

Understanding the dynamics of accessing chronic medicines in the public sector: Implications for policy in South Africa

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Table of contents

Abstract	iv
Declaration	viii
Dedication	ix
Acknowledgements	x
Abbreviations	xiii
1. Introduction	1
1.1 Defining concepts.....	1
1.2 A global perspective on access to medicines.....	3
1.3 Access to medicines in low-and-middle income countries.....	4
1.3.1 Access to medicines in S. Africa.....	5
1.3.1.1 Why consider access to medicines in for chronic conditions?.....	5
1.3.1.2 What is already known about the state of chronic medicines in S. Africa?.....	6
1.4 The AMASA project as the research context.....	9
1.4.1 Study setting.....	12
1.5 Problem statement.....	14
1.6 Aim and objectives of the study.....	14
1.7 Research questions.....	15
1.8 Relevance of the study.....	16
1.9 Methodological choice: implementation research.....	16
1.10 Thesis overview.....	17
2. Literature review	17
2.1 Access to medicines, a complex issue?.....	17
2.2 Conceptual framework.....	19
3. Methodology overview	24
3.1 Emergent design.....	25
3.2 Data collection methods.....	27
3.3 Data analysis.....	27
3.4 Rigour and reflexivity in qualitative research.....	31
3.5 Ethics.....	33

References.....	33
4. Results	44
5. Discussion	46
5.1 Summary of the main findings.....	46
5.2 Situational analysis of the state of chronic medicines in the public sector.....	49
5.2.1 Chronic care models and access to medicines: exploring the link.....	52
5.3 Innovative models to improve ATM: key lessons from and for other contexts.....	54
5.4 How providers influence implementation of ATM programmes at the front-line.....	59
5.5 Strengths and limitations of this PhD thesis.....	61
6. Conclusions, recommendations and implications for future research	62
References.....	63
Annex	69
 Paper 1	
 Paper 2	
 Paper 3	
 Paper 4	
 Paper 5	
 Paper 6	
<div style="text-align: center;">  <p>UNIVERSITY of the WESTERN CAPE</p> </div>	
Tables (in main document)	
Table 1: Health facilities included in the PhD study.....	13
Table 2: Data sources for development of conceptual framework.....	20
Table 3: Outline of methods used in the PhD thesis.....	29
Table 4: Interventions according to the barriers they sought to address.....	55
Figures (in main document)	
Fig 1: Research areas for the AMASA project.....	11
Fig 2: Map of South Africa and selected population statistics.....	12
Fig 3: Conceptual framework.....	23

Abstract

Background

Access to medicines (ATM), specifically for those medicines that are related to the priority health needs of a population has been cited as a fundamental part of universal health coverage and a key element for service delivery and high-quality care. Therefore, ensuring reliable access to and appropriate use of safe, effective and affordable medicines is one of the core functions of an effective health system. With the rising demand for treatment of chronic diseases (e.g. HIV, diabetes and hypertension), ATM has increasingly received global attention. Yet as of 2011, it was estimated that at least one third of the world's population had no regular access to medicines. Globally, there is a dearth of in-depth country level evidence to influence policy responses, coupled with inadequate understanding of how pharmaceutical systems operate within broader health systems. This thesis comprises two main parts: 1) **a situational analysis of the state of chronic medicines provision in the public sector in the Eastern Cape and Western Cape provinces of South Africa;** and (2) **an evaluation of an existing ATM model in one province.**

To situate this study within the ATM discourse, a conceptual framework was developed from a review of empirical and theoretical literature. The framework incorporated six ATM dimensions (*availability, affordability, acceptability, accessibility, accommodation and quality*) and their interplay at multiple levels including: *health facility, individual, household and community* levels. Then, at a health system level, the interaction of *medicines* (a health system building block) with other building blocks (*information, financing, human resources, infrastructure and governance*).

Methodology

A combination of qualitative methods (in-depth interviews, focus group discussions, non-participant observations and document review), supported by a review of routinely collected data were employed. Qualitative research methods allow a deeper understanding of the world as seen and experienced by respondents. The emphasis is on a focussed and bounded phenomenon embedded in its context and produces rich data with strong potential to reveal complexity. Given the predominantly qualitative nature of the study, an emergent research design was selected to allow for flexibility to adapt inquiry as the study progressed and as understanding deepened.

Data analysis

The data analysis process was a hybrid of inductive and deductive coding and theme development, involving multiple cycles of reading and re-reading of the data in order to identify emerging major and minor themes. The dimensions presented in the study's conceptual framework provided a useful lens for understanding the results and served as an initial coding manual (deductively derived codes). However, there were other issues that emerged for which additional codes were developed (inductively derived codes). Interview transcripts were imported into Atlas Ti 7, a data analysis software. Text relevant for a particular code were matched. The codes were then grouped according to broader themes. Routine data were analysed descriptively using MS Excel.

Results

A situational analysis of the state of chronic medicines provision in the public sector in the Eastern Cape (EC) and Western Cape (WC) provinces

Stock-outs emerged as a barrier to ATM in both provinces. Since medicines procurement is a centralised function, inefficient national level supply chain activities were identified among causes of stock-outs. The EC faced additional barriers, i.e. weak distribution structures to deliver medicines to hard-to-reach areas with underdeveloped transport infrastructure, limited resources for efficient functioning of the health system and a patient population constrained by poverty. Healthcare practitioners (HCPs) at the frontline responded to some of the barriers empathically by devising context-specific innovative informal solutions, outside of policy. This included flexible prescribing and dispensing for longer periods and aligning clinic and social grant appointments to minimise patients' routine costs.

In the WC, the Department of Health (WCDoH) identified many ATM barriers prior to this study, including: limited pharmacy human resources; and challenges with *affordability, acceptability and accessibility* of services on the patients' side. Consequently, two innovative strategies were introduced, i.e. (i) an out-sourced centralised dispensary known as the Chronic Dispensing Unit (CDU) to address the human resource issues and (ii) community-based distribution (CBD) models for delivering medicines nearer to where people live to address demand-side barriers.

While both interventions were commended for improving ATM and with potential to be replicated in other provinces, implementation was challenging in various ways. CBD models were still evolving and their processes and structures varied. Furthermore, the governance of these models was weak (including relatively weak documentation systems) and there was

variation in the way implementation was carried out, including involvement of informal providers, making it difficult to assess the *quality* of services provided.

The CDU on the other hand, was dispensing approximately 300 000 patient medicine parcels each month and reported at least 8%-12% cases of non-collection by patients who missed appointments and an unknown number of unreported cases. This increased the cost of running the service and potentially has negative therapeutic outcomes for patients. These problems informed the second part of this study.

2) Evaluating the Chronic Dispensing Unit

Placed as a starting point to the evaluation enquiry, missed appointments were attributed to a combination of socio-economic factors including mobility and work commitments, aspects that were not considered during intervention design. Some barriers seemed to be of a temporary nature as many patients who missed appointments presented voluntarily to obtain medicines at a later time. However, that did not ease implementation because the administrative process for missed appointments was resource consuming and the parallel pharmacy information systems were not well-integrated to inform decision-makers about what was happening. In addition, it also became evident that a range of implementation-related issues led to some patients being erroneously recorded as appointment defaulters, which provided an impetus for a comprehensive evaluation of the CDU's implementation processes, using theory-driven evaluation principles.

From the evaluation results, implementation was influenced at a macro level by inefficient contracting procedures; at the frontline by actors' (un)preparedness to embed the intervention coupled with a variety of contextual factors, including political pressure and high prevalence of unstable patients. While there were implementation guidelines and protocols, implementers' decisions were guided for the most part by contextual realities. Furthermore, the following elements emerged as necessary for effective implementation: *communication, cooperation, willingness to change, ownership, leadership commitment and trust*.

Overall, the results of this PhD study in many ways reflected key dimensions of the theory of street-level bureaucracy, which aids in the explanation of policy implementation, i.e. where policy is implemented in unexpected and unintended ways and gives policy makers and policy implementation managers insight into why certain policies are not always implemented as intended. Healthcare practitioners in both provinces navigated ATM barriers, i.e. challenging

work environments plagued by limited resources and a high demand for services and challenging socio-political, economic and cultural contexts.

Recommendations and conclusions

This study lends itself to the following recommendations, which should be contextualised in order to effectively improve ATM:

Macro-level (policy)

- a) Concerted effort is required to make comprehensive care for chronic conditions a reality. To achieve this, a multi-sectoral stakeholder engagement approach involving the formal health sector, informal providers of health services, community-based organisations, and relevant non-health sectors such as those involved in infrastructure development is required.
- b) Strengthening procurement of medicines and contracted healthcare services is required in order to minimise stock-outs and to ensure that services remain functional during change-over periods.

Meso-level (service delivery and community)

- a) Revisit the patient care model to ensure that it is responsive to socio-economic and cultural realities of patients. Furthermore, introduce a two-way communication system between patients and the health system so that the health system can be better prepared to respond to patients' needs.
- b) Develop monitoring systems, including chronic disease registers for non-communicable diseases where patients' outcomes can be routinely captured and periodically analysed to facilitate timely interventions where required.
- c) Integrate the two facility-based pharmacy information systems so that the system is able to provide a holistic picture on collected and non-collected medicines at any given time (WC).
- d) Strengthen medicines distribution networks in order to improve delivery of medicines in hard-to-reach-areas (EC).

Micro-level (individuals and households)

- a) Conduct population-based research in order to understand the characteristics of the population served because treatment access occurs within a context of patients' everyday realities. As such, acknowledging socio-economic and cultural factors that affect health facility attendance and invariably health status will facilitate management of at-risk patients and inform contextual approaches to addressing public health problems.

Declaration

I declare that “*Understanding the dynamics of accessing chronic medicines in the public sector: Implications for policy in South Africa*” is my own work, that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references. The results section of this thesis comprises six manuscripts which have either been published, in press or submitted for publication. All papers are included and reprinted with the copyright holders’ permission. This serves to confirm that I am listed in all the manuscripts as the first and main author.

Full name: Bvudzai Priscilla Magadzire

Date: December 2016

Signed:

Bvudzai Priscilla Magadzire



Dedication

To my family.

To all those with chronic disease, who wake up to fulfil their life's purpose despite the circumstances.



Acknowledgements

“It takes a village to raise a child” is one of the most popular African proverbs, which depicts the close connections between communities. I believe one of the reasons why it’s so famous is it rings true for many people. In some sense, it also rings true for my PhD journey. There are many people who have been an integral part of my journey in different ways. For some reason, I’ve been writing the acknowledgements *“in my head”* for the last couple of years as I was walking the journey. My hope is that as I pen it down now, I will recall all that has been written on the script of my brain.

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Bruno, “I am grateful that I could work with you. You always had the voice of reason, and took things simply. Whether it was reviewers’ comments from a journal or whatever else,

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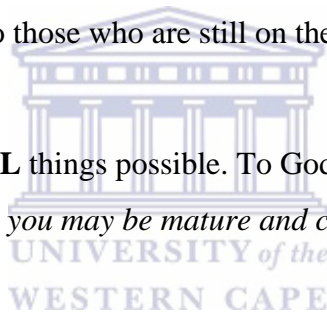
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Finally, unto Him who makes **ALL** things possible. To God be the glory! “*Let perseverance have her perfect work in you, that you may be mature and complete, lacking nothing.*” James 1:4, that was my PhD inspiration!



Abbreviations

AMASA	Accessing Medicines in Africa and South Asia (project)
ART	Antiretroviral treatment
ATM	Access to medicines
CBD	Community-based distribution
CCM	Chronic Care Model
CCMDD	Central Chronic Medicine Dispensing and Distribution
CDU	Chronic Dispensing Unit
CHC	Community Health Centre
CHWs	Community Health Workers
EC	Eastern Cape
EMP	Essential Medicines Programme
FGD	Focus group discussion
GBD	Global Burden of Disease
GPP	Good Pharmacy Practice
HCPs	Healthcare Practitioners/Providers
ICCC	Innovative Care for Chronic Conditions
ICDM	Integrated Chronic Disease Management
ITT	Implementation Task Team
LMICs	Low-and-middle-income countries
MDD	Multi dose drug dispensing
NCDs	Non-communicable diseases
NDoH	National Department of Health (South Africa)
NGOs	Non-Governmental Organisations
NHI	National Health Insurance
NHP	Non-Health Professionals
Pas	Pharmacist's assistant
PHC	Primary healthcare
QA	Quality assurance
SA	South Africa
SOP	Standard Operating Procedures
TB	Tuberculosis
TPSA	Tracing Pharmaceuticals in South Asia (project)

TWG	Technical Working Group
UHC	Universal Health Coverage
UN	United Nations
WC	Western Cape
WCDoH	Western Cape Department of Health
WHO	World Health Organisation



1. Introduction

In sum, the intended contribution of this thesis to the field of public health is to (1) characterise barriers to accessing medicines for chronic illnesses; (2) to evaluate existing innovative ATM models and (3) establish whether existing models are fit for purpose, i.e. do they address the prevailing challenges and/or have new challenges arisen as a result of the intervention(s)?

To put this thesis in context, some common terms are defined in this chapter, i.e. the concept of access to medicines (ATM), medicines supply chain and the application of chronic diseases in this study. This is followed by an overview of ATM at a global level, then in low- and middle-income countries (LMICs). Thereafter, the status of ATM in South Africa (SA) is presented, highlighting the current situation and gaps in the literature, followed by a brief history of the origins of this PhD study, its aim, objectives and methodological considerations are provided. Finally, an outline of the rest of the thesis is presented.

1.1 Defining concepts

What is access to medicines?

There is no single, clear definition for ATM. However, some authors have suggested that it may be considered as a collection of interrelated dimensions such as accessibility, affordability, acceptability and availability [1]. The notion of “access” has been researched in healthcare in general, and a critical aspect is the consideration of both supply and demand factors [2]. Jacobs & colleagues defined supply and demand factors as follows:

“Demand-side determinants are factors influencing the ability to use health services at individual, household or community level, while supply-side determinants are aspects inherent to the health system that hinder service uptake by individuals, households or the community” [3].

This is the approach taken in considering ATM in this study. A detailed exploration of the concept of access is provided in more detail in Chapter 2.

Medicines supply chain

For the purposes of simplicity, the term ‘*medicines*’ is used to refer to essential medicines as defined by the World Health Organisation (WHO), i.e. those medicines that satisfy the priority healthcare needs of the population [4]. The medicines supply chain can be defined as follows:

“Set of activities involved in moving a product (in this case medicines, diagnostics and other health supplies) and its associated services from the ultimate supplier to the ultimate consumer”. [5]

Chronic diseases and their application to this study

It is widely agreed that diseases such as diabetes, hypertension and HIV contribute to the large and growing proportion of the burden of disease in low- and middle-income countries and amongst all social groups [6, 7]. Historically, the term ‘chronic disease’ was used to define non-communicable diseases (NCDs) of long duration and generally slow progression [8]. However, over the last couple of years, HIV has also come to be considered a chronic disease because of its long-term nature [9, 10], although some scholars have raised concerns over the implications of this interpretation on the global HIV response, specifically how global actors understand and address HIV [11]. While the potential difficulties of grouping HIV and NCDs together are acknowledged in this study, the diseases in question share the life-long condition attribute. For this study, the term ‘chronic diseases’ refers to ‘life-long conditions requiring long-term medical interventions and adherence to medication and adjustments in life’ [12]. A wide range of diseases qualify under this category but diabetes, hypertension and HIV are the selected tracer conditions¹ for this study. There are a few reasons that explain the choice of tracer conditions, including the origins of this research and findings from preliminary research explained later in this chapter, but the most important is that these conditions pose long-term treatment and care demands. In addition, being common conditions, these are likely to provide a useful lens with which to understand ATM. An anticipated advantage of looking at ATM within the lens of multiple conditions was the opportunity for ‘cross-fertilisation’ of lessons across programmes [13, 14].

¹ Tracer conditions have been defined as common health problems which can be described accurately in local illness terms and a well-defined treatment norm exists for the condition. Available from: <http://apps.who.int/medicinedocs/en/d/Js2232e/4.4.html#Js2232e.4.4>.

1.2 A global perspective on access to medicines

Access to medicines, specifically for those medicines that are related to the priority health needs of a population (also referred to as essential medicines), has been cited as a fundamental part of universal health coverage (UHC)² and a key element for service delivery and high-quality care [15]. Hence, ensuring reliable access to and appropriate use of safe, effective and affordable medicines is one of the core functions of an effective health system [16] and a contribution to the fulfilment of the fundamental right to health [17].

ATM has received global attention and continues to rank highly on the United Nations (UN) agenda. Late last year (2015), the UN Secretary-General convened a **High-Level Panel on Access to Medicines** whose objective is to: “*review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies*” [18]. Previously, the UN also cited ATM as one of the five indicators to measure progress in the progressive right to health; yet as of 2011, the WHO estimated that at least one third of the world’s population had no regular access to medicines [19]. Another study reported that 15% of the world’s population consumes 91% of the world’s production of pharmaceuticals, an indication of gross inequities [20].

Insufficient ATM is an even bigger problem in many low-and middle income countries (LMICs) [21, 22], compared to the high income countries. The UN estimated that from 2007-2014, on average, generic medicines were available in 58 % of public health facilities in LMICs [23]. Part of the problem is that many countries still do not recognize the right to health in their national constitutions [19]. A review in LMICs found that in countries that made constitutional and human rights provisions (mostly in Central and Latin America), ATM was legally enforceable [24]. However, although having constitutional and human rights provisions could be helpful, countries need to move beyond these to practical implementation. The WHO has since the early 1980s advocated for the introduction of the Essential Medicines Programme (EMP) to address this gap [25]. With the EMP, the WHO recommends that all countries formulate and implement a comprehensive national medicines policy in order to address pharmaceutical sector issues under a common framework. This

² “Universal coverage means quality health care for all delivered in ways that protect users from financial ruin or impoverishment.” Chan M: Remarks at the Launch of the World Health Report 2013: Research for Universal Health Coverage. Beijing; 2013. [Dated 15 August 2013]. Available from: http://www.who.int/dg/speeches/2013/whr_20130815/en/index.html.

approach has required an engagement by WHO on a range of issues deemed to be hindering ATM, including the effect of international trade agreements on ATM and research and development to ensure availability of new essential medicines [26]. Evidence from four countries, most of which were LMICs has shown the importance of political buy-in for appropriate policies to be passed [25].

Other issues hindering ATM include a dearth of in-depth country level evidence to influence policy responses [19, 27] coupled with a general lack of understanding of how pharmaceutical systems operate within broader health systems [28]. Additionally, some authors have argued that acknowledging the unpredictable and ever changing nature of health system components and actors can lead to a fuller understanding of how medicine policies and medicines interventions affect and are affected by the system's constant adaptation and complexity [29].

While it is clear that ATM is a key concern for all, much of the discourse at global level is about medicines affordability [30-33]. The alternative discourse is grounded in considerations of intellectual property and barriers to pharmaceutical production, distribution and research innovation. These two elements dominate the policy discourses worldwide but the reality is there are a host of other reasons why people fail to access medicines [18], most of which are tied to local contexts. In the next section, the barriers hindering ATM in LMICs are discussed followed by the issues related to SA more specifically.

1.3 Access to medicines in low-and-middle income countries

Many studies have been undertaken to explore access to healthcare services in general [2, 34], for which medicines might be an inherent component. However, there are much fewer studies focussing specifically on ATM and even less when considering only chronic medicines. A few LMIC-based studies focussing on ATM were found, and are highlighted here.

A study conducted in Senegal (West Africa) identified critical issues affecting ATM including stock-outs (events of medicines unavailability); insufficient infrastructure and unaffordable medicines costs [35]. Another study in the West African country of Nigeria found that although there was a drug policy, the implementation framework was not aligned to the policy [36]. In Pakistan (South Asia), ATM barriers were linked to weaknesses in the health care system and weak pharmaceutical regulation [30]. In Ghana (West Africa), one

study found that the introduction of the National Health Insurance Scheme had increased ATM and medicines utilisation by reducing cost barriers for patients [37]. However, some challenges still remained, i.e. low reimbursement rates for medicines resulted in providers asking patients to pay supplementary fees and inadequate participation of the private sector providers [37]. A study in Ethiopia (Horn of Africa), also reported frequent stock-outs of HIV medicines, which were an indication of weak supply chain management [38]. On the other side of the spectrum, some studies in a couple of LMICs have found social and cultural factors to pose barriers to ATM [20, 39]. Below, we focus on ATM issues in South Africa.

1.3.1 Access to medicines in South Africa

1.3.1.1 *Why consider access to medicines for chronic conditions?*

South Africa has been described as a country with four colliding epidemics, which include chronic communicable (HIV) and non-communicable diseases (NCDs), e.g. diabetes and hypertension [40, 41]. The latter have increased with lifestyle changes and urbanization [42], which has led some experts to suggest a different focus and approach to Public Health policy and action, and a re-orientation of service delivery [43]. The 2013 Global Burden of Disease (GBD) study found SA's top ten causes of premature mortality to be significantly above the mean when compared to 19 other countries with similar GBD, trade and income rankings [44]. In this study, HIV ranked as the highest cause of premature mortality, followed closely by NCDs such as diabetes and ischemic heart disease. Local evidence from the national statistical service (Stats SA), which analyses the cause of mortality annually based on the death notification records, is also available. The 2014 analysis ranked tuberculosis first followed by chronic diseases such as HIV, diabetes and hypertensive diseases, which were all in the top 10 [45]. Our assumption is that the GBD and the Stats SA studies had differing diseases for the highest ranking (HIV and TB in this case), because TB could have been documented as the immediate cause when HIV was in fact the underlying cause given the high rates of HIV/TB coinfection in this country [46]. Although the death notification allows for up to six causes to be recorded, over 50% only recorded one cause [45].

Previous studies have indicated that the HIV epidemic is more generalised [47], while proportion of years of life lost due to NCDs is highest in the metros and least-deprived districts [48]. Overall, it is evident that SA's burden of chronic disease warrants attention and makes a case for improved ATM in order to treat disease and prevent premature deaths.

1.3.1.2 What is already known about the state of chronic medicines provision in South Africa?

A free primary healthcare (PHC) policy and subscription to the Essential Medicines Programme are among some of the listed accomplishments of SA's public health sector restructuring post-1994 [49]. In addition, the National Health Act (2003) requires the national health department to provide a framework for a structured health system [50].

The public health sector caters for over 70% of the population [51]. It is estimated that just over 85% of the health budget goes towards (i) the HIV programme – of which SA has the world's largest antiretroviral (ART) programme [40, 52]; (ii) revitalising primary healthcare facilities (under which NCDs are a sub-programme) and (iii) specialised tertiary services [53]. It is not clear from the estimates of national expenditure what proportion of the health budget goes to medicines and medical supplies.

The National Department of Health (NDoH) suggests that access to ART has contributed to a decrease in AIDS-related deaths over the years [54] and increased life expectancy. However, challenges remain [52, 55] as South Africa's life expectancy is still below that of most upper middle income countries [53]. This is a clear indication that more efforts are required to address the health needs of the population. This is not surprising given that previous research has acknowledged that few health systems in poorly resourced settings are organized to fully meet the needs of patients with chronic diseases [56], because health systems are already burdened with other demands such as the unfinished agenda of maternal and child health problems [6, 41]. Hence, the increasing burden of chronic disease, coupled with the incapacity of the health system to address adequate supply and demand-side factors impose challenges in provision of treatment. Below the supply- and demand barriers are explored in turn.

(a) Supply-side issues

An important consideration in the subject of ATM is the availability of medicines. South Africa has experienced several stock-outs for treatment of major chronic diseases as evidenced by a spate of media and civil society reports on lack of medicines at the primary healthcare level in recent years [57-59]. A 2012 national assessment by the NDoH reported a 54% failure in compliance with measures addressing availability of medicines and recommended priority attention to supply chain management [60]. As a result, confidence in the public sector among users has waned. It has been reported that the mal-distribution of pharmacy workforce

(private-public, urban-rural) [61], and emigration of health professionals to developed countries [62] undermine the efficiency of the public health sector. As of 2010, vacancy rates for pharmacists in the public sector were up to 76 % in one province and only 29 % of registered pharmacists in the country were working in the public sector [63]. One of the ways to deal with the human resources crisis was the introduction of a category of mid-level workers known as pharmacist's assistants since the late 1980s. This cadre is at two levels – basic and post-basic and each category has a defined scope of practice [64]. An important distinction between the two levels is that post-basic pharmacist's assistants are permitted to operate under indirect supervision of a pharmacist in some settings [64].

Other responses to expand ATM and related pharmaceutical products have been proposed in National Health Insurance (NHI) White Paper which intends to bring about improved healthcare delivery once its implemented. In relation to ATM, part of the NHI package is the accreditation and contracting of private retail pharmacies in order to enable them to order products at subsidised prices and dispense to NHI patients [65]. In addition, also under the NHI, is contracting the private sector to perform centralised dispensing in order to facilitate community delivery of medicines through the Central Chronic Medicine Dispensing and Distribution (CCMDD) programme [65]. An innovative model with almost similar characteristics to the CCMDD is the Chronic Dispensing Unit (CDU), a public-sector model of centralised dispensing which was introduced in the Western Cape Province in 2005 in order to address the pharmacy workforce shortage, reduce patients' waiting times and facilitate decongestion of PHC facilities [66-68]. The replication of these innovations seem to suggest that centralised dispensing is the preferred direction by government for improving ATM [69]. Although these developments are only currently being piloted for the NHI, they bear origins in the 1996- published, National Drug Policy[70] which mentions as a strategy private sector distribution of public sector medicines.

Another critical aspect that has been raised over the years is that most health service delivery models were created at a time when acute diseases accounted for the largest disease burden and were often not designed to deliver routine quality care for patients suffering from chronic diseases [43]. Consequently, health systems have to some degree been unresponsive to the needs of patients with chronic diseases. To enable care for patients with chronic diseases, health care systems need to have certain characteristics that are different from acute care systems. Nolte and McKee (2008) have indicated some of the important requirements: efficient clinical

management strategies (routine appointments, patient rosters, adherence monitoring), different modes of staff functioning (interdisciplinary coordination, patient-centered care, performance monitoring), innovative drug supply systems and strengthened community linkages (family and community supports, novel types of outreach) [70].

Quality of care has also been cited as an important aspect in the delivery of health services. There has been considerable focus on providers and their interactions with patients, most of which is negative [71, 72]. Some scholars have suggested that providers should have a detailed knowledge of the barriers faced by patients, their own roles in these barriers and ways to overcome them [72, 73].

(b) Demand-side issues

In some instances, it is difficult to tease out issues pertaining solely to access and those of patient adherence to medication (post access/collection of medicines). While there is a likelihood of these two aspects being linked, the primary focus in this study was the distribution, i.e. the process of getting the medication delivered to the patient.

It has been well argued that patients' perspectives on the difficulties of accessing care need to be better understood, particularly in poorly resourced settings [74]. Despite medicines being provided without user-fees in SA, some studies have cited a range of barriers encountered by patients. Previous research has shown that inequalities in healthcare are exacerbated by the huge socioeconomic disparities across social classes and location because rural populations face the greatest barriers to health care, longer distances and travel times than their urban counterparts [75-77]. They also have limited mobility due to underdeveloped transport infrastructure [78]. Affordability of transportation costs associated with accessing medicines in public facilities has been a subject of concern [75, 79] and many studies have highlighted this as a major cause for patients' defaulting on treatment and the subsequent effect on health outcomes [80]. Related to financial barriers, one longitudinal study in a rural setting found that many patients with chronic illnesses were not receiving medicines because their financial resources had been exhausted from previous illness and death and they had weak social networks [81]. In addition, poor provider-patient interaction led to inadequate understanding of illness and subsequently inappropriate treatment action, 'healer shopping', and sometimes patients simply gave up on the public health system [81].

Some studies have documented patients' coping mechanisms and found that the majority of patients rely on support from significant others to assist in continuing treatment [82], an indicator that illness is not an individual issue but affects households and communities. A submission by a consortium of Non-Governmental Organisations (NGOs) working in rural South Africa has proposed provision of transport subsidies for health care in rural areas as an appropriate response to enabling access to health facilities by rural citizens and a reduction in loss to follow-up as part of the NHI package. This consortium has cited similar interventions in Mexico, China, Taiwan, Korea and Nicaragua [83].

There are some global debates that are relevant to SA. One of such debates pertains to reconsidering models of care [84]. In some parts of the country, we are already witnessing the implementation of community-based models of medicines delivery to support treatment expansion [85].

Summary of findings from LMICs including South Africa: Assessment of the available literature confirmed that there is limited literature that focuses on ATM. A previous review which sought to investigate the relevance of systematic reviews on pharmaceutical policy to low- and middle-income countries found only one review that utilised a study conducted in a developing country [86]. This seems to suggest quite limited evidence to inform pharmaceutical policies in LMICs. However, it is also possible that in some cases, ATM is part of broader healthcare studies or that different terminology has been used as the term "access to medicines" has only become popular in recent years. For instance, some authors have indicated that at the time of the Alma-Ata International Conference on Primary Health Care in 1978, "Health for All" was the slogan that encompassed essential medicines [19]. In any case, the literature available focuses more on HIV and there is limited literature on access to NCD medicines. Furthermore, challenges of rural populations seem to be fairly well articulated compared to those of urban dwellers; yet, we are aware that there is rapid urbanisation in South Africa and other LMICs. Studies like those of Nteta & colleagues can easily give an impression that access is better for urban populations in South Africa [77]. Perhaps it is in some aspects, but there is a need to interrogate this issue in greater detail.

1.4 The Access to Medicines in Africa and South Asia (AMASA) project as the research context

The origins of this PhD study are nested within a large multi-country project: *The Access to Medicines in Africa and South Asia project (AMASA)*, which ran for three years (2010-2013). AMASA was a collaborative research study, involving seven institutions in six different countries, funded under the European Union's Framework Programme 7. The AMASA project was stimulated by an earlier research project conducted by the University of Edinburgh, called "*Tracing Pharmaceuticals in South Asia*" (TPSA), which took a whole-system perspective grounded in public health and population approaches to health care and medicines delivery [87].

One of the main findings of the TPSA was the need for further investigation of the complex interplay between regulations that govern pharmaceutical production and delivery and the formal and informal networks of health care. Informed by these earlier findings, the overall objective of the AMASA research project was to investigate how the interplay of patent regimes, pharmaceutical regulation, availability of drug production facilities, health care infrastructure and service provision, and engagement by foreign donors influence appropriate, affordable access to medicines in South Asia and Sub-Saharan Africa [88]. Patterns of production, distribution, supply and consumption of medicines were mapped within seven health care areas – HIV, Malaria, Reproductive Health, Tuberculosis (TB) control, Mental Health, Pain Management and Diabetes. This PhD study focuses on chronic diseases that were originally selected for the AMASA study (HIV and diabetes) together with hypertension because of patterns of chronic multi-morbidity in South Africa [89].

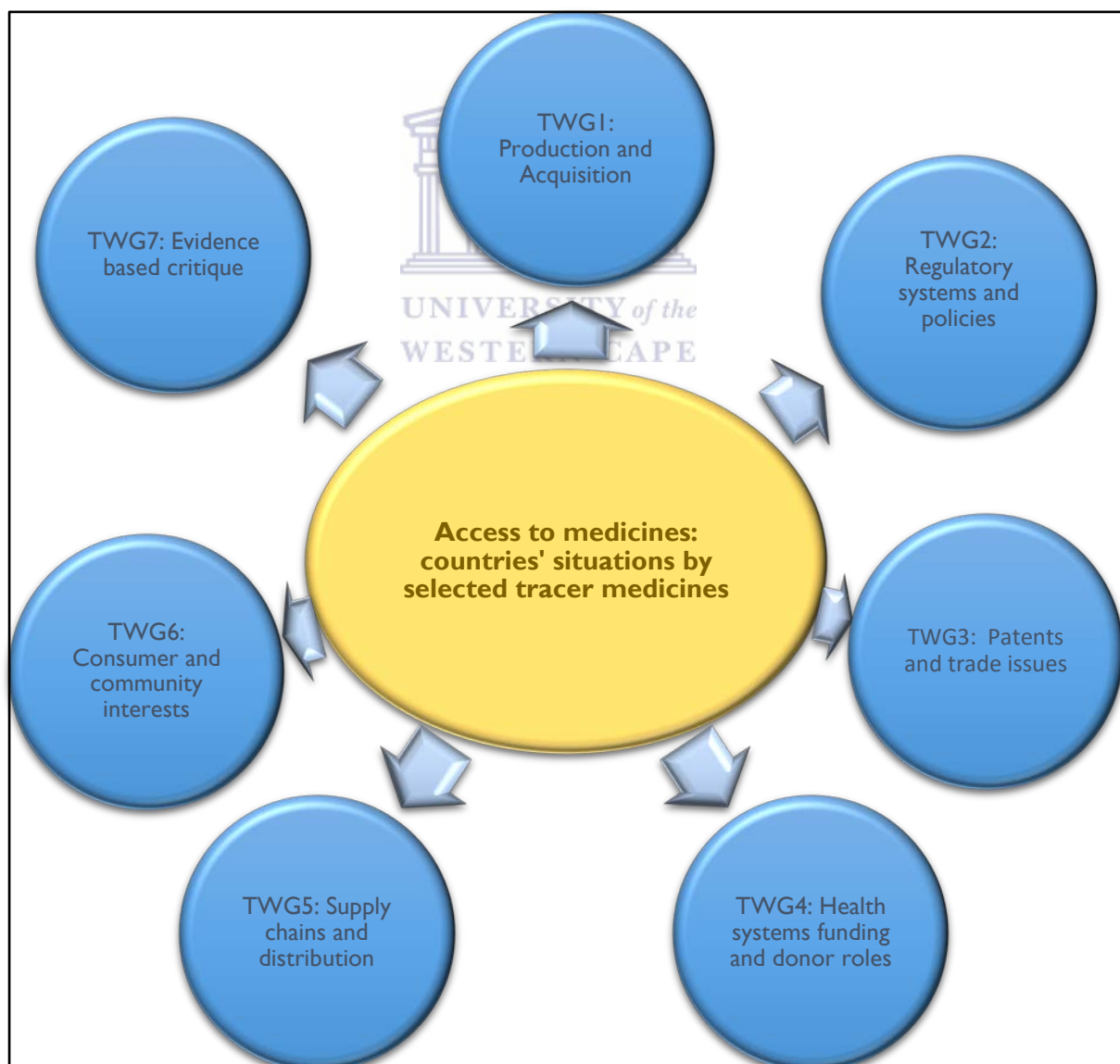
Through a series of workshops, the AMASA consortium developed a general research framework and drew specific research questions and operational objectives. The research questions focused on seven areas, which were later referred to as Technical Working Groups (TWG) (Fig 1.)

I was actively involved in TWG 5 and 6, hence the objectives and activities at that level influenced the conception of this PhD project. *TWG 5: Supply chains and distribution* focussed on describing the structure of the existing supply chains and identifying the strongest and weakest links influencing ATM, while *TWG 6: Consumer and community interests* focused on the effects of higher level policy and supply chain on access and use of medicines by patients. In addition, how multiple access dimensions such as availability,

acceptability, affordability, quality of services, and other factors such as cultural concepts of illness affect consumption-related behaviour was studied.

I was employed on the AMASA project for the three-year duration (2010-2013) as a researcher. My role included development of the study design and research tools, recruitment, training and supervision of Research Assistants, data collection, data management, data analysis, presentation of results and writing of manuscripts. The results from the AMASA study informed the situational analysis phase of this PhD study. Following the situational analysis, I developed an independent follow-up study as will be shown in the upcoming chapters.

Fig 1: Research areas for the AMASA project

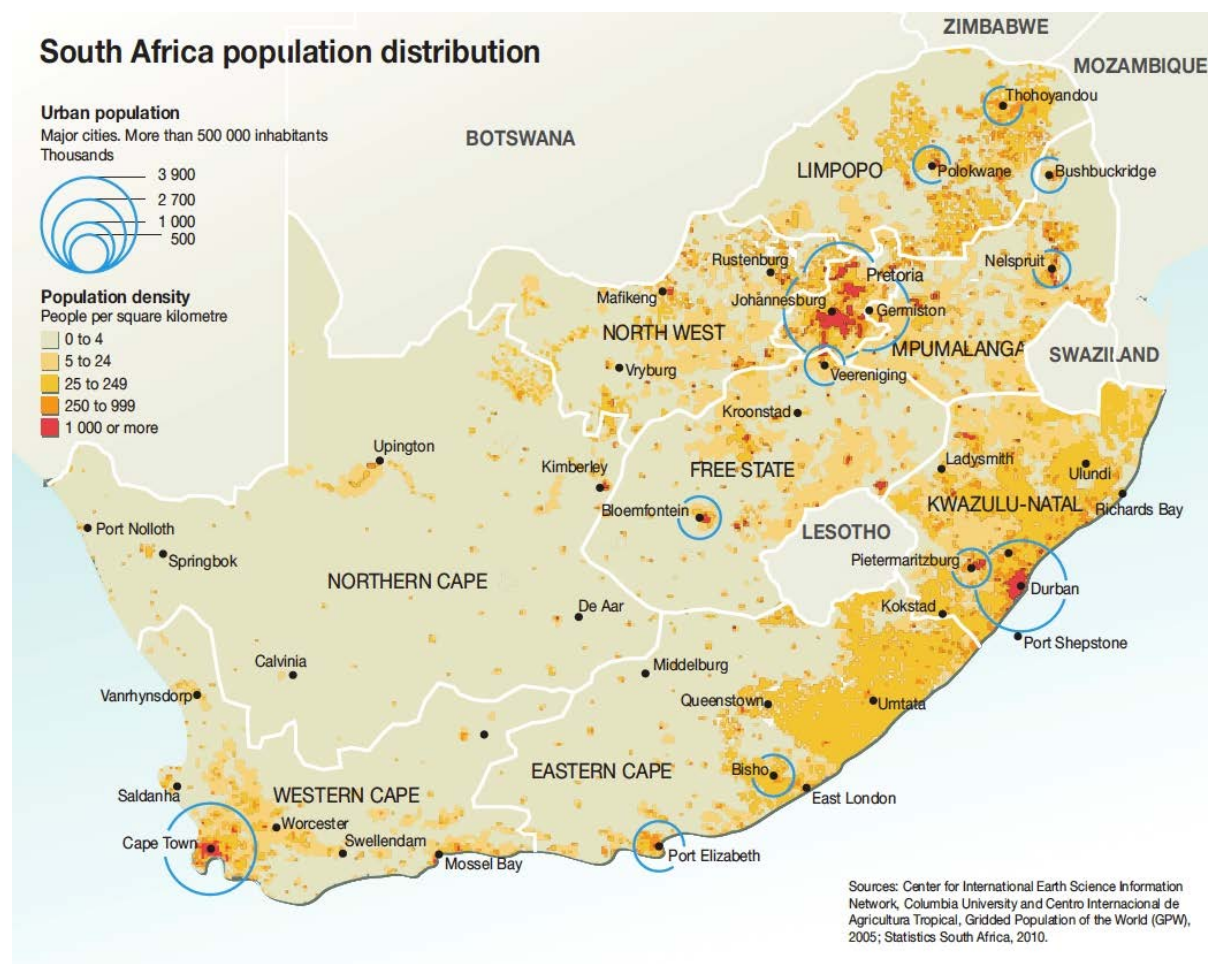


In all study countries, engagement of policy makers was key in order to solicit buy-in and to ensure that the study was aligned to priority health issues. As such, in the early phases of this project, the South Africa country team engaged the office of the Director-General for Health and provincial leadership in selected provinces.

1.4.1 Study setting for South Africa

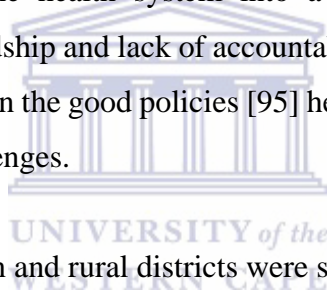
For the South African study, sampling was to include at least a rural and an urban district within two of the nine provinces. As such, the Eastern Cape (EC) and the Western Cape (WC) provinces were selected (*fig 2*). Past census data (2001) reported the former to be predominantly rural (39%) while the latter had a larger urban population (91%) [90]. These figures might have altered over the years as we are aware that there is rapid urbanisation and urban growth in South Africa, coupled with considerable levels of health inequities [91, 92].

Fig 2: Map of South Africa and selected population statistics



Source: [93]

The historical differences in governance between the Western Cape and Eastern Cape are worth noting, in particular the inherited health system dysfunction in the Eastern Cape which can be traced back to historical policies during periods of colonial subjugation and apartheid dispossession. Issues of race and gender prejudice, the migrant labour system, the destruction of family life, vast income disparities, and extreme violence have all formed part of South Africa's troubled past, and all have inexorably affected health and health services [95]. Even though South Africa is over 20 years into its democracy, the past policies of apartheid and the separation of homeland (mainly rural areas, including parts of the Eastern Cape) and national governments and governance have left legacies in both these provinces that affect the wider delivery of care. The Western Cape Province is generally better-resourced (financial, infrastructure, human resources) than the Eastern Cape. The two provinces are also governed by different political parties. These political structures affect capabilities and capacities across South Africa and the ability to implement sustainable innovation also differs. It is evident that despite the transformation of the health system into a comprehensive national service, weaknesses in leadership, stewardship and lack of accountability mechanisms have resulted in inadequate implementation of even the good policies [95] hence the health system is still faced with massive and persistent challenges.



Within these two provinces, urban and rural districts were selected and within each district a select number of health facilities were chosen (*Table 1*). The AMASA projected covered about 20 facilities inclusive of PHC facilities and tertiary hospitals but for this PhD study, only PHC facilities were of interest. Primary healthcare facilities are the first port-of-call for patients in the hierarchical public health sector health system [94]. This is the level at which diagnosis, stabilisation, treatment and routine patient management takes place. The PHC system is a predominantly nurse-driven service because of the human resource shortages in the public sector [95]. There are approximately 3100 PHC facilities across the country's 11 provinces, each serving a population of between 2500 to nearly 20 000, with an average of 12 000 per facility [94]. Primary healthcare facilities, i.e. clinics or community health centres have been distinguished as follows:

- Clinics: facility providing a range of PHC services and normally opens for eight hours. Certain staff may be required to be on-call in-case of emergencies

- Community health centres: a facility offering PHC services and in addition a 24-hour maternity, accident and emergency services and up to 30 beds where patients can be observed for up to 48 hours [96].

The mandate of PHC facilities is provision of preventive, promotional, curative and rehabilitation services. Chronic care, maternal health services, immunisation, family planning, treatment of sexually transmitted infections and minor trauma [96]. The populations utilising the selected health facilities are predominantly of a Black African and Coloured ethnic groups based on the Statistics South Africa classifications. In general, the Black African population comprises 76% of the country's population, followed by White and Coloured at 9% each and Asian at 2.5% [97].

Table 1: Health facilities included in the PhD study

Province	District (Urban (U); Rural (R))	Sub-structure	Health facility name
Phase I			
Western Cape	Metro (U)	Eastern/Khayelitsha	Michael Mapongwana CHC
		Klipfontein/Mitchells Plain	Gugulethu CHC
		Eastern/Khayelitsha	Khayelitsha Site B CHC
		Klipfontein/Mitchells Plain	Dr Abdurrahman CHC
Eastern Cape	Alfred Nzo (R)	Mbizana	Mbizana CHC
		Ntabankulu	Ntabankulu CHC
	Amathole (R)	Mnquma	Ngqamakhwe CHC
			Macibe/Centane CHC
	Metro (U)	Buffalo City	Duncan Village Day Hospital
			Empilweni Clinic
Phase II			
Western Cape	Metro (U)	Eastern/Khayelitsha	Michael Mapongwana CHC
		Eastern/Tygerberg	Mfuleni CHC
		Klipfontein/Mitchells Plain	Gugulethu CHC
		Klipfontein/Mitchells Plain	Mitchells Plain CHC

1.5 Problem statement

Increased efforts to reduce disparities in ATM through understanding and acting on barriers facing communities are required. Unless the full range of access barriers are investigated, efforts to promote equitable access to health care (medicines included) are unlikely to succeed [98]. There is currently limited research conducted in SA to characterise ATM challenges [57, 58], yet, inadequate ATM can pose a threat to clinical outcomes in the event of interrupted treatment cycles [58]. Also, negative experiences with the health system could

discourage patients from accessing services in future [99]. Adequate understanding of access barriers is foundational to the development of effective strategies to address them.

As stated by Seiter (2010), recognizing typical “patterns of dysfunction” in the pharmaceutical sector is necessary and this could inform strategies to quickly deal with the most urgent problems while at the same time building a platform for sustainable long term policy [21]. Yet current evidence seems to suggest that little of the in-country research informs health policy and practice on ATM and health services in general. In 2012, the Western Cape province estimated spending R0, 3 billion (approximately 30 million United States dollars at the time) per annum on research, but relatively little of that funding addressed the operational and systems challenges facing health services. The report further stated that while the government was aware that patient experiences with health services were largely negative, authorities were unaware of how to use this feedback constructively in provincial planning processes and shaping of policies and practice [100]. This study therefore seeks to generate evidence on prevailing ATM barriers and their causes in order to inform policy and practice.

1.6 Aim and objectives of the study

Based on the initial review of literature (section 1.3.1.2), we recognised that SA faces multiple ATM barriers (known and unknown) despite some efforts by the government to address some known barriers. Therefore, the aim of this study was to further characterise those barriers and also identify the innovative strategies that already exist to enable (facilitate) ATM in order to inform policy and practice.

The specific objectives of this study are to:

1. Conduct a situational analysis on the state of chronic medicines provision in public sector facilities in the Eastern and Western Cape provinces, specifically to:
 - a. identify barriers to ATM at macro- (policy/national), meso- (service delivery and community) and micro- (individuals and households) levels;
 - b. map out existing innovative strategies to improve ATM;
2. Analyse and/or evaluate both policy and implementation aspects of innovative medicines delivery models (referred to under sub-objective 1b) and their contribution (or lack thereof) to improving ATM).
 - a. With the CDU, the specific sub-objectives were to:

- i. estimate the magnitude of non-collected medicines (missed appointments by patients) and to describe the variability across sites, condition, age, gender, method of distribution;
 - ii. identify facilitators and constraints to ATM for CDU beneficiaries;
 - iii. explore the CDU's implementation dynamics across the health system spectrum (policy, actors and context)
- b. With the CBD models, the specific sub-objectives were to:
- i. outline perceived facilitators and barriers to implementation;
 - ii. inform future policy on CBD.

The specific focal areas for research as identified under 2a and 2b were informed by the results from objective 1b. In section 3.1, we show how this process was facilitated by the application of an emergent research design.

In sum, the intended contribution of this thesis to the field of public health is not only the characterisation of ATM barriers and evaluation of intervention models, but also interrogating whether existing models are fit for purpose, i.e. do they address the prevailing challenges and/or have new challenges arisen as a result of the intervention?

1.7 Research questions

The overarching question that this research sought to answer is: **What are the gaps between the current ATM situation and the interventions that already exist?** To adequately answer this research question, the following intermediate questions emerged:

- What are the dynamics (actors and factors) that enable or hinder ATM?
- What are the existing strategies to improve ATM?
- What are the major strengths and constraints to effective implementation of these strategies (policy or implementation related) and how could the constraints be overcome?

1.8 Relevance of the study

Previous research acknowledged that ATM barriers occur at multiple layers in the health system. However, much of the research carried out was fragmented: barriers to ATM were often investigated through the prism of one or just a few elements, e.g. individual patient characteristics or structural factors, while neglecting the interplay of different variables [101].

In this PhD study, I attempted to address this problem by considering multiple tracer conditions as earlier stated and to a reasonable degree considered the national (macro-), meso- and micro-levels. I was aware that it was impossible to assess all possible layers influencing ATM adequately. In setting the delimitations, I recognized that a country's pharmaceutical system is typically made up of both international and local actors at various levels. My focus is therefore set on the lower levels of the supply chain, specifically distribution with a limited focus on national level activities (regulatory and procurement) only as it relates to distribution. This decision was in keeping to the overarching objective to influence policy and practice in South Africa. Therefore, I focused on in-country activities where leadership could introduce change. In addition, I was interested in activities of national relevance, i.e. innovative strategies for improving ATM were tabled in the NHI draft policies at the time [102], out of a growing realisation by stakeholders that health problems require not just better coordination of traditional roles but also new ways of working in order to achieve a synergistic combination of the strengths, resources and expertise of the different sectors.

1.9 Methodological choice: implementation research

Some scholars have referred to the systematic identification of real-life problems in order to search for solutions as operational research [103], while others termed it implementation research [104]. Regardless of the different terminology, the objective to inform decisions about health policies, programmes and practices is quite similar. Since this research was set-up for a similar purpose, stakeholder consultation formed an important part in the development of research objectives. The intention was to address existing issues as identified by the potential users of the research in order to overcome the challenges of non-utilization of research evidence [105] and to emphasize engagement between research and policy.

Therefore, the strategy approach was to engage stakeholders who make policy, implement policy and experience the consequences of policy as it relates to ATM in the selected provinces. This approach has been suggested for other types of policy relevant research [106]. To achieve this goal, a data-driven emergent research design was appropriate [107], starting with broad objectives and refining them as informed by research findings. This is described in more detail in Chapter 3.

1.10 Thesis overview

The next chapters are structured as follows:

- ✚ Chapter 2: A literature review illustrating theories that informed the development of the conceptual framework
- ✚ Chapter 3: A brief overview of the research design and methods
- ✚ Chapter 4: The results presented in an article format (six in total) - some have been published in international peer-review journals (3), while some are still under-going peer review (2) and others still in draft format (1)
- ✚ Chapter 5: This final chapter concludes by discussing the implications of the results on ATM in South Africa.

2. Literature review

2.1 Access to medicines, a complex issue?

An understanding of the structure of national pharmaceutical systems is integral to the ATM discourse [28]. Roberts and Reich (2011) have identified eight sequential processes that make up national pharmaceutical systems as follows:

“The set of medicines available in a country begins with (1) research and development and proceeds through (2) clinical trials to (3) registration. Registration occurs at the national level, but the first two processes may occur in other countries. After registration, the next stage is (4) where and how the product is manufactured (including its formulation and packaging). Then, for each country, (5) procurement and importation, both public and private, determine which medicines are available nationally. Those medicines flow through (6) multiple supply chains to various outlets (including vendors, shops, stalls, clinics, and health centers), where (7) dispensing and sales occur. The final process is (8) how patients use the medicines once they have acquired them.” [28].

Pharmaceutical systems are complicated, because decisions at each of the processes might be taken by different government entities at different times, resulting in incoherent policies. Even specialists may not be aware of the impact of government decisions on pharmaceutical system performance, hence the need to explore connections and help governments manage their choices and actions more effectively [28].

Given this reality, it seems logical that we are witnessing increased attention towards understanding ATM within a health system perspective in order to explain the interconnections between medicines and other health system components. Proponents of the

health system approach to ATM suggest that most health system strengthening interventions ignore these interconnections [15]. As argued by Bigdeli et al. (2014: p11):

“...a systems approach makes it possible to situate medicines against the full complexity of a health system, understanding how interventions in the pharmaceutical sector influence the rest of the health system and vice versa” [29].

Some of the earlier work advocating for more systems thinking when thinking about ATM was spearheaded by the WHO [108]. In this work, medicines were identified as a key pillar of the health system alongside health workforce, governance, information, service delivery and financing, notwithstanding the role of context and other underlying determinants (*see text box 1 for definitions*). Simply put, this framework suggests that effective provision of medicines is dependent on other building blocks. Furthermore, people are at the centre of the system as mediators, beneficiaries and actors driving the system itself [108]. Given that there are multiple actors at play, an understanding of the context of relationships between different actors is required [103]. Increasingly, the systems approach is being applied in analysis of ATM interventions in LMICs, as reported for studies in Cambodia [109], Uganda [110] and Tanzania [111]. There is room to apply this lens in other contexts such as South Africa in order to facilitate a better understanding of ATM issues and policies to better integrate ATM interventions in existing health systems. This has been done in this study as is illustrated in 2.2.

Textbox 1: Definitions of health system building blocks

Service delivery: including effective, safe and quality personal and non-personal health interventions that are provided to those in need, when and where needed (*including infrastructure*), with a minimal waste of resources.

Health workforce (human resources): responsive, fair and efficient given available resources and circumstances and available in sufficient numbers.

Health information: ensuring the production, analysis and dissemination and use of reliable and timely information on health determinants, health system performance and health status.

Medical technologies: including medical products, vaccines and other technologies of assured quality, safety, efficacy and cost-effectiveness and their scientifically sound and cost-effective use.

Health financing: raising adequate funds for health in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them.

Leadership and governance: ensuring strategic policy frameworks combined with effective oversight, coalition building, accountability, regulations, incentives and attention to system design.

Source: [108]

2.2 Conceptual framework

A conceptual framework to guide a study can be developed from a review of relevant empirical and theoretical literature and is useful for identifying relevant concepts or issues for investigation [112]. Such a framework is not static: it can be modified as the data collected are analysed [112]. The conceptual framework underpinning this study was influenced by a combination of health systems [101, 113], access [17, 114, 115] and chronic disease frameworks, whose assumptions are provided in Table 1 below.

Table 2: Data sources for development of conceptual framework

Framework	Relevance to this study
Bigdeli et al. (2012): ATM from a health systems perspective [101]	<p>Adopts a health systems approach to ATM and is a product of a critical review of multiple ATM frameworks. The following principles are acknowledged:</p> <ul style="list-style-type: none"> ○ ATM barriers are complex and occur at multiple levels of the health system, i.e. (i) population; (ii) health service delivery; (iii) health sector; (iv) public policies and (v) international and regional level ○ complex and dynamic relationships between medicines and other components of the health system (i.e. human resources, health information, health financing, health infrastructure, governance) ○ determinants of ATM operate within national, regional and international contexts.
van Olmen et al. (2012): Analysing health systems to make them stronger [113]	<p>A normative framework for analysis of health systems at national, intermediate or local level:</p> <ul style="list-style-type: none"> ○ Also a product of a critical review of multiple health systems frameworks ○ acknowledges complex relationships between medicines and other health systems components (<i>governance</i> - policies, regulatory frameworks; <i>resources</i> – medicines supply, human resources, health information system; <i>organisation of services</i> - delivery models, referral processes) ○ <i>acknowledges population</i> (people) as having multiple roles: beneficiaries creating a demand; citizens with rights and obligations; funders and suppliers of care who contribute to the functioning of the health system ○ <i>context</i>: policies, reforms, supporting actors, social determinants of health.
Thomas & Penchansky (1981): The Concept of Access. Definition and Relationship to Consumer Satisfaction [114]	<p>Defines the dimensions of access as follows:</p> <ul style="list-style-type: none"> ○ availability (fit between existing resources and clients' needs) ○ accessibility (fit between physical location of healthcare and location of clients) ○ accommodation (fit between the organisation of services and clients' practical circumstances) ○ acceptability (fit between clients' and providers' mutual expectations and appropriateness of care) and ○ affordability (fit between cost of care and ability to pay).
WHO (2007)	<p>Like Thomas & Penchansky (1981), the WHO framework also identifies some similar dimensions (availability, accessibility, acceptability and affordability) and introduces the quality dimension as described below:</p>

Elements of “Right to health” [17]	<ul style="list-style-type: none"> ○ availability: functioning public health and health-care facilities, goods and services, as well as programmes available in sufficient quantity ○ accessibility: non-discriminatory to all especially the most vulnerable or marginalized sections of the population; physical accessibility; information accessibility (includes the right to seek, receive and impart information and ideas concerning health issues) ○ affordability: (payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households ○ acceptability: health facilities, goods and services must be respectful of ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned ○ quality: health facilities, goods and services must be scientifically and medically appropriate and of good quality. This requires, <i>inter alia</i>, skilled medical personnel, scientifically approved and unexpired drugs and equipment.
Peters et al. (2008) Poverty and Access to Health Care in Developing Countries [115]	<ul style="list-style-type: none"> ○ geographic accessibility: the physical distance or travel time from service delivery point to the user ○ availability: having the right type of care available to those who need it, such as hours of operation and waiting times that meet demands of those who would use care, as well as having the appropriate type of service providers and materials ○ financial accessibility: the relationship between the price of services (in part affected by their costs) and the willingness and ability of users to pay for those services, as well as be protected from the economic consequences of health costs ○ acceptability: the match between how responsive health service providers are to the social and cultural expectations of individual users and communities ○ quality: cross-cutting theme which is related to the technical ability of health services to affect people's health. There are more distal determinants of health service access, shown at the policy or macro-environmental level, as well as the individual and household levels.
Chronic Disease Framework [116]	<ul style="list-style-type: none"> ○ Medicines for treatment are provided within a particular chronic disease programme in any given context. In addition to aspects raised by other frameworks above, i.e. role of health service organisation, resources, policies and the community (which in some cases is covered under context); this framework brings to the fore front the importance of considering patient characteristics (informed, activated and with a realisation that they face multiple and complex needs in treatment); a proactive health systems team with productive interactions between patients and providers.

The concepts described above were applied in the development on this study's conceptual framework as shown in *fig 3*. In summary, the assumption made is that to reduce ATM barriers, the strategy needs to take into account the context and have the right resources and governance structures. Similarly, barriers to ATM can to some degree be traced back to the structure of ATM models (or lack thereof) and/or anomalies in health system components. A key aspect

which shaped this thinking is that of recognizing health systems as social systems comprising of people and organisations, and their interactions. This lens facilitated recognition that events in the health system could occur in a non-linear fashion as a result of people also referred to as actors or agency, a key element of complex systems [113].

Actors at different levels shape the “health system hardware” (structures, resources, policies) and their values, interests, norms and relationships (health system software) also influence the ultimate character of the system [117]. This means even a well-crafted strategy could fail at implementation, where the interplay of software and hardware occurs. Linked closely to the issue of public policies is the political discourse within which these policies are implemented (as alluded to under the historical context section). ~~I acknowledge that p~~Political will, including the buy-in of health workers is acknowledged as an important driver for change.



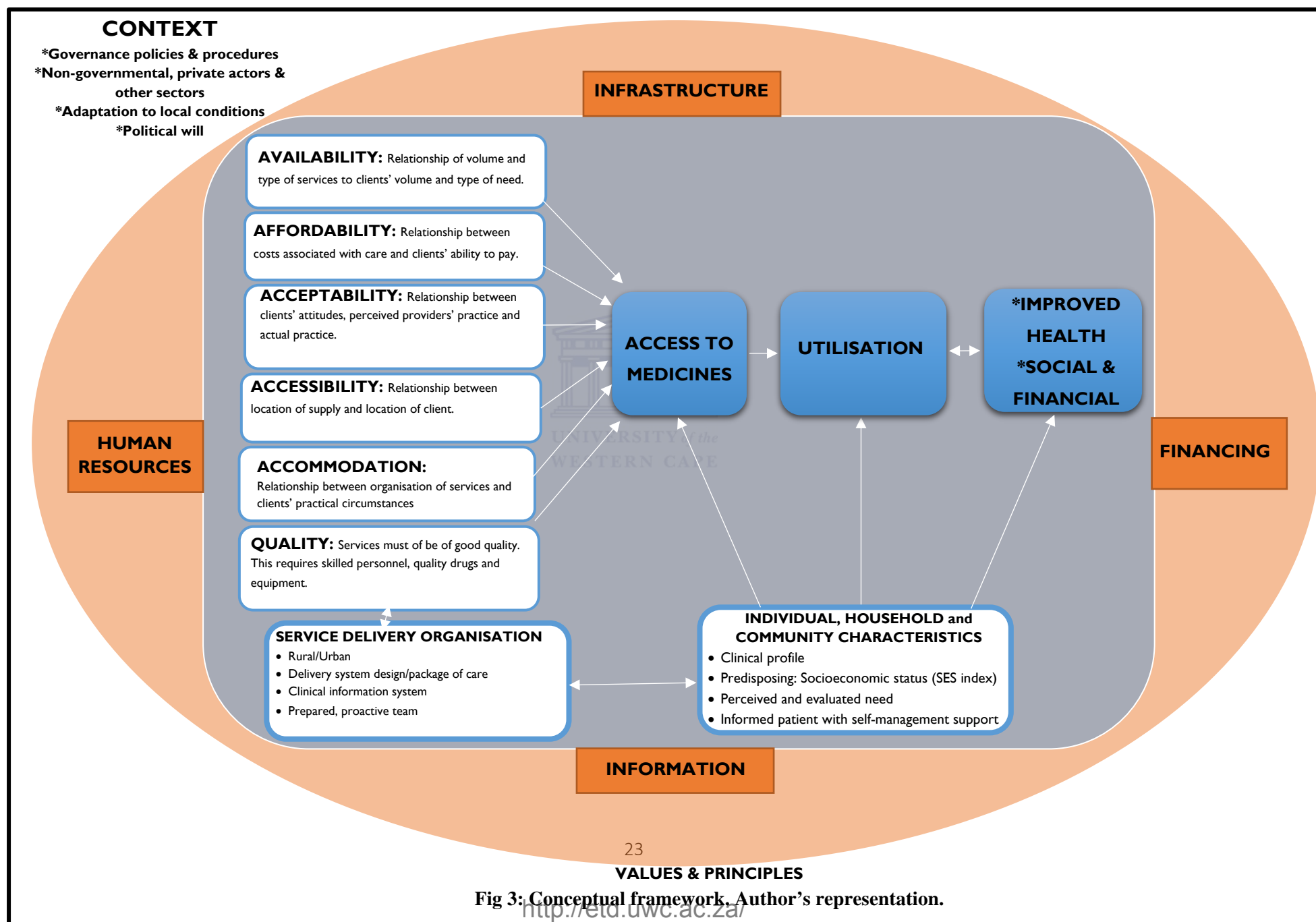


Fig 3: Conceptual framework, Author's representation.

Conceptual framework narrative summary: This conceptual framework suggests that ATM is a means to high quality care (not an end in itself). The six access dimensions (*availability, affordability, acceptability, accessibility, accommodation and quality*) are all required for optimum ATM. *Health facility characteristics and individual, household and community characteristics* also affect access. The assumption is that if patients can access essential medicines, this contributes to utilisation and ultimately positive clinical outcomes. The outside circle illustrates the complementary health system building blocks (*information, financing, human resources and infrastructure*), which are all required for effective medicines supply. In the outer layer, *governance (policies and regulatory frameworks)* apply to every aspect of the framework. Finally, this framework depicts the mechanical hardware processes, but as mentioned earlier, *people* are at the centre of the system as mediators, beneficiaries and actors driving the system.

3. Methodology overview

This study was conducted in the context of NDoH reforms and actual implementation of some ATM interventions in SA. This research sought to explore the perspectives of patients, frontline healthcare providers (HCP) and policy makers, their experiences and their views and meanings of ATM in their respective contexts. As such, a mix of qualitative methods (in-depth interviews, focus group discussions, non-participant observations and document review), supported by a review of patients' retrospective medical records were employed. The choice of methodological approach was informed by the research objectives.

A question might be asked, "*What is the value of qualitative research in healthcare?*". Qualitative research methods allow a deeper understanding of the world as *seen and experienced* by respondents. The emphasis is on a focussed and bounded phenomenon embedded in its context and produces *rich data* with strong potential to reveal *complexity* [118].

The epistemological approach was largely interpretive, given that I endeavoured to understand meanings, contexts and processes as perceived from different perspectives, and individual and shared social meanings of the issues under review [119].

Much of the health services research community is convinced of the value of interpretive, context-sensitive research because of its ability to capture meanings, summarise them into essential themes of understanding and capture the important aspects of the phenomena,

giving plausible insights, rather than theory, into the experience of a phenomenon [120]. In addition, some scholars have argued that healthcare decisions, including clinical decision-making, should be informed by broader social, political and systemic contexts of healthcare which consider relationships and complexity in health systems rather than through simple causality models, an issue that was raised in our conceptual framework development process. As such social science approaches can contribute to uncovering these broader relationships and complexities [121, 122].

3.1 Emergent research design

Creswell (2003: p20), states the following:

“Qualitative research is emergent rather than tightly prefigured. Several aspects emerge during a qualitative study. The research questions may change and be refined as the inquirer learns what to ask and to whom it should be asked. The data collection process might change as doors open and close for data collection, and the inquirer learns the best sites at which to learn about the central phenomenon of interest. The theory or general pattern of understanding will emerge as it begins with initial codes, develops into broad themes, and coalesces into a grounded theory or broad interpretation. These aspects of an unfolding research model make it difficult to prefigure qualitative research tightly at the proposal or early research stage.” [123]

Health policy and systems research methodologists affirm the need for flexible research designs [112]. I therefore adopted a flexible approach in order to adapt inquiry as understanding deepens [124]. The emergent research design which was adopted for this study is one example of a flexible design. Emerging results from the *first phase of exploratory research (situational analysis)* in the two provinces provided direction for the *succeeding phases*, which took place in the Western Cape Province only and focused on analysing and evaluating innovative models for improving ATM, the centralised dispensing model (i.e. the Chronic Dispensing Unit (CDU)) and community-based models (CBD) of medicines distribution. These models are intrinsically linked as CBD models depend on the CDU for medicines supply and are necessary to improve collection of CDU medicines. The decision to proceed with the WC only in the second phase was based on the following reasons:

- i. the situational analysis identified ad hoc, informal strategies for improving ATM in the EC while the WC models had more structure and could be evaluated; and

- ii. relevance to national policy debates: although the the CDU and CBD models had only been implemented in the WC when we initiated this research, there was already interest at a national level to implement similar strategies in other provinces. During the course of our research, the draft NHI policy had been introduced [102] and both centralised dispensing and CBD were implemented as part of the NHI pilot programme in other provinces [65, 69]; but with little application of the WC's implementation experiences.

This led to a two-fold aim: (i) to evaluate these two innovative models in order to improve implementation and also (ii) to provide lessons which could be applied in implementation of similar models in other settings. With regards to the former, the Western Cape Department of Health (WCDoH) gave specific direction pertaining to the issues that required attention. For instance, the CDU was faced with a challenge of non-collected medicines (missed appointments) by the intended beneficiaries (patients). In addition to evaluating the CDU's implementation dynamics across the health system spectrum (policy, actors and context), other tasks were to include:

- a. estimating the magnitude of non-collected medicines and describe the variability (across: sites, condition, age, gender, method of distribution) and
- b. identifying facilitators and constraints to ATM for CDU beneficiaries.

Even with a somewhat targeted approach to answer specified questions pertaining to the CDU, it was anticipated that these questions would be a window to explain many other issues pertaining to the health system. On the other hand, CBD models were implemented in the absence of a formal policy, therefore, we conducted a situational analysis with the intention to inform future policy.

Upon reflection of the study's aim and objectives and the realisation that there was limited literature on ATM in SA to adequately inform the study, the emergent, flexible research design proved more appropriate than a fixed design. For instance, it was evident by the end of the first phase of the study that it would be difficult to incorporate a 'positive deviance' methodology to the evaluation of the CDU as had been initially anticipated. Positive deviant behaviour is defined as an uncommon practice that confers advantage to the people who practise it compared with the rest of the community [125]. This methodology requires the development of case definitions, identification of cases that have achieved an unexpected high risk and interrogating enabling factors that could explain the good outcomes and

recommending them for adoption by other cases [125]. After reviewing preliminary results, it was evident that routinely collected data could not sufficiently inform the selection of cases. Therefore, it was necessary to gather analyse results from earlier phases of the study in order to inform the next phases as previously stated.

3.2 Data collection methods

- ✚ In-depth interviews: These are useful for gathering information facts, people's beliefs and perspectives; past and present events [126]. With the aid of an interview guide containing open-ended questions, I conducted interviews with purposefully selected informants. Interviews presented the opportunity to explore in-depth with each participant the matters of interest. The interview guide ensured consistency across interviews and with the opportunity to compare results [124]. However, I still maintained the flexibility to probe on isolated issues that participants raised.
- ✚ Focus group discussions (FGDs): I limited the use of FGDs to the early phases of the study as a means to develop narratives of supply chain processes and priority issues in the health system and during the discussion of preliminary findings. FGDs are useful when interaction among participants might be more informative than individually conducted interviews [126].
- ✚ Observations: With a list of key elements of interest, I observed how processes unfold in health facilities, patient-provider interactions and the nature of queries that patients raised with HCPs.
- ✚ Retrospective record reviews: A tool in which routinely recorded data is used to answer one or more research questions. Results are useful for directing prospective studies [127].

Table 3 provides an overview of the main methods used in each paper. More details are described in each of the papers.

3.3 Data analysis

The data analysis process was a hybrid of inductive and deductive coding and theme development [128]. There were multiple cycles of reading and re-reading of the raw data in order to identify emerging major and minor themes. The dimensions presented in the study's conceptual framework (Fig 3) provided a useful lens for understanding the results and served as an initial coding manual (deductively derived codes). However, there were many other issues that emerged for which additional codes were developed (inductively derived codes).

Interview transcripts were exported as project documents into Atlas Ti 7, a data analysis software. Text relevant for a particular code were matched. The codes were then grouped according to broader themes. Routine data was analysed descriptively in MS Excel.

Previous studies have reported that a limitation of doctoral studies compared to other research studies is that data coding and theme development is the sole responsibility of the student and could fail to provide multiple perspectives from people with varied expertise [128]. One of the ways in which this challenge was mitigated to a reasonable degree was through discussion of themes with both supervisors and other co-authors who were involved in manuscript development.



Table 3: Outline of methods used in the PhD thesis

Paper Title	Objectives of the paper (linked to broad thesis objectives)	Methods	Data Sources	Data Analysis	Period	Study area
Broad objectives of the thesis: Situational analysis on the state of chronic medicines provision in public sector facilities in the Eastern and Western Cape provinces and mapping out and analysing existing strategies for improving access to medicines						
1. Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa – BMC Health Services Research (2014)14:520	Identify supply- and demand-ATM barriers from the provider perspective and highlight strategies for addressing ATM barriers	In-depth interviews	Frontline healthcare providers	Content analysis which combined structured coding and grounded theory approaches	2012	Eastern Cape (urban and rural)
2. Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa - BMC Health Services Research (2015)15:513	Describe a strategy for improving ATM, i.e. an innovative model for medicines delivery (CDU) and other innovative community-based models that are supported by the CDU. Finally, highlights issues for future research	Case study design incorporating: focus group discussions, in-depth interviews and document review	Senior and mid-level managers, private-sector service provider	Descriptive narrative accounts and descriptive statistics	2013-2014	Western Cape
3. Novel models to improve access to medicines for chronic diseases in South Africa: an analysis of stakeholder perspectives on community-based distribution models – Journal of Pharmaceutical Policy and Practice (2016)9:28	Describe and analyse strategies for improving ATM, i.e. innovative community-based models for medicines delivery, identify policy priorities and issues for future research	In-depth interviews; non-participant observations and document review	Frontline healthcare providers, policy, supply chain and public health experts	Deductive thematic analysis	2012-2014	Western Cape (urban)
4. Medicines supply interruptions are a barrier to efficient functioning of access to medicines interventions in the Western Cape Province, South Africa – South African Medical Journal (under review)	To identify critical incidents which aid in understanding the role of macro-level barriers on access to medicines interventions at the distribution level	In-depth interviews	Frontline healthcare providers, policy, supply chain and public health experts	Descriptive narrative accounts	2012-2014	Western Cape
Broad objective of the thesis: Evaluation of an innovative medicines delivery model (the Chronic Dispensing Unit)						
5. Reasons for missed appointments linked to a public-sector intervention targeting patients with stable chronic conditions in South Africa: results from in-depth	Characterise patient and health system factors linked to missed appointments (acting as barriers to ATM) and assess whether missed	In-depth interviews and patients' records reviews	Patients, frontline healthcare providers, senior and mid-level managers	Hybrid of deductive and inductive thematic analysis; and descriptive statistics	2014-2015	Western Cape

interviews and a retrospective review of medical records – BMC Family Practice (under review)	appointments are indicative of loss-to-follow-up					
6. Analysing implementation dynamics using theory-driven evaluation principles: Lessons learnt from a South African centralised chronic dispensing model – (draft)	Evaluate what was planned vs. actual implementation; establish causal mechanisms and contextual interactions and their interactions, refine the intervention's programme theory	In-depth interviews and document reviews	Frontline healthcare providers, senior and mid-level managers, private-sector service provider, NGO representatives	Hybrid of deductive and inductive thematic analysis	2014-2015	Western Cape (urban)



3.4 Rigour and reflexivity in qualitative research

Judging the quality of research has much to do with the nature of the research and how the researcher understands the world [112]. The WHO methodology reader for Health Policy and Systems Research was a useful tool for informing the quality aspect of this research [112]. The reader suggests that four questions are critical for assessing research quality in flexible designs as shown below. These questions were kept front of mind during the research process.

Textbox 2: Criteria and questions for assessing research quality

Confirmability: Do the data confirm the general findings and lead to their implications?

Dependability: Was the research process logical and well documented?

Credibility: Is there a match between participants' views and the researcher's reconstruction of them?

Transferability: Do the findings generate insights that are transferable to other settings?

Source: [112]

How these questions are answered is dependent on the approach taken. I took a *relativist approach*, which contends that the phenomena being studied are a result of interaction among social actors. As such, phenomena do not exist independently of these actors but are constructed through the way actors interpret or make meaning of their experience, and these interpretations change over time [112]. A common alternative approach (positivist) asserts that phenomena exist independently of how they are viewed by people, therefore there can be a set of facts that can be observed and measured by the researcher, that patterns and regularities exist within them, causes and consequences that can be detected, that remain 'true' in different contexts and times, by describing them and testing hypotheses against the evidence [112].

As a qualitative researcher, I exercised *reflexivity*, defined as the process of examining both oneself as a researcher (i.e. one's assumptions, preconceptions and "conceptual baggage") and the research relationship (examining one's relationship to the respondent and how the relationship dynamics affect responses to questions) [129]. Through this process, I acknowledged although I have both epidemiological (positivist) and social science (relativist) training. However, extensive work experience in social science research has shaped my relativist inclination. From personal reflection, at many points in the study, the *positivist* vs.

relativist tension emerged because my audience was mostly from a biomedical field. A typical example was how some key informants mentioned that for an identified problem (patients' missed appointments), they expected a 'list' of causes (A) which could be resolved by targeted interventions (B) to get an expected outcome (C). Applying a relativist approach meant discarding of a strictly linear approach and taking into account context and other factors which influence implementation of health policies and programmes. As I interacted with the key informants over time, an appreciation of my relativist approach grew and our 'differences' became a strength and not a threat to the study.

Historically, being reflexive has been an attempt to guard against potential bias. However, Freshwater (2005) suggests that it is more important for a researcher to be *subjective* rather than neutral [130]. In order to be *subjective*, I had to be aware of my position, i.e. as a health policy and systems researcher who is not a practising frontline HCP: I am an 'outsider' to the everyday occurrences at the frontline. This had both pros and cons. The pros were that coming in as an 'outsider', I was perceived to have limited bias in my assessment of issues as there was no conflict of interest or prior influences. The cons were that I could be perceived to have limited understanding of the everyday occurrences at the frontline. Therefore, I incorporated stakeholder engagement at strategic points in the lifecycle of the study, e.g. in the initial phase to ensure that I had the correct understanding of processes and in the latter stages as a means to validate the results (member checking) [131].

Overall, rigor was ensured at different stages of the research process as summarised below:

- ✚ Continuous engagement with key informants
- ✚ Use of a conceptual framework derived from previous work to guide the research
- ✚ Selection of research sites with variable characteristics and different stakeholder groups in order to capture views of different actors
- ✚ Mix of a variety of research methods (interviews, observations, FGDs, record and document reviews), which facilitated triangulation
- ✚ De-briefing with research assistants to ensure coherence in thought process and interpretation of questions
- ✚ Analysis of conflicting evidence across sites and key informants
- ✚ Member checking to obtain feedback from key informants
- ✚ Establishing an audit trail of methods and analysis processes.

3.5 Ethics

Ethics approval for this study was granted by the Senate Research Committee at the University of the Western Cape, South Africa (Ref: 11/7/8). All participants were taken through the informed-consent procedure prior to interviewing, including a request to record the interview if the participant was willing. Participants were also informed of their right to withdraw at any time without any consequences in accordance with the requirements of the Helsinki Declaration of 2008.

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4. Results

The results section of this thesis comprises of **six papers**, all of which have undergone external peer-review in local and international journals. Four have been published and two are accepted for publication. Papers 1 to 4 report on results from the situational analysis in the EC and WC provinces, specifically barriers to ATM and existing strategies to improve ATM. Papers 5 and 6 report on an evaluation of the CDU. Below is a synopsis of each paper, the full versions are in the **Annex**.

Situational analysis on the state of chronic medicines provision in public sector facilities in the Eastern and Western Cape provinces

Paper 1 – **Magadzire BP**, Budden A, Ward K, Jeffery R, Sanders D. *Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa*. BMC Health Services Research. 2014, 14:520. <http://www.biomedcentral.com/1472-6963/14/520> - identifies the barriers to ATM through the lens of access dimensions identified in the study's conceptual framework (availability, affordability, acceptability, accessibility), and highlights the ad hoc, empathic responses employed by frontline HCPs to mitigate challenges faced by patients in the EC province.

Because of the link between this PhD project and the AMASA project (section 1.4), this paper looks at ATM for chronic diseases (HIV and diabetes) and also tuberculosis and depression, which were a focus for AMASA. Most of the issues raised were similar across diseases, especially pertaining to the supply-side. There were some differences affecting the demand-side because of the structure of disease control programmes. In this thesis, we will focus on the issues pertaining to chronic diseases.

Paper 2 – **Magadzire BP**, Marchal B, Ward K. *Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa*. BMC Health Services Research. 2015, 15:513. DOI 10.1186/s12913-015-1164-x – describes an innovative model for medicines distribution identifies implementation challenges, i.e. missed appointments by patients and describes the variability across sites and finally provides implications for future research.

Paper 3 – **Magadzire BP**, Marchal B, Ward K. *Novel models to improve access to medicines for chronic diseases in South Africa: an analysis of stakeholder perspectives on community-based distribution models*. Journal of Pharmaceutical Policy and Practice. 2016, 9:28. DOI 10.1186/s40545-016-0082-6 – describes the typology of CBD models in the Cape metropole. These models are alluded to briefly as models supported by the CDU. In this paper, we highlight implementation facilitators and barriers then finally discusses the implications for policy and practice.

Paper 3 was published as part of a thematic issue entitled “**Medicine in health systems: advancing access, availability and appropriate use.**” As stated on the journal website (www.biomedcentral.com/collections/MHS), this collection of papers examines medicine access, affordability and use from a health system perspective, creating a deeper understanding of how interventions in the medicines sector influence the rest of the health system and vice-versa. Furthermore, the collection as a whole illustrate diverse country experiences that have contributed to an increased understanding of the complex environment of medicines in LMICs’ health systems.

Paper 4 – **Magadzire BP**, Ward K, Leng HMJ, Sanders D. *Medicines supply interruptions are a barrier to efficient functioning of access to medicines interventions in the Western Cape Province, South Africa*. South African Medical Journal. 107(7):581-584. doi:10.7196/SAMJ.2017.v107i7.11356. – reports on macro-level barriers to ATM, specifically procurement processes and how they in turn affect the functioning of ATM models described in papers 2 and 3.

Evaluation of an innovative medicines delivery model (the Chronic Dispensing Unit)

Paper 5 – **Magadzire BP**, Mathole T, Ward K. *Reasons for missed appointments linked to a public-sector intervention targeting patients with stable chronic conditions in South Africa: results from in-depth interviews and a retrospective review of medical records*. BMC Family Practice (accepted) – follows up on the issue of missed appointments as introduced in paper 2 by highlighting the causes as reported by patients who had defaulted on a previous appointment and HCPs who deal with patients. In addition, assesses the trends of patients who miss appointments to establish whether they are late presenters or are lost-to-follow-up.

Paper 6 – **Magadzire BP**, Marchal B, Matthys T, Laing RO, Ward K. *Analysing implementation dynamics using theory-driven evaluation principles: Lessons learnt from a*

South African centralised chronic dispensing model. BMC Health Services Research (submitted) – building up from the results from papers 2 and 5, this paper presents results of a comprehensive evaluation of the CDU using a policy across the health system spectrum (policy, actors and context).

5. General Discussion

This chapter provides some reflections on the main findings of the six papers presented in the Results chapter and recommendations to improve access to medicines (ATM) in South Africa. It also delineates the methodological limitations of this PhD.

The main discussion builds on the structure of the Results section which focuses on the state of chronic medicines provision in the public sector in two South African provinces, specifically, identifying barriers to access followed by a discussion of existing innovative models for improving ATM, i.e. the Chronic Dispensing Unit and community-based (CBD) models. The key objective of this chapter is to glean insights from and for other contexts especially where implementation of innovative models is concerned. In concluding this chapter, some reflections on future recommendations to improve ATM in South Africa are presented.

In this chapter, the phrase ‘this study’, refers to this PhD thesis.

5.1 Summary of the main findings

Access to medicines is a key element for treatment of chronic diseases and a right to health [1]. How medicines are made accessible and the barriers to accessing them vary from one context to another as evidenced by this study in two South African provinces. Through a review of literature, it was evident in the beginning of this study that there are multiple dimensions of access that contribute towards effective access to medicines (ATM) and this informed the development of a conceptual framework which was applied in this study. These dimensions are: *availability, affordability, acceptability, accessibility, accommodation and quality* [2]. The impact of these ATM dimensions are experienced at *health facility; individual, household and community* level. In addition, at a health system level, there are important interconnections between *medicines* and other health system components, i.e. *human resources, information, infrastructure, financing and governance* [3]. A key lesson from this study was that although the framework presented access dimensions as having

equal importance, it was often difficult to address all dimensions adequately in any given setting. As such, both providers and beneficiaries of healthcare prioritised what barriers to respond to.

A health systems approach to this study was necessary, taking into account the relationships between medicines and other health system components as highlighted in the conceptual framework (fig 3, section 1.2). This study's results show the importance of each of these components, in some cases more explicitly than in others. In this discussion chapter, the conceptual framework is re-visited to make sense of the results.

The investigation of ATM with a focus on chronic diseases was necessitated by the growing prevalence of chronic diseases in South Africa in the face of supply and demand related challenges. In **paper 1**, we show that rural and other hard-to-reach areas still face compounded access barriers on both the supply and demand side compared to urban areas. Medicines *availability* emerged as a challenge because the structures that were meant to support the supply chain were not in place. Healthcare practitioners (HCPs) at the frontline experienced challenges of operating in areas with limited *human resources*, underdeveloped *infrastructure* and patients who were constrained by *poverty*. They responded empathically by devising practical and innovative solutions for their contexts, some of which were outside of what policy stipulates. These included flexible prescribing and dispensing periods and aligning clinic and social grant appointments to minimise patients' routine costs.

As the burden of chronic disease continues to escalate, this calls for reflection on the organization of care. To facilitate ATM in South Africa, innovative strategies have been introduced. One of such innovations is the outsourcing of medicines dispensing through the CDU, which has been implemented in the Western Cape for the past 10 years. In **paper 2** we show how this model of centralised dispensing has attempted to address the shortage of critical *human resources* in the public sector, with a focus on reducing pharmacists' workload [4]. In addition, the CDU programme aimed at making public sector health services more *acceptable* to patients by addressing the problems of long waiting times and overcrowding at health facilities. Implementation has been challenging in some respects e.g. there were at least 8%-12% of reported cases of missed appointments by patients and a suspected unknown number of unreported cases, a problem that motivated the commissioning of this study.

The CDU has also facilitated further innovation in the form of community-based distribution (CBD) models- formal and informal - which rely on the CDU for medicines supply. Although

specific CBD models target different aspects of ATM, in general, they aim to address one or more of the following: to take medicines closer to where people live, improve *physical access and affordability and accommodating* patients' needs (e.g. adding convenience). In addition, the formal models aim to address the *human resource* shortage by facilitating task-shifting from pharmacists to other cadres such as pharmacist's assistants and community-health workers (CHWs) to address the increasing healthcare needs. As CBD models are still evolving, their processes and structures vary. Furthermore, the governance of these models is weak (including relatively weak documentation systems) and there is variation in the way implementation is carried out, making it difficult to assess the *quality* of services provided. A key recommendation from this study is the development of a policy in an effort to standardise services for quality assurance purposes (**paper 3**).

The two innovative models discussed above (CDU and CBD) have been spearheaded at the provincial level in the WC. This has been possible because medicines distribution is a provincial function. However, although provinces have autonomy on medicines distribution, there is still an important connection with national level supply chain activities because medicines procurement is a centralised function in South Africa [5]. Delays in awarding national pharmaceutical tenders, suppliers' inability to satisfy contractual agreements adequately and the absence of national contracts for certain essential medicines contribute to stock-outs that affect all provinces and notably, the innovative strategies discussed above (**paper 4**).

In **papers 5 and 6**, the focus is on implementation related aspects of the CDU in order to inform improvements as well as future interventions in other settings. **Paper 5** specifically addresses an important problem that encountered in the WC during CDU implementation, i.e. that of missed appointments by patients and raises questions regarding how patients' practical circumstances should be *accommodated* in order for the service to be effective. Results suggested that social factors, e.g. mobility, work commitments and forgetting appointments presented a barrier to medicines collection. That said, results from the folder review suggested that these barriers were of a temporary nature as most patients who missed appointments presented voluntarily to obtain medicines at a later time. The caveat is although patients eventually presented, implementation was still challenged given that the administrative processes for missed appointments were resource consuming. It was also clear that a range of implementation related issues were at play as some patients were erroneously recorded as appointment defaulters. Based on these results, it was clear that there was a need

for more detailed interrogation of the CDU's implementation processes. This led to a comprehensive evaluation using theory-driven evaluation principles (**Paper 6**). In addition to macro-level processes (already presented in **paper 4**), implementation was influenced at the frontline by actors' readiness to embed the intervention and a variety of context factors. Human elements necessary for influencing implementation included: *communication, cooperation, willingness to change, ownership, leadership commitment and trust*. These were present at varying degrees at health facilities. While there were implementation guidelines and protocols, implementers' decisions were guided for the most part by contextual realities.

5.2 Situational analysis of the state of chronic medicines provision in the public sector in the Eastern Cape and Western Cape provinces

The nature of a health system plays an important role in ATM. Some authors have suggested that access is improved when public facilities are available and function effectively, and when private care is affordable [6]. However, the increasing prevalence of chronic diseases has exposed some weaknesses in LMIC health systems, including that of South Africa [7]. Much of the criticisms are about the nature and design of health systems, which are not adapted to provide the care required [8]. Also, sub-optimal health outcomes have been attributed to a generally inequitable society [9, 10]. Furthermore, it has been argued that management of chronic diseases is fundamentally different from acute care and that it depends on several attributes, including a combination of pharmacological and psychosocial interventions and long-term follow-up with regular monitoring and promotion of adherence to treatment [11]. While all these factors are true and of importance, this study shows that there has also been inadequate consideration of the medicines supply chain.

Stock-outs emerged as a common occurrence in the South African public sector, for many reasons which include: inefficient business processes at macro level (**paper 4**) and logistical bottlenecks hampering delivery of medicines to rural healthcare centres at the district level (**paper 1**). Although contracting out transport services for medicines delivery has been cited as a means to achieve efficiency and economy of scope [12], this was not working seamlessly in the Eastern Cape province. Other South African studies have also reported similar issues with stock-outs [5, 13]. An analysis of access to antiretroviral treatment in rural South Africa by Gray and colleagues (2014) reported that stock-outs disrupted organisation of care, which in turn affects quality of care and patient quality of life [13].

Beyond South Africa, there is evidence that the determinants of stock-outs are multi-layered, with overlapping and interconnected threads of causes [5, 14]. An examination of supply chains in LMICs by Dowling (2011) found their performance to be suboptimal and to contribute to poor health outcomes. The causes of stock-outs were deemed to be complex and included lack of human resources, finance, weak health systems and poor access to services [15], again illustrating the interdependent relationship between medicines and other health system components. A study in Nepal also found problems with access to NCD medicines, especially in rural areas [16]. Similarly, a study in Senegal found medicines supply to be inadequate and health infrastructure to be insufficient to cater for the needs of the population, creating high opportunity costs [17]. A study in Malawi found that a strong policy commitment to free medicines is insufficient: on average, 75% of facilities experienced stock-outs [18]. Reasons for stock-outs might vary from one context to another, but remains a challenge requiring attention in the ATM discourse. Stock-outs remain a public health concern because they represent a failure within the health system [19]. Although stock-outs still exist, there have been some efforts to address this problem. An International Summit on Medicines Shortage held in Canada in 2013 produced a list of recommendations, including the need for each country to have a publicly accessible means of providing information on stock-outs of critical products, urging procurers to move towards active procurement processes that ensure uninterrupted medicines supply and the need for countries to develop evidence-based risk mitigation strategies which could include buffer stockpiles, contingency plans and other strategies relevant to country needs and establishment of a national body responsible for gathering and sharing information and demand and supply of medicines [20]. It remains to be seen whether and how countries have taken up those recommendations and the results thereof.

In South Africa, a consortium of civil society organisations has taken an active role in monitoring stock-outs of essential medicines and regularly producing a list of critical products in the public sector through the Stop Stock Outs Project and other independent projects. Some of the evidence seems to suggest that although provinces such as the Eastern Cape have experienced medicines crises in the last few years [21], there seems to be a steady reduction in stock-out incidents [22]. The Western Cape on the other hand seems to consistently be the province with the lowest percentage of facilities reporting stock-outs [22]. This could support the findings in **paper 4** suggesting that stock-outs were mostly predictable in this province as a result of national level procurement challenges. These provincial

scenarios illustrate the consequences of historical contexts and different governance structures as presented in section 1.4.2.

While medicines availability was an important issue as discussed above, at times medicines were available but patients were constrained by other barriers linked to, *inter alia*, *acceptability* and *accommodation* of services. In the EC for example, there was an assumption by local authorities that decentralisation of services (also referred to as down-referral) to remote health centres would be a solution to challenges of affordability and physical access for the rural population. While this could have solved some of the access barriers, at times there was little motivation to encourage patients to attend the nearest health centre. Transport networks were not well developed hence there was limited public transport to those facilities. Also, the prevalence of stock-outs created negative perceptions of service and quality among the patients and hampered the success of the this programme in the Eastern Cape. These and other factors led to patients opting to attend distant facilities which in turn increased health-related expenditure and exerted additional work pressure on urban facilities (**paper 1**). These results tend to suggest that patients sometimes addressed one barrier by creating another (e.g. in the case where a patient might deal with *acceptability* of services by going to a distant facility and increasing health-related expenditure). The downside is that the ‘preferred’ facilities continue to be over-crowded and with time their capacity to offer good *quality* services might diminish.

HIV programmes in South Africa have produced many lessons on the decentralisation of services. One study conducted in rural South Africa using a healthcare accessibility framework found almost similar results to this study, i.e. down-referral of patients on antiretroviral treatment was associated with reduced transportation and travel time, reduced waiting times, positive relationships with HCPs and showed a higher level of adherence. However, patients still preferred doctor to nurse consultation (something we also found in this study) and were more likely to visit private physicians and practise self-care leading to increased health-related expenditure [23]. Possible stigma and lack of privacy emanating from decentralised programmes was an important issue raised in both the Eastern Cape (**paper 1**) and the Western Cape (**paper 3**) provinces and has also been reported in other studies [24]. The reason being, decentralised services tend to usually have a specific known disease focus and if a patient has not publicly disclosed their status this can present a challenge. This is yet another illustration that the dynamics of medicines access are beyond

the individual, and include households and communities as indicated in this study's conceptual framework.

A study conducted in Mozambique alluded to the challenge of decentralising services with chronic disease without careful planning, i.e. without improving processes, clinic infrastructure, monitoring and patient preparation. The result was patient loss-to-follow-up [25].

Overall, this study's results and those described above show both positive and negative aspects of service decentralisation, indicating that this strategy is not a panacea for improving access. Further, evidence shows the interaction of *context* factors with interventions. Decentralised services and other ATM strategies call for multi-sectoral collaboration with stakeholders such as those who can improve transport infrastructure.

5.2.1 Chronic care models and access to medicines: exploring the link

Medicines provision is often nested within chronic disease programmes. The way care is organised within these programmes can influence ATM, therefore, a point of interest is to discuss the implications of chronic care models on ATM. Various chronic care models have been proposed over the years but we discuss our results in light of a few.

One of the most prominent models is the Chronic Care Model (CCM) which was developed by a group of experts who were part of the Improving Chronic Illness Care project [26]. The CCM framework *“brings to the forefront the importance of recognising that patients face multiple and complex needs in treatment and the role of a proactive health systems team with productive interactions between patients and providers”* [27]. The ICC framework led to the development of subsequent frameworks, including, the WHO's “Innovative Care for Chronic Conditions” (ICCC) framework. This incorporates community, patient, healthcare and policy environment perspectives. This framework forms the cornerstone of South Africa's primary health care re-engineering and strategic plan for chronic disease management integration [28]. Some scholars have criticised the ICC framework for failing to incorporate complexity associated with multi-morbidity and proposed some modifications both to the framework and to the South African Integrated Chronic Disease Management (ICDM) plan [28]. The ICDM was specifically introduced as a tool to leverage lessons from the HIV programme in order to improve quality of chronic non-communicable disease care [29]. Early findings suggest that structure and processes are not yet well developed for

chronic non-communicable disease programmes in South Africa, e.g. equipment for monitoring therapeutic outcomes is regularly malfunctional and there are frequent reports of medicines stock-outs as previously discussed [29].

The last framework that we discuss is that of Van Omen and colleagues (2012). It emphasizes four dimensions of chronic diseases: *the biomedical, the health provider, the patient and the environment* [30].

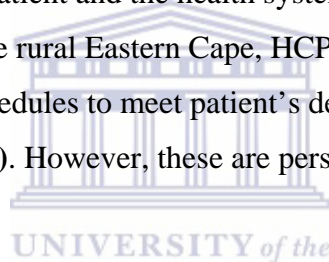
All these frameworks bring out some important dimensions required for optimum chronic care, incorporating health system, patient and environmental needs. While there is acknowledgement of these many dimensions, the challenge is to merge and address all the needs [31]. In assessing this study's results in light of the assertions made by these frameworks, it is evident that some ATM challenges in South Africa are a result of either little attention towards some of the dynamic interactions between the elements of the health system or a difficulty to operationalise the recommendations. For instance, the issue of temporary and long-term migration between provinces is one that seems to be well understood (**papers 1 and 5**) but current chronic care programmes have difficulties addressing this. There have been some efforts to accommodate people over festive seasons with more than one month's supply of medicine [32], but the real challenge is managing unplanned patient migration between provinces at other times during the year. The ability of the health system to recognise the influence of contextual factors and competing priorities in patients' ability to access medicines is part of what the CCM addresses. Once more, the challenge and major gap is the "how to" in practice.

Further thinking about creating a proactive team of HCPs with productive interactions between patients and providers as addressed by the CCM [26] and about the connections between patient and provider dimensions, another central element of frameworks discussed above, points to the need for a *regular two-way system of communication* between patients and HCPs in relation to their medicines supply. As reported in **paper 5**, there was sometimes limited awareness of why patients missed appointments. Some patients who missed appointments subsequently reported to health facilities spontaneously without provider follow-up, although many were possibly lost-to-follow up. Even HIV programmes which have been commended for having fairly well advanced patient monitoring and follow-up systems are by no means watertight. A review of adults loss-to-follow-up in ART

programmes in LMICs reported substantial unaccounted for self-transfers and deaths amongst patients lost-to-follow-up [33].

At present, the health system lacks a follow-up mechanism for patients who fail to access their medicines and there are minimal reports of patients officially informing HCPs if they are facing access barriers, whether temporary or long-term. However, even if patients were to inform HCPs, there is currently no strategy in place to deal with access barriers. The lack of chronic disease registers for patients with non-communicable diseases and some form of follow-up mechanisms (which are mostly attributed to *human resource shortages*) make patient monitoring particularly challenging in our context.

As reported in **papers 2 and 5**, the assumption was that clinically ‘stable patients’ kept clinic appointments and would therefore consistently keep medicine collection appointments scheduled by the CDU but this has not always proven true. There needs to be some practical and proactive ways for both the patient and the health system to deal with unforeseen events that create barriers to ATM. In the rural Eastern Cape, HCPs attempted to prevent treatment interruption by synchronising schedules to meet patient’s demands, such as patients’ grant collection appointments (**paper 1**). However, these are personalised responses to individual cases.



5.3 Innovative models to improve ATM: key lessons from and for other contexts

Over the years, alternative strategies have been introduced to cope with the increasing demand for chronic disease treatment in South Africa. In this thesis, the strategies are grouped into two categories: *formal and informal*, with the former referring to strategies that are officially recognised and initiated by local health authorities. The latter are both demand-oriented (HCPs aim at satisfying the client therefore strategies emanate at the frontline where HCPs interact with patients) and demand-driven (clients take the initiative and pursue their ideals in healthcare and welfare) [34]. In table 4, we summarise the strategies and indicate the ATM barriers that each of these strategies seeks to address.

Table 4: Interventions according to the barriers they sought to address

Barriers		Interventions
Formal		
Supply	Limited pharmacy human resources, overcrowded health facilities, high patient waiting times	Outsourced centralised automated dispensary (Chronic Dispensing Unit) to dispense medicines for stable patients with chronic diseases in order to: <ul style="list-style-type: none"> - eliminate routine tasks by pharmacists and create more time for patient counselling - make distribution more time-efficient - utilise private sector efficiencies in the public sector Papers 2,5 and 6
Supply	Overcrowded health facilities, high patient waiting times	- community-based distribution models (CBD) involving community health workers from non-governmental organisations or healthcare professionals (nurses, pharmacists' assistants)
Demand	Physical access, poverty (affordability), time and cost investment	Paper 3
Demand	Physical access	- mobile clinics in the community (although they were not functional at the time of research)
		Paper 1
Informal		
Demand	Time and cost investment	- community-based distribution models (CBD) involving private distributors delivering medicines at patients' homes
		Paper 3
Demand	Poverty (affordability), physical access	- flexible prescribing for longer periods
		- aligning clinic and social grant appointments
		- assisting patients with monetary support
		Paper 1

This study shows that ATM is a site of complex intersection of different actors (public sector, private-for-profit and private-not-for-profit organisations). Collaboration between various stakeholders, has been cited as key to improving ATM in LMICs [6]. On the other hand, other scholars have suggested that involvement of many intermediaries in the distribution chain as is the case with LMICs can lead to an exceptionally expensive and inefficient system [35] and multiple parallel distribution systems [36]. Developed countries tend to have one coordinated distribution chain whereas LMICs have many small chains and companies at every step.

In the context of South Africa (as with other LMICs), the existence of multiple strategies seems to suggest that different players mitigate against access barriers and that people at risk of poor access negotiate barriers to seek care in their settings, an aspect that has also been

cited to be of importance in understanding ATM [6]. The evidence of plural systems of medicines distribution could be seen as a means to address inequities in this setting. However, as we noted from this study's results it can introduce some difficult dynamics where there is a lack of *governance and accountability procedures* to monitor and govern processes and balancing different *actor interests*.

Somewhat similar ATM interventions are available in other countries albeit to a limited degree. Also, the rationale and context vary. A recent review by Spinks and colleagues (2016) found that automated (computerised) dispensing interventions have mostly been at a localised level, such as hospitals and single-site community pharmacies in developed countries [37].

In Scandinavian countries, automated multidose drug dispensing (MDD), (the technology which organises doses of tablets and capsules according to when they should be taken) is motivated by expected savings in terms of medication dispensing errors and drug expenses [38].

In LMICs, the South African CDU is novel [39, 40] and Spinks and colleagues [41] referenced **paper 1** of this thesis in describing this model. In terms of scope, the Scandinavian models were not as extensive as the CDU [41]. Similarly, in South Africa localised interventions as those earlier described also exist, although they are not well documented.

With growing pressure from the United Kingdom government, the proposed '*hub and spoke*' model, also a centralised and automated dispensing model is on the table [42]. However, the discussion is currently shrouded with much debate and scepticism [43] .

Although there is growing interest in centralised, automated dispensing, the review by Spinks and colleagues (2016) points to the impact of automation on the pharmacist workforce and frames the concept of automated dispensing as potentially disruptive and a threat to community pharmacy because it could lead to a 'technology shock', making some pharmacists roles redundant or creating new roles or significantly impacting on funding for pharmacies [41]. Furthermore, the authors caution on the need to carry out more work in the realm of pharmacy workforce planning to ensure that the introduction of new technology provides optimal outcomes to consumers (patients) and the profession at large.

Notwithstanding these valid points, some views on centralised automated dispensing (specifically in the case of the CDU) are more positive.

Christensen and colleagues (2015) describe disruptive innovation in a competitive business sense as follows:

“...whereby a smaller company with fewer resources is able to successfully challenge established incumbent businesses. Entrants that prove disruptive begin by successfully targeting those overlooked segments, gaining a foothold by delivering more-suitable functionality—frequently at a lower price. ... When mainstream customers start adopting the entrants’ offerings in volume, disruption has occurred.”[44]

The authors cautioned that many researchers use “disruptive innovation” to describe any situation in which an industry is shaken up yet the actual meaning is when there is competition with other businesses as quoted above [44]. In the CDU’s case, it is a collaboration between the private and public sector, leveraging on private sector strengths, a method that has been promoted for improving the last-mile distribution (most vulnerable stage of distribution) [45, 46].

Spinks and colleagues (2016) further present some rather useful provocative issues around the impact of service organisation alterations on consumer interaction with pharmacists [41]. As evident in this study’s results, the issue is somewhat controversial even in South Africa. With the CDU and CBD models specifically, the argument has been that because ‘*stable patients*’ are the target group, minimum interaction with the pharmacist is required (**papers 2, 3, 5 and 6**). This may work in theory, but in practice it is difficult to operationalise due to a variety of contextual issues as indicated. For example, there is variation on the very definition of what constitutes a stable patient in the context of CDU implementation (**paper 6**). Additionally, patients are hindered by many barriers of a social, cultural and economic nature in medicines collection and therefore miss appointments (**paper 5**).

Further to patient classification and suitability, the MDD intervention in Scandinavian countries, was shown to improve medicines management but some scholars have found that they are not suitable for all patients [47]. This is particularly true for patients who are already constrained by other barriers to adherence or medication errors. It has been suggested that patient’s preferences and attitude to medicines and their suitability for an intervention are key criteria for such interventions [47]. Similarly, with the CDU, these issues require further interrogation. Elliot (2014) further suggests that when there are third parties involved in dispensing, patient education and monitoring are vital to minimise the risk of problems [47]. The same applies to CBD models in South Africa which involve third-party providers.

A Swedish study on elderly patients with chronic illnesses whose medication was dispensed using the MDD method indicated that patients were exposed to potential inappropriate drug use. These results were partly explained by polypharmacy in the elderly target group than the ordinary prescription users [48]. Similarly, CDU patients in South Africa who have an average of five-to six items per prescription (**paper 1**) were often reported to have more unused medicine due to lack of adherence to treatment regimens (**paper 5**). Ensuring a high quality of drug therapy within the health system is of utmost importance [48].

Another study on MDD in Norway, focussing on different groups of health personnel [38] brings out some interesting parallels with the CDU evaluation (**paper 6**) and analysis of CBD models (**paper 3**). First, the Norwegian study reported on the importance of actors' trust in new technology and in collaborating partners. The authors emphasize that:

“Building trust has to be a process that runs in parallel with the introduction of new technology and the establishment of new routines for improving the quality in handling of medicines and to facilitate better cooperation and communication.”[38]

Interestingly, the principles of trust, cooperation and communication also emerged as facilitators for success in CDU implementation (**paper 6**).

Second, the Norwegian study reported that checking the multi-dose bags arriving from the pharmacy was considered unnecessary in the written routines dealing with multi-dose dispensing. However, home-care nurses experienced errors and continued to manually check the bags [38]. Similarly, with the CDU, a common complaint from HCPs was the time ‘lost’ checking patient medicine parcels which was perceived to remove the benefit of the intervention. The question is how could quality be ensured in centralised dispensing interventions in the face of current incidents of dispensing errors? In addition, what safeguards could be put in place to ensure rational medicine use and consumer safety more broadly [41]?

Third, a finding in the Norwegian study which is of interest to CBD services in South Africa is how nurses in the home-care service felt under-equipped to provide medical information to patients and to monitor the effects of the drugs. Also, the home-care services' routines for medicine handling were not always trusted by the other groups of health personnel involved [38]. Similar issues were raised in South Africa regarding the capacity of non-health professionals to conduct certain tasks (**paper 3**).

5.4 How providers influence implementation access to medicines programmes at the frontline: a cross-cutting theme

Decision-making by HCPs at the frontline emerged as an important cross-cutting issue in the overall study. It was apparent that their decisions facilitated or hindered ATM policy outcomes. The dimensions of this study's conceptual framework could be taken as representing mostly, the technical side of ATM. People, in this case frontline HCPs, determine how these technical dimensions' work. Hence, understanding the drivers of certain actions (or lack thereof) is important for policy makers and programme planners.

Other health policy studies have described similar scenarios through the application of the theory of street-level bureaucracy [49]. This theory aids in the explanation of policy implementation, i.e. where policy is implemented in unexpected and unintended ways and gives policy makers and policy implementation managers insight into why certain policies are not always implemented as intended. Frontline workers or policy implementers in government agencies such as health service (e.g. doctors, nurses) are street-level bureaucrats. "Street-level bureaucrats have regular and direct interaction with service users and have the power to exercise discretion over the services, benefits and sanctions received by those recipients"[50]. Lipsky's theory of street-level bureaucracy [49] has been summarised by Erasmus (undated) [51] into the following key principles, which resonated with this study:

- ✚ Decisions and actions of street-level bureaucrats, actually 'become', or represent, the policies of the agencies they work for because service users most often and directly experience policy as the decision that the street-level bureaucrat makes about their particular case
- ✚ Policy becomes the benefit that the street-level bureaucrat gives them access to, or the sanction that the street-level bureaucrat applies to them. It is not the abstract document that states what should be done or a decision by an unseen high-ranking official.
- ✚ Street-level bureaucrats can 'make policy' in this way because they can exercise discretion (make a choice about how they will exercise their power). Their discretion comes partly from the fact that they are regarded as professionals and therefore expected to exercise their own judgement in their fields of expertise. However, it also arises from the fact that they are often relatively free from organisational oversight and authority, and perform complex tasks that cannot be completely scripted or reduced to formulae.

- ✚ Street-level bureaucrats may be in conflict with, or have perspectives that differ from, other groups in the organisation such as their managers. They may be able to resist organisational expectation or apathetic attitudes that affect how they do their work. This combination of discretion and a degree of freedom from organisational authority, can lead to street-level bureaucrats ‘making policy’ in unwanted or unexpected ways, for the better or the worst. In the worst case, their actions and decisions may not conform to policy directives and so their agencies could end up performing contrary to their stated policies, intentions or goals.

The results of this study in many ways reflected key dimensions of the theory of street-level bureaucracy, as HCPs navigated their difficult work environments, plagued by *limited resources* and a high demand for services among other issues and working in a particular *socio-political context* with unique *personal beliefs and values* [50].

- ✚ In **paper 1**, we drew on the work of Long and colleagues (2013) to illustrate how HCP enact the brokerage role in promoting ATM [52]. Furthermore, the role played by HCP was influenced by personal values and principles such as empathy, hence HCPs adopted informal strategies ‘rule breaking’ and patient categorisation in order to meet patients’ needs. While extended dispensing intervals was something that we found to be already happening in the Eastern Cape in 2011, a similar issue was raised in the Western Cape a few years later [32].
- ✚ In **paper 2**, we found that the reporting rates for medicines non-collection were low (ranging from 24-67% each month) and this was attributed to work pressure and the fear of obtaining a negative reputation since medicines collection statistics were regarded as a performance indicator (a socio-political issue).
- ✚ In **paper 3**, we found that selected CBD strategies were favoured by frontline HCPs, because of the perceived benefits to both the health system (discretion) and the patient yet many senior managers were against them (conflict with managers).
- ✚ In **paper 6**, we discuss how actors exercised discretion in patient selection driven by both the socio-political factors and work pressures (e.g. political pressure to enrol many patients on the CDU programme, differences in interpretation when it comes to defining stable patients).

In sum, the results from this study are in line with results of another South African study which found that frontline HCPs views and values inform their implementation of health

policy and they sometimes feel excluded from the process of policy change [53]. Unlike in other studies, where the actions of street-level bureaucrats had negative outcomes [54], in this study at times the actions of HCPs were perceived to have positive outcomes (improved access).

5.5 Strengths and limitations of the PhD thesis

The strengths of this study is in its design as an operational research study which responded to real-life challenges in the South African health system. Stakeholder consultation formed an important part in the conceptualisation of the research. The intention was to address existing issues as identified by the potential users of the research in order to overcome the challenges of non-utilization of research evidence [55] and stimulate engagement between research and policy. Therefore, part of our approach was to engage stakeholders who make policy, implement policy and experience the consequences of policy as it relates to ATM in the selected provinces. This approach has been suggested for other types of policy relevant research [56]. To achieve this goal, we adopted a data-driven emergent research design [57], starting with broad objectives and refining them as informed by research findings. To illustrate this, in **paper 2**, a problem was identified (missed appointments) which led to an in-depth study to investigate the causes (**paper 5**) and an evaluation of the implementation of the CDU in the Western Cape province (**paper 6**). The results were discussed with the relevant stakeholders and some immediate decisions were taken during the course of the research, including changing of the packaging material for patient medicine parcels as a means to simplify the quality assurance process (**paper 6**). **Paper 3** also provides concrete recommendations for thinking about community-based distribution policy in South Africa. Another benefit of this study was the possibility to apply existing theory through comparative literature analysis [58], evident in 5.4 (applicability of results to street-level bureaucracy theory) at the end of the study to illuminate policy implementation [50].

This is a predominantly qualitative study with the exception of the record review reported in **paper 5**. As earlier mentioned (chapter 3), qualitative research methods are appropriate for exploring various actors' perspectives and experiences in order to gain a deeper meaning to a complex phenomenon rather than seeking for generalisability, in the conventional sense [58]. This methodology also had limitations. A commonly acknowledged limitation of qualitative studies is that the results are mostly not generalizable outside of the context which the study was conducted [59]. Those intending to apply the results of this study would require an in-depth understanding of their own settings.

The second limitation was the unavailability of reliable routine data relevant for this study, such as rates of missed appointments which were under-reported. Also relating to data, was the fragmented systems (CDU system and JSC pharmaceutical system at health facilities), which were unable to provide information on patients who truly missed appointments and those who obtained medication through the alternative system. The challenge of data reliability and availability is not unique to this setting but is common in many LMICs [60].

6. Conclusions, recommendations and implications for future research

In summary, this research contributes to evidence on improving access to medicines in public sector healthcare service delivery in the Eastern Cape and Western Cape provinces of South Africa. This study has identified barriers to ATM and assessed innovative models for improving ATM. In addition, the study generated lessons from implementation of innovative models and provided guidance for future policies. Future research could explore quantifiable outcomes from the identified interventions once systems are in place to adequately provide reliable data. In conclusion, this study lends itself to the following recommendations, which should be contextualised in order to effectively improve ATM:

Macro-level (policy)

- a) Concerted effort is required to make comprehensive care for chronic conditions a reality. To achieve this, a multi-sectoral stakeholder engagement approach involving the formal health sector, informal providers of health services, community-based organisations, and relevant non-health sectors such as those involved in infrastructure development is required.
- b) Strengthening procurement of medicines and contracted healthcare services is required in order to minimise stock-outs and to ensure that services remain functional during change-over periods.

Meso-level (service delivery and community)

- a) Revisit the patient care model to ensure that it is responsive to socio-economic and cultural realities of patients. Furthermore, introduce a two-way communication system between patients and the health system so that the health system can be better prepared to respond to patients' needs.

- b) Develop monitoring systems, including chronic disease registers for non-communicable diseases where patients' outcomes can be routinely captured and periodically analysed to facilitate timely interventions where required.
- c) Integrate the two facility-based pharmacy information systems so that the system is able to provide a holistic picture on collected and non-collected medicines at any given time (WC).
- d) Strengthen medicines distribution networks in order to improve delivery of medicines in hard-to-reach-areas (EC).

Micro-level (individuals and households)

- a) Invest more resources to conduct population-based research in order to understand the characteristics of the population served because treatment access occurs within a context of patients' everyday realities. As such, interventions should adequately acknowledge socio-economic and cultural factors that affect health facility attendance and invariably health status. Identifying these factors will facilitate management of at-risk patients and inform contextual approaches to addressing public health problems.

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Annex



UNIVERSITY *of the*
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PAPER I



UNIVERSITY *of the*
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RESEARCH ARTICLE

Open Access

Frontline health workers as brokers: provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa

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Abstract

Background: Front-line health providers have a unique role as brokers (patient advocates) between the health system and patients in ensuring access to medicines (ATM). ATM is a fundamental component of health systems. This paper examines in a South African context supply- and demand- ATM barriers from the provider perspective using a five dimensional framework: *availability* (fit between existing resources and clients' needs); *accessibility* (fit between physical location of healthcare and location of clients); *accommodation* (fit between the organisation of services and clients' practical circumstances); *acceptability* (fit between clients' and providers' mutual expectations and appropriateness of care) and *affordability* (fit between cost of care and ability to pay).

Methods: This cross-sectional, qualitative study uses semi-structured interviews with nurses, pharmacy personnel and doctors. Thirty-six providers were purposively recruited from six public sector Community Health Centres in two districts in the Eastern Cape Province representing both rural and urban settings. Content analysis combined structured coding and grounded theory approaches. Finally, the five dimensional framework was applied to illustrate the interconnected facets of the issue.

Results: Factors perceived to affect ATM were identified. Availability of medicines was hampered by logistical bottlenecks in the medicines supply chain; poor public transport networks affected accessibility. Organization of disease programmes meshed poorly with the needs of patients with comorbidities and circular migrants who move between provinces searching for economic opportunities, proximity to services such as social grants and shopping centres influenced where patients obtain medicines. Acceptability was affected by, for example, HIV related stigma leading patients to seek distant services. Travel costs exacerbated by the interplay of several ATM barriers influenced affordability. Providers play a brokerage role by adopting flexible prescribing and dispensing for 'stable' patients and aligning clinic and social grant appointments to minimise clients' routine costs. Occasionally they reported assisting patients with transport money.

Conclusion: All five ATM barriers are important and they interact in complex ways. Context-sensitive responses which minimise treatment interruption are needed. While broad-based changes encompassing all disease programmes to improve ATM are needed, a beginning could be to assess the appropriateness, feasibility and sustainability of existing brokerage mechanisms.

Keywords: Access to medicines, Provider perceptions, Health services, Broker, Empathy, HIV, Diabetes, Depression, TB, South Africa

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Background

South Africa is in the midst of a profound health transition that is characterised by a multiple burden of disease that includes communicable and non-communicable diseases [1]. This has increased demand for essential medicines in the public health system which caters for almost 70% of the country's population [2]. The South African health system is plagued by a human resources crisis and the primary health care system is a mainly nurse-driven service [3]. Nurses together with other frontline health providers (hereinafter referred to as providers) i.e. pharmacy personnel (pharmacist or pharmacist assistant) and doctors where present, play a strategic and key role as brokers (usually as patient advocates) between patients and the health system at the point of care. Thus, understanding their perspectives and actions can strengthen planning and provision of future services [4]. We draw on the work of Long et al. in analysing the role of brokers and their capacity to link disparate groups in the provision of health care [5].

We explore the brokerage aspect in ATM, a fundamental component of health systems. Although no universal definition of access exists [6], for our purposes, we adopt a definition which describes access as the fit between supply and demand of healthcare along five dimensions: *availability* (fit between existing resources and clients' needs); *accessibility* (fit between physical location of healthcare and location of clients); *accommodation* (fit between the organisation of services and clients' practical circumstances); *acceptability* (fit between clients' and providers' mutual expectations and appropriateness of care) and *affordability* (fit between cost of care and ability to pay) [7].

Many studies in South Africa highlight supply- and demand-side barriers to ATM such as treatment-related costs [8-10], waiting times at health sites [11], poor provider-patient interaction [12,13], and structural inequities, particularly among rural populations [14]. Most of these findings derive from patient reports. In this study, however, we explore provider perspectives, within the same framework commonly utilised to understand patient perspectives, to ascertain their perceptions of these barriers to accessing essential medicines, i.e. those medicines that satisfy the priority health care needs of the population [15]. The literature on providers and their interactions with patients tends to cast them in a negative light [16-19]. However, little attempt has been made to investigate how providers view and attempt to mitigate the daily challenges they encounter in patient care. The objective of this paper is to address this gap by highlighting the views of primary health care providers on supply- and demand-related ATM barriers in the Eastern Cape Province. A second objective is to highlight the ad hoc, empathic responses that providers in

their broker capacity employ in their day-to-day practise to mitigate challenges faced by patients.

Methods

Study setting

The Eastern Cape Province has an estimated population of 6.8 million, contributing about 13.5% of the country's population [20]. 62% of its population is rural and highly deprived, contributing significantly to poor health outcomes [14]. At the time of the study, primary level facilities were managed by two local authorities, the Provincial Department of Health (responsible for the majority of sites) and municipalities in urban areas. However our sample consisted of only the Provincial Department of Health sites.

Design

This research is a component of a larger research project on Accessing Medicines in Africa and South Asia (AMASA), which investigated supply and access to essential medicines for TB, HIV, Type-2 diabetes and unipolar depression. The present cross-sectional, qualitative study is based on key informant interviews with nurses (health centre managers also commonly known as facility managers and disease programme managers), doctors and pharmacy personnel (pharmacists or pharmacist assistants or dispensing nurses). Thirty-six providers were purposively recruited from six public sector Community Health Centres (CHCs) in two districts (one rural and one urban) in the Eastern Cape Province. CHCs were selected because they are the first level of care in the health system and provide a broad range of essential medicines and primary health care services in the public system. Recruitment of respondents from rural and urban settings aimed to consider varying conditions of access in different geographic locations. Four of the sites were rural and two were urban. Key informant interviews addressed themes regarding access to selected essential medicines which are available in the public sector: lamivudine (3-TC), part of the first line anti-retroviral therapy (ART) for adults infected by Human Immunodeficiency Virus (HIV); rifampicin, an antimycobacterial drug for tuberculosis (TB); metformin, a blood glucose lowering drug for type 2 diabetes; and two antidepressants, fluoxetine and amitriptyline. At each CHC, the facility manager, pharmacy personnel and one or more representatives per essential medicine (nurse and/or doctor) were recruited. Unlike in towns where providers manage a single disease programme, in rural areas, they manage multiple disease programmes because of human resource shortages. Sufficiency of sample size was determined by saturation, i.e., when the collection of new data did not shed any further light on the issue under investigation.

Interviews were conducted during the months of March and April of 2012. This study protocol was approved by the University of the Western Cape Ethics Committee and both the National and Provincial Department of Health Committees. Each participant gave both verbal and written consent to participate in the research and was given information leaflets with a brief description of the study and contact details of the responsible institution and contact person.

Instruments

Key informant interviews with providers were conducted using a semi-structured interview guide. Interview guides for each stakeholder group contained a set of broader themes with corresponding questions and probes as informed by the study objectives. However, the common lines of enquiry among all stakeholder groups that were relevant for this paper focussed on identifying the most significant health system and patient level barriers to accessing essential medicines and how these differ or are similar across settings (rural and urban); type of medicine (or disease condition); and the strategies that exist within the health system to overcome these barriers, including the availability of alternative medicines access points such as mobile clinics. Key informant interviews were digitally recorded and transcribed.

Data analysis

The transcripts were imported to a computer programme, MAXQDA version 10 for organisation and content analysis. Content analysis is a standard approach to analysing qualitative data to identify patterns, themes and biases in that material [21]. The analysis applied structured coding and grounded theory approaches to the narratives. Coded segments of transcripts were then retrieved and further analysed for recurrent or conflicting response patterns. Finally, coded segments were categorised according to the five dimensional framework. The coding frameworks were discussed with the authorship team at both stages.

Results

The sample and background characteristics of respondents are shown in Table 1 below.

Various supply- and demand-side barriers to essential medicine access were identified.

Providers also discussed the ad hoc strategies that they employ to address these challenges. Notably, although the investigation aimed to consider essential medicines for HIV, TB, diabetes and depression, we found minimal prescribing of antidepressants in this context. When prescribed, it is usually on a short term basis. However, we still included the findings with regard to antidepressants in the analysis. Below we elaborate provider perspectives

Table 1 Characteristics of respondents N(36)

Antiretroviral Therapy (ART) programme nurses	7
Tuberculosis (TB) programme nurses	6
Chronic care nurses (responsible for management of diabetes and/or mental health programmes)	8
Doctors	3
Pharmacist/pharmacist assistant/dispensing nurses	6
Facility/health centre managers (nurses)	6
Sex	
Male	6
Female	30
Age (years)	Range: 24-63 Median: 52
Number of years working at the facility	Range: <1-29 Median: 8
Number of years working in the health profession	Range: <1-30 Median: 26

with reference to the five dimensional framework and their mitigating strategies and recommendations.

Availability

Stock outs (i.e. when health centres run out of medicines) were viewed, as a major challenge particularly in rural clinics. Providers in rural CHCs highlighted the lack of dedicated vehicles to transport medicines from CHCs that act as temporary storage for rural clinics as a hindrance to efficient distribution. Each of the four rural CHCs visited provided temporary medicine storage for more than 20 peripheral clinics located in the deep rural areas. However, at the time of the research there were no dedicated vehicles for transportation of medicines from the CHCs to the clinics. Vehicles allocated for other tasks were also expected to deliver medicines. In the past, medicines delivery was outsourced to a private company by the Provincial Department of Health, however, the contract with the service provider had expired (reportedly a couple of months before our research) and no other strategy had been put in place to address delivery of medicines more sustainably. As one health centre manager explained,

"There is no challenge getting the drugs from the depot to here, the challenge is getting the drugs from here to the clinics because we have shortage of transport. All our vans are attached to programmes. They are used by mobile clinics, school health, circumcision so when there is a need for the clinics to get some drugs we have to borrow a van from that person. And the clinics are so many. We are having 18 clinics at the moment and they will soon be 22. We are short of vehicles

because even the clinic supervisors don't have a dedicated vehicle. The one that they are using, we used to take it when there is gas, it's the only long base van so when we have to deliver gas to the clinics we need that van and when we need to deliver medication then you have to borrow". (Facility manager, CHC 1, rural)

In the event of stock outs, providers reported that they either referred patients to alternative facilities or gave them another appointment date to return to the facility. Erratic supplies were reportedly one of the main factors leading to patients' loss of confidence in local clinics. At one of the urban CHCs, it was reported that pharmacy personnel had conducted a study to determine the amount of money spent on travel to facilities and the number of taxis taken per trip. Their investigation found that 60% of patients on ART lived outside the catchment area and generally took up to two taxis to reach the CHC. Among the reasons for not attending the nearest clinic, stock outs and perceived quality of service ranked highly. Accounts from TB and ART programme nurses corroborate this finding:

"We refer them to the local clinics but they come back because there is a shortage of treatment in the local clinics...we cannot chase them away because we know they need to take this treatment". (TB nurse, CHC6, urban)

"We have got so many facilities around here and they (patients) don't want to go to those clinics even though they are only walking distance...Sometimes they say there are no drugs there...we are still trying to investigate because we are always told that drugs are being taken to the clinic, how come the patients say there are no drugs?" (ART nurse, CHC 2, rural)

Accessibility

Key informants agreed that public transport to peripheral clinics, which public sector patients rely on heavily, is either absent or limited. According to providers, the district boundaries in rural locations, in particular, are out of sync with public transport networks. As a result patients opt for CHCs in town which are more accessible and safer to visit. The following accounts illustrate this point:

"There is a challenge because this CHC is very far from other clients. Now the problem is there are residential clinics (small, rural clinics) and the client will give the report that there is no transport from my area to the clinic so I only get the transport from my area to town so in the morning it's better to come to town, whereas they don't belong to this catchment

area, they belong to residential clinics...in the morning transport is going to town, maybe a bus or a van and you will find that they will be short of money and they will come after their old age pension grant and miss their appointment. We are having that problem with clients far away from us but we do register them because we don't know what to do. We do accept them with their problem we give them the return date three days before the treatment is finished so that there is a buffer in case they are late". (ART nurse, CHC1, rural)

"...we are not only serving this area, our so called catchment, they (patients) say to us it's better to take a taxi to come here than to go to the rural clinics because in the morning, transport wise it's not very easy and with other localities they don't have transport. They are afraid of being raped, so they prefer taking a taxi for twenty rand (approximately two United States dollars at time of research) to come to East London, and mind that is dependent maybe on the mother to get the money to come here". (Chronic care nurse, CHC5, urban)

Lack of transport is largely attributed to poor infrastructure and is the reason for transport operators avoiding certain routes. The following sentiments were captured regarding difficulties for patients in the Transkei region, a former homeland and a deeply deprived area in the province:

"... our roads are still not tarred, so some patients have to travel more than 50 km. You know 50 km in the rural areas is a lot, they can even take up to two hours because of the gravel roads...and in the rural areas by 5 p.m. the transport gets finished, so these people won't have transport to go back home. Some of the patients have to wake up at 3 a.m. when they come to visit the clinic, like for reviews...it's not fair". (Chief medical officer, CHC3, rural)

Accommodation

The down referral program which transfers patients to facilities nearest to their homes was implemented as a national strategy to improve ATM. There were mixed opinions about the success of down referral but there was consensus that uptake of services at the lower levels of care could increase if the quality of services, including the availability of medicines improved. Here accommodation of patient perceptions play a key role in the uptake of the intervention as illustrated below:

"People want to go to a place where there is a doctor, where there is availability of medicines. Even if they are not going to be seen by that doctor...as long as

they know that in the event that a condition warrants you to be seen by the doctor, the doctor will be there. There are people who don't want to go to clinics on that basis; they know there are nurses only".

(Pharmacist, CHC6, urban)

"...with the municipal clinics for example, they don't have a doctor every day, they don't have an x-ray machine, and they have certain days for immunization, for minor ailments, for chronics for example. Now here... you can come any day for immunization, you can come any time...and I think that is one of the reasons why they flock here. We've got many doctors, we've got six permanent doctors...they want a doctor, they want an x-ray, they want to come whenever they want to come".

(TB nurse, CHC5, urban)

"We do transfer them (patients) to the local nearest clinic, but sometimes they don't want to go there, they prefer to come here, they don't get the treatment at the nearest clinic, they say the treatment was out of stock so they decided to come here, but we are trying to take (refer) them back to the nearest clinic so they can afford money-wise".

"We are doing down referrals to the near sites but it's not proper because patients are going there in those clinics and they say they didn't get their medication".

(ART nurse, CHC4, rural)

In the context of working with the poor, proximity of health services to social services emerged as important because social grants are central to poor people's livelihoods. Many informants associated patients' choice of a health care facility with its closeness to other services such as social grant collection points and shopping centres. Providers reported that many patients rely on their or a family member's social grant to cover transport expenses. This was confirmed by the research team when a particular facility waiting area was relatively empty on the day of grant collection compared to other days. The ability to combine medicine collection appointments with other personal business made it more appealing as indicated by the following accounts:

"There are some clinics in other rural areas, but they say this is their town, Home Affairs is here, Social Development is here, Shoprite [supermarket] is here, so they say they will rather come to town, so they do everything and then come to the clinic".

"We have got eleven communities that we are serving. They are very far from here, it's more than 30 km...they

are rural and they are struggling to come here, others are not getting any grant and they don't have any money to come".

(Chronic care nurse, CHC4, rural)

Another important aspect in the organisation of disease control programmes is their inability to recognise that circular migration is a key feature among patients. Circular migrants are people who move between their places of origin to nearby urban centres or to other provinces in search of economic opportunities or for social reasons. For example, many people from the Eastern Cape Province move to the Western Cape Province seeking for economic opportunities and they travel between those provinces regularly. The provinces in some cases use different treatment protocols and this confuses not only the patients, most of whom recognise their medication by its physical appearance rather than generic names, but also providers, who feel overwhelmed by such scenarios as indicated by two nurses in rural settings.

"In the Western Cape they have their own regimen, which is not the same as ours here because even for transfers, we always have that problem because we many not know that regimen. You will find that the drug that is in our regimen two, they are using it for regimen one. Now that is confusing".

(TB nurse, CHC2, rural)

"Our concern is for people coming from KZN (Kwa-Zulu Natal province) who are on ATRIPLA (fixed-dose ART), that is one tablet and we are still using three separate drugs".

(ART nurse, CHC1, rural)

In some cases, patients travel without referral letters and as a result default on their treatment because they are apprehensive about going to the health centre without a referral letter. They delay seeking medical attention until they become seriously ill. The following narratives echo this point.

"With diabetes and hypertension, patients will say I was in Cape Town to see my sick child, and we will ask them but why didn't you carry your own clinic card, what about your own health?"

(Chief medical officer, CHC3 rural)

"...we tell them if you have to go somewhere come and report so that we provide extra medicine supply and if you are staying for a longer period then take the transfer letter. They don't come and report and they don't take their transfer letters. When they reach KZN, they are expecting the client to have the transfer letter so that they know exactly what is going on with him or her. Even if you trace by phone she says oh I am taking the

medication here. How? Because you didn't come to collect your medication and your transfer letter but they say no they are giving me. But then when she comes in two months later the card is still with that last date when she came here". (TB nurse, CHC2, rural)

"...they will tell you they have been to Cape Town but they don't come with a card from Cape Town so we don't know if they have taken the treatment or not". (Chronic care nurse, CHC3 rural)

"The patients are moving up and down that is why they are not adhering". (ART nurse, CHC2, rural)

Acceptability

Socio-cultural influences were also highlighted as fuelling stigma and the reason for some ART patients choosing to go to facilities that are further away from their homes, rather than nearer facilities. This was common among HIV patients and was not reported for other conditions. These three illustrations highlight this situation:

"...they (ART patients) are not happy about being seen taking HIV treatment in their clinics...if one persists, you observe and if you find out that they might end up not taking the treatment, we admit that one". (Facility manager, CHC4, rural)

"They stigmatise this condition (HIV) and we need to educate the people. I have got a brother who is HIV positive. I didn't know he was HIV positive until today...he has been getting treatment from an NGO in town. Now that NGO has closed because of financial issues, now they are referred to the hospital. I don't know whether he is running away from me or the centre itself". (Facility manager, CHC6, urban)

"We have a patient that comes once a month; she's an HIV positive lady and had TB also. She comes here ... for her treatment. So patients will go where they want to go even if you made hundred packs to leave at the (local) clinic, they won't go there. She spends five hundred rand (approximately 56 United States dollars at the time of research) to come here when it's time for her checkup. When it's not her checkup, her son comes but because she had TB she had to come two weekly you know but with the ARV, her son collects her ARVs. ARV's are expiring in other clinics because they don't want to go to there... That's why we have an overflow of patients here". (TB nurse, CHC5, urban)

Affordability

Although essential medicines are available free of charge in the public sector, unaffordable transport costs were

identified as a cross-cutting theme. In some instances patients could not afford to pay for transport to the nearest facility because of poverty. However, many other times, their circumstances were exacerbated by barriers identified under other dimensions of availability, accessibility, accommodation and acceptability. Differences in how medicines are distributed within various disease control programmes were viewed as an influence on the cost of accessing medicines i.e. ART availability in strictly accredited facilities poses a challenge for patients who have to travel longer distances because the nearest clinic does not offer ART. TB patients are among those who face the biggest transport challenges during their treatment period as they are required to make daily or weekly visits to the facility for their medicines. A TB nurse in East London estimated that some patients coming from afar pay approximately R60 (approximately seven United States dollars at the time of research) a day on transport and this was contributing to the defaulting rates.

Empathic provider responses to address ATM barriers

The providers' perspectives highlight the inadequacy of the existing formal responses in addressing many of the circumstances that impinge on equitable ATM. In confronting these challenges in their daily provision of care, providers adopt ad hoc decisions to meet the needs of their patients. There was agreement that because of patients' low incomes and dependence on social grants, household savings are almost depleted before their next clinic appointment. Some providers attempted to align clinic appointments with social grant collection dates so that patients can collect their medicines and social grants on the same day. Others highlighted that this was helpful for the patients but it was impractical with large numbers of patients as it would create an imbalance in patient load and insufficient health personnel to deal with patients on the busier days.

In other cases, providers reported that they assessed the patient profile and provided what they termed 'buffer' stock for a few additional days (usually less than one week) in case patients come late for their appointment. In most cases, however, providers dispensed medicines for longer than the stipulated policy to patients they deemed stable, but cautioned them to return to the facility if they felt the need for medical attention before their next scheduled appointment. This was at the discretion of the prescriber, usually the nurse. There were variations in terms of how much stock patients received but between two weeks and a month were common for TB treatment that would otherwise be collected daily and two to three months for HIV and diabetes treatment which would otherwise be collected monthly. Although the decisions were

made by prescribers, facility managers and pharmacy personnel were aware of this practice and supported it as highlighted below:

"The sister in the chronic[care department] has now developed a system of giving the treatment to those that are stable...she must give them for three months ...and then the fourth month they come for observations but those who are unreliable they must come monthly". (Facility manager, CHC4, rural)

"We do have those that are adhering so we give them their monthly supply. And because ...they don't want to use their (local) clinics, they come here and it is very far". (TB nurse, CHC2, rural)

Occasionally, providers reported assisting desperate patients with their personal finances to enable them to return to their homes. An illustration that was given by a nurse in an urban facility:

"...really we are stuck at times here with the patient, you will have to take your money, give patients to take taxis to their respective areas, because they are stuck here, maybe they are taken by the ambulance at night...there's no money, there's no escort, so you have to see to the finish. It is not easy to be a nurse, and when you look at us here, we are in an urban setting, think about the nurse who is working in the rural area; it is very much more difficult". (Chronic care nurse, CHC5, urban)

Provider views on future strategies to improve ATM

Providers described strategies that could be employed in the future to address poor quality of services in rural clinics, for example, having more sites accredited for ART or use of non-accredited sites merely as medicine collection sites and incentivizing doctors to work in rural sites so that staffing levels can be improved. One doctor indicated that she was the only doctor working at 27 clinics and this gave her an unreasonable work load. At the time of the research there was anticipation of a shift toward having all sites in the province managed by the Provincial Department of Health including those previously managed by the municipality. There was agreement that this move would improve coordination in the delivery of services and even resource sharing as indicated by one respondent:

"...there was no cooperation between us and the municipality; it is going to be better now. Even if there is a shortage in a particular clinic, if I am here as a manager, I could allocate my nurses to that clinic". (Facility manager, CHC6, urban)

We enquired about the potential role of mobile clinics in improving distribution of medicines although none of our tracer medicines had been distributed through the mobile clinics. Providers felt that mobile services have been geared toward dealing with minor ailments and as a result patients with comorbidities collect part of their medication from the mobile clinic and additionally, have to travel to the facility to collect their chronic medicines. This results in patients abandoning the mobile clinic completely and going to the facility where they can collect all their medicines simultaneously.

At an operational level, mobile clinics have been plagued by many challenges such as unavailability of vehicles committed to this service, bad roads and weather conditions which hinder physical accessibility and shortages of staff at the facility level which results in community appointments being cancelled as highlighted by these respondents:

"Our staff shortages mainly affect the mobile services where we only have two professional nurses and one nursing assistant. According to the organogram, we are supposed to have two teams with five professional nurses". (Facility manager, CHC2, rural)

"...at times they (service providers) have transport challenges so they will be disappointing those patients. They used to wait a long time, so they decided not to wait for the mobile clinic, they decided to come and get their treatment here. So if the mobile is not coming if that appointment date is cut, they wait there because of the transport problems". In addition, "...sometimes they (patients) used to say we are not getting all the treatment, others are out of stock, so they do come (to the CHC) for other treatment". (Chronic care nurse, CHC3, rural)

Issues pertaining to resources might be easier to address but addressing the needs of patients with comorbidities remains a challenge in areas where mobile clinics are not a supplementary service to the local clinic but are the only available means of service nearest to the people. While it is acknowledged that mobile clinics have the potential to address access barriers in hard to reach areas, some providers were sceptical about providing medicines such as ART through the mobile clinic citing intense administrative procedures associated with ART programmes, potential lack of privacy and limited contact time between patients and providers as the mobile vans move to different locations.

Discussion

Our findings emphasize the role of providers as health-care brokers with respect to their creative responses in

addressing patient needs and mitigating health system shortfall. A key benefit of this study was the ability to draw experiences across different essential medicines in both urban and rural settings and with providers who have different roles in the care pathway. The reported perspectives were largely shared across providers of different essential medicines. Our key informant interviews highlight important bottlenecks and system failures that correspond to the multiple dimensions of access [7] and the practical dilemmas that providers face in dealing with them. Providers are directly impacted by these challenges on the frontline of care and this study highlights the proactive strategies that they employ to ensure that patients obtain and remain on treatment. How providers enact the role of broker between the system and their patients is critical to consider in terms of the broader problem of medicine accessibility and health services in general. There is a need for broad-based changes encompassing all disease areas to improve ATM. In doing so, however, there is a need to take into account three tiers of brokerage: (i) ATM barriers with no solutions offered yet (e.g. bottlenecks in the medicines supply chain and socio-economic and cultural factors), (ii) ATM barriers with potential solutions outside the health providers' power (e.g. building improved transport networks) and (iii) ATM barriers with solutions already being implemented (e.g. flexibilities in prescribing and dispensing to suit patient needs). Implications for practice are discussed through presentation of a number of mechanisms with a set of critical questions to ask when addressing ATM.

First, the medicines supply chain is undermined by severe resource constraints and structural weaknesses often leading to stock outs and provision of inferior services. Patients respond to system barriers by 'shopping' for better services within the system or with alternative providers if they can afford the associated costs. Otherwise, they give up [12]. Similar to another study in South Africa [22], providers highlighted haphazard movement of patients within the health system as one of the threats to the down referral program. This emerged as a key factor that prohibits efficient planning related to medicines supply at primary level facilities. The supply chain needs to be equipped to deal with the growing demand for consistent supply of medicines, especially chronic medicines and this involves proper planning at all levels.

Second, context and patient characteristics play an important role in provision of medicines. For example, circular migration emerged as a key feature of the patient population yet health services tend to assume that patients are permanently situated in a particular locus. As a result, many patients are lost to follow up or default on treatment when they temporarily migrate from one place to the other. Also, relative to urban patients, rural

patients face more access barriers as a result of poverty and underdeveloped transport infrastructure. Peters and colleagues found that the poor in low and middle income countries (LMICs) are consistently at a disadvantage in each of the dimensions of access and their determinants [23]. Another South African study also highlighted the financial burden of costs associated with health care on patients [8]. Both supply- and demand-side barriers carry a financial consequence for patients, particularly with respect to transportation. For example, patients incur costs for greater distances travelled in dealing with underdeveloped transport infrastructure or medicine stock outs in more proximate clinics. Patients' ability to afford health related costs depend, among other things on any earnings, the composition of the social grants that a household receives, the size of the household and the household priorities. In light of this, improving access to medicines requires engaging in intersectoral actions between health, welfare and infrastructural development. Organization of "circular" public transport, instead of only "centripetal" transport, which gives users incentives to travel to town, instead of to the local health centre, is required.

Implications for policy and practice

Findings from this study suggest that many providers are aware of the existing barriers to accessing medicines. They are taking advantage of the flexibilities within the health system, which enables them to make critical, responsible and responsive decisions in practice. They are attempting to address these challenges in creative and empathic ways. Indeed, clinical empathy is a quality that is deemed critical in determining patients' ability to cope with both illness and quality of care and to improve health outcomes [24,25]. Our findings allude to the commitment of providers and the important role that they are playing in discovering the needs of the populations they serve and the efforts to address them. This draws attention to the social reality of relationships and interactions occurring at the patient and provider level and offers a different view to previous studies which found this relationship to be largely negative [12,26]. It is plausible that continuous patient-provider interaction, as evidenced by the average of eight years that health providers work in the same facility, promotes nurturing of positive relationships wherein providers better understand the challenges that patients face.

However, the practice of prescribing and dispensing for periods beyond what is lawfully allowed deserves careful attention, given the consequent impact of less frequent monitoring and patient follow-up. Providers however, suggest that dispensing medicines to stable patients with chronic conditions for up to six months would help reduce travel costs and de-congest health centres. They do not view this strategy as a threat to

public health because patients are free to return to the facility as needed. Although prescribers have devised ways of evaluating patient stability through assessing health outcomes over time, the standard differs from place to place. The current variation in dispensing practices in order to address patient concerns raises important questions for policy and suggests a need to look into whether there is merit in institutionalising the informal strategies currently employed from an evidence-based point of view. Recent studies report that with the right kind of community support, it is feasible to provide treatment for longer periods [11]. Also, a recent program in South Africa has piloted provision of ART for longer periods with good results [27]. In the absence of standardised and evidence-based dispensing practices in order to address patient monitoring, the informal strategies reported in this paper may not produce optimum patient therapeutic outcomes.

It is also worth noting, that the current strategies employed by providers favour patients who are deemed stable and might further discriminate against patients who are unable to visit health centres because of multiple barriers. Diversification of strategies to improve ATM is absolutely critical. Diversification involves looking beyond the conventional facility-based approach by considering, among others, community based models which maintain identifiable links with the health system to increase the trust of the users.

Finally, the emergence of chronic non-communicable diseases and multiple morbidities is fast becoming the rule rather than the exception and efforts to pre-engineer the system towards a comprehensive, integrated, horizontal primary health care system should be considered. For instance, a recent analysis of mortality causes in South Africa has highlighted more deaths resulting from non-communicable diseases such as diabetes than from HIV [28]. A responsive system takes into account the limitations of a vertical system while at the same time ensuring that medicines for priority conditions are not compromised [29]. Responsiveness also requires taking into account characteristics of the population served to ensure that circular migrants have continuous ATM and to address other social, cultural and economic barriers more appropriately. Ultimately, addressing these ATM barriers creates a healthier working environment for providers and protects them from situations where, for example, they occasionally feel obligated to assist stranded patients.

Conclusion

Effective ATM to minimise treatment interruption requires addressing supply- and demand- barriers concurrently with a consideration for context. The evidence presented in this paper shows the importance of all five access barriers (availability, accessibility, accommodation,

acceptability and affordability) and the complex ways in which they interact with each other. Issues that require further research include diversifying methods for distributing medicines in rural settings, understanding whether the brokerage mechanisms adopted by providers actually improve ATM, and determining whether such practices are appropriate, feasible and sustainable. It is also critical to understand the characteristics of the population served to ensure that circular migrants have continuous ATM. Finally, the brokerage role of providers is underutilised and we recommend that as ongoing practice, they should be actively engaged in intersectoral discussions aimed at improving the health care response.

Abbreviations

CHC: Community Health Centre; AMASA: Accessing Medicines in Africa and South Asia; TB: Tuberculosis; ART: Anti-retroviral treatment; KZN: Kwa-Zulu Natal; WHO: World Health Organisation; LMICs: Low-and-middle income countries.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed to the conceptualisation of the research. BM conducted the field research. BM, KW and DS contributed to the conceptualisation of the manuscript. BM undertook qualitative data analysis and drafted the first draft of the article. All authors contributed to the intellectual content of the article. BM finalised the article. All authors read and approved the final manuscript.

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Paper II



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Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa

Bvudzai Priscilla Magadzire^{1*}, Bruno Marchal^{1,2} and Kim Ward³

Abstract

Background: The Chronic Dispensing Unit (CDU) is an out-sourced, public sector centralised dispensing service that has been operational in the Western Cape Province in South Africa since 2005. The CDU dispenses medicines for stable patients with chronic conditions. The aim is to reduce pharmacists' workload, reduce patient waiting times and decongest healthcare facilities. Our objectives are to describe the intervention's scope, illustrate its interface with the health system and describe its processes and outcomes. Secondly, to quantify the magnitude of missed appointments by enrolled patients and to describe the implications thereof in order to inform a subsequent in-depth empirical study on the underlying causes.

Methods: We adopted a case study design in order to elicit the programme theory underlying the CDU strategy. We consulted 15 senior and middle managers from the provincial Department of Health who were working closely with the intervention and the contractor using focus group discussions and key informant interviews. In addition, relevant literature, and policy and programme documents were reviewed and analysed.

Results: We found that the CDU scope has significantly expanded over the last 10 years owing to technological advancements. As such, in early 2015, the CDU produced nearly 300,000 parcels monthly. Medicines supply, patient enrollment processes, healthcare professionals' compliance to legislation and policies, mechanisms for medicines distribution, management of non-collected medicines (emanating from patients' missed appointments) and the array of actors involved are all central to the CDU's functioning. Missed appointments by patients are a problem, affecting an estimated 8 %–12 % of patients each month. However, the causes have not been investigated thoroughly. Implications of missed appointments include a cost to government for services rendered by the contractor, potential losses due to expired medicines, additional workload for the contractor and healthcare facility staff and potential negative therapeutic outcomes for patients.

Conclusions: The CDU demonstrates innovation in a context of overwhelming demand for dispensing medicines for chronic conditions. However, it is not a panacea to address access-to-medicines related challenges. A multi-level assessment that is currently underway will provide more insights on how existing challenges can be addressed.

Keywords: Centralised dispensing, Access to medicines, Medicines supply chain, Medicines distribution, Chronic diseases, Pharmaceutical services, Chronic Dispensing Unit, Missed appointments, Western Cape, South Africa

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Background

Access to essential medicines is considered a fundamental part of universal health coverage and a key element for the delivery of services and high-quality care [1]. A 2012 assessment of the South African health system underscored the need to give a higher priority status to medicines supply chains as they affect various dimensions of access to medicines and health care utilisation in general [2]. Although South Africa offers free primary health care (PHC) services in the public sector, subscribes to an essential medicines programme [3] and provides free medicines at PHC level [4], there are persistent challenges that hinder sustainable access to medicines. The increasing burden of disease [5], coupled with a general shortage and maldistribution of health professionals (private-public, urban-rural) [6], for example, threaten the ability of supply chain systems to function optimally. Shortages in all areas of pharmacy practice are common. Vacancy rates for pharmacists in the public sector of up to 76 %, were reported in one province and only 29 % of pharmacists were working in the public sector as of 2010 [7]. Various reforms and interventions have been implemented to address shortages of pharmacists, such as the introduction of incentives, the impact of which is yet to be determined on pharmaceutical human resource trends [8] and new models of centralised dispensing of medicines for chronic conditions [9, 10]. In this article, we report on a centralised dispensing intervention in the Western Cape Province, in South Africa.

Western Cape Province's response to strengthen access to medicines

Each of South Africa's nine provinces has its own legislature, premier and executive council, and specific population and economical characteristics. The Western Cape is South Africa's most cosmopolitan province, with a population of just under six million in 2011 [2]. The 2010 mortality profile reported that about 65 % of deaths occurred in the metropolitan district of Cape Town [11], which has the greatest proportion of patients and the greatest pressure on health services [9]. HIV/AIDS and non-communicable diseases (NCDs), account for a large proportion of premature mortality [12]. The healthcare system is two-tiered, consisting of a public and a private sector. However, the vast majority of the population (more than 75 %) is dependent on the public sector for, inter alia, supply of medicines [13].

The Western Cape Department of Health (WCDoH) established an out-sourced, centralised dispensing intervention known as the Chronic Dispensing Unit (CDU). Introduced in December of 2005, the CDU dispenses medicines for stable, public-sector patients with the aim to: reduce pharmacists' workload (by relieving pharmacy

staff from repetitive and time consuming tasks that detract from patient-focussed elements), decongest health facilities (hereafter referred as facilities) and improve the patient experience by reducing waiting times [9, 10]. The contractor, is responsible for specific supply chain functions which are elaborated on in later sections of this article.

The CDU was initially implemented as part of the province's first strategic vision for health care (Health Care 2010), which acknowledged the necessity to substantially improve the quality of care of the health service, while recognising that *"One of the biggest challenges facing the Department is the need to ensure that its workforce meets the challenges of service delivery within a changing environment with a sizeable burden of disease."* [14]. Since its establishment in 2005, the CDU has remained a significant part of the province's plans. The current provincial strategy (Health Care 2030) states that *"...it is expected that the CDU will be well-established in future and will assist to address the increasing demand for efficient dispensing of chronic medicines, which are expected to form the bulk of the burden of disease in the next two decades"* [15]. In light of this, the CDU has been presented as part of the motivation for an increase in the health budget allocation [16], and a huge financial investment towards this service has been made. The current five-year contract between the government and the contractor, which commenced in 2012, is valued at 500 million South African rands [17], which was approximately 62,5 million United States dollars in 2012.

Despite the leadership's commitment and efforts, several operational challenges exist. Among these challenges, the trend of missed appointments by patients is a concern to the WCDoH and our study was commissioned to investigate this issue. Within the context of this intervention, the term "non-collected medicines" is used to refer to pre-packed Patient Medicine Parcels (PMPs) that are not picked up by patients on or close to the scheduled date and are subsequently returned to the CDU. Monthly collection statistics are a key monitoring indicator of the intervention's performance.

In this paper, we provide a comprehensive description of the operations of the CDU and seek to gain a better understanding of the current issue of concern—i.e. missed appointments. Earlier articles described the CDU in its initial stages of implementation focusing mostly on the dispensing processes [9, 10]. We set out to elicit the programme theory (defined as processes planned to achieve certain outcomes), which according to Van Belle et al. [18] is useful for understanding complex interventions. More specifically, this study aims to identify the actors' interpretations of how the CDU's activities are linked to the outcomes. Therefore, our

objectives are: (1) to illustrate the CDU's interface with the health system and describe its coverage, dispensing capacity and beneficiary profile; (2) to quantify the magnitude of missed appointments by patients and (3) to describe the implications thereof in order to inform a subsequent in-depth empirical study on the underlying causes.

Methods

Design

We adopted the case study design. This approach is appropriate because of the limited literature on the intervention and the need to understand how certain processes take place in order to comprehend the phenomenon [19].

Data were collected from multiple sources using focus group discussions, key informant interviews and document and literature reviews. We consulted 15 purposively selected key informants: senior and mid-level managers within the WCDoH involved in policy development and implementation of the intervention; and the current contractor (UTI Pharma).

The breakdown of respondents is provided in Table 1. Key informant perspectives were complemented by a review of published articles. We also carried out a review of CDU-related documents, including service level agreements, standard operating procedures, quarterly reports, conference proceedings, press statements, academic theses as well as routine data collected by the CDU. We developed a data collection tool that listed pre-determined variables of interest (e.g. coverage, dispensing capacity, demographics of beneficiaries and non-collected medicines). It also contained open-ended questions on processes and the issue of medicine non-collection. Data was collected between 2013 and 2014.

We started the analysis of qualitative data by developing descriptive narrative accounts to map the intervention processes. We analysed the quantitative data using descriptive statistics in Microsoft Excel, including means and frequencies on age, gender, coverage, dispensing capacity and non-collected medicines. For data on non-collected medicines, we focused only on 2014 data, post introduction of the revised "returns policy" for healthcare facilities as data quality was expected to improve as

a result of the policy revisions. For validation, we used member checking [20]. We circulated the draft manuscript to implementers of the intervention and invited comments.

Ethics approval for this study was granted by the Senate Research Committee at the University of the Western Cape (Ref: 11/7/8). Consent to interview and record interviews was obtained from participants. They were also informed of their right to withdraw from the interview at any time. To ensure anonymity, participants were assigned codes that were known only by the first author.

Results

Implementation context

The administration of public sector health services in the Western Cape Province falls under either of two jurisdictions. The provincial authority (WCDoH) administers a number of urban and rural facilities at the primary, secondary and tertiary levels of healthcare. The Cape Town Metropolitan municipality administers most primary healthcare clinics within its jurisdiction.

Healthcare facilities in this province rely on two complementary methods of medicines dispensing. Traditionally, patients with acute conditions and patients who are not yet stabilised on therapy for chronic conditions obtain their medicines at the dispensary of the healthcare facility that they use. On the other hand, the CDU is designed to dispense medicines for stable patients.

Key informants estimated that about 60 % of all patients with chronic conditions in the province obtained medicines through the CDU, although this is yet to be verified empirically by the WCDoH. Medicines dispensed by both the CDU and public-sector healthcare facilities are sourced from the government-owned Cape Medical Depot (CMD).

Mapping the intervention processes

We mapped the key processes between the CDU, the CMD and healthcare facilities, and identified the corresponding actors/stakeholders such as clinicians, the contractor and patients. Furthermore, we identified each actor's responsibility and the relationships between the different actors (Fig. 1). Full narrative descriptions of the actors and processes are provided as Additional file 1.

Table 1 Study participants

Level	Participant description	Number of participants	Research method used
Senior management	Western Cape Department of Health personnel	3	1 focus group discussion
Middle management	Sub-structure pharmacist managers	5	Key informant interviews (2 face-to-face and 3 telephonic)
Implementation team and support	Western Cape Department of Health personnel and the contractor	7	2 focus group discussions

Although we depicted one healthcare facility as an example, this process is similar for all facilities registered with the CDU.

An implementation team, comprising WCDoh personnel and the contractor is at the core of the implementation strategy. This team orients new facilities to CDU policies in order to promote effective uptake of the intervention. Thereafter, implementation support is maintained by liaison officers appointed by the contractor to facilitate smooth roll-out of the intervention.

Scope of the intervention

Coverage

The CDU has and continues to apply a phased approach to enrolling healthcare facilities. Using various WCDoh reports, we tracked the increase in this enrollment. The CDU commenced with eight urban healthcare facilities in 2005. By mid-2008, just over 40 facilities were enrolled and later that year, the incorporation of rural regions started. By the end of 2013, over 100 facilities were enrolled, reaching 216 facilities in early 2015. The CDU more recently focused on

enrollment of rural facilities and supporting decentralised pick-up points. Although PMPs are generally delivered to a healthcare facility, actual distribution is also occurring at alternative sites, such as mobile clinics, community clubs, old age homes and workplaces, most of which are linked to the nearest healthcare facilities. When healthcare facilities register alternative distribution sites with the CDU, PMPs are labelled separately from those distributed from the healthcare facilities. The CDU had 2724 registered alternative sites at the end of 2014.

Dispensing capacity

With an average of five to six items per prescription (which are all packaged in one PMP), the CDU dispensed over one million items each month in early 2015.

The first batch of PMPs in 2005 was 984 in total. This increased to almost 20,000 PMPs by the end of 2006 and almost 80,000 by the end of 2007. Over the next 4 years (up to 2011), 100 % growth occurred (80,000 to 160,000). Growth slowed down to 25 % between 2011 and 2013 (160,000 to 200,000 per month). This was most likely due

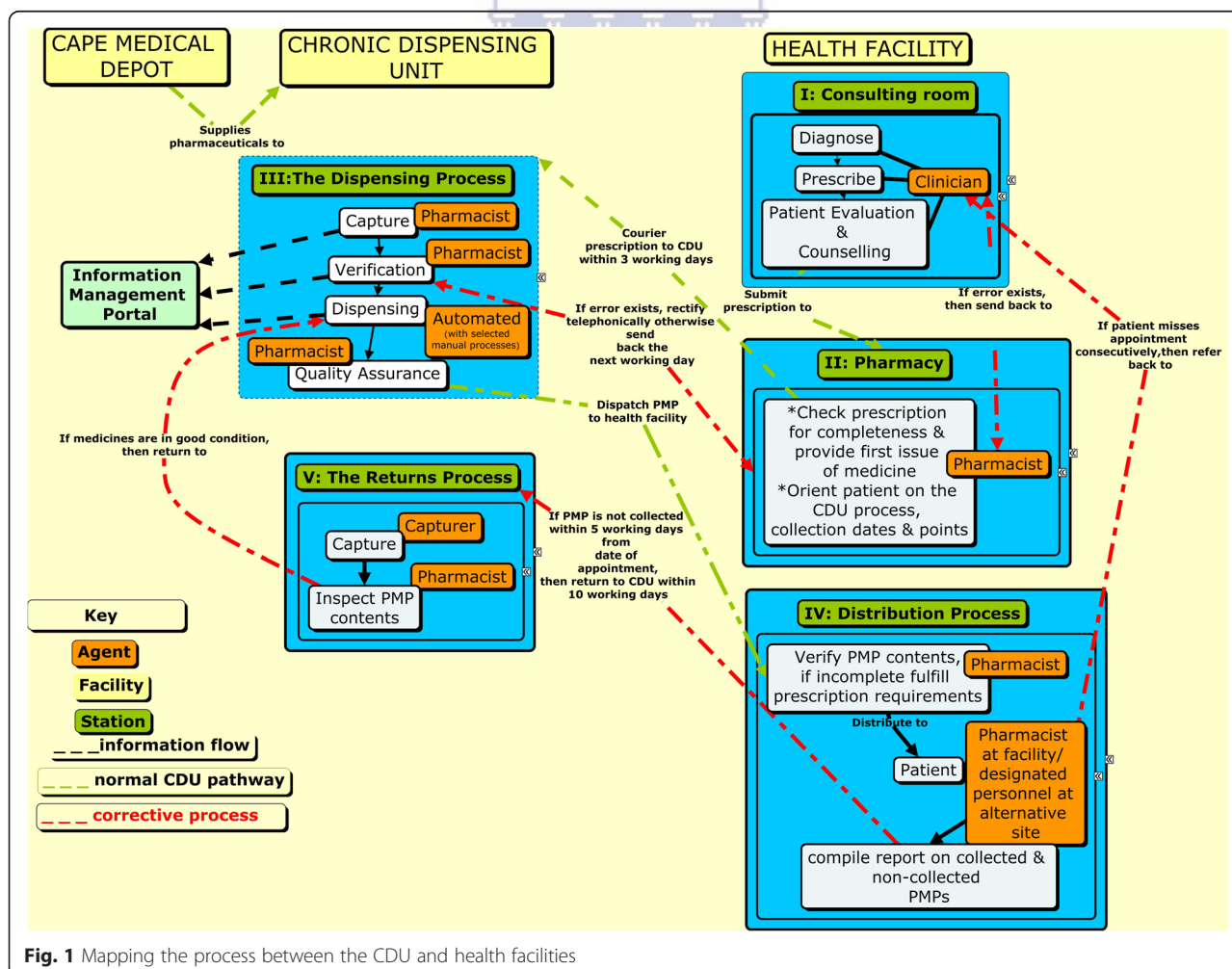


Fig. 1 Mapping the process between the CDU and health facilities

to the change-over processes to a different contractor. Complexity of data transfer between the out-going and incoming contractors partly affected the new contractor's ability to continue the service efficiently. This was further compounded by the implementation of new business processes and the commissioning of sophisticated dispensing equipment [21]. For the first few weeks of the transition, the new contractor and WCDoh jointly reverted to manual dispensing as an interim measure. WCDoh suspended some facilities from the CDU for about 3 months to allow the service to stabilise again.

Between 2013 and 2014, the dispensing capacity steadily increased with over 350,000 PMPs produced in October 2014. This high volume of PMPs was partially explained by the four months' supply of antiretroviral therapy to accommodate the December/January festive period which is associated with patients travelling to their home provinces. The dispensing volume per month in the first quarter of 2015 was approximately 300,000 PMPs.

About 77 % of PMPs were delivered to urban healthcare facilities and 23 % to rural ones. The number of PMPs delivered to each facility ranged from under 1,000 to about 15,000 per site, per month. The increased dispensing capacity was facilitated by technological advancements, including largely automated processes for certain functions such as picking, packaging and labelling of medicines.

Enrollment of patient beneficiaries

According to the procedure, patient enrollment should be based on a clinician's assessment of the patient's clinical stability. Patients who fail to achieve clinical stability and those with conditions demanding more regular monitoring (e.g. certain mental health conditions) or taking medicines requiring stricter control (e.g. benzodiazepines) should be excluded.

Patient characteristics: age, gender and disease profile

In early 2015, the CDU had 213,682 active patients (85 % urban and 15 % rural). Males constituted 34 % and females 66 % of the cohort. Slightly more than 80 % were over the age of 40 years, illustrating that the CDU served a predominantly adult population (Fig. 2).

It was not possible to evaluate the disease patterns from the CDU data since up to this point; the CDU does not capture patient diagnosis data. However, dispensed items were classified according to the Medi-Span Generic Product Identifier (GPI) classification. This is a hierarchical identifier, which provides specific information about medicines [22] and which may, to some extent, provide insights into patient diagnosis. We found that in 2013 and 2014 anti-hypertensives, diuretics, anti-diabetic agents, analgesics/antipyretics as well as bronchodilators constituted more than 50 % of the items dispensed each month. About 12 % of the PMPs contained HIV treatment.

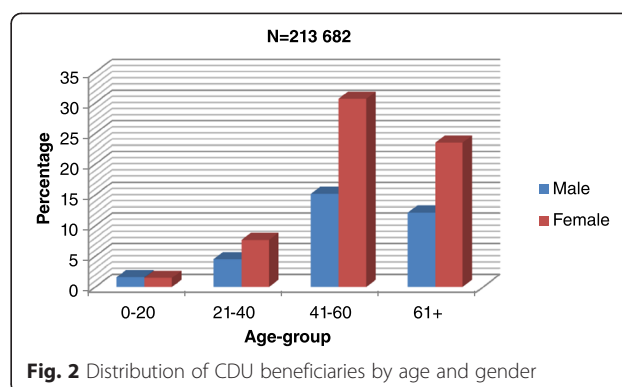


Fig. 2 Distribution of CDU beneficiaries by age and gender

Missed appointments by CDU beneficiaries

At inception, a monthly allowance of 4 % "non-collection" was factored in to accommodate for loss-to-follow-up or death. However, we found that for the year 2014, an estimated 8 % to 12 % of PMPs were returned to the CDU as a result of non-collection. These were likely to be conservative estimates, since many facilities under-reported on collection statistics: the percentage of facilities that duly reported each month was only in the range of 24 % to 67 %. Furthermore, rural areas were excluded in the analysis since enrollment of most facilities was recent and the intervention had not stabilised. Some key informants suspected that since PMP collection statistics were regarded as a performance indicator, there was a disincentive to report statistics that could potentially be viewed negatively. In 2014, the WCDoh revised the "returns policy", requiring healthcare facilities to strictly adhere to the returns time-frame i.e. within 10 working days from the scheduled collection date. Previously, some healthcare facilities kept non-collected PMPs for months to over a year before returning them to the CDU.

We found that missed appointments had several implications. First, medicines expired before they could be redistributed by the CDU. Second, the CDU's average monthly consumption data were being distorted and subsequently impacted negatively on forecasting. Third, missed appointments imposed a financial burden on the government as the service provider is paid on a "fee-per-PMP-delivered" basis, meaning that every PMP that is not collected is still to be paid for yet it does not reach the patient. Fourth, missed appointments increased the contractor's workload due to additional administrative processes and the efforts required to re-integrate stock into the dispensing system. At the healthcare facility level, missed appointments also generated more work for the pharmacy personnel, as they had to absorb medicines into the local pharmacy (if PMPs were not returned to the CDU). Furthermore, facility-based pharmacists dispensed medicines from the pharmacy or dispensary if the patient presented late and in some cases

the clinician also had to consult with the defaulter patient. This undermined the efficiency benefit of the CDU. Finally, there were concerns of possible negative outcomes if patients missed appointments and subsequently defaulted on treatment.

We enquired about the possibility of identifying “best practice” facilities for benchmarking purposes. Key informants suggested that missed appointments were a widespread problem and that the variation between facilities was difficult to discern because of under-reporting, as alluded to earlier. However, respondents suggested that inclusion of urban healthcare facilities in benchmarking attempts was more ideal as the intervention has entered into the routine stage in these facilities. Cohort size was also perceived to influence patient management practises, i.e. larger patient cohorts were presumably more challenging to manage. One informant said, *“If you can solve it for these (large) sites, then you have solved it for the rest.”* There was a general interest to focus on improving collection of medicines for treating NCDs, since the disease burden was higher than that of HIV in this province and disease programmes were presumably much less developed for NCDs than for HIV.

Discussion

This paper describes the gradual expansion of the CDU over the last 10 years. It also shows how missed appointments by patients are an important problem in CDU implementation [9] and that the causes of this have not been investigated thoroughly. In general, limited studies have been conducted on the CDU, there are no baseline data and a comprehensive evaluation is yet to be conducted. To prepare for further in-depth research, we carried out this exploratory case study, which provides a detailed description of the actors and components of the intervention. It points to some preliminary explanations about how the CDU is expected to work (the underlying assumptions, planned intervention and expected results). It also shows how the programme is actually running and it explored the actual results.

This study has some limitations. First, we are as of yet unable to present clear trends of missed appointments. Data quality was questionable due to under-reporting by healthcare facilities and conflicting data sources. In addition, data on patient diagnosis and outcomes which could have informed some aspects of our study have not been captured up to this point.

Despite these limitations, our preliminary results are in line with the (scant) publications. Missed appointments are not a new phenomenon to this intervention [9] or in healthcare provision in general [23–27]. If the same problem has persisted, what should be done differently to attain a different outcome? Some authors have suggested that unexpected results could be because a good intervention theory is not being carried out well or the problem is the theory itself [28]. In the case of the

CDU, existing evidence suggests to some degree that the CDU objectives have been achieved and cite benefits such as reduced waiting times [9, 10, 29], patients’ improved experiences with healthcare services and their motivation to remain stable, increased time for patient counselling [9, 10], and pharmacists’ ability to serve more than double the number of people they served prior to CDU implementation [29]. Despite these reported benefits, however, we report the difficulty to ascertain how most of the conclusions were reached, the sustainability of the gains and the inability to generalise the findings. There are also differing views which show that implementation results might be variable. For instance, Munyikwa’s study found that pharmacists’ workload had not decreased as anticipated. Instead, pressure shifted from dispensing to managerial and administrative tasks and pharmacists reported that the patient base had increased. As a result, time for patient counselling was still limited. In addition, only a few patients reported reduced travelling costs [29]. This was not surprising given that the sample only consisted of patients who collected medicines from the healthcare facility and not from alternative sites in the community.

Implications for further research

There is a dearth of literature on models of centralised dispensing. Also, out-sourcing of selected supply chain activities is considered to be minimal in low-and-middle-income countries [30]. While we are aware that centralised dispensing occurs in the private sector in other countries, particularly high-income countries, this has not been documented in Africa. To our knowledge, the CDU is the first public sector, large-scale, centralised dispensing model in South Africa, and the only such model in Africa. As a result, implementing it without experiences from similar interventions to learn from was cited as a challenge [9]. However, despite this limited evidence, -centralised dispensing is gaining momentum in South Africa, especially as a part of the on-going National Health Insurance pilot programme in other South African provinces [31]. This underscores how centralised dispensing is a preferred strategy for improving access to medicines for public-sector patients in South Africa [32]. This paper advances the understanding of the CDU and lays a foundation for future work that aims to improve the intervention and provide lessons for similar models. This is crucial because the challenges that led to the establishment of the CDU are not unique to South Africa. Many countries with low economic indicators tend to have relatively similar challenges in their health systems [33].

The lack of evidence to explain possible causes for missed appointments call for in-depth research into CDU implementation. Placing the known implementation problem (in this case, missed appointments) as a

starting point to enquiry has been cited as a useful way to understanding interventions [28]. It is likely that implementation results will be variable across healthcare facilities. Investigating facility-specific characteristics, such as human resources, infrastructure and staff motivation [34] and the impact of the intervention on the healthcare provider, patient access to treatment and difficulties in implementation could also be necessary [35].

Conclusion

The CDU in the Western Cape province in South Africa reflects innovation in organisation, structure and delivery of healthcare in a middle-income country with a substantial demand for medicines for chronic conditions. Such a model has the potential to increase access to medicines in other settings. However, it is not a panacea for overcoming all challenges pertaining to access to medicines. This study informed a multi-level assessment that is currently underway to understand the problem of missed appointments within the context of implementation related factors.

Additional file

Additional file 1: Process description of the Chronic Dispensing Unit (CDU) and health facilities. (DOCX 15 kb)

Abbreviations

CDU: Chronic Dispensing Unit; CMD: Cape Medical Depot; LMICs: Low-and-Middle Income Countries; NCDs: Non-Communicable Diseases; PMP: Patient Medicine Parcel; WCDoh: Western Cape Department of Health.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BPM, BM and KW contributed to the conceptualisation of the research and this manuscript. BPM conducted the research, analysed the data and drafted the article. All authors contributed to the intellectual content of the article. BPM finalised the article. All authors read and approved the final manuscript.

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Paper III



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Novel models to improve access to medicines for chronic diseases in South Africa: an analysis of stakeholder perspectives on community-based distribution models

Bvudzai Priscilla Magadzire^{1*} , Bruno Marchal^{1,2} and Kim Ward³

Abstract

Background: The rising demand for chronic disease treatment and the barriers to accessing these medicines have led to the development of novel models for distributing medicines in South Africa's public sector, including distribution away from health centres, known as community-based distribution (CBD). In this article, we provide a typology of CBD models and outline perceived facilitators and barriers to their implementation using an adapted health systems framework with a view to analysing how future policy decisions on CBD could impact existing models and the health system as a whole.

Methods: A qualitative exploratory study comprising in-depth interviews and non-participant observations was conducted between 2012 and 2014 in one province. Study participants consisted of frontline healthcare providers (HCPs) in the public sector and a few policy, supply chain and public health experts. Observations of processes occurred at two CBD sites. We conducted deductive analysis guided by the adapted framework.

Results: Models varied in typology ranging from formal (approved by the Department of Health) to informal (demand-driven) and with or without user-fees. Processes and structures also differed, as did HCPs' perceptions of what is appropriate. HCPs perceived that CBD models were largely *acceptable* to patients and *accommodating* of their needs. *Affordability* of services linked to charging of user-fees was a contested issue, requiring further exploration. CBD models operated in the absence of formal policy to guide implementation, and this, coupled with the involvement of non-health professionals, issues regarding medicines handling and storage; and limited patient counselling raised concerns about the quality of pharmaceutical services being delivered. Policy decisions on each of the health system elements will likely affect other elements and ultimately influence the structure and operational modalities of models. In anticipation of a future CBD policy, stakeholders cited the need for a *context specific* lens in order to harmonise with current implementation efforts.

Conclusion: A formal policy on CBD is required in an effort to standardise services for quality assurance purposes. Frontline HCPs should be involved in the development of such policy to ensure that existing arrangements already working well are not undermined. Further research will seek to contribute towards evidence-based development of policy and service delivery guidelines for CBD activities in South Africa.

Keywords: Community-based distribution, Access to medicines, Pharmaceutical policy, South Africa

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Background

South Africa shares with the rest of sub-Saharan Africa a high burden of chronic diseases, including HIV and non-communicable diseases [1]. This has led to an increasing demand for medicines for treatment of disease in a context of a weak health system [2]. The increased burden of disease has illuminated the need for the government to be more responsive to population needs and to ensure that people obtain health services (including accessing essential medicines) without suffering financial hardship. The latter are in line with principles of universal health coverage (UHC) [3].

The South African government released the National Health Insurance (NHI) White Paper in December 2015. This policy document discusses various health insurance modalities and reforms aimed at strengthening the country's health system. These include: expanding access to pharmaceutical products, a primary healthcare re-engineering strategy and establishment of an office of health standards compliance. Furthermore, it describes a vision of what is required for the successful implementation of NHI [4].

Against this background, we have witnessed a shift in the local access to medicines (ATM) domain, from a largely health facility-based approach to providing medicines for chronic diseases to novel community-based distribution (CBD) models, also referred to as alternative distribution or out-of-clinic models [5]. While the term “distribution” within the broader medicine supply chain context encompasses ordering, transportation and logistics management at various levels [6], its use in this article is confined to logistics activities to get patient-ready pre-packaged medicines to patients. This has been referred by some authors as the “last mile”, where services are delivered to patients and often at the most vulnerable stage of distribution [7].

CBD models use community halls and similar gathering places as sites for medicine distribution, exploiting the proximity of these venues to patients' homes. Sometimes, they also include home deliveries. These models are geared towards addressing various supply- and demand-side barriers to accessing medicines [8]. Such barriers include: long waiting times, overburdened health centres which discourage patients from collecting medicines and reducing travel costs to distant health facilities. Furthermore, CBD models can allow for task-shifting to mid-level cadres or even to expert patients in order to address human resource shortages [9, 10]. The latter is facilitated by the choice of target beneficiaries, i.e. stable patients not requiring regular contact with a healthcare provider (HCP). Such patients can be sufficiently empowered to self-manage [11] and have six-monthly consultations. CBD is not only recognised in South Africa as an interesting solution to restricted access to medicines [12, 13], but in many other developing countries, [14–16] including Mozambique [5, 17–19], Zambia [20] and Kenya [21]. CBD models are driven by non-

governmental organisations (NGOs) in the majority of cases.

While CBD is gaining momentum in South Africa, the range of models and the pace of implementation are variable across provinces. This could be explained in part by the health system's governance structure, which allow provinces a fair degree of autonomy in the administration of health services [22]. The Western Cape is one province where CBD has been widely implemented. In this province, CBD falls under the umbrella of community-based services, an important component of the broader primary healthcare (PHC) platform that features in the provincial strategy for health, Healthcare 2030 [23]. CBD is facilitated by centralised dispensing of patient-ready medicine packages by a private distributor to health facilities [24–27]. These packages can easily be transported to CBD points.

This article draws on selected findings from a broad exploratory study commissioned by the Western Cape Department of Health (WCDoH) to improve access to medicines (ATM). The overall study sought to identify strategies to address the challenge of missed appointments among patients with chronic diseases in the metropolitan district of Cape Town [24]. We also sought to understand the structure of ATM strategies and the facilitators and barriers to effective implementation. We targeted frontline healthcare providers (HCPs), most of whom engage with patients on a regular basis. These stakeholders have a critical role in the attainment of policy outcomes yet their role is often overlooked [28, 29]. Our research showed that many HCPs identified CBD (among a few others) as an existing innovative strategy for ensuring that medicines reach patients. However, they also cited challenges, of which the most important was the lack of policy to govern CBD activities even though their implementation was actually underway. The implication was that certain issues related to CBD could be open to multiple interpretations. We discovered early on that governing CBD activities was far from being simple, given that these are “non-traditional” mechanisms for medicines distribution.

As the development of a CBD policy is a current priority in South Africa, in this article we seek to contribute to the policy-making process by exploring how CBD models currently operate in the Western Cape Province's local health system and identifying the perspectives of frontline HCPs regarding CBD models. In order to provide evidence that could inform policy design, we have adapted the health systems framework of van Olmen et al. (the framework) [30] as an analytical tool for the following reasons:

- a) Its ability to assist us to identify and discuss the key elements of CBD models (e.g. medicines supply, human resources, infrastructure and population) and

to draw the interconnections between the elements which will be of relevance to the design of CBD policy;

- b) Its ability to frame CBD operations within the context of the broader health system;
- c) The importance it attaches to values and principles in policy-making [22].
- d) Its recognition of health systems as social systems which comprise people and organisations, and their interactions with others. As such, actors' values, interests, norms and relationships also influence the ultimate character of the system [31].

In this article we use the framework to provide a systematic description of CBD models and to illustrate how the configuration of the elements in each CBD model contributes to its effectiveness. Finally, we explore how our findings could inform the development of an impending CBD policy by drawing upon the perspectives of stakeholders.

Methods

Study design

This exploratory qualitative study was conducted between 2012 and 2014 in the metropolitan district of Cape Town, which has the greatest proportion of patients and the greatest pressure on health services in the Western Cape Province [24, 25].

Data collection

We used in-depth interviews, non-participant observations of two CBD sessions and document review as the data collection methods for this study.

Key informants

For this article, we drew from 45 in-depth interviews, which were conducted by the first author using a semi-structured interview guide. We purposively sampled informants who were most knowledgeable about the issues of interest from the following categories: (1) frontline HCPs, including doctors, nurses, pharmacists and pharmacist's assistants (PAs) from four PHC facilities, (2) policy makers, (3) sub-district and provincial managers from the WCDoH, (4) private sector pharmacists, (5) academics with expertise in pharmaceutical policy and public health and (6) NGO staff (Table 1). Interviews were conducted in English and each interview lasted about one hour. All the interviews were conducted at a place convenient for the respondents, i.e. their place of work. Where possible, interviews were recorded; alternatively, notes were taken. Three participants refused to be recorded as a matter of preference. Once no information was generated from the interviews and saturation was reached, no further interviews were conducted.

Table 1 Respondents' breakdown by professional category

Category	Number of respondents
National level policy maker in pharmaceutical regulation	1
Senior provincial directors and policy makers	5
Academic in public health	1
Provincial managers of the medicines supply chain	2
Mid-level managers (sub-structure pharmacists; primary healthcare managers)	4
Frontline health workers (clinicians, health promoters, NGO workers)	28
Private sector pharmacists	4
Total	45

Non-participant observations

The first author conducted observations on two occasions. The first session was for distribution of HIV treatment and another for distribution of medicines for non-communicable diseases (e.g. diabetes and hypertension). Both sessions took place in Khayelitsha, one of the largest townships in South Africa. During observations, the first author took note of patient-patient and patient-provider interactions and the process in general. Other items that were recorded included the queries that were posed by patients and any information related to patients' knowledge about their medication.

Document review

We reviewed guidelines and standard operating procedures for CBD in order to understand how the models are currently implemented [32, 33].

Data analysis

The recordings were transcribed verbatim and deductive analysis was applied. We sought for : (a) structure of CBD models, and used the main elements of the *analytical framework of van Olmen et al.* [30], (Fig. 1) which links the central elements required for models to function optimally i.e. *resources* (medicines, human resources, infrastructure, financing, monitoring and evaluation) to the performance of the service delivery platforms. All these elements require good *governance* (policies, regulatory frameworks) and *leadership*, taking into account the population's needs and demands [34] to attain ATM in terms of its different access dimensions or *outcomes*; i.e.: availability, affordability, accessibility, acceptability and quality) [35, 36] and ultimately improved health status and social and financial protection. Access outcomes can be broadly defined as follows:

- *acceptability*: fit between clients and providers' mutual expectations and appropriateness of care;

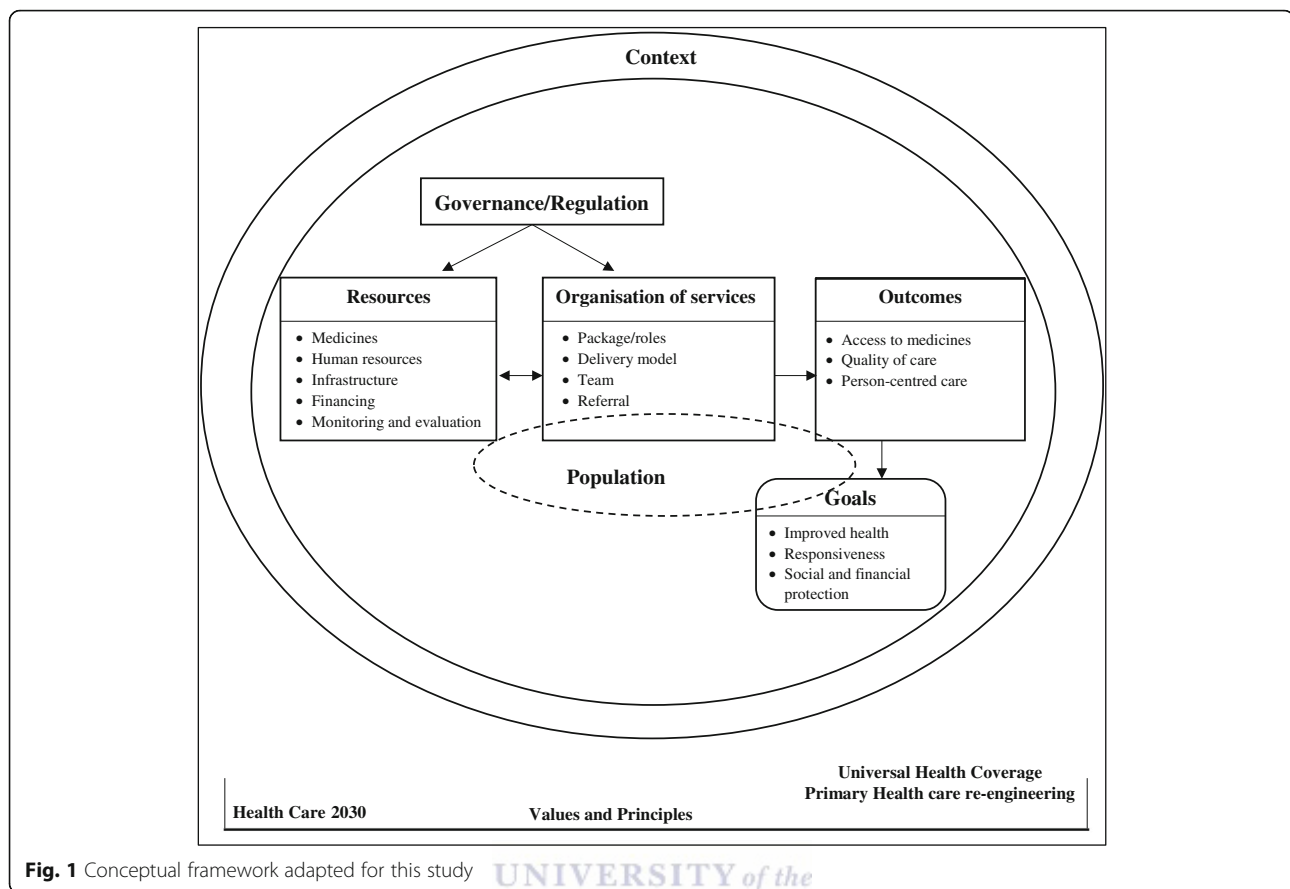


Fig. 1 Conceptual framework adapted for this study

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- *accommodation*: fit between organisation of services and clients' practical circumstances;
- *availability*: fit between existing resources and clients' needs;
- *accessibility*: fit between physical location of healthcare and location of clients;
- *affordability*: fit between cost of care and ability to pay [35].

Outcomes are expressed both quantitatively and qualitatively by our adopted framework [30]. However, in the absence of objective outcome- and impact-level data for CBD models, we assessed selected outcomes only qualitatively, from the perspectives of informants. Accessibility is an inherent design feature of CBD models and as such this was not assessed. Using data from interviews and observations, we assessed how models were perceived by informants and patient engagement with CBD services. Our assumption was that if models increase ATM, this could be a proxy for utilisation. In addition, we considered *facilitators and barriers to effective implementation* and *context factors* because CBD models are embedded within a broader health system and these factors can influence outcomes and goals (Fig. 1). Quality was a cross-cutting issue

addressing the issues of scientifically and medically appropriate and good quality services. This is determined by aspects such as human resources and good quality medicines.

Data from document review and observations were used to triangulate key informant data.

The first author conducted the initial analysis (coding, retrieving of quotations representative of major themes and interpretation) using Atlas. TI version 7. Emerging themes were discussed with selected key informants through three feedback sessions (participant checking).

Results

This section starts by presenting an overview of how CBD services are organised (*Typology of CBD models*) then presents the remaining findings according to the elements of the framework (*human resources, medicines, infrastructure and population*). Finally, we present our findings related to *governance*, taking into account the implementation context.

Typology of CBD models

From the interviews with key informants, we found variation in focus and structure of CBD models implemented

in the Western Cape Province. Regarding geographical spread, some areas had a single model while others had a combination of models. The mix of models available in an area was primarily dependant on the presence and mandate or interests of particular stakeholders whose activities tended to be geographically demarcated. However, they were all linked to nearby PHC facilities for medicines supply. In this article, we categorised them as formal and informal as explained below:

- I. **Formal:** Models officially recognised and approved by the WCDoH. Services were provided free of charge to the patient. Formally recognised providers were expected to facilitate referrals and linkage to care for patients at risk who require consultation with the health provider. Some models were based on direct involvement of trained HCPs (i.e. nurses and/or post-basic pharmacists), while others were driven by community health workers (CHWs) with some basic health training, linked to NGOs.
- II. **Informal:** Models driven by entrepreneurs with no basic training in health. They charged a service fee to the patient and were not officially recognised by the WCDoH. Informal providers could be described in two ways: either operating under the 'approval' of mid-level management or known anecdotally, but not easily identifiable. The latter operated on a small-scale and could not be easily distinguished from a relative or friend collecting medicines on behalf of the patient. At the time of research, service fees charged by the known informal providers ranged from ZAR10.00–20.00, which was equivalent to approximately US\$1.00–2.00. It was unclear how informal providers market their services or initiate services in the absence of the approval of senior provincial leadership.

Patient enrolment in all the CBD models was facilitated by nurses and health promoters during club

sessions (group-based education), and patients were asked to provide consent for their information to be supplied to the service provider of their choice. Table 2 shows the range of models that we identified at our study sites. We acknowledge that this list may not be exhaustive for the Cape Town metropolitan area.

Resources

Human resources

As illustrated in Table 2, task shifting from pharmacists to other HCPs and Non-Health Professionals (NHPs) is a common feature in CBD models. There was contention between participants about the involvement of NHPs and their permitted scope of practice.

Proponents for task-shifting in CBD models argued that this mechanism could address existing human resource shortages in the South African public sector by “de-medicalising” treatment to ensure sustainability of models. Informants cited a situation illustrating lack of sustainability of medicalised models: a clinical nurse practitioner was asked to urgently return to the health facility from a CBD site leaving patients unattended and necessitating their referral back to the health facility.

Another stakeholder (academic) argued that patient counselling by pharmacists, though desired, was in most cases impractical. The informant's own research showed that pharmacists in the Western Cape spend an average of only three minutes (range: 2–4 min) of face-to-face contact with a patient due to workload pressures. In light of these health workforce issues, stakeholders suggested the need for greater efforts towards empowering patients to manage their own therapy thereby reducing the need for regular contact with HCPs.

Those who opposed involvement of NHPs in CBD cited their lack of accountability to statutory bodies as a major concern in delivering pharmaceutical services. This is currently a grey area in the task-shifting discourse because

Table 2 Overview of models for community based distribution of medicines

Type of model	Classification	Human resources	Financing	Beneficiary population as per disease state
1. Distribution in community halls, churches, old-age homes or mobile clinics	Formal	Pharmacist's assistants, nurses	Health facility budget therefore government funding	HIV and/or NCDs
2. Distribution in small municipal clinics that do not offer NCD services	Formal	Pharmacist's assistants	Health facility budget therefore government funding	NCDs
3. Home delivery	Informal	Local social entrepreneurs	Out-of-pocket payments	NCDs
4. Home delivery or other community venues ^a	Formal	Community health workers ^b	A few organisations have international funding while the rest receive grants from the Department of Social Development (DSD) and other local businesses.	NCDs

^aPlaces where the elderly meet for skills development and social activities, also termed Chronic Disease of Lifestyle clubs which the WCDoH identified through the DSD

^bAttached to NGOs with service level agreements with the WCDoH

statutory bodies only regulate personnel who are registered with them.

Other concerns raised by participants related to the capacity of NHPs to: (i) conduct quality assurance (QA) processes (e.g. verifying medicines before handing them over to the patient), (ii) monitor therapeutic outcomes and (iii) link at-risk patients to appropriate care. These tasks are outside their scope of practice therefore, perhaps a more pertinent question is: which tasks should NHPs be expected to carry out? Many informants argued that QA processes should be ensured by the Chronic Dispensing Unit (CDU), a centralised dispensary responsible for dispensing and pre-packing of medicines in the public sector in this province. If performed optimally by ensuring minimal prescribing and dispensing errors, this would eliminate the need for checking parcels at the distribution point upon issue to patients. With QA processes out of the way, this would technically not be a full dispensing process, allowing NHPs to comfortably participate in the process.

It seemed even pharmacists who were responsible for checking the pre-packed medicine packages felt that the QA demands were time consuming and detracted from the intended benefits of both the CDU (which was established to reduce pharmacists' workload) and of CBD (which was established to take the pressure off health facilities and to improve access for patients).

While some informants mentioned that they would feel comfortable relying on CHWs to issue medicines that were already checked at the CDU, some clinicians were still reluctant. They suggested that CBD activities be placed under the responsibility of registered pharmacy mid-level workers known as pharmacist's assistants (PAs) as opposed to CHWs. A further suggestion was engagement of private-sector pharmacies to distribute public-sector medicines. In subsequent years, this model was proposed under the NHI scheme [37].

Medicines supply management

Our findings show that inefficiencies in procurement (a macro-level issue) affected medicines availability at the CDU where dispensing for CBD programmes takes place. As such, medicines omitted from parcels would require manual dispensing at health facilities, another reason why informants were sceptical about NHPs involvement as the final link to patients. As stated by a senior manager:

"I wouldn't like at this stage for community health workers to give medication, because, once in a while, something is missing, because of the out-of-stock situation. Now we got a serious situation as well...the Cape Medical Depot cannot always supply because of change of tender."

Another contentious issue raised was the handling and storage of "non-collected" medicines, i.e. parcels

not collected by the patient on the appointment date. The handling of medicines by untrained personnel and their storage in transient unregistered sites casts doubt on the integrity of non-collected medicines and as such, these medicines are usually disposed of with resultant cost implications. Informants were of the opinion that some of these risks could be obviated if sites met minimum standards for medicine storage.

Infrastructure and logistics

Securing reliable venues for CBD activities emerged as another important aspect of CBD. During the time of our study, services were interrupted at one site because it was no longer available for CBD. The PA at the site expressed concern about the potential loss of confidence by patients experiencing service disruption. In addition to securing venues, opening times for the venues needed careful consideration. This often called for negotiation with the owners of the venue to ensure that times were suitable for the patients.

Reliable transportation for medicine delivery to CBD sites was also identified as a need. Government vehicles could be requested by PAs linked to formal CBD models, but this transportation mode was not accessible to CHWs who often walked to sites and carried the supplies. According to informants, the latter not only posed security risks and environmental risks for the medicines, but created inefficiencies for CHWs with home-based care duties who were often late for CBD activities. Informal providers used bicycles and this was also feared to potentially render medicines vulnerable to environmental risks.

Outcomes

Acceptability of CBD models and accommodation to clients' practical circumstances

We used our observation data related to patient-provider and patient-patient interactions during the CBD process to look into the *acceptability* of the models. Interactions between patients and providers and between patients were largely positive. Patients showed no restraint in engaging with the providers involved in CBD (both HPs and NHPs) even when they presented late for their appointments. In some cases, CHWs reported taking the initiative to deliver medicines to patients' homes when they failed to collect at community venues, a means of *accommodating* patients' practical circumstances. These deviations from formal processes were merely acts of goodwill facilitated by positive patient-provider relationships, but were noted to contribute to *acceptability*. Furthermore, CHWs reported using cost-effective social media methods such as the instant messaging application "WhatsApp" to remind patients of their appointments and to follow-up with those who missed appointments. In this regard, the close

patient-provider interactions allowed for some degree of patient follow-up where there had been limited to no follow-up mechanisms in the health system. These experiences also reveal a form of grassroots innovation that could improve patient retention-in-care in the long-run.

Informants collectively felt that CBD models are suitable for patients who are empowered to take responsibility for the management of their illness. From observation during CBD operations, some patients were able to accurately identify their medicines, including identifying any missing medicines when there were medicines availability challenges.

Despite the positive aforementioned aspects, there were some concerns with stigma. At one site (a small municipal clinic which traditionally offered HIV services and was later also used as a distribution site for NCD medicines), patients on ART raised concerns about privacy because their appointments overlapped with patients enrolled in NCD programmes. With medicine collection points for ART being distinct, patients with HIV were easily identifiable and this was a huge concern for those who had not disclosed to family and friends. This raised questions about the appropriateness of integrating HIV and NCDs in the design of CBD models.

At a second site, providers also noticed similar reluctance from clients on ART. The pharmacist's assistant in charge of CBD at the site said:

"...we told them that it's only them who are going there; there are a lot of offices so no one will know why you are walking through that building, what you are going to do there..."

While in principle, patients should be offered the choice to collect medicines at CBD sites or at the health facility, in practice there seemed to be pressure to enrol all patients onto CBD models, because of the perceived benefits for both the health system and the patients. Asked if patients had a choice regarding their collection point, one PA stated *"...we don't prioritise that freedom"*. In their view, once patients experienced the benefits of CBD, they appreciated the system and in most cases were no longer interested in the facility-based model.

Affordability to patients: to pay or not to pay for CBD services?

As stated earlier, the critical difference between the formal and informal CBD models was that the former provides services at no charge to the patient while the latter levies a user-fee. Many stakeholders grappled with the issue of paid services: some senior managers expressed disapproval of imposing out-of-pocket payments on the premise that medication was free and no direct charges should be introduced to the patients, while others feared that the absence of regulation on

levying fees could result in patient exploitation. Indeed, some patients had apparently mentioned to informants that the services were expensive for them but some HCPs still argued that paid services were demand-driven and that many patients were willing to pay for a service offering convenience. One nurse and PA were of the opinion that the elderly derived particular benefits since they often have impaired mobility, lack family and other support to collect medicine on their behalf and many stayed in areas that are not served by formal models. Also, the formal models had limited capacity to serve a large population. Some respondents felt that paid services offset the usual indirect costs for transport fees to the health facility and thus had no objection to charging fees for CBD services.

At the time of our study, one of the four study sites had no history of "fee-for" services, a second site still charged a fee and the remaining two sites had been mandated to cease services that attached a fee. Although some frontline HCPs approved of services levied for a fee at the second site, senior managers had strong reservations. However, HCPs reported that some patients still enquired about the service and attributed increased non-collection of medicines to the management's decision to stop these paid services. One pharmacist elaborated as follows:

"A few years ago, we had a courier service that was privately run and we had an objection from the government that it's unconstitutional to charge patients from a primary health care level. Then we stopped it. The patients benefited a lot from it and up to this day, patients are still asking "When is it coming back and why can't we have it back?", because they were prepared to pay. But the department said it is criminal for patients who can't afford the service. It didn't make sense to us but it came from the top level to be stopped basically, but it was working well and we were pushing almost 200 parcels a day from the facility." [Pharmacist]

In essence, views on paid services were quite divergent, with provincial managers expressing the need to safeguard patients against exploitation and with some frontline HCPs indicating that paid for services are demand-driven and should remain an option to patients.

Governance: Policy and regulatory issues

As stated earlier, for any service delivery model to function effectively, all health system elements require good governance in the form of policies and regulatory frameworks which consider the population's needs and demands.

At the time of this study, there was no policy to institute CBD models and guide the implementation efforts in the Western Cape. Stakeholders were not aware of

policies in other parts of the world enabling the use of non-registered sites for distribution of medicines for chronic diseases and as an interim measure, they developed standard operating procedures (SOPs), based loosely on available pharmacy and health regulations. Stakeholder views on these SOPs varied. As one provincial manager explained:

"... this (CBD) is new ... There was, like, really no definite law to guide the Pharmacy Council. So, whatever has happened has been an interpretation of the law by someone (provincial stakeholders) ..."

We were informed by a key actor during this study that some engagement between provincial and national stakeholders responsible for the policy making process had commenced by 2014. The South African Pharmacy Council (SAPC), which is the statutory professional body for pharmacy, together with the National Department of Health (NDoH) which has oversight of health activities and legislation, were cited as the two governance bodies responsible for drafting legislation. While recognising that CBD policy development is a national priority and that the process of policy-making can be slow, stakeholders insinuated that the process has not been altogether transparent. We found there was limited consultation of frontline HCPs on the issue and that no feedback on progress of the policy development process was given at this level. One senior manager had some information on the process and reported that a task team had been set-up and was steadily working on developing the policy.

Stakeholder perspectives on the future CBD policy

In general, informants envisaged that the policy will define organisation of CBD services to ensure the delivery of quality pharmaceutical services as defined by the Good Pharmacy Practice (GPP) standards [38]. There were some shared concerns that some aspects inherent to CBD models do not meet GPP standards, *inter alia*, medicines handling and storage and possible lack of patient counselling.

Some stakeholders justified the current structure of CBD services while others showed disfavour towards some aspects of CBD and offered suggestions for improved organisation and structure. Despite varying opinions on what the content of the CBD policy ought to be, a critical issue that was raised was the need for the policy to be *context specific and pragmatic*. There were concerns that existing CBD models could be jeopardised if the upcoming policy prescribed the use of qualified personnel (HCPs) and/or distribution from health sites only. It must be understood, however, that the call for flexibility is not akin to accepting sub-standard service. Rather, it is a call to be realistic regarding what is both *feasible and sustainable* in the local context. As one manager said:

"...they (regulators) need to draft the legislation to reflect pharmaceutical services as they are delivered in 2015, and going forward not in 20 years ago and in 30 years ago. Medicines are not ordinary commodities. The integrity of the medicine has to be maintained... but our request collectively to council (SAPC) has been could one look at a framework where one could legally issue the medicines that are not on a health site... and have a set of norms and standards for the issuing of medicines ... as long as rules and standards are met and maintained and monitored."

Furthermore, the call for regulators' flexibility stemmed from the simple realisation that more diversification is required if the province (and indeed the country at large) is to truly expand ATM. A private-sector pharmacist elaborated on this aspect as follows:

"I said to somebody from council (SAPC): we are trying to put down first world standards which is very noble, but we are a resource lacking third world, essentially, third world country. We have a component of first world, but ninety per cent is third world. We are a developing country. I hope it gets taken into consideration, because I think it's going to make implementation of a lot of what national health (insurance) wants to do almost impossible to start."

The quote above called into question the degree of alignment between the province's and country's goals of improving ATM and the focus by professional statutory bodies on what were sometimes perceived as rigid standards. There was also a prevailing view that perhaps professional bodies were minimally consulted in the development of CBD strategies and that subsequent disagreements are arising between policy stakeholders:

"...how much dialogue is actually happening between national, what national (NDOH) is trying to bring through the National Health Insurance versus what Pharmacy Council (SAPC) is saying and the statutes to everybody in terms of best policy. I don't think they are on the same page as to what the best practice is. (private-sector pharmacist)"

On a positive note, despite a lack of consensus among stakeholders on certain issues, there was notable commitment from the WCDoH leadership to engage with SAPC and eventually align with the future CBD policy. Stakeholders also anticipated that CBD implementation could eventually cost more than is currently envisaged if provinces have to invest in training personnel and adapting venues to meet requirements for medicine handling and storage for example.

Discussion

CBD models are regarded as a useful way to improve ATM in the Western Cape Province. In this article, we described a range of formal and informal CBD models present using the framework by van Olmen et al. [30]. The framework enabled us to illustrate how the configuration of the elements in each CBD model could contribute to its effectiveness and furthermore, to illustrate the interconnections between the CBD models and the wider health system elements, indicating how policy decisions on each of these elements will likely affect other elements. For example, the framework argues for the need to recognise patients' own contributions to their personal well-being [30]. Through our research, we noted demand-driven operations by informal providers in a context where senior managers were opposed to the idea. Some differences between formal and informal models were that the formal models are a health system response and therefore, at least in theory resourced and accountable to the system while informal models are grassroots driven, self-funded and with no accountability mechanisms to the health system. However, both have the same goal of improving ATM.

Another key lesson from the application of the framework is that it is the combination of different health system elements that makes a model work well. For example, a decision on the human resource cadre(s) could influence the structure and operational modalities of CBD models, particularly when task-shifting is

introduced and mechanisms for accountability and quality assurance become essential. Table 3 summarises what we identified to be facilitators and barriers associated with each CBD element in its current form, an approach we envisage will inform the policy debate.

Despite increased interest in CBD by stakeholders in the WC, medicines are governed by pharmaceutical policy, therefore, who handles them and how they are handled becomes a matter of regulatory interest. This dimension needs to be carefully navigated to ensure safety of the population. As there is currently no CBD policy, we explored how our findings could inform the development of a future policy, through knowledge of context needs and demands. Through this study, we have brought the voices of frontline HCPs to the policy discussion on ATM. As stated by Gilson & Raphaely, "*Policy actors are not just those officially tasked with policy development; they also include those with concern for particular policy issues or likely to be affected by policy developments...*" [39]. We identify HCPs as such because of their important role at the coal-face of the health services and as such as the actual implementers of policy.

We identified some lessons from this study which could inform the policy development process. First, reaching a consensus requires broad stakeholder consultation as part of the policy development process, which to our knowledge has not yet been conducted in this case. Despite some stakeholders being aware that the policy development process had commenced, we found that consultation

Table 3 Summary of how CBD elements facilitate or constrain CBD implementation

CBD element	Facilitators	Barriers
Medicines	<ul style="list-style-type: none"> Centralised dispensing simplifies distribution process. 	<ul style="list-style-type: none"> Quality assurance processes must be fulfilled by HCPs prior to "last mile" distribution; Stock-outs of medicines cripples CBD models; Non-collected medicines cannot be re-dispensed.
Human resources		
Community Health Workers	<ul style="list-style-type: none"> Positive, close relationships with patients which can facilitate active follow-up when necessary. 	<ul style="list-style-type: none"> Not able to conduct quality assurance processes.
HCPs	<ul style="list-style-type: none"> Missing medicines from patient-ready parcels can be dispensed manually by the HCP at the CBD site. 	<ul style="list-style-type: none"> General shortage of HCPs undermine sustainability of deploying them to CBD sites.
Informal providers	<ul style="list-style-type: none"> Demand-driven therefore likely to suit beneficiary needs. 	<ul style="list-style-type: none"> No governmental oversight which could lead to financial exploitation of patients; no accountability to professional statutory body which could compromise quality of pharmaceutical services.
Infrastructure and logistics	<ul style="list-style-type: none"> Government vehicles available for transportation of medicines for some models. 	<ul style="list-style-type: none"> Poor transport systems for CHWs causing delays and posing security and environmental risks to medicines; Availability of venues not always guaranteed.
Patient (population)'s engagement with CBD models	<ul style="list-style-type: none"> Positive patient-patient; patient-provider relationships; Some patients knowledgeable about their treatment regimen and proactive in addressing medicine-related concerns. 	<ul style="list-style-type: none"> Stigma associated with HIV still a reality.

and feedback on the progress of the process was not inclusive and that frontline HCPs who are responsible for implementing policies were not involved. Acknowledging that policy processes are in essence political, how much influence actors have might be contingent on their position in the political hierarchy, more than their knowledge and understanding of the issue [40]. Hence in this study, we have sought to elevate the voice of frontline HCPs, who possess knowledge and understanding of grassroots issues. This stakeholder group has been referred to as “street-level bureaucrats”: they are tasked with policy implementation and often have to balance policy demands with the realities of their context [41]. Considering their perspectives during the policy development process could result in more responsive policies. As echoed by Morrow (2015), the process of formulating a pharmaceutical policy is as important as the policy document in ensuring collective ownership [42].

Second, the resistance by some stakeholders to aspects of CBD corroborates findings in other countries. Indeed, previous studies have shown that diversion from traditional ways of delivering pharmaceutical services and task shifting in the pharmaceutical sector in its different forms has in many instances met with resistance [43, 44]. Experiences of resistance to different CBD models were documented in Mozambique with the introduction of self-forming patient groups [19] and in Tanzania with the implementation of community retail drug shops, but this changed with time [45]. In Mozambique, as stakeholders gained knowledge and confidence in the model and the benefits became apparent, endorsement increased [19]. In Tanzania, retail drug shops which are a major source of medicines in rural and underserved areas also initially faced resistance, then catalysed development of policies. Of note, the Tanzania model illustrated that even informal providers can be assisted to comply with regulatory standards [45]. Whether or not this will become the experience of providers in our context, remains to be seen.

Implications for future research and the policy agenda

The current provincial [32, 33] and national [4] goals for UHC in South Africa include both CBD and a commitment to provision of quality services [46], presenting an opportunity to leverage the existing political window. However, while the need to develop a policy to govern CBD activities in South Africa is evident, it is uncertain what changes the anticipated policy will bring to existing models. As earlier indicated, many of our informants hoped that the introduction of policy will not pose a barrier to further implementation of current CBD models. This has been experienced in other contexts where innovation in community-based services began outside of public regulation [47]. We argue that despite the diverging stakeholder views, CBD must be assessed within

the lens of what it is endeavouring to achieve - sustainable ATM. The World Health Organisation (WHO) has recommended in other instances that implementing regulation targeted at innovative models should neither decelerate the speed at which action is already taking place nor usher in restrictions that may have a constraining effect on public health service delivery effort [48]. That said, there is need to conduct accurate assessments of the effectiveness of these models and to ensure that they are implemented in a way that ensures patient safety.

In addition, informal models present an additional set of challenges, i.e. the lack of accountability mechanisms and the potential financial burden on patients caused by paid services. While it is true that there are high poverty levels in this context, the paid option is voluntary. Perhaps the critical question is: “Why do patients choose to pay for medicines delivery when they can get a ‘free’ service?”. Since we did not interview patients paying for this service as part of this study, we can only speculate that the parallel system tends to thrive because there is an opportunity cost related to the informal system, i.e. it offers benefits (e.g. the convenience of not having to take time off work, which could result in a cost of a different kind) that might not be present within the formal ‘free’ system. Future studies could assess whether this system imposes a financial or any other burden on patients. If it does, but has other benefits to patients, the next issue is whether the government can lend support to informal providers so that they operate at a lower or no cost to patients.

Finally, further research is required to identify how CBD models have been implemented in other settings and their cost to health systems. Therefore, as a follow-up study, we have designed a scoping review which aims to obtain systematic evidence about design and implementation of CBD models in low resource settings and hard to reach populations in high income countries. We intend to assess whether the issues raised in this article were identified and if so, how they were or could be managed or overcome.

Study limitations

A limitation of this study was the adoption of the analytical framework after data collection; therefore, not all components were addressed equally during interviews with stakeholders. This is particularly true for monitoring and evaluation of CBD models, an area that requires attention in future studies. Second, the lack of accurate data on outcomes imposed some limitation.

Conclusion

Improving medicines delivery is integral to attaining UHC and the introduction of CBD in South Africa is one mechanism to achieve this goal. To achieve the

intended benefits of CBD, frontline HCPs should be consulted in policy development and consideration should be given to similar models in other contexts. Further research will seek to contribute towards evidence-based development of policy and service delivery guidelines for CBD activities in South Africa within the frameworks of pharmaceutical policy and practice.

Abbreviations

ATM: Access to medicines; CHW: Community health worker; DSD: Department of Social Development; HCP: Healthcare provider; NGO: Non-governmental organisation; NHP: Non-health professional; PA: Pharmacists' assistant; PHC: Primary Healthcare; QA: Quality assurance; SOPs: Standard operating procedures; UHC: Universal Health Coverage; WHO: World Health Organisation

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Authors' contributions

BPM conceptualised the research, conducted the fieldwork and data analysis. All authors contributed to the conceptualisation of this manuscript. BPM drafted the first draft of this article. All authors contributed to the intellectual content of the article. BPM finalised the article. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Ethics approval for this study was granted by the Senate Research Committee at the University of the Western Cape, South Africa (Ref: 11/7/8). All participants were taken through the informed-consent procedure prior to interviewing, including a request to record the interview if the participant was willing. Participants were also informed of their right to withdraw at any time without any consequences in accordance with the requirements of the Helsinki Declaration of 2008.

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Inefficient procurement processes undermine access to medicines in the Western Cape Province of South Africa

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Background. South Africa (SA) has experienced several stock-outs of life-saving medicines for the treatment of major chronic infectious and non-communicable diseases in the public sector.

Objective. To identify the causes of stock-outs and to illustrate how they undermine access to medicines (ATM) in the Western Cape Province, SA.

Methods. This qualitative study was conducted with a sample of over 70 key informants (frontline health workers, sub-structure and provincial health service managers). We employed the critical incident technique to identify significant occurrences in our context, the consequences of which impacted on access to medicines during a defined period. Stock-outs were identified as one such incident, and we explored when, where and why they occurred, in order to inform policy and practice.

Results. Medicines procurement is a centralised function in SA. Health service managers unanimously agreed that stock-outs resulted from the following inefficiencies at the central level: (i) delays in awarding of pharmaceutical tenders; (ii) absence of contracts for certain medicines appearing on provincial code lists; and (iii) suppliers' inability to satisfy contractual agreements. The recurrence of stock-outs had implications at multiple levels: (i) health facility operations; (ii) the Chronic Dispensing Unit (CDU), which prepacks medicines for over 300 000 public sector patients; and (iii) community-based medicines distribution systems, which deliver the CDU's prepacked medicines to non-health facilities nearer to patient homes. For instance, stock-outs resulted in omission of certain medicines from CDU parcels that were delivered to health facilities. This increased workload and caused frustration for frontline health workers who were expected to dispense omitted medicines manually. According to frontline health workers, this translated into longer waiting times for patients and associated dissatisfaction. In some instances, patients were asked to return for undispensed medication at a later date, which could potentially affect adherence to treatment and therapeutic outcomes. Stock-outs therefore undermined the intended benefits of ATM strategies.

Conclusion. Addressing the procurement challenges, most notably timeous tender awards and supplier performance management, is critical for successful implementation of ATM strategies.

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Medicines shortages (stock-outs) have been cited as a complex global problem. Evidence suggests that the causes vary greatly and include issues that government agencies often do not have control over, such as supplier shortages.^[1] Stock-outs appear to be worsening with time globally, which presents a threat to patient wellbeing and could result in loss of life.^[2] At a global level, multi-stakeholder activities to evaluate the causes of stock-outs and to develop appropriate mitigating strategies have been initiated.^[2]

Like many other countries, South Africa (SA) has experienced several stock-outs of life-saving medicines. There has also been a spate of media reports on stock-outs of essential medicines for treatment of HIV and major chronic non-communicable diseases.^[3,4] A 2012 publication by the National Department of Health (NDoH)^[5] reported a 54% failure in compliance with measures addressing availability of medicines and recommended priority attention to supply chain management. Local research has found that confidence in the public sector has waned as a result of stock-outs.^[6]

These and other ongoing challenges in the SA medicines supply chain served as the impetus to investigate the supply chain and to identify barriers to access to medicines (ATM) and existing strategies for improving ATM under the Accessing Medicines in Africa and South Asia project.^[7] In this quest, we acknowledged that ATM

barriers are multi-layered, with overlapping and interconnected causes,^[2,8] and that the supply chain in SA is diverse and complex. Notwithstanding these complexities, it is expected to reliably supply pharmaceuticals from manufacturers to provincial depots and sub-depots (in some cases), and directly or indirectly to all levels of health facilities, centralised dispensaries and other non-health facilities. This is crucial for meeting the growing demand for medicines, particularly for treatment of chronic diseases, among others.^[9] Given the various interconnections in the supply chain, our approach was to investigate how the complex interplay of ATM dimensions, including pharmaceutical regulation, medicines distribution and demand-side barriers, influenced ATM in SA. We selected tracer medicines commonly used in the public sector that could aid in identifying the relevant issues in the supply chain. These were rifampicin (antituberculosis), metformin (antidiabetic, type 2), lamivudine (antiretroviral), fluoxetine (antidepressant) and oxytocin (labour induction).^[7]

Previous articles emanating from this research reported on policy implications for medicine registration^[10] and equity in the geographical distribution of community pharmacies in SA.^[11] We also identified supply and demand barriers to ATM^[12] and existing strategies for mitigating these barriers.^[12,13] In the Western Cape

(WC) Province, we identified two distinct strategies for improving ATM: the Chronic Dispensing Unit (CDU) and community-based medicines delivery models. The CDU, a model for centralised dispensing of medicines in the public sector, was introduced to address the shortage of pharmacists, reduce patient waiting times and decongest health facilities.^[13-15] Community-based medicines delivery models were aimed at distributing medicines closer to patients' homes, thereby addressing barriers associated with physical accessibility and affordability of transport costs. These models are fully described elsewhere.^[16-18] Despite these advances in the WC, public sector stock-outs hampered the efficiency of ATM strategies and disrupted service provision. Among the reasons offered for stock-outs were inefficiencies in procurement, a centralised function. In this article we therefore demonstrate how inefficient procurement processes have undermined ATM.

Medicines procurement in SA

Procurement of medicines in SA is centralised and managed by the NDoH, with some variation in organisation between procurement of HIV medicines and that of other medicines. Pharmaceutical tenders are advertised, awarded and monitored by the NDoH. Provinces submit quantification figures to the NDoH for the contract period, where the figures are then aggregated. Contracted suppliers deliver directly to depots and in some cases (for selected items) directly to the CDU and health facilities.

Methods

This qualitative study was conducted between 2012 and 2014 with a purposeful sample of over 70 key informants representing front-line health workers, sub-structure and provincial level health service managers.

Application of the critical incident technique

We employed the critical incident technique^[19] to identify occurrences that have special significance in our context. The method focuses on gathering data that are potentially useful in solving practical problems. Critical incidents were described by Flanagan^[19] as:

- an extreme behaviour, either outstandingly effective or ineffective with respect to attaining the general aims of an activity
- an incident that is complete in itself to permit inferences and predictions to be made, and the consequences of which are sufficiently definite to leave little doubt concerning its effects.

In this research, the critical incident was defined as any such incident having special significance in our context.

Data collection. The critical incident technique consists of a set of procedures for collecting information that allow participants to 'tell the story' (what) and then generate details by posing probing 'when', 'where' and 'why' questions. The technique is commonly used to collect data on observations previously made that are reported from memory – which is usually satisfactory when the incidents reported are fairly recent. However, in some situations adequate coverage cannot be obtained if only very recent incidents are included.^[19] As such, we requested the informants to reflect on a longer period (5 years) to identify incidents positively or negatively affecting ATM. To allow for this detailed exploration, we used a semi-structured interview guide containing open-ended questions as a data collection tool.

Data analysis. Our process involved listing the incidents identified, then making a judgement based on the principles of the critical incident technique as described earlier. We then developed descriptions of the selected incidents.

Ethics approval and consent to participate

Ethics approval for this study was granted by the Senate Research Committee of the University of the Western Cape (ref. no. 11/7/8). Consent to interview and record interviews was obtained from participants. They were also informed of their right to withdraw from the interview at any time.

Results

Overview of the general state of medicines availability in the WC

Informants recognised the positive role by the WC Department of Health in instituting measures to minimise stock-outs in the province. They reported that in general, stock-outs at the provincial depot had reduced significantly from over 160 out-of-stock items each week a few years before to an average of 10 - 20 items at the time of the study, some of which could be substituted by the use of different pack sizes of the same medicine. Frontline health workers received regular updates on the stock situation from the depots, which enabled them to make alternative arrangements where possible. Sometimes buffer stock was available in the health facilities, enabling pharmacists to continue dispensing activities without disruption in the event of stock-outs at the depot.

However, poor forecasting at the level of health facilities was sometimes regarded as a challenge, particularly during times of policy changes or strategic service delivery decisions that led to increased demand for specific medicines and medical devices without the necessary adjustments to the quantification and ordering processes. Such events occurred when health managers developed programmes or campaigns and neglected to liaise timeously with the provincial supply chain team, which could in turn result in stock-outs. One such incident was described by a pharmacy manager as follows:

'... last month we had a problem with Accu-check sticks [for blood glucose testing] because the province started testing everyone for glucose and nobody told the depot "Listen, we need more ...", and the depot didn't know to tell the company [supplier], so now we've got this snowball effect and ... we don't have enough to give the patient.'

Although the above example referred to medical devices, similar experiences occurred with tracer medicines, and the informant raised it in that context.

Besides province-specific issues, processes at central level caused stock-outs at particular time periods. Two of our tracer medicines, i.e. metformin and rifampicin, were affected by these processes, and so were other medicines. This in turn had implications for ATM.

Perceived causes of procurement inefficiencies

Stock-outs were attributed to: (i) delay in award of pharmaceutical tenders; (ii) removing national contracts for certain medicines on provincial code lists; and (iii) supplier failure to meet contract obligations. We elaborate on these three factors below, and discuss the implications of stock-outs for ATM strategies in the WC.

Delay in award of pharmaceutical tenders

Delayed award of pharmaceutical tenders by the NDoH emerged as one of the key challenges facing the pharmaceutical system. Some informants attributed tender challenges to a lack of manpower in the NDoH to timeously renew tenders – a function previously performed by National Treasury. During our research, we witnessed the knock-on effect of late tender awards in 2012 and 2014. Informants reported that this was a common occurrence every 2 years when

pharmaceutical contracts expired. By 2014, some informants had witnessed the impact of late tender awards over a number of cycles, which led to an increase in the number of out-of-stock items.

As indicated by one informant:

'... we had dues out [out-of-stock medicines] down to about 10 to 15 at one stage for quite a long period at depot side. Now it's started creeping up to 60 ... in a crisis 2 years ago it was over 100. But it is on the increase because of these tender problems.' (Senior provincial manager)

Another informant added:

'Every 2 years when the contracts expire we go through these (stock) problems ... at the moment we're sitting with a 66 item dues-out at depot [medicines unavailable from the depot], and this is because of the tendering system ... And that's the biggest gap in the system ... they [the NDoH] know exactly when the tender is going to end, but the process takes so long. Then they have to ask current tender companies to extend their contract for 1 or 2 months. The company's response could be, "I don't want to do it, and I don't have the capacity." Then they have to look for another company and this usually leads to problems.' (Mid-level manager, district substructure)

In an effort to understand reasons for suppliers' unwillingness to extend contracts, one informant shared the following insights:

'I think there is a lack of understanding with our tender guys [procurement officials] that these pharmaceutical manufacturers sometimes plan 2 years in advance. And when they plan, when they have been allocated the contract that obviously has a major impact on their production planning – and we must remember that they don't produce only one item or two items, they've got a variety of products that they manufacture. They have timeslots and certain machines for all these, and one machine might be used for two different products. So there are major challenges for them as well, but from a planning point of view it really has a negative effect on these guys [suppliers].' (Mid-level manager, medicines procurement)

Informants also added that suppliers tend to downscale production in the last few months of their contract because of uncertainties around successful rebidding. In view of the tough economic climate, it is no longer financially viable for suppliers to produce excess stock, whereas in the past they held significant amounts of buffer stock, allowing them the flexibility to extend their contracts. Suppliers are also sometimes reluctant to extend their contracts because of the unplanned production upscaling and the associated risk of being penalised should they fail to meet the prescribed timelines. Interim options to source large volumes of medicine from alternative pharmaceutical companies that are not contracted to the NDoH are limited, since these companies tend to downscale manufacturing of a particular medicine if they fail to secure a national contract.

Absence of national contracts for medicines on the provincial code list

According to informants, at times there was poor communication between provincial and national stakeholders. A case in point: about 70 items were excluded from the most recent national tender at the time of the study (2014) without first consulting provinces, which was the usual practice in order to allow health providers to prepare for the change. Informants thought this action was a result of efforts by the NDoH to align medicines tenders to the Essential

Medicines List. At the same time, a decision was taken to include only one item per medicine class, which placed a strain on the industry to increase production of these items and also meant that there were no alternatives for the provinces in the event of shortages. While provinces could lobby for the medicines to be placed back on national tender and/or to procure directly from suppliers (sometimes involving importation of medicines), these processes often took a long time, with resultant delays in supply. In other cases, guideline modification through the Provincial Pharmacy and Therapeutics Committees was required to allow for medicines substitution. The positive note reported by our informants was that the NDoH acknowledged the risk of only including one item per class.

Failure by suppliers to meet demand

Suppliers failed to meet contractual obligations due to: (i) global shortages of active pharmaceutical ingredients (APIs) (e.g. the shortage of APIs for antituberculosis medicines during the study period); and (ii) lack of capacity, especially during the start-up phase, after a contract is awarded, when demanders procure large volumes to compensate for stock-outs imposed by delayed contracting. General capacity constraints also became evident during the course of the contract when a supplier failed to meet demands, and although these incidents were reported to the NDoH, it was not unusual for the contractor to be reappointed during the next tender cycle. One informant said:

'We are tied [left with no option] ... the most we can do is inform the National Department of Health that they have been bad suppliers ... but history has shown us and our experience has shown us that those suppliers do get reappointed with contracts again and we sit with the same problems again.' (Mid-level manager, medicines procurement)

When a supplier provides a substandard/inferior product and a medicine recall ensues, a severe disruption in supply may result. An incident cited by informants was when the state received supplies of rifampicin tablets containing substantially less than the specified amount of active ingredient.

Implications of stock-outs for ATM strategies

Strategies for improving ATM in the WC were affected by stock-outs. First, the CDU system, which dispenses medicines for over 300 000 patients, operates on a set production schedule and stock received after commencement of the production process cannot be introduced into the dispensing system. Stock-outs resulted in batches of patient medicine parcels (PMPs) being dispatched to health facilities without all the prescribed medicines. Consequently, pharmacists at health facilities manually dispensed the missing medicines from buffer stock or provided alternative therapy under the authorisation of a prescriber. Owing to the high burden of chronic diseases in the province, this meant that several hundreds of PMPs at each health facility required additional medicines. While it was commendable that health facilities sometimes had buffer stock that allowed them to minimise the impact of stock-outs on patients, workload in the pharmacies increased due to the additional dispensing tasks and caused frustration among pharmacists. Accordingly, patient waiting times increased. In instances where no buffer stock was available, patients had to return at a later date when the medicine was expected to be available. Also, community-based services rely on the CDUs' prepacked PMPs, and these services were affected when stock-outs occurred. Stock-outs caused service interruption, forcing patients who benefited from community-based services to attend the health

facility for their medicine supply. This imposed additional transport costs on patients and is likely to have impacted negatively on their welfare.

Stock-holding at depots (up to 6 months) and health facilities (4 - 8 weeks) generally created a buffer to procurement and other challenges in medicine supply, ensuring that patients had access to their medicines. In recognising the importance of maintaining buffer stock, there were some concerns that the recommendation from the NDoH for the public sector to migrate to a 'push' model, which supplies pre-defined and standard volumes of medicine down to health facilities based on demand planning, as opposed to a 'pull' model, which relies on orders from health facilities, could preclude holding buffer stock.

Discussion

The challenges imposed by stock-outs are becoming more evident against the backdrop of increased demand for chronic disease treatment in SA,^[20] but they are not new.^[21] While some studies have reported that pharmaceutical systems in low- and middle-income countries are generally strained and weak,^[22-24] there has been a limited focus on procurement processes, yet the critical incidents identified in our study were linked to this issue.

The interconnected nature of different levels of the health system (provincial and national) was clear. Based on the issues raised by this research, minimising stock-outs requires action at a national level, where procurement takes place, to ensure that tenders are awarded timeously and supplier performance is monitored. Also, the provinces (not only the WC) have a responsibility to provide accurate forecasts to the NDoH.

Existing ATM strategies^[13-17] depend on a consistent, secure and reliable source of medicines to function optimally, yet they are regularly interrupted by stock-outs. Addressing the prevailing challenges will be of benefit to the country as a whole given that medicines will continue to play an integral role in the health system, not only of the individual provinces but also to achieve the ATM goals under the proposed National Health Insurance scheme in SA.^[25]

Conclusion

Addressing causes of stock-outs, starting at the national level, is critical for successful implementation of ATM strategies in SA and to ensure that patient care is not adversely affected. The recurrence of stock-outs due to predictable events warrants continued attention to the underlying issues. Addressing the procurement challenges, most notably timeous tender awards and supplier performance management, is critical for successful implementation of ATM strategies.

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Conflicts of interest. None.

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Paper V



Reasons for missed appointments linked to a public-sector intervention targeting patients with stable chronic conditions in South Africa: results from in-depth interviews and a retrospective review of medical records

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Abstract

Background: Missed appointments serve as a key indicator for adherence to therapy and as such, identifying patient reasons for this inconsistency could assist in developing programmes to improve health outcomes. In this article, we explore the reasons for missed appointments linked to a centralised dispensing system in South Africa. This system dispenses pre-packed patient-specific medication parcels for clinically stable patients to health facilities. However, at least 8%-12% of about 300 000 parcels are not collected each month. This article aims to establish whether missed appointments for collection of medicine parcels are indicative of loss-to-follow-up and then to characterise the patient and health system factors linked to missed appointments.

Methods: We applied an exploratory mixed-methods design in two overlapping research phases. This involved in-depth interviews to yield healthcare practitioners' (HCP) and patients' experiences and medical record reviews. Data collection was conducted during the period 2014-2015. Qualitative data were analysed through a hybrid process of inductive and deductive thematic analysis which integrated data-driven and theory-driven codes. Data from medical records (N=89) were analysed in MS excel using both descriptive statistics and textual descriptions.

Results: Review of medical records suggests that the majority of patients (67%) who missed original appointments later presented voluntarily to obtain medicines. This could indicate a temporal effect of some barriers. The remaining 33% revealed a range of CDU implementation issues resulting from, among others, erroneous classifications as defaulters. Interviews with patients revealed the following reasons for missed appointments: temporary migration, forgetting appointments and work commitments. Most HCP confirmed these barriers to collection but identified some to be beyond the scope of health services and a lack

of patient responsibility, under-utilisation of medicines and use of plural healthcare sources (e.g. traditional healers).

Conclusion: We suggest developing a patient care model reflecting local context, attention to improving CDU's implementation processes and strengthening information systems in order to improve patient monitoring. This model presents lessons for other low-and-middle income countries with increasing need for dispensing of medicines for chronic illnesses.

Key words: missed appointments, access to medicines, non-communicable diseases, Chronic Dispensing Unit, pharmaceutical systems, Western Cape, South Africa, low-and middle-income countries.



Introduction

Missed clinic appointments by patients are a common phenomenon in healthcare provision globally and across different types of diseases [1-4]. The problem with missed appointments is that continuity and effectiveness of healthcare delivery is compromised, appropriate monitoring of health status lapses, and the cost of health services might increase [3]. Furthermore, some studies have shown a relationship between missed appointments and sub-optimal clinical outcomes among patients with chronic diseases [3, 5, 6]. Missed appointments serve as a key indicator for adherence to therapy and as such, identifying patient reasons for inconsistency in meeting appointments could assist in developing programmes to improve health outcomes [5].

In this article we explore the reasons for missed appointments linked to a public sector, access to medicines intervention in the Western Cape province of South Africa - the Chronic Dispensing Unit (CDU). Established in 2005, the CDU was designed to dispense medicines for clinically stable patients with HIV and/or non-communicable diseases. The CDU was born out of an increasing demand for medicines to treat chronic diseases in a context of severe healthcare practitioner (HCP) shortages, over-burdened healthcare facilities and long patient waiting times in the public sector - challenges that are widely acknowledged in other settings. The CDU was developed to overcome these challenges through the establishment of a private-sector outsourced, centralised medicines dispensary. At the time of our study, over 200 health facilities and about 300 000 patients were registered for this intervention.

In summary, the CDU process begins with the contracted service provider collecting prescriptions from health facilities. These are prescriptions of patients deemed to be stable on their therapies and therefore require minimal follow-up by clinicians. [7] The dispensing process, including prescription evaluation and interpretation and automated picking and

packing ensues. These patient- and health facility- specific parcels are delivered to facilities for distribution to patients at the facility or alternative sites (e.g. community halls) [8-10].

According to legislation, a patient receives a prescription which is repeatable for up to six months and a six-month follow-up appointment with the clinician to assess therapeutic outcomes ensues. According to the CDU policy, the first issue of medicine from the eligible prescriptions is always dispensed at the health facility, and thereafter repeats (generally monthly and bi-monthly in urban and rural areas, respectively) are dispensed by the CDU. As such, beneficiaries of the CDU have monthly or bi-monthly appointments for medicines collection. In some instances, this appointment is strictly for medicines collection, while in other cases, it might include symptom screening and a brief educational session by the healthcare practitioner (HCP). Based on the clinician's evaluation at follow-up stage, the same process described above is repeated after review. If the patient's clinical status changes and the clinician deems regular monitoring a necessity, the patient will be referred back to mainstream care with the possibility of being enrolled with the CDU again at the clinician's discretion.

Once patients have been enrolled, those who miss medicine-collection appointments consecutively and fail to report to the health facility within five days from date of scheduled appointment should be de-registered from the CDU and requested to consult with the HCP more regularly. De-registered patients can be offered the opportunity to enrol again at the HCP's discretion. Designers of the CDU intervention factored in a monthly allowance of 4% missed appointments (in relation to medicines collection) to accommodate loss-to-follow-up, death or other unforeseen circumstances. This target of 4% was informed largely on the principle of economic efficiency, given that the cost of (potentially) unused medicine would be unacceptably high. While reviews of studies on missed appointments have shown much higher rates of missed appointments (up to 55% in some settings) [11], the assumption was

that the CDU would target stable patients, who require minimum follow-up care [12], are adherent to clinic appointments and well controlled on treatment. In reality, at least 8 to 12% of nearly 300 000 medicine parcels are not collected every month [10]. This figure is a conservative estimate, as many facilities under-report on collection statistics. Missed appointments for medicine collection are a concern to government, not only because of associated cost and potential losses due to expired medicines but due to the additional workload that is generated for both the service provider and HCP at health facilities and the potential negative patient therapeutic outcomes [10].

The Western Cape Department of Health (WCDOH) commissioned this study to investigate the unexpected rates of missed appointments. Chen (2006) has suggested that the success of an intervention is affected by the arrangement of multiple components, including aspects of the target population, programme implementers, programme planners and community partners [11]. In this article we explore the challenge of missed appointments using a combination of routine data and perspectives and experiences of the target population (patients) and programme implementers (HCP). Specifically, we aim to establish whether missed appointments are indicative of loss-to-follow-up; and to characterise the patient and health system factors linked to missed appointments.

We focussed on type-2 diabetes and hypertension because the prevalence of these non-communicable diseases (NCDs) are highest in the CDU population and because of their global prominence [12-14].

Methods

Study Design

We applied an exploratory, cross-sectional mixed-methods design in two overlapping

research phases. This involved in-depth interviews to yield HCP and patients' experiences, perceptions and feelings [15]. In addition, we conducted medical record reviews (MRR) in order to establish whether missed appointments were temporary or indicative of loss-to-follow-up. Data collection was conducted during the period 2014-2015 after getting ethical clearance from the Senate Research Committee at the University of the Western Cape, South Africa and permission to do research from the relevant structures within WCDOH.

Characteristics of the patient population

The majority of the South African population (more than 75 %) is dependent on the public sector for, inter alia, supply of medicines [16] and CDU patients are part of this constituent. This research was conducted in relatively indigent areas (Gugulethu, Mfuleni, Mitchells Plain and Khayelitsha).

Facility and Participant Selection

In early 2015, the CDU supported approximately 77% of the total PHC facilities in the province, which included 44 urban facilities administered by the WCDoH. In most cases, diagnosis of NCDs and stabilisation on chronic medicine occurs at this level [17]. For this study, we focused on urban community health centres (CHCs) where the CDU roll-out was initiated and is therefore better established. Facilities were categorized according to monthly medicine parcels received from the CDU: less than 4 000 (small); 4 000-10 000 (medium) and more than 10 000 (large). These were then stratified according to the history of reported missed appointments. For variability of experiences, we selected one small-, two medium- and one large site(s) – two with a documented history of missed appointments and two without. During the time of the research, there were 210 296 active CDU beneficiaries, of which more than 80% were over 40 years of age and about 66% were female [10]. The four selected facilities represented approximately 10% of the total active CDU population.

Participants for in-depth interviews were sampled purposively as follows:

- a) **Patients:** type-2 diabetes and/or hypertension patients who had missed their previous CDU appointment (N=23). All patients had voluntarily presented at the facility and were identified by HCP during the triaging process.
- b) **HCP:** provincial mid-and senior-level managers involved in the care continuum (N=9); frontline HCP - physicians, nurses, pharmacists and health promoters (N=22).
- c) **CDU service provider:** (N=4).

Medical record reviews were conducted at two out of the four facilities with a well-functioning electronic pharmaceutical system to allow for follow-up [18]. This approach was employed in order to establish whether patients were lost-to-follow up. This included establishing the time taken by patients from the time of scheduled (missed) appointment to the time of next visit or establishing whether the patient was lost-to-follow-up. In addition, demographic characteristics of the patients (age, gender) were obtained.

Data Collection Processes and Tools

Phase 1a: For the MRR, we selected a sample of 112 CDU patients who had missed their appointments on two randomly selected days in May and June 2014. We followed-up two months after the date of missed appointment. A template was developed in Microsoft Excel to capture patients' identifiers. These details were used for a record review that was done by a pharmacist at two out of the four health facilities. During this exercise, the pharmacist captured patient age, diagnosis, last date of presentation prior to or after the missed appointment and outcomes at last assessment.

Phase 1b: We targeted patients who had missed their previous appointment using type-2 diabetes and hypertension as the primary tracer conditions. The tool used in this phase was guided by selected constructs adapted from the Explanatory Model Interview Catalogue (EMIC). This is a cultural epidemiology framework which aims to capture descriptive accounts of local interpretations of illness, its meaning and associated illness behaviour, and emphasises

the need for a holistic assessment of the patient, including the role of culture in long-term illnesses [19].

In addition, we captured reasons for missing medicine collection appointments. The EMIC framework allowed us to obtain reasons for missed appointments and to contextualise patient behaviour beyond the immediate reasons for missing appointments. As such, we profiled patients' illness experiences, focussing on path to diagnosis, access to services and/or information, self-treatment, treatment experience and social support, as any one or all of these factors might influence behaviour. Tools were tested in a pilot study and subsequently refined (see Additional file 1).

Phase 2: Semi-structured interview guides were developed for interviews with provincial managers and frontline HCP and focussed on patient-related and health system factors contributing to missed appointments (see Additional file 2).

Interviews were conducted face-to-face, except for one respondent who relocated to another province and completed a telephonic interview. Interviews were conducted at participant's work settings or at CHC in the case of patients and frontline HCP. Interviews with HCP were conducted by the first author, who is a qualitative researcher with a background in public health. Once no new information was generated from the interviews (saturation), no further interviews were conducted. All participants were taken through the informed consent procedure prior to interviewing, including a request to record the interview if the participant was willing. Three participants refused to be recorded and notes were taken for those interviews. Participants were also informed of their right to withdraw at any time without any consequences.

Medical record reviews (MMR) were conducted by a pharmacist and patient interviews were conducted by a trained fieldworker proficient in local vernaculars.

Data Analysis

Data from MRR were analysed in MS Excel using both descriptive statistics and textual descriptions. 22 folders were excluded from the final analysis as a result of incomplete data (N=20) and capturing error (N=3). This resulted in a final sample of 89.

For the qualitative interviews, data analysis was, as is common in qualitative research, a continuous process [15]. This meant that issues of relevance emerging from an interview were included in subsequent interviews.

The audio-taped interviews were transcribed verbatim and patient interviews were translated into English. Thematic analysis [20] was used to analyse qualitative data. This process involved a hybrid process of inductive and deductive thematic analysis [21] which integrated data-driven with theory-driven codes based on the domains of the EMIC framework.

The data was then coded, compared and contrasted, and recurring elements were matched to generate categories, these were further collapsed to form themes that are presented in this article. Atlas.TI version 7 was used to organise the data. The transcripts were independently read by the first author, and emerging themes were discussed with all authors. Further analysis (drawing relevant meanings, and searching for relationships among and within data) was then conducted. Finally, the results were discussed with selected participants through feedback sessions with HCP and patients as a way of conducting participant validation [22].

Results

Status of a sub-sample of patients who missed appointments

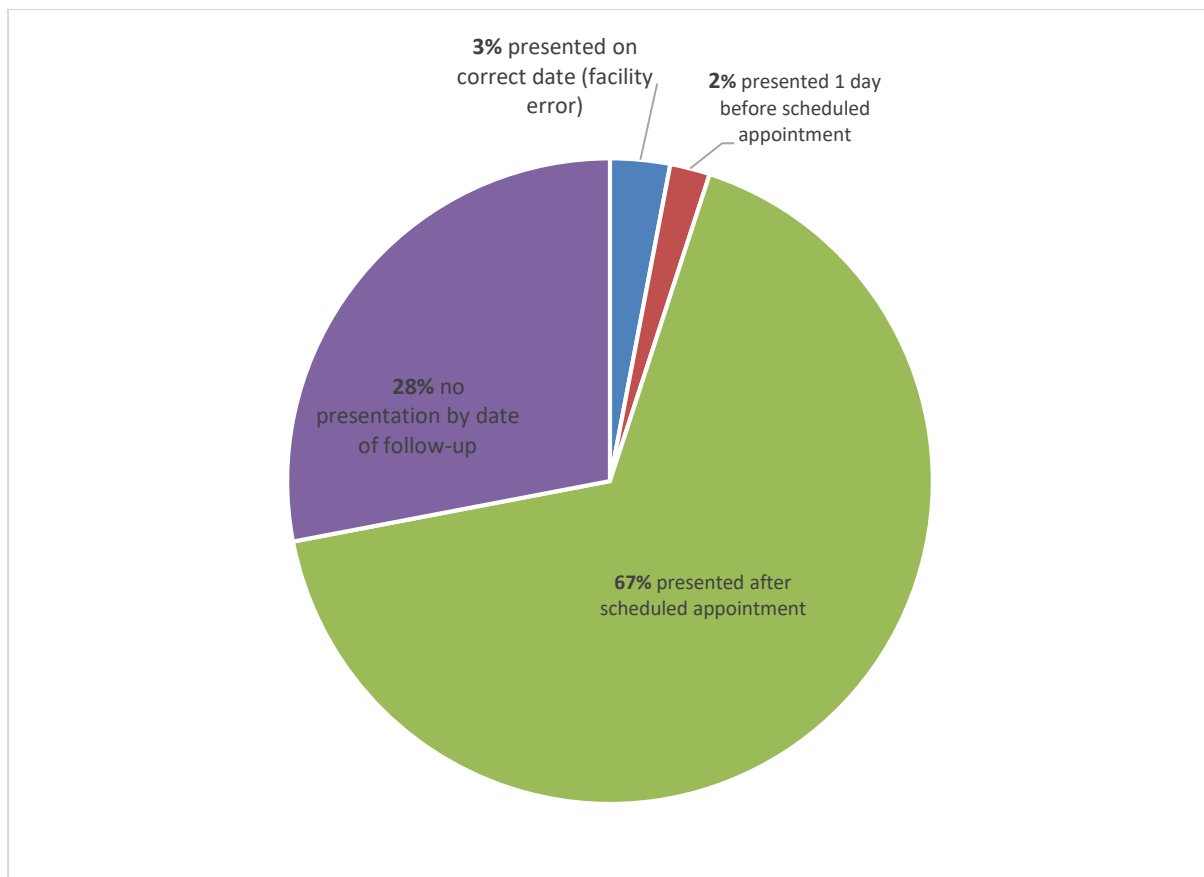
The majority of patients who missed appointments were female (66%), with a median age of 56, suffering from mainly diabetes and/or hypertension (table1). This aligns to well to the characteristics of the general CDU population which was shown in a previous analysis to be predominantly female (66%) and over 40 years of age (+80%) [10].

Table 1: Characteristics of patients sampled for medical record reviews

Gender	Female (66)
	Male (23)
Age (years)	Range: (23 -86)
	Median age: 56
Chronic condition (not exclusive, some patients had multiple morbidityes)	Diabetes (34%)
	Hypertension (73%)
	Diabetes and hypertension co-morbidity (34%)
	Others, e.g. chronic obstructive pulmonary disease (56%)

During the MRR, we identified four categories of patients, i.e. (i) those who presented after their scheduled appointment; (ii) those who had not presented by the time of the study; (iii) those who presented on the correct date but were (erroneously) recorded as defaulters and (iv) those who presented earlier than the scheduled appointment. **Figure 1** represents the different proportions for each category.

Figure 1: Presentation status of patients who missed appointment dates (N=89)



The majority of patients who missed appointments (67%) reported to the facility after the scheduled date (figure 1) - times ranged from 1-84 days with a median of 28. However, 28% had not reported to the facility by the time of the study and times ranged from 10-149 days with a median of 56. A small percentage (3%) presented on the correct date while even fewer (2%) presented one day early.

Results pointed to the need to distinguish between true defaulters and others who were possibly misclassified as a result of inefficient facility processes. The latter was evidenced by patients who attended the CHC on the correct date or within the permitted time-frame (≤ 3 days before or ≤ 5 days after) but obtained medicines from the traditional (internal) pharmacy system instead of their CDU parcel. Also, the median number of days between a missed appointment and the next or most recent date of presentation (28 and 56 respectively), suggests that some

patients who kept appointments may have received medicines through the traditional pharmacy system, given that patients operate on a 28 and 56-day medicine collection appointment cycle.

Further assessment of medical records for patients who had not reported to the facility by date of follow-up (N=24), revealed possible health system inefficiencies which contributed to missed appointments. For example, two patients had been transferred to other facilities but their parcels had not been cancelled at the CDU. Healthcare practitioners suggested that either the cancellation process had not been carried out or was delayed, hence the parcels were still delivered to the facility. Another example was that of a patient who was newly-diagnosed and enrolled onto the programme - contrary to the CDU policy of enrolling only patients who have been stabilised on therapy. This defaulting incident could possibly be attributed to inadequate awareness of treatment-related issues. Eight patients collected medicines through the internal pharmacy system and followed a different appointment system. One of the reasons offered by HCP to explain the latter was that these patients could have reported for acute conditions during their treatment trajectory and when they received treatment for acute conditions, they were also given chronic medication through the pharmacy, hence another treatment cycle began which was not in sync with their CDU appointments. This could have been done to reduce the frequency of patient visits to the facility and the associated costs of transport.

With the remaining 13 (out of 24) patients, it was not clear why they had not returned to the facility. However, 11 of them were not clinically stable based on local diabetes and hypertension guidelines for at least one condition at last assessment, therefore HCP suspected that they could have been hospitalised or died. Existing information systems were not synchronised to flag patients hospitalized elsewhere or even when collection had been done through the traditional pharmacy system in the same facility. Attempts to contact patients who

had not presented by the date of follow-up were unsuccessful because of missing or wrong personal information.

In summary, from an analysis of this small population, the majority of patients (72%) were not lost-to-follow-up; they were either misclassified as a defaulter or encountered individual or health system related barriers, all of which need to be better understood.

Reasons for missed appointments – insights from in-depth interviews with patients and healthcare practitioners

The majority of patients in this sample were female (91%), with a median age of 54, and most had multi-morbidities (table 2).

Table 2: Demographic characteristics of patients interviewed N= 23

Gender	Female (21) Male (2)
Marital Status	Widowed (8) Married/Co-habiting (8) Divorced/Separated (3) Never married (4)
Highest level of education obtained	Secondary (23)
Employment status	Not working (11) Informal employment (12)
Age (years)	Range: 35-83 Median: 54
Number of self-reported chronic conditions	Range: 1-4 Median: 2
Self-reported duration on treatment	Less than five years (6) Six-ten years (7) More than ten years (10)

The immediate reasons for missed appointments as expressed by patients were: mobility and temporary migration, forgetting or mixing up of appointments, work commitments and switch to private medical insurance.

The most common reason for missing appointments was mobility and temporary migration. Given that the Western Cape is an economic base for people from other South African provinces, it is common for people to travel back and forth from their provinces of origin for planned holidays (especially during the festive season), religious activities and employment seeking as was reported by study participants or unplanned events such as funerals. At least seven patients indicated that their appointment was at a time when they were travelling to or already in another province.

The second most common reason for missed appointments as expressed by patients was forgetting or mixing-up appointment dates partly because of poorly written appointment cards. A Short Message Service (SMS) appointment reminder system had been designed as a strategy to mitigate this challenge. However, we did not establish whether patients who were subscribed to the SMS reminder system adhered to their appointments better than those who were not. What was clear was that this service benefited only a small number of patients. The service provider estimated that of between 13 000 and 14 000 parcels that were dispatched to facilities daily, only about 12% were linked to contact numbers and of that proportion, 15% of the messages were undeliverable. Maintaining an up-to-date database of contacts at the facility level proved challenging. Furthermore, some facilities had voluntarily unsubscribed from the service because it created confusion among patients when the messages were misinterpreted.

The third factor causing missed appointments was linked to work commitments. Unskilled workers such as domestic workers who reside with their employers faced the greatest challenge. Our results suggest that their jobs might have limited flexibility hence they rely on others, such as family members, to collect their medication. Similarly, reliance on family members or even other community members was a coping strategy for the elderly with debilitating illness, another cause for missed appointments. As one elderly female said:

“Today, I had to come myself but I used to send a young man from the neighbourhood...now he died so I have no one to take my medication.” [P13, 83- year old]

Despite making prior arrangements, this strategy can fail due to other barriers. Speaking on this issue, one patient said:

“...once, I sent my grandchild to pick up the medicine for me and they did not give her. They said they wanted my original ID.” (P10, 71- year old)

The last reason for missed appointments, i.e. temporary migration to a private medical scheme, was mentioned by an elderly patient (77 years old). The patient's daughter had enrolled her onto a private medical scheme because it was perceived that she could obtain better quality of care in this sector. However, she was still registered on the public system and returned when private funds were depleted. Although an uncommon reason for missed appointments in this study, migration to the private sector flagged some dissatisfaction with public health services, an important contributor to missed appointments. The patient in question complained of long waiting times at her local CHC. Other patients also cited long waiting times at the pharmacy:

“The pharmacy should try to speed up things there or do something also because that is where I wait long time.” (P6, 43-year old)

In contrast, other patients accepted long waiting times as the status quo:

“It can't be a concern because that's how our clinics operate.” (P1, 61-year old)

“It's something that is so common in waiting and crowding is something that I have accepted and it's no concern.” (P22, 59-year old)

Healthcare practitioners gave additional reasons for missed appointments. They concurred that long waiting times for medicines collection could be a contributor to missed appointments. In

two of the sampled facilities, HCP mentioned that the patient load was still significantly high, with waiting times of five hours or more at the pharmacy alone despite some efforts to decongest CHCs by introducing alternative medicines distribution strategies.

In addition to the reasons for missed appointments given by patients above, some HCP felt addressing reasons for missed appointments was complicated by patients who were perceived to give 'socially desirable' responses when questioned about reasons for missing appointments. For example, travelling to another province for a funeral would possibly garner more sympathy than admitting to having forgotten. They also expressed concern about patient attitudes, such as perceived lack of patient responsibility and under-utilisation of medicines (leading to over-supply) which they felt also contributed to missed appointments. Triangulation of this view with observations and patients' treatment experiences which were captured through the EMIC constructs, did show possible underutilization of medicines. An incident was recorded in the field by the first author, where family members of a deceased patient returned a large bag of unused medicines. This was confirmed by HCP to be a regular occurrence because some patients did not take the medicines as prescribed. Lastly, the use of plural healthcare sources emerged as an important aspect of some patients' treatment experiences. Specifically, the use of alternative medication sourced through informal providers (herbalists and traditional healers) was reported. Some of the remedies that were obtained from informal providers were described by patients as "*cleansing the body and purifying the blood*" or "*calms the hypertension*". We inferred that the use of plural healthcare sources could result in missed appointments because patients could under-prioritise their clinic appointments.

Looking ahead

Overall, the range of access barriers was not adequately taken into account during the design phase of the CDU intervention, hence there were limited strategies to address them. Our results suggest that missed appointments emanate from a combination of individual and

health system barriers. Also, some cases recorded as missed appointments emanate from inefficiencies in implementation of the intervention, an issue requiring the attention of all stakeholders involved in the CDU process. The individual barriers, however, while acknowledged by HCP, were perceived to be beyond the scope of care provided by health services; pointing to the link between health and welfare and the necessity of inter-sectoral strategies as illustrated in the quotes below:

“The clinician can only do so much in interventions – some of what is required are socio-economic interventions that deal with societal factors and lifestyle changes.”

[Physician]

A health manager also said:

“Health can do so much; inter-sectoral collaboration is required because poverty plays a role, your circumstances, economic factors and all of that.”

[Senior Manager, WCDoH]

Discussion

Driven by the need to address the challenge of missed appointments by beneficiaries of the CDU in South Africa, this study begins to question some of the initial assumptions made about this intervention. Programme planners envisaged that beneficiaries would be adherent to their appointments with an allowance of 4% defaulter rate monthly, adherent to medication and ultimately exhibit stable clinical outcomes. In a previous study, we established that rates of missed appointments were higher than 4% [10] and in this study, there was some evidence of non-adherence to medication (although this was not a central focus of the study) and some patients exhibited unstable clinical outcomes. Also, some cases recorded as missed

appointments are not truly so, rather they emanate from inefficiencies in implementation of the intervention, which is a separate issue.

Role of context factors in the chronic illness experience

We identified individual patient factors tied to contextual realities which impacted on medicines collection and potentially on clinical outcomes. These included forgetting appointments and work commitments for people in the informal sector and other factors that are well described in literature [23, 24]. Through the use of the EMIC framework[19], we could also identify potential threats to patients' keeping appointments such as those related to emotional distress emanating from poverty and self-treatment.

In our view, although some issues have been acknowledged in literature, their incorporation into frameworks or strategies designed to improve access to medicines finds little space in the NCD literature and were not adequately considered during the design of this intervention. This is evidence that chronic disease management extends beyond mechanistic implementation of purely technical interventions such as the CDU [25], and that failure to address social factors impacting on patients leads to failure to effectively serve the population. From our study, HCP's mistrust of patients' reasons for missing appointments could also have implications about how they react to patients. In line with our findings, a recent study in the United States of America found a discrepancy between the identifiable social factors and health providers' ability to address them [26].

Notably, despite prevailing challenges, most patients – and all interviewed in this study - who missed appointments returned to the CHC without follow-up. Similarly, over 60% of patients who were included in the folder review also reported to the CHC, albeit late. This could be an indication of some degree of patients' willingness to cooperate with the policies of the intervention. However, it presents challenges given that patients can go for an indefinite period without medication, which can affect their health status. Other studies have reported

that an opportunity for patients to cancel/postpone appointments can lessen missed appointments [27] and inform the development of strategies to better address the issues faced by patients. In the case of the CDU, a two-way communication system is lacking to allow patients to communicate with health services if they cannot make it for an appointment.

Contribution of CDU implementation-related factors

Through our study, we were able to identify problematic process-related issues contributing to missed appointments. It was clear that there were some patients whose parcels were returned to the CDU under “missed appointments”, yet the patients attended the CHC and received medicines via the parallel dispensing system, at times on the correct date or within the permitted time frame. Also, incidents showing that transferred patients and/or those who no longer required medication were not easily identifiable pointed to the need for integrated information systems. In addition, issues such as enrolment of newly diagnosed patients and those not well controlled on therapy who were kept on the programme, called into question the overall patient management strategy. More specifically, the 14% classified as poorly controlled on therapy at last assessment were at risk of being lost-to-follow-up yet there was no information about their status. Such patients’ circumstances may have predisposed them to needing more care than the health system provided or they required linkage to non-health services. These findings seemed to support the view that unexpected results could be due to an intervention theory that has not been carried out well; or the problem could be with the theory itself [28]. This study presented evidence on underlying implementation problems which require further study in order to unravel the interplay of multiple components of the intervention [11].

Strengths and limitations of this study

Our study is part of a service improvement process and our findings were disseminated to relevant stakeholders for immediate consideration. We highlight an oversight on the role of

social factors and also make a case for an in-depth process evaluation of CDU implementation. The study also has some limitations. Our results should be interpreted in context as they might not be reflective of the range of barriers faced by CDU patients because we captured reasons for missed appointments linked to a specific event. Also, the majority of respondents in the patient population were female. This was not surprising given that the majority of beneficiaries are female. However, their experience might not be reflective of their male counterparts.

Implications for Policy and Practice

On reflection, an imperative issue was whether the 4% rate of missed appointments assumed by the service was appropriate for this context. This was not easy to answer given that some missed appointments were a result of health system inefficiencies not actual missed appointments. However, the MRR still showed at least 28% who were lost-to-follow-up. Furthermore, for this type of intervention, late presentation by patients and misclassification has implications on implementing costs.

The reality is there are some prevailing barriers causing missed appointments. The single intervention that exists to reduce missed appointments (use of SMS) has been reported to improve attendance [29], however, it was not clear if this was the case with this intervention. After all, SMS reminders would only solve part of the problem.

This article concludes by highlighting three priorities that could address the problem of missed appointments and for the broader management of NCDs in our context. These issues are also of relevance to other stakeholders seeking to strengthen health systems by provision of differentiated care for patient groups in other contexts.

First, the assumptions made about patients and the health system are not aligned with the reality. Socio-economic factors affect health facility attendance in the long run and invariably

undermine health status. An appropriate method for establishing these barriers must be found in order to improve management of at-risk patients and to inform the development of contextual approaches to addressing public health problems [30]. This could be achieved by undertaking population-based studies to inform the development of an appropriate, patient-centred package of care. For example, while labour migration is common throughout South Africa and the southern African region, the Western Cape is unique in that the majority of its migrants come from and regularly visit the same part of South Africa (the Eastern Cape). This provides an opportunity to implement patient support strategies specific to this migration route to ensure that patients on chronic medication can be assisted to timeously collect their medication. The NCD care package currently fails to normalise travel as an expected part of many patients' lives.

Second, routine cohort monitoring of patients is essential. Currently clinical outcomes are recorded using a paper-based system in the public sector. Consequently, there is no opportunity to monitor the cohort in order to identify patients who might be defaulting or lost-to-follow-up. Such information can inform health managers about patient status. There is a huge potential to improve NCD care through eHealth [14]. Given the availability of affordable mobile electronic options, the incorporation of electronic medical record technology appears to hold promise for the rapid implementation for monitoring of NCD cohorts [31]. A combination of an efficient electronic system and support for systematic collection of routine NCD data is likely to yield positive results.

Third, it is necessary to revisit the patient care model as a whole to ensure that it is responsive to the needs and realities of the patients. If care for stable and at-risk patients is to be differentiated, then appropriateness of the care package and quality of care become critical elements of service delivery. A number of issues raised in this study are relevant in the development of an appropriate package that responds to patient and health system needs. To

date, we see pockets of interventions [32, 33] but no comprehensive approach. While these are useful, a single factor approach will likely have limited effectiveness. Given the shared barriers and challenges faced by health programmes, some of the approaches developed for HIV programmes have the potential to contribute to models needed to address NCDs in resource-limited settings [34]. We acknowledge that HIV programmes have been fairly well resourced compared to NCDs; however, there is opportunity to adapt interventions to available resources.

Conclusion

The challenges highlighted in this article should not underplay the contribution of the CDU as a useful intervention to address patient and health system barriers to accessing medicines. We suggest developing a model of care reflecting local context, attention to improving CDU's implementation processes and strengthening information systems in order to improve patient monitoring. This model presents lessons for other low-and-middle income countries with increasing need for dispensing of medicines for chronic illnesses.

Declarations

Ethics approval and consent to participate

Ethics approval for this study was granted by the Senate Research Committee at the University of the Western Cape, South Africa (Ref: 11/7/8). Permission to conduct research in the health facilities was also granted by the Western Cape Research Committee. All participants were taken through the informed consent procedure prior to interviewing, including a request to record the interview if the participant was willing. Informed consent was provided through verbal and written consent. Participants were also informed of their right to withdraw at any time without any consequences in accordance with the requirements

of the Helsinki Declaration of 2008. A plan for anonymising data collected through medical records was also in place.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BPM and KW contributed to the conceptualisation of the research. BPM conducted the research. BPM, TM and KW analysed the data. BPM drafted the article. BPM, TM and KW contributed to the intellectual content of the article then BPM finalised the article. BPM, TM and KW read and approved the final manuscript.

Availability of data and materials

The research tools that were employed to generate the data referred to in this article are available as additional files. The datasets generated and/or analysed during the current study are not publicly available due to sensitivities with patient-related clinical information but are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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Abbreviations

CDU: Chronic Dispensing Unit; HCP: Health Care Practitioners; NCDs: Non-Communicable Diseases; PHC: Primary Healthcare; WCDoH: Western Cape Department of Health; WHO: World Health Organisation.

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Paper VI



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Analysing implementation dynamics using theory-driven evaluation principles: Lessons learnt from a South African centralised chronic dispensing model.

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Abstract

Introduction: Centralised dispensing of essential medicines is one of South Africa's strategies to address the shortage of pharmacists, reduce patients' waiting times and reduce over-crowding at public sector healthcare facilities. This article reports findings of an evaluation of the Chronic Dispensing Unit (CDU) in one province. The objectives of the evaluation were to: (1) compare what was planned vs. the actual implementation and (2) establish the causal elements and contextual factors influencing implementation.

Methods: This qualitative study employed key informant interviews with the intervention's implementers (clinicians, managers and the service provider) [N=40], and a review of policy and programme documents. Data were thematically analysed by identifying the main influences shaping the implementation process. Theory-driven principles were applied as a theoretical framework to explain implementation dynamics.

Results: The overall participant response about the CDU was positive and the majority of informants concurred that the establishment of the CDU to dispense large volumes of medicines is a beneficial strategy to address healthcare barriers because mechanical functions were automated and distribution of medicines was quicker. However, implementation was influenced by the context and consequently, discrepancies between planned activities and actual implementation were noted. Procurement inefficiencies at central level caused medicine stock-outs and affected CDU activities. At the frontline, actors were aware of the CDU's implementation guidelines regarding patient selection, prescription validity and management of non-collected medicines but these were adapted at their discretion to accommodate practical realities and deliverables (e.g. patient enrolment targets) attached to the intervention. Implementation success was a combination of 'hardware' (e.g. training,

implementation support and appropriate infrastructure) and ‘software’ (e.g. ownership, cooperation between HCP and trust).

Conclusion: This study shows that health system interventions have unpredictable paths of implementation. Discrepancies between planned and actual implementation reinforce findings in existing literature suggesting that while tools and defined operating procedures are necessary for any intervention, their successful application depends crucially on the context and environment in which implementation occurs. We anticipate that this evaluation will stimulate wider thinking about the implementation of similar models in low- and middle-income countries.

Keywords: Chronic Dispensing Unit; centralised dispensing; medicines supply chain, theory-driven evaluation; access to medicines; Western Cape; South Africa.



Background

Access to medicines (ATM) has attracted increased global attention as a key component of universal health coverage. ATM has also been incorporated into national constitutions, as part of the Millennium Development Goals (Number 8e) [1] and more recently embedded in Sustainable Goal 3, which includes the target to reduce premature mortality from chronic diseases [2]. Furthermore, medicines have been identified as a key pillar of health systems [3]. Frameworks have been developed to represent ATM, with the most recent one by Bigdeli et. al proposing that ATM be viewed within a health system perspective [4]. However, challenges remain in low- and middle-income countries (LMICs) and reflect shortcomings in the health and supply systems in which medicines are distributed and delivered [1]. One key challenge is the pharmacy workforce shortage, which could undermine the performance of the medicines supply chain [5]; yet the growing burden of chronic disease demands efficient life-long medicines supply systems for patients.

To address some of these challenges, a novel centralised dispensing system has been applied to repetitive technical processes in the South African public sector, where dispensing services are contracted out to a private healthcare logistics company. In a previous article [6], we described the processes and actors involved in CDU implementation. In summary, the CDU collects prescriptions from over 200 healthcare facilities (hereinafter referred to as “facilities”) for about 300 000 patients with chronic illnesses each month, prepares individual patient parcels that are then distributed from either the facilities or community distribution points [6, 7].

A recent article by Spinks et al. (2016) reported that to date, most automated dispensing innovations have been applied at a local level, such as hospital pharmacies or community pharmacies [8]. South Africa is among the few countries that have embarked on large-scale centralised dispensing in the public sector [8], however, little is documented on this

intervention. In this article, we focus on the results from a process evaluation of the Chronic Dispensing Unit (CDU), the first large-scale automated dispensing system to be introduced in the South African public sector. The CDU was introduced in one province (Western Cape) in 2005 [6, 9, 10].

This qualitative evaluation was conducted in response to a request by the Western Cape Department of Health (WCDoH) in 2012 to inform process improvement. This study sought to compare what was planned with the actual implementation and to attempt to establish the causal elements and contextual factors influencing implementation.

Methods

We used theory-driven evaluation (TDE) principles as outlined by Chen [11, 12] and Van Belle et. al [13] to guide this evaluation. Theory-driven evaluation as a methodological approach has the ability to contribute knowledge about how and why the intervention worked or failed; evidence that could be useful for understanding the intervention outcomes, for strengthening future implementation strategies, and for developing transferable lessons regarding barriers and facilitators to effective implementation [14]. A key principle of TDE is the development of a programme theory, to explain how the planners or designers expect the intervention to be implemented and why it would lead to the desired outcome [15], which informs the choice and design of the intervention [13]. This detailing of assumptions is also referred to as the *action model*, which includes the assumptions related to how the planned intervention is to be implemented so as to lead to the desired outcome. The action model becomes a hypothesis that can be tested and further refined based on empirical findings [13]. Through this testing, the causal processes and the intervening contextual variables that produce change are referred to as the *change model* [13]. The *change model* provides the explanation of how and why the desired outcome would be obtained. To that end, the process

of constructing the CDU's programme theory was inherent in the study design and was elicited through a process of document review, key informant interviews and a review of literature [6]. In summary, the programme theory was as follows: bringing together various actors and initiating appropriate implementation procedures within a supportive micro-, meso and macro-climate increases access to medicines. In this context, the actors were: the private sector with advanced logistical capability, a provincial implementation task team, frontline healthcare practitioners, community-based organisations, a stable and adherent patient population. Increased access to medicine occurs by reducing pharmacists' workload through relieving pharmacy staff from repetitive and time-consuming tasks; increasing time for patient-counselling; decongesting facilities and reducing patient waiting times. These factors ultimately contribute to improved health outcomes.

Since the focus of this study was to examine implementation dynamics, taking into account issues of context, a multiple, embedded case study design [16] was employed. We defined the case as the implementation of the CDU programme and selected four facilities as the unit of analysis. Our study focused on urban facilities where CDU roll-out was originally initiated and was therefore deemed to be better established. Four primary facilities of different sizes were selected based on the monthly Patient Medicine Parcels (PMP) received from the CDU: <4 000 (small); 4 000-10 000 (medium) and more than 10 000 (large). For variability of experiences, we selected four sites: one small, two medium and one large.

Data collection processes and tools

Theory-driven evaluation is flexible and methods-neutral: the choice of methods is informed by the study objectives [13]. Our data collection methods included: (a) in-depth interviews with representatives of selected actor groups [11], (*Table 1*); (b) a document review and (c) three feedback sessions with participants. The data collection was conducted during the

period 2014-2015. All data collection tasks were conducted by the first author, a qualitative researcher with a background in public health.

Table 1: Study participants

Stakeholder group	Description and relevance to this study	Number of participants
Implementing organisation (Implementation task team for our purposes) : Provincial directors/managers, facility liaison officers and managers from the current and previous contracted service provider)	Responsible for organising resources and coordinating implementation activities. The capability of this organization affects the quality of implementation.	8
Implementers (actors) : mid-level managers, i.e. sub-structure pharmacists, primary healthcare managers; frontline healthcare practitioners - clinicians and health promoters	Responsible for implementation at the frontline.	32

(a) Key-informant interviews

Key informant interviews were conducted face-to-face at the respondent's preferred location, with the exception of two whom we interviewed telephonically: one had moved to another province and the other was not available for a face-to-face interview. The initial task of developing the programme theory [6] informed the aspects that were followed up in semi-structured discussions guided by the researchers' understanding of how the intervention was supposed to work. We focussed on the intervention as it had actually been implemented, the processes (e.g. patient selection and orientation, quality of prescriptions, feedback between the CDU and facilities, and management of non-collected medicines), contextual factors and intervention outcomes and recommendations for improving implementation.

Where possible, interviews were recorded; alternatively, notes were taken. Three participants refused to be recorded as a matter of preference. Once no new information was generated from the interviews (saturation), no further interviews were conducted.

(b) Document analysis

We carried out a document review of programme and policy documents and reports, including standard operating procedures and provincial chronic disease audit reports, in order to triangulate some of the respondents' perspectives.

(c) The feedback sessions with participants

Preliminary results were discussed with respondents in order to allow for member checking, an important validation technique in qualitative research [17]. The process was participatory: we presented at pre-scheduled provincial stakeholder meetings (in two cases) and organised a separate meeting (one case). This process allowed participants to engage with and add to our interpretation of results. Since this was a commissioned study knowledge co-construction with the intended users of the research was an important aspect of the research.

Ethics

Ethics approval was granted by the Senate Research Committee at the University of the Western Cape and provincial government approval to conduct research in facilities was granted by the WCDoH. All participants were taken through the informed-consent procedure prior to interviewing and were also informed of their right to withdraw at any time without any consequences in accordance with the requirements of the Helsinki Declaration of 2008.

Data analysis

The recorded interviews were transcribed verbatim. A hybrid approach of inductive and deductive coding and theme development was applied [18] to analyse the transcripts. This approach was appropriate because it is data-driven and uses pre-determined codes while also allowing for the addition of newer codes. Broad pre-determined codes were drawn from the

components of the initial programme theory covering CDU processes such as patient selection and management of non-collections. At the same time, emergent codes were identified during the analysis. The first author coded the data using Atlas. TI version 7 software. Reports were made for each facility, and a comparison looking at responses to similar questions by respondents from different facilities was done to ascertain how the initial programme theory could be refined.

Results

A key statement made by a provincial director is fundamental to understanding both the successes and challenges of the CDU, that is, the CDU is influenced by the characteristics of the health system within which it is embedded:

“The CDU is dependent upon a lot of interventions that collectively make the system, but if the building blocks [referring to the World Health Organisation’s health system building blocks] are not in place, then it doesn’t matter how pretty the CDU package looks. [The] CDU is not a plaster that you stick on a wound. You’ve got to fix the building blocks, your [medical] depot got to work, your staff and your facilities got to be present and working, your referral system has to work, the contract management of your medicines supply has to be done properly. It’s a complex system, but if the little bits are done, then cumulatively, the CDU works.”

Implementation successes and challenges

Key informants held overwhelmingly positive perceptions about the CDU and reported that the establishment of the CDU was a useful strategy to address prevailing barriers to accessing medicines. The majority indicated that the CDU was a part of their operational routine upon which they were dependent and without which the health system would be weakened.

Automation of the dispensing process was perceived by some informants as useful to improve the dispensing rate and relieve pharmacists of mundane dispensing tasks, as reported by the following two pharmacists:

“If those 300 000 prescriptions [dispensed by the CDU monthly] needed to be done [manually], I can tell you, on a daily basis, the pharmacist can do only a 100 prescriptions. So, you can do the calculations. Even 200 prescriptions are a huge workload, even if we were able to pay salaries ... and now we have an influx problem [with patients].” (Sub-structure pharmacist manager).

“When I worked in the facility in 2001 there was no CDU and you know we did six hundred scripts a day on our own, and when I returned to the system in 2008 there was this amazing system and it was just fantastic because it took that repetitive work away from the pharmacist - not doing the same scripts every month, you actually had a little bit more time to spend with the patients and actually answer their questions. It also reduces the pressure on the pharmacist. You know in the facilities there’s so much pressure on you that you eventually take your frustration out on the patient. So I think it has helped the pharmacists to reduce their workload and I hope that it makes us better pharmacists at the end of the day, able to focus more on the patient more than just focusing on getting that big pile of folders down.” (Provincial pharmacist manager)

There were conflicting views about whether the CDU created more time for patient counselling as referred to in the above quote but it seemed that the intervention increased the health system’s capacity to accommodate newly-diagnosed patients. In addition, the intervention allowed more time for the non-technical phases of dispensing such as face-to-face counselling that would have been difficult for pharmacists to fulfil without assistance.

All four facilities in this study were reported to still have high patient volumes, with patient waiting times for medicine collection still reaching up to five hours at the largest facility. However, facilities with multiple distribution points or a separate “fast-track” queue for CDU patients managed to significantly reduce waiting times. This meant that CDU beneficiaries had separate queues from other patients at designated times in the facility or PMP were distributed from a separate building on the facility premises or outside the facility (community-based distribution). One pharmacist stated that they were able to distribute in excess of 200 parcels within two hours. Whether the designated times were convenient for all patients remains unanswered.

Other benefits included the flexibility of the dispensing system to accommodate special requests from facilities e.g. dispensing for multiple months for migrant populations was appreciated by HCP. This benefit was achieved in small increments from an initially rigid system to one with improved functionality.

In addition, one informant referred to the CDU as a “*control tower*”, capable of providing the information necessary for health planning and management such as prescribing practices and medicine usage. However, this information was underutilised at the time of the study.

Information that was used consistently was about medicines expenditure per facility and identifying ‘clinic hopping’ patients who had a tendency to collect medicines from more than one facility.

The CDU programme also encountered multiple challenges pertaining to contracting of suppliers and the operating context. The former, although outside the direct control of the intervention influenced its implementation significantly as shown below.

Role of macro-level processes

Contracting of CDU service provider

The CDU service is a contracted service, whereby the appointed service provider is given a five-year term. Thus far, the service has been through one cycle of contractual change in 2011/12 and the second cycle is due 2016/17. During interviews, many respondents mentioned how the first tender change-over disrupted the service greatly, while also presenting lessons for the future. One informant specifically described this first tender change-over experience as the “...the straw that broke the camel’s back...”, implying that this event exposed an already faulty system and caused the ultimate collapse in the health system. This transition period was shrouded in controversy: service disruptions were caused by delays in the appointment of a service provider, loss of electronic patients’ records and a prolonged lead time required by the new service provider to become operational. Further details are provided in *Additional file 1*.

Role of contracting procedures on medicines supply

Delay in public sector medicines procurement was identified as a contributor to stock-outs of medicines which inadvertently affected the CDU’s operations. Orders for CDU medical supplies are coordinated by the provincial depot. Many respondents cited the importance of investigating the reasons for delays in procurement in the public sector and interventions to address prevailing challenges. However, it is necessary to cite briefly in this article the implications of stock-outs on the overall functioning of the CDU. The norm for stock-outs was reported to be between 10-20 items, but this increased to between 60-100 items during the tender changeover.

Stock-outs at the CDU resulted in PMP being dispatched without some essential medicines.

When a PMP was dispatched to the facility without all the prescribed items, the local pharmacist would either dispense a suitable generic medicine if readily available in the pharmacy or an alternative under the authorization of a prescriber. This supplementary

dispensing for patients registered with the CDU was not well received by healthcare practitioners (HCP) as it created additional workload for pharmacy personnel.

Implementation at the frontline

Planned vs. actual activities and results

In many instances, there were discrepancies between planned and actual activities as indicated in *Table 2*. Furthermore, selected quotes from participants are provided in *Additional file 2* to explain these discrepancies.

Table 2: Planned vs. actual activities and results

Dimension	Planned activities and expected results	Actual activities and results
Patient selection	Selection of stable patients	Enrolment of patients who are not clinically stable because strict guideline application proved difficult within a context of: (a) multi-morbidities (b) high prevalence of patients with sub-optimal outcomes (c) changing outcomes and (d) patients' needs perceived to be beyond clinical care. In addition, non-medical factors such as service pressures, enrolment targets by management, intention to save on the facility's budget by putting more patients on the CDU budget.
Prescription quality	Clinicians issue prescriptions in accordance with legislation and policies	Overall rate of prescription rejection was an estimated 4-5% (of approximately 14 000 prescriptions each day). Errors were attributed to: (a) cumbersome administrative processes (b) misunderstanding of processes between HCPs and the service provider.
	Pharmacists check all new prescriptions for compliance with legislation and policies	Pharmacists did not always check prescriptions before submitting them to the CDU because they felt it was time consuming.
Dispensing and dispatch of patient medicine parcels (PMP)	Prescription verification, dispensing and delivery to the facility three working days before the collection date	Except when a prescription had been rejected for reasons earlier stated, PMP were delivered on time.

Medicines distribution	Pharmacist fulfils the prescription requirements in case of stock-outs using pharmacy stock. Distribution of PMP follows at the facility or in the community.	Pharmacists did not check all parcels – the process was deemed to be time consuming and consequently to reduce the benefits of the intervention. Pharmacists recommended use of transparent instead of opaque packaging and inclusion of prescriptions in the PMP to facilitate easier checking.
Health system causes for non-collected medicines	Patients are given 5 working days should they miss their scheduled appointment. Thereafter, PMP are returned to the CDU within 10 working days from the date of collection or is absorbed into the pharmacy.	Challenges resulted from: (a) clinicians who were resistant to change (b) locum doctors who were not familiar with processes (c) patients who reported for acute care prior to their CDU appointment often led to establishment of new appointment systems. Clinicians recommended marking CDU patient files differently from other patient files so that they could be easily identifiable.
Management of non-collected medicines	If a patient misses 2 appointments consecutively, the prescription is stopped and the patient must consult the clinician for counselling and assessment. Reports on non-collected PMP should be submitted to the CDU.	Some pharmacy staff returned non-collected PMP while others opened PMP that were not collected. The reasons given for the latter were: (a) shortage of space to keep the parcels (b) to discourage patients from missing appointments [coercion] Pharmacy staff who opened PMP believed that the same patients would come to the facility even if late so they could re-dispense medicines and save on their facility budget. Unstable patients who missed appointments were not removed from the system as per protocol for similar reasons earlier mentioned (saving on facility budget and high prevalence of unstable patients).
Monitoring and Evaluation	Data on all activities	Mid-level managers found it difficult to comprehend routine data and in some cases doubted its accuracy. Statistics on collection of PMP were still under reported because HCP considered reporting a time-consuming task and feared negative views.

Health system 'hardware' and 'software' influencing implementation

We expand on some aspects of the health system's 'hardware' and 'software' because these contextual factors are key to understanding the implementation results presented above. With regard to 'hardware', limited storage space was a major determinant of how pharmacy personnel managed PMP at the facility. Referring to early days of implementation, one respondent said:

"If you have a container of a 100 pills in your shelf it takes up a fairly small space on your shelf but when you take a 100 pills and divide that up into 20 you need space for 5 containers. The fridge items were also a huge problem because facilities had these little fridges for their own purposes. If you deliver a prescription which contains fridge items, you have to put the whole PMP into the fridge so the fridge becomes full. Facilities had to buy new fridges but didn't have the budget." (Former Implementation Task Team (ITT) member)

Limited storage space was further exacerbated by missed appointments by patients. One informant estimated that at least 40% of patients initially did not collect PMP which created a challenge for facilities to keep stock as well as create space for new stock. Over the years, the WCDoH facilitated installation of additional shelving in facilities. Improved shelving and storage, and clear labelling of parcels by the service provider led to improved retrievability of PMP. Previously, facilities had no system in place to organise the PMP, therefore boxes containing PMP piled up and it took a long time for pharmacy personnel to locate PMP for distribution. Consequently, they opted to re-dispense from facility stock, which frustrated both HCP and patients as patient queues grew longer.

Although we focused on urban facilities for this study, HCP made some useful comparisons between urban and rural facilities with regards to preparedness. They indicated that the patient load in urban facilities is much higher, hence the infrastructure demands are also high. Secondly, before CDU roll-out in some rural facilities, those facilities mimicked the CDU

process on a local level by pre-packing two-month medication supply for patients. As a result, minimal infrastructure and process adjustments were required when the CDU was introduced.

On the ‘software’ side, human interactions were key. Pressure from provincial management emerged as a factor that worked against facility preparedness for the intervention. Respondents collectively highlighted that the fast-paced roll-out to facilities was to meet enrolment targets. Also, the number of enrolled CDU patients at each facility was used as an indicator of good performance, which in part contributed to enrolment of patients whose suitability might be questionable. This is an area requiring further research.

Another issue, particularly in the early years of implementation, was inadequate orientation of facilities. Because the CDU demanded the adoption of new administrative processes and new ways of working, an orientation to these processes and willingness of actors to adapt to new ways of working was necessary. An informant who was closely involved in the early years of implementation indicated that in the beginning, much attention was given to ensuring that the dispensing processes, the product and implementation protocols (hardware) were in place but facility preparation was neglected:

“The CDU could deliver a perfect product, but if it’s received in chaos, that product will also be seen as chaotic... I always say: in the first six months, when the CDU was implemented (2005-6), it did so much more harm to the reputation of the CDU than it did good.” (Former member of the ITT)

Facility preparation improved over time and standard operating procedures were revised owing to the lessons learnt from implementation in urban facilities. At the time of this research, an assigned ITT was conducting two to three training sessions at each facility prior to enrolment and regular follow-up from facility liaison officers was provided. Also, implementation is now being conducted in a phased approach to allow for more investment

towards supporting facilities prior to and during implementation. Healthcare practitioners identified the implementation support offered by facility liaison officers as a strength of the intervention. The quote below illustrates positive relationships between HCP and facility liaison officers.

“Okay, what is working and needs to continue, it’s direct support from CDU like [name] and [name] they are playing a very excellent role actually, they are very important people and whoever is taking care of CDU parcels in the facilities got someone to phone, to talk to and then they’ve got those weekly schedules to visit facilities and check - is everything okay, providing training and support, this is very important to continue...” (Senior manager, pharmacy services)

Finally, we identified the following set of essential elements for successful CDU implementation: ownership, trust, cooperation, communication, willingness to change and leadership. In *Table 3*, we provide some key informant voices and our own interpretations to illustrate their role.

Table 3: Essential health system ‘software’ elements

<p>Joint ownership: “When I went to various facilities to see what the problems were, the question that I kept asking myself was “who owns the CDU?”. In the facilities where the relationships and the system were more collaborative ... when that worked well, the CDU was implemented with less resistance. The problems were still there but they were resolved amicably. When it was only [regarded as] a pharmacy issue in the grand scheme of things ... had nothing to do with the facility manager, the structure and the line function it didn't work.” (ITT member)</p>
<p>Trust: “... I always say have the name of the person first and always be consistent with that person and build a relationship with them because I know for me I just call [name of facility liaison officer]. [Name] knows what to do and by now you know how long it takes for [name] to get back to you because you have that trust.” (Pharmacist, facility 4)</p>
<p>Cooperation: “You find that in facilities, there is a disjuncture, with people working in silos, when you look at the CDU process, for example and how it’s supposed to work, it also requires team work in terms of the doctor, the nurse, the person in the pharmacy, the patient and often, you’ll find for example, you’ll end up having your chronic patient coming in for acute [care]getting another prescription when they are supposed to be coming in for another parcel but that’s</p>

because the people at work are not speaking to each other. I wonder how we can get these multi-disciplinary teams to work together for the system to work better than it is working at the moment because I think that some of the problems can be resolved in that way. Some of these non-collected parcels are not true defaulting, it's system issues.” (Senior manager, WCDoH)

Communication: “Yah you want to minimise the number of people involved (referring to involvement of locum doctors in the CDU process), because from the clinician’s perspective there is a lot of frustration because of that poor communication between different actors. I don’t know ‘Did the patient pick up their medication at the end of the month?’ the only way I know is if they have another appointment. So now what we have instructed them is just to cross out the date for the next CDU appointment if we change the medication, so that’s one way to communicate to the pharmacist. That communicates to the pharmacy staff, don’t issue the parcel, the prescription has changed. Now, I don’t know if all pharmacy staff are aware of that.” (Physician and Advisor to WCDoH)

Willingness to change: Changing some traditional practices e.g. in prescription writing was influenced by perceived individual and organisational benefits. When tasks were considered to be time consuming, there was a lack of motivation to do them.

Leadership: “I have come to the conclusion that it's the "captain of the ship" or the manager of the pharmacy who influences success. If he's not performing well, then that pharmacy won't function well”. (former ITT member)

Discussion

Our findings suggest that the CDU has, to some degree, contributed to addressing barriers to access to medicines in the Western Cape province despite many challenges faced by the initiative. This study also adds to the limited body of work examining centralised dispensing models. Its strength lies in its ability to not only show how things worked well (or did not work), but also to identify elements that promoted the intervention’s success, and context factors that influenced implementers’ decisions at the frontline. Furthermore, it shows that health system interventions have unpredictable paths of implementation [19] as evidenced by a range of issues highlighted at the frontline and tied to how actors responded to both the intervention and contextual influences. In addition, there was evidence of macro-level influences, which had not been anticipated at the design phase of the intervention.

Understanding actor responses during implementation

While there were implementation guidelines and protocols, HCP's decisions were guided mostly by contextual realities. A typical example was how HCP exercised discretion in patient selection rather than use standard criteria. Evidently, there were tensions between the 'planned and the actual' when assessing the action model. These tensions were caused by multiple factors including recruitment targets set by management, service pressures and facilities' budgetary constraints.

In literature, HCP have been identified as street-level bureaucrats [20], faced with the immediate consequences of new interventions and having to reconcile management's demands for example, with the reality in the service delivery environment. In that sense, they have the ability to exercise discretionary power in either accommodating or resisting policy initiatives and in shaping them in ways that fit with their everyday realities [21]. Depending on the context and circumstances, HCP's exercise of discretionary power is not necessarily viewed negatively [22], as it might be what is deemed "best" in a particular situation rather than what is "right" in some absolute sense [23]. We reported in another study how contextual factors influenced HCP's decision-making despite the availability of guidelines [24] and we see a similar trend here.

Understanding actor responses also requires acknowledging the key elements that form the change model and influence implementation. In this study, *communication and cooperation between actors, willingness to change, ownership, leadership commitment and trust* were influential in driving the intervention's success. This is evidence that relationships between actors are not purely 'technical', but are influenced by human dynamics as has been reported in other interventions [25]. Then there were also unexpected negative outcomes as a result of,

inter alia, an oversight to acknowledge complexity [26] and macro-level processes such as those for procurement.

Overall, this study presents lessons for informing similar interventions. Key among these lessons was the use of a theoretical model that allows for a deeper level of explanation and offers a source of external validity [27], an approach which has been cited as important for understanding public health initiatives [28]. Since this was a process evaluation, findings from this study were discussed with actors involved in implementation, including management. Some of the challenges identified such as clinicians' difficulty to identify CDU patient folders; pharmacists' request for transparent packaging (instead of opaque bags) for PMP and inclusion of prescriptions in PMP to facilitate easier quality assurance checks at facility level were well understood by the WCDoH and different solutions were being explored. Of note however, although the case for use of transparent packaging for PMP was clear, management raised concerns about a potential breach of patient integrity and confidentiality rights hence alternative solutions will be sought. Macro-level challenges were acknowledged but require targeted interventions at national and provincial level.

Implications for future research

Evidence on centralised dispensing is growing and urgently required to guide implementation in other settings. Some studies from Scandinavia have presented early implementation experiences [25]; and there are on-going debates in the United Kingdom about the introduction of centralised dispensing on a larger scale [8]. Although there is still much to learn, there is already some evidence that such interventions could improve dispensing efficiency and reduce dispensing incidents [29]. With increasing dispensing needs resulting from a growing burden of disease, there will be space for similar interventions and

evaluations in LMICs. Our evaluation of CDU implementation in the Western Cape province of South Africa has relevance for thinking about process improvement and consideration of both ‘hardware’ and ‘software’ elements of the health system.

Study limitations

We were unable to quantify the intervention’s intended outcomes (e.g. reduced pharmacists’ work load, patient waiting times) because these were not measured prior to and during implementation.

Conclusion

This study shows that health system interventions have unpredictable paths of implementation. Clear differences between what was planned and actual implementation emerged in all facilities that were researched. The differences were primarily contextual, and a combination of ‘hardware’ (e.g. training and infrastructure) and ‘software’ (e.g. ownership, cooperation between HCP and trust). Our conclusion reinforces what some studies on implementation of health interventions have found, that while tools and standard operating procedures are necessary and valuable, their successful application depends crucially on the context and environment in which implementation occurs [30]. To our knowledge, this is the first article to evaluate the South African CDU and we anticipate that this theoretically-framed evaluation will stimulate wider thinking about the implementation of centralised dispensing models in other settings in LMICs.

Abbreviations

CDU: Chronic Dispensing Unit; HCP: Health Care Practitioners; ITT: Implementation Task Team; LMICs: Low-and-middle income countries; PHC: Primary Healthcare; PMP: Patient Medicine Parcel; Theory-driven evaluation: TDE; WCDoH: Western Cape Department of Health.

Declarations

Ethics approval and consent to participate

Ethics approval for this study was granted by the Senate Research Committee at the University of the Western Cape, South Africa. All participants were taken through the informed-consent procedure prior to interviewing, including a request to record the interview if the participant was willing. Participants were also informed of their right to withdraw at any time without any consequences in accordance with the requirements of the Helsinki Declaration of 2008.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BPM, BM and KW contributed to the conceptualisation of the research. BPM conducted the research, analysed the data and drafted the article. All authors contributed to the intellectual content of the article. BPM finalised the article. All authors read and approved the final manuscript.

Availability of data and materials

Not applicable.

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Additional file 1

Textbox 1: Key events linked to the CDU's first tender change-over process

(2011/12)

- ❖ **Delay in appointment of service provider:** To alleviate challenges, interim service providers including the first service provider, were appointed until a new service provider was appointed.
 - ❖ **Legal issue on intellectual property rights between the out-going service provider and WCDoh:** The provincial high court's ruling was in favour of the service provider in accordance with the court's interpretation of the service level agreement. However, there were consequences:
 - data that had been electronically captured in the first five years of implementation was forfeited.
 - the outgoing service provider handed over hard copies of prescriptions (for over 200 000 patients) to the WCDoh. The complex data transfer process had further implications on the next service provider's ability to efficiently continue the dispensing service in the initial phase.
 - ❖ **The next service provider took longer than anticipated to adjust to service requirements:** This was a result of the issues stated above and was further compounded by the implementation of new business processes and commissioning of new equipment. In addition, the demand for the service was much higher than had been anticipated, which resulted in omitted or late deliveries.
- The impact was felt at the facility level, increased patient waiting times were experienced, undoing some gains that had been achieved. It took some months for the service to stabilise again.
- ❖ **WCDoh's response:**
- The Department issued press statements to alert patients of the situation, set-up a temporary telephone helpline for patients to call with queries and instituted interim measures to ensure that patients obtained medicines until the system had stabilised again. For the first weeks of the transition, the new service provider and WCDoh jointly reverted to manual dispensing. WCDoh also suspended some facilities from the CDU for about three months to allow the service to stabilise again.

Additional file 2

Table A1: Selected quotes and observations to support views expressed in table 2.

Patient selection

Selection based on budget: “The other thing that makes us (to) put patients on CDU is to do with the budget. We have a different budget for patients on CDU which comes from provincial level and we have our own budget serving the patients coming through the facility. So the more people we get on CDU the more we can save on (our) budget. The facility budget is not increasing and the patients are increasing every year and we encourage the clinicians to put patients on CDU”. (Pharmacist, facility A)

Patients’ needs perceived to be beyond clinical care: “Health can do so much, inter-sectoral collaboration is required because poverty plays a role, your circumstances, economic factors and all of that.” (Senior Manager, WCDoH)

Service pressures: “...definitely there are people who are put on CDU who are not completely within the criteria of controlled blood pressure, controlled blood sugar. You got people who are fairly controlled but not perfectly controlled and if you have to see everybody every month who have their reading abnormal, it is not practical.” (Physician 1, facility C)

Service pressures: “It happens also that we would like to decongest facilities, the doctors sometimes are putting patients on CDU sooner than the patient is really stable, just for the sake of obtaining medication from CDU...the patient is not yet very compliant maybe he needs more checks on the blood pressure, or glucose levels.” (Senior Manager, Pharmacy services)

Changing outcomes: “I think that the assumption is that if the doctor puts them (patients) on a six-month prescription then the blood pressure is going to be stable for the entire six months, which you can’t be sure of.” (Physician 2, facility C)

Varying perspectives on what is appropriate: “It depends on the clinicians, some clinicians don’t have a problem of putting someone (on CDU) who has a diastolic of 110, I’ve seen it and it makes no sense to me.” (Physician and Advisor to WCDoH)

Prescription quality

Poor prescription writing: “...we’ve got prescribers who aren’t always writing legible prescriptions and then pharmacists are just assuming that they can read it and therefore this person at the CDU is going to be able to read it and I’ve captured some scripts and I was alarmed at how poor our prescriptions looked.” (ITT member)

Deliberate decisions by clinicians: “Yah that whole communication between clinician and pharmacy I must say in other facilities you get away with “murder” ...you know they (clinicians) don’t stick strictly to the code list restrictions... I don’t know if I should admit this (laughing) but the Drs and specialists are getting away with prescribing (items that are not on the code list) ...” (Physician and Advisor to WCDoH)

Prescription writing considered a cumbersome task: “That is why I have arthritis in my right shoulder because of writing a lot and especially now we don’t have stickers (with pre-written titles). You have to write the name the surname, the folder number, the age, the ID number. You have to write everything down and it is very easy to make a mistake. After

seeing 30-40 patients you can make mistakes very easily. That is a bit of a problem I must say and I don't know when is this going to end, not having stickers is a big problem. (Nurse, facility D)

Pharmacists not checking prescriptions: “I usually don't get the time to check all the scripts. I'm the only Pharmacist and the 2 assistants. I will not check each and every script especially with patients waiting outside.” (pharmacist, facility D)

Rate of prescription errors: “...we do about 14 000 scripts a day, and between four to five percent of that will be rejected every day. So that's quite a substantial amount... 150 scripts minimum a day are rejected, so that's 150 patients that on the next collection day will not have a parcel waiting for them.” (ITT member)

Quality assurance

“...you still find scripts that are not dispensed by CDU, you still find those that the patient didn't receive a parcel, so they ask us to fill the query form, but there is no time, that's extra admin work... why don't they have a quality assurance system to check on the pharmacy?” (Pharmacist, facility D)

Medicines distribution

Missing PMP: “...they (facilities) report that they didn't receive a PMP (parcel) then when we investigate we see that it was delivered to this site and someone signed for it, and then they phone back, and say ok we found it. So it could also be how they are managing the process at the facility and you can see there is a common pattern in some of the facilities. Some of the facilities will keep them in the box with all the details and all the paper work in there so it makes it easy to maintain. Some of the facilities will take it out of the boxes that we have provided and pack it, and then it becomes a little bit more difficult to find. (Name of ITT member) is really working hard at teaching best practice, some facilities have got a fantastic way of organising parcels, they put up manifests, patients come in and they say: “I am here to fetch my parcel it's (in) box 653.”” (ITT member)

Case 1 (facility C): On the 26th of February 2014, the pharmacist assistant (also CDU champion) reported 16 missing PMP (i.e. not delivered by the CDU) for that day's distribution. The researcher followed up on this case and two days later, the pharmacist assistant reported that only 5 were actually missing (for reasons unknown at that stage). The other 11 had been reported as missing as a result of facility errors i.e. patients had been given wrong dates (for 10) and for the 1, the prescription had not been sent to the CDU.

Non-collected medicines policy: Why some pharmacists either return parcels earlier or absorb stock into facilities.

Why absorb rather than return PMP? “Some patients do come to collect their medicines later (after their appointment date) so we need the medicines otherwise we will go over our budget.” (Pharmacist, facility C)

Why return PMPs earlier than 10 working days (every second day): “We try to return the manifest every second day because of resource constraints... In any case the number of patients who will come is 2-3 so it makes little difference.” (Pharmacist, facility C)

Observations from the dispensary: “We see it here we get stuff (PMP) back, not five days after, we get it the next day. Yah so they just, at the end of the day say these are the patients that didn't collect, they put it all into one box, tape

it up and the next day our driver comes they say there you go take it out because they want space. There is no space in these facilities.” (ITT member)

Monitoring and evaluation information barely usable from the managers’ perspective: “...we need to revisit the information that we are getting, the information is unmanageable, reports are very difficult (to interpret). The system is not user friendly and with time constraints people will not go there, that is one thing... If we could draw results by your facility, that could be helpful.” (Sub-structure manager, Pharmacy Services)

Need for better patient monitoring: “It also comes back to chronic disease management. We should start off by having chronic disease registers so that we have a code that these patients are on CDU and we know what is happening (to them). (Sub-structure manager, Pharmacy services)



End

“After climbing a great hill, one only finds out there are many more hills to climb.”

– Nelson Mandela

