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Implementation fidelity of HIV care continuum among healthcare workers in Agincourt healthcare facilities

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UNIVERSITY OF THE WITWATERSRAND
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TITLE:

IMPLEMENTATION FIDELITY OF HIV CARE CONTINUUM AMONG HEALTHCARE WORKERS IN AGINCOURT HEALTHCARE FACILITIES

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DATE: JUNE 2018

DECLARATION

I, Lorraine Mabotse Molepo declare that this thesis is my own, unaided work. It is being submitted for the Degree of MSc Epidemiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

(Signature of candidate)

03 day of June 2018 in Johannesburg

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DEDICATION

To every individual who has invested their time, money and efforts in me, this is for you; thank you for believing in me!

To my brother, Raphael Masilo Molepo, this one is for you.

The sky is the platform, there are no limits!!!

ABSTRACT

Introduction

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has set a target to end the Acquired Immuno-Deficiency Syndrome (AIDS) epidemic by 2030, following their proposed 90-90-90 goals. In line with this, the HIV Care Continuum (HCC) was implemented as the standard of care by the South African National Department of Health to be practiced in all government facilities with HIV positive patients. A conceptual framework for Implementation Fidelity (IF) was used to determine the extent of fidelity to the HCC in rural Mpumalanga Province, northeast South Africa.

Methods

A convergent parallel mixed-method approach was used to collect information from two primary healthcare facilities (PHC). Quantitative data were collected from 200 patient record files through an IF checklist toolkit (based on the 2015 HIV treatment guidelines (HTGs)); and qualitative data were collected through in-depth interviews with eight healthcare workers (HCWs) attending to HIV positive patients at these facilities. Interviews were designed in line with the IF framework to explore factors affecting fidelity to the HCC. A fidelity score was generated by tallying all the 'yes' responses to the IF checklist toolkit, and a final fidelity score was ranked as high or low fidelity, based on the fidelity mean score. We used logistic regression models to identify predictors associated with the outcome of treatment adherence. Quantitative analyses were done using STATA 14. MAXQDA 12 was used to analyse the HCWs' interviews.

Results

Females comprised 72.0% of the study sample and approximately 2/3 of the participants had a CD4 count of 350 and below (CD4≤350) upon HIV diagnosis. The average overall fidelity

score was 32 out of 37, with 10% of the participants being defaulters. Females were more likely to be retained in care compared to males (OR 0.47, 95% CI 0.22-1.03, p=0.06) as were older patients. For every age increase of 10 years, participants were more likely to be retained in care (OR 0.71, 95% CI 0.51-0.99, p=0.045). Those not due to start ART according to the 2015 HTGs (CD4>500) were also less likely to be retained in care, though this was not statistically significant (OR 1.47, CI 0.52-4.17, p=0.460). Gender and age interaction was not statistically significant (OR 0.73, 95% CI 0.39-1.35, p=0.315).

Findings from the interviews revealed that guidelines were being followed; that is, patients were counselled and blood specimens drawn according to the guidelines. HCWs stated that they had difficulties in retaining patients in care. They further reported that although following the guidelines is a time consuming task, they do follow them because their priority is patients' health and wellbeing. HCWs continue to welcome referral systems to hospitals, as this aided in treating patients that could not be treated at their healthcare facilities, but stigma continues to be a challenge and contributes to the difficulties in retaining patients in care.

Discussion

Although a positive attitude and a willingness to follow the guidelines was reported by the HCWs, they still struggled to ensure patients' adherence to care and to trace patients who defaulted. Stigma continues to contribute to retention failure. Socio-demographic factors and moderating factors contribute to the extent of retention in care. Factors contributing to HIV retention failure should be addressed to ensure that fidelity to the HCC is maintained to decrease challenges in executing the new Universal test and treat (UTT) guidelines currently being practiced across government healthcare facilities in South Africa.

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LIST OF ABBREVIATIONS

AIDS:	Acquired Immune Deficiency Syndrome
ART:	Antiretroviral Therapy
ARV:	Antiretroviral
HCC:	Health Care Continuum
HCT:	HIV Counselling and Testing
HCW:	Healthcare Worker
HIV:	Human Immunodeficiency Virus
HTG:	HIV Treatment Guidelines
IF:	Implementation Fidelity
IR:	Implementation Research
NIMART:	Nurse-Initiated Management of Antiretroviral Treatment
PHC:	Primary Health Care
PI:	Principal Investigator
SD:	Standard Deviation
UNAIDS:	The Joint United Nations Programme on HIV/AIDS
UTT:	Universal Test and Treat
WHO:	World Health Organization

CHAPTER 1

INTRODUCTION

In this chapter the impact of Antiretroviral therapy (ART) in treating the human immunodeficiency virus (HIV) is reviewed. The Health Care Continuum (HCC) is defined and the role of Implementation Fidelity (IF) is explained. A conceptual framework is integrated in reviewing published literature on measuring IF. The chapter concludes with the aims and objectives of the study.

1.1 Background

HIV and AIDS continue to cause major health problems in the world, especially in developing countries like the Eastern and Southern African regions, which collectively contribute to more than half (51.8%) of the world's HIV positive population. As of 2015, there were 36.7 million people living with HIV in the world, 19 million of them from Eastern and Southern African regions (1). The current overall HIV prevalence in South Africa is 12.7%. More specifically, the prevalence among the adult population 15-49 years old is 18.9%, among women 15-49 years old is 22.3%, and among the young population 15-24 years old is 5.6% (2).

ART has played a pivotal role in reducing deaths of HIV infected people. South Africa alone has supplied approximately 3.4 million people with antiretroviral (ARV) treatment and continues to supply more ARV treatment with new infections. As a result of ART, AIDS deaths in South Africa declined from 207 685 in 2010 to 110000 in 2016 (3). This supports the effectiveness and importance of ART. ART requires high and strict level of adherence, i.e. taking the correct dosage at the correct time and regularly attending clinic appointments.

In 2014, UNAIDS set new and ambitious targets to end the AIDS epidemic by 2030 – these are often referred to as the 90-90-90 targets. The goal is that by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving ART will be virally suppressed (4). Together with these goals, South Africa has adopted and implemented the World Health Organization (WHO) HIV guidelines (Universal test and treat-UTT) of testing and treating upon diagnosis (irrespective of CD4 count) as of September 2016 (3). With these new guidelines there is a requirement for a strengthened healthcare system for testing, linking and retaining the infected people in care.

The HCC is an HIV care delivery system that comprehensively incorporates biomedical and social services to cater for people infected and living with HIV at the different stages of the illness. This continuum of care is a succession of stages that are incorporated from the moment an individual is diagnosed with HIV through to treatment of their infection (5).

The South African National Department of Health adopted the following HIV treatment guidelines to address the HIV epidemic in the country:

1. *HIV diagnosis: diagnosis of HIV infection through HIV testing.*
2. *Linkage and access to care: Connecting individuals who are diagnosed with HIV, to an HIV healthcare provider/ healthcare facility, where treatment and support can be offered.*

   (An individual is said to be successfully linked to care when they are connected to a healthcare facility within 3 months after diagnosis).
3. *Retention in care: ensuring that the linked individuals receive on-going clinical monitoring;* since treatment is a lifelong process, HIV infected clients need to receive regular HIV medical care.

Continuous monitoring also ensures early detection of defaulters or 'loss to follow up candidates'. Poor retention is defined as failure to retain linked and ART initiated patients in care for 12 months. Those who failed to attend a total of 4 clinic visits in 12 months will be classified as 'not retained' and those who attended at least 4 clinic visits in 12 months will be classified as 'retained'(6).

4. *Antiretroviral therapy (ART): Ensuring that eligible HIV infected individuals are on treatment to prevent HIV from making more copies of itself.*

Poor ART initiation of linked patients is failure to initiate ART after 3 months of diagnosis.

5. *Viral suppression: The optimal goal for ART; lowering the amount of virus in infected individuals thus keeping them healthy and helping prolong their lives* (7, 8).

Due to the effectiveness of ART in sustaining the lives of infected individuals, HIV has become a chronic and manageable condition, which has already resulted in millions of years of lives being saved and infected people leading productive lives when maintained on treatment (9). In the South African context, HIV care has been decentralised from hospitals to primary healthcare facilities (PHC). Extensive training has been conducted for healthcare workers (HCWs) to increase coverage and reach of HIV care and to also increase staff capacity in under resourced communities (10). This decentralisation of healthcare facilities to treat HIV patients at the clinic level has eased access to care for patients within communities (11). Facilities are more readily within reach for patients to get tested, diagnosed and treated.

Access to care soon after diagnosis would greatly improve survival (12). Therefore, HIV diagnosis has to be followed by appropriate treatment because without linkage to appropriate services, individuals living with HIV would not be initiated on ART and consequently retained in care and would not achieve viral suppression, which is necessary to live a longer and healthier life.

Given the positive understanding that increased treatment of HIV infected persons slows transmission of the virus, HIV treatment guidelines (HTGs) are used as a mechanism to facilitiate testing, linking and retaining patients in care, which is crucial for decreasing the epidemic (8, 13). To that end, HTGs have been distributed and mandated to be followed by healthcare facilities in South Africa when caring for HIV patients.

1.1.1 Implementation Research

Implementation research (IR) examines the scientific approach to carrying out an intervention conclusively. It looks into what factors affect implementation and what the processes and outcomes of implementing an intervention are, with the goal of ensuring that the intervention is sustainable in its setting. The overall goal of IR is to understand how interventions operate in the real world and how these can be constantly improved. In IR, context (psycho-sociocultural and / or environmental) plays a pivotal role. All stakeholders associated with an intervention are also important in IR (14).

Implementation outcomes are deliberate actions that are employed to bring about an expected and desirable end. They serve as indicators for the success of an intervention. Examples of these are: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, coverage, and sustainability. IR uses these outcomes in order to assess the extent to which an intervention was implemented (15).

This study focuses on fidelity, the extent to which an intervention or programme is implemented in accordance with the protocols and procedures that were originally designed by the organisers of the intervention (16). Fidelity is the extent to which patients are provided the precise intervention that was intended to be delivered to them at the outset (17). It is also

referred to as delivering the instructions as intended (18). Other terms used to describe the concept of fidelity are adherence or integrity of a programme. Fidelity further informs patterns that are outliers from the original intended intervention (19). In this study, fidelity will help determine if following the guidelines results in improved adherence to ART by patients. This will assist in assessing how far the HCC intervention will produce desired results in HIV patients.

1.2 Literature Review

Our literature review was conducted through searching Pubmed, Science Direct and Google Scholar search engines. We searched for literature from medical journals such as British Medical Journal, South African Medical Journal, Journal of Infectious Diseases, BMC public, Implemenation Science and other similar medical journals, as well as the National Department of Health (South Africa) website. We searched for articles using key words such as HIV/AIDS, diagnosis, linkage, retention in care, adherence, treatment, ARVs, ART, implementation, fidelity. The focus of our study was measuring fidelity of the HIV Care Continuum; thus, our literature review addressed how fidelity is measured and how this will be used in our study to meaure fidelity.

Numerous ways of measuring fidelity of an intervention have been shown in the literature: five main components include adherence, quality of (care) delivery, participant responsiveness, facilitation strategies and intervention differentiation/complexity (20). Carroll et al. 2017 elaborate on these components by formulating a conceptual framework for implementation fidelity. This framework proposed that within the components of measuring fidelity, some of the components can be classified as moderating factors that influence implementation fidelity. Their study proposed four moderating factors of implementation fidelity: participant responsiveness, complexity of an intervention, facilitation strategies, and quality of (care) delivery, and that these moderating factors influence a fifth component, namely adherence. They argue that these four components rather facilitate adherence and are not a measure of fidelity on their own (Figure 1). Our study adopted this conceptual framework.

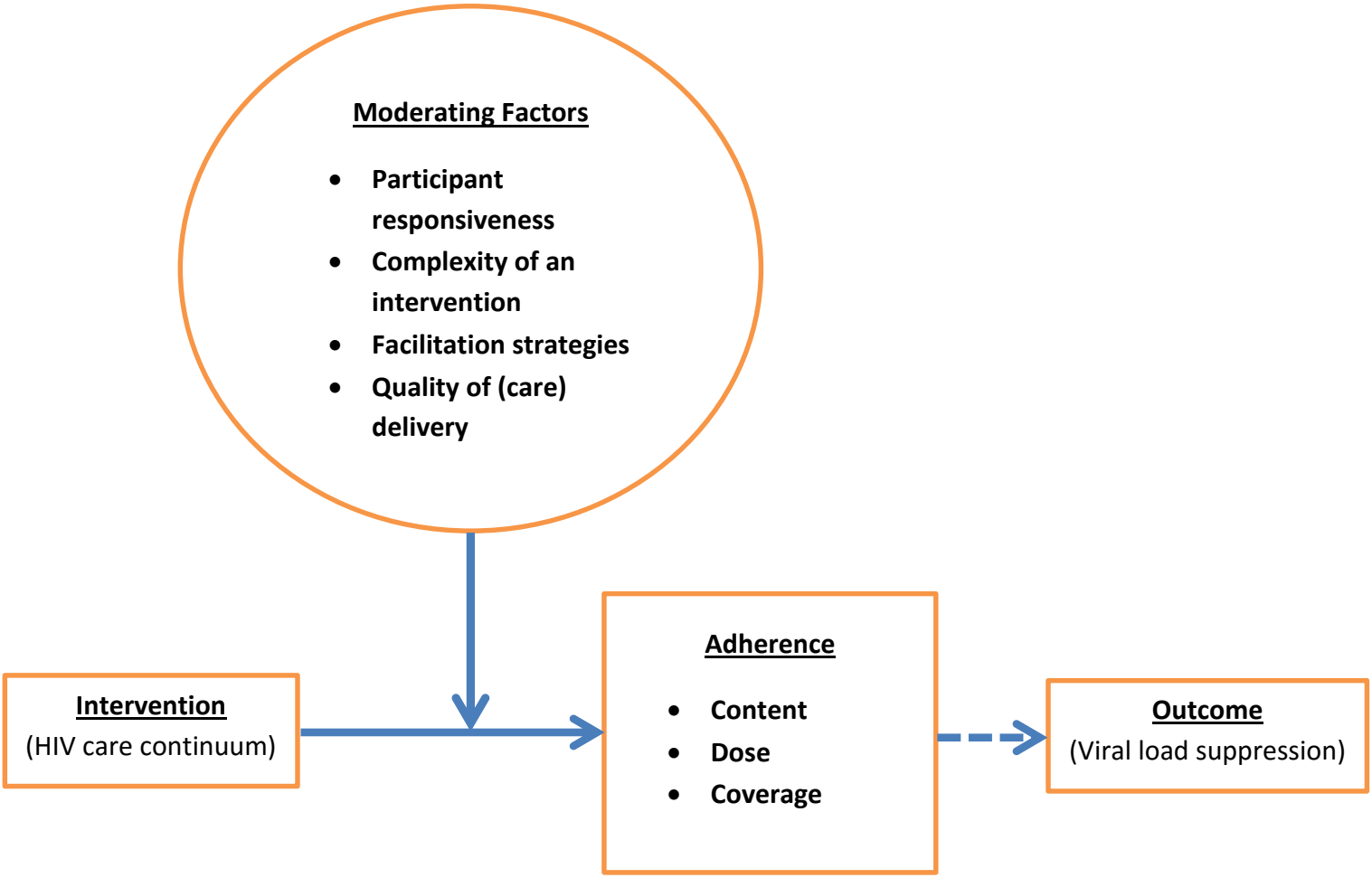

Figure 1. Conceptual framework of implementation fidelity (adopted from Carroll et al. 2007)

1.2.1 Adherence

Adherence in implementation research is defined as the extent to which the components of an intervention are delivered as prescribed by the protocol, it is be the main measure of fidelity (21). Adherence is further subdivided into more specific elements: content, coverage and dosage.

Content is the ingredients of the programme given to the recipient. In the context of the HCC intervention, content will include counselling the patient, testing the patient, educating and referring the patient, as per the HIV treatment guidelines.

Exposure / dosage is the amount of intervention delivered in relation to the amount prescribed by the protocol; this includes frequency and duration of the intervention, and whether the frequency and duration of the HCC is as prescribed by the guidelines or not. There are numerous ways of measuring dosage in adherence to interventions. A study by Elliott and Mihalic (2004) used interviews and surveys to determine exposure. Their study determined if interventions were implemented for as long and as often as were prescribed. Another study used logs to record the number of times an intervention was carried out (22). These helped the researchers to assess the frequency of implementing their respective interventions as was prescribed by each intervention.

Coverage refers to all patients who are recorded to be successfully diagnosed, linked into care and are actually receiving the care (23). For example, a study by Reed JB, et al, 2009 showed that 28.0% of HIV infected persons were delayed entry into care, i.e. three months after their initial diagnosis, implying a decrease in coverage of HIV infected individuals (24).

There are many factors which have been reported to influence adherence to ART negatively, namely: stigma – patients become reluctant to freely visit clinics for treatment and care; relationship with HCW – lack of rapport between HCW and the patient can contributes to high

patient defaulter rate; financial constraints – lack of finances to travel to clinics results in patients defaulting and not being successfully retained in care; side effects – patients find the side effects of some medication unbearable and as a result they stop treatment; migration – patients move to a different city and can no longer be traced or confirmed to be still in care or not (25-27); HCW attitude – when HCWs have a negative attitude towards their patients, this makes it difficult for patients to be open and share their challenges (28).

1.2.2 Quality of Care Delivery

The manner in or extent to which the content of an intervention is carried out include provider preparedness, respectfulness and confidence (29). Studies suggest that high IF can be achieved if staff members are appropriately selected and given adequate training, coaching and support, as these factors would enable them to deliver the intervention at a higher quality level (30). Continuous programme evaluation will also improve quality of intervention delivery, as referring back to an evaluation report can help identify gaps that transpired (30). One study suggests that poor IF can be a result of poor staff training and uncommitted staff members (31). Another study noted that lack of leadership from managers, in playing a supportive role in the clinic, contributed to ineffective practices of caring for patients in the clinic (32).

1.2.3 Participant Responsiveness

Participant responsiveness is how well participants (HCWs) respond to an intervention, as well as their judgment about the relevance of the intervention (21). The manner in which participants react to or engage in an intervention, their level of interest as well as attitude towards the intervention, affects how an intervention is executed. Other factors such as the relationship between the HCW and recipient of the intervention, and willingness of the HCW to engage the recipient in the intervention, also contributes to how an intervention is carried out (33, 34).

Studies have shown however, that it is not only the implementer of the intervention who determines responsiveness to the intervention, but the recipient's perspective should also be measured to determine whether the intervention was received as intended (35). In a 2010 study by Kempf et al., participants were likely to return to their respective clinics if they were treated well by the clinic staff. Also, if HCWs were respectful, patients were more likely to honour their clinic appointments (36, 37). On the contrary, if patients felt they were disrespected (38), not empathised with (36), or the HCW didn't care about them (37), they were less likely to honour their appointment. Patients appreciate respectful treatment by their HCWs which encourages them to keep clinic appointments (37). When patients are disheartened, it affects the level of fidelity in which the intervention is implemented.

1.2.4 Facilitation Strategies

These are measures employed to ensure that standardised interventions are implemented in a uniform manner (21). Studies have not conclusively shown that facilitation strategies can indeed ensure effectiveness of interventions (41); however, some studies have shown that the fidelity of interventions increases after facilitation strategies in the form of training and external support were made available. This supports the notion that when added strategies are incorporated in an intervention, better results can be achieved (22, 28, 42) and, increased fidelity can result (43).

Furthermore, research has shown that moderating factors – quality of care delivery, participants' responsiveness, complexity of an intervention and facilitation strategies – may positively or negatively affect the implementation process and its fidelity; that is, the effect of one moderating factor on fidelity may be influenced by another moderating factor thus reducing implementation fidelity (43).

In order to have confidence in the effectiveness of the HTGs, the fidelity of the guidelines would have to be measured and reported on, so that we will be able to attribute the success or lack thereof of the outcome to the intervention (in this case, the HCC). When an intervention is being implemented, it is important to know if it was implemented as was initially planned or not (39). This way, if the intervention outcome is futile, appropriate measures can be taken to focus on the element(s) which may have contributed to its failure.

1.2.5 Complexity of an Intervention

This is the extent to which an implementer of an intervention finds the contents of the intervention understandable enough to carry out with ease. Studies have shown that if interventions are comprehensive, they will be implemented with high fidelity, compared to interventions that are unclear and ambiguous (40, 41). Additionally, Dusenbury et al. (2003) and Mihalic (2004) assert that, "interventions that are well structured and less complex, produce higher fidelity compared to those that are unstructured" (23, 29). Therefore, in the case of the HCC intervention, the extent of fidelity will be determined by how the HCWs experienced the intervention ─ whether they found the intervention easy, vague or complex to carry out.

The moderating factors described above illustrate how fidelity of interventions can be effectively measured. These will be used in our study to measure the extent of fidelity to the HCC by the HCWs of healthcare facilities in the Bushbuckridge region.

1.3 Problem Statement

Evidence-based interventions have shown that the HCC can be implemented effectively when guidelines are followed, and that if not implemented well, poor outcomes and failure to link

and retain patients in care will prevail, ultimately resulting in poor viral load suppression.Even though HTGs are readily available in the National Department of Health database and hard copies accessible to South African health facilities, there is still poor HIV diagnosis, linkage to care and retention in care especially among the male population (42). HIV continues to be a problem despite the fiscal and human resources allocated by the Department of Health to tackle the epidemic (3). Other studies that measure fidelity in implementation have been conducted for various programmes (43); however, there is a gap in the literature for studies measuring fidelity in the HIV continuum of care.

1.4 Justification

In order to achieve the 90-90-90 goals, it is crucial for the HCC to be implemented with maximum fidelity. It is important to have an understanding of the extent to which the HCWs adhere to the HCC. Because HCWs make use of HTGs when attending to patients, understanding their experiences and perception of the guidelines is essential as it will give an indication of how feasible these guidelines are at the HCW-patient level interactions. Our study examined the extent of implementation fidelity of the HCC within two rural healthcare facilities in Mpumalanga Province. Our study will assist in identifying gaps that exists in healthcare facilities when attending to HIV positive patients. It will also highlight determining factors affecting HCWs in executing the HTGs. Furthermore, the study provides an opportunity to identify the gaps that have to be addressed to stay aligned with the UNAIDS targets. This will aid in understanding fidelity from a PHC level and how this translates to the standard of HIV care in South Africa, since PHCs are where the majority of patients receive their HIV care. This study also adds to the existing literature on factors affecting implementation fidelity and how moderators of an intervention affect fidelity, to inform how these moderators can be effective and transferable in real life setting.

1.5 Research Question

What is the extent of implementation fidelity of the health care continuum among healthcare workers at two healthcare facilities in rural Mpumalanga Province?

1.6 Aim

To assess the extent of implementation fidelity of the Health Care Continuum, and to explore how moderating factors influence implementation fidelity of this continuum of care in two healthcare facilities in rural Mpumalanga Province.

1.7 Objectives

1. To determine the extent of adherence to the Health Care Continuum by healthcare workers using patient record files from August 2015 to December 2016 in two healthcare facilities in Agincourt, rural Mpumalanga Province.

2. To explore, through in-depth interviews with HCWs, how the moderating factors of implementation fidelity affect healthcare workers' adherence to the Health Care Continuum in two healthcare facilities in Agincourt, rural Mpumalanga Province.

This chapter has highlighted on the role that ARTs has played in South Africa to date and how the HCC continues to be met with challenges to execute. We reviewed the literature to see how we can best identify these challenges. We explored the conceptual framework of implementation fidelity to give direction on how we'll go about answering our research question, and also on how to measure fidelity to the HCC. The next chapter will focus on the methodology used to address our objectives and to answer our research question.

CHAPTER 2

METHODOLOGY

This chapter presents the research design used, study setting and target population for the study, data collection tools and procedures, data management, study variables and analysis plan.

2.1 Study Design

A cross-sectional, convergent parallel mixed-method study approach was used (Figure 2). This was best suited for the type of research conducted, as the HCC is a multifaceted intervention. Using either quantitative or qualitative methods alone would not have provided all the required information (44), whereas combining both methods provided a more comprehensive analysis better able to answer the research question (45). Our approach involved secondary analysis of routinely collected data from patient record files at two primary care facilities in Agincourt, Mpumalanga Province, as well as in-depth interviews with HCWs at the same two facilities to further explore the factors contributing to implementation fidelity.

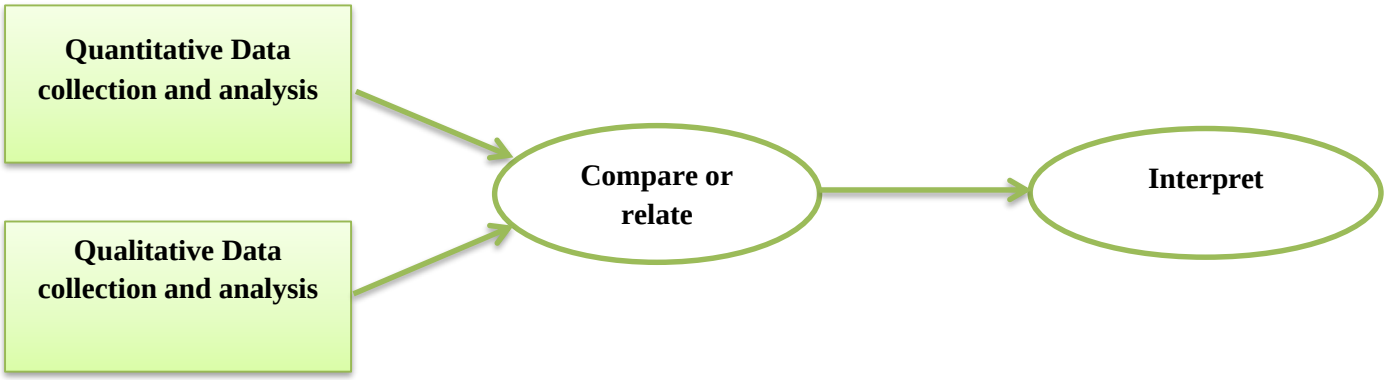

Figure 2. The convergent parallel mixed-method design by Creswell at al. 2007

2.2 Study Setting

This study was conducted at two Primary Healthcare Clinics (PHCs) in the Agincourt area in the sub-district of Bushbuckridge in the Mpumalanga province of South Africa. The area is covered by a health and socio-demographic surveillance system (Agincourt HDSS) established in 1992 and run by the Medical Research Council/Wits University Rural Public Health and Health Transitions Research Unit (MRC/Wits Agincourt).

2.3 Study Population

All patients 18 years and older from two PHCs in the Bushbuckridge sub-district were sampled. The sampling was based on the daily operational functions and the organization of the PHCs, as well as the quality of their filing systems. For the purposes of answering objective one, the study reviewed 200 patient record files from patients 18 years and older; 100 from each healthcare facility. For objective two, eight HCWs who attend to HIV positive patients at the chosen PHCs were recruited, four HCWs per PHC. These HCWs were a mix of professional nurses and lay counsellors.

2.4 Sampling

STATA 14 was used to calculate the required sample size of patient record files to review at a 95.0% confidence interval; assuming a 50.0% prevalence of fidelity and 80% power. Based on these sample size and power calculations, a minimum of 200 patient record files were required. Simple random sampling was conducted and 250 files were selected for review (46). These files are kept in a specified HIV-file cabinet in each facility and are filed alphabetically per patients' surnames. We randomly selected 20 files each day for a total of 22 days. We selected files at random from the filing cabinets, as well as files from out-patients who had completed their consultation with the HCWs at the facilities on the day of data collection. Each file in the health facility has a file number, which assisted in avoiding duplication of selecting

files on alternative days of data collection. If the file met our inclusion criteria, data was collected from it; if criteria were not met, the file was returned to the facility's filing cabinet but the file number noted to avoid selecting that file again in the future. The final counts of files selected for data collection were 100 patient record files per healthcare facility.

Exclusion criteria:

- Patient files of individuals 18 years of age and older whose record files were incomplete (missing pages)
- Patient files of antenatal patients.

For objective two, purposeful sampling (47) to recruit four eligible HCWs per healthcare facility was undertaken. This was conducted through consultation with the nursing sister in-charge of each facility to advice on which HCWs were directly involved in attending to HIV positive patients.

2.5 Data Collection and Tools

Quantitative and qualitative data were concurrently and independently collected. For the first objective, an electronic-based fidelity checklist toolkit (Appendix 1) was used to collect data from the record files of patients attending the healthcare facilities during the August 2015-September 2016 period. Data collected prior to the implementation of UTT in September 2016, were reviewed retrospectively. The toolkit used was adapted from an already published fidelity implementation study (43). The fidelity checklist toolkit was formulated with statements derived from the HIV treatment guidelines algorithm, as stated in South Africa's National Treatment Guidelines (8).

The first section of the toolkit collected patient demographic data. The second section collected data pertaining to the patient's adherence. Adherence is measured across the spectrum of the

three phases of the HCC intervention. The fidelity checklist toolkit was structured according to each step in the continuum of care; each step outlined the adherence variables. A ‘yes’ variable was allocated to the steps in the continuum which were followed, a ‘no’ variable was allocated to the steps which were not followed, and an ‘other’ variable was allocated to the steps which were partially followed. The ‘other’ responses were further re-coded as ‘yes’ or ‘no’ depending on the extent of compliance to the HIV treatment guidelines. The ‘yes’ or ‘no’ answers were then tallied using STATA 14. Data was collected by the principal investigator (PI).

The study principal investigator (PI) piloted the fidelity checklist toolkit with three patient record files to assess if the toolkit would gather all the needed information. Post piloting, the PI amended the toolkit by removing those questions which were not relevant or could not be answered by reviewing patient record files alone (Appendix 1).

For the second objective, eight in-depth interviews were conducted by the PI with the selected HCWs (four per healthcare facility). Informed consent was obtained (Appendix 2) from the HCWs prior conducting the interviews. The interviews explored how moderating factors of HCC would influence adherence to the intervention and ultimately fidelity to the whole intervention. Unstructured open-ended audiotaped interviews were conducted in English and transcribed by the PI; with the exception of one interview which had to be conducted in Sepedi (also by the PI), then translated to English and transcribed. An interview guide from a similar study which explored factors influencing implementation fidelity, was adopted and modified for this study (48). The interview guide was piloted with other HCWs prior to use and adjusted accordingly (Appendix 3).

2.6 Study Variables

The study's overall outcome variable is fidelity; overall fidelity score and fidelity scores for each phase of the HCC were computed. The scores were obtained by tallying the total 'yes' answers based on yes/no answers from the fidelity checklist toolkit. The scores were presented as continuous variables and then recoded into categorical variables (high and low fidelity).

The mean score was used as the determining factor for low or high fidelity score, where scores below the mean were categorised as low fidelity and those above the mean as high fidelity. The categorised fidelity scores were computed for regression analysis. Out of the fidelity scores generated, regression analysis was conducted with the outcome of fidelity retention (the third phase) because retention was used as a proxy for adherence to ART.

The predictor variables were all the other variables in the fidelity checklist toolkit. These variables were used to calculate overall fidelity scores as well as fidelity scores at each phase of the HCC. These variables were also used to test for associations.

Coverage was measured to determine the proportion of patients in care as of August 2015, who were still in care at the time of data collection.

Patient characteristics - including age, gender, marital status, occupation as well as HIV status (CD4 count at time of diagnosis) and indicators for measuring adherence (on-going adherence support, adherence noted, collected all prescriptions, side effects, stigma disclosure, caregiver support group, quarterly counselling and patient adherence>/=95%) - were collected.

The qualitative measure of fidelity was conducted via in-depth interviews through exploring the four moderators of fidelity: 1) quality of (care) delivery, 2) participant responsiveness, 3) facilitation strategies, and 4) complexity of an intervention. Coding of the interviews was done and themes derived from the codes using thematic analysis. The themes were then coded into the four moderating factors for further reporting and analysis. The in-depth interviews sought

to explore how the moderating factors impacted on the HCWs' ability to adhere to the HCC. The interviews covered an array of issues from the different stages of the HCC, including factors hindering or facilitating HCWs daily activities, what HCWs perceive as the main benefits of the HCC, and how HCWs document the work they do on a daily basis.

2.7 Data Management

Data coding, data entry, verification and cleaning was conducted by the PI. Data was entered into an Access database and cross-checked by exporting it into an Excel spreadsheet to check for completeness and consistency through filtering each variable to check for any missing values. The Access database is safely stored under password-protected archives in the MRC/Wits-Agincourt Research Unit's server. The head of the Data Section at the Research Unit, as well as the PI's study supervisors, have access to the data.

The PI transcribed the digitally-recorded interviews verbatim, and double-checked the transcripts for accuracy by reviewing them multiple times against the recordings.

Reliability: Capturing of the quantitative data into the Access database, data export to Excel, and checking for missing variables was conducted by the PI. The PI designed the Access database used for data-capture, and set validation rules for each variable to prevent capturing of incorrect data. Coding and recoding of the qualitative in-depth interviews was conducted by the PI with two other qualitative researchers to ensure trustworthiness of the codes produced.

Validity: To ensure validity, similar checklist toolkits for measuring fidelity and interview guides from other published work were adapted, modified and adjusted for the purposes of this study.

2.8 Data Analysis

Quantitative and qualitative data were also concurrently and independently analysed. STATA 14 was used to analyse the quantitative data. Descriptive analysis of summary statistics, and frequency tables of the demographic characteristics were reported in order to describe the characteristics of the participants. Continuous variables were summarised with sample size (n), mean, standard deviation (SD) and range (maximum and minimum). Categorical variables were computed into frequency and percentage for each category observed.

Content and Dose variables were coded as 'yes' and 'no'. These were summarised into frequency tables and calculated into percentages. Fidelity scores of the different phases of the HCC (i.e. Counselling; Testing and Diagnosing; Linkage to care and ART initiation; and Retention in Care) were tallied, calculated and reported as the mean (average scores), SD and range (maximum and minimum). From the fidelity score of retention, an adherence score was generated.

A chi-squared test or Fisher's exact test was used to test for associations of the content and dose variables. Since retention is a proxy of the ultimate goal of viral suppression in the HCC, further analysis was conducted with the fidelity retention score as the final outcome (Table 1).

A summary of the retention fidelity score was determined; minimum, mean and maximum values were produced; all values above the mean were classified as high fidelity score; all values below the mean were classified as low fidelity score; and regression analysis was conducted. Univariable analysis was computed for occupation, marital status and CD4 count status at time of diagnosis. Some of our variables could not be analysed because they generated empty cells when computed. The reason for the empty cells was because answers from the checklist were either all yes or all no; these types of outputs could not be fitted into the univariable regression model and ultimately the ordinal regression model used for analysis.

When testing for normality of our outcome variable, the results presented a histogram graph skewed to the left, warranting the use of an ordinal regression model (see Figure 3 in Results section below).

Further univariable analyses were conducted to select variables to be included in the multivariable analysis. Variables which were found to be significantly associated with the adherence score were retained in the final multivariable logistic regression model.

Coverage looked at the proportion of patients who were diagnosed with HIV and linked to care, the proportion of patients linked to care and initiated on ART, and the proportion of ART initiated patients retained in care. Proportionality test was used to analyse and report coverage data, where the numerator was the number of patients retained in care, and the denominator the number of patients initiated on ART.

The in-depth interviews were transcribed verbatim, the raw data transcribed was then reviewed, synthesised and codes identified by hand using a thematic analysis.

An initial (top-down) broad coding framework using a thematic approach was developed based on the study research questions (49) and Carroll et al. 2017's implementation framework (21).

From the broad codes, we proceeded to apply fine (specific) codes to all transcripts, initially manually and then using MAXQDA 12. (50) The fine codes were used to derive themes which were coded into Carroll et al. 2017's moderating factors framework. An analytical summary of each theme using illustrative quotes to support key emerging conclusions was developed.

The interview guide and the final themes reported are based on these moderating factors: participant responsiveness, facilitation strategies, complexity of an intervention and quality of deliverance. Triangulation of the quantitative and qualitative results is presented in Table 1 below.

Table 1. Summary of data collection and analysis

	Quantitative	Qualitative
Data Collection Tools	Fidelity Checklist Toolkit	Interview guide
Variables / Themes	**Content & Dose:** Variables under content and dose derived from the guidelines were given statements 'yes' & 'no' codes. **Coverage:** the numerator is the number of patients retained in care, the denominator is the number of patients initiated on ART.	Quality of care delivery, participant responsiveness, facilitation strategies, complexity of an intervention
Data Analysis	**Content and Dose:** Chi-squared, Fischer's exact test, Univariable and Multi-variable analyses. **Coverage**: Proportion of **coverage** calculated.	Codes derived from the interviews and categorised. Themes generated based on Carroll's conceptual framework (21).

2.9 Ethical Considerations

Our study protocol was submitted to the Wits Human Research Ethics Committee (HREC) for review. Data collection began only after ethics clearance was obtained; our HREC certificate number is M1611105 (Appendix 3). Permission was also obtained from the Mpumalanga Province Research and Ethics Committee – our certificate number is PHREC REF MP_2017RP49_123 (Appendix 4); as well as from the study site (Appendix 5). Consent for reviewing the patient record files was previously obtained by the research Unit. An information sheet was provided to the study participants explaining the nature of the study and what was required of them for participation (Appendix 6). All participants consented prior to being interviewed, using approved consent forms (Appendix 7). In addition to informed consent, permission from the participants to allow recording of the interviews was also obtained (Appendix 8). Participation was voluntary – participants (HCWs) were free to withdraw from the study if they wished to do so at any stage. Pseudo-names were used throughout the analysis and in this research report, in order to protect the identity of the participants. The signed consent forms are kept in locked filing cabinets at the Research Unit Voice recorded interviews are kept

in password-protected audio files in the Research Unit's secured server, and will be kept for a period of two years and not made available for any member of the clinic facility.

HCWs were told that there was no direct benefit in participating in the study, but that the information obtained could help them improve care and management of patients at the facility in the future.

Patients' records were kept confidential; no patient number or names were used for reporting purposes. Patient record files were reviewed at the facilities, and never taken out of the facilities during the duration of the study.

In our methodology, we identified the study design suitable for answering the research question at our study sites. We proceeded to statistically determine our sample, clearly stating the inclusion and exclusion criteria for our study. Data collection tools were developed to assist in collecting the appropriate data needed. The data collected were analysed statistically and the results produced and interpreted in the next chapter.

CHAPTER 3

RESULTS

3.1 Introduction

This chapter reports on the findings of our study. The quantitative section reports findings through tables and figures, with the major findings highlighted in the text. The qualitative section reports findings through quotes from the participants. The letters "PN" (professional nurse) and "LC" (lay counsellor) with unique numbers were assigned to each respective participant's quote to distinguish the respondents while retaining confidentiality.

3.2 Quantitative Analysis

A total of 200 patient record files of eligible patients were randomly selected for review and data collection, 100 record files per healthcare facility.

Table 2 summarises descriptive statistics of the participants. Females made up 72.0% of the sample population and more than half of the population (51.0%) was unemployed. The average age of the participants was 43.7, ranging from 22 to 87 years (SD 12.7), and the average number of years in HIV care was 3.5 years. Approximately two thirds of the participants had a CD4 count of 350 and below upon HIV diagnosis. Based on the 2015 HTGs, 10% of the participants who were on ART were not supposed to be initiated in care because their CD4 count was greater than 500, and 3.5% of the study population were active TB patients at the time of HIV diagnosis.

Table 2: Descriptive statistics of socio-demographic characteristics of the participants

Continuous Variables				
Variable	**No. of Observation**	**Mean (SD)**	**Min**	**Max**
Age	200	43.70 (12.70)	22	87
No. Years in Care*	200	3.54 (2.02)	0.34	11.74

Categorical Variables	
Variable	**Frequency [N] (Percentage)[%]**
Gender	
Male	56 (28.0)
Female	144 (72.0)
Occupation	
Employed	46 (23.0)
Unemployed	102 (51.0)
Student	4 (2.0)
Other	48 (24.0)
Marital Status	
Single	111 (55.5)
Married	70 (35.0)
Divorced / Widowed	19 (9.5)
HIV Category (CD4 Count at Time of Diagnosis)	
CD4 ≤ 350	135 (67.5)
CD4 351-500	25 (12.5)
CD4 > 500	20 (10.0)
CD4 < 350 Active TB Disease	7 (3.5)
CD4 < 200 WHO Stage 3 or 4	13 (6.5)
Age Category	
20-30	24 (12.0)
31-40	73 (36.5)
41-50	49 (24.50)
51-60	32 (16.0)
61-70	15 (7.5)
71-80	5 (2.5)
81-90	2 (1.0)

HCWs in South African healthcare facilities adopted the HCC approach by following updated HTGs provided to them by the National Department of Health. Patients in both healthcare facilities we visited were receiving HIV care under these guidelines. These guidelines were divided into 3 Phases: 1) HIV counselling and testing, 2) linkage to care and ART initiation, and 3) retention in care. Our data shows that for Phase 1 of the care continuum, 7.0% of the participants tested for hepatitis B; 7.5% of these had CD4 < 350 and 0.5 % categorised under WHO stage 3 or 4 upon diagnosis of HIV. None of the HCWs in the two healthcare facilities conducted additional regular counselling sessions after the patient was found to be HIV positive. All patient files scored 0.0% for the HCT conducted timeously variable (Table 3).

Ninety-four percent of the participants diagnosed were linked to care within three months of HIV diagnosis; they were successfully linked to a healthcare facility and initiated on ART (Table 3). Furthermore, 68.7% of those successfully linked to care had a CD4 count of 350 or less upon diagnosis. Of the 6.0% not linked to care, 5.0% were female, 1.5% were married while 4.5% were single. Of those not eligible for ART initiation according to the 2015 HTGs, only 3 out of 20 were not successfully linked into care.

For Phase 1 of the care continuum, the average fidelity score was 15 out of a total of 17 items checked (Table 4). For Phase 2, all patients were reminded to honour their appointments through clinic cards, and they were continuously counselled about risky sexual behaviour, TB co-infection, other co-infections, and disclosing their HIV status to friends or family members. Only 35.4% of the female participants were tested for cervical cancer (Table 3). For Phase 2, the average fidelity score was 10 of 12 items checked (Table 4). For Phase 3, patient record files revealed different retention levels. Of the patient record files reviewed, 89.5% showed that the patients underwent monitored adherence support; that is, when patients visited the healthcare facility for their monthly check ups, they were monitored for their general well-

being, TB and any adverse events from their medication. However, less than half (47.0%) of the patients collected all their prescriptions on the stipulated date, with a lower proportion of males (39.0%) compared to females (50%) collecting their prescriptions on time. In relation to marital status, 40.0% of participants who were single collected their prescriptions on time compared to 54.0% of the married participants. However, neither of these demographic characteristics was statistically significant, p=0.173 and p=0.119 respectively. Sixty seven percent of participants were linked to some sort of support group. Patient adherence level of >95.0% — patients having attended approximately 95.0% of their clinic visits according to their patient record files — was reported to be achieved by 80.5% of the participants (Table 3). The average fidelity score for Phase 3 was six out of a total of eight checked items (Table 4).

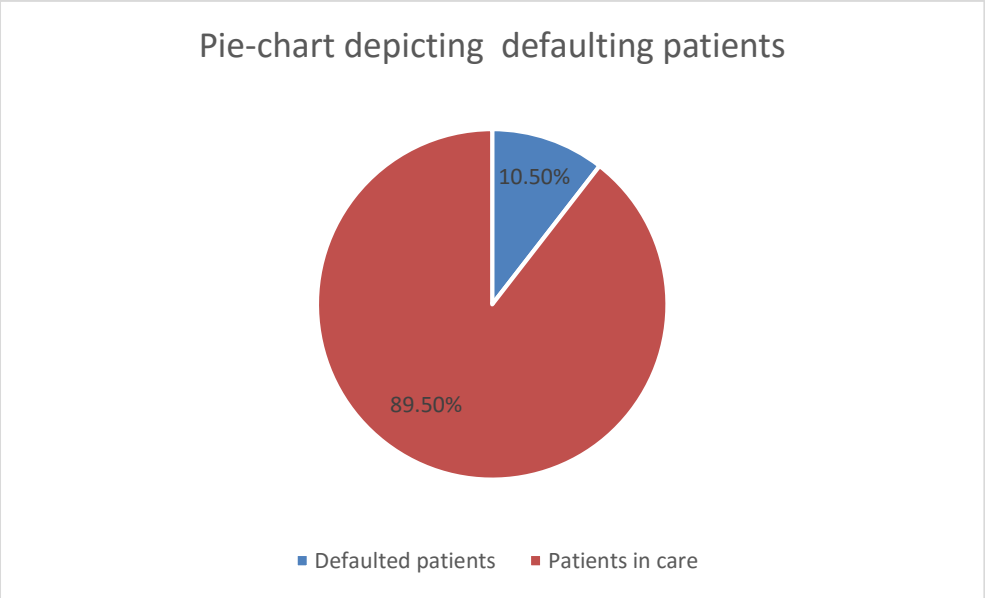

Figure 3. Percentage of patients not retained in care

Table 3: Fidelity scores for the HIV treatment guidelines descriptors

Variables	Yes	No
	N (%)	N (%)
Phase 1: HIV Counseling and Testing		
Consent prior testing	200 (100.0)	0 (0.0)
Positive 1st test retest	200 (100.0)	0 (0.0)
Elisa test conducted for final results	200 (100.0)	0 (0.0)
Post-test counseling conducted	200 (100.0)	0 (0.0)
TB_Screening	200 (100.0)	0 (0.0)
HIV_Education	200 (100.0)	0 (0.0)
CD4 cell count tested	200 (100.0)	0 (0.0)
Hepatitis	14 (7.0)	186 (93.0)
Creatinine	200 (100.0)	0 (0.0)
Clinical staging	200 (100.0)	0 (0.0)
Viral load tested	200 (100.0)	0 (0.0)
Continuous support and retesting	200 (100.0)	0 (0.0)
HCT conducted timeously	0 (0.0)	200 (100.0)
Provider decision making	200 (100.0)	0 (0.0)
Provider treatment plan	200 (100.0)	0 (0.0)
Provider care linkage	188 (94.0)	12 (6.0)
Provider support group	196 (98.0)	4 (2.0)
Phase 2: Linkage into Care and ART Initiation		
SMS technology (clinic card)	200 (100.0)	0 (0.0)
TB screening at every visit	200 (100.0)	0 (0.0)
Clinical staging	200 (100.0)	0 (0.0)
Screening for STIs	200 (100.0)	0 (0.0)
Counseling about partner	200 (100.0)	0 (0.0)
Information risk reduction	200 (100.0)	0 (0.0)
Support for disclosing	200 (100.0)	0 (0.0)
Information on fertility/contraception	200 (100.0)	0 (0.0)
Counseling on nutrition	200 (100.0)	0 (0.0)
Screening comorbidity NCDS	200 (100.0)	0 (0.0)
CD4 retesting 6monthly	200 (100.0)	0 (0.0)
Cervical Cancer Screening for women*	51 (35.4)	93(64.6)
Phase 3: Retention in Care		
Monitor ongoing adherence support	179 (89.5)	21 (10.5)
Adherence noted	179 (89.5)	21 (10.5)
Collected all Rxs	94 (47.0)	106 (53.0)
Side effects	179 (89.5)	21 (10.5)
Stigma disclosure	180 (90.0)	20 (10.0)
Caregiver support group	134 (67.0)	66 (33.0)
Quarterly counseling	179 (89.5)	21 (10.5)
Patient adherence>/=95%	161 (80.5)	39 (19.5)

*only includes females; n= 144

Table 4 shows how the participants scored on each phase of care. Both facilities fared favourably in terms of the overall fidelity score, but on average facility 2 fared slightly better (32.97 score) than facility 1 (32.36 score).

Table 4: Fidelity score for the different Phases of the Health Care Continuum

Variable	Facility 1		Facility 2		Overall Facility Score	
	Mean (SD)	**N (min-max)**	**Mean (SD)**	**N (min-max)**	**Mean (SD)**	**N (min- max)**
Person overall fidelity score	32.36 (2.77)	100 (24-35)	32.97 (1.89)	100 (26-35)	32.67(2.39)	200 (24-35)
Fidelity Score for Diagnosis	15 (0.45)	100 (13-16)	14.98 (0.28)	100 (14-16)	14.99(0.37)	200 (13-16)
Fidelity Score for Linkage	10.2 (0.40)	100 (10-11)	10.3 (0.46)	100 (10-11)	10.25(0.47)	200 (11-12)
Fidelity Score for Retention	6.16 (2.63)	100 (0-8)	6.69 (1.84)	100 (0-8)	6.43 (2.28)	200 (0-8)

The Fidelity Score for Diagnosis was calculated from 17 diagnosis predictor variables from Phase 1; the Fidelity Score for Linkage, from 12 linkage predictor variables from phase 2 and the Fidelity Score for Retention, from 8 retention predictor variables from phase 3 of the HCC (Table 4). The fidelity score for phase 3 was used to determine the level of adherence. The demographic variables (gender, occupation, marital status) were not found to be associated with fidelity retention score (Table 5).

Table 5: Associations between demographic variables and the retention in care outcome

Variables	Low Fidelity Score on Adherence: N (%)	High Fidelity Score on Adherence: N (%)	Chi^2 & Fisher's Exact p-value
Gender			
Male	9 (16.1)	47 (83.9)	0.341
Female	16 (11.1)	128 (88.9)	
Occupation			
Employed	4 (8.7)	42 (91.3)	0.108
Student	2 (50.0)	2 (50.0)	
Unemployed	14 (13.7)	88 (86.3)	
Other	5 (10.4)	43 (89.6)	
Marital Status			
Married	57(10.0)	63 (90.0)	0.347
Single	17 (15.3)	94 (84.7)	
Divorced / Widowed	1 (5.3)	18 (94.7)	
HIV Category (CD4 Count at Time of Diagnosis)			
CD4 ≤ 350	19 (14.1)	116 (85.9)	0.599
CD4 351-500	2 (8.0)	23 (92.0)	
CD4>500	3 (15.0)	17 (85.0)	
CD4<350 Active TB Disease	1 (14.3)	6 (85.7)	
CD4<200 WHO Stage 3 or 4	0 (0.00)	13 (100.0)	

Since the retention score variable showed a skewed distribution (Figure 3), a logistic regression rather than a linear regression was computed.

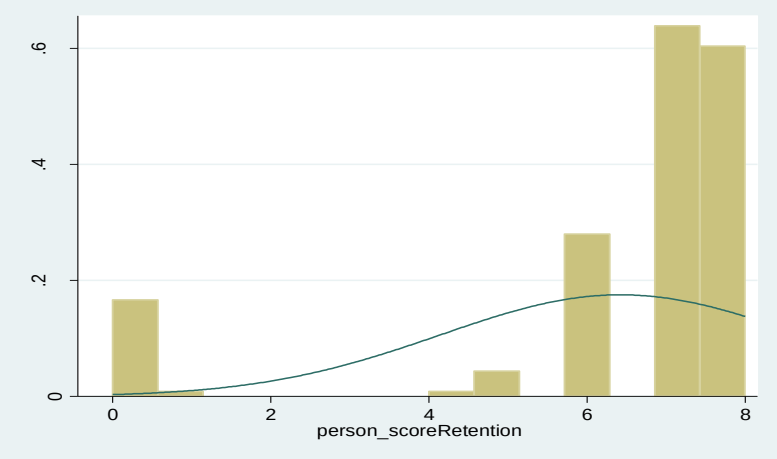

Figure 4: Distribution of person retention score

Table 6 describes how univariable and multivariable analyses of demographic factors relate to retention score, through fitting logistic regression models. A fidelity score of 6 and below was categorised to be failure of retention in care and a score of 7 and above was categorised as successful retention in care. The important factors from our univariable and multivariable analyses were gender and age. Females were more likely to be retained in care compared to males (OR 0.47, 95% CI 0.22-1.03, p=0.06) as were older patients. For every age increase of 10 years, participants were more likely to be retained in care (OR 0.71, 95% CI 0.51-0.99, p=0.045). Participants who were single were less likely to be retained in care compared to married participants in univariable analysis (OR 1.9 95% CI 0.96-3.75, p=0.064), but after adjusting the model into a multivariable analysis this was not statistically significant (OR 1.47, 95% CI 0.69-3.19, p=0.319). Although not statistically significant, those not due to start ART according to the 2015 HTGs were less likely to be retained in care (OR 1.01, 95% CI 0.31-3.33, p=0.980). There was also no evidence of marital status having an impact on retention failure.

Table 6: Unadjusted and adjusted odds ratios of determinants associated with the retention phase of Health Care Continuum

Variables	Unadjusted/Univariable*	p-value	Adjusted /Multivariable*	p-value
Gender				
Male	1 (Reference)		1 (Reference)	
Female	0.65 (0.33-1.24)	0.194	0.47 (0.22-1.03)	0.06
Occupation				
Employed	1 (Reference)		1 (Reference)	
Student	-		-	
Unemployed	1.12 (0.51-2.5)	0.768	1.28 (0.55-2.99)	0.319
Other	1.05 (0.42-2.63)	0.913	1.24 (0.45-3.45)	0.329
Marital Status				
Married	1 (Reference)		1 (Reference)	
Single	1.9 (0.96-3.75)	0.064	1.47 (0.69-3.19)	0.319
Divorced / Widowed	0.39 (0.82-1.90)	0.248	0.67 (1.3-3.44)	0.329
HIV Category (CD4 Count Status at Time of Diagnosis)				
CD4</= 350	1 (Reference)		1 (Reference)	
CD4 351-500	0.55 (0.19-1.57)	0.268	0.55 (0.18-1.67)	0.291
CD4>500	1.47 (0.56-3.88)	0.429	1.01 (0.31-3.33)	0.980
CD4<350 Active TB Disease	0.37 (0.43-3.16)	0.363	0.37 (0.42-3.40)	0.386
CD4<200 WHO Stage 3 or 4	0.40 (0.85-1.90)	0.250	0.45 (0.84-2.42)	0.354
Age increase of 10 years	0.63 (0.48-0.85)	0.002	0.71 (0.51-0.99)	0.045

* OR(95%CI)

We generated interaction terms to further explore the relationship and associations between our study variables and retention score (Table 7). Our tested hypotheses are as follows: 1) being female and single is associated with higher fidelity retention score, 2) being female and eligible for ART according to the 2015 HTGs is associated with higher fidelity retention score, and 3) being female and older is associated with higher fidelity retention score. Our results show that single females are more likely to be retained in care but this was not statistically significant

(OR 0.72, 95% CI 0.16-3.14, p=0.957). Results also show that females who are not eligible for ART are less likely to be retained in care; this was also not statistically significant (OR 1.42, 95% CI 0.57-35.43, p=0.832). Finally, although our results revealed statistical significance with the variables ‘gender’ and ‘increment in age’ in our multivariable analysis, interactions of these two factors did not show statistically significant results (OR 0.73, 95% CI 0.39-1.35, p=0.315).

Table 7: Adjusted odds ratios of the interactions between determinants associated with retention in care to the Health Care Continuum

Variable	Adjusted OR*	p-value
Gender # Marital Status		
Male # Divorced/Widowed	-	
Females # Single	0.72 (0.16-3.14)	0.957
Gender # Eligibility for ART		
Male	1 (Reference)	
Female # ART	1.42 (0.57-35.43)	0.832
Gender # Age Increment		
Male	1 (Reference)	
Female # Age Increment	0.73 (0.39-1.35)	0.315

* OR(95%CI)
# Interactions symbol

Defaulter Status

Ten percent of the study population were defaulters (Figure 3). Sixteen percent of the male participants were defaulters whilst 7.0% were female. Nine percent of the defaulters were unemployed and 11.0% were employed. Fourteen percent of the defaulted participants were single whilst 4.0% were married, and 11.0% of the defaulters had CD4 count < 350 upon diagnosis of HIV whilst 5.0% had CD4 count >500 upon diagnosis.

The overall proportion of patients retained in care in each healthcare facility at the time of data collection was 64.0% at Facility 1 and 78.0% Facility 2. These proportions were calculated as the number of patients retained in care divided by the number of patients initiated on ART in each healthcare facility.

3.3 Qualitative analysis

This section of the report summarizes the qualitative approach used to address the question 'What is the extent of implementation fidelity of the HIV care continuum among the healthcare workers at two healthcare facilities in rural Mpumalanga Province?'. In-depth interviews with HCWs were done to explore how the moderating factors of implementation fidelity affect adherence of HCWs to the HCC under the themes: 1) quality of care delivery, 2) participant responsiveness, 3) facilitation strategies, and 4) complexity of an intervention, all derived from Carroll et al.'s conceptual framework for implementation.

3.3.1 Descriptive analysis

Eight HCWs who attend to HIV positive patients at Facilities 1 and 2 were interviewed. The HCWs comprised six professional nurses and two lay counsellors. At least two of the professional nurses was trained in 'Nurse Initiated Management of Antiretroviral Treatment' (NIMART) at each facility. All the professional nurses had prior experience in all disciplines of the nursing field, and all but one had prior hospital working experience. Working experience of the professional nurses ranged from 2 to 15 years. None of the lay counsellors had post-secondary school education.

3.3.2 Quality of Care Delivery

This is the manner in or extent to which the content of the HTGs were carried out by the HCWs, including their preparedness, respectfulness and confidence when attending to patienst.

All the HCWs reported that they conduct pre- and post- HIV counselling as well as test also confirmed conducting a confirmatory test after an initial HIV test has a positive result:

"you tell the patient about the testing kits…that this is 'advance quality' and this is 'repeat test'…I'm going to test you with this one ['advance quality'], this one ['repeat test'] is to confirm (LC2)."

"*They [lay counsellors] counsel the patients and test them, though in their absence we (the nurses) do what they are doing (PN4)"*

"if you have given them a health talk in the morning… then you counsel them… again after 6 weeks [the patients] come and test (LC1)."

Professional nurses mainly reinforce what lay counsellors discuss with HIV positive patients. Blood tests are drawn from patients and they are told to come back for their results, as outlined in the guidelines:

"When we initiate the patient we collect blood for viral load at 6 months and from there at 12 months and from there on a yearly basis (PN4)."

"We collect baseline, then you wait for the baseline…you come back and in 3 days' time you contact the patient to say 'can you come back so that we can check the results, to check whether you are fit to continue with the treatment?'(PN4)."

The importance of patients accepting their HIV status and agreeing to start ART depends primarily on the HCW counselling patients appropriately, making sure that they understand their status and are aware of health changes happening to them and how to proceed when these changes occur. HCWs also ensure that they supply the patients with a return date for treatment and re-evaluation:

"…you let patient explain what, they were taught [during their initial counselling session] and you just add on to it…if you see this kind of side effects, it means there's a problem so, you must address it (PN1)."

"We phone the patient to come for initiation. So when they come for initiation, they go straight via the counsellor's room again, then they will be taught or given the second lesson then they come this side, we reinforce the second lesson. Then we check the social readiness to start treatment then we initiate (PN3)."

Counselling sessions are conversational and include asking questions to ensure that patients understand what they were being counselled on. HCWs are also not confined to one job description – they test, counsel and draw blood from patients as required:

> *"When I counsel, I ask. It's a conversation (LC1)."*
>
> *"Thorough counselling of (about) taking medication when and how, and when a regimen has to be changed and under what circumstance, is what the HCWs do on a daily basis (PN5)."*
>
> *"I tell them everything…I give them time to also talk… then I fill in the rest of the information they missed (LC2)."*

Matters of concern regarding quality of healthcare were the non-availability of data capturers on weekends. This jeopardised the quality of care in that files could often not be retrieved and HCWs sometimes have to send patients home without their required medication:

> *"Things that hinder us, like during the weekend we don't have a data capture, we don't have anybody to retrieve the files. You don't really know whether the patient is on Bactrim because there's no record, there's nobody to retrieve the file. You can't even get the file even if you try (PN4)."*

3.3.3 Participant Responsiveness

Participant Responsiveness is how well HCWs interacted with patients during their consults, as well as the HCWs' judgment of the HTGs.

HCWs interact with their patients and counsel them to ensure that they adhere to their medication. They start this process when patients are newly diagnosed and initiated on ART. HCWs explain to the patients the processes involved in taking their medication (when and how much), until the patient feels confident in taking their medication on their own.

> ***"****I think that's good, you know to sit down with your patient you know. If you need to do pill count monthly, it's good, do it. So that the patient will understand, you know. You go through [everything] every time you… you're with the patient. You remind them, 'no you're not supposed to… to miss pills. You know. Every day you must take your pills' (PN1)."*

> *"…so you must sit with the patient and give them again the adherence [re-enforce counselling] again the initiation they must have the adherence again [adhere to the HCC] (PN5)."*

Even though some HCWs give their patients all the support they can in terms of patients adhering to treatment, other HCWs become discouraged when patients stop adhering to medication because they feel they have done all they could to ensure patients were well educated regarding adherence:

> *"Ah! patients are still the same…cannot change a person…yes even if they can change the guidelines but the person, you cannot change them (LC1)."*

On the other hand, other HCWs seem of the notion that encouragement should be given to patients who were adherent to their medication as a way of reinforcement.

> *"You must praise your patient… they are encouraged you know (PN1)."*

In general, HCWs seem keen to look after HIV positive patients and to ensure that these patients are retained in care, but they also had complaints of work overload having increased with the new guidelines of test and treat:

> *"There's a lot of work…. we are always tired" …. The work is too much but we are trying (PN2)."*
>
> *"So it's a… it's more workload at the Primary healthcare level (LC1)."*
>
> *"But at the very same time this hell lot of work has come with a lot of papers (PN4)."*
>
> *"…me, I think they must be more staff (PN5)."*

Only one HCW did not seem to have complaints with the amendments of the guidelines:

> *"Writing TDF 3TC Efavirenz…we just write FDC; one tablet daily times 28 days and then they go. It's less now; I can say it's less (PN6)."*

HCWs also presented contradictory perceptions on working with the guidelines. Some welcomed the guidelines and engaged with them to the best of their ability to ensure a patient is provided the appropriate care:

> *"Do the best, help the patient" (PN1)."*
>
> *"We really want to work and we are happy to see our people's health becoming better (PN4)."*

Others were disgruntled about the guidelines, because they see them as time-consuming and patients are not pleased with the waiting time:

> *"And the other thing it [new guidelines] even add some stress to us, you know when people are just screaming outside, you know, 'yey you are just playing in the consulting room', and they are saying all these things, you hear them inside here (consultation room) (PN4)."*

However, overall, HCWs' attitudes were more favourable toward their patients getting healthy than they were concerned about the workload:

"Our patients mustn't fall sick they must get treatment… me myself I'm happy when the viral is 'LDL', lower than the limit (PN5)."

"…because we want people to live long… (PN6)."

HCWs were also very optimistic because prior to the new guidelines they attended to a lot of sickly patients; many patients were hospitalised or dying due to not being on ARVs whilst HIV positive:

"*We are no more seeing patients who are now losing weight, we are no more seeing patients who are having those signs of HIV symptoms…The benefits, our patients are living long (PN5)."*

With the availability of treatment, patients can now live longer and healthier lives. HIV positive patients cannot be easily identified as they now look healthy and they live longer:

"For now everybody is the same you won't identify…Main benefit, it's even boosting economically because people are getting better they go to work (PN6)."

HCWs took it upon themselves to initiate age-appropriate support groups amongst individuals who were treated for HIV, but these support groups were dissolved due to stigma arising against the patients within their communities.

3.3.4 Facilitation Strategies

These are measures employed to ensure that there is standardisation in implementing the HTGs if and when added assistance is needed by the HCWs.

HCWs also encounter instances where they are unable to treat patients effectively depending on the severity of the case. These complicated patients are referred to the nearest hospital to be attended to by doctors:

"*But if there are… some results are high or very low that's where we refer the patient to see the doctor…so if the patient, eh let's take creatinine is very high, then we'll refer the patient to the doctor (PN1)."*

"…we do refer them, like the one whose viral load is not controlled (PN2)."

Referring patients assist the HCWs in effectively managing HIV patients and also ensures that guidelines are appropriately adhered to. Primary HCWs' scope of work does not allow them to attend to very ill patients, thus, referral ensures that these ill patients get the treatment they need at the secondary or tertiary level:

"…just like those patients who are really sick, you find that they have a very low CD4 count in a way that they have to be referred to the hospital (LC1)."

At each healthcare facility, all information about patient treatment is recorded in each patient file. Documentation of the information assists in ensuring that paper trail is maintained at all times and that whenever HCWs need to refer to any medication history about a patient, they can easily refer to the patient file:

"We write everything we did then after that the capturer will take the files and capture them in the system, in our register (LC1)."

Patient record files and registers assist HCWs in effectively tracking patients and following them up. They also help in ensuring that patients are given the correct treatment.

The HCWs also find working with guidelines helpful in treating patients, because the guidelines explain all aspects of caring for an HIV positive patient:

"*…Because you always refer [to the guidelines] whatever you don't understand, you always go to the index. So me I feel like it makes things more simple … maybe the part where, I can say the part where they (guidelines) eh, explain to you (PN1)."*

"The guidelines help you to have a conversation with your patients…because it was difficult when you counsel, you were supposed to counsel lots of people, you were giving more information, but now it's sort of a conservation (with the patient) (LC1)."

HCWs also found the guidelines important as they aid in giving direction on what to do to effectively care for a patient:

"I think it's the most critical one because every day we deal with eh, maybe initiating patients, so that part for me is critical (PN1)."

"*The guideline now they help us... the guidelines are fine; the guidelines help you to have a conversation with your patients (LC1)."*

HCWs also appreciate the support they receive from fellow colleagues as well as from the district level and NGOs. Workshops they attend occasionally ensure that they are up to date with current treatment guidelines:

"*By having support, even to (from) our colleague, if there is something you don't understand, you are going to one of the colleague (PN5)."*

"When we have a workshop at the higher places, maybe we're having the workshop at the district or sub-district….it makes it easier for the team to work (PN3)."

"I think there is support in a way that you may find that there's a workshop maybe for Highly Active Antiretroviral Therapy (HAART) (PN2)."

Assistance from other colleagues also means that one nurse is not overwhelmed with all the processes involved in caring for the patient.

"Yah I think that they are helping us better because if you can look at it, you don't do this thing (caring for patients) alone, there's uhm the vital signs area, it has been done, the height it has been done for you (PN1)."

3.3.5 Complexity of an Intervention

This is extent to which HCWs experienced challenges or executed their duties with ease when attending to patients in their facilities.

There are many patients who default from their medication and from the HCC all together, making the intervention more complex and not as straight forward as expected:

> *"The other thing that demotivates us is the high defaulter rates of patients due to patient mobility. You are moving from one clinic to another, like now the patient initiates here, after 2 months you'll receive a call from maybe Johannesburg (PN4)."*

HCWs experience challenges in ensuring that patients understand and take ownership of their own health and ensure that they take their medication as prescribed:

> *"So hence we have got increased rate of unsuppressed viral load, because people do not really understand (PN4)."*

The process of retaining patients in care goes beyond just ensuring that patients take their medication – HCWs need to constantly reinforce counselling and ensure patients collect their prescriptions on the due dates and take medication as prescribed:

> *"…the patient needs serious re-adherence [reinforcement] again, maybe they are taking (their medication) but they are not sticking to the time (PN5)."*

Furthermore, HCWs not only cater for the clinical aspect of the patient, psychosocial interventions must also be considered by the HCWs as these are some of the reasons why patients default from their treatment.

> "*Sometimes they (the patient) have loss of appetite, sometimes they don't have anything to eat at home…sometimes they don't have source of income (PN6)."*

HCWs also find it difficult to retain patients in care. When patients default, they have to ensure that they follow up on these patients, which they perceive as a task outside of their scope of work:

> "*…but most of the time they [patients] use a phone, when we have some time we do call them and many a time the response to the call may be negative (PN5)."*

HCWs then make use of home-based carers to trace the defaulting patients and bring them back to be re-adhered back into treatment:

> *"And then we…call, we also have uh, the home based carers(PN1)."*

> *"If we call the patient and they don't, come, then the home based carers will go there…Ya, to check what's going on, because sometimes you find that maybe the patient is sick or they are admitted [in hospital], but most of the time we'll call and then the patient will come and then when they come, what we do we need to step up adherence (PN1)."*

> *"They [home based carers] go to the individual houses to go and check them (LC1)."*

Another factor contributing to the complexity of the HCC is the mobility of patients, migration due to work or due to stigma:

> *"They are not consistent, [a patient will say] I'm not there I'm at Johannesburg, now I'm taking a job (PN5)."*

> "*Even on the forms we are not saying, concerning the HIV, just that we're tracing the patients to come to the clinic, that's where we're going to tell the patient why are we tracing them (P7)."*

Despite the complexity of retaining defaulting patients, HCWs find the guidelines easy and straight forward to work with:

> "*It's not complex, its straight forward to be honest with you, because we do have guidelines to guide us, those with the challenges we refer… Simple and straight forward (PN1)."*

Because of the perceived simplicity of the guidelines by some HCWs, their patients are compliant to the medication:

> *"…but for now as they are taking 1,1,1, (one tablet each) … ah there's no problem, they are complying now (PN6)."*

Another HCW believes that technology makes it easy to trace defaulters:

> *"So you don't have a lot of people that are on' loss to follow' or patients whom you don't know what happened to them, because even those that are far like Jo'burg [Johannesburg] or wherever, we call them through to come by the phone (PN5)."*

As it is evident from our report, different opinions were raised about the guidelines. Some HCWs feel they make the HCC simpler:

> *"for me I think…uhm the guidelines make things simple (PN1)."*

Some feel that the guidelines slow their working progress:

> *"…it will make you work slow but you will be doing the right thing because it's there (PN3)."*

Others feel the frequent changes to the guidelines make them difficult to follow and confusing:

> *"The guidelines are changing, every time, now and then sometimes it confuses because you'll still stick to that guideline meanwhile guidelines are changing every day (PN6).*"

This chapter summarised our results from the quantitative and qualitative data collected. Our analyses revealed a high HIV diagnoses and linkage to care rate, but a lower retention in care rate. This low retention in care rate also includes patients who defaulted from care. HCWs were also interviewed to share their experiences on making use of the HTGs when attending to HIV+ patients. The following chapter will further elaborate on these experiences and the overall interpretation of our findings.

CHAPTER 4

DISCUSSION

4.1 Introduction

The aim of our study was to assess the extent of implementation fidelity of the HCC in two different healthcare facilities in Agincourt, rural Mpumalanga, and to explore how moderating factors influence implementation fidelity of this care continuum. Our study found that overall implementation fidelity of the HCC was high in both settings, and HCWs were prioritising patients' health and wellbeing despite the challenges they were facing with retaining patients in care.

4.2 Discussion

The two healthcare facilities that participated in the study were selected based on their level of functioning: one was assessed better and one worse in terms of their operating systems. The two healthcare facilities have different filing systems and retrieve and store patient data in different ways that we hypothesised could influence the smooth operation of the facilities and ultimately the ease of carrying out the HCC. However, our results revealed that healthcare facility operating systems did not have a significant effect when determining implementation fidelity of the HCC carried out by the HCWs in each facility.

Both healthcare facilities displayed a high implementation fidelity score, in that the HCWs were adherent to the HTGs given to them by the Department of Health. Higher implementation fidelity scores were observed in Phase 1 (HIV counselling and testing) and Phase 2 (linkage to care and ART initiation), while Phase 3 (retention in care) had a moderate to lower score.

The high fidelity score of Phase 1 implies that the HCWs followed this phase of care diligently; this was supported by findings from the interviews conducted with the HCWs. However, this high score likely reflects a bias because our study extracted data from patient record files – by virtue of a patient having a record file, that patient was already tested and diagnosed.

The high score of Phase 2 also portrays the diligence of HCWs in following the HTGs. HCWs through the interviews emphasised counselling, empathy and HIV education. Findings from the checklist toolkit as well as from the interviews were in agreement regarding patient involvement in decision making during ART initiation processes; this ensured that patients were actively engaged in their care and that they knew when to return to the healthcare facility to be initiated into care.

Similar studies which assessed efficacies (62) and challenges (63) of linking patients into care assert that involving patients in their own care and giving them specific appointments for ART initiation, further improved linkage to care. This current practice of patient involvement in care will prove to be very useful with the current UTT guidelines rolled out on 1st September 2016. This practice will ensure that more patients are effectively linked to care and initiated on ART as soon as they are diagnosed.

The fidelity score for Phase 3 (retention in care) was moderately lower. HCWs reported facing challenges in retaining patients in care. They cited stigma and failure to trace defaulted patients as some of their major challenges. This finding is corroborated by other studies assessing adherence to HIV treatment and care. These studies found stigma, medication side effects and lack of support to be challenges in retaining patients in care and to achieving adherence (6, 51). In our study, peer support groups were noted by the HCWs as an intervention that assisted in reducing stigma amongst patients attending these groups; patients talked about the different challenges they are faced with as people living with HIV/AIDS and how they tackle these

challeges. Members of the support groups easily freely talked about their HIV status without feeling stigmatised by other peers in the group. Resources should be channelled to such interventions in order to reduce stigma and increase retention in HIV care.

Findings from the fidelity checklist toolkit reveal that the HTGs were appropriately followed. HCW interviews also confirmed that quality of care was provided in attending to patients; the high fidelity scores for Phases 1 and 2 showed that the HCC processes were indeed conducted by the HCWs; that is, content and dose of Phase 1 and 2 of the continuum were executed effectively.

HCWs displayed thorough knowledge of the HTGs as they were able to relay the information they share with patients during their consultations (content). The HCWs also showed knowledge of how often and how many times certain processes are administered to the patient according to the HTGs (dosage).

HCWs, however, deviated from the guidelines when conducting timeous counselling sessions. Although they reported counselling patients timeously in the interviews, the fidelity checklist toolkit found contrary findings. The fidelity checklist toolkit showed a 0.0% score for 'HIV Testing and Counselling (HCT) conducted timeously'. It transpired that the practice in these facilities is that once patients are tested positive and are taken to the NIMART nurses, they do not return back to the lay counsellors for further counselling, reaffirming the 0.0% HCT score. As evident in the interviews, this could be due to lack of time in attending to patients, as well as the perception that once a patient has been attended to and counselled by a professional nurse; there is no need to go back to the lay counsellors for further counselling during follow up consultation meetings. Our fidelity checklist toolkit further confirmed that Phase 3 (retention in care) is where most challenges arise in the care continuum. Difficulties in retaining patients in care negatively affect monitoring of viral load and viral load suppression (6).

Our results show that the level of fidelity is not only determined by the interaction of the HCWs with the HTGs when attending to patients; patient factors also influence the level of adherence to the care continuum. In our study, patient socio-demographic factors are found to be contributing factors in determining whether patients were adhering to care or not. We looked at age, occupation, gender, marital status and HIV status /category at time of diagnosis, to determine if the demographic factors contributed to adherence to treatment. As in other studies, our study also found gender and age to be contributing factors of retention; that is, females and older patients were more likely to remain in care (52, 53). Unlike other studies, (54, 55) we did not find occupation and marital status statistically significant in retaining patients in care, possibly due to small sample size .

There is a challenge in linking patients with CD4>500 into care, i.e those patients not eligible for ART prior to the new UTT guidelines. HCWs should take note of patients who do not appear ill, as they may pose a challenge to being initiated into care, despite improved linkage processes at the healthcare facilities (56, 57).

In addition to assessing the demographic factors that contribute to the fidelity score, we employed Carroll et al.'s framework of implementation fidelity to determine how moderating factors of the framework affected the fidelity score on HCWs' daily practices at the facilities. This is discussed below.

4.2.1 Quality of Care Delivery

Our findings indicate that HCWs have executed the HCC to acceptable quality, displaying knowledge of what was expected from them in caring for HIV patients. During our interviews with the HCWs, they appeared confident in responding to questions and in verbally outlining their daily practices, detailing how they attend to and treat patients.

Each facility has at least two NIMART trained nurses to ensure high quality implementation of the HCC. In order to ensure that expertise and skills are appropriately distributed, lay counsellors are appointed as the first line of contact; they counsel and test patients for HIV. The distribution of skills and expertise ensures that the NIMART nurses get to focus on the clinical aspects of the HIV positive patient while also reinforcing that patients receive the appropriate counselling from the lay counsellors at the first point of contact.

4.2.2 Participant Responsiveness

HCWs had different perceptions about the use of the guidelines to treat patients. Some HCWs complained of the impracticality of using the guidelines ─ the guidelines are not easy to navigate through ─ thus, they often have to rely on experience or on each other when attending to patients. They also found the guidelines to be time consuming but prioritised patient health above everything. Some found the guidelines to be confusing as they were amended quite often, while others welcomed the guidelines and did not have problems following them. Moreover, HCWs reported that having good rapport with patients contributes to patients honouring their appointments at the healthcare facilities.

HCWs also reported that they encourage patients who are doing well and empathise with those who are not. They would also reprimand patients who are not adhering to their treatment. HCWs stated that it was through this HCW-patient relationship that they learned how to react to or help patients who struggle adhering to care. Kristofco et al. (1998) and Chesney (2000) also found that a good relationship between HCW and patient influences interventions positively.

Compassion and empathy encourages patients to stay in care. These findings are supported by Bogart et al. (2013) and Kempf et al. (2013) who reported that "if HCWs were respectful, patients found this an incentive to honour their clinic appointments". One HCW relayed an

experience with a patient thanking her (HCW) for taking care of him (patient) when he was sick; this encouraged the patient to continue with care.

4.2.3 Facilitation Strategies

The HTG is a standardised tool disseminated across all facilities in South Africa according to their respective classification – whether they are a tertiary, secondary or a primary health facility (58) – to ensure standardization of treatment in the HCC. Roen et al. (2003) stated that standardisation of interventions helps ensure their effectiveness and fidelity. Findings from our study corroborates Roen's findings in that through the standardisation of referral systems put in place across all healthcare facilities, patients are able to still receive the appropriate care and to remain in the continuum of care no matter how complicated their HIV status.

The referral systems in place have helped ease the load at these two PHCs in dealing with 'complicated' patients, and to ensure that patients receive the care they need at the hospital level, as NIMART nurses at the PHC level are not equipped to attend to all complications experienced by a patient. As research has shown, referring patients ensures that they remain in care and do not default due to not seeing progress in their health status (59-61).

We have learned from our study that healthcare facilities need to have well-managed filing systems in place, as this will aid HCWs in their practice. If patient record files are easily accessible to HCWs, and if these files are easy to navigate through, this will lessen the burden for HCWs as they will spend less time doing administrative work and more time examining the patient (60).

HCWs have welcomed HTGs as tools to guide them in effectively managing patients and improving their work towards quality of care. HCWs also appreciated external aid from the district offices and NGOs. These are facilitation strategies that acted as a form of support in

assisting HCWs to render quality care. External support is seen as an enabler to carry out functions more efficiently (62, 63).

4.2.4 Complexity of an Intervention

Our results showed that the HCC was delivered with high quality of care ─ given the high fidelity scores for HCC's phases 1 and 2 ─ and that facilitation strategies aid HCWs in executing daily practices. However, the interaction between HCW and patients is not as easy as the guidelines portray. The HCW counsel patients and instruct them on when and how to take their medication, but a patient will not necessarily follow a HCW's instructions. Our study showed that although the majority of patients who were diagnosed with HIV were linked to care, it was also difficult to retain patients in care. Emphasis on patient education and empowerment should be reinforced because it is ultimately up to the patients if they will adhere to HCWs' instructions or not. Though other factors such as environmental and societal factors also play an important role, patient empowerment is vital (64, 65).

Retention factors affect implementing the HCC with high fidelity. The guidelines advise HCWs on what to do in order to ensure a patient is retained in care, but we found that fewer patients collected their refill prescriptions on time and fewer patients agreed to be included in some form of support group. HCWs were also inconsistent in counselling patients on side effects during follow up appointments.

Adding to the complexity of the HCC, HCWs need to counsel patients on psychosocial difficulties and on their clinical ailments due to medication side effects, as these factors may contribute to patients not adhering to treatment and eventually defaulting. Age-appropriate support groups were started by the HCWs to ensure patients received peer support in addition to clinical support, but these support groups were cancelled due to the stigma arising in the

community (66). HIV-related stigma continues to be a major challenge to be addressed in communities.

At the two facilities observed, there was also consistent tracing of patients in order to maintain the continuum of care. HCWs often assumed the role of telephonically calling patients to trace them in the absence of home-based carers who visit the defaulted patients. HCWs found this additional work a challenge, as there was not enough time nor personnel to attend to matters outside of clinical ailments of patients. Despite the engagement of HCWs in tracing defaulting patients, the defaulter rate in our sample was 10%. Thus, better and more innovative strategies could be employed, such as actively making use of mobile devices that send timely reminders, or initiating WhatsApp groups to engage patients with and to contact the defaulting patients. Guidelines could also be amended to include patients' next of kin who is actively involved in patient care ─ this would provide HCWs with a contact person they can call to assist in sharing information regarding the whereabouts of the defaulting patient. Such interventions can assist in retaining patients in care (67).

Furthermore, even though the guidelines are welcomed by HCWs, having to readjust to new guidelines also posed a challenge. Some HCWs feel that they have to unlearn what they are already practicing in order to adopt new guidelines, whilst also ensuring that patients adapt to the changes as well. Some patients may be keen to adopt new guidelines, for example in moving from multiple to single regimen (reported by the HCWs during interviews). However, some patients may not welcome a change, for example those who do not feel sick may not see the need in being initiated on treatment as per the new 'test and treat' guidelines.

4.2.5 Implementation Science Practice

There were some adaptations to the guidelines that were being practiced at these two healthcare facilities, to ensure that patients received quality care even with limited resources. For example,

both facilities made use of a ‘patient green card’ instead of an SMS system to remind patients of their appointment. Knowing that patients stayed far from the healthcare facilities, HCWs also ordered double testing of patients’ bloods (testing for CD4 count and also instructing the lab to test for Hepatitis B if the CD4 count was below 100) – this ensured that patients did not have to travel numerous times to have their bloods tested and also ensured that they followed the guidelines. This contextualising of the intervention aligns well with implementation science theory. Adaptation is encouraged in implementation science, as long as it does not deviate from the core elements of an intervention. The HCWs made sure that even with limited recourses and under circumstances unique to their facilities, patients still receive the best possible care.

4.3 LIMITATIONS

Our study had some limitations. Selection of healthcare facilities for conducting the study was purposive rather than random, and the sample size was small. There was no data in the patient record files which stated reasons for defaulting patients, this would have assisted in further exploring reasons behind the low fidelity score of retention, in addition to the retention factors already collected for this study. In addition, given high migration in the Bushbuckridge area, it is likely that some residents will be classified as loss to follow-up or as defaulters when they may have moved out of the area and are receiving care elsewhere.

Patient record data entered by the HCWs (i.e. when a patient is due for CD4 count collection or when a patient is deemed a defaulter) was inconsistent in the files; this was overcome by standardising the fidelity checklist toolkit, collecting the raw data as it was and then applying the adaptation model after completion of the interviews with the HCWs.

Reporting biases by HCWs could not be conclusively avoided. The fidelity checklist toolkit was used to confirm as well as to note similarities and discrepancies between the findings.

From our findings, even though the two healthcare facilities had different filing systems this did not result in different daily operating systems in the facilities. As a result, our findings were similar in the two facilities. We found that HCWs were able to diagnose and link patients to care through active interaction with the patients, but stigma from the community was found to be a challenge. HCWs stated that stigma contributed to the low retention in care of patients. HCWs also appreciated the support from their district office as well as knowing that they can refer patients to tertiary hospitals whenever they were unable to treat the patient at their facility. From our study we were able to deduce when implementation practices employed, such as adaptation of some of the HTGs to fit the context. We were also able to identify gaps for better knowledge and improvement for future studies.

CHAPTER 5

5.1 CONCLUSION

This study aimed to determine the fidelity with which HCWs at two healthcare facilities in the Agincourt area of rural Mpumalanga Province implemented the HCC. Our study assessed the extent to which the HCWs adhered to the HTGs in order to retain patients in care. This was done by using a fidelity checklist toolkit derived from the 2015 HTGs. The toolkit was used to generate implementation fidelity scores for both facilities in each phase of the continuum of care, as well as an overall fidelity score. In addition, HCWs were interviewed about their interaction with and attitudes towards the treatment guidelines, using an implementation fidelity framework to develop the interview guide.

The study examined how the two healthcare facilities performed in achieving the 90-90-90 goals. The overall fidelity score of the two healthcare facilities was generally high; however, when breaking down the score to assess the extent of fidelity in the phases of the care continuum, retention in care showed a lower fidelity score. Missed prescriptions, stigma, lack of support groups, and defaulting patients were some of the predictors measured in our checklist toolkit which contributed to the lower retention fidelity score. Although HCWs feel they have good support and delivered quality of care to their patients, they also reiterated having difficulty retaining patients and tracing defaulters. The quality of the HCW-patient relationship was noted by HCWs as a contributing factor to patients remaining in care.

The role that patients play in the continuum of care is also critical to achieving maximum adherence, and socio-demographic factors such as age, gender, marital status and occupation, as well as HIV status (CD4 count status at time of diagnosis) should also be taken into account by contextualising care when attending to different socio-demographic groups.

Through assessing implementation fidelity, we were able to examine the role of implementation science. We were able to determine how we can adopt what is already known as an effective intervention (in this case the HCC) ─ tailor and contextualise it to similar facilities ─ to ensure that results are achieved while we still retain the core elements of the main intervention. This is of great importance as South Africa is now implementing the new UTT guidelines. Our study assisted in identifying some challenges that HCWs are faced with on a daily basis when working with the older guidelines. From our findings, enhanced staff capacity, user-friendly guidelines, better filing systems and better strategies of disseminating guidelines are needed to effectively implement UTT.

Mobile health technology is currently being used by HCWs in some countries when attending to patients(68). Diagnosing, monitoring and prescribing for patients at a distance has now become possible. This can be a valuable stratergy to increase adherence among HIV+ patients. Stigma continues to be a problem in our study site community even with the adherence clubs being present. Making use of technology such as WhatsApp groups or other social media chats, can assit with creating non-contact adherence clubs, which can provide needed support to HIV+ individuals. What would normally be discussed at the physical adherence clubs or with HCWs could easily be discussed through these virtual media. Patients would continue to receive emotional support and encouragement without physical contact. These forms of support groups can be tailored for different seetings and populations. Stigma could be reduced, as it will not be known by community members when HIV infected people are meeting for their adherence clubs.

5.2 RECOMMENDATIONS

Further implementation fidelity studies should include interviews with patients as well as with HCWs, and thorough review of patient record files. This will provide further insight from the patients' and providers' experience, and can help inform better decision-making with respect to tackling ART adherence. There is also a need for more qualitative research that explores HIV positive patients' reasons for defaulting on ART and to understand what factors help patients adhere to ART. This can inform policy on how to better serve defaulters and how to increase the number of virally suppressed patients.

Quality improvement interventions on HCWs' execution of the HCC should be conducted to strengthen support systems that aid HCWs to provide high quality care when attending to HIV patients. These could include: reviewing and developing more user-friendly guidelines for HCWs; permitting alterations to guidelines so that HCWs can adapt and improve their service; and required attendance of HCWs at regular in-service trainings. These interventions should be evaluated pre- and post-implementation to assess their impact on the HCC and on the provision of care that is relevant and appropriate to patients' needs.

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APPENDICES

Appendix 1: Fidelity Checklist Toolkit

A Study about Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Healthcare Facilities

HIV Continuum of Care Fidelity Assessment Tool Kit

Instructions

- This tool has two sections; 1 addresses the demographic profile of the patient and 2 addresses adherence to fidelity using content and dose.
- Scores are given for each statement that is present in the patient record.
- Scores of 1 or 0 for yes and no answers respectively, are allocated.
- There are no maybe or half-points answers.
- Scores will be tallied separately under content and dose, per stage of care.

---

1. **Facility ID……**

2. **Demographic profile**

1.Patient ID…… (for record purposes only and to aid traceability) 2.Age……..

3.Gender: male / female/ transgender/unspecified/other…….

4.Occupation: employed/ unemployed/ employer/student/ none/ other…….

5.Level of education: (primary/ secondary/tertiary /none)

6.Which category does this patient fall under at the commencement of diagnosis?

a) Eligible to start ART

- CD4 count ≤500 cells/μl irrespective of clinical stage
- CD4 ≤350 cells/μl patient prioritised? (Yes/No)
- Severe or advanced HIV disease (WHO clinical stage 3 or 4), started on ART regardless of CD4 count
- Active TB disease (including drug-resistant and EPTB)
- Pregnant and breastfeeding women who are HIV-positive

- Known hepatitis B viral (HBV) co-infection

Date when patient entered continuum of care……

3. Measuring of adherence to the HIV treatment cascade using content and dose :

Stage 1. HIV COUNSELLING AND TESTING

HIV COUNSELLING AND TESTING	YES	NO	COMMENTS
1.Was consent given prior testing			
First HIV test (If applicable):			
2. If test was negative, which of the following was done?			
• Post-test counselling			
• Repeat HIV test after 3 months			
• Educate on window period and HIV risk reduction			
• Repeat HCT for women on PMTCT program			
3. If test was positive, was second rapid test conducted?			
4. Was an Elisa test conducted to confirm the final results?			
5. If the final Elisa was positive, which of the following were conducted:			
• Post-test counselling			
• Same day TB screen (if not done already)			
• HIV education			
• CD4 cell count			
• HBsAg			
• Creatinine			
• Clinical staging			
• If a pregnant/breastfeeding, ART initiated on same day			
6. If the patient refused to test, what steps were followed:			
• Post- refusal counselling			
• Continuous offering of provider initiated counselling and testing with each visit			
7. HCT is repeated as per guidelines and timelines depending on the type of patient you are. Was HCT repeated timeously,(choose the applicable patient as per the medical record to check timeline of repeated HCT:			
• Pregnant and breast feeding women (to detect HIV sero-conversion)- every 3 months throughout pregnancy			
• Key population (every 6-12 months)			
• If exposed to HIV (after 6-12 weeks)			
• General population (every 6-12 months)			
8. At the time of HIV diagnosis, which of the following were communicated to the patient:			
• ART decision making with patient			
• Entire treatment plan explained and follow-up visit scheduled			
• Identified and addressed possible linkage to care			
• Advised patients about post-diagnosis support groups			
• Register pregnant women on MomConnect at the first antenatal care (ANC) visit (if applicable)			
• Use of SMS technology to remind patients of appointments			
Each yes answer is given a score of 1 and each no answer is given a score of 0, non-applicable answers are given a value of 99. Scores will be tallied on both content and dose and analysis will be conducted at this stage of the care continuum. Extent of fidelity of HCT implementation will be calculated.			

Additional comments

Stage 2. LINKAGE TO CARE AND PRE ART INITIATION

When patients have been diagnosed with HIV but are not yet eligible for ART initiation, they should be kept within the wellness programme where they are encouraged and given support to live a healthy lifestyle. Their CD4 cell count should be checked regularly, at least 6-monthly to assess eligibility for ART.

LINKAGE TO CARE AND PRE ART INITIATION	YES	NO	COMMENTS
9. Which of the following were included in the pre ART initiation programme			
• TB symptom screening at every visit: test all who have a positive symptom screen; initiate INH prophylaxis if eligible and give TB treatment if tested positive for TB			
• Conduct clinical staging (at every visit)			
• Screening and management of sexually transmitted infections			
• Counselling on how to avoid HIV transmission to sexual partners and children			
• Information and counselling on risk-reduction and combination HIV prevention approaches			
• Support for disclosure and partner notification			
• Information and counselling related to fertility, including planning for conception or contraception, as needed			
• Counselling on nutrition and healthy lifestyle			
• Screening and management of co-morbidities and non-communicable diseases			
• Repeat CD4 testing and WHO clinical staging 6-monthly in adults and adolescents			
• An annual cervical cancer screening (pap smear) for all HIV-positive women			
Each yes answer is given a score of 1 and each no answer is given a score of 0, non-applicable answers are given a value of 99. Scores will be tallied on both content and dose and analysis will be conducted at this stage of care continuum. Extent of fidelity of Linkage to care and pre ART initiation will be calculated.			

Additional comments

Stage 3. ART THERAPY AND RETENTION IN CARE

Education on adherence to treatment starts at the beginning of the treatment cascade, when a patient is diagnosed as HIV-positive. Adherence includes taking treatment as prescribed, keeping to appointments for test results, referrals and further investigation. The patient's motivation to continue engaging with care regardless of eligibility for ART is influenced by their experience with the healthcare system and the attitude of healthcare providers.

Viral load suppression, clinical outcome and adherence should be explained to the patient. Adherence to treatment requires on-going assessment and monitoring, which should be part of each clinic.

ART THERAPY AND RETENTION IN CARE	YES	NO	COMMENTS
10. Which of the following are conducted to ensure viral load suppression?			
• Monitor and offer on-going adherence support.			
• Adherence goal is >95% of doses taken. Patients with adherence <80% require more adherence support, was adherence noted			
• Are there any missed appointments for prescription collection			
• Counselling on side effects conducted			
• Adverse events, interim illness and issues around stigma and disclosure is continually addressed were these addressed			
• Was caregiver participation in a support group encouraged			
• Monthly counselling visits for the first 3 months			
• Quarterly counselling visits conducted after the 3 months			
11. Which other strategies were employed to increase adherence of all patients with <80% adherence at any visit and those with first VL>1000 copies/ml (choose those which were conducted)			
• re-education of patient, caregiver and their 'buddy' about the importance of adherence			
• Re-emphasising of long-term benefits of adherence			
• Evaluate the support structures in place; whether they are appropriate, how they can be improved and explore other options			
• Encourage the patient to consider the use of pillboxes and/or a daily dosing diary			
• Encourage the patient to participate in a support group or create a link with a patient advocate			
• Looked at the psychological profile of the patient, to assess mental health issues/substance misuse			
• Increased home visits by therapeutic counsellors/patient advocates to daily or weekly at a minimum			
• Initiate spot pill counts to be conducted at home			
Each yes answer is given a score of 1 and each no answer is given a score of 0, non-applicable answers are given a value of 99. Scores will be tallied on both content and dose and analysis will be conducted at this stage of care continuum. Extent of fidelity of ART therapy and retention in care will be calculated.			

Additional comments

----------THE END----------

Appendix 2: Interview Guide

Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Health Care Facilities

Participant ID…….

Background and demographic information

1. Could you tell me about your background in terms of education and work experience?
2. Could you tell me about your current work?

Quality in delivery

3. What is your role in the HIV Care Continuum?
4. Could you describe the work you are currently doing in the project?
5. Do you have some work descriptions for your work, (your scope of practice)? (if yes, these are collected to the document analysis)
6. How do you document the work you are doing? (all documentation mentioned is collected to the document analysis)
7. Have there been any other changes in the HIV Care Continuum model since you started work in the HIV treatment cascade?
8. (If there were changes) Why were these changes made? Did these changes affect how you conduct your daily routine? if yes, how?

Participant responsiveness

9. What are your perceptions about the HIV Care Continuum protocols?
10. Do you feel sufficiently informed about what you are expected to do?
11. Do you feel sufficiently supported to carry out work in this Care Continuum?

Facilitation strategies

12. Could you describe any factors that hinder or facilitate your work in the care continuum ?
13. What conditions do you see as critical to the care continuum's success?
14. Do you have any concerns regarding the implementation of this care continuum? If yes, what are they?

Complexities of an intervention

15. What are the main issues that this care continuum can focus on to achieve adherence?

16. What activities in the care continuum lead to the desired effects? Name specific activities which you are/ should be practising in your facility.
17. What do you think are the main benefits of this care continuum?
18. Is there anything else that you would like to elaborate on or share regarding the HIV Care Continuum?

----------THE END----------

Appendix 3: Wits Ethics Certificate

R14/49 Ms Lorraine Mabotse Molepo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M1611105

NAME: (Principal Investigator)	Ms Lorraine Mabotse Molepo
DEPARTMENT:	Epidemiology and Biostatistics Agincourt, Bushbuckridge Mpumalanga Province
PROJECT TITLE:	Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Healthcare Facilities
DATE CONSIDERED:	25/11/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	13/01/2016

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 Research Office Secretary in Room 301 Third Floor, Faculty of Health Sciences, Phillip Tobias Building 29 Princess of Wales Terrace Parktown, 2193, University of the Witwatersrand. 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 deviations 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. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

29/01/2017
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 4: Mpumalanga Ethics Certificate

health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

No.3, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel I: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

Enquiries: Themba Mulungo (013) 766 3511

22 February 2017

Dr. Xavier Gomez-Olive
MRC/Wits Agincourt Research Unit
Tintswalo Hospital Street 11 B
Acornhoek
BUSHBUGRIDGE
1320

Dear Dr. Xavier Gomez-Olive

APPLICATION FOR RESEARCH & ETHICS APPROVAL: IMPLEMENTATION FIDELITY OF HIV CARE CONTINUUM AMONG HEALTHCARE WORKERS IN AGINCOURT HEALTH CARE FACILITIES

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

PHREC REF: MP_2017RP49_123

Kindly ensure that the study is conducted with minimal disruption and impact on our staff, and also ensure that you provide us with the soft and hard copies of the report once your research project has been completed.

Kind regards

MS. T.Z MADONSELA
MPUMALANGA PHRC

2017/2/22
DATE

MPUMALANGA
THE PLACE OF THE RISING SUN

Appendix 5: Agincourt Permission Letter

MRC/Wits Rural Public Health and Health Transitions Research Unit
School of Public Health, Education Campus, 27 St Andrew's Road, Parktown 2193, South Africa
Telephone: +27 11 717 2085 (Johannesburg) +27 13 795 5076 (Acornhoek) www.agincourt.co.za

4 November 2016

Wits Human Research Ethics Committee (Medical)

To Whom It May Concern

Re: Permission for research study

Lorraine Molepo is a student in the MSc Implementation Science programme, School of Public Health. Her research report is titled: "Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Healthcare Facilities".

Her proposed work complements the Tsima study currently underway – an NIH-funded cluster randomised trial of a community mobilisation intervention to increase testing, linkage to care and adherence to treatment.

We have granted Lorraine permission to conduct data collection for her research in the MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt), Bushbuckridge, Mpumalanga.

Please don't hesitate to contact me for further information.

Yours

Kathleen Kahn

Professor, School of Public Health
Senior Scientist, MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt)

Appendix 6: Information Sheet

A study about Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Healthcare Facilities

Greeting.

I/we [name(s) of persons conducting the research]…….

are doing a research on processes involved in caring for HIV patients in your facility. The study aims to evaluate your experiences with the existing protocols for caring for HIV patients.

The research will involve looking at patient records and clinic registers at your facility as well as interviewing you. A healthcare worker from each department involved in caring for HIV patients are recruited to take part in this interview. This is a once-off interview which will take approximately 30 minutes of your time.

This information will be conducted in the form of a recorded interview where you will be asked a series of questions to answer to the best of your ability. The recording is to ensure that all that is discussed during the session is captured. The tape would be kept strictly confidential and would be destroyed immediately after transcription. This study is purely for scientific purposes. Your name and identity will not be publicised in the result analysis and discussion.

Participation in this study is voluntary, and you may stop with the interview if you do not feel comfortable answering any of the questions.

This study will help us understand your everyday experiences which hinder or facilitate your work in caring for HIV positive patients.

In order to participate, it is requested of you to sign on the consent form overleaf.

If you have any questions or concerns about the research, please feel free to contact:

Lorraine Molepo or my supervisor(s): msbotse2@gmail.com ; Kathleen.kahn@students.wits.ac.za; ajuliens@email.unc.edu

Appendix 7: Informed Consent Form

A study about Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt Healthcare Facilities

---

Participant declaration:

I hereby confirm that I have been informed by the study staff (_____) about the nature, conduct, benefits and risks of the study.

I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study, including any personal details such as those regarding my name or job title will be anonymously processed into a study report.

In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by Wits study staff or on their behalf.

I may, at any stage, without prejudice, withdraw my consent and participation in the study.

I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

_____	_____	_____
Signature of participant	Place	Date

Statement by the researcher:

I have provided written information regarding the study project. I agree to answer any further questions regarding the research study project. I shall adhere to the approved protocol.

_____	_____	_____
Name of researcher	Signature	Date

Appendix 8: Recording Consent Form

A study about Implementation Fidelity of HIV Care Continuum among Healthcare Workers in Agincourt healthcare facilities

---

Participant declaration

In addition to the informed consent signed, I hereby confirm that I have been informed by the study staff (_____) that this interview will be recorded, and I consent for the tape recorder to be used during my interview.

_____ _____ _____

Signature of participant Place Date

Statement by the researcher

I hereby declare that the information gathered using the recording device is for purposes of gathering information efficiently and will be used for transcribing purposes only. The recording device will be securely protected and information kept confidential.

_____ _____ _____

Name of researcher Signature Date