2014). They are an established approach for assessing organizational and operational capabilities in industries where there exists a strong emphasis on evolution and levels of process formality (Srai *et al.*, 2013). For more than 40 years, maturity models have been used as assessment frameworks to help improve processes and ensure better process outcomes in the software engineering industry (Hofmann *et al.*, 2012). Since their initial application in the software engineering industry, maturity models have gained popularity in other domains such as supply chain management, innovation networks, knowledge management, and project management (Lahti *et al.*, 2009). They are widely used in different domains to measure, plan, monitor and benchmark processes (Caralli *et al.*, 2012). According to Brookes *et al.* (2014), the value of a maturity model lies in its use as both an analysis and benchmarking tool.

Maturity models are useful for organizations that aim to implement change or improvement strategies in a well-structured way which will ensure tangible transformation (Caralli *et al.*, 2012). According to Van Dyk & Schutte (2012), maturity models are a way of measuring the status quo and providing an improvement approach that is specifically catered to an organization while prescribing the best practices parameters of the industry in which it operates. Comparing the "as-is" maturity of an organization to the "to-be" maturity helps to develop a staged plan which prescribes which maturity levels need to be attained and in which sequence to ensure sustained process improvement initiatives (Cleven *et al.*, 2014). Using a maturity model as a standard measurement approach helps organizations to determine

[1]Capabilities predict the most likely outcomes and results of a process (Paulk *et al.*, 1993).

where in the improvement journey they find themselves (Caralli *et al.*, 2012). When applied in a broader setting, maturity models also allow organizations to benchmark their performance against other organizations in the same domain, which helps to drive positive competition and encourages continuous improvement.

A maturity model describes the typical behaviour exhibited by an organization at a specific level of maturity (Lahti *et al.*, 2009). It consists of discrete maturity levels for dimensions that represent the anticipated, desired or typical evolution path for an organization's practices (Schriek *et al.*, 2016). According to Brookes *et al.* (2014), there is vast evidence which supports the efficacy of maturity models, which is reflected in the exponential growth in the development and application of these models.

Appendix B

Interview questions

Interviewee information

1. What is your qualification?
2. How many years of experience do you have in the field of pharmacy?

Research topic

1. Do you think essential medicine shortages and stock-outs are a problem in public healthcare facilities?
2. What do you think is the main problem?

Framework

1. Do you think the dimensions and sub-dimensions included in the maturity model are sufficient to assess essential medicine supply management?

Framework assessment

Dimension: Selection

Sub-dimension: Selection process

No.	Maturity level requirements	Useful (Yes/No)	Realistic (Yes/No)	Comment
1	The facility is responsible for essential medicine selection.			
2	The facility has a defined process for the selection of essential medicines.			
3	The selection process is based on the observed disease prevalence of the population group in which the facility operates.			
4	The facility has a comprehensive evidence-based standard treatment guideline (STG) for the most effective and cost-effective treatment and prevention of prevalent diseases.			
5	The facility has an essential medicine list (EML) based on its comprehensive STG for the treatment and prevention of prevalent diseases.			
6	The facility has a multidisciplinary team of healthcare professionals consisting of doctors, nurses, pharmacists, specialists and experts in public health or health economics which is responsibility the development of STGs and EMLs and ultimately the essential medicine selection process.			
7	The multidisciplinary team considers patterns of prevalent diseases, the treatment facility, the training and experience of available personnel, financial resources, demographics and environmental factors in the selection of essential medicines.			

8	STGs are adhered to by all practitioners.			
9	Procurement of medicine is based on and limited to the facility's EML.			
10	The facility has a monitoring and evaluation system to assess the performance of the selection process in selecting essential medicines that meets the needs of the facility.			
11	The selection process is formally documented in the form of a guideline or policy which is in line with the country's National Health Policy.			
12	EML and STGs are updated every two to three years.			
13	The multidisciplinary team is continuously developing guidelines and policies to improve the selection process.			
14	Cost-saving is observed due to a limited list of medicine procured and economies of scale.			
15	The facility experiences fewer stock losses, medicine shortages and stockouts as a result of the consistently applied essential medicine selection process.			

Dimension: Selection

Sub-dimension: Selection criteria:

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility has a selection criterion for essential medicines.			
2	All essential medicines selected are evaluated and approved by a national drug regulatory authority.			
3	Essential medicine is selected base their International Non-proprietary Name (INN) (generic names).			
4	Essential medicine selection is based on the cost of the medicine.			
5	The facility selects essential medicines based on their clinical efficacy and effectiveness, cost-effectives, budget impact, quality, and safety.			
6	The facility considers the total cost of treatment not only the unit cost of medicine.			
7	Essential medicine criteria are based on relevant, recent and unbiased information.			
8	The selection criterion is developed by a multi-dispensary committee with access to relevant information on cost and quality assurance.			

9	The facility's selection criterion is closely linked to the WHO essential medicine selection criteria: relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, adequate quality, favourable cost-benefit ratio, desirable pharmacokinetic properties, possibilities for local manufacture and availability as a single compound.			
10	The selection criterion is developed based accurate information regarding public health relevance, comparative cost-effectiveness, and pharmaceutical advances.			
11	The facility's essential medicine selection criteria are evidence-based.			
12	All medicines in the facility adhere to the selection criteria.			
13	The facility's selection criteria are continuously reviewed to account changes in healthcare needs.			

Dimension: Quantification

Sub-dimension: Data management

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility has a data management system.			
2	A needs assessment is conducted to determine which information and data are needed.			
3	The facility has a standardised data collection process.			
4	The facility makes of use of information technology to collect and store data.			
5	Data is collected in a timely manner.			
6	Data collection is the responsibility of trained personnel.			
7	Data is available and presented in a useful form.			
8	Data collected is sufficient for the quantification of essential medicine needs.			
9	The data meet established quality standards of timeliness, completeness, and accuracy.			
10	The facility has an information system to analyse and validate the information and data required for quantification.			
11	Quantification data is available in real-time.			
12	Data collection and analysis is guided by standard operating procedures.			

13	Data management process is monitored and evaluated to determine its ability to accurately estimate the medicine needs of the facility.			
14	Data collected is analysed to inform the decision making of the supply system.			
15	Data collected is reliable and complete.			
16	Data management process is continuously reviewed to determine if the practices in place are effective in producing accurate quantification outcomes.			

Dimension: Quantification

Sub-dimension: Forecasting

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility is responsible for forecasting the essential medicine needs of the system.			
2	Medicines forecasted form part of the facility's essential medicine list.			
3	Essential medicine forecasts are developed with the use of forecasting software.			
4	Quantity estimates are made for each type of essential medicine.			
5	Data used in the forecasting process is validated and is of high quality.			
6	The facility makes use of the consumption method to forecast essential medicine needs.			
7	Forecasting is conducted by well-trained personnel.			
8	Consumption data used for forecasting is adjusted to account for morbidity patterns, seasonal factors, services level, prescribing patterns, and patient attendance.			
9	Forecasting assumptions are informed by consumption data, service data, morbidity data, demographics data, policies, strategies, and plans.			
10	Assumptions are evidence-based and clearly stated.			
11	Forecasting is a collaborative effort by a multi-disciplinary team of administrative and planning staff along with both clinical and pharmacy staff.			
12	Forecasting outcomes are used to inform supply plans.			

13	Forecasting outcomes are reviewed and updated every six months to incorporate changes demand.			
14	The forecasting process is monitored and evaluated for accuracy in predicting the essential medicine needs of the facility.			
15	Forecasts are reviewed every six months and adjustments are made to meet the medicine demand.			
16	Forecasts are accurate in predicting the essential medicine needs of the facility.			
17	The facility experiences fewer shortages and stock-outs as a result of the accuracy of the forecasts.			
18	The multi-disciplinary team reviews the forecasting process to identify inefficacies.			

Dimension: Quantification

Sub-dimension: Supply planning

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility is responsible for developing supply plans.			
2	Supply plans are based on the outcome of the forecasting process.			
3	The facility determines the quantities and delivery schedules of essential medicines.			
4	Supply plans incorporate variables such as supplier lead times and performance.			
5	Supply planning is conducted by well-trained personnel.			
6	Supply plans are based on inventory levels.			
7	The facility's supply plans are based on the financial resources available.			
8	Suppliers chosen to provide adulate pricing, terms, delivery times, are dependable, quality service, return policy and packaging.			
9	Supply plans consistently ensure that stock levels remain between the established maximum and minim stock levels of the facility.			
10	Data used for supply planning is adjusted to account for morbidity patterns, seasonal factors, services level, prescribing patterns and patience attendance.			

11	Assumptions are informed by consumption data, service data, morbidity data, demographics data, policies, strategies and plans.			
12	Assumptions are evidence-based and clearly stated.			
13	Deliveries arrive before the stock reaches the established minimum level.			
14	Stock ordered brings the stock level back to the maximum stock level.			
15	Supplier selection, delivery schedules, product availability, quality and supplier performance are monitored.			
16	The facility makes use of supply planning software to improve the accuracy of the supply planning process.			
17	Orders are delivered on time and in full on a consistent basis.			
18	Supply plans are reviewed every six months and adjustments are made to incorporate changes in the availability of financial resources and demand.			
19	The multi-disciplinary team reviews the supply planning process to identify inefficacies.			

Dimension: Storage

Sub-dimension: Storeroom requirements

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility has a separate or designated weatherproof storeroom to store essential medicines.			
2	The storeroom is dry, clean and well ventilated with temperatures between +15 and +25 degrees Celsius.			
3	Essential medicine is not exposed to direct sunlight.			
4	The storeroom is fitted with shelves.			
5	The storeroom is fitted with infrastructure to control the climate.			
6	Shelves are fitted with stock card and labels of essential medicines.			
7	Narcotics and controlled products are kept in a locked area.			
8	The storeroom is fitted with firefighting requirement and personnel is trained on how to use the equipment.			

9	The storeroom has security measures to avoid theft.			
10	The storeroom is only accessible to authorised personnel			
11	Storeroom has a designated area for receiving stock, main storage area, expired products, controlled substance, and cold chain products.			
12	The facility has alternative energy sources in the event of power shortages.			
13	Storeroom is routinely monitored and evaluated for compliance with storeroom requirements.			
14	Essential medicines maintain their effectiveness throughout the storage period.			
15	All medicines are stored according to the conditions specified by the manufactures.			

Dimension: Storage

Sub-dimension: Storeroom management

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility's storeroom follows a defined procedure for receiving, inspecting and storing essential medicines.			
2	Stock is inspected for quality upon arrival in the storeroom.			
3	There is a clear procedure to report discrepancies of medicines received.			
4	Essential medicines are systematically arranged according to the FEFO rule.			
5	Each medicine is accompanied by a stock card.			
6	Stock records are kept and updated regularly.			
7	Stock records are reconciled with physical stock takes.			
8	Storage management is conducted by trained personnel.			
9	The facility has effective guidelines which contain standard operation procedures for receiving stock, quality assurance inspections and systematic storage practices.			
10	Information systems are in place to track products in the facility.			
11	Storeroom management practices are monitored and evaluated based on their ability to maintain the integrity of essential medicines before distribution			
12	The facility does not experience excessive essential medicine losses due to expiry, poor quality products or theft.			

13	The facility thoroughly investigates inefficiencies in storeroom management practices to identify new ways to improve the storage capacity of the facility.			

Dimension: Storage

Sub-dimension: Inventory control

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility has an inventory control system in place.			
2	The facility regularly monitors and evaluates inventory levels.			
3	The facility's inventory records are complete, reliable and accurate enough to be used to inform inventory control decisions.			
4	Monitoring inventory levels is the responsibility of well-trained personnel.			
5	The facility has a standard operating procedure for monitoring and evaluating stock levels.			
6	The facility has a well-calculated minimum and maximum inventory level.			
7	Reorder quantity is based on the desired stock levels for two to four months of stock.			
8	Safety stock and lead-time are taken into account when determining the minimum and maximum inventory levels.			
9	Medicine review period ensures medicine does not fall below-established minimum stock levels.			
10	Inventory control takes into account the storage capacity of a healthcare facility.			
11	Personnel responsible for inventory control have received adequate inventory management training.			
12	Safety stock policy is adequate to withstand an increase in demand.			
13	Order quantities consistently last for the period between when orders are placed and when orders arrive.			
14	Inventory control system prevents the facility from being over-or-under-stocked.			
15	The system rarely places emergency orders.			
16	Inventory control practices are reviewed and updated regularly through consultation with various stakeholders.			

Dimension: Distribution

Sub-dimension: Distribution process

No.	Maturity level requirements	Answer (Yes/No)	Realistic (Yes/No)	Comment
1	The facility has defined a process for distributing essential medicines to inpatients.			
2	Medicine distribution is initiated by an order in the form of a prescription.			
3	Medicine is distributed in unit-doses from the hospital's central pharmacy.			
4	The facility makes use the unit-dose dispensing to dispute medicine to inpatient.			
5	The facility has effective guidelines which contain standard operation procedures for dispensing medicine.			
6	Medicine distribution is only for 24-hour supply.			
7	Medicine is distributed after review of a prescription by pharmacists.			
8	Reliable records are kept off to track consumption of medicines.			
9	Data is collected in a timely manner.			
10	The turnaround time between a patient's prescription and administer medication is short.			
11	The facility experiences fewer distribution errors.			
12	The distribution process ensures minimum losses due to spoilage.			
13	The distribution process formally defined and consistently applied.			
14	Pharmacy and clinical personnel consultation are helping to identify inefficiencies in the distribution system.			

General:

1. Is this assessment framework easy to understand?
2. Do you think this assessment framework will be useful in improving access to essential medicines?

Appendix C

Framework use example

Appendix C presents a fictitious healthcare facility setting to illustrate how the assessment framework developed should be used in practice. Sections C.1 and C.2 present the case description and assessment results, respectively.

C.1 Case Description

District Hospital is a public healthcare facility. The hospital has been experiencing frequent medicine shortages and stock-outs since its budget for the 2018/2019 financial year was not increased due to the economic state of the country. An annual performance assessment found that the hospital had a 94% medicine availability rate. This figure is relatively high when compared to other district hospitals in the province. However, shortages and stock-outs still occur. The hospital's management team does not know the root cause of the problem and attribute the frequent shortages and stock-outs to insufficient financing.

In recent months the hospital's senior pharmacist and two pharmacist assistants were dismissed after allegations of theft. The hospital currently relies on three junior pharmacists to conduct all medicine management activities. The lack of managerial experience coupled with limited personnel has left the pharmacists overwhelmed with administrative work which has affected the efficiency of the hospital negatively.

The following paragraphs provide an overview of the District Hospital's medicine management practices.

Selection process: District Hospital's pharmacy department is solely responsible for the selection of essential medicines. The selection process is based on the experience of the personnel and it is not explicitly defined. The hospital uses a comprehensive, evidence-based STG; which was developed when the hospital opened in 2003. The national EML guides the selection and procurement of medicines in the facility. The hospital often also procures medicines which are not on the national EML because each doctor makes their own lists of the products they need to treat patients.

Selection criteria: The hospital does not have a medicine selection criteria. However, all medicines in the facility are selected based on the latest national EML which was last revised in 2013. All medicines in the hospital are approved by the National Drug Regulatory Authority. Senior nurses have taken over some of the medicine management responsibilities due to the personnel shortage in the pharmacy. The pharmacists do not have the time or capacity to train the nurses on using Non-proprietary Names, therefore, the hospital has been ordering brand name medicines which are more expensive than generic medicines. This has increased the hospital's medicines costs significantly.

Data management: The hospital recently received a donation of a healthcare information system which is used for data management. Before the system was implemented the hospital used a manual data management system. The conversion to the new system has been challenging as the donor only provided training for one personnel member. This makes it difficult to have up to date quantification data. The facility has a standardised data collection process which is guided by standard operating procedures. Trained personnel only collect the data required for quantification purposes. Even though the data is not readily available the validation system in place ensures that quality data is produced and used to make informed quantification decisions.

Forecasting: The facility forecasts its own essential medicine needs using sophisticated forecasting software and quality data. The consumption data used for forecasting is adjusted to account for morbidity patterns, seasonal factors, services level, prescribing patterns, and patient attendance. Due to the limited personnel available in the pharmacy, forecasts are not prepared for all medicines. Some medicines

are ordered in batches to save time. The forecasting outcomes are reviewed and updated every six months to incorporate changes in demand.

Supply planning: The facility is responsible for developing its own supply plans. The supply plans developed are based on the outcomes of the forecasting process, inventory levels and funding available. The supply plans determine the quantities, cost and delivery schedules of essential medicines. Supply planning is conducted by well-trained personnel. The data used for supply planning is adjusted to account for morbidity patterns, seasonal factors, services levels, prescribing patterns, and patient attendance. The facility makes use of supply planning software for the supply planning process. Unfortunately, orders are not consistently delivered on time and in full. Supply plans are reviewed every six months and adjustments are made to incorporate changes in the availability of financial resources and demand.

Storeroom requirements: The facility has weather proof storeroom which is fitted with labelled shelves and each shelf contains stock cards for the medicines on it. All medicines are stored according to the conditions specified by their manufactures. After the dismissal of the pharmacy personnel, the hospital has upgraded its security measures and the storeroom is now only accessible to authorised personnel. The pharmacy personnel routinely monitor and evaluate the storeroom for compliance with storeroom requirements. Due to the increase in electricity outages in the region, the Department of Health installed generators in the hospital.

Storeroom management: The facility's storeroom follows a defined procedure for receiving, inspecting, and storing essential medicines. Storeroom management is conducted by trained personnel who inspect stock for quality upon arrival in the storeroom. The hospital has a clear procedure to report discrepancies of medicines received. The facility conducts annual physical stock counts to reconcile inventory data. The last stock count found that a lot of medicines in the facility were expired or damaged.

Inventory control: The hospital has an inventory control system in place but the facility finds it difficult to maintain desired stock levels. In recent months the facility has placed numerous emergency orders which have been very expensive. Unfortunately, the

facility does not have the capacity to conduct an investigation to determine the cause of the problem and has opted to overstock the storeroom in an attempt to mitigate shortages and stock-outs.

Distribution process: District Hospital has recently started distributing essential medicines to inpatients using the unit-dose dispensing system. The process is defined and is conducted using standard operating procedures. The distribution system works well, but due to the limited personnel, medicines are sometimes distributed using the ward stock system to save time. This practice results in distribution errors and medicine wastage. The medicine distribution process is initiated by an order in the form of a prescription which is accompanied by a patient's medical records. The limited personnel has also made it difficult to keep accurate consumption and distribution data records.

C.2 Results

The maturity instrument was used to assess the essential medicine management practices at the District Hospital. Figure C.1 summarises the outcome of the assessment and the actual assessment instrument outcomes can be seen on Page 149.

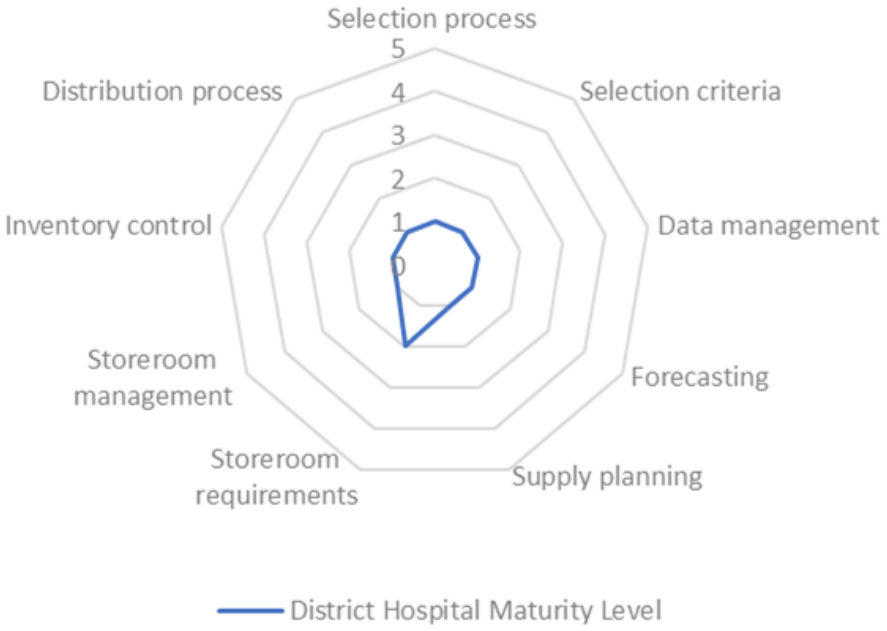

Figure C.1: Assessment results

Dimension		
Selection		
Sub-dimension		
Selection process		
Maturity level requirement	**Answer (Yes/No)**	**Maturity Level**
The facility is responsible for its own essential medicine selection.	Yes	Level 1
The facility has a defined process for the selection of essential medicines.	No	
The selection process is based on the observed disease prevalence of the population group the facility treats.	No	Level 2
The facility has a comprehensive, evidence-based, standard treatment guideline (STG) for the most cost-effective treatment of diseases.	Yes	Level 3
The facility has an essential medicine list (EML) based on its comprehensive STG.	No	
The facility has a multidisciplinary team of healthcare professionals responsible for the development of STGs and EMLs and ultimately the essential medicine selection process.	No	
The multidisciplinary team considers patterns of prevalent diseases, the type of treatment facility, the training and experience of available personnel, financial resources, demographics and environmental factors in the selection of essential medicines.	No	
The facility's STGs are adhered to by all practitioners.	No	Level 4
The procurement of medicine is based on and limited to the facility's EML.	No	
The facility assesses the performance of the selection process by reporting on its ability to select essential medicines that meet the needs of the facility.	No	
The selection process is formally documented in the form of a guideline or policy which is in line with the country's National Health Act.	No	Level 5
The facility's EML and STGs are updated every two to three years.	No	
The multidisciplinary team of healthcare professionals continuously review the selection process to identify opportunities for improvement.	No	
The facility observes cost saving due to a limited list of medicines procured.	No	
Dimension		
Selection		
Sub-dimension		
Selection criteria		
Maturity level requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a selection criterion for essential medicines.	No	Level 1
All essential medicines selected are approved by a national drug regulatory authority.	Yes	Level 2
The facility selects essential medicines according to their International Non-proprietary Name (INN) (generic names).	No	Level 3
The facility selects essential medicines based on their quality and cost-effectives.	No	

The facility considers the total cost of treatment not only the unit cost of medicine.	No	
The facility's selection criterion is based on relevant, recent and unbiased information.	No	
The facility's selection criterion was developed by a multi-dispensary committee of healthcare professionals.	No	
The facility's selection criterion is closely linked to the WHO essential medicine selection criteria: relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, adequate quality and favourable cost-benefit ratio.	No	Level 4
The facility's essential medicines selection criterion is evidence based.	No	Level 5
All medicines in the facility adhere to the selection criteria.	No	
The facility's selection criteria are continuously reviewed to identify opportunities for improvement.	No	
Dimension		
Quantification		
Sub-dimension		
Data management		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a data management system in place.	Yes	Level 1
The facility conducted a needs assessment to determine the type of information and data required for quantification.	Yes	Level 2
The facility has a standardised data collection process which is conducted according to formally defined standard operation procedures.	Yes	
The facility makes use of information technology to manage data.	Yes	
The data is collected in a timely manner.	No	
The facility has a system to analyse and validate the information and data required for quantification.	Yes	
The facility's data management is the responsibility of trained personnel.	Yes	
The data is available in real-time and presented in a useful form.	No	Level 3
The data meets established quality standards of timeliness, completeness and accuracy.	No	
The facility's data management system enables reasonably accurate quantification outcomes on a consistent basis.	No	Level 4
The facility's data is used to inform supply management decision-making.	Yes	
The facility's data management processes are continuously reviewed to identify opportunities for improvement.	No	Level 5
Dimension		
Quantification		
Sub-dimension		
Forecasting		

Maturity requirement	Answer (Yes/No)	Maturity Level
The facility is responsible for forecasting its own essential medicines needs.	Yes	Level 1
All medicines forecasted form part of the facility's essential medicines list.	No	Level 2
The facility's forecasts are developed using forecasting software.	Yes	
Demand estimates are made for each essential medicine.	No	
The facility makes use of the consumption method to forecast essential medicines demand.	Yes	
Forecasting is conducted by well-trained personnel.	Yes	
The consumption data used for forecasting is adjusted to account for morbidity patterns, seasonality factors, service level, prescribing patterns and patient attendance.	Yes	Level 3
The assumptions made during the forecasting process are evidence based and informed by consumption data, service data, morbidity data, demographics data, policies, strategies and plans.	No	
The forecasting process is a collaborative effort by a multi-disciplinary team of administrative- and planning staff along with both clinical- and pharmacy staff.	No	
The forecasting outcomes are reviewed and updated every six months to incorporate changes in demand.	Yes	Level 4
The forecasting process predicts the facility's medicine demands with marginal lag time.	No	
The multi-disciplinary team reviews the forecasting process continuously to identify opportunities for improvement.	No	Level 5
Dimension		
Quantification		
Sub-dimension		
Supply planning		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility is responsible for developing its own supply plans.	Yes	Level 1
The supply plans developed are based on the outcome of the forecasting process, inventory levels and funding available.	Yes	Level 2
The supply plans determine the quantities, cost and delivery schedules of essential medicines.	Yes	
The supply plans incorporate supplier lead times and performance.	No	
Supply planning is conducted by well-trained personnel.	Yes	
Supply plans consistently ensure that inventory levels remain between the facility's established maximum and minim levels.	No	Level 3
Supply planning is a collaborative effort by a multi-disciplinary team of administrative- and planning staff along with both clinical- and pharmacy staff.	No	
The data used for supply planning is adjusted to account for morbidity patterns, seasonal factors, services levels, prescribing patterns and patient attendance.	Yes	

The facility makes use of supply planning software to improve the accuracy of the supply planning process.	Yes	
The assumptions made during supply planning are evidence based and informed by consumption data, service data, morbidity data, demographics data, policies, strategies and plans.	No	
The facility monitors the performance of suppliers based on pricing, terms, delivery times, dependability, quality service, return policy and packaging.	No	Level 4
Supply plans are reviewed every six months and adjustments are made to incorporate changes in the availability of financial resources and demand.	Yes	
Supply planning practices ensure orders are consistently delivered on time and in full.	No	
The multi-disciplinary team reviews the supply planning process to identify opportunities for improvement.	No	Level 5
Dimension		
Storage		
Sub-dimension		
Storeroom requirements		
Maturity requirement	**Answer (Yes/No)**	**Maturity Level**
The facility has a designated weatherproof room to store essential medicines.	Yes	Level 1
The storeroom is dry, clean and well ventilated with temperatures between +15 and +25 degrees Celsius.	Yes	Level 2
The storeroom is fitted with equipment to control environmental conditions.	Yes	
The environmental conditions of the storeroom are monitored and reported.	No	
Narcotics and controlled products are kept in a locked area.	Yes	
The storeroom is fitted with firefighting equipment and personnel is trained on how to use equipment.	Yes	
The storeroom is fitted with shelves.	Yes	
Each shelf contains stock cards and labels of the medicines on it.	Yes	
The storeroom is only accessible to authorised personnel	Yes	
The storeroom has security measures to avoid theft.	Yes	
Essential medicines are not exposed to direct sunlight and never stored on the floor.	Yes	
The storeroom has designated areas for: receiving stock, a main storage area, expired products, controlled substance and cold chain products.	No	Level 3
The storeroom is routinely monitored for compliance to storeroom requirements.	No	Level 4
The facility has alternative energy sources in the event of power shortages.	Yes	Level 5
All medicines are stored according to the conditions specified by their manufactures.	No	
Dimension		
Storage		
Sub-dimension		

Storeroom management		
Statement	**Answer (Yes/No)**	**Level**
The facility's storeroom follows a defined procedure for receiving, inspecting and storing essential medicines.	Yes	Level 1
Stock is inspected for quality upon arrival in the storeroom.	Yes	Level 2
There is a clear procedure to report discrepancies of medicines received.	Yes	
Essential medicines are systematically arranged according to the FEFO rule.	No	Level 3
Stock records are kept and updated regularly.	No	
The stock records are reconciled with physical stock takes at least every quarter.	No	
Storeroom management is conducted by trained personnel.	Yes	
The facility has effective guidelines in which contain standard operation procedures for receiving stock, quality assurance inspections and systematic storage practices.	No	Level 4
The facility has an information system in place to track movement of medicines in the storeroom.	Yes	
The facility does not experience excessive essential medicine losses due to expiry, poor quality products or theft.	No	Level 5
Essential medicines maintain their effectiveness and shelf life throughout the storage period.	No	
The facility's storeroom management practices are continuously reviewed to identify opportunities for improvement.	No	
Dimension		
Storage		
Sub-dimension		
Inventory control		
Statement	**Answer (Yes/No)**	**Level**
The facility has an inventory control system in place.	Yes	Level 1
The facility has standard operating procedures for monitoring stock levels.	Yes	Level 2
The facility regularly monitors inventory levels.	No	
The facility's inventory records are complete, reliable and accurate and are used to inform inventory control decisions.	No	
Monitoring inventory levels is the responsibility of well-trained personnel.	No	
The facility has a well-calculated minimum and maximum inventory level that consistently ensures few shortages and stock-outs.	No	Level 3
The safety stock and lead times are considered when determining minimum and maximum inventory levels.	No	
The facility's reorder quantity is based on the desired inventory levels for two to four months of inventory.	No	
The facility has an information system in place which sends notifications when inventory levels reach the established reorder quantity.	No	

The medicine review period ensures medicines do not fall below established minimum stock levels.	No	
The inventory control system considers the facility's storage capacity and financial resources available.	Yes	
Personnel responsible for inventory control have received adequate inventory management training.	No	
The facility's safety stock policy is adequate to withstand increase in demand.	No	Level 4
The order quantities consistently last for the period between when orders are placed and when orders arrive.	No	
Inventory control system prevents the facility from being over-or-under-stocked.	No	
Inventory control practices are continuously reviewed and updated through consultation with various stakeholders to identify opportunities for improvement.	No	Level 5
The system rarely places emergency orders.	No	
Dimension		
Distribution		
Sub-dimension		
Distribution process		
Statement	**Answer (Yes/No)**	**Level**
The facility has defined process for distributing essential medicines to inpatients.	Yes	Level 1
The medicine distribution process is initiated by an order in the form of a prescription which is accompanied by a patient's medical records.	No	Level 2
The facility distributes medicines in unit-doses from the facility's central pharmacy.	No	
The facility makes use of the unit-dose dispensing system to distribute medicine to inpatients.	Yes	Level 3
The medicine distributed is only for a 24-hour period.	No	
The facility's personnel are well-trained and efficient in preparing unit-dose carts.	No	
The facility has effective guidelines which contain standard operation procedures for distributing medicines.	Yes	
The medicine is only distributed after the review of a prescription and patient records by pharmacists.	No	
Reliable records are kept to monitor the consumption of medicines.	No	
Distribution data is collected in a timely manner.	No	
The turnaround time between receiving an order and administering medication is short.	No	Level 4
The facility experiences fewer distribution errors and medicine losses due to spoilage.	No	
The distribution process is formally defined in a facility policy and consistently applied.	No	Level 5
Pharmacy and clinical personnel consultation help to identify inefficiencies in the distribution system and opportunities for continuous improvement.	No	

Table C.1 presents a brief discussion of the results for two[1] sub-dimensions, namely: selection process and inventory control.

Table C.1: District Hospital maturity results

Sub-dimension	**Result**	**Discussion**
Dimension: Selection		
Selection process	**Level 1: Initial**. The healthcare facility does not have an essential medicine selection process or the process in place is inadequate.	The District Hospital could be experiencing frequent essential medicine stock-outs because the selection process in place does not select the correct medicine to prevent or treat prevalent diseases of the population group the hospital serves. Since the hospital has a 94% medicine availability rate it is assumed that the hospital is performing optimally. However, this figure could represent wrong medicines that are made available in the facility which do not help the hospital deliver quality healthcare. The maturity assessment instrument provides a guide and recommendations for improving the selection process.
Dimension: Storage		
Inventory control	**Level 1: Initial**. The healthcare facility does not have an inventory control system in place or the system in place is inadequate.	The District Hospital's inventory control fails to maintain the desired stock levels because practices in place are reactionary and not standardized. The healthcare facility does not monitor stock levels regularly which means that the 94% medicine availability could be significantly overstated. It should be noted that to improve inventory control, the quantification practices i.e. data management, forecasting and supply planning need to be adequate. This will ensure that the quantity of essential medicine needed in a healthcare facility is known which will allow the desired inventory levels to be defined. It is impossible to maintain desired inventory levels when the desired levels are not established. The maturity assessment instrument provides a guide and recommendations for improving inventory control.

[1]Only two sub-dimensions were discussed to present the reader with an example of how results can be analysed in practice.