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A realist evaluation of a clinic based Lay Health Worker intervention to improve the management of Hypertension in rural South Africa

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Date: 30th October 2017

Candidate declaration

I FELIX LIMBANI declare that this thesis is my own work. It is being submitted for the Degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Signature: _____

Date: 30TH OCTOBER 2017

Dedicated to

my mother Linley Limbani

she has taught me to work hard and be determined

my source of inspiration

she has inspired many in her 34 years of primary school teaching career

that achieving goals take passion and commitment

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To God be the glory.

Presentations

i. Mpumalanga chronic disease forum and provincial conference on hypertension: screening, detection and management, Mpumalanga, South Africa, 28th November 2013 – oral presentation
ii. Agincourt research scientific meeting, Mpumalanga, South Africa, 18th March 2015 – oral presentation
iii. Global Alliance for Chronic Diseases annual scientific meeting, Xian, China, 13th November 2015 – oral presentation
iv. University of the Witwatersrand, School of Public Health research day, Johannesburg, South Africa, 25th August 2015 – poster presentation
v. Global Alliance for Chronic Diseases annual scientific meeting, Mexico City, Mexico, 13th November 2015 – poster presentation
vi. University of the Witwatersrand, Faculty of Health Sciences research day, Johannesburg, South Africa, 1st September 2016 – Oral presentation
vii. Global Alliance for Chronic Diseases annual scientific meeting, Sydney, Australia, 20th October 2016 – oral presentation

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Abstract

1. **Background**

Hypertension prevalence is high in Africa and is one of the commonest cardiovascular ailments. A cluster randomized control trial (RCT) was run in the Bushbuckridge sub-district, Mpumalanga, in South Africa, to test whether lay health workers (LHW), working alongside nurses in rural clinics can improve management of hypertension. The trial's programme theory was thus management of hypertension would improve since LHWs would free up nurses by taking up some of their tasks. Nurses would then focus on clinical management of the patients. In this area, nearly half of adults are hypertensive, but only 9% have the blood pressure well controlled.

In my PhD, I have used realist evaluation approach to understand the impact of the LHWs and explain "what worked for whom, under what conditions and how". I have also discussed the practicality of combining realist evaluations and RCTs, contributing to an ongoing debate.

2. **Aims**

To understand under what context and through what mechanisms a clinic based lay health worker intervention will enhance integrated chronic care for hypertensive patients and will modify patient outcomes in a cluster randomized trial in primary health care clinics.

3. **Methods**

This study was a theory driven realist evaluation. It was based in realism approach which focused on explaining "why" and "how" improvements happened (or not). I used Medical Research Council's (MRC) framework for process evaluation of complex interventions to understand and present how the different constituents of the intervention, implementation, context, mechanisms and outcomes are interconnected. My programme theory was adapted from Pawson and Tilley's realist approach that considered outcomes from the

intervention, as a configuration of the context and the mechanisms through which the intervention was implemented (context + mechanisms = outcomes). I also used other theories that describe factors for ideal chronic care (Wagner model) and effects of complexity in organizations (theory of complex adaptive system).

I used a case study approach to compare and contrast experiences in the eight case clinics. The intervention and operation of the clinics were explored over time during the pre-trial period, during the preparation and development phase of the intervention, mid-way through the implementation of the intervention and towards the closure of the trial. Data collected was largely qualitative using detailed, observation of clinic activities and patient pathway, focus group discussions with community health workers and community members, semi-structured interviews Clinic Managers, Clinic Supervisors and sub-District Manager, in-depth interviews with LHWs and the Implementation Manager, semi-structured interviews with three cohorts of purposively selected hypertensive patients in their homes, patient exit structured interviews, and Implementation Manager's and researcher diaries. Qualitative data was analyzed using Nvivo and data extraction sheets that pulled together data from different sources. Quantitative data from patient exit structured interviews was analyzed descriptively using simple statistical tests.

4. Findings

At the time of the study, implementation of a government initiative called Integrated Chronic Disease Management (ICDM) model was underway in all clinics. There was rapidly increasing demand for chronic disease care as HIV management and management of stable chronic patients was referred down from hospitals to clinics. The trial clinics were swamped by HIV and hypertensive patients with 53% of the clinic visits by patients with chronic diseases done by HIV patients and 47% done by hypertensive patients. More support is available for HIV patients as compared with hypertensive patients such as tracing of patients that default treatment, counselling and testing by lay counsellors and data capturing.

Clinics were affected by constant break down of BP machines and cuffs that were torn. There was limited maintenance of equipment and supply of materials i.e. patient files and

packs for prepacking medication. Supply of hypertension drugs increasingly became erratic in all clinics. There was perceived shortage of nurses with some clinics being better off than others. Limited space and dilapidated Infrastructure affected chronic pathways in some clinics. Clinic management differed from clinic to clinic which affected relations among staff, relationship between staff and patients, and day to day operation of the clinic. Performance and motivation among LHWs varied across clinics and largely depended on support from other clinic staff.

LHWs had background in community health work, were residents of villages served by respective clinics and had attained grade 12 (Matric). LHWs supported the nurses with appointment booking, pre-retrieval of files and filing back, measuring blood pressure, health education and prepacking of medication. They also reminded hypertensive patients prior to their appointment and followed up with those that missed appointment. The LHWs were supervised by an Implementation Manager who was a Professional Nurse by training. During the intervention, LHWs played an important role of identifying and following up with acute and other chronic patients with raised blood pressure.

I placed the clinics into well, medium and poor functioning categories, although there was no clear cut difference between well and medium functioning clinics, and between medium and poor functioning clinics. However, my analysis showed that clinics require at least one of the following: strong management, teamwork, or a committed chronic care nurse, to get reasonable outcomes. If none of these exist, clinics perform poorly.

5. Discussion and conclusion

The LHW programme theory ***partially*** worked as expected. The intervention was not successful in improving population levels of BP but successfully changed the functioning of clinics and delivery of care to patients with chronic diseases. The success in improving functioning of clinics varied across the intervention clinics. The LHW programme theory has explained the causal pathways that led to these differences in the programme outcomes and effects. These were mainly as a result of differences in context, mechanisms and implementation process.

Using the MRC framework for process evaluation of complex interventions, the following configuration of intervention, context and mechanisms explains the study: Clinics with observed better contextual factors i.e. infrastructure, equipment, good clinic management, nurse levels, low patient loads; were clinics with positive effects in the work of the LHWs i.e. appointment booking, reminding and following up with patients, prepacking medication and filing. These were also clinics where staff related well among themselves and with patients, supported the work of LHWs and had motivated and skilled LHWs. Such clinics had positive clinic level proximal outcomes (collected through clinic link) that included patients adhering to their appointment dates and identifying patient with raised BP.

Use of theories in this study has helped me to understand that health care facilities are complex organizations and are always evolving and changing. A complex mix of different factors i.e. relations, management, resources, resulted in no linear path of implementation and outcomes. Chronic care depends on positive interaction between the health system, the providers and the users. When carrying out health care interventions, implementers should consider the unique nature of facilities and strengthen the interactions between the health system, the providers and the users.

I support the notion that realist evaluations can be used with RCTs and can be used to explain and strengthen findings from the trial. Trials should routinely include a process evaluation which should describe the context in detail and review how the contexts of the trial affect the implementation and outcomes, while understanding the mechanisms by which the intervention works.

LHWs provided useful support to nurses in providing integrated care for chronic patients compared to usual clinics. However, the effectiveness of LHWs was affected by limited resources, increasing patient load and poor clinic management. The realist evaluation has reflected on policy and practice implications for effective chronic disease management. Such issues include, (a) lay persons can take up socially and medically oriented tasks of nurses with proper selection, training and supervision, (b) measuring vital signs for every patient that comes to the clinic has left the BP machines overwhelmed and often broken

down, (c) despite introduction of integrated chronic disease management, programmes are still implemented vertically at clinic level with special attention given to HIV. The innovative methodological contribution in this PhD has been this additional level of information about the causal pathway in implementing the LHW intervention which otherwise could not have been identified just with a randomized controlled trial.

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Glossary of abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Treatment
ASW	Adherence Support Workers
BMI	Body Mass Index
BP	Blood Pressure
CAG	Community Advisory Group
CAS	Complex Adaptive System
CDF	Community Development Forum
CHW	Community Health Worker
CMO	Context, Mechanisms and Outcomes
CMOc	Context, Mechanisms and Outcomes Configuration
CVD	Cardiovascular diseases
DHS	District Health System
DHMT	District Health Management Team
DM	Diabetes Mellitus
DoH	Department of Health
FGD	Focus Group Discussion
GACD	Global Alliance for Chronic Diseases
HBC	Home Based Care
HBP	High Blood Pressure
HDSS	Health and Demographic Surveillance System
HIV	Human Immunodeficiency Virus
HPT	Hypertension
ICDM	Integrated Chronic Disease Management
LHW	Lay Health Worker
LINC	Learning, Information, Dissemination and Networking with the Community
LMIC	Low and Middle Income Countries
MCH	Maternal and Child Health
MRC	Medical Research Council
NGO	Non-governmental organization

NHI	National Health Insurance
NIMART	Nurse Initiated Antiretroviral Treatment
OPD	Out-patient Department
PC 101	Primary Care 101
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
PMDS	Performance Management Development System
RCT	Randomized Controlled Trial
SAGE	Study on Global Ageing and Adult Health
SARRAH	Strengthening South Africa's Response to HIV and Health
SMS	Short Message Service
TB	Tuberculosis
HCT	HIV Counselling and Testing
WBOT	Ward Based Outreach Teams
WHO	World Health Organization

Preface

I have had a wealth of experience in development work. As head of programmes for Youth Net and Counselling, a local NGO in Malawi, I led a team of programme managers in identifying gaps and devising interventions that would address factors affecting development of youth, women and children. Through this experience, among others, I participated in the first ever President Barack Obama's presidential forum with young African leaders at the White House in August 2010. In implementing a variety of community development programme, one common question I was always faced with was to show the impact our interventions had on the target population.

I later worked for Dignitas International, a Canadian NGO in medical programme and research, as their first ever Knowledge Translation coordinator. My role involved engaging policy makers and researchers in generation and utilization of health sector research in Malawi for evidence based interventions and decision making. I became a member of Evidence Informed Policy Network (Evipnet) under WHO and I pioneered the establishment of a Knowledge Translation platform for Malawi in collaboration with the Ministry of Health. All these efforts were aimed at enhancing health programme interventions that have proved to be successful based on research evidence.

In 2012 when I attended interviews at Witwatersrand as researcher and programme manager for the lay health worker research intervention in Mpumalanga, South Africa, I had aimed at getting experience in implementing a programme in a different cultural setup and studying for the PhD. Little did I know that the experience would be part of understanding the impact of programme interventions and evidence based programming as was expected in my earlier work experience.

Carrying out a Realist Evaluation of such a complex clinic based lay health worker randomised controlled trial has helped to gain the skills and expertise of not only understanding whether an intervention would be successful or not, but to whom it would be successful, under what conditions and how. This realist thinking requires one to be critical of own work in order to understand and explain different patterns of programme

implementation and outcomes. Process and realist evaluations are a growing field in research approaches. They tend to very well compliment with other research approaches of studying effectiveness by presenting and explaining causal pathways of programme implementation. I have learnt from this study that understanding implementation context and mechanisms in detail is prerequisite to a successful programme intervention.

Thesis overview and structure

Chapter 1: Introduction

In this chapter I summarize the aims of the study and its methodological approaches. I also indicate how the thesis is nested in a randomized controlled trial and the focus of the PhD within the trial. I briefly described the study site and I reflect on my roles during the study, my background and how it might have influenced the study.

Chapter 2: The Trial in which the PhD study is nested

This chapter presents the randomised controlled trial in which this PhD study is nested. It explains the primary outcome of the trial and the different components of the trial including its design, population surveys before and after the intervention, and randomization of clinics. I also briefly explain the preparations for the intervention, quantitative data collection at clinic level and the trial's programme theory.

Chapter 3: Study setting

In this chapter, I describe the setting and context in which I conducted the study. I look at how the South Africa's health system has evolved broadly and its primary health care operates. The chapter also includes specific reforms currently underway within the South Africa's health system aimed at strengthening the primary health care. Among others, it reviews strengths and weaknesses of the Integrated Chronic Disease Management (ICDM) and Primary Health Care Re-engineering that are aimed at improving management of chronic diseases. I discuss and relate ICDM to Wagner's theory of ideal chronic care. My interest is to understand the extent at which ICDM achieve goals set out by Wagner.

Chapter 4: Literature review

This chapter presents a review of literature relevant to the study. It presents why hypertension is a problem and public health concern globally and in South Africa. I have included brief overview of blood pressure management and treatment. I describe problems with hypertension and generally chronic management in South Africa, previous efforts to improve it and how it relates to the lay health workers (LHW) intervention.

In this chapter, I also examine work that has been done by clinic based LHWs globally, in Sub Saharan Africa and South Africa. I review literature on LHWs, specifically in chronic disease management in low and middle income countries. I look at the successes registered and challenges experienced. I also present findings from the studies on enablers and limitations to effective LHW interventions.

I review literature on the role of programme theory in implementation and its evaluation and, the importance of fidelity and dose. I discuss literature on understanding the health system as a complex adaptive system (CAS) and its influence on how we understood change would take place in the clinics. I reflect on the realist approach in the broader field of process evaluations of complex interventions. I also review current debate among researchers for and against combining realist evaluation and randomised controlled trials.

Chapter 5: Research design and methods

In this chapter, I present the main aim and specific objectives of the realist evaluation of the LHW trial. I link each specific objective to the kind of data that was collected to answer the objective and the data collection method used. This also chapter covers methods that I considered and used in my study. I explain the case study approach in the evaluation of the intervention. The chapter also covers methods that I used in collecting and analysing both qualitative and quantitative data. I explain the sampling techniques used. I describe how data collection was structured in four phases throughout the implementation period. I also explain data management processes including the team that supported me in data collection and transcription.

Chapter 6: Results - Developing and establishing the intervention

In this chapter, I discuss the background to the LHW intervention, the pre-trial situation analysis, the programme theory, and the intervention development process. The intervention development process looks at elements like recruitment of LHWs, their training, randomization of clinics and clinic specific intervention development workshops. I discuss how these workshops varied across intervention clinics and how they affected functioning of the clinics.

Chapter 7: Results – Contextual factors that affected the implementation of the trial

The chapter covers the environment in which the intervention was implemented and the clinic contextual factors at the beginning and throughout the implementation period that affected the functioning of the clinics and the LHW intervention. Those factors are discussed on how they differed (or were similar) across the eight case clinics.

Chapter 8: Results - Engagement of clinic staff and patients with the lay health worker intervention (Mechanisms)

In this chapter, I discuss how staff in the clinics interacted with the intervention. I look at how they related to LHWs, supported them and their general response to the changes brought about by the intervention. I further link their reasoning, the clinic context and other factors like individual performance of LHWs to look at intermediary outcomes in the clinics.

Chapter 9: Results - Clinic-level outcomes

In this chapter, I present the proximal outcomes at clinic level collected through clinic link (e.g. the percentage of chronic patients adhering to their appointment dates) and I relate them to individual clinic performance and operation as explained through chapters six (Intervention), seven (Context) and eight (Mechanisms).

Chapter 10: Results – How functioning of clinics and behaviour of patients were affected by context, mechanisms and the intervention.

This is the final results chapter that pulls together and connects data from the preceding four results chapters. The chapter is a summary of at how the LHW intervention affected the functioning of clinics and behaviour of patients. I summarize the chapter by categorizing the clinics into well, medium and poor functioning categories based on different levels of context, engagement and patient outcomes.

Chapter 11: Discussion and conclusions

In this chapter, I summarise the findings of the study. I reflect on the theories described in the literature review and how I have used them in the study to explain the causal pathway of the intervention. I present how the hypothesized programme has worked in this study. I explain how context and mechanisms impacted on the intervention process and outcomes. I present the innovative methodological contribution this PhD has made. Finally I reflect on the strengths and weaknesses of the study.

The chapter has presented the key thematic areas arising from the results and their potential influence on policy and practice related to LHW interventions and chronic disease management. I also include recommendations at different levels (both policy and practice).

CHAPTER 1: INTRODUCTION

The research described in this thesis was nested in a three-year cluster randomized controlled trial (RCT) known as the Nkateko trial (meaning "blessing" in the local Shangaan language). The trial tested whether providing two LHWs in the clinics, working alongside the nurses, could improve hypertension management (1). As part of the trial I conducted a detailed realist evaluation, aiming to understand the context and mechanisms around how the LHW intervention influenced the barriers and facilitators to accessing health care for hypertension (see further details in Chapter 5 Research Design and Methods). The focus was to understand 'for whom did the intervention work, under what conditions and how'. This evaluation will also discuss to the practicality of combining realist evaluations and RCTs, contributing to an ongoing debate.

The trial took place in a situation of high prevalence of HIV and steadily rising prevalence of hypertension in South Africa. Pressure at clinic level is increasing with new demands on primary care as HIV patients were down referred from hospitals to primary care clinics and a "step down programme" referred back all stable chronic patients from the local hospitals to their local clinics. As the burden of non-communicable diseases has increased, providing effective primary care to the large and increasing numbers of people with chronic diseases is an immense challenge. In this situation, many affected individuals are not using any medication and very few have controlled blood pressure (2).

In this intervention, LHWs supported chronic care nurses in primary care clinics in booking patients for their appointment, retrieving patients' files before their appointment, reminding patients for their appointment, following up with patients that missed appointment, health education, measuring blood pressure (BP) and assisting with pre-packing of medication. This work was carried within a new government initiative of Integrated Chronic Disease Management (ICDM).

This realist evaluation is guided by a realist framework that views outcomes from the intervention, as a configuration of the context and the mechanisms through which the intervention was implemented (context + mechanisms = outcomes) (3) based on Pawson

and Tilley's realist theory (4). I have used Medical Research Council's (MRC) framework for process evaluation of complex interventions (5) to understand and present how the different constituents of the intervention, implementation, context, mechanisms and outcomes are interconnected. The MRC framework explains an intervention and its causal assumption in logic model to understand the causal pathway of the intervention outcomes. The design, implementation and evaluation of the intervention is also informed by two other theories aimed at further understanding different factors that would affect the implementation of the intervention and its outcomes. These are the theories of Complex Adaptive System and the Wagner model for ideal chronic care. The theory of Complex Adaptive System (CAS) states that non-linearity of the implementation-outcome relationship is seen as due to the adaptability (or unpredictability) of actors and the wide range of influencing elements (6). This theory recognizes that such non-linearity is as a result of the learning, inter-connections, self-organizations and co-evolving taking place in complex organizations. Wagner model of ideal chronic care views successful chronic care as a result of productive interaction between the health system, providers and users (7). All these theories will be described in detail in chapter 3 on Literature review.

The realist approach is also reflected in the objectives and results of my thesis. In chapter six (results), I have discussed the intervention, its development process and how it affected the intervention in different clinics. In chapter seven, I have presented how context varied across the clinics and how it facilitated or hindered the intervention. The eighth chapter discusses the mechanisms in terms of how different actors responded and interacted with the intervention and what facilitated the interaction. In the ninth chapter, I have presented the proximal outcomes at clinic level and how the intervention affected patient outcomes. The tenth chapter pulls together data from the preceding four results chapters to describe how the intervention affected functioning of clinics.

The study was situated in Bushbuckridge, a rural sub-district of Mpumalanga Province in north-east South Africa, where the Agincourt Health and Demographic Surveillance System (HDSS) is based. The MRC/Wits Rural Public Health and Health Transitions Research Unit, part of the School of Public Health of the University of the Witwatersrand, has been running a Health and Demographic Surveillance System (HDSS) since 1992. The MRC/Wits Agincourt

Research Unit has collected population data, with vital events (births, deaths and migrations) updated yearly (8). Data from Agincourt HDSS shows an increase in the mortality of non-communicable diseases related deaths from 209 in men and 172 in women per 100,000 population between 1992-1994 to 270 in men and 180 in women, between 2002-2005 (9). A study in 2007 found that nearly half (46%) of adults in the HDSS site have hypertension and only on-in-ten (9%) of them have blood pressure well controlled using medication (2).

As a researcher for the realist evaluation, my main roles included developing the protocol for the realist evaluation, obtaining ethical clearance from both the University of the Witwatersrand and the Mpumalanga Provincial Government, recruiting and training fieldworkers, personally collecting data, supervising the fieldworkers in their data collection and entry processes, analyzing data and report writing. Though I could not speak the local language (Shangaan), my background as a black African public health researcher from within the Southern Africa region (Malawi), helped me to be familiar with the traditional values of the local communities. I also lived in the Province during the three-year study period which helped me to further understand cultural dynamics among the study participants. Secondly, over ten years in public health research, knowledge translation, development programmes and community engagement, helped me to understand the primary health care system and the growing burden of chronic diseases which have similar trends in other Southern African countries, the sub-Saharan region and low and middle income countries generally.

It is against this background that this thesis goes beyond just understanding whether the LHW intervention played a role in reducing prevalence of hypertension and increasing proportions of people receiving treatment for control of hypertension. It explores what would be an enabling context for the implementation of such an intervention by understanding the design of the LHW intervention, the contextual factors through which the intervention was implemented and how different actors interacted and responded to the change brought about by the intervention. This realist evaluation has served two purposes: (a) it has tested the causal assumptions and the intended (and unintended) pathways that led to changes in the trial, (b) I have used findings from this study to contribute to the global debate on the practicality of synthesizing realist evaluations and RCTs.

CHAPTER 2: THE PROJECT IN WHICH THE PHD STUDY WAS NESTED

In this chapter, I present a brief overview of the cluster randomised controlled trial (RCT) in which my PhD was nested. I will present the trial design, aims and intended outcomes based on the population surveys prior and after the intervention. I will also discuss the intervention's programme theory preparations for the intervention (more detail to come under results chapter 6). I will include a description of another component of the trial called 'clinic link' that collected quantitative data at clinic level on clinic level outcomes.

2.1 Study design for the trial

The cluster randomized controlled trial tested the effectiveness of adding a clinic-based LHW to a clinic to supplement government initiatives and support care of patients with chronic diseases. The health facility and its surrounding catchment population were used as a unit of randomization. Eight health facilities were randomized, with four receiving two LHWs and four control clinics. The primary outcome of the trial was to increase the proportion of the population under active management for their hypertension as well as reducing the level of blood pressure in those patients already receiving care. For this reason the outcome of the trial was the reduction in the proportion of the population at moderate or greater cardiovascular risk as a result of their blood pressure and other risk factors. A population survey was conducted before the intervention and another after the intervention to be used to assess population level effects of the intervention. The measurement of the primary outcome of the trial was not the subject of the PhD study; hence the population surveys are not described in detail in this thesis. I have co-authored the trial paper which is in the process of being submitted for publication (1). Figure 1 below presents the trial design.

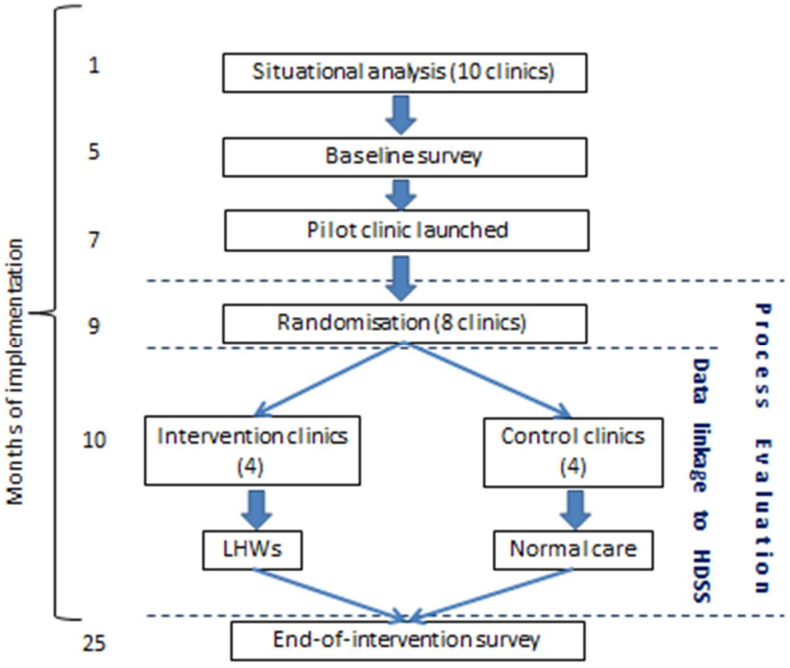


Figure 1: Study design

2.2 The trial's programme theory

There is increasing prevalence of hypertension in the Agincourt HDSS (2, 10-12). The primary care clinics are overwhelmed with increasing number of patients with chronic diseases which has made it difficult to provide effective care to patients. This is how the trialists anticipated the intervention would work: The trial introduces two LHWs to work alongside nurses to improve management of hypertension in intervention clinics as compared with usual care and support ICDM. It is expected that this would lead to patients that are empowered to adhere to their appointment dates, adhere to medication and follow clinic advice, providers that are empathetic to the needs of the patients, and ultimately increase the proportion of hypertensive patients under active management for their hypertension as well as reducing the level of blood pressure in those patients already receiving care at population level. The trial's programme theory is thus to try out a new clinic based LHW intervention to improve management of hypertension and control of BP at population level.

2.3 The Lay Health Worker intervention

LHWs provided support to the chronic disease nurses and patients, acting as 'health system navigators'. They provided adherence counselling, helping to improve treatment literacy, using text messaging to remind patients of appointments (13) and following up with patients that missed their appointment, assisting with the prepacking of medication in the clinics, booking patients in the appointment register, measuring BP, helping with queuing and patient navigation, and assisting with filing (pre-retrieval of patient's records and filing them back). These tasks were carried out by nurses in usual/ control clinics.

2.4 Preparing for the intervention

Following the situation analysis, the intervention was developed in partnership with local communities, health staff and the Department of Health. An Implementation Manager (health professional) was responsible for establishing the intervention and supervising and supporting the implementation staff (the LHWs). Intervention development encompassed material development including the tracking systems for appointments, and defaulters, training materials for nurses and LHWs, mobile phone text health and adherence messages. Recruitment of the LHWs and Data Clerks and a pre-service training programme was implemented, which allowed LHWs and clinic staff to discuss system barriers to the provision of care, reviewing existing patient-provider relations, understanding the aims and hypotheses underlying the intervention; practicing required skills, as well as contributing to further refinement of the intervention. The intervention was piloted in a ninth clinic outside the study site.

2.5 Census clinic link

Clinic link is process of electronically linking enumerated population based information, collected in HDSS sites, with datasets from local health facilities (14). The aim of integrating these two datasets is to enhance comprehensive data covering health, social and economic indicators and people's access to health services. This linked data is a very useful tool for policy and research interventions (14). As part of the Nkateko trial, data entry clerk was

placed in each of the eight trial clinics throughout the intervention period. Data entry clerks in both the intervention and control clinics, collected identifiers of all chronic patients attending at the clinics who consented on linking their clinic information with the Agincourt census database. The linked data was used to understand patterns of clinic use, as well as differences in clinic use associated with gender, age, and relative wealth and to monitor whether patterns of clinic use changed over the 15 months of the duration of the trial. Moreover, these clerks collected quantitative data on areas like patients with elevated BP and adherence of chronic patients to their appointment dates. These proximal outcomes will later be related to the functioning of the clinics in the results chapter 10.

2.6 Selection process for the clinics

The public health system in the Agincourt HDSS consists of six clinics and one health centre. For this trial, we included a further clinic, adjacent to the HDSS, together with the population it served partly in the HDSS area). The eight health facilities with their associated communities comprise the clusters. A ninth clinic (outside the HDSS) was used as a pilot site. Randomization for the four intervention clinics for the trial was done at a public meeting. This was to avoid any suspicion that the allocation had been influenced in any way by the research team (refer to chapter six for details). Table 1 below is a brief description of the setting for each one of the eight trial clinics at the introduction of the trial. In this thesis, I have changed the actual names for the clinics.

Table 1: Clinic settings for the trial

Clinic name	Approximate population	Staffing level at situation analysis
Intervention clinics		
Troy	27,000	Professional Nurses = 12 Enrolled Nurses = 4 Enrolled Nursing Assistants = 5 Data Clerks = 3
Orange	14,000	Professional nurses = 6 Enrolled Nurses = 2 Enrolled Nursing Assistants = 2 Data Clerks = 0
Timber	12,000	Professional Nurses = 3 Enrolled Nurses = 3 Enrolled Nursing Assistants = 1 Data Clerks = 0
Hillard	13,000	Professional Nurses = 3 Enrolled Nurses = 2 Enrolled Nursing Assistants = 1 Data clerks = 0
Control clinics		
Faith	10,000	Professional Nurses = 3 Enrolled Nurses = 2 Enrolled Nursing Assistants = 1 Data Clerks = 1
Moghan	13,000	Professional Nurses = 5 Enrolled Nurses = 2 Enrolled Nursing Assistants = 1 Data Clerks = 0
Arlington	11,000	Professional Nurses = 4 Enrolled Nurses = 3 Enrolled Nursing Assistants = 0 Data Clerks = 1
Yang	13,000	Professional Nurses = 4 Enrolled Nurses = 1 Enrolled Nursing Assistants = 0 Data Clerks = 1

CHAPTER 3: STUDY SETTING

In this chapter I discuss the settings in which I conducted the study. This includes South Africa's current health system reforms towards successful care for chronic patients, the HDSS site where the study took place and, primary health care clinics in South Africa.

Literature on the South African health system will particularly focus on past and current reforms to improve on care for patients with chronic diseases. In the recent past, the Department of Health in South Africa has introduced a series of policy and programme reforms at primary health care (PHC), sub-district, district, provincial and national levels as a means of strengthening the health care system. Understanding the South African health system was relevant because it formed part of the causal pathway that would affect the LHW implementation process and its outcomes. I therefore needed to understand the current environment in the health system, its background and how it would affect the intervention. I also wanted to see how the LHW intervention fitted in a body of several other initiatives and reforms currently underway in the country. When I later analysed the data, it helped me to understand how much of the trial effects were as a result of LHW intervention or other initiatives.

3.1 South Africa's health system and health sector reforms since 2011

South Africa comes from a background of a fragmented health system designed along racial lines which benefited the white minority prior to 1994 democratic government (15). Since democracy was established there has been an integrated and comprehensive transformation of the public health system aimed at providing equitable and accessible health care to its growing population, currently estimated at 54.96 million (16), and the government has published a plan for health system change (17).

Among others, there has been success in consolidating previous 14 health administrations into one national and nine provincial health departments; developing the district health system as key to delivery of free primary health care; building 1345 new clinics and upgrading 263 clinics through the clinic infrastructure programme; organizing mass

immunization campaigns; developing essential drug lists and standard treatment guideline for both primary and hospital levels of care; improving the availability of key drugs in public health facilities; passing of several progressive legislations i.e. the HIV and AIDS 2007 – 2011 strategic plan (17); and spending on primary health care increased to over 22% of total public sector health-care expenditure in 2005.

South Africa is a middle income country in terms of its economy; but with health outcomes that are worse than those in many lower income countries for example Brazil (18, 19). The four main health problems facing the country at the moment create what has been known as the quadruple burden of diseases that include diseases of poverty (infectious diseases, maternal and child disease), non-communicable diseases, HIV/AIDS and TB, and violence and injury (17, 20). The health outcomes have been blamed on South Africa's history of racial and gender discrimination, income inequalities, migrant labour, the destruction of family life, and violence pre-1994 (17). Inequalities in health and health care still exist between public and private health sector, urban and rural areas, among and within provinces (19). The National Development Plan (21), a 20 Year Review by the Presidency (22), and the 2015 White Paper on National Health Insurance (NHI) (23) identify these inequalities and the urgent need to address them (19).

However, other factors have emerged after attaining democracy and include; inadequate human resource capacity and planning, poor stewardship, weak leadership and management, increased stress on the public health system caused by the AIDS epidemic and lack of a functioning district health system (DHS) (17, 24). Lack of implementation of the core health policies has also been a setback. In the next sections, I will describe the district health system and; development and progress in some of the core policies and programmes relevant to the LHW programme.

3.1.1 The District Health System (DHS)

The district health system in South Africa was introduced during the advent of democracy. It was instituted to decentralize administrative authority of implementing personal health services on four different tiers namely; the national department of health, the provincial

department of health, the district health system and, the sub-district health system (25-27). The national department is responsible for strategic oversight of the health system and formulation of policy and standards while the nine provincial departments are for policy implementation and supporting the district health system (25, 28, 29).

The districts are termed as corner stones for implementation of primary health care (PHC) (30). Districts are led by district health management teams (DHMT), headed by generalist district managers at both district and sub-district levels (32,37). "*The term 'district manager' denotes: frontline managers located within districts – the overall head of the district, sub-district heads, PHC managers, and local area managers (also referred to as Clinic Supervisors as they supervise clusters of clinics)" (25). S*ervices delivered at district level include; primary care through 8-hour clinics and 24-hour community health centres led by nurses and supported by medical doctors and; secondary care is delivered through district hospitals which act as referral centres for the clinics and community health centres (25, 31).

These reforms were formulated to propel an equitable and accessible primary health care that promotes community participation in health (19, 30, 32, 33). Although the DoH has focused on strengthening the DHS (34-36), the DHS has not become fully functional, 22 years into democracy (19). Van Rensburg et al has argued that the roles of national, provincial and local government health departments have not been clearly defined, there are poor relations between staff at provincial and local government health departments, inadequate funding, limited capacity and, ineffective and inefficient management systems (19, 33). On the other hand, Naledi et al observed that the DHS are yet to be fully decentralised as the heads of provincial departments of health are still the accounting officers (37). Gray et al has also noted that district councils and clinic or community committees are either non existent or non functional and, there is poor coordination between district hospitals and PHC services (19).

3.1.2 The National Health Insurance (NHI)

In August 2011, the Department of Health embarked on a health policy drive of healthcare financing known as National Health Insurance (NHI) to guarantee every person's

accessibility to appropriate, efficient and quality health services (15). The initiative, which was planned to be rolled out over a period of 14 years, is aimed at revamping the service delivery structures, administrative and management systems. A policy paper for the NHI (green paper) was developed in August 2011 by the NDoH to give direction on the implementation of NHI. In December 2015, a final policy paper (white paper) was released aimed at addressing gaps identified with the green paper and, to indicate on the financing mode of the NHI (38).

There are several basic principles through which NHI was conceptualised and intended to achieve including promoting access to a comprehensive package of healthcare services, provided through accredited and contracted public and private providers, with a strong focus on health promotion and prevention services at the community and household level. The initiative is being piloted in 11 health districts, not including Enhlazeni district in which Bushbuckridge sub-district is situated, across the country for the first phase of five years. Rispel et al has argued that implementation of the NHI in the pilot districts have not been in line with the decentralisation approach in the health sector reforms but that there has been a direct implementation of NHI by the NDoH, challenging the policy implementation authority of the provincial departments of health (39).

3.1.3 Three streams of Primary Health Care Re-engineering

The need for a vibrant primary health care dates back to the 1978 World Health Organization (WHO) Alma Ata Declaration on primary health care (PHC). Thirty years later, WHO reported global failure to successful implementation of PHC and South Africa was not an exception. However WHO still recognized PHC's relevance in improving health outcomes (40). Seventeen years into democracy, South Africa's PHC continued to perform poorly with poor health outcomes mainly as a result of weak district health system (DHS) (41). Proposed WHO reforms to strengthen PHC, coupled with a change in leadership in South Africa's Ministry of Health, paved way towards addressing challenges affecting PHC (24).

Since taking office in 2009, Dr Aaron Motsoaledi, the current Minister of Health, with support from health service managers, has provided charismatic and energetic leadership in

reforming the health sector (39, 42). Among others, he pioneered development of a 10 point plan (2009 -2014) in addressing health system challenges (36). PHC re-engineering was eventually conceived in 2011 in line with the objectives of this 10-point plan. Primary health care re-engineering has three streams which include: "(a) deployment of ward based PHC outreach teams (WBOT); (b) strengthening of school health services; and (c) deployment of district clinical specialist teams (DCST) aimed at improving maternal and child health (MCH)" (43). In the next two paragraphs, I will describe the progress, achievements and challenges in implementing WBOT within two years of the implementation (since it is relevant to the LHW intervention).

There have not been many studies on WBOT. However, experiences from the North West Province, which can also apply in other Provinces, has shown both achievements and impediments in implementing WBOT. The stream was structured to comprise a Professional Nurse (team leader), 5-6 community health workers, a health promoter and environmental health practitioner where possible. The teams were to be responsible for health promotion and disease prevention, as well as identifying individuals and families at high risk (43). It was argued that this would be possible since there were almost 72,000 trained and paid CHWs across the country that did not have a clear job description. By engaging the CHWs in the outreach teams, the department hoped to define a course of work for the CHWs (43).

As of March 2014, 227 WBOT had been established and trained in North West Province (1617 CHWs and 206 Professional Nurses). Most of these Professional Nurses were released from their clinical work and led the teams on full time basis and CHWs were put on 12 months fixed term contract (44). Rapid assessment has shown high levels of knowledge and ownership of WBOT strategy. On the other hand, there are also financial and human resources challenges that might affect its sustainability in the province (44). There were no new funds for the implementation and districts were expected to absorb WBOT into existing budgets. There was need for additional resources to cater for i.e. transport. Stipend for CHWs was mostly interrupted and seen as low (44). The assessment has also shown that it was unrealistic to have Professional Nurses taken from clinics to lead the teams, considering the low numbers of Professional Nurses in the clinics (44). Support from facility managers

varied as a result of being oriented way after implementation had already started. They felt side-lined and burdened to release a nurse and allocate space for the WBOT in the clinics.

3.1.4 The Integrated Chronic Disease Management model (ICDM)

In 2011, Bushbuckridge sub-district in the Ehlanzeni district of Mpumalanga province was selected as one of the three pilot Districts for the Integrated Chronic Disease Management model (ICDM). This was an initiative of the Department of Health with support from US President's Emergency Plan for AIDS Relief (PEPFAR). Utilizing South Africa's adopted policy for re-engineering primary health care (as explained in the section above), an integrated chronic disease management (ICDM) model, was implemented as a vehicle to improve the management of chronic conditions, based on the WHO health system building blocks (45) of health service delivery, health workforce, health information systems, access to essential medicines, health systems financing and leadership and governance (46).

The DoH defines ICDM as a model of chronic care that provides for integrated prevention, treatment and care of chronic patients at primary healthcare level (PHC). It adopts diagonal approach to health system strengthening, i.e. technical interventions that improve the quality of care for chronic patients coupled with the strengthening of the support systems and structures to enhance the health system and achieve optimal clinical outcomes for patients with chronic diseases (45). The term "diagonal approach" originates from Julio Frenk and Jaime Sepúlveda who describe it as a strategy in which explicit intervention priorities are used to drive the required improvements into the health system, dealing with such generic issues as human resource development, financing, facility planning, drug supply, rational prescription, and quality assurance (47). The diagonal approach focuses on disease- specific results through improved health system, compared to vertical and horizontal approaches which focus on disease-specific results and improved health services respectively.

Implementation of ICDM was preceded by provincial, district and facility preparations and baseline assessment and analysis; and followed by monitoring and reporting. The ICDM manual (45) described ICDM as aiming to achieve the following four connected phases: (a)

Facility re-organization to improve service delivery, (b) Clinical supportive management to improve quality of clinical care, (c) "Assisted" self-support and management of patients through the PHC ward-based outreach teams (WBOT) to empower individuals to take responsibility for managing their own conditions and increasing awareness of chronic diseases at the population level and (d) Strengthening of support systems and structures outside the health facility to ensure a fully functional and responsive health system. ICDM was implemented/ piloted in all eight clinics (control and intervention clinics) where the hypertension LHW trial took place. Implementation of ICDM started two years before the Nkateko LHW intervention.

In this literature review I will mainly focus on facility reorganization as it directly relates to the activities that LHWs performed in the clinics in this trial. The manual described facility re-organization as involving the following changes at clinic level; (a) re-organizing of the flow of chronic patients i.e. designated waiting, designated consultation area and, designated vital signs station; (b) clinical records i.e. pre-appointment retrieval of clinical records and Integration of care by use of single file for one patient for all conditions and; (c) clinic care i.e. appointment scheduling done by Professional Nurse (monthly appointments for unstable patients and 2-3 months for stable patients), pre-dispensing of medication (pre-packed by Professional Nurse 2 days to consultation in a brown or clear bag) and; scheduling of Professional Nurses (monthly to quarterly rotation according to number of nurses. The Professional Nurse should be Primary Care 101 (PC 101) or PHC trained).

Mahomed et al. described how facility reorganization was aimed at reducing patient waiting time and patient load as a way of improving operation efficiency of clinics. Ultimately, this would improve patient flow and planning of services in the clinics (48). However, a recent paper by Ameh et al. on the quality of ICDM from provider and user perspectives, pointed to persistent structural challenges i.e. malfunctioning BP machines, staff shortage and drug outage. There were also irregularities in some of the clinic processes i.e. prepacking of medication. This led to long waiting times from the patient perspective (49). The study was conducted in the seven primary care facilities serving communities in the Agincourt HDSS site. An earlier assessment by Mahomed et al. also found that lack of essential equipment at facility level was one of the impeding factors to implementation of ICDM (50). Others

factors included incapability among Clinic Managers to shift activities at clinic level from the norm, and perceived extra load from the nurses.

How did ICDM relate to the LHW intervention and trial? The role of LHWs was to support nurses in primary care clinics in management of patients with chronic diseases. Since these patients were being managed under the ICDM initiative, LHWs were to directly support the implementation of ICDM. Thus, it was important to understand the success of ICDM in LHW supported clinics compared to usual clinics and how much of that was attributable to the LHW intervention. This support was to be offered to all patients with chronic diseases in areas of appointment booking, pre-retrieval of files, pre-packing of medication and managing designated vital signs station. Based on these tasks that LHWs performed in the clinics, in section 4.3, I will review literature on work that has previously been done by LHWs and research studies that have evaluated such work. See further discussion in Chapter 10 on how ICDM functioned in the trial clinics and how LHWs supported the implementation of ICDM.

3.1.5 The Ideal Clinic initiative

In July 2013, the national department of health through a national programme called Strengthening South Africa's Response to HIV and Health (SARRAH) introduced an initiative called "the Ideal Clinic" aimed at strengthening primary care clinics and supporting the national health insurance programme (51).

The national department of health defines an ideal clinic as "*a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes and adequate bulk supplies that use applicable clinical policies, protocols, guidelines as well as partner and stakeholder support, to ensure the provision of quality health services to the community" (52)*. An ideal clinic is made up of different components and sub-components that must all be in place. Such components include; Administration, Integrated Clinical Services Management, Pharmaceuticals and Laboratory Services, Human Resources for Health, Support Services, Infrastructure, Health Information Management, Communication, District Health System Support, Partners and stakeholders (52). Integrated

clinical services management includes ICDM which is relevant to this PhD. A clinic undergoes a series of assessments of these components and their sub-components to qualify as an "ideal clinic".

The period July 2013 to March 2014 was for concept design of the ideal clinic implementation. During this period, the initiative was piloted with 10 PHC facilities in four pilot districts of the national health insurance. Lessons learnt in this process were to be scaled up to all 3,632 primary health care clinics in the country (51). Lessons learnt during the concept design led into development of work streams for scale up and implementation. The lessons and work streams among others focused on identifying solutions to; reduce waiting times to a maximum of three hours (53); ensure that all PHC facilities have world class infrastructure that is well maintained (54); create equitable distribution of trained workers (human resource for health) (55); ensure continuous availability of medicines and supplies (supply chain management) (56).

A national overview of ideal clinics status determination conducted between April and August 2015 by DoH and Health Systems Trust showed that KwaZulu-Natal was the highest best performing Province at 66% and Mpumalanga was the worst at 50%. Nationally, only four clinics achieved the ideal clinic status. At district level, the best performing district was Harry Gwala (KwaZulu-Natal Province) at 74% and the worst performing district was Capricon (Limpopo Province) at 47%. Ehlanzeni district, where the LHW intervention was conducted, was among the worst performing districts at around 48%, with no facility obtaining the ideal clinic status. Only one clinic within the Agincourt HDSS scored above 50%. The National Health Council has since expressed the intention that all clinics should attain ideal clinic status in the next three years beginning from April 2015 (57).

3.2 How public clinics in South Africa work

In South Africa, primary care is provided through 8-hour clinics and 24-hour community health centres that are led by nurses called Clinic Operation Managers. These nurses were initially selected as the most senior nurse in terms of year of qualification, but recently, the DoH has started competitive interviewing for these positions. From the clinic observations

and semi-structured interviews with the Clinic Managers, it is apparent that their roles have been more of patient care (consultation of patients) than managerial tasks (financial and human resource management, and quality control). Most clinic operation managers reported that the shift in the focus of their tasks has been as a result of an increasing patient load against a perceived limited number of nurses.

There is a cadre of Professional Nurses also known as Registered Nurses. These have either a diploma or degree in general nursing. They can further specialize in a particular field such as midwifery. Their role includes consultations with patients. They assess, screen, diagnose and give treatment. They also supervise the junior nurses. The junior nurses comprise Enrolled Nurses (also known as Staff Nurses) and Enrolled Nursing Assistants. They help Professional Nurses with taking vital signs, dressing of wounds, immunization of children, and family planning among others. Enrolled Nurses can help with consultations of patients under supervision of Professional Nurses. Enrolled Nursing Assistants undergo a one year training and another year long training to upgrade to an Enrolled Nurse. An Enrolled Nurse undergoes a two-year bridging course to become a Professional Nurse.

What I have just described is the ideal roles and responsibilities of nurses in the clinics. However, in practice I have observed that responsibilities vary according to available staff in the clinic. When Professional Nurses are few, Enrolled Nurses consult with little or no supervision. When Enrolled Nurses are few, Professional Nurses take up both the roles of Professional Nurses and enrolled nurses thereby delaying the patients. In clinics without clerks, the nurses are responsible for retrieving and replacing the files. Based on the need and gap, nurses reorganize and take up tasks they are not meant to perform.

Clinics are situated within communities they serve. Medical care in South Africa is free of charge. The structures are fenced and private companies provide security. The structures mainly include a reception, 3-4 consultation rooms, a labour room, a pharmacy, a filing room and a separate structure called the nurses' home, where nurses have their lunch and tea breaks. These vary across clinics and the variations in the study clinics will be explained in detail under infrastructure section.

When patients arrive at the clinic in the morning, they queue outside the fence until the gates open at 7am. They obtain queuing numbers from the security guards and proceed to queue at the main waiting area/ reception. All patients (both acute and chronic) are in one queue except women coming for antenatal care. Patients receive their files which contain their records before having their vital signs measured. Measuring *vital signs* entails approaching a station (mostly located at the reception in view of other patients) and having blood pressure, temperature, pulse and weight measured. This is done every time for all patients attending the clinic. For known diabetic patients, it includes blood glucose and for pregnant women, it includes urine. All this is recorded in the patient file. Patients then proceed and queue again for consultation. For most clinics, patients receive medication in the consultation room before leaving the clinic and only in a few; the medication is distributed using the pharmacy.

Some authors on the status of rural clinics in South Africa have described what affects delivery of primary care services. A recent (2016) study has highlighted among other issues; shortage of health care workers with overwhelming workload, lack of drugs, stationery and inadequate workspace (infrastructure) due to poor designs, as some of the factors affecting the implementation of NIMART in primary health care clinics of Limpopo Province in South Africa(58). In another study on experiences of nurses working in a rural primary health-care setting in Mopani district, Limpopo Province, among others nurses mentioned shortage of nurses and inadequate supplies of drugs as barriers to patient care(59). As earlier stated, another 2016 study identified that malfunctioning of BP machines and staff shortages were affecting ICDM implementation within the LHW study clinics(49). Munyewende et al (60) engaged primary health care nursing managers in South Africa to explore their work experiences by use of diaries. She found out that shortage of medicines and lack of running water were some of the impeding factors to management of primary health care.

Other authors have noted other contextual factors affecting operations of clinics. Insubordination, lack of professionalism, and avoidable mistakes by staff have affected clinic operations (60). Others include negative remarks by supervisors, demands for health information (monthly statistics) and difficulties in managing staff and their performance

(60). On the other hand, high workload, limited resources i.e. equipment and lack of recognition and communication with management are key factors affecting nurses (61).

Systematic reviews on turnover of nursing staff, job satisfaction and leadership style have raised similar factors affecting the nursing profession. Worldwide, reasons why nurses leave their work places are complex but summarized as a result of work and the nature of work environment, economic and, personal reasons (62). Among others it includes lack of relational and transformational leadership styles that is supportive and considerate of the nurses' needs and that focusses on building relations (63), workplace stress as a result of high workloads or poor relations with colleagues, and workplace locations i.e. rural areas with limited services. Personal reasons might be as a result of 'personal' experiences outside the work place i.e. availability of accommodation and schools for kids especially in rural areas and economic reasons includes perceived low remuneration (62).

3.3 The study site

The study was situated in Bushbuckridge, a rural sub-district of Ehlanzeni District in Mpumalanga Province, north-east South Africa. The Bushbuckridge sub-district is the "Homeland" for Shangaan people and was formally part of the Gazankulu Bantustan (64). This is where the Agincourt Health and socio-Demographic Surveillance System (HDSS) is situated. The MRC/Wits Rural Public Health and Health Transitions Research Unit, is part of the School of Public Health, University of the Witwatersrand and has been running the HDSS since 1992. At the time of this study, the HDSS site covered 420 square kilometres of semi-arid scrubland with 31 villages, 20,000 households and 115,000 individuals. There were six primary care clinics and one health centre within site, and 2 additional clinics bordering the HDSS site. Figure 4 below is the Agincourt study site.

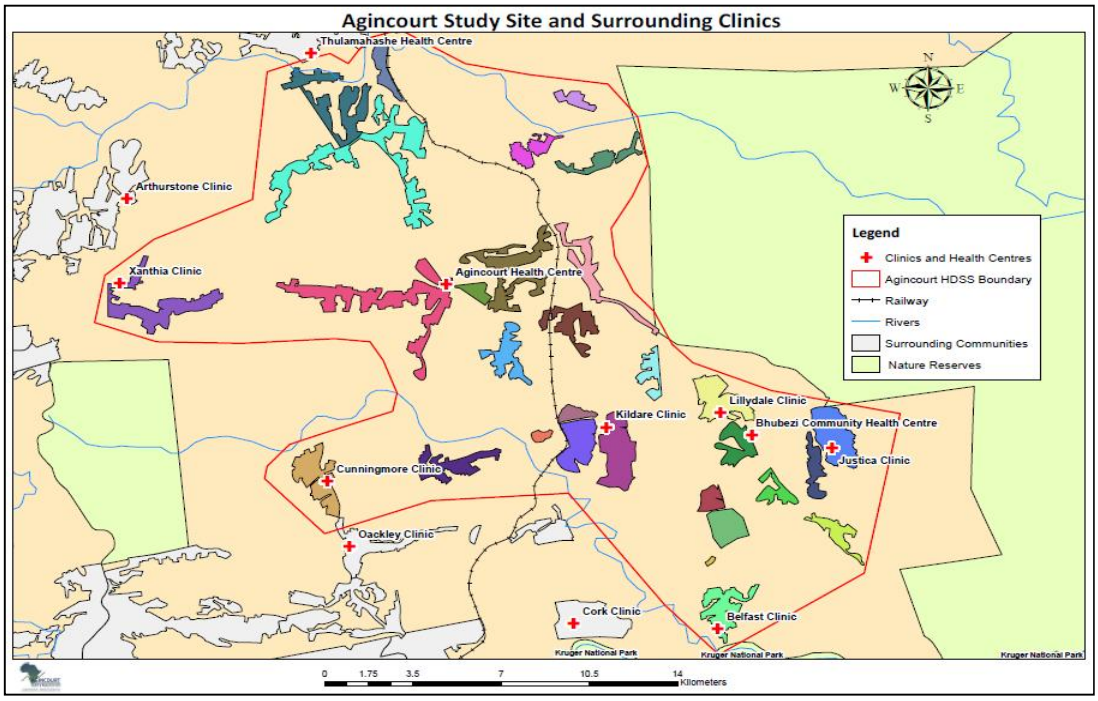


Figure 2 Agincourt study site

Implementing the study within the MRC/Wits Rural Public Health and Health Transitions Research Unit had several advantages. The Unit provided a sampling framework for the baseline survey of the trial; it also ensured adequate infrastructure and platform for logistical support throughout the implementation period. The research management team of the Unit, led by the Research Manager, held weekly management meetings and monthly project managers meeting to understand progress in research projects. The administration team assisted in finances, recruitment and management of field staff.

3.4 Conclusion

Reviewing literature on the study setting was important as it explained the context in which the LHW intervention was implemented. It has presented challenges currently facing the PHC facilities and different initiatives aimed at addressing them. It also further prepared me to understand and identify these initiatives in the causal pathway of the intervention and how it affected its implementation. The realist evaluation findings will also be important to these other clinic level initiatives (government or not) aimed at strengthening primary health care as a means to addressing the growing burden of chronic diseases.

CHAPTER 4: LITERATURE REVIEW

In this chapter I review literature relevant to the LHW intervention and the realist evaluation methodological approach. There are three main interconnected sections in this chapter which include: (a) trends in hypertension prevalence, treatment and management, (b) previous work on clinic based LHWs and (c) methodological issues.

I will start by presenting an overview of trends in hypertension globally and in South Africa. Reviewing literature on hypertension is on the basis that the trial's ultimate goal is to control population's level of high blood pressure (HBP). It is therefore important to understand how hypertension impacts on South Africa and the world. I will also review its prevalence, risk factors and approaches to its management. I will mainly focus on how care for chronic patients is currently delivered in primary care clinics in rural South Africa in comparison to ideal model for chronic care as adapted from Wagner theory (7). Understanding the burden and current trends in hypertension will help to appreciate the need for innovative interventions in addressing it and the contribution to be made by the LHWs in a broader area that require a variety of interventions.

Review and discussion on previous work by clinic based LHW/community health workers (CHWs) will be in line with the intervention in this trial where LHWs were based in clinics and supported nurses by taking up some medically and socially oriented tasks. Reviewing previous work on clinic based LHWs was important as some literature has questioned the contribution that untrained people can make, while others have applauded their successful and cost effective contribution. It was also necessary to understand this body of literature and the contribution my research will make to that effect.

Finally, this realist evaluation is theory based. Thus, I have adapted and used different theories to design the study and understand the causal pathway in the LHW intervention. In this section, I will review and discuss the different theories that I have used in this evaluation, what other authors have written about them and how other authors have used them. I will review literature on process evaluations and a broader field of understanding implementation process in trials. I will also review the theory of complex adaptive system

and its link to realist evaluations. I will review current discussions and arguments around using realist evaluations in randomized controlled trials of complex public health interventions. Reviewing literature on these methodological issues was important to appreciate work that has already been done with the methodological approach that I have used in this PhD and the potential to further strengthen it. In view of the literature reviewed, I will present the gap that my study aims to address (the problem statement).

4.1 Understanding hypertension and its trends

4.1.1 Global trends in hypertension

High blood pressure or hypertension is defined as a condition when blood vessels (arteries) have persistent raised pressure due to the force of blood pushing against their walls as the heart pumps blood (65). Uncontrolled hypertension can result in risks to health which includes heart attacks, stroke, and heart and kidney failure (66). An individual is considered hypertensive when systolic blood pressure (highest pressure in blood vessels when the heart contracts) is equal to or above 140 mm Hg (millimetres of mercury) and/or diastolic blood pressure (lowest pressure in blood vessels in between heartbeats) is equal to or above 90 mm Hg (66). These are written as a fraction of systolic above diastolic (140/90).

Factors that are associated with hypertension are largely behavioural and include obesity, too much intake of salt and fats, harmful use of alcohol, physical inactivity and poor stress management. Related to these behavioural factors are socioeconomic factors i.e. unemployment can raise levels of stress thereby influencing HBP (66). Societal management of hypertension is from two fronts; reducing the risk factors of hypertension and encouraging regular blood pressure check-up especially among the high risk community members (67). This thesis focuses on the clinical management of hypertension which involves early diagnoses, the use of medication, providing support to encourage adherence and giving lifestyle advice (67) .

Hypertension is a major health concern worldwide. Almost half of 17 million annual cardiovascular deaths are associated with hypertension (66) and it is the greatest risk factor

for global burden of disease (68). The world population of adults diagnosed with hypertension rose from 600 million in 1980 to 1 billion in 2008 and is expected to rise to 1.56 billion by 2025 for adults aged 25 and above (66). Low and middle income countries (LMIC), where the burden of managing hypertension is exacerbated by their weak health systems and increasing levels of population growth, bear the greatest percentage of this burden. Over 80% of deaths from elevated blood pressure already occur in LMIC (69). Elevated blood pressure has had a substantial health and economic burden globally estimated at nearly 1 trillion USD over the next decade if not adequately controlled (70).

Hypertension prevalence is high in Africa (66) and is one of its commonest cardiovascular ailments as indicated by extensive epidemiological studies (71). A recent international comparative paper from the Study on Global Ageing and Adult Health (SAGE) examined patterns of hypertension prevalence, awareness, treatment and control for people aged 50 years and over in China, Ghana, India, Mexico, the Russian Federation and South Africa. The researchers found 52.9% prevalence rate ranging from 32.3% in India to 77.9% in South Africa (72). Hypertension seems more common with increasing urbanization, while rural dwellers seem relatively protected. It is, however, the urbanized persons who have better access to modern antihypertensive care. Recent studies have shown that both lower-income groups (because of socioeconomic stress, lack of access to facilities, poor diet, obesity, alcohol consumption, and lack of exercise) and higher income groups (because of obesity, dietary excess, alcohol consumption, and lack of exercise) may be at increased risk of developing hypertension. (73, 74)

4.1.2 Hypertension in South Africa

High blood pressure is a common condition in South Africa. Many people are unaware that they have hypertension and it is therefore referred to as a 'silent epidemic' (75). Moreover, hypertension frequently co-exists with other chronic diseases of lifestyle, such as diabetes and obesity (67). Unlike the SAGE study that indicated rural populations as being protected due to their low levels of hypertension (72), a 2009 study on the burden of non-communicable diseases in South Africa suggest otherwise (20). This study established increasing levels on non-communicable diseases in rural communities in South Africa. It

shows that non-communicable diseases are also disproportionately affecting poor people in urban settings, and are driving a rise in the demand for chronic disease care in primary clinics. The study, which was based on the review of different sources of data from different demographic surveillance sites in South Africa including Agincourt, established that the burden of non-communicable diseases will increase due to roll out of ARVs and subsequent reduction in HIV and AIDS mortality.

4.1.3 Care for chronic patients in primary care clinics

Hypertension and all other chronic diseases require long term medication and care but until recently the primary care clinics in South Africa were mainly organized to deal with acute conditions. Lack of follow up of defaulters, inadequate patient records, and the lack of continuity of care, has resulted in inadequate levels of care (17). As the burden of non-communicable diseases has increased, providing effective primary care to people with chronic diseases is an immense challenge. The South African government has recognized the problem and is reorganizing clinics to respond to the needs of patients with chronic conditions (17). Among others, the Department of Health (DoH) has introduced the Integrated Chronic Disease Management model (ICDM) aimed at reducing patient waiting time and patient load (50) (as discussed in section 3.1.4 above) and the Ideal Clinic initiative (as discussed in section 3.1.5 above). The South African government has also set targets for reducing non-communicable diseases by the year 2020 and among others it includes; reducing prevalence of hypertension by 20% through lifestyle modification and medication and increase proportions of people receiving treatment for control of hypertension by 30% (76).

4.1.4 Wagner's ideal chronic care model

Conceptual frameworks for ideal chronic disease care emphasize the need for productive interactions between patient, provider, and the broader health system. This is one theory that I used to understand the delivery of care for chronic patients in the clinics. It was thus important to understand what literature says about this model. Figure 2 (7) below illustrates this interaction as adapted from Wagner's theory of ideal chronic care.

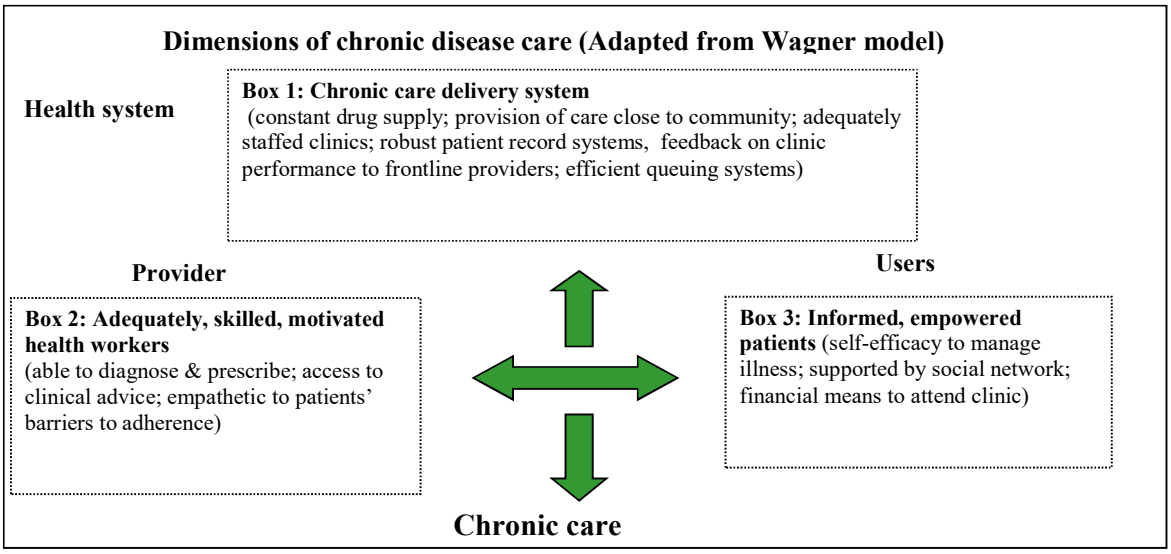


Figure 3 Wagner ideal chronic care model

Chronic care delivery systems need to include: a reliable drug supply; robust systems for patient records to monitor care over time and assess clinic performance; provision of quality care close to the community; and adequately staffed clinics (Figure 2, Box 1). Health workers need to be able to: diagnose and prescribe; have access to clinical advice when necessary; and, have understanding and knowledge of the local community to provide effective adherence support and counselling (Figure 2, Box 2). Lastly, effective chronic care requires patients with sufficient self-efficacy to manage their illness; support from their social network; and, financial and physical means to attend the health facility (Figure 2, Box 3).

The LHW intervention was implemented in an environment (clinics) where several actors had different roles. These actors included both patients with chronic diseases who accessed services from the clinics and staff in the clinics who were the frontline providers of health services. Staff in the clinics also received support from different officials from the DoH. The success of care for chronic patients and effectiveness of the LHW intervention was thus dependent on the positive interaction among these actors as expressed in the Wagner's ideal chronic care model. Understanding the Wagner model has two advantages: It was important to understand how much of the LHW intervention contributed towards

productive interactions of these actors. It will be vital to understand the impact of the intervention in contributing towards effective chronic care delivery system (health system), adequate, skilled and motivated health workers (providers) and informed and empowered patients (users). Secondly, it was also necessary to understand the extent of existing interaction among these actors before the LHW intervention and how much of current health system reforms in South Africa are influencing chronic care. In the next sections I will look at the health system in South Africa and reforms that have happened in the health sector since 2011. Reviewing these reforms will help in understanding the extent that policy and programme initiatives i.e. the (ICDM) have contributed towards ideal care for chronic patients as suggested by Wagner theory.

4.2 Previous work on clinic based Lay Health Workers

Globally, there is diverse literature on the work of LHWs based on different LHW programmes that have been implemented and research studies that have examined or evaluated those programmes. I will specifically focus on clinic based LHWs in chronic disease management, in low and middle income countries (LMIC). My primary interest was in three broad categories;

a) Understanding the range and types of activities LHWs are doing in LMICs (both inside and outside of the clinic).
b) Looking specifically at other studies where LHW are doing similar tasks to the ones that the Nkateko LHWs are doing which are: (a) counselling, (b) taking clinic measurements i.e. vital signs, and (c) assisting with the functioning of the clinic i.e. booking patients.
c) Examining evidence of effectiveness of LHWs in those activities and what factors would facilitate such effectiveness and positively affect health outcomes.

For purposes of this thesis, LHWs refer to paid or volunteer health care workers, with no professional training but who are trained on tasks that are related to their job. Different authors recognize LHWs by different names i.e. community health workers, lay health promoters, village health promoters, peer counsellors. In this thesis, I will use the term

LHWs. In this trial, LHWs were clinic based and they performed a wide variety of tasks, more than just counselling and education.

Articles in the review were from LMIC published between 2000 and 2015. The articles were searched from Web of Science, Pubmed and Google Scholar. Main search terms included lay health worker OR community health worker. These were combined in the process with other words that reflected the roles of LHWs in the Nkateko intervention i.e. patient files, vital signs, health education, appointment booking, counselling, screening chronic patients, working in clinics, clinical measurements, defaulters, reminders, follow-up and task shifting.

The search came up with over 1000 articles on the work of LHWs/CHWs broadly. However, there were fewer than 100 articles when I combined with the roles of LHWs in this intervention i.e. clinic measurements, filing, prepacking medication. I eventually selected 14 articles through reading their abstracts. These articles had LHWs based in clinics, focusing on counselling, taking clinic measurements and assisting with the functioning of the clinics. I also included five systematic reviews on the work of LHWs. Due to limited literature specifically focusing on clinic based LHWs and their role in chronic disease management; I eventually included articles and reviews on broad health areas i.e. MCH as this is the area where most LHW effectiveness studies have been done.

4.2.1 Background to lay health worker programmes globally and in South Africa

Literature has shown a diverse background in LHW programmes. In China and Thailand there were barefoot doctors and village health volunteer programmes respectively, that recognized local and nonprofessional people as agents in community health care services in the 1950s (77). In South Africa specifically, local people were trained and worked as malaria assistants in 1930s in Natal and Zululand (78). In the 1940s, the Kark family (Sydney and Emily) pioneered a community-oriented primary health care at Pholela Health Centre in Natal. This was set up by the Ministry of Health but worked independently of government services. Their approach, which combined primary care and community outreach, engaged local people as CHWs and nurse aides focusing on communicable disease control and

community health education (79). The National DoH regarded this approach as a good model in defining the future of South African health service.

However, CHWs only came into formal recognition in many countries after the 1978 Alma Ata declaration on primary health care. The Alma Ata declaration stirred many countries to start recognizing CHWs as an important cadre within the formal and informal health system as a means towards addressing the health workforce shortage through a process called task shifting. Task shifting entails moving tasks from appropriate and highly qualified to less qualified cadres (80). The WHO reported that the health workforce was at a deficit of more than four million globally as of 2007. This was also in the light of increasing demand of health services, especially to rural and poor populations, in the advent of HIV pandemic. CHWs were thus engaged to take up medically and socially oriented tasks of stressed and inadequate health professionals in this process called task shifting (77).

In South Africa, CHW/LHW programmes started to expand in the advent of HIV and AIDS when there was no antiretroviral treatment. People were dying in large numbers in health facilities and communities and LHWs provided home based care. Around year 2000, LHW programmes continued to expand in response to additional funding from Global Fund that increased HIV antiretroviral services. Since then, LHWs continue to significantly grow in numbers. Around the same year, the government of South Africa started allocating grants to expand home and community- based care and consequently saw a rise in community care givers employed by non-profit organizations (81). Recently, the DoH has recognized CHWs in ward based teams through South Africa's PHC re-engineering strategy. They are working alongside Professional Nurses at community level (82).

In South Africa, LHWs were initially in different categories mainly specializing in a particular field i.e. counselling and trained for a specific purpose, but later moved into generalist roles. Unlike other lay health work, counselling was mainly facility based. Historically, their funding was heavily donor dependent (81). Around 2003, the DoH started moving LHWs from being volunteers to receiving a monthly stipend. This was as a result of increasing dependence on LHWs in the day to day functioning of the health system. There were also proposals to have them as regular employees which would affect health expenditure. However, LHWs

continue to be less recognized within the health workforce. There is no standardized training or career path.

4.2.2 Lay health worker activities and effectiveness in low and middle income countries

In this section, I describe the research which has found a variety of outcomes (positive and negative) from the use of LHWs. Such research is mainly from systematic reviews and other specific clinic based interventions which had similar approaches and activities to the Nkateko LHW intervention. In 2008 WHO report on task shifting to community health workers, which was based on review of literature, recognizes two broad categories of CHW activities and these included: (a) medically oriented (usually facility based) - taking vital signs, weighing, filling out patient registries etc. and; (b) socially oriented - health education, counselling etc. Medically oriented tasks have been found to require competence and adequate training while socially oriented tasks require building trust and rapport with the clients (77). Review of studies has also shown LHW/ CHW have conducted more socially oriented tasks than medically oriented tasks.

Literature that has shown positive effects for the tasks designed to be performed by LHWs or shifted from being performed by health worker professionals to being performed by LHWs, has had the positive effect categorized in five areas: (a) LHWs improved health/ treatment outcomes of patients, (b) LHWs improved access to health services, (c) LHWs improved or maintained quality of services being offered, (d) LHWs relieved burdened health worker professionals and, (e) LHWs were cost effective.

LHWs have been found to be effective in *improving health/ treatment outcomes*. Lewin et al. established moderate to high quality of effectiveness of LHWs in increasing uptake of immunization in children, reducing child morbidity and mortality, promoting breastfeeding and, improving TB outcomes compared to usual care. His findings were based on a rigorous global systematic review of RCTs (despite recognizing that several evaluations of LHWs programmes have not been controlled hence difficult to assess impact). The review included 48 trials in testing the effects of LHW programmes in improving maternal and child health in

LMICs (83). The findings of this review were similar to another systematic review where LHWs increased immunization coverage as well (84).

LHWs have also played a significant role in *improving access to health services*. Use of adherence support workers (ASW) in HIV programme in Zambia, improved retention of patients from 85% to 100%. ASWs contributed to shorter waiting time for clients and reduced workload for health care workers as well. The study on task shifting assessed the effectiveness of adherence support workers (ASW) who took up the task of HIV counselling from health care workers (85). These were generally socially oriented tasks, carried out at facility/ clinic level.

In certain instances, LHWs have *improved or maintained quality of services*. In Benin, lay nurse aides maintained the quality and levels of recommended MCH messages compared to those provided by nurse midwives. A study on task shifting in maternal and new born care in Benin, examined changes in levels of quality when the task of maternal and new born counselling (using job aids) was shifted from nurse-midwives to lay nurse aides (86).

LHWs have also been significant in *relieving burdened health worker professionals.* A systematic review of 53 qualitative studies by Glenton et al. in 2013 had most health professional appreciating reduced workload on their side as a result of LHWs. The review focused on factors affecting LHW programmes in MCH. Most of the studies were conducted in different settings. In Malawi, roles of health surveillance assistants moved from prevention/ disease surveillance/ community based (socially oriented) to include curative/ treatment/ clinic based (medically oriented) i.e. TB and HIV testing, dispensing of drugs, drug store management among others. Most of these tasks were undocumented/ not initially planned for, with no prior training and were added at clinic level based on clinic needs and the need to support burdened health worker professionals (87).

Use of LHWs has been *cost effective* in some instances. For example, LHWs covered the health worker gap in Lesotho and the number of patients visiting clinics doubled as a result of introducing HIV testing and treatment services. LHWs were engaged in translation, adherence counselling, food distribution, home visits (socially oriented tasks) and patient

intake, assessment of vital signs, triage, HIV Testing and Counselling (HCT), medication distribution, maintaining registries, processing laboratory samples (medically oriented tasks). This was based on a field report on the role of clinic based LHWs in increasing access to HIV care and treatment in Lesotho (88).

A review of studies on task shifting and community health workers in low income countries published between 2006 -2010, took an economic approach. It looked at health worker skill mix literature, especially at the balance between costs and productivity and how different ratios of nurses, doctors and other health workers can affect cost and productivity. The review included 31 papers. There was a general agreement that task shifting to new cadre of health workers is successful and cost effective, although there were few intervention studies. Challenges identified included quality and safety concerns, professional and institutional resistance, the need to sustain motivation and performance (89).

4.2.3 Barriers and facilitators to lay health worker effectiveness

In designing and implementing LHW interventions, it is necessary to understand factors likely to facilitate and hinder the intervention. In their recommendations, most of these studies have outlined factors that facilitated or enabled the success of CHW programmes. Most of these facilitating factors identified from the different studies, have been summed up in a Brazil, Ethiopia, Malawi, Namibia, and Uganda multi country study on effectiveness and sustainability of CHWs in delivery of HIV services. In the study, CHWs performed tasks that were medically (i.e. dispensing of drugs and conducting and interpreting rapid HIV testing), and socially oriented (i.e. counselling and education) (90). A report by WHO (2008) on task shifting has also highlighted similar enabling and hindering factors. Both the multi country and the WHO report present the following factors as summarized in table 2 below.

Table 2: Facilitators and barriers to LHW interventions

Enabling factors for LHW interventions	Barriers to LHW interventions
• Strong management and supportive supervision • Appropriate selection and education requirements • Suitable training • Adequate remuneration, retention and incentive structures • Good relationship with other healthcare workers • Community embeddedness (community participation essential in performing socially oriented tasks) • Collaborative planning involving all stakeholders • Definition of CHWs' scope of practice • Performance evaluation	• Task shifting happening at local level without proper recognition and regulation from Ministry of Health • Resistance from higher level cadres who feel their skills is being threatened • Poor referral system • Inadequate supply of commodities.

Other barriers and facilitators are outlined in a systematic review of 53 qualitative studies that focused on factors affecting LHW programmes in maternal and child health. The studies in the review were conducted in different settings. The review has shown that LHW programmes were mainly affected by acceptability, appropriateness and credibility, and health system constraints. For *programme recipients*, though they appreciated the roles of LHWs, they were concerned about confidentiality, and relevance of some of the LHW tasks i.e. promotional activities. Due to lack of professional training, they were worried that LHWs might not be able to exercise confidentiality as demanded of health professionals. *Health professional* appreciated the reduced workload and LHW communication skills. However, they feared loss of authority (that patients would recognize and respect LHWs more than nurses). *Lay health workers* appreciated social recognition, knowledge gain and career

development. However, they recognized the need to review salary approaches, quality of training and, quality of supervision (91)

Although some studies have shown a positive effect in LHW interventions and their roles in taking up tasks of professional health workers, there is recognition of limited RCTs being done. Although there are generally many systematic reviews of the work of CHW, there have been fewer systematic reviews for clinic based work for LHWs. LHWs that have operated at clinic level, have mainly focused on HIV and maternal and child health. In most articles, LHW tasks focused on counselling and health education (socially oriented task). In some cases, medically oriented tasks came up as undocumented and untrained tasks for LHWs. As I evaluate the LHW intervention, it is also important to take cognizance of enabling and limiting factors for effective LHW interventions as identified by several studies. The realist evaluation in this LHW intervention will contribute to the global evidence on enablers and limitations when clinic based LHWs take up both medically and socially oriented tasks. It will also look at the differences among the enablers and limitations based on different context in which the LHWs operated.

4.3 Methodological and theoretical issues

There are several approaches to health programme evaluations. In this section, I review literature on realist approach to evaluations within a broader field of process evaluations. I will also examine the theory of complex adaptive system (CAS) that helped in understanding and explaining the implementation of the intervention and the complex nature of the environment in which the LHW intervention was implemented. CAS also literature refers to the fact that the (health) system has its own momentum outside the control of those implementing an intervention.

4.3.1 Process evaluations

While randomized controlled trials are seen as gold standard in evaluations that provide high quality data, they often lack detailed information about structures, processes and resources necessary for implementing an intervention in a particular context (5). Process

evaluations provide this additional information on how an intervention was implemented, what and how different factors affected the implementation process and how actors participated in implementing the intervention (5, 92). Such information is crucial for policy makers and programme planners as it goes beyond just understanding whether a programme can work or not but further explains how it can be implemented and in what context it can be successful (92). This additional information from process evaluations is seen to compliment high impact evaluations like RCTs. Recently, the MRC has come up with detailed guidelines on how process evaluations can be conducted for complex health interventions as summarized below.

The guidelines explain that in planning for process evaluations, it is necessary for evaluators to be independent of but maintain close relations with trial developers and implementers. The intervention and its causal assumptions should be described in a diagrammatic logic model to understand the flow of the intervention and how different components connect to one another. Evaluators should use both qualitative and quantitative questions to explain how the intervention is implemented and any other unanticipated pathways experienced. Evaluators should consider collecting data throughout the implementation process at different time intervals. Analysis of data should consider quantitative data to explain fidelity, dose and reach, and qualitative data to explain experiences during the implementation process (5).

Different authors have also demonstrated how process evaluations respond to questions and provide answers about fidelity, dose and reach (93-95). Through qualitative and quantitative data, researchers are able to understand: the extent to which the programme was implemented as intended (fidelity), the quantity of the intervention that was delivered (dose) and how much of the target audience came into contact with the intervention (reach) (5, 96). Although the focus on fidelity, reach and dose could be seen as standardizing the complex intervention rather than letting it to be adapted across different contexts, examining fidelity, dose and reach can help as a valid test of the intervention theory (5).

4.3.2 Complex adaptive system (CAS)

Health systems are complex systems as a result of being made up of multiple components that interact to produce change. Intervening in such complex setup often results in complex interventions that target different behaviours, different levels of the organization and expects varied outcomes (5). The theory of complex adaptive system (CAS), explained in this section helps to understand the complex nature of health system organizations. The theory of complex adaptive system expresses that non-linearity of the implementation-outcome relationship is seen as due to the adaptability (or unpredictability) of actors and the wide range of influencing elements within a complex adaptive system. Such elements in a CAS include the learning, inter-connections, self-organizations and co-evolving taking place in a particular organization. These elements are deemed to differ in different clinic environments hence intervention processes and outcome are unique to specific clinics (97). Table 3 below summarizes the four characteristics of a complex adaptive system (97).

Table 3: Characteristics of a complex adaptive system (97)

Characteristic	Definition
Agents who learn	Actors in an intervention are seen as agents who will not just follow what the intervention and its guidelines dictate. They will try to understand information pertaining to the intervention, process it and act according to their understanding and available supporting resources. Thus, the implementation of the intervention will depend on how individual actors continuously learn and interpret the intervention.
Interconnections	There are always particular and existing forms of interactions among different actors in health facilities. New interventions which mostly come along with new/additional actors will influence and alter such interactions. Relations, verbal and non-verbal communication and team work will eventually affect how the agents will support (or not) the implementation process.
Self-organization	This is the ability to maintain order in an institution's work without constant following by those in supervisory positions. This characteristic acknowledges differences among actors in the way they approach work. There are those that are made to work and those that work willingly. The success of an intervention will depend of how self-organized are agents in a particular organization.
Co-evolution	Organizations and their agents change in their work practices based on internal and external forces and the environment. This characteristic acknowledges that even with the same intervention, difference in the work environments i.e. patient load and other resources will eventually lead the agents into different approaches to the implementation process.

Conceptualizing healthcare organizations as complex adaptive systems (CAS) has important implications for how we think about intervening in such systems, as the CAS framework reinforces the idea that each system is unique, and that interventions cannot easily be moved from one organization to the next with predictable results (97). There is evidence that adherence to guidelines is poor among most providers (98) and that interventions that

employ characteristics of CAS in their design and implementation, are likely to improve patient outcomes (97).

The design and implementation of the LHW intervention incorporated characteristics of complex adaptive system. The intervention was developed according to individual clinic contexts and let to adapt to respective clinic environments. In this evaluation, I would like to understand how the intervention influenced the way agents learnt, interconnected, self-organized and co-evolved. I will also find out how dynamic the intervention was in the various study sites and how it eventually affected study outcomes at different levels. It is due to this complexity that I considered using a realist approach in the process evaluation of the LHW intervention.

4.3.3 Realist evaluation

Different authors, including Pawson and Tilley who developed the first realist approach in 1997, have described and justified the use of realist evaluations;

"when one evaluates realistically one always returns to the core theories about how a programme is supposed to work and then interrogates it – "is the basic plan sound, plausible, durable, practical and, above all, valid?". This is the basic concept behind realist evaluation; it has an explanatory quest that not only provides answers but further helps to refine the programme intervention. Realist evaluation, grounded on realism, move beyond asking 'did the intervention work? Towards understanding, 'what works for whom under what conditions'?" (99) page two.

Rather than just focusing on the intervention and its outcomes, realist evaluations present the need to take into consideration external and internal factors affecting the intervention. Such factors are classified as context and mechanisms. Pawson and Tilley also expressed that;

Programme "context" refers to such elements as social, economic and political structures, organizational context, program participants, program staffing, geographical and historical

context, etc. A programme "mechanism" is when programme actors'/participants' reasoning (values, beliefs, attitudes, or the logic applied to a particular situation) combines with available programme resources (information, skills, material resources, and support). This is how the actors engage and interacts with the intervention and what motivates such interaction. The combination of 'reasoning and resources' is what enables the program to 'work' (3) page one.

Realist evaluations focusses on understanding the mechanisms through which outcomes are attained and the role that context plays (100). Alteration in reasoning among the programme participants (both implementers and beneficiaries), done in a particular context, is called programme mechanisms by realist evaluators. This is also viewed as the combination of programme/ intervention resources and reasoning of actors within their context (101). Realist evaluators have expressed that programme impact or outcomes do not come about from a vacuum. They are as a result of the interface between context and mechanisms: "Context + Mechanism = Outcome (CMO)" (3). This pattern of context, mechanisms and outcomes, also known as "the CMO configuration", is a theory/ hypothesis that the intended results (O) can only come about as a result of actions of some mechanisms (M), operating in a specific context (C) and changes based on new evidence emerging from the programme implementation process (102, 103) as noted by Pawson and Tilley below;

"In realist terminology, there will always be multiple Ms – proliferation of ideas within a programme. There will always be multiple Cs – a huge range of different individual circumstances and institutional conditions, which shape the actions of assorted mechanisms. There will always be multiple Os – an uneven pattern of success and failure associated with the underlying causal dynamics (103) page 184."

4.3.4 Combining realist evaluations and randomized controlled trials

Researchers have argued on the practicalities of synthesizing RCTs and realist evaluations in complex public health interventions as is the case of the LHW intervention. Realist evaluators study the impact of programmes as a result of varied interaction of mechanisms

and context in an open and complex society (104). On the other hand, randomized trials focus on the effectiveness of programmes by finding specific products that work. The strength and validity in their findings, among others, is based on ensuring that there is no systematic difference in intervention and control group, as a way of reducing bias (105).

In evaluating complex public health interventions, Bonell et al. 2012 (105), quoting (Blackwood, O'Halloran et al., 2010) have argued that realist and randomized evaluations need to be more synergetic than oppositional (105). The authors gave an example of a youth development programme that aimed at reducing teenage pregnancies. The programme activities among others included mentoring and supplementary education on academic and life skills. The programme was implemented in USA and England. It was successful in New York City but not all parts of the USA (106), (107). In England, rates of teenage pregnancy increased instead of being reduced (108). The authors concluded that that might have been as a result of exposing the same intervention to different contexts whose mainstream services responded differently. This could be explained with a realist approach.

Jamal et al. in 2015 supported Bonell's argument. Jamal has viewed the combination of realist evaluations and randomized controlled trials design as an opportunity of explaining both crude questions of what works and at the same time presenting the process of implementation and how it will vary according to different actors and different environment. Jamal observed that generalising findings of interventions that are complex in their design and implementation, and that interact with a wider and diverse environment, misses out important elements of how different structures interacted and how different actors responded in shaping the implementation (109).

In contrast, Sara Van Belle et al. in 2016 questioned Jamal on the practicality of combining realist evaluations with randomized controlled trials design. Van Belle has argued that realist evaluations are feasible for complex interventions whose causations are based on interactions which are not controlled unlike in RCTs. As such, they require a case based than variable based analysis. She believes RCTs cannot be realist based on their reliance on randomization and control (110). Similarly, Marchal (101) has argued that RCT are only

meant for effectiveness of programmes and their methodology excludes the process of implementation. Other authors have pointed out the fact that RCTs cannot identify causal mechanisms, hence the need to restrict them in their own class of comparing simple and single interventions (111-113).

In summary, *realists* that are against the combination of RCTs and realist evaluations in this debate, argue that RCTs are standardised and therefore one cannot see the interaction going on since the intervention has been forced to certain standards. Secondly, RCT chose units at random without distinguishing them. This is a different approach to realist evaluation where one already has theories that assume that certain factors/ processes exist in the units (i.e. clinics) and therefore purposefully selecting the clinics i.e. selecting some clinics in rural areas and others in urban areas. In relation to the LHW intervention, much as clinics might seem the same in their operation hence randomization, I know that they are different based of different factors i.e. level of resources, staff attitude, which would make them respond to an intervention differently. Although the clinics in the LHW were randomized, I further wanted to understand how people engaged with the intervention. This is similar to interventions where patients can be randomized to receiving a drug but how they take/ swallow them would be different.

Although Marchal and Van Belle argue that RCTs are only appropriate for accrediting specific products as effective; and realist evaluations should only be used for studies with a realist philosophy (101), In my opinion, bringing together RCTs and realist evaluations, explains the study findings from a wider perspective. On one hand, the approach gives out the probability and plausibility parts of the study hence better positioning researchers in explaining the validity of the study outcomes. On the other hand, the approach is also able to explain how mechanisms in the intervention will produce outcomes through their interaction with different contexts. In other words, realist findings will be used to explain RCT variables and RCT variable will be used to quantitatively validate explanations from realist findings.

4.3.5 Conclusion

This chapter has recognized the growing burden of chronic diseases and hypertension in particular, in South Africa and globally. It appreciates the need for concerted efforts in strengthening the primary healthcare as a means of fostering high quality, equitable and accessible chronic care. Understanding Wagner's model of ideal chronic care was important to compare current delivery of chronic care in the primary health services to what is viewed as ideal in order to identify existing gaps.

Reviewing previous work of clinic based LHWs was important to understand approaches and their successes and challenges that have been experienced with similar interventions before. This was ideal for the LHW intervention to capitalize on the successful approaches and work towards minimizing the challenges. For instance, such successful approaches include the need for strong supervision support and such challenges include resistance from other cadres of health workers. The literature review has shown that there has been very few clinic based LHW intervention targeting patients with chronic diseases. Most interventions have been in areas of maternal and child health. This LHW intervention therefore becomes ideal to explore a field that has not been addressed by many researchers hence lacking scientific evidence.

Literature on the process and realist evaluation methodological approaches and CAS theory that I have used in this study was necessary to understand their background, the context in which they can be used and what will be the strengths and weaknesses of using them in my study. The theories have helped in determining the key data to look out for that would help to explain the causal pathways in the LHW intervention. This literature review has also presented the current debate on combining realist evaluations and randomized controlled trials. Understanding this debate will later help to present my contribution and position to this growing research field using finding from my research.

4.4 Problem statement (the gap that this study will address)

In view of this literature, this study aims at addressing the following two gaps:

a) The RCT will be able to answer questions on whether the LHW intervention was successful or not but it will not be able to provide additional information on the context and causal mechanisms that led to the trial outcomes. The realist evaluation will explain how the work of the LHWs will improve (or not), trial outcomes. Thus, the knowledge gap in this realist evaluation is the contribution of this additional level of knowledge to understand the effect of the trial.

b) The realist evaluation contributes to the global debate on validity and practicality of using realist evaluations in pragmatic trials. I will discuss how I synthesized the realist evaluation and the RCT, and the advantages and disadvantages of the approach that I used.

In order to address these two gaps, in the next chapter I present a detailed account of the specific objectives I intend to achieve. I also present the type of data needed for each objective and methods that I will use to collect the data. The objectives will help to understand the effect of the trial by describing the intervention development process, describing how context and mechanisms affected implementation of the intervention and, explaining the process leading to trial outcomes.

CHAPTER 5: RESEARCH DESIGN AND METHODS

This PhD recognises the growing focus on the role of *context and mechanisms* in research in understanding complex health service programmes. This thesis focussed on the context and mechanisms associated with the LHW intervention. The intervention is a case study in one setting of a realist evaluation in a cluster randomised controlled trial that is studying an intervention of lay health workers in rural clinics focussed on chronic diseases as part of task shifting. In this chapter I present the overall aim and specific objectives of the realist evaluation. I also present the strategies and methods that were considered, data collection and analysis approaches to the realist evaluation data that was collected during initial situation analysis, programme development phase and implementation of Nkateko trial.

5.1 Overall aim

The aim of the study is to understand under what context and through what mechanisms a clinic based lay health worker intervention will enhance integrated chronic care for hypertensive patients and will modify patient outcomes in a cluster randomised trial in rural primary health care clinics.

5.2 Specific objectives

a) To analytically compare how the intervention development process affected the functioning of the LHWs for each clinic, its process of development by clinic staff and the Implementation Manager and its adaptations to the local context (*setting up the intervention - design and introduction);*

b) To analytically compare the provision of chronic care, different clinic context and general functioning of four intervention and four control case study clinics, before and throughout the intervention period (*the context*);

c) To analytically explain how the different mechanisms in the clinics, and broader health systems factors, affected the implementation of the intervention in the study clinics over the intervention period (*mechanism over time and intermediary changes)*;

d) To analytically explain the processes that led to change (or not) in the patient and related outcomes

5.3 Objectives, data collection method and data

Table 4 below presents data collection methods that were used and the specific data that was collected for each of the four research objectives above.

Table 4: Objectives, data collection methods and data

Objective	Data collection method	Data
1. To describe and compare how the intervention development process affected the functioning of the LHWs for each clinic, its process of development by clinic staff and Implementation Manager and its adaptations to the local context (*setting up the intervention);*	Observation of LHW intervention development (recruitment, training, deployment, clinic workshop); Observation of clinic activities; In-depth interviews with LHWs and Implementation Manager; semi-structured Clinic Managers and Clinic Supervisors; Diaries for the researcher and Implementation Manager	Explanatory descriptions of; • Programme development process and how this differed for each clinic; • Factors that were considered in each clinic setting in regard to the agreed implementation process; • Roles of different actors/ players in influencing the shape of the programme.
2. To describe and compare the provision of chronic care, different clinic context and general functioning of 4 intervention and 4 control case study clinics, before and throughout the intervention period (*the context*);	Observation of clinic activity and consultations; Semi-structured interviews with Clinic Managers and supervisors; In-depth interviews with LHWs and Implementation Manager; Patient exit structured interviews; Patient cohort semi-structured interviews; Diaries for the researcher and Implementation Manager	Explanatory descriptions of; • Condition and availability of resources in the clinics to support BP patients; • Status of clinic infrastructure and pathway for chronic patients; • Supply of medication for hypertensive patients; • Human resource and patient load; • Approaches to clinic management; • Staff attitude and patients/ health provider interaction.

Objective	Data collection method	Data
3. To explain how the different mechanisms in the clinics, and broader health systems factors, affected the implementation of the intervention in the study clinics over the intervention period (*mechanism over time and intermediary changes)*;	Observation of clinic activities; In-depth interviews with LHWs and Implementation Manager; Semi-structured interviews with nurses, Clinic Managers, Clinic Supervisors and sub-district staff; Patient exit structured interviews; Patient cohort semi-structured interviews; Diaries for the researcher and Implementation Manager.	Explanatory descriptions of; • Relations between LHWs and the rest of clinic staff and how the staff responded to the intervention; • Performance among the LHWs and how it affected the intervention; • Role and influence of clinic management in clinic context; • Health systems factors that facilitated or prevented access to care in clinics; • Effects on clinic operation and patient management including filing, prepacking of medication, and appointment system.
4. To explain the processes that led to change (or not) in the patient and related outcomes.	All data collection methods above as described for objectives 1 to 3.	Explanatory descriptions of; • Patient outcomes at clinic level; • How LHW intervention activities influenced health outcomes; • The context and mechanism through which the programme was implemented in each clinic and its effect on health outcomes.

5.4 Strategies and methods that I considered

5.4.1 Overall methodological approach

The realist evaluation was a theory driven mixed method study that used both qualitative and quantitative data. The realist evaluation focused on the question; for whom was the LHW intervention successful? In what respects? and how? (4) This was to ensure that any further decision on the LHW programme, will consider the mechanisms and context in which it can or cannot work. See section 11.5.1 page 200 (Discussion Chapter) further details on why realist evaluation was best suited for this study. Pawson and Tilley (99) presented a generic strategy and methodology that most realist evaluations use as presented in figure 3 below. The strategy views realist evaluation as an approach for testing a programme hypothesis. The LHW realist evaluation adapted and incorporated this approach.

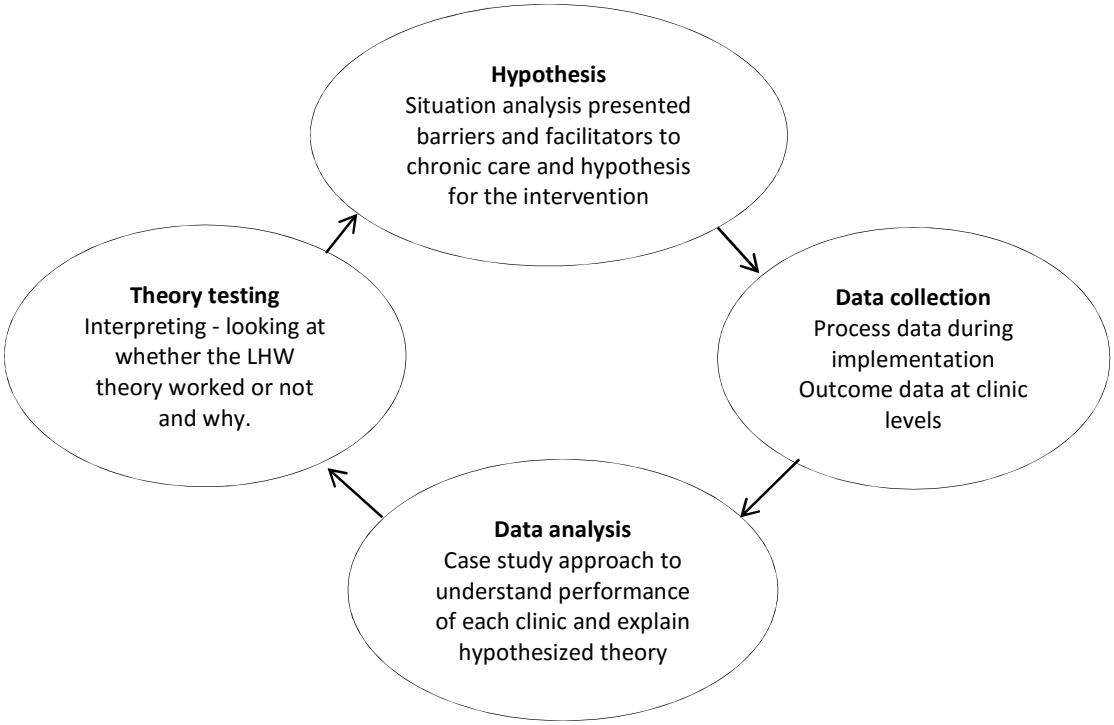


Figure 4: Evaluation as hypothesis testing in the LHW intervention

In the hypothesis stage, Pawson and Tilley explain that the aim is to formalize the programme theory to be tested based on the identified gap (4). The LHW realist evaluation incorporated a number of approaches to this effect. It instituted a situational analysis to understand chronic care as it was provided before the intervention. The situation analysis interviewed hypertensive patients, health workers at different levels and community members. It helped to understand the barriers and facilitators, and suitable hypothesis for the intervention. The hypothesized programme theory is explained in section 6.3 below.

Data collection on appropriate mechanisms and contexts in the LHW intervention was done in the course of implementing the programme. This included qualitative data from in-depth and semi-structured interviews, observations and quantitative data from structured interviews and clinic link. Data collection on the outcomes was collected at clinic level and population level prior to and after the intervention. Combining these two approaches helped in understanding both programme implementation process and impact.

The third stage involves data analysis. The evaluation of the LHW programme paid particular interest to the context and mechanisms in which the programme was implemented and the role of context, mechanism and outcome configuration – CMOc (please refer to section 5.6 page 58 for details on data analysis for this study). The LHW evaluation carefully considered several factors in the context in which the programme was implemented: including accessibility and how well-resourced clinics are; interactions among the actors and how they learn and adapt to the intervention. These have been brought into interface with different elements of the intervention and how actors interacted with the intervention

The final stage (theory testing) involved interpreting the findings. As Pawson and Tilley noted; *"this looks at whether the theory about the programme worked or not. In realist evaluation, there are always varying and mixed outputs and outcomes for different contexts and mechanisms. This then calls for the refining of the theory and reengaging the circle again. The distinguishing factor between realist evaluations and ordinary process evaluations is the use of cross-case analysis to compare contexts" (4).*

5.4.2 Study design

This detailed realist evaluation was embedded in a cluster-randomized trial (92, 114). The evaluation used a case study approach to compare and contrast experience in the different clinics and the populations they serve. The four intervention and four control clinics and the population they serve were included as cases for evaluation. The realist evaluation mainly used a qualitative approach, including in-depth and semi-structured interviews and observation of clinic activity. The PhD study was conducted through a four-year period (2013 – 2016). The initial preparations including situational analysis were done in the first year. Data collection started from June 2013 with the situation analysis, through November 2013 – June 2014 during intervention preparation and development to August 2015 when the intervention ended. Data analysis and report writing was done from September 2015 to end 2016.

5.4.3 The case study and narrative approaches to data inquiry

Case study research focuses on contextual analysis of complex issues (115). A case study is often 'an account and an analysis of particular events and decisions' (115). It can be used to illuminate a decision or set of decisions like why the decisions were taken, how they were implemented, and with what result (116). A case study approach develops an in-depth description and analysis of a case or multiple of cases. Data collection uses multiple sources including observations and interviews (117). The realist evaluation in this hypertension study incorporated a case study approach called "the one next door'' (115). In this approach, I was interested in the detailed workings of a clinic with no prior reason to differentiate one from another. Each selected intervention clinic in the study was a case on its own. My interest was to look at interrelations involved and the inner workings; and clearly understand the patient, intervention and implementation factors at each clinic level, and explain 'why' and 'how' improvements happened. This eventually helped to understand why the intervention was more successful in one case than another. Multiple cases were involved, therefore in analyzing the data; (a) a detailed description was provided for the eight cases that were randomized for intervention and control. A detailed description and

themes within the case was considered through ***within-case analysis***. (b) There was also a thematic analysis across all the eight cases/ clinics (***cross case analysis***)

Narrative research focuses on exploring the life of an individual by telling stories of individual experiences (117). Data is collected primarily by using interviews and documents and the unit of analysis is one or more individuals (117). In order to understand the process of delivery of chronic care and the operation of these individual cases, exploring the life of individual patients and staff by telling stories of their experiences with the clinics was paramount. This entailed incorporating narrative research in the data inquiry. Narration of such experiences was through in-depth and semi-structured interviews with patients, nurses and the LHWs. This helped to draw a full picture of how the clinics evolved prior to the LHW intervention and throughout the intervention.

5.4.4 Data collection phases

Data collection was divided in four phases. During the pre-trial period, I conducted a situation analysis and collected data on the current delivery of chronic care in the trial clinics to inform the design of the LHW intervention. The second phase was the trial preparation and development phase of the intervention. Data collected during this phase helped to understand the influence that the preparation period would have on the rest of the functioning of the clinics and how the intervention performs. The third phase was full implementation phase. I collected data midway through the intervention focused on how the different clinic contexts, and broader health systems factors, affected the implementation in the clinics six to twelve months into the intervention. During the final trial closure phase, collected data focused on the functioning of the clinics during the last five months of the intervention (see table 5 below).

Table 5: Data collection methods and phases (intervention and control clinics)

	Timeframe	Qualitative methods	Quantitative methods
Phase 1 Pre-trial period (situation analysis)	June 2013 to October 2013	Clinic observations Observing patient consultations Semi-structured interviews with Clinic Managers and with Clinic Supervisors Focus group discussions	Review of the booking register
Phase 2 Trial preparation and development	November 2013 to June 2014	Clinic observations Observing patient consultations Semi-structured interviews with Clinic Managers and with Clinic Supervisors In-depth interviews with LHWs and with Implementation Manager Researcher diaries Implementer diaries	Patient exit structured interviews Clinic staff motivation structured interviews Clinic link
Phase 3 Full implementation	July 2014 to March 2015	Clinic observations Observing patient consultations In-depth interviews with LHWs and with Implementation Manager Researcher diaries Implementer diaries Patient cohort semi-structured interviews	Patient exit structured interviews Clinic link
Phase 4 Trial closure (LHWs working with little supervision from Implementation Manager).	April 2015 to August 2015	Clinic observations Semi-structured interviews with Clinic Managers and with Clinic Supervisors In-depth interviews with LHWs and with Implementation Manager Researcher diaries Implementer diaries Patient cohort semi-structured interviews	Timing patient consultations Patient exit structured interviews Clinic staff motivation structured interviews Clinic link

5.5 Qualitative data collection

The study used the following qualitative data collection methods and sources: observation of clinic activities and patient pathway, focus group discussions with community health workers and community members, semi-structured interviews Clinic Managers, Clinic Supervisors and sub-District Manager, in-depth interviews with LHWs and Implementation Manager, semi-structured interviews with three cohorts of hypertensive patients in their homes, and Implementation Manager's and researcher diaries.

5.5.1 Observations in the clinics

a) Clinic activity observations

These were non-participant and semi- structured observations. A team of five fieldworkers who spoke the local language, conducted observation of clinic activities, patient pathway and hypertensive patients' consultations prior to the trial (situation analysis) and at six-months interval spread over the 18 months of the intervention (this was at the beginning, midway and towards the end of the trial). The field workers gave me translated observation reports, but I also sat in the clinics some of the time to observe what was going on. The planned and actual number of observation days varied at different stages of the trial (table 6 below). During the pre-trial period (situation analysis), I planned and conducted observations for three days (n=30 days for all 10 clinics). During each of the next three phases (trial preparation and development, full implementation and trial closure), I planned to conduct observations for 9 days in each clinic (n = 8 clinics x 9 days x 3 phases = 216 days). However, I changed the number of observation days in control clinics during the trial preparation and development phase to 3 days as I anticipated fewer activities in control clinics. After the trial preparation and development phase, I changed the observation days to 6. This was further changed in the trial closure phase to 3 days. These changes were as a result of reaching the saturation point so quickly (no new information being collected after the second week of observations). I ended up with n = 120 days.

Table 6: Planned and actual number of observation days per clinic

Observation period	Planned days per clinic		Actual days per clinic	
	Intervention	Control	Intervention	Control
Pre-trial period	3	3	3	3
Trial preparation period	9	9	9	3
Full implementation	9	9	6	6
Trial closure	9	9	3	3

b) Patient consultation observations

These were also non-participant and semi-structured observations. Although I originally planned to have the fieldworkers observe 1230 hypertensive patients' consultations, this was changed as the study progressed (see table 7 below). They ended up observing 443 consultations due to the following reasons. In some clinics, the number of booked hypertensive patients was fewer than five per day. Secondly, since the numbers of observation days were reduced as explained above, the number of observed patients was reduced as well. During the trial closure phase of the intervention, no patients' consultation was observed. I decided to have the fieldworkers observe and record consultation time length for each chronic patient consulting on a particular day. This was decided upon to understand the workload that chronic nurses face in their delivery of chronic care. For each of the eight clinics, such observations were conducted for 3 days. A total of 889 patients had their consultation time recorded and was based on the total numbers of patients with chronic diseases that came to the eight clinics during each clinic's three days of observation.

Table 7: Planned and actual number of patients' consultations observed for all clinics

Observation period	Planned patients	Actual patients
Pre-trial period	150	114
Trial preparation period	360	238
Full implementation	360	91
Trial closure	360	0

My aim was to observe the delivery of chronic care prior to the intervention and operation of intervention activities during the intervention, to describe the patient pathway in each clinic, and to describe the health system facilitators and barriers to hypertension care. I observed the functioning of the clinic, its organizational culture, the relationship between nurses, the LHWs, and the patients. I was interested in different points along the patient pathway where there are barriers to access to care. An observation tool (appendices B.1 and B.2) provided a guide in understanding the chronic care pathway, whether, where, and when blood pressure is measured of patients attending the chronic disease clinic, procedures for following up with patients that default treatment; patient management, the filing system, the appointment and booking system and availability of resources

Although I decided on the initial figures on number of observation days and number of patients whose consultations were to be observed, these were preliminary. The initial figures were based on observing a wide range of different patients who are booked on daily basis and a wide range of different nurses who go for off duty on weekly basis. The figures also considered a period that clinic staff might change in their operation due to the presence of observers, then get used to the observers and revert to their normal operation. However, observations were done until a point of redundancy (118) was reached (i.e. no new information was emerging). This led to reducing the number of observation days and number patients from 9 to 6 to 3 and from 45 to 10 respectively. Sampling was purposeful. During the situation analysis, observations were done to all 10 clinics in the study site. During the intervention; observations were done at all the four intervention and four control clinics. In identifying the five patients observed in a day, observers tried to balance; booked and unbooked patients, male and female patients, observing different consultation rooms and patients coming at different times throughout the day.

5.5.2 Focus group discussions (FGDs)

Fieldworkers conducted FGDs at the beginning of the trial (situation analysis) to understand the functioning of the clinics prior to the intervention. Two focus groups were identified. One group included members of HDSS community advisory group (CAG) chronic care sub-

committee and clinic committee members[1]. The second focus group with community health workers identified their activities and roles and the problems they face in their work In relation to chronic care.

The eleven participants from the community advisory group were purposively sampled to include members of a subcommittee that advice and review research on chronic care and other members of the executive committee. There were ten community health workers groups that participated in the FGDs. Each group represented a clinic and surrounding villages the clinic serves. There were eight to twelve people that participated in each FGD. Members participating in the CHW were conveniently sampled as it included only CHWs that were available at the time of the interview.

5.5.3 Semi-structured interviews with Clinic Managers, supervisors and the sub-District Manager

I carried out four sets of interviews with the senior nurses in clinics, twice during the situation analysis, once early in the trial period and once towards the end of trial (n = 36 interviews). All clinical staff were fluent in English. I interviewed the Clinic Managers twice during the situation analysis as there were certain areas that need more information i.e. filing systems, patients' doctor review and equipment. I conducted these interviews with 10 managers from the 10 clinics in the study site. However, during the intervention, I only interviewed 8 managers from the 8 intervention and control clinics. I also carried out three sets of interviews with the Clinic Supervisors and sub-District Manager once during the situation analysis, once early in the trial period and once towards the end of the trial (n = 3x3). These interviews had 100% response rate.

The baseline interviews included exploring changes to clinic routines, their expectations of the research, and any concerns they have, as well as their perception of how the clinic currently manages patients with hypertension, problems and how best to address them.

[1] Clinic committees (as established in the 2003 South African Health Act) consisting of community members, clinic staff, and local ward councillor, are intended to facilitate engagement between health clinic and the community.

The final interview explored their experiences of taking part in the research and their perceptions of whether there has been any change.

For these health personnel, as is standard in qualitative methods, sampling was generally purposive but designed to ensure representation of a range of views and inputs. The two Clinic Supervisors and the sub-District Manager were all responsible for clinics that participated in the trial.

5.5.4 In-depth interviews with the lay health workers and the Implementation Manager

I planned for monthly one to one in-depth interviews using a less structured interview guide with each of the eight LHWs and their Implementation Manager. The aim of the LHWs interviews was to get a monthly account of the implementation progress from the implementers. This gave a story of how the intervention begun, where it was midway and 15 months down the line. It detailed their day to day experience in the clinic and how the clinics were changing. The Implementation Manager was better placed to explain how differently the intervention was running from one clinic to another. The interviews focused on the progress of the intervention across the clinics, her role and the role of the sub-district.

Sampling was purposeful (119) to ensure that the interviews covered all the intervention clinics. I planned to conduct 135 interviews. However, 60 were eventually conducted. The number of actual interviews was fewer than those planned as midway of the intervention, I reached the saturation point. To avoid repetition on information collected I decided to move the frequency of the interviews to once every two months. Later, fieldworkers took over and conducted LHW interviews due to increased commitment I had in the broader trial and partly because I thought the LHWs might tell fieldworkers different things. These were in-depth semi structured interviews running for 45 to 60 minutes. There was 100% response rate for these interviews.

5.5.5 Semi-structured interviews with three cohorts of patients

The fieldworkers and I interviewed three cohorts of purposefully selected patients with a semi-structured topic guide twice across the 18-months period; at around 3-5 months and again at around 12-15 months. The semi-structured topic guide incorporated at 'Grand Tour' question to help respondents to be at ease and begin the interview by explaining a varied of issues as they wish pertaining to the topic.

a) The first cohort was recruited through the LHWs in the intervention clinics and comprised both patients who only intermittently adhere to their appointment (16 patients) and patients who had a high level of adherence (16 patients) (n=32).
b) The second cohort was recruited from the results of the baseline population survey and comprised individuals who reported that they normally attended one of the clinics in the control arm of the study and reported that they had hypertension when interviewed (n=32).
c) The third cohort, also recruited from the baseline survey, was identified by the Agincourt data manager and included individuals with measured raised blood pressure who either did not report that they have hypertension, or who knew their diagnosis but were not taking treatment (n=32).

The recruitment of the three cohorts was stratified by age group (two groups), gender and household asset scores (two groups). Four patients were recruited in each of the eight strata. For cohort two, 28 of the 32 patients were interviewed because of low numbers of men under 50 years with low social economic status identified from Agincourt HDSS for some clinics. The semi-structured interviews with all three cohorts explored experience of care including the LHW service, patient and health system barriers to care, patient costs of accessing care, in order to explain differential access to health care. For all the three cohorts interviewed twice during the study period, there was an average of 91% response rate.

5.5.6 Implementation Manager's and researcher diaries

Although the weekly Implementation Manager's dairies were not in the study protocol, they became paramount in capturing detailed and necessary information for the process

evaluation that could otherwise be missed by the other data collection methods. These were supplemented by diaries from my visits to the clinics. These diaries contained information about individual clinic encounters or experiences across the four clinics (Implementation Manager's) and eight clinics (mine) whenever we visited them. Other engagements with the sub-district and stakeholders were also reported in form of diaries.

5.6 Qualitative data analysis

Steps that were considered for analysing evaluation data

Although there are a range of views, the common and central steps involve: preparing and organizing the data, coding the data (reducing the data into meaningful segments and assigning names for the segments), combining the codes into broader categories or themes and displaying and making comparisons in the data graphs, tables and charts (117). The following steps were considered in the data analysis;

a) **Data management** – all the field notes that were collected through observations, in-depth and semi-structured interviews, focus group discussions, and diaries were organized by type of encounter (data collection method), clinic name and date of encounter, as computer files. A guide for naming the files was developed to facilitate easier way of tracing/ locating them (appendix D).

b) **Data extraction** – I developed a data extraction sheet (appendix E) in Microsoft word on which all relevant information on each clinic was drawn together into one place. For each clinic, there was a data extraction sheet for (a) the situation analysis; (b) setting up the intervention and (c) main period of the intervention. Each data source had its own row (in chronological order). Each source of data was kept separate and page numbers were recorded so as to be able to go back to the original. Information that was extracted included a summary of a key event, or a specific quote but not necessarily a whole interview or a whole set of observations notes. I only extracted information/ text that was relevant to understanding how a clinic functions.

c) **Review of data summary sheets** – I later analysed these data extraction sheets and developed theories and made judgments. I was able to go back to the original data to confirm analyses as they were developing – but, since the summary sheets were done well, this was a much more manageable data set to work with. This was done to assess the evidence as to what leads to changes in chronic care management. I reviewed and developed the theory for one clinic, and then compare it with the evidence from another clinic (including intervention and controls). I then generated summary tables to make the comparisons much easier. At this point, I went back and identified the important quotes.

d) **Coding –** Qualitative data from cohorts of patients (refer to methods section) was analysed using Nvivo. I decided on a different strategy patient cohort semi-structured interviews as working with Nvivo was easier in allocating responses according to a theme and according to a clinic. I started with some broad coding of analysing the data on some themes (nodes). This entailed going through the data and looking for issues pertinent to answering the research question. The themes I pre-developed were based on the research questions. This process ensured familiarity with the data, and how to use these nodes later when coding. At the end of the process, there was a more 'aggregated data set' – that was very useful in the next phase of the analysis. This data was linked to each clinic to help understand chronic care at clinic level and matched with other sources of data.

5.7 Quantitative data collection

The study used the following quantitative data collection methods and sources: (a) review of chronic appointment register in the clinics, (b) patients exit structured interviews, (c) nurses and Data Clerks motivation structured interviews, and (d) Agincourt HDSS clinic link[2].

[2] Data typists were placed in all of the eight clinics who were part of the Agincourt Health and Demographic Surveillance System site. They collected information on all chronic disease patients in order to match them to the census records and to understand patterns of clinic use.

5.7.1 Review of the chronic booking register

I reviewed nine booking registers[3] for chronic patients with chronic diseases for nine clinics during the situation analysis for the period of May to July 2013. Nine registers were reviewed representing nine clinics were included for the situation analysis. One clinic was found not to have started the ICDM booking system and was not included. Review of booking registers was decided at a later stage as it was felt it would be necessary to understand level of patients' adherence to appointment dates, prior to the intervention (done during the situation analysis). As such, I used Microsoft excel and looked at total number of chronic patients booked and number of patients attended on each day of the three months that were reviewed. I further looked at hypertensive patients separately.

Comparative data was collected throughout the 15 months of implementation. The Agincourt data manager placed data typists in each of the eight trial clinics who collected information on all chronic disease patients who were part of the Agincourt Health and socio-Demographic Surveillance System site in order to match to census records (also known as clinic link) (1, 14). As for the realist evaluation, clinic link also provided data about levels of hypertensive patients in the clinics and their adherence to their appointment dates in comparison to earlier data collected through review of chronic registers during the situation analysis. Clinic link recorded blood pressure readings as well during every patient's visit to the clinic to help understand changes in blood pressure throughout the intervention. However, data from on-going interviews, observations and diaries revealed that blood pressure machines were in poor state i.e. torn cuffs. We therefore could not rely on the measurements although the intervention, through its implementing manager, replaced the cuffs in all eight clinics.

5.7.2 Patient exit structured interviews

Brief exit interviews with patients who had attended the chronic disease clinic and had a diagnosis of hypertension were carried out. Thirty patients were planned to be interviewed

[3] Clinic records showing the appointment schedule for chronic patients - Monthly appointments for unstable patients and 2-3 months for stable patients.

per clinic observation period, leading to a total sample of 720 (30 interviews x 8 clinics x 3 days). However, and due to low numbers of daily hypertensive patients in some clinics, we could not get 30 patients exit interviews in a visit day. Eventually, a total of 703 interviews were conducted (see table 8 below). All patients that were approached agreed to be interviewed representing 100% response rate.

Table 8: Planned and actual number of patients exit interviews

Observation period	Planned patients	Actual patients
Trial preparation period	240	223
Full implementation	240	240
Trial closure	240	240

The interviews focused on their experience of care in the clinic and their engagement with the LHWs, nurses and staff in general. They were asked whether they had their blood pressure measured, what advice they had been given, whether they had been given any medication (drug stock-outs were reportedly a problem), whether a return visit had been booked and their opinion on the role of the LHWs. A survey quantitative questionnaire was used (appendix B.4).

Identification of these patients was through convenience sampling based on the first 10 patients who agreed to be interviewed in a day (10x3days = 30 patients). Note that some clinics could see fewer than 10 hypertensive patients in a day).

5.7.3 Nurses and Data Clerks motivation structured interviews

I conducted two sets of structured interviews with clinic staff (Clinic Managers, Professional Nurses, Enrolled Nurses, and Enrolled Nursing Assistants and Data Clerks) in all 8 trial clinics using a structured tool that was tested and validated in other contexts (120). The interviews were conducted once early in the trial period (n = 46) and once towards the end of trial (n = 63). The interviews aimed at understanding how motivated the staff is in working in the clinics, focusing on availability of equipment in the clinics, staff appraisal, rewards for good

performance, access to training, respect of their rights among others. The interviews were done twice in order to get comparable data prior to and after the intervention.

Identification of these staff was through convenience sampling. The interviews aimed at interviewing all nurses and Data Clerks in the clinics. This was not possible as some nurses either had gone for long term bridging and PHC trainings or were off duty during the days of the interviews. However, in each of the target clinics, 80% of staff was interviewed and there was a response rate of 100%.

5.7.4 Clinic link

A description about what clinic link is and its process of collecting data has already been provided earlier in section 2.5. Data collected through clinic link included number of patients with chronic diseases in the eight case clinics, number of clinic visits, patients identified with raised BP and patients with a diagnosis of hypertension, appointment dates, appointment reminders, and availability of medication. Participants included all patients with chronic diseases that consented to be captured included in the clinic link dataset.

5.8 Quantitative data analysis

I used descriptive analysis, using simple statistical tests in analysing this quantitative data. Descriptive analysis of this data involved examining within and across cases (clinics) of one variable at a time. The limited quantitative data in the process evaluation was mainly shown in two or three-way tables of frequency (counts).

5.9 Building the cases – bringing qualitative and quantitative data together to develop theories and doing cross case analysis

To answer my research question, I drew together all the information I had on a particular clinic (from the situation analysis, developing the intervention, from diaries, patient interviews, exit interviews, observations, attendance data, LHW data, etc.). I triangulated across all different data sets, and different time periods in order to explain the outcomes.

For example, I may have decided that clinic A had both hard working effective LHW and patients who generally came when booked, and so it is the combination of these two factors that led to a positive effect. I then looked at clinic B - if clinic B had both hard working and effective LHW, and patients who generally came when booked but didn't have a positive effect, then I would revise my theory that I developed for clinic A and look for differences between clinic A and B to explain their difference in outcomes. I may have decided that in clinic A there was also a good implementation start-up phase, and good clinic management, but in Clinic B there wasn't, and this explains the different outcomes.

The developed theories were based on the phenomena in the intervention clinics. However, being a randomized controlled trial, the whole purpose of having the control clinics was to compare the intervention theory and the outcomes in the control clinics. For example; if control clinic E had a positive effect on BP management, even without the LHW, I wanted to understand the reasons behind. Was it good clinic management and patients who come on time? This led to revising our theory to a third version which might say actually that the LHW made little difference.

Combining qualitative data from observations and interviews with quantitative data from patient exit interviews and clinic staff, allowed the development of within and across-cluster analyses to explain and interpret outcomes. The patient data, aggregated to clinic level, was linked to information on clinic factors (such as staff turnover, motivation, organizational culture, drug stock outs, as well as availability of equipment) as well as descriptions of how the various aspects of the intervention function, in order to explain outcomes

5.10 Data validation

Based on the multiple sources for data collection, it is evident that the large volumes of data generated, required a systematic approach in understanding and interpreting it. One of the key questions I was to answer in the trial is: What is it that happened in clinic A that explains why that clinic was able to improve the BP management of those that visited it? To answer this question from the large amount of data, it required; triangulating – testing one source

of information against another to prove a hypothesis (121); crystallization – convergence of similarities that spontaneously strike as relevant or important to the study (121).

I also aimed to identify similar patterns from different data sources as a form of data reliability and key events as a way of understanding clinic organization culture. Reliability/ consistency were an important aspect in the analysis process as it required checking the data by following the lines of analysis and deducting backwards i.e. how replicable the findings are (121). I also looked for the contrary cases. This is data that doesn't fit with our arguments and following it up and to understand it better. I also did member checking which entails going back to clinics and other stakeholders to present the findings and ask if they make sense.

5.11 The data collection team

I was assisted by two fieldworkers with both qualitative and quantitative skills and fluent in both Shangaan (the local language) and English. An additional fieldworker and transcriber were included to speed up data collection and transcription. The three fieldworkers conducted clinic observations, observation of patient consultation, semi-structured interviews with cohorts of patients, patient exit structured interviews and FGDs. Eight data entry clerks (one per clinic) were responsible for collecting patient record data for the broader trial, and were reporting to Agincourt HDSS data manager.

5.12 My role in data collection

The data collection tools were initially developed by the trial principal investigators. I reviewed the tools in line with expectations for my study and I piloted them in another clinic outside the Agincourt study site. I trained the fieldworkers prior to the study and supervised their work throughout data collection. I come from Malawi and as such, all interviews with patients, FGDs and observations were done by Shangaan speaking field workers. The same fieldworkers transcribed the interviews and FGDs into English verbatim. In cases where I needed to directly communicate to patients or community members, the fieldworkers acted as translators. I personally collected data for clinic observation, in-depth interviews with

LHWs and Implementation Manager and semi-structured interviews with health personnel. These respondents were fluent English speakers.

Apart from the PhD research study, I was also Project Manager for the whole trial. My background in health policy research and better understanding of health dynamics in Southern Africa rural context helped me to better engage the fieldworkers, clinic staff and patients. However, unlike the fieldworkers who were local residents, staff in the clinics viewed me as an external person and were cautious talking about negative things happening in the clinic or with the Department of Health. Due to my position as a Project Manager, sometimes my presence in the clinics made nurses change from the norm of their work approach i.e. trying to see patients as quickly as possible. My age and gender did not in any way affect interviewees of behaviour of others during observations.

CHAPTER 6: RESULTS – DEVELOPING AND ESTABLISHING THE INTERVENTION

The design of the intervention was informed by findings from a pre-trial situation analysis. This chapter covers how the LHW intervention was designed and introduced in the clinics and different aspects of the intervention development process such as its conceptualization, the randomization process, actors that were involved, community engagement and programme development workshops with the clinics. With reference to my first objective, data from this phase will help to analytically describe how the intervention development process affected the functioning of the LHWs for each of the intervention clinics, its process of development by clinic staff and the Implementation Manager and its adaptations to the local context. Data for the situation analysis and development stage of the intervention was from observations, in-depth and semi-structured interviews, FGDs, researcher and implementer diaries. Table 5 above summarises the data collection methods.

6.1 Overview of the lay health worker intervention concept

The LHW intervention aimed to test whether providing an extra LHW, to work alongside the nurses in the clinics, focusing on the care of chronic conditions, would help to improve the care of people with hypertension. This was against a background where fewer than half of those affected were aware they had hypertension, and only a small percentage achieved appropriate blood pressure levels (122), in low-resourced South African rural settings. Quality of clinical management varied due to poor functioning of primary care services, which centred on the management of acute, rather than chronic conditions (1, 20). Adherence to medication was sub-optimal, and long-term patient retention was low (20).

A clinic based LHW was to act as a 'health system navigator'. Building on experience with lay counsellors in antiretroviral treatment (ART) delivery (123) within South Africa's ART programme, the intervention expected LHWs to provide adherence counselling, help to improve treatment literacy, use text messaging to remind patients of appointments[4] (13),

[4] Already by 2007, some 85% of the population in the Agincourt research site had access to a mobile phone (Gómez-Olivé - personal communication). This study did not assess the cost-effectiveness of mobile technology in supporting adherence directly; instead it assessed the effectiveness of a package of activities of which mobile technology was one component.

and assist with filing of patient records. The intervention was designed to function as part of the integrated management of chronic disease system (ICDM) (45).

The intervention planned to engage the services of an Implementation Manager to supervise the LHWs, with assistance from the senior clinic nurses. An Implementation Manager was to be responsible for establishing the intervention in each clinic and for supporting the LHWs. The trial team was of the view that the role of the Implementation Manager was a sustainable component of the intervention, as any health system reform requires either a temporary 'change manager', or for existing managers to take on such a role. It was therefore necessary to understand the importance of the Implementation Manager in improving patient outcomes.

This was designed as a cluster randomized controlled trial. Eight health facilities that provided care for the population of the Agincourt HDSS, together with the communities they served were to be randomized to usual care (four clinics) or to the provision of two chronic-care focused LHWs (four clinics). The intervention was to run for 15 months.

6.2 Situation analysis for the trial

I conducted a pre-trial situation analysis, necessary to assist with the design of the most appropriate LHW intervention. The analysis aimed at; describing chronic care that was currently provided in primary health clinics in the Agincourt HDSS; understanding what factors facilitated effective chronic care from the perspective of the clinic nurses, district and province staff and whether any barriers remain; understanding, from the patient's perspective, the key factors that have facilitated (or continue to hinder) access to care, and being adherent to medication; and, using the findings to design possible activities of a clinic-based LHW intervention to support chronic care, particularly for those with hypertension.

I conducted the situation analysis between June and October 2013, five months prior to the intervention. I included all the nine clinics, eight of which later became part of the trial and the ninth clinic became a pilot clinic. The situation analysis included two to three days of observation in clinics, semi-structured interviews with senior nurses in clinics and Clinic

Supervisors, and focus group discussions with members of the community, patients, and the community health workers who supported the work in the clinics. I also reviewed the appointment registers for patients with chronic diseases to see effectiveness in booking patients and the rate of attendance between May and July 2013. I placed findings from the situation analysis in three categories, (a) availability of resources (i.e. staff, equipment, drugs), (b) patient flow (i.e. filing, appointment, queuing) and (c) staff and patient interaction.

I learnt from the situation analysis that the number of Professional Nurses in the clinics ranged from 3-12. Almost half of the clinics did not have Data Clerks. Seven out of the nine clinics had CHWs assisting the clinics mainly in tracing and caring for HIV patients in their homes. Others assisted nurses in the clinics. Only one clinic did not have a functional electronic BP machine. The rest had recently received the machines. Nurses reported that availability of medication had improved. Conditions of clinic infrastructure were poor in some clinics. There was limited space, patients queuing outside, and paint peeling off and in some clinics, two nurses working in one consultation room.

For the patient flow, two clinics did not have separate consultation room for patients with chronic diseases because of staff shortage rather than lack of space. In almost all the clinics, patients with chronic diseases queued with all other patients to have their BP measured. There was no prepacking of medication for patients with chronic diseases in most clinics. On average, 60% of patients attended on their booked day. A clinic could have ten to twelve patients coming to the clinic unbooked. The number of patients with chronic diseases ranged from 9-52 per day. In a third of the clinics the appointment system was not always working because nurses were not operating it. Almost half of the clinics retrieved patient files a day before. There were different filing approaches in the clinics.

Clinic observations showed that nurses were generally caring and concerned about patients especially during consultations. However, there were a few instances of poor attitude from the nurses. From the patients' perspective, they felt that nurses' attitude towards patients was not good at times. They felt there was no confidentiality due to different colours of stickers which were placed on patients' files for different illnesses. They were also

concerned about favouritism by nurses and that at times they abandoned patients by all nurses going for tea or lunch breaks at the same time.

I disseminated these findings to the clinics, District, sub-District and the Province, for comments and feedback. These findings helped to better understand the clinics ranging from poorly to better functioning. When I presented the clinic specific findings during LHW intervention development workshops, the Implementation Manager and staff in the respective clinics focussed on how the intervention would help address some of these challenges in management of patients with chronic diseases. The situation analysis prepared better the implementation team about the anticipated problems and on where much effort would be need i.e. the appointment and filing systems. The findings also helped to better understand the pathways for patients with chronic diseases, where LHWs would be placed and how they would effect changes in the pathway. Results from the situation analysis led to the development of the following programme theory.

6.3 The conceptual framework (Hypothesized lay health worker programme theory)

Programme theories are assumptions on the causes of particular problems and what actions need to be done to address the problems (5). They are also known as conceptual frameworks or logic models. In the LHW intervention, trialists assumed that increasing prevalence of uncontrolled BP in the study communities might have been as a result of poor quality of care in the primary care clinics, which are overwhelmed by increasing number of patients with chronic conditions. By introducing LHWs in the clinics, it would free up nurses to focus on clinical management of patients, resulting in increased control of BP and increased identification of raised BP. This eventually would reduce no-controlled BP and prevalence of BP at community level. In my conceptual framework, I use MRC's framework for process evaluation of complex interventions to assess and explain both the outcomes and process of implementing the intervention. The framework examines the implementation process, the mechanisms and context (CMO configuration) (5). The LHW theory is clarified in the following diagrammatic illustration also known as the 'logic model' (124). Table 9 below presents the programme theory into its constituent and interconnected elements:

Table 9: The conceptual framework - context, mechanism, outcome configuration

Intervention ✚	*Context* ✚	*Mechanisms* 〓	*Outcomes*
• Appointment reminders • Adherence counselling • Prepacking of medication • Defaulter tracing • Managing appointment system • Recording keeping • Implementation manager support	• Accessible and well-resourced clinics. • High standards of clinic management • Motivated clinic staff • Positive experience of clinic care by patients	• Agents who learn and adapt to the intervention • Reliable interactions among actors • Active participation by staff and patient	• Improved access to care • Adherence to treatment • Controlled BP • Empathetic health providers

I hypothesized that the role of LHWs in the clinics i.e. appointment reminders, adherence counselling, managing appointment system *(intervention*), will only improve control of BP and quality of care in the clinics (*outcomes*), if the intervention is implemented in well-resourced clinics, well managed clinics, among motivated staff (*context*) where the intervention participants are able to learn and adapt the intervention to their context and support the implementation process (*mechanism*).

Definition of outcomes in the programme theory

- **Improved access to care:** increased proportion of hypertensive patients under active management for their hypertension as well as reducing the level of blood pressure in those patients already receiving care
- **Adherence to treatment:** Proportion of hypertensive patients who adhere to their appointment days and are able to come and collect their medication.
- **Controlled BP:** Proportion of hypertensive patients with a blood pressure described as Low Added Risk of cardiovascular disease as defined by a modified version of South African Hypertension guidelines 2011
- **Empathetic health providers**: Perceived positive relationship and interaction between health providers and hypertensive patients through clinic observation, observation of patients' consultation and patient exit structured interviews.

6.4 Implementation actors involved

The intervention recruited an Implementation Manager, a qualified senior Professional Nurse with more than ten years of nursing experience in Primary Health Care (PHC) in similar health facilities as those in the study. Apart from being familiar with the local health care system and structure, she had experience in initiating and managing a district wide programme on promoting access and adherence to antiretroviral treatment for HIV positive patients. The study also recruited LHWs who were residents of villages within which their respective clinics were serving, had a matric certificate and had experience in home based care, community health work or clinic work, and were able to speak, read and write English and Shangaan (the local language). LHW positions were advertised locally in clinics and community centres. The applicants were first shortlisted and those selected invited to face to face interviews. The interviewing panel comprised the Implementation Manager, human resource officer from MRC/Wits Agincourt Research Unit, clinic operations managers or their representative and a member of the clinic committee to ensure project ownership and local participation in the recruitment process.

6.5 Training and selection of lay health workers

From the face to face interviews, four candidates per clinic were selected to undergo training. The training was also planned as a second assessment phase from which two LHWs per clinic were finally selected. Within the training session, candidates were exposed to three phases of assessment: pre-test assessment, assignments during the training period and post- test assessment. The pre- test assessment was designed to test their knowledge and therefore was not used to rate the candidates' performance. Ongoing assignments were designed to see the LHWs' creativity in facilitating change in the clinics to ensure better care of chronic patients. The post-test assessment was to assess their understanding of the content delivered during training, especially concepts related to hypertension.

The week-long training was facilitated by the Implementation Manager and had a participatory approach. The actual content included; (a) defining hypertension and basic physiology of the flow of blood to the heart and the circulatory system, blood pressure

ranges, and systolic and diastolic blood pressure terminology; (b) factors affecting blood pressure control including life style modification and how LHWs can engage patients on diet, stress management and physical activity; (c) blood pressure monitoring tools that included both electronic and manual blood pressure machines. This also included the technique in measuring, recording and interpreting blood pressure reading; (d) drugs commonly used for hypertension in South Africa and adherence to treatment. Emphasis was placed on factors affecting adherence and how LHWs can support patients; (e) confidentiality especially working in a clinic environment and dealing with patients' information; (f) principles of good and bad communication; (g) responsibilities of LHWs in the clinic; (h) and basic information about other chronic diseases i.e. diabetes mellitus, asthma, tuberculosis and HIV. LHWs were selected based on their good performance during the assignments and post-test assessment.

Names for clinics and LHWs used in this report are pseudonyms. All the LHWs had attained grade 12 (matric). Half of them were computer literate. Six of the eight LHWs had experience in community health work (CHW) mostly as home based carers. They also had CHW related certificates mainly in areas of palliative care and HIV and AIDS. Three of these six LHWs had gone beyond community health work positions and became local project coordinators. The remaining two, though without experience in community health work but had experience working in the clinic environment. One had previously volunteered in the clinic as a data capturer, while another was a trained auxiliary nurse.

There was only one male applicant and only male LHW, which might be a reflection that community health work is mostly done by women. The majority of the LHWs had their age ranging from 40 to 50. For two LHWs whose age was 26, the Implementation Manager raised concerns on how they would effectively communicate with chronic patients who were mostly the elderly. In summary, based on academic attainments and work experience, all the LHWs were qualified for the position.

Limitations in the recruitment process

Two problems were experienced during the recruitment process; (a) despite having relevant background and experience, candidates from Orange clinic did not perform well during the interview process. During the training, the Implementation Manager struggled to identify suitable LHWs for Orange as she was uncertain on how they would perform in the clinic; (b) although both LHWs for Troy clinic performed well during the recruitment process, and had relevant background and experience; none of them had ever closely worked with Troy clinic and were not members of the local Non-Governmental Organization (NGO). This created tension between the Implementation Manager and the local NGO as they felt side-lined and not appreciated in their efforts in supporting the clinic. Later, I will explain how the LHW capacity in Orange clinic affected the implementation process and how the Implementation Manager addressed them. See section 8.3 page 125 for further details on the performance of LHWs in Orange clinic.

6.6 Introducing the lay health worker intervention

Local participation in the programme development process was at three levels;

a) Public Randomisation. A public randomization meeting was held and randomly selected 4 out of 8 clinics to receive the Intervention. The process ensured that clinic staff and the wider Agincourt population are confident that the process was truly random and was not influenced by any members of the intervention team. Participants to the meeting included, Clinic Managers and supervisors, members of the clinic committee, members of community development forums (CDF) and members of the Agincourt community advisory group (CAG);
b) Engagement with local NGOs or HBCs working with the intervention clinics. The Implementation Manager held separate meetings with these organizations to introduce the LHW intervention and strengthen the clinic referral system. The Implementation Manager also invited two CHWs from each of the four organizations who participated in the week long LHW training. All the organizations, except Troy (refer to limitation 'b' above) expressed interest and pledged their support to the

intervention. Secondly, the Implementation Manager consulted with the organizations on their conditions of service to help in determining salaries for LHWs.

c) Participation of intervention clinics in the LHW programme development workshops. Clinic Managers and nurses participated in clinic specific workshops which were based on the initial intervention design and ideas as conceptualised in the research development process. The workshops aimed at; presenting clinic specific findings of earlier conducted situation analysis, brainstorming on the activities that LHWs can and cannot do in the clinics, reviewing the patient flow in the clinics and reorganizing it where necessary and discussing LHWs supervision and reporting system.

6.7 Lay health worker activities as suggested by nurses

Box 1 below is a summary of LHW activities as suggested during LHW programme development workshops at clinic level. Later in the thesis I will explain how these plans were actually implemented and differences that existed among clinics.

Box 1: LHW activities as suggested by nurses

Filing – generally, nurses in all the clinics agreed that LHWs' primary responsibility would be retrieving files for patients with chronic diseases a day before their appointment date, issuing to them when they arrive and filing them back. However, there were some exceptions across the clinics. Troy clinic already had three Data Clerks but, due to high numbers of patients, staff felt that LHWs should also support Data Clerks in issuing out files for other patients with acute conditions especially in the morning. In Orange clinic, filing, which had been the responsibility of nurses was now going to be handed over to LHWs. Lay counsellors and nurses were managing the filing system in Timber and Hillard clinics. In Timber clinic, LHWs were to take over management of files for patients with chronic diseases but also assist in managing other files. In Hillard clinic, the Clinic Manager felt LHWs should only focus on files for patients with chronic diseases and let the lay counsellors continue with all other files. Troy was the only clinic with Data Clerks among intervention clinics.

Measuring vital signs – at the time of the programme development workshops, all four intervention clinics had one vital signs station for all the patients. Participants to each clinic workshop agreed on setting up a dedicated second vital signs station for chronic patients. However, the idea was to face hindrances in three of the four clinics. Troy and Timber clinics had their electronic BP machines not functioning. LHWs were only trained to use electronic BP machines and could not use manual ones. Troy and Orange clinics needed additional table and chair if the second vital signs station was to be operational. Finally, in all these three clinics, there was lack of space to accommodate vital signs station for chronic patients only. The workshops agreed that, when problems of electronic BP machines and furniture were solved, a second vital signs station would be placed at the same main waiting areas for the clinics. They would only reserve certain chairs for chronic patients. None of these problems were raised in Hillard clinic. Taking of vital signs, as per LHW training, entailed measuring the patient's BP and recording it in their files.

Health Education – all clinics reported giving health talks to all patients in the morning before consultations begun. These were talks focusing on a variety of health topics. They were being delivered by nurses and lay counsellors. Nurses and lay counsellors in all clinics agreed that LHWs can join in and give talks on hypertension on certain days. The Implementation Manager suggested to the Clinic Managers to develop week long rosters to guide the clinics on who was to give health talks. Specifically, Clinic Manager in Troy suggested that, apart from morning health talks, there should be targeted health talks to chronic patients at their specific waiting area after vital signs. Clinic Manager for Hillard suggested that health talks should not be limited to the morning session only but rather to run throughout the day when new patients arrive on the queue. Clinic Manager for Timber particularly mentioned that LHWs should focus on emphasizing to chronic patients not to miss their appointment date as this was the main problem in the clinic. She also wished LHWs joined nurses in community campaigns.

Appointments and booking – All clinics were using the appointment forms introduced by Integrated Chronic Disease Management model in booking patients for their next visit. Dates for the next visit depended on how stable patients' chronic conditions were. Booking was done by nurse in-charge of the consultation room for chronic patients for that particular day. All workshop participants agreed on the same approach to changes in booking for appointment. This task was to be managed by LHWs. Chronic care nurse for a particular day, was to discuss with the LHW responsible for booking, on number of patients to be booked on a particular day. After consulting a chronic patient, the chronic care nurse would write the next appointment date on the patient's file. The patient would take the file to the LHW who would record the appointment date on the booking form. Throughout the process, the nurse would be consulting with the LHW to ensure they don't exceed the required number for a particular date. A new appointment form was introduced (appendix C) that included capturing a patient's BP measurements.

Appointment reminders and follow up - Related to booking, LHWs were to remind hypertensive patient of their appointment a day before their appointment through text messaging. They were also to follow-up with hypertensive patients who missed their appointment a day after the booked appointment through text messaging. If necessary LHW would contact the defaulter patients by a phone call on the second day. Finally, they would refer defaulter patients to CHWs if the LHWs fail to get hold of the patients. Just as was the case with the booking, Clinic Manager for Troy wished reminding and tracing patients was planned for all chronic patients.

Prepacking of medication – Prepacking of medication was to remain the responsibility of nurses. LHWs were only to support the nurses i.e. in wrapping the medication together using a cellotape. LHWs were not to prepack on their own. Prepacking was planned to happen for all chronic patients and a day before appointment. In Hillard, prepacking was to continue to be done by nurses over the weekend and slowly introduce the daily prepacking with the help of the LHWs.

Data from the researcher and implementer diaries showed that the participatory approach in designing activities for LHWs stimulated greater understanding, interest, acceptance and support towards the intervention by the nurses. On the other hand, it provided an opportunity to foresee challenges LHWs would face in implementing the activities. Such challenges included the division of tasks among the LHWs, and with lay counsellors and nurses without the other feeling side-lined i.e. the case of filing in Hillard (refer to filing in box 8 below). Taking of vital signs and appointment booking revealed the challenge of space and furniture in the clinics (apart from Hillard). In all discussions nurses were uncertain on where LHWs would be stationed. Despite welcoming the idea of opening of a second vital signs station, challenges of non-functional electronic BP machines were surfaced as limiting factors in two of the four intervention clinics. The workshop process also led to a general understanding and agreement that LHWs could not prepack medication on their own, LHWs would be reporting to the Clinic Manager or any nurse in-charge for that particular day and, LHWs to be identified by uniform.

6.8 Alterations in the pathway for patients with chronic diseases

Apart from brainstorming on LHW activities, nurses suggested changes in the pathway for chronic patients with the coming in of LHW. These changes varied across the four clinics based availability of space and equipment (BP machines, weighing scales) in the clinics. In some clinics, the pathways did not immediately change. Box 2 below presents such alterations.

Box 2: Alternations in pathway for chronic patients

In **Troy clinic**, the coming in of LHWs did not immediately change the pathway. The chronic queue was to remain the same until the electronic BP machine (which had broken down) became functional and a new vital signs station opened. Thereafter, decisions would be made to change the pathway. In **Orange clinic**, nurses suggested to have chairs spared for chronic patients only at the main waiting area for vital signs. Chronic patients were then to have their files handed over to them and have a LHW measure their vital signs on a separate station. They would then wait at separate waiting area for consultations. From the consultation, they would hand over their files to the LHW in nurses' duty station for booking. In **Timber clinic**, chronic patients were to still queue together with all patients for vital signs. There wouldn't be a separate vital signs stations as the electronic BP machine was not functioning. LHWs would be issuing them files that they retrieved the previous day, right on the queue. After consultations, they would meet a LHW at the end of the corridor to drop the file and for booking. **Hillard clinic**, chronic patients would use the same pathway. Two changes would be effected and these include; opening a dedicated vital signs station for chronic patients, managed by LHWs, and after consultations, letting chronic patients go via a LHW room with their files for booking.

6.9 Structure and process of lay health worker programme development workshops

These were clinic specific two days' workshops. The first day of the workshop was held at the MRC/Wits Agincourt Research Unit offices. It was attended by a Clinic Manager and one nurse. It reflected on delivery of chronic care in the clinics. The second day, which was held in the respective clinics and was attended by the rest of staff, focused on discussing LHW activities and chronic patient pathways. Conducting the workshop away from the clinic on the first day ensured that the workshop was free from any disturbance. However, very few nurses turned up as others continued with services at the clinic. Having the workshop in the clinic on the second day ensured wide participation of the nurses. However, there were cases where some nurses did not participate as they still had to attend to patients. This scenario raised a practical aspect of challenges in involving nurses in trainings and workshops away from their clinics or within the clinic but during work hours. It further burdens on already strained nurses who have to cover up on those nurses that are away.

Box 3 below is a description of how the process of conducting LHW programme development workshop varied across the four intervention clinics;

Box 3: Variations in LHW programme development workshops

Troy clinic – There was balanced participation of all members in the discussion although the Clinic Manager dominated from the clinic side. The workshop spent a lot of time discussing the challenge of space than what actually the LHWs will be doing in the clinic. The Clinic Manager constantly raised the challenge of space in the clinic while expressing that there is need for extra staff in the clinic. The Professional Nurses were positive about the programme. By the end of the workshop, it was still not clear on how the LHWs were going to operate in the clinic. The Clinic Manager kept on pushing things forward to wait for the LHWs until they are in the clinic.

Orange clinic - Nearly all nurses that were available in the clinic on the second day, came to the workshop. However, two Professional Nurses left to attend patients just after the introduction as there was no nurse that remained in the clinic. The remaining participants participated well in the workshop. There was positive enthusiasm from a male Enrolled Nurse in supporting the programme. This was the first time the Clinic Manager attended the project meeting as previously she delegated to her deputy.

Timber clinic – The Clinic Manager and an Enrolled Nurse were the only active participants while others listened actively. The Clinic Manager positively contributed to the discussion and made critical observations and suggestions. The Enrolled Nurse, who also was sometimes responsible for chronic care, displayed high levels of understanding of chronic care in the clinic. He was positive about the programme and made positive contributions.

Hillard clinic –The first day was attended by the Clinic Manager only due to fewer nurses in the clinic. This affected the process of reflecting on the procedures in the clinic and generating a meaningful discussion. Other nurses and lay counsellors joined on the second day. They seemed excited about the programme and were involved in the discussion. The Clinic Manager and Nurses presented adequate knowledge of the clinic and its operations.

6.10 Conclusion

In conclusion, I reflect on some topics identified in the situation analysis, design and implementation of the LHW intervention and these include: the role of the situation analysis in the design of the trial and the importance of a consultative approach in developing the intervention and how the trial attempted to do that.

The situation analysis prior to the intervention was ideal in understanding the current operations of the primary health care clinics and how the LHW intervention would fit in such context. Among others, the situation analysis identified challenges with: resources, non-functioning of ICDM, staff and patients relations. When we presented this to the DOH and the primary health care clinics, it helped in a consultative planning of the intervention based on existing challenges and how we would intervene in the clinics. The World Health Organization recognises that conducting situation analysis prior to health care intervention helps in realistically assessing strengths, weaknesses, opportunities and threats of the current situation and their root causes and effects. It is evidence-informed basis for developing a solution.(125)

The design and implementation process of any complex intervention, contributes to its success or failure. Limited effects may be as a result of weakness in the design of a programme or improper implementation (5). This trial was designed and implemented taking into account individual clinic context. To achieve this, there was participatory approach and strong relationship with clinic staff and community members in the design and throughout the implementation of the LHW intervention across all the intervention clinics. Both members from the community and staff from clinics participated in randomizing clinics to intervention and control. Clinic Managers and members of respective clinic committees also participated in selecting LHWs for their respective clinics. The Implementation manager led clinic specific workshops in developing the LHW intervention. As part of programme designing, Clinic Managers and nurses participated in deciding LHW activities and training needs that resonated with their clinic context.

In most of the interventions that have been reported, strong relationship with community and collaborative planning were some of the enabling factors for clinic based LHW

interventions (77). The WHO (2011) report on task shifting quoted Schenider, Hlophe and van Rensburg (2008) and expressed that strong relationship is essential to socially oriented tasks for LHWs (77). Participation of the community is also important in understanding local needs and interests (77). The use of LHWs as extension health workers in Ethiopia and in family health programmes in Brazil, had community participation as a key factor to the success of the programmes (90). Studies in Tanzania, Ethiopia and Ghana involved community health committees and community members in selecting and supervising LHWs (76, 126, 127)

This chapter relates to my first study objective of analytically comparing how the intervention development process affected the functioning of the LHWs for each clinic, its process of development by clinic staff and the Implementation Manager and its adaptations to the local context. In the next chapter, I focus on the different contexts of the clinics during the implementation period and how they affected the intervention.

CHAPTER 7: RESULTS - CONTEXTUAL FACTORS THAT AFFECTED THE IMPLEMENTATION OF THE TRIAL

The last chapter explored the situation analysis and development of the intervention. This study uses a conceptual framework for the realist evaluation that focusses on context, mechanisms and outcomes. This chapter focusses on the context of the intervention. I discuss clinic contextual factors throughout the implementation period that affected the functioning of the clinics and the LHW intervention. In this chapter, I will be addressing the second study objective by analytically comparing the provision of chronic care, different clinic context and general functioning of four intervention and four control case study clinics, before and throughout the intervention period.

Clinic contextual factors that I identified as affected functioning of the clinics included; infrastructure, equipment and materials, supply of medication, human resource, clinic management, and, patient management. Later in chapter eleven (mechanisms), I will explain how these factors impacted on the LHW intervention and operation of the LHWs. The findings presented in this section are mainly from information sourced through in-depth interviews with the Implementation Manager and LHWs, semi-structured interviews with Clinic Supervisors, Clinic Managers, nurses and, patients. Other sources of data were observations of clinic activities and patient consultation, researcher and implementer diaries.

7.1 State of clinic infrastructure

There were variations across the clinics in terms of infrastructure and space. Data on clinic infrastructure showed that all eight clinics were in three categories. Only one clinic had spacious and modern infrastructure (Hillard). The second category was of clinics that had good infrastructure but with limited space (Troy, Timber, Faith and Arlington). Such clinics were modern but their limited space could not house all clinic services in their respective rooms. Patients were also affected as they mostly waited outside the clinic. The third category was of clinics that had both dilapidated infrastructure and limited space (Orange,

Moghan and Yang). The dilapidated infrastructure had the paint peeling off, the ceiling falling off and produced bad smell.

Box 4 below summarizes the state of clinic infrastructure in all the clinics and how it affected the clinic operation. I will start describing clinics that were better off in their infrastructure to those that were worse off.

Box 4: Clinic infrastructure

Hillard was a modern and spacious clinic compared to the rest of intervention and control clinics. The issue of space was not a problem as was raised with other clinics. Among others, it had four consultation rooms, nurses' room, Clinic Manager's office, admission rooms, dressing room, vital sings room, LHWs' room, two spacious waiting areas, and neat, tidy and spacious filing room. When other clinics struggle to find space for booking and taking vital signs, separate unoccupied rooms for these were identified in Hillard during the workshop.

Troy had a modern infrastructure but with limited space. The clinic had a mobile park home, which was initially used for chronic care. It was in a damaged state at the introduction of the intervention. The clinic was using emergency and filing rooms for consultations. As a result of this, both chronic and acute patients queued for one vital signs station. An ideal station for the LHWs was not found. An open space identified by the Clinic Manager outside the clinic to use for booking and taking vital signs, was not suitable during extreme weather conditions. Midway through the implementation, the mobile park home got repaired with external support. Consultations for chronic patients moved to the mobile park home. Later, chronic care nurses moved again chronic consultations from the mobile park home to the pharmacy window at the reception. The Clinic Manager expressed that:

"The infrastructure was built long time ago. The clinic was never full. And there were not many chronic patients like nowadays. Almost 80% of clients coming to the clinic these days are chronic patients." **20150923_intcm_tro**

Faith clinic had fairly adequate space. Chronic patients had their own consultation room. In case of only one Professional Nurse in the clinic, all patients still queued separately but alternated in one consultation room. This was also observed on days when other nurses were available but were busy compiling statistics for reports. Among others, the clinic had separate office for the Clinic Manager, filing room with good filing cabinets, HCT room, nurses' home, two waiting areas and four consultation rooms.

Arlington clinic had adequate space compared to Moghan, Timber, Orange and Yang. All sections and clinic services had their own rooms. There was a big waiting area, four consultation rooms, pharmacy, admission room, and Clinic Manager's office, filing and administration block. A separate building was used as nurses' home just like in all clinics.

Timber had a relatively modern infrastructure but with limited space. The initial idea to place LHWs near the exit door, blocked the exit way. The Clinic Manager identified a room. Later, officials from the DoH moved the LHWs from their booking room to the reception/ waiting area which was an open space. The officials moved the vital signs station at the reception to the booking room. They argued that taking of vital signs needed privacy. LHWs could no longer privately counsel patients. The space was limited at the main waiting area. They combined both chronic and acute patients on the same queue which delayed the process. There was limited space to wait for consultation. As such, patients whose BP had already been taken, went back to wait at main waiting area ending up confusing the queuing

Orange had the most limited space and a dilapidated old infrastructure. LHWs failed to talk to individual patients on their BP status due to limited space at the reception. There were few chairs as well. Many patients usually stood on their feet while waiting to be taken vital signs or to go into the consultation room. Others waited outside the clinic. When they finally got inside, they were fighting because some misplaced their queuing numbers. And when there was a space they all wanted to sit down and they didn't want to queue according to their queuing numbers because they had been standing for a long time and they ended up fighting. The situation in Orange was similar to Moghan and Yang clinics in the control arm. Different services shared a room as expressed by the Clinic Manager in Orange clinic.

"In June, we had visitors from the national office. They were so upset to find our filing room being used as a dressing room. They asked us why we don't have a new clinic, why are we not having files." ***20150914_intcm_ora***

Moghan clinic had limited space. When the clinic was very full, it became confusing and patients were uncomfortable. Some patients waited outside the clinic. This resulted in having many patients on days they felt the clinic was not full i.e. Friday than their booked date. Nurses complained that the clinic structure was not beautiful. The vital signs station was situated at the waiting area in front of patients. It was so compacted and there was no privacy. After vital signs, chronic patients waited at the same waiting area there by confusing the queuing system. The clinic pharmacy was inside the chronic consultations room. Nurses usually came in and out to collect medication while consultations were in progress. The filing room also housed the HCT office. Sometimes patients waited for long time whenever HIV counselling sessions were in progress. Patients as well complained of the limited space in the clinic as expressed in the following quote.

"I don't like it when there is no space at the clinic. Sometimes you find that we have to stand outside the clinic until there is an open space inside the clinic." ***intpc_cohort2_1049_05052015***

Yang clinic had a small and dilapidated infrastructure. There was bad smell as a result of Bats in the ceiling. The initial separate building meant for patients with chronic diseases (as observed during the situation analysis) was abandoned for its dilapidated state. Eventually, the small main building became congested. Nurses morale dropped and wished they could leave the clinic. Because of the congestion in the main building, the pathway for chronic patients delayed and became confusing to the patients. Chronic patients queued together with acute patient. Now and again they were observed asking about where to sit. There was no running water. This affected their hygiene when they had no water to wash hands after i.e. dressing wounds. Nurses brought water from their homes. There were very few rooms. In case of enough professional nurses on a particular day, two nurses would all be consulting in one room (no privacy).

Almost 88% of the trial clinics had their infrastructures in a state that required either expansion or renovation. In some clinics, limited space resulted in having a single room being used for different services i.e. dressing of wounds and filing. This situation delayed patients as others services had to wait. It also affected the privacy and confidentiality of the patients in case of two or more patients being attended in one room. Limited space inconvenienced patients who waited outside the clinic when the clinic was full. Limited space also affected the intervention as a station for LHWs could not be found in most clinics.

In summary, clinics with limited space and dilapidated infrastructure are likely to affect the level of motivation for both patients and staff. Chronic patients are likely to be discouraged to come to clinics and face such conditions and eventually be lost to care. There is need to review clinic infrastructure against patient load. Current infrastructures were relevant at a time when specific clinic services had specific days. The current approach where all services are provided every day and the growing number of chronic patients (refer to quotation **20150923_intcm_tro** in box 4 above), has seen clinics ever full.

7.2 Clinic equipment and materials for chronic patients

The state of equipment and materials in the clinics was an important factor in understanding and describing the clinic context and the role such resources played in facilitating or limiting chronic care. In this section, I will discuss the state of BP machines and other equipment that was relevant to the LHW intervention.

7.2.1 Electronic BP machines

When the LHW intervention was introduced into the clinics, all the clinics had one electronic BP machine for almost a year. These had recently been supplied with the introduction of Integrated Chronic Disease Management (ICDM) programme. The machines (vital signs monitors) were commonly known as Dinamap by the nurses but were of different brands. These brands included Edan and BLT M7000. Throughout the implementation period, these machines constantly broke down and were being taken for maintenance by the Implementation Manager (refer to box 5 below).

The electronic BP cuffs were worn out. There were two scenarios that were observed: i) some clinics had completely damaged cuffs and resorted to using cuffs meant for manual BP machines on electronic machines; ii) other clinics had worn out cuffs which were sewn. Data from clinic observations showed that some cuffs became damaged as a result of the staff using only one sized cuff for all patients, including obese patients. The situation was similar across the four control clinics. Later after the first six months of implementation, the trial management team made a decision to find money and supply cuffs to the clinics as the damaged cuffs and cuffs for manual machines were likely to give wrong BP readings. The cuffs were delivered to both control and intervention clinics. Figure 5 depicts a sewn cuff:

Figure 5: Sewn cuff



Nurses expressed lack of confidence in the BP readings they got from the electronic machines. Patients also suspected that the BP machines at the clinics could be faulty:

"Sometimes when I go at the clinic they say they will not measure me because my BP is in good condition. They say, by checking on my file record they can see that my BP hasn't changed. This surprises me. Sometimes they say their BP machine is not working correctly. And sometimes when they measure us they will say that; all of you today your blood pressure is too high. Maybe it's the machine that is having a problem. And sometimes I don't know which is right or wrong and I don't know what to do." ***intpc_cohort1_1013_29072014***

Box 5 below presents the state of electronic BP machines in the intervention clinics throughout the intervention implementation period. In this box, the information is for intervention clinics only based on detailed account of the Implementation Manager's diaries on her day to day experience with the intervention clinics.

Box 5: BP machines in intervention clinics

Troy clinic had an electronic BP machine with a damaged cuff at the introduction of the intervention. Nurses and the LHWs were using a burst cuff which a nurse has sewn. A designated vital signs station for chronic patients could therefore not be opened hence affecting the length of time they stayed in the clinic. The cuffs continuously became worn out. The Implementation Manager supplied new cuffs to the clinic. The electronic BP machine became functional. Within the third phase of the implementation, the electronic BP machine broke down. The Implementation Manager took it for maintenance at Mapulaneng hospital. When it came back, the thermometer attached to the machine also had been broken. Since then, the machine was always on and off to the end of the intervention.

Orange clinic was using an electronic BP machine at the beginning of the intervention although the cuffs were wearing out. Later into the project, the intervention purchased new sets of cuffs. The electronic BP machine broke down midway the implementation period. The problem was with the switch button. The Implementation Manager took it to Mapulaneng hospital for maintenance. The machine had been overused and the button had broken and according to the technician, the button needed replacing. It couldn't be fixed because it was an Edan brand and all Edan brands couldn't be fixed. The Implementation Manager later took it to a bigger maintenance workshop at Themba hospital where it got repaired. At the end of the intervention, the machine had broken down again and taken for maintenance.

Hillard clinic had their electronic BP machine in good working condition at the beginning of the trial. However, its cuff was wearing out. The Implementation Manager, through the LHW project, supplied new cuffs just like in all eight clinics. When the intervention went into the third phase, the electronic BP machine started breaking down now and again (this is the only machine that had been stable across the clinics). It was switching itself off from nowhere. The switch button became stuck sometimes and a pin on the machine broke down.

In **Timber clinic**, the electronic BP machine was not working and its cuffs were worn out at the beginning of the intervention. Although the nurses were happy to have a second vital signs station, this was not possible with the non-functional machine. The Clinic Manager reported that all clinics received new electronic BP machines called dinamap while Timber received an old non-functional machine. Despite receiving new cuffs from Nkateko project, the machine couldn't function well. Some buttons were very stiff and slow to respond. The Implementation Manager took it for servicing. After a short while, it broke down again. At the time the intervention ended, the machine had been sent to the sub-district for repair.

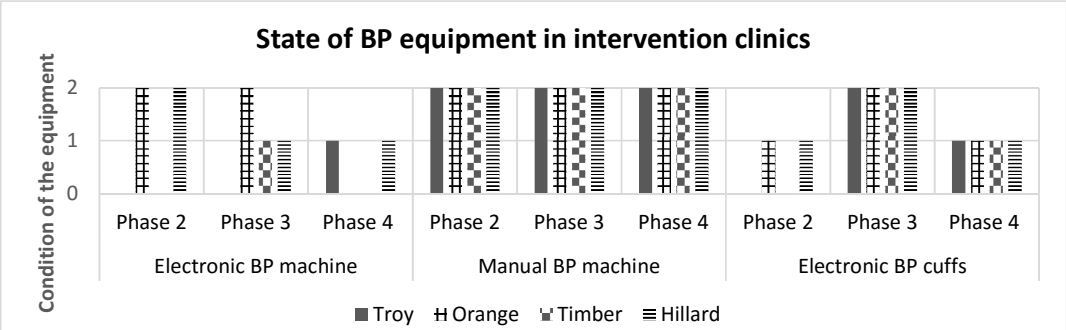
As presented by the data, there were difficulties concerning the use of electronic BP machines. The state of the electronic BP machines questioned the reliability of the BP readings. Such unreliable readings could have affected proper diagnosis and management of hypertensive patients and all patients generally. There were possibilities of wrongly putting people on treatment and missing out on rightful people. The situation might have denied patients proper care and management of their chronic conditions, led to inefficient use of financial resources allocated to purchase of medication and inappropriate use of nurses' time.

7.2.2 Manual BP machines

In addition to the electronic BP machines, all clinics had between three and seven manual BP machines. Troy had the highest number of manual machines (seven) but also had the largest catchment area. Two factors affected use of manual BP machines; i) although all the manual BP machines were in perfect working condition, they had cuffs that were either completely damaged or were wearing out; ii) nurses were not willing to use manual BP machines. They said that the stethoscope was painful in their ears. More than half of the Clinic Managers thought that the nurses were just lazy in using manual BP machines. The Implementation Manager (later I will explain how the Implementation Manager trained LHWs to use manual BP machines) and two Clinic Managers from control clinics supported nurses' claims as expressed in the following;

"Nurses don't like using the manual BP machines saying that it is affecting their ears. That is true. Initially we were measuring 15 – 30 patients in a day. We are now measuring more than 200 patients in a day which can easily affect one's ears. The world is moving with technology and there is no need to stick to the manual machines unless it's just for confirmation."

With reference to the Clinic Managers' quote above, it is evident that nurses are required to measure BP for a greatly increased number of patients compared with the time before clinics started providing anti-retrovirals. When using a manual machine, the nurse has to use a stethoscope, which is uncomfortable in the ears. If only one nurse listens for the blood pressure sounds on 200plus patients in a day, it is understandable that the nurses' ears will hurt. A better situation was to have two people using the manual machine at vital signs station. However, this was not possible with the low number of nurses in some clinics. On the other hand, the electronic BP machines, and particularly the cuffs, were rapidly torn due to measuring every patient that visited the clinic every day. Figure 6 below depicts the state of BP machines in the clinics. There is need to consider the possibilities of not measuring BP for every one that comes to the clinic. These include acute patients without risk factors e.g. those aged less than 35 years. Chronic patients who have had stable BP readings could also be measured once every six month during their reviews.



Level 2 (good): working in a perfect condition without any reported case of malfunctioning**.**
Level 1 (fair): had once in a while stopped working. Cuffs were reported wearing out.
Level 0 (non-functional): had completely stopped working and were not in use.

Figure 6: State of blood pressure machines in the clinics

7.2.3 Other Equipment

There were several other equipment and materials that affected chronic care and these included bags for prepacking medication and files for keeping patients' records which were not available in the clinics. Later on, I will explain these under sections on prepacking medication and management of patients' records respectively. Others were photocopiers; two intervention clinics (Troy and Orange) had their photocopiers breaking down during the implementation period. Staff in these clinics were photocopying in nearby clinics. However, these were quickly fixed by an external consultant who was on contract and supplied photocopiers in all the clinics.

The clinics had weighing scales in good condition. The only challenge was that in some clinics they only had one scale which posed a challenge in opening a second designated vital signs station for chronic patients. On the other hand, the Implementation Manager was able to discover some equipment i.e. a scale in Orange and an electronic BP machine in Troy, kept in their storeroom in good condition yet nurses were not aware of their existence.

Future researchers should explore whether nurses are given proper instructions on how to operate the machines, carry out some routine services i.e. changing of batteries and how they put such information into use. Data on photocopiers has shown that sub-contracting such services to an external and private consultant ensured timely maintenance of the photocopiers in case of break down. Future research should also explore this experience.

7.2.4 Maintenance of equipment

There was unclear maintenance and servicing system for equipment in the clinics. Staff responsible for maintenance based at Themba hospital informed the Implementation Manager that they had a system of regularly going around the clinics to check on the equipment. The Clinic Supervisor said that there was no regular maintenance of equipment, and several Clinic Managers expressed that servicing of equipment stopped sometime back;

"The District promised us a technician to maintain our medical equipment. Presently when the equipment is not functioning well, we report to the Asset officials to be collected and brought to the Sub-district, and then arrangements must be made with the district technician. When he (district technician) started, he was drawing a programme of his visit to the Sub-district. Otherwise currently there's no regular maintenance of the equipment." ***20151019_intsup***

"There is no system in place for servicing or maintenance. We once took some of the equipment to the hospital for maintenance, and until now, nothing is coming back. Some of the equipment was collected in all the clinics to the Sub-district, but nothing came back" **20150923_intcm_tro**

Lack of clear and reliable maintenance and servicing system for equipment affected functioning of the equipment. With no technician on site in the clinics, those responsible for servicing equipment needed to be responsive and accessible to the clinics. Clinic Managers must be aware and confident of the processes to have the equipment maintained.

7.2.5 Procurement challenges

Clinic Managers and supervisors expressed that procurement and cost curtailment challenges were affecting supply of equipment and resources in the clinics.

"*Every clinic is having a budget, and that budget is supposed to be utilized by the same clinic, but the clinic and the Sub-district do not have power on the budget. When the budget is out, we are called to procure. We send specifications to the Sub-district, they even send them further to the suppliers, but a note or a report from the higher levels will come saying "You have exceeded your budget, or give us reasons why you ordered files" and to me as an Operational Manager, I'm not responsible to my budget, I'm relying on other people, to say: you can order, now the order is been cancelled, then at the end of the day we receive things that we did not order."* ***20150908_dairycm_fai***

In conclusion, several factors affected availability and proper functioning of equipment and materials in the clinics during the implementation period. There is need to improve the servicing and maintenance of the equipment. There is also need to improve orientation and use of the equipment, and procurement and supply processes.

7.3 Availability of medication

The situation on availability of medication was the same in all clinics during the intervention period. During the first six months of the intervention, relevant hypertensive drugs were available in the clinics. Depending on BP readings, patients with controlled BP were given 2-3 months of medication but if the BP was not controlled they were given for one month. Things changed during the third phase of the implementation. I observed, and LHWs reported, shortage of chronic medication in the clinics including hypertensive drugs. For instance, Prexum plus, Simvastatin, Adalat (which was being phased out but clinics were not aware), Nifedipine and Aspirin were likely to be missing in the clinics. Patients were advised to go to nearby clinics or to be called once the drug arrived. This resulted in patients booked for one month for rationing purposes. Hence the clinics had more patients on regular basis. Initially clinics could share medication but some clinics started refusing to share theirs. The situation became worse towards the end of the intervention. LHWs agreed that in some instances, patients went back home without some or no medication. The following quote was from observing patients discussing in a clinic;

"They call us to come to the clinic and when we are here, we are told that there are some medications that are not available". **20150803_obscli_tro_pm.**

In five clinics, data from patient exit structured interviews showed a rise in the percentage of people who reported that they had been told that some medication was not in stock at the clinic. For the remaining three clinics, it might be as a result of patients being interviewed on a day when medication was available in the clinic. Table 11 below shows data from the patient exit structured interviews. Although I had a small sample size for the interviews, it shows that there was a problem and it was unpredictable and it varied from clinic to clinic.

Table 10: Percentage of patients who reported shortage of medication in the clinics

Arm of the trial	Clinics	Some drugs out of stock (%)		
		% Phase 2[5] (n)	% Phase 3 (n)	% Phase 4 (n)
Intervention	Troy	23.9 (46)	33.3 (33)	43.3 (30)
	Orange	32.5 (40)	70.0 (30)	3.3 (30)
	Timber	24.3 (37)	16.6 (30)	36.7 (30)
	Hillard	25.0 (44)	6.6 (30)	40.0 (30)
Control	Faith	40.0 (10)	3.3 (30)	73.3 (30)
	Moghan	80.0 (15)	6.6 (30)	16.6 (30)
	Arlington	46.6 (15)	66.6 (30)	3.3 (30)
	Yang	13.3 (15)	50.0 (30)	13.3 (30)

In 2015, shortage of medication was the most common problem mentioned by patients during patient cohort semi-structured interviews, while in 2014, it was the second most common. Patients complained that they were told that the order was not delivered. They were told to go and buy or come another day to check. In certain circumstances, when they come again, they would find that the medication in still not available. When drugs were few, patients felt nurses kept some drugs for their friends and families.

It was not clear whether shortage of medication was as a result that there was no medication at the depot or the clinic lacked proper organization in ordering and collecting medication. The Clinic Supervisor was surprised with the issue of stock out of drugs. She said that there was weekly drug stock out monitoring that happened in the clinics. She had only heard about stock out of certain ART drugs and not for hypertension. She suspected that either the clinics did not report or there was late delivery from the depot (which she said normally happened), and the clinics indicated it as stock out. All Clinic Managers agreed that there was drug stock out in some days for certain medication, including for hypertension, which was as a result of inefficiencies and poor communication from the depot. The Clinic Manager from Troy expressed that;

[5] Phase 1 of the intervention was the situation analysis (refer to Methods section). Patients exit interviews started in Phase 2 (development and introduction phase).

"It was depot issue. The system has changed and they are no longer manufacturing those drugs. They were supposed to give us a note indicating that they have replaced the drugs by other drugs but that did not happen. It was a challenge because we thought the depot was not having those drugs. Whenever we ordered we were told they were out of stock. This happened for all clinics. But now things are improving. The changes are being communicated. The replacements are being delivered" **20150923_intcm_tro**

Another Clinic Manager felt that the depot was not fairly distributing medication;

"The depot which supplies us with the medication, was not fairly distributing the medication. For example: Bushbuckridge has 38 facilities, and then when you order HCTZ, it is going to be supplied only in one local area, and then the other clinics will be told it is out of stock. It is not easy for us to argue with the depot, because we are told it is out of stock. But a certain local area will tell you "We've got lots and lots" of whatever drug." **20150908_intcm_tim**

However, a clinic supervisor was not aware that there was shortage of drugs in the clinics;

"I don't know, every week we are doing weekly drugs stock out monitoring, Drugs that were mostly out of stock were for ART and not hypertension. May be they fail to report. About the depot, sometime we experience problem of late delivery and if it is out of stock from the depot we are encouraging facilities to ask from each other. Otherwise we did not experience gross shortage" ***20151019_intsup***

In conclusion, unavailability of hypertensive medication in the clinics can be linked to several factors affecting management and care for hypertensive patients. Firstly, it affected adherence to medication. It led to patients missing on taking medication which was out of their control. Secondly it might have affected patients to adhere to their appointment. Patients might have decided to miss their appointment knowing they will not be able to get medication. Thirdly, the situation was an expensive experience for some patients that resorted to buying the medicine from private pharmacies. Finally, patients were likely to lose confidence in their local clinics. Unavailability of medication questions level of communication that existed between local clinics and the depot that distributed the

medicine (refer to quote **20150923_intcm_tro).** This might also be a reflection of communication with other service providers that supported clinics. The situation also questioned challenges of developing and adhering to routines. LHWs continued calling and inviting patients for their appointment without checking whether medication was available or not in the clinic (refer to quote **20150803_obscli_tro_pm).** This is similar to the issue of nurses who continued measuring BP on every patient that visited the clinics despite the frequent breakdown of BP machines and wearing out of cuffs. There is need to further explore on how routines need to take account of local context.

7.4 Human resource and patient load

The study reviewed levels of staff in the clinics and patient load. Figure 7 below illustrates levels of staff in the clinics as captured at different periods of the intervention;

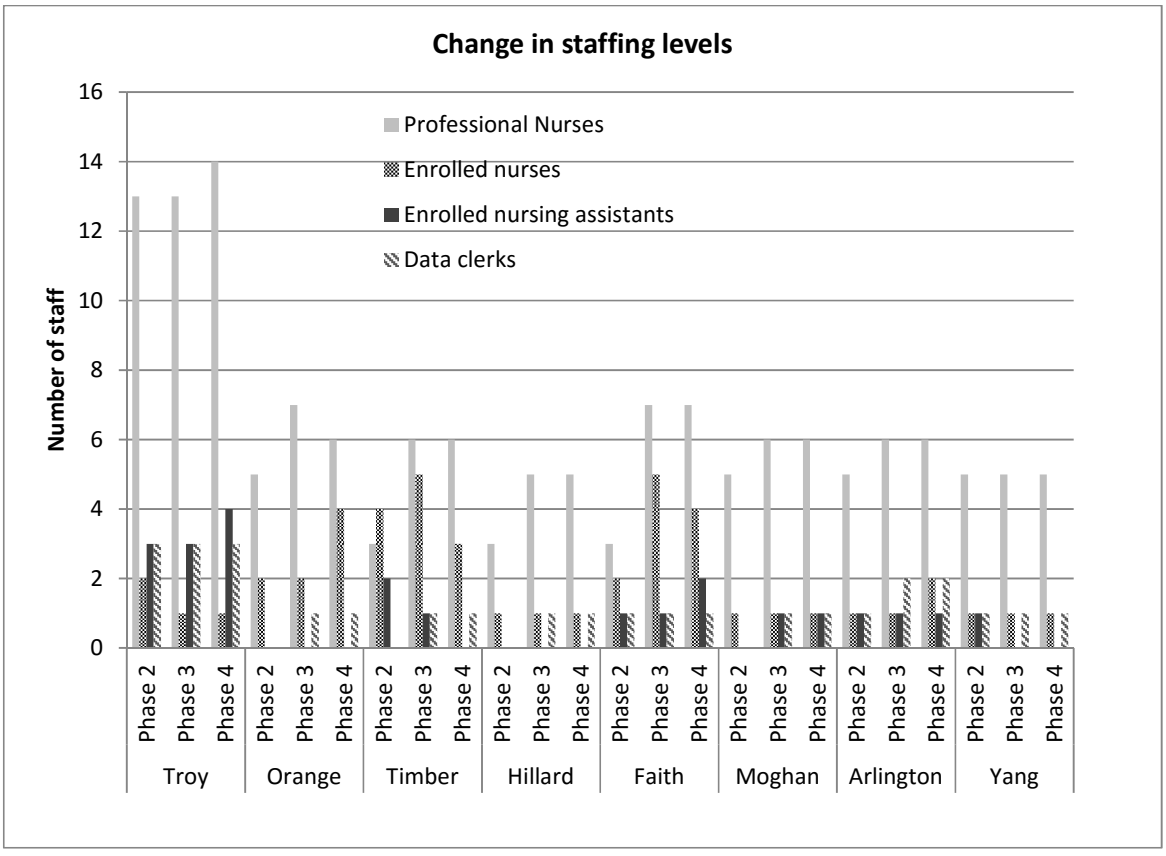


Figure 7: Changes in staffing levels over the intervention period

7.4.1 Nurses

Figure 7 above indicates that clinics maintained almost the same number of nurses throughout the implementation period. Nurses alternated with some going to long term trainings and others coming back. However, Clinic Managers in all the clinics complained of having shortage of nurses, below their staff establishment and resulting in current staff being overworked. They complained that nurses had limited time to do all the requirements for ICDM i.e. prepacking of medication and booking, since they finished seeing patients late. Across all the clinics, most nurses took days off on Mondays and Fridays[6]. As a result, many chronic patients were booked between Tuesday and Thursday. Box 6 below presents how perceived shortage of nurses affected operation of specific clinics.

Box 6: Shortage of nurses and clinic operation

Timber, Hillard and Faith clinics had the lowest number of Professional Nurses (three). One of these clinics had two midwives out of three Professional Nurses. An Enrolled Nurse who was not trained to prescribe medication would be consulting patients and this delayed the process as the Enrolled Nurse needed to consult the Professional Nurse now and again. There were also situations where one nurse consulted all patients. The sub- district decided to close the clinic on weekends. Sometimes they could send a Professional Nurse from another clinic on relief if there was transport. Nurses performed tasks beyond their scope i.e. non-midwives delivering babies. I made the following observation in one clinic;

"A pregnant teenager arrived in the clinic in labour and delivered though there was no midwife in the clinic. Other nurses conducted the delivery process. But they did it in hiding so that other people should not know. The scenario underlines how nurses in a rural clinic, with limited human resource capacity would shift and taken up tasks they are not trained for. It highlights the quick decision and coordination nurses have to make when faced with a challenge beyond their capacity. Some of these nurses stay within the community – they are faced with a dilemma of saving people they stay with (from a social perspective) and abiding to the conditions of their service, (from the legal perspective.) ***20141125_diaryres_tim_fl***

[6] Clinics in study area operated everyday including weekends.

Shortage of nurses had its own implications in Hillard clinic. Chronic patients were only booked between Tuesday and Thursdays. It became a problem if she had to make a difficult decision about a patient. Otherwise when they are two, they could share ideas. Nurses no longer had access to trainings. The sub-district officers no longer even bothered to invite them. They knew the clinic wouldn't have nurses remaining. There were also chaotic scenes reported in Hillard clinic as a result of shortage of staff. The Implementation Manager reported the following observation where the clinic came to a standstill;

"This morning the clinic came to a standstill because one Professional Nurse who was on duty was called at home for an emergency. The clinic was then left in the hands of the Enrolled Nurse. The Enrolled Nurse phoned one Professional Nurse who was off duty but could not come immediately as she was attending to something until 9am. LHWs kept reassuring the patients, and kept them busy with health education. The Professional Nurse managed to arrive between 10:30 and 11:00" ***20140528_dairyim_hil_zm***

Troy, Orange and three control clinics were better off in terms of levels of nurses. The high numbers of nurses in some of these clinics was as a result of having high patient load. Orange lent one professional nurse to Faith clinic. However, there were unique cases in Troy, Yang and Faith where nurses resigned/transferred and there were replacements done. Most of the new nurses were coming from hospitals and had no knowledge of ICDM and PC 101. The following expression by a Clinic Manager describes how the situation was in Troy and Yang clinics;

"I received seven new nurses versus nine that left. They are blank and are without Midwifery. They were working in hospitals, depending on a Doctor and they were not Professional Nurses*. They have just recently passed. They have no experience working in a clinic setup. Now they have to prescribe. All the seven, no PC 101, no TB, no HIV related information, they are only being orientated as they are working"* **20150923_intcm_tro**

7.4.2 Nurses and patient load

I attempted to understand the average number of chronic patients that were attended by a Professional Nurse per day. In each of the eight clinics, I observed the total number of chronic patients that Professional Nurses consulted and noted the amount of time for each observation. These observations were made for three consecutive days during the final phase. However, the findings were not conclusive. In almost half of the clinics, nurses also either fully or sometimes looked after non-chronic patients. Secondly, usually more patients were booked between Tuesday and Thursday as these were the days likely to have more nurses in the clinics. Despite the limitations, these estimates give a picture of patient load per nurses per day. Table 12 below summarizes the three days observation for chronic patient load in clinics. I present information for five clinics only as these were the only clinics that had designated consultation rooms for chronic patients;

Table 11: Average number of chronic patients per day and average consultation time per patient in clinics with designated consultation rooms for patients with chronic diseases

Arm of the trial	**Clinic**	**Total number of patients seen by a nurse responsible for chronic patients**					
		Day 1	**Day 2**	**Day 3**	**Average number of chronic patients per day per nurse**	**Average time**	**% unbooked**
Intervention	Troy (Thurs, Fri, Tues)	69	54	66	63	4.5 mins	42
	Timber (Fri, Mon, Tues)	16	25	20	20	6.8 mins	34
Control	Faith (Tues, Wed, Thurs)	40	45	26	37	10 mins	N/A
	Arlington (Tues, Wed, Thurs)	34	29	44	35	8.1 mins	63
	Yang (Tues, Wed, Thurs)	33	25	18	25	10 mins	33

In table 12 above, the highest number of chronic patients in Troy was as a result of having the highest catchment area among the clinics. However, Troy had the lowest chronic patient consultation time, based on its approach of just issuing medication to chronic patients through the pharmacy window. This approach reduced the interaction time between nurses and patients that happen in consultation rooms. The amount of consultation time in control clinics was longer than intervention clinics. Refer to section 11.1 summary of study findings on how LHWs impacted on the time patients spent in the clinics. This might have been as a result that nurses in intervention clinics had the help of LHWs for instance in prepacking medication.

With reference to table 12 above, for most clinics, the average number of chronic patients consulting per Professional Nurse per day was generally within the 40 patients that an individual Professional Nurse is expected to consult in a day as expressed by the sub-District Manager. Although this contradicts with earlier sentiments of shortage of nurses in the clinics, it should be understood that data in the table 12 above excluded three clinics that did not have designated consultation room for chronic patients. Some of the data was also collected on Mondays and Fridays when there were fewer nurses and chronic patients in the clinics. Later in chapter 9 I will show how the slight improvements in levels of nurses were against visits by patients with chronic diseases that doubled.

However, in clinics where there were fewer nurses and where acute and chronic patients consulted in one consultation room/ were seen by a single nurse, nurses were overburdened because the total number of patients they should see per day was already covered by chronic patients. The sub-District Manager indicated that:

"I think you know that our norm is to have 1 Professional Nurse to 40 patients per day but we haven't been there yet. Nurses are seeing more than 40 patients in a day. The efficiency indicators say: if you have 60% of staff in each facility it means that facility can operate, but for how long? Because there is burn out, people go on leave, and attending workshops."

7.4.3 Data Clerks and lay counsellors

Half of the clinics had Data Clerks at the beginning of the intervention. The situation improved midway during the implementation period as all clinics had Data Clerks from DoH. Despite having the clerks in all the clinics, there were challenges in record management especially in control clinics. This will be described later under record management (chapter 8 section 8.4.1). However, in some cases poor record management was as a result of the Data Clerks expressing that they were contracted by DoH to capture HIV data and not to manage files.

There were also at least two lay counsellors in each of the eight clinics that were mainly responsible for HIV counselling and testing (HCT). In all the intervention clinics, when not busy with their HCT work, lay counsellors also supported the nurses in issuing files and measuring vital signs. This was a similar case for three control clinics. In one particular control clinic (Yang), lay counsellors only worked on their HCT work and this is how other staff felt about them:

"The DoH should come up with a plan because the lay counsellors are not doing much of work, they should assist in retrieving files, prepacking of medication because if no one want to be tested for HIV they don't have anything on that day. Can you imagine you are working hard and there's someone you see that is not busy and that person can assist you but she's not." ***20150115_obscli_yan_ns***

7.4.4 The step-down programme

Early in 2014, at the time the LHW intervention was introduced in the clinics, there was a health service and system related plan from national department of health called "step down programme" taking ground in the clinics. All stable chronic patients (and even acute patients) were rendered to continue getting their treatment at their local clinic. One such hospital was Matikwana. The hospital was a referral centre servicing clinics in the study site. The step-down programme had mixed reactions across both control and intervention clinics with patients praising the decision as it eased pressure on their side in terms of transport

costs and long queues at the hospital. On the other hand, nurses expressing worry over increased pressure in their work as a result of attending to an increased number of chronic patients. A Clinic Manager in a control clinic explained how the step-down programme had affected her clinic operations:

"We were supposed to have two consultation rooms for chronic patients because Matikwana hospital is referring a lot of patients back to us. But the clinic is small, so I cannot allocate two Professional Nurses. The number of chronic patients is growing but we still have the challenge of shortage of staff and the rooms. Every day, we have four or five stable patients returning from Matikwana" ***20140617_intcm_yan***

In summary, seemingly shortage of nurses in some instances in the clinics and increasing patient load did not only inconvenience nurses but patients, as well as the whole functioning of the clinic. It affected the quality and access of services delivered. For instance, closing a clinic over the weekend became a problem to hypertensive patients who were working and could only manage to get their medication over the weekend. In cases of one Professional Nurse in the clinic, delayed and slow queues might motivate chronic patients to miss out on their appointment. Nurses working under pressure are likely to be stressed and ignore important procedures to follow. However, there was also contradictory data from observations and patient interviews (to be discussed later under section on staff attitude) that showed that nurses did not want to work in the afternoons. Further research should explore nurses' approach to work against the work demand in the clinics.

7.5 Clinic management

In this section, I will describe how the clinics were managed throughout the intervention period. I will start by describing clinics that had reported and observed challenges in their management, followed by those that seemed better off. Box 7 and 8 below presents how specific Clinic Managers managed their clinics.

Box 7: Clinic management in intervention clinics

In **Troy clinic,** staff felt they did not get enough support from their Clinic Manager, who was more interested in statistics and clinic indicators than staff welfare. Nurses felt the Clinic Manager spent a lot of time criticizing them for failure to meet targets than supporting them and understanding their concerns. Nurses said there was no feedback on their complaints. During the development stages of the intervention, the Clinic Manager focused on lack of space in the clinic than how LHWs would work. The Implementation Manager felt that the intervention was not welcome.

In **Orange clinic**, the Clinic Manager was very supportive and enthusiastic of the intervention. She was patient focused and alternated in consulting patients and doing other administrative work. She communicated passionately to the patients. However, there was lack of innovativeness and pro-activeness in addressing challenges faced in the clinic. Generally the clinic operated at a slow pace. Managing the clinic in a way that patients moved faster along the queues, was a big challenge for the nurses. Informal discussions by nurses were also observed discrediting how the Clinic Manager was managing the clinic. Both the Clinic Supervisor and the sub-District Manager identified that management style in the clinic was a big problem. They said clinic indicators were not good.

Timber clinic had a strong and committed Clinic Manager who was seemingly strict in ensuring that nurses were committed to their work and patients got the necessary support in the face of limited resources. From the LHW programme development process, she took a leading role on how LHWs would operate in the clinic. However, because of her strictness, all staff in the clinic did not like the Clinic Manager. They gossiped and discussed her. They accused her of abusing the nurses. They said that she denied them leave and break time. Towards the end of the intervention, the Clinic Manager was transferred to Faith. This is how the LHWs differentiated the old Clinic Manager and the one that replaced her;

"Nurses respected the first Clinic Manager, and everything in the clinic was going smoothly. You couldn't find nurses sitting in the kitchen in the morning. Everyone was aware that seven o'clock I must be at the clinic to start working. She was a great leader. As for the second one, they don't respect her" ***20140831_intlhw_tim_lin***

Hillard clinic had a very active and enthusiastic Clinic Manager. She was very passionate about LHW intervention. The Clinic Manager was calm but seemed to be in control of the clinic. She mostly stayed in her office in the morning and after finishing some administrative work, she would go and consult patients. Staff respected her. No observation was made or any incidents reported where nurses were complaining or gossiping about the Clinic Manager. In case of misconduct, she called the staff in her office and talked to her. The Implementation Manager felt the Clinic Manager was a good leader.

"She is a very good leader. She is not talkative but maintains her role as a manager. Other Clinic Manager*s cannot tell the staff what to do because they form friendship with the staff. Whereas in Hillard, even if she talks with them you can see that she's maintaining that I am the manager here so I'm the leader and therefore I cannot befriend you. When she says something, everybody knows that she means it. She doesn't have to go around following people. Things just happen with no one being followed."* ***20140311_intim_zm***

Box 8: Clinic management in control clinics

Faith clinic experienced leadership of two Clinic Managers over the intervention implementation period. The first Clinic Manager experienced a lot of resistance from nurses (especially junior nurses). Nurses spoke rudely in her face and refused to take instructions. She failed to discipline the nurses and resorted to doing all the work in the clinic. The chronic care coordinator for the sub-district said the Clinic Manager was old, forgetful and was resisting going for pension. Later she retired and a new Clinic Manager moved in from Timber (an intervention clinic). She was the same strict manager that her Clinic Supervisor had commended for managing Timber well (she might have been sent to Faith to correct the situation). The new Clinic Manager expressed that she found the clinic in poor state. She said she found nurses that knew what to do i.e. patient management but would not do it.

Moghan clinic though with dedicated staff, the Clinic Manager was quiet and kept herself a distance from other staff. Nurses did not respect the Clinic Manager. Nurse would sometimes just leave for home without telling the Clinic Manager. An Enrolled Nurse was free to come for work without uniform. The Clinic Manager was someone who didn't talk much. Because of the seclusion, nurses usually gossiped about her during lunch in the nurses' home. They also described her of being unable to manage staff. Patients as well questioned the capacity of the Clinic Manager. One day, officials from DoH visited the clinic and the following observation was made;

"Officials from DoH asked if the patients know what to do if there is anything urgent to be addressed in the clinic. The patients were advised to go to the Clinic Manager. One patient said that that cannot help because even the nurses don't respect the Clinic Manager. Immediately the patient was stopped, and the officials left." ***20141022_obscli_mog_pm***

Yang clinic had two in-charges heading the clinic over the intervention period. The first Clinic Manager was similar to the Clinic Manager in Hillard. She was calm but in control of the clinic. She ensured that all the processes were followed and patients were promptly attended to. She was liked by staff as well. The new Clinic Manager towards the end of the intervention seemed to lack control of the clinic and how certain processes were to be done. She had no experience in clinic management. Since most nurses were new in the clinic, they just appointed her as the most senior Professional Nurse to be sister in charge. This change resulted in a decline in some processes that were observed to be better with the old staff i.e. no retrieving of filing, no updating of booking system.

Arlington clinic had a strong Clinic Manager. She displayed a supervisory role. At times she could move around checking how different sections were operating. She also had time to interact with the patients and hearing their concerns. Apart from her administrative role, she also consulted patients. Being part of the team that developed ICDM and heading ICDM at district level, she tried to ensure that certain ICDM processes were followed at the clinic. Unfortunately, she doubled as chronic care coordinator for the sub-district. This made her to be more often out of the clinic on her role at the sub-district. At times, she could be away for six weeks. There were many challenges in Arlington clinic when the Clinic Manager was away. Nurses did not like her deputy who did not interact with the nurses. Nurses worked the way they wanted; taking long break and leaving the clinic any time they wanted.

Despite these differences in clinic management, the sub-district indicated that they followed the same process of recruiting Clinic Managers and developing their capacity.

"Those who were in charge of the facilities were re- allocated to be Operation Managers. It was because of the experience that they were having, being a Chief Professional Nurse in that facility and being the person who has been there for a longer period. As sub-district, we conduct leadership and management workshops to try empower Managers. But it will also depend on the individual - you can take a horse to the river and it can come back thirsty. It depends also on the dedication and commitment of the person." **Sub- district Manager**

In summary, all the clinics in the trial were under Bushbuckridge sub-district headed by a sub-District Manager. There were two area supervisors (each one of them managed two intervention and two control clinics) from the sub-district who frequently visited and supported the clinics. There were also other coordinators for specific programmes i.e. chronic care that supported the clinics. All the clinics had specific operation managers who were promoted from sister in-charges. They were responsible for day to day clinic management. Some managed bigger clinics with more staff i.e. Troy while others managed smaller clinics i.e. Hillard.

Boxes 7 and 8 above present variations in the management styles by Clinic Managers: (a) Clinic Managers that were calm and in control of their clinics. They ensured that all processes and procedures were followed. They engaged their staff and patients very well in case of problems. They balanced between administrative work and patient care. These were managers that were able to get nurses to work together and to engender a positive attitude. This was the case for Hillard, Yang and Arlington clinics. (b) Clinic Manager that ensured that nurses are still committed to their work and patients are adequately supported in the face of limited resources. As such she was seen as being harsh to the nurses. The manager seemingly got nurses to work through intimidation. This was the case for Timber clinic. (c) Clinics where there was a gap between the Clinic Manager and staff in the clinic. They had Clinic Managers that failed to control staff and provide direction on clinic operation. Staff did not respect Clinic Managers. This was the case Orange, Moghan, Faith (first manager) and Arlington (when the manager was away). (d) Clinic Manager where there was disconnect between administrative tasks and support towards patient care. The Clinic Manager that did not adequately support nurses in addressing problem faced with patient care but focused on ensuring the targets in different indicators are met and statistical reports are compiled and submitted. This was the case for Troy clinic.

Several factors need to be considered. These include understanding and assessing the needs of the Clinic Managers, their leadership capacities and what support structures are in place to support their development. Understandably, some Clinic Managers manage bigger while others manage smaller clinics. It is also important to understand requirements for Clinic Managers based on size of the clinic. Finally, there is need to further understand what is and how much time is expected from Clinic Managers to dedicate toward clinic and patient management and problems experienced in the process.

7.6 Patient management

The evaluation explored nurses' conduct and their day to day management of patients. Though not conclusive, it gives a picture of how clinics operated and how nurses executed their duties. Strengths and challenges with patient management as observed and reported by patients and LHWs have been summarized in table 13 below in identified topical areas.

Table 12: Patient management and nurses' conduct in the clinics

	Troy	Orange	Timber	Hillard
Patient management				
Nurses ignoring acute and other chronic patients with elevated BP	Reported	Reported	Reported	Reported
Chronic patients lost to care because their chronic records were not inserted into their files.	Reported	Reported	Reported	Reported
Health education and advice from nurses skewed towards how to take medication and little on lifestyle	Reported	Reported	Reported	Reported
Mistakes by nurses when writing appointment dates or forgetting certain information i.e. medication		Reported	Reported	Reported
Patients with co-morbidities i.e. hypertensive and HIV. Nurses just focusing on one condition		Reported		Reported
Nurses giving 2 months' supply of medication to patients just because the patients have complained	Reported			
Patients coming for Doctor's appointment and Doctors not coming to the clinic	Reported			
Nurses ignoring patients to compile reports during months end		Reported		
Nurses just issuing medication to patients coming on weekend without referring to files			Reported	
Professional nurses showing care and compassion during consultations with hypertensive patients	Reported	Reported	Reported	Reported
Nurses giving lifestyle modification advice during morning health talks and clinic consultations	Reported	Reported	Reported	Reported
Nurses' conduct				
Shouting and ridiculing patients. Patients feeling that it was as a result of disagreement in the community	Reported	Reported	Reported	Reported
Patients expected to come in the morning. Those coming in the afternoon, queued for a long time	Reported	Reported	Reported	
Favouritism. Nurses prioritizing their relatives, friends and those with status in the community i.e. teachers	Reported		Reported	Reported
Nurses were mostly busy in the morning. They relaxed in the afternoon and did not want to work	Reported		Reported	
Nurses taking a long time in seeing patients. Sometimes just be chatting in the consultation rooms	Reported		Reported	
Nurses leaving patients on the queue when going away i.e. break without relieving each other	Reported		Reported	
Nurses constantly consulting with LHWs about booking dates for chronic patients	Reported		Reported	Reported

Box 9: Complexities with patient management

"I *came across a patient whom the LHWs had indicated that hypertension medication had been stopped. The patient was started on treatment in September and the chronic patient record was not inserted in the file. When the patient came back, she complained of headache, and so she was treated for the symptoms."* **20141027_diaryim_tro_zm**

"We came across two ART patients but also on hypertension medication. The sheet where they write medication in the patient file was completed (full) and a new one was opened but hypertension medication was not copied across. This made the patients not receive their hypertension medication for some time (possible fallout in treatment). They were discovered by the LHWs checking the vital signs and were originally assumed to be new raised blood pressure patients. In one case, the patient had been without hypertension medication for six months. ***20140922_diaryres_mt***

"A patient file was missing and the vital signs were recorded on plain piece of paper. In the consultation room; the Professional Nurse asked the patient if he knew his medication and the patient agreed. The nurse took out all hypertension (HPT) medication and placed them on the table, the patient took simvastatin instead of Enalapril. Later the nurse found the patient's file while the patient had gone. The nurse realized that the patient took out wrong medication. The nurse went to LHWs and asked her to call the patient to come back to the clinic." **201500203_obscli_ora_wgn**

With reference to table 13 and quotations in box 9 above, such identified complexities in patient management had undesirable consequences and challenges to chronic care and the intervention. These were incidents that required nurses and staff in the clinic to be more careful and focused in their work. (a) Cases of forgetting to insert records of chronic patients on initiation of treatment, might have led to some patients being lost to care or being treated as acute patients. (b) Cases of important records missing in a patient's file i.e. information about medication, resulted in loss of medical history and affected continuity of care. (c) Others incidents where patients were lost to care were cases of hypertensive patients who were later discovered to be HIV positive. Nurse just focused on one illness (HIV), ending up giving patients medication just for one illness. (d) Fourthly, incidents of

mistakes done by nurses in writing appointment dates where is some instances did not match with the medication given might have resulted in patients missing their medication in some days.

Data from the evaluation has also shown other areas in chronic patient management that require further review, understanding and engagement with different stakeholders, including the nurses. Such areas include (a) identifying acute or other chronic patients with elevated BP. There were variations among nurses in identifying such patients in relation to BP readings. Most nurses only considered a patient to have an elevated BP when the diastolic was above 90[7]. (b) Despite most patients reporting that nurses gave health education and advice, data from patient exit structured interviews showed that such health education and advice skewed towards how to take medication and little on lifestyle modification. This also reflected in patient cohort semi-structured interviews. Some nurses gave no health education. There is need to further understand what determines what kind of health education a nurse gives at the point of contact with a patient. (e) Across all clinics, nurses were unwilling to work in the afternoon. On the other hand, data has shown that clinics were generally full in the morning hours. Although there was a likely possibility that nurses' unwillingness to work in the afternoon was as a result of being overworked in the morning, there is need to further engage the nurses on this.

The final focus area was of incidents that were avoidable to the nurses. There is need to understand why nurses engaged in such practices despite being seen as avoidable. Such incidents included (a) cases of letting patients identify their medication in a pool of several medication (refer to quote **201500203_obscli_ora_wgn**). (b) Nurses giving patients two months' supply of medication not as a result that the patient qualifies for that but because the patient has complained. This section also includes all the unprofessional conduct by nurses as highlighted in table 11 above which among others include nurses favouring and prioritizing their relations.

[7] 2011 abridged South Africa hypertension guidelines targets < 140/90 mmHg BP for antihypertensive management and <130/80 mmHg for those with end-organ damage, co-existing risk factors, and co-morbidity.

Similar and a lot more evidence on nurses' conduct in the clinic came out from patient cohort semi-structured interviews. There were varying views among patients towards the support and care they receive from nurses during both 2014 and 2015 interviews. Some had positive perceptions while others had negative perceptions. This might suggest that either the nurses attend to patients differently or different nurses behave differently. Despite the variations, negative perceptions outweighed positive perceptions.

Nurses' good conduct

Despite the aforesaid challenges, Professional Nurses working in consultation rooms, displayed characteristics of being polite, caring and understanding. Observation of patients' consultations noted that Professional Nurses very well engaged the patients. Nurses openly showed displeasure to unbooked patients.

In summary, it is easy for nurses to become immersed and overwhelmed by long queues in the day-to-day operations of the clinics and overlooks other important procedures. Despite the broader achievements in patient care, this section has shown how patients can easily be lost to care as a result of nurses missing certain records in patients' files. It has also shown the need to understand variations that exist among nurses in following certain procedures i.e. identifying acute patients with elevated BP. Finally, this section has displayed other undesirable and avoidable practices among nurses that require further understanding why they are practiced.

7.7 Conclusion

In this chapter, I have discussed how different contextual factors affected delivery of chronic care and functioning of the clinics generally. As Pawson and Tilley 2004 noted, certain contexts supports programme theories and others do not (99). I therefore presented contexts that supported the LHWs programme theory and contexts that did not. Understanding these circumstances is important in interpreting and generalizing the findings of the evaluation(92). These contexts have been categorized into two groups namely: conditions of the clinics and clinic operations.

7.7.1 Condition of the clinics

The conditions of the clinics were crucial and likely to impact on the delivery of the programme. Infrastructure contexts enabled and constrained the implementation of the intervention (*context 1a*). Clinics with limited space and dilapidated infrastructure resulted in patients standing on long queues that spilt outside the clinic. LHWs struggled to find space to operate from. Such conditions also resulted in two patient consultations happening in one room in some cases. Staff and patients' motivation was likely to be affected hence likely to experience increasing levels of defaulters and staff turnover.

The lack of functional and adequate BP machines negatively affected the implementation of the LHW programme (*context 1b*). Increased control of blood pressure and increased identification of raised BP, which was the primary aim of the trial, largely depended on functional BP machines. Conversely, the situation was different in most of the clinics throughout the implementation period. Electronic BP machines frequently broke down. Cuffs for both electronic and manual BP machines were constantly wearing out. Nurses were shunning manual BP machines since the stethoscope affected their ears (as a result of measuring every patient that came through the clinic door).

This evaluation has also come up with other clinic specific or other challenges that affected all clinics as far as equipment and materials were concerned (*context c1*). Patients' files and bags for prepacking medication were some of the materials that were in short supply in almost all the clinics.

Effective BP control and general care for chronic patients can only be achieved with adequate supply of relevant medication (*context 1d*). The findings from this realist evaluation have presented conflicting information about availability of medication for hypertension in the study clinics. Qualitative data from observations, patient, nurse and LHW interviews and quantitative data from patient exit interviews showed unavailability of certain hypertensive medication across all clinics. On the contrary, data from clinic link has shown that almost 100% of hypertensive patients received medication on every visit they made to the clinic during the intervention period. All in all, this evaluation points out to

challenges in supply of medication. This evaluation has also found that constant and adequate supply of medication can be strengthened with improved communication between the clinics and the local deport that distributes the medication.

Number of staff slightly improved in some clinics while in others, it remained the same throughout the implementation period (*context 1e*). These staff served patients with chronic diseases that almost doubled in their numbers and clinic visits. Some of the implications of shortage of staff included closing the clinics over the weekend and lower cadres of nurses performing work that they were not trained for without supervision. There were also complaints from some Clinic Managers who expressed that most of the experienced nurses in the clinics were replaced by newly qualified nurses that needed time to get proper orientation. My observations and the interviews I conducted showed a scenario of shortage of staff against a growing patient load. Growth in patients' load has been as a result of several factors including the introduction of Nurse Initiated Antiretroviral Treatment (NIMART) programme that has seen HIV patients being initiated on treatment and managed from their local clinics other than hospitals.

7.7.2 Clinic operations

The observations and interviews I conducted showed variations in clinic management ranging from poorly to better managed clinics (*context 2a)*. This was also expressed by the sub-District Manager who indicated that despite exposing the Clinic Managers to the same capacity development initiatives there are differences in their performance. Some challenges experienced in poorly managed clinics included poor staff relations, poor relations between staff and patients, staff that were not willing to work, staff that had no respect for the Clinic Managers and, Clinic Managers that failed to discipline staff.

Proper procedures in patient management are critical in attaining effective care for patients with chronic diseases. This intervention was implemented in clinic contexts where there were variations in management of patients with chronic diseases (*context 2b*). There were variations among nurses in different clinics in identification of patients with raised BPs and management of hypertensive patients. For instance, nurses differed on BP readings to

consider as raised BP. This evaluation has observed that although clinics have PC 101 trained nurses who were expected to train nurses in the clinics, nurses are faced with different cases/ experiences every day that require ongoing on job training to keep up to the challenges. There are also new nurses in the clinics (especially those from hospitals) that have not been exposed to the PC 101 training and have their own way of thinking in managing patients with chronic diseases.

In this chapter I have set out an analysis of the clinic context focusing on the conditions and operations of the clinics. Most of the clinics in the study were particularly affected by dilapidated infrastructure with limited space, limited levels of resources including malfunctioning of BP machines, lack of team work among staff in the clinics, poor clinic and patient management. However, there were also some clinics that had modern and spacious infrastructure, better resourcing and operation. The chapter addresses objective two of the study focussing on the context with the CMO approach. The next chapter will focus on mechanisms with the CMO approach, addressing objective number three.

CHAPTER 8: RESULTS - ENGAGEMENT OF CLINIC STAFF AND PATIENTS WITH THE LAY HEALTH WORKER INTERVENTION (MECHANISMS)

In this chapter, I look at the mechanisms of impact and intermediary changes during implementation. As earlier described, programme mechanisms involve a change of reasoning (values, beliefs, attitudes, or the logic applied to a particular situation) on the part of actors in a particular context, sometimes described as an interaction between the resources (information, skills, material resources, and support)provided by the programme and the reasoning of participants in a particular context (101). The combination of 'reasoning and resources' is what enables the program to 'work' (3).

In this chapter, I will explain how the actors in the LHWs intervention (Clinic Managers, nurses, Implementation Manager, LHWs, Data Clerks, patients and all other people that were part of the intervention) interacted and responded to the change that was brought about by the LHW intervention. I will also highlight intermediary changes that were experienced as a result of such interaction. These will be expressed in the following four broad categories: staff attitude and conduct; how LHWs related with other staff and patients; performance of LHWs; and intermediary changes that happened in the clinic as a result of varying engagements. Such changes are in areas of management of patient records/ filing system; appointment and booking system; chronic pathway, and prepacking of medication. Sources of data for this section included; observation of clinic processes, observation of patient consultations, researcher diaries, implementer diaries, patient cohort interviews, patient exit interviews and, interviews with Clinic Supervisors, Clinic Managers, Implementation Manager, nurse, and the LHWs.

8.1 Staff attitude and conduct

In this section, I analyse the clinic environment in terms of relations. I analyse how staff related among themselves and how they related with patients. I will look at their general approach and attitude towards work and how all this impacted on chronic care.

8.1.1 Relationship between staff and patients

Clinic observations and patient cohort interviews for Troy, Orange and Timber clinics, showed a generally poor relationship between patients and staff. There were observed arguments between nurses and patients as a result of long queues, perceived delays by nurses and patients trying to cheat on the queues. On several occasions clinic staff was heard speaking rudely to patients. This included clinic clerks in Troy who shouted at patients for forgetting their file numbers. Some patients who came for monitoring rather than an acute problem found it worthless staying on a queue for a long time yet they were not 'sick'. Relationship between staff and patients was worst in Faith clinic. At one point, community members took up the issue of the nurses' poor attitude to the media and the DoH sub-district office. Many patients expressed displeasure at how rude some nurses were to patients. Others said that nurses denied proper care for those whom they have disagreements at home (in the community).

These difficulties were mostly between junior nurses and patients rather than with senior nurses. Junior nurses described how they were frustrated by Clinic Managers for being denied opportunities to advance their career. This might have affected their attitude towards work and relationship with patients. Most junior nurses were harsher towards patients than senior nurses. There were elements of care and compassion among senior nurses towards patients which was especially observed during consultations. Senior nurses were kind, accommodating and empathetic to needs of patients. Professional nurses gave lifestyle modification advice and encouraged patients to adhere to their appointment. Junior nurses were disgruntled with chronic patients that made minor mistakes. In return, patients were generally humble and respectful to the nurses. Though in all clinics they complained of long queues, staying long time in the clinic and nurses being slow, this was in the absence of the nurses. A few patients confronted the nurses for delay of services. The following two observations were made to a junior and senior nurse in the same clinic.

"A chronic patient came on Friday and was sent back by an enrolled nurse. The patient came again on Saturday and was told to come on Monday. The patient was really booked for the previous Saturday. When the enrolled nurse was asked why he sent the patient back, he said he was only joking. Other patients joined in and complained that the enrolled nurse does not respect patients" ***20150722_obscli_ora_ns***

"The professional nurse in the consultation room takes a lot of time with the patients. The nurse seems to be very caring and most patients prefer to be seen by him. On the queue, patients were talking about his kindness that he gives them enough time to express themselves. Other patients argue that despite being caring, he does not consider the long queues in the clinic." **20140610_obscli_cor_wgn**

8.1.2 Relationship among staff

Relationship among staff varied across clinics. In box 10 below, I present different scenarios of how staff related to one another and its implication on clinic operation.

Box 10: Different examples of relationship among staff

Good teamwork

Hillard and Yang clinics had by far a better working relationship among staff and between staff and patients. This was observed and reported throughout the implementation period. Nurses communicated well with patients. There were times that patients became rude and impatient because of delays, but nurses politely explained reasons behind the delays. Nurses were very fast in seeing patients. Whenever they had finished seeing their respective patients, they were joining to help the other nurses. All nurses were busy with their work and no one interrupting them. Nurses and staff seemed happy and willing to help.

Good teamwork but with a lot of backbiting

This was an example of Moghan clinic. Nurses related well and treated each other with respect. When one needed support, they quickly rushed to help. The Clinic Supervisor appreciated the team work. However, there was a lot of backbiting especially during lunch time. All staff; nurses, Data Clerks, general workers had their lunch together at the nurses' home. Their talks centered on those that were not present. Most of the time the Clinic Manager had her lunch on her own which made her to be the centre of their discussion.

Conflicts between Enrolled and Professional *Nurses*

At nurses' level in Orange and Faith clinic, there was an observed gap and conflicts between Enrolled and Professional Nurses, however, both groups seemed to work closely within their category. Enrolled Nurses were mostly busy gossiping and refusing to take instructions from Professional Nurses. Professional Nurses mostly concentrated on their work. In Faith, Enrolled Nurses were particularly rude to the Clinic Manager. Fieldworkers made the following observation in Orange and Faith clinics respectively;

"A patient went to the consultation room and had a raised BP. A Professional Nurse in the consultation room went to the waiting area, and asked the Enrolled Nurse to measure the patient again. The Enrolled Nurse was not happy. She said in a low voice that the Professional Nurse should do it by herself. The Professional Nurse asked the Enrolled Nurse what she was saying. The Enrolled Nurse said she was singing." ***20150202_obscli_ora_wgn***

"The Enrolled Nurse started shouting at the Clinic Manager*, and said she is a witch because she went behind her back, and told officials at the DoH that she must not go on study leave because they already have shortage of staff at the clinic. The Enrolled Nurse told the* Clinic Manager *that God cursed her by making her to have no husband and to be barren due to her heartlessness. The* Clinic Manager *got provoked and started shouting as well. The Enrolled Nurse went to the kitchen where she had support of her friends."* ***20141029_obscli_fai_wgn***

Lack of teamwork

There was generally lack of team work among staff in Timber, Arlington and Troy clinics. In Timber, LHWs felt there were divisions among the nurses. There were incidents of disagreements, arguments and lack of respect among the nurses. In Arlington, there was no cooperation across all staff including general workers and there was no coordination among Professional Nurses. Each one of them was doing their work without any interaction. There was a lot of tension in the clinic. The situation improved towards the end of the intervention (it might be as a result of having the Clinic Manager in the clinic – refer to section 7.5 on clinic management). In Troy, the Clinic Supervisor pointed out lack of team work among staff.

"*The nurses in Troy are working well but it seems like most of them are tired. They lack teamwork. They are fond of leaving tasks that someone will do. The Clinic Manager does not have support from the other staff. I don't know whether it is the manager who is not involving the nurses or the other way round."* **20151019_intsup**

Box 10 above illustrate that there was a good working relationship among staff in some clinics, while extreme poor working relationship existed in others. Junior staff were reluctant in supporting senior staff and refused to take instructions.

The most common poor relationship existed between staff and management (Clinic Manager, supervisor and sub-district officials). Nurses felt management was unappreciative of their hard work and spent a lot of time criticizing them for failure to meet targets than supporting them and understanding their concerns.

In Timber, mid-way during the implementation period, the Clinic Manager organized a team building session at Kruger national park and LHWs said it helped them to know each other better and strengthened relationship among staff. This could also be linked to the context of better clinic management.

8.1.3 Performance Management Development System (PMDS) and staff motivation

Nurses across both intervention and control clinics went through quarterly performance appraisals (PMDS). The process involved an individual nurse, rating himself/herself before discussing the ratings with a supervisor. Monetary bonuses/ awards were given to individuals that passed a set grade. There were varied views among nurses over how the awards were given. Nurses who had never received an award were more likely to be unsure about how the process goes and to label it more unfair and selective, than those that had received the award before. A nurse who had not received the awards expressed that;

"We know that nurses that perform well in their PMDSes are supposed to receive monetary awards. We have not seen that happening. Though we do well with our indicators, all we get from the supervisors is bashing us that we are not doing well." ***20140320_diaryres_arl_fl***

Varied views among nurses about the awards might imply that the PMDS system did not work well. This might have affected nurses' morale and attitude towards work.

In conclusion, the data shows a range of staff relations and behaviour. (a) These data have shown how team work among staff, positively impacted on the patients. Staff that supported each other were likely to quickly attend to patients in a polite and friendly manner. With reference to the previous section, these were also likely to be well managed clinics. (b) Poor relations between staff, was more likely to happen in clinics that were poorly managed. This was also more likely to lead to poor relations with community and patients.

8.2 How lay health workers related with staff and patients

Good relationship between LHWs and the rest of staff in the clinics, and a supportive clinic environment was central to the implementation of the intervention. In this section, I explore how patients, nurses and, the rest of staff in the clinics related to the LHWs and, how supportive the clinic environment was to the intervention and, how all this affected the intervention. I will start by looking at clinics where there was reported and observed good

relationship to those that were poor. Box 11 below is a description of how LHWs related to staff in the clinics.

Box 11: Relations of LHWs

In **Hillard** clinic, nurses quickly understood the roles of LHWs and coordinated with them very well. LHWs related and communicated well with nurses in a mature way and at professional level. There was a case where some files remained in the consultation room and LHWs were unable to book them. LHWs talked to the chronic care nurses and they ensured that all files were taken to LHWs. Field workers observed chronic care nurses going to LHW booking office every morning before consultation begun to discuss the booking dates. The nurse kept on checking with the LHW throughout the day if everything was ok. All staff were also observed helping LHWs. One of the LHWs got ill for some weeks. One LHW remained in the clinic and was being assisted by lay counsellors especially with measuring vital signs. LHWs also intervened in case of quarrels between staff and patients or among staff;

"One of the nurses shouted at a chronic patient for not coming with her booklet. I was busy searching for the patient's file and I was surprised to find that the patient had left the clinic. I went to the nurse and told her to call the patient and beg her to come back to the clinic because it was clear that the patient was not happy. I then gave the phone number to another nurse who apologized and begged the patient to come back to the clinic. The patient sounded that she was not interested to come back to the clinic, but the nurse managed to convince her. When the patient came back, I approached her and apologized on behalf of that nurse. What I like about this, is that the patient consulted and she was given the medication and she was happy when she was leaving." ***20150213_intlhw_hil_th***

In **Timber clinic**, relations among staff in the clinic was better compared to Orange and Troy. LHWs related very well with nurses responsible for consultation of chronic patients. The Implementation Manager ranked Timber on position one in terms of cooperation from staff hence easy clinic to work in. For instance, the nurses had their own calendar and allocated the dates to the patient. If a patient was given a weekend date, the LHWs were going back to the nurse to change. When a LHW noted that a particular date was full (according to required number of patients), she would go and talk to the nurse to start giving a new date. In case of anything to discuss, a nurse would leave her room and go to the LHWs to discuss;

"The nurse came to the LHW in the booking room with a hypertensive patient. She informed the LHW that the husband to the patient came to the clinic a day before. The LHW should change her booked date and put her on the same date as her husband's which is in two months' time." ***20140423_dairyres_tim_fl***

LHWs participated in staff meetings where they discussed the work of the nurses and the work of the LHWS. LHWs thought they interacted well with staff because they were all from the same village. However, there were times LHWs had disagreements with junior nurses. At some point, LHWs also complained that nurses were using them as messengers. They complained to the clinic and Implementation Manager and things changed.

In **Troy clinic**, most nurses did not understand the work and aim of LHWs despite the initial programme development workshop with the nurses. LHWs were excluded from certain meetings because they were separate employees from Wits University who were in the clinic for research purposes. They could not integrate very well, including separately taking their breaks and meals. This could be as a result that there was no proper orientation to the rest of the nurses that did not attended the programme development workshop. This lack of understanding was evidenced at the vital signs area where nurses were sending all chronic patients to LHWs and were not interested in identifying acute patients with elevated BPs. LHWs were afraid to approach nurses fearing they would be intruding in their (nurses) work (Just like in Orange). LHWs were only participating in quarterly staff meetings. They stopped participating in daily meetings as they found them relevant to nurses only.

Staff in **Orange clinic** regarded LHWs as a very low cadre of support staff. They were not invited to participate in staff meetings. Nurses used LHWs anyhow and were disrupting them when doing their work. LHWs complained that nurses would just call them to bring them an item or go search for a file while doing other work. There was no coordination between the LHWs and nurses i.e. in deciding the number of patients to book per day. LHWs were afraid to approach nurses even when LHWs saw unclear information on patients' files. The Implementation Manager talked to the LHWs and nurses on the importance of coordination and there were slight improvements. However, relationship challenges persisted. LHWs and nurses sometimes landed into arguments in front of patients as expressed in the following observation notes;

"An enrolled nurse came and asked a LHW why she had started taking vital signs in the morning before testing patients' urine. The LHW said that there was nobody to test urine so she started with vital signs instead of keeping patients waiting. The nurse was unhappy and told the LHW to familiarise herself with clinic procedures" **20150121_obscli_ora_wgn**

There was also poor relationship between the LHWs. They worked in isolation and did not want to help each other. At the end of the intervention, one LHW expressed not being liked by her fellow LHW and by the nurses, including the Clinic Manager. However, patients and LHWs related well.

The data shows variations in how LHWs related to other staff in the four intervention clinics. There was very close and good relationship between LHWs and other staff in Hillard than the rest of the clinics. In Timber, although the relationship was good as well, especially with senior nurses, LHWs often had arguments with junior nurses and blaming each other over tasks that were not done. In Troy, LHWs mostly worked in isolation and were excluded in some clinic activities. LHWs were not comfortable to approach nurses unlike in Hillard and Timber where LHWs, for example, would go to the nurses with a patient to get a return date if not given by the nurses. In Orange, LHWs did not relate well with nurses. Nurses used LHWs as messengers to do work that sometimes were not related to the role of the LHWs. Relations between LHWs and staff in all these clinics were as a result of relations that

already existed in the clinics before the LHWs. Clinics with better relations among staff, related well and supported the LHWs.

8.2.1 Lay heath workers' relationship with patients

During patient cohort interviews, patients across all the four intervention clinics appreciated the assistance from LHWs and the change it had brought in the clinics. Among others, patients recognised and appreciated the following roles of LHWs: they found that their medication was already packed; they quickly got their files hence now spending lesser time in the clinic; they appreciated that LHWs were calling them or sending Short Message Service (SMS) to remind them of their appointment and followed up when they missed their appointment (exception a few patients who had both hypertension and HIV who didn't want to be called due to confidentiality concerns). Some patients admitted that they used to have problems in remembering their appointment dates. LHWs were measuring them vital signs in the clinic; health education and counselling; monitoring the queues; helping patients find their way through the clinic and in case there is no nurse to attend to the patient, a LHW would go to call the nurse; recording their booked dates in the booking book and cross checking that patients have really been given appointment dates; and one patient said that LHWs were good people. They talked to patients in a good manner and made patients feel comfortable in the clinic. Particularly in Timber, one patient was happy that LHWs were born and raised within the community. She had taught them at school and had now become her 'nurses'. Patients were worried of the end of the intervention.

"One patient asked the LHW why they will be stopping to call them and he explained to them that the intervention was coming to an end at the end of August. Another patient said she was used to being called every time when her appointments were due and she did not worry much about finding people to check the dates for her". ***20150716_obscli_hil_pm***

In conclusion, data on LHWs' relationship with nurses presents two scenarios. (a) LHWs that related to nurses and other staff in a mature way and at a professional level (refer to Hillard and Timber in box 13). Such relationship ensured good communication and engagement. Nurses recognised the skill in LHWs and consulted with them as peers. (b) LHWs that were

seen as low cadre of unskilled staff hence nurses could use them the way they wanted i.e. like messengers (refer to Orange in box 13). Such relationship created a gap between LHWs and nurses where LHWs mostly were afraid to approach nurses and nurses did not consult LHWs. These two scenarios could be as a result of how LHWs were introduced and understood in the clinics, how LHWs carried and conducted themselves in the clinics and, how they previously related to the nurses as CHWs. These scenarios might also have been as a result of how nurses decide to treat the LHWs. Nurses might have ensured that LHWs did not go above their station and begin to think they were nurses (refer to quote **20150121_obscli_ora_wgn**, box 13). Otherwise in clinics where LHWs related well with other staffs, the staff was likely to support the LHWs and intervention as a whole.

The relationship between LHWs and patients has raised an important issue worth noting. Patients were likely to appreciate the role of LHWs and relate well to them based of the added advantage they experienced in the clinics as a result of LHWs.

8.3 Performance of lay health workers

LHWs were the key actors and face of the intervention in the clinics. The level of performance and expertise of the LHWs was paramount in understanding how they interacted with the intervention. In this section, I will explore strengths and weaknesses that existed among the LHWs in their day to day operation and how they subsequently affected the intervention. Box 12 below summarises how LHWs performed in the different clinics.

Box 12: Performance of LHWs in different clinics

In **Orange clinic,** the concern of the capacity of LHWs as identified during the recruitment process, manifested in their operation. There were more mistakes and problems identified by the Implementation Manager than the other clinics. These included incorrect filling of forms. Generally the LHWs were slow compared to other LHWs. LHWs worked in isolation unlike in Troy where if one finishes her task, would go and help the other. The high number of unbooked patients was not improving. There were a lot of files that were left in the consultation rooms by nurses and were not captured by LHWs. LHWs did not approach nurses to discuss such problems. Clinic observations showed that patients underrated LHWs. LHWs in Orange mostly sent other people to remind patients of their appointments, which was not effective. When they called patients, the call was very brief and lacked communication skills. The Implementation Manager described LHWs in Orange as the lowest in performance. The Implementation Manager expressed the following;

"One time we had an argument. I would ask her something that she's written with her own hand, and she won't know. O*kay you have sent an SMS to this patient because this patient is supposed to come; now I want to know what you did when this patient didn't come. She said I can't remember"****20140527_intim_zm***

In **Troy,** the background and experience of the two LHWs complemented very well in their work. The maturity and experience in community health work in one LHW, eventually led to patients being comfortable with her and ably completing all the paper work as required. The clinic experience as an Auxiliary Nurse in the other LHW, led to staff being confident in her. She helped in measuring BP using a manual BP machine in the absence of an electronic one. The Implementation Manager described them as being among the best performing LHWs despite having the highest workload. There was teamwork among the LHWs. They expressed confident in their work without being monitored. LHWs became bold and courageous in their work unlike at the beginning of the intervention. Both nurses and patients in Troy had all praises for the LHWs. The Implementation Manager felt that LHWs in Troy had mastered medication and were able to screen most chronic patients which was possible with training from the nurses;

"The nurses have oriented the LHWs very well. The LHW was screening the patients and I watched. She would get the file, and see that this is an ARV patient. Okay, when was the last blood taken? And what was the viral load? I'm going to put her medication and take her file to the consulting room. This one needs to be seen by the nurse. This is a hypertensive patient. Let me check how was the previous BP, oh… this BP is rounded in red and this BP is not so good as well today. I'm going to put one month supply and report her to the Professional Nurse." ***20150125_intim_zm***

In **Timber clinic**, LHWs were ranked as best performing by the Implementation Manager. The Implementation Manager described LHWs as committed and hardworking. Despite finding that a number of things were not working properly in the clinic, they worked hard in putting them in order i.e. the booking and filing systems. LHWs also mastered the medication and sometimes they could prepack on their own and a nurse confirmed (this was also the case in Troy). Field workers observed that almost 90% of hypertensive patients were not missing their appointments. Among the LHWs that were trained to use manual BP machines, LHWs in Timber were confident to use them. During patient cohort interviews, most respondents raised the issue of love, respect and care shown by LHWs. They always welcomed patients at the waiting area with a smile and showed them where to go. LHWs in Timber well skilled in understanding concepts and their performance was at same level as observed by the Clinic Manager;

"It's difficult to differentiate the two LHWs in the way they are working! If it is time to pre-pack medication or time to book patients, I don't have to follow them up. They are always doing their job. Some of the nurses always want to be told what to do. That is not the case for the two (LHWs). When they come on duty, they are the earliest. I even wish they were nurses. They have got good communication skills with the clients, especially the smile that they are giving to their patients" ***20140731_intcm_tim***

Hillard was one clinic whose LHWs displayed high standards in their capacity from the initial recruitment. Though one LHW performed well during the recruitment process, the interview panel feared on how the LHW would work having had other responsibilities in the community. When the LHWs started working in the clinic, there was a great difference in their performance. The Implementation Manager and the Clinic Manager noted that the other was more reserved, was very slow and had problems with clerical work i.e. recording, than care work i.e. health education. On the other hand, the other LHW had an exceptional performance, quickly and very well got along with the job, was more open and communicated so often in case of problems. The capacity of the second LHW was important in assisting the other LHW to improve in work. Towards the end of the second phase, the LHW improved. Several positive effects of the roles of LHWs were observed; patients rarely missing their appointment and patients appreciating the health education from LHWs. During the in-service training, nurses appreciated the role of LHWs as sometimes they got busy and forgot to document important details, but the LHWs reminded them. The Implementation Manager summarised the performance of the LHWs in this way;

"Thembi was a team player, when things were not going well between the LHWs and lay counsellors, the LHW stood up and said "Guys we are here as a team, let's find a way of making sure that the person in between which is the patient does not suffer, let's make a plan as who is supposed to retrieve the files and what happens to the files. Rose was more quite but was always striving to do the best including going to work on Saturday to check if work had been done properly. The LHW was also more willing and interested in the LHW activities" ***20151002_intim_zm***

8.3.1 Additional tasks given to lay health workers

Despite variations in the performance of LHWs, managers and nurses in the clinics generally recognized LHWs as a cadre that could help with several other tasks in the clinic apart from those they were trained in and were expected to perform. In a day to day operation of all the clinics, nurses trained and supervised LHWs in other tasks which they ably performed in the clinic. Such tasks included; measuring weight, height, temperature and other vital signs;

weighing babies and pregnant women; measuring body mass index (BMI), measuring blood glucose; testing urine; collecting sputum from consultation rooms and storing in the refrigerator; helping lay counsellors in filling forms for collecting blood and giving patients their results, being requested to carry drugs to the pharmacy when the delivery truck delivers and, helping in the dressing of wounds. Additionally, they were opening new files and registering patients. There were also other ad hoc activities that LHWs were engaged in i.e. completing forms for ART patients and conducting patient interviews for the DoH on time spent in the clinic (these interviews happened in all clinics).

LHWs in Timber had more clerical work that included; time keeping (as requested by Clinic Manager) to remind staff when its lunch time so that they are able to relive each other, writing on and off duties (indicating who is on and who is off duty every day), typing clinic documents i.e. PMDSes, doing mum connect for pregnant women(a new initiative of DoH), helping in compiling all monthly statistics for chronic patients(calculating and making additions to help nurses do their reports to DoH). LHWs felt they were working as Enrolled Nurses and they didn't have time to rest. LHWs became confident in doing this extra work.

"At the beginning the nurses didn't want us to measure temperature. One day, one of the Enrolled Nurses did not come to work. I went to the Clinic Manager to find out what needed to be done because there were patients waiting to be measured. But I told the Clinic Manager that I know how to take temperature because one of the nurses had showed me. The Clinic Manager was reluctant. But then she started to show me how to take temperature. She said to me: "now take the temperature and show me" I did and showed her. She said "go and measure the patients their temperature. But if you see officials from the department of health coming, you must stop". ***20140604_intlhw_ora_li***

On the other hand, LHWs complained when such extra tasks were given to them at the expense of the intervention tasks. At one instance, LHWs in Timber complained to the Implementation Manager on how such extra tasks made them not to call patients and remind them of their appointment. In Hillard and Troy, LHWs refused to follow up on HIV patients who missed their appointment as they realized they would not be able to complete

some of their tasks. Extra tasks given to the LHWs were likely to affect the effectiveness of the intervention.

8.3.2 General performance of lay health workers

There were certain specific characteristics that LHWs displayed that facilitated the intervention. (a) LHWs were innovative. After noticing that the SMSes were not successful, LHWs in Hillard conceptualized the idea of calling patients to remind them of their appointment through the use a less expensive promotion service run by one of the South African phone companies. Some patients admitted that they were not reading the SMSes either because they were just ignoring them or because they did not know how to read. Some phone numbers were not working and LHW couldn't know by sending SMS. By calling patients, there was an improvement in adhering to appointment dates. LHWs also started circling BP readings of acute patients with raised BP with red ink when they noted that nurses were missing them. (b) LHWs took an extra mile in their work. In Hillard, though the LHWs didn't work on weekends they would come to help with pre-packing of medication over the weekend if nurses failed to prepack during the week due to staff shortage. In Timber, LHW would pass by patients' home to remind them of their appointment if they failed to get hold of them on the phone. In Troy, due to high patient load, LHW sometimes carried appointment lists to their homes and reminded patient of their appointment in the evening.

Several other lessons were learnt in the performance of LHWs and how they interacted with the intervention. Being members of respective communities made it easier for them to interact with both patients and nurses. In this study, younger LHWs were vibrant and active in their work. The Implementation Manager played an important role in supervising the LHWs and developing their capacity.

8.4 Intermediary changes in the clinics as a result of varying engagements

In this section I will discuss how staff, LHWs and patients engaged in different activities in the clinics. I will also present different intermediary changes that happened in those

activities as a result of varied engagements across the clinics. These activities were in line with ICDM requirements and included management of patient records, management of the appointment system, the pathway for patients with chronic diseases and, prepacking of medication.

8.4.1 Management of patient records/ filing system

Management of patient records was one of the key areas that were affected by the introduction of the LHW intervention. In this section, I will present how management of patient records differed across clinics, how different actors interacted with the filing systems, the challenges experienced and successes registered. I will finally categorise the clinic with seemingly better and poor filing systems.

a) Filing systems

Across the eight trial clinics, I identified three different types of filing systems. (a) Most clinics used file numbers. However, clinics also differed in how they used/wrote the file numbers. Use of file numbers had its own complications. Staff in the clinic struggled to find patients' files when patients forgot their file number or lost their clinic card/booklet where the file number was recorded. (b) Some clinics filed their files according to patients' surnames. Files, whose patients had the same first three letters of their surnames, were put together. Such system was prone to patients consulting using someone else's file. (c) Filing by use of date of birth. In this system, patients were more likely to be sent back home if they didn't bring along their national identity to the clinic because most patients did not know their date of birth. Some clinics combined some of these filing systems.

b) Filing responsibility

At the introduction of the intervention, half of all the eight clinics had Data Clerks. Apart from capturing ART data, they also managed the filing system. Files in such clinics were likely to be properly filed with fewer cases of files missing. Files were better managed with most of them retrieving files for chronic patients a day before. Three of the remaining four

clinics without Data Clerks had both nurses and lay counselors responsible for filing. There were more cases of files missing in such clinics as staff would just drop the files anywhere after using them. Patients were more likely to wait longer to get their files as no one felt responsible. Most lay counselors shunned the task saying it was not their core responsibility. One clinic (Hillard) had only lay counselors responsible for filing.

c) Challenges with filing in the clinics

There were several similar challenges cross all eight clinics in their filing system at the introduction of the intervention. Such challenges included; files missing in the clinics, ending up with opening new files and losing patients' medical details. Missing of patients files also resulted in patients having multiple files in the clinic when the lost files were later found. Secondly, there were no proper brown files and files were photocopied on A3 paper. These were files of poor quality and difficult to file. A year later, files were supplied in all clinics though they were of poorer quality than the previous files. Thirdly, almost two-thirds of the clinics had limited filing space in terms of filing room and filing cabinets. Some clinics used rooms for other services to keep files while in other, files were kept in boxes or on top of tables. Finally, there were some files that did not have complete contact details for patients.

d) Lay health worker support toward filing

Each one of the four intervention clinics presented a unique case when LHWs joined the clinics. (a) In Timber clinic, LHWs took total control of filing and the clinic improved better than the rest of the clinics. Files for chronic patients were retrieved a day before and filed back the following day. There were no reported cases of files missing in the clinic. (b) In Troy, there were already three Data Clerks, proper filing space, filing cabinets and adequate and proper files. LHWs did not fully support filing in the clinic as they were initially blamed for missing files by the clerks. There were cases of files missing in the clinic and LHWs accused the clerks of not adequately searching the files. This resulted in patients having multiple files. Files were erratically retrieved a day before. (c) Hillard was also better off before LHWs with adequate filing space, files retrieved a week before and lay counsellors supporting with filing. However, LHWs joined the lay counsellors in handling files with no

specific person responsible for files. This resulted in continued missing of files and blaming one another when files were lost. Patients were also sometimes left stranded as one person thought another person would handle the files. (d) Orange was the worst clinic among the intervention clinics in handling files. After the coming in of LHWs, every staff continued to be responsible for files. Cases of files missing were more often than the other clinics. Nurses blamed LHWs and LHWs blamed nurses for missing files. Patients had multiple files as a result of opening new files.

e) Data clerks from department of health and MRC/Wits Agincourt Research Unit

In all clinics, there were Data Clerks that were provided by the DoH towards the end of the intervention. Some of the clerks supported with management of files in the clinics while others were reluctant and only considered capturing of ART data as their responsibility. In all clinics there were also clerks from the MRC/Wits Agincourt Research Unit that captured Nkateko project data. These clerks also supported in issuing out files and filing them back. They were also helpful in cases where files were lost. They cross checked the filing numbers and type of medication a chronic patient was taking, with their computer system. Yang clinic had a unique experience with their Data Clerk. The clerk (from DoH) did not want to be involved in filing. Everyone was then handling files the way they wanted. Files were not properly filed and were found all over the filing room hence difficult to search for files. The following observations were made in Yang clinic;

"There are files that are kept on the bed linen and these files are for the patients that came to the clinic in May and early in June. These files were waiting to be filled back to the cabinets. The clinic clerk doesn't do anything in the clinic but moving up and down. He says he is responsible for capturing ART data and not filing." ***20150629_obscli_yan_pm***

Table 13: Filing systems in both intervention and control clinics

Clinic	Filing system	Filing responsibility	Problems	Successes
Troy	Files had file numbers that begun with letters e.g. AR-149. The letters were not for patient's names but just for identification. Some of the file numbers used year of birth of the patient, e.g. 1955-139. Chronic patients carried green cards to the clinic where their number was written. Files were retrieved a day before, put in a box and handed to patients when they come. In the afternoon, LHWs took the files back to the data capturer.	Troy had highest number of clerks (three) responsible for filing. When LHWs came in, they supported the clerks. Later the clerks accused LHWs of misplacing files. LHWs still supported with filing but sparingly.	Files often missing around the clinic, new ones were opened and medical history lost Sometimes files were not filed back the same day, when LHWs have not finished booking One LHW in the clinic on a particular day hence files were not retrieved Files with no contact details (these were updated by LHWs). Patients sharing file numbers. Mixing up of old and new numbers on patient files.	Adequate human resource capacity (three clerks and LHWs) Proper filing cabinets Proper brown files throughout the implementation period (because it was a pilot site for use of files hence they received a lot of files at the beginning). Files for chronic patients retrieved a day before by LHWs
Orange	The system worked with numbers. Files for ART and TB patients were labelled with an alphabet and a number e.g. A50. The alphabets were for purposes of differentiating ART and TB files from other. Files for other chronic illnesses were written chronic, followed by numbers e.g. chronic 100. Patients carried their cards where the file number was indicated and used to retrieve files. Files for chronic patients were retrieved a day before.	No Data Clerk when the intervention begun. Everyone was responsible for files. When LHWs came, they became responsible for filing. All other staff still handled files resulting in blaming each other for missing files. A clerk joined later, but he was not involved in filing	A lot of people involved in files and when some staff finished using the files they dropped them anywhere resulting in a lot of files missing (more than other intervention clinics). Room for dressing of wounds was used as filing room Files with no contact details (these were updated by LHWs). Old and torn files with no new files. Staff photocopied files on A3 paper ART patients complained lack of confidentiality as they were given files separately by lay counsellors.	LHWs started retrieving files a day before (previously this was not done). The issue of missing files was discussed during the in-service training and there were improvements Towards the end of the intervention, new files were supplied to the clinic.

Clinic	Filing system	Filing responsibility	Problems	Successes
Timber	The filing system worked with surnames (alphabets). They placed stickers on the filing cabinet, with the first three letters of the patients surnames whom their files are stored in that drawer e.g. MAK for Makhubela. The files for chronic patients were pulled a day before the patients come to the clinic by LHWs. This was not done before LHWs came to the clinic. Other Patients carried their cards where the file number was indicated and used to retrieve files.	Nurses and lay counsellors responsible for filing before LHWs. LHWs took up the responsibility. Later they were joined and supported by a Data Clerk who initially did not want to be involved in filing until the Clinic Manager intervened	A lot of problems were identified when LHWs had just started working. Just like other clinics, there were; Files often missing around the clinic, new ones were opened and medical history lost Files with no contact details (these were updated by LHWs). Uniquely, patients sharing the same names and surnames were likely to be given files that were not theirs. After LHWs had started working, files would usually miss over the weekend when LHWs were not working	There was sound filing system than the rest of intervention clinics with very few files missing after LHWs started working. Towards the end of the intervention, new files were supplied to the clinic.
Hillard	The filing system worked with file numbers and surnames. ART files used numbers while others used names and surnames. (In cases where two patients had the same name and surname, date of birth and the residential address were used). Patients carried booklets and cards to the clinic. Files were retrieved a week before (on Fridays) and placed in boxes labelled Tuesday, Wednesday and Thursday since they booked patients only on these three days	No Data Clerk when the intervention begun. Lay counsellors were responsible for filing but every nurse could also handle them. Later LHWs and a clerk joined. They all worked as a one team in retrieving and issuing files.	Use of names and surnames (like Timber) led into patients using other people's files if the shared the same name and surname. Lack of proper person responsible for files led into blaming each other for missing files or shunning the filing so that another person would handle them. The clinic had run out of proper files and staff photocopied files on A3 paper which was of poor quality. Files with no contact details (these were updated by LHWs).	Hillard had a better filing system even before LHWs. Adequate filing space. Files for chronic patients retrieved a week before. Later towards the end of the intervention, proper files were supplied to the clinic. A Data Clerk from DoH later joined the clinic and supported with filing.

Clinic	Filing system	Filing responsibility	Problems	Successes
Faith	The filing system in this clinic worked with the use of patient's date of birth e.g. the people who were born in 1990; their files were stored in a box with a label or tag written (1990). If the patient didn't have a book or the card with them, the data capturer would ask them their date of birth. Patients carried cards or booklets where their return dates were written. Files were not retrieved a day before since the booking system was in disarray	Data clerk was responsible for filing throughout the implementation period. Faith, Yang, Arlington and Troy were the only clinics with clerks before LHWs	Filing system complex and unfair to patients. If the patient doesn't know their date of births (this was likely to happen to HPT patients, because most of them were elderly people) the Data Clerk sent them back home to fetch their identity card to see the date of birth from the national ID. Some patients never came back. There were a lot of case of files missing in the clinic and patients having many files as a result of opening new files. Nurses were unwilling to handle files over the weekend hence attending to patients without referring to files	Faith had adequate space and cabinets for filing cabinets. Later towards the end of the intervention, proper files were supplied to the clinic
Yang	The filling system of the chronic patients worked with numbers. Chronic patients carried booklets to the clinic. The booklets had the name and surname of the patient, as well as the unique file number of the patient. In the initial stages of the intervention, filing was better with fewer files missing and files retrieved a day before. When a new clerk and manager came in, this changed to the worst.	Data Clerk was responsible for filing throughout the implementation period. However, the clerk shunned the filing. As a result, nurses, lay counsellors and Data Clerk from Wits were also handling the files.	Limited filing space and cabinets. The filing room was away from the clinic. So many problems during the final phase when the clinic had a new Data Clerk who did not want to do filing. There were a lot of cases of files missing in the clinic. The clinic had run out of proper files and staff photocopied files on A3 paper which was of poor quality False information found on files i.e. BP reading when patient had sent someone to collect medication	Later towards the end of the intervention, proper files were supplied to the clinic

Clinic	Filing system	Filing responsibility	Problems	Successes
Arlington	All patients had a unique file number but were filed in an alphabetical order of the surnames of the patients. ART patients used file numbers Chronic patients with multiple illnesses had files in the clinic with different file numbers e.g. Sol More file No. 123(HPT), Sol More file No. 345ART and for the two files each one had its own card or booklet which they carried to the clinic.	Data Clerk was responsible for filing throughout the implementation period. Arlington Faith, Yang and Troy were the only clinics with clerks before LHWs. The clerk in Arlington was borrowed from Department of Agriculture.	Chronic patients having two or more files made patients not to be specific in using the right file. There are several instances of files missing in the clinic. In such cases, nurses used patients' booklets to record medical records. Patients had several files in the clinic as a result of files missing When clerk was not at work, filing became chaotic. Nurses mixed up files and did not file properly. There were no proper brown files.	The clerk retrieved files a day before. Files for patients coming over the weekend were retrieved on Fridays. There was a dedicated filing room with filing cabinets Later towards the end of the intervention, proper files were supplied to the clinic
Moghan	Patients' files had unique file numbers i.e. Psych 50-100, ART 1-100, TB 1-200 These file numbers were also written on the cards and booklets of the patients to make it easy for the lay counsellors who retrieved their files. On each chronic patient file, the kind of treatment the patient was taking was written. All hypertensive patients' files were written HPT on the outside. If they were taking medication for hypertension and diabetes; the file was written "HPT + DM".	There was no Data Clerk in the clinic. Lay counsellors were responsible for files and supported by nurses. Later, when clerks from Wits and DoH joined the clinic, they all became part of the team and were also involved in filing	There was storage of space. Some files were stored in card boxes and put on top of the cabinet. There were few and broken cabinets. Filing room also used as HCT room. Some files were mixed together on one shelf regardless of the filing number. Just like most clinics, cases of missing files and records inside patients' files Files were not retrieved a day before as nurses said there was a high number of unbooked patients. There were no proper brown files.	The clinic received new filing cabinets but were not enough Later towards the end of the intervention, proper files were supplied to the clinic

In conclusion, evaluation data showed that even with LHWs in the clinics, there were still problems with the filing system i.e. having files missing. However, there was clear added advantage of LHWs to improving the clinics' filing systems. Clinics with LHWs were more likely to have fewer cases of files missing in the clinic, files for chronic patients retrieved a day before and properly filed back after use, files handed over to patients as soon as they arrive in the clinic and have files with complete details of the patients.

However, the evaluation also identified other areas that require further consideration by the DoH and other stakeholders. (a) There is need to consider adequate availability of filing resources in the clinics i.e. filing cabinets and the files themselves. (b) A review of the filing system and approach would help clinics adopt a common approach in filing, one that is not complex and with fewer challenges. (c) Identifying individuals responsible for filing (even with already existing staff in the clinics) and clarifying their roles in filing would help manage files better. (d) There is need for proper care and safety of patients' records as they present the history of one's health and determines the appropriate care one is supposed to get.

8.4.2 Appointment and booking system

Data from observations and interviews showed differences in the management of appointment and booking system in the clinics before and after the intervention. There were also variations across the intervention clinics after the introduction of the LHWs. In this section, I will explain those variations. I will explain how LHWs impacted of the booking and appointment system and how the rest of staff and patients responded and interacted with the changes. I will start by looking at clinics that still had challenges in their booking system, then those that greatly improved, and compare with the control clinics. Box 13 below presents the appointment system in the clinics.

Box 13: Appointment system in the clinics

At the introduction of the intervention, nurses in **Orange clinic** expressed that booking for patients with chronic diseases was a challenge especially on days where there are a lot of patients for only one nurse. On such days, the nurse was just consulting, issuing appointment dates and kept the files to book later and ended up not booking at all. The clinic admitted that a lot of patients missed on their appointment. When LHWs started booking patients with chronic diseases, the appointment system improved but the clinic continued experiencing the greatest number of patients missing their appointment among intervention clinics. Though files were retrieved a day before, it didn't make any difference as most patients were likely to miss their appointment. A lot of unbooked patients came over the weekend. On weekends, there were few booked patients so patients preferred coming on weekends in order not to wait long on the queue. Despite these challenges, there was a decline in the number of unbooked hypertensive patients than the other patients with chronic diseases. LHWs attributed this to health education and reminding patients through phone calls. Those that missed appointments usually came earlier when going away or attending to funerals.

In **Troy clinic**, one enrolled nurse was fully responsible for booking chronic patients at the beginning of the intervention. LHWs came at an ideal time as this Enrolled Nurse left for a yearlong training. The Clinic Manager said that initially nurses were booking but were very busy, so it was not regular and consistent. A LHW responsible for booking was stationed outside the consultation room. Due to changes in chronic pathway (to be described later), the LHW moved to the mobile park home while patients were consulting in the pharmacy. There was no longer interaction between the LHW responsible for booking and the patients due to the distance between the pharmacy and the mobile park home. There were high numbers of chronic patients in Troy than the other clinics. Sending of reminders and following up with hypertensive patients that missed appointment, registered success in the clinic. LHWs noted that booking of chronic patients started to be comprehensive. Patients missed appointment for 1 or 2 days unlike previously when they missed for 1 or 2 months. Patients alluded to the fact that they were reminded to come to the clinic. Very few hypertensive patients missed their appointment as expressed in the observation below;

*"*Total *of 73 chronic patients booked on this day – 23 of them were hypertensive. 32/73 patients came – 17 of them were hypertensive. Six hypertensive patients that did not come were followed up by a LHW around 2pm by a phone call."* **20150803_obscli_tro_pm**

At the beginning of the intervention, nurses in **Hillard clinic** also expressed experiencing a lot of chronic patients missing appointments. Chronic patients were booked from Tuesday to Thursday and a few over the weekend. LHWs found a problem of having patients booked on their files and not on the appointment form. This was a common problem in all clinics. Nurses ended up attending to more patients than they expected. Prepacking of medication and retrieving of files were affected. A LHW was stationed in the booking room, booking patients on the appointment form and checking if next appointment date is written on the card. The Clinic Manager commended LHWs that the clinic had a distinct number of patients to book per day. Initially nurses were booking without a limit. LHWs agreed with nurses to have a limit number. If they reached that number, they went to tell the chronic care nurses to stop and move on to another date. Very few chronic patients missed appointment and field workers rarely observed hypertensive patients missing appointment. Eventually patients adhered to their appointments even without being called.

Among the problems that nurses in **Timber clinic** raised at the beginning of the intervention included experiencing a high number of patients not coming on their booked dates. When LHWs started booking, they found that the booking system was in disarray. Since many people did not appear on appointment register, they could not retrieve their files a day before and they could not prepack their medication. LHWs booked chronic patients in the appointment register and checked that they had an appointment date recorded in their booklet. Timber clinic made the greatest improvement in appointment system among all clinics because of the good coordination between the LHWs and the chronic care nurses. Every day before starting to book, they discussed with the nurse responsible for chronic care for the day, on the suitable dates to book patients and continued to check if a particular date was full. When patients came from consultation room, LHWs checked the booked day on the card then copied it into the booking register. At the end of the intervention, LHWs said that there were very low numbers of hypertensive patients missing appointment.

For **control clinics**, booking in the appointment register was a problem (just as was the case for all intervention clinics before LHWs). Nurses claimed to be busy and having no time for booking patients. In all control clinics, almost half of the patients missed their appointment (also refer to clinic link data in chapter 9, section 7). In **Faith**, there was no record in the clinic on number of patients booked and number of patients that came. Appointment dates were given to patients but the appointment register was not used. In **Arlington,** the Clinic Manager said that nurses didn't book there and then. They piled the files and booked at the end of the day. Nurses were just giving appointment dates without checking what day it was. **Yang** and **Moghan** were the only clinics whose booking systems were better off though with high numbers of unbooked patients. The booking system in Yang got worse when clinic management changed and there were new nurses in the clinic. The appointment list was not updated to show how many patients came or not. In all control clinics, following up on patients who missed appointment was erratically done to ART patients only. The Clinic Manager in Yanga said that;

"Nurses are supposed to book and counsel patients. She starts filling the book then patients would come requiring her attention. She would leave that and attends to patients. Then that is not completed till the next day. The next day there are also patients to be booked" **20140617_intcm_yan**

a) Summary of appointment system in the clinics

Box 13 above indicates that across all intervention and control clinics, appointment scheduling for patients with chronic diseases was done by Professional Nurses throughout the implementation time. Unstable patients were given monthly appointment visits and stable patients were given 2-3 month appointment visits. When LHWs were introduced in the clinics, they supported the nurses by checking that the appointment date has been given, the appointment date tallied with the quantity of medication given, and they recorded the appointment date in the appointment register and patient's booklet/ card. Additionally, LHWs reminded patients of their appointment and followed up with those that missed their appointment. The appointment system was always up to date and number of

chronic patients missing their appointment reduced in intervention clinics. There were greater improvements in Timber clinic than the rest of the clinics as a result of good coordination between the LHWs and chronic care nurses. Complexities continued in control clinics. Nurses waited to book patients at the end of the day. When they finished attending patients at late hours, nurses ended up not booking at all. There were also high numbers of patients missing their appointment.

b) Other lay health worker initiatives that supported the appointment system

LHWs sent SMSes as reminders for appointment and following up with hypertensive patients that missed appointment. But for older ones who couldn't read, they were calling them. Reminders were sent a day before. Follow-up was done on the same day around 3pm. If no show, they followed-up again the next day in the afternoon. If they failed to get hold of them, they would pass by their home if they knew where they stay. In case of no show after 3 days, LHWs referred the patient to CHWs. However, they had problems with patients residing outside their catchment area. In Orange, if these patients were from other villages, they called the chairpersons for HBCs in those villages (outside Orange). Usually this happened to patients without cell phones. LHWs identified that calling patients was effective as most patients would only come after being called. All LHWs later started calling all hypertensive patients using power hour promotion (as explained under section on LHW performance). SMSes were found not to be effective as most of the patient were elderly people and could not read the SMSes.

c) Challenges experienced by lay health workers with appointment system

Despite registering remarkable success with the appointment system, LHWs also experienced challenges in the process. (a) As earlier reported, sometimes nurses made mistakes of writing a return date in one month time yet they gave a patient medication for three months. This became a problem when LHWs called to remind the patients of their appointment. (b) Nurses completely left the booking system to LHWs. They left patients that came over the weekend to be booked by LHWs on Monday. This made LHWs to have a lot of work on Mondays. Patients that came over Christmas holiday when LHWs were on leave,

were only booked on the file and not in the booking register. (c) LHWs in Orange noted that patients who were both hypertensive and on ART got angry when LHWs called them. They perhaps did not want to be identified with their HIV condition. (d) LHWs struggled in the first week to send the SMSes because most of patients' files did not have contact details. They later updated them. (e) Clinic Supervisors and manager wanted LHWs to follow with all chronic patients that missed appointment than hypertensive patient only. Most LHWs declined as they felt they already had a lot of work.

d) Reasons for missing appointment

Across all clinics, patients that missed appointments gave different reasons. Some were not at home on the day of their appointment. Some had travelled, while others had gone to attend funerals. There was another group that said they simply forgot. When asked whether they saw the SMS reminders, some said that they cannot read. Others included family responsibilities like going to fetch firewood. Some patients came to the clinic prior to their appointment dates because either they were going away or they had run out of medication. Other patients that missed appointment for longer periods were those that travelled to far places like Johannesburg. LHWs could not do anything apart from waiting.

In conclusion, the experience with appointment system and how nurses and LHWs interacted with the changes raised important lessons for review. There is need to review how practical is to have nurses to be responsible for the booking system. Data has shown failure of the system when managed by nurses than when managed by LHWs. There is need to understand if such a task further burdened nurses or nurses just viewed it as not their responsibility. Secondly, missing of appointment by patients had a direct link to challenges in adhering to medication and eventually defaulting treatment. This could be worsened by lack of any initiative to follow up on patients that missed appointment (apart from some ART patients). Thirdly, there were a lot of chronic patients across all clinics that finished their medication before their appointment dates. This indicated that something was wrong with the schedule of taking their medication. Fourthly, there was a group of patients that worked and missed their appointment because their employers couldn't allow them to go to the clinic every month. There is need to understand how clinics planned to accommodate

such patients. Finally, I have learnt that despite growing coverage in the access to mobile phones, use of SMS to communicate with elderly chronic patients could not work.

Data have shown that clinics whose appointment systems were managed by LHWs were more likely to have fewer patients missing their appointment, nurses attending to a distinct number of patients with chronic diseases according to number of nurses present in the clinic on a particular day, the appointment register being up to date and, limited mistakes by nurses when giving appointment date. Good coordination between the nurses and the LHWs further facilitated a comprehensive appointment system.

8.4.3 Pathway for chronic patients

The pathways for chronic patients largely depended on the clinic infrastructure, space in the clinic and number of nurses available in the clinic on a particular day. These factors made almost all clinics to have unstable chronic pathways throughout the intervention period. The coming in of LHWs also affected the chronic pathways. In this section, I will describe how the pathways changed from time to time and reasons behind the changes. I will also describe how staff and patients responded to the changes in the pathways brought about by the introduction of LHWs. Presented below in box 14 is a description of how different clinics operated their chronic pathways throughout the intervention period.

Box 14: Pathways for chronic patients in the clinics

Troy clinic had a mobile park home, which was initially used for chronic care, but was in a damaged state. The clinic was using emergency and filing rooms for consultations. Both chronic and acute patients queued for one vital signs station. After vital sign, they went and sat on their own waiting benches outside the clinic which was not ideal during extreme weather conditions. Midway through the intervention, the mobile park home got repaired. Consultations for chronic patients now moved to the mobile park home. Chronic patients had their own vital signs station (operated by LHWs). The chronic queue became faster than before. Three months later, chronic care nurses moved again chronic consultations from the mobile park home to the pharmacy window at the reception. Nurses and patients talked through the window. They wanted to see patients as quickly as possible as the mobile park home was very far from the clinic entrance. Though the system was good in terms of reducing the waiting time, nurses and LHWs did not have enough time/ space with the hypertensive patients in educating them and emphasizing on adherence. Patients also complained of these changes through patient cohort interviews;

"They give us the medication on a window while other patients are waiting behind you. They don't ask you how you feel and we are no longer having privacy. They are not even telling us how to take our medication. They just write on the box of medication. What about those who can't read because there are elderly patients who are on medication. There's no chance to face a nurse in consultation room and tell her how you feel. Now they don't even care about how our body is reacting to the medication. The LHWs just give us the medication and we leave. The nurse has nothing to do with us anymore." **intpc_cohort1_1013_30032015**

When the intervention begun, chronic patients in **Orange clinic** were mixed with acute patients when queuing for vital signs and only separated when going for consultation. A week into the intervention, a designated vital signs station for chronic patients was opened. After vital signs, chronic patients queued for their designated room for consulting chronic patients. Finally, they went via the LHW room for booking. This changed pathway had its own challenges. Vital signs stations for both acute and chronic patients were at the waiting area with limited space. There was no proper waiting area before consultation and patients waited along the corridor. This made the queuing system complicated and confusing. Eventually, the new pathway was abandoned. All patients queued for one vital signs station. They waited at the main waiting area where there were very few chairs (many patients ended up standing). After vital signs, they proceeded to queue for one consultation room together with acute patients. This remained the pathway to the end of the intervention.

Timber was the only clinic that did not use queuing numbers. This complicated the queuing at the main waiting area. Some patients cheated (especially youth) there by affecting the elderly chronic patients. One of the challenges in the clinic was having limited space (as described in box 1). The following was therefore the pathway in the initial stages of the intervention; Chronic and acute patients had mixed queuing for vital signs at the main waiting area. Chronic patients had their vital signs taken by an Enrolled Nurse; they proceeded for their designated consultation room, and then passed by LHW room for booking. Since there was a designated consultation room but mixed vital signs queue, a chronic patient at the far end of the vital signs queue could not consult until vital signs were taken even with no chronic patient queuing for consultation. Later LHWs were moved from their booking room and stationed at the reception. Chronic and acute patients still mixed when waiting at main waiting area. Acute patients went to the old booking room for vital signs while chronic patients had their vital signs at OPD. The queuing at main waiting area was complicated. The LHWs just called the chronic patients to come in front when they saw them to have vital signs taken. Then they went to the consultation room. Although there was a separate vital signs queue, vital signs station, consultation queue and separate consultation room, the Implementation Manager complained of limited space in the clinic which made the pathway look complicated.

Despite having adequate space in **Hillard clinic,** there was unstable chronic pathway. Chronic pathway changed from time to time based on the number of nurses available on a particular day. It was therefore not easy to understand a common approach. The intervention introduced a second vital signs station which eventually collapsed when an Enrolled Nurse left for training. The Implementation Manager expressed that, the nurses understood the importance of a second vital signs station, but there was very little they could do due to shortage of staff. Initially chronic patients had their own consultation room. However, in case of one Professional Nurse in the clinic, all patients would queue for one vital signs and one consultation room. Eventually, despite receiving two additional Professional Nurses, which resulted in having two or three consultation rooms operating at once sometimes, nurses preferred mixing acute and chronic patients on one queue to all the consultation rooms. That remained a status quo to the end of the intervention.

For **control clinics**, Faith and Arlington were better off. **In Faith**, vital signs queue had both acute and chronic patients mixed. There was one vital signs station along the corridor, with no privacy. There was limited space at vital signs station and some patients waited outside. After vital signs, patients separated, chronic patients had their own queue along the corridor to their consultation room. **Arlington** was spacious and had a sound chronic pathway with different designated area for chronic patients (apart from the vital signs station). They all (chronic and acute patients mixed) queued at main waiting area for vital signs. After vital signs, they queued for different consultation rooms. However, when nurses were few in the clinic, chronic and acute patients were put on one consultation queue.

Moghan and Yang had complicated pathways due to space limitations. In **Moghan,** acute and chronic patients queued separately for their vital signs though they queued for the same BP machine. They just alternated. After vital signs, they separated again and queued for different consultation rooms. In case of many nurses in the clinic, a second consultation room for chronic patients was opened. The room for consulting chronic patients was also a pathway to pharmacy and times consultations got disturbed as nurses stopped and chatted.

In Yang, both acute and chronic patients were put on one vital signs queue. They were also on one queue for consultation. However, they entered two different consultation rooms. It depended on whose turn it was. The chronic pathway was confusing and delaying to the patients. Now and again chronic patients asked where to sit. In case of enough nurses in the clinic but due to limited at times, two Professional Nurses were consulting in the same consultation room, both of them separately seeing chronic patients.

In conclusion, pathways for chronic patients were unstable and confusing throughout the intervention period. Hillard was the only clinic that had designated waiting areas just for chronic patients because it was spacious. These areas were situated both before vital signs and consultation. The rest of the clinics had chronic and other patients on the same queue for vital signs and only separating for consultation rooms. Orange clinic had mixed queuing throughout the clinic. Troy, Moghan and Yang were observed throughout the observation period, maintaining a designated consultation room for chronic patients. For most clinics sometimes, when there were few nurses in the clinic, both chronic and acute patients were consulted in one room by one Professional Nurse.

Patients and nurses slowly adjusted to the alterations to the pathways brought about with the introduction of LHWs. An additional station was made for chronic patients where they were expected to go via the LHW station for booking and health education after consultations. Initially nurses and the Implementation Manager were sceptical of the additional station as it would have increased patients' waiting time in the clinic. When LHWs started working, some patients forgot to go via LHW station and some nurses forgot to tell patients to go via LHWs. Both nurses and patients slowly adjusted and it no longer became a problem. No complaints were raised by patients about increased waiting time in the clinic.

Instability of the chronic pathway across all clinics signifies how contextual factors and staff engagement need to be considered when introducing programmes or changes in clinic operations. In the case of the eight trial clinics, space, equipment and number of nurses in the clinic largely determined the chronic pathway. Nurses also looked out for ways that were both easier and quicker in seeing patients.

8.4.4 Prepacking of medication

Prepacking of medication was one of the requirements for the ICDM. Nurses in the clinics were expected to prepack medication at least a day prior to a chronic patient's appointment. LHWs were required to support nurses in the prepacking of medication but they were not supposed to prepack medication on their own. In this section, I will explain how nurses perceived and approached prepacking of medication prior to the intervention and how they interacted with LHWs in prepacking medication throughout the intervention period. I will start by explaining clinics that had challenges in prepacking medication.

At the introduction of the intervention, the Clinic Manager in **Orange** reported that the clinic did not prepack medication as a result of high numbers of patients missing appointment. That gave them an extra task of unpacking and getting medication back to pharmacy for all prepacked medication. The Implementation Manager hoped LHWs would help get patients come on their appointment date hence get back the nurses into prepacking. Despite improvements in having patients coming on their appointment dates, prepacking did not happen throughout the intervention time. Nurses did not want to prepack even though LHWs reminded them and offered to help. During patient cohort interviews, patients felt that if medication was prepacked in advance, they would not delay and stay for a long time in the clinic. Additionally, there were no brown paper bags for prepacking in the clinic. Observations also showed that limited space in Orange might have affected the clinic in finding a place to keep the prepacked medication.

When the intervention started, nurses in **Troy clinic** were not prepacking medication. LHWs started assisting nurses in prepacking medication. However, prepacking was done in the morning for patients that had already arrived in the clinic to avoid returning medication of patients who missed appointment. Nurses also claimed that they were busy the whole day. LHWs packed medication for patients that came later in the day. They took the file and went to chronic care nurse and asked her what to prepack. As the intervention went on, prepacking of medication became erratic. Nurses seemed not interested. One day a nurse refused saying it was of no use since chronic patients still complained of other illnesses whose medication they still had to collect at pharmacy. When consultations moved to the

pharmacy, LHWs packed medication on their own in the morning and only referred to the chronic care nurse for confirmation. The following observation was made;

"LHWs collect about 10 files at a time from the chronic patients, goes and pack medication and give the Professional Nurse one file at a time for confirmation. Then the LHW gives the medication to the patient through the window. She explains how to take them, writes return date, and for patients with unstable BP, she gives lifestyle advise" **20150120_obscli_tro_pm**

LHWs expressed confidence in prepacking medication as expressed in the following statement; "*My problem is with other treatment for epilepsy and those for psychiatric patients. That is where I need assistance. But for hypertension, diabetes and HIV, they showed me the treatment. Some of the treatment has their packaging changing now and again, so they teach me that, if you see this, it's for this treatment and so on".* **20140603_ntlhw_tro_khe**

In **Timber clinic**, chronic care nurses always prepacked medication throughout the implementation period either in the morning or in the afternoon assisted by the LHWs. The nurse looked on the file and told the LHW the kind of medication to put on that file. LHWs became familiar with the medication. At times, LHWs prepacked hypertensive and ART medication without a nurse. If they met a challenge, they asked the nurses. But they could not prepack other medication i.e. Asthma without a nurse. The clinic had also run out of brown packing bags. They used cello tape to wrap medication. Just like in Troy, LHWs in Timber also expressed confidence in prepacking medication;

"W*hen we first came to the clinic, we used to pre-pack medication with the nurses because we were not familiar with the medications. Later we did not have any challenge and the nurses have never complained to us that we did not pre-pack well. When there is something that we do not understand, we just ask the nurses to help us."* ***20150218_intlhw_tim _rh***

Nurses in **Hillard clinic** were already prepacking medication. They prepacked over the weekend. Just like retrieving of files, they prepacked medication for the whole week. When LHWs joined the clinic, prepacking was done by a Professional Nurse and assisted by LHW.

LHWs assisted in wrapping the medications with cellotape and put them in the drawers in the chronic room. For those that missed appointment, medication was kept for 3 days then taken back to defaulters' box. Unlike in Timber and Troy, throughout the intervention, LHWs emphasized that they couldn't prepack on their own since they didn't know the medication. There were no packing bags in the clinic but towards the end of the intervention, all the clinics were provided with brown bags for repacking medication.

There was no prepacking of medication in **Faith, Arlington and Moghan control clinics**. Medication was directly taken from the cabinet which was in the consultation room. Sometimes the nurse would go to the pharmacy to collect medication which was not in the cabinet. Nurses claimed they had no time to prepack. They were seeing patients sometimes until 5pm. Patients complained during patient cohort interviews that nurses were delaying to start attending to patients in the morning because they are busy preparing their work. Patients wished nurses prepacked medication a day before since they knew who was coming the next day. In Arlington, officials from "Right to Care" programme discouraged use of masking tapes for prepacking because when the patients removed the tape, it also removed the name and expiry date of the medication. The Clinic Manager in Moghan said that;

"Pre-packing of medication is mainly affected by shortage of staff. Sometimes you find that we have pre-packed three months' supply medication for a patient, and when that patient comes that day, you find that the BP is high and you can't give them that three-month packet. You have to unwrap the pack, and give him/her for a month" ***20150916_intcm_mog***

Yang was the only clinic among control clinics where medication was prepacked, though not consistent. Sometimes medication was prepacked in the morning and put inside patient's files. The Clinic Manager explained that nurses had no time to prepack in the afternoon. They were seeing patients sometimes until 4pm. Through-out the intervention period, prepacking of medication was happening but in the morning just like some intervention clinics, for patients that had come. During patient cohort interviews, patients explained that for booked patients, their medication was prepacked in the morning.

In Summary, prepacking of medication varied across the intervention clinics (prepacking in the morning in Timber and Troy, prepacking for 3 days in Hillard and no prepacking in Orange and most control clinics). For clinics that did not prepack medication, they brought medication from the pharmacy in a trolley, in the morning. There were two general feelings across the clinics; either nurses were very busy till the end of the day and had no time to prepack or they were demotivated with high numbers of patients missing their appointment dates hence saw no need of prepacking. All the clinics also had run out of brown prepacking bags. Some used cello tape to bind the medication together.

There are three other issues that I noted in relation to prepacking of medication. (a) The capacity of LHWs, contrary to the general feeling among Clinic Managers and supervisors during the intervention development workshops that LHWs could not prepack medication, LHWs in half of the intervention clinics eventually prepacked medication on their own and only consulted nurses when not sure. This points out to the power of on job training that LHWs received from nurses. (b) Secondly, data has shown the need for coordinated efforts among different aspects of chronic care. Prepacking of medication was largely affected by patients that missed appointment. Unless efforts were in place to make patients come on their appointment dates, nurses found prepacking of medication as a waste of time. Even in the intervention clinics, there were limitations to the intervention. LHWs reminded hypertensive patients only of their appointments. Other chronic patients were more likely to miss their appointment hence rendering prepacking of medication a waste. (c) Thirdly, the role of LHWs in prepacking medication reaffirms why it was important to include 'confidentiality' as a topic in the initial training of the LHWs. Apart from prepacking medication confidentiality was required as LHWs handled patient files and booked patients for their appointment. Since LHWs had experience working as CHWs or in a clinic setup, it helped to identify individuals who already had experience in exercising confidentiality.

8.5 Conclusion

Mechanisms of impact refer to how intervention activities, and participants' interactions with them, trigger change. The recent MRC guidelines on evaluating complex interventions observes that participants are not passive recipients of interventions but rather interact

with them(5). This interaction is what is called mechanisms and what makes programmes to 'work' (4). This intervention has demonstrated how positive mechanisms led to positive intermediary changes in the clinics. The following are the identified mechanisms through which the LHW programme might work; good relations among staff and with patients (M1), motivated staff (M2), supportive staff to the LHWs and their activities (M3) and, skilled and motivated LHWs (M4).

This evaluation has shown that the intervention had higher effects in clinics where there was team work among staff and good relationship between staff and patients. Staff that related well were able to support, relieve and cover each other in order to quickly see the patients through. LHWs had the support of other staff in such clinics. LHWs in these clinics were more effective in their work compared to clinics that lacked teamwork. LHWs that worked in clinics with good teamwork, consulted with nurses in deciding the number of patients to book, approached nurses in case of mistakes done by the nurses, supported the nurses in prepacking medication, and generally performed well. However, there were other clinics i.e. Timber where though nurses related well with LHWs, they did not relate well with their clinic manager and patients.

Motivated staff were work focused and were willing to work outside their normal schedule. This was unlike in other clinics where nurses were willing to work during morning hours only and when the Clinic Manager was in the clinic. There were also positive effects of the intervention in clinics where there was a supportive environment to the LHWs and their work. LHWs performed better with increased involvement in clinic activities, good and professional relationship with other staff and, nurses that were closely involved in the work of the LHWs.

Staff attitude and conduct is a complex subject that affects clinic operations. Understanding the motive behind staff conduct and attitude requires a longer and closer engagement with the staff. In this evaluation, clinics with poor relationship among staff were more likely to poorly relate with patients and vice versa. Among others, in some clinics staff were observed speaking badly to one another and to patients, refusing to take orders/ instructions from those in authority, leaving and arriving at work any time they wanted and

taking long break periods. On the other hand, in other clinics staff spoke politely to one another and to patients, staff worked as a team and helped each other in case of need and, disciplinary procedures were adhered. As earlier expressed poor relations between staff, was more likely to happen in clinics that were poorly managed. There is need to further understand motives behind poor staff attitude but from this evaluation, staff was more likely to be disillusioned as a result of; limited opportunities to upgrade their career, feeling overworked due to high patient load, the feel of unsupportive Clinic Managers and supervisors, lack of/ limited resources, demands for health information and unappreciative patients.

Issues of staff motivation, teamwork and support go in circles as they also depend on other factors mentioned earlier in this chapter. Other authors have expressed that staff motivation, teamwork and support, depend on several factors including the work environment i.e. availability of resources, support from management and, workload. In this study for instance, clinics that were better managed before the coming in of LHWs and throughout the implementation time, were likely to have good teamwork. Good clinic management was thus seen as an enabling factor for staff to relate well among themselves, with the patients and support LHWs in the implementation of the intervention.

On the other hand, there were some clinics that had limited resources but were better managed and there was good team work. There were also some clinics with better resources but they were poorly managed and there was poor team work. This is an important point for implementation of any reform where its success can not only depend on adequate resources but good management and teamwork

Motivation and skill among the LHWs themselves was also an important mechanism for the intervention. Despite a generally common approach in recruiting, training and supporting LHWs, there were differences in the performance of the LHWs. Clinics where the implementation team struggled to recruit and train suitable candidates, were clinics that needed more supervision and support i.e. Orange clinic. LHWs with wider exposure to different trainings than just CHW training, displayed higher standards in their work capability.

In recruiting the LHWs, the implementation team ensured a set standard in the qualification and experience of the LHWs. As discussed in Chapter six, LHWs had attained grade 12 (Matric), had experience working as CHWs or working in a clinic and were residents of the intervention communities. Selection of LHWs was in three phases and these included shortlisting of applicants, interviews and final selection during training. The week-long training aimed at imparting knowledge and skills as was related to the work of LHWs in the clinics. There were also supervisory support visits and in-service trainings/ refreshers that were conducted by the Implementation Manager and external facilitators for both LHWs and nurses throughout the implementation period that aimed at strengthening the delivery of the intervention. The confidence and other skills that LHWs gained, was as a result of on job training that they received from nurses in the clinics which supplemented LHW's qualification and initial training.

In other LHW interventions, there are variations in the qualification requirements, selection processes and training approaches of LHWs based on variations in the programme focus area. For instance, other interventions have engaged LHWs with no any professional training while others have recruited university graduates (90). All in all, these interventions recognize initial and on-going refresher trainings throughout the implementation period (128). Some authors have noted incentives like refresher trainings as factors for increasing job satisfaction (129). In other interventions that have been reported, on job trainings offered by nurses have led to the evolution on the tasks of the LHWs from their initially trained tasks based on needs of the clinics (90) which also manifested in this LHW intervention.

The LHW intervention was managed by an Implementation Manager independent of the DoH structures. Findings from this realist evaluation has shown that engaging an individual external to the DoH system ensured her commitment to the programme without other demands that could come from the DoH. The independence of the Implementation Manager was also important as she freely and directly engaged with different managers at District, Sub-district and Provincial levels without going through bureaucratic hierarchical procedures. This ensured that some of the challenges experienced during the implementation i.e. malfunctioning of BP machines (to be discussed in the next chapter),

were quickly attended to. However, in a real situation, I recommend that the position of an Implementation Manager be mainstreamed within DoH structures or be occupied by already existing managers for purposes of sustainability. It is also ideal to have the position occupied by existing managers especially in settings with shortage of health workforce and as a way of avoiding verticality in health programmes.

In contrast to this approach, most LHW interventions (community or clinic based), have used structures within DoH/ MoH to manage and supervise LHWs. A systematic review of 48 studies of LHWs in primary and community health care showed that in some studies, management of LHWs was the responsibility of nurses (83). Another systematic review that included three RCTs on task shifting intervention for CDV risk reduction in LMICs (130), did not clearly explain how the CHWs were supervised. Other LHW interventions in Benin, Zambia and Lesotho used nurses and physicians to train and supervise the LHWs (85, 86, 88). However, WHO has expressed that sustained supportive supervision and mentoring is key to the success of CHW task shifting. The WHO has further observed that there are better outcomes when supportive supervision is within the structures of the health system. Unfortunately, this is challenged by lack of competency and adequate supervisory skills among medical professionals. This is also seen as extra burden for the medical professional hence the need to hire extra workers to undertake supervisory responsibilities (77, 80).

In this chapter, I have looked at how LHW skills, capacity and support and staff motivation, attitude and relations, were essential towards the reasoning of LHWs and other staff and how they engaged with the intervention. In the next chapter, I analyse patients' outcomes at clinic level which was part of the outcomes in my conceptual framework of context, mechanisms and outcomes.

CHAPTER 9: RESULTS - CLINIC LEVEL OUTCOMES

In this chapter, I will present the proximal outcomes at clinic level, collected through clinic link. Such proximal outcomes will among others include numbers of acute and other chronic patients identified with elevated BP and percentage of chronic patients coming on their appointment dates. I will also include descriptive information about the numbers of chronic patients in the trial clinics and changing levels of clinic visits throughout the implementation period. The aim of the chapter is to understand the impact of the intervention at clinic and patient levels. I was unable to relate clinic performance with changes in patients' blood pressure at clinic level based on clinic link data. This was as a result of having unreliable BP machines in the clinics which often broke down as reported by nurses and the Implementation Manager. Thus, the BP readings could have been affected.

9.1 Patients with chronic diseases by age group, sex and diagnosis

Patients exclusively with hypertension comprised 32% of all patients with chronic diseases in the clinics. There were also another 6% of patients with chronic diseases that were both hypertensive and had HIV. For both hypertensive and non-hypertensive chronic patients, there were significantly more female (about 74%) than male patients. From 2014 Agincourt census data, I am are aware that there are more women (52%) in the HDSS site (131). It might be as a result out-migration of men from their homes for work purposes (132).

This data has also shown that there were more hypertensive patients for patients of 50 years and above than the rest of patients with chronic diseases. There were more patients with other chronic diseases for patients of 49 years and below than were hypertensive patients. This indicates that, in the study area, hypertension was more prevalent in the older population. On the other hand, the majority of those without hypertension were being treated for HIV. For chronic care, this concludes that clinics in the study site were swamped by HIV and hypertensive patients.

Table 14 below presents the total number of patients with chronic diseases that were registered and received treatment and care from the eight trial clinics between the period of May 2014 and July 2015.

Table 14: Number of patients with chronic diseases in the trial clinics

		Hypertension with no HIV	HIV with no hypertension	HIV plus hypertension	Neither HIV nor hypertension
Total		**2,976 (32%)**	**4,848 (53%)**	**516 (6%)**	**877 (10%)**
Sex	Male	662 (22%)	1,291 (27%)	113 (22%)	362 (41%)
	Female	2,314 (78%)	3,557 (73%)	403 (78%)	515 (59%)
Age	<18	3 (0.1%)	438 (9%)	0 (0%)	53 (6%)
	18-49	675 (23%)	3,724 (77%)	259 (50%)	515 (60%)
	50-69	1,295 (44%)	616 (13%)	219 (43%)	214 (24%)
	70+	938 (32%)	65 (1%)	37 (7%)	73 (9%)

9.2 Clinic visits by patients with chronic diseases

Table 15 below presents the total number of clinic visits by patients with chronic diseases for each of the trial clinics for the period May 2014 and July 2015.

Table 15: Total and mean monthly clinic visits for patients with chronic diseases

	Visits per clinic from May 2014 to July 2015			
		Total N	**Monthly mean**	**95% CI**
	all clinics	81895	5460	(5063 - 5857)
Intervention	Troy	21075	1405	(1270 - 1540)
	Orange	9214	614	(536 - 692)
	Timber	5864	391	(360 - 421)
	Hillard	9158	611	(558 - 664)
Control	Faith	6616	441	(399 - 483)
	Moghan	11568	771	(711 - 831)
	Arlington	10048	670	(619 - 721)
	Yang	8352	557	(518 - 596)

Troy clinic had the highest number of clinic visits (21075) than the rest of the clinics. Two clinics, one from the intervention arm (Timber) and another from the control arm (Faith) had the lowest levels of clinic visits (5864 and 6616 respectively). The rest of the five clinics (two intervention clinics and three control clinics), had similar levels of clinic visits ranging from 9214 to 11568. Of these clinic visits, 75% were done by female patients of 18 years and older. Figure 8 below shows that across all the eight clinics most visits by patients with chronic diseases were either by hypertensive patients or HIV patients. Moreover, it should be noted that some patients were both HIV and hypertensive.

Generally, 2014 and 2015 comparative data on clinic visits showed that clinic visits increased during the trial implementation period. Prior information indicated increased number of patients with chronic diseases in clinics as a result of the 'step down programme' and HIV

patients being managed in PHC clinics. Clinic link data came up with similar results (figure 8 below). This concludes that clinic visits had not just increased before the trial, but there was still an ongoing rapid increase of clinic visits.

I related data on clinic performance and percentage increase of the clinic visits. Clinics whose qualitative data showed poor performance of the intervention i.e. Orange clinic, had the highest percentage increase around 79% than Timber clinic which was the lowest in clinic visits but had better performance of the intervention. Other control clinics like Arlington had higher increase in clinic visits than some intervention clinics. This indicates that different factors i.e. the Nurse Initiated Antiretroviral Treatment (NIMART) and 'step down programmes', influenced the increase in clinic visits than just the intervention. On the other hand, the increase in the number of patients might have resulted in more work for the nurses hence poorer services.

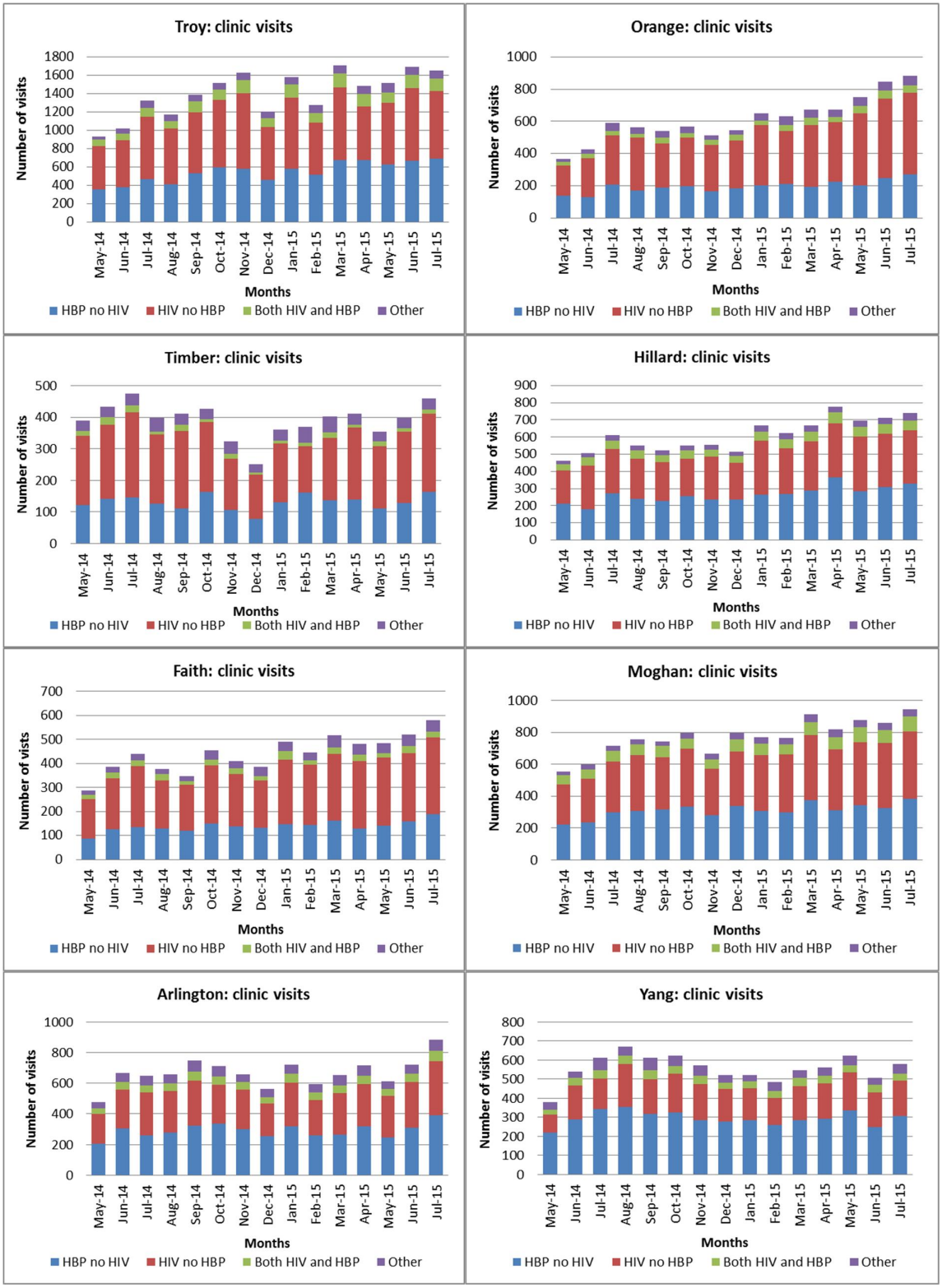


Figure 8: Clinic visits made by chronic patients between May 2014 and July 2015

9.3 Giving of appointment dates

Clinic link data showed that in both intervention and control clinics, nurses were likely to give return/ booking dates for the next visit to chronic patients (99% of clinic visits). Almost half of the visits were made by hypertensive patients. Data has shown that 99% of the visits by hypertensive patients were given return dates and 99% as well of other chronic visits were given return dates. In my earlier findings (section 8.4.2), most control clinics where the appointment system was managed by nurses, had non-functional appointment registers compared to intervention clinics where the system improved with the coming in of LHWs. This contradiction might be as a result that nurses assign a date, tell the patients about the date, record it in the patient's file but don't record it in the appointment book. This indicates that regardless of a chronic condition and regardless of a clinic, all patients with chronic diseases were given dates for their next appointment. In subsequent sections, I will explore on chronic patients' adherence to the return/ appointment dates and relate to barriers and facilitators to adherence to appointment dates as explained in earlier chapters.

9.4 Appointment reminders for patients with a diagnosis of hypertension

One of the roles of LHWs were to send reminders to hypertensive patients prior (a day before) their appointment. As explained in earlier chapters, the initial idea as decided during the intervention development workshops with the nurses, was that LHWs would send SMSes to the patients as reminders. When the intervention begun, LHWs found that the SMSes were not effective because some patients could not read and others shared their phones with their relatives. SMS reminders were then changed to actual phone calls as reminders. Data presented in this section shows the proportion of visits by hypertensive patients in the intervention clinics where SMS and phone calls were sent. The data shows intervention clinics which were effective/ less effective in sending the reminders.

Table 16: Percentage of visits by patients with hypertension in intervention clinics where there is a record of a reminder having been sent in their second and subsequent visits

Clinic name	Total clinic visits by patients with a diagnosis of hypertension	Total visits by patients with a diagnosis of hypertension where a reminder was sent (phone calls and SMSes)	Percentage of visits by patients with a diagnosis of hypertension where a reminder was sent
Troy	9929	7353	74%
Orange	3440	2412	70%
Timber	2169	1777	82%
Hillard	4713	3735	79%
Total	**20251**	**15277**	**75%**

Data from table 16 above shows that 75% clinic visits made by hypertensive patients, had reminders sent prior to their appointment through phone calling and/or SMS. At clinic level, Timber clinic was more effective at sending reminders (82%) while Orange was the least effective at 70%. These findings directly relate to the capacity and effectiveness of LHWs as observed by the Implementation Manager. In term of performance, she rated LHWs in Timber high and LHWs in Orange low in filing, managing the appointment system and reminding patients among others.

9.5 Patients identified with raised BP and patients with a diagnosis of hypertension.

Tables 17 and 18 below shows total numbers of patients found with raised BP and patients who ended up confirmed with diagnosis of hypertension and were successfully put on medication. This data is for intervention clinics only since LHWs took a leading role in identifying, documenting and following up with all acute and other chronic patients found with raised BP compared to usual clinics where there was no recording and following up of the patents.

Table 17: Frequency table of acute patients found with raised BP by sex and age group

		Patients found with raised blood pressure
Total		**789**
Sex	Male	212 (27%)
	Female	577 (73%)
Age group	<15	0 (0%)
	15-19	14 (2%)
	20-24	21 (3%)
	25-29	46 (6%)
	30-34	55 (7%)
	35-39	75 (10%)
	40-44	80 (10%)
	45-49	114 (15%)
	50-54	83 (11%)
	55-59	65 (8%)
	60-64	63 (8%)
	65+	150 (19%)
	Missing	23 (3%)

In the four intervention clinics, a total of 789 patients were found with raised BP for the period between May 2014 and July 2015. A total of 671 people was found with raised BP on their first entry into the chronic disease database (presumably because they came to the clinic as acute patients and got picked up by the LHW), and a further 118 people had other chronic diseases when their raised BP was found, giving a total of 789 patients. Of these patients, 396 ended up with a diagnosis of hypertension, representing 50% of those found with raised BP. This 50% is of the total number of patients found with raised BP (789). However, of the 789 patients, 394 came back to the clinic for a second BP measurement within three months. Out of the 394 patients that returned, 301 patients were confirmed with a diagnosis of hypertension (76.4%)

Age categorized data has shown that over 50% of those found with raised BP were above 50 years, whose population was lower than those below 50 years. This can be seen as another pointer for considering efficiency and cost effectiveness of routine and universal BP measurement in clinics as earlier discussed in section 7.2.2 paged 90 and later discussed in section 11.9.1 (b) page 209. Most patients (73%) found with raised BP were females.

Table 18: Total number of patients found with raised BP and number of patients who ended up with a diagnosis of hypertension at clinic level

Clinic name	Patients found with raised BP	Patients with diagnosis of hypertension	% of patients diagnosed with hypertension
Troy	363	189	52%
Orange	189	82	43%
Timber	76	36	47%
Hillard	161	89	55%
Total	**789**	**396**	**50%**

Table 19 presents number of patients found with raised BP and diagnosed with hypertension at clinic level. Troy had the highest and Timber had the lowest numbers. These findings were not surprising as they were related to levels of clinic visits. However, across all clinics, almost half of all patients found with raised BP ended up with a diagnosis of hypertension. It should be noted that similar numbers could have existed in control clinics based on similar numbers of clinic visits as identified in table 16.

9.6 Adherence to appointment dates

Tables 20 and 21 present data on proportion of visits by all chronic patients and hypertensive patients respectively that were made on exact booked dates. The data only includes second and subsequent visits as there were no reminders sent on the first visit. Data had shown that almost half of all chronic patients (57%) visited the clinics on their exact appointment dates. For hypertensive patients, a higher percentage (65%) came on their appointment date compared to all chronic patients combined. At baseline prior to the

intervention, 59% of chronic patients and 61% of hypertensive patients came on their appointment dates.

At project arm level (See table 20), intervention clinics had a higher proportion of patients coming on their exact booked dates both for all chronic patients (intervention = 61%, control = 53%) and for hypertensive patients (intervention = 71%, control = 57%)

Table 19: Proportion of visits by chronic patients done on exact booked dates

	All clinics	Intervention clinics	Control clinics
Visits by all chronic patients on exact booked date	57% 42080	61% (25,045/40,763)	53% (17035/31,915)
Visits by hypertensive patients on exact booked date	65% 22721	71% (13,404/18,855)	57% (9,317/16,248)

At clinic level, there were similar levels for all chronic patients coming on their exact booked dates across all eight intervention and control clinics. An average of 56% of visits by patients with chronic diseases was made on exact dates. The lowest clinic was Faith (37%) and the highest was Hillard (66%). However, all intervention clinics had higher levels of visits done on exact dates for hypertensive patients only, which ranged from 67% (Orange) to 76% (Hillard). Control clinics had their proportions ranging from 40% (Faith clinic) to 62% (Arlington) (See table 21).

Table 20: Percentage of visits from chronic patients keeping appointment (clinic specific)

Clinic name		Visits by all chronic patients on exact booked date	Visits by hypertensive patients on exact booked date	Visits by hypertensive patients where reminder was sent
Intervention	Troy	63% (11,861/ 18,799)	70% (6,413/ 9,150)	74%
	Orange	56% (4,468/ 7,944)	67% (2,087/ 3,122)	70%
	Timber	56% (2,976/ 5,345)	72% (1,491/ 2,070)	82%
	Hillard	66% (5,740/ 8,675)	76% (3,413/ 4,513)	79%
Control	Faith	37% (2,044/ 5,491)	40% (833/ 2,076)	NA
	Moghan	56% (5,624/ 10,044)	58% (2,950/ 5,068)	NA
	Arlington	58% (5,303/ 9,079)	62% (2,910/ 4,684)	NA
	Yang	56% (4,064/ 7,301)	59% (2,624/ 4,420)	NA

I looked at visits by hypertensive patients on exact booked dates based on different times of the intervention for both intervention and control clinics. These different periods (as explained in table 22 below) were identified in relation to factors that might have affected reminders for appointment that were sent to hypertensive patients. Data showed that there were similar levels of patients missing their appointment dates in control clinics across all periods of the intervention. For intervention clinics, with an exception of the initial month of May 2014 when the intervention had just begun and SMSes were not effective, the rest of the periods maintained higher and similar proportions of hypertensive patients coming on exact booked dates. This could have been as a result that; (a) patients got used to adhering to their appointment dates even without reminders and, (b) LHWs continued working normally and reminding patients even with minimal supervision from their Manager.

Table 21: Percentage of visits from hypertensive patients keeping appointment at different periods of the intervention

Period	Description	Visits by all hypertensive patients on exact booked date (intervention)	Visits by all hypertensive patients on exact booked date (control)
May 2014	Intervention had just begun. Sending of SMS as reminder was not effective	49% (249/509)	47% (81/172)
June – Nov 2014	Full implementation. Reminders were sent through phone calls	69% (4,721/6,813)	59% (3,701/6,277)
Dec 2014 - Jan 2015	LHWs were mostly out on Christmas holiday. Few patients got reminders	70% (1,707/2440)	58% (1,365/2,369)
Feb – March 2015	Full implementation. Reminders were sent through phone calls	74% (2,107/2,830)	57% (1,314/2,325)
April – July 2015	Last four months of the intervention with minimal supervision from IM	74% (4,620/6,263)	56% (2,856/5,105)

9.7 Availability of medication

Clinic link data showed that the number and percentage of clinic visits where medication was not given, was negligible. For all chronic patients, hypertensive patients separately and HIV patients separately, data has shown that almost 100% of the patients received medication during every visit they made to the clinic during the intervention period. However, I couldn't tell from the clinic link data whether all necessary medication was given. This could probably explain the contradictory evidence from the patient exit and patient cohort interviews where most respondents reported unavailability of medication in the clinics.

9.8 Conclusion

The first three sections in this chapter give an overview of the patient load in the clinics. These data correspond to earlier qualitative data captured through in-depth and semi-structured interviews about increasing number of chronic patients in the clinics against levels of nurses in the clinics that did not greatly improve. Comparative data from the time the intervention started in May 2014 to the time the intervention closed in August 2015 has shown that the number of chronic patients almost doubled. The rate of increase in the number of chronic patients was similar across all intervention and control clinic.

This data has also shown that the local clinics have been swamped by HIV and hypertensive chronic patients with almost 53% and 47% of the clinic visits by chronic patients done by HIV and hypertensive patients respectively. However, qualitative observation data showed that most of the clinic and community level intervention are aimed at supporting HIV patients only. Such interventions included activities by CHWs in the community i.e. tracing defaulters, activities by lay counsellors in the clinics i.e. HCT and data capturing by Data Clerks in the clinics.

Clinic link data has also shown increasing prevalence levels of hypertension among females of 50 years and older. This is against a background of frequent breakdown of BP machines and wearing out of BP cuffs, which was partly as a result of measuring BP for every patient coming through to the clinics as shown by observation data.

The follow-up sections (sections four to seven), have presented how clinics performed in different categories. In some instances, there are comparisons among intervention clinics and in other instances I have compared intervention from control clinics. Despite having no denominator in determining how clinics performed in identifying acute and other chronic patients with raised BP, LHWs in the four intervention clinics had similar levels of performance. Numbers of acute and other chronic patients found with raised BP in the intervention clinics were congruent to numbers of visits made by chronic patient during the intervention period. There was also similar proportion of patients that ended up with a

diagnosis of hypertension, at around 50% of those found with raised BP across the intervention clinics.

This data has shown the link between appointment reminders and adherence to appointment dates by hypertensive patients. It has shown the importance of the role of LHWs in reminding patients for their appointment. At intervention arm level, clinics to the intervention (where reminders were sent) were more likely to have hypertensive patients coming on their exact booked dates. Clinics within the intervention arm that had a higher rate of sending reminders (Hillard and Timber) had corresponding higher rates of patients who came on their exact booked dates.

In this Chapter, I have presented clinic and patient outcomes at clinic level. In the next Chapter, I will explore how the LHW intervention affected functioning of the clinics.

CHAPTER 10: RESULTS – HOW FUNCTIONING OF CLINICS AND BEHAVIOUR OF PATIENTS WERE AFFECTED BY CONTEXT, MECHANISMS AND THE INTERVENTION

In this chapter I analyse how the LHW intervention, clinic context and mechanisms affected the functioning of the clinics and behaviour of patients. This links to the fourth objective of the study that analytically explains the processes that let to change (or not) in the patient and related outcomes. Within the conceptual framework of CMO configuration, I explore how the interplay of context, mechanisms and the intervention, affected functioning of clinics and led to clinic and patient outcomes. Data for this chapter is a synthesis of data from the three preceding chapters.

I have placed the clinics into well, medium and poor functioning categories, using final percentage among hypertensive patients in adhering to their appointment dates. I also considered how the LHWs and intervention functioned, in placing the clinics in the three categories. As is the case with the use of a case study approach in qualitative research (115), and using the science of complexity (133), there was no clear cut difference on these features between well and medium functioning clinics, and between medium and poor functioning clinics. Though with somehow blurred distinctions, below I present how I used a cluster of features to decide which clinic fell into which category.

The “well-functioning clinics” had the highest appointment adherence rate ranging from 72% to 76%. They had all the different components of the intervention functioning well compared to the time previous to the intervention. These included an appointment system, a filing system and prepacking of medication. Well-functioning clinics had skilled, motivated and good performing LHWs that supported each other and related well with clinic staff and patients.

The “medium functioning clinics” had appointment adherence rate ranging from 58% - 67%. They had some (at least one) of the intervention components working adequately. Some clinics only had the appointment system functioning well, while in others it could only be the filing system or prepacking of medication. For intervention clinics, LHWs also had lower

performance and more distant relationship with clinic staff than those in well-functioning clinics.

The only “poor functioning clinic” had appointment adherence rate of 40%. None of the intervention components functioned well. The appointment system, filing system and prepacking of medication were all dysfunctional. Most or all processes in the clinic did not function well, despite having some resources available in the clinic, for instance good infrastructure.

Although there was a complex mix of factors that I considered when placing the clinics in different categories, these data have shown that well-functioning clinics with better patients’ adherence to their appointment dates, were clinics likely to have a combination of functional context and mechanisms. These were also clinics likely to have better performing LHWs that positively influenced changes on how the intervention functioned. However, the relationship between well-functioning clinics and better performing LHWs was not always linear. For instance, based on recruitment, training and supervision reports, Troy clinic had the best performing LHWs and Troy did not come out as a well-functioning clinic because clinic context affected LHW performance**.** I would therefore look at this relationship in three ways; (a) better functioning clinics enhanced performance of LHWs, (b) better functioning clinics may have attracted better performing LHWs and, (c) better performing LHWs may have contributed to better clinic functioning. Table 23 below is a summary of this explanation and how the clinics functioned.

Table 22: Categorization of clinics into well, medium and poor functioning clinics

Clinic name		Context						Mechanisms				Outcomes		
		Clinic infrastructure	**BP machines**	**Other materials (files, drugs)**	**Clinic management**	**Visits per nurse per month (% change)**	**Existing manager, staff and patients relations**	**Skills of LHWs**	**LHW workload: visits per LHW per month**	**LHW and clinic staff relations**	**Team work between LHWs**	**Chronic care pathway**	**Other aspects of chronic care**	**Patients coming on booked date**
Well-functioning	Hillard	Modern and spacious building.	Broke down few times	Erratic supply	Strong clinic manager and in control of the clinic.	528 to 429 (-23%)	Good relationship among staff and with patients.	Skilled and innovative	792 to 1074 (+26%)	Good relationship. Supportive staff	Good team work	Functional: clear pathway Erratic: chronic consultation room Didn't happen: designated vital signs station	Functional: filing, appointments and prepacking of medication, SMS	76%
	Timber	Modern building but with limited space.	Often broke down	Erratic supply	Strong clinic manager/ not liked by nurses.	433 to 202 (-144%)	Poor relations among staff and with patients.	Young, skilled and innovative	650 to 606 (-7%)	Good relationship. Supportive staff	Good team work.	Functional: chronic consultation room Erratic: designated vital signs station Didn't happen: clear Pathway	Functional: filing, appointments and SMS Erratic: Prepacking medication	72%
Medium functioning	Troy	Modern building but with limited space	Often broke down	Good supply of some materials	Weak clinic manager.	252 to 347 (+27%)	Poor relations among staff and with patients.	Skilled and innovative	1639 to 2427 (+32%)	Few senior nurses were supportive	Good team work	Erratic: chronic consultation room and clear pathway Didn't happen: designated vital signs station	Functional: filing, appointments and SMS Erratic: Prepacking medication	70%
	Orange	Dilapidating building with limited space.	Often broke down	Erratic supply	Weak clinic manager.	276 to 413 (+33%)	Poor relations among staff and with patients.	Unskilled and not creative.	691 to 1239 (+44%)	Few senior nurses were supportive	Poor team work	Functional: chronic consultation room Erratic: clear pathway Didn't happen: designated vital signs station	Functional: SMS, filing and appointments but with some mistakes. Didn't happen: prepacking of medication.	67%

Clinic name		Context						Mechanisms				Outcomes		
		Clinic infrastructure	**BP machines**	**Other materials (files, drugs)**	**Clinic management**	**Visits per nurse per month (% change)**	**Existing manager, staff and patients relations**	**Skills of LHWs**	**LHW workload: visits per LHW per month**	**LHW and clinic staff relations**	**Team work between LHWs**	**Chronic care pathway**	**Other aspects of chronic care**	**Patients coming on booked date**
	Arlington	Modern and spacious building.	Did not break down	Erratic supply	Strong manager but often absent from clinic	359 to 370 (+3%)	Very poor relations among staff and with patients.	Not applicable	Not applicable	Not applicable	Not applicable	Functional: clear pathway, chronic consultation room Didn't happen: designated vital signs station	Functional: filing, Erratic: appointments Didn't happen: prepacking of medication.	62%
	Yang	Dilapidating building with limited space	Did not break down	Erratic supply	Strong manager replaced by weak clinic manager	306 to 342 (+11%)	Good relations among staff and with patients.	Not applicable	Not applicable	Not applicable	Not applicable	Erratic: chronic consultation room Didn't happen: clear pathway and designated vital signs station	Erratic: appointments, filing and prepacking medication	59%
	Mohgan	Dilapidating building with limited space	Did not break down	Erratic supply	Weak clinic manager.	374 to 447 (+16%)	Good relations among staff and with patients.	Not applicable	Not applicable	Not applicable	Not applicable	Functional: chronic consultation room Erratic: clear pathway Didn't happen: designated vital signs station	Functional: appointments Erratic : filing Didn't happen: prepacking of medication.	58%
Poorly functioning	Faith	Modern and spacious building.	Frequentl y broke down	Erratic supply	Weak manager	372 to 227 (-64%)	Poor relations among staff and with patients.	Not applicable	Not applicable	Not applicable	Not applicable	Functional: chronic consultation room and clear pathway Didn't happen: designated vital signs station	Erratic : filing, appointment Didn't happen: and prepacking of medication.	40%

10.1 How the lay health worker intervention worked

Table 23 above shows that functioning of the eight case clinics was affected by different clinic specific factors. I have used the summary of the different factors to develop different eight case scenarios (boxes 15 – 17) about how the LHW intervention might have worked or not in these clinics. I have finally differentiated these case scenarios with what would be an ideal scenario for the implementation of the LHW intervention.

10.1.1 Well-functioning clinics: clinic management and capacity of lay health workers overcoming a difficult environment

Box 15: Clinic management and capacity of LHWs overcoming a difficult environment

Case 1: Hillard – good infrastructure, management, LHWs, teamwork and patient outcomes.

The Hillard clinic had modern and spacious infrastructure and fairly well functioning BP machine. It had a strong Clinic Manager who was able to discipline and support staff accordingly. Staff and patients appreciated how the Clinic Manager managed the clinic. There was strong motivation and team work among staff, staff related well with patients, staff supported and involved the LHWs. Most staff were residents of the villages that were served by the clinic. The clinic was easily accessible by both staff and patients with a taxi drop off[8] at the main entrance of the clinic. The clinic was closer to a referral hospital and shopping centre. LHWs performed well, were dedicated and supported each other (refer to section 8.3 for details). There were improvements in systems of appointment, filing and prepacking of medication as a result of the intervention, and the 76% of patients attended on their appointed day.

8 South Africa's minibus system that serves as public transport to the general population, also referred to as Taxis. Drop offs are any points along the taxi route that a passenger can decide to alight or drop from the taxi.

Case 2: Timber – poor infrastructure and team work, but strong management, LHWs and good patient outcomes

In contrast, Timber clinic had poor clinic infrastructure, the BP machine frequently broke down and there was an erratic supply of other materials. It is located to the far east of the study site, where most of the residents are immigrants from Mozambique, living in informal settlements with poorer public services, including the condition of the roads. Most nurses complained about the services in the area, and as a result resided out of the village. There was a lack of team work among nurses, and poor relations between nurses and patients could have affected patient attendance. Perhaps in recognition of their difficult circumstances, the number of Professional Nurses doubled during the intervention, despite a decrease in clinic visits. This resulted in a fall in nurses' workload. Moreover, LHWs were skilled and innovative in response to challenges. Among others, they made efforts following up with patients in their homes when they couldn't get them on cell phones (refer to section 8.3 on how LHWs performed). Combined with a strong Clinic Manager, the result was 72% of patients attended on their appointed day.

10.1.2 Medium functioning clinics: how chronic care nurse champions, strong management, teamwork and relations contributed to similar levels of clinic functioning

Box 16: Chronic care nurse champions, strong management, good teamwork and relations

Case 3: Troy – Poor teamwork, weak management but strong chronic care nurse and better patient outcomes

Troy clinic had a better infrastructure but with limited space. The BP machine often broke down. The Clinic Manager did not on challenges affecting delivery of chronic care and motivation of nurses. Most nurses lamented lack of support from the Clinic Manager and Clinic Supervisor. Some nurses resigned and others were transferred. This resulted in having a lot of recently graduated Professional Nurses with no work experience. There were poor relations between staff and patients and among staff. LHWs were hard working but the high patient load in the clinic affected their work like timely updating of the appointment register. High patient load coupled with lack of teamwork among staff also resulted in erratic prepacking of the medication, an unstable chronic pathway and missing patient files. However, Troy had committed chronic care nurse who fully supported the LHWs and ensured that they coordinated very well in attending to patients with chronic diseases. This resulted in having 70% of patients attending on their appointed day. The intervention's Implementation Manager noted the following:

"The chronic care nurse is very passionate about chronic care and she expressed her gratefulness for the LHWs. She is willing to assist the LHWs and also ensure that the patients don't stay long in the clinic. She came out with very useful ideas on how to work with the LHWs. She keeps on checking how LHWs are booking patients and reminding them how booking should be done" ***20140416_diaryim_agi_zm***

Case 4: Orange – Poor infrastructure, poor teamwork, weak management, weak LHW but strong chronic care nurses and better patient outcomes

Similarly, Orange clinic had the worst infrastructure among intervention clinics. The BP machine often broke down and there was erratic supply of other materials. Clinic management was weak. There was lack of innovativeness and pro-activeness from the Clinic Manager in addressing challenges faced in the clinic. Junior nurses were disillusioned and did not relate well with senior nurses and rest of staff. They felt that the Clinic Manager did not adequately support them for instance in going for further training. Performance of LHWs in Orange was the lowest among all intervention clinics. There were a lot of mistakes identified in their filing and appointment systems. Furthermore, LHWs did not relate well among themselves and with the clinic staff. However, just like in Troy, chronic care nurses championed proper chronic care. They related well with patients and supported the LHWs. During clinic observations, patient conversations often praised care and commitment from the chronic care nurse. The percentage of patients attending on their appointed day was at 67%.

Case 5: Arlington – Poor teamwork but strong Clinic Manager, better infrastructure, and better patient outcomes.

Arlington clinic in the control arm had a better and spacious infrastructure than Orange, Yang, Timber and Moghan clinics. The BP machine functioned well though the cuffs were wearing out. The clinic was among few clinics that had a clerk at the beginning of the intervention and as a result, it had a better filing system. The Clinic Manager was strong and made sure that patients were quickly attended to, so it was not surprising that Arlington and Hillard (well-functioning clinic) were the only clinics that received high score in the "Ideal clinic" (chapter 3, section 3.2.4) assessment among the clinics in the study site (50% Arlington and 55% Hilliard). However, staff in Arlington had negative attitude towards work. There was poor teamwork and staff did not relate well with patients. The Clinic Manager, though strong, was often absent from the clinic because she had other responsibilities at the sub-district office. Staff in the clinic were thus made/ coerced to work when the Clinic Manager was available. Strong clinic management coupled with better resources might have resulted in the highest attendance rate among control clinics at 62%. However, with management by coercion, functioning of the clinic was uneven and conditional. A field worker made the following observation:

"A new Professional Nurse in the clinic, expressing to another Professional Nurse – I don't understand what is happening in the clinic. We were supposed to exchange when giving health talks in the morning and we were supposed to alternate in consultation rooms but that doesn't happen. We don't help each other. One nurse was supposed to help with the prepacking because mostly the person who is working in the chronic care room needs to collect blood and prepack yet others are not doing anything." ***20150612_obscli_kil_ns***

Case 6: Yang – Strong teamwork and better patient outcomes. Poor infrastructure and changes in management and staff weakened clinic functioning.

Yang clinic was in the control arm of the intervention. The clinic had a very poor infrastructure in a dilapidated condition and had limited space. Patient pathways were always unstable, unclear and confusing. Cuffs for BP machine had worn out and there was erratic supply of other materials. When the intervention started, the clinic had a strong Clinic Manager and a motivated team of nurses that related well among themselves and with patients. The appointment system functioned very well. Prepacking of medication and filing system was also good. Mid-way through the intervention, all the nurses but one either retired or were transferred. All Professional Nurses were new and had come from hospitals with no experience working in clinics. The Clinic Manager that took over did not have experience and capacity in clinic management. She failed to discipline the clinic's Data Clerk who did not want to be involved in managing the filing system. Despite changes in staff, strong team work continued in the clinic among the new, young and energetic nurses. Patients appreciated the care they received from the new nurses and attendance on the appointed date was at 59%.

Case 7: Moghan – Poor infrastructure, weak management, but strong teamwork and better patient outcomes

Moghan clinic was in the control arm and was among clinics with worst infrastructure. Limited space resulted in unclear pathway for chronic patients. The cuffs for electronic BP machine were worn out. There was erratic supply of medication and other materials. Clinic management was weak. The Clinic Manager secluded herself from the rest of staff and cared less of what was happening in the clinic. However, Moghan clinic had a team of dedicated nurses and staff. Relations among staff and with patients were better with no major conflicts. Staff supported each other. The clinic had its appointment system functioning very well before and throughout the intervention period. Strong teamwork, good engagement between nurses and patients, and better functioning of the clinic resulted in increased number of visits and nurse workload against the number of nurses that was almost the same during the intervention. Patients' attending on their appointment date was better at 58%.

10.1.3 Poorly functioning clinics: combined poor relations, lack of teamwork, weak clinic management and limited resources were detrimental to functioning of clinics.

Box 17: Poor relations, lack of teamwork, weak management and limited resources

Case 8: Good infrastructure but lack of teamwork, poor relations, weak management and poor patient outcomes

Faith clinic in the control arm control clinic had a better infrastructure than other medium and well-functioning clinics. The clinic had spacious infrastructure, located close to tarmac road, good filing cabinets and higher numbers of nurses. Conversely, there was gross lack of team work in the clinic. Poor relations resulted in staff shouting at each other in front of patients. There were poor relations between patients and nurses. Staff felt demotivated by lack of support from clinic management i.e. being prevented from accessing opportunities to upgrade their education. Clinic management was weak. The Clinic Manager failed to discipline staff and bring the clinic into order. The scenario resulted in non-functional of appointment system, no prepacking of medication, missing of patients' and only 40% of patients attended on their appointment dates (as recorded by Nkateko data capturers from patient files). Increase in clinic visits (42%) might have been as a result of the ongoing increase across all clinics due to the 'step-down programme' that moved patients from hospitals to clinics. Decrease in nurse load (39%)[9] was as a result of a doubling in the number of Professional Nurses. The Clinic Supervisor in Faith clinic made the following observation:

"There is no team work at Faith clinic. I visited the clinic last week. I have tried to do a mini survey to check on what is it that makes them not to provide proper care to the patients. There's insubordination to those in authority in that facility. The Clinic Manager is crying everyday. Nurses are fighting in front of patients" ***20151019_intsup***

[9] Calculated as percentage increase in the number of clinic visits by chronic patients per professional nurse

Conclusion/ lessons learnt

In summary, I draw the following lessons from experiences of the eight case clinics on functioning of clinics and enabling environment for the implementation of the LHW intervention: (a) Health systems are complex organizations. A complex mix of different factors i.e. relations, management, resources, resulted in no linear path of implementation and outcomes. This is in line with the theory of complex adaptive system (chapter 3, section 3.4.2). Specific clinics had unique functioning and outcomes. Key attribute of the CAS theory is that the dynamic nature of systems comes from other areas external to the intervention. In this LHW intervention, this has been reflected in the increase in number of patients with chronic diseases, down referrals of patients and turnover of staff among others. (b) Despite varied differences across clinics, and between intervention and control clinics, some intervention and control clinics had similar outcomes i.e. Orange and Arlington clinics. From such scenarios, it was clear that despite the contribution made by LHWs, there were certain specific factors that facilitated clinic outcomes i.e. strong clinic management. (c) From the eight case clinics, I have also learnt that clinics require one of the following: strong management, teamwork or at least one committed chronic care nurse, to get reasonable outcomes. Clinics with all these factors are positioned to function well. However, if none of these exist, clinics perform more poorly. (d) Although each factor is important in its own realm and helps as a piece to the puzzle when brought together, I have learnt that there are some that are more important than others. For instance, although modern and spacious infrastructure is an important factor in functioning of clinics, team work and good relationships are more important

10.1.4 A desired scenario: good infrastructure, availability of other materials, strong teamwork, good relations, strong management and capable LHWs.

The preceding clinic scenarios demonstrate the extent at which clinics were successful in achieving different levels of patient outcomes. Results from this study have shown that, even for well-functioning clinics, there was no single clinic that had all the contextual factors and

mechanisms of impact in proper and commendable condition. I therefore anticipated that with all contextual factors and mechanisms of impact in good condition, clinics could have attained a desired case scenario for the intervention.

For a desired case scenario, the LHW intervention would have been successful in improving patient outcomes and improving functioning of clinics in a clinic *context* where there was good clinic management, adequate number of staff, spacious and modern infrastructure, functional BP machines and, regular supply of drugs. The intervention would have been successful in clinics where this context was combined with ideal *mechanisms* of impact where there was good relationship among staff and between staff and patients, where staff had positive attitude towards work and supported the work of the LHWs and, where LHWs were skilled, motivated and supported to exceptionally perform their tasks. I anticipated that such combination of this context and mechanisms would have improved *functioning of clinics* that included a functional appointment system, filing system, prepacking of medication and functional pathway for patients with chronic disease. This would have eventually improved *patient level outcomes* and behaviour including increase in the number of hypertensive patients keeping their appointment dates and increase in clinic visits for hypertensive patients under management of clinic care.

However, in real situations, it is unlikely for clinics to attain this desired scenario. I have learnt from the theory of CAS that due to agents who are constantly learning, interconnections, self-organizations and co-evolution taking place in system, same programme interventions are likely to have unique implementations processes and outcomes in different clinics. On the other hand, Wagner provides an ideal chronic care model that reinforces on positive interaction of the health system, providers and users. In the next chapter, I discuss the contribution this study has made to the knowledge of combining Wagner and CAS theories. In the Discussion chapter, I present a summary of the findings; I discuss how the programme theory and the methodological approaches worked.

CHAPTER 11: DISCUSSION AND CONCLUSIONS

In terms of the realist evaluation, the intervention was successfully delivered as intended and successfully changed the working of the clinics (see details on fidelity and dose in section 11.2 below). However, the LHW intervention was not successful in improving population levels of blood pressure with reference to the main aim of the trial. This scenario is a reflection of the recent Standards of Reporting Implementation Studies (StarRI) statement in which one of the key elements is the need to separate outcomes that examine the success of the implementation strategy, from the outcome that assesses the success of the intervention itself (134). For instance, in this LHW intervention, improvements in patients' clinic attendance on appointment dates could be as a result of a successful implementation strategy. However, the intervention did not improve health outcomes.

This realist evaluation concludes that the LHW intervention might not have been successful as a result of different system elements that were ignored during the development of the intervention including BP machines that did not work, erratic supply of medication and other resources, poor working relations. In this discussion, I will focus on how the intervention was delivered and how it affected the functioning of the clinics.

I will firstly present a summary of the study findings. Secondly, I will discuss levels of fidelity and dose for the intervention. Thirdly, I will use the MRC process evaluation framework for complex interventions to understand how the earlier hypothesized programme theory has worked (chapter 6, section 3). Fourthly, I will discuss how the different methodological approaches and theories that I discussed in the Literature Review chapter, explain these findings and what my reflections are. Such methodological approaches include Pawson and Tilley's realist approach, and such theories include the complex adaptive system and Wagner model for ideal chronic care. Finally, I will discuss the methodological contribution that this study has made to the body of knowledge of realist evaluations of complex interventions.

11.1 Summary of study findings

The development of the LHW intervention involved staff from clinics in randomizing clinics, selection of LHWs and, clinic specific workshops that developed the intervention. LHWs attended a week long training prior to the intervention. During implementation, there were supervisory support visits and in-service trainings that were conducted by the Implementation Manager and external facilitators. Nurses also trained the LHWs whilst working in the clinics. The Implementation Manager was a Professional Nurse by qualification and had experience in managing clinic based interventions. She was conversant with the local context and approach to chronic disease management.

The conditions of the clinics were crucial and likely to impact on the delivery of the programme. Clinic contexts that constrained the implementation of the intervention included: dilapidated clinic infrastructure and clinics with limited space, non-functional and inadequate BP machines and other equipment/ materials i.e. patients' files and bags for prepacking medication, erratic supply of relevant medication and, shortage of staff. Other clinic contexts that related to the operations of the clinics included: poor management of clinics and improper management of patients with chronic diseases. However, these contexts varied across the clinics.

In terms of mechanisms, the intervention had higher effects in clinics where there was team work among staff, good relationship between staff and patients, positive staff attitude and conduct and, where there were motivated staff. There were also positive effects in clinics where there was a supportive environment to the LHWs and their work. LHWs performed better with increased involvement in clinic activities, good and professional relationship with other staff and, nurses that were closely involved in the work of the LHWs. Motivation and skill among the LHWs themselves was also an important mechanism for the intervention.

How did the intervention improve the functioning of clinics? In terms of management of chronic diseases as delivered through ICDM, LHWs supported nurses in improving management

of the appointment system, filing system, vital signs stations, prepacking of medication, and delivery of health education and generally quickly attending to patients. At patient's level, the intervention improved patients' adherence to appointment dates, identification of acute patients with elevated BP and it improved patients' access to life style modification advice. Findings from this study have demonstrated the role of the intervention, context and, mechanisms in improving outcomes of an intervention

Different authors have come up with similar contextual factors affecting delivery of primary care services in South Africa. Such factors include; shortage of health care workers, overwhelming workload, lack of drugs, stationery, inadequate workspace and malfunctioning of BP machines (49, 58-60). Others have identified Insubordination, lack of professionalism, avoidable mistakes by staff have affected clinic operations and poor relations with colleague (60-62). See section 3.2 page 19 for more details. This evaluation has explored the link between clinic management, team work, relationships and patients' adherence to appointment. Trust between staff and between providers and patients have been shown in other studies to impact on management of health facilities and of adherence by patients (135). Although strong team work and relations are seen as emanating from increasing trust, future realist evaluations should explore broadly how trust impacts on chronic care interventions in primary health care clinics.

11.2 What was the level of fidelity and dose in the lay health worker programme

Although this LHW intervention was a pragmatic RCT, it was important to understand how flexibility influenced the intervention, and it was paramount to also understand the extent to which the programme was implemented as intended (fidelity) and the quantity of the intervention that was delivered (dose) (5). Although the focus on fidelity and dose could be seen as standardizing the complex intervention rather than letting it to be adapted across contexts (5), in this evaluation, examining fidelity and dose helped in understanding the intervention theory (5). Thus, this evaluation focused on programme fidelity and dose in

particular contexts. I thus acknowledge the ongoing discussion between fidelity to, and adaptation of the implementation strategy and intervention (134). The two seemingly contradictory concepts are all important in implementation studies. In this view, Standards of Reporting Implementation Studies (StarRI) statement concludes that interventions must define elements to which fidelity is expected and elements that can be adapted (134).

Some authors have expressed that high programme fidelity is associated with positive programme outcomes (136, 137). On the other hand, interventions can be implemented in a way that is very true to their original design and have no impact. However, understanding how a programme is adhering to its original design helps in defining the components of the programme that are responsible for programme outcome (137, 138). Findings from this realist evaluation have shown variations in levels of fidelity to the intervention design. The recruitment process for LHWs, training, refresher trainings, programme development workshops, supervision and support were all in accordance to the intervention plan. However, there were slight diversions that happened. In all clinics, the intervention was extended for another 6 months due to malfunctioning of BP machines. All clinics were supplied with new cuffs for electronic BP machines. Troy clinic was provided an additional LHW due to high patient load. In all clinics, LHWs had additional tasks from the initially agreed activities and LHWs switched from sending SMSes to calling patients.

Programme *dose* focusses on whether all the intervention components were delivered (139). Key intervention deliverables were LHW activities that included; filing, taking vital signs, health education, appointments and booking, appointment reminders and follow up through SMS, prepacking of medication. Programme dose also varied across the clinics. There was no prepacking of medication in Orange clinic since nurses were not interested. The rest of the activities happened in all the clinics. However, LHWs in Timber were fully responsible for files while in others clinics, LHWs were supported by lay counsellors and nurses. In Hillard, LHWs were fully responsible for taking vital signs while in other clinics, they were supported by

nurses. These variations in both fidelity and dose were mainly as a result of differences in clinic contextual factors i.e. levels of staff, patient load, and state of equipment.

11.3 How the LHW programme theory worked

The MRC framework for process evaluations of complex intervention (5) is the key framework in which the programme theory for this realist evaluation was based. In this evaluation, I have used the MRC framework to understand how different outcomes of the trial have been affected by context and mechanisms in the study. I have further explored the role of the intervention itself, its process of design and implementation. Figure 9 below presents the LHW programme theory as adapted from MRC guidelines on process evaluation of complex interventions (5). It illustrates the logic model of how the different components of implementation, context and mechanisms influenced the outcomes (also known as CMO configuration).

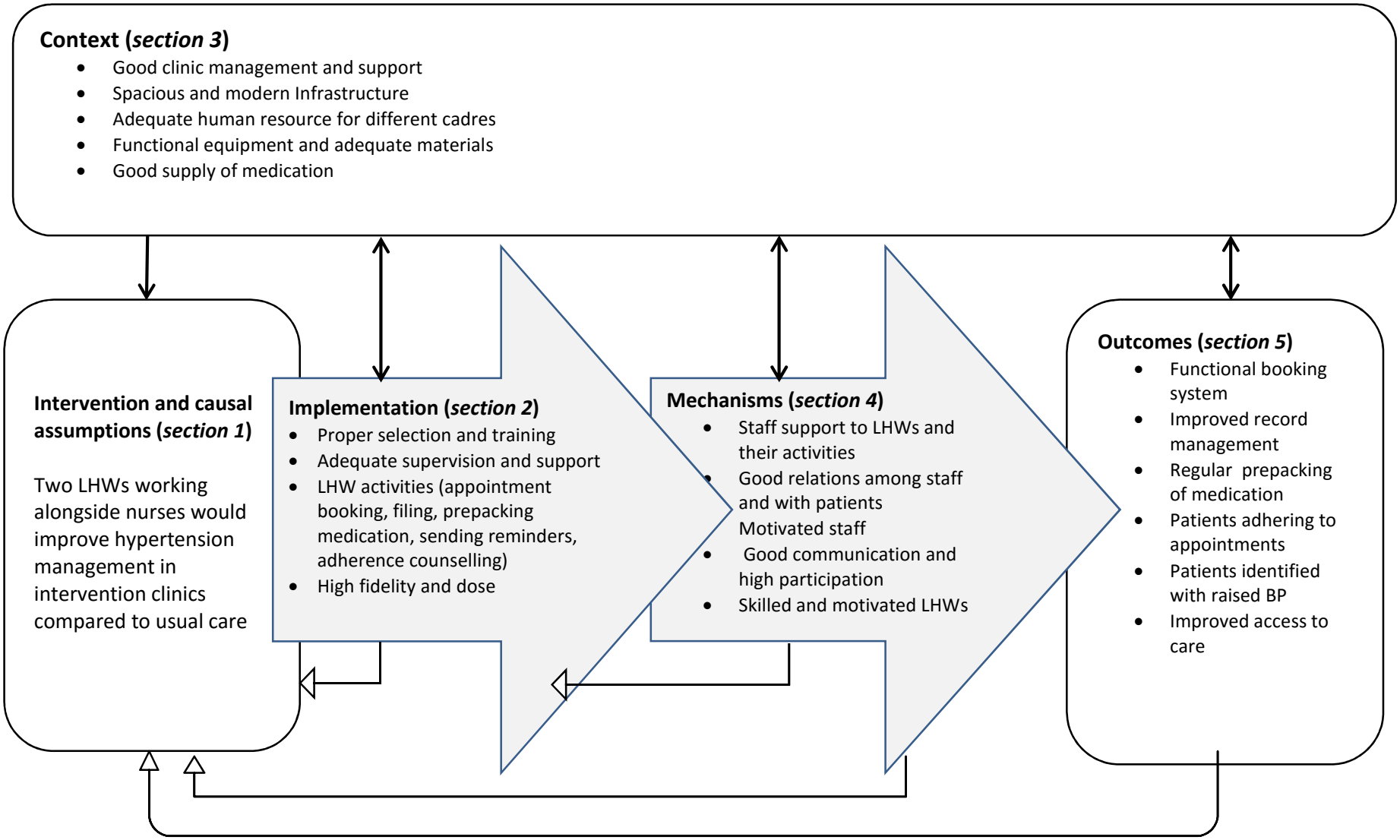


Figure 9: LHW programme theory adapted from MRC process evaluation framework

A review on my methodological approach has shown that the programme theory *partially* worked as expected. As explained earlier, the intervention (*figure 9, section 1*) was not successful in improving population levels of BP but successfully changed the functioning of clinics. The success in improving functioning of clinics varied across the intervention clinics. The theory has explained the causal pathways that led to these differences in the programme outcomes and effects. There has been a manifestation of configuration of these complex factors of intervention, context and mechanisms in this intervention that have influenced the outcomes. For instance, clinics with observed better contextual factors i.e. infrastructure, equipment, good clinic management, adequate number of nurses, low patient loads (*figure 9, section 3*), were clinics with better implementation of the work of the LHWs i.e. appointment booking, reminding and following up with patients, prepacking medication and filing (*figure 9, section 2*). These were also clinics where staff related well among themselves and with patients, where staff supported the work of LHWs and had motivated and skilled LHWs (*figure 9, section 4*). Such clinics had better functioning of ICDM and positive clinic level proximal outcomes (collected through clinic link) that included patients adhering to their appointment dates and identifying patients with raised BP (*figure 9, section 5*).

11.4 Other theoretical approaches used in this study

11.4.1 Wagner's ideal chronic care model

The Wagner theory of ideal chronic care is one theory that was considered in the design of the trial and the realist evaluation as earlier presented in chapter 4, figure 2. The theory expresses that successful chronic care is as a result of productive interactions between patients, providers and the broader health system. Patients must be empowered and informed to manage their illnesses and access care. Providers must be adequately skilled and motivated. The health system must have the required resources including drugs and staff (7). Figures 10 below presents an illustration of the influence made by the LHW intervention towards ideal chronic care in the study site adapted from Wagner's model for ideal chronic care in figure 2 above.

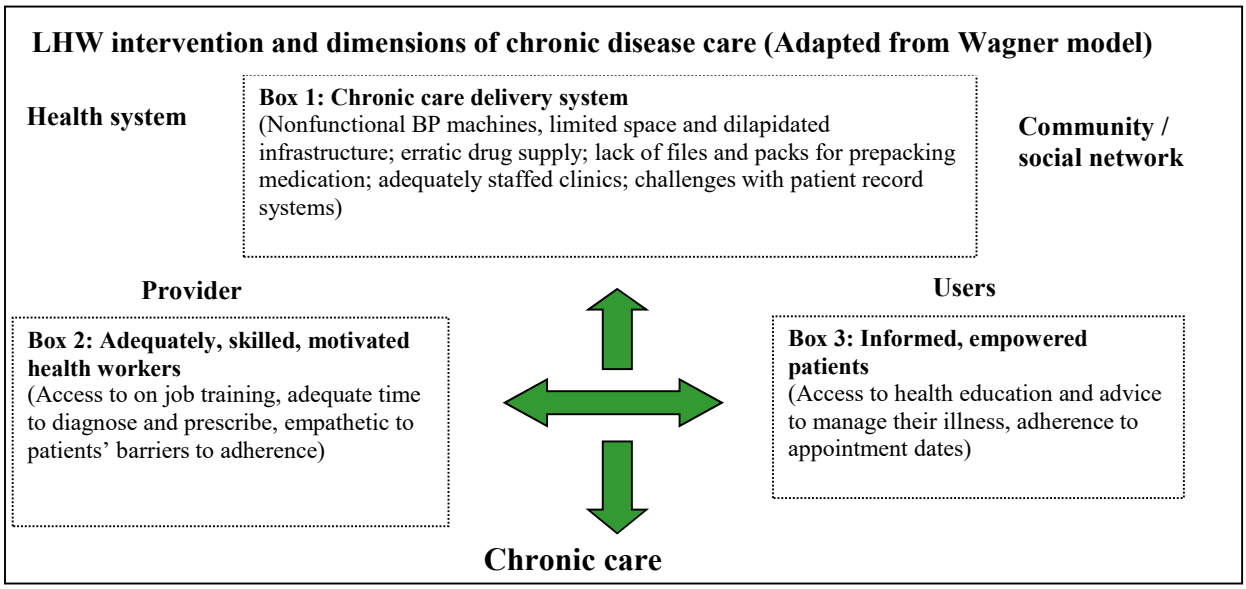


Figure 10: Illustration of the LHW intervention through Wagner ideal chronic care model

In this realist evaluation, the Wagner theory was useful in reminding us of all the three elements (health system, provider and user) that must productively interact in order to have successful care for people with chronic diseases. The theory was helpful in, (a) understanding how the LHW intervention influenced this interaction and (b) how it contributed to strengthening each of the three elements. Findings from this study have showed that the intervention positively influenced the conduct of the providers (box 2) and the behaviour of the users (box 3). It had minimal influence over the health system (box 1).

The intervention relieved the nurses of other tasks thereby giving them adequate time for clinical advice, diagnosis and prescription. Through the Implementation Manager and other external facilitators, nurses accessed refresher and on job trainings on management of chronic patients and day to day challenges they experienced in the clinics. LHWs assisted patients to adhere to their appointment dates through appointment reminders and follow-up. Through health education and counselling, patients accessed information on diet, adherence to medication and stress management. Strengthening of these two elements (providers and users) improved the interaction between them. Nurses appreciate changes among patients in keeping

their appointment dates while patients appreciated the time spent with nurses to understand their conditions and advice given. This situation was different from experiences in most of the control clinics

The LHW intervention was unable to influence better functioning of the health system. Across both intervention and control clinics, generally the chronic care delivery system was affected by limited resources as expressed earlier in this chapter under the 'context' section. These included malfunctioning of BP machines, inadequate space in the clinics, erratic supply of drugs, shortage of nurses and weak clinic management. Although the Implementation Manager helped i.e. in repairing the BP machines, these were short term solutions to assist in the implementation of the intervention. As successful chronic care depended on the interaction of the health system, providers and users, malfunctioning/unresponsiveness of the health system affected the entire cascade of the chronic care model. With limited resources in the clinics, nurses' motivation was affected and patients could not access the required care for better management of their illnesses.

11.4.2 Theory of complex adaptive system (CAS)

The design of the trial and the realist evaluation of the LHW intervention considered the theory of complex adaptive system. As expressed in chapter 6, section 1, the theory recognizes that implementation of interventions and their outcomes do not take a linear path as a result of adaptability (or unpredictability) of actors and the wide range of influencing elements within a complex adaptive system (97). The theory of complex adaptive system focusses on how the system adapts, changes and learns from an intervention. Literature has shown that due to organizational challenges i.e. limited resources, most providers do not adhere to set guidelines (140). The science of CAS which allows providers to implement interventions as adapted to their local context, may improve patient outcomes (97). This discussion focusses on how the LHW intervention employed the CAS theory and how it affected the intervention.

Experiences and findings from the realist evaluation have shown that the LHW intervention was implemented in clinics that varied in different ways. The four intervention clinics had different patient load and numbers of staff. Approaches to clinic management also differed ranging from poorly to better managed clinics. Differences in relationship among staff resulted in differences in team work. Though with generally limited resources across all clinics, some clinics were better off than others i.e. having modern and spacious infrastructure. This setup presented a scenario where the intervention would not be a one-size fit all for all the clinics and made it ideal for the implementers to incorporate the science of CAS in the design and implementation of the intervention. In this discussion, I explore how the theory of CAS was employed.

During the design and development stage of the intervention, there were clinic specific workshops that developed the LHW activities according to the clinic needs and designed the new pathways for patients according to the setups of the clinics. The implementation process was also let to adapt to the clinic context. As agents who are constantly *learning*, nurses realized the potential in LHW, their impact to the clinics and this resulted in further changes to the LHW activities with some clinics involving LHWS with more additional tasks. Existing relations in the clinics affected *interconnections* that happened during the implementation period. LHWs generally related well and had support of senior nurses than junior staff that were seen as competitors. The intervention worked better in clinics with strong teamwork. There were also differences in how LHWs and nurses *self-organized* themselves in the implementation process without waiting for direction from the Implementation Manager based on the immediate need i.e. calling patients instead of sending SMS. *Co-evolution* was among others, evidenced in pathways for patients with chronic conditions that were never static in all clinics due to number of nurses and space in the clinic available on a particular day.

How was the theory useful to this study? Despite implementing the intervention in clinics that were in the same sub-district and the same local area, the clinics were distinct within their environment and in their operation. This uniqueness in the clinics resulted in clinics adapting the intervention to their context in order to achieve the intended results. This theory was also

useful in understanding the motivation among staff in the clinics to change, learn and adapt to new initiatives introduced in the clinics. Clinics where nurses were disillusioned with limited resources, lack of support and feedback from clinic management and had limited access to trainings were clinics that were likely to resist changes brought about by the intervention and not support the LHWs. This could be as a result of lack of motivation among the nurses or the available resources could not support such an intervention.

Literature on CAS also refers to the fact that (health) systems have their own momentum outside the little world of clinics and programme interventions. In this evaluation, components outside of the clinics also had an effect on the intervention and these included the down referral, increase in number of patients and turnover of staff. Therefore, the CAS theory was not just about influencing factors in the clinics but the whole health system.

Using theories of Wagner and Complex Adaptive System in this Intervention

Combining these two different theories in this LHW intervention strengthened both the delivery of the intervention and the methodological approach used in evaluating and understanding the impact of the intervention. The two theories complimented each other. The complex adaptive system acknowledges that organizations are always evolving and changing i.e. the rapid increase in the number of patients with chronic diseases in the study site, while Wagner theory presents organizations as static and just emphasizes on positive interaction between different elements. It does not consider the different environments i.e. resources that organizations are exposed to. It was thus necessary in the design and implementation of this intervention to holistically consider the clinics both as evolving institutions, whose effects could be unique in each clinic, as well as strengthening the different components that must interact for an ideal chronic care. Subsequently, in the evaluation, I aimed at understanding how the intervention operated in such a complex adaptive system in the clinics, at the same time assessing the productive interactions between patient, provider, and the broader health system in such different clinic setup and how it affected the trial.

Learning from the implementation of the LHW intervention, I therefore propose that Wagner model would only be effective if it employs elements of CAS. Figure 11 below is an illustration of an updated Wagner model that includes elements of CAS. The figure shows the interaction of the initial three boxes (health system, providers and users) in a system that is unique to their setting (CAS elements). As presented in this figure, it is ideal to strengthen the health system, the providers and the user (as presented by the boxes) in order to stir positive interaction, and at the same time, letting that such interaction to adapt to clinic environments (as presented by the clouds).

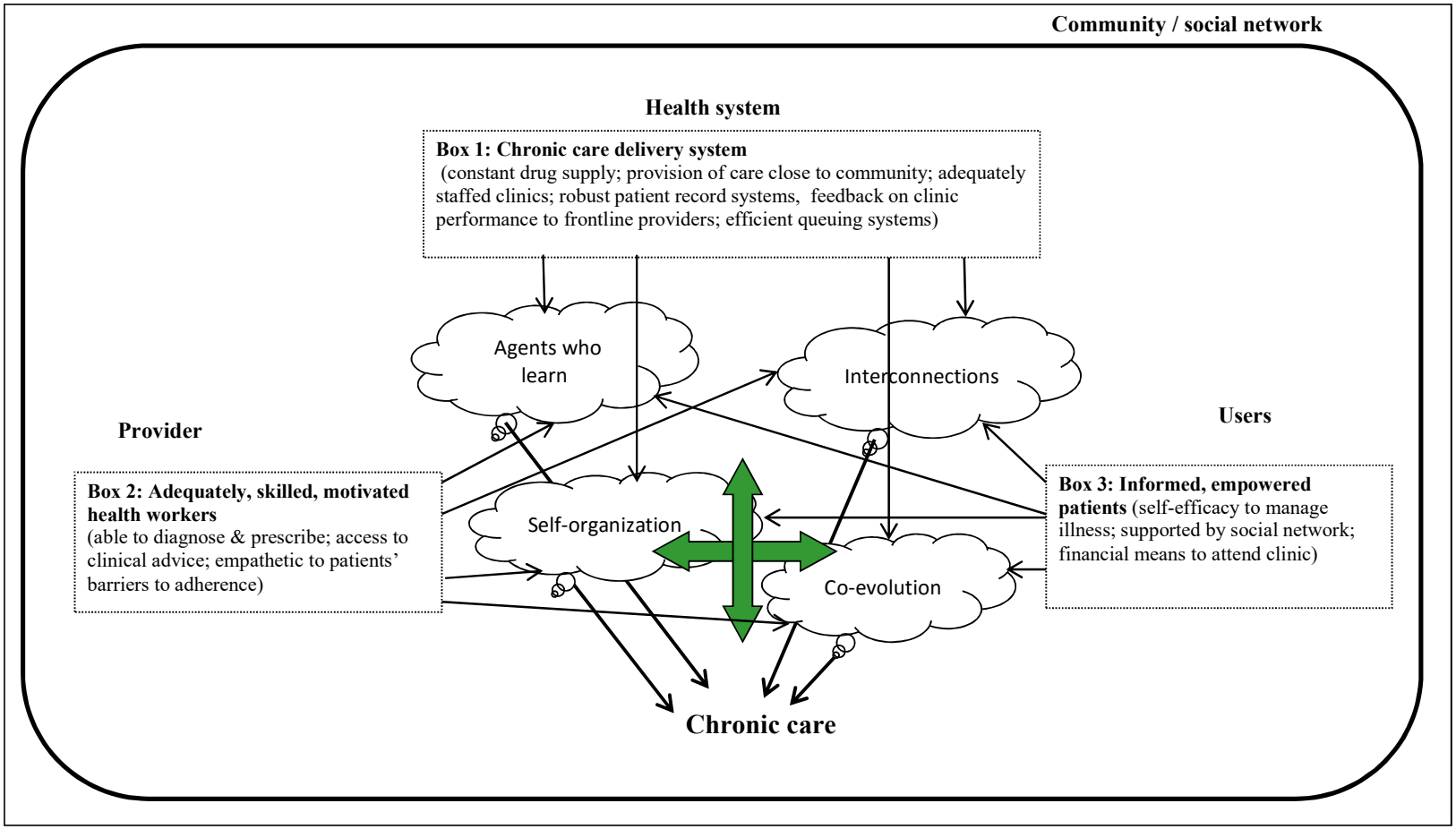


Figure 11: Updated Wagner model for ideal chronic care that includes elements of complex adaptive system

11.4.3 Realist evaluation theory

Pawson and Tilley's realist thinking aims at identifying the role of context and mechanisms in shaping the outcomes of an intervention, also known as CMO configuration (99). In this evaluation, I have used this realist theory to understand how different outcomes have been affected by context and mechanisms in the study. I have further examined 'for whom would the intervention work and under what conditions'. As is the case with realist evaluation, there are always different CMO explanations that can be identified from a single intervention (99). Presented below, are the possible CMO explanations identified from this evaluation.

a) *First CMO explanation*

With strong clinic management, primary health care facilities in rural South Africa can attain greater care for patients with chronic diseases by among others, ensuring that patients adhere to their appointment dates and successfully identifying patients with raised BP. Strong clinic management will engage both staff and patients to understand their needs, will focus on developing the capacity of staff, will appraise and discipline staff accordingly, and will delegate work appropriately. When management of clinics is strong, staff will be motivated and will support the Clinic Manager and supervisor. Staff will work as a team and offer each other support to quickly see patient through even in cases of staff shortage. Staff will work with dedication regardless of the Clinic Manager being in the clinic or not. The best way to address the systematic issues in clinics is to promote better leadership and management by among others training the existing senior nursing staff in leadership and management.

b) *Second CMO explanation*

Clinic based LHWs can be a necessary and effective low cost intervention in rural South Africa to facilitate successful ICDM implementation if the LHWs are to operate in well-resourced clinics and have support of the nurses. Keeping the facilities well-resourced includes; having modern

and spacious infrastructure, functional equipment including BP machines, adequate human resource capacity, adequate supply of medication and other materials like files. When these resources are available in the clinics, LHWs will ably manage the vital signs station (with functional BP machines), help in prepacking medication (with adequate supply of medication and prepacking bags), manage the filing system (with adequate files and filing space). LHWs will also effectively manage the appointment system and have fewer people missing their appointment. Nurses will also be motivated to work is such well-resourced clinics and eventually offer their support to the work of the LHWs

c) *Third CMO explanation*

LHWs can ably operate in clinics and effectively relieve burdened nurses by taking up both socially and medically oriented tasks of the trained health professionals; with proper recruitment, and adequate training, supervision and support. As has been manifested with the role of the Implementation Manager in this intervention, her constant monitoring, supervision and support towards the LHWs developed the confidence and skills in the LHWs. LHWs also became motivated with the appraisal they received and they also improved in their performance. They eventually worked even with little supervision. The improved performance gave nurses confidence to train the LHWs in other fields which they also successfully performed. Training, supervision and support is therefore an important ingredient in any task shifting especially to non-professional and untrained health professionals.

11.5 PhD contribution: methodological innovation of evaluating complex interventions for chronic disease management

In this section, I will discuss three levels of how this PhD has contributed to the body of knowledge on innovative methodological approaches of evaluating complex clinic based interventions for improving management of chronic diseases.

11.5.1 Unpacking the 'black box' of the randomised controlled trial

I have learnt that trials are able to answer questions on whether interventions were effective or not but are not able to provide additional information that are critical and useful to the implementation of the trial. As earlier expressed, there is increasing knowledge that realist evaluations can contribute to this knowledge. So the knowledge gap that is addressed in this realist evaluation has been the contribution made through this additional level of knowledge to understand the effect of the trial. It has contributed to the understanding of the trial results by unpacking the black box containing contextual factors and mechanisms that affected the implementation.

Thus, although the trial has generally presented that the outcome of the trial was not effective as it did not have an impact in controlling population level of HBP, the realist evaluation was valid and useful in understanding what happened during the implementation period and how it affected the outcome of the trial. The realist evaluation has explained the intervention, the causal pathways and their effects on the outcomes. Rather than just identifying barriers and facilitators, it has unpacked the interaction between context and how actors engaged with the intervention (mechanisms). Thus the contribution of this thesis: *"that trials cannot answer contextual questions but realist evaluations can.* In so doing, I have been able to understand the impact of the trial on the functioning of the clinics and further categorize the clinics that functioned better than those that did not function better, rather than having a blanket conclusion that the trial was not effective.

Unlike other approaches to programme evaluation, a realist evaluation is not necessarily a method but logic of inquiry (141). Realist evaluations are based on theories. They generate a theory prior to the evaluation, test it and end with a theory about how the programme worked (100). This process helps in analysing and understanding what mechanisms will lead to outcome and what factors in the context will affect the mechanisms (100). To achieve in-depth inquiry, realist evaluation employs a mixed methods approach to data collection. The data is collected

throughout the implementation process, from different sources and requires a wide range of research expertise. This approach is unlike other qualitative evaluation methods that are: impact focussed, aims at just understanding barriers and facilitators to implementation and are usually conducted at the end of an intervention.

Different studies that have either used realist evaluations or nested realist evaluation into RCTs have had different experiences in their approach. Some authors have identified that in complex interventions, complexity is associated more with the context than the intervention itself. (102, 142) Similarly, the context in which the LHW intervention was implemented was more complex than the intervention itself. This PhD therefore argues that most often, it is the complexity of the implementation context i.e. level of resources and relations that contribute to the complexity of interventions. There is also need to reflect upon how context influences mechanisms. (102) The experience from the LHW intervention demonstrates how resources and the broader clinic context impacted on the reasoning among participants. For instance, stronger clinic management was likely to motivate good relations and support for the intervention.

11.5.2 Contribution to the global debate on combining realist evaluations and trials

This is the first time a realist evaluation of a complex clinic based LHW intervention has been undertaken in rural primary care clinics in South Africa. I believe that lessons learnt from this study and its approach could be relevant for other complex health interventions nationally. This is an approach of using realist evaluations within RCTs also known as 'realist trials'. Although this is a growing field, it is a field that has a lot of debate currently underway with realists opposing the idea of combining realist evaluations and trials while trialists support the idea. It was therefore necessary that this PhD contributes to this global debate and present its position based on primary data generated from implementing a complex health intervention.

What is the debate? *Realists* focus on finding out 'who' the intervention would work for and 'why' (99). To achieve this, the intervention is implemented in a wide range of contexts and exposed to different mechanisms. For instance, some trial sites can be purposely selected in urban areas while others in rural areas and some sites can be in poor communities while others in wealthier communities. *Trialists* aim at just finding out if a specific product/ intervention works or not (105). They do this by identifying two groups (intervention and control) at random from a large number to make sure that there is no systematic difference between the two and to reduce bias (105). *Trialists* argue that they can use process evaluation to describe their context in detail so that somebody else in another context can make a judgment whether it would work in their context or not. *Realists* argue that by cancelling out differences among the intervention and control groups, it is difficult to ascertain whether the intervention will be effective across the country or in specific areas.

In this LHW intervention, we partially combined the RCT and realist evaluation as we did not purposively choose our sites based on their differences. However, I do know that even within the same site, clinics have varied differences in their context and mechanisms. Therefore, I was able to know who the intervention worked for in terms for the clinics and patients. The intervention was successful in clinics with better resources, management and relations. The intervention also worked better for patients who were older and patients who were female, attending intervention clinics. Among others, they adhered to their appointment dates. As a contribution to this debate, I support the notion that realist evaluations can be used with RCTs and can be used to explain and strengthen findings from the trial. However, trialists should consider more about context and describe it in detail while understanding the mechanisms by which the intervention works as suggested by the recent MRC process evaluation guidelines for complex intervention (5).

Different authors have written on realist or process evaluations that have been nested in RCTs. Such studies aimed at examining the intervention implementation process and its relationship to trial outcomes. A Process Evaluation of an Efficacious Family-Based Intervention to Promote

Healthy Eating noted that most often, participant engagement is not reported in process evaluations yet it predicts programme outcomes (93). In the LHW study, we had a critical review of participant engagement and reasoning in particular contexts. A multi-center, multi-faceted RCT to decrease type 2 diabetes mellitus in middle school children had no significant differences in the main outcome measures between control and intervention groups. However, process evaluation data showed a lot of positive changes. Similarly, despite having no impact on primary outcomes, the LHW trial improved functioning of clinics. This demonstrates the wide acceptance that nesting process evaluations in RCTs unearths critical elements that works in a seemingly unsuccessful trial (95).

11.5.3 Demonstrating how to use a wide range of theories and conceptual frameworks

The methodological approach in this PhD has also shown an understanding of a wide range of approaches, theories and conceptual frameworks in conducting realist evaluations of complex health interventions. This PhD experience presents a methodological approach in realist evaluations that adapted and combined different reasoning from different authors. Its innovativeness has been the ability to adapt and use different theories and frameworks that strengthened the realist approach in this evaluation. These include the MRC process evaluation framework for complex health interventions and Pawson and Tilley's realist methodological approach, and Wagner's ideal chronic care model and the theory of complex adaptive system. Although each one of these have a unique focus as explained earlier in this chapter, their combined use has strengthened the methodological approach in this study. For instance, while the Wagner theory only covers the elements that must interact for an ideal chronic care, the complex adaptive system has complemented by considering unique nature of individual clinics as a result of learning, changing and co-evolving taking place in the clinics.

Van Belle et al have supported the use of theories in implementation studies (143). They have noted that using existing theories to inform research helps in understanding the effectiveness and implementation process of policies, programmes and interventions. It also highlights causal

processes for such interventions (143). The theories help researchers in developing hypotheses for theirs studies, which act as a guide in testing the hypothesized causal pathways. Realist evaluation is acknowledged as one theory driven approach that develops a theory during analysis by considering different other social science theories and concepts (143). In this way, realists are able to explain the intervention, context, mechanisms and outcomes (143). Use of different theories and frameworks in this thesis has helped me to be critical of my own work presented in this report. It has helped me in reorganizing a complex mix of factors affecting the intervention and make meaning of a particular scenario in a particular context. For instance, while I look at how 'objects' like BP machines and their effects on motivation, management and relations in a clinic (with reference CMOs in realist evaluation), I have had to understand that would require health service providers intervening at District/ Provincial level (Wagner theory) and that the situation is not the same across all clinics (CAS theory).

11.6 Weaknesses and limitations of the study and how they were addressed

In this section I reflect on challenges experienced during the evaluation and potential limitations that affected the conduct of the evaluation. I will also explain how I tried to address or limit the potential negative influences of these challenges and how they were actually addressed. I identified three main challenges: a) clinic observations and observation of patients' consultation as a data collection method, b) my conflicting roles as researcher and project site manager and, c) deciding whether the study findings were a representation of South African context. As a researcher, I was aware of these challenges and that they might have subsequently influenced the writing of this report.

11.6.1 Clinic observations and observation of patients' consultation as a data collection method

This was one of the key data collection methods in understanding clinic operations. The process involved a fieldworker staying in the clinic and observing different activities taking place in the

clinic. It also involved the fieldworker sitting in a consultation room and observing a consultation process of a hypertensive patient. With having a fulltime external person watching over the work of clinic staff, the staff was likely to change their approach and attitude towards work. They were likely to give out their best and perform to expected standards (Hawthorne effect). Such changes could eventually influence data collected through this process. I addressed this potential problem by ensuring observation period run from one to three weeks spread across the whole implementation period. After the first week, nurses were likely to revert to their normal practices i.e. not willing to work in the afternoon, without the feeling of being watched. Use of local fieldworkers/ observers was also important as they understood conversations and practices in the clinic. Observers were also seen as peers by most of the clinic staff hence easier to integrate as part of clinic staff.

11.6.2 My conflicting roles as researcher and project site manager

I had two seemingly conflicting roles in the study that might have influenced the process of collecting data and writing of this report. As a researcher, my primary role was to conduct the realist evaluation for the trial upon which this PhD is based. I developed the protocol for the realist evaluation, applied for ethics approval, led a team of field workers in data collection, analysed the data and wrote the report. On the other hand, I was also employed as the project site manager for the whole trial. This role involved administrative management of the trial including management of the baseline and end of intervention population surveys. It involved ensuring that all resources for the trial are available. Consequently, staff in the DSS, staff in the clinics and the implementation team at times viewed this role as covering management of the intervention itself (which was the role of the Implementation Manager). At times, the Implementation Manager consulted me on issues concerning the intervention. However, I noted this conflict and tried to keep my role as a researcher and management of the intervention apart. For instance, the Implementation Manager was excluded from all discussions pertaining research data during project management meeting. During intervention team meetings and workshops, I limited my role to that of an observer.

11.6.3 Deciding whether the study findings were a representation of South African context

One key contribution this study can make is to improve of management of patients with chronic diseases in South Africa as a whole and not limited to the study site context. Understandably, the idea of realist evaluations is to determine particular contexts and mechanisms through which the intervention can be effective, which are bound to vary across South Africa. On the other hand, realist evaluations do not present a 'one size fits all' solutions but rather specific elements that can work in particular context. I believe findings from this evaluation will help policy makers and program planner in deciding specific elements to strengthen for a successful LHW intervention in particular and chronic care generally. There have also been several studies (49, 58-60) whose findings have presented similar challenges related to primary health care as contextual challenges affecting the clinics in South Africa i.e. issues of infrastructure, equipment, drug supply, clinic managements etc. This confirms that findings from this study have potential of being applied to a broader South African context.

11.7 Strengths of the study

11.7.1 Conducting the study in a health and demographic surveillance site

As earlier discussed on the section on 'study site', it was advantageous to conduct the study with a well-established HDSS site. Since 1992, the MRC/Wits Agincourt HDSS has built a strong relationship and trust with people in the study site and different service providers including clinics. This trust ensured credible, reliable and trust worthy data, provided by the respondents who freely participated in the study. There is also a team of experienced field workers from within the communities. These are individuals that have grown up in the communities and understand the local language and context very well. They also understand the different transitions that have taken place in the community including health care. There was timely administrative support from Agincourt management team including linking and introducing the

trial at Provincial, Sub-district, facility and community level through its Learning, Information, Dissemination and Networking with the Community (LINC) office.

11.7.2 My experience with health policy and systems in Southern Africa

My background and experience with health policy and systems research and programme implementation work in Southern Africa was significant to the implementation of this study. Particularly, as a member of staff and researcher for Centre for Health Policy at Wits School of Public Health, it has exposed me to several discussions, debates and literature on the background and current status of the South African health system. I have also worked on other multi-country research work in areas of HIV and AIDS, sexual and reproductive health and maternal and child health. I have closely worked with Malawi's Ministry of Health in championing uptake of research into policy and practice (knowledge translation). My other current role includes chairing a Process Evaluation working group for Global Alliance for Chronic Diseases (GACD) – an alliance of over 30 research projects focusing on understanding and addressing the burden of chronic diseases globally. During the three-year study implementation period of the Nkateko study, I worked full time and stayed within the Bushbuckridge sub-district. This helped me to further understand the local context and the primary data that I collected.

11.8 Could I have done the study better?

If I were to do the study again, what would I do differently? This is an important area to reflect upon for the benefit of other researchers planning to embark on studies with similar methodological approaches. There are a few areas that would have needed thorough review if I was to conduct the study again. Firstly, I would have cut down on the number of observation days and maintained them at 10 days for each observation period. I noted that the one week (5 days) observation period was too short to come up with substantive data and the three weeks (15 days) observation period was too long and reached saturation point very quickly.

To strengthen the qualitative data collection methods and get valuable data about functioning of clinics, I would also engage LHWs in writing diaries as was the case with the Implementation Manager. I noted that during the monthly interviews, LHWs had problems in recalling everything that happened in the clinics during the month. Although they still provided useful data which was collaborated with observation notes, diaries and interviews with the Implementation Manager, LHWS diaries might have given additional valuable information about day to day functioning of the clinics that I might have missed.

11.9 Conclusion (How study finding affect policy and practice)

In conclusion, I have learnt that the LHW intervention was implemented in different ways based on the specific clinic needs and individual capacities of LHWs and nurses. The LHW intervention was more effective in some clinics compared to others based on the different moral and resource support that the LHWs received. The intervention worked better in well-resourced clinics that had motived and well-related nurses. The intervention had other unintended consequences like LHWs being trained in several other tasks and supporting the clinic in broader terms than designed. The effects of the LHW intervention are unlikely to be sustained without the LHWs in the clinics. The intervention clinics will thus operate as control clinics by having nurses taking back the tasks of LHWs just as was the case before the intervention.

Findings from this realist evaluation have raised a number of issues with implications on policy and practice for the South African health system and that contributes to the various debates at policy level. The following are the key areas that researchers and decision makers need to consider:

11.9.1 Task shifting from nurses to lay health workers

This is an important area in the face of growing debate on the extent of the contribution LHWs can make at a low cost when certain medically and socially oriented tasks are shifted from trained nurses to the LHWs at clinic level. As explained in preceding sections, with proper selection, training, supervision and adequate remuneration, LHWs have proved an effective and low cost intervention in supporting and relieving burdened nurses in chronic care management in rural clinics. This evaluation therefore supports a policy reflection on how the health system can engage a cadre of clinic based LHWs to support implementation of the ICDM initiative. As earlier explained, we should also take cognizant that such a clinic based LHW intervention can only be effective in a clinic with adequate infrastructure, functional equipment i.e. blood pressure machines, adequate supply of medication and other materials.

11.9.2 Measuring vital signs

Policy makers need to reflect on the consequences of measuring vital signs for every patient that comes along in the clinics. Much as the practice could be likened to population screening of HBP with the intension of increasing on identification of raised blood pressure, I have learnt from this research that on the other hand, the practice has further strained the rural clinics. I have learnt that due to the increased number of patients with chronic diseases and the increase of the older population with higher risk of chronic diseases, nurses have had to measure vital signs for an increased number of patients. Resultantly, the vital signs monitors have been overwhelmed. They have often broken down without any maintenance. There is no regular functioning process of servicing the BP machines. BP cuffs have frequently become worn out against a bureaucratic process of procurement to replace them. Nurses have become reluctant to use the manual BP machine as they claim the stethoscope hurts the ears when used on a large number of patients. This research therefore suggests targeted screening where blood pressure measurement is only done to those at risk of developing HBP.

11.9.3 Verticality in programme delivery

Thirdly, there is need to reflect on vertical management of programmes at district and health facility level. Kawonga et al (25) has noted that there are high degrees of verticality within the district health system that hinder advances towards integrated health services. This evaluation experienced in practice, effects of some of the vertical programmes. Though the ICDM is championing an integrated approach to management of chronic diseases, there are still other programmes that focus on specific diseases (i.e. HIV) and ignore others (i.e. hypertension). I have primary data that shows that follow-up of patients that default treatment is only done to HIV patients. Data entry clerks only wanted to handle files and enter data for HIV patients amidst shortage of staff and lay counsellors that could not help in other clinics tasks apart from HIV counselling and testing. On the other hand, I also have data that showed positive effects with LHWs supporting all patients with chronic diseases i.e. in appointment booking, file management and measuring vital signs. This evaluation supports ICDM and lobby for continued progressive integration of health services.

11.9.4 Strengthening primary health care services for effective chronic care management

This research has confirmed that chronic care management in primary health care clinics is faced with a variety of impediments. Central to these challenges has been an increase in the number of chronic patients as identified in this and other studies. Such an increase is against limited levels of human and material resources. Apart from the increasing patient load for chronic diseases, this evaluation has established several other factors that further weaken the rural primary health care clinics for effective chronic care management. These factors include; weak clinic management, limited supervision and motivation among clinic staff, deteriorating infrastructure, erratic supply of medication, limited supply of materials and maintenance of essential equipment.

Several of these factors are not new to the primary health care clinics in South Africa and have been raised in various literatures. Some authors have suggested "*induction and peer-mentoring for newly appointed facility managers, ongoing peer-support once in post and continuous reflective practice"* (144) as a way of supporting leadership development among Clinic Manager who mostly have a nursing background with no management experience. Strengthening relations between Clinic Managers, Clinic Supervisors, management of the sub-district and different service providers is one way of strengthening primary health care clinics. There is also generally need to improve on procurement and maintenance approaches – to have processes that urgently respond to the needs of local facilities. I believe that improvements in these areas would subsequently improve the primary health care facilities which are the faces for health care service delivery at local level.

11.9.5 Potential programme uptake in the health system (feasibility, sustainability, and acceptability)

The realist evaluation has presented data on whether the complex LHW intervention program was a feasible, acceptable and sustainable model for this context. These are important elements for policy makers and programme implementers when reflecting upon taking up the initiative into the health system. Feasibility, scalability, sustainability and acceptability entails whether the LHW intervention is capable of being well implemented, can be expanded, its benefits can be maintained/ sustained over time and, whether it is socially and culturally acceptable among the citizenry. In this evaluation, I have data to support or object to these assertions.

The findings from this realist evaluation have shown that the LHW intervention can be implemented and generate the required results. Although with no impact on population control of hypertension, clinic link data supports the *feasibility* of the intervention through clinic level outcomes. The outcomes have shown that patients in the intervention clinics were more likely to adhere to their appointment dates. Other qualitative data from observations and interviews

has also shown intermediary outputs i.e. changes in prepacking medication, management of files, improvements in management of appointment systems and generally better functioning of ICDM. I believe that these benefits can be expanded on a larger scale with proper supervision and support.

I have also seen the intervention maintaining the same LHWs throughout the implementation period, LHWs performing to the expected standard even with little supervision and working relationship with other staff and patients improving over time. This supports the notion that the intervention is a *sustainable* adventure especially on the premise of involving local people from within the community both in the development and as implementers (LHWs).

I have also evidence on how both staff and patients appreciated the role of LHWs in the clinics and how both staff and patients were worried about the intervention coming to an end. There were not any reported cases of the programme infringing on the social and cultural life of the community. All this evidence shows how *acceptable* the intervention was and supports potential programme uptake in the health system if implemented within the ideal context

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APPPENDICES

Appendix A: **Ethics clearance certificate**

Appendix B: **Data collection tools**

Appendix C: **Booking and appointment registers in clinics**

Appendix D: **Guide for naming data files**

Appendix E: **Data extraction sheet**

Appendix F: **Turnitin report**

Appendix A: Ethics clearance certificate

M140619

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140619

NAME: (Principal Investigator)	Mr Felix Limbani
DEPARTMENT:	School of Public Health Agincourt, Mpumalanga
PROJECT TITLE:	A Realist Evaluation of a Clinic Based Lay Health Worker Intervention to Improve the Management of Hypertension in Rural South Africa
DATE CONSIDERED:	27/06/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Jane Goudge
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 22/08/2014

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

DECLARATION OF INVESTIGATORS

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

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

Principal Investigator Signature M140619Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B: Data collection tools

B.1 Clinic observation framework

1. Name of facility	
2. Name of person making observations	
3. Date	

Notes to observers

- Detailed field notes must be kept for each visit. This tool includes a list of issues for you to consider in the observation. Please write detailed descriptions of what you see. In places you will also need to answers the questions below.
- During the observation, detailed attention should be paid to the 'who, what, where and when' of the different processes taking place at the facility. Here, a detailed description of the steps an average patient goes through from arrival to leaving the health facility. The what, with whom, where and when should be derived from observing several individual patients and should be summarized, e.g. in tabular form.
- After these more general observations, the focus of the observation should shift to the interactions between people in the facility (providers and patients, providers and each other, patients and each other).
- This is not JUST a questionnaire. Rather, it is a set of categories/themes to guide the observation process.

Pathway of care	**Problem along pathway that leads to loss of patient from care**
Step 1: Hypertensive patient in the community	**Problem 1:** Doesn't go to clinic for hypertension or for any other reason
Step 2: Patient goes to clinic, for hypertension or another reason	**Problem 2:** BP not measured
Step 3: BP taken by receptionist or health care worker	**Problem 3:** BP not recorded; **Problem 4:** Patient and/or nurse not told BP level **Problem 5:** Patient not given medication, adherence counselling, and/or lifestyle advice, **Problem 6:** no return appointment made
Step 4: Given diagnosis, medication, and/ or asked to come back for another test	**Problem 4:** Doesn't come back (no money, doesn't think it is serious) **OR** only comes irregularly (because of money, access, ill health, migrant worker)
Step 6: Comes back regularly >> but various problems prevent access to care or deter patient from regular attendance	**Problem 6:** Drug supply is erratic; **Problem 7**: Patient file is lost, so don't know patient history; **Problem 8:** Long queues / no drugs **Problem 9:** Nurses are overwhelmed by HIV patients, pay little attention to HT patients; **Problem 10:** Nurses are rude to patients /indifferent to needs to patients
Step 7: Comes back regularly	**Problem 11:** Collects but doesn't take pills (BP is not reduced)
Step 8: BP is reduced	

MAP OF CHRONIC PATIENT PATHWAY AND STATIONS ALONG THE WAY

Please develop your own KEY. These are some examples:
N=nurse; LHW=lay health worker; DC=Data capturer
eg. LHW (vital signs) = a roving LHW who is doing the vital signs temporarily
eg. LHW (booking) = a LHW who was doing the booking most of the day

PLEASE DESCRIBE WHAT IS HAPPENING ALONG THE PATIENT PATHWAY IN YOUR OWN WORDS

Include patients, clinic staff, how the various forms and files are being used.

PLEASE DESCRIBE THE FOLLOW UP OF PATIENTS WHO DON'T COME ON THEIR APPOINTED DAY

1. Is any follow up done; who does it; how?
2. Please describe the follow up process;
3. What happens when a chronic patient comes when they don't have an appointment

PLEASE DESCRIBE HOW MINOR AILMENT PATIENTS WITH RAISED BLOOD PRESSURE ARE BEING FOLLOWED UP

DESCRIPTION OF THE CHRONIC DISEASE FILING

1. Please describe how the filing system works?
    - Does it work with numbers, or name, or ID
    - Are patients' files pulled out prior to the patient's arrival?
    - Are files filled back again the same day?
    - Describe what the patients carry with them;

2. Are there problems with the filing system that you can see? If yes please describe...
    - What happens if a person doesn't have their card or book?

THE NATURE OF THE INTERACTION: Amongst health workers, and with patients in general

Please describe interactions between staff to illustrate your conclusion

Include an account of the discussions at the staff meeting

DAILY TASKS

Please describe examples

1. How do people go about their jobs on a day-to-day basis (with diligence, calmly, carelessly, distractedly)?
2. Do staff members seem happy, willing, resentful, disinterested, afraid?
3. How often do staff members take breaks? How long are these breaks? Do they take them at the same/different times?
4. How busy do providers seem to be? Are they all equally busy? Are they busy at certain times, or the whole day?
5. Are staff members given 'freedom' to conduct their duties in an uninterrupted way or do supervisors interrupt arbitrarily?

GENERAL CLINIC OPERATION

How many patients were in the queue as the clinic was opening

How many patients are in the queue one hour after opening?

How many patients are in the queue at 11am?

How many patients did the nurse tell to come back tomorrow?

Number of nurses present today?

Is there a chronic care clinic today?

Number of nurses in chronic disease treatment room (s)?

Are there any CHWs at the clinic? How many?

Please describe their activities?

How many working BP machines are there? What type of machines are they (electronic or sphygmomanometer?) If electronic, are replacing the batteries a problem, please describe

Are there both big and small cuffs

MEDICATION

Please describe the system for giving the patients their medication

Remember the difference between objective and subjective notes

1. Is the medication given to patients in the consultation room? ; Is it prepared ready before the patient comes?
2. Who is doing this and where?

Does the clinic have the following drugs

Name of drug	**Is this drug in the clinic?**
Hydroclorotiazide (HCTZ, RIDAC)	
Perindopril (Prexum, Coversyl)	
Indapamide (Prexum plus, Coversyl plus)	
Enalapril (Pharmapress)	
Atenolol (Tenblocka)	
Nifedipine (Slow release, Adalat XL, Amloc)	

OTHER OBSERVATIONS

About the context

About the time taken to do some processes

About the processes and interactions

About the actors involved

Other issues?

B.2 Patient observation framework

OBSERVATION OF CONSULTATION WITH HYPERTENSIVE PATIENTS

Please complete this check list for 5 consultations with hypertensive patients. Approach a patient in the queue (or ask nurse to introduce you) and ask if you may accompany them. **SOME QUESTIONS YOU WILL HAVE TO ASK THE PAPTIENT DIRECTLY (E.G. ABOUT BP IS MEASURED BEFORE CONSULTATION)**

	Patient 1
0. Nurse descriptor (red shoes / braids etc)	
1. Brief description of patient (gender, age,)	
2. whether and who measures blood pressure;	
3. where is this information recorded;	
4. Whether patient was told reading,	
5. whether the reading is explained to the patient,	
6. relevant life style advice is given (reduce salt, exercise, lose weight)	
7. Is medication given?	
8. whether a return appointment is booked;	

Patient 1
Describe engagement between nurse and patient, patient's language, body language, eye contact, facial expression, was nurse concerned about patient?

B.3 Patient observation framework (consultation length)

OBSERVATION OF NUMBER AND LENGTH OF CONSULTATION WITH CHRONIC PATIENTS

Please complete this form for **ALL** consultations with chronic patients on this particular day. **Sit outside the chronic room. Observe the number of chronic observations made in each chronic room and the length of each consultation.** At the end of the day, confirm with the LHW/chronic care nurse on the total number of booked and unbooked patients for the day. These observations must take place for all the 3 days of clinic observations.

4. Name of facility	
5. Name of person making observations	
6. Day and Date	

Patient No.	Chronic room 1 (time in minutes)		Patient No.	Chronic room 2 (time in minutes)
1.			1.	
2.			2.	
3.			3.	
4.			4.	
5.			5.	
6.			6.	
7.			7.	
8.			8.	
9.			9.	
10.			10.	
11.			11.	
12.			12.	
13.			13.	
14.			14.	
15.			15.	
16.			16.	
17.			17.	
18.			18.	
19.			19.	
20.			20.	
21.			21.	
22.			22.	
23.			23.	
24.			24.	
25.			25.	
26.			26.	
27.			27.	
28.			28.	
29.			29.	
30.			30.	

B.4 Questionnaire for patient exit structured interviews

NKATEKO TRIAL
PATIENT EXIT INTERVIEWS

Questionnaire
Fieldworker: I I I I
Date: Y Y Y Y M M D D

0a	Mbuyelo wa mbhurisano *Interview outcome*	**1** = Interview complete **2** = Interview partly completed (write down why not completed) 3= Refusal	**0a** 1
0b	Comment		

Yana emahlweni na ntirho tani hi laha papilla ra mpfumelelo ri vuleke ha kona.
Now carry out the process of getting informed consent as instructed.

Introduction to the questionnaire: The following questions ask about your experience of care at the clinic.
DO NOT INTERVIEW SOMEBODY WHO HAS COME ON BEHALF OF THE PATIENT

PATIENT EXIT INTERVIEW

1	*Date and time of interview*	**yyyy/mm/dd/ hr/mins**	**1** Y Y Y Y M M D D h h m m
2	*Vito ra kliniki* *Clinic name* (interviewer to complete)	**1**= Agincourt **4** = Cork **7** = Lillydale **2** = Arthurstone **5** = Cunningmore **8** = Justicia **3** = Belfast **6** = Kildare **9** = Xanthia	**2** 1
3	*Rimbewu* *Gender (interviewer to complete)*	**1 =** male ; **2 =** female	**3** 1 1
4	*Xana u na malembe mangani?* *How old are you?*	Age in completed years **(write 00 if not known)**	**4** 1 1
5	*Xana u nga va u tiva nkarhi lowu u teke hi wona laha kliniki namunthla?* *Do you know what time you came to the clinic today?* *(probe if respondent unsure using questions like "Were you here when the clinic opened?" or "Were you here when there was health talk in the morning?")*	hrs/mins **(write 99 99 if respondent doesn't know)**	**5** h h m m
5a	*Xana munghenelerí a ti tshemba ku fika kwihi mayelana na nkarhi lowu a fikeke hi wona ekliniki?* *How confident the respondent was in relation to time of arrival to the clinic?*	1=respondent confident of the time 2=respondent uncertain 3=respondent unable to give time at all	**5a** 1
6	*Xana mabelo ya wena ya mbilu ma pimiwile namunthla?* *Was your blood pressure measured today?*	**1** = Yes **2** = No	**6** 1
7	*Xana u kumile marungula hi riqingho ku tsundzuxiwa leswaku u ta ekliniki namunthla ku suka eka un'wana wa vatirhi va laha kliniki?* *Did you receive an SMS reminding you to come to the clinic today?*	**1** = Yes **2** = No	**7** 1
8	*Xana u nga va u foneriwile ku tsundzuxiwa leswaku u ta ekliniki namunthla ku suka eka un'wana wa vatirhi va laha kliniki?* *Did you receive a phone call reminding you to come to the clinic today?*	**1** = Yes **2** = No	**8** 1
9	*Xana u n'wana wa vatirhi a nga va a vulavurile na wena ku ku tsundzuxa leswaku u endzela kliniki namuntlha?* *Did someone from the clinic speak to you reminding you to come to the clinic today?*	**1** = Yes **2** = No **(--->Q11)**	**9** 1
10	*Xana marungulo hi riqingho,kumbe ku foneriwa na switsundzuxo swi ku pfunile e ku ku tsundzuxeni ku ta ekliniki?* *Was the SMS/phone call/reminder helpful in reminding you to come to the clinic'*	**1** = Yes **2** = No	**10** 1
11	*Xana u na nkarhi wo fika kwihi u ri karhi u teka vutshunguri bya mavabyi ya high blood?* *How long have you been receiving treatment for hypertension?*	**1** = Less than 6 months **2** = From 6 months to less than 1 year **3** = 1 year to less than 2 years **4** = 2 years to less than 5 years **5** = 5 years and above	**11** 1
Xana u vulavurile na mutirhi wa swa rihanyu mayelana na swin'wana swa leswi swi landzelaka?(hlaya nxaxameto) *Did you talk to a health worker today about any of the following? (read out list)*			
12	*Swilo leswi u swi dyaka?* *The things you eat*	**1** = Yes **2** = No	**12** 1

13	*Ku hunguta mpimo wa munyu eka swakudya swa wena?* *Reducing the amount of salt in your food?*	**1** = Yes **2** = No	**13**	1
14	*Ku endla vutiolori?* *Doing exercise*	**1** = Yes **2** = No	**14**	1
15	*Maphilisi/vutsunguri lebyi u byi tekaka na leswi u faneleke ku tekisa xiswona?* *The pills you take and how you should take them*	**1** = Yes **2** = No	**15**	1
If ALL questions from Q12 to Q15 the response is NO, skip to Q17				
16	*Xana u ehleketa leswaku u ta cinca swin'wana swa leswi u swi endlaka hikwalaho ka leswi mutirhi wa swa rihanyu a ku nyikeke swona?* *Do you think you will change anything you do because of the advice the health worker gave you?*	**1** = Yes **2** = No	**16**	1
17	*Xana u vone onge mutirhi wa swa rihanyu a ri na ku khumbeka leswaku u van a rihanyu lerinene?* *Did you feel the health workers cared that you have good health?*	**1** = Yes **2** = No	**17**	1
18	*Xana ku nga va ku ri na vutshunguri/mirhi yo karhi leyi muongori a fanele a ku nikile kambe yi nga ri ki kona laha kliniki?* *Is there any medication that the nurse should have given you but is out of stock?*	**1** = Yes **2** = No	**18**	1
19	*Xana masiku ya wena ya ku endzela laha kliniki nakambe ma rini?* *When is your return date?*	Y Y Y Y M M D D		
QUESTIONS FOR PATIENTS AT INTERVENTION CLINICS only Sweswi ndzi lava ku ku vutisa swivutiso swin'wana mayelana na vapfuneti va swa rihanyu. I tintombhi leti mbaleke (muhlovo) wa mahembe. Now I want to ask you some questions about the lay health workers in the clinic. They are the ladies wearing the (colour) shirts				
20	*Xana u twile tidyondzo ta swa rihanyu ku suka eka mupfuneti wa swa rihanyu namunthla?* *Did you hear a health talk from a lay health worker today?*	**1** = Yes **2** = No	**20**	1
21	*Xana u vulavurile na mupfuneti wa swa rihanyu namunthla?* *Did you talk to a lay health worker today?*	**1** = Yes **2** = No **(end of questionnaire)**	**21**	1
Xana I yini leswi u swi vulavuleke na mupfuneti wa swa rihanyu? (hlaya nxaxameto) *What did you talk to the **lay health worker about**?**(READ OUT THE LIST)***				
22	*Ku va mabelo ya mbilu ya wena ma pimiwa?* *Having your blood pressure measured?*	**1** = Yes **2** = No	**22**	1
23	*Ku endla siku ro vuyela ekliniki nakambe?* *Making an appointment to come again?*	**1** = Yes **2** = No	**23**	1
24	*Ku landza vutshunguri bya wena?* *Collecting your medication?*	**1** = Yes **2** = No	**24**	1
25	*Swakudya leswi u swi dyaka?* *The things that you eat?*	**1** = Yes **2** = No	**25**	1
26	*Ku hunguta mpimo wa munyu eka swakudya swa wena?* *Reducing the amount of salt in your food?*	**1** = Yes **2** = No	**26**	1
27	*Ku endla vutiolori?* *Doing exercise?*	**1** = Yes **2** = No	**27**	1
28	*Maphilisi/vutsunguri lebyi u byi tekaka na leswi u faneleke ku tekisa xiswona?* *The pills you take and how you should take them?*	**1** = Yes **2** = No	**28**	1
29	*Xana ku nga va ku ri na swin'wana?* *Anything else the Lay health worker talked about?*	**1** = Yes **(give details)** **2** = No **(---> Q31)**	**29**	1
30	*Comment*			
31	*Xana u ehleketa leswaku u ta cinca swin'wana swa leswi u swi endlaka hikwalaho ka leswi mutirhi wa swa rihanyu a ku nyikeke swona?* *Do you think you will change anything you do because of the advice the lay health worker gave you?*	**1** = Yes **2** = No	**31**	1
32	*Xana u nga va u twe onge mupfuneti wa swa rihanyu a ri na ku khumbeka leswaku u va na rihanyu lerinene? (nhlamulo yin'we)* *Did you feel the lay health worker cared that you have good health? (single answer)*	**1** = Yes **2** = No	**32**	1
33	*Is the patient **booked** or **unbooked**?*	**1** = booked **2** = unbooked	**33**	1

B.5 Semi-structured Interview guide for patient cohort interviews

Instructions to fieldworkers

In this interview please can you describe the overall subject of the interview to the respondent, using the "grand tour" question? Once you have broadly informed the respondent what we are interested in, the respondent is then free to choose which sections they wish to talk about, which issues are most relevant to them. With this more open structure, it is easier to for respondents to describe specific events or examples.

Cohort 1: at intervention clinics, intermittently adherent & those with high level of adherence

Grand tour question

I would like understand about your experience of having high blood pressure and the care you receive at the clinic? For example, you tell me about taking pills, the difficulty (or not) of going to clinic regularly, or to the hospital. We are particularly interested in hearing about your experience of receiving care at the clinic, both the good and the bad things from the time you started your medication.

.

To prompt with the following if topics don't come in conversation:

Taking pills; keeping appointments
Experience of care in the clinic; (what you like and what you don't like about the clinic)
Changing diet? / exercise?
6 monthly visits to hospital
Role and support from the LHWs
Support from the nurses
Support from family and community
Other problems that you face in controlling your BP or getting the care you need

Cohort 2: attending control clinics

Grand tour question

I would like understand about your experience of having high blood pressure and the care you receive at the clinic? For example, you tell me about taking pills, the difficulty (or not) of going to clinic regularly, or to the hospital. We are particularly interested in hearing about your experience of receiving care at the clinic, both the good and the bad things from the time you started your medication.

To prompt with the following if topics don't come in conversation:

Taking pills; keeping appointments
Experience of care in the clinic; (what you like and what you don't like about the clinic)
Changing diet? / exercise?
6 monthly visits to hospital
Support from the nurses
Support from family and community
Other problems that you face in controlling your BP or getting the care you need

Cohort 3: Found with elevated BP during cross sectional survey but not on treatment - Attending either clinics.

Grand tour question

I would like understand about your experience of the care you receive at your clinic. If you have been to the clinic recently, how did nurses and other staff attend to you? What measurements/ examinations did they perform on you? What did they tell you about their findings? We are particularly interested in hearing about your experience of receiving care at the clinic, both the good and the bad things.

To prompt with the following if topics don't come in conversation:

Have you been to the clinic since the last time we measured your BP here last year?
If not, why? What have been the limiting factors?
If yes, what happened there?
Tell me what happened since then?
Do you think you will go back?
If not, why not?
Other problems that you face in controlling your BP (if the respondent is on BP treatment) or getting the care you need

B.6 Guide for monthly in-depth interviews with lay health workers

Main question: Please can you tell me what has been happening in the clinic?
Aim with this main question is to get the person talking...so may need to be silent and wait for them to talk. Once the LHW has said what is on their mind...then you can ask some more specific questions, such as:

- Can you tell me what have been your main activities this last month?
- Have they changed from the previous months? Why did you make these changes?
- Let's discuss each of those activities in detail.... (also ask to see forms/ card/filing system how and how it is working)
- What about non-LHW activities you have been engaged with in the clinics and why were you involved in those activities?
- Can you tell me about particular successes you have had in the last week or last month?
- Can you tell me about particular problems or challenges you have had?
- Tell me about how the clinic has been functioning this last week / month.
    - Major / notable events;
    - Shortage of nurses/patient load / appointments;
    - drugs/ equipment/ non-Nkateko CHW;
- Can you tell me about atmosphere/ relationship between different staff,
    - between staff and patients;
    - Staff meetings – how are they conducted and issues discussed

B.7 Guide for monthly in-depth interviews with the Implementation Manager

- What has been happening this month in X clinic?
- What are you spending your time doing?
- How are the clinics functioning?
- What are the LHWs doing, and is it helping? Successes / challenges?
- What other activities / changes are taking place in the clinic?
- Please describe the involvement of the facility manager

To prompt with the following if topics don't come in conversation:
Performance of LHW;
LWH Taking initiative;
LHW responding to problems;
Activities are co-evolving
Engagement between LHW and patients
Engagement between LHW and nurses;

REPEAT FOR EACH CLINIC

B.8 Interview guide for semi-structured interviews with clinic operation managers

Questions for clinic managers in intervention clinics only

I would like to hear from you, your experience with the programme - the roles of the LHWs, their performance, successes, changes, and challenges experienced in the clinic. What are the main contributions the LHWs and the programme in general, has made to the clinic

- Contributions
- Challenges
- Performance of LHW
- Engagement LHW and patients; LHW and nurses
- Role of implementation manager
- Change over time.
- If the programme was to be re-introduced, what would you recommend to change in its design and approach? And how?

Questions for clinic managers in intervention and control clinics

Staffing level: Staff working at the facility (even if not present on day of interview)

Number	Position / qualification	If attended recent training (if so what)	Responsibilities	Notes (if for example actual activities differ)

- What is your comment on the current level of staff in the clinic
- Last year (2014), there were stories of nurses resigning to get early pension. How did that affect your clinic?
- How does a clinic motivate to be allocated a nurse? Who makes the decision?
- What works well/ not so well with performance appraisals?
- PMDS – do nurses respond at individual or clinic level? Are they expected to put up same answers?

Chronic care

I would like to learn from you how chronic care is provided in this clinic. Every clinic has an 'ideal plan' of how things are meant to work, of what province wants to see when they come. But we all know in reality that life in a clinic is difficult. Sometimes you have enough nurses, sometimes you don't… even with the best will in the world, things don't go as you would like. So in answering my questions I would really appreciate it if you tell me your challenges and struggles…not just what you would like to achieve or where you think the district wants the clinic to be…but what really happens. So, how is chronic care provided in the clinic/ how are chronic patients managed? *Please probe if the following does not come out;*

Appointment system – what works well and what doesn't?

- Is there an appointment system in the clinic? Can you show me? Who is responsible?
- Are you able to follow up patients who don't come back regularly? If so how...
- Are chronic patients booked to come on every day of the week...or on specific days of the week?
- Are hypertensive patients booked for Doctor's review? How often? What happens when a patients does not go for doctor's review? Does the clinic continue to give more medication to the patient? And how long for?

Filing systems- what works well and what doesn't?

- How does the filing system work? Who is responsible? Are files pre-retrieved?
- What is the history of the filing systems in the clinics?
- What are Wits DTs generally doing in the clinic? How are they supporting the clinic?
- What happens if there is no any other space in the files for patients?
- How is the supply of files in the clinic? What happens when the clinic runs out of files?
- What happens when a photocopier runs out of ink, or breaks down?

Queuing/ chronic pathway - what works well and what doesn't?

- What does the receptionist do, if there is one?
- How does the vital signs station operate? Who is responsible?
- Can you explain how the chronic disease room operates? ...explain for HIV patients, TB patients, and hypertensive patients?

Patient management

- Explain to me the standard procedure of managing a minor patient who has been found with elevated BP.
- How helpful has PC 101 been? How confident are the nurses in using it?
- When did the hospitals start moving patients to clinics? What has been the impact? What had been the extra demand?

Difficulties from the health system

- What works well/ not so well with drug supply for chronic patients?
- What works well/ not so well with the referral system?
- What works well/ not so well with supply and maintenance of equipment including BP machines?
- What do they do when equipment breaks down? How do they get things repaired? Do they have any routine equipment maintenance

Role of community health workers (CHW)

- Are there any CHW associated with the clinic? How many? What activities do they do?
- Do some CHW conduct medical in the clinics like dressing wounds, taking vital signs (blood pressure, weight), If yes, have the CHW received related training?
- Do some CHW conduct administrative related activities e.g. filing?
- Who are they answerable to? Who pays them? DoH or NGO?
- What problems do you face with respect to the CHW programme?
- Apart from HIV counselling and testing, what other activities are performed by lay counsellors in this clinic?

Conclusion

- What are other difficulties you face in providing chronic are?
- Is there anything else to tell me?

B.9 Interview guide for semi-structured interviews with clinic supervisors, sub-district staff & PHC programme staff

Instructions to Interviewer

In this interview please can you describe the overall subject of the interview to the respondent, using the "grand tour" question? Once you have broadly informed the respondent what you are interested in, the respondent is then free to choose which sections they wish to talk about, which issues are most relevant to them. With this more open structure, it is easier to for respondents to describe specific events or examples.

Grand tour question
I would like to understand your experience and views of the Lay Health Worker programme. For example, tell me about how the clinics are functioning, the differences between clinics with LHWs and those without. Which clinics are doing well and why? What are the challenges and successes in the clinics? For Clinics with LHWs I am particularly interested in hearing what the LHWs are doing. So, what can you say about the LHW programme?

Please probe if the following does not come up;

- Which clinics are doing well and why?
- What the LHWs are doing?
- What the implementation manager is doing?
- What are the challenges / successes?
- Whether the management of the clinic is changing?
- Whether management of hypertension is improving?

Other areas to explore:

- What is the history of the filing systems in the clinics?
- Staffing levels – how does a clinic motivate to be allocated a nurse? Who makes the decision?
- What do they do when equipment breaks down? How do they get things repaired? Do they have any routine equipment maintenance?
- Explain to me the standard procedure of managing a minor patient who has been found with elevated BP.
- What qualifies one to become a clinic manager – any career development programme for the clinic managers?
- I also want to understand your own career history….What path to your current post, and your own experience of being a supervisor/ manager.

B.10 Guide for focus group discussions with community health workers

How many CHW are there in your team (group composition, probe about gender)? How many clinics are you working with? Name them.

What is the training that you have attended? (How recently, what topics – let the participants recall and discuss)

What type of patients do you normally see? What services do you provide (follow up questions to clarify?

Please can you describe your average day? What are the activities that do you normally do?

Do you deliver medicines from the clinic to patients? What type of patients...How many?
How many patients is each CHW responsible for? How many do you visit in a day? Do you manage to see all the patients you need to?

What distances do you manage to cover in a day? Walking/taxi? What are the problems?

Who do you report to? Please describe the NGOs you work for? Who works there and what do they do?

Apart from your work in the community, what work do you do in the clinic? Please describe your role. How were you oriented to this work?

How do you work with the nurses in the clinic? Do you go in every day? Do you talk to the nurses about specific patients? Please explain how this works (Is there a form you have to complete?)

What is your experience of patients who default on treatment? Is defaulting a big problem? Why do they default? What do you do to help them?

What challenges do you face in your work? Can you describe some specific examples of patients or events?

Are there any other problems that you face?

Is there anything else to tell me?

B.11 Guide for focus group discussions with members of community advisory group and clinic committees

The focus group discussion will be guided to cover the following topics:
Understanding of hypertension
What problems do patients face in getting to the clinic? Patients in general and Hypertensive in particular
What problems do chronic patients face at the clinic (e.g. HIV, TB, Hypertension and diabetes?)
What problems to patients face in taking hypertensive medication regularly over a long time?
What is their experience of using clinics e.g. process inside the clinic (queuing, filing system, and appointment system), attitude of the nurses, availability of drugs, doctors review (where do patients have to go to and difficulty of going there)
Is there anything you would like to see changed in the way the clinic is run?
What additional things would really improve the care that hypertensive patients receive?
Is there anything else to tell me?

If they have not earlier said anything about the following, also enquire:

- *What problems do hypertensive patients face every day in their communities where they stay?*
- *Chronic patients' experience in adhering to drugs and changing their lifestyle. How do they access such information?*
- *Explore about interaction between Hypertensive patients and Community Health Workers.*

B.12 Questionnaire for motivation interviews with nurses and data clerks

NKATEKO TRIAL
CLINIC STAFF INTERVIEWS

Questionnaire: ____
Fieldworker: ____
Date: Y Y Y Y M M D D

S1	Age	**S1**	1 1
S2	Gender	**1** = Male **2** = Female	1
0a	*Interview outcome*	**1** = Interview complete **2** = Interview partly completed (write down why not completed)	**0a** 1
0b	Comment		

Now carry out the process of getting informed consent as instructed.

Introduction to the questionnaire: We would like to ask you a variety of questions about your experience with your current work as a nurse.. **THIS QUESTIONNAIRE IS COMPLETELY ANONYMOUS.** Your supervisor or employer will **not** receive any information about your answers to these questions.

NURSES/ CLINIC STAFF INTERVIEW

1	*Clinic name*	**1**= Agincourt **2** = Arthurstone **3** = Belfast **4** = Cork **5** = Cunningmore **6** = Kildare **7** = Lillydale **8** = Justicia **9** = Xanthia	**1** 1
2	*Professional title*	**1** = Asst enrolled nurse **2** = Enrolled nurse **3** = Professional nurse **4** = PHC or other specialized nurse **5** = Other ➔ **Q2b**	**2** 1
2b	*If other, specify*		
3	*How many years worked as a nurse/ staff?*	**1** = Less than 6 months **2** = From 6 months to less than 1 year **3** = 1 year to less than 2 years **4** = 2 years to less than 5 years **5** = 5 years and above	**3** 1
4	*How many years worked at this facility?*	**1** = Less than 6 months **2** = From 6 months to less than 1 year **3** = 1 year to less than 2 years **4** = 2 years to less than 5 years **5** = 5 years and above	**4** 1
5	*How many years have you worked at current position?*	**1** = Less than 6 months **2** = From 6 months to less than 1 year **3** = 1 year to less than 2 years **4** = 2 years to less than 5 years **5** = 5 years and above	**5** 1
6	*Highest level of education?*	**1** = Professional training **2** = University degree **3** = PHC or other specialized nurse **4** = Other ➔ **Q6b**	**6** 1
6b	*If other, specify*		
7	*Were you born in this district?*	**1** = Yes **2** = No	**7** 1
7b	Where did you grow up?		
7c	Where do you leave now?		
8	*Are you?*	**1** = Single **2** = Divorced/ widowed **3** = Married but not living together due to work **4** = Married and living together	**8** 1
9	*How many dependents are you financially responsible for?*		**9** 1 1
10	*Do you have any other job apart from this one?*	**1** = Yes➔ **Q10b** **2** = No	**10** 1
10b	*Describe the employment*		

I will read some statements to you, please can you tell me to whether you strongly agree, agree, disagree or strongly disagree with the statements

MANAGEMENT ASPECTS:

Work Organization

11	This facility provides everything I need to perform well at work	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**11**	1
12	There are enough health providers to do the work in this facility	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**12**	1
13	***(For nurses only)*** Too often the referral system does not work efficiently	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**13**	1
14	Maintenance of broken equipment at this facility is prompt and reliable	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**14**	1
15	My job duties and responsibilities are clear and specific	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**15**	1
Competence strengthening				
16	***(For nurses only)*** - Relevant protocols for care are easy to access at this facility (e.g. PC101)	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**16**	1
16b	If yes, how do you use PC 101?			
17	***(For nurses only)*** - I often feel left alone when I have to make difficult decision about a patient's care;	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**17**	1
18	I regularly have access to relevant training to keep my skills up to date;	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**18**	1
Role of Performance				
19	My performance is appraised regularly	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**19**	1
20	Salary awards for good performance are made in this clinic	**1** = Yes **2** = No	**20**	1
21	Merit awards do not depend on how well or badly one works on the job **(write 9 if there are no merit awards)**	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**21**	1
Self – Efficacy				
22	It is difficult for me to speak openly to my supervisors about how things are really going at work	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**22**	1
23	***(For nurses only)*** - Suggestions made by nurses on how to improve the facility are generally ignored	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**23**	1
Health worker feels valued / exploited				
24	My salary level has reduced my willingness to go the extra mile in my work	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**24**	1
25	Our rights as health care workers are generally not respected	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**25**	1
26	People in management shows very little concern for me	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**26**	1

PERFORMANCE ASPECTS				
Competence strengthening				
27	I do not get feedback from my supervisors so it is hard to improve my performance	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**27**	1
Role of Performance				
28	Good performance is recognized by our superiors	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**28**	1
29	Some of the team members work well, yet others do not and so this facility doesn't perform well overall	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**29**	1
30	We do not know how our facility is performing compared to others in the district	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**30**	1
31	Our facility has clear goals that we are working towards	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**31**	1
32	This facility has a good reputation in the community	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**32**	1
Attitudes of Patients				
33	I get cross when patients don't do what they are told	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**33**	1
Pride/ shame				
34	I am proud to be working for this health facility	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**34**	1
35	I am proud to tell others that I work in health care	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**35**	1
INDIVIDUAL ASPECTS				
Self-efficacy				
36	I usually cope well with changes at work	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**36**	1
Commitment				
37	I intend to leave this facility as soon as I can find another job	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**37**	1
38	I would recommend to my children that they choose a profession in health care	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**38**	1
39	I am willing to put a great deal of effort to make this facility successful	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**39**	1
General & intrinsic				
40	These days I feel motivated to work as hard as I can	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**40**	1

41	My profession helps me to achieve my goals in life	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**41**	1
Job Satisfaction				
42	Overall, I am very satisfied with my work in this facility	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**42**	1
43	I am very satisfied to have a position where one works closely with the community	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**43**	1
44	The problems in this facility makes me want to give up trying to improve things	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**44**	1
45	In this facility we work as a team to make sure that no patient has to wait a long time before being seen	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**45**	1
46	I get on well with my supervisors at work.	**1** = Strong Agree **2** = Agree **3** = Disagree **4** = Strongly Disagree	**46**	1
WE REALISE THAT HEALTH WORKERS CANNOT ALWAYS FULFILL THEIR DUTIES AND STICK TO THEIR SCHEDULES				
47	Approximately how many hours did you work in the last 7 working days?		**47**	1 1
48	In the past 4 weeks did you not come to work due to	**1** = Illness **2** = Leave **3** = Training **4** = Other → **Q56b**	**48**	1 1 1 1
48b	*If other, specify*			
49	In the past 7 days, how many days did you arrive late? **(write 99 if don't know)**		**57**	1 1
50	In the past 7 days, how many days did you leave early? **(write 99 if don't know)**		**58**	1 1
51	*Am in charge at this facility*	**1** = Yes **2** = No	**59**	1

Appendix C: Booking and appointment registers in clinics

DATE OF APPOINTMENT:												
FILL OUT WHEN BOOKING APPOINTMENT						**DAY BEFORE**	**On date of appointment** **Outcome of visit code**: 1=given meds; 2=refer to hospital; 3=appt in less than a month for check up					
NO	File number	Name & surname	Cell number	Diagnostic condition	Investigations to be conducted next visit	SMS sent	**Patient came Y/N**	Systolic	Diastolic	**Outcome of visit**	**Return date**	**If didn't come**, Follow Up Sheet completed Y/N

NOTE: Lay health worker to write in details of un-booked patients that consult on this day.

Appendix D: Guide for naming data files

The Nkateko Trial

Guidelines for naming files for situation analysis and process evaluation

The situation analysis and process evaluation for the Nkateko trial uses a variety of qualitative approaches for collecting data. Such approaches include; clinic observation, patient consultation observation, in-depth interviews and focus group discussions. Data collection for the trial is ongoing throughout the three year study period. It is envisaged that there will be a considerable amount of data at the end of the trial. It is thus paramount to consider a documented guide for naming and storing this data for easier tracing and coding at a later stage. Below is a standard guide that will be used for naming files for qualitative data for the Nkateko trial;

Acronyms used in the file names

Data collection methods and positions	
LHW	Lay health worker
Int	Interview
Intlhw	Interview lay health worker
Cm	Clinic manager
Intcm	Interview clinic manager
Sup	Clinic supervisor
Intsup	Interview clinic supervisor
Im	Implementation manager
Intim	Interview implementation manager
Obs	Observation
Cli	clinic
Obscli	Clinic observation
Pat	Patient
Obspat	Patient observation
FGD	Focus group discussion
fgdhpt	Focus group discussion with hypertensive patients
Fgdchw	Focus group discussion with community health workers
Fgdcag	Focus group discussion with community advisory group
Clinic Names	
tro	Troy
fai	Faith
ora	Orange
mog	Moghan
tim	Timber
arl	Arlington
yan	Yang
hil	Hllard

Field Team	
FL	Felix Limbani
PM	Princess Makhubela
WGN	Willy Glen Nkuna
BU	Brenda Ubisi
WM	Warren Ndhuli
NS	Nomsa Sibuyi
Implementation team	
ZM	Zola Myakayaka
RO	Rose
TH	Thembi
LIN	Linda
RH	Rhandzu
NO	Nomsa
KHE	Khensani
Li	Lilian
TS	Tsakani

In-depth Interviews

1. Interviews with LHWs : *Intlhw_clinicinitial_lhwinitial_date*
2. Interviews with clinic managers : *Intcm_clinicinitial_date*
3. Interviews with clinic supervisors : *Intsup_clinicinitials_date*
4. Interviews with implementation manager : *Intim_iminitial_date*
5. Interviews with patient cohorts : *Intpc_cohortnumber_patientcode_date*

Observations

1. Clinic observations : *obscli_clinicinitial_fieldworkerinitial_date*
2. Patient observations : *obspat_clinicinitial_fieldworkerinitial_date*
   Note: fieldworker name is included since some observations can be done by two field workers in one clinic on the same day.

Dairies

1. Dairies by implementation manager : *dairyim_clinicinitial_iminitial_date*
2. Dairies by researcher : *dairyres_clinicinitial_researcherinitial_date*
3. Dairies by investigators : *dairyinv_investigatorinitial_date*

Focus Group Discussions

1. FGDs with community health workers : *fgdchw_clinicinitial_chwgroupname_date*
2. FGD with HPT patients : *fgdhpt_date*
3. FGD with CAG : *fgdcag_date*
4. FGDs with fieldworkers (feedback sessions) : *fgdfw_feedbacksession_clinicnames*

Appendix E: Example of data extraction sheet used in qualitative data analysis

Focus area	DESCRIPTIONS OF FULL IMPLEMENTATION PHASE
SECTION B	**Aim: To summarise data on how the different clinic contexts, and broader health systems factors, affected clinic function in both intervention and control clinic over the 9 months period after the preparation phase**
IM diaries	**20140716_diaryim_hil_zm:** In-service training for staff and LHWs on 16/07/2015 • Patients missing appointments – mostly from other villages and cannot be traced. Usually they don't have phone numbers and CHWs cannot trace them. Agreed to offer them a transfer to their local clinic. But if patients are not willing, they will not be forced. • Files left in consultation room – LHWs complained that this leaves some patients unbooked. PNs agreed to ensure that all patients are booked and that whenever they want the files, they will ask the LHWs to return to them. • Minor raised BPs – Nurses have different opinions of raised BP management…everyone use their own discretion, and the guideline is not always followed. Agreed that proper identification is necessary, and to attract nurse attention, a red pen will be circled around a raised BP. Patients 140/90 and above to be given review date. • CM thanked everyone for supporting the programme…sometimes they get busy and forget to document, but the LHWs remind them, and as nurses, they appreciate that.
LHW Interviews	**20140804_intlhw_hil_th** **Activities** • Initially the form for raised BPs was with nurses to record all raised BPs…nurses were not writing …it might be as a result of being busy….Now LHW took the forms from the nurses and are writing them on their own at the vital signs station…wait for a return date when patient is out of consultation room. • Filing – problems with photocopied files…they are too tiny and sometime when LHW retrieves file he combines two files and give the patients….sometimes it becomes better if the patient realises that he has 2 files… **Challenges** • Usually minor patients coming for BP review…they don't come even after reminding them…especially those outside Xanthia…it might be transport problem …story on page 5…even for others...even if LHWs send CHWs, they promise to come by ending up not coming. • Back referrals from the hospitals to the clinics…usually, hospitals are not giving referral letters for patients to take them back to their clinic….when patients are back from hospital….they just stay at home instead of reporting to the clinic…they come when their medication is finished only to realise the clinic doesn't have that medication.
Obs day 1	**Clinic observation – 20141118_obscli_hil_pm** • Chronic pathway – Firstly patients meet guards at the veranda of the clinic entrance…..register their details…then given queuing numbers to use throughout the clinic ✓ Patients then proceed to main waiting area to queue. Here, there are 3 painted footprints indicating which patient should queue where….yellow/ orange is for child care, green is for acute patients and blue is for chronic patients. ✓ While in the main waiting area, clinic staff were in a meeting. Soon after the meeting, there was health talk from LC….then later given files by DTs for DoH and Nkateko (these were only for booked patients)

Appendix F: **Turnitin report**

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ORIGINALITY REPORT

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